



CONVERSATION RECORD

03042019

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU Stephen M. Williams, R.Ph., Radiation Safety Officer (RSO)		DATE OF CONTACT 03/4/2019	TYPE OF CONVERSATION <input type="checkbox"/> E-MAIL <input checked="" type="checkbox"/> TELEPHONE <input type="checkbox"/> INCOMING <input checked="" type="checkbox"/> OUTGOING
E-MAIL ADDRESS Stephen.M.Williams@ge.com		TELEPHONE NUMBER (616) 544-5717	

ORGANIZATION Medi-Physics, Inc., d/b/a GE Healthcare	DOCKET NUMBER(S) 030-34090
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LICENSE NUMBER(S) 21-26707-01MD	CONTROL NUMBER(S) 611050
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SUBJECT  
Discussion regarding a license Amendment to add a RadioGenix™ Medical Radioisotopes, Mo-99/Tc-99 Generator System

SUMMARY  
This is in reference to your request dtd. Jan. 10, 2019 to amend your license to add the NorthStar RadioGenix™ Molybdenum-99/ Technetium-99m Generator System to your license. As discuss, please provide the following additional information:

1. Please confirm that your current possession limit for uranium-depleted in uranium will be adequate for shielding with the addition of the NorthStar RadioGenix™ System.

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ACTION REQUIRED (IF ANY)

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NAME OF PERSON DOCUMENTING CONVERSATION  
Cassandra F. Frazier

SIGNATURE

CONVERSATION RECORD (continued)

SUMMARY: (Continued from page 1)

2. Please confirm that you understand and will adhere to the posting requirements as stated in Section 4.4 "Posting Requirements," as stated in the licensing guidance for the NorthStar RadioGenix™ Molybdenum-99/Technetium-99m Generator System, dated February 2018.
3. Please provide the specific model number of the NorthStar RadioGenix™ Molybdenum-99/Technetium-99m Generator System, that you wish to be authorized for on your license.
4. In regards to your "Emergency Procedures, Section A," please confirm that the regulatory reporting should also include "10 CFR 30.50 and 10 CFR Part 21 as stated in the licensing guidance.
5. Provide your facility diagrams and include a description of rooms both above or below the RadioGenix™ System.
6. 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 as described in the licensing guidance. (Note that this authorization is not required or mandatory) 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.

As discussed, please provide your response on company letterhead with a date and signature via email (letter must be signed by management and scanned into a pdf format) to my attention before or no later than March 18, 2019. We will continue the review of the amendment request upon receipt of the requested information. If you have any questions, please feel free to contact me at (630) 829-9830 or at [Cassandra.Frazier@nrc.gov](mailto:Cassandra.Frazier@nrc.gov).

In accordance with 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this telephone conversation will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.