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

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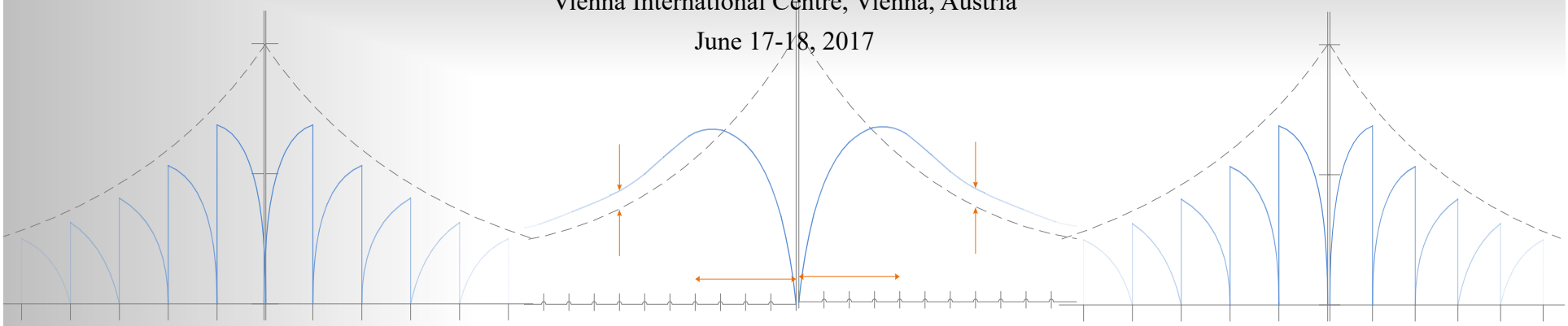

Near Term and Long Term Solutions

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

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 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

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

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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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