



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

January 16, 2020

ALL AGREEMENT STATES

AVAILABILITY OF REVISION 1 OF THE NORTHSTAR MEDICAL RADIOISOTOPES, LLC, RADIOGENIX™ MOLYBDENUM-99/TECHNETIUM-99M GENERATOR SYSTEM, LICENSING GUIDANCE FOR MEDICAL USE LICENSEES, MEDICAL USE PERMITTEES, AND COMMERCIAL NUCLEAR PHARMACIES (STC-20-006)

Purpose: To notify the Agreement States of the publication of revision 1 of the NorthStar Medical Radioisotopes, LLC, RadioGenix™ Molybdenum-99/Techneium-99m Generator System Licensing Guidance for Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies.

Background: On February 2018, the U.S. Food and Drug Commission approved the NorthStar Medical Radioisotopes, LLC, RadioGenix™ Molybdenum-99/Techneium-99m Generator System (hereafter the RadioGenix™ System), and the U.S. Nuclear Regulatory Commission (NRC) published the licensing guidance for the RadioGenix™ System models 1.0a and 1.1. The RadioGenix™ System was determined to be regulated for medical use under Title 10 Code of Federal Regulation Part 35 Subpart K "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." At that time, it was also determined that a commercial nuclear pharmacy that is not specifically authorized for the RadioGenix™ System would 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. The guidance document provided applicants with an acceptable means of satisfying the requirements for a license for the use of the RadioGenix™ System models 1.0a and 1.1 and was not intended to be the only means of satisfying requirements for a license.

Subsequently NorthStar Medical Radioisotopes, LLC, developed the RadioGenix™ System Model 1.2 which contains hardware, software, and firmware changes that require additional training, operational changes and safety procedures. As a result, a working group consisting of NRC and Agreement State staff developed revision 1 of the licensing guidance.

Discussion: Enclosed is revision 1 of the RadioGenix™ System licensing guidance. The major changes to the guidance are: 1) the inclusion of the model designations in applying for a license, but not listing the model number on the license; 2) use of the Safety Evaluation Report (SER) to include information on new models, including a table in the SER describing the specific model number with its required training and experience and the appropriate version of the licensing guidance for that model; 3) revision of the training and experience section of the licensing guidance to clarify the type of training needed to use and operate both the current and future models; 4) adding new optional programs that the applicant can apply for and receive authorization for without future amendments; 5) restructuring of the guidance to move the optional programs (e.g., Sections 7.4 and 7.5 in the original guidance) into Sections 7 and 8 of the commitment sections of the guidance; 6) adding new license conditions; and 7) clarifying when the authorizations are listed on the license and when the commitments are included in the tie down conditions of the license.

The guidance document will be posted on NRC's public Web site at:

<https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>.

The SER can be accessed through the NRC's Sealed Source and Device Registry home page at: (<https://scp.nrc.gov/ssdr.html>). If you have any questions, please contact me at 301-415-0324, or Donna-Beth Howe at (301) 415-5441 or donna-beth.howe@nrc.gov.

Sincerely,

/RA/

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State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:

Revision 1 of NorthStar Medical
Radioisotopes, LLC RadioGenix™
Molybdenum-99/Technetium-99m
Generator System Licensing Guidance for
Medical Use Licensees, Medical Use
Permittees, and Commercial Nuclear
Pharmacies

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

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

January 15, 2020

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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 NorthStar RadioGenix® Molybdenum-99/Technetium-99m Generator System (hereafter the RadioGenix® System) (Mo-99/Tc-99m). It only applies to medical licensees or commercial nuclear pharmacy licensees that possess and use the RadioGenix® System to produce 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 *Code of Federal Regulations* (10 CFR) 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 bulk doses of Tc-99m radiopharmaceuticals, rather than use the NorthStar RadioGenix® System.

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 the particular RadioGenix® System 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. It 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. An SER will be issued for each model of RadioGenix® System. The SER identifies the differences between past and present models, and the appropriate version of the licensing guidance and the resulting differences in protocol and safety training for each model. The SER is located on the Sealed Source and Device Registry website so that it is accessible to NRC and Agreement State license reviewers and inspectors. Applicants may request a copy of the SER from NorthStar.

Note: As NorthStar updates the NorthStar RadioGenix® System from one model number to another, this licensing guidance may not change, but different training may be needed for the new model. The associated SER will describe appropriate training for each model. 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 this requirement, the applicant must provide additional documentation of the successful completion of new training for the authorized individuals, Radiation Safety Officer, 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.

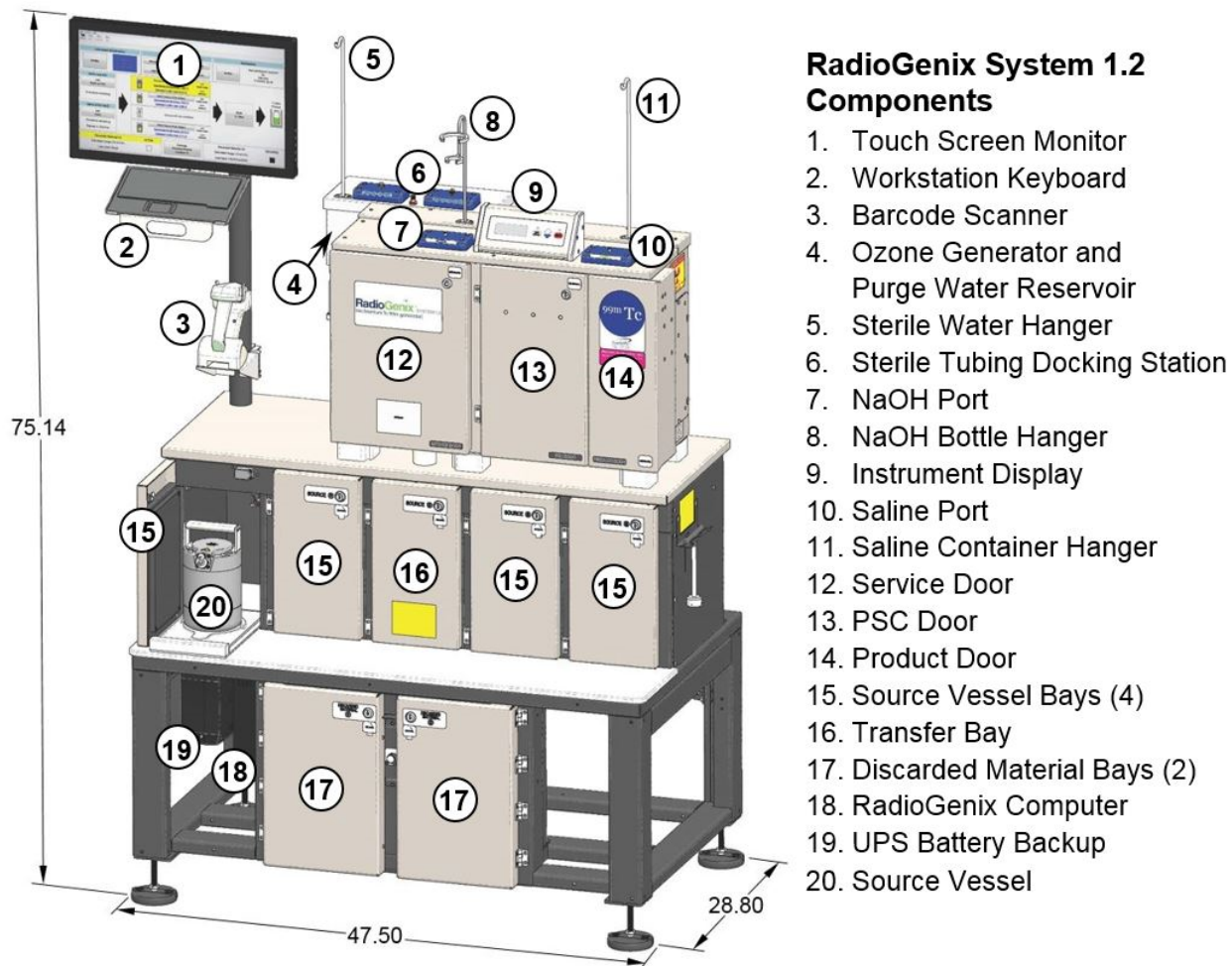


Figure 1. The NorthStar RadioGenix® Mo-99/Tc-99m Generator System Model 1.2¹ with the major components labeled. Component 20, the source vessel (on the left and inside the first of the four components numbered 15), is approximately the same size as a conventional generator containing fission-produced Mo-99. The generator system weighs 3,011 pounds and is approximately 48 inches wide, 29 inches deep, and 75 inches tall.

Mo/Tc-99m flow through the NorthStar RadioGenix® Mo-99/Tc-99m Generator System

- The Mo/Tc-99m liquid is received inside its shielded source vessel (component 20), which may also be referred to as the source transport vessel. The vessel is placed in one of the four “Source Vessel Bays” (components 15) on the middle row.

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

- 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 12) on the top row.
- The Mo/Tc-99m is moved behind the “PSC Door” (component 13) 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 16)
 - The Tc-99m adheres to the column behind the “PSC Door” (component 13)
- 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 13) and then through a second column behind the “Product Door” (component 14) 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 17) on the bottom row.
- At the end of the process the Mo is returned to the source vessel (component 20) for reuse.
- Once the Mo-99 is no longer usable or reaches its expiration date, it is returned in component 20 the source vessel (or source transport vessel) to the manufacturer.

Protocol

The term “protocol” used by NorthStar 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® series of pumps and operational steps. The protocols for initialize system, add/change reagent kit, add source vessel, produce Tc-99m, remove source vessel, sterilization, and exchange used reagent 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

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 such 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 regulated under 10 CFR Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."² Therefore, this licensing guidance applies to the medical use applicants and licensees that request or possess the NorthStar RadioGenix® System.

² This regulation at 10 CFR Part 35, Subpart K, 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

The unique design, construction, materials specifications, and use features that differentiate the RadioGenix® System from a conventional fission Mo-99/Tc-99m generator results in the need for additional information and commitments that 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

This guidance provides applicants with an acceptable means of satisfying the requirements for a license for the use of the RadioGenix® System and is not intended to be the only means of satisfying requirements for a license. While the guidance refers generically to the RadioGenix® System, under 10 CFR 30.33(a)(3), the applicant must document the model that will be possessed and used, but the NRC will not include the model number on the license. 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 licenses issued pursuant to 10 CFR 35.1000 must still meet the general requirements in Part 35, Subparts A, B, C, L, and M, except as specified in this guidance. In addition, several provisions in 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.

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. For example, the following provides the format for an acceptable request.

Radionuclides, Form, Possession Limits

Radionuclides: (NRC Form 313 Item 5)	A. Molybdenum-99/Technetium-99m B. Depleted Uranium*
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. 7.5 curies of Molybdenum-99/Technetium-99m per source vessel, not to exceed 40 curies total (includes waste and decayed source vessels)** B. 162 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*** NorthStar RadioGenix® System." or For the commercial nuclear pharmacy applicants – "Elution of Technetium-99m in a Model 1.2*** NorthStar RadioGenix® System." B. For shielding in a NorthStar RadioGenix® System.

* 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.

**The Safety Evaluation Report should be checked to see if the maximum possession limit per source vessel listed changed based on review of changes between RadioGenix® System models. 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.

*** The applicant should clearly identify the correct model of the NorthStar RadioGenix® System to be used.

4.3. Facility Address and Description [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.

4.4. 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 that the radiation levels will vary at different times based on the set up and the Tc-99m production processes, and in different areas around the unit. If the RadioGenix® System can be accessed on all 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 individuals and the Radiation Safety Officer (RSO). 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 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 his/her 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. [Note: The NRC Form 313A series of forms were revised to

conform with the January 2019 revisions to 10 CFR Part 35 and they will temporarily be unavailable while the U.S. Office of Management and Budget is approving them. Either the interim training and experience instructions or the OMB approved NRC Form 313A series of forms can be found on the NRC public Web site for the Medical Use Licensee Toolkit (<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:

A. Is:

- (1) An **authorized user** that the applicant is requesting authorization to use the same model of the RadioGenix® System for which the individual is already authorized³ 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) An **authorized nuclear pharmacist** that the applicant is requesting authorization to use the same model of the RadioGenix® System for which the individual is already authorized⁴ 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 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;
- (3) Already authorized for a different model⁵ of the RadioGenix® System, and the individual successfully completed training on the differences between the two RadioGenix® System models’ operation, safety, and emergency procedures. The individual also successfully performed 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 or an individual certified by NorthStar to proctor all the protocols of the different model of the RadioGenix® System. This training provided by NorthStar 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, Authorized Nuclear Pharmacist] for the specific model of RadioGenix® System must be dated and signed by NorthStar or an individual certified by NorthStar to provide the training and proctor the protocols. The

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

⁴ Information on the model number will be in a document referenced in the tie down condition.

⁵ Information on the model number will be in a document referenced in the tie down condition.

applicant must provide training and experience documentation that the authorized individual was authorized to use the other model of the RadioGenix® System.

OR

- B. (1) 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) 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 individual may also be identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy authorized to identify authorized nuclear pharmacist; or
- (3) 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) Meets the requirements in 10 CFR 35.55, "Training for an authorized nuclear pharmacist," or
- (5) 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 Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist."

AND

- (6) In addition to B(1) through (5) above, 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 NorthStar or an individual certified by NorthStar to provide the training,

AND

- (b) Perform each of the protocols (i.e., initialize system, produce Tc-99m, add/change reagent kit, exchange used reagent container, add source vessel, remove source vessel, and sterilization) 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,” and “add/change reagent kit”) 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) Has a written attestation, that he/she has satisfactorily completed the requirements in B.(6) of this section and is able to independently operate and perform the radiation safety related duties of an authorized individual for the specific model of the RadioGenix® System. The written attestation must be dated and signed and it should be signed by NorthStar or an individual certified by NorthStar to provide the training and proctor the protocols. Because there were no units of the RadioGenix® System approved for medical use or commercial nuclear pharmacy use in the United States at the time the original licensing guidance was published, there are no preceptors other than NorthStar and individuals certified by NorthStar to provide the training and proctor the protocols available to sign attestations. Therefore, the NRC is not requesting written attestation from others until February 2023 (5 years after issuance of the original guidance). NRC will continue to review the availability of preceptors and may revise this guidance if it determines that sufficient preceptors have become available.

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 individuals are qualified to be the RSO. 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 following:

- A. Is identified as an RSO for the same model of the RadioGenix® System⁶ for which the applicant is requesting. The 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 Radiation Safety Officer was qualified to be an RSO for the same model of the RadioGenix® System.

OR

- B. Is already authorized as an RSO for a different model⁷ of the RadioGenix® System, and the individual successfully completed training on the differences between the two RadioGenix® System models' radiation safety, regulatory issues, administrative controls, and emergency procedures. The individual also successfully practiced the emergency procedures applicable to the RSO that are different from the original emergency procedures at least once 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 the individual is able to independently perform the radiation safety related duties of an RSO for the specific model of RadioGenix® System must be dated and signed by NorthStar 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 RSO was authorized to be the RSO for the other model of the RadioGenix® System.

OR

- C. (1) Is identified as an 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 listed on NRC's web site under 10 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(b)(1), 35.50(c)(1), or 35.50(c)(2),

AND

- (4) In addition to C (1) through (3) above, successfully completed the following training and experience for the same model the applicant will possess and use and is provided at a

⁶ Information on the model number will be in a document referenced in the tie down condition.

⁷ Information on the model number will be in a document referenced in the tie down condition.

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 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 practice the emergency procedures applicable to the RSO at least once in the physical presence of a NorthStar representative or an individual certified by NorthStar to proctor the emergency procedures appropriate for an RSO, and
- (c) The proposed Radiation Safety Officer has a written attestation that he/she has satisfactorily completed the requirements in C.(4) of this section, and is able to independently perform the radiation safety related duties of a RSO for the specific model of RadioGenix® System. The written attestation is dated and signed by NorthStar or an individual certified by NorthStar to provide the training and proctor the emergency procedure. Because there were no units of the RadioGenix® System approved for medical use or commercial nuclear pharmacy use in the United States at the time the original licensing guidance was published, there are no preceptors other than NorthStar and individuals certified by NorthStar to provide the training and proctor the emergency procedure tasks available to sign attestations. Therefore, the NRC is postponing requesting written attestations from others until February 2023 (5 years after issuance of the original guidance). The NRC will continue to review the availability of preceptors and may revise this guidance if it determines that sufficient preceptors have become available.

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 shall receive the model specific training and hands-on experience listed in the "Authorized Individuals" training and experience paragraphs 5.1.B.(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 also successfully performed 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-99m source vessel and producing Tc-99m. The four protocols ("sterilization," "add source vessel," "remove source vessel," and "add/change reagent kit") 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 shall 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.

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 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 specific model of the RadioGenix® System. This training shall 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 shall 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 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 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 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 shall 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 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 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 model in use. Examples of non-routine activities that are not 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 specific model of the RadioGenix® System to perform non-routine maintenance activities.
6. Not modifying the device from the original design.

6.2. Mo-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 report this to NRC within 7 days. The applicant must also commit to maintain a record of the Mo-99 concentration tests in accordance with 10 CFR 35.2204. If the concentration of Mo-99 exceeds the limits in 10 CFR 35.204, then the license must commit to making the necessary report and notification in accordance with 10 CFR 35.3204. [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 RadioGenix® System, commensurate with the individual's duties to be performed. This training is in addition to the training required for operating the 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 shall commit, under the guidance, to provide instructions in emergency procedures, initially and at least annually, to all individuals who operate the RadioGenix® System, as appropriate to the individual's assigned duties. The applicant shall 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 staff 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 RSO for a specific model⁸ of the RadioGenix® System will 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. This paragraph does not apply to individuals who must receive the additional training described in section 5.1.A(3) 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 to see if it will accept the following commitments in lieu of an amendment.]

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 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 shall 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.

⁸ Information on the model number will be in a document referenced in the tie down condition.

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 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 Requesting Amendments to Allow Future Radiation Safety Program Changes Without Additional Amendments.

[Note: The Agreement State applicant or licensee should check with the Agreement State to see if it will accept the following commitments described in paragraphs 7.1 through 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 Radiation Safety Officer 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. 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 Radiation Safety Officer, 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 licensee/applicant 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 Radiation Safety Officer, 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 NorthStar 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 amendments that will permit the licensee to notify NRC of changes in experienced individuals and installation of a new model of the RadioGenix® System. [Note: The Agreement State applicant or licensee should check with the Agreement State 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 AUs and ANPs Begin Working at the 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 authorized⁹ for that model, the individual should be allowed to work under a different 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 authorized¹⁰ 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 authorized¹¹ 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
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

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

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

¹¹ This authorization and information on the model number will be in a document referenced in the tie down condition.

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 a New Model of the RadioGenix® System is Installed at the Facility.

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

The particular model of Radiogenix™ System that the licensee has and that the individuals using the new model are properly trained on should be clearly specified in the license application. However, the NRC has determined that the NRC licensee/applicant (both a medical use and commercial nuclear pharmacy licensee) does not need to apply for an amendment to possess and use the new model of the RadioGenix™ System provided the applicant or licensee commits to and is authorized for the notification process and program described below.

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

1. Notify the NRC within 30 days of installation, of the new model of the RadioGenix® System¹².
2. Ensure the following for the new model:
 - a. Additional training is provided for all authorized individuals, the Radiation Safety Officer, RadioGenix® System Administrator and RadioGenix® System Administrator designee and supervised individuals.
 - b. Individuals listed in (a) must successfully complete the training on the new model prior to first operation of the system.
 - c. The training is provided by NorthStar or an individual certified by NorthStar to provide the training on the new model of the RadioGenix® System.
 - d. Records of the successful completion of this training are maintained by the licensee for the life of the license for the authorized users, the authorized nuclear pharmacists, and the Radiation Safety Officer, and for 3 years for all others. The record as a minimum includes the model number of the RadioGenix® System, a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction. For the authorized users, authorized nuclear pharmacists, and Radiation Safety Officer, the record must also include, a written attestation that the individual satisfactorily completed the requirements in 5.1.A(3) or 5.2.B of this section, and is able to independently perform the radiation safety related duties of a [Authorized User, Authorized Nuclear Pharmacist, or Radiation Safety Officer] for the specific model of RadioGenix® System. The written attestation is dated

¹² 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.

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

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

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 Mo-99/Tc-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

10.3.1. Radionuclides, Form, 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. 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 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

The following license conditions should be added to the license:

12. [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

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

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

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

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

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.

YY. The licensee applied for and is authorized to:

1. Notify NRC within 30 days when experienced AUs and ANPs begin working at the facility.
2. 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.

ZZ. **[Note:** This license condition is only included on the license if the applicant applied for and is authorized for YY.2. above.] When a new model RadioGenix® System is installed,

the licensee shall ensure the following before first use of the new model RadioGenix® System:

1. Additional training is provided for all authorized individuals, the Radiation Safety Officer, RadioGenix® System Administrator and RadioGenix® System Administrator designee and supervised individuals.
2. Individuals must successfully complete the training on the new model prior to their first operation of the system.
3. The training is provided by NorthStar 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 this training are maintained by the licensee for the life of the license for the authorized users, the authorized nuclear pharmacists, and the Radiation Safety Officer, and for 3 years for all others.
5. The record as a minimum includes the model number of the RadioGenix® System, a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction. For the authorized users, authorized nuclear pharmacists, and Radiation Safety Officer, the record must also include, a written attestation that the individual satisfactorily completed the requirements in 5.1.A(3) or 5.2.B of this section, and is able to independently perform the radiation safety related duties of a [Authorized User, Authorized Nuclear Pharmacist, or Radiation Safety Officer] for the specific model of RadioGenix® System. The written attestation is dated and signed by NorthStar or an individual certified by NorthStar to provide the training and proctor the procedures.

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 Information Services 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: oir_submission@omb.eop.gov.

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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.