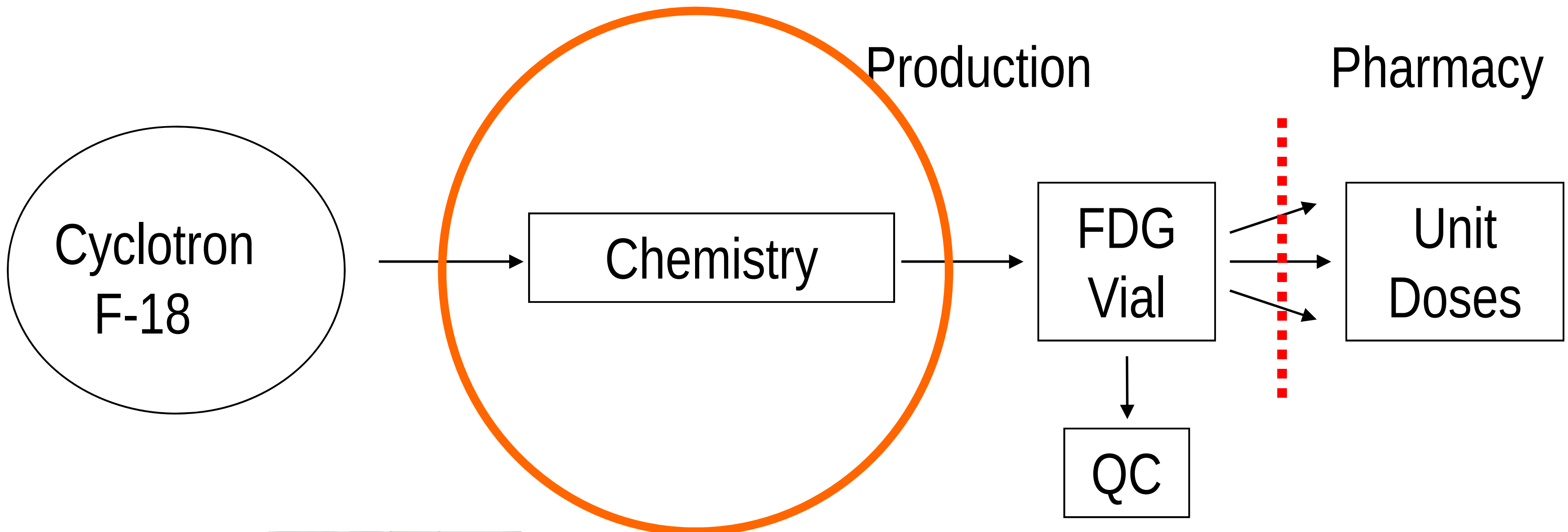
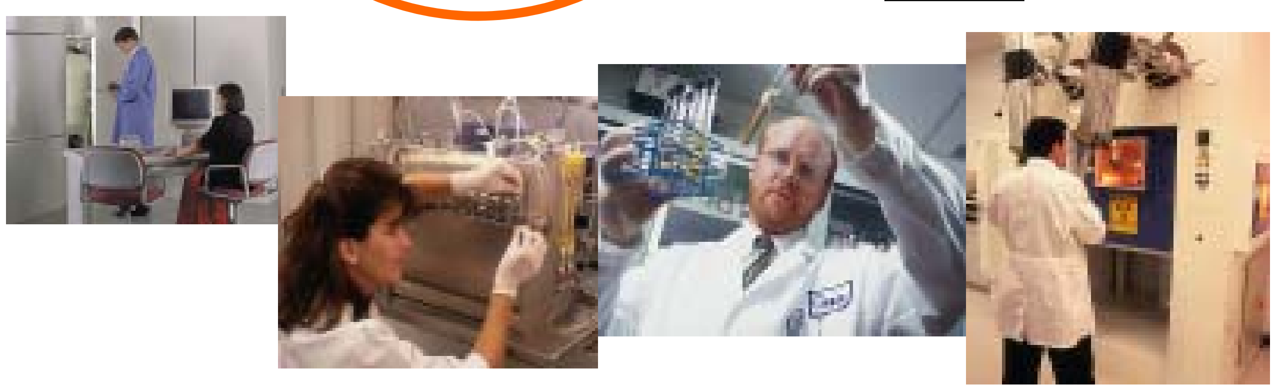
Overview of Production Process for FDG





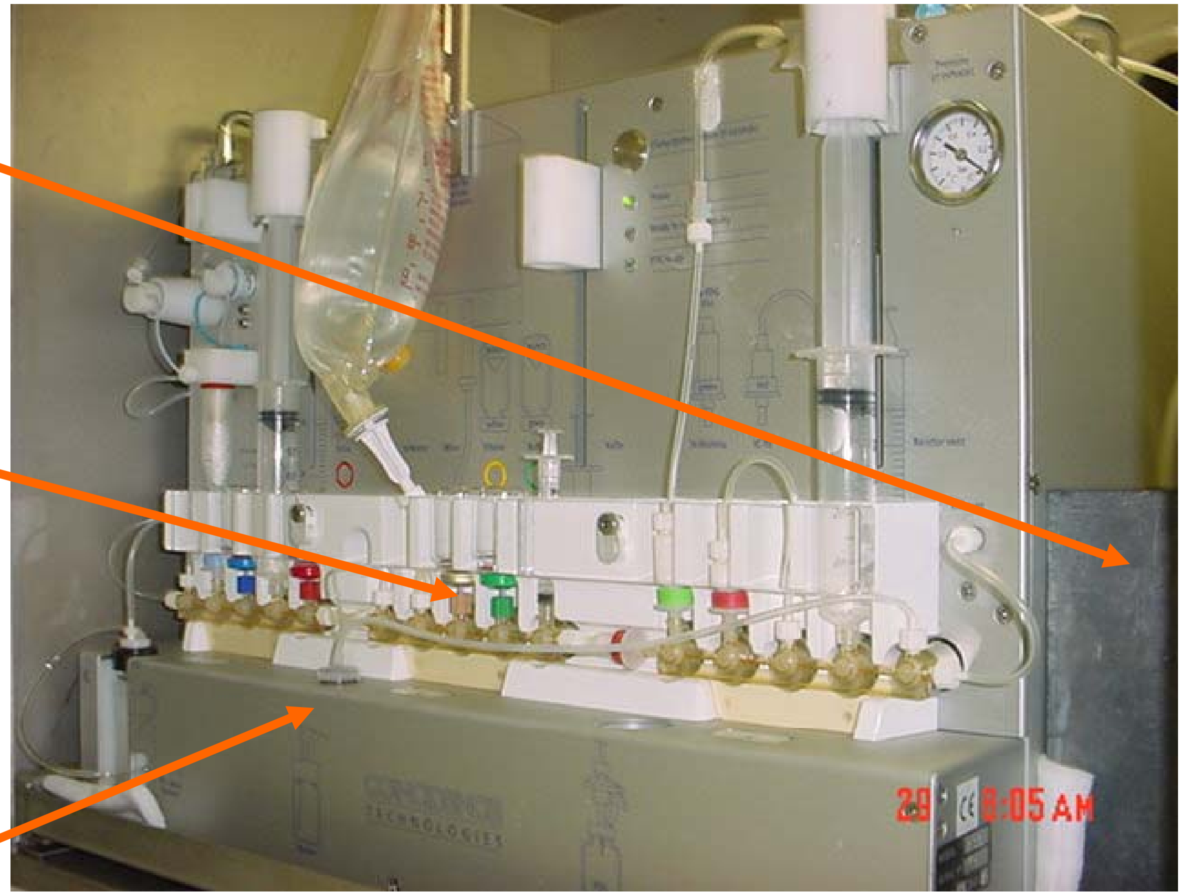
Automated Chemistry

- Commonly used for FDG synthesis
  - Coincidence Technologies (GE)
    - 1 synthesis & then replace “kit”
    - Approximately 30 minutes to FDG
  - Explora (Siemens)
    - 4 synthesis runs before replacing chemicals
    - Approximately 40 minutes to FDG
  - Synthera (IBA)
    - Multiple synthesis runs with kit replacement

Coincidence Technologies Chemistry Module

Waste vial

“kit”



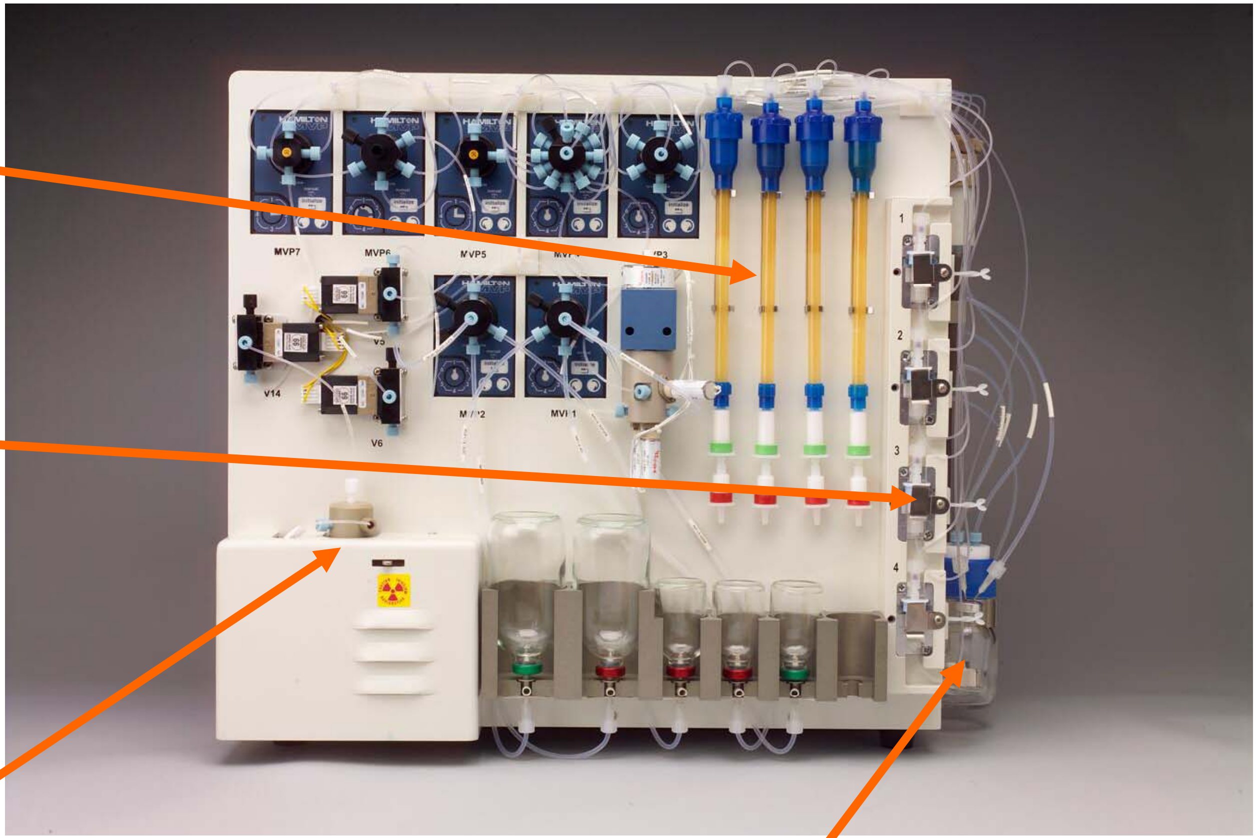
Reaction
vessel

Explora FDG4 Chemistry Module

purification
columns (4)

QMA
columns
(4)

Reaction
vessel



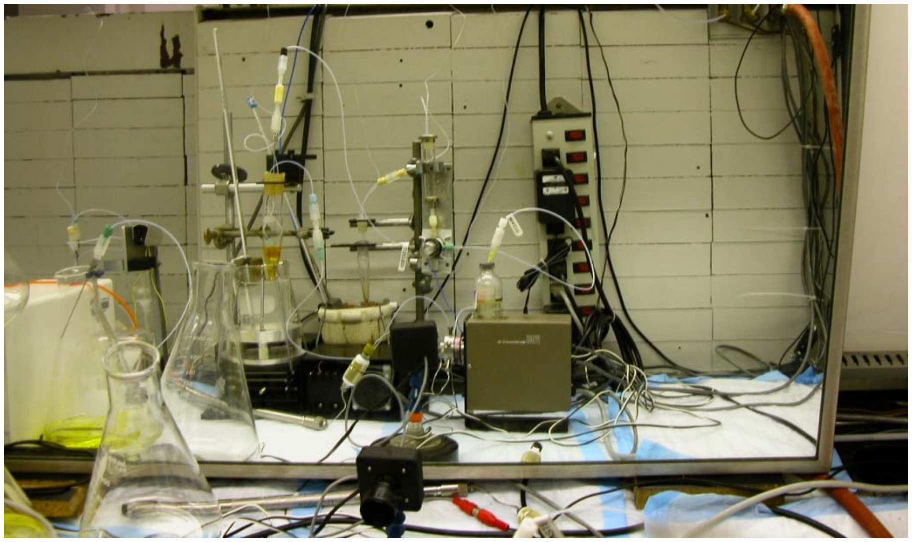
Waste vial

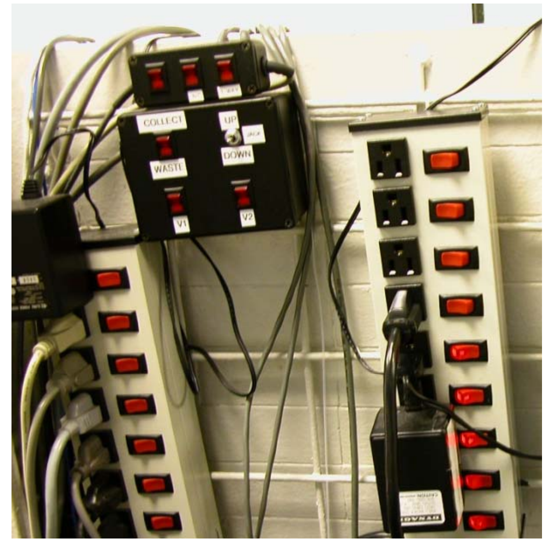
Shielded & Ventilated Chemistry Enclosure

75 mm Pb

Approximately 4.5 Ci of ^{18}F went into waste vial instead of staying on the trap, radiation field around handle 1 mR/h, elsewhere 0.5 mR/h with one hot spot on back 50 mR/h

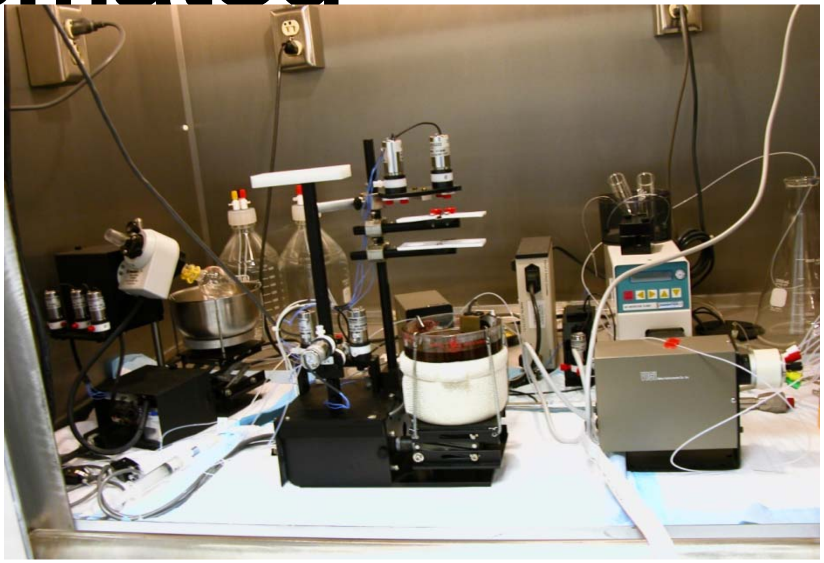
Radiochemistry Methods: Manual





- Common for experimenting with new radiochemistry techniques
- Uses manual movements of fluids and gasses
- Tongs and other remote manual handling devices might be used to transfer liquid to collection vials

Radiochemistry Methods: Semi–Automated



- More routine radiochemistry runs in common with other synthesis runs, often semi-automated controls for reactions are created
- Can include electrical switches to control values to deliver reactants, direct gas or liquid gas flows, control temperature
- Computer monitoring of valve states and radioactivity locations
- Often dedicated to the production of a specific probe and are not frequently moved around

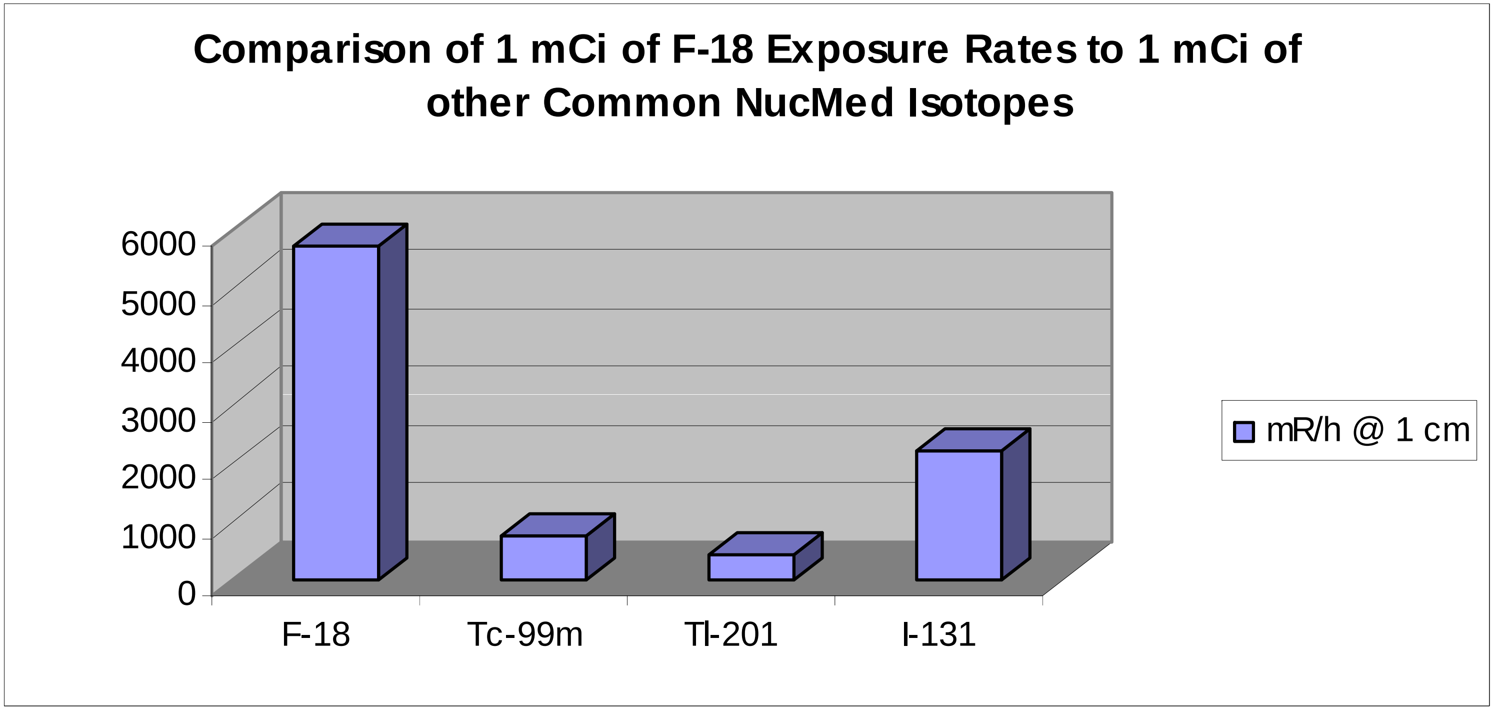
Other PET radiopharmaceuticals

- Little Processing Required
  - Ammonia (Nitrogen-13)
  - Carbon-11 carbon dioxide
  - Oxygen-15

Exposure Rates for ^{18}F versus ^{99m}Tc

10 mCi source (mR/h)			
	2 inches		8 inches
Tc-99m	565		35
F-18	3200		200
F-18 Exposure = ***6 times*** Tc-99m			

Exposure rates for F–18 versus Traditional NucMed



Use of Tongs to Handle Loaded Syringe Shields

24 inch tongs

Gamma Exposure Reduction

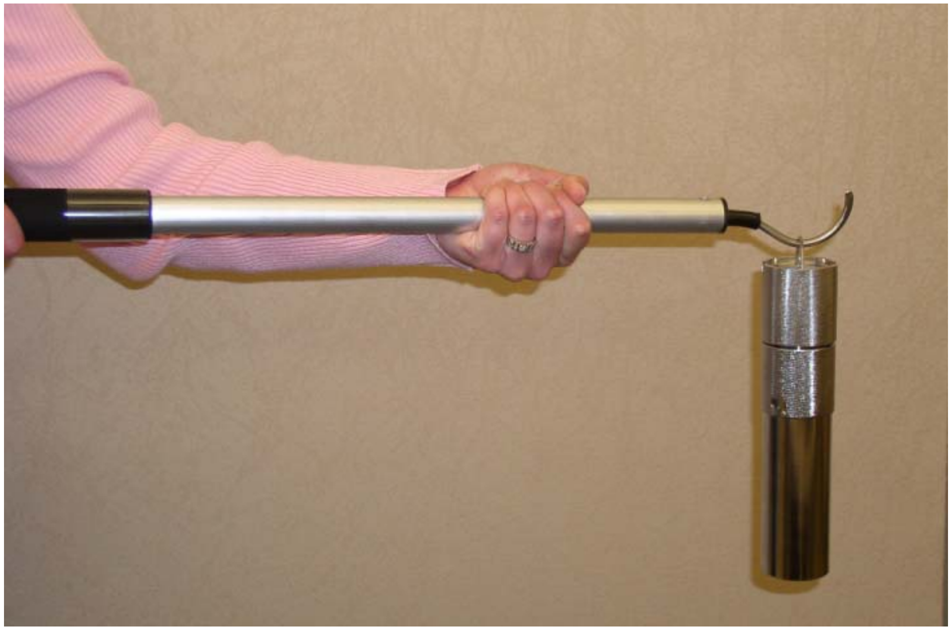
At Shield Contact: 400 mR/hr

At End of Tongs: 35 mR/hr

^{18}FDG in syringe: 102 mCi

Extremities Dose Reduction by a Factor of 12

Use of Tong to Handle Loaded Syringe Shields



Captain Hook

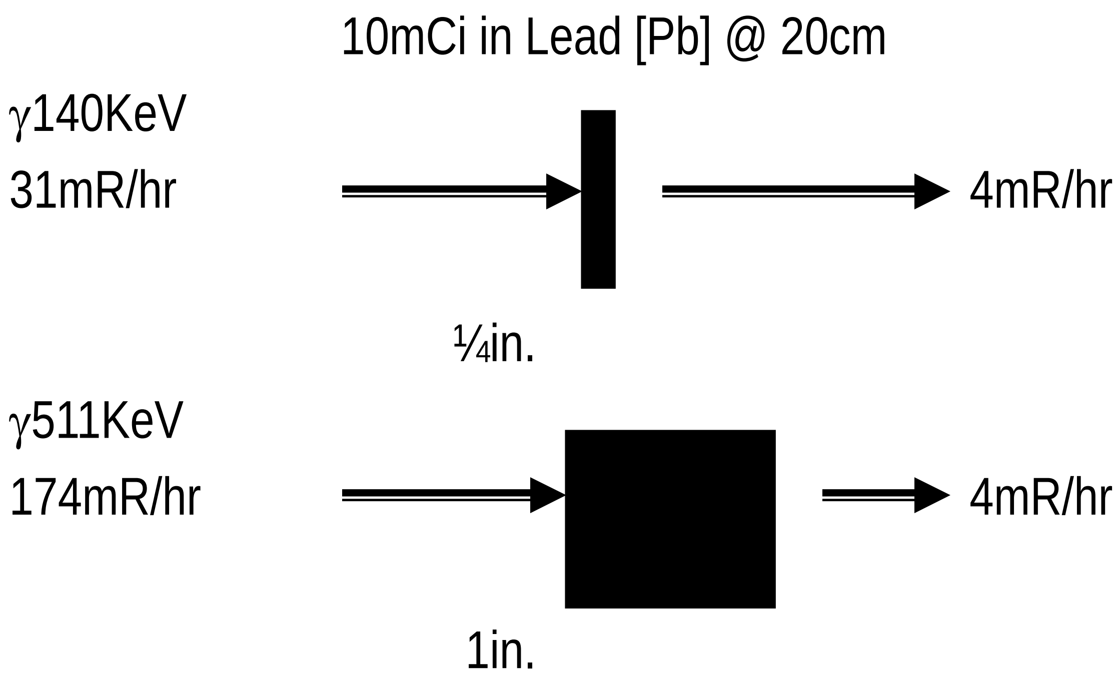
Exposure Rate at contact = 2 R/hr
Exposure Rate at hand = 180 mR/hr

The Claw

Half Value Layer for ^{18}F versus ^{99m}Tc

millimeters			
	lead		tungsten
Tc-99m	0.26		0.18
F-18	4		2.8
HVL of F-18 = 15x Tc-99m Tungsten = 1.4x Shielding Capability of Lead			

SHIELDING COMPARISON



PET NUCLEAR PHARMACY DESIGN

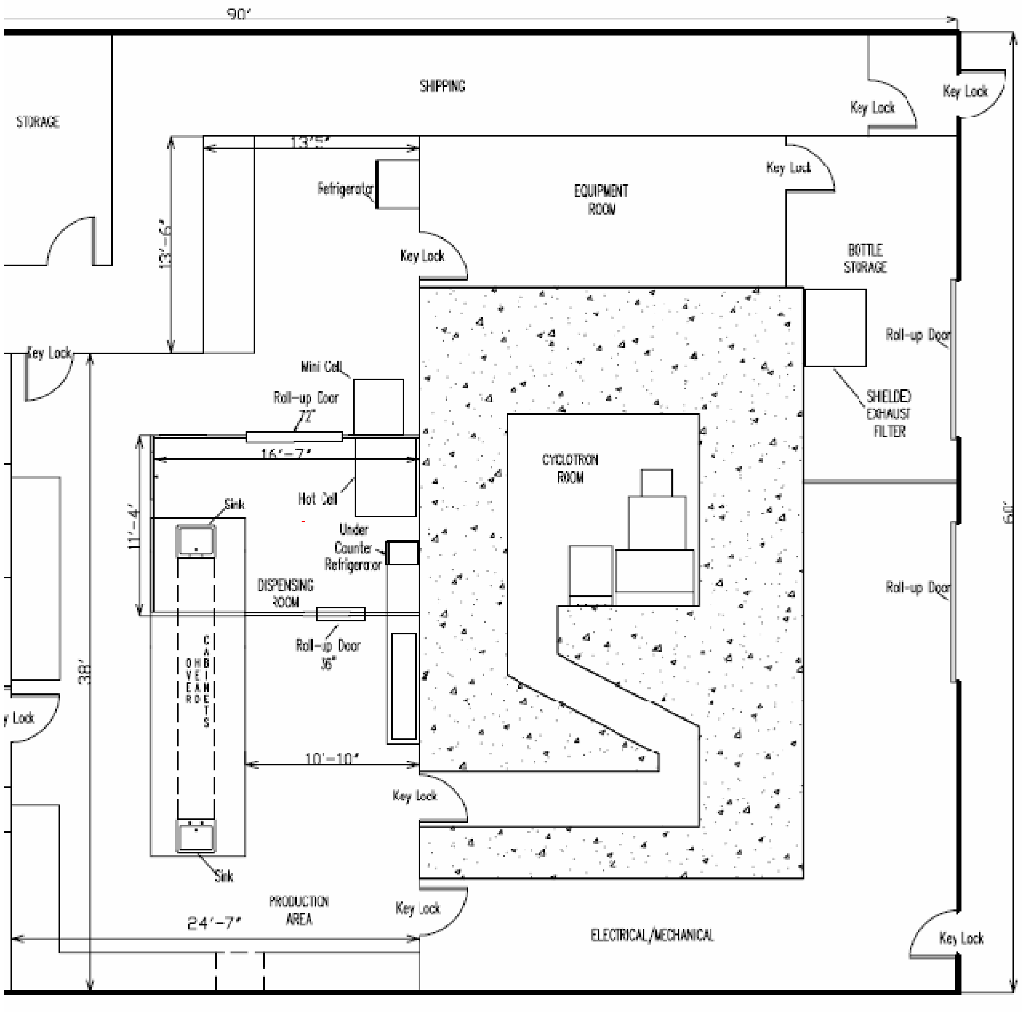
PET Manufacturing/Pharmacy Design

- Workflow is a very important consideration in design
- Cyclotron manufacturer will provide guidance on shielding requirements based on site specific conditions
  - Bunker design is fairly standard for all sites
  - Cyclotron room wall thickness for self-shielded cyclotrons will depend on use and control of adjacent spaces

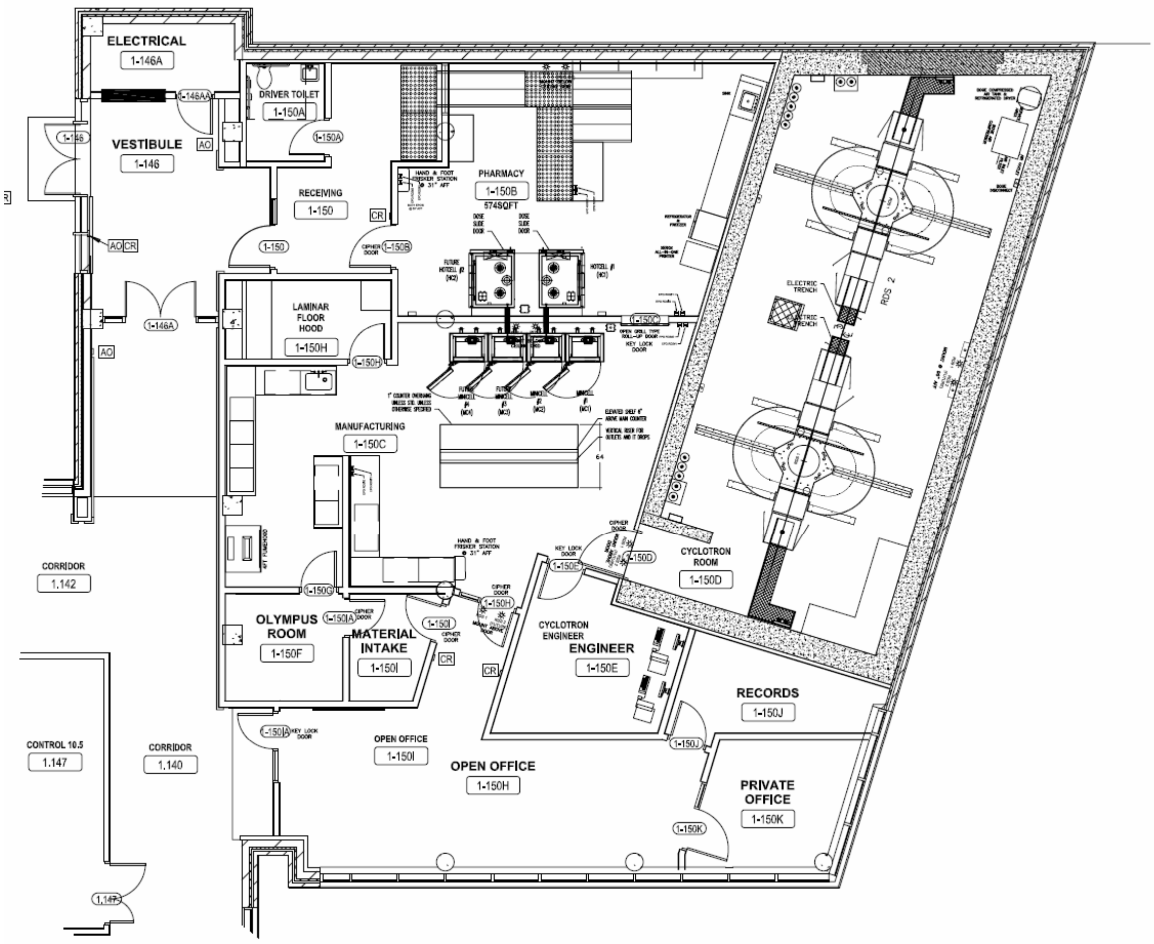
PET Manufacturing/Pharmacy Design

- Effluent Control
  - Consideration must be given to effluent release point, and nearest receptor location
  - Once receptor location identified, releases should be modeled to determine controls required to maintain effluents within limits & ALARA
- Design so that unrestricted areas are not solely reachable through restricted space i.e. offices
- Place QC and target rebuild stations on interior walls bordering restricted space to avoid issues with public dose
- Consider ingress and egress routes for couriers

Bunker Shielded Cyclotron

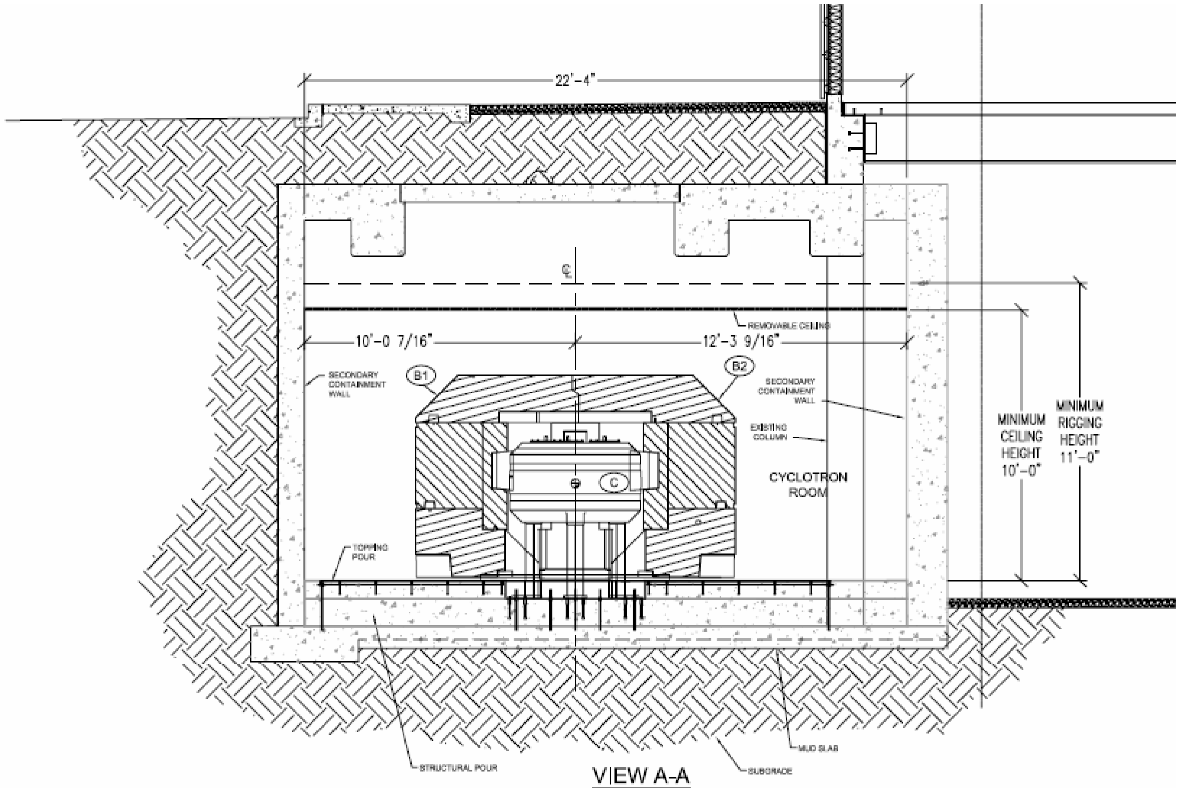


Dual Cyclotron Floor Plan



Cyclotron Shielding Considerations

- Underground placement
  - Dirt provides surprisingly good shielding
  - Limit potential for occupancy above with landscaping

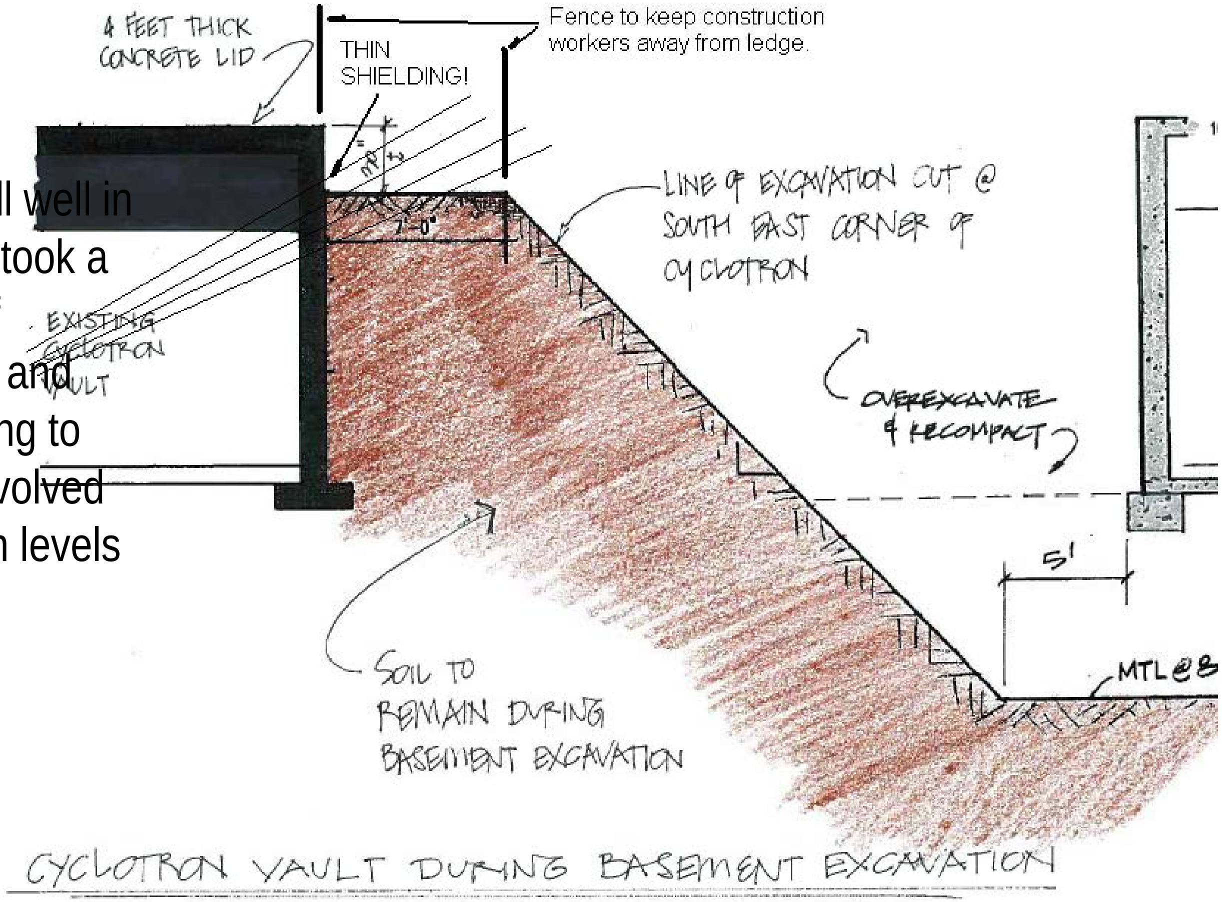


Cyclotron Shielding Considerations

- Underground placement
  - Dirt provides surprisingly good shielding – until removed
- MC-17 located underground and off back side of building

Cyclotron Shielding Considerations

All worked all well in the end, but took a great deal of coordination and surveys during to assure all involved that radiation levels were fine



RADIOACTIVE WASTE STORAGE

SPECT Pharmacy

- Group waste held for decay-in-storage (DIS) based on half-life
- Four or five groups, each with their own shielded storage drum – clearly label each drum as to contents and date filled
- Waste consists of process waste from the pharmacy operations as well as return waste from customers if authorized
- Sharps and biohazard concerns – use proper storage containers as well as disposal options
  - Some States have additional requirements and/or permits required for return waste beyond NRC/Agreement State licensing
  - Never attempt to retrieve an object dropped into a waste container

Segregation of Radioactive Waste

Group Code	Radionuclide	Form	Half-Life Range	Decay Time
A	^{99m}Tc	liquid	6 hours	3 days
B	^{201}Tl ^{67}Ga ^{90}Y ^{123}I ^{111}In	liquid liquid liquid liquid, solid liquid	13 to 78 hours	33 days
C	^{133}Xe ^{131}I	gas liquid, solid	5 to 8 days	80 days
D	^{32}P ^{51}Cr ^{125}I ^{89}Sr	liquid liquid Liquid liquid	14 to 60 days	2 years
E	^{153}Sm, ^{57}Co, Or any other radionuclide whose half-life exceeds license decay in storage limitation	liquid, solid	> License decay-in-storage half-life limitation	NA

Waste Containers & Label

Container Number: ____________________

Group Code: _______________________

Date Opened: _______________________

Date Closed:

____

Attach this label to container when closed

Do Not Dispose Before:

____

Return Customer Waste

- Breakdown packages in designated area and with proper PPE
- Survey and segregate according to radionuclide
- Disinfect reusable components as required by procedure
- Discuss proper shipping requirements with customer if issues with labeling or shipping papers identified

27

Table of Limited Quantities for common SPECT radionuclides

Limited Shipment Quantities for Each Commonly-used Radiopharmaceuticals

Radionuclide	Limited Shipment Quantity (mCi) A_2 x 10^{-4}
Co-57	27.0
Co-58	2.7
Cr-51	81.0
Ga-67	8.1
I-123	8.1
I-125	8.1
I-131	1.9
In-111	8.1
Mo-99	1.6
P-32	1.4
Sm-153	1.6
Sr-89	1.6
Tc-99m	11.0
Tl-201	11.0
Xe-133*	2.7
Y-90	0.81

*(gases, A_2 x 10^{-3})

The above values have been calculated using information from 49 CFR 173.423, Table 7, and 49 CFR 173.435, Table of A_1 and A_2 values for radionuclides (2005). When shipping more than one type of radioactive material in the same package, the limit on the total activity that may be shipped is determined by using the unity equation for each radionuclide and its Limited Quantity activity limit.

SOP RC-69 Attachment 3 Radioactive Waste Container Label

Container Number: ____________________

Group Code: ____________________

Date Opened: ____________________

Date Closed: ____________________

Attach this label to container when closed

Do Not Dispose Before:

____

Survey of DIS Waste

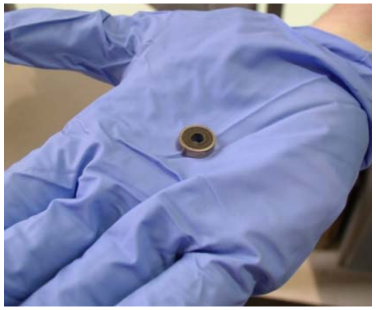
- Ensure surveys are conducted in a low background area
- Carefully survey waste and obliterate all labels if indistinguishable from background
- Maintain written records of waste disposed of through DIS

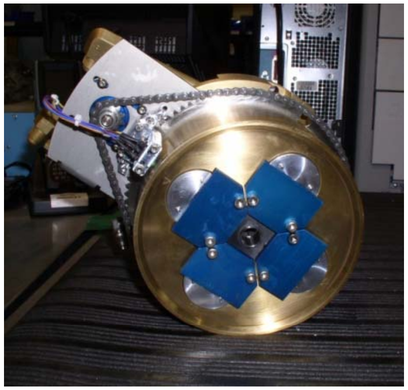
PET Pharmacy

- All leftover PET radionuclides are held for DIS
- Some of the replaceable cyclotron parts and consumable chemistry module components will contain radionuclides with a half-life > DIS limits and must be held for off-site shipment to a licensed disposal site
- Target windows will require extensive shielding due to ^{56}Co, hold for two years if possible leaving ^{57}Co as the most significant radionuclide remaining
- Trap and release columns will contain small amounts of material from target windows and bodies, particularly if silver target bodies are used

Cyclotron Components

- Examples of Cyclotron components that must be held for off-site disposal
- Ensure cyclotron components are segregated from other sources of waste
- Maintain records of items placed into storage





Cyclotron Components

- Example storage containers – uses one inch thick lead vial shields internally for storing target windows