US Domestic Mo99 Production Update

James Harvey
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presented at

Opportunities and Approaches for Supplying Molybdenum-99 and Associated Medical Isotopes to Global Markets
Vienna International Centre, Vienna, Austria
June 17-18, 2017
Near Term and Long Term Solutions

• Near Term Solution – neutron capture
  o Missouri University Research Reactor (MURR)
    o MURR originally produced Mo99 with nat-Mo via neutron capture
    o NorthStar has been active in this option since 2009

• Long Term Solution – photon transmutation
  o NorthStar’s electron accelerator methodology for the production of Molybdenum-99

• Once up and running both solutions will be used to supply not only the US market but also could supply ROW.

• Both program are supported by NNSA Cooperative Agreements

• Neither process utilizes uranium target material; only stable molybdenum targets are used significantly minimizing production and waste costs

• Utilize NorthStar’s RadioGenix™ generating system
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
  o Microbiological Control
  o 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
  o 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 has commenced in preparation for approval and subsequent launch
**NorthStar Production Readiness**

- Began producing Mo99 at MURR in late 2011

- NorthStar completed its first full production run in May 2015 under revised DMF

- Since May 2015
  - 51 full production runs completed
  - Produced ~20,000 Ci Mo99 meeting the EU Mo99 monograph
  - Shipped ~385 NorthStar Type A Source Vessels
  - Mounted Source Vessels on RadioGenix producing >40,000 Ci Tc99m
    - Meets USP sodium pertechnetate Tc99m definition
    - Tagged multiple Ceretec, Sulphur Colloid, MAA, MAG-3, Sestamibi, Disofenin, DTPA, MDP, HDP, Mebrofenin, Myoview, PYP kits

- Completed purchase of Type B Casks
$\textbf{NorthStar RadioGenix Training}$

- 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 training classes attended by clients
  - Each of seven protocols run three times by each attendee
  - Training completed early 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 ready to initiate production with FDA approval of RGx NDA
NorthStar Beloit Facility

50,000 sqft building with planning of an additional 35,000 sqft underway
Summary

• NDA resubmitted to FDA

• Pre Approval Inspections by FDA underway

• Potential customer RadioGenix training underway

• Ready to initiate production

• Production start upon approval of NDA
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