



# NorthStar Progress Towards Domestic Mo99 Production

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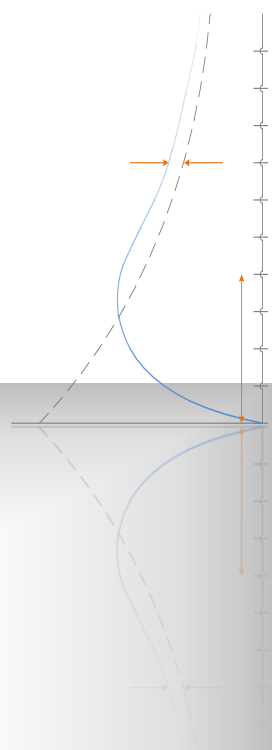
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**Mo-99 2014 TOPICAL MEETING ON  
MOLYBDENUM-99 TECHNOLOGICAL DEVELOPMENT**

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

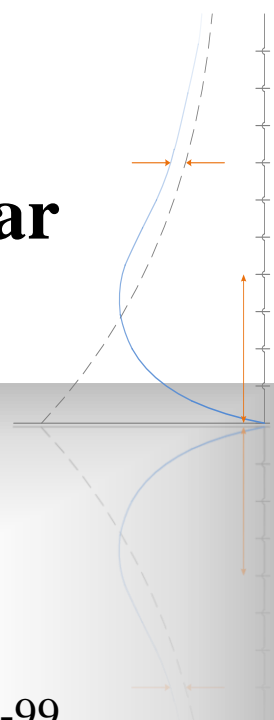
# Topics

- Background on Mo99 Production at NorthStar
  - Neutron Capture Effort (neutron capture technology track)
  - Photon Capture (LINAC) Effort (accelerator technology track)
- Status Update
- Summary & Discussion



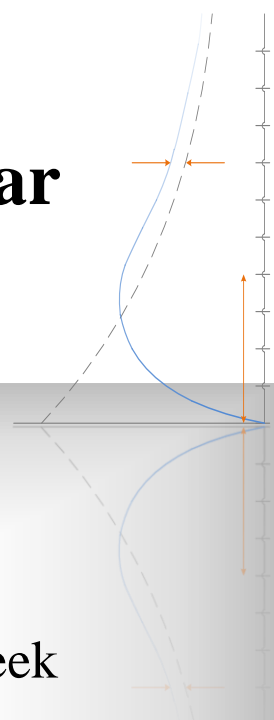
# Background on Mo99 Production at NorthStar

- **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*



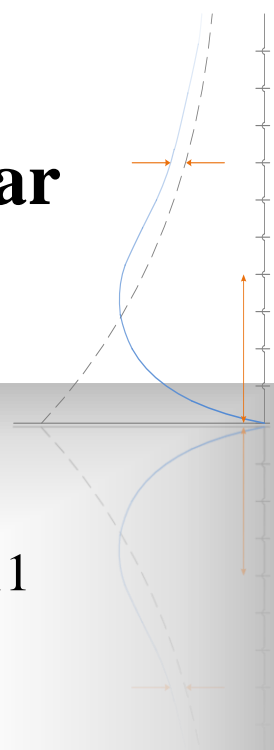
# Background on Mo99 Production at NorthStar Neutron Capture

- 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



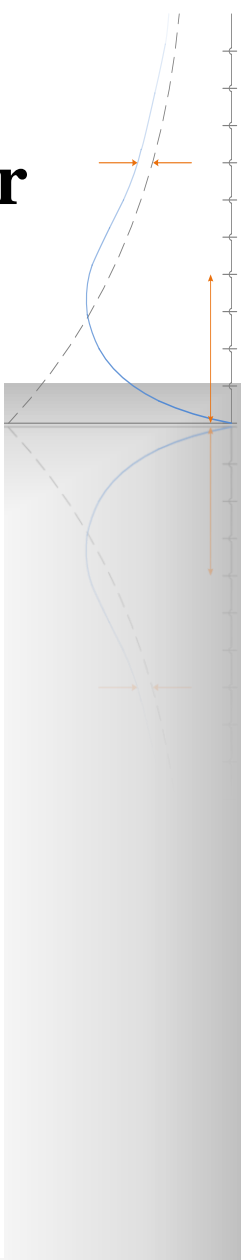
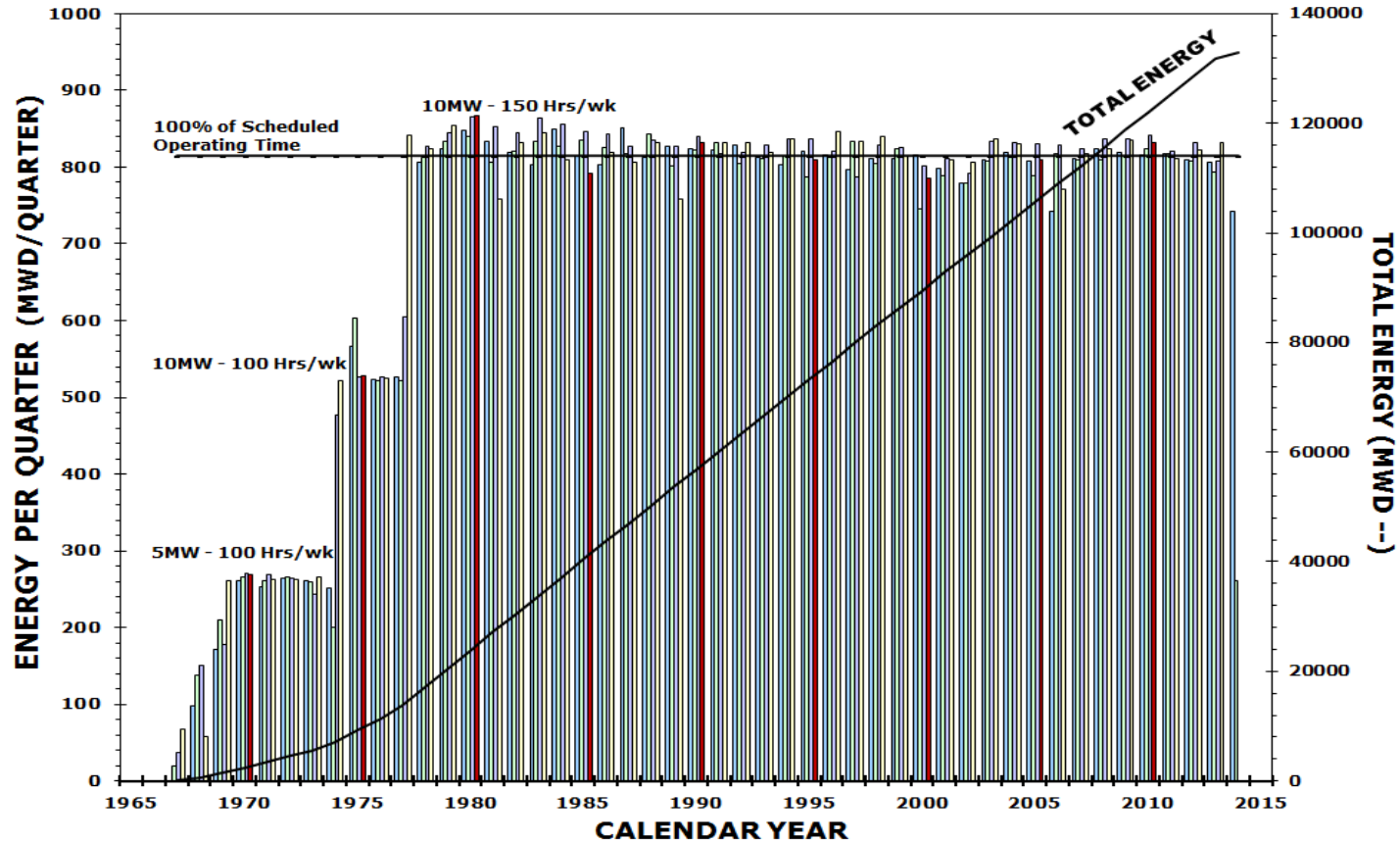
# Background on Mo99 Production at NorthStar Neutron Capture

- MURR has outstanding operational record,
- MURR/NorthStar production agreement announced March 1<sup>st</sup>, 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.



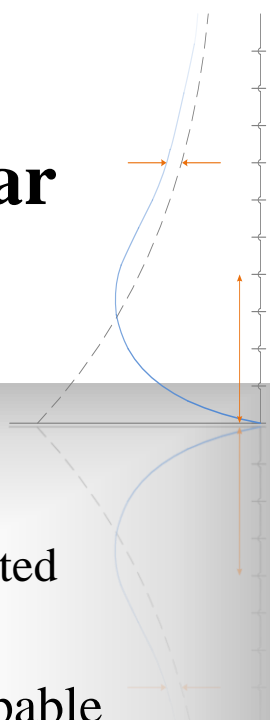
# Background on Mo99 Production at NorthStar Neutron Capture

## 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
  - NorthStar funded effort at RPI in early 2008 to validate the 1999 INL publication
  - 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
  - SA of Mo99 ~10Ci/g potentially
  - one target set per day (~2,500Ci Mo99) processed
  - steady, redundant production on a daily basis
  - Site expansion space set aside for additional 16 LINAC machines as needed
  - NNSA supported via Cooperative Agreement
- Facility location - Beloit, WI
  - Located immediately adjacent to a new power substation being built with NorthStar requirements incorporated in the design



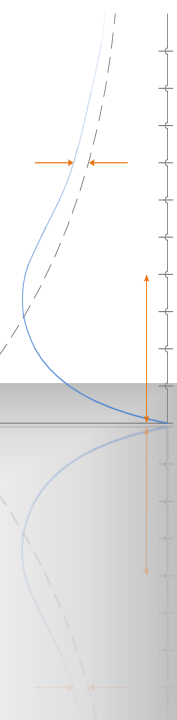
# Status Update

## Neutron Capture

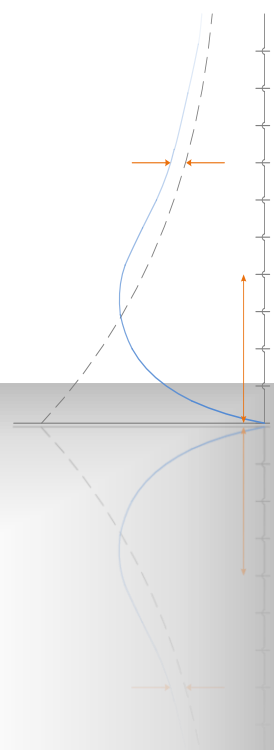
- MURR has filed the scale-up DMF with the FDA on July 2, 2013
  - Original DMF filed in September 2012
- NorthStar in process of completing setup of the Mo99 dispensing line at MURR
  - Physical install complete
  - Validation hot runs scheduled for completion 3QTR14
  - Dispensing Line Amendment ready 1QTR15; submitted as part of Final Amendment to NDA 2QTR15
  - Inspection ready 1QTR15
- Certification of NorthStar's Type A shipping system completed in 4QTR13



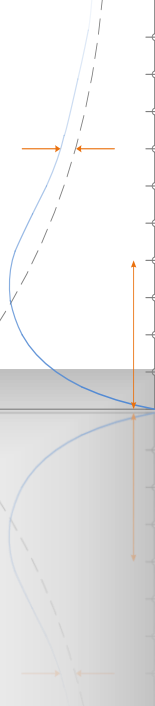
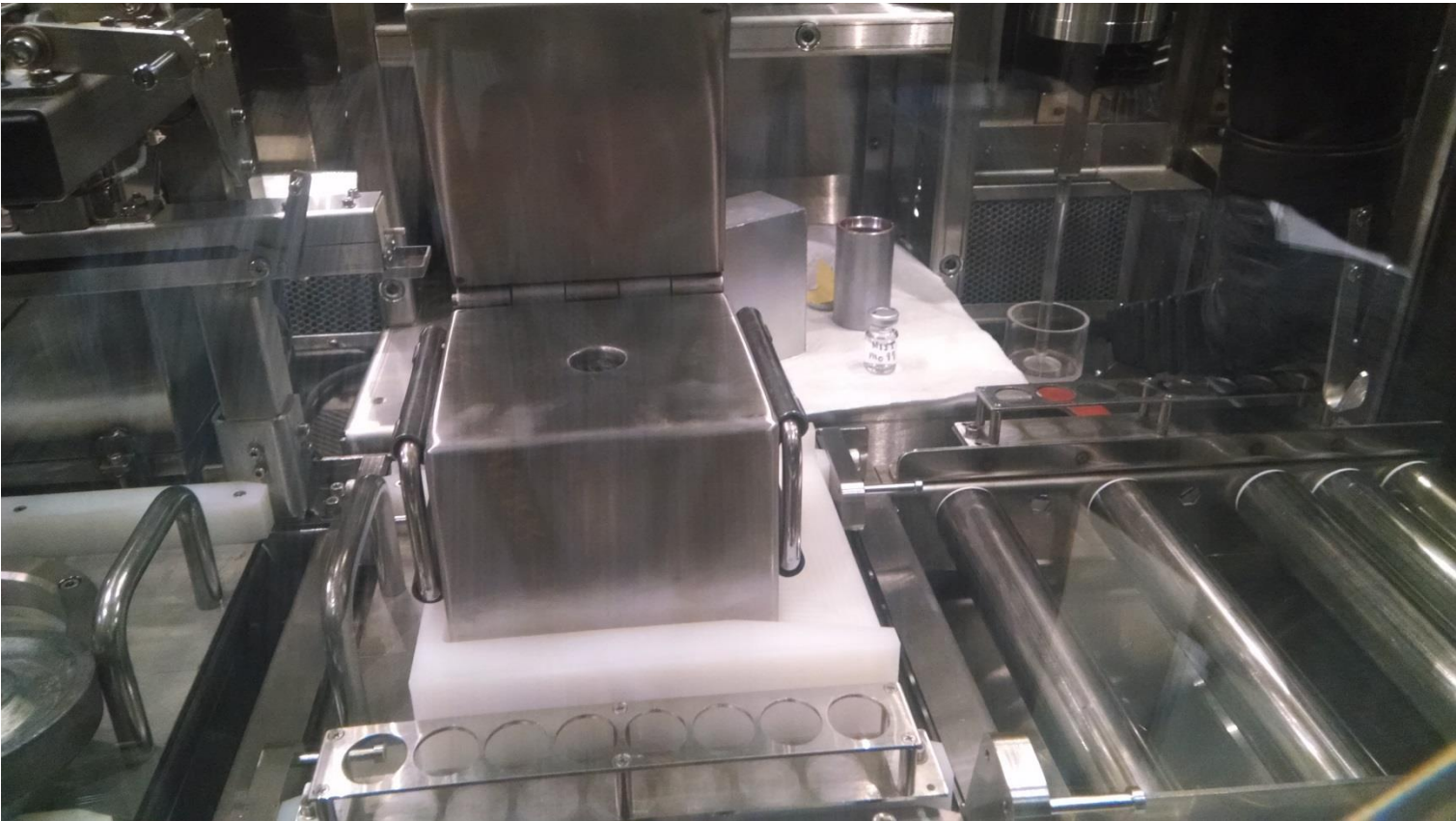
# Status Update Neutron Capture



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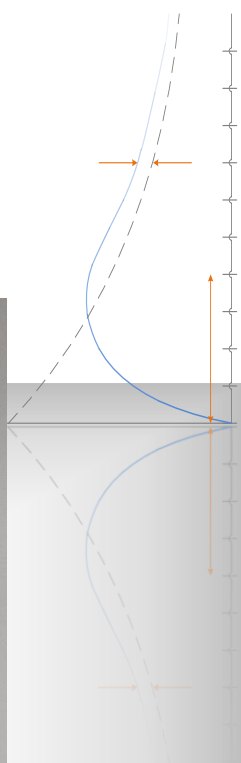
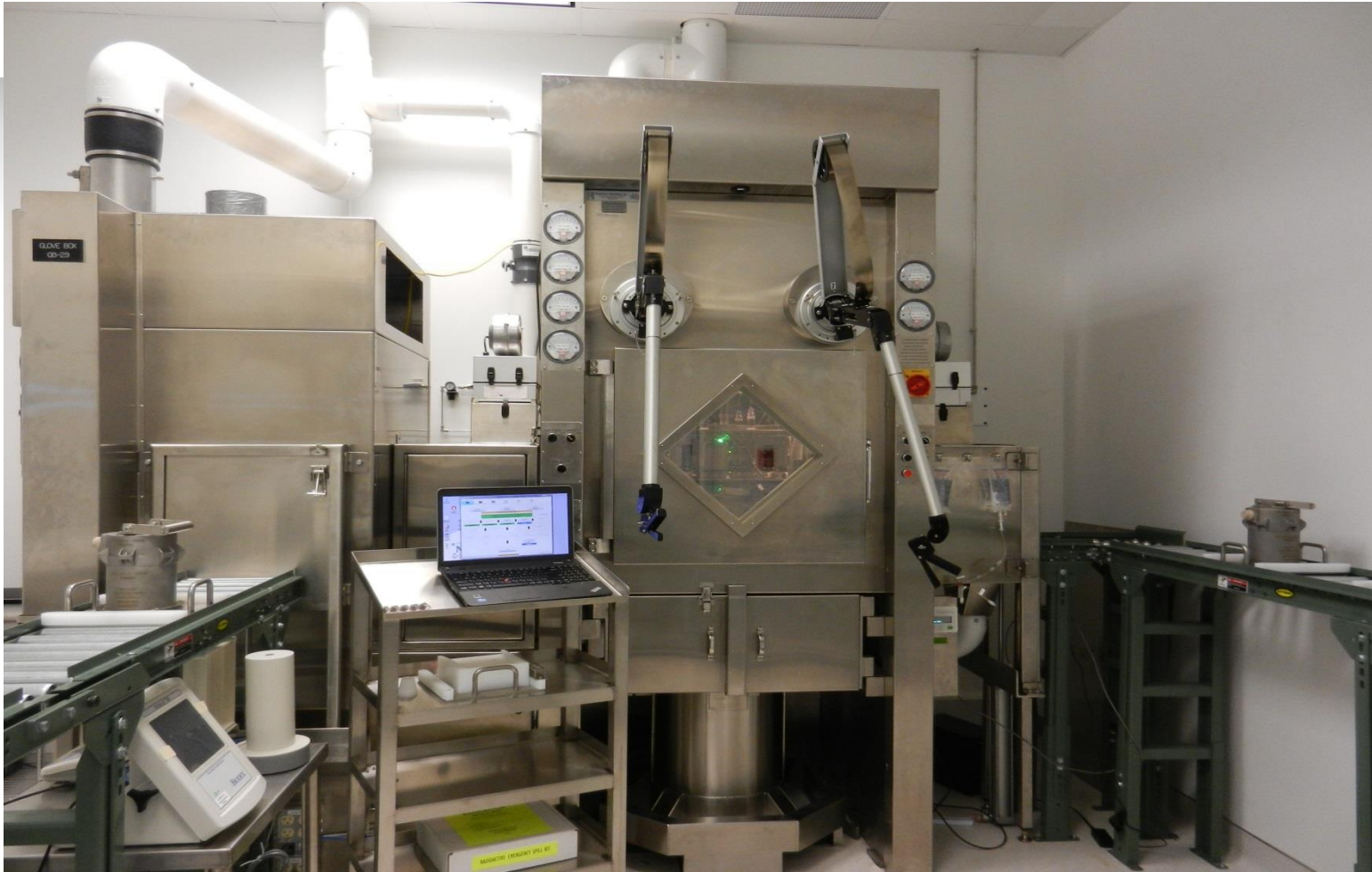


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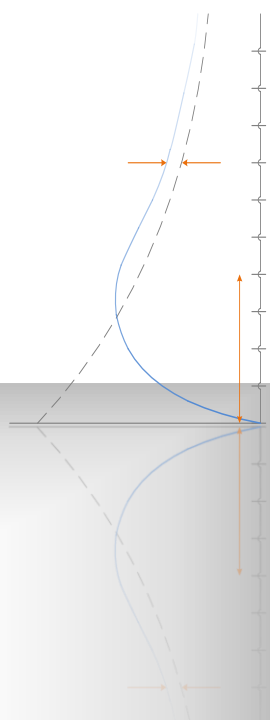
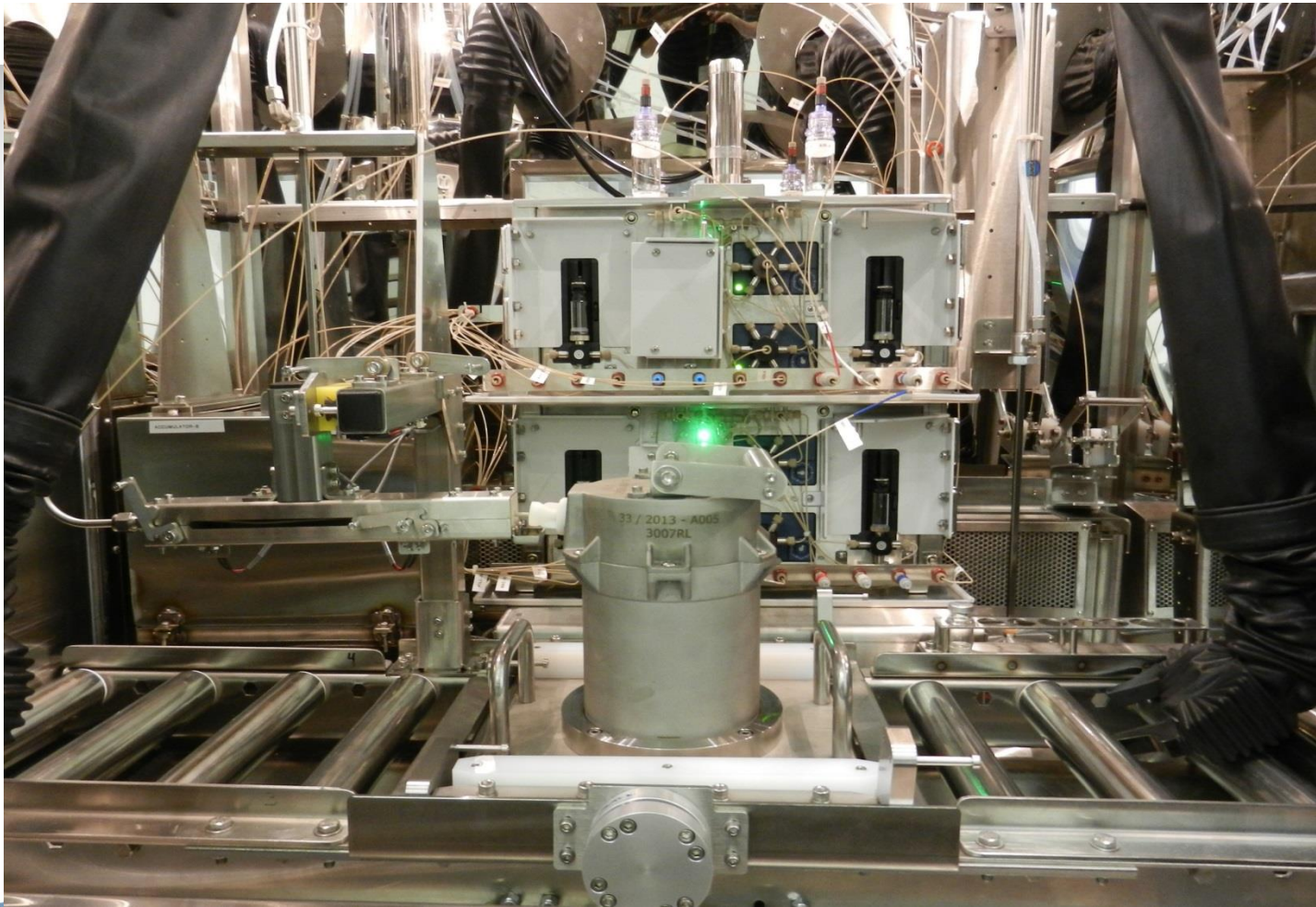




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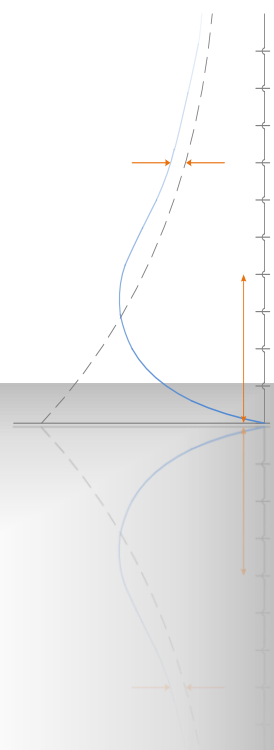
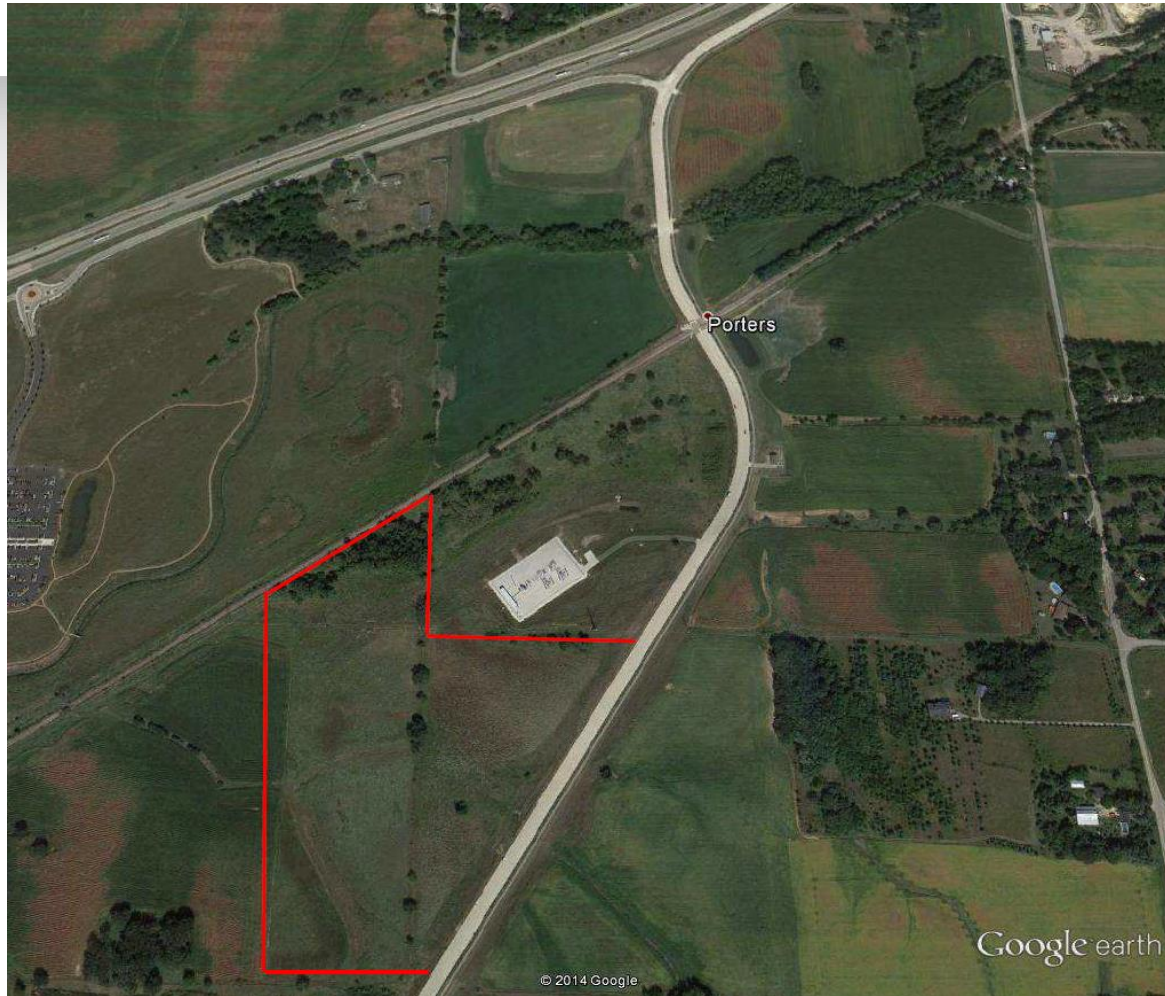


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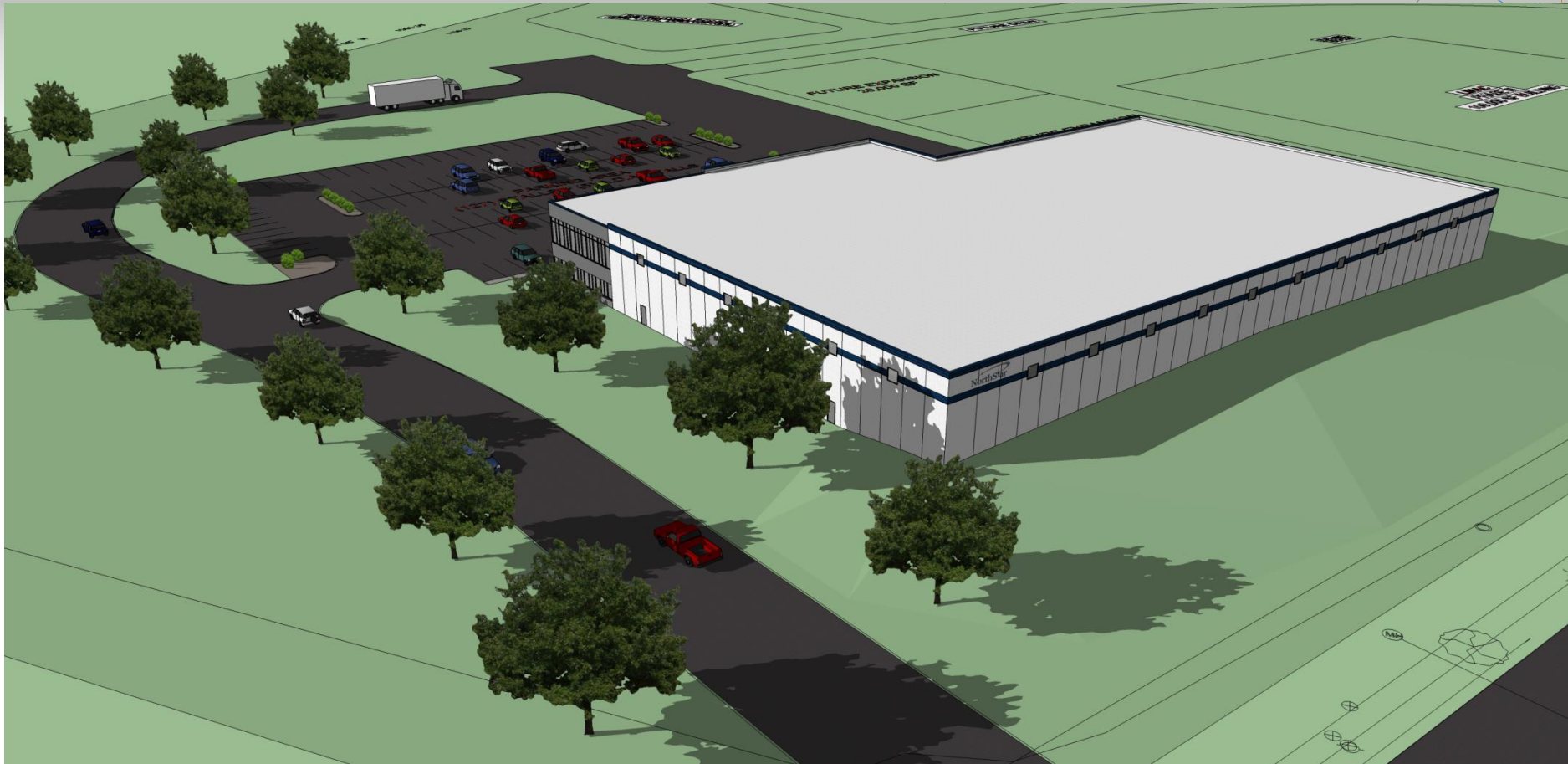




# Status Update Beloit Facility



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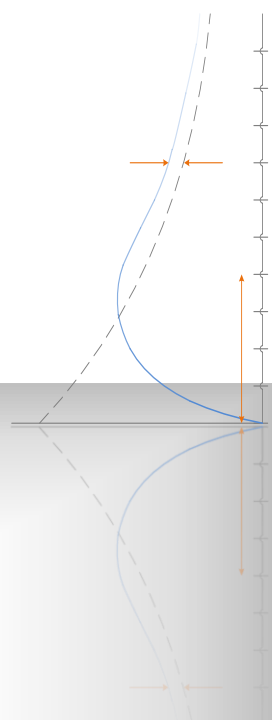




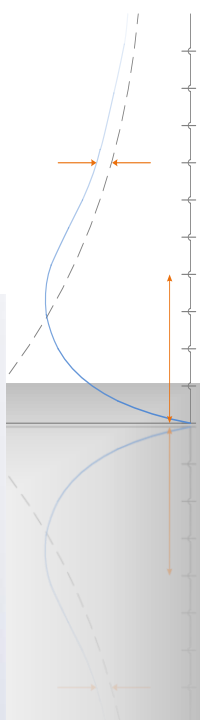
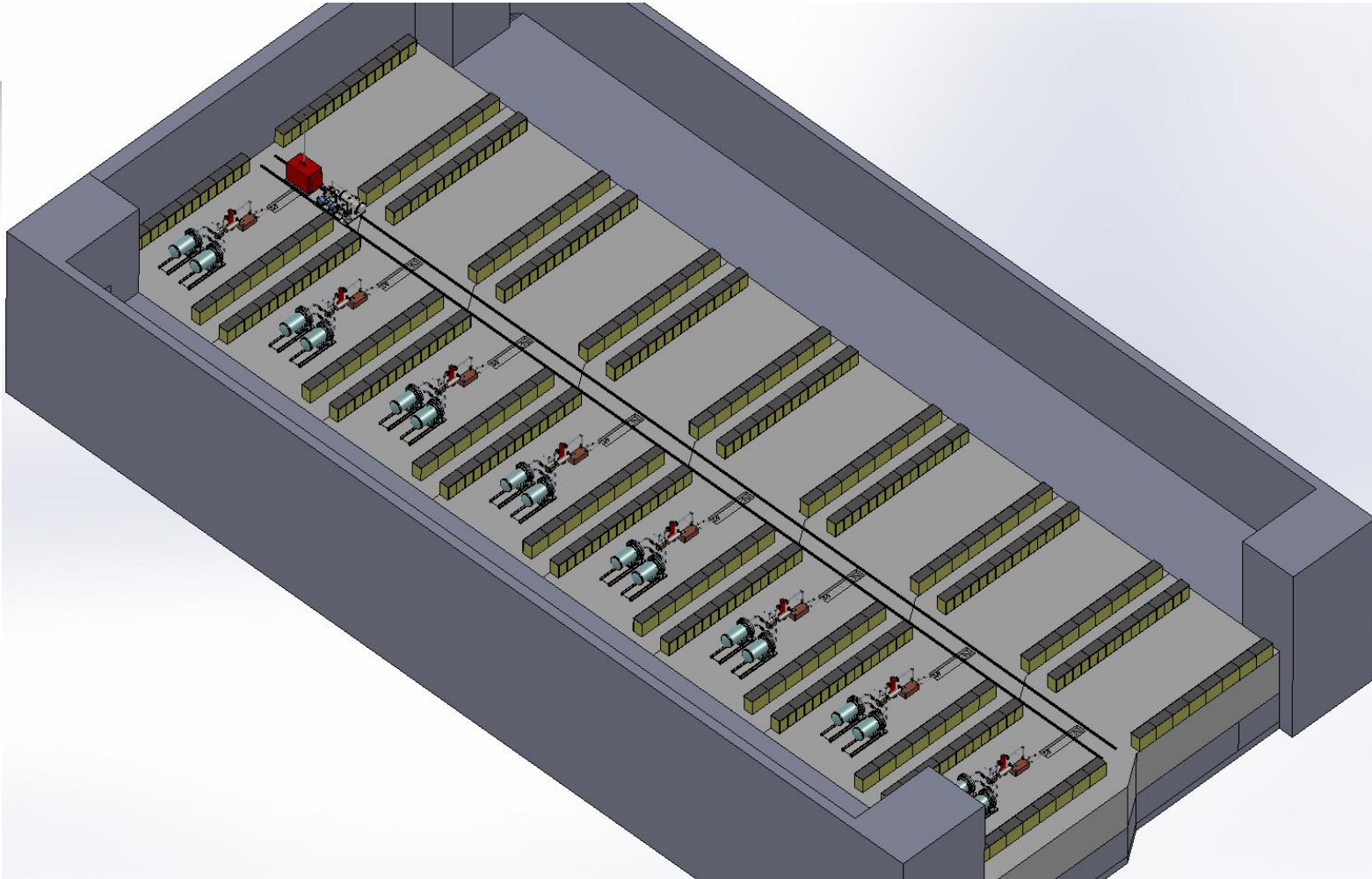
# Status Update

## Photon Transmutation

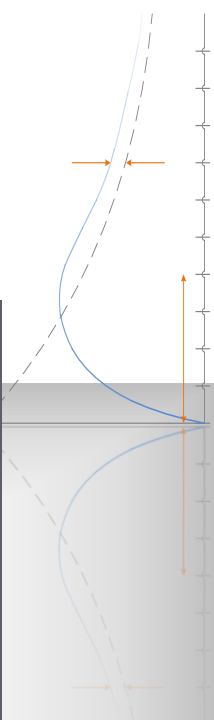
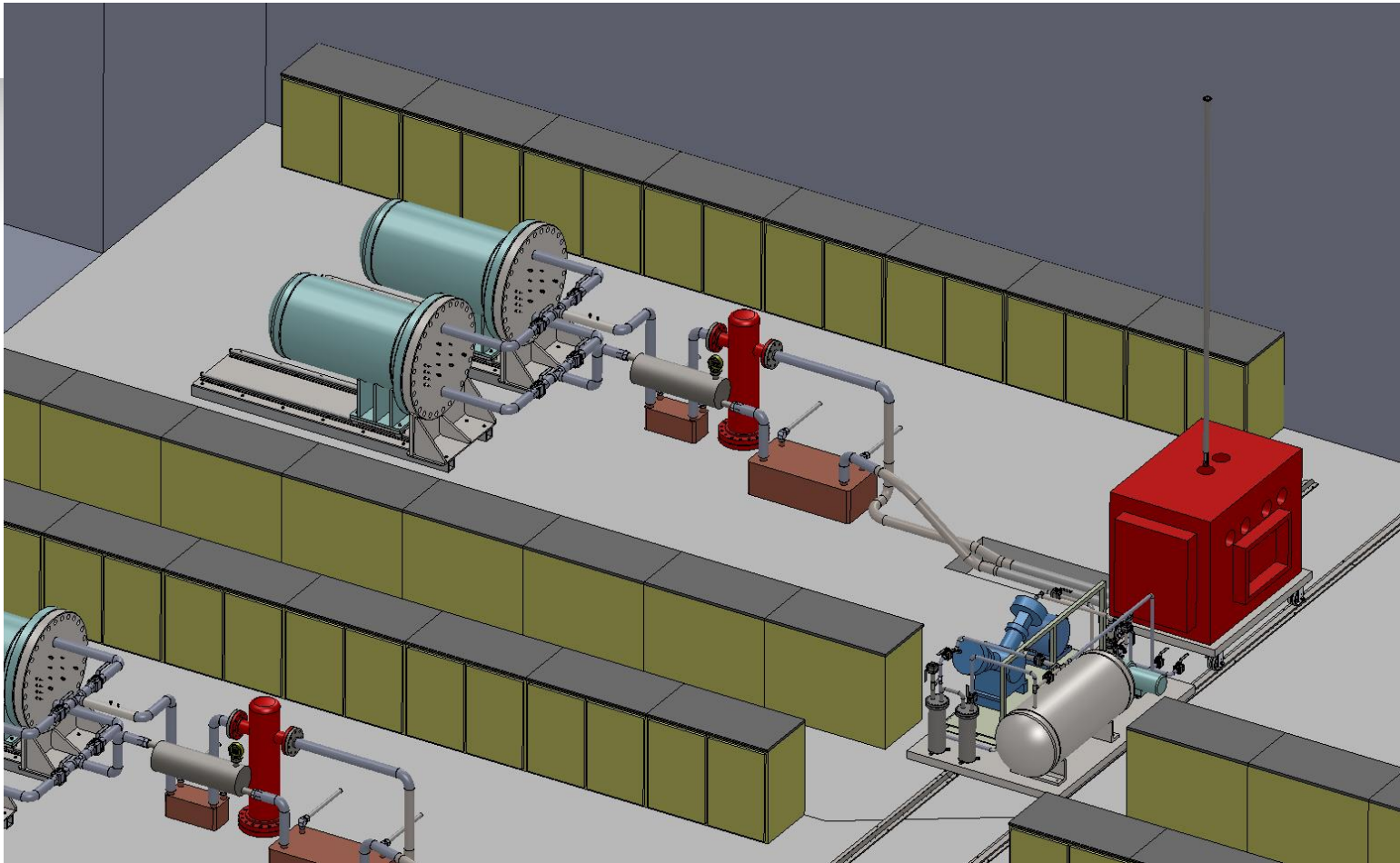
- Production relevant thermal tests at both 35MeV and 42MeV performed at ANL LINAC facility 2QTR14
  - Production testing scheduled to start next month
    - ❖ 5 – 24 hour irradiations
    - ❖ 1 – 6.5 day irradiation
    - ❖ Load processed Mo99 on generating system and run for 14 period
      - ✓ Product testing per USP
- Beloit Gateway facility design continues
  - 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
  - 100 6D Ci/wk at introduction w/ high purity nat-Mo targets
  - Ramp to 750 6D Ci/wk within 6 months of start
  - Transition to eMo98 targets in 2016
    - ❖ Additional DMF and Supplement to NDA required
  - Production capability goal of up to 3,000 6D Ci by 4QTR16
- NorthStar announced on June 7<sup>th</sup> 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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