Frequently Asked Questions

Indication and Important Risk Information

What is the RadioGenix® System indicated for?
The RadioGenix® System is a technetium Tc-99m generator used to produce Sodium Pertechnetate Tc 99m Injection, USP. Sodium Pertechnetate Tc 99m Injection is a radioactive diagnostic agent and can be used in the preparation of FDA-approved diagnostic radiopharmaceuticals.

Sodium Pertechnetate Tc 99m Injection is also indicated in

- Adults for Salivary Gland Imaging and Nasolacrimal Drainage System Imaging (dacryoscintigraphy).

- Adults and pediatric patients for Thyroid Imaging and Vesicoureteral Imaging (direct isotopic cystography) for detection of vesicoureteral reflux.

Important Risk Information

- Allergic reactions (skin rash, hives, or itching) including anaphylaxis have been reported following the administration of Sodium Pertechnetate Tc 99m Injection. Monitor all patients for hypersensitivity reactions.

- Radiation risks associated with the use of Sodium Pertechnetate Tc 99m Injection are greater in children than in adults and, in general, the younger the child, the greater the risk owing to greater absorbed radiation doses and longer life expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

Long-term cumulative radiation exposure may be associated with an increased risk of cancer.

- Temporarily discontinue breastfeeding. A lactating woman should pump and discard breastmilk for 12 to 24 hours after Sodium Pertechnetate Tc 99m Injection administration.

- Sodium Pertechnetate Tc 99m Injection should be given to pregnant women only if the expected benefits to be gained clearly outweigh the potential hazards.

- Follow step by step directions for use provided in the RadioGenix® System Operator Guide. Only use potassium molybdate Mo-99, processing reagents, saline and other supplies, including kits, provided by NorthStar Medical Radioisotopes. Do not administer Sodium Pertechnetate Tc 99m Injection after the 0.15 microCi of Mo-99/mCi of Tc-99m limit has been reached or when the 12 hour expiration time from elution is reached, whichever occurs earlier.

- Sodium Pertechnetate Tc 99m Injection contributes to a patient's long-term cumulative radiation exposure. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure. Use the lowest dose of Sodium Pertechnetate Tc 99m Injection necessary for imaging and ensure safe handling and preparation to protect the patient and health care worker from unintentional radiation exposure. Encourage patients to drink fluids and void as frequently as possible after intravenous or intravesicular administration. Advise patients to blow their nose and wash their eyes with water after ophthalmic administration.

In the event there were to be adverse events, who should I contact?

To report SUSPECTED ADVERSE REACTIONS, contact NorthStar

Medical Radioisotopes, LLC at 1-844-438-6659 or contact FDA at 1-800-332-1088 or www.fda.gov/medwatch.

Full RadioGenix® System prescribing information is available at: www.northstarnm.com.

Quality and Purity

How does the quality of SPECT or Planar images using Tc-99m produced from the RadioGenix® System compare to those images using uranium-based Mo-99 and Tc-99m?

The Tc-99m solution produced by the RadioGenix® System is U.S. Pharmacopeia (USP) compliant Sodium Pertechnetate Tc-99m in the same form that is offered today by all other suppliers, which is expected by today's nuclear pharmacist.

- There is no evidence to suggest that there is any difference in image quality using HEU, LEU or non-uranium Mo-99 for Tc-99m production.

How pure is the Tc-99m produced from the RadioGenix® System?

With the recent U.S. Food and Drug Administration approval of the RadioGenix® System, NorthStar is the first company approved to produce commercially relevant quantities of Mo-99 in the United States in more than 25 years.

- The RadioGenix® System is *FDA-approved* and *available now* to produce U.S. Pharmacopeia (USP) compliant Tc-99m in the same form that is offered today by all other suppliers, which is expected by today's nuclear pharmacist.

RadioGenix® System Overview

What is the RadioGenix® System and what does it do?

NorthStar's RadioGenix® System is the first of its kind -an innovative, high tech radioisotope separation platform for use in producing the widely used, and medically important radioisotope technetium-99m (Tc-99m) from non-uranium produced molybdenum-99 (Mo-99).

- NorthStar's Mo-99 is not subject to the issues incurred with current uranium-based Mo-99 such as supply shortages and outages, intercontinental transportation and waste disposal costs.
- Furthermore, NorthStar's approach provides an environmentally friendly solution for Mo-99 supply. Because it is non-uranium based, it does not create the long-lived radioactive waste associated with uranium-based production methods.

When was the RadioGenix® System approved by the U.S. Food and Drug Administration (FDA)?

- The RadioGenix® System was approved by the U.S. FDA on February 8, 2018.

Process and Production

Are there benefits to Tc-99m produced using the RadioGenix® System?

- There are several benefits. The RadioGenix® System provides a reliable, environmentally friendly, domestically supplied source of the important medical radioisotope Tc-99m, critical for patients' diagnostic tests.
- Radiopharmacies and the patients they service can know that imaging procedures using Tc-99m will be less subject to scheduling delays and interruptions based on erratic supply.
- Our radiopharmacy customers finally have access to a domestic product which the marketplace has needed for many years.

- NorthStar has an integrated supply chain, and this completely domestic and simplified supply chain minimizes uncertainly around global reactor status, transportation challenges and the overall fragility of Mo-99 supply.

How does NorthStar produce molybdenum-99 (Mo-99) without uranium?

- A Mo-98 target, which is a small, stable and non-radioactive metal disk about the size of a quarter, is exposed to neutrons, transforming a portion of it into Mo-99. The irradiated target is dissolved and purified, and then moved to NorthStar's filling operation housed in the same facility. Waste created during Mo-99 production is minimal and relatively benign, making its disposal safe and inexpensive.
- Source vessels are then filled with a Mo-99 solution and shipped to radiopharmacies for use with the RadioGenix® System. The RadioGenix® System is used to extract the Tc-99m from the Mo-99, giving the radiopharmacy the key ingredient needed to prepare patient-ready doses.

In the simplest terms, how is NorthStar's RadioGenix® approach different from the conventional approach to Tc-99m production?

- We do not use uranium as our starting material, but stable molybdenum-98 (Mo-98).
- All of our production is done in the United States, unlike other Mo-99 suppliers who have to produce and transport materials from as far away as Europe, South Africa and Australia.
- The use of stable Mo-98 means our waste streams are much less toxic and easier to manage than those of all other suppliers, who use uranium as their starting material.
- The final product from our production and processing methodologies is U.S. Pharmacopeia (USP) compliant Tc-99m in the same form that is offered today by all other suppliers, and is expected by today's nuclear pharmacist.

Availability and Support

How do I acquire a RadioGenix® System?

- The RadioGenix® System is available through NorthStar Medical Radioisotopes. For further information, please contact Lisa Holst, VP Sales and Marketing at: 1-844-438-6659 (1-844-GET MOLY).

When will the RadioGenix® System be commercially available?

- NorthStar Medical Radioisotopes expects to be shipping product to customers within weeks..
- Initial RadioGenix® Systems will be placed in a controlled and measured way at select radiopharmacies to ensure optimal use experience. Our product introduction plan includes training programs with distribution partners, many of which are already underway.
- The RadioGenix® System will become increasingly available nationally as we continue our phased roll out plan.

How can my hospital get Tc-99m from NorthStar?

- NorthStar provides the RadioGenix® System to commercial radiopharmacies, or large Medical Centers with their own radiopharmacy, who then use it to produce Tc-99m. The radiopharmacies in turn supply hospitals or their own nuclear medicine departments with patient doses. Please contact Lisa Holst, VP Sales and Marketing at: 1-844-438-6659 (1-844-GET MOLY) for more information.

What if I have technical Issues with the RadioGenix® System?

- NorthStar's customer-centric approach for RadioGenix® System support includes a highly educated, experienced and disciplined team of customer-focused Field Service Engineers with a variety of technical backgrounds, including Biomedical and Electrical Engineering.
- NorthStar's Technical Support Contact Center operates 24x7.Remote linking and diagnostic capabilities enable rapid

RadioGenix® System analysis and resolution of most customer questions.

Does NorthStar Medical Radioisotopes plan expanded features for the current RadioGenix® System?

- Yes, absolutely. The RadioGenix® System platform is intentionally designed as an evolving technology. Based on continuous customer feedback, NorthStar has a well-established development roadmap already well underway for RadioGenix® System enhancements, designed to be implemented as field upgrades that are backwards compatible to further enhance utility to our customers.
- It is important to note, the current RadioGenix® System is based on a design that was locked in place many months in advance of the NDA submission to the U.S. Food and Drug Administration (FDA). As a result, design changes could not be incorporated in the months prior to FDA approval.
- Regulatory approval of NorthStar's new Mo-99 manufacturing processes is simplified when compared to the initial New Drug Application (NDA). Supplements to the initial NDA can be used, and reviews are often completed in months or less.

Reimbursement

Is the Tc-99m produced by the RadioGenix® System reimbursed?

- Yes, diagnostic tests using Tc-99m produced by the RadioGenix® System will be reimbursed through Medicare and private payers exactly as they are today.

Does the Tc-99m produced by the RadioGenix® System qualify for the add-on code with CMS?

- Tc-99m patient doses from NorthStar's RadioGenix® System are not derived from uranium source material and are therefore eligible for the Medicare Hospital Outpatient

Prospective Payment System $10 add on payment for HCPCS "Q9969 Tc-99m from non-highly enriched uranium source full cost recovery add-on, per study dose."
- Use of this add-on payment has been extended through 2018.

Is it fair that NorthStar has been awarded two Cooperative Agreements by the DOE/NNSA totaling $50M; more than any of your competitors?

- Under provisions of the American Medical Isotopes Production Act of 2012 (AMIPA), NNSA is directed to carry out a technology neutral program to evaluate and support projects for the domestic production of Mo-99 without the use of highly enriched uranium.
- The funding by NNSA is a 50/50 cost shared support through Cooperative Agreements consistent with Congressional direction provided in AMIPA.
- When NNSA issued its Funding Opportunity Announcement in 2010, the competition for NNSA support was available to **all companies** that could present a viable, technical plan assessed by independent technical experts.
- NorthStar is extremely proud to have been awarded two of these Cooperative Agreements, validated by independent technical experts, one for the production of Mo-99 using a neutron capture technology and one for the production of Mo-99 using an accelerator technology. Each Cooperative Agreement has separate scopes of work and each has been awarded with a $25 million contribution limit from NNSA and a $25 million of matching funds contribution from NorthStar.
- Partial funding from the NNSA for the development of the RadioGenix® System was provided consistent with the scope of work under the $25 million Cooperative Agreement for development of the neutron capture technology.