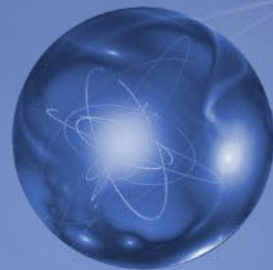




Production of Mo-99 without the use of Uranium

NNSA Mo-99 Stakeholders Meeting
Washington, DC
29 August 2023



James T. Harvey
Chief Science Officer
NorthStar Medical Technologies, LLC

RadioGenix® System (technetium Tc 99m generator)

Indication

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.

For RadioGenix® System version 1.2 Full Prescribing Information, including Warnings and Precautions, visit <https://www.northstarmn.com/wp-content/uploads/2023/02/RadioGenix-System-version-1.2-Package-Insert-Rev-08-Jan-2023.pdf>.



55 Acre Campus Designed with a Purpose in Beloit, Wis.

Living our Mission to Provide Patients Global Access to Game-Changing Radiopharmaceuticals

Non-carrier added (n.c.a.) Ac-225
Production facility
(construction underway)

Accelerator
Production facility

cGMP-Compliant
Manufacturing facility

Isotope Processing facility

Corporate HQ

Radiopharmaceutical
CDMO facility



Two R&D facilities in Madison, WI

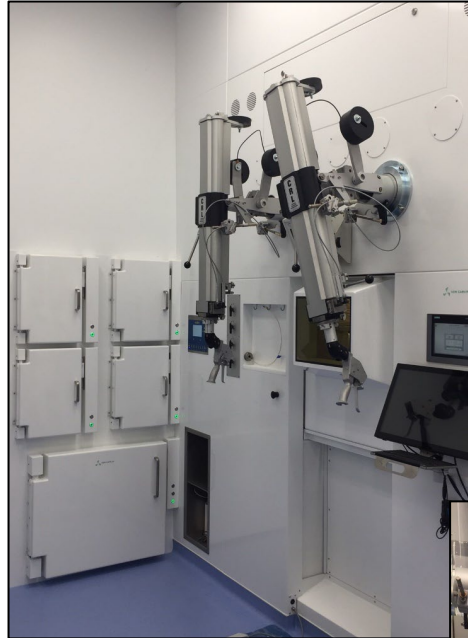


Production facility in Columbia, MO

NorthStar Production of Mo-99

- Focused on the U.S. supply of Mo-99/Tc-99m
- FDA approved – only non-uranium based process approved
- Commercial production, first domestic Mo-99 shipments to customers in November 2018
 - > Nearly 5 years of Mo-99 deliveries to our customers
 - > RadioGenix® System Tc-99 generators in use across the United States
 - > Monday production at Columbia MO, using Mo-98 and neutron capture
 - EOI to delivery to customers is <24 hours
 - Customers receive product by 1am Tuesday
 - > Offer 7.5 Ci, 12 Ci, 15 Ci & 19 Ci Mo-99 ordering options
 - > Have been able to help many patients during periods of supply issues since launch
- In final stages of qualifying accelerator production of Mo-99 in Beloit
- Well advanced in efforts to develop next generation RadioGenix System
- Complexity of getting to efficient commercial production should not be underestimated

Fill Line at NorthStar Columbia Operations*



The RadioGenix® System
(technetium Tc 99m generator)

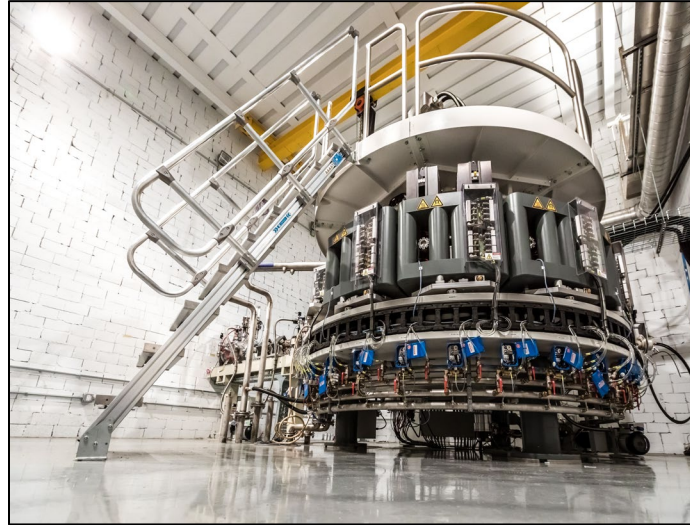


*FDA approved

Accelerator Production Design and Layout

- **Accelerators and beamlines**

- > 2x IBA TT-300HE Rhodotron
- > Firsts-of-their-kind
- > 40 MeV
- > 125 kW average power on each
- > Beam ~12mm FWHM Gaussian at target



- **Vaults**

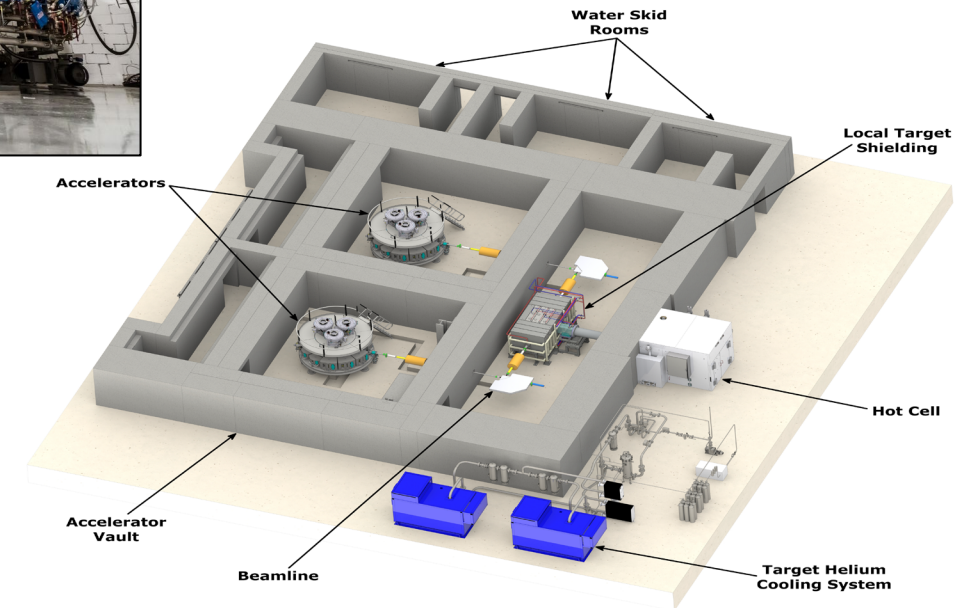
- > Separated to allow for easier maintenance

- **Target cooling**

- > High velocity, high pressure helium gas

- **Target manipulation**

- > Steel hot cell and push/pull chain
- > Local shielding around target



Hot Cells & Fill Line at NorthStar Beloit, Wis.* Operations



*Not FDA approved

©2023 NMR. All rights reserved.



Mo-99/Tc-99m Economics

- Market economics remain challenging; global market unsustainable long term under current conditions
 - > Levels of investment to ensure a reliable sustainable supply of Mo-99/Tc-99m are significant
- Improved market pricing can be implemented through two primary mechanisms:
 - > Full Cost Recovery (FCR) being implemented on a global basis throughout the supply chain
 - > Reimbursement being restructured in a manner that allows an economic return to all involved in the supply chain
 - In the United States, the supply chain includes Mo-99 producers, Tc-99m generator manufacturers, radiopharmacies and hospitals/clinics
- Market price for Mo99/Tc99m needs to increase to justify investments necessary to support the market

Summary

Many impressive accomplishments

- > Nearly 5 years steady domestic Mo-99 production with MURR[®] partner
- > NorthStar's Columbia operations continuously upgraded – a project takes time to be truly “Done”
- > First pair of electron accelerators for Mo-99 production in routine use
 - Can support Sunday production; complementing Monday production at Columbia
- > Qualification of Beloit Processing facility to further increase Mo-99 capacity is nearing completion
 - Successful “end-to-end” irradiation and processing runs in July/August generated ~1,300 Ci of Mo-99 each run
- > Established enriched Mo-98 and Mo-100 reclamation processes; successful development runs completed
- > Numerous regulatory inspections and approvals, both FDA and WI nuclear, completed

Market Economics

- > Market economics remain challenging; market unsustainable under current financial conditions
- > Improved market pricing that includes FCR and reimbursement model that provides adequate returns to all participants in the Mo-99/Tc-99m supply chain



Production of Mo-99 without the use of Uranium

NNSA Mo-99 Stakeholders Meeting
Washington, DC
29 August 2023



James T. Harvey
Chief Science Officer
NorthStar Medical Technologies, LLC