



# Update on Domestic Production of Mo-99

NNSA/IAEA Mo-99 Topical Conference  
Vienna

6-7 October 2022



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

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# 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



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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

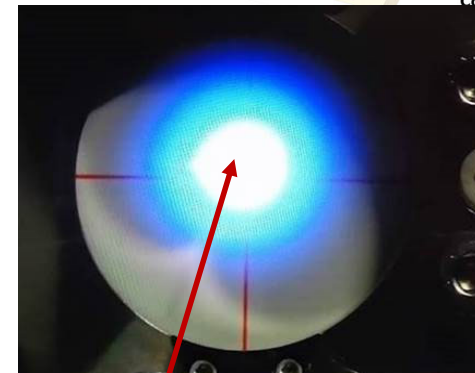
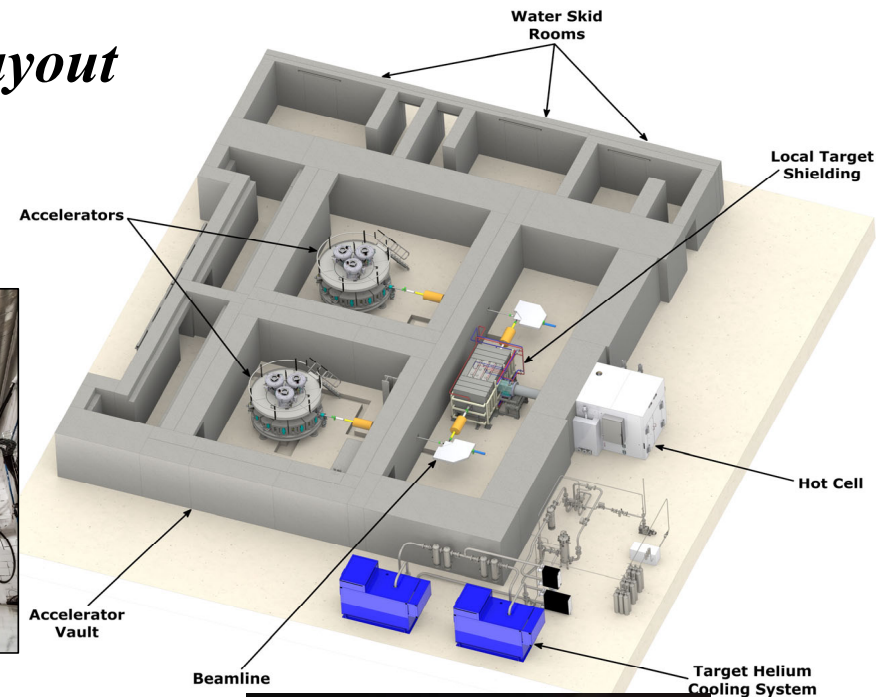
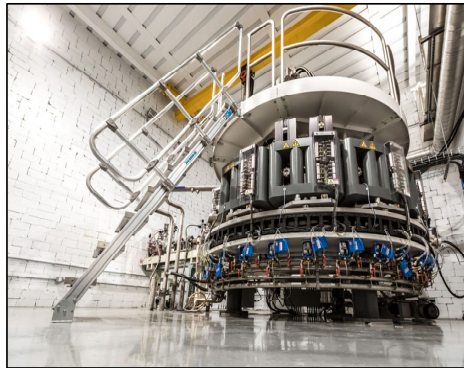
[Processing Building Video Link](#)

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# *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

[Accelerator Building video link](#)

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# 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



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