SPECT PHARMACY DESIGN & HP CONSIDERATIONS

Typical layout for a SPECT Pharmacy

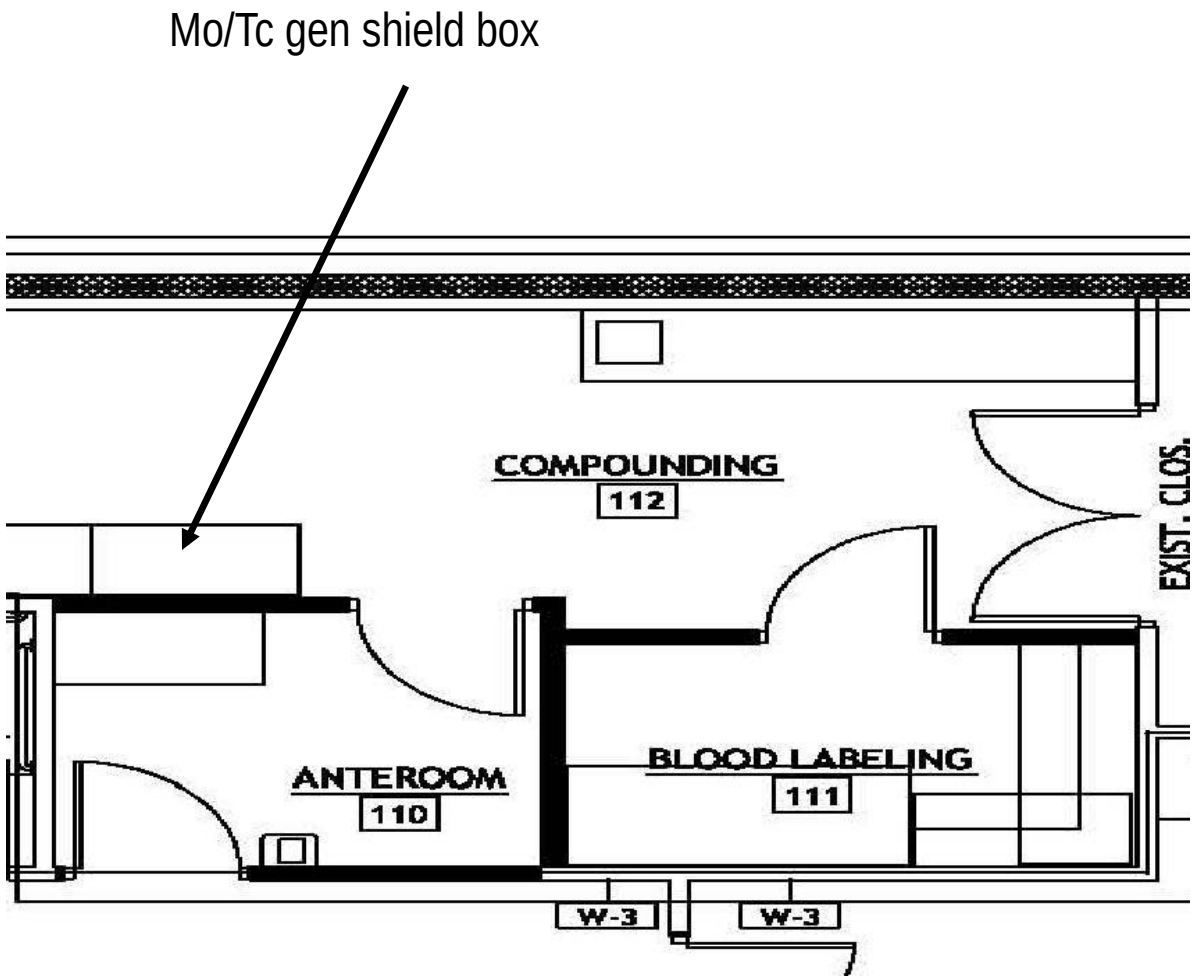
General Design Considerations

- Consider workflow in layout
- Restricted areas contiguous where possible
- Maintain negative air pressure differential between unrestricted and restricted space, and within between iodine compounding and the remainder of the restricted space, to prevent spread of contamination
- Carefully engineer ventilation to meet above demands and demands of ventilated enclosures such as glove boxes and hoods

General Design Considerations

- Placement of iodine room filter, shielding, and public exposure potential
- Look at potential for public exposure from other aspects of the operation
- Blood room should be separate
- Space for Decay In Storage (DIS)
- Easy access for couriers
- Consider neighboring use if multi-tenant building
  - No day-cares next door!
  - Look at building intake locations

Typical layout for a SPECT Pharmacy



Typical layout for a SPECT Pharmacy

Shielded boxes for generators (coffins)

Typical layout for a SPECT Pharmacy

Elution shield for use with generators

Typical layout for a SPECT Pharmacy

Elution shield in place on generator

Generators

- "Jammed" Generators
  - No Flow
  - Substantial activity on column for large sizes
  - Never should they be opened
- Frozen Generators
  - Heating can be very dangerous
- After hours delivery
  - Security
  - Background and public dose

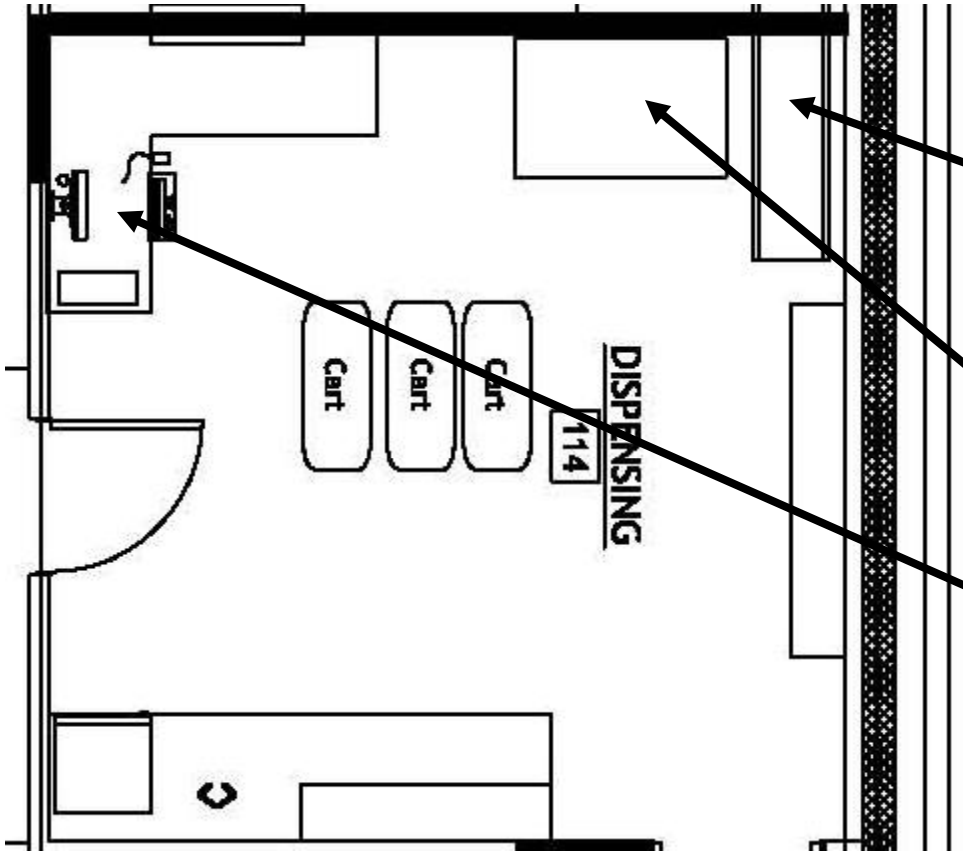
Blood Labeling Room

- Blood is drawn from patient and delivered to pharmacy
- Several techniques used to separate specific cells
- Radiopharmaceutical used to label cells
- Returned to patient for injection
- Concerns about contamination – generally staff are limited to only working on blood labeling and only one at a time
- Segregation of supplies
- BBP
  - CAH incident in Baltimore (see handout)

Excerpt from SOP on Leukocyte Labeling

- No more than one sample can be processed by one trained individual at a time. Attention to the WBC procedure is to be given priority over interruptions once the procedure has been started. It is required that the same team stays with the procedure until completion. One dedicated pharmacist will be responsible for overseeing NO more than 2 blood samples at a time and will stay with each procedure until completion.

Typical layout for a SPECT Pharmacy



Typical layout for a SPECT Pharmacy

Dispensing station with dose calibrator

Typical layout for a SPECT Pharmacy

Dispensing station showing shielded waste drum

Typical layout for a SPECT Pharmacy

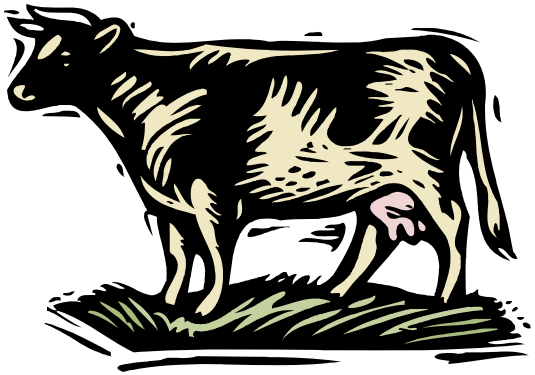
Racks used to keep the different products separated

Typical layout for a SPECT Pharmacy

Labeled vial shields for different products

Dispensing Concerns (^{99m}Tc)

- ^{99m}Tc Compounding
  - "Milk" or elute the generator
  - Inject pertechnetate into drug vial and remove air
- Either:
  - Shake and dissolve
  - Shake and bake



Dispensing Concerns (^{99m}Tc)

- Significant Number of Doses Drawn per Day (>500)
- Vial shields to hold compounded products
- Syringe shields for drawing doses
- Ease of shielding CAN lead to a cavalier attitude
  - Concern about unshielded openings
  - The Distance Principle
  - Proper handling of shields
  - Placement of finger rings
  - Correction of dosimeter readings

Dose Drawing Syringe Shield and Vial Shield

Dispensing Concerns (^{99m}Tc)

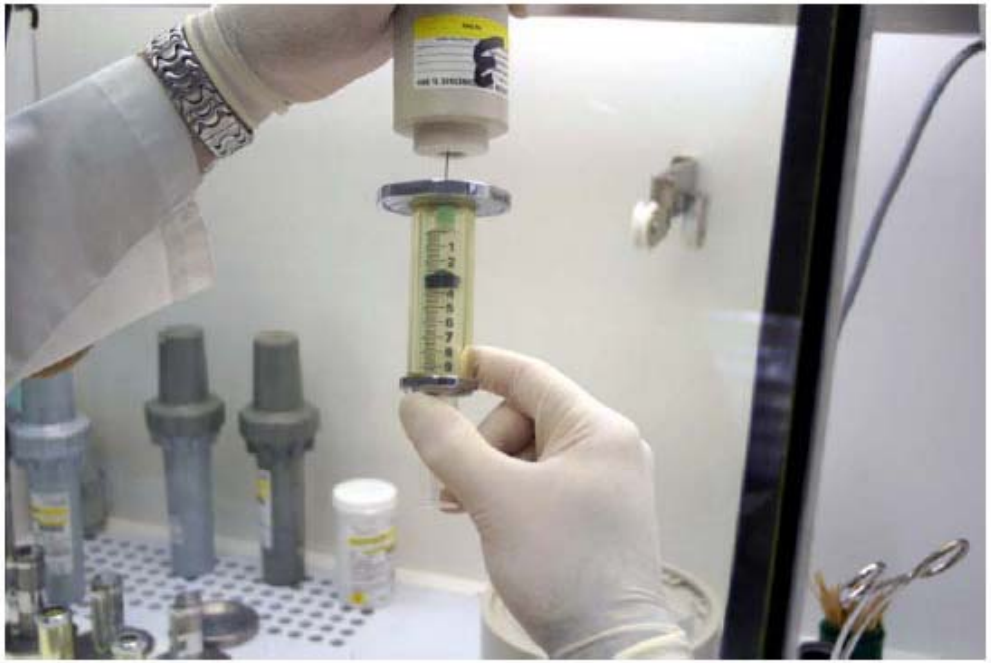
- Cardinal Health Completed a comprehensive extremity dose modeling study for dispensing
  - Used multiple TLDs on a glove on each hand
  - Compared to ring badge results
- US NRC has completed Monte Carlo studies – awaiting issuance of guidance on assessing the results from ring badges

Dispensing Concerns (^{99m}Tc)

- Typical placement of fingers during uncapping & recapping syringes

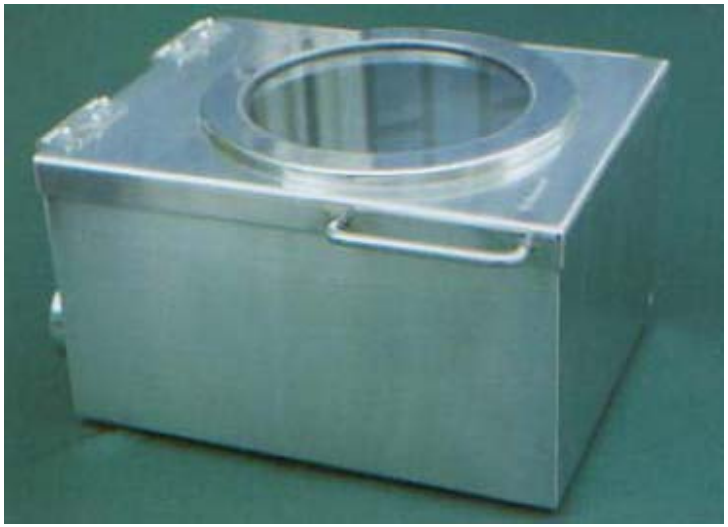
Dispensing Concerns (^{99m}Tc)

- Drawing up a dose

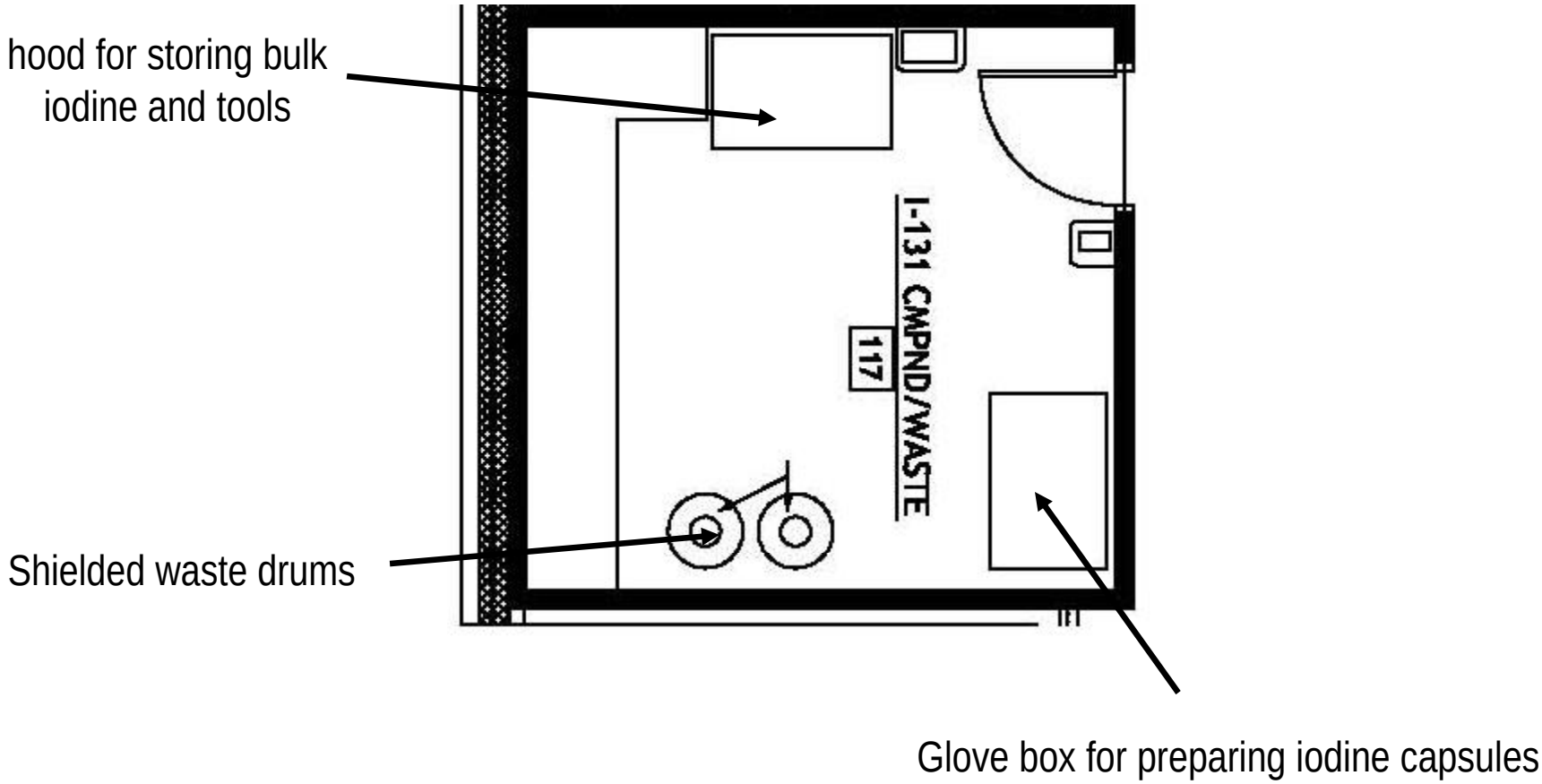


Dispensing Concerns (^{99m}Tc)

- Recapping and needle sticks
  - Proper technique
  - Avoiding needle sticks
  - Sharps/Medical Waste/BBP
- Heated Vial Ruptures
  - Tc is not volatile
  - Instantaneous “poof” of steam
  - HotBox (unshielded)



Typical layout for a SPECT Pharmacy



Typical layout for a SPECT Pharmacy

Glove box for preparing iodine capsules

Typical layout for a SPECT Pharmacy

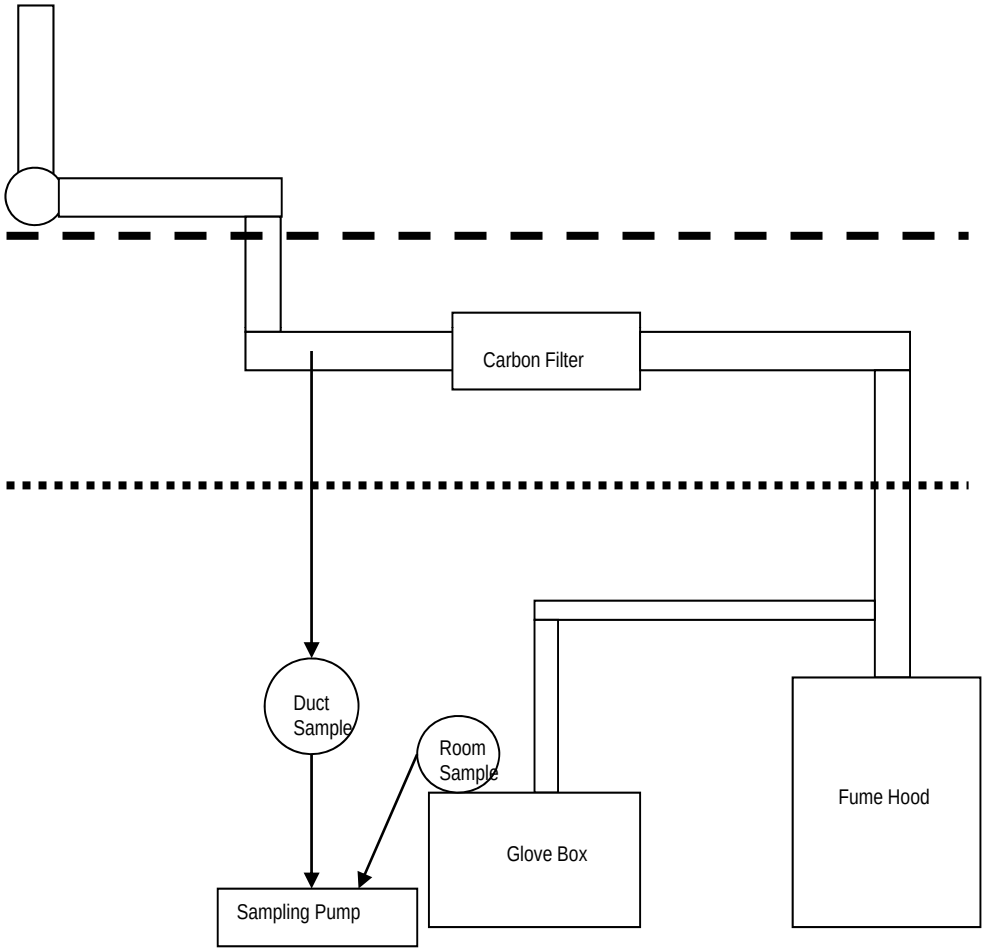
Hood for storing bulk iodine and tools

Dispensing Concerns (^{131}I)

- Sodium Iodide solutions are volatile
  - Very High Concentrations
  - Special ventilation systems
  - Room and Effluent Monitoring
  - Thyroid Monitoring
  - Waste (volatility/radiation)
  - Clean up after each session

- No good solution for syringe shield
- Contamination and needle sticks are more serious

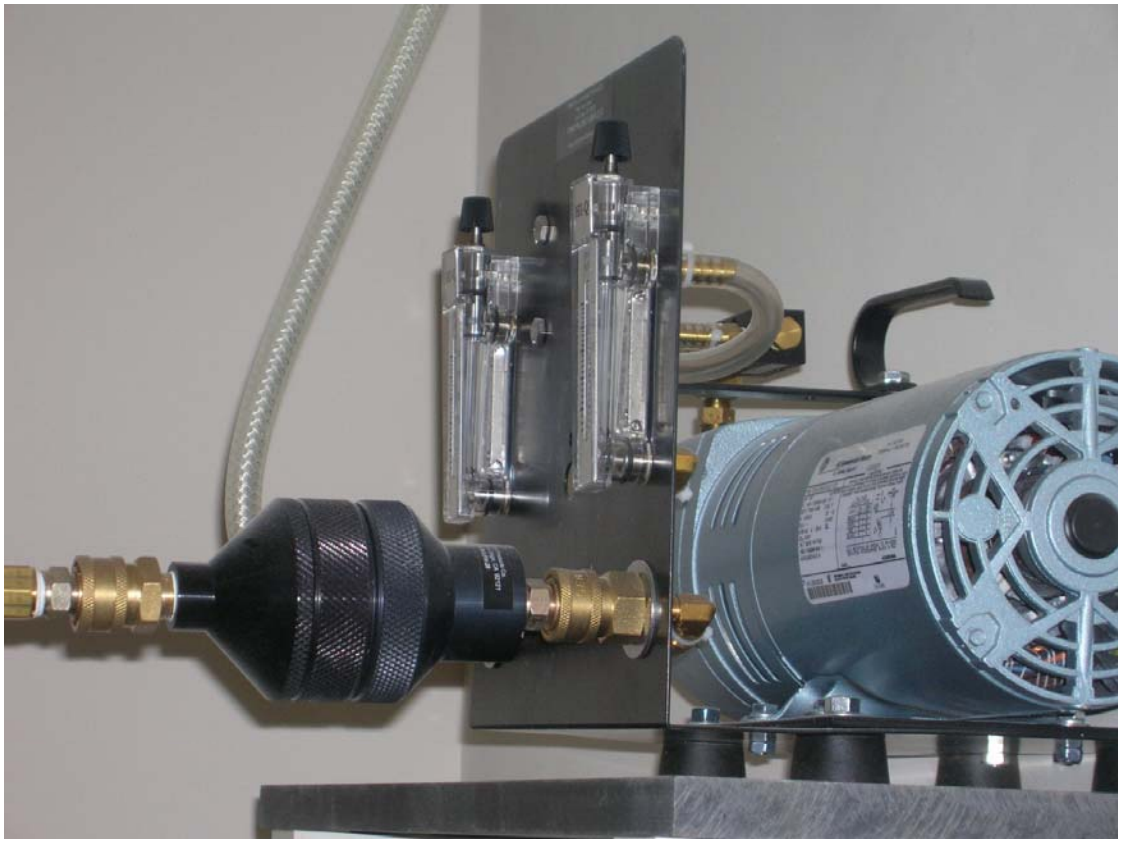
Ventilation for ^{131}I



Ventilation for ^{131}I

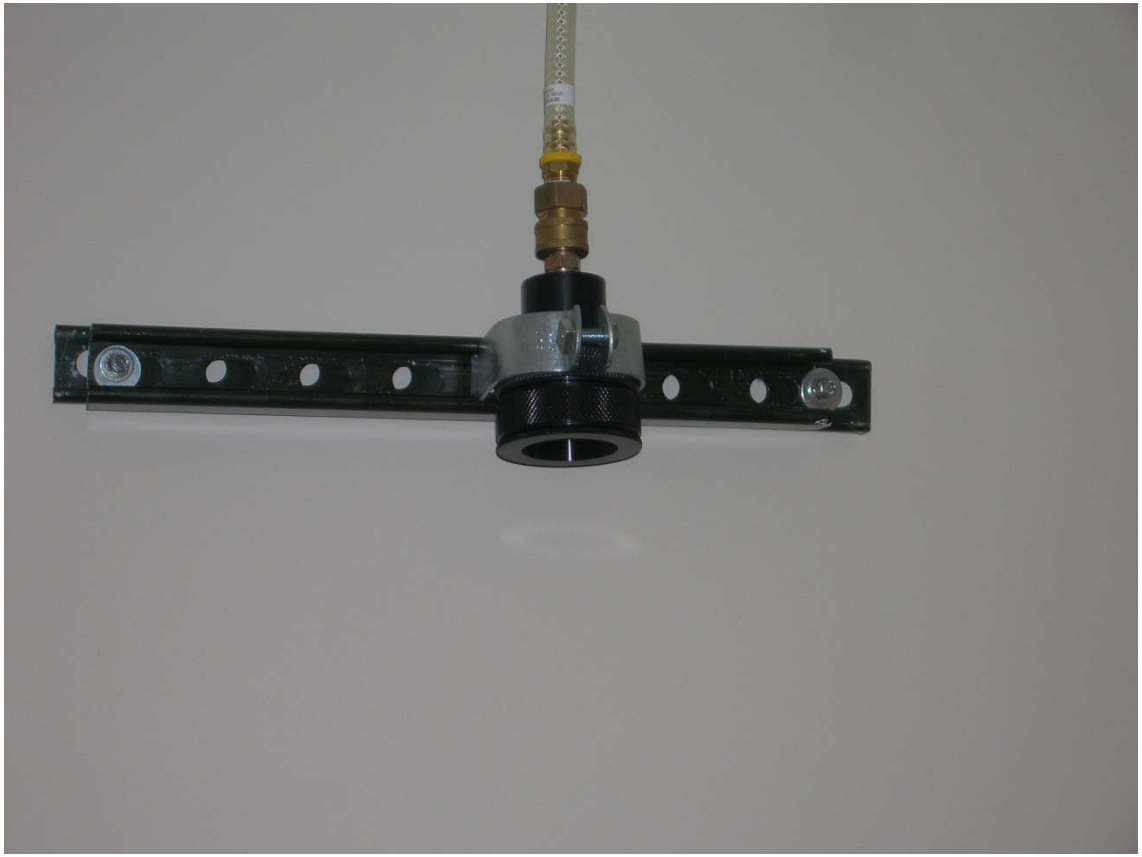
Iodine effluent filter box & duct sampling

Ventilation for ^{131}I



Iodine effluent sample pump

Ventilation for ^{131}I



Room air sample head in Iodine room

Ventilation for ^{131}I

- Determining concentration of radioiodine in the duct and total discharged activity
- Class exercise

Radioiodine Air Monitoring

- Sample Collection Weekly
  - Obtain a copy of the Worksheet for Radioiodine Air Monitoring.
  - Record time removed and air flow reading
  - Turn the pump off and remove old cartridge, place in bag
  - Place new TEDA impregnated carbon cartridge in holder for the room air sampler and the duct sampler. Place flow arrow on cartridge in direction of air flow through holder.
  - Turn on pump and record time and initial air flow
  - Every seven days remove the used cartridges and replace with new cartridges. Note the ending time and ending flow rate before removing old cartridge. Wear disposable gloves to remove old cartridge.

Radioiodine Air Monitoring Worksheet

Performed by:		Date:		
Counting Instrument:				
Make:				
Model:				
Serial No.:				
Sample Cartridge Description (i.e. room or duct air sampler):			Duct air sampler	
	Time/Date On	**Time/Date Off**	**Total Minutes**	
	12/4/06 12:00 PM	12/11/06 1:30 PM	10170	
	Initial Flow Rate (ft^3/min)	**End Flow Rate (ft^3/min)**	**Average Flow Rate (ml/min)**	
	600	590	595	
	Initial Flow Rate (ml/min)	**End Flow Rate (ml/min)**	**Average Flow Rate (ml/min)**	
	16980000	16697000	16838500	

Radioiodine Air Monitoring

- Typical Counting Procedure for Cartridge
  - Calibrate the scintillation counting system, as follows:
    - Place the Ba-133 cartridge standard source in front of the detector.
    - Set region of interest between 254keV and 434keV.
  - Place the standard cartridge directly on the scintillation probe housing. Ensure that the side of the standard that gives the highest count rate faces the detector. Record the count rate.
  - Remove the standard and obtain a background count. Record the background count rate
  - Place the sampling cartridge (the previous week's sample cartridge) on the scintillation probe in the same geometrical configuration as the standard source, and obtain a count on the cartridge, record result.
  - Record the sampling pump airflow in milliliters from the measured flow through the vacuum pump
  - Record the activity (uCi) of the Ba-133 standard

Determine the activity on air sample cartridge

Background count rate (bkg) = 25 cpm

Gross count rate for standard cartridge = 120 cpm

Net count rate for standard cartridge x R_p = 95 cpm

Ba-133 Standard cartridge activity = 2.42 µCi on **11/1/06 12:00 AM (Cal. Date)**

Time elapsed since source date= 40.56 days

decay factor= 0.99

Current activity for Ba-133 standard cartridge = 2.40 µCi

$$F_e = \frac{\text{Net count rate for standard cartridge} \times R_p}{\text{Current activity for standard cartridge}} = 39.54 \text{ cpm/µCi}$$

Gross count rate for sample cartridge= 110 cpm

Attachmen

Net count rate for sample cartridge= 85 cpm

t = ½ of the sampling period = 3.53 days

$$\text{Sample cartridge activity}(\mu\text{Ci}) = \frac{\text{Net count rate for sample cartridge(cpm)}}{F_e\left(\frac{\text{cpm}}{\mu\text{Ci}}\right)} \times e^{\lambda t} = 2.91$$

Radioiodine Air Monitoring

- Calculating Concentration of Volatile Radioiodine
- Calculate 'pump on duration" compare the date/time of the previous air sampling to the date/time of the current to obtain the total number of minutes between samples.
- Calculate the activity on the sample cartridge in µCi using the following equation:

$$\text{Sample Activity (µCi)} = \frac{\text{Net cpm (cartridge) } e^{\lambda t}}{(Fe)(Rp)}$$

where,

t = ½ of the sampling period, in days

Fe = the efficiency for the Ba-133 standard in cpm/µCi

λ = the decay constant for I-131 in days-1

$e^{\lambda t}$ = the correction factor for decay. Back decays to the midpoint of the sampling period

Rp = ratio of photon yield =

- For the configuration used in these air sampling procedures using Ba-133, Rp has been determined to be approximately equal to "1".
- Determine the airflow through the sampling pump in ml from pump flow data in ml/min x sampling time in minutes.

Determine the total flow through the sampling pump

Measured sample pump flow rate= 16838500 ml/min

Pump-on duration = 10170 min

Pump flow = (Measured sample pump flow rate) x (Pump-on duration)

Pump flow = 1.71248E+11 ml

Determine the concentration of radioiodine in air

$$\text{Concentration in Air Sample} = \frac{\text{Radioiodine Activity (uCi)}}{\text{Pump flow (ml)}} = 1.70\text{E-}11 \ \mu\text{Ci/ml}$$

For room air		
Action Level = 30% of the DAC or	**6.00E-09**	µCi/ml
Concentration in room air sample		µCi/ml
Exceeds Action Level	**NO**	

For duct air		
Action Level = 40% of Effluent Limit or	**8.00E-11**	µCi/ml
Concentration in duct air sample	1.70E-11	µCi/ml
Exceeds Action Level	**NO**	

RSO Review: _____

Ventilation for ^{133}Xe

- Glass ampoules are stored for shipment
  - If they break, it will quickly escape packaging
  - Must determine the clearance time and evacuate lab
  - This should be posted in pharmacy
  - Store in hood with I-131

Ventilation for ^{133}Xe

PRCP No. D0008375 Rev. A
Attachment 2

Emergency Procedures in Case of a Xe-133 Release

1. Immediately evacuate all personnel in the area of the spill.
2. Notify all personnel, close all doors, and evacuate the room for 3 minutes (see calculations below).
3. Upon re-entry, survey all areas, especially the area around the Xe-133 storage area where the release occurred. If high readings are still obtained indicating that the air is still overly contaminated, evacuate for another 3 minutes or until normal background for the area is observed.
4. Notify the facility RSO and the corporate Radiological Compliance Department. Document the incident.

Evacuation Time: The amount of time that is required to bring the Xe-133 concentration to below the regulatory limit (1 x 10^{-4} µCi/ml) if a unit dose is broken is given by:

$$t = -\frac{V}{Q} * \ln\left(C * \frac{V}{A}\right)$$

where,

t = time in minutes
V = room volume in milliliters
Q = room exhaust rate in ml/min
A = activity of gas possible in a vial, µCi
C = DAC for Xe-133, µCi/ml

As an example, for the specifics of this facility:

If a 40 mCi vial of Xe-133 was dropped and broken, the evacuation time would be determined as follows:

V = 152 ft^2 x 10 ft = 1520 ft^3 = 1.2E7 ml

Q = 600 ft^3/min * 2.83E4 ml/ft^3 = 1.7E7 ml/min

C = 1.0E-4 µCi/ml for restricted area

A = 40,000 µCi

t = 2.5 minutes

Material Handling Systems

Material Handling Systems

QUALITY CONTROL (SPECT)

Quality Control

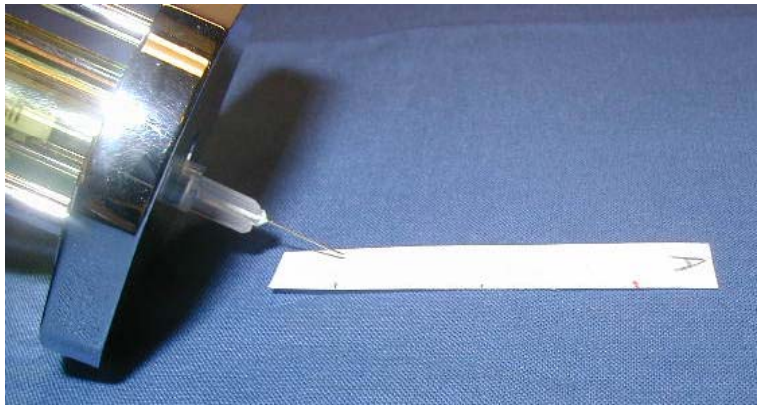
- Numerous drugs and lots, therefore many QC tests
  - Various radionuclides, different shielding needs
  - Typically done with a TB syringe – no good syringe shields available
  - Importance of marking TLC strip so top and bottom cannot be confused
  - Often results are not known before drivers leave pharmacy – clear communication essential

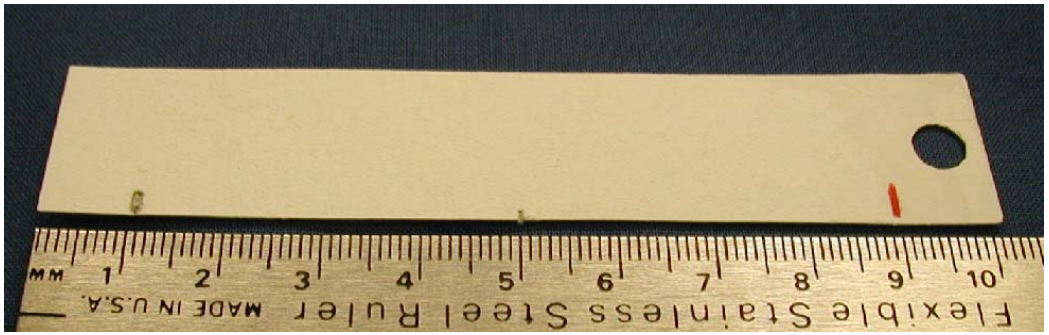
Quality Control

- With the wide variety of nuclides and drugs, there is a real potential for cross contamination.
- Vials are shielded so labels are covered. Organization and secondary labels (color coding) are essential to prevent dispensing wrong drug to wrong patient.
- Use racks with clearly labeled columns
- Multiple drugs being dispensed in same hood
- Separation of blood work from all other activities
- Segregation of saline solutions

Quality Control

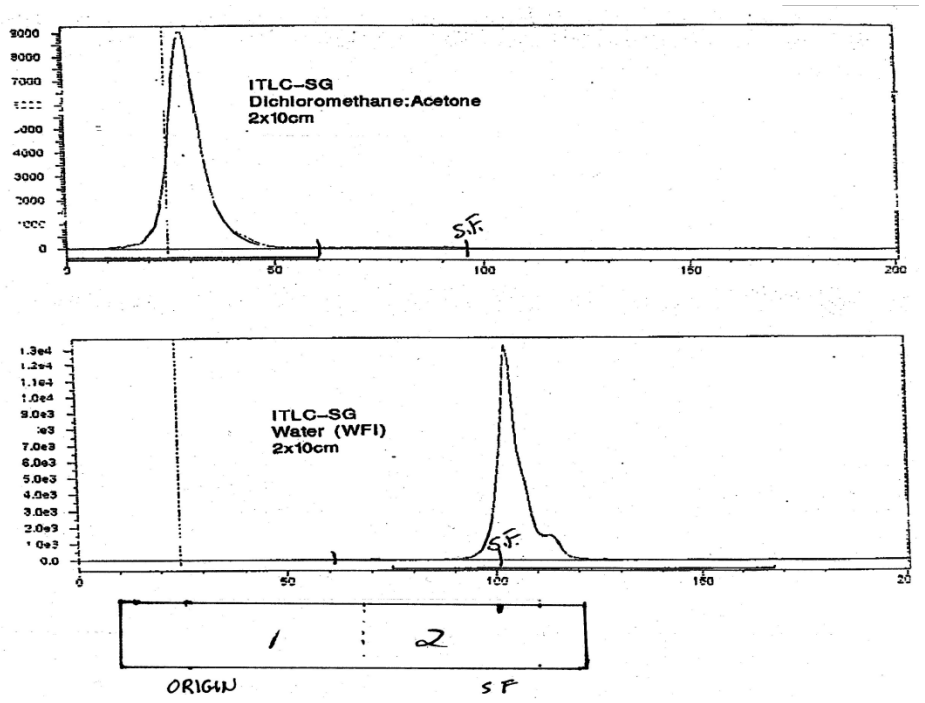
- Radiochemical Purity: The amount of radioactivity in the desired chemical form
    - Usually accomplished using Thin Layer Chromatography (TLC)





Quality Control

- **Example TLC test**



QUALITY CONTROL (PET)

Quality Control

- For FDG – United States Pharmacopeia (USP)
  - Radionuclide ID – determined by half-life
  - Radiochemical identity – thin layer chromatography
  - Bacterial Endotoxins
  - sterility – results available only after use
  - pH – between 4.5 and 8
  - Chemical purity – measure unwanted by-products
  - Membrane filter integrity test – assures sterility via filtration of final product

Quality Control

- HP concerns
  - Typically the QC activities are a low source of external exposure to staff – typical assignment for a declared pregnant worker
  - Use of a QC station with shielding designed for PET
  - Membrane filter integrity testing should be done behind shielding