



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

July 10, 2019

MEMORANDUM TO: Christopher J. Palestro, M.D., Chairman  
Advisory Committee on the Medical Uses of Isotopes

FROM: Andrea L. Kock, Director  
Division of Materials Safety, Security, State  
and Tribal Programs */RA Kevin Williams for/*  
Office of Nuclear Material Safety  
and Safeguards

SUBJECT: RESPONSES TO THE ADVISORY COMMITTEE ON THE  
MEDICAL USES OF ISOTOPES' SEPTEMBER 2016  
RECOMENDATIONS ON THE DRAFT NORTHSTAR MEDICAL  
RADIOISOTOPES, LLC, RADIOGENIX™ MOLYBDENUM-  
99/TECHNETIUM-99M GENERATOR SYSTEM, LICENSING  
GUIDANCE FOR MEDICAL USE LICENSEES, MEDICAL USE  
PERMITTEES, AND COMMERCIAL NUCLEAR PHARMACIES

Below are the U.S. Nuclear Regulatory Commission's (NRC) staff responses from the September 2016 Advisory Committee on the Medical Uses of Isotopes (ACMUI) Report (ML17293A249) on the draft "NorthStar Medical Radioisotopes, LLC, RadioGenix™ Molybdenum-99/Technetium-99mGenerator System, Licensing Guidance for Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies" (hereafter, the guidance). The Committee provided nine recommendations. The NRC accepted two recommendations, partially accepted one recommendation, and did not accepted six recommendations.

The Licensing Guidance was issued in February 2018 (Agencywide Documents Access and Management System Accession No. ML17338A449).

- 1. ACMUI Recommendation:** The Committee recommended that NorthStar provide a training module video clip showing how the system operates.

CONTACT: Donna-Beth Howe, Ph.D., NMSS/MSST  
301-415-5441

**Staff Response: Not accepted.** The NRC staff did not accept this recommendation as this document serves as guidance to license reviewers and applicants on how to obtain a medical use license, medical use permit, or commercial nuclear pharmacy license. NorthStar provides video clips showing a person performing the steps in each protocol as part of the computer operating system, and may use these video clips in its training.

- 2. ACMUI Recommendation:** Given the unique design and operation of the NorthStar system, the Committee agreed that NorthStar should have sole responsibility for the content of the training course and certification.

**Staff Response: Accepted.** Given the unique design and operation of the NorthStar system, the NRC staff agreed with this recommendation. The guidance includes training requirements for Authorized Individuals 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.

- 3. ACMUI Recommendation:** The Committee stated that it is important to clarify that a System Administrator can be any individual assigned by the Authorized User (AU) without a specifically defined educational or training background. Given the unique role of the System Administrator, perhaps that individual should be named on the license.

**Staff Response: Not accepted.** The NRC staff did not accept this recommendation because the System Administrator cannot be any individual assigned by the AU without a specifically defined educational or training background. The guidance states that the applicant's RadioGenix™ System Administrator has to, among other things, successfully complete the training and experience of an authorized individual, i.e., AU or authorized medical physicist (AMP).

- 4. ACMUI Recommendation:** The Committee recommended an explicit statement regarding the System Administrator Designee, although it may not have been intended, one could infer from the description of the system administrator designee that there can be only one designee. Presumably, there can, and should, be multiple System Administrator designees.

**Staff Response: Not accepted.** The NRC staff did not accept this recommendation because the intent is to have as few individuals as possible responsible for the key to access the service and transfer doors, and assign user roles in the RadioGenix™ Application. Therefore, the guidance includes only one System Administrator designee.

- 5. ACMUI Recommendation:** The Committee recommended that the appropriate time period allotted for training on the "changes" and the responsibility of the vendor/manufacturer to inform and train the applicants on changes in a timely manner be specified.

**Staff Response: Not accepted.** The NRC staff did not accept this recommendation because NorthStar is responsible for making software, hardware, or procedural changes to the licensee's RadioGenix™ System. If these changes affect the safety and operation of the NorthStar RadioGenix™ System, NorthStar has to provide the training before the system can be used. After these changes are made and before use at the licensee's facility, training must be provided to key individuals (i.e., at least one authorized individual, the Radiation Safety Officer, supervised individuals initially using the updated

system, RadioGenix™ System Administrator and RadioGenix™ System Administrator designee). No time period was specified in the guidance because the time needed will depend on the number of individuals needing training and the complexity of the training.

6. **ACMUI Recommendation:** The Committee recommended that the guidance clarify whether the generator will be “non-operational” until all individuals handling the generator are trained in the changes, including the AU, Radiation Safety Officer, system administrator, etc. or whether it requires only the AU to be trained on the “changes.” If the latter, once the AU is trained on the “changes,” is the AU then solely responsible for training all others on these changes? This should be stated.

**Staff Response: Accepted.** The NRC staff agreed with this recommendation and made a change to state that the unit cannot be used until there are sufficient individuals (at least one authorized individual, the Radiation Safety Officer, supervised individuals initially using the updated system, the RadioGenix™ System Administrator and RadioGenix™ System Administrator designee). All other individuals need to complete the training before they can use or supervise the use of the RadioGenix™ System. The licensee can have the remaining individuals trained by NorthStar or individuals certified by NorthStar to provide the training. The AU cannot provide the training if the AU is not certified by NorthStar to provide the training.

7. **ACMUI Recommendation:** The Committee recommended using the term, “individual tasks” throughout the document for consistency and to clarify that there is only one protocol and software program with this system.

**Staff Response: Partially accepted.** The NRC staff agreed with this recommendation, but used the term “protocol” instead of “individual tasks.” The term “protocol” has been clarified in the introductory section of the guidance. The NorthStar protocols refer to discrete portions of the software program containing multiple steps that have to be performed by the user to complete a certain function. Thus, the protocols include multiple steps and tasks under a single heading, and the term “protocol” is still used to designate these activities.

8. **ACMUI Recommendation:** The Committee recommended that the manufacturer’s procedures be reviewed and incorporated into the Licensing Guidance itself.

**Staff Response: Not accepted.** The NRC staff did not accept this recommendation because the NRC believes that the performance-based criteria for the applicant to commit to develop, implement, and maintain written procedures based on information specific to the RadioGenix™ system’s likely failure modes is adequate. Further, the manufacturer designed the liquids to move through the system at low pressure and added physical barriers within the cabinets to keep spills and leaking fluids contained.

9. **ACMUI Recommendation:** The Committee recommended that the term “higher than expected” be defined in terms of a maximum specific exposure or exposure-rate limit which a survey meter should be capable of measuring.

**Staff Response: Not accepted.** The NRC staff did not accept this recommendation because the criterion “higher than expected” is performance-based. Depending on the source vial activity within the device and changes with the radioactive materials transfers during processing, the licensee would be familiar with the typical radiation levels of the device. Hence, “higher than expected” is a relative term that would be recognized by the licensee. A related example would be monitoring of radioactive materials packages. A licensee would be familiar with the radiation levels associated with typical shipments, but would be alerted by a “higher than expected” radiation level that the contents of a package might no longer be contained as it should and additional precautions may need to be implemented.

