



US Domestic Mo99 Production Update via Neutron Capture

James Harvey
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NorthStar Medical Technologies, LLC

presented at

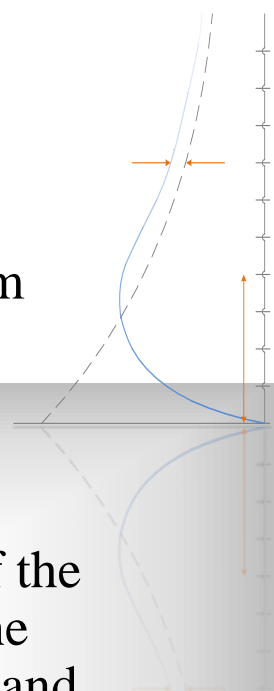
2017 Mo-99 Topical Meeting on
Molybdenum-99 Production Technology Development
Montreal, QC Canada
September 10-13, 2017

Near Term and Long Term Solutions

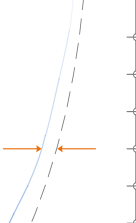
- Near Term Solution – neutron capture ($\text{Mo}^{98}(\text{n},\gamma)\text{Mo}^{99}$)
 - Missouri University Research Reactor (MURR)
 - MURR originally produced Mo99 with nat-Mo via neutron capture
 - NorthStar has been active in this option since 2009, extensively modernizing the process (subject to NDA approval)
 - Purification process to produce high purity natural moly target material
 - Implementation in 2018 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
 - Tailored logistics options to optimize ship time to client
- 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

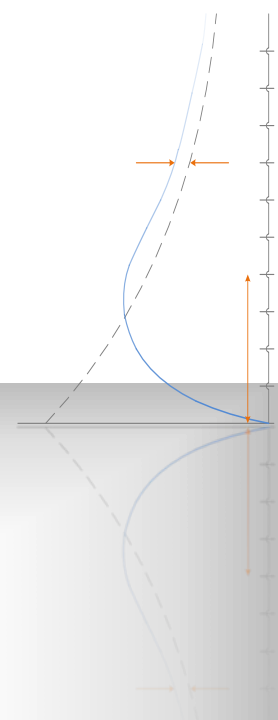
- Neither process utilizes uranium target material; only stable molybdenum targets are used significantly minimizing production and waste costs
- Utilize NorthStar's RadioGenix™ generating system
- As a result of NorthStar's technical advancements in the enhancement of the neutron capture and accelerator process along with the introduction of the platform technology RadioGenix, NorthStar is bringing neutron capture and accelerator Mo99 production into the 21st century without use of the fission process and its associated costs and waste issues.
 - **This is the first real technical advancement in Mo99/Tc99m production the industry has seen in over 30 years**



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



RadioGenix



RadioGenix Approval Pathway

- October 2010 NorthStar met with the FDA to outline a path to NDA submission
- January 2013 NorthStar submitted the NDA
- NorthStar received its Complete Response letter from the FDA late 2013 outlining deficiencies primarily in two areas
 - Microbiological Control
 - User Manuals
- NorthStar met with the FDA numerous times between Feb 2014 and July 2015 to gain understanding of FDA concerns and appraise the agency of NorthStar's approach to address those concerns
- Concurrently during this period NorthStar held multiple User's Group Focus Sessions attended by more than 200 industry professionals to gain knowledge of features nuclear pharmacists desired
 - Incorporated many of these desired features in RadioGenix
- NorthStar has resubmitted the revised NDA to FDA for review
- Pre-approval Inspections are in process by FDA
- Production underway in preparation for commercialization upon approval

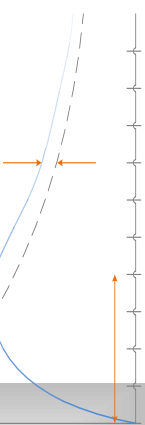
NorthStar Production Readiness

- Began producing Mo99 at MURR in late 2011
- NorthStar completed its first full production run in May 2015 under revised DMF
 - Validated technical advancements to enhance the productivity and modernize the Mo-99 neutron capture production process.
- Since May 2015
 - 52 full production runs completed
 - Produced >21,000 Ci Mo99 meeting the EU Mo99 monograph
 - Shipped ~400 NorthStar Type A Source Vessels
 - Mounted Source Vessels on RadioGenix producing >40,000 Ci Tc99m
 - Meets USP sodium pertechnetate Tc99m definition
 - Tagged kits requested to be evaluated by FDA
- Completed purchase of Type B Casks

NorthStar RadioGenix Training

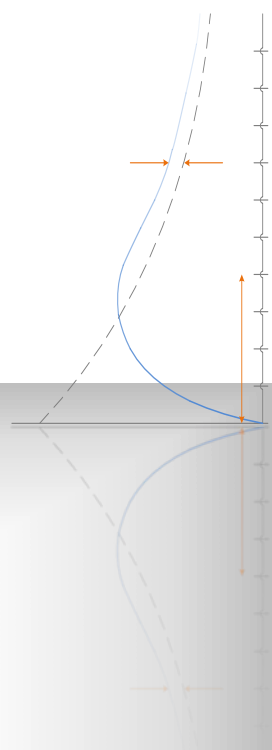
- NorthStar training personnel will provide required training in accordance with the NorthStar RadioGenix requirements at NorthStar Beloit facility for client authorized user certification
- NorthStar has already held multiple training classes attended by clients
 - Each of seven protocols run three 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

NorthStar Beloit Facility



Summary

- NDA resubmitted to FDA
- Pre Approval Inspections by FDA underway
- Potential customer RadioGenix training underway
- Commercialization upon approval of NDA





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