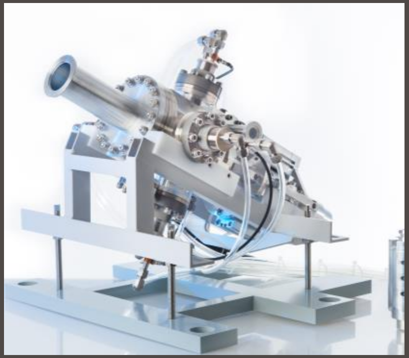
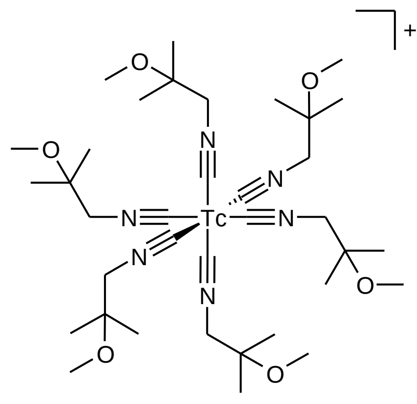




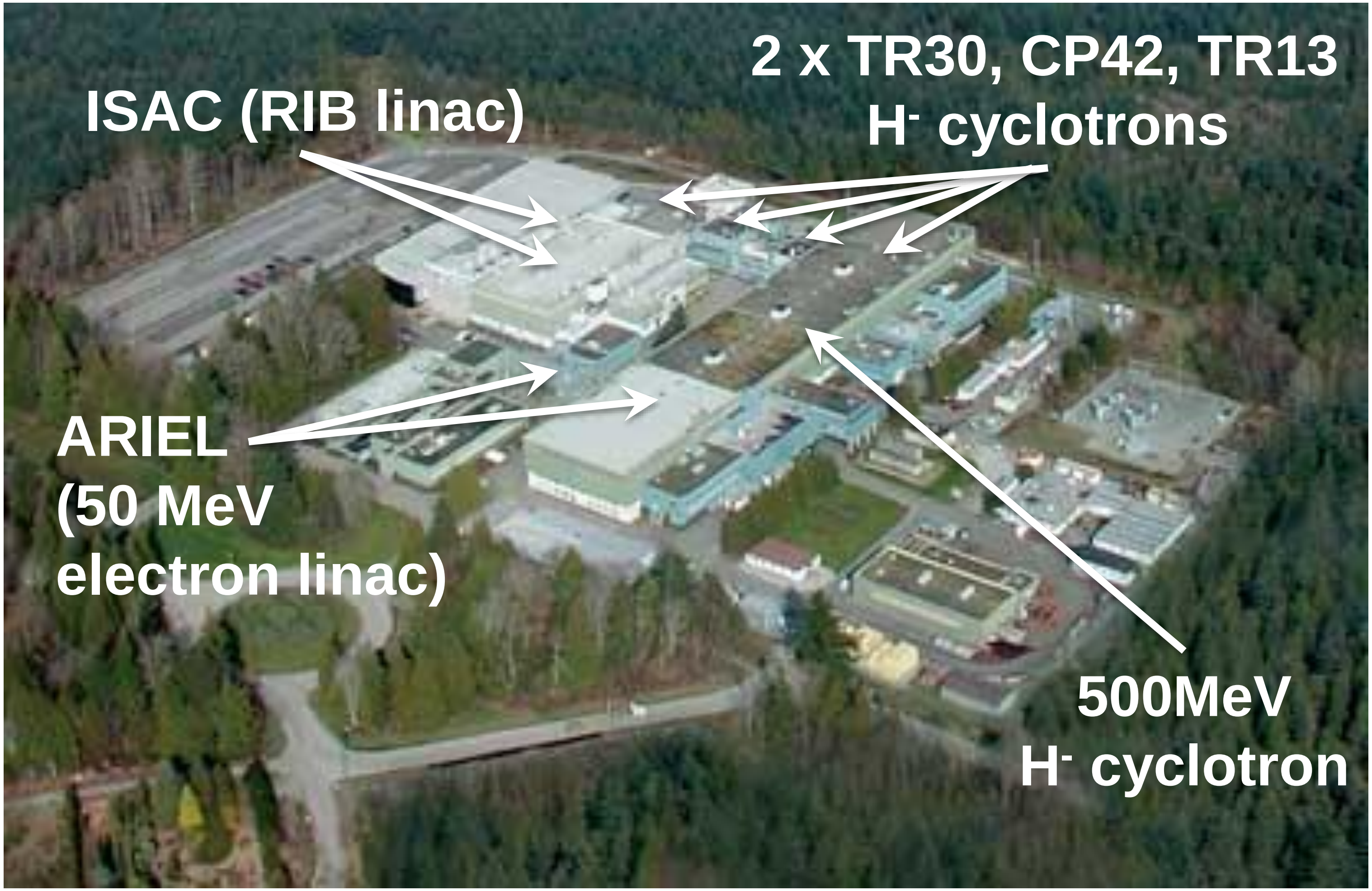
Accelerator-Based Isotope Production at TRIUMF

CAP Conference

June 16th, 2015

Paul Schaffer
Head, Nuclear Medicine
TRIUMF

Accelerators at TRIUMF



New addition: TR24; to be installed

CP42, TR30, TR13 Operations

TRIUMF Capabilities:

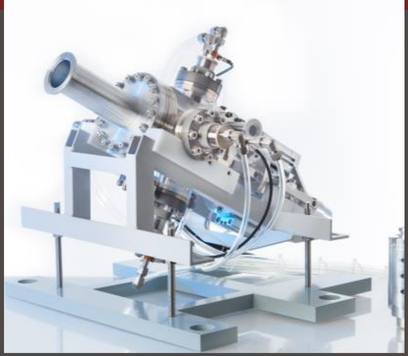
- **CP42**: up to 42 MeV and 200 µA, installed 1980
- **TR30-1:** up to 30 MeV and 900 µA, installed 1990
  - first TR30 designed, assembled by TRIUMF, components manufactured by EBCO, commissioned by TRIUMF
- **TR30-2:** up to 30 MeV and 1000 µA, installed 2003
  - Manufactured, installed by EBCO, commissioned by TRIUMF
- **TR13:** 13 MeV, 25µA, installed 1986 (UBC Neurology)
  - Capable of ^{11}C, ^{18}F, ^{13}N, ^{68}Ga, ^{89}Zr, ^{64}Cu, ^{44}Sc, ^{86}Y, ^{55}Co, ^{52}Mn…solid, liquid, gas targets
- **TR24:** 24 MeV, 500+ µA, to be installed

Overall

- 5 solid target, 3 gas stations operating at 30 MeV
  - Commercial production: ^{67}Ga, ^{111}In, ^{123}I, ^{103}Pd, ^{201}Tl
- Future commercial production: ^{99m}Tc

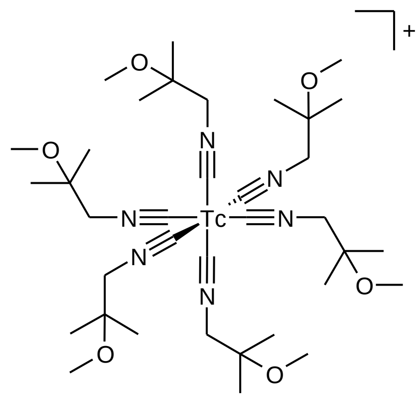
TRIUMF

Canada's national laboratory for particle and nuclear physics
Laboratoire national canadien pour la recherche en physique nucléaire
et en physique des particules



Direct, multi-Curie production of ^{99m}Tc on three different cyclotrons

1) TRIUMF
2) University of British Columbia;
3) BC Cancer Agency;
4) Lawson Health Research Institute;
5) Centre for Probe Development and Commercialization



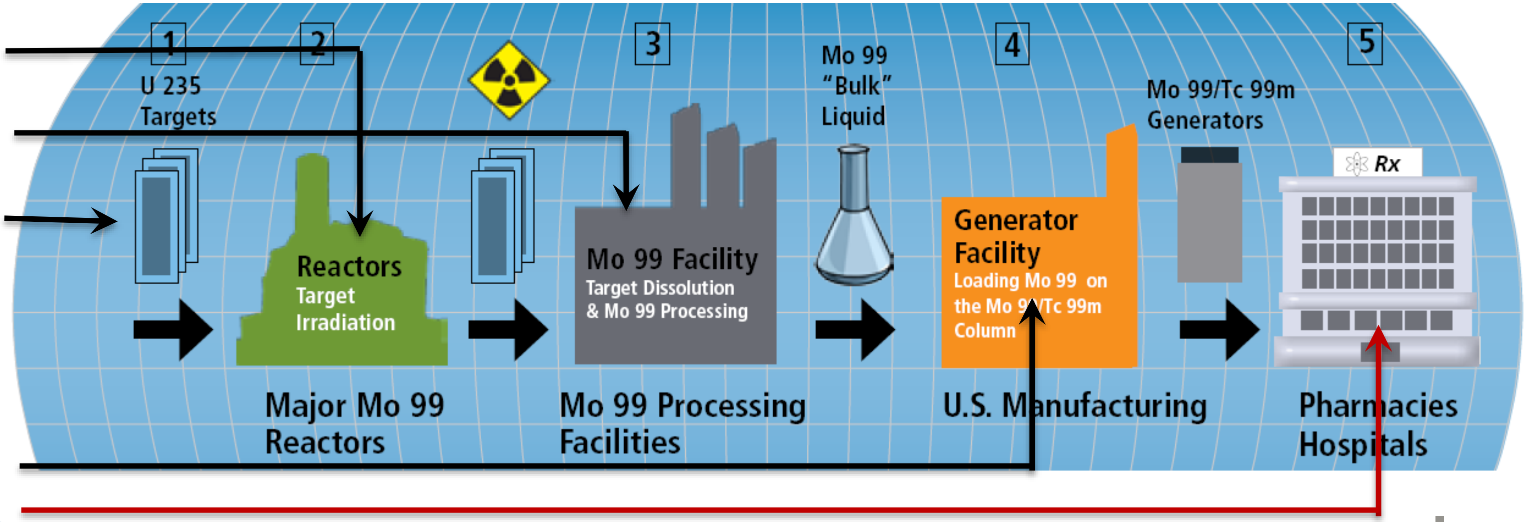
Accelerating Science for Canada
Un accélérateur de la démarche scientifique canadienne

Owned and operated as a joint venture by a consortium of Canadian universities via a contribution through the National Research Council Canada
Propriété d'un consortium d'universités canadiennes, géré en co-entreprise à partir d'une contribution administrée par le Conseil national de recherches Canada

Tc-99m Alternatives: Many options

- $^{99}\mathrm{Mo}/^{99m}\mathrm{Tc}$ in high demand (~ 40M doses/yr)
- Gov't owned reactors produce majority of $^{99}\mathrm{Mo}$ supply
- NRU going offline Oct. 2016 (~40% of global supply)
- Capacity emerging (existing reactors, new technology
- Projections range from oversupply to shortages[1]
- Must move to full-cost recovery

Alternatives:



$^{98}\mathrm{Mo}(n,\gamma)^{99}\mathrm{Mo}$

$^{238}\mathrm{U}(\gamma,F)^{99}\mathrm{Mo}$

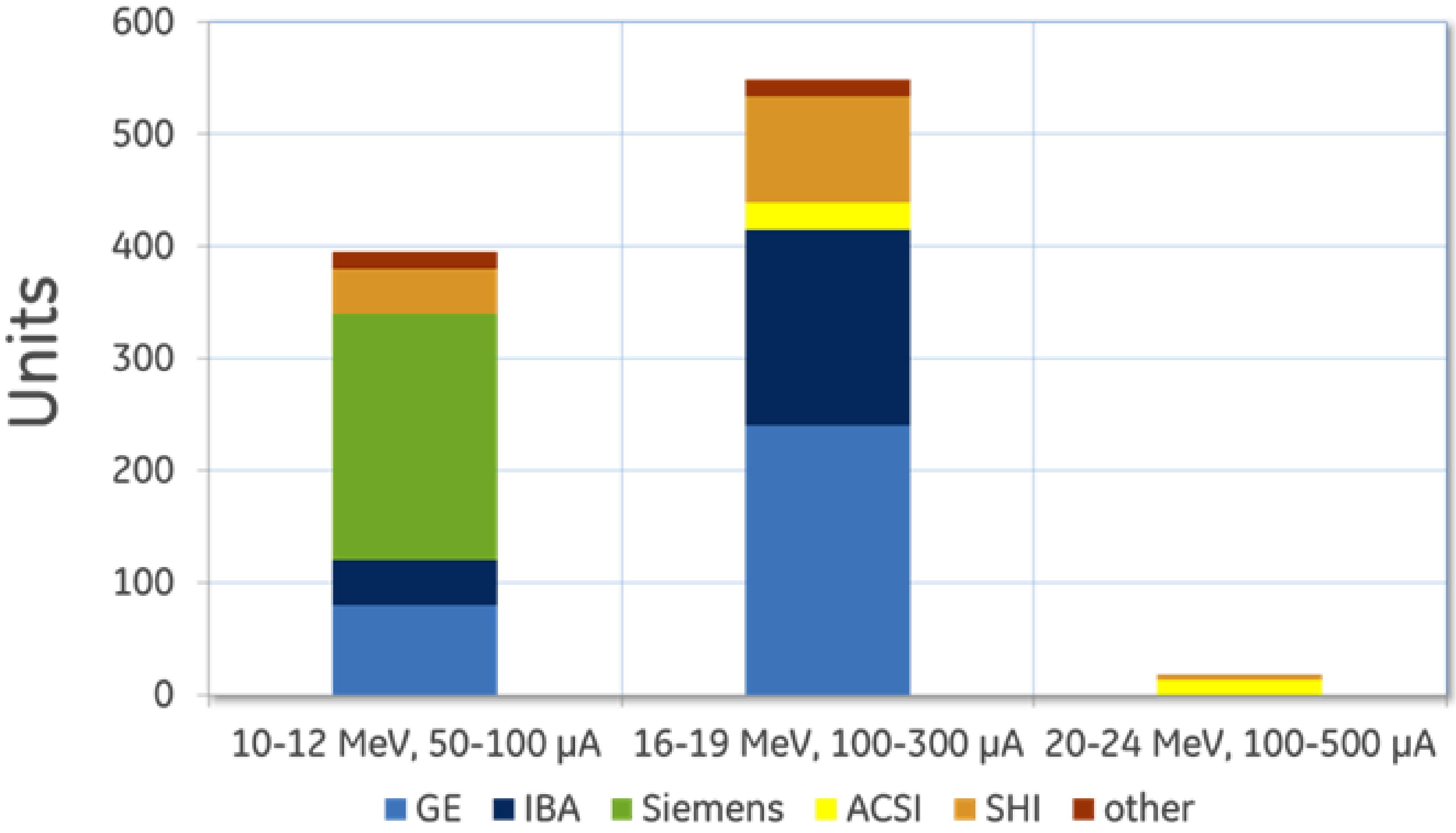
LEU $^{235}\mathrm{U}(n,F)$

$^{100}\mathrm{Mo}(\gamma,n)^{99}\mathrm{Mo}$

$^{100}\mathrm{Mo}(p,2n)^{99m}\mathrm{Tc}$

1) OECD - NEA/SEN/HLGMR(2014)2
graphic from http://www.covidien.com/

Cyclotrons By the Numbers



Estimated global cyclotron numbers by various manufacturers (with data from ACSI, GE, IBA and Siemens, Sumitomo data estimated)

Schaffer et al. Phys. Proc. in press (2014).

Direct Production of ^{99m}Tc

- ^{100}Mo Target
- Cyclotron Modification
- Optimize Irradiation
- Purify $^{99m}TcO_4$
- Regulatory QA/QC
- ^{100}Mo Recovery

Goals:

- Demonstrate routine, reliable, commercial-scale production of ^{99m}Tc via ^{100}Mo(p,2n) at multiple sites, multiple brands;
- Obtain regulatory approval for clinical use in humans;
- Establish a business plan;
- Disseminate, commercialize the technology

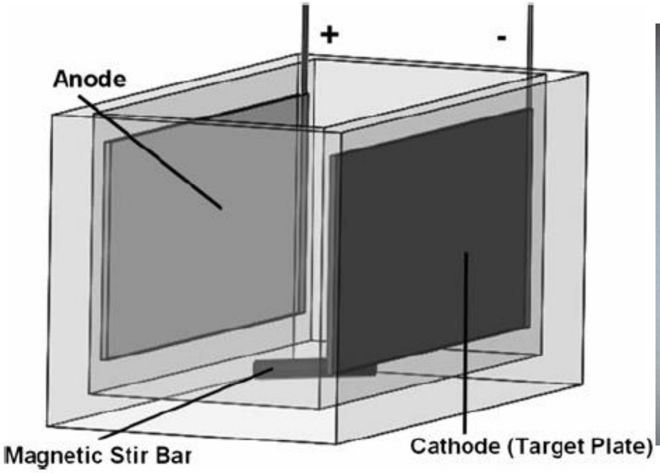
Hypothesis: Future production will be from variety of sources (neutron, proton, electron) and market driven

J. Beaver, H. Hupf, J Nucl Med 1971;12:739-741

Target Manufacturing

- **^{100}Mo Target**
- Cyclotron Modification
- Optimize Irradiation
- Purify $^{99m}TcO_4$
- Regulatory QA/QC
- ^{100}Mo Recovery

Electrophoretic deposition



Press-Sinter-Braze

Maximizing ^{99m}Tc production, minimizing impurities:

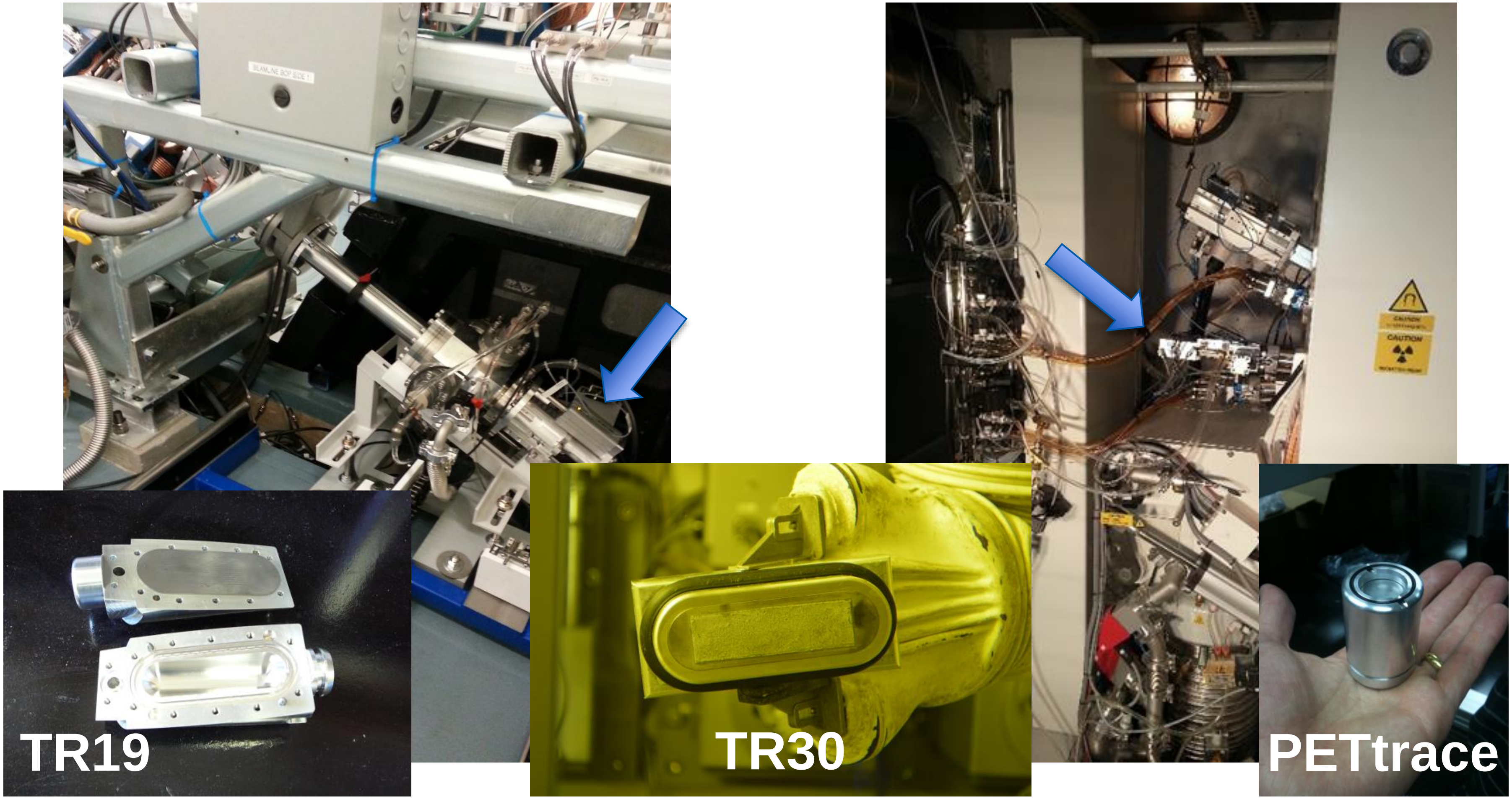
<19 MeV proton energy entering ^{100}Mo
>8 MeV proton energy exiting ^{100}Mo
Stopping power of Mo: Requires <1.2 g of metal
Reduce density, balance thermal conductivity

Bénard et al., J. Nucl. Med. 2014, 55, 1017-1022

Schaffer et al. Phys. Proc. in press (2015).
Zeisler et al. WTTC 2014

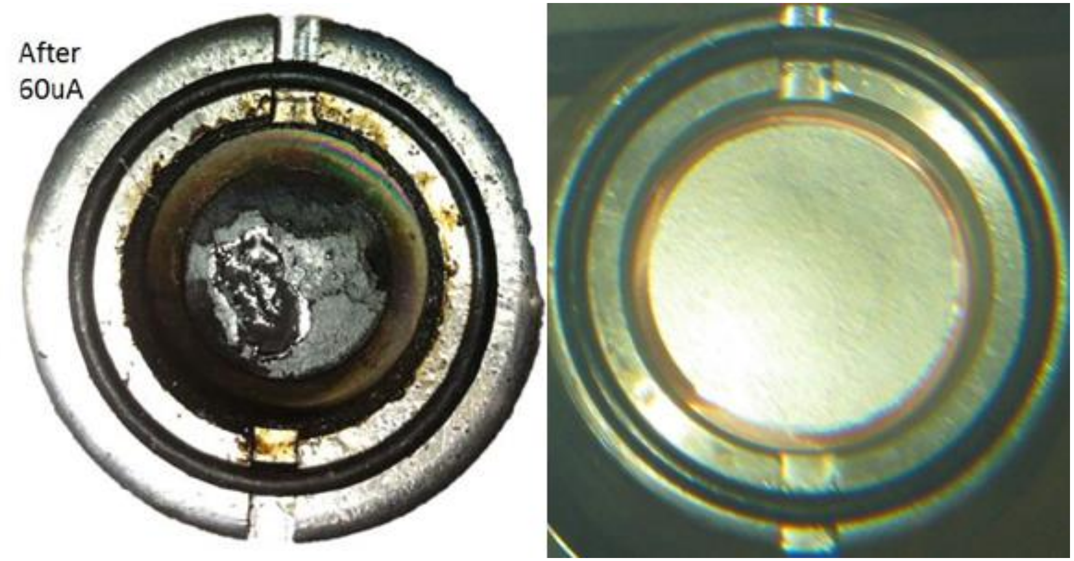
Retrofit Existing Infrastructure

- ^{100}Mo Target
- **Cyclotron Modification**
- Optimize Irradiation
- Purify ^{99m}TcO$_4$
- Regulatory QA/QC
- ^{100}Mo Recovery



Target Type vs. Cyclotron Power

- ^{100}Mo Target
- Cyclotron Modification
- **Optimize Irradiation**
- Purify $^{99m}TcO_4$
- Regulatory QA/QC
- ^{100}Mo Recovery



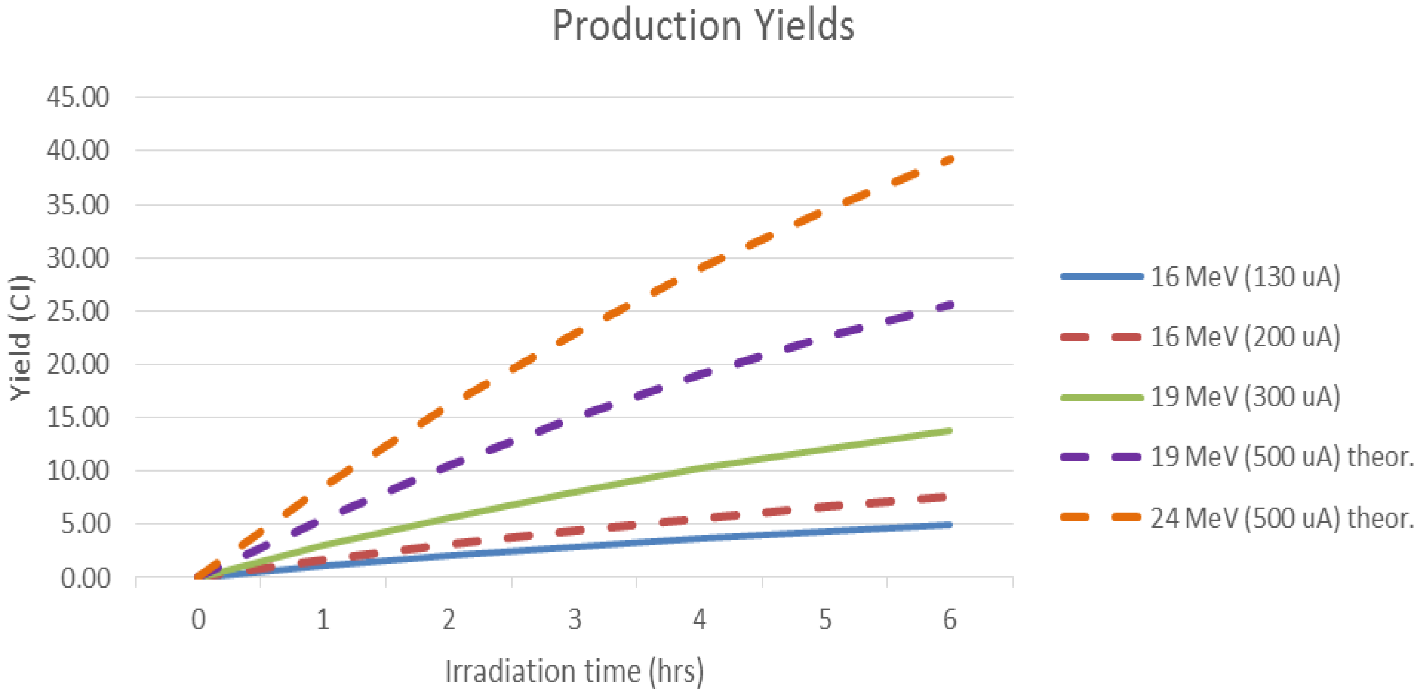
TR30 (@24 MeV) target power: 10.8 kW @ 0.6 kW/cm^2

TR19 target power: 5.4 kW @ 0.3 kW/cm^2

PETtrace target power: 2.1 kW @ ~1.2 kW/cm^2

Real and Projected Yields of ^{99m}Tc

- ^{100}Mo Target
- Cyclotron Modification
- **Optimize Irradiation**
- Purify $^{99m}TcO_4$
- Regulatory QA/QC
- ^{100}Mo Recovery



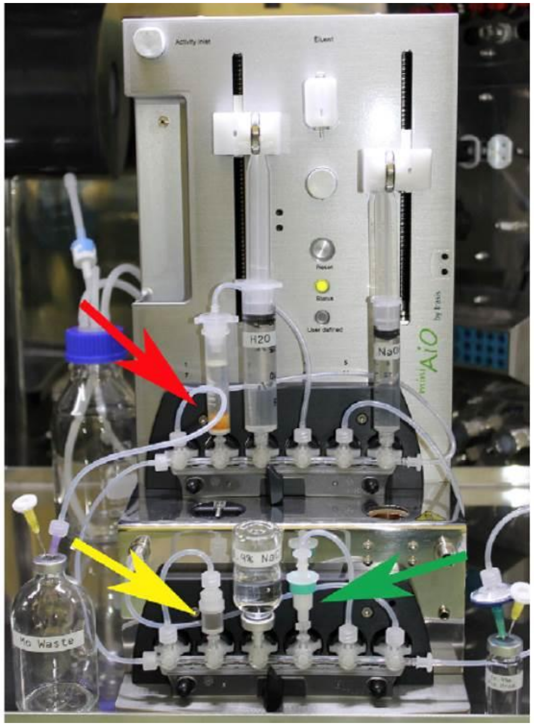
GE PETtrace
16.5 MeV, 130 μA
Theoretical 4.9 Ci (6h)
Achieved 4.7 Ci
Sat^n: 75.6 mCi/μA

TR19
18 MeV, 300 μA
Theoretical 15.4 Ci (6h)
Achieved 9.4 Ci (@ 240 μA)
Sat^n: 103 mCi/μA

TR30 (@24 MeV)
24 MeV, 500 μA
Theoretical 39 Ci (6h)
Achieved ~32 Ci (@ 450 μA)
Sat^n: TBD

Purification of ^{99m}Tc

^{100}Mo Target | Cyclotron Modification | Optimize Irradiation | **Purify $^{99m}TcO_4$** | Regulatory QA/QC | ^{100}Mo Recovery



- **SPE-based method:**
  - original work: Dowex™ vs ABEC
  - new alternative resin: ChemMatrix™
- **Process Time:** complete in <90 min.
- **Efficiency Range**: 92.7 ± 1.1%
- **Radiochemical Purity:** >99.99% TcO_4
- **Trace analysis:** <10 Bq Mo-99, <5 ppm Al^{3+}
- non-Tc impurities removed

Disposable fluid path for GMP

Inherent Resin Versatility: Vendor Agnostic

Morley et al. Nuc. Med. Biol. 2012, 551-559

Bénard et al., J. Nucl. Med. 2014, 55, 1017-1022

Regulatory Process: CTA nearly complete

^{100}Mo Target | Cyclotron Modification | Optimize Irradiation | Purify $^{99m}TcO_4$ | **Regulatory QA/QC** | ^{100}Mo Recovery

- Not currently approved by Health Canada, FDA, etc.
- CTA preparation underway:
  - GLP preclinical rodent data (complete);
  - documentation (complete),
  - acceptance criteria: RNP, RCP, Al, Mo, H_2O_2 (complete);
  - process validation (complete)
- Shelf life (18 hrs), irradiation parameters are based on projected patient dose (objective <10% add'l vs. pure ^{99m}Tc)
  - Enrichment and irradiation parameters are interrelated and should not be considered independently
- CTA submission – June 2015 (60 patient trial)
- Fall 2015 - NDS submission

^{100}Mo Raw Material/Irradiation Specifications

Isotope	Proposed max. isotopic impurity to maintain patient dose increase of ~10% compared to pure $^{99m}TcO_4$		
	≤ 20 MeV[1]	20 – ≤22 MeV[2]	22 - ≤24 MeV[3]
^{92}Mo	0.03	0.03	0.02
^{94}Mo	0.03	0.03	0.02
^{95}Mo	0.03	0.03	0.02
^{96}Mo	0.03	0.03	0.02
^{97}Mo	0.03	0.03	0.02
^{98}Mo	7	0.8	0.5

[1] Maximum increase in patient dose of 9.8 % at 20 MeV, 18 hours after EOB.
[2] Maximum increase in patient dose of 10.1% at 22 MeV, 18 hours after EOB.
[3] Maximum increase in patient dose of 10.6% at 24 MeV, 18 hours after EOB.

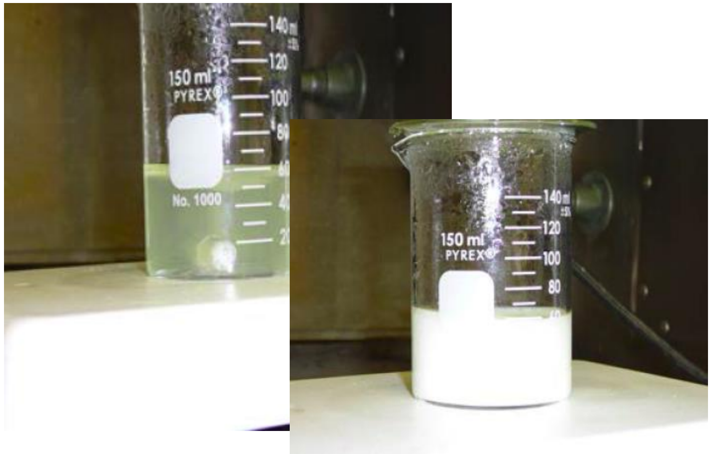
- *Based on theoretical yield calculations with ^{99m}Tc pertechnetate*
- *Mitigates the impact of dose due to ^{98}Mo(p,3n)^{96}Tc reaction at higher E*

We Recycle

^{100}Mo Target
Cyclotron Modification
Optimize Irradiation
Purify $^{99m}TcO_4$
Regulatory QA/QC
^{100}Mo Recovery

- High efficiency recovery process for multi-gram quantities of $^{100}MoO_4^{2-}$ required
- Some trace long-lived radionuclidic impurities
- Target dissolution waste stream (liquid, 10’s of mL/batch)
- Original method: ion exchange

  >90% efficiency (non-optimized), large column volumes, slow
- Currently using acidic precipitation, thermal decomp. process
- Routine recovery yields >99%
- Analysis of recovered ^{100}Mo underway

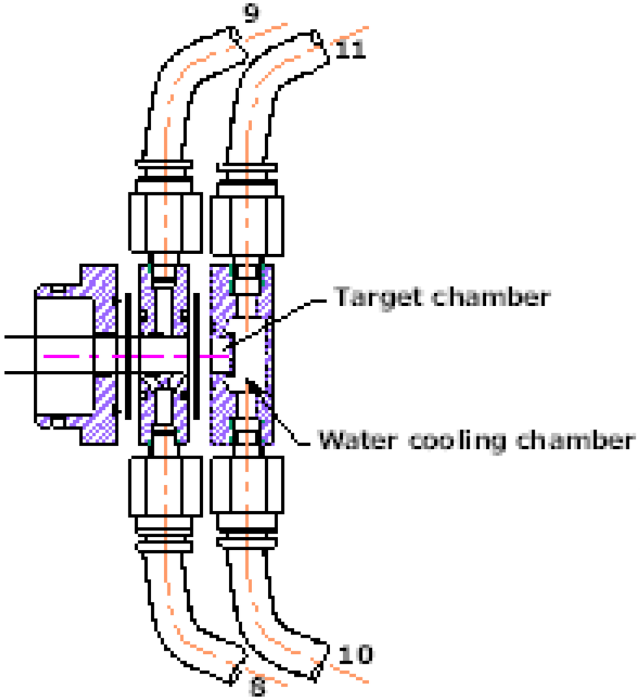


Remaining Challenges for Cyclotron Production of ^{99m}Tc

- Process: Long-term reliability (machine and target)
- Quality Control: Decentralized production inherently leads to a greater likelihood of product variability, dose uncertainty
- Regulatory: Considerations need to include target isotopic enrichment, but also batch-to-batch target consistency, irradiation energy/duration, shelf-life (patient dose)
- Economic: Arguments in one region may not apply in others but FCR must apply
- Availability: A viable alternative/backup needs to be used regularly

Canada's national laboratory for particle and nuclear physics
Laboratoire national canadien pour la recherche en physique nucléaire
et en physique des particules

Production, Purification and Radiolabelling of Radiometals Produced in a Liquid Target on a 13 or 19 MeV Medical Cyclotron



Proposal

- Hypothesis: Established cyclotron centers can obtain research, and possibly clinical quantities of various radiometals by irradiating salt solutions in modified liquid targets
  - Leverage existing liquid target infrastructure for the production of other PET isotopes (^{18}F)

Accepted trade-off:

Lower production yields in exchange for isotope versatility

Vogg ATJ, et al. Proceedings of the Sixth International Conference on Nuclear and Radiochemistry, 2004; Aachen, Germany.

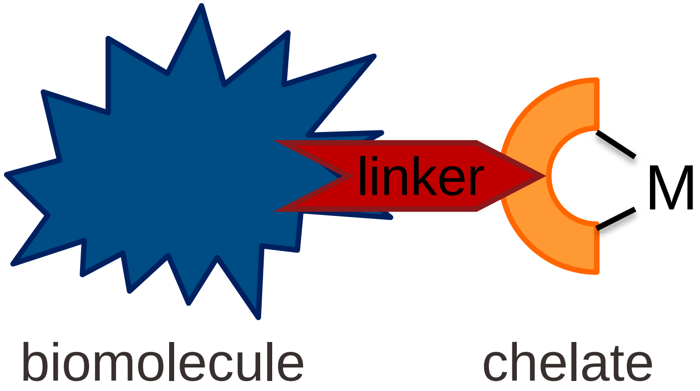
Jensen M, Clark J. Proceedings of the 13th International Workshop on Targetry and Target Chemistry, Roskilde, Denmark, July 26-28, 2010.

DeGrado TR, et al. J Label Compound Radiopharm 2011. 54, S248

Project Goals

- **Goals:**
  - Allow broader access to a variety of radiometallic isotopes
  - Radiometal production without generators, solid-target installation
  - Enable faster optimization of vector-isotope pairing

Isotope-Biomolecule Pairing



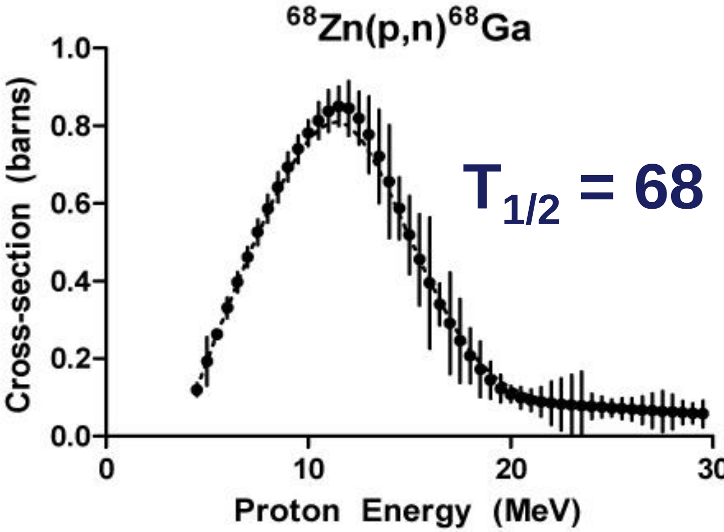
- Proposed application: labeling and *in vivo* analysis of novel proteins/peptides targeted toward HER2 variants/isoforms
  - Larger/slower-clearing constructs → longer-lived isotopes
  - Smaller/faster-clearing constructs → shorter-lived isotopes

*D Mitra D et al *Mol Cancer Ther.* 2009;8(8):2152-2162.

Project Overview

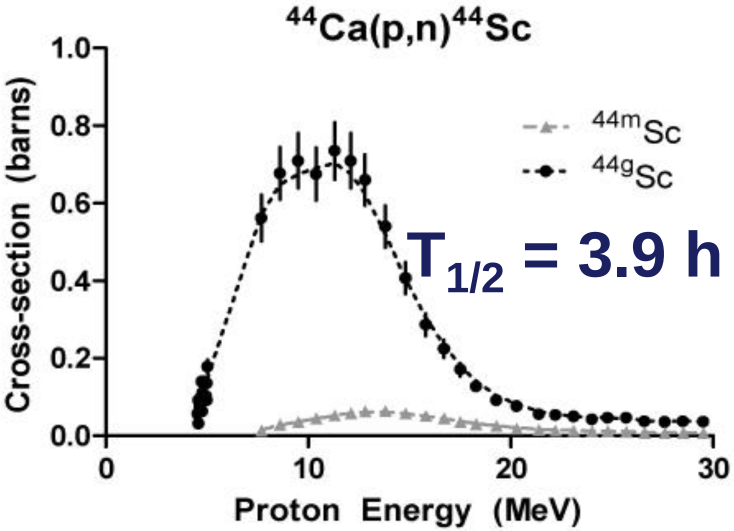
- Specific Interests:
  - ^{94}Mo(p,n)^{94m}Tc (half-life: 52.5 min)
  - ^{44}Ca(p,n)^{44}Sc (half-life: 3.9 h)
  - ^{86}Sr(p,n)^{86}Y (half-life: 14.7 h)
  - ^{89}Y(p,n)^{89}Zr (half-life: 78.5 h)
  - ^{68}Zn(p,n)^{68}Ga (half-life: 68 min)
- Approach:
  - TRIUMF: TR13 (13 MeV, 20 µA), standard water target (testing, feasibility)
  - BCCA: TR19 (19 MeV, 300 µA), large volume water target (application: HER2Δ16 binders)
  - New target design (i.e. syphon targets)

Assessing Feasibility: Cross-sectional Considerations



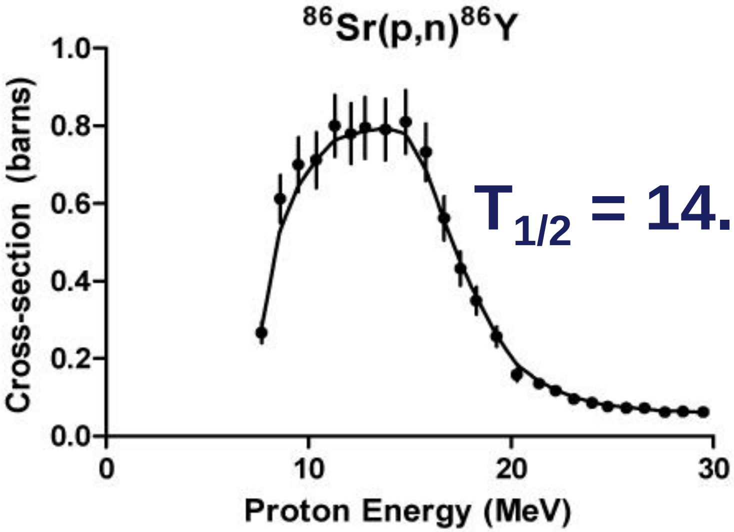
^{68}Zn(p,n)^{68}Ga

$T_{1/2}$ = 68 min



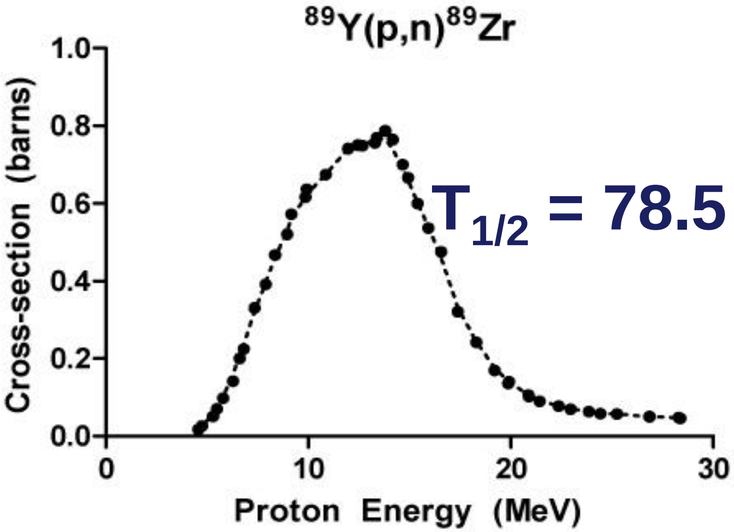
^{44}Ca(p,n)^{44}Sc

$T_{1/2}$ = 3.9 h



^{86}Sr(p,n)^{86}Y

$T_{1/2}$ = 14.7 h



^{89}Y(p,n)^{89}Zr

$T_{1/2}$ = 78.5 h

Production Summary

Prod	Production route	Metal salt	Density (g/mL)	Beam current (μA)	Time (min)	Yield (MBq)	Sat. yield (MBq/ μA)
^{94m}Tc	$^{94}Mo(p,n)^{94m}Tc$	$(NH_4)_6Mo_7O_{24}$	1.66	5	60	110±20	40±6
^{44}Sc	$^{44}Ca(p,n)^{44}Sc$	$Ca(NO_3)_2$	1.55	7.6	60	5.55±0.22	4.6±0.3
^{68}Ga	$^{68}Zn(p,n)^{68}Ga$	$Zn(NO_3)_2$	1.65	6.8	60	275±1	68±5
			1.56	6.96	60	480±30	141±6
^{89}Zr	$^{89}Y(p,n)^{89}Zr$	$Y(NO_3)_3$ x HNO_3	1.49	7.3	60	32±2	360±9
^{86}Y	$^{86}Sr(p,n)^{86}Y$	$Sr(NO_3)_2$	1.43	4.6	60	7.4±0.5	31±1

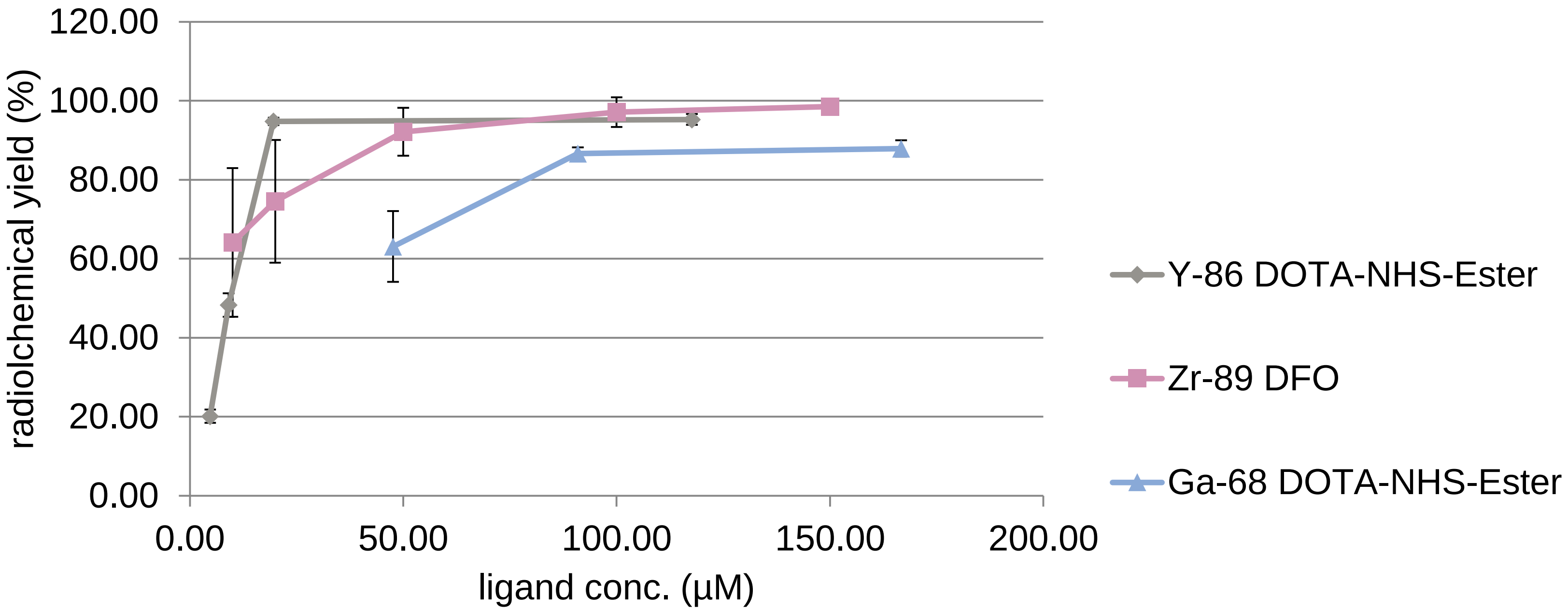
Purification – All metals

Prod.	Irradiated metal salt	Column 1	Column 2	Final Eluate		
				Activity received from target (%)	Vol. (mL)	Eluent
^{44}Sc	$Ca(NO_3)_2$	DGA	-	88 ± 6 (n = 5)	2.5	0.05M HCl
^{68}Ga	$Zn(NO_3)_2$	AG 50W-X8	DGA	92 ± 8 (n = 3)	1.0	H_2O
^{89}Zr	$Y(NO_3)_3$	Hydroxamate resin	-	82 ± 5 (n = 4)	0.75	1M Oxalic Acid
^{86}Y	$Sr(NO_3)_2$	DGA	-	99 ± 4 (n = 3)	1.0	H_2O
^{94m}Tc	$(NH_4)_6Mo_7O_{24}$	ABEC-2000	SCX/ Alumina	70.9 ± 0.7 (n = 4)	6.0	saline

Specific activity: ^{44}Sc (1.4 TBq/μmol), ^{68}Ga (5.2TBq/μmol), ^{89}Zr (0.015 TBq/μmol), ^{86}Y (0.41 GBq/μmol, 94mTc ()

TRIUMF

Radiolabelling chemistry



Radiolabelling conditions				
Isotope	**Temperature**	**Time**	**pH**	**Buffer**
Y-86	95 ^{0}C	30 min	pH=6	0.33M HEPES
Zr-89	r.t.	15 min	pH=7	
Ga-68	95 ^{0}C	10 min	pH=4	0.33M HEPES

Preparation of Liquid Target Solutions

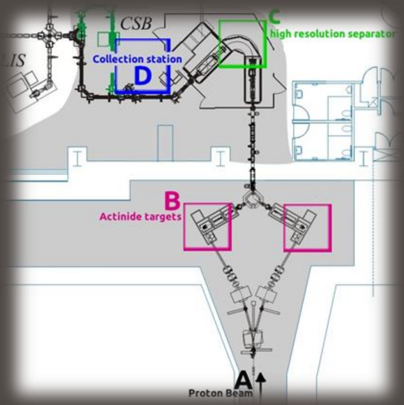
- Gas evolution during irradiation = high target pressures in a closed target body
  - Radiolysis of water, O_2, H_2
  - 1M nitric acid for ^{nat}Zn and ^{nat}Sr salt irradiations*
- Compatibility between salt solutions and target components
  - Havar foil (Co-based, Cr, Ni, Fe, W, Mo, Mn)
    - Failed with Cl^- salts (etching evident)
  - Al vacuum foil (failed in boil tests)
  - Target body (Al) – evidence of corrosion
    - Switch to Nb target body
- Precipitation
  - Need thorough flushing protocol between runs

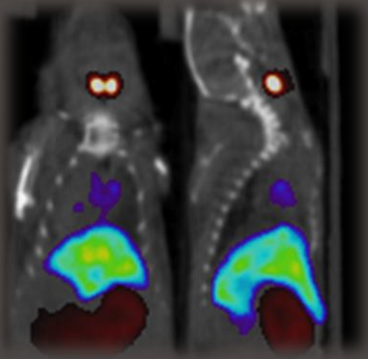
* Pandey MK, et al., Nucl. Med. Biol. 2014;41:309-16.

Summary

- A simple method for the production of research quantities of various radiometals using a modified liquid-target system.
- Salt solutions of natural isotopic abundance were irradiated in a standard water target on our 13 MeV cyclotron for 60 min. After irradiation, all solutions were withdrawn from the target and purified using cation exchange or chelating resins.
- Several isotopes (^{68}Ga, ^{89}Zr, ^{44}Sc, ^{89}Y, ^{94m}Tc) were produced in a standard water target on our 13 MeV cyclotron
- **Future work:** labeling and biodistribution analysis of breast cancer (HER2) binders; novel target designs (higher production)

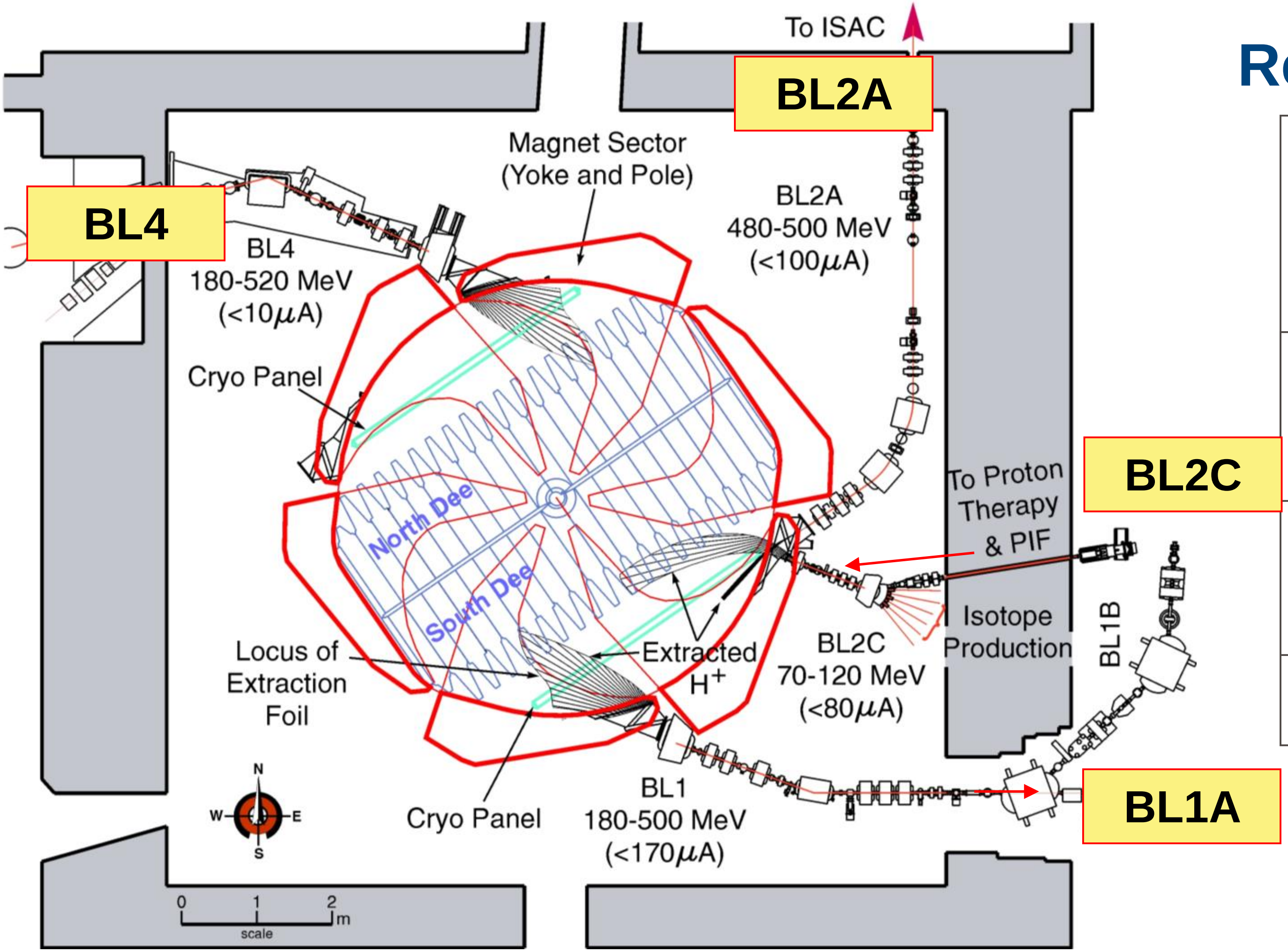
Production and assessment of radiotherapeutic isotopes





500 MeV Cyclotron Capabilities

Previous decade: routine operation at 220-250μA



Recently achieved:

Materials science,
500 MeV isotopes:
- **BL1A (100μA)**

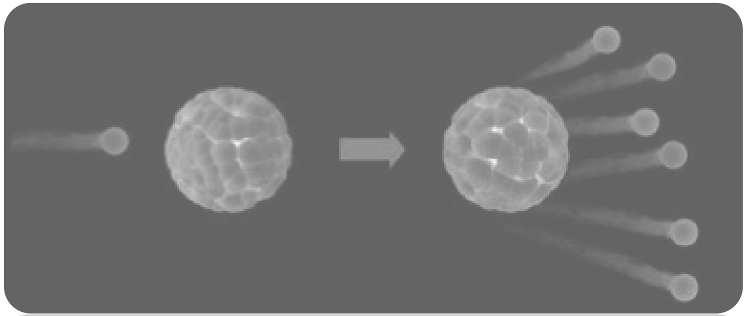
ISAC program:
- BL2A (100μA)

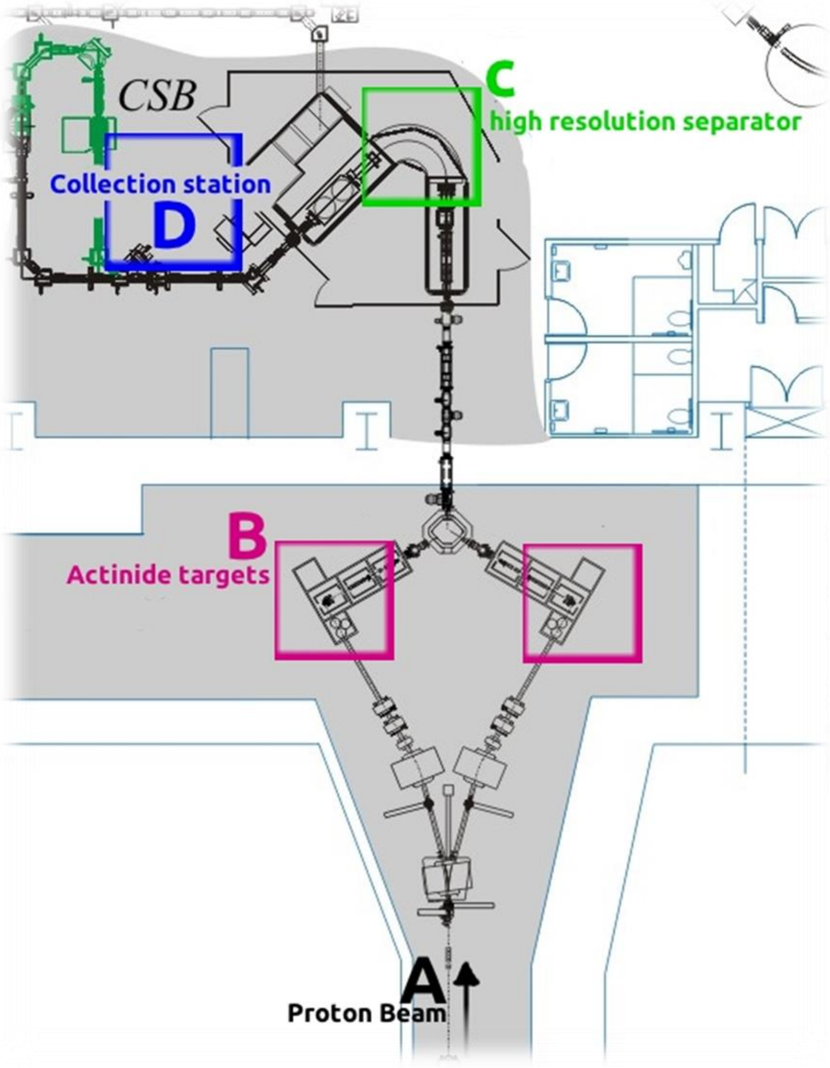
Sr production:
- **BL2C (100μA)**

- **Total (300μA)**

Isotope Accelerator Program (ISAC): 50 kW ISOL Facility

Isotope production via spallation of uranium:





Implementation of ISOL technique:

- Uranium carbide, thorium oxide
- 480 MeV protons, 10 µA
- Various available ion sources
- ~2500:1 mass separation resolution (~10^6–10^9 ions/s)
- Ion energy = ~20-60 keV

Candidate α-emitters for therapy

Isotope	Half-life	Considerations	Production
^{149}Tb	4.2 h	Good chemistry, alt. isotopes	Spallation, heavy-particle accelerator
^{211}At	7.2 h	No stable isotope, Thyroid uptake	α-cyclotron
^{212}Bi	1.0 h	Renal uptake	Generator (^{224}Ra/^{212}Bi)
^{213}Bi	0.76 h	Renal uptake	Generator (^{225}Ac/^{213}Bi)
^{223}Ra	10 d	4 α-decays, bone targeting	Generator (^{227}Ac/^{223}Ra)
^{225}Ac	10 d	4 α-decays,	Generator (^{229}Th/^{225}Ac)

^{209}At-based imaging to establish ^{211}At α-therapy

^{209}At identified as novel SPECT isotope

Therapy

^{211}At

$t_{1/2}$= 7.2 h

(α-emitter)

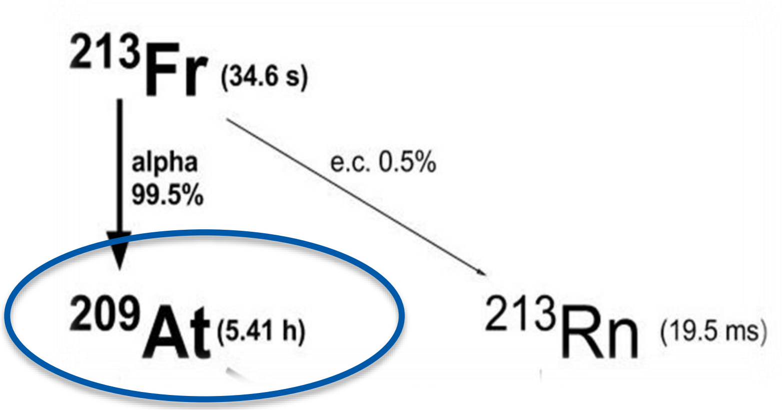
Imaging

^{209}At

$t_{1/2}$= 5.4 h

(γ-emitter)

^{209}At collected from ^{213}Fr ion beams



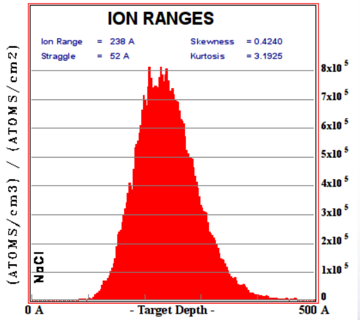
TRIUMF

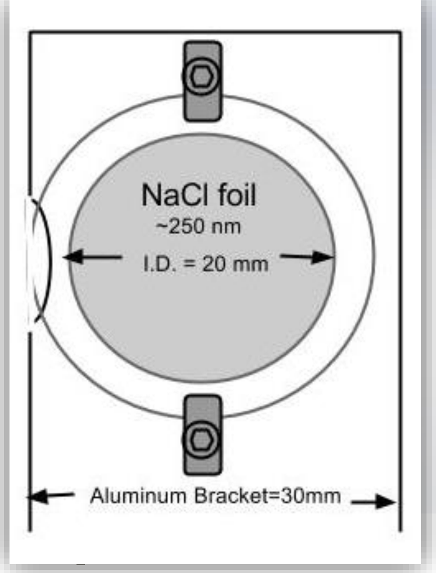
Ion beams of therapeutic α-emitters

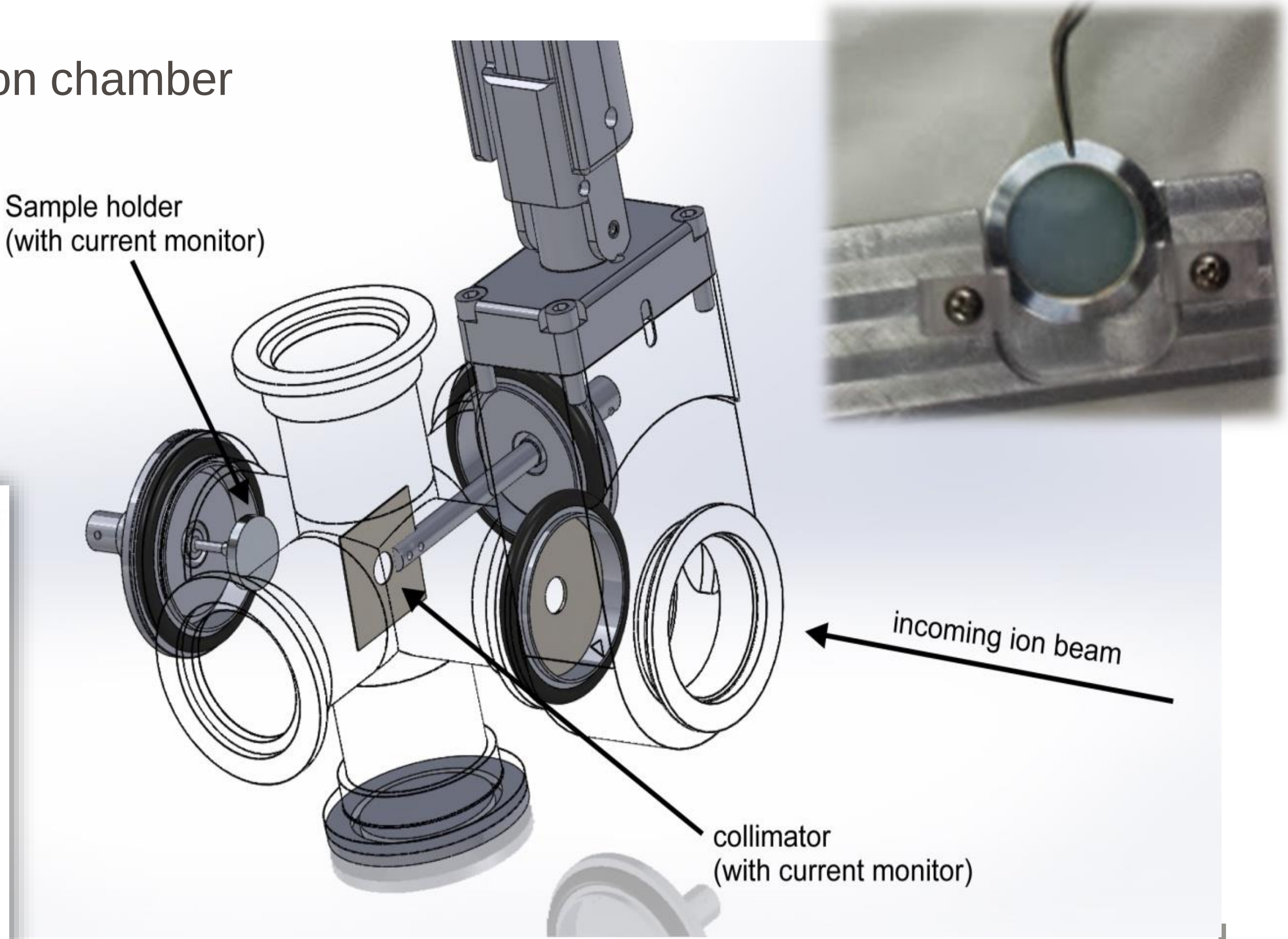
Isotope	1st Ionization energy	Ion Source
TANTALUM TARGET		
^{149}Tb	5.86 eV	Re surface ionizing
URANIUM TARGET:		
^{211}At	9.54 eV	Plasma/Resonance ionization laser
$^{212/213}$Bi	7.29 eV	Plasma (aka FEBIAD)
$^{223/225}$Ra	5.28 eV	Re surface ionizing
^{225}Ac	5.28 eV	Re surface ionizing
Note:		
$^{211/213}$Fr	**3.94 eV**	Re surface ionizing **(Most Intense!)**

ISOL pilot study: ^{209}At

Implantation chamber







Sample holder
(with current monitor)

incoming ion beam

collimator
(with current monitor)

Credit to: Peter Kunz, TRIUMF

From bench to (pre-clinical) bedside

10^9 ions/s of ^{213}Fr collected for up to 9.5 h

↓

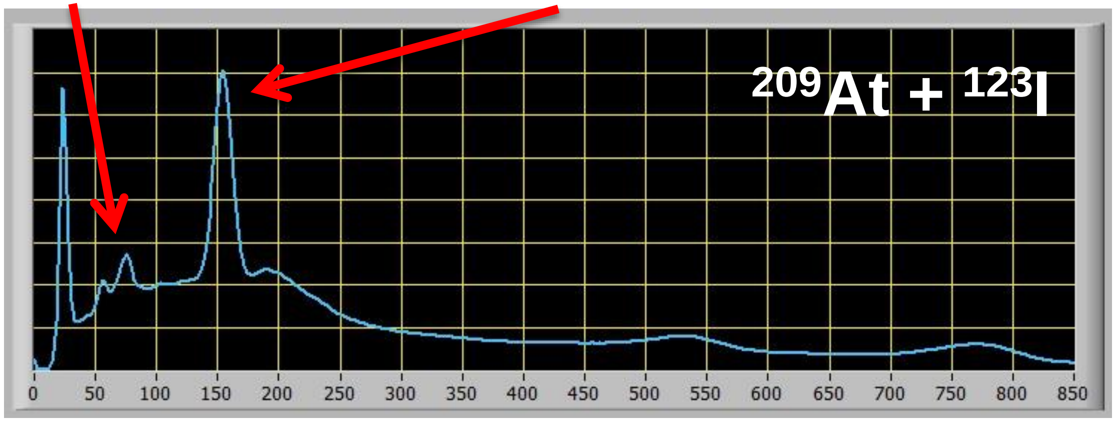
^{209}At recovered by dissolving NaCl targets in 0.1 N NaOH (< 300 μL)

↓

Up to 8.9 mCi ^{209}At (EOB)
(Measured by γ-ray spectroscopy)

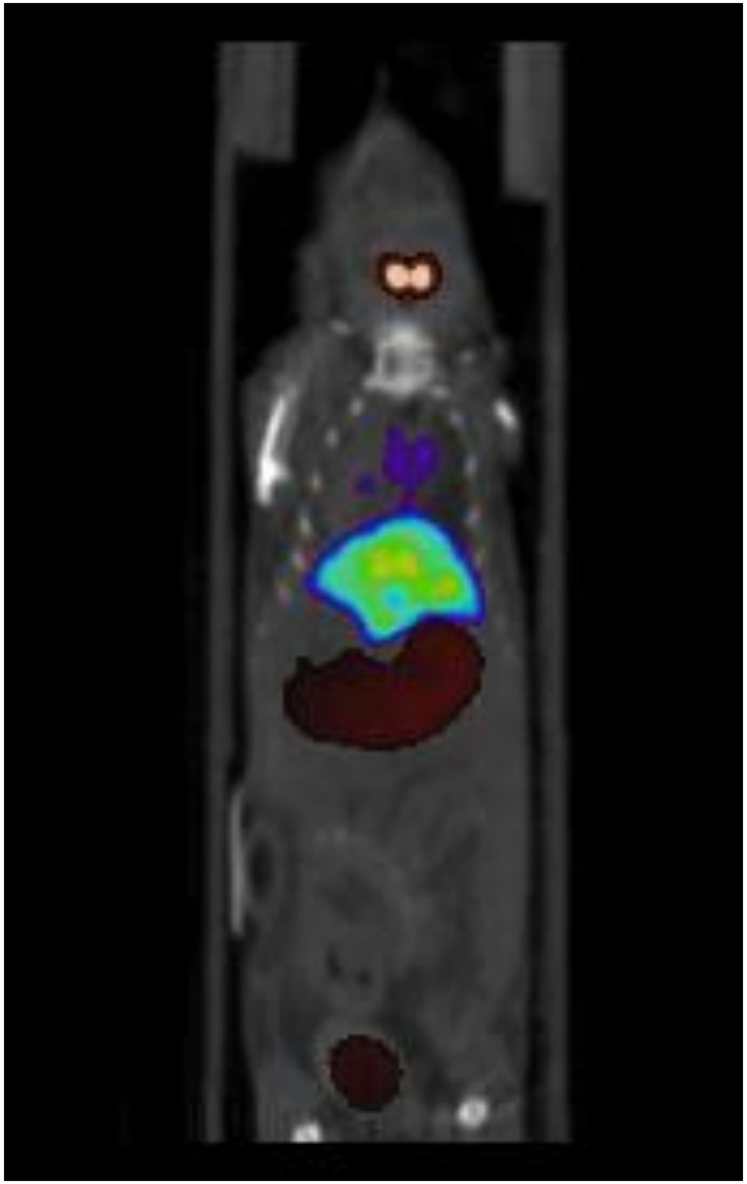
↓

Labeling Chemistry



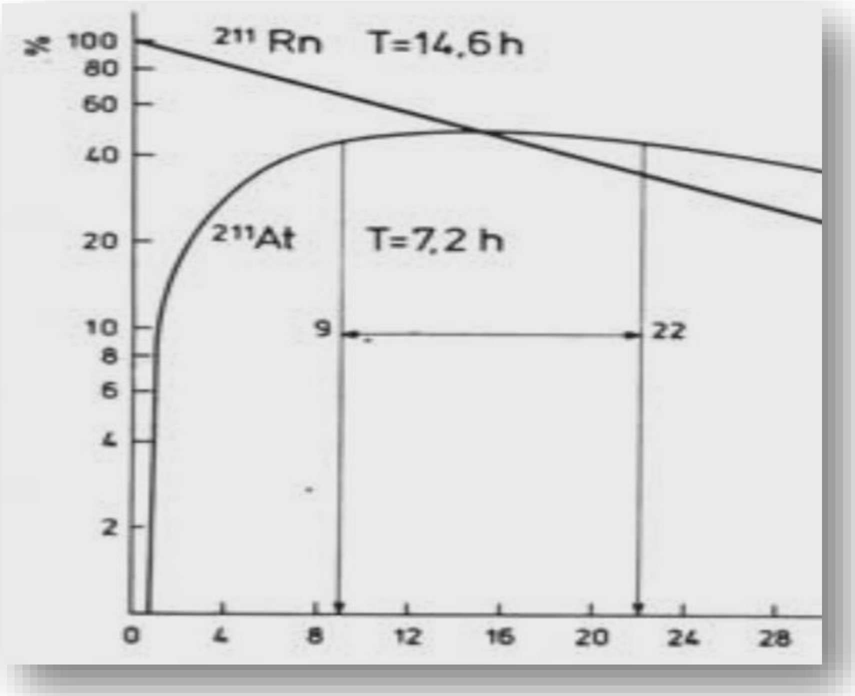
^{209}At: 80 keV peak

^{123}I: 159 keV peak

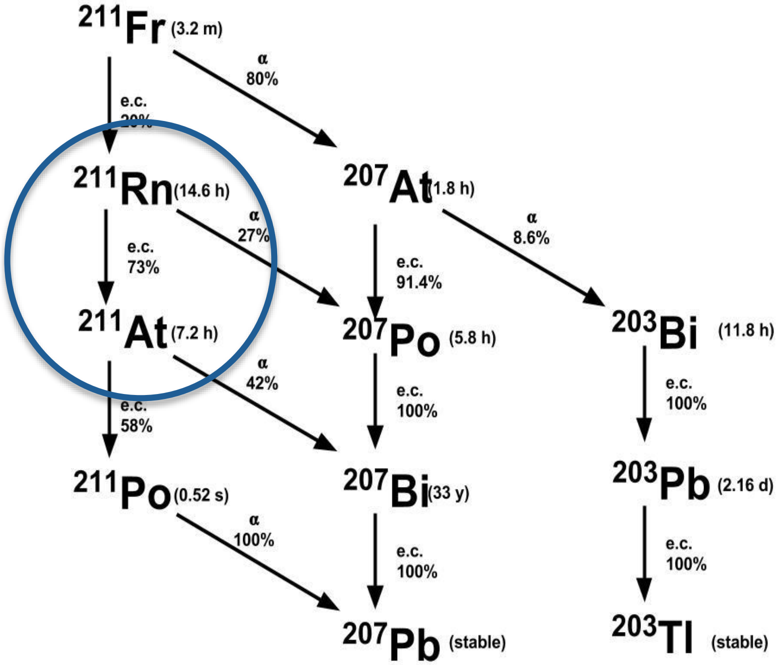


^{211}Rn/^{211}At generator system from ^{211}Fr ion beams (>10^9 ions/s)

^{211}Rn/^{211}At generator could increase ^{211}At supply and opportunities for distribution



The ^{211}Fr decay chain provided a novel approach to ^{211}Rn production

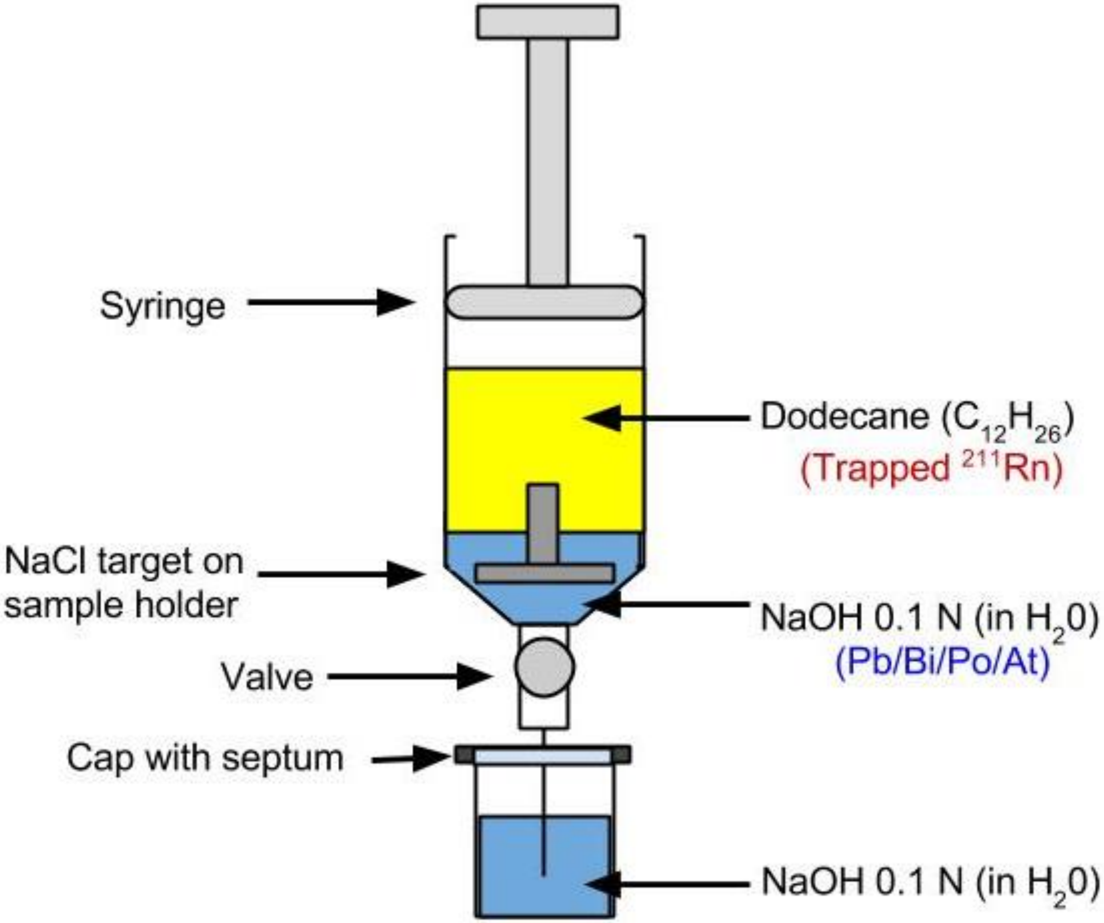


^{211}Rn was isolated in dodecane, other radioactive inventory was washed away with aqueous solution

↓

^{211}At progeny recovered
after several hours of grow-in

^{211}Rn isolation design



Implant ^{211}Fr in NaCl

↓

Submerge target in dodecane

↓

Dissolve NaCl in dilute NaOH

↓

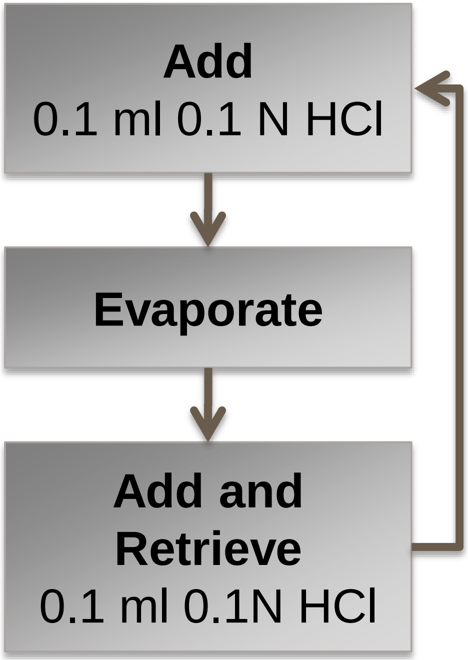
Mix and remove aqueous solution (Pb/Bi/At/Po)

↓

^{211}Rn isolated in dodecane $\rightarrow{}^{211}$A

Adapted from Maeda et al, 2015 Radioanal Nucl Chem, 303:1465-1468 (Kanazawa U.)

Moving on to feasibility of ^{225}Ra/^{225}Ac

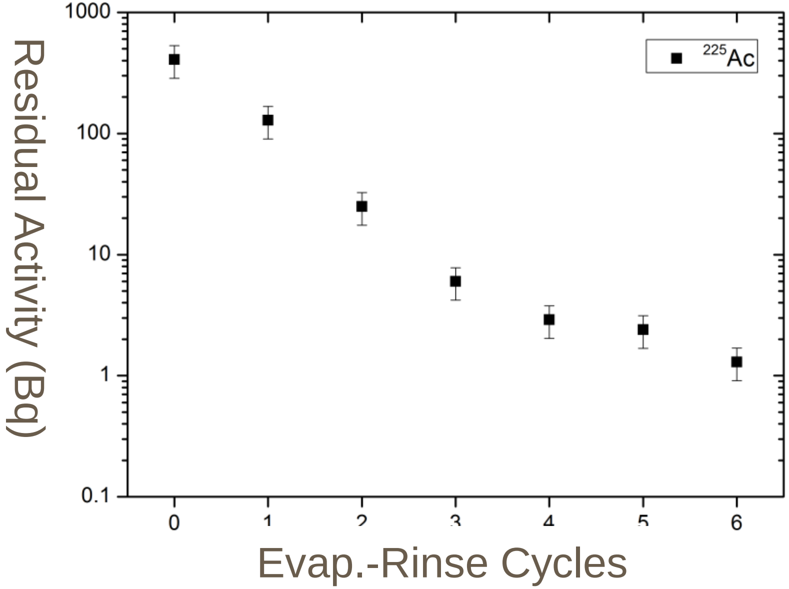


Add
0.1 ml 0.1 N HCl

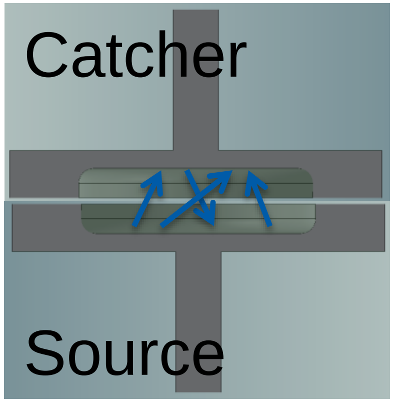
Evaporate

Add and Retrieve
0.1 ml 0.1N HCl

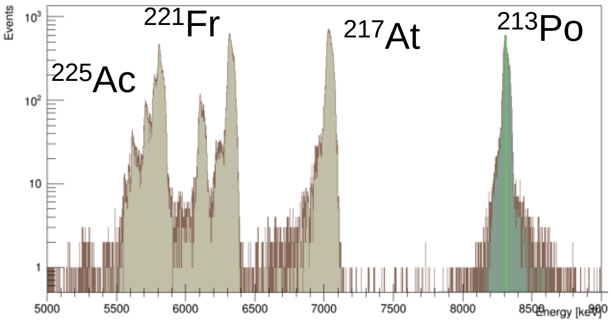
Extraction using 0.1N HCl solution



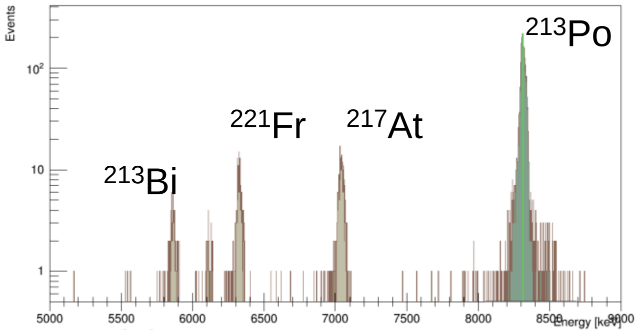
Recoil transfer in vacuum



Source



Catcher



Efficiency ~30%

Future Direction: ^{225}Ac/^{213}Bi

- ISOL and Target Dissolution/Extraction

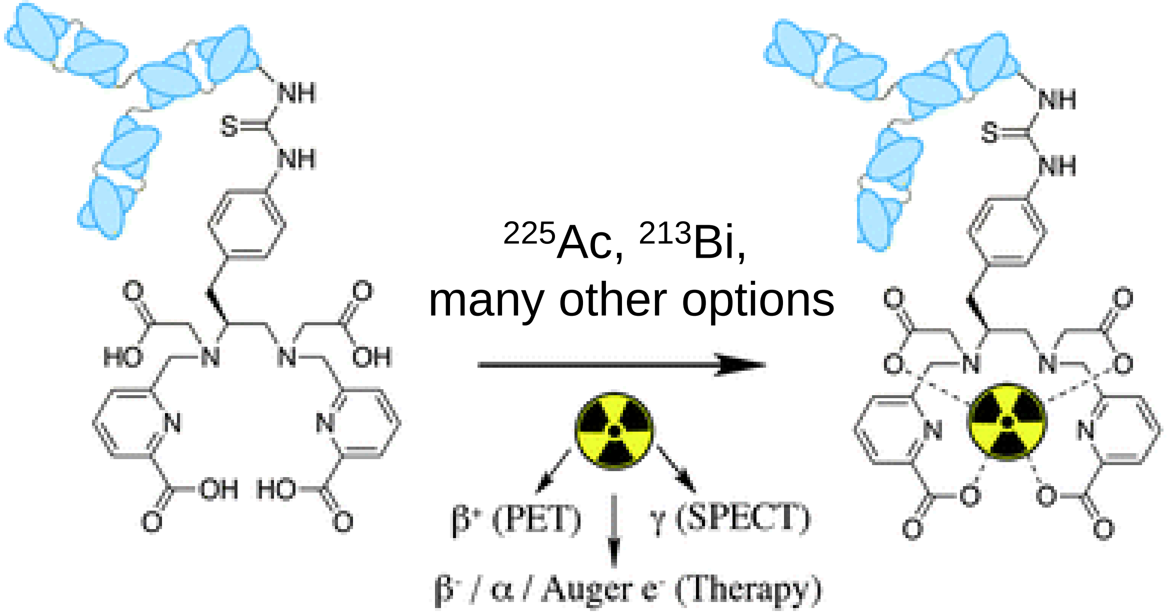
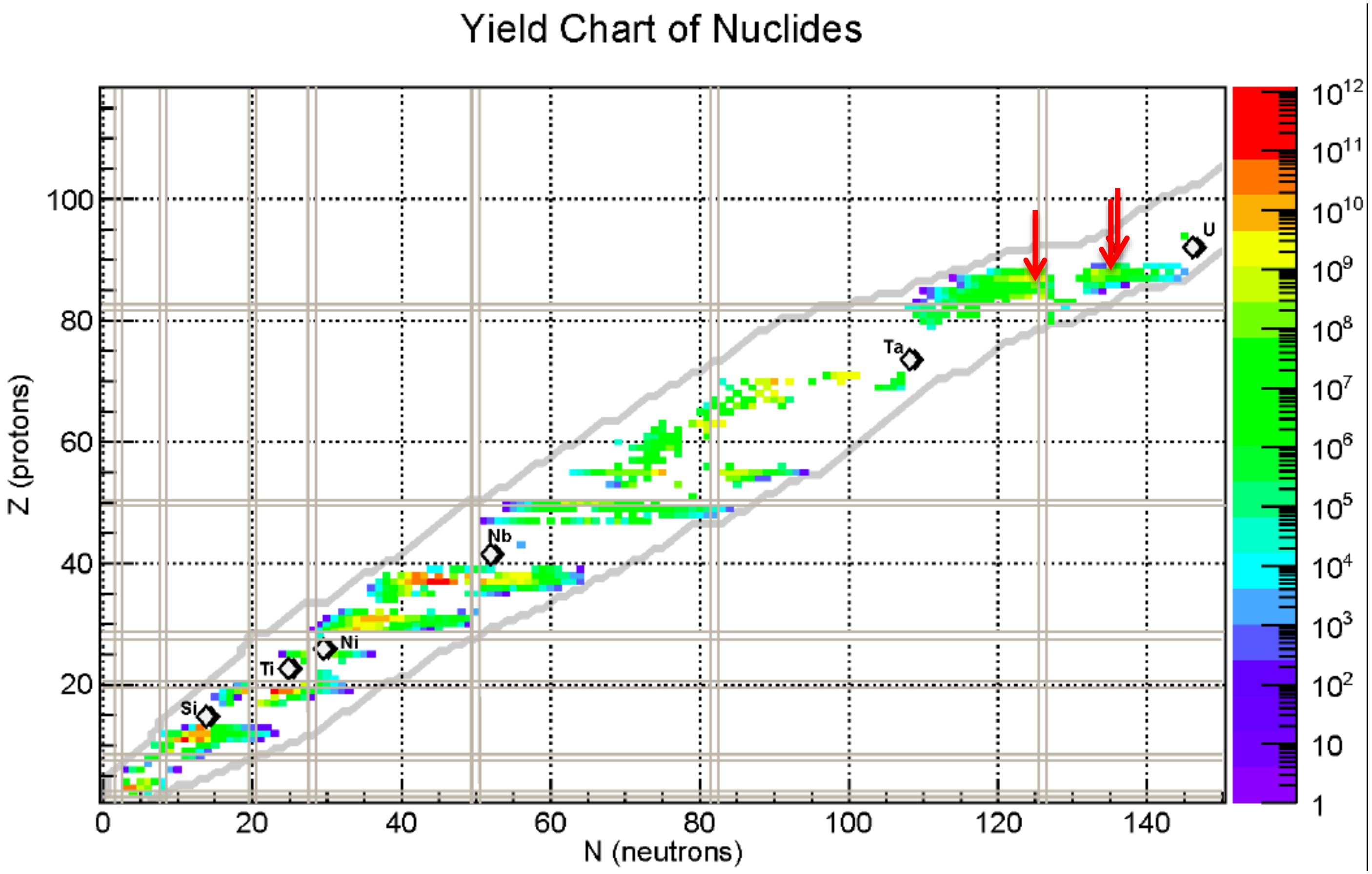


Image taken from: E Price, C Orvig, ***Chem. Soc. Rev.***, 2014,**43**, 260-290

- **TRIUMF capable of producing large (Ci) quantities of isotopes such as ^{225}Ac, ^{223,225}Ra, ^{213}Bi, ^{211}Rn**
- Possible to ship targets for off-site processing (short-term)
- Effort in early stages, infrastructure, regulatory capabilities being pursued/implemented (long-term)

Medical Isotopes from ISAC/ISOL

- **Generators: ^{211}Rn/^{211}At; ^{225}Ra/^{225}Ac; ^{225}Ac/^{213}Bi**



Feasibility/Chemistry in lead up to full target harvest:

Acknowledgements: Tc-99m

- **The Team:**

  PIs: F. Bénard, T. Ruth, A. Celler, J. Valliant, M. Kovacs,

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CARE & RESEARCH
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