Revision 2

NorthStar Medical Radioisotopes, LLC
RadioGenix® Molybdenum-99/Technetium-99m Generator System

Licensing Guidance for Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies

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U.S. Nuclear Regulatory Commission
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Introduction

Technetium-99m is the radionuclide used for millions of diagnostic nuclear medicine patient scans performed each year in the United States. This guidance is specific to the NorthStar RadioGenix® Molybdenum-99/Technetium-99m Generator System (hereafter the RadioGenix® System) (Mo-99/Tc-99m). This guidance only applies to the possession and use of the RadioGenix® System, which produces Tc-99m. The Tc-99m produced by the RadioGenix® System is interchangeable with Tc-99m produced by existing fission generated Tc-99m when used for the preparation and use of radiopharmaceuticals under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required." This guidance does not apply to medical use or commercial nuclear pharmacy licensees or applicants that only elute fission-based Mo-99/Tc-99m generators or only receive unit or multidose doses of Tc-99m radiopharmaceuticals.

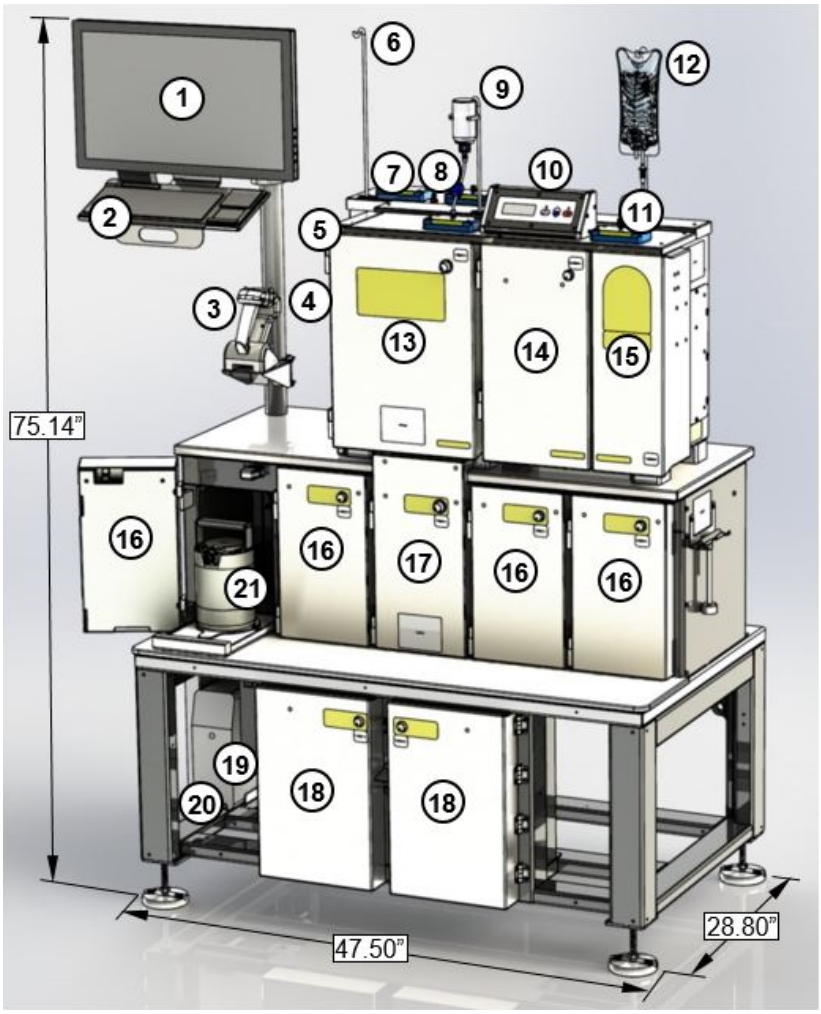
The NorthStar RadioGenix® System is a device designed as a closed system to contain, move, and shield all Mo-99 (as a mixture of radioactive Mo-99/Tc-99m and nonradioactive Mo-98 or Mo-100) during a computer-driven process of isolating Tc-99m from all the molybdenum (Mo) before delivering Tc-99m into an elution vial. The Mo in this system is not derived from the fission of uranium and requires a different system to isolate and concentrate the Tc-99m than the existing fission Tc-99m generators.

Information concerning the technical basis for licensing each RadioGenix® System model can be found in both this guidance document and the RadioGenix® System Safety Evaluation Report (SER). This licensing guidance provides an acceptable approach for meeting U.S. Nuclear Regulatory Commission (NRC) regulations. This licensing guidance consists of general considerations, specific radiation safety aspects of the RadioGenix® System, and training and experience expectations for those authorized to use the RadioGenix® System. The RadioGenix® System SER provides a description of the RadioGenix® System from a technical engineering and radiation safety point of view. The SER focuses on the manufacturer's component and system descriptions and commitments that include, but are not limited to, software, internal components, reagent solutions, materials of construction, dimensions, tolerances, activity level, isotopes, radiation safety components, manufacturing process, Quality Assurance, and Quality Control program.

The SER will be updated periodically when there is a significant change, such as a new model or an important engineering change to the RadioGenix® System. As the SER is updated, the SER may contain information on multiple models of the RadioGenix® System, the resulting differences in protocol and safety training for each model, the differences between past and present models, and other significant changes. The SER will also identify the appropriate version of the licensing guidance to be used with the specific NorthStar RadioGenix® System model. The current SER and all previous versions will be identified by the date of issuance and located on the nonpublic National Sealed Source and Device Registry Web site (https://scp.nrc.gov/ssdr.html), so that they are accessible to NRC and Agreement State license reviewers and inspectors. Applicants may request a copy of the SER from NorthStar for the associated NorthStar RadioGenix® System they will have.

Note: As NorthStar updates the NorthStar RadioGenix® System from one model number to another or implements a significant engineering change, this licensing guidance may not make the corresponding change, but different training may be needed for the new model or significant engineering change. The associated SER will describe appropriate training for each model or significant engineering change. Users are required to have training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to

life or property pursuant to 10 CFR 30.33(a)(3). This guidance describes when, under 10 CFR 30.33, the applicant must provide additional documentation of the successful completion of new training by the authorized individuals, the RSO, supervised individuals operating the RadioGenix® System, the RadioGenix® System Administrator, and RadioGenix® System Administrator Designee to be authorized to use the new model of the RadioGenix® System. The SER will also clarify whether any changes are needed to the license terms, such as the maximum possession limit per source vessel. The licensing guidance may change if there are changes to the training and experience processes, standard license conditions, or other significant processes.



RadioGenix System Components

1. Touch Screen Monitor
2. Workstation Keyboard
3. Barcode Scanner
4. Purge Water Reservoir (on side)
5. Ozone Generator (in back)
6. Sterile Water Hanger
7. Sterile Tubing Docking Station
8. NaOH Port
9. NaOH Bottle
10. Instrument Display
11. Saline Port
12. Saline Container
13. Service Door
14. PSC Door
15. Product Door
16. Source Vessel Bays (4)
17. Transfer Bay
18. Discarded Material Bays (2)
19. RadioGenix Computer
20. UPS Battery Backup
21. Source Vessel / Source Transport Vessel

Figure 1. The NorthStar RadioGenix® Mo-99/Tc-99m Generator System Model 1.2[1] with enhanced shielding and with the major components labeled. Component 20, the source vessel (on the left and inside the first of the four components numbered 15), is approximately the same size as a conventional generator containing fission-produced Mo-99. The generator system with enhanced shielding weighs 4,100 pounds and is approximately 48 inches wide, 29 inches deep, and 75 inches tall.

[1] Both the Model 1.2 and the Models 1.1 and 1.0a figures are in the associated SER. When the design changes for subsequent models, new figures will be included in the SER.

Molybdenum/Technetium-99m flow through the NorthStar RadioGenix® Molybdenum-99/Tecnetium-99m Generator System

- The Mo/Tc-99m liquid is received inside its shielded "Source Transport Vessel" (component 21), which may also be referred to as the "Source Vessel." The vessel is placed in one of the four "Source Vessel Bays" (components 16) on the middle row.

- The vessel is connected to tubes to move the Mo/Tc-99m liquid by computer driven valves and a syringe pump located behind the "Service Door" (component 13) on the top row.

- The Mo/Tc-99m is moved behind the "PSC Door" (component 14) where the chemical solution(s), depending on the model, located on top of the PSC cabinet react with the Mo/Tc-99m solution and column to make the Mo pass through the first chromatographic column in the PSC cabinet.

    - The Mo goes to the "Transfer Bay" (component 17)
    - The Tc-99m adheres to the column behind the "PSC Door" (component 14)

- The additional chemical solution(s), depending on the model, are used to wash the Tc-99m from the first column behind the "PSC Door" (component 14) and then through a second column behind the "Product Door" (component 15) into the Tc-99m collection vial behind the production door.

- The chemical wash(es) are pumped through valves to a container in one of the two "Discard Material Bays" (components 18) on the bottom row.

- At the end of the process, the Mo is returned to the "Source Vessel" (component 21) for reuse.

- Once the Mo-99 is no longer usable or reaches its expiration date, it is returned in component 21 which is the source transport vessel (or source vessel) to the manufacturer.

Protocol

The term "protocol" used by NorthStar, in the SER and in this guidance refers to discrete portions of the software program that focus on performing a specific function. In order to perform these protocols, the operator must perform specific operational tasks in conjunction with the software running the RadioGenix® System series of pumps and operational steps. The protocols for system initialization, add/change sodium hydroxide (NaOH) and primary separation cartridge (PSC), add saline, add source vessel, elute Tc-99m, remove source vessel, sterilization, and exchange discard material container all involve opening the shielded doors, or handling and disposal of radioactive materials and potentially contaminated components. NorthStar provides short instructional videos in each protocol that can be reviewed from the touch screen (component 1).

1. 10 CFR 35.1000 Use[2]

The engineering specifications for the materials and components of the NorthStar RadioGenix® System are designed to maintain the entire device's integrity as a closed system; withstand high radiation fields for extended periods; and maintain adequate shielding of the radioactive material when all the RadioGenix® System doors are closed, latched, and secured, as well as when the supplemental shielding is in place. Built-in safety features are designed to ensure that, if the device fails, the radioactive material will remain shielded. The RadioGenix® System is designed and constructed so that its components and operation differ significantly from conventional Mo-99/Tc-99m generators using fission-produced Mo-99 regulated in 10 CFR Part 35, Subpart D, "Unsealed Byproduct Material-Written Directive Not Required."

Examples of the unique features that differentiate the RadioGenix® System from fission-produced Mo-99/Tc-99m generators regulated in 10 CFR Part 35, Subpart D, include the following:

- Licensee receives the source vessel with the liquid Mo containing Tc-99m daughter products that are both specifically produced for NorthStar;
- Licensee adds new and removes old source vessels from the system;
- Licensee, not the manufacturer, performs the automated steps to process the low specific activity Mo liquid solution to isolate and concentrate the Tc-99m for medical use;
- Materials move by the computer driven syringe pump through a multichannel distribution valve;
- Routine licensee replacement of the first chromatography column, which is the column that captures the Tc-99m;
- Routine licensee replacement of the second chromatography column, which is the column that captures the residual Mo;
- Routine ozone sterilization procedures; and
- Both liquid radioactive and non-radioactive waste solutions used in the isolation of the Tc-99m are collected and held for decay in the device before disposal.

As a result of these unique features, the NorthStar RadioGenix® System is not regulated under 10 CFR Part 35, Subpart D, but instead placed under the regulatory purview of 10 CFR Part 35, Subpart K., "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." Therefore, this licensing guidance applies to the medical use applicants and licensees that request or possess the NorthStar RadioGenix® System.

[2] 10 CFR 35.1000 use is the medical use under 10 CFR Part 35, Subpart K, "Other medical uses of byproduct material or radiation from byproduct material." This regulation is designated as Compatibility Category D. Agreement States are not required to adopt these regulations for purposes of compatibility.

2. Commercial Nuclear Pharmacy Use under 10 CFR 30.33

There are unique design, construction, materials specifications, and use features that differentiate the RadioGenix® System from a conventional fission Mo-99/Tc-99m generator. The unique features of the RadioGenix® System results in the need for additional information and commitments, which are not required to safely use a conventional fission Mo-99/Tc-99m generator. Therefore, a commercial nuclear pharmacy applying to use the RadioGenix® System will not meet the requirements in 10 CFR 30.33, "General requirements for issuance of specific licenses," without providing additional training and experience for individuals and making certain commitments to address specific training and safety provisions. All sections of this guidance pertain to the commercial nuclear pharmacy applicant as well, unless specified otherwise.

3. Licensing Guidance

3.1 General Information

This guidance provides applicants with an acceptable means of satisfying the requirements for a license/amendment to authorize the use of the RadioGenix® System and is not intended to be the only means of satisfying requirements for a license. This guidance refers generically to the RadioGenix® System. Even though the NRC will not include the model number on the license, under 10 CFR 30.33(a)(3), the applicant must document the model that will be possessed and used. There are provisions and commitments in sections 6, 7 and 8 of this guidance that, if authorized on the license, will permit the licensee to possess and use upgraded features and models, as appropriate. The applicant must submit the information required by 10 CFR 30.33 and 35.12, as described below. The applicant should submit additional information and the commitments requested below or may, unless the information is specifically required by regulation, submit alternative information and commitments for review by the NRC staff to make a licensing determination. The commitments incorporated into the applicant's license by license condition will be reviewed during routine inspections.

Applicants are reminded that licensees authorized for a use issued pursuant to 10 CFR 35.1000 must still meet the general requirements in Part 35, Subparts A, B, C, L, and M for that use, except as specified in this guidance. In addition, several provisions in Part 35, Subpart D are appropriate for use of the RadioGenix® System, as discussed below. Commercial nuclear pharmacy applicants must meet the requirements in 10 CFR 32.72. Additionally, both medical use and commercial nuclear pharmacy applicants must meet applicable requirements of 10 CFR Parts 19, 20, and 30.

3.2 Single-step and Two-step Licensing Processes

Revision 1 of this guidance document included a single-step licensing process. The single-step licensing process has a corresponding single-step training and experience process described in Section 5. Under this single-step licensing process, once NRC receives all the information and documentation necessary for a complete license application (or amendment request) that includes the successful completion of the single-step training and experience process and attestations for the authorized individual(s) and the RSO, then the NRC can issue the license or amendment to possess and use the RadioGenix® System. For an applicant that has never had a RadioGenix® System and does not have any individuals authorized for use of a RadioGenix® System, the single-step licensing and single-step training and experience processes would permit the training for the authorized individual(s) and the RSO to be given at NorthStar's facility in Wisconsin.

This guidance (Revision 2) includes both the original single-step licensing process described above and the newer two-step licensing process that is compatible with issuing a new license or new authorization in two steps. The two-step licensing process, with its corresponding two-step training and experience process described in Section 5, provides flexibility for new RadioGenix® System applicants (e.g., an applicant that has never had a RadioGenix® System and does not have any individuals authorized for use of the RadioGenix® System). It can also be used by a RadioGenix® System licensee having a new model installed but that is not preapproved for the paragraph 8.3 new model notification process with both the single-step and two-step training and experience processes. For the applicant and existing RadioGenix® System licensee, the two-step licensing process first permits training by NorthStar for the authorized individual(s), the RadioGenix® System Administrator, and the RSO on a cold unit (a fully functional RadioGenix® System of the same model requested but containing no radioactive material). NorthStar usually provides this training at, or near, the applicant's facility. The applicant/licensee must submit to NRC all the information and documentation necessary for a complete license application (or amendment), including successful completion of the first step of the two-step training and experience for the authorized individual(s) and the RSO, and the attestations for each. Once the NRC receives the complete license application (or amendment), then the NRC can issue a conditional license (or authorization) to possess the NorthStar RadioGenix® System for installation and training only (see paragraph 10.3).

This conditional license (or authorization) includes the standard authorization for the RSO because the Radiation Safety Officer is responsible for the licensee's entire radiation safety program and the conditional RadioGenix® System license authorization limits the RSO's oversight to only installation and training for the RadioGenix® System. The conditional license will list the RadioGenix® System authorized individual(s) for only training on the NorthStar RadioGenix® System (see paragraph 10.4).

Both the conditional authorization in paragraph 10.3 (authorization 9.A.1) and the conditional license condition in paragraph 10.3 (license condition 10.b for the authorized individuals) have two parts. The first part of authorization 9.A.1 permits the licensee to have Mo-99/Tc-99m in the form of liquid NorthStar Mo-99/Te-99m in the specific model[3] of NorthStar RadioGenix® System for possession, installation, and training. The second part is the provision that, in accordance with license condition "AA" (see paragraph 10.4), the licensee is authorized to either elute the Tc-99m for a medical use licensee or use the RadioGenix® System to prepare and distribute radioactive drugs for a commercial nuclear pharmacy. The first part of license condition 12.b permits the RadioGenix® System authorized individual(s) to use the RadioGenix® System only for training. The second part is a provision that the authorized individual(s) can, in accordance with license condition "AA," elute the Technetium-99m from the RadioGenix® System.

The second step of the licensing process is for the licensee to have at least one authorized individual and the RSO successfully complete their training provided by a NorthStar representative on a hot unit (a fully functional RadioGenix® System containing Mo-99 that can elute Tc-99m). The licensee must then meet all of the criteria in license condition "AA" to override the conditional authorizations and license conditions. The three criteria in license condition "AA" that must be met are: (1) the completion of the two-step training and experience process, (2) the documentation that must be submitted, and (3) the submission and NRC acknowledgement conditions. Once these criteria are met, the licensee is authorized for the full use of the new RadioGenix® System, the named RadioGenix® System authorized individual(s) can perform elutions, and the RSO has oversight for the entire RadioGenix® System radiation

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

safety program. After the three criteria are met the licensee can use the RadioGenix® System before NRC revises the license to remove Licensee condition "AA," replace the conditional authorization with authorization 9.A.2 and replace the conditional license condition 12.b with license condition 12.a.

[Note: Applicants/licensees in Agreement States should check with the Agreement State regulators to see if it will accept the two-step licensing process described above.]

4. General

4.1. Sensitive Security-Related Information:

Certain sensitive security-related information such as information about quantities and locations of radioactive materials at licensed facilities is no longer released to the public.

Additional information on procedures for handling and marking security-related information and any updates are available at: http://www.nrc.gov/reading-rm/sensitive-info.html.

4.2. Radionuclides, Form, Possession Limits, and Purpose of Use Submitted by the Applicant:

Pursuant to 10 CFR 30.33, the applicant shall identify the radionuclides, chemical/physical form, requested maximum possession limit, and purpose of use. NRC Form 313, "Application for Materials License," may be used to submit this information. The following provides an acceptable format for submission of the information required in Items 5 and 6 in NRC Form 313.

Table 1. Applicant Submission for Radionuclides, Form, Possession Limits

Radionuclides: (NRC Form 313 Item 5)	A. Molybdenum-99/Technetium-99m B. Depleted Uranium[4]
Chemical/Physical Form: (NRC Form 313 Item 5)	A. Liquid Molybdenum-99/Technetium-99m produced by NorthStar to be used in the NorthStar RadioGenix® System B. Metal
Maximum Possession Limit: (NRC Form 313 Item 5)	A. XX[5] curies of Molybdenum-99/Technetium-99m per source vessel, not to exceed YY[5] curies total (includes waste and decayed source vessels) B. ZZZ[6] kilograms total (includes all the depleted uranium that the licensee will possess including the NorthStar RadioGenix® System)
Purpose: (NRC Form 313 Item 6)	A. For medical use applicants – "10 CFR 35.1000 medical use elution of Technetium-99m in a Model 1.2[6] NorthStar RadioGenix® System." or For the commercial nuclear pharmacy applicants – "Elution of Technetium-99m in a Model 1.2[7] NorthStar RadioGenix® System." B. For shielding in a NorthStar RadioGenix® System.

4.3. Facility Address and Description[8] [10 CFR 30.33(a)(2) and 10 CFR 35.12(b)(1)]

Provide an address of use and submit a facility diagram and description of the location where the RadioGenix® System will be used, and any other areas where the radioactive materials associated with the RadioGenix® System will be stored. The facility diagram should be drawn to scale, including dimensions, and provide directional orientation. This information should include a description of adjacent areas and rooms both above and below the unit, whether the areas and rooms are unrestricted or restricted, and, if necessary, a description of any shielding and shielding calculations. The applicant may choose to either add additional shielding for ALARA purposes or ensure that any public dose limits are not exceeded or both.

[4] Depending on the model used, depleted uranium may or may not be used in either the source vessel or the source transfer vessel. NorthStar is phasing out the use of depleted uranium in the RadioGenix® System.
[5] The applicant or licensee should check the SER for the activity per source vessel and corresponding total activity values appropriate for the model being requested. Note: The SER should also be checked to see if the maximum possession limit or maximum possession limit per source vessel listed changed based on review of changes between RadioGenix® System models or loading limits for the source vessel. If the change is greater than the maximum possession limit or maximum possession limit per source vessel on the license, then an amendment will be necessary to revise the maximum possession limit.
[6] ZZZ is just a place holder tor the total depleted uranium for which the licensee is authorized.
[7] The applicant should clearly identify the correct model of the NorthStar RadioGenix® System to be used. This should include any other characteristic of a model that is important to identify the specific NorthStar RadioGenix® System requested such as the Model 1.2 with enhanced shielding.
[8] The description of the facility may include sensitive security-related information see paragraph 4.1 above.

4.4. Posting Requirements

The unit produces a non-uniform radiation field while it is being operated. Therefore, the applicant is reminded that, when determining how to post the unit and area in accordance with 10 CFR 20.1902, the radiation levels will vary at different times and in different areas around the unit based on the set up and the Tc-99m production processes. If the RadioGenix® System can be accessed on multiple sides, then appropriate radiation markings and controls will be needed for each accessible side.

5. Training and Experience

Under 10 CFR 30.33 and 35.12, the applicant must submit documentation of the training and experience for the authorized individual(s) and the RSO. This Section of the guidance includes both the single-step and two-step training and experience processes. Any applicant or licensee can request to add an authorized individual(s) or the RSO on the license if the individual has successfully completed either the single-step or two-step training and experience process. In addition to adding a new authorized individual(s) or a new RSO to the license this includes updating the training and experience qualifications of an experienced authorized individual or RSO for a different model[9] of the RadioGenix® System.

Note: As described in Section 8, "Additional Applicant Commitments and Requesting Amendments to Allow Notifications without Additional Amendments," there are benefits for a new applicant or existing RadioGenix® System licensee to apply for and be authorized on the license for all the notification processes described in Section 8. For example, benefits include that the licensee can use either the one-step and two-step training and experience processes and the notification process to add new authorized individual(s) or update additional training documentation for authorized individual(s) or the RSO that are already trained on a different model of the RadioGenix® System. The notification processes cannot be used to approve and list a new RSO on a license or review and approve the training and experience of an individual that has never been authorized to be an authorized user or authorized nuclear pharmacist.

The applicant must also provide the appropriate commitments describing the training and experience for the supervised individuals operating the RadioGenix® System, the RadioGenix® System Administrator, and the RadioGenix® System Administrator Designee described below.

Note: While this document comprises the licensing guidance, a separate document, the SER, which is available to the NRC and Agreement States on the nonpublic National Sealed Source and Device Registry Web site (https://scp.nrc.gov/ssdr.html), includes a table identifying the appropriate licensing guidance document and training for each model number of the RadioGenix® System. The licensee or applicant can obtain the SER from NorthStar. License application reviewers should confirm the applicability of a SER to the model in the particular application they are reviewing.

5.1. Authorized Individuals [10 CFR 30.33(a)(3) and 10 CFR 35.12(b)(1)]

The NRC has determined that individuals meeting the guidance provided below will be considered qualified and can be authorized for the use of a specific model of the RadioGenix® System. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case

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

basis by NRC staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that the individuals are qualified to be authorized individuals.

Identify each individual for whom the applicant is seeking recognition as an authorized individual **(physician authorized users [AUs] and authorized nuclear pharmacists [ANPs])** for the specific model of the RadioGenix® System and provide documentation of the individuals training and experience. NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation for uses defined under 35.200 and 35.300," and NRC Form 313A (ANP), "Authorized Nuclear Pharmacist Training and Experience and Preceptor Attestation [10 CFR 35.55]" or other formats may be used to document this training and experience (https://www.nrc.gov/materials/miau/med-use-toolkit.html).

If qualified, the authorized individual will be listed on the license for the RadioGenix® System. The individual will be considered qualified for use of the specific model of the RadioGenix® System if the licensee provides documentation that demonstrates that the individual meets the requirements in 10 CFR 35.59, "Recentness of training," and the following:

> **Note:** Paragraphs A.(1) and (2) are for the requested authorized individual(s) that are already authorized on another license to use the same model of the RadioGenix® System being requested. Paragraph B is for the requested authorized individual that is authorized for a different RadioGenix® System and the paragraph has two pathways.
>
> The pathway in paragraph B. (1) describes the single-step training and experience process and the pathway in paragraph B. (2) describes the two-step training and experience process that involves training on both a cold unit and a hot unit (that is producing Tc-99m).

A. The requested authorized individual is already authorized on a different license for the same RadioGenix® System model requested.

   (1) The requested **authorized user** is already authorized[10] to use the same model of the RadioGenix® System by a: (i) Commission or Agreement State medical use license, or (ii) medical use permit issued by a master material licensee, or (iii) permit issued by a Commission or Agreement State medical use broad scope licensee or (iv) permit issued by a master material license medical use permittee of broad scope. The applicant must provide training and experience documentation that the authorized user was authorized to use the same model of the RadioGenix® System; or

   (2) The requested **authorized nuclear pharmacist** is already authorized[11] to use the same model of the RadioGenix® System by one of the following that authorizes medical use or the practice of nuclear pharmacy: (i) a Commission or Agreement State license, or (ii) a permit issued by a Commission master material licensee, or (iii) a permit issued by a Commission or Agreement State broad scope licensee, or (iv) a permit issued by a master material license permittee of broad scope. The individual may also be identified as an

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

authorized nuclear pharmacist for the same model by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacist. The applicant must provide training and experience documentation that the authorized nuclear pharmacist was authorized to use the same model of the RadioGenix® System.

B. The requested authorized individual is already authorized for a different model.

(1) Single-step training and experience process.[12] The requested authorized individual is already authorized for a different model[13] of the RadioGenix® System and successfully completed training on the differences between the two RadioGenix® System models' operation, safety, and emergency procedures. The requested authorized individual also successfully performed each protocol (on a fully functional RadioGenix® System connected to a Mo-99/Tc-99m source vessel and producing Tc-99m) 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 SER that can be obtained from NorthStar) in the physical presence of a NorthStar representative or an individual certified by NorthStar to proctor all the protocols for the new model or the different model of the RadioGenix® System. This training provided by a NorthStar representative or an individual certified 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 or Authorized Nuclear Pharmacist] for the specific model of RadioGenix® System must be dated and signed by a NorthStar representative or an individual certified by NorthStar to provide the training and proctor the protocols. The applicant must provide training and experience documentation that the authorized individual was authorized to use the other model of the RadioGenix® System.

OR

(2) The two-step training and experience process.

(a) Step one of the two-step training and experience process is for a requested individual that is already authorized for a different model[14] of the RadioGenix® System. In this step, the requested individual must successfully complete training using a fully functional cold unit on the differences between the two RadioGenix® System models' operation, safety, and emergency procedures. The requested 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 SER that can be obtained from NorthStar) in the physical presence of a NorthStar representative proctoring the protocols. This training provided by a NorthStar representative 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 a NorthStar representative.

[12] In the case of the installation of a new RadioGenix® System under the provisions of license condition "ZZ," the training, proctoring and attestation for first authorized individuals to use the RadioGenix® System using the single step training and experience criteria must be by a representative of NorthStar.
[13] Information on the model number will be in a document referenced in the tie down condition.
[14] Information on the model number will be in a document referenced in the tie down condition.

AND

(b) After the requested individual has already satisfactorily completed the cold unit training and experience and has the written attestation described in 5.1.B(2)(a), the requested individual must complete step two. In step two, the requested individual must successfully complete training on the differences between the two models in the areas of operation, safety, and emergency procedures using a fully functional hot unit (producing Tc-99m). The requested individual must also perform each protocol that is different from the protocol originally trained on using a fully functional hot unit (producing Tc-99m) at least once in the physical presence of a NorthStar representative proctoring the protocols. If the protocol that changed included the one or both of the two protocols – "remove source vessel" and "exchange discarded material container" – was successfully performed on the cold unit, it is not necessary to perform the protocol(s) again on the hot unit. This training provided by a NorthStar representative 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 requested individual is able to independently perform the radiation safety related duties of an [Authorized User or Authorized Nuclear Pharmacist] for the specific model of RadioGenix® System must be dated and signed by a NorthStar representative. The applicant must provide training and experience documentation that the requested individual was authorized to use the other model of the RadioGenix® System.

OR

C. For a physician or pharmacist that has never been an authorized individual for a RadioGenix® System.

[Note: Paragraphs C.(1) or (2) below provide general requirements for the individual that has never been an authorized individual for a RadioGenix® System but is already an Authorized User or Authorized Nuclear Pharmacist. Paragraphs C.(3), (4), or (5) are the requirements that all physicians and pharmacists must meet if they have never been a physician authorized user or authorized nuclear pharmacist. Paragraphs C.(6) and C.(7) describe the additional RadioGenix® System specific training and experience needed to be authorized to use a specific RadioGenix® System. Paragraph C.(6) describes the single-step training and experience process, and paragraph C.(7) describes the two-step training and experience process.]

(1) The requested individual is identified as an **authorized user** for medical uses in 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required," or 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required," provided the authorized user successfully completed the training and experience requirements in 10 CFR 35.290(c)(1)(ii)(G). This authorization must be on a: (i) Commission or Agreement State medical use license, or (ii) medical use permit issued by a master material licensee, or (iii) permit issued by a Commission or Agreement State medical use broad scope licensee or (iv) permit issued by a master material license medical use permittee of broad scope; or

(2) The requested individual is identified as an **authorized nuclear pharmacist** on one of the following that authorizes medical use or the practice of nuclear pharmacy: (i) a Commission or Agreement State license, or (ii) a permit issued by a Commission master

material licensee, or (iii) a permit issued by a Commission or Agreement State broad scope licensee, or (iv) a permit issued by a master material license permittee of broad scope. The requested individual may also be identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacist; or

(3) The requested individual meets the requirements in 10 CFR 35.290, "Training for imaging and localization studies," or 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required," with additional training and experience for 10 CFR 35.290(c)(1)(ii)(G); or

(4) The requested individual meets the requirements in 10 CFR 35.55, "Training for an authorized nuclear pharmacist;" or

(5) The requested individual is a physician who can be authorized for 10 CFR 35.200 medical uses or a nuclear pharmacist who can be authorized as an authorized nuclear pharmacist under the provisions of 10 CFR 35.57, "Training for experienced RSO, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist."

AND

(6) Single-step training and experience process. In addition to paragraphs C.(1), (2), (3), (4) or (5) above, the requested individual has successfully completed the following training and experience for the same model of the RadioGenix® System the applicant will possess and use and provided at a facility authorized to possess the same model of a RadioGenix® System which is also a fully functional generator connected to a Mo-99/Tc-99m source vessel and producing Tc-99m:

(a) Training in the RadioGenix® System operation, safety, and emergency procedures. This training shall be provided by a NorthStar representative or an individual certified by NorthStar to provide the training,

AND

(b) Perform each of the protocols (i.e., system initialization, add/change sodium hydroxide (NaOH) and PSC (primary separation cartridge), add saline, add source vessel, elute Tc-99m, remove source vessel, sterilization, and exchange discard material container) at least three times in the physical presence of a NorthStar representative or an individual certified by NorthStar to proctor all the protocols. The four protocols ("sterilization," "add source vessel," "remove source vessel," "add/change NaOH and PSC," and "add saline") may be performed using a "dummy source vessel" (i.e., a vessel that does not contain radioactive material) provided the vessel contains material that can be detected in the event of loss of control of the liquid, e.g., contamination, leaks, or spills.

AND

(c) The requested individual has a written attestation, that the individual has satisfactorily completed the requirements in paragraph C.(6)(a) and (b) of this section and is able to independently operate and perform the radiation safety related duties of an [Authorized User or Authorized Nuclear Pharmacist] for the

specific model of the RadioGenix® System. The written attestation must be dated and signed by a NorthStar representative or an individual certified by NorthStar to provide the training and proctor the protocols.

OR

(7) Two-step training and experience process. In addition to paragraphs C.(1), (2), (3), (4), or (5) in this guidance, the requested individual has successfully completed the following two-step training and experience process for the same model of the RadioGenix® System the applicant will possess and use.

(a) Step one involves successfully completing the following training and experience provided on a cold unit 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 a NorthStar representative; and

(ii) Performing each of the protocols (i.e., system initialization, add/change sodium hydroxide (NaOH) and PSC (primary separation cartridge), add saline, add source vessel, elute Tc-99m, remove source vessel, sterilization, and exchange discard material container) at least three times in the physical presence of a NorthStar representative proctoring all the protocols; and

(iii) Receiving a written attestation that the requested individual has satisfactorily completed the requirements in paragraph C.(7)(a)(i) and (ii) of this section for the cold unit. The written attestation must be dated and signed by a NorthStar representative.

AND

(b) Step two of the training and experience involves successful completion of step one of the training and experience on the cold unit of the same model (including the attestation signed by a NorthStar representative) and successfully completing the following training provided on the hot unit model of a RadioGenix® System producing Tc-99m.

(i) Reviewing the training again in the RadioGenix® System operation, safety, and emergency procedures. This training shall be provided by a NorthStar representative; and

(ii) Performing the following protocols again: system initialization, elute Tc-99m, add/change NaOH and PSC (primary separation cartridge), add saline, add source vessel, and sterilization at least once on the hot unit in the physical presence of a NorthStar representative proctoring all the protocols. If either or both of the two protocols remove source vessel and exchange discard material container have already been successfully performed on the cold unit, the protocol(s) do not need to be performed again; and

(iii) In addition to the written attestation from paragraph C.(7)(a)(iii), receiving a written attestation that the requested individual has satisfactorily completed the requirements in paragraph C.(7)(b)(i) and (ii) of this section for the hot unit and is able to independently operate and independently perform the radiation safety related duties of an [Authorized User or Authorized Nuclear Pharmacist] for the specific model of the RadioGenix® System. This written attestation must be dated and signed by a NorthStar representative.

5.2. Radiation Safety Officer

The NRC has determined that individuals meeting the guidance provided below will be considered qualified to be the RSO for a specific model of the RadioGenix® System. Applicants may also submit alternative training and experience commitments to be reviewed on a case-by-case basis by NRC staff. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates that the individual is qualified to be the RSO. The applicant should identify the individual for whom the applicant is seeking recognition as the RSO. If qualified, the individual will be listed on the license as the RSO authorized for the RadioGenix® System. The individual is considered qualified to be the RSO for a specific model of the RadioGenix® System if the licensee provides documentation that demonstrates that the individual meets the requirements in 10 CFR 35.59, "Recentness of training," and the individual:

[Note: Paragraph 5.2.A. applies when an applicant requests an individual that is already identified on another license as an RSO for the same model of the RadioGenix® System requested, Paragraph 5.2.B.1. describes the single-step training and experience process needed when the requested individual is identified as a RSO for a specific model of a RadioGenix® System and the applicant is seeking to identify the requested individual as RSO for a different model. Paragraph 5.2.B.2. describes the two-step training and experience process for the RSO moving to the different model.]

A. Is the Radiation Safety Officer for the same RadioGenix® System model requested?

Is identified as the RSO for the same model of the RadioGenix® System[15] for which the applicant is requesting. The requested individual must be already identified as the RSO by a Commission or Agreement State medical use or commercial nuclear pharmacy license that possesses and uses the same model or a medical use permit issued by a Commission master material license that possesses and uses the same model. The applicant must also provide training and experience documentation that the RSO was qualified to be the RSO for the same model of the RadioGenix® System.

OR

B. Is the Radiation Safety Officer for a different model of the RadioGenix® System?

(1) Single-step training and experience process.[16] Is already authorized as the RSO for a different model[17] of the RadioGenix® System, and the requested individual successfully

[15] Information on the model number will be in a document referenced in the tie down condition.
[16] In the case of the installation of a new RadioGenix® System under the provisions of license condition "ZZ," the training, proctoring and attestation for the single step training and experience criteria must be by a NorthStar representative.
[17] Information on the model number will be in a document referenced in the tie down condition.

completed training on the differences between the two RadioGenix® System models' radiation safety, regulatory issues, administrative controls, and emergency procedures. The requested individual also successfully practiced the emergency procedures applicable to the RSO that are different from the original emergency procedures at least once on a fully functional generator connected to a Mo-99/Tc-99m source vessel and producing Tc-99m. These procedures must be performed in the physical presence of a NorthStar representative or an individual certified by NorthStar to proctor the emergency procedures appropriate for an RSO. This training provided by a NorthStar representative or an individual certified by NorthStar to provide the training 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 that the requested individual is able to independently perform the radiation safety related duties of a RSO for the specific model of RadioGenix® System must be dated and signed by a NorthStar representative or an individual certified by NorthStar to provide the training and proctor the protocols for the new model. The applicant must provide training and experience documentation that the requested individual was authorized to be the RSO for the other model of the RadioGenix® System.

OR

(2) Two-step training and experience process. Is already authorized as the Radiation Safety Officer for a different model[18] of the RadioGenix® System.

i. Step one involves the requested individual successfully completing training on the differences between the two RadioGenix® System models in the areas of radiation safety, regulatory issues, administrative controls, and emergency procedures, using a cold unit. The requested 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 a NorthStar representative 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 a NorthStar representative.

AND

ii. After successful completion of step one of the training and experience, step two of the training and experience involves a review of the differences between the two RadioGenix® System models in the areas of radiation safety, regulatory issues, administrative controls, and emergency procedures, using a hot unit (producing Tc-99m). To complete step two of the training, the requested individual must successfully demonstrate the emergency procedures on the hot unit (producing Tc-99m) 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 a NorthStar

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

representative 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 that the requested individual is able to independently perform the radiation safety related duties of a RSO for the specific model of RadioGenix® System must be dated and signed by NorthStar.

OR

C. Has never been a RSO on a license that authorizes a RadioGenix® System or medical use or nuclear pharmacy use.

The requested individual must meet the criteria in paragraphs C.(1) or (2), or (3) below to be a RSO, and then meet the criteria in either paragraph C.(4) or (5) below to be the RSO for the specific model of the RadioGenix® System. Paragraph C.(4) describes the single-step training and experience process, and paragraph C.(5) describes the two-step training and experience process for the individual to be the RSO for a specific model of the RadioGenix® System.

(1) Is identified as the RSO on a Commission or Agreement State medical use or commercial nuclear pharmacy license or a medical use permit issued by a Commission master material license, or

(2) Is certified by a recognized specialty board (list posted on NRC's web site) in accordance with10 CFR 35.50, "Training for Radiation Safety Officer," or in 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist," or

(3) Meets the criteria in 10 CFR 35.50(d) as well as the criteria in 10 CFR 35.50(b) or 35.50(c).

AND

(4) Single-step training and experience process. In addition to C.(1), (2), or (3) above, successfully complete the following training and experience for the same model the applicant will possess and use, with such training and experience provided at a facility authorized to possess the same model of the RadioGenix® System, which is also a fully functional generator connected to a Mo-99/Tc-99m source vessel and producing Tc-99m:

(a) Training in the areas of radiation safety, regulatory issues, administrative controls, and emergency procedures for the specific model of the RadioGenix® System. This training is provided by a NorthStar representative or an individual certified by NorthStar to provide the training, and

(b) Satisfactorily demonstrate the emergency procedures applicable to the RSO on the generator connected to a Mo-99/Tc-99m source vessel and producing Tc-99m at least once in the physical presence of a NorthStar representative or an individual certified by NorthStar to proctor the emergency procedures appropriate for a RSO, and

(c) The requested individual has a written attestation that the individual has satisfactorily completed the requirements in C.(4) of this section, and is able to independently perform the radiation safety related duties of the RSO for the specific model of RadioGenix® System. The written attestation is dated and signed by a NorthStar representative or an individual certified by NorthStar to provide the training

and proctor the emergency procedure.

OR

(5) Two-step training and experience process. In addition to C.(1), (2), or (3) above, successfully complete the following two-step training and experience process for the same model the applicant will possess and use:

(a) Step one of the training and experience involves:

(i) Training in the areas of 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 a NorthStar representative; and

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

(iii) The requested individual has a written attestation that the individual has satisfactorily completed the requirements in C.(5)(a)(i) and (ii) using the cold unit. The written attestation is dated and signed by a NorthStar representative; and

(b) After successful completion of step one, step two of the training and experience involves:

(i) Review of the areas of radiation safety, regulatory issues, administrative controls, and emergency procedures for the specific model of the RadioGenix® System using a hot unit (producing Tc-99m). This training is provided by a NorthStar representative, and

(ii) Satisfactorily demonstrate the emergency procedures on the hot unit (producing Tc-99m) that are applicable to the Radiation Safety Officer at least once in the physical presence of a NorthStar representative who can proctor the emergency procedures appropriate for a RSO, and

(iii) The requested individual has a written attestation that the individual has satisfactorily completed the requirements in C.(5)(b)(i) and (ii) of this paragraph and is able to independently perform the radiation safety related duties of a RSO for the specific model of the RadioGenix® System. The written attestation is dated and signed by a NorthStar representative.

5.3. Supervised Individuals Operating the RadioGenix® System [10 CFR 30.33(a)(3) and 10 CFR 35.27]

The NRC has determined that individuals may work under the supervision of an authorized individual. The applicant must commit to provide training to all supervised individuals working under an authorized individual in the operation of any component or handling of licensed material associated

with the specific model of the RadioGenix® System commensurate with the individual's duties to be performed pursuant to 10 CFR 33(a)(3). To provide flexibility for the licensee, these individuals operating the RadioGenix® System will not be listed on the license.

Under this guidance, the applicant must commit that any individual that performs protocols will receive the model specific training and hands-on experience listed in the "Authorized Individuals" training and experience paragraphs 5.1.C.(6)(a) and (b). Or if the individual has already received training on a different model, the individual must receive training 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 that is included in the SER that can be obtained from NorthStar) in the physical presence of a NorthStar representative or an individual certified by NorthStar to proctor all the protocols. This training and hands-on work experience is to be on the same specific model of a RadioGenix® System which is also fully functional and connected to a Mo-99/Tc-9m source vessel and producing Tc-99m. The four protocols ("sterilization," "add source vessel," "remove source vessel," and "add/change NaOH and PSC") may be performed using a "dummy source vessel" (i.e., a vessel that does not contain radioactive material) provided the vessel contains material that can be detected in the event of loss of control of the liquid, e.g., contamination, leaks, or spills.

Under this guidance, the applicant must commit that the records of the successful completion of the protocol training and experience will be maintained for 3 years after the individual is no longer working under the supervision of an authorized individual. The record must include the model 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.

5.4. RadioGenix® System Administrator and RadioGenix® System Administrator Designee [10 CFR 30.33(a)(3)]

The RadioGenix® System is fully computer driven with specific protocols that must be performed in a set sequence and by individuals with specific radiation safety training and experience for each protocol. Because of this, the RadioGenix® System software application limits what protocols can be initiated, and the software hierarchy allows a System Administrator (system administrator account) to assign what protocols an individual with an account (i.e., user account) can initiate. These protocols may be different for different models of the RadioGenix® System.

The applicant is responsible for ensuring that an individual initiating a protocol meets the training and experience outlined in the SER for that protocol and the specific model of the RadioGenix® System. The NRC recognizes that the System Administrator may not always be available when there is an equipment failure that requires access to the service door and transfer door, and has identified another individual, the System Administrator designee, who has control of the key for the service door and transfer door in the absence of the System Administrator. To provide the licensee flexibility in training and appointing a replacement System Administrator and System Administrator designee, the individual will not be listed on the license for either of these positions, but the System Administrator designee will have the same training and experience criteria as the System Administrator.
The applicant must commit to the following:

1. Use the accounts and roles structure of the licensee's specific model of the RadioGenix® System's software to limit what protocol can be initiated by an individual.

2. Assign a unique user account to each individual using the system.

3. Designate an individual, who meets the following criteria, as the applicant's RadioGenix® System Administrator.

    - Successfully complete training in the radiation safety, the training and experience requirements of an authorized individual, the administrative controls, and the emergency procedures for the licensee's specific model of the RadioGenix® System. This training must be provided by a NorthStar representative or an individual certified by NorthStar to provide the training for that model, and

    - Satisfactorily demonstrate how to assign user roles in the RadioGenix® Application and identify when the RadioGenix® key for the service door and transfer door may be used by the licensee. The evaluation of this demonstration for the licensee's current model of the RadioGenix® System will be determined by a NorthStar representative or an individual certified by NorthStar to provide the training.

4. Designate an individual who has successfully completed the training and experience described in paragraph 5.4.3 above as the System Administrator designee.

5. Designate the following responsibilities to the applicant's RadioGenix® System Administrator:

    - Assign and maintain the user roles assigned to each user account in the RadioGenix® software application.

    - Ensure that an individual's assigned user role is limited to their qualified training and experience for the licensee's current model of the RadioGenix® System as outlined in this guidance.

6. Designate the following responsibility to the applicant's RadioGenix® System Administrator (or to the RadioGenix® System Administrator designee in the absence of the RadioGenix® System Administrator):

    - Ensure that the RadioGenix® key for the service door and transfer door is only used in the physical presence or in the direct audio or video communication of a NorthStar service representative.

7. Have the RadioGenix® System Administrator and System Administrator designee agree, in writing, to their respective responsibilities listed in paragraphs 5.4.5 and 6 above.

8. Maintain a record of the successful completion of the training and experience described above for the RadioGenix® System Administrator and RadioGenix® System Administrator designee. Records must be maintained for 3 years after the individual is no longer the RadioGenix® System Administrator or RadioGenix® System Administrator designee. The record must include the model of the RadioGenix® System being trained on, 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.

9. Maintain the signed record that the individual accepted the responsibilities of the RadioGenix® System Administrator or RadioGenix® System Administrator designee for 3 years after the individual is no longer the RadioGenix® System Administrator or RadioGenix® System Administrator designee.

6. License Commitments for the RadioGenix® System

The NRC has determined that the commitments provided below will provide the basis for an adequate radiation safety program for the use of the RadioGenix® System. Applicants may also submit alternative information and commitments for review on a case-by-case basis by NRC staff to make a licensing determination. The alternative information should include an explanation of why the applicant believes the alternative information demonstrates an adequate radiation safety program. The information will be included in the license and reviewed during routine inspections.

6.1. Routine and Non-routine Activities

The applicant must commit to the following:

1. Complying with the provisions of 10 CFR 35.200 (for the medical use applicant/licensee).

2. Following the manufacturer's daily and routine quality assurance procedures and routine maintenance processes for the licensee's specific model of the RadioGenix® System. Routine maintenance does not include checks or handling of any components that are normally inaccessible to the licensee such as behind the service door, transfer door, or enclosed in permanent shielding.

3. Using only manufacturer approved consumable replacement parts for the licensee's specific model of the RadioGenix® System. Authorized consumables are verified by integrated barcode and Radiofrequency Identification systems and the compatible kit part numbers are listed in the RadioGenix® System Operator Guide (Operator Guide).

4. Only performing routine activities specified in the manufacturer's current operator guide for the licensee's model in use. Examples of non-routine activities that are <u>not</u> authorized include: replacing fluid control device, component replacement /troubleshooting opening sterile fluid path, component replacement /troubleshooting opening non-sterile fluid path, replacing supporting hardware, etc.

5. Only allowing individuals specifically trained and authorized by the manufacturer for the licensee's specific model of the RadioGenix® System to perform non-routine maintenance activities.

6. Not modifying the device from the original design.

6.2. Molybdenium-99 Concentration Measurements at Time of Elution

The applicant must commit to measuring the Mo-99 concentration at the time of each elution to demonstrate compliance with 10 CFR 35.204 and if the concentration exceeds the limits in that section, to notify and report this to NRC in accordance with 10 CFR 35.3204. The applicant must also commit to maintain a record of the Mo-99 concentration tests in accordance with 10 CFR 35.2204.

[Note: In addition to having to report the concentration at the time of elution, the medical use licensee may not administer to humans a radiopharmaceutical that contains more Mo-99 than the concentration limit in 10 CFR 35.204.]

6.3. Training in Licensee Procedures

The applicant must commit to provide training in the licensee's procedures to all individuals involved in the use of the licensee's RadioGenix® System, commensurate with the individual's duties to be performed. This training is in addition to the training required for operating the licensee's RadioGenix® System and includes, as a minimum, performing surveys, responding to spills, determining maximum permissible concentrations of Mo-99 for each elution, and reporting of generator elution concentrations that exceed the limits in 10 CFR 35.204 within 7 days of the measurement.

6.4. Annual Emergency Procedures Refresher Training

The applicant must commit, under the guidance, to provide instructions in emergency procedures, initially and at least annually, to all individuals who operate the licensee's RadioGenix® System, as appropriate to the individual's assigned duties. The applicant must also commit that the records of this training be maintained for 3 years and as a minimum, the records include 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.

6.5. Revision to NRC's Training and Experience Guidance

If the NRC revises the training and experience criteria (for example, in subsequent revisions to this guidance), an individual who was previously considered qualified to be an authorized individual or the RSO for a specific model[19] of the RadioGenix® System does not have to meet the revised criteria for that model. However, the applicant, under this guidance, must commit that such individuals will receive additional training and experience before the first use of the RadioGenix® system if NorthStar made software, hardware, safety, or operational changes to that specific model as described in paragraph 7.2. This paragraph does not apply to individuals who must receive the additional training described in section 5.1.B and 5.2.B for the new model of the RadioGenix® System.

[Note: The Agreement State applicant or licensee should check with the Agreement State regulator to see if it will accept the notification commitments in Section 8.1 in lieu of an amendment when adding a qualified individual to the license.]

6.6. Specific Information on Radiation Safety Precautions and Instructions

The applicant must submit the information required by 10 CFR 35.12(d) [or 10 CFR 30.33(a)(2) and (3)]. The applicant may simplify its submission by confirming the following:

6.6.1. Surveys/survey meters/monitors: Because the RadioGenix® System can contain up to four Mo sources (each containing curie quantities of Mo-99) at any one time and elution of the generator involves replacing certain components on a frequent basis, workers have to routinely

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

open eight of the shielded cabinet doors and remove certain shields. Therefore, it is necessary for the licensee to routinely perform additional surveys to identify higher radiation fields than normally associated with conventional fission Mo-99/Tc-99m generators and system failures.

Therefore, applicants, under this guidance, must commit to develop, implement, and maintain survey procedures that as a minimum address:

1. Having radiation monitor(s)/survey meter(s) (in addition to the radiation monitor in the RadioGenix® System) with the ability to monitor and detect greater than expected transient radiation levels.

2. Ensure that each radiation monitor/survey meter is checked every day before use of the RadioGenix® System to verify it is calibrated and operational.

3. Ensure that a radiation monitor/survey meter is on, operating, the readout is visible and readable, and within arm's reach of the RadioGenix® System.

4. Surveying/monitoring must be performed immediately before approaching the RadioGenix® System, running any protocol, servicing the unit, and after removal of the final product.

5. Radiation monitor/survey meter has an audio indicator that is on and used when the monitor/meter readout is not in the operator's line of sight, after the surveys in item (4) above are performed.

6. If only one stationary radiation monitor/survey meter is used, it must meet all five criteria above and the readout is visible and readable before entering a potential radiation field.

Note: If the applicant/licensee believes there is equipment, such as an electronic personnel dosimeter with audible/alarm capabilities, that can take the place of the radiation monitor/survey meter under 10 CFR 30.33(a)(2), then the applicant/licensee needs to submit the basis for using that equipment in place of a radiation monitor/survey meter and their procedures for the use of the equipment.

6.6.2. Emergency Procedures

To reflect the unique components and operation of the RadioGenix® System, the applicant must, under the guidance, commit to develop, implement, and maintain written emergency procedures that are based on information specific to the specific RadioGenix® System's likely failure modes (this includes but is not limited to spills and loss of shielding). In addition to the standard components such as notifying the RSO the emergency procedures should also as a minimum address the following:

1. Specific examples in the emergency procedures that address when the licensee has to report under 10 CFR Part 20, 10 CFR 30.50, and 10 CFR Part 21.

2. Confirm compliance with the Operator Guide and additional safety recommendations from the manufacturer (such as revisions to the Operator Guide, safety recommendations and technical service bulletins) that improve and do not reduce safety. Specifically, the licensee will commit to the following:

- Performing an assessment to determine if a NorthStar representative is needed to assist in returning the licensee's RadioGenix® System to a serviceable state in situations when the stop button has been used.

- Contacting NorthStar for any system faults or perceived faults to determine the severity, and to provide corrective action, when needed.

- Contacting NorthStar for any fluid leaks that occur.

- Not removing permanent shielding or modify existing shielding, ensuring that all required shielding is in place prior to operating the device.

- Confirming that individuals will not under any circumstances tamper with, modify, or extract the internal materials of the device.

- Confirming that no open, used, or partially used disposables containing radioactive materials will be returned for evaluation without prior approval from NorthStar.

3. Written emergency procedures that provide instructions for responding to major and minor spills or leaks of radioactive materials. These could result from but are not limited to process line failures and leaks, general spills, spillage of source container contents, accidental withdrawal of tube from source container, dropped vials and columns, and operator/human errors.

   At a minimum, these procedures must, under the guidance:

   - Provide operator instructions in the event of an emergency or apparent system failure to:

     - Press and hold the stop button.

     - Close all cabinet doors (if possible) to ensure that any possible spills or leaks of radioactive materials are retained within the recessed cabinets and to reduce elevated radiation levels by maximizing use of available shielding in the cabinet doors.

     - Notify adjacent personnel in case of the leakage or spillage of radioactive material and elevated radiation levels in the vicinity of the RadioGenix® System, to evacuate the immediate vicinity and to establish access controls.

     - Address surveying personnel for contamination and the means for personnel decontamination, if necessary.

   - List all available emergency response equipment (e.g., spill kits).

   - Provide instructions for notifying personnel in the event of an emergency which include the NorthStar contact information.

7. Additional Applicant Commitments and Amendment Requests to Allow Future Radiation Safety Program Changes Without Additional Amendments.

[Note: The Agreement State applicant or licensee should check with the Agreement State regulator to see if it will accept the following commitments described in paragraphs 7.1 and 7.2 in lieu of an amendment.]

7.1. Permit Revisions to Existing RadioGenix® System Radiation Safety Programs to Conform to Future Changes in Licensing Guidance and Safety Recommendations from the Manufacturer.

Requesting authorization in accordance with the following guidance will permit a licensee to make certain changes under 10 CFR 35.26, "Radiation protection program changes," to the RadioGenix® System safety program that might otherwise require a license amendment. This authorization may also be used by the commercial nuclear pharmacy to make limited changes to the radiation safety program without needing to submit a license amendment.

The above licensing guidance and safety recommendations from the manufacturer may be revised as additional experience is gained regarding medical use of the RadioGenix® System by the regulator and manufacturer. A medical use or commercial nuclear pharmacy licensee already authorized to use the RadioGenix® System and committed by license condition to follow the provisions in the guidance and Operators Guide existing at the time of the commitment must apply for and receive an amendment to its license prior to making changes to conform to the revised guidance and additional radiation safety recommendations.

An applicant initially applying for authorization for medical or commercial nuclear pharmacy use of the RadioGenix® System (or a licensee applying later for an amendment to conform to revisions in this guidance) may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

(1) The revision is in compliance with the regulations of the NRC or Agreement State;

(2) The revision is based on the current guidance for the RadioGenix® System medical use under 10 CFR 35.1000 or commercial nuclear pharmacy use posted on the NRC website or the current operators manual and additional safety recommendations from the manufacturer;

(3) The revision has been reviewed and approved by the licensee's RSO and management;

(4) The affected individuals are instructed on the revised program before the change is implemented;

(5) The licensee will retain a record of each change for 5 years; and

(6) The record will include a copy of the appropriate website guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee's management representative who reviewed and approved the change.

If this authorization is approved, the authorization will be incorporated as a license condition in the license. The specific commitments will be included in the tie down condition.

7.2. Permit Individuals to Use the RadioGenix® System After Completing Training on Safety and Operational Changes Made by the RadioGenix® System Manufacturer.

With use and increased operational experience, NorthStar has, and is expected to continue to make software, hardware, or procedural changes to the RadioGenix® System that affect the safety and operation of the system. This section does not apply to changes that result in a new model number or significant engineering change. After these changes are made and before use at the licensee's facility, training will be provided for key individuals (i.e., at least one authorized individual, the RSO, supervised individuals initially using the updated RadioGenix® System, RadioGenix® System Administrator and RadioGenix® System Administrator designee). Under this guidance, all other individuals need to complete the training before they can use or supervise the use of an updated RadioGenix® System. This authorization may also be used by both medical use and the commercial nuclear pharmacy licensees.

With respect to training, the NRC has determined that the NRC applicant/licensee does not need to apply for an amendment to use the RadioGenix® System as a result of these changes provided the applicant or licensee commits to the program described below.

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

1. Additional training is provided for all authorized individuals, the RSO, RadioGenix® System Administrator and RadioGenix® System Administrator designee and supervised individuals if there are software, hardware, or procedure changes to the RadioGenix® System that affects the safety and operation of the RadioGenix® System.

2. Individuals must successfully complete the training on the changes prior to first operation of any component or first handling of licensed material associated with the updated system.

3. The training is provided by a NorthStar representative or an individual certified by NorthStar to provide the training on the changes to the safety and operation of the RadioGenix® System.

4. Records of the successful completion of this training are maintained for 3 years and that the record as a minimum includes 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.

If this authorization is approved, the authorization will be incorporated as a license condition in the licensee's license. The specific commitments will be included in the tie down condition.

8. Additional Applicant Commitments and Requesting Amendments to Allow Notifications without Additional Amendments.

The applicant or licensee may apply for the following license authorizations, which will permit the licensee to notify NRC of:

- Changes in experienced individuals;

- Installation of a new model of the RadioGenix® System using either the single-step or two-step training and experience process; or

- Successful completion of training and experience for a different model for an experienced or new authorized individual or experienced RSO already listed on the license for the RadioGenix® System.

The licensee can only use the notification process to add a new authorized individual to the license or update the training and experience qualifications for an authorized individual or RSO. The licensee must submit an amendment request to name a new RSO for the RadioGenix® System, and the NRC must review and approve the training and experience of the requested individual before listing the individual as the RSO for the RadioGenix® System.

If an authorized notification process is used correctly, the NRC will update the license at a later date to add the licensee's new authorized individual(s) to the license or documentation to the licensing file. If the licensee does not follow the commitments agreed to in a notification authorization, the NRC will inform the licensee that it cannot use the RadioGenix® System under that particular notification until the NRC receives the information required under this guidance.

[Note: The Agreement State applicant or licensee should check with the Agreement State regulator to see if it will accept the following commitments described in paragraphs 8.1 through 8.3 in lieu of an amendment.]

8.1 Notify NRC Within 30 Days when Experienced RadioGenix® System AUs and ANPs for the Same Model as the Licensee Begin Working at the Licensee's Facility.

The NRC recognizes that if an AU or ANP satisfies the training and experience listed in the NRC's licensing guidance for a specific model of the RadioGenix® System and is currently authorized[20] for that model, the individual should be allowed to work under a different medical use license using the same model without the submission of a license amendment. This authorization may also be used by the commercial nuclear pharmacy to permit ANPs to use the same model for which they are authorized[21] under a different license without the submission of a license amendment.

The commercial nuclear pharmacy or limited specific medical use applicant initially applying for authorization for the use of the specific model of the RadioGenix® System or an existing licensee applying for an amendment may request authorization to notify the NRC in the future that it has permitted an AU or ANP to work at its facility without the need for an additional license amendment.

To receive this authorization, the applicant (or licensee) shall commit to the following:

1. The AU or ANP meets the training and experience criteria listed in NRC's licensing guidance for the specific model of the RadioGenix® System; and

2. The AU or ANP is currently authorized[22] for use of the same model of the RadioGenix® System by a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State licensee of broad scope, a permit issued by a Commission master material license broad scope permittee, or a commercial nuclear pharmacy licensee authorized to list its own ANPs; and

[20] Information on the model number will be in a document referenced in the tie down condition.
[21] Information on the model number will be in a document referenced in the tie down condition.
[22] This authorization and information on the model number will be in a document referenced in the tie down condition.

3. The licensee must provide the NRC with a copy of the license or permit authorizing the individual for the RadioGenix® System and a copy of completion of the training for the specific model of the RadioGenix® System and the preceptor attestation that the individual successfully completed the training and experience requirement for the specific model and able to independently perform the radiation safety related duties of [Authorized User, or Authorized Nuclear Pharmacist] for the specific model of the RadioGenix® System; and

4. The licensee will provide documentation to the NRC for each AU or ANP of the above listed conditions no later than 30 days after the date that the licensee allows the AU or ANP to work as an AU or ANP for use of the same model of the RadioGenix® System.

If this authorization is approved, the authorization will be incorporated as a license condition in the licensee's license. The specific commitments will be included in the tie down condition.

8.2 Notify NRC Within 30 Days When an AU or ANP or Experienced RadioGenix® System Authorized Individual Successfully Completes Training Under the Single-Step Training and Experience Process for the Licensee's Model of the RadioGenix® System and Begins Working at the Licensee's Facility.

An applicant or licensee can apply for this notification process, but it can only be used once the notification process is authorized on the license to possess the RadioGenix® System. This notification applies only to individuals already recognized as authorized individuals under paragraphs 5.1.(a) or (b), or authorized users or authorized nuclear pharmacists under paragraphs 5.1.(c)(1) or (2). It does not apply to individuals whose training and experience must be reviewed by the NRC under the provisions of paragraphs 5.1.(c)(3), (4), or (5).

The single step training may be provided by a NorthStar representative or an individual certified by NorthStar. NorthStar certifies individuals to provide the training, proctor the training, attest to the successful completion of the training, and attest to the ability of trainees to function independently as an authorized individual on specific RadioGenix® Systems. If the licensee has access to an individual certified by NorthStar to provide these functions for the licensee's specific RadioGenix® System, then the training and experience could be provided for AUs and ANPs at the licensee's facility using the single-step training and experience process. If the applicant or licensee applied for and is authorized to use the notification process to document this training and experience, the licensee would not need to apply for an amendment to have already recognized AUs or ANPs or authorized individuals experienced on a different RadioGenix® System model[23] authorized to use the licensee's RadioGenix® System.

The commercial nuclear pharmacy or limited specific medical use applicant initially applying for authorization for the use of a specific model of the RadioGenix® System or an existing licensee applying for an amendment may request authorization to notify the NRC in the future that it has permitted an AU or ANP to work at its facility without the need for an additional license amendment.

[Note: If this notification process is used correctly, the NRC will revise the license to add the authorized individual(s) that are new to the license after NRC receives the appropriate documentation. If the licensee does not follow the commitments in this notification, the licensee will be notified that the individuals in question are not authorized to use the RadioGenix®

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

System until NRC determines they meet the training and experience requirements in this guidance.]

To receive this authorization, the applicant (or licensee) must commit to the following:

1. Provide the NRC with a copy of the license or permit authorizing the individual as an AU or ANP for the following uses:

> (a) authorized user for medical uses in 10 CFR 35.200, "Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required," or 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required," provided the authorized user successfully completed the training and experience requirements in 10 CFR 35.290(c)(1)(ii)(G); or
>
> (b) authorized nuclear pharmacist for the practice of nuclear pharmacy or identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacist; or

2. If the individual is already an authorized individual (AU or ANP authorized to use a RadioGenix® System) for a different model of the RadioGenix® System, provide the NRC with a copy of the documentation that the individual successfully completed the training and experience requirement for that model of the RadioGenix® System;

AND

3. Provide documentation of the successfully completion of training and experience for the licensee's specific model of the RadioGenix® System and the preceptor attestation that the individual successfully completed the training and experience requirement for the licensee's specific model and is able to independently perform the radiation safety related duties of [Authorized User, or Authorized Nuclear Pharmacist] for the specific model of the RadioGenix® System; and

4. Provide documentation that the individual providing the training and attestation is a NorthStar representative or an individual certified by NorthStar to provide the training, proctoring, and attestation for that specific model of the RadioGenix® System; and

5. Provide the documentation described above to the NRC for each AU or ANP no later than 30 days after the date that the licensee allows the AU or ANP to work as an AU or ANP for use of the licensee's model of the RadioGenix® System.

If this authorization is approved, the authorization will be incorporated as a license condition in the licensee's license. The specific commitments will be included in the tie down condition.

8.3 Notify NRC Within 30 Days of Installation of a new Model of the RadioGenix® System and Successful Completion of the Training and Experience Process for the Radiation Safety Officer and First Authorized Individual(s) to use the new Model.

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 or significant engineering change for the specific RadioGenix® System. The NRC is providing flexibility by permitting an existing RadioGenix® System licensee to use

either the single-step or two-step training and experience process to train authorized individuals and the RSO on the differences between the licensee's existing and new RadioGenix® System's radiation safety, regulatory issues, administrative controls, emergency procedures, and protocols.

The NRC has determined that an applicant applying for initial authorization to use a RadioGenix® System or an existing RadioGenix® System licensee can apply for this notification procedure for a future installation. The notification process can only be used if it is specifically authorized on the license. The medical and commercial nuclear pharmacy RadioGenix® System licensee does not need to apply for an amendment to possess and use a new model of the RadioGenix® System in the future, if the licensee commits to, is authorized for the notification process, and meets all the notification conditions described below.

[Note: Existing RadioGenix® System licensees currently authorized to notify NRC of the installation of a new RadioGenix® System model under the commitments for the training and experience criteria described in Revision 1 of this guidance are only authorized for the single-step training and experience process. A RadioGenix® System licensee that has not applied for and received prior authorization for the new model notification process described in this revision of the guidance (i.e., including both the single-step and two-step training and experience process) must submit an amendment request to install a new model under the two-step licensing process and the two-step training and experience process.]

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

1. For a licensee with a different model of the RadioGenix® System, notify the NRC within 30 days of installation and provide the model number of the new RadioGenix® System[24].

a. Ensure the following for the new model:

1. Additional training is provided for all authorized individuals, the RSO, RadioGenix® System Administrator and RadioGenix® System Administrator designee and supervised individuals.

2. All individuals listed in (a) must successfully complete the single-step or two-step training on the new model prior to their first operation of the system.

3. The training is provided by a NorthStar representative or an individual certified by NorthStar to provide the training on the new model of the RadioGenix® System.

4. Records of the successful completion of the single-step or two-step training are maintained by the licensee for the life of the license for the authorized users, the authorized nuclear pharmacists, and the RSO, and for 3 years for all others. 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.

    i. <u>For the single-step training and experience process</u>. For the authorized users, authorized nuclear pharmacists, and the licensee's listed RSO, the record must also include, a written attestation that the individual satisfactorily completed the

[24] The document notifying the NRC of the new model becomes part of the license when it is added to the tie down condition on the license.

requirements in 5.1.B.(1) or 5.2.B.(1) when authorized to use a different model of the RadioGenix® System or 5.1.C.(6) when an authorized user or authorized nuclear pharmacist on a medical use or commercial nuclear pharmacy license but not previously authorized to use a RadioGenix® System, and a second written attestation that the individual is able to independently perform the radiation safety related duties of a [Authorized User or Authorized Nuclear Pharmacist or the Radiation Safety Officer] for the specific model of RadioGenix® System. The written attestation is dated and signed by a NorthStar representative or an individual certified by NorthStar to provide the training and proctor the emergency procedure. The licensee must also provide a copy of the license or permit documentation identifying the individual as an authorized user or authorized nuclear pharmacist if the RadioGenix® System training was provided under the provisions of paragraph 5.1.C.(6).

ii. <u>For the two-step training and experience process</u>.

1. The first individuals (authorized individual(s), the Radiation Safety Officer, RadioGenix® System Administrator and RadioGenix® System Administrator designee and supervised individuals) to use the new model, must receive the NorthStar training provided by a NorthStar representative under the two-step training and experience process described in paragraph 5.1 and 5.2 of this guidance, and

2. All other individuals must receive the NorthStar training provided by a NorthStar representative or an individual certified by NorthStar to provide the training on the new model of the RadioGenix® System.

3. For the RSO and either the first authorized users or the first authorized nuclear pharmacists using the new model, the record must also include, two written attestations that the individual satisfactorily completed the appropriate requirements in 5.1.B.(2) or 5.2.B.(2) when authorized to use a different RadioGenix® System or 5.1.(C)(7) when the authorized users or authorized nuclear pharmacists listed on a medical use license or commercial nuclear pharmacy license are not previously authorized to use a RadioGenix® System for the cold unit and hot unit training, and the third written attestation that the individual is able to independently perform the radiation safety related duties of a [Authorized User or Authorized Nuclear Pharmacist or the Radiation Safety Officer] for the specific model of RadioGenix® System. The written attestations are dated and signed by a NorthStar representative. The licensee must also provide a copy of the license or permit identifying the individual as an authorized user or authorized nuclear pharmacist if the training was provided under the provisions of paragraph 5.1.(C)(7). and

4. For all other authorized users, and authorized nuclear pharmacists the record must also include, two written attestations that the individual satisfactorily completed the requirements in 5.1.B.(2) when authorized to use a different RadioGenix® System or 5.1.(C)(7) when not previously authorized to use a RadioGenix® System, and a third written attestation that the individual is able to independently perform the radiation safety related duties of a [Authorized User or Authorized Nuclear Pharmacist] for the specific model of RadioGenix® System. The written attestations are dated and signed by a NorthStar

representative or an individual certified by NorthStar to provide the training and proctor the emergency procedure. The licensee must also provide a copy of the license or permit identifying the individual as an authorized user or authorized nuclear pharmacist if the training was provided under the provisions of paragraph 5.1.(C)(7).

5. Provide the NRC with the training and experience documentation described above for the first authorized individual(s) and RSO to use the new model of the RadioGenix® System as part of the notification process for the new model. This documentation must be provided to the NRC no later than 30 days after the installation of the new RadioGenix® System. In this case, installation means the date the first individuals to use the RadioGenix® System complete their training or the physical installation of the new model is completed, whichever is later. The documentation for all other authorized users and authorized nuclear pharmacists is provided when they complete the training and experience described 5.1.B.(2) or 5.1.(C)(7).

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.

9. Notes to Licensees

9.1. Alterations to the RadioGenix® System

This licensing guidance is based on the engineering evaluations summarized in the SER. Under this guidance, medical or commercial nuclear pharmacy licensees cannot make any changes to the specific model of the RadioGenix® System or to the associated commitments by NorthStar that form the basis of the SER for that model. The manufacturer's commitments include, but are not limited to, software, internal components, reagent solutions, materials of construction, dimensions, tolerances, activity level, isotopes, radiation safety components, manufacturing process, Quality Assurance, and Quality Control program.

9.2. Use of Other Molybdenum-99/Technetium-99m Solutions or Other Generator Systems

The licensee's authorization, under this guidance, will only be for the use of the NorthStar Mo-99/Tc-99 solution in the RadioGenix® System. Use of any other Mo-99/Tc-99m solution with the RadioGenix® System or any other device with the NorthStar Mo-99/Tc-99m solution will require an amendment to a limited specific medical use or commercial nuclear pharmacy license. A broad scope licensee will have to perform its own engineering and radiation safety evaluation if any other Mo-99/Tc-99m solution is used with the RadioGenix® System or any other device is used with the NorthStar Mo-99/Tc-99m solution.

9.3. Change in Physical Conditions of Use

If the physical conditions of use exceed those evaluated in the SER for the specific model, the limited specific medical use licensee should request an amendment for the new conditions, and a broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

9.4. Waste Disposal

Most medical use licensees use the provisions of 10 CFR 35.92 to hold short half-life radionuclides such as Mo-99 and Tc-99m for decay-in-storage before disposal without regard to their radioactivity. Commercial nuclear pharmacies have a standard license condition that also permits decay-in-storage of short half-life radionuclides before disposal without regard to their radioactivity. Applicants are reminded that they must perform surveys to verify that the radioactivity cannot be distinguished from background before disposal. These surveys are necessary because impurities in the nonradioactive Mo used to produce Mo-99 may become activated and have longer half-lives.

10. Notes to Regulators

10.1. Inspection Frequency

A new licensee authorized for the RadioGenix® System will receive an initial inspection. An initial inspection is usually conducted within one year after a new license is issued. For an existing licensee, the regulator may perform a near-term onsite inspection for a significant licensing action. Significant licensing actions include, but are not limited to, the licensee recently increasing the types, quantities, or uses of radioactive material. Adding the RadioGenix® System to a medical use or commercial nuclear pharmacy license would be a significant change to its licensing program.

In accordance with Enclosure 1 of Inspection Manual Chapter 2800, medical use licenses authorizing emerging technology under 10 CFR 35.1000 are assigned a Priority 2 inspection code. Therefore, medical use licensees who are authorized the RadioGenix® System will be inspected every 2 years. The commercial nuclear pharmacy licensees who are authorized for the RadioGenix® System will also be inspected every 2 years. This is the normal inspection frequency for a commercial nuclear pharmacy.

10.2. Program Code

NRC regions should use program code 02240 for medical use licensees authorized to use the RadioGenix® System. The commercial nuclear pharmacies will continue to use the program code 02500.

10.3. License Authorizations

If the licensee has authorization for the new model notification, the NRC does not have to amend the license for the new model because the license does not identify the model[25]. However, the NRC will have to list any new authorized individual(s) on the license included in a notification. The notification process for an existing RadioGenix® System licensee installing a new model only permits the existing RSO on the license to be authorized for the new model and not an individual that was not listed on the license as the RSO. If the licensee intends to name a new individual as the RSO for the RadioGenix® System, the licensee must submit an amendment request.

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

10.3.1. Radionuclides, Form, Possession Limits* Used for the Single-Step or Two-Step Licensing Process.

Before issuance of the first step of a two-step license for an applicant that was never authorized for a RadioGenix® System and using the two-step training program, the applicant must submit a complete licensing application including documentation of the successful completion of step one training for the RSO and at least one authorized individual. The license will include the conditional "Authorization 9.A.1." in Table 2, which is in effect until the licensee meets all the training and experience requirements and conditions in license condition "AA" that removes the conditional use of the particular RadioGenix® System.

Before issuance of the license for an applicant that was never authorized for a RadioGenix® System and using the single step training program, the applicant must submit a complete license application and documentation for the RSO and at least one authorized individual of the successful completion of the training and experience and attestation that the individual can function independently. The license will include the "Authorization 9.A.2." in Table 2.

A current RadioGenix® System licensee intending to install a new model using the two-step training and experience process, but that is only authorized for the single-step training and experience process described in Revision 1 of this guidance, must submit a license amendment request to use the two-step licensing process in order to use the two-step training and experience process. In this case, the NRC will, upon submission of a complete amendment request, issue a conditional use license for the new model, replacing the licensee's current authorization with that in paragraph 9.A.1, the authorized individual current statements with license condition 12.b, and add license condition "AA" to the license. This licensee may apply at the same time for the notification process that includes the single-step and two-step training and experience process for use during future installation of a new RadioGenix® System model.

A RadioGenix® System licensee anticipating getting a new model in the future, but only authorized for the notification process using the single-step training and experience process described in Revision 1 of this guidance, can apply in advance to receive authorization for the new model notification process using both the single-step and two-step training and experience process. In this case, the NRC will replace the RadioGenix® System licensee's single-step license condition with the combined single-step/two-step license condition.

Table 2. License Authorizations for Radionuclides, Form, and Possession Limits.*

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. 1. 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). or 2. For 35.1000 medical use elution of Tc-99m in a NorthStar RadioGenix® System (or for the commercial nuclear pharmacy - For use of the NorthStar RadioGenix® 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/Tc-99m 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 separate 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.

10.4. License Conditions

If the licensee has authorization for the new model notification (license conditions YY.3 and ZZ), the region does not have to amend the license for the new model because the license does not identify the model. However, the NRC will have to list any new authorized individual(s) on the license included

in a notification. The notification process for an existing RadioGenix® System licensee installing a new model only permits the existing RSO on the license to be authorized for the new model and not an individual that was not listed on the license as the RSO. If the licensee intends to name a new individual as the RSO for the RadioGenix® System, the licensee must submit an amendment request.

The applicant or existing licensee using the two-step licensing process can use the standard authorization for the RSO because the RSO is responsible for the licensee's entire radiation safety program, and the conditional RadioGenix® System license authorization limits the RSO's oversight to only installation and training of the RadioGenix® System. The licensee's successful completion of the requirements in license condition "AA" permits full use of the RadioGenix® System and thus automatically expands the responsibilities of the RSO to the full use of the RadioGenix® System.

The NRC will remove the conditional authorizations for the use of the RadioGenix® System (9.A.1), license condition 12.b for the authorized individual(s), and license condition "AA," at some point after the licensee's successful completion of the requirements in license condition "AA." The RadioGenix® System license will then have authorization 9.A.2 and license condition 12.a for those individuals authorized to elute the new RadioGenix® System model. If the licensee has not applied for and received authorization for the new RadioGenix® System model notification process with the single-step and two-step training and experience processes, then the licensee that wants to use the two-step training and experience process in the future for a new model will need to submit a new amendment to use the two-step licensing process.

[Note: If this two-step licensing process is used correctly, and all the conditions in license condition "AA" are successfully met, the NRC will revise the license to give the authorized individuals full authorization to elute the RadioGenix® System, add the authorized individual(s) that are new to the license, and remove license condition "AA."

If the licensee does not provide all the information requested in License Condition "AA," the licensee will be notified that the individuals in question are not authorized to use the RadioGenix® System until the NRC determines that they meet the training and experience requirements in this guidance. If there are no qualified authorized individuals, then the RadioGenix® System can only be used for installation and training.]

The following license conditions should be added to the license:

Note: "12." is the number of the standard license condition that NRC uses for listing authorized individual(s).

Note to reviewers:

Condition 12.a is the traditional way to list fully trained individuals. This condition is used with the traditional use authorization in 9 A.2. These individuals may have successfully completed their training and experience criteria through either the single-step or the two-step process. The documentation of the completion of these processes must be received by the NRC in the original application, or by an amendment request, or through an authorized notification pathway. The authorized individual(s) listed on the license must have completed their training and experience for the licensee's current RadioGenix® System model. Any other authorized individual previously authorized for an earlier RadioGenix® System model must be removed from the license until his/her training and experience on the new model has been completed, documented, and provided to the NRC.

Condition 12.b is for listing an individual under the two-step licensing process. This condition is used with the conditional use authorization in 9 A.1. It applies to either a new licensee or an existing licensee that is not authorized for the notification process for the two-step training and experience process. The RadioGenix® System authorized individual(s) listed on the license must have successfully completed step one of the two-step training and experience process. All other authorized individuals previously authorized for an earlier RadioGenix® System model must be removed from the license until their training and experience on the new model have been completed, documented, and provided to the NRC.

License Condition:

12.a.1. [Authorized User physician's name] 10 CFR 35.100; 10 CFR 35.200; [other uses if appropriate]; for the elution of Technetium-99m from the RadioGenix® System. or

a.2. [Authorized Nuclear Pharmacist's name] for the elution of Technetium-99m from the RadioGenix® System.

12.b.1 [Authorized User physician's name] 10 CFR 35.100; 10 CFR 35.200; [other uses if appropriate]; for training on the RadioGenix® System – and in accordance with license condition AA for the elution of Technetium-99m from the RadioGenix® System. or

b.2. [Authorized Nuclear Pharmacist's name]; for training – and in accordance with license condition AA for the elution of Technetium-99m from the RadioGenix® System.

OR

Add new license condition "AA"

Note to reviewers: This license condition is placed on a new RadioGenix® System license (or on an existing license that does not authorize the notification process in license condition "ZZ" below) when the applicant (or licensee) uses the two-step licensing process. The licensee has to provide a complete license (or amendment) application that includes documentation of the successful completion of the first step of the two-step training and experience process for the authorized individual(s) and the RSO. License condition "AA" establishes the three criteria that must be met: (1) the completion of the training and experience process, (2) the documentation that must be submitted, and (3) the submission and acknowledgement condition.

Once the licensee successfully provides the documentation to meet these criteria, the licensee is authorized for the full use of the new RadioGenix® System, the named authorized individual(s) can perform elutions, and the RSO has oversight for the radiation safety program of the RadioGenix® System. After the licensee's successful completion of the requirements in license condition "AA," the NRC will revise the license to replace the conditional authorization 9.A.1 and the authorized user statements in 12.b and remove license condition AA.

If the licensee does not provide all the information requested in license condition "AA," the licensee will be notified that the individuals in question are not authorized to use the RadioGenix® System until the NRC determines that they meet the training and experience requirements in this guidance. If there are no qualified authorized individuals for the licensee's model of RadioGenix® System, then the RadioGenix® System can only be used for installation and training.

License Condition:

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). Additionally, when the criteria are met, the individuals meeting the criteria below are authorized for the elution of Technetium-99m from the RadioGenix® System and the RSO is responsible for the radiation safety program and overseeing the full use of the RadioGenix® System.

1. Before the first use of the RadioGenix® System, the **first** authorized individual(s) **to use** the RadioGenix® System have successfully completed both the first step and second step of the two-step training and experience process; and

2. The licensee provides written documentation to the NRC that is signed and dated by a NorthStar representative attesting that the first authorized individual(s) has satisfactorily completed the hot unit (producing Tc-99m) training requirements in paragraph 5.1.C.(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 of the RadioGenix® System, the RSO has successfully completed both the first step and second step of the two-step training and experience process; and

4. The licensee provides written documentation to the NRC that is signed and dated by a NorthStar representative attesting that the RSO has satisfactorily completed the hot unit (producing Tc-99m) training requirements in paragraph 5.2.C.(5) and is able to independently perform the radiation safety related duties of a RSO for the specific model of RadioGenix® System; and

5. The licensee receives **confirmation** from the NRC that the documentation was received.

6. The licensee provides the NRC with the training and experience documentation described above for **all other authorized individuals** (except the first authorized individual(s) to use the new model of the RadioGenix® System) when they complete their training and experience requirements described 5.1.C.(7).

License Condition:

WW. The licensee cannot modify the RadioGenix® System from the manufacturer's design and must only use manufacturer approved consumable replacement parts.

The following license conditions, if applicable, should be added to the license:

License Condition:

XX. **The licensee applied for and is authorized to revise its radiation safety program to:**

1. Permit revisions to existing RadioGenix® System radiation safety programs to conform to

future changes in licensing guidance and additional safety recommendations from the manufacturer.

2. Permit individuals who have received training resulting from safety and operational changes to the RadioGenix® System to use the RadioGenix® System after these changes are made by the manufacturer.

Note to Reviewers: If the license contains license condition YY.1 or 2 to notify NRC within 30 days when experienced AUs and ANPs for the same RadioGenix® System model at the licensee's facility begin working at the facility, the licensee may use these provisions to add new authorized individual(s) to the license. If the licensee has the authorization YY.1 and 2 on the license, the commitments will be in the tie down condition. If the licensee does not have this authorization on the license, an amendment request will be needed to add new individuals to the license.

License Condition:

YY. **The licensee applied for and is authorized to:**

1. Notify NRC within 30 days when experienced AUs and ANPs for the same RadioGenix® System model at the licensee's facility begin working at the facility.

2. Notify NRC within 30 days when an AU or ANP or experienced RadioGenix® System AU or ANP successfully received training under the single-Step training and experience process on the licensee's model of a RadioGenix® System and begins working at the facility.

3. Notify NRC within 30 days when a new model of the RadioGenix® System is installed at the facility and ensure training is completed before each individual's first use of the new model.

Note to Reviewers: License condition ZZ is only included on the license if the applicant applied for and is authorized for YY.3. above. Any other authorized individual previously authorized for an earlier RadioGenix® System model must be removed from the license until his/her training and experience on the new model has been completed, documented, and provided to NRC.]

License condition:

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

1. Additional training is provided for all authorized individuals, the RSO RadioGenix® System Administrator and RadioGenix® System Administrator designee, and supervised individuals.

2. All individuals listed in paragraph 1 above must successfully complete either the single-step or two-step training on the new model prior to their first operation of the system.

   a. For the RSO and **the first** authorized individual(s) **to use** the new model, the single-step training [5.2.(B).(1) or 5.1.(B).(1), respectively] or the two-step training [5.2.(B).(2) or 5.1.(B).(2), respectively] must be provided by a NorthStar representative.

i. Each individual's documentation for the training must include all attestations of the successful completion of the training and the ability to independently perform the radiation safety related duties of a/an [Authorized User, Authorized Nuclear Pharmacist, or the Radiation Safety Officer] for the specific model of RadioGenix® System. The written attestations must be dated and signed by a NorthStar representative.

iii. Documentation of successful completion of the training for the first authorized individual(s) to use the new model and the RSO must be submitted to the NRC with the installation notification process.

b. For **all other individuals** the single-step training [5.1.(B)(1)] or the two-step training [5.1.(B)(2)] is provided by a NorthStar representative or an individual certified by NorthStar to provide the training on the new model of the RadioGenix® System.

i. Each authorized individual's documentation of successful completion for the training must include all attestations of the successful completion of the training and the ability to independently perform the radiation safety related duties of an [Authorized User, or Authorized Nuclear Pharmacist,] for the specific model of RadioGenix® System dated and signed by a NorthStar representative or an individual certified by NorthStar.

ii. Documentation of successful completion of the training for the authorized individual(s) must be submitted to the NRC within 30 days of completion of the training.

2. Records of the successful completion of the single-step or two-step training processes are maintained by the licensee for the life of the license for the authorized users, the authorized nuclear pharmacists, and the RSO; and for 3 years for all other individuals. 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 training. These records will also include the dated and signed attestations for the authorized individual(s) and RSO.

Note: "WW, XX, YY, and ZZ" are the place holders for the actual license condition number(s).

AND

Note: The specific commitments for the above authorizations in sections 7. and 8. and other commitments made by the licensee in section 6. 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.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

Attachment 1 – Revision History for "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 Number	Description of Change	ADAMS Accession Number	Issue Date
1	Document was revised to: - Address the RadioGenix® System Model 1.2, which contained hardware, software and firmware changes that require additional training, operational changes, and safety procedures.	ML20009C049	January 15, 2020
N/A (Temporary Addendum)	Issued to provide the option of a two-step training and experience program process and a two-step licensing process for use during the COVID-19 public health emergency.	ML21134A082	September 29, 2020
2	Document was revised to: 1. Integrate the Temporary Addendum into the existing text of Revision 1 of the licensing guidance. 2. Include the option of the two-step training and experience and two-step licensing processes permanently available to the NRC licensees, while retaining the single-step licensing and training and experience processes. 3. Rearrange some of the text and rephrased some of the concepts to provide additional clarification, provide additional notes to applicants, licensees, and license reviewers, and make minor editorial changes to provide a coherent document.	ML21350A064	December 17, 2021