



NorthStar
The new producer and distributor of Mo-99

James Harvey
Chief Science Officer
NorthStar Medical Technologies, LLC

presented at

2019 Mo-99 Stakeholders Meeting

Chicago, IL

September 12, 2019

RadioGenix[®] System (technetium Tc 99m generator) Indication¹

- 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.

¹ RadioGenix[®] System [package insert]. Beloit, WI: NorthStar Medical Radioisotopes, LLC July 2019

RadioGenix[®] System (technetium Tc 99m generator) Important Risk Information

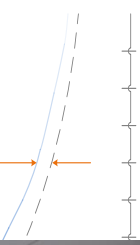
- Allergic reactions (skin rash, hives, or itching) including anaphylaxis have been reported following the administration of Sodium Pertechnetate Tc-99m Injection. Monitor all patients for hypersensitivity reactions.
- Radiation risks associated with the use of Sodium Pertechnetate Tc 99m Injection are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

Please see additional important risk information in the package insert provided at the beginning of this talk.

Production and Distribution of Domestic Mo-99

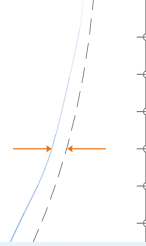
- Have been producing and distributing domestic, non-HEU, non-uranium sourced Mo-99 for last 10 months
 - *40+ weeks of deliveries to customers on day customer requested*
 - *Uninterrupted supply of domestic Mo-99 to market*
 - *Multiple RadioGenix® Systems installed in nuclear pharmacies*
- Multi-tiered expansion of production capabilities underway
 - New fill line in NorthStar's Columbia Operations on-line late 4Q2019 - early 1Q2020; 4X production capacity
 - New Beloit Processing building completed; equipment installation underway
 - Introduction of enriched Mo-98 targets in late 2020; another 4X increase
 - Ground breaking for accelerator building on 19 September
 - *Contract executed with IBA for up to 8 TT-300HE Rhodotrons*
- NorthStar efforts supported by multiple NNSA Cooperative Agreement awards
- Multiple FDA Approvals

*NorthStar Neutron Capture Domestic Production New Fill Line at NorthStar Columbia Operations**



**Pending FDA approval*

NorthStar Company Headquarters, Beloit, WI



Accelerator Production Facility (Groundbreaking Sept. 2019)
20,000 sq.ft., expand as needed in future

Corporate HQ & Manufacturing
50,000 sq.ft., expand as needed in future

Isotope Processing Facility
20,000 sq.ft., expand as needed in the future



Building 4 (TBD; other future products)

Beloit Expansion Building II – new Processing building

Once Fully Commissioned and Approved by the FDA, building will house:

- State of the art hot QC lab
- Multiple processing hot cells & Multiple Fill Lines housed in an ISO 8 Clean Room
- Automated packaging and shipping lines to support target dissolution, filling, and shipment of Mo-99 produced from enriched Mo-98 targets
- Reclamation of enriched Mo-98 target material

Processing Building Equipment

Decay in Storage Vaults for
line 1, installed in July

Beloit Dissolution line 1 Hot Cell Train
as seen at FAT



Processing Building Equipment

Beloit Fill lines 1
& 2 under
assembly at
factory



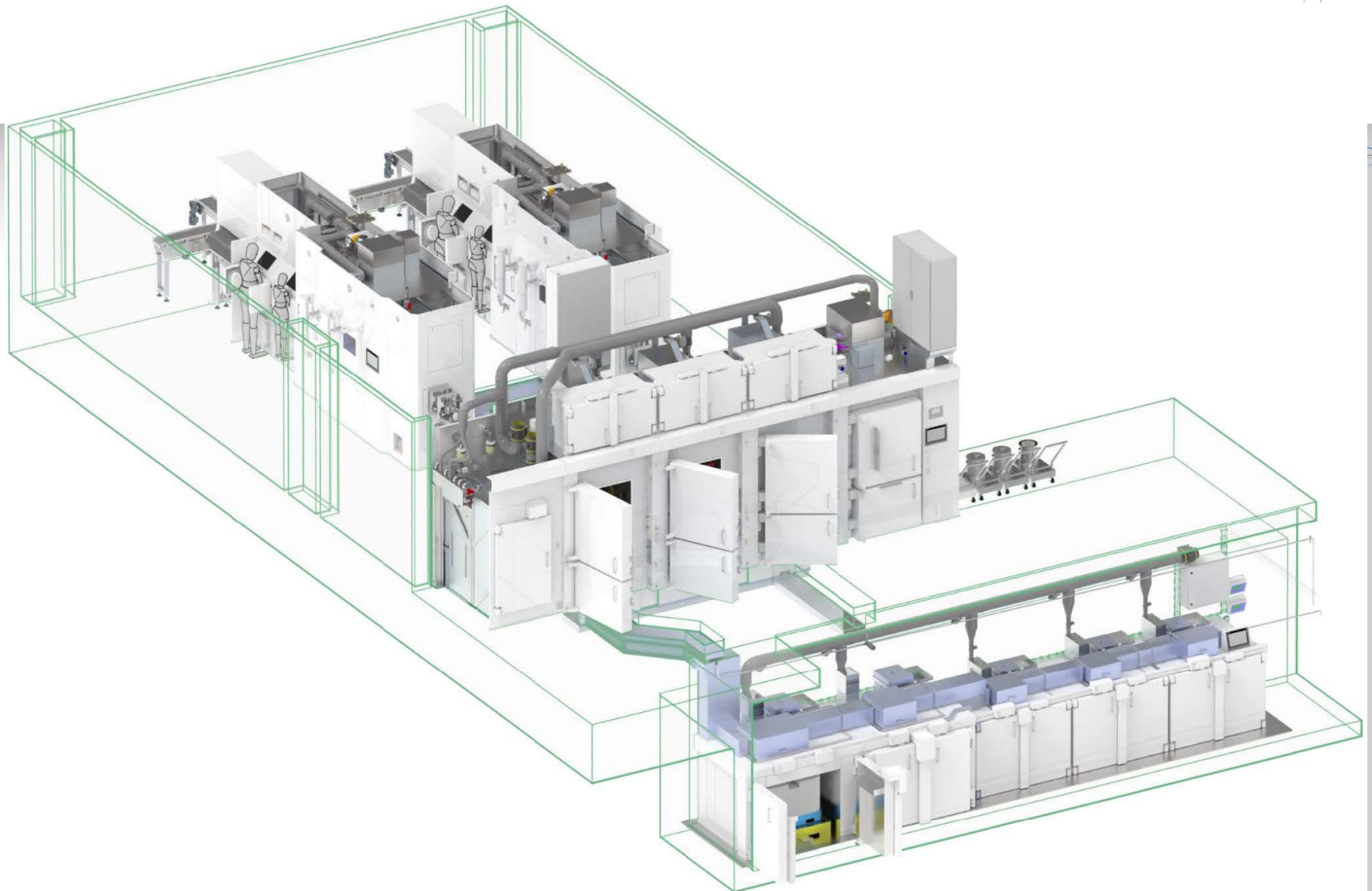
Processing Building Equipment

Enriched Molybdenum
process vaults

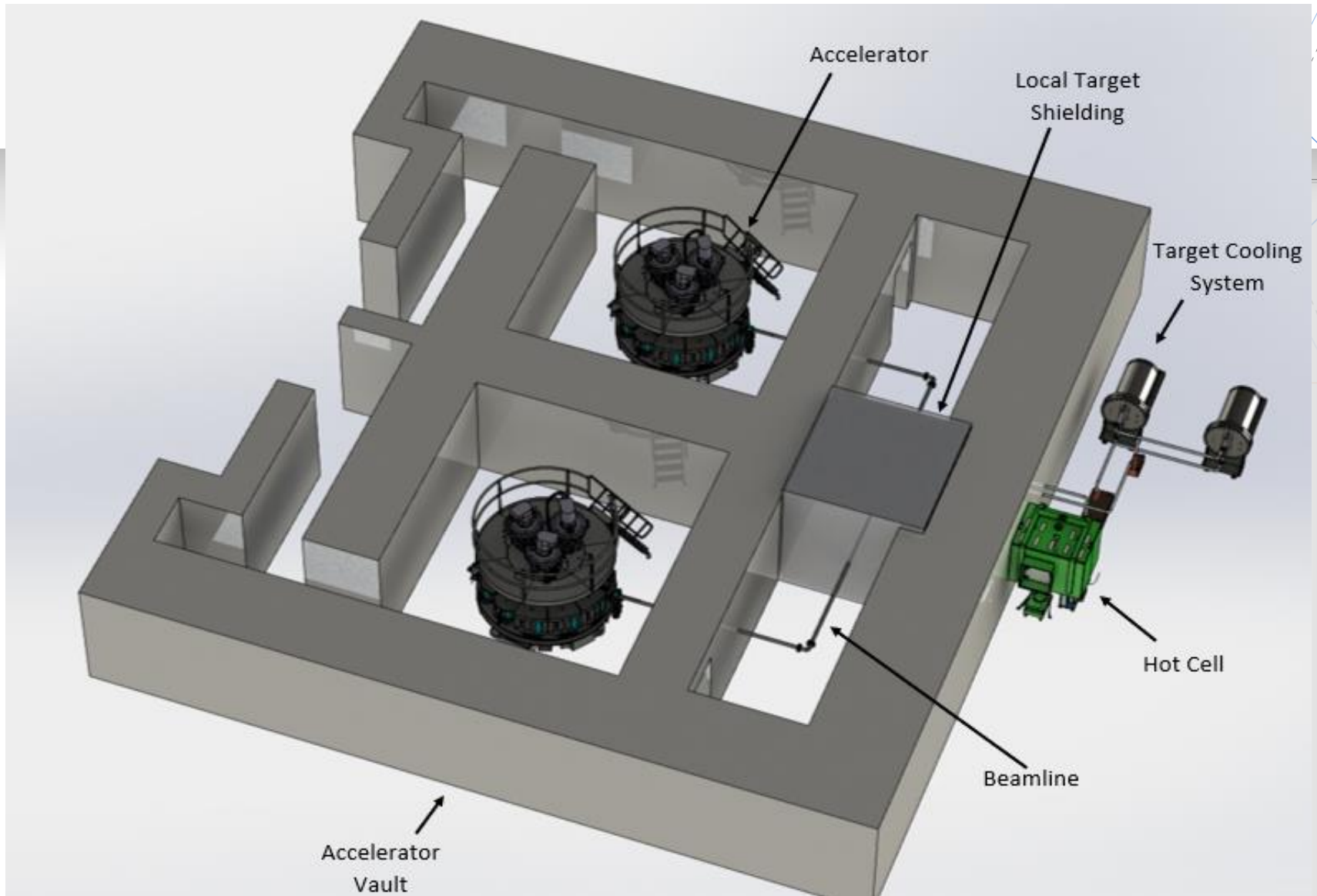


Enriched Molybdenum process
equipment installation

Processing Building Equipment



Accelerator Building Layout



Key Takeaways

- U.S. nuclear pharmacy customers **need and want reliable Mo-99/Tc-99m generator supplies**
- Commercially available and in use at radiopharmacies now, the RadioGenix[®] System is using MURR/NorthStar produced Mo-99 to generate FDA-approved, Sodium Pertechnetate Tc 99m Injection (USP)
- NorthStar is growing into a **reliable** and **vertically integrated supplier** of the medically important radioisotope Mo-99/Tc-99m

Summary

- Domestic Mo-99 production & distribution underway for almost 1 year
 - 40+ weeks of uninterrupted supply to market
- Supported by multiple NNSA Cooperative Agreements
- Multiple FDA approvals since Feb 2018
- NorthStar supports the AMIPA HEU ban due to go into effect 2 January 2020



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