

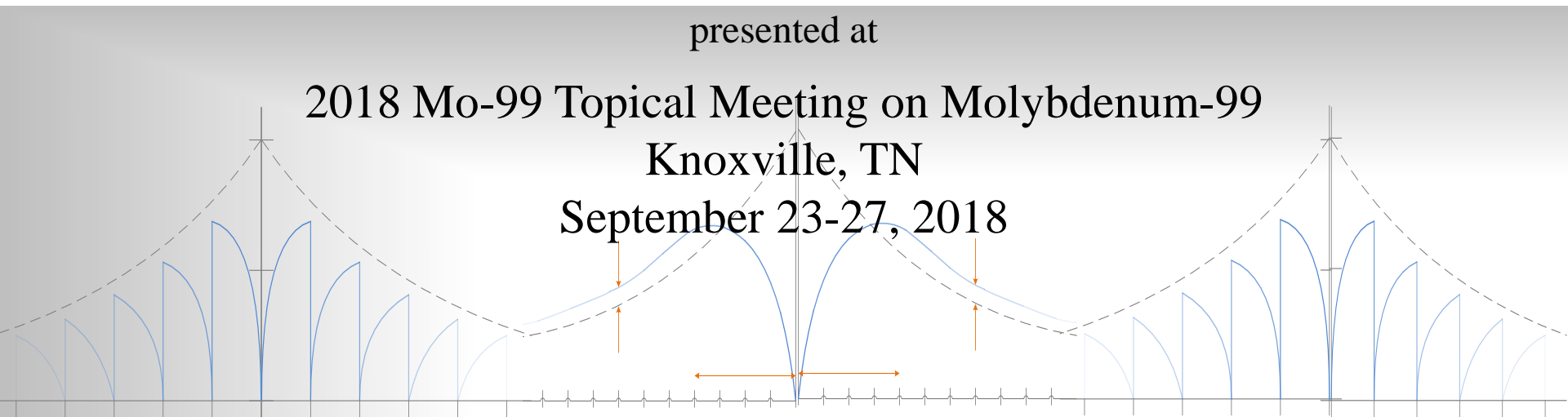


US Domestic Mo99 Production Update via Neutron Capture

James Harvey
Chief Science Officer
NorthStar Medical Technologies, LLC

presented at

2018 Mo-99 Topical Meeting on Molybdenum-99
Knoxville, TN
September 23-27, 2018



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; March, 2018

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.

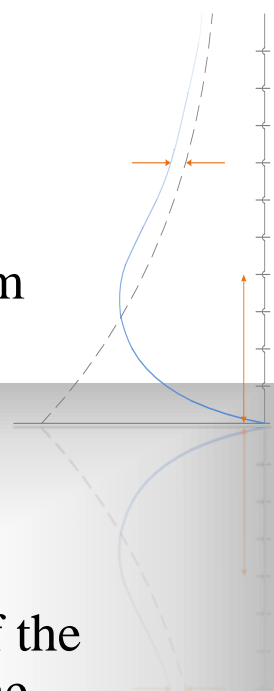


Near Term and Long Term Solutions

- Near Term Solution – neutron capture ($\text{Mo}^{98}(\text{n},\gamma)\text{Mo}^{99}$)
 - Missouri University Research Reactor (MURR)
 - MURR originally produced Mo99 with nat-Mo via neutron capture
 - NorthStar has been active in this option since 2009, extensively modernizing the process
 - Purification process to produce high purity natural moly target material
 - Implementation pending of >98% enriched Mo^{98} target material
 - Improved target manufacturing processes enabling metallic moly targets of greater than 90% theoretical density
 - Improved target processing and purification processes enabling time between EOI and ship to under 18 hours
 - Modernized and automated fill process developed and installed
- Long Term Solution – photon transmutation ($\text{Mo}^{100}(\gamma, \text{n})\text{Mo}^{99}$)
 - NorthStar's electron accelerator methodology for the production of Mo99
 - NorthStar has been active in this option since 2007
- Once up and running both solutions will be used to supply the US market and potentially ROW.
- Both program are supported by NNSA Cooperative Agreements to the \$50 million maximum

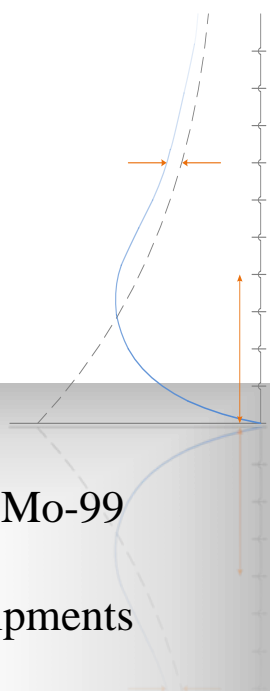
Near Term and Long Term Solutions

- Neither process utilizes uranium target material; only stable molybdenum targets are used significantly minimizing production and waste costs
- Utilize NorthStar's RadioGenix[®] generating system
- As a result of NorthStar's technical advancements in the enhancement of the neutron capture and accelerator process along with the introduction of the platform technology RadioGenix, NorthStar is bringing neutron capture and accelerator Mo99 production into the 21st century.



NorthStar Production

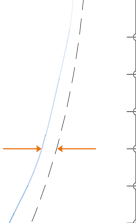
- Began producing Mo99 at MURR in late 2011
- NorthStar completed its first full production run in May 2015
 - Validated technical advancements to enhance the productivity and modernize-the Mo-99 neutron capture production process
 - More than 80 full production runs since; more than 850 Type A source vessels shipments
- FDA approvals received in 2018
 - NDA 202158 for RadioGenix System (technetium Tc99m generator) - 8 Feb
 - S-001 supplement to NDA for use of Beloit, WI as manufacturing facility - 8 Jun
 - S-004 supplement to NDA for use of RadioGenix v1.1 - 9 Aug
- OAS/NRC Working Group Guidance Document issued – 9 Feb
- Completed purchase of Type B Casks



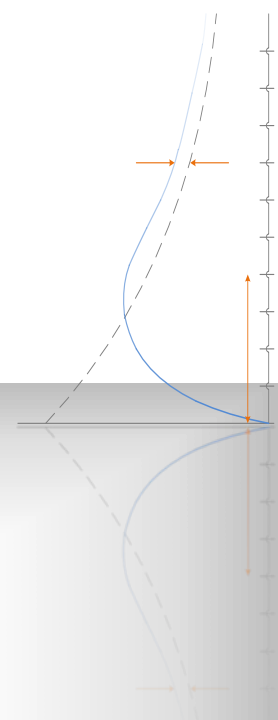
NorthStar RadioGenix Training

- NorthStar training personnel will provide required training in accordance with the NorthStar RadioGenix requirements at NorthStar Beloit facility for client authorized user certification
- NorthStar continues to hold training classes attended by clients
 - Each of seven protocols run three times by each attendee
 - Training completed easily due to intuitive easy to use interface with RadioGenix
- At install of RadioGenix, NorthStar install engineers will train additional client users at client site
- Each customer receives one (1) RadioGenix though largest customers may desire two (2)

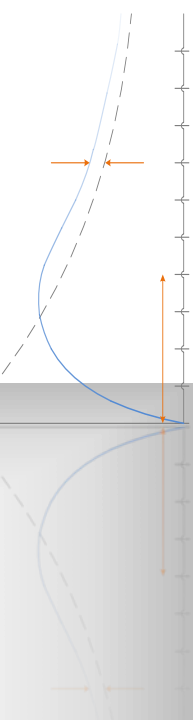
NorthStar Neutron Capture Production Efforts New Fill Line at NorthStar Columbia Operations



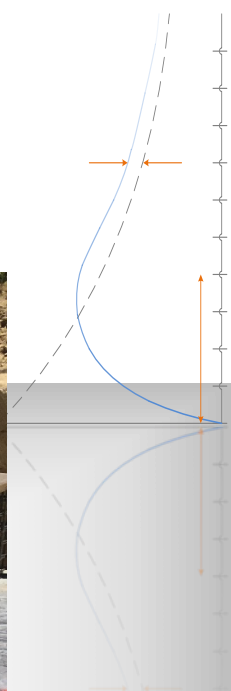
RadioGenix®



NorthStar Beloit Facility



NorthStar Beloit Facility Processing Building Construction Progress

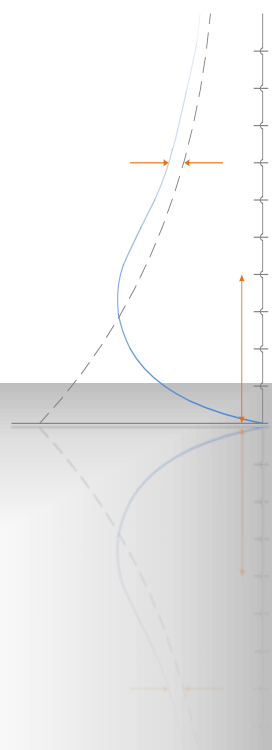


NorthStar Beloit Facility Processing Building Construction Progress



Summary

- Multiple FDA approvals in 2018
- Domestic Mo99 production underway
- RadioGenix training & installation underway





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