



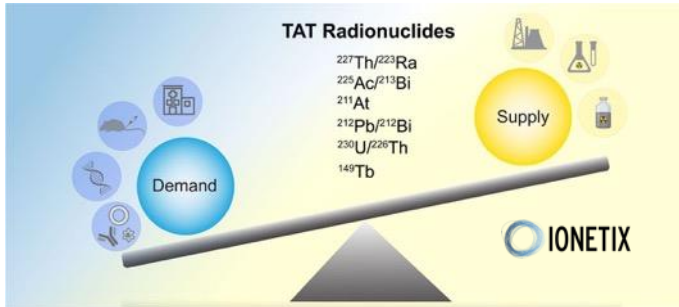
Recent Progress in Cyclotron R&D for Commercial Production of **Astatine-211** at Ionetix

Astatine-211 User Group Meeting
October 3, 2023

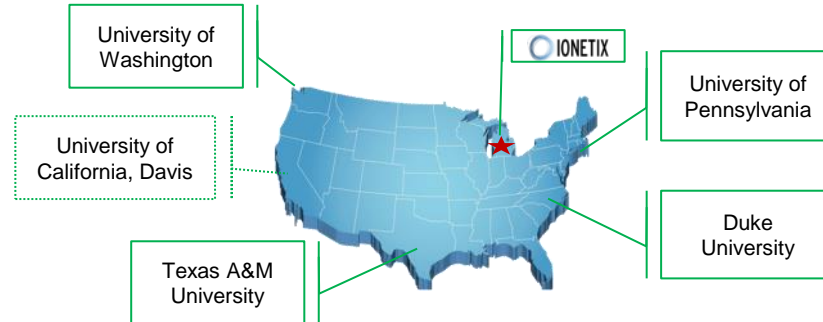
Xiaoyu Wu, PhD
VP, R&D

Targeted Alpha Therapy Radionuclide Supply: Astatine-211 (David Eve - DOE meeting 2022)

Growing demand in TAT raises need for supply

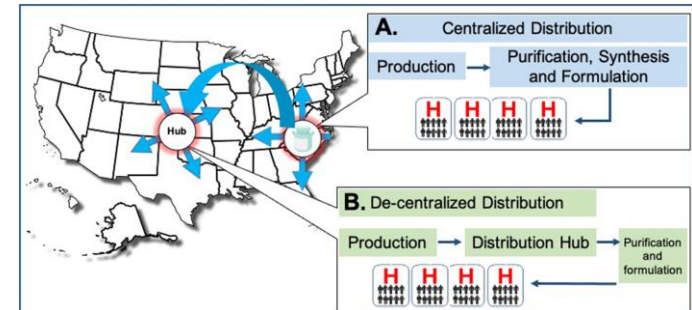


Astatine-211 production in the U.S.



Ionetix commercial Astatine-211 supply

1. New facility in **Lansing, Michigan** dedicated to high-yield alpha isotope production and distribution
2. Optimization of **existing cyclotron** technology for improved At-211 production
3. Planned growth for **Regional Production Facilities** for expanded access & availability
4. Development of **new cyclotron** system to support regional growth



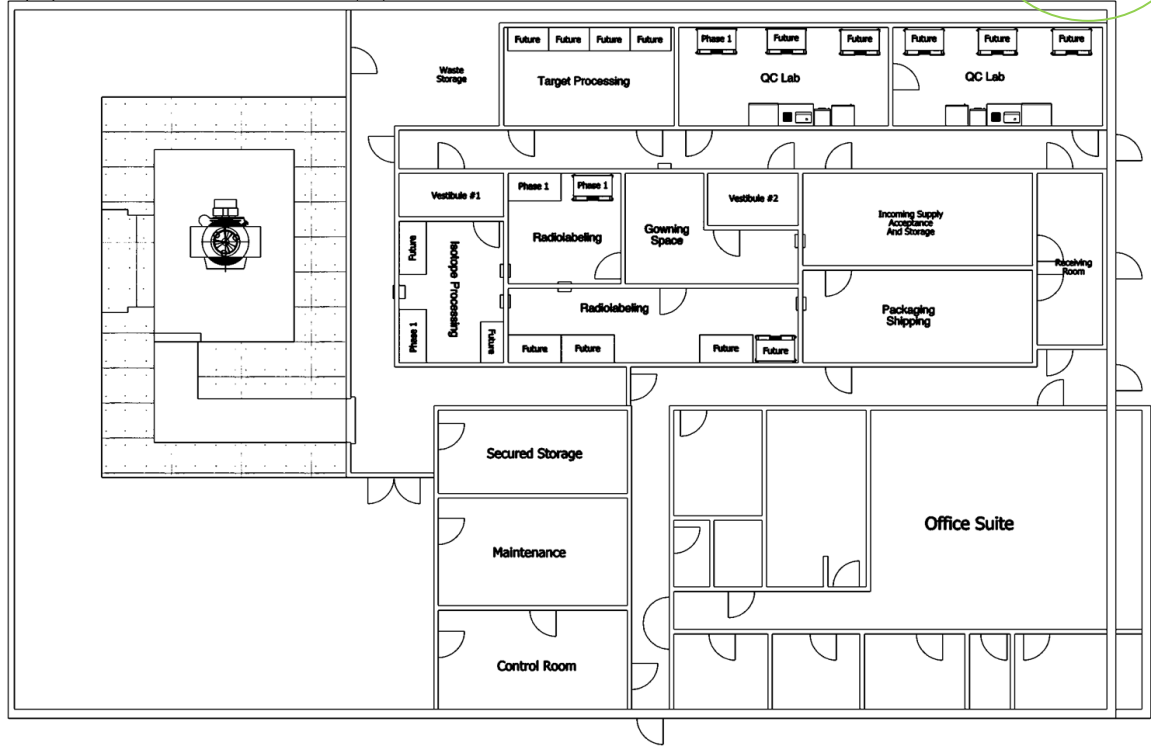
Radchenko, V. et al. "Production and Supply of alpha-Particle-Emitting Radionuclides for Targeted Alpha Therapy". J Nucl Med. 2021 Nov;62(11):1495-1503.
Feng Y. et al. "Production, Purification and Availability of ²¹¹At: Near Term Steps Towards Global Access". Nucl Med Biol. 2021 Sep-Oct; 100-101: 12-23.

New Ionetix TAT Facility (David Eve - DOE meeting 2022)



Lansing, Michigan

Site Acquired March 2021



Google Maps

Ionetix Cyclotron Solutions

R&D Development Portfolio

Highly Experienced Ionetix Cyclotron Design and Engineering Team:

2013

- **Medical Isotope Production – Positron Emitting**

- Ion-12SC
- Ion-20SC

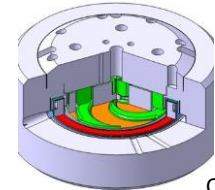
Isotope	Nuclear Reaction	Half-Life	Target
N-13	$^{16}\text{O}(p,\alpha)^{13}\text{N}$	10 minutes	Liquid
F-18	$^{18}\text{O}(p,n)^{18}\text{F}$	109.7 minutes	Liquid
Ga-68	$^{68}\text{Zn}(p,n)^{68}\text{Ga}$	68 minutes	Liquid



Ion-12SC

- **Proton Cancer Therapy**

- Pronova K250
- CIM SC240



CIM SC240

2021

- **Medical Isotope Production – Alpha Emitters**

- Ion-30SC
- CS-30
- Ionetix/CIM-22

Isotope	Nuclear Reaction	Half-Life	Target
At-211	$^{209}\text{Bi}(\alpha,2n)^{211}\text{At}$	7.2 hours	Solid
Ac-225	$^{226}\text{Ra}(p,2n)^{225}\text{Ac}$	9.92 days	Solid

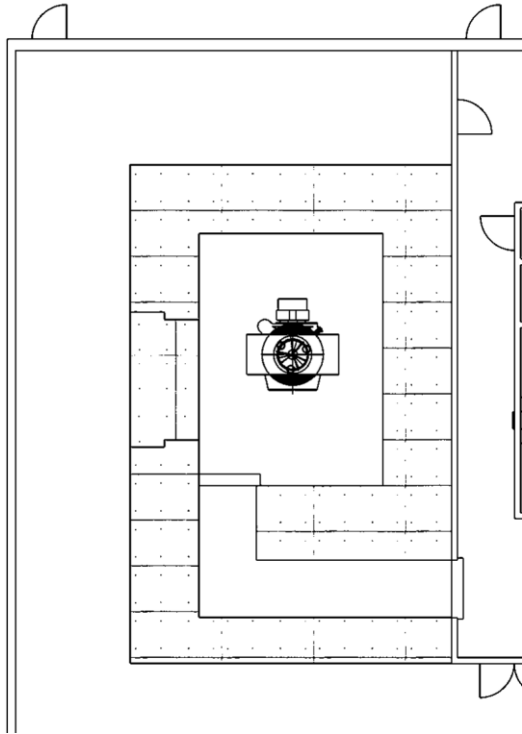


CS-30

New Ionetix TAT Facility (David Eve - DOE meeting 2022)



Lansing, Michigan



Google Maps

September 2022

Cyclotron Assembly and Installation

Magnet Installation and Magnetic Field Mapping Completed in May 2022



Cyclotron Vault

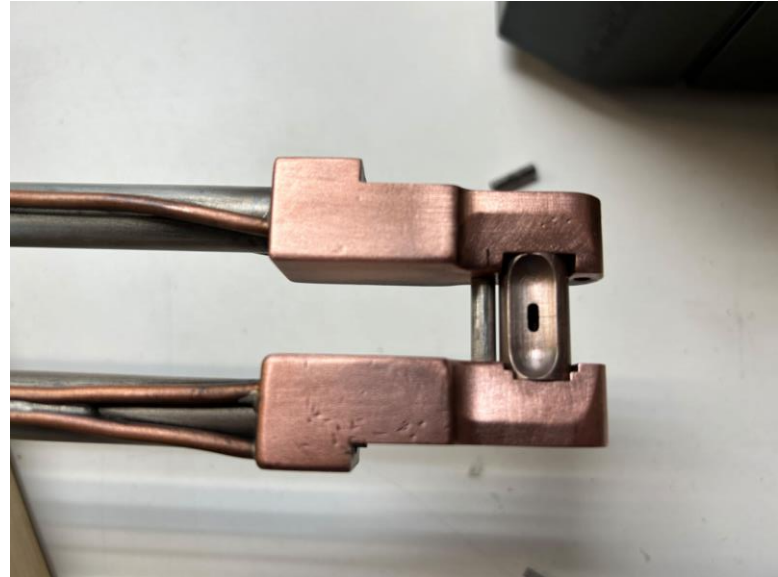
Vault Completed in August 2022



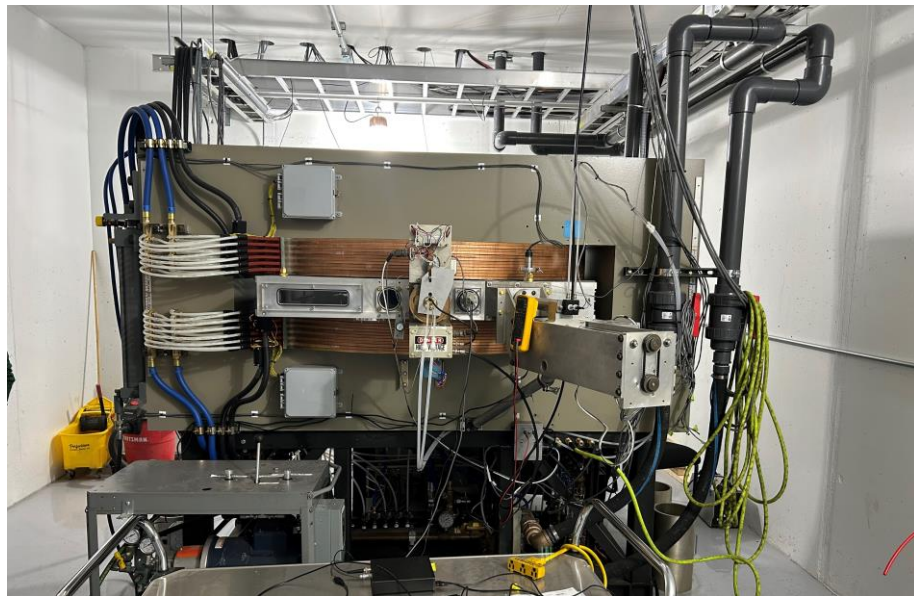
CS-30 Accelerator Subsystems Assembly, Test and Installation

June – December 2022 (During/after cyclotron vault construction period)

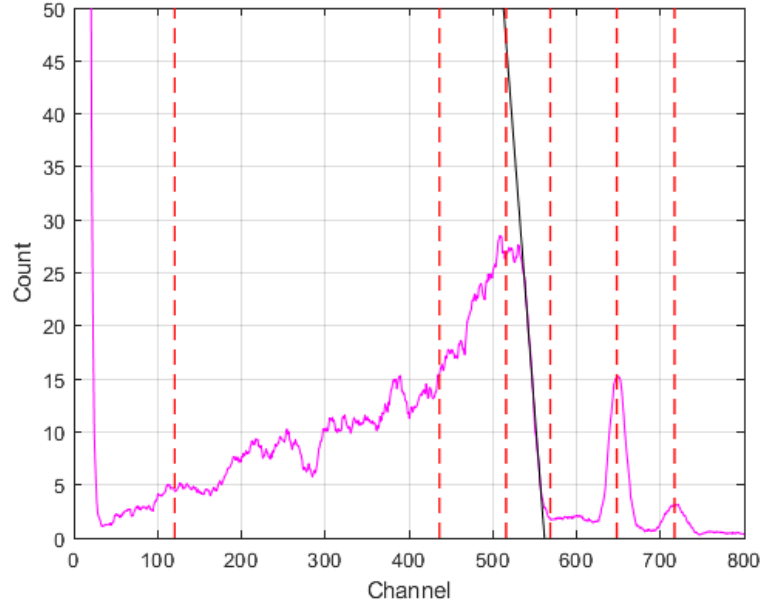
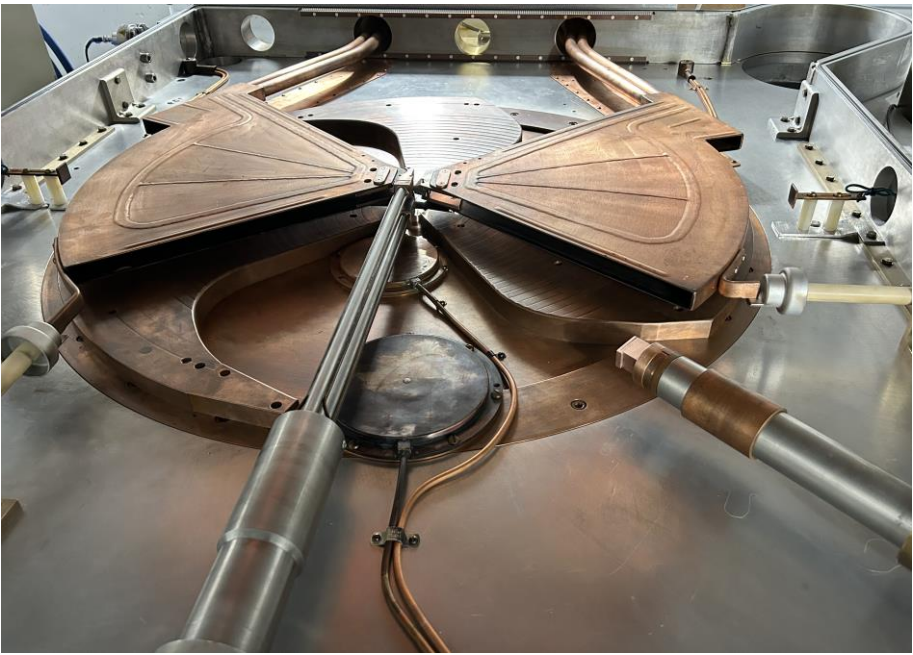
- Vacuum chamber/pumps
- RF oscillator and resonator cabinet
- Dee and central region structure
- Ion source
 - Gas flow
 - Cooling water
 - Electrical
 - Vacuum
- Beam probe
- LCW cooling system
- Power supplies and new Control system
- Cable trays, electrical, water cooling, and compress air connections



All subsystems installed and the cyclotron commissioning started January 2023



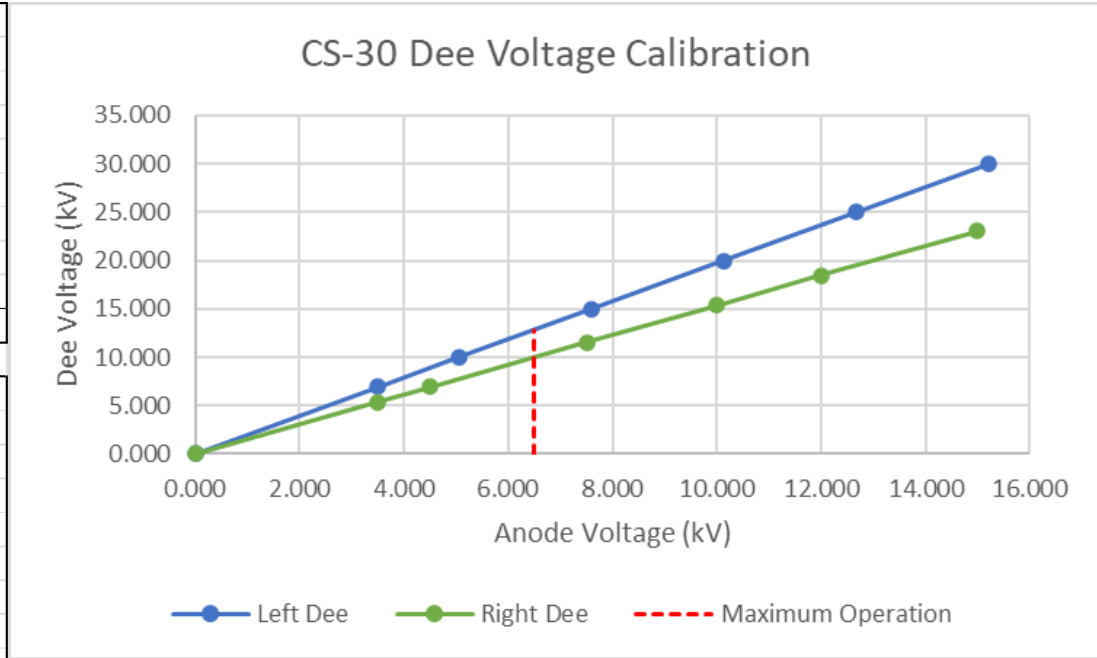
CS-30 Dee Voltage Calibration with X-Ray Detector



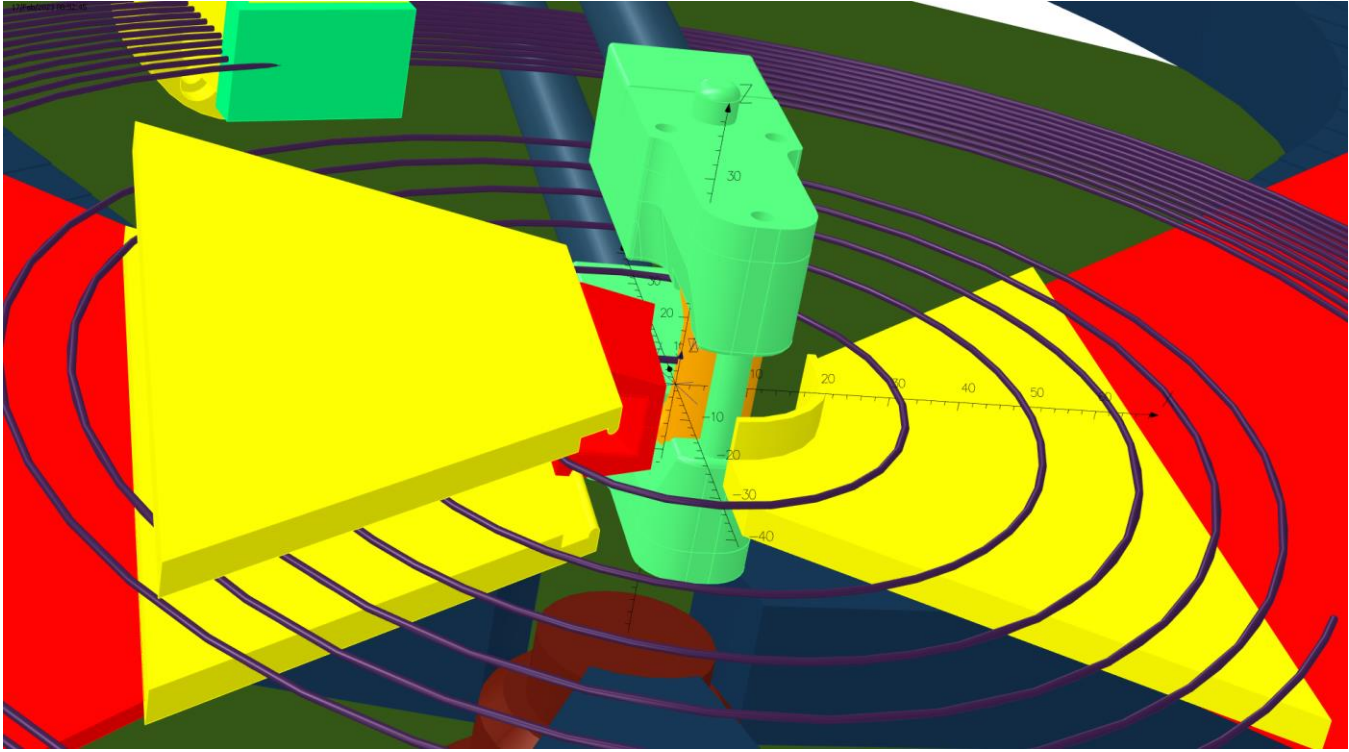
CS-30 Dee Voltage Calibration with X-Ray Detector

Left Dee	Anode Voltage (kV)	Dee Voltage (kV)
	0.000	0.000
	3.500	6.909
	5.066	10.000
	7.599	15.000
	10.132	20.000
	12.665	25.000
	15.198	30.000

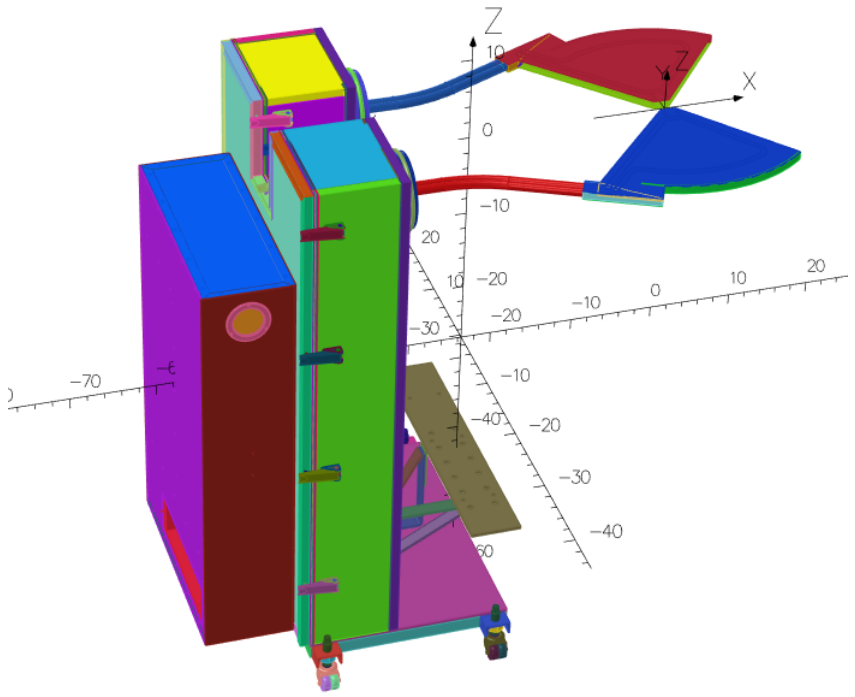
Right Dee Puller	Anode Voltage (kV)	Dee Voltage (kV)
	0.000	0.000
	3.500	5.374
	4.500	6.909
	7.500	11.515
	10.000	15.353
	12.000	18.424
	15.000	23.030



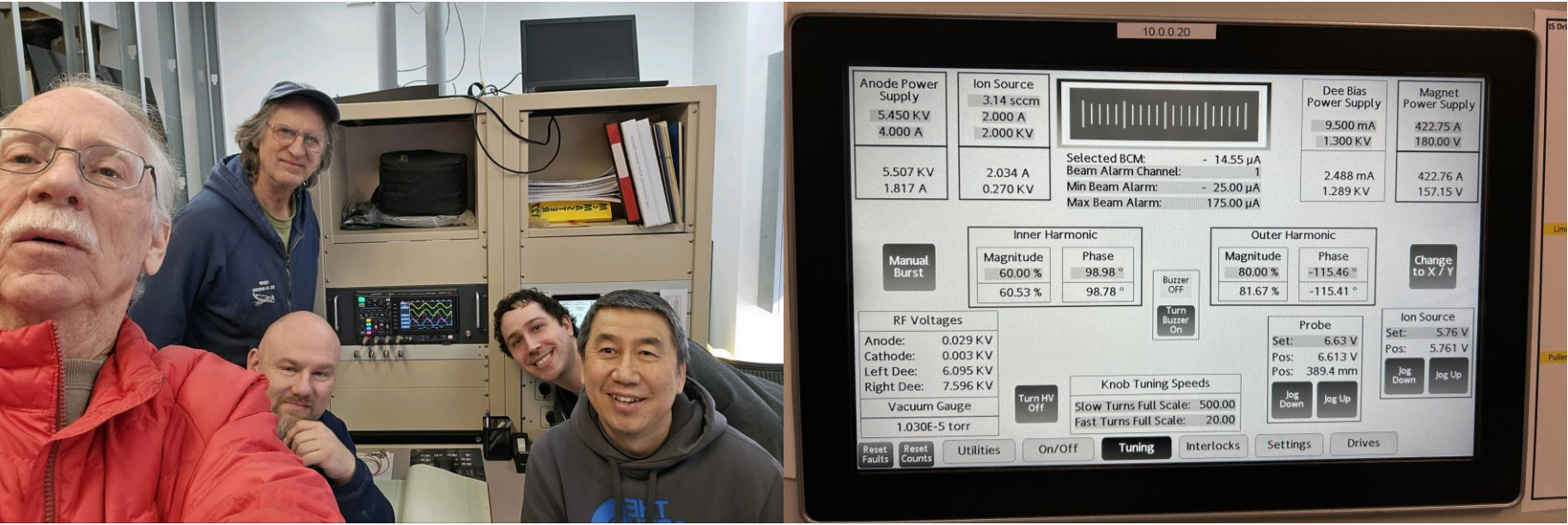
CS-30 Central Region Adjustments Guided by Beam Simulations



New RF system for CS-30



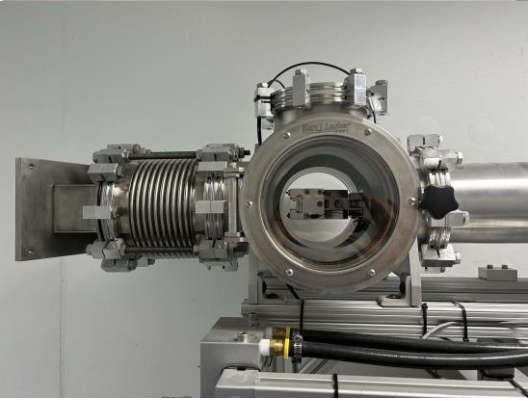
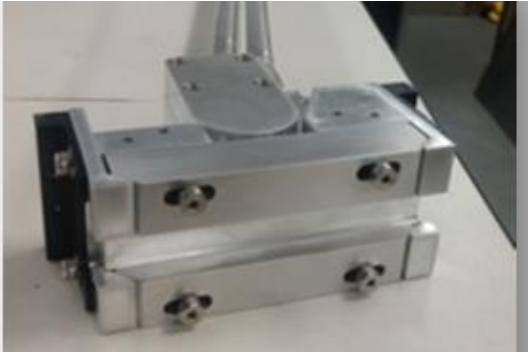
CS-30 Beam Commissioning



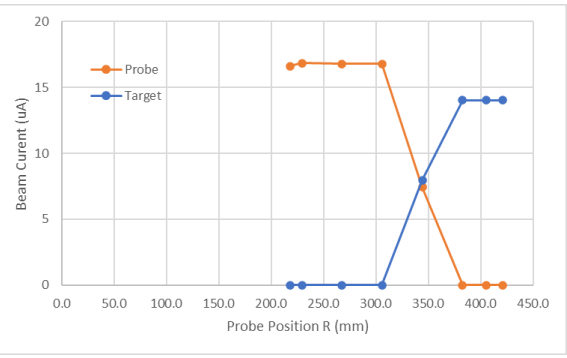
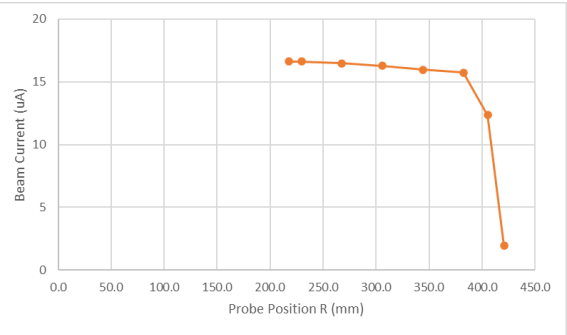
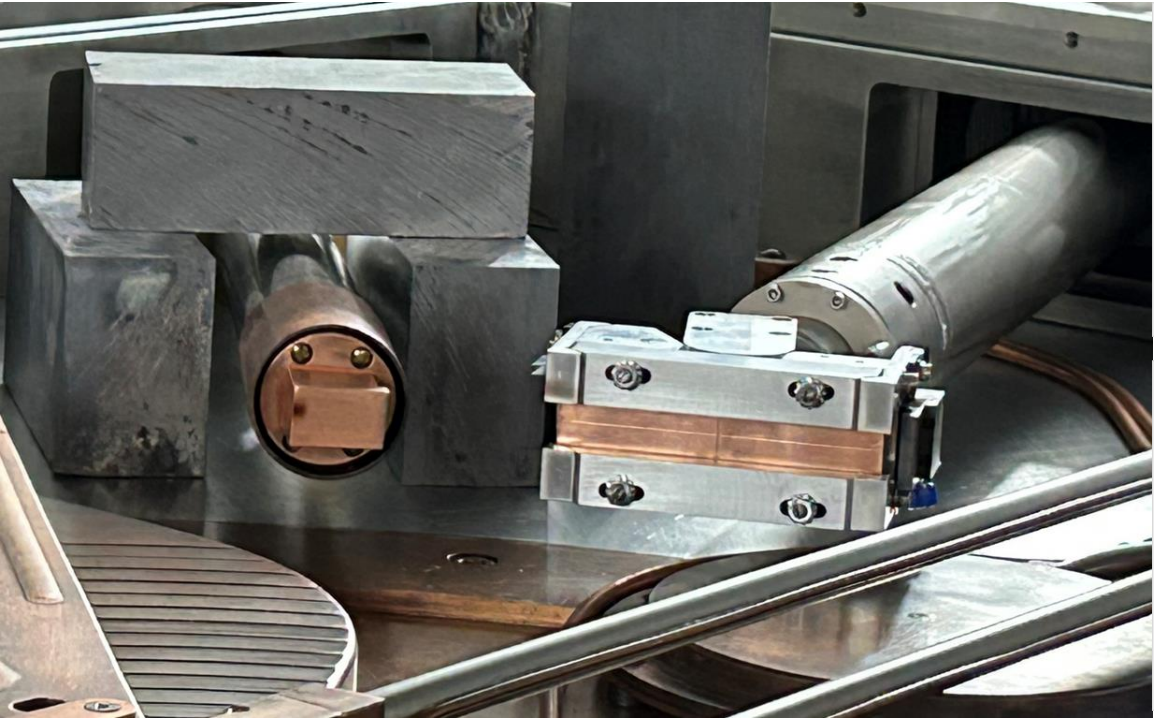
At 4:00 pm on 3/24/2023, an alpha beam was successfully accelerated to ~ 27 MeV with a beam current of ~ 14.5 uA on the probe at R=390 mm.

At-211 Production Validation at Ionetix TAT

Install the Internal target system

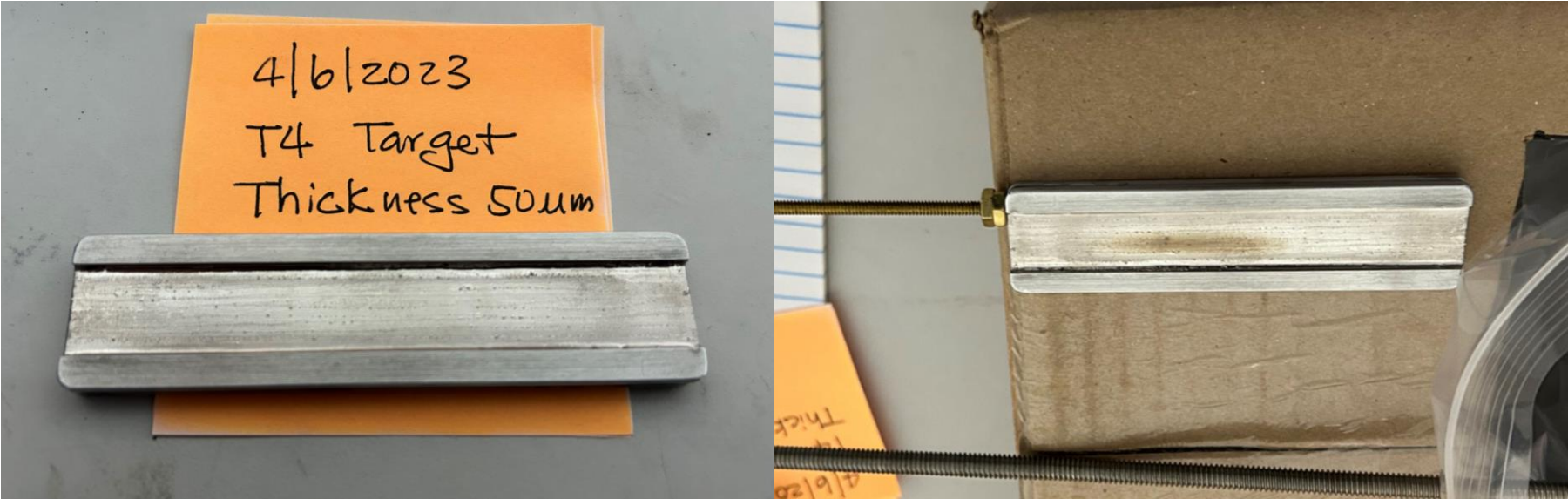


At-211 Production Validation at Ionetix TAT



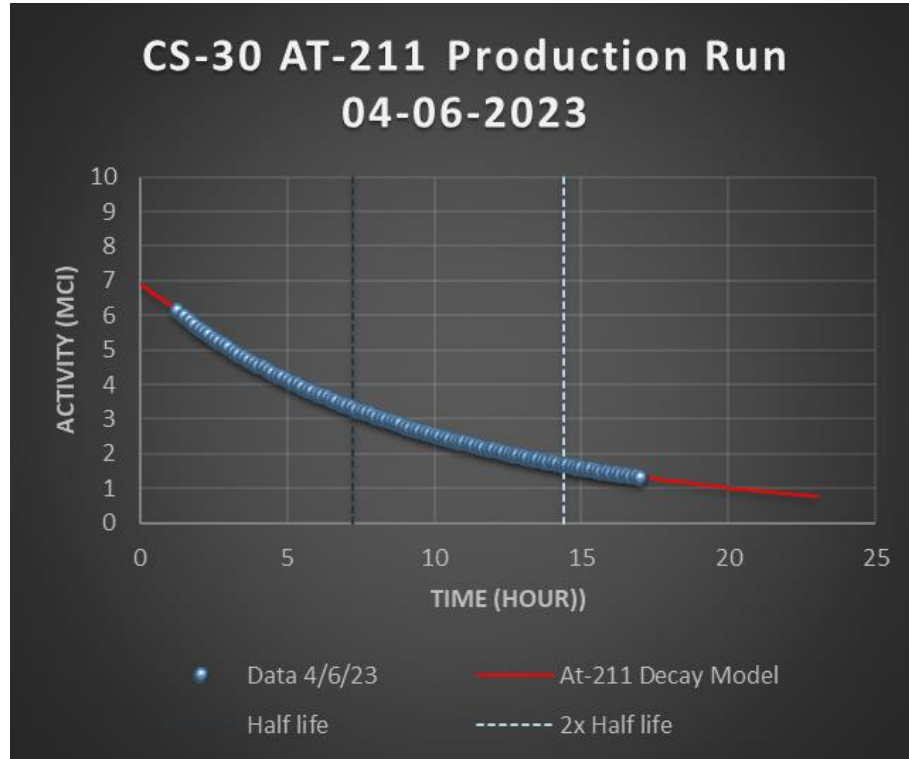
At-211 Production Validation at Ionetix TAT

Bismuth target and beam mark after validation run on 4-06-2023



At-211 Production Validation at Ionetix TAT

Bismuth target activity measurement after EOB on 4-06-2023



At-211 Production Validation at Ionetix TAT


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Ionetix completes commissioning of a 30 MeV cyclotron and produces Astatine-211.

Lansing, MI, April 18, 2023 — Ionetix, a leading cyclotron technology innovator, isotope producer and radiopharmaceutical manufacturer, announced today the successful production of Astatine-211 at its new Alpha Isotope Manufacturing facility located in Lansing, Michigan.

This first-of-its-kind facility is highly specialized and dedicated exclusively to producing alpha-emitting radionuclides using cyclotrons. The company completed the installation of the first of two cyclotrons at the facility earlier this year and initial commissioning was successfully completed in March. The cyclotron is a multiparticle, 30 MeV cyclotron and, once fully optimized by Ionetix, it will be used to generating high-yields of Astatine-211 (At-211) and Actinium-225 (Ac-225).

Ionetix Alpha Isotope Supply Chain Solution – (David Eve - DOE meeting 2022)



Lansing, Michigan



At-211 Production beginning in 2023

- Upgraded CS-30 Cyclotron for near term At-211 Production



Alpha Radionuclide API Supply

- Commercial Processing and Purification Solutions
- DMF for At-211
- Batch Quality Control / Certificate of Analysis release



Full cGMP Facility for Radiolabeling

- Contract Manufacturing
- Manual and Automated Commercial Synthesis Solutions
- Independent Clean Room available for Research Work



Regional Production and Distribution Model

- Ship target, processed At-211 or final drug product

Ionetix Alpha-Emitting Radionuclide Production Team

Acknowledgements:

Isotope Production Team

Xiaoyu Wu, Ph.D. VP of R&D, Senior Physicist
 Mark Leuschner, Ph.D., VP of Special Projects and Strategy
 John Vincent, Ph.D. Consultant
 Gary Horner, Accelerator Staff Engineer
 Rick Hart, Cyclotron Operation Lead
 Brandon Mclean, Cyclotron Engineer
 Gabe Blosser, Mechanical Engineer
 Zachary Neville, Mechanical Engineer
 Robbie Schreur, Mechanical Engineer
 S. Vorozhtsov, Ph.D., Consultant Scientist
 V. Smirnov, Ph.D., Consultant Scientist

Radiochemistry and Regulatory Team

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 Alex Yordanov, Ph.D, Director of CMC, Product Development
 Jill Wilson, VP, Regulatory Affairs & QA
 Shannon Phillips Ph.D, Director of Quality
 Milan Stika Ph.D, Senior Radiochemist



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