NorthStar Progress Towards Domestic Mo99 Production

J.T. Harvey, G.H. Isensee, S.D. Moffatt, G.P. Messina

NorthStar Medical Technologies, LLC
5249 Femrite Drive, Madison, WI 53718 – USA

Mo-99 2014 Topical Meeting on Molybdenum-99 Technological Development

June 24-27, 2014
Washington D. C.
Topics

• Background on Mo99 Production at NorthStar
  o Neutron Capture Effort (neutron capture technology track)
  o Photon Capture (LINAC) Effort (accelerator technology track)

• Status Update

• Summary & Discussion
Background on Mo99 Production at NorthStar

• Near Term Solution – Neutron Capture
  • Missouri University Research Reactor
    • Contract in place effective March 2011

• Long Term Solution – Photon Capture
  • NorthStar’s LINAC methodology for the production of Molybdenum-99

• It is expected that this solution will eventually be able to produce 50+% of the US requirement

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

➢ These two approaches require NorthStar’s RadioGenix™ technology in order to guarantee success
Background on Mo99 Production at NorthStar Neutron Capture

- NorthStar has been active in this option since 2009
  - MURR originally produced Mo99 with nat-Mo

- NorthStar/MURR capable of producing up to 3,000+ 6D Ci per week
  - SA of Mo99 1Ci/g – 6Ci/g potentially,
  - one target set per week (100 6D Ci – 3,000+ 6D Ci Mo99; nat or enriched Mo dependent) processed,
  - steady weekly production, and
  - Dedicated shipping to client pharmacies; UPS/FedEx Ground can handle return of spent Mo99 solutions for recovery & recycle (if enriched Mo98 used); otherwise dispose of after DNS by NorthStar
Background on Mo99 Production at NorthStar Neutron Capture

- MURR has outstanding operational record,
- MURR/NorthStar production agreement announced March 1st, 2011
  - Extension to 2019 being finalized
  - Batch size scale-up under review
- Production upon FDA approval,
- Supported by NNSA Cooperative Agreement, and
- No licensing issues.
Background on Mo99 Production at NorthStar

Neutron Capture

OPERATING EXPERIENCE
UNIVERSITY of MISSOURI RESEARCH REACTOR
Background on Mo99 Production at NorthStar Photon Capture (LINAC)

• NorthStar has been active in this field since Nov 2007
  o NorthStar funded effort at RPI in early 2008 to validate the 1999 INL publication
  o Produced small quantities of Mo99 in that study and validated calculated estimates and experimental results were comparable

• NorthStar facility will house up to 16 LINAC machines initially capable of producing >3,000+ 6D Ci per week
  o SA of Mo99 ~10Ci/g potentially
  o one target set per day (~2,500Ci Mo99) processed
  o steady, redundant production on a daily basis
  o Site expansion space set aside for additional 16 LINAC machines as needed
  o NNSA supported via Cooperative Agreement

• Facility location - Beloit, WI
  o Located immediately adjacent to a new power substation being built with NorthStar requirements incorporated in the design
Status Update
Neutron Capture

- MURR has filed the scale-up DMF with the FDA on July 2, 2013
  - Original DMF filed in September 2012

- NorthStar in process of completing setup of the Mo99 dispensing line at MURR
  - Physical install complete
  - Validation hot runs scheduled for completion 3QTR14
  - Dispensing Line Amendment ready 1QTR15; submitted as part of Final Amendment to NDA 2QTR15
  - Inspection ready 1QTR15

- Certification of NorthStar’s Type A shipping system completed in 4QTR13
Status Update
Neutron Capture
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Beloit Facility
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• Production relevant thermal tests at both 35MeV and 42MeV performed at ANL LINAC facility 2QTR14
  o Production testing scheduled to start next month
    ❖ 5 – 24 hour irradiations
    ❖ 1 – 6.5 day irradiation
    ❖ Load processed Mo99 on generating system and run for 14 period
      ✓ Product testing per USP

• Beloit Gateway facility design continues
  o Currently in permitting process to begin construction of first building on the site
Status Update
Beloit LINAC Facility
Status Update
Beloit LINAC Facility
Summary

• All MURR operations supporting NorthStar to be inspection ready by 2QTR15

• Neutron capture production upon FDA approval of NorthStar’s NDA for the generating system
  o 100 6D Ci/wk at introduction w/ high purity nat-Mo targets
  o Ramp to 750 6D Ci/wk within 6 months of start
  o Transition to eMo98 targets in 2016
  ◆ Additional DMF and Supplement to NDA required
  o Production capability goal of up to 3,000 6D Ci by 4QTR16

• NorthStar announced on June 7th at SNMMI execution of an LOI with Triad Isotopes to supply domestic non-HEU Mo99 to Triad nuclear pharmacies once FDA approval is achieved
Summary

- Photon transmutation efforts continue with optimization of production parameters including curie level production and generator system runs 3QTR14

- Facility construction starting as soon as permits granted
  - Building to support initial ISO 8 manufacturing and administrative needs of 50,000 sqft
  - First of planned site expansion that includes supports production growth needs and LINAC building
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