U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

HRTD
Human Resources
Training & Development

Radiopharmacy and PET Production Inspections

Radiopharmacy Inspections

- **Purpose**

- **To determine if licensed activities involving the manufacture and distribution of radiopharmaceuticals are being conducted in a manner that**
  - **will protect the health and safety of workers and the general public.**
  - **are conducted in accordance with USNRC or AS requirements.**

Radiopharmacy References

- A Radiopharmacy is licensed under provisions of 10 CFR Parts 30 (…Domestic Licensing of Byproduct Material) and 32 (…Licenses to Manufacture or Transfer Certain Items…)

- Radiopharmacy is <u>not</u> licensed under 10 CFR Part 35 (Medical Use of Byproduct Material) <u>except</u> the training requirements for Authorized Nuclear Pharmacist (ANP) [referenced in 10 CFR 32.72(b)]

PET Production

- Using an accelerator (cyclotron) to produce radionuclides for medical use or research activities is a manufacturing activity, licensed under provisions of 10 CFR Parts 30 and 32

- NRC policy requires that the cyclotron-produced materials be licensed and activities conducted under a separate license from the radiopharmacy activities; but inspection guidance is in IP87127 “Radiopharmacy Programs”

Inspection References

- The license and the licensee's application and/or amendment document(s).
- 10 CFR 20, 30, 32, 71, etc regulations or State equivalents, and 49 CFR (DOT regulations)
- NUREG-1556, Vol. 13, Program-Specific Guidance About Commercial Radiopharmacy Licenses, Rev. 1, Nov. 2007
- NUREG-1556, Vol. 21, Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator, Oct. 2007

Inspection Procedures

- **Inspection Procedure (IP) 87127 Radiopharmacy Programs**
  - **Applies if the licensee operates as a radiopharmacy - work performed under supervision of pharmacists licensed by the State Board of Pharmacy**
- **Inspection Procedure (IP) 87125 Materials Processor/Manufacturer Programs**
  - **Applies if the licensee operates as a manufacturer – work performed using cGMPs *(current Good Manufacturing Practices)* approved by the FDA**

Commonly Used Radionuclides

- Molybdenum 99/Technetium 99m
  - approx. 80% of nuclear studies worldwide
- Thallium 201
- Iodine 123 & 131
- Fluorine 18

Less Commonly Used Radionuclides

- Xenon 133
- Gallium 67
- Indium 111
- Cobalt 57
- Strontium 82/Rubidium 82 generators
- Other PET isotopes – Carbon 11, Nitrogen 13, Oxygen 15

Therapeutic Radionuclides

- Iodine 131
- Samarium 153, Strontium 89 & Rhenium 186
- Palladium 103 & Iodine 125
- Iridium 192
- Yttrium 90

Sealed Sources

- Calibration and reference sources for own use
- Calibration, transmission, and reference sources for customers
- Brachytherapy sources (I125 seeds, Pd103 seeds, others)

millicurie quantities, small volumes…

…but many of them

Also multi-curie quantities

Production & Supply

- Shortages of Mo-99 (Tc-99m) is a worldwide issue
- Over 90% is produced in only 5 reactors around the world (Canada, Netherlands, Belgium, South Africa & France)
  - All 5 of those reactors are well over 40 years old.
  - Recent shutdowns and maintenance problems have caused severe worldwide shortages at times over the last few years.

Production & Supply

- This has created new interest in other and newer production sources and different technologies.
  - Interest in USA for production of Mo99 by variety of facilities
  - One license application in; others only in discussion
- More use of Tl201 and Rb82 instead of Tc99m for cardiology, due to shortages

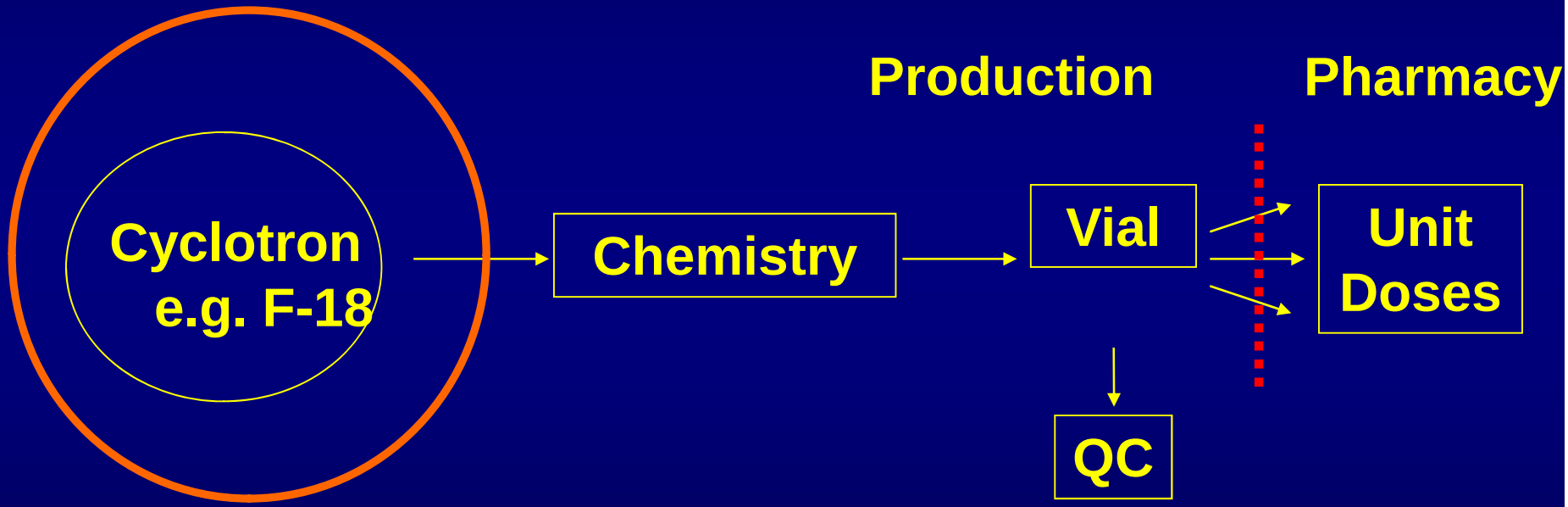
Production of PET radionuclides

- Starts with an accelerator
  - Usually between 10 and 20 MeV proton cyclotron
  - Most “proton” cyclotrons now accelerate negative ions
    - Proton with two electrons attached
    - Lower activation
  - Can also be produced using deuterons

Target Reactions

- (proton, neutron) reactions
  - $^{18}O(p,n)^{18}F$ (liquid or gas targets)
  - $^{15}N(p,n)^{15}O$ (gas target)
- (proton, alpha) reactions
  - $^{16}O(p,alpha)^{13}N$ (liquid target)
  - $^{14}N(p, alpha)^{11}C$ (gas target)

Overview of Production Process for FDG



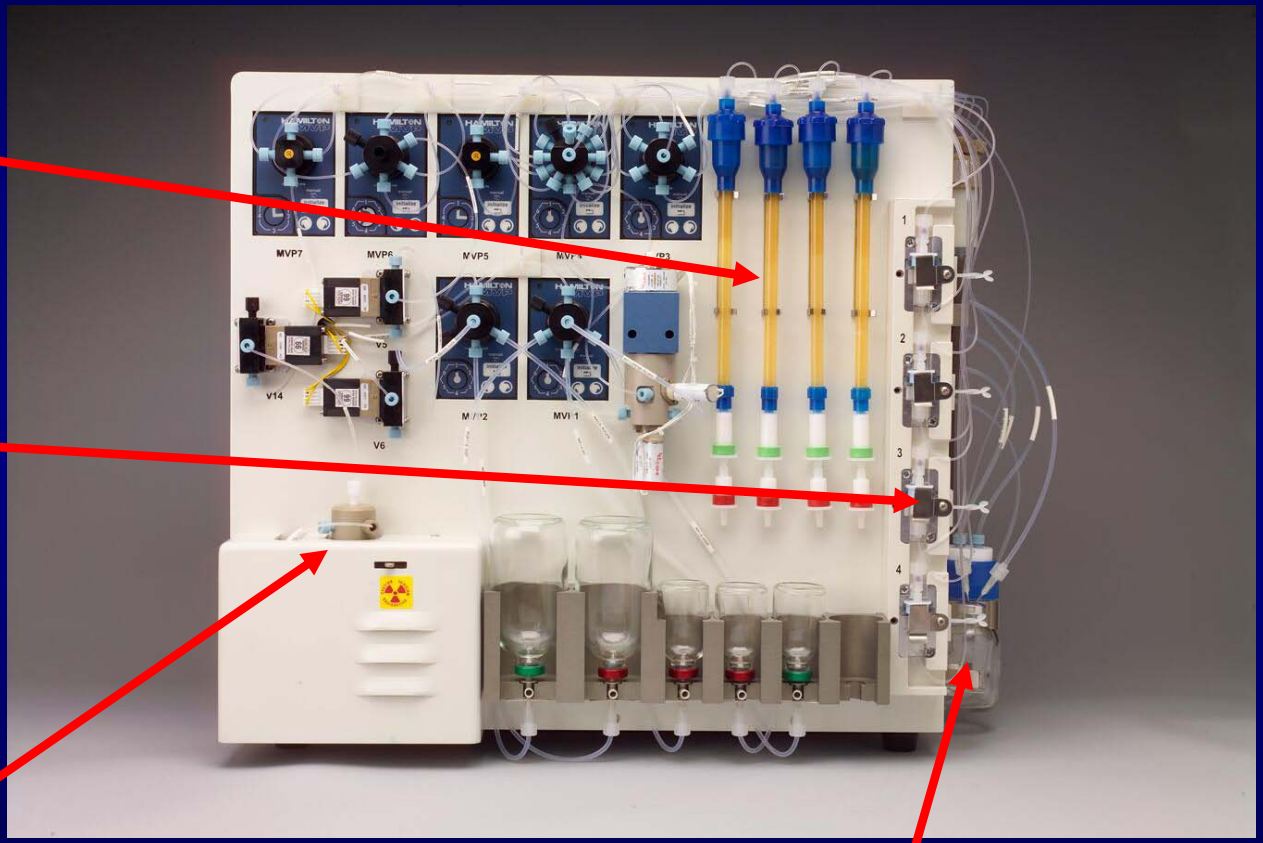
Typical Activity Yields

O-18 (p,n) F-18	60 min	1000 mCi
O-16 (p,a) N-13	10 min	100 mCi
N-14 (p,a) C-11	50 min	1500 mCi
N-15 (p,n) O-15	10 min	2000 mCi
O-18 (p,n) F-18[F2]	60 min	500 mCi

Explora FDG4 Chemistry Module

Purification columns (4)

QMA columns (4)



Reaction vessel

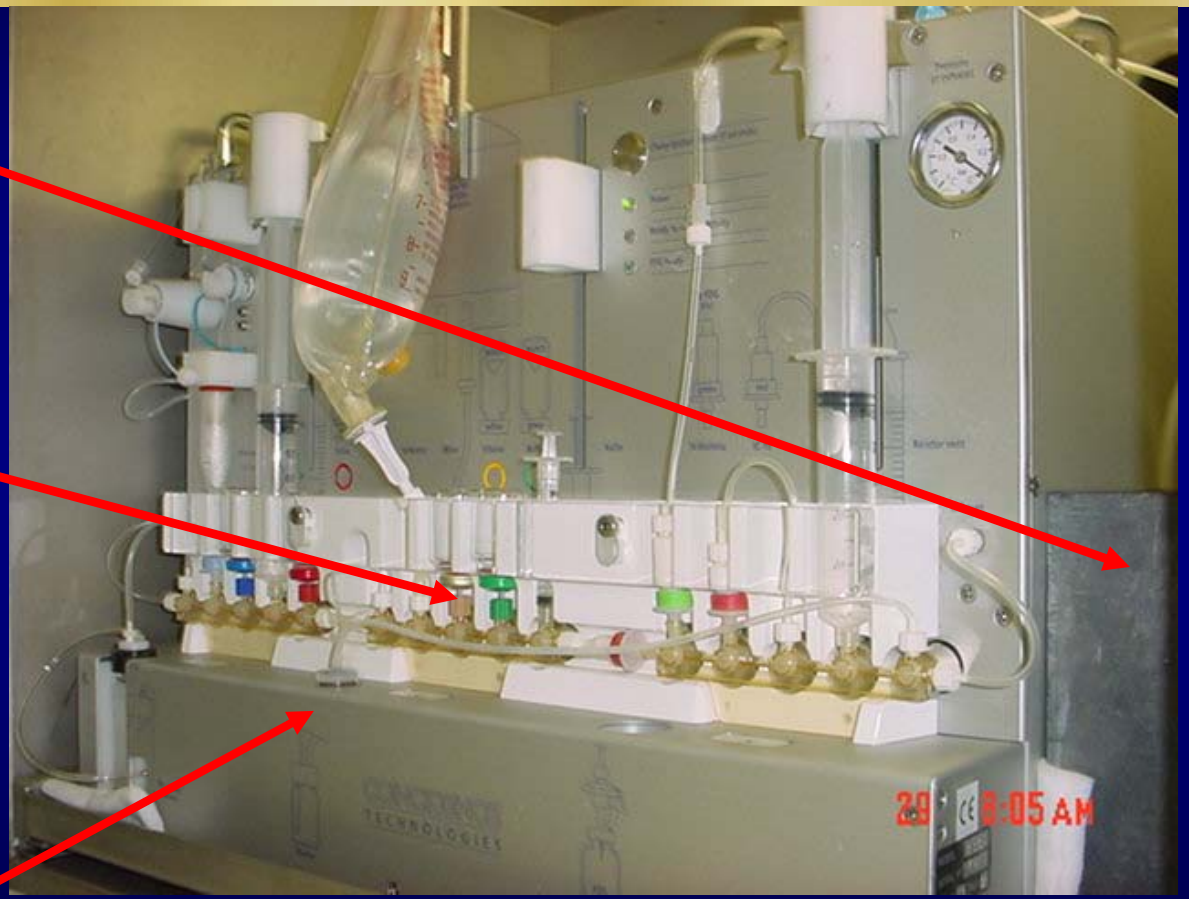
Waste vial

Coincidence Technologies Chemistry Module

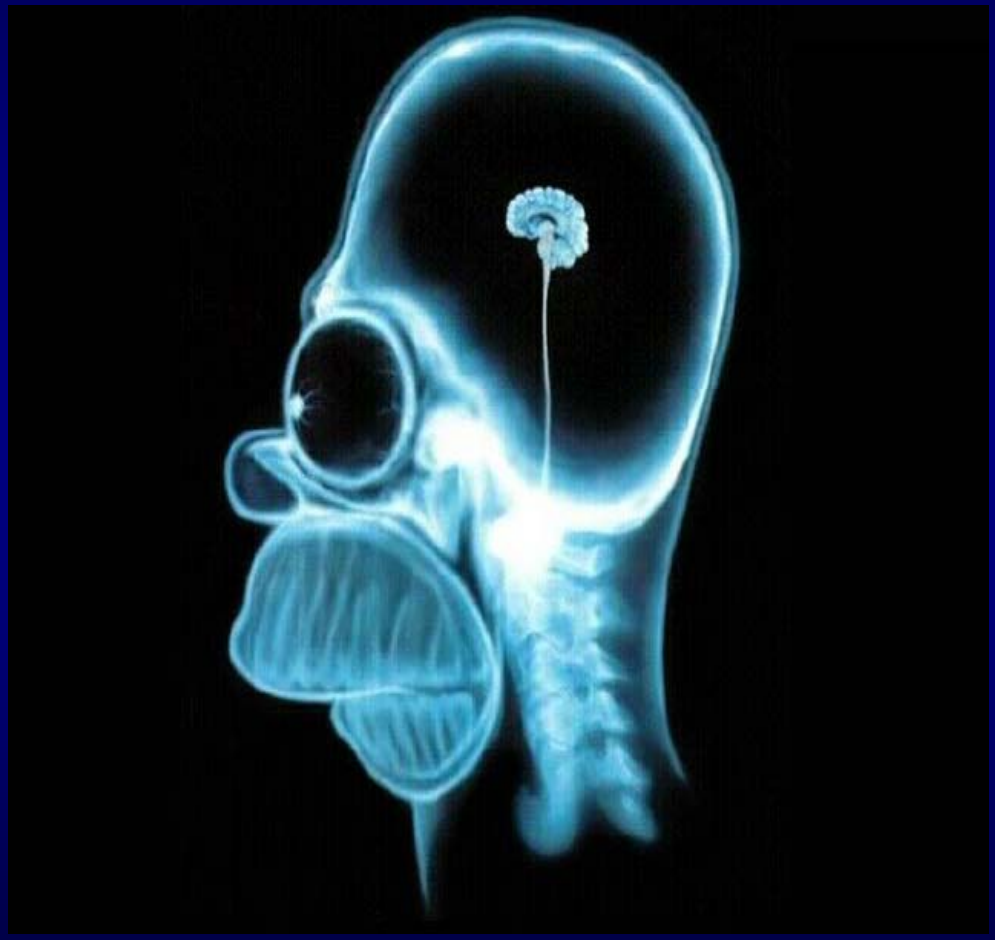
Waste vial

"Kit"

Reaction vessel



Inspection Identification



What you are trying to find… (figuratively, of course)

IP Focus Elements

1. Security / Prevent Loss of Licensed Materials
2. Maintain Shielding of Licensed Materials
3. Comprehensive Safety Measures
4. Radiation Dosimetry Program
5. Radiation Instrumentation
6. Knowledgeable Workers
7. Management Systems & Oversight

IP Focus Element 1

Security/Prevent Loss of Licensed Materials

- **Access to facility:**
  - facility and/or designated areas (Hot Lab) may be limited access: who has keys? Who has access?; who is trained?
  - Are there “restricted areas”?

IP Focus Element 1

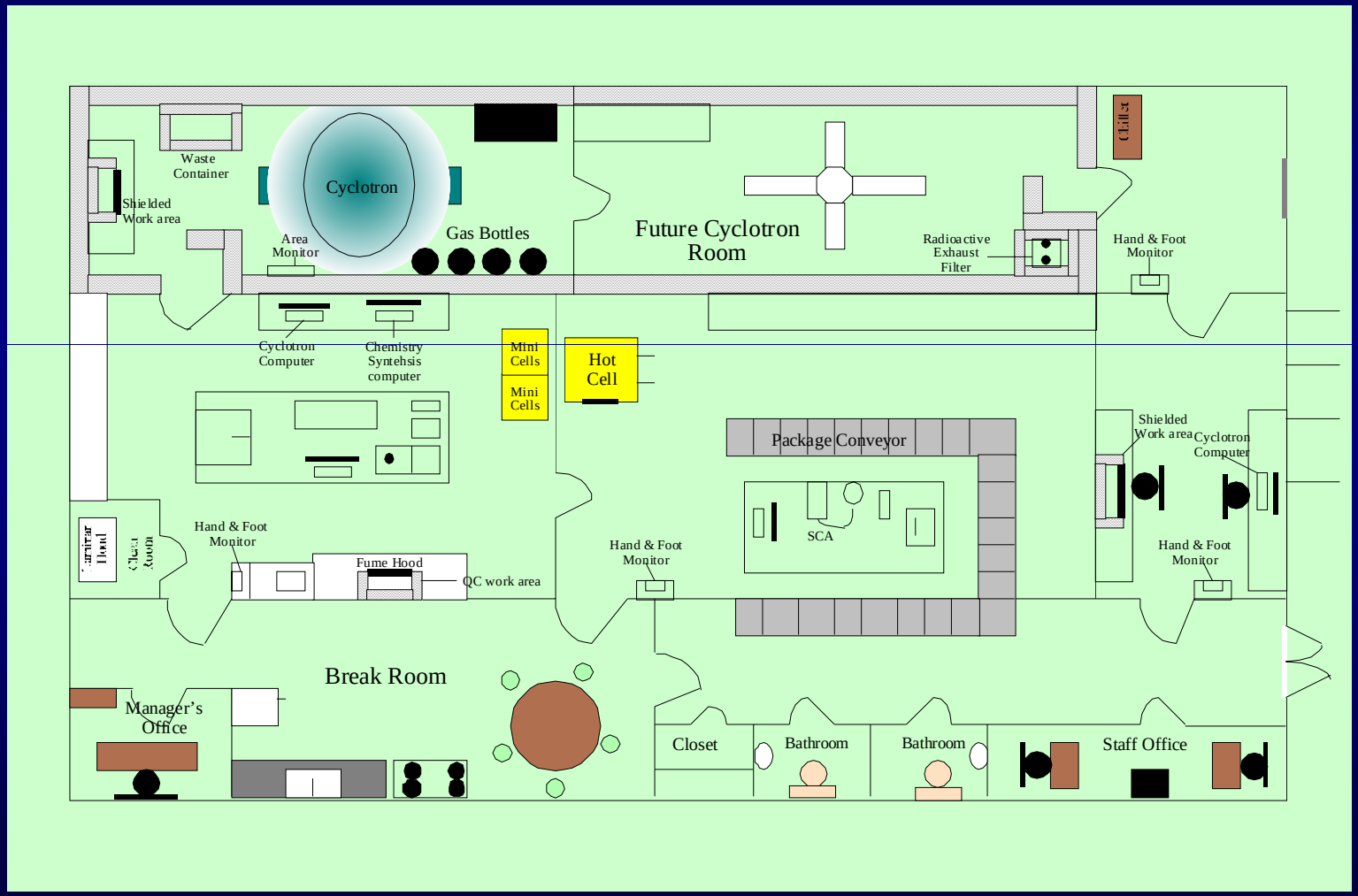
Security/Prevent Loss of Licensed Materials

- **Storage and control of materials:**
  - Secured when not attended in unrestricted areas
  - Attended when not secured in unrestricted areas
  - In restricted areas

- **Receipt/transfer/inventory:**
  - who/when/how receive material (i.e., new generators, returns from customers);
  - Who/when/how verifies customer licenses for transfer
  - records

Typical Pharmacy Layout

PET Production & Radiopharmacy



Focus Element 1 – Access Control

Multiple Access Points

- How many and how often are they used?
- Are there “over the counter” access points?
- Which access points are within the restricted area? Who has access to the restricted area?

Focus Element 1 – Access Control

RAM Drivers

- Do the Drivers secure the RAM at the point of drop-off?
- Do they stop for breaks?
- Vehicle Accidents?

Focus Element 1 – Access Control

Transfer of Licensed Material

- How does the pharmacy receive orders?
- How do they check to ensure RAM limits for customers are not exceeded?

IP Focus Element 2

Maintaining Shielding of Licensed Materials

- **Hot cells, mini-cells, glove boxes:** access; engineering controls; adequate number and size; properly maintained
- **Generator and waste storage areas** access; engineering controls; adequate number and size; properly maintained
- **Cyclotron room and work areas:** access to RAM; engineering controls for transfer of targets; control of incidentally activated materials
- **Product containers/shipping packages:** adequate for DOT; properly maintained and used

IP Focus Element 2

Maintaining Shielding of Licensed Materials

- **Shielding appropriate for type of RAM:**
  - lead for gamma, plastics/low-Z for betas
- **amounts of shielding**
  - Adequate for max loads of cells, glove boxes, storage areas, etc
  - ALARA – transfer lines shielded, remote handling equipment available and used
  - Shielding on outer walls if needed

IP Focus Element 2

Shielded boxes for generators

IP Focus Element 2

Hood for storing bulk iodine and tools

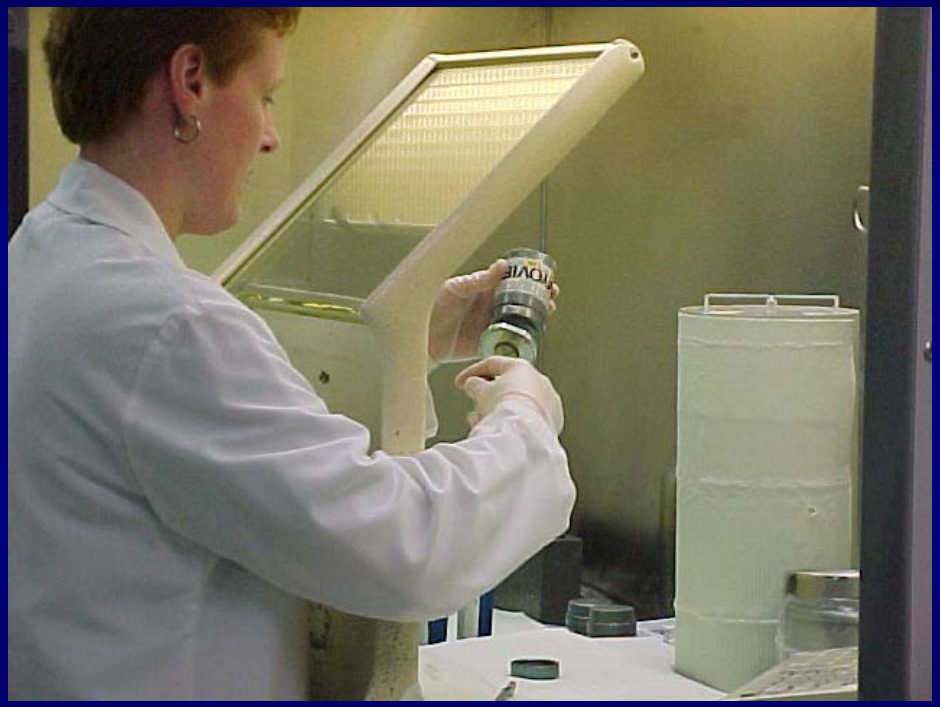
IP Focus Element 2

Dispensing station with dose calibrator

IP Focus Element 2

Dispensing station showing shielded waste drum

IP Focus Element 2



↑ L-block (shield)

← Syringe shields,
shielded bulk dose vial

IP Focus Element 2

- **Self-Shielded Cyclotron**

IP Focus Element 2

Maintaining Shielding of Licensed Materials

- Cyclotron Shielding (self-shielded)
  - Constructed with concrete/borated poly/lead mix
  - Cyclotron room may require additional shielding in the walls for compliance with public dose limits
  - Interlocks on movable shields
  - Scram buttons
  - Refer to manufacturer's site planning guide

IP Focus Element 2

Maintaining Shielding of Licensed Materials

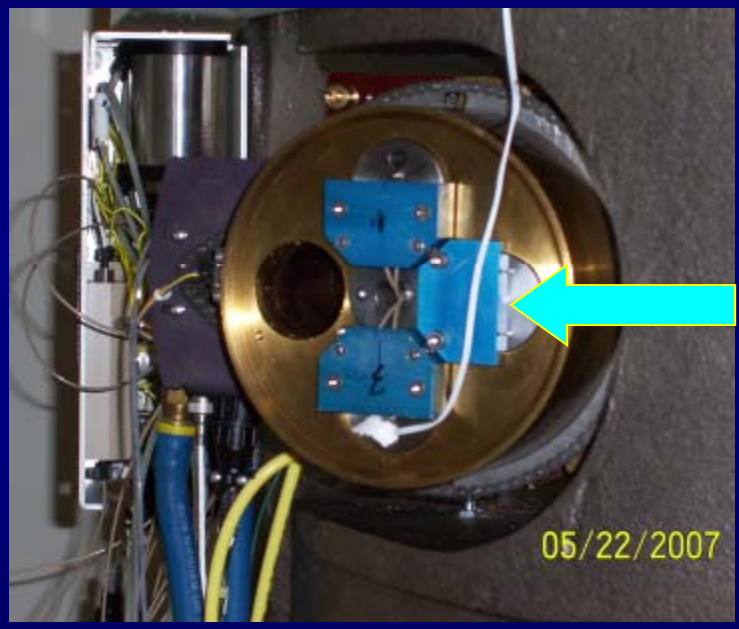
- Prompt Radiation Fields (outside shielding)
  - Primarily photon with some neutron component
  - Dependent on reaction taking place – highest for (p,n) process
  - Do not rely on surveys taken while operating onto beam stops or using O-16 water

Gamma Exposure Rates
RDS Eclipse Target

58 uA, 3 hr Bombardment

40 minutes after bombardment:
At contact 110 mSv/hr
6 inches 20 mSv/hr

150 minutes after bombardment:
At contact 50 mSv/hr
6 inches 10 mSv/hr



IP Focus Element 2

Maintaining Shielding of Licensed Materials

- Neutron Activation
  - Widespread throughout cyclotron and shielding
  - Much lower levels than from proton activation

IP Focus Element 2

Maintaining Shielding of Licensed Materials

Target Rebuilding Areas

- Radiation fields can be very high – up to 30 mSv/h
- Additional targets to allow for decay prior to rebuilding
- Technique
  - Remove entrance windows and place in shielded storage
  - Awareness of radiation fields
  - Keep work area clean

IP Focus Element 2

Maintaining Shielding of Licensed Materials

Storage areas for components

- **Often parts are reused**
- **Frequent surveys of storage areas and work benches**

PET Shielded & Ventilated Chemistry Enclosure

75 mm Pb

IP Focus Element 2

- Remote handling tool, and transfer carts at PET production facility

Use of Tongs to Handle Loaded Syringe Shields containing F-18

24 inch tongs

Gamma Exposure Reduction
At Shield Contact: 400 mR/hr
At End of Tongs: 35 mR/hr

F-18 FDG in syringe: 102 mCi

Extremity Dose Reduction by a Factor of 12

IP Focus Element 2

- **Shielded HEPA unit at PET production facility**

IP Focus Element 2

Typical radiopharmacy packages, in process

IP Focus Element 2

PET packaging

IP Focus Element 2 - Inspector

Maintaining Shielding of Licensed Materials

- **General Radiation Fields:**
  - Use your survey meter
  - Outside of building – Use and Storage Areas
  - NOTE: Try not to survey in adjacent buildings not owned by the licensee unless necessary

IP Focus Element 3

Comprehensive Safety Measures

These are "*measures to limit other hazards from compromising the safe use and storage of licensed material*"

- **Fire protection: combustibles, flammables, up-to-date extinguishers, sprinklers, relationship with local fire dept.**
- **Other industrial/chemical/biological/etc hazards considered: lighting, noise, sharps controls, chemical storage, ergonomics**

IP Focus Element 3

Comprehensive Safety Measures

- **Transportation**
  - **IAW DOT regulations: shipping containers, shipping papers, surveys, labeling, driver training includes HAZMAT, block and brace, emergency procedures**
  - **Transfers: do they pick up waste? If so, do they become the shipper to relieve customer of shipping issues? How do they handle?**

IP Focus Element 3

Typical Transportation / Shielding Containers

IP Focus Element 3

IP Focus Element 3

Typical Blocking and Bracing

IP Focus Element 3

Other Cyclotron Safety Issues

- **Interlock Testing**
  - **Maze entrances (bunker) and movable shield blocks (self-shielded)**
  - **Failure in interlock combined with software bug created potential for potentially life-threatening whole-body irradiation**
- **Emergency Shutdown testing**
  - **Reluctance to test due to potential for equipment damage**

IP Focus Element 4

Radiation Dosimetry Program

- **External exposure:**
  - **External dosimetry is a very important area to look at due to the safety significance – radiopharmacists are often close to limits**
  - **With the increased use of unit doses and newer materials with higher specific activity, dose from preparation has shifted from thousands of NMTs in thousands of hospitals and clinics to the pharmacy personnel in 100+ facilities**

IP Focus Element 4

Radiation Dosimetry Program

- **External exposure:**
  - Look closely for proper use and proper storage of dosimeters
  - Review actual exchange frequency of dosimeters since doses often approach annual limits
  - Observe how dosimeters (whole body, extremity ring, others as needed) are worn; they should be placed to receive highest doses.
    - Over or under lab coats, lead aprons, etc
    - Facing syringes etc

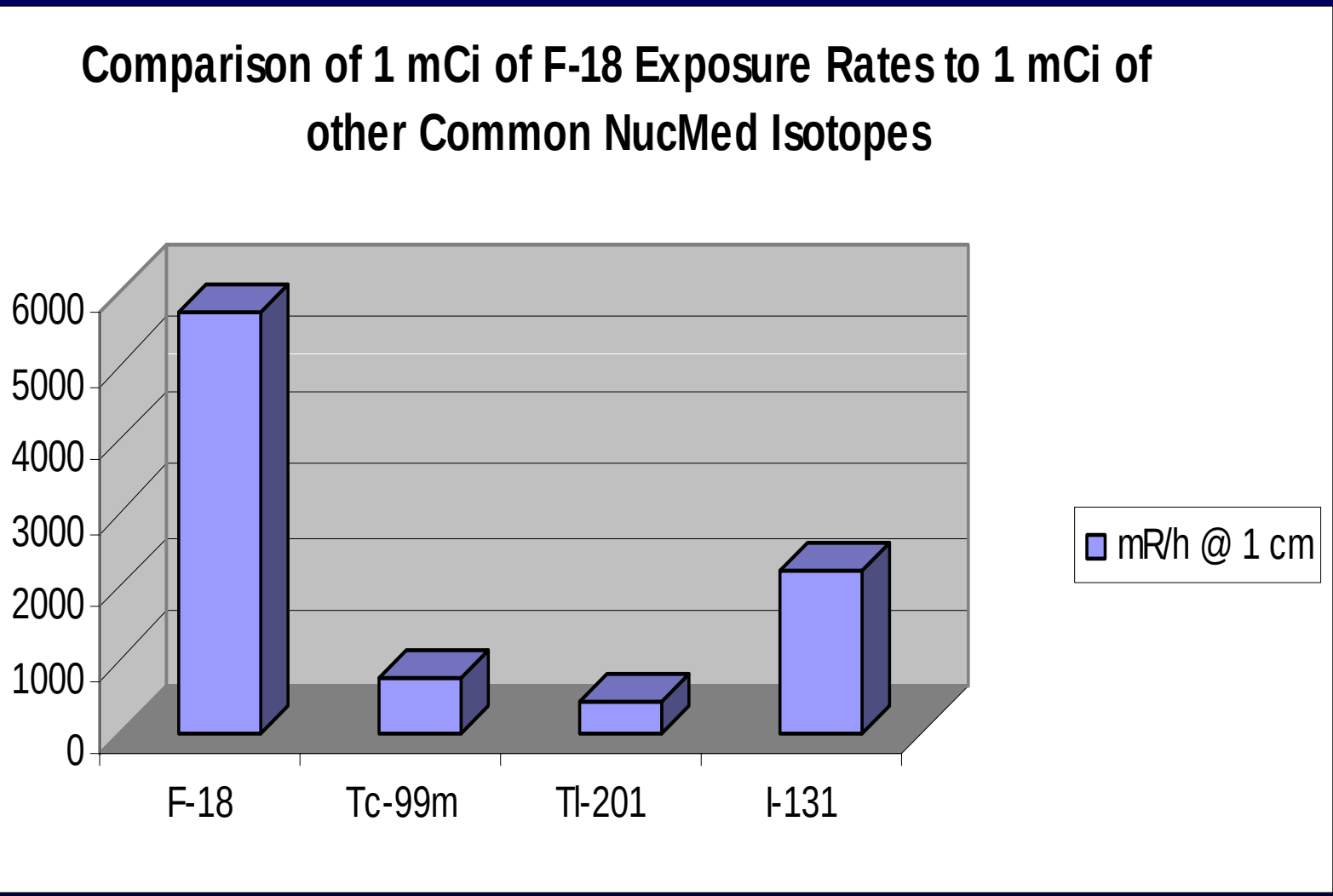
IP Focus Element 4

Radiation Dosimetry Program

- **External exposure:**
  - **Ask how assessments are made for missing dosimeters**

* **Review records for trends**
  - **Ask about any significant trends or changes**
  - **Look for wide differences in doses between individual wearers in a group, as well as between groups of wearers (radiopharmacists, drivers, accelerator workers, office staff)**
  - **Look for discrepancies from 'usual' doses**

IP Focus Element 4



IP Focus Element 4

Radiation Dosimetry Program

- Extremely high exposures with unshielded F-18
  - Contact exposure for F-18 = 23 Rad/Ci/Sec @ Contact
  - Exposure @ 1 cm for F-18 = 1.15 Rad/Ci/Sec
  - RDS-111/112 Targets (3.5Ci) = 115 Rad/Sec @ Contact
  - RDS-111 Eclipse (7Ci) = 161 Rad/Sec @ Contact
- Finger Tip Exposure vs. Ring Badge Results

External Dosimeters

IP Focus Element 4

Radiation Dosimetry Program

- **Internal exposure:**
  - **Internal dose assessment is typically only needed if they are compounding iodine or other volatiles**
  - **If used, look for appropriate procedures and analysis depending on compound and radionuclide**
  - **Beware of "GIGO" – poor sample collection won't be improved by complex computer dose models**

Thyroid Bioassay System

IP Focus Element 4

Radiation Dosimetry Program

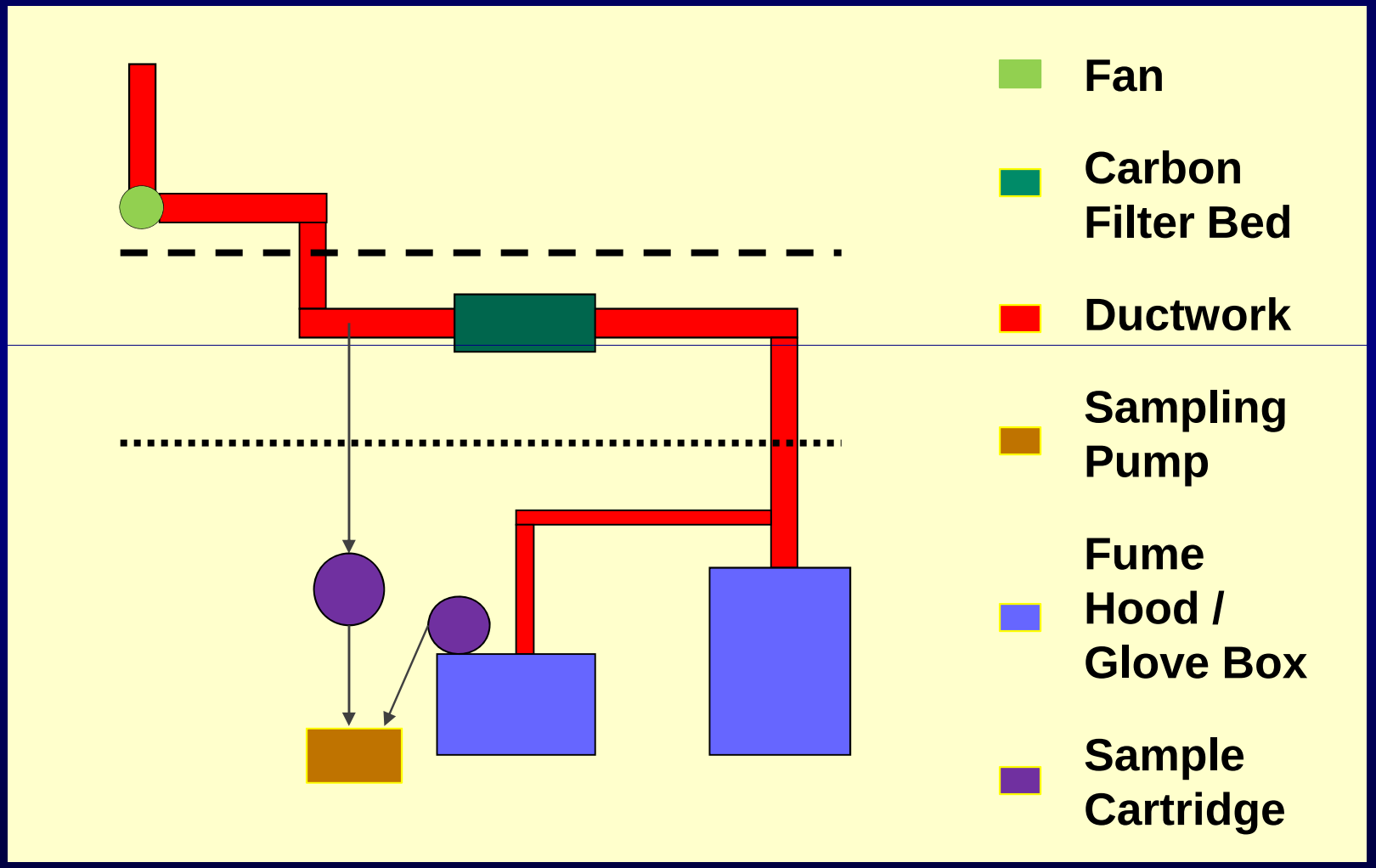
- **Internal exposure:**
  - **Engineered controls**
    - **ventilation systems, hoods/cells, room air intakes and exhaust vents**
    - **Air flows and filters properly checked/maintained**
    - **Have them demonstrate airflows where appropriate**

IP Focus Element 4

Radiation Dosimetry Program

- **Internal exposure:**
  - If the need for internal dose assessment is monitored by air sampling, review
    - Locations of air samplers
    - Calibration and operational checks of air monitoring systems (pumps, flow rate meters, collection efficiency determination, instrument sensitivity, etc)
    - Collection and analysis procedures, depending on compound and radionuclide

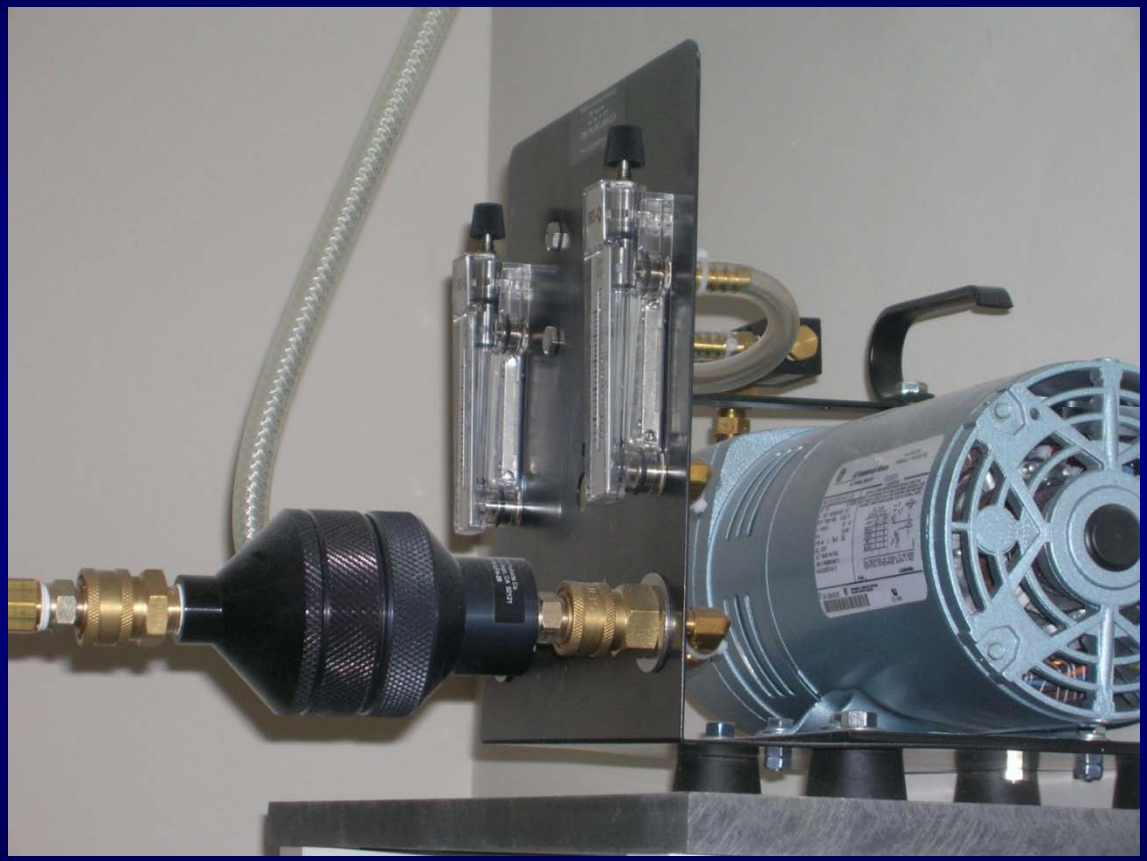
IP Focus Element 4



IP Focus Element 4

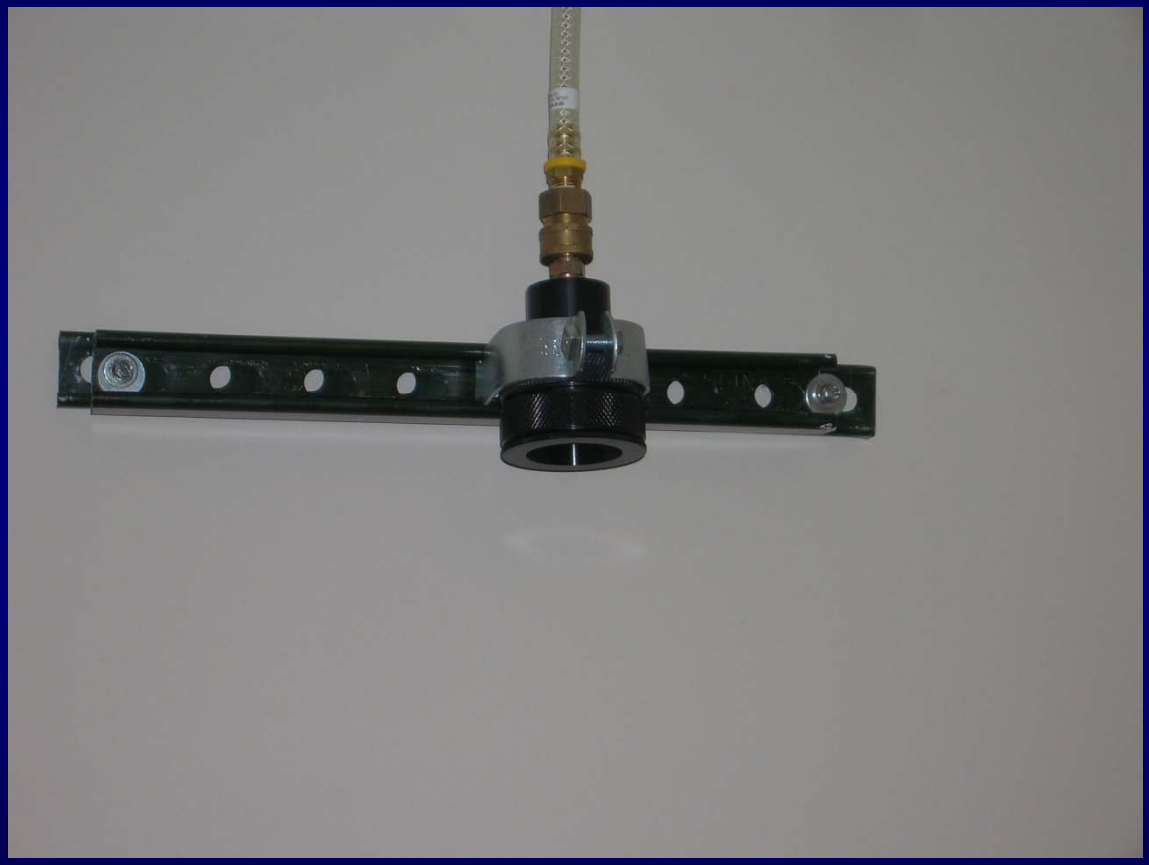
Iodine effluent filter box & duct sampling

IP Focus Element 4



Iodine effluent filter box & duct sampling

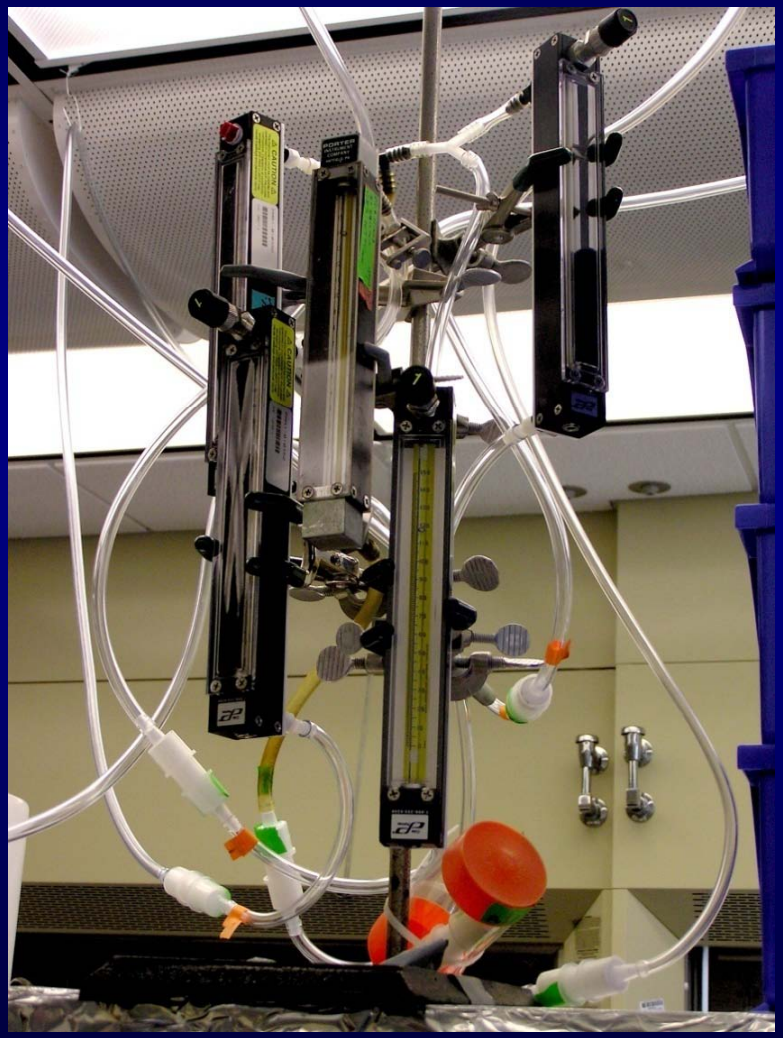
IP Focus Element 4



Room air sample head in Iodine room

IP Focus Element 4

- Personnel monitoring System, area air samplers



IP Focus Element 4 - Licensee

Radiation Dosimetry Program

- **Contamination controls depend on types, forms, quantities, and procedures performed:**
  - **good housekeeping**
  - **lots of “in and out” – observe personnel surveys**
  - **area surveys adequate**
  - **ALARA – action levels**

IP Focus Element 4 - Licensee

Typical Hand and Foot Monitor System

IP Focus Element 4 - Inspector

Radiation Dosimetry Program

- **Contamination controls:**
  - **Use your survey meter in expected areas (hoods, waste storage, packaging, etc) and in unexpected areas (break room, unrestricted hallway adjacent to restricted area, etc.)**
  - **Compare with licensee's survey meter readings**

IP Focus Element 4

Radiation Dosimetry Program

- **Waste management:**
  - **decay-in-storage (DIS) for short-lived (≤120 days) – used for most radiopharmaceutical wastes**
  - **sewerage disposal – must be soluble or biological dispersible**
  - **solid waste transfer to burial site**
  - **effluent releases**

IP Focus Element 4

Radiation Dosimetry Program

- **public dose assessment MUST be done and recorded**
  - **Dosimetry:** location of public area monitors, assumptions for total/max public doses; and/or
  - **Effluent monitoring:** location of samplers, type of sample, collection time/volume/etc; and/or
  - **Calculations:** EPA Comply code, other; and/or
  - **Surveys:** appropriate instruments, locations, assumptions
  - **Emergency Plan:** review, if applicable

IP Focus Element 4

Radiation Dosimetry Program

- **Public Dose Assessment:**
  - Understand the engineering controls: Exhaust stacks, filtration systems, hold-up systems, etc
  - Verify that all hood/cell flows are directed to the exhaust stack; if not, review monitoring of alternate exhausts
  - Don’t forget 20.1101(d) – EPA constraint on air emissions – must be below 10 mrem

IP Focus Element 4

Radiation Dosimetry Program:

Public Dose Assessment:

- **Releases During Cyclotron Operation**
  - Target Water between 80% and 96% ^{18}O
    - $^{18}O(p,n)^{18}F$; Remainder is ^{16}O
  - **$^{16}O(p,alpha)^{13}N$**
    - Chemical form – unknown but at least some fraction as N_2 gas – quantity very dependent on enrichment level
    - Released during venting of target prior to unload or in the event of target failure

IP Focus Element 4

Radiation Dosimetry Program:

Public Dose Assessment:

- **Target Failures (O-18)**
  - **Much will get trapped in vacuum system but a sizeable quantity may go out the air exhaust**
  - **Very reactive and will plate-out along the duct**
  - **Gives a false release signal to stack monitor**

Cyclotron Effluents

Radiation Dosimetry Program:

Public Dose Assessment:

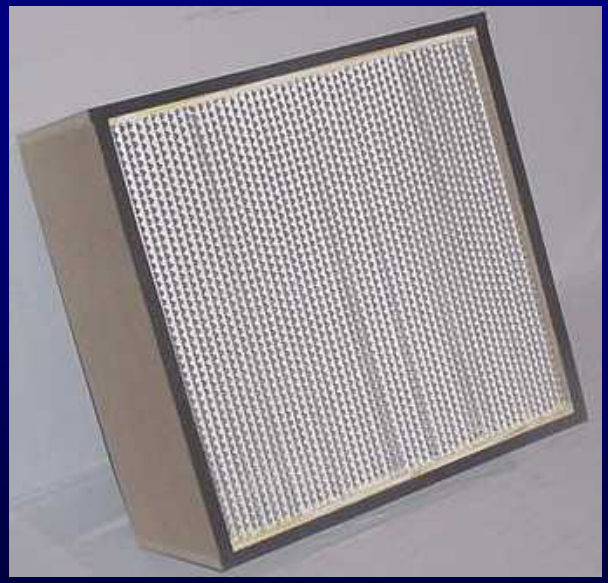
- **Delivery or Load line failures**
  - **High levels of contamination in vicinity**
  - **Very reactive and will plate-out along the duct**
  - **Gives a false release signal to stack monitor**

Controlling Effluents

Filtration:

- **Charcoal**
  -Type
  -Quantity

- **HEPA**



Controlling Effluents

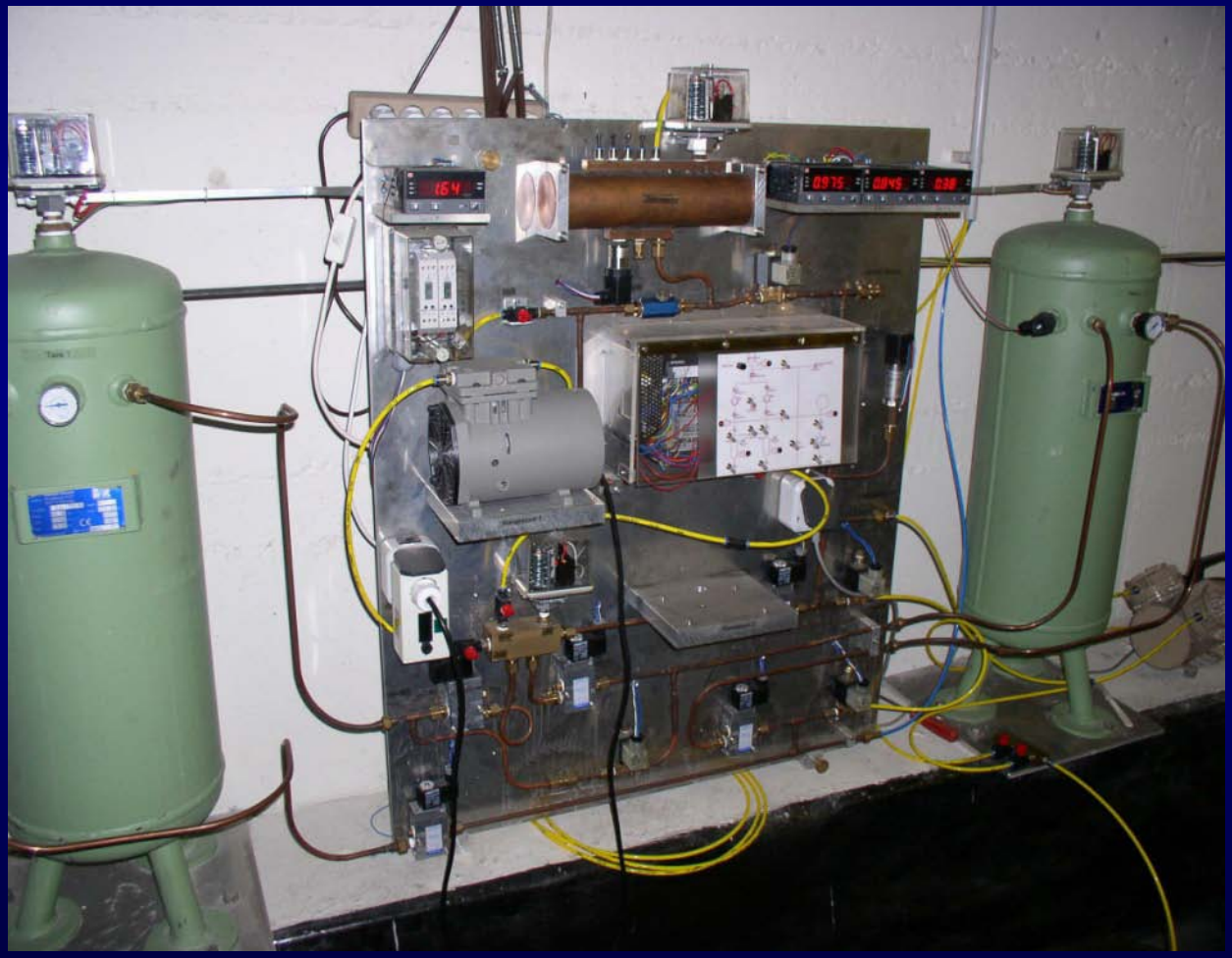
Collection:

- **Passive Collection (bags)**

- **Active collection into compressed gas tanks**

Air Filter Bed Bank

Tank Collection System



IP Focus Element 5

Radiation Instrumentation

- **Observe/check for sufficient number and types**
  - appropriate, available, operable, used (properly)
  - may be for
    - detection (LEG or GM ratemeters for contamination identification)
    - measurement (dose calibrators for product; energy-compensated GM or ion chamber for package surveys; scaler GM for air sample media counting)
  - other equipment: air samplers, rotometers, liquid samplers, bioassay collection, etcetera

IP Focus Element 5

Radiation Instrumentation

- **Measurement instrumentation**
  - sufficiently sensitive: check MDA/LLD
  - calibrated for required geometries, RAM
  - dose calibrators: constancy accuracy, linearity, geometry
  - QA/QC programs where applicable
- **Calibration**
  - Frequency, including maintenance of instruments
  - compare measurements

The Ideal PET Effluent Monitor

- Insensitive to “undesirable” radiation
- Easy to calibrate and verify operation
- Linear response
- Accurate
- Wide measurement range
- Stable under varying environmental conditions
- Simple display of results and an easy comparison to action levels for the end-user
- Compact
- Easy retrieval of stored data

Types of Detectors for In-Line Monitoring [^{18}F] [FDG] Effluents

Flow-through Ion Chamber

- Pros:
  - Somewhat insensitive to external radiation
- Cons:
  - Difficult to calibrate in-situ
  - False readings due to loss of charge in the plates.
  - Disrupts airflow – this causes a flow rate dependent calibration factor
  - Operational experience very poor
  - Manufacturer's support very limited

Types of Detectors for In-Line Monitoring [^{18}F] [FDG] Effluents

NaI(Tl) Scintillation Detectors

- **Pros:**
  - **Inexpensive**
  - **Commonly available**
- **Cons:**
  - **Temperature dependence**
  - **Sensitive to nearby radiation sources**
  - **Higher background**
  - **Limited support from manufacturers**

Types of Detectors for In-Line Monitoring [^{18}F] [FDG] Effluents

Plastic Scintillation Detectors

- Pros:
  - Fairly inexpensive
  - Low temperature dependence
- Cons:
  - Sensitive to nearby radiation sources
  - Higher background
  - Large size

Types of Detectors for In-Line Monitoring [^{18}F] [FDG] Effluents

Combinations (GM + NaI, GM + Ion chamber)

- **Pros:**
  - **Covers a wider measurement range**
- **Cons:**
  - **More expensive**
  - **Possibly sensitive to nearby radiation sources**
  - **Cross-over point**

Types of Detectors for Off-Line Monitoring [^{18}F] [FDG] Effluents

- Potential for line losses due to the reactive nature of fluorine compounds.
  - Study being developed to quantify
- Short-half life would necessitate frequent sample collection media changes and counting or continuous counting.
- Some chemical forms can not be trapped on collection media.

Types of Detectors for Off-Line Monitoring [^{18}F] [FDG] Effluents

Continuous monitoring works well using Laboratory Impex Systems

Pros:

- **Small size makes for easier installation in existing sites**
- **Easy to shield if background issue**

Con:

- **Data retrieval somewhat cumbersome**

Thermo FHT 3511 Positron Stack Monitor

- Four plastic scintillation detectors operating in coincidence counting mode, energy windows & arranged on outside of duct.
- Standard PC running Windows® software for operation, display and data storage.
- Solid ^{68}Ge disk source for calibrations and operational verification.
- Data stored in an ACSII file

Thermo FHT 3511 Positron Stack Monitor

Thermo FHT 3511 Positron Stack Monitor

IP Focus Element 4

Charcoal Filtration System on the stack of PET production facility

IP Focus Element 6

Knowledgeable Workers

******* OBSERVE, ASK, VERIFY *******

- **Knowledgable in radiation uses and safety practises**
- **Skilled in radiation safety practises under normal and accident conditions**
- **Empowered to implement the radiation safety program**

IP Focus Element 6

Knowledgeable Workers

- **General Training**
  - Initial training scope, method(s), testing
  - Refresher frequency, method(s)

  - Knowledge of site radiation safety practices
  - Knowledge of regulatory issues pertinent to their licensed activities

  - Driver training, including HAZMAT

IP Focus Element 6

Knowledgeable Workers

- Able to detect/assess radiation and contamination:
  - good survey technique
  - correctly read meter face
  - Appropriate use of “cpm” versus “dpm”
- Able to identify and investigate events: review/discuss surveys/inspections/audits - do they identify events, how do they follow-up?

IP Focus Element 6

Knowledgeable Workers

- **Emergency Procedures**
  - **Ask about real incidents (typically spills/contamination or driving accidents)**
  - **Ask for the accident or incident file**
  - **Ask about hypothetical situations**

IP Focus Element 7

Management Systems and Oversight

- The licensee is responsible for the radiation protection program; senior management delegates authority to RSO to implement
- Management focus should include: awareness of events; safety and compliance; providing adequate resources; human performance issues; communications with the NRC

***INTERVIEW MANAGEMENT ***

IP Focus Element 7

Management Systems and Oversight

- **RSO:** Interview "local" RSO (usually a pharmacist), if available. Call (at a reasonable hour!!) if necessary.
- **ANP:** Interview and observe ANP – ensure they provide adequate supervision of non-pharmacist employees preparing doses
- **Staff:** Interview staff about management involvement in radiopharmacy activities

IP Focus Element 7

Management Systems and Oversight

- **Annual Program Review and other audits**
  - Review/understand licensee's review program; may be internal or external, annual or segmented
  - Understand the role of corporate audits and reviews, if any
  - **Ensure that management is aware of annual program review and audit results**

Radiopharmacy Inspections - Oddities

- **Getting to Observe Radiopharmacy Activities**
  - You should be at the pharmacy during peak operations, which could mean backshift, during the midnight to 6 am window. ☹ Overlapping shifts is good, too.
  - Before inspection, you might want to find the location in daylight.
  - Bring your I.D. so you can identify yourself to the staff when you arrive.
  - You may need a cell phone to call them when you get there, if they don't hear the doorbell; or go around the back, where the courier vehicles are parked.

Radiopharmacy Inspections - Oddities

Entrance with Local RSO or ANP

- **Be quick and informal – they're busy and both of you know why you are there!** – tell them how long you plan to be there
- **Discuss current scope of program:** number of doses/clients; number of runs; staff size; types of processes
- **Ask about activities happening during the inspection** – there may be something non-routine you want to see (compounding, filter change-out, etc)

Radiopharmacy Inspections - Oddities

Interview Licensee Personnel

- Observe without getting in the way. Peak operations are VERY busy.
- Ask questions, but let them get the work done. They will take breaks or be available at end of shift
- Interview as you follow the process: From orders to dose production to packing to surveying to loading to transporting to returns of customer doses
- Talk to each type of personnel – pharmacists, techs, drivers, and administrative staff
- LISTEN!!

Radiopharmacy Inspections - Oddities

Make Independent Measurements

- Take measurements as you observe, but don't be alarmed if you find radiation! ☺
- Are the levels you're seeing consistent with the operations?
- Look more at their technique
- Do some side-by-side comparisons, taking types of equipment, etc., into account
- Follow their rules for personal surveys in and out of areas

Radiopharmacy Inspections - Oddities

Review Representative Records

- Easier to look at records after major operations are completed for the night/day
- Look at records where you can also observe activities, especially while staff is busy
- Focus on most safety significant items:
  - Effluents
  - Dosimetry
  - Surveys
- Look at enough to be satisfied – you don't need to see it all!!

Radiopharmacy Inspections - Oddities

Pre-exit with the Local RSO/ANP (and staff):

- ensure they are aware of all your findings
- allow the staff to ask questions/clarify issues
- allow discussion of major and minor issues in technical detail, including issues that will not be discussed at the exit

Radiopharmacy Inspections - Oddities

- **Exit with the highest possible level of management:** Probably after the inspection, by phone, with corporate personnel. Corporate RSO may or may not be a pharmacist, so tailor your discussions to minimize unnecessary technical detail.
- **Explain the inspection process and any follow-up**
- **Discuss what you found**
  - opportunity to highlight positive findings
  - give perspective to negative findings
  - be open; accept comments; answer questions


Questions???