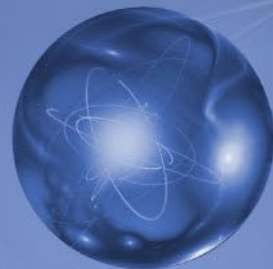




Production of Mo-99 without the use of Uranium

NNSA Mo-99 Stakeholders Meeting
Chicago, IL

22-23 June 2022



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://is.gd/BrYQyq>.

Two R&D facilities
in Madison, WI
Production facility
in Columbia, MO

Accelerator
Production Facility

Isotope Processing
Facility

RadioGenix® System
Manufacturing
Facility

Corporate HQ

Therapeutic Radioisotope
Production Facility
Groundbreaking September, 2021

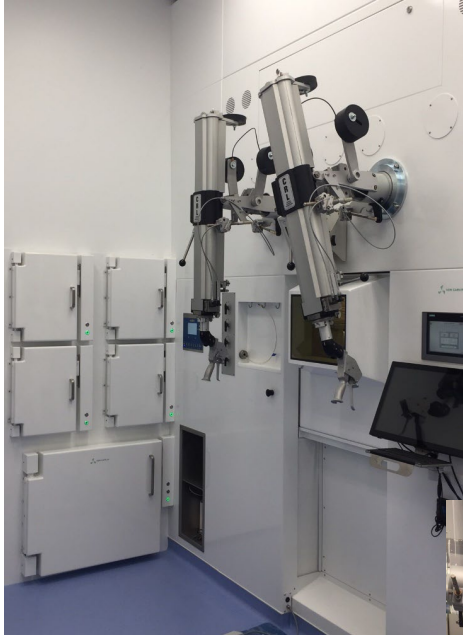


33 Acre Campus located
In Beloit, WI
cGMP Compliant
Manufacturing Facilities

NorthStar Production of Mo-99

- Focused on the U.S. radioisotope market supply of Mo-99/Tc-99m, with strategic ability to expand beyond Mo-99/Tc-99m
- FDA approved (6 approvals to date) – Only non-uranium based process approved
- Commercial production, first domestic Mo-99 shipments to customers in November 2018
 - > 3+ years of Mo-99 deliveries to our customers using a RadioGenix® System
 - > Added new fill line at our Columbia, Mo operations allowing increased throughput and reduced fill times
 - > Further program expansions underway for both the approved neutron capture and accelerator production efforts in Columbia, MO and Beloit, WI
 - > Will recover and recycle enriched molybdenum target material
 - > Now offer 7.5 Ci, 12 Ci, 15 Ci & 19 Ci Mo-99 ordering options
- Company facts
 - > Headquartered in Beloit, WI, additional facilities in Madison, WI and Columbia, MO
 - > Approximately 300 employees

New Fill Line at NorthStar Columbia Operations*



The RadioGenix® System
(technetium Tc 99m generator)



New Hot Cells & Fill Line at NorthStar Beloit* Operations



*Not FDA approved

[Processing Building Video Link](#)

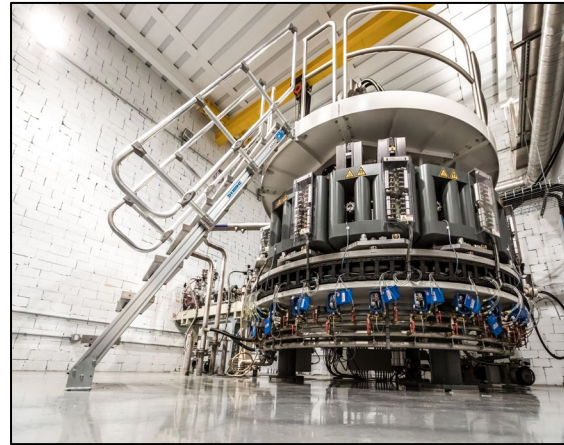
©2022 NorthStar Medical Radioisotopes, LLC. All rights reserved.



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

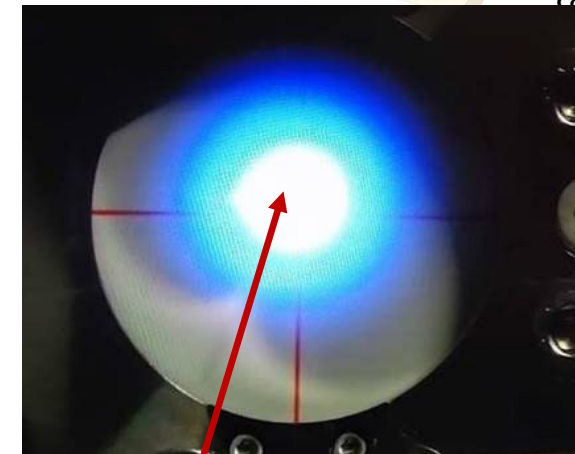
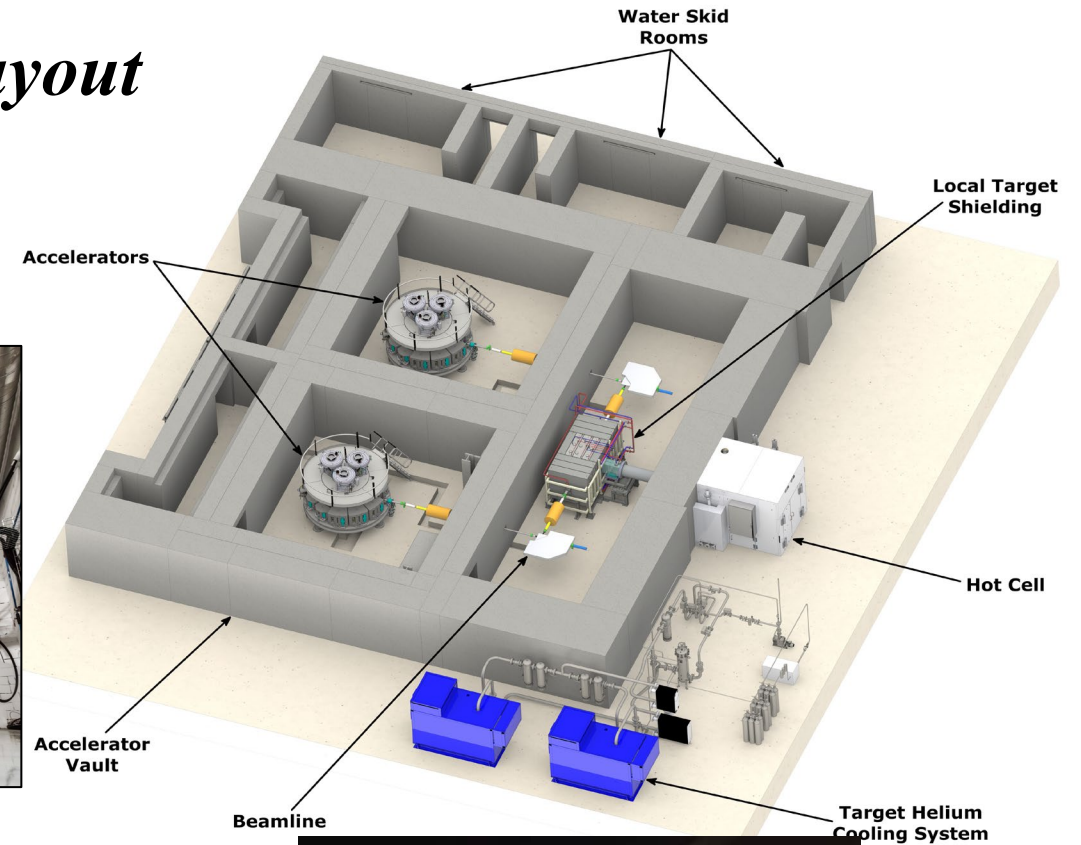
- > Separated to allow for easier maintenance

- Target cooling

- > High velocity, high pressure helium gas

- Target manipulation

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



40 MeV Beam



Waste Management

- All radioisotopes produced by NorthStar are from non-uranium processes
 - > No uranium fission product waste
 - > No uranium waste
 - > No TRU waste
- Mo-99 production
 - > Zr-95/Nb-95 is primary rad waste product due to purity of target material
 - > Minor activation products from transition metal contaminants in target material at sub micro curie per curie Mo-99 produced
 - > Minimal >120 day half life contaminants produced
 - > Long lived Tc-99 (215,000 years) can be in waste at very low levels
 - > All Class A waste
- Waste Disposal
 - > Radioactive and/or hazardous materials are NOT released to public land fill or sewer
 - > Waste is shipped off-site via licensed hazardous/radioactive materials waste brokers to licensed sites

Summary

- **Key accomplishments**

- > 3+ years steady domestic Mo-99 production with MURR partner
- > Upgraded throughput at NorthStar's Columbia operations
- > Commissioning Beloit Processing building to further increase capabilities
- > Commissioning first pair of electron accelerators for Mo-99 production; adding delivery capability any day of the week including Sunday delivery
- > Commissioning enriched Mo-98 and Mo-100 reclamation processes
- > Numerous regulatory inspections and approvals, both FDA and WI nuclear, received

- **Activities/Challenges moving forward**

- > Complete commissioning of both Beloit processing and electron accelerator systems
- > Submit DMF/PAS documents to FDA/WI-DHS for approval to initiate Mo-99 production in Beloit
- > Initiate commercial Mo-99 production upon approvals

- **Commercial Operations**

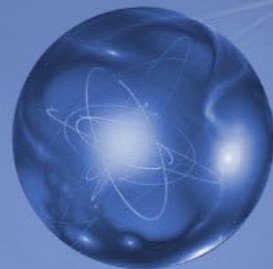
- > NorthStar does not foresee and impediments to successful commercial operation of our Beloit facilities



Production of Mo-99 without the use of Uranium

NNSA Mo-99 Stakeholders Meeting
Chicago, IL

22-23 June 2022



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