



# ***Status of Domestic Production of Mo99 via Neutron Capture***

***NorthStar Medical Technologies, LLC***

***presented at***

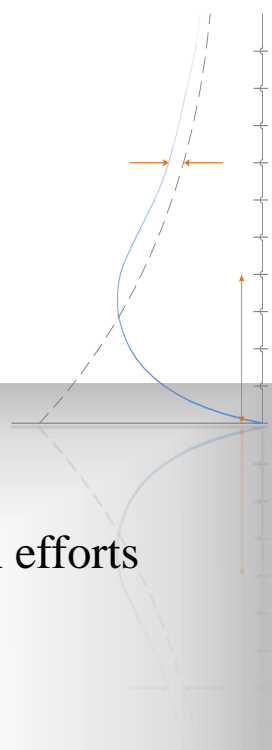
***2016 NNSA Mo99 Topical Conference***

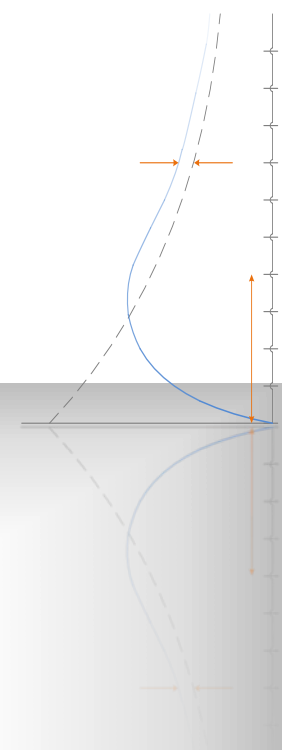
***St. Louis, Mo***

***11-14 September 2016***

# *Topics*

- NorthStar's technology for producing Mo-99
- Current status of technology, infrastructure development and implementation efforts
- Current status of regulatory approval efforts
- Discussion

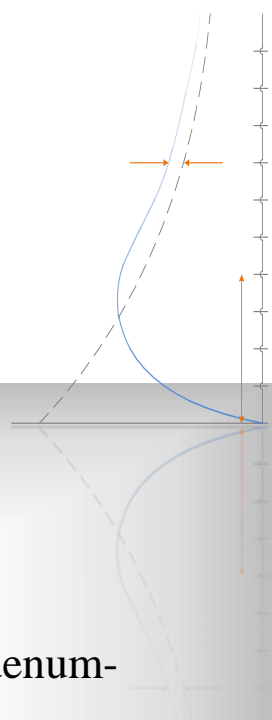




# ***Mo99 Program Background***

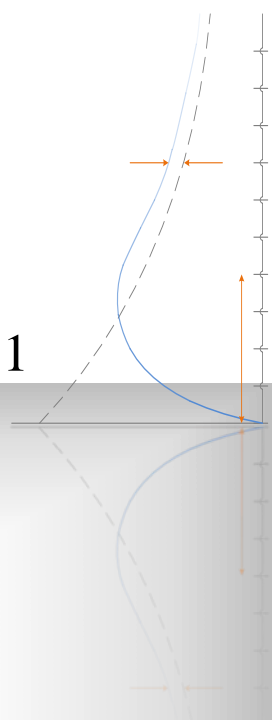
# *Near Term and Long Term Solutions*

- 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
  - Investigating use of PWR with Westinghouse
- 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 programs are supported by NNSA Cooperative Agreements
  - Neutron capture \$25,000,000 (max share; 50/50 cost sharing)
  - Accelerator currently ~\$6,000,000 with Plus Up under evaluation to raise to \$25,000,000 (max share; 50/50 cost sharing)

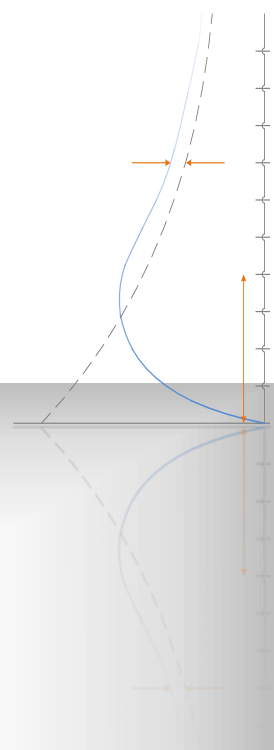


# *Production of Mo99 via Reactor at MURR*

- MURR has outstanding operational record
- MURR/NorthStar production agreement announced March 1<sup>st</sup>, 2011
  - Extension to 2019 executed August 2014
- Production upon FDA approval
- Spent Mo99 solutions returned ground for recycle/SV recovery
- Operating under MURR license
- 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 (60 6D Ci – 3,000+ 6D Ci Mo99; nat or enriched Mo dependent) processed
  - steady weekly production

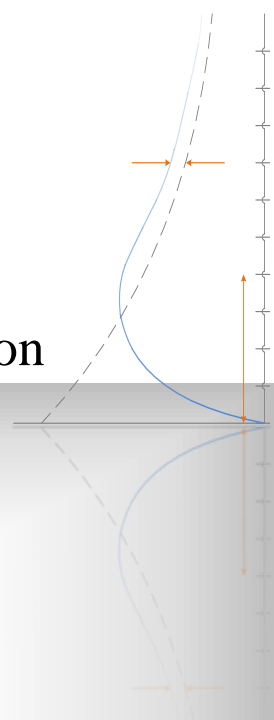


# *Readiness Status*



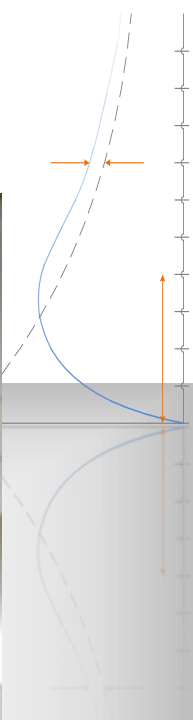
# *Missouri University Research Reactor (n,γ)*

- Since May 2015 NorthStar has completed in preparation for initiation of production upon FDA approval of NDA
  - ~30 production runs of 100 6D Ci each
  - Prepared >13,000 Ci Mo99
  - Filled ~300 SV
  - Shipped overnight SV
  - Mounted and run Mo99 produced at MURR on NorthStar's RGX system
- Initiated clean room SV production operations at Beloit
- Initiated expansion of the MURR fill line operations to 4X current production rate





# *MURR Hot Cells*

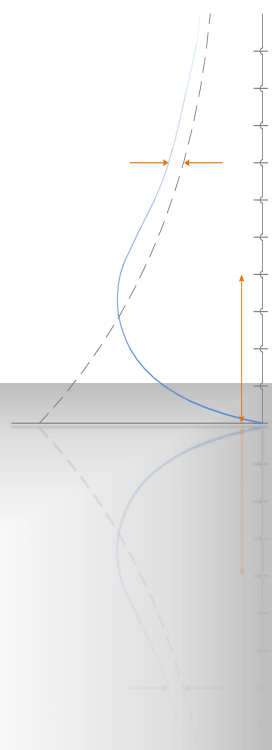




# *MURR NorthStar Dispensing Line #1*



# Type A Source Vessel



## ***MURR NorthStar Dispensing Line #2***

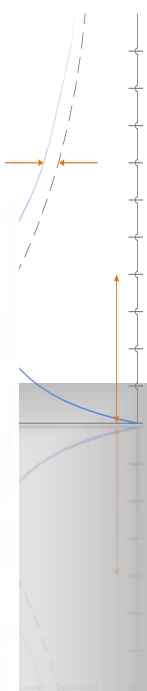


First Beloit SV Build



Completed source vessels ready to ship

## ***MURR NorthStar Dispensing Line #2***





## ***MURR NorthStar Dispensing Line #2***



MURR2 fill line - rear

## *MURR NorthStar Dispensing Line #2*



MURR2 side



## ***MURR NorthStar Dispensing Line #2***



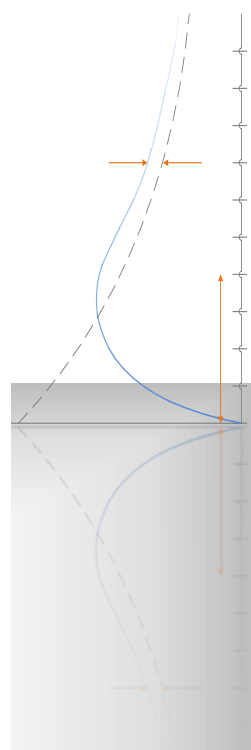
**MURR2 – fill line; front w/ conveyor**



## *MURR NorthStar Dispensing Line #2*



MURR2 – source vessel inspection glove box



## ***MURR NorthStar Dispensing Line #2***

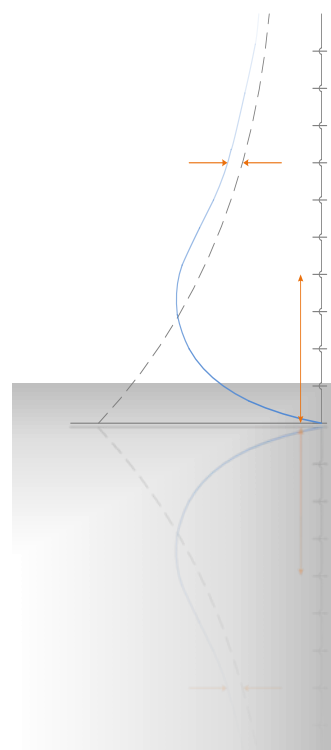


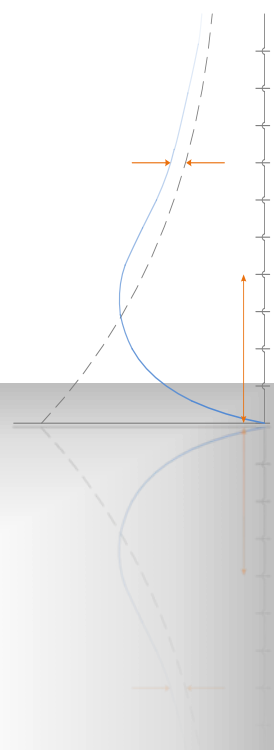
Conveyor belt details (simulated SV on left, drive motor on right)

## ***MURR NorthStar Dispensing Line #2***



Manipulators in Box ready for Install

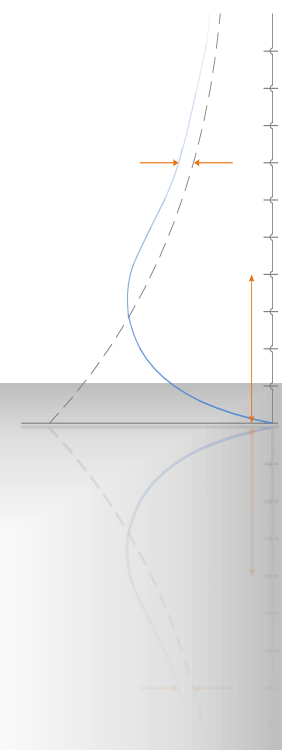




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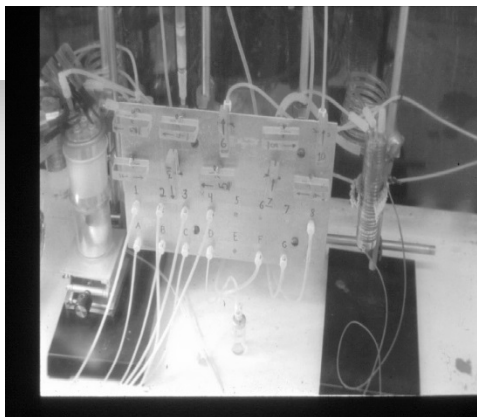
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# *RadioGenix*





# *RadioGenix™ Evolution*



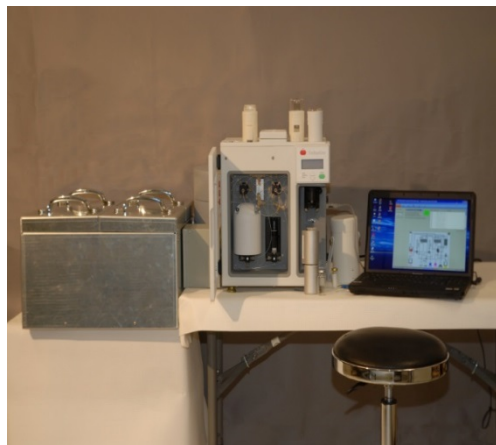
Mid 1990's



2000-2005



2008-2010

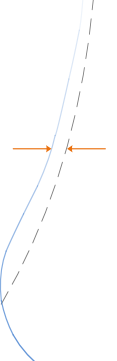


2011-2012



2014

# *RadioGenix™*

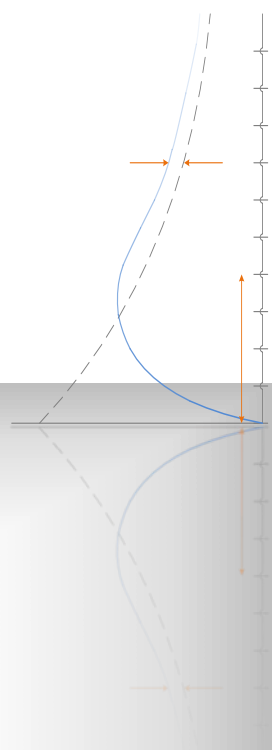




## *RadioGenix™ FDA Timeline*

- October 2010 NorthStar met with the FDA to outline a path to NDA submission
- MURR submitted DMF for production via neutron capture in September 2012
- NorthStar submitted *RadioGenix™* (TechneGen) DMF in October 2012
- January 2013 NorthStar submitted its NDA
- NorthStar received in March 2013 from FDA a PDUFA date of November 4, 2013
- NorthStar received its Complete Response letter from the FDA on November 4, 2013 outlining deficiencies primarily in two areas
  - Microbiological Control
  - User Manuals
- NorthStar met with the FDA on February 27, 2014 to gain clarity on the CR letter
  - NorthStar has submitted to FDA its revised Microbiological Test Plan (MTP) for comment
  - Met with the FDA July 2, 2014 to MTP
- NorthStar added ozone sterilization to the system and made other enhancements as a result
- NorthStar will complete submission of our responses to the FDA's Complete Response letter 4QTR16

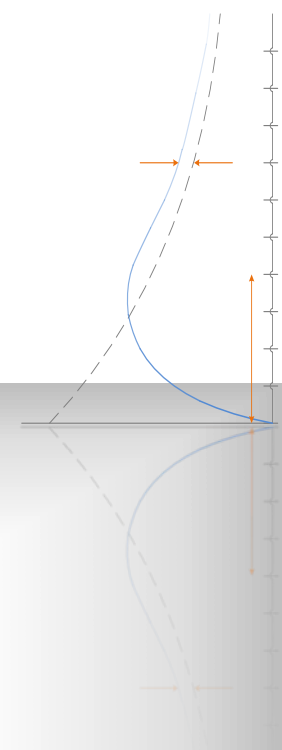
# *Summary*



# Summary

- Numerous production runs completed last 15 months
  - ~30 production runs of 100 6D Ci each
  - Prepared ~12,000 Ci Mo99
  - Filled ~300 SV
- Initiated clean room SV production operations at Beloit
- Initiated expansion of the MURR fill line operations to 4X current production rate

***NorthStar is ready to initiate domestic production of Mo99 upon FDA approval of RGX***



## *Discussion*



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