NRC FORM 699 (03-2013)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

DATE OF SIGNATURE: 06/11/2018

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
Brain Hardesty, R.Ph., MBA, RSO	6/11/2018	☐ E-MAIL ☑ TELEPHONE ☐ INCOMING ☐ OUTGOING
E-MAIL ADDRESS: bhardesty@rpofindy.com	TELEPHONE NUMBER: (317) 347-0102	

ORGANIZATION	DOCKET NUMBER(S)
Guardian Pharmacy of Indianapolis Nuclear, LLC	030-37428
LICENSE NUMBER(S)	**CONTROL NUMBER(S)**
13-32637-01MD	602705

SUBJECT

License Amendment to add a Northstar Medical Radioisotopes, Mo-99/Tc-99 Generator System

SUMMARY

This is in reference to your application dated March 18, 2018, to add the NorthStar RadioGenix™ Molybdenum-99/Technetium-99m Generator System to your license and our telephone conversation on June 11, 2018, to discuss additional information that will be needed to complete our review. As discuss, please provide the following additional information regarding your request:

(See Attached Requests For Information)

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ACTION REQUIRED (IF ANY)

As discussed, a dated and signed response to this letter will be provided on or before, May 15, 2017. You may submit your response with the reference control number 602705 via email (letter must be signed by management and scanned into a pdf format). We will continue our review upon receipt of the requested information. If you have any questions, please feel free to contact me at (630) 829-9830 or cassandra.frazier@nrc.gov.

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NAME OF PERSON DOCUMENTING CONVERSATION

Cassandra E. Frazier

SIGNATURE

6/11/2018

ATTACHMENT

1. Facility Description

As discussed in our telephone conversation, this is to confirm that there are no rooms above or below the RadioGenix™ System.

2. RadioGenix™ System Administrator and Administrator Designee

In regards to the designation of Brian Hardesty, R.Ph, as the RadioGenix™ System Administrator and the mention of a System Administrator designee, please revise the designation to state 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**. We will identify a System Administrator designee, who has control of the service door and **transfer door** key in the absence of the System Administrator.

In reference to your commitments to designate an individual, who meets the criteria, as your System Administrator, please provide the following commitments:

A. 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.

B. Ensure that assigned user roles are limited to their qualified training and experience **as outlined in the guidance.**

C. 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.

3. License Commitments for the RadioGenix™ System

A. In reference to routine and non-routine activities in the use of your RadioGenix™ System, please commit to the following:

(1). Complying with the provisions of 10 CFR 35.200.

(2). Following the manufacturer's daily and routine quality assurance procedures and routine maintenance processes. 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. 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.

(4). Only performing routine activities specified in the manufacturer's current operators manual 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 to perform non-routine maintenance activities.

(6). Not modifying the device from the original design.

B. For Molybedenum-99 concentrations at time of elution, please commit to:

Maintaining a record of the Mo-99 concentration tests for 3 years. The record will include for each measured elution of Tc-99m, the ratio of the measures expressed as kilobecquerel of Mo-99 per megabecquerel of Tc-99m (or microcuries of Mo per millicurie of Tc-99m), the time and date of the measurement, and the name of the individual who made the measurement of the results of the test.

C. For Updated training for individuals resulting from safety and operational changes to the RadioGenix™ System:

Confirm that 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 affect the safety and operation of the generator.

D. Revisions to NRC's Training and Experience Criteria Guidance:

Please revise your commitment to read: If the NRC revises the training and experience criteria, an individual who was previously considered qualified to be an authorized individual or RSO for the RadioGenix™ System will not have to meet the revised criteria, but we commit that such individuals will have to receive training and experience on **new or different RadioGenix™ System to include** software, hardware, safety, and operational changes before the first use of the system.

E. Surveys/Survey Meters/Monitors:

Please revise and/or include in your commitments the following statements:

(1). Have radiation monitor(s)/survey meters (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 on, operating, **the readout is visible and readable**, and within arm's reach of the RadioGenix™ System.

(3). Radiation monitor/survey meter have 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 the above item (4).

(4). Please confirm that if a (only one) stationary radiation monitor/survey meter is used, it **must meet all five criteria above** and the readout must be visible and readable before entering a potential radiation field.

4. Emergency Procedures Commitments:

A. As discussed, please provide clarification on whether you intended to commit that no open, used, or partially used disposables **containing radioactive materials** will be returned to Northstar **or** that no open, used, or partially used disposables **containing radioactive materials** will be returned for evaluation without prior approval from NorthStar.

B. As discussed in our telephone conversation, this is to confirm that your commitment to notify adjacent personnel in case of the "loss of containment" means "leakage and spillage."

5. Minor Revisions to your RadioGenix™ System program

As discussed, please confirm if you wish to be authorized to make minor revisions to your RadioGenix™ System program, and that you will follow the conditions below. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

A. The revision is in compliance with the regulations of the NRC or Agreement State;

B. 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;

C. The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;

D. The affected individuals are instructed on the revised program before the change is implemented;

E. The licensee will retain a record of each change for 5 years; and

F. 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.

6. Please confirm that the NRC regulatory guide that is referenced through-out your application refers to NorthStar Medical Radioisotopes, LLC RadioGenix™ Molybdenum-99/Technetium-99m Generator System. Licensing Guidance for Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies, **February 2018.**