

**Bart's Hospital  
Radiopharmacy**

**Functional Design Specification**

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# Functional Design Specification - Contents

- 1) Basis: User Requirement Specification
- 2) Design development
  - Iterative process with HOK Architects
  - 1:50 Drawing
  - Room Data sheets
- 3) Layout
- 4) Personnel, Material & Waste Flows
- 5) Design constraints:
  - Fire Zones
  - Security
  - Radiation shielding

# Functional Design Specification (cont)

## 6) Building Elements

- Floor, wall & ceiling specifications
- Hatches
- Glazed screens
- Security Doors
- Clean room Doors & interlocks
- Escape panels
- Furniture:
  - Worktops
  - Cabinetry
  - Shelving
  - Step over Benches

# Functional Design Specification (cont)

## 7) Mechanical Services:

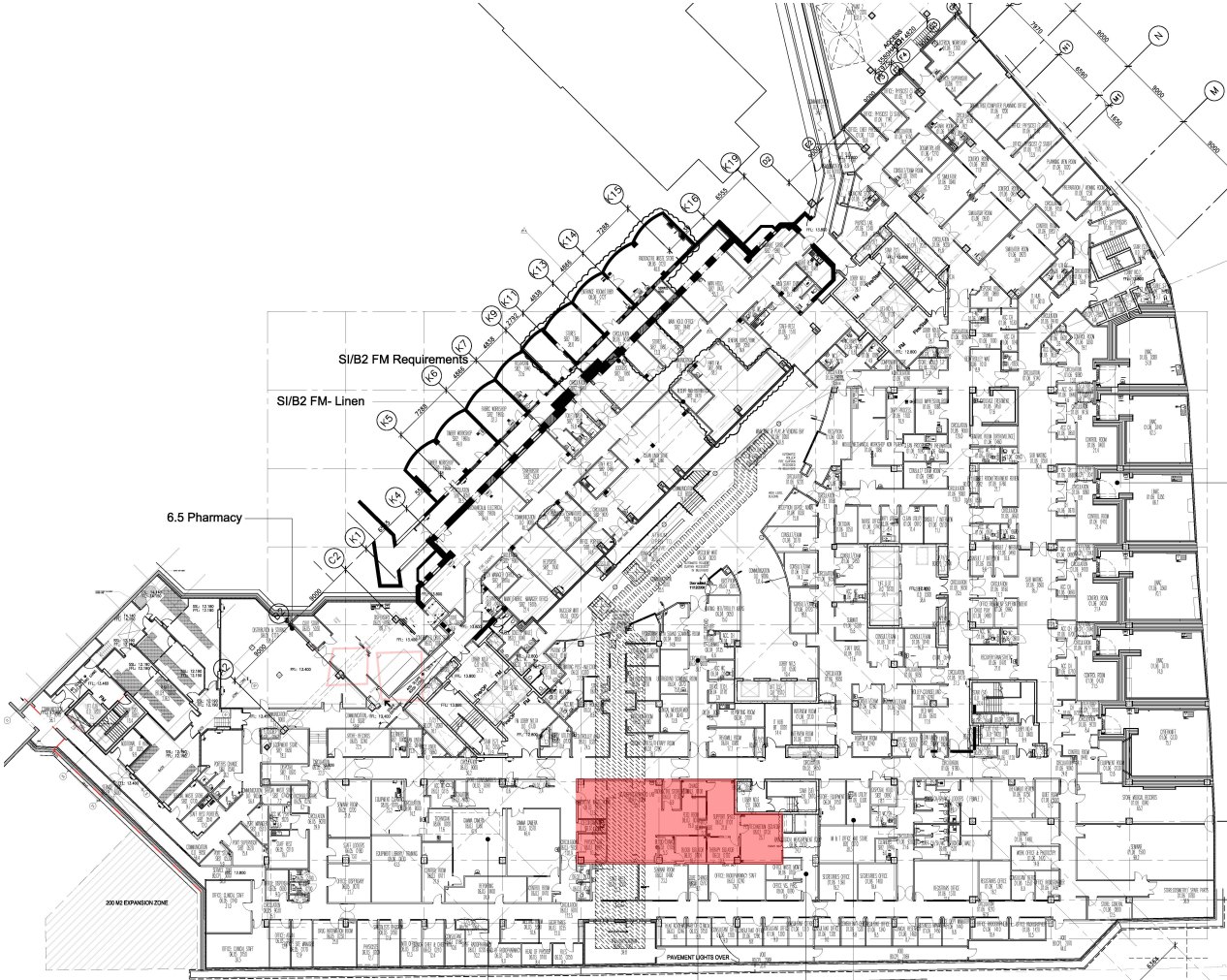
- Ventilation systems
- Sprinklers
- Environmental Monitoring system

## 8) Electrical Services:

- Lighting
- General Power
- Telephone & Data
- Intercoms
- Security:
  - Access Control
  - CCTV
  - Interlocks



# Barts Radiopharmacy location - Level B1



## Basis of the design: User Requirement specification

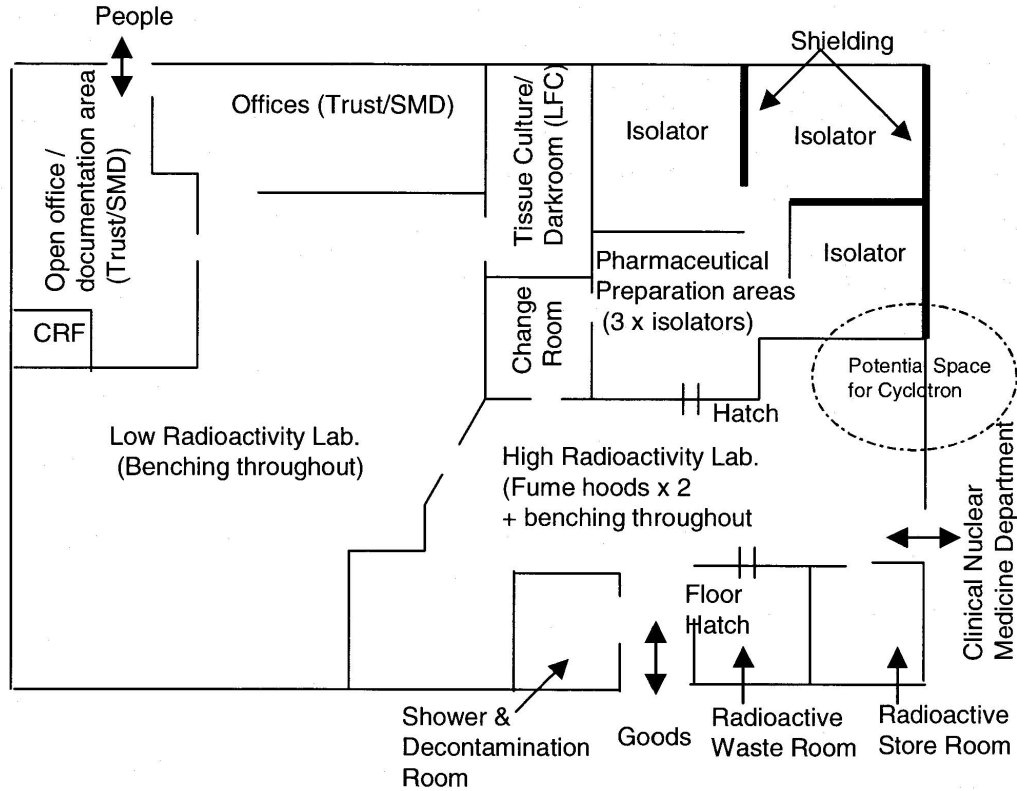
The initial “URS” called for a substantial part of the Radiopharmacy to be devoted to basic scientific research. The Trust’s initial brief for the Nuclear Medicine department called for a Radiopharmacy with “a major R&D function in the development of new Radiopharmaceuticals.”

The following diagram illustrates what accommodation was required in the Radiopharmacy Laboratory area.

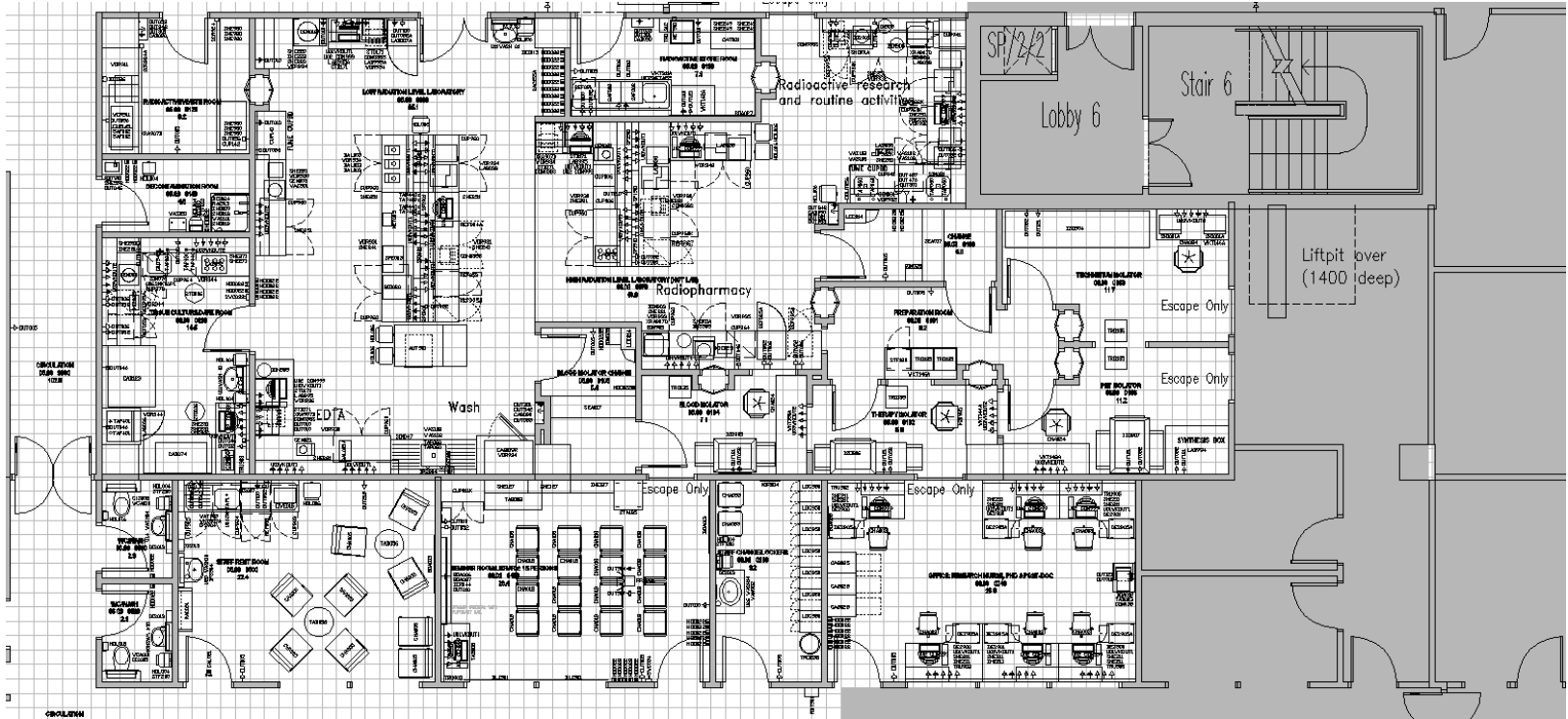
# Initial URS

**Laboratory Area**

Laboratory key adjacencies  
 Diagram illustrative only



# Early 1:50 layout



## Final URS

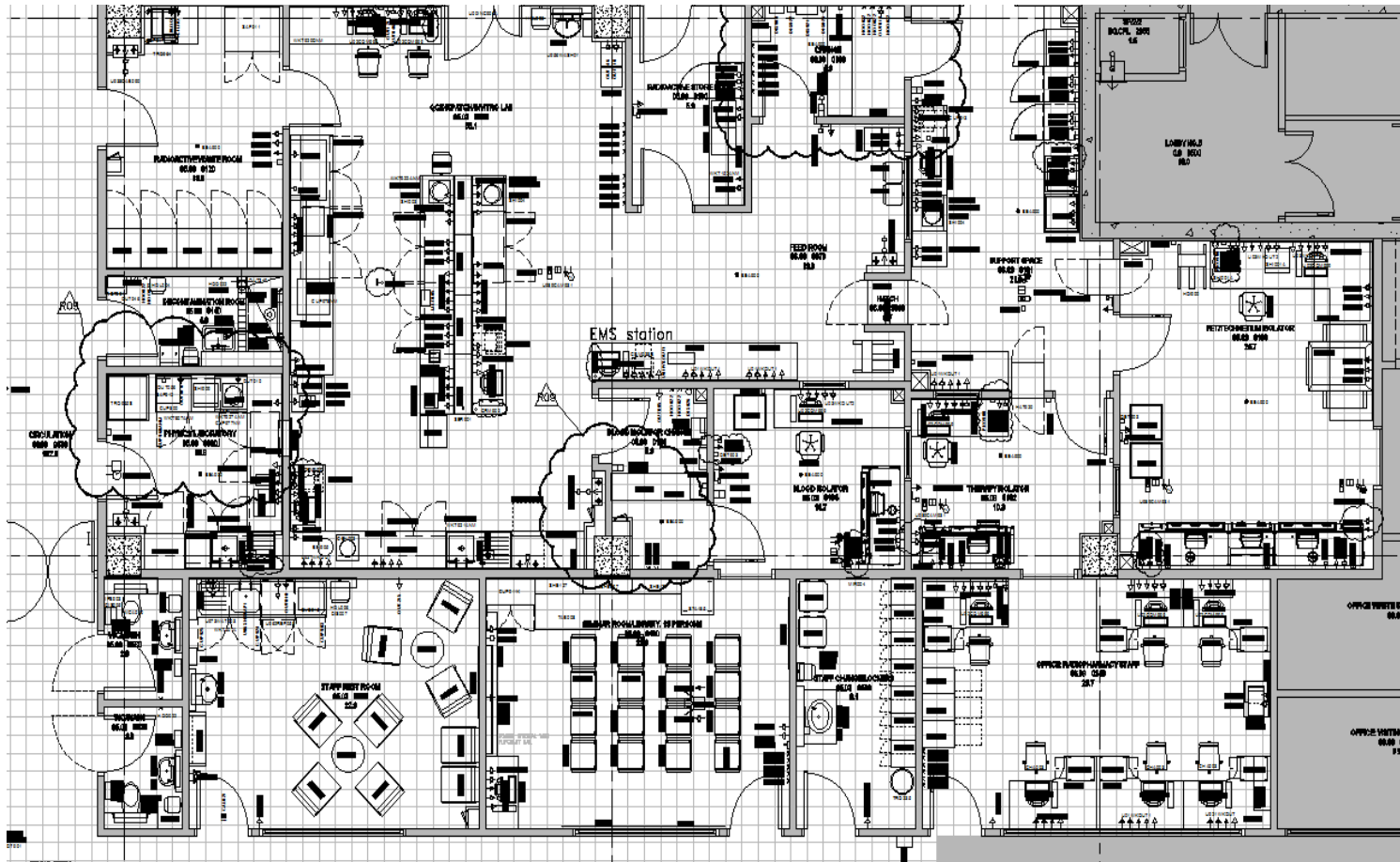
As the years have gone on the shift has been to concentrate on daily production of routine clinical “specials” pharmaceuticals rather than IMPs (Investigational Medicinal products).

Consequently in 2011 changes were made to the design altering spaces which had been designated for the R&D function, and enlarging the production areas, creating:

- A QC/Dispatch/Invitro Lab;
- A Feed room;
- A “Support space” within the Classified area to set up production equipment, check and release radiopharmaceuticals; transfer equipment, etc.
- The 3no. Isolator rooms & associated Change rooms
- Radioactive Store
- Radioactive Waste room
- Decontamination room

Classification of the clean rooms: EU GMP Grade D = ISO Class 8

# Barts Radiopharmacy 1:50 layout



# URs for Specific elements

In addition User Requirement Specifications were issued for the following specific elements:

- Isolators
- Environmental Monitoring system
- Hatches
- CCTV
- Intercoms

# URS for Isolators

## **ISO904 ISOLATOR; Technetium Module**

### **Purpose**

- Aseptic preparation of Technetium-99m radiopharmaceutical injections.
- Isolator module design to provide product, operator and environmental protection

### **Construction / quality**

- Module comprising five interconnecting stainless steel chambers – one central technetium storage/elution chamber, two processing chambers and two transfer hatches



# URS for Isolators

## **ISO905A ISOLATOR; blood; with centrifuge; 1800x1650x730**

- **Purpose**
- Aseptic Radiolabelling of blood products
- Isolator module design to provide product, operator and environmental protection. Module comprising two interconnecting chambers –one processing chamber and one material transfer hatch

# URS for Isolators

## **ISO906 ISOLATOR; therapy; 2150x2250x740**

- **Purpose**
- Aseptic Preparation of high dose radiopharmaceutical injections
- Isolator module design to provide product , operator and environmental protection
- Module comprising two interconnecting chambers –one for processing and one for material transfer

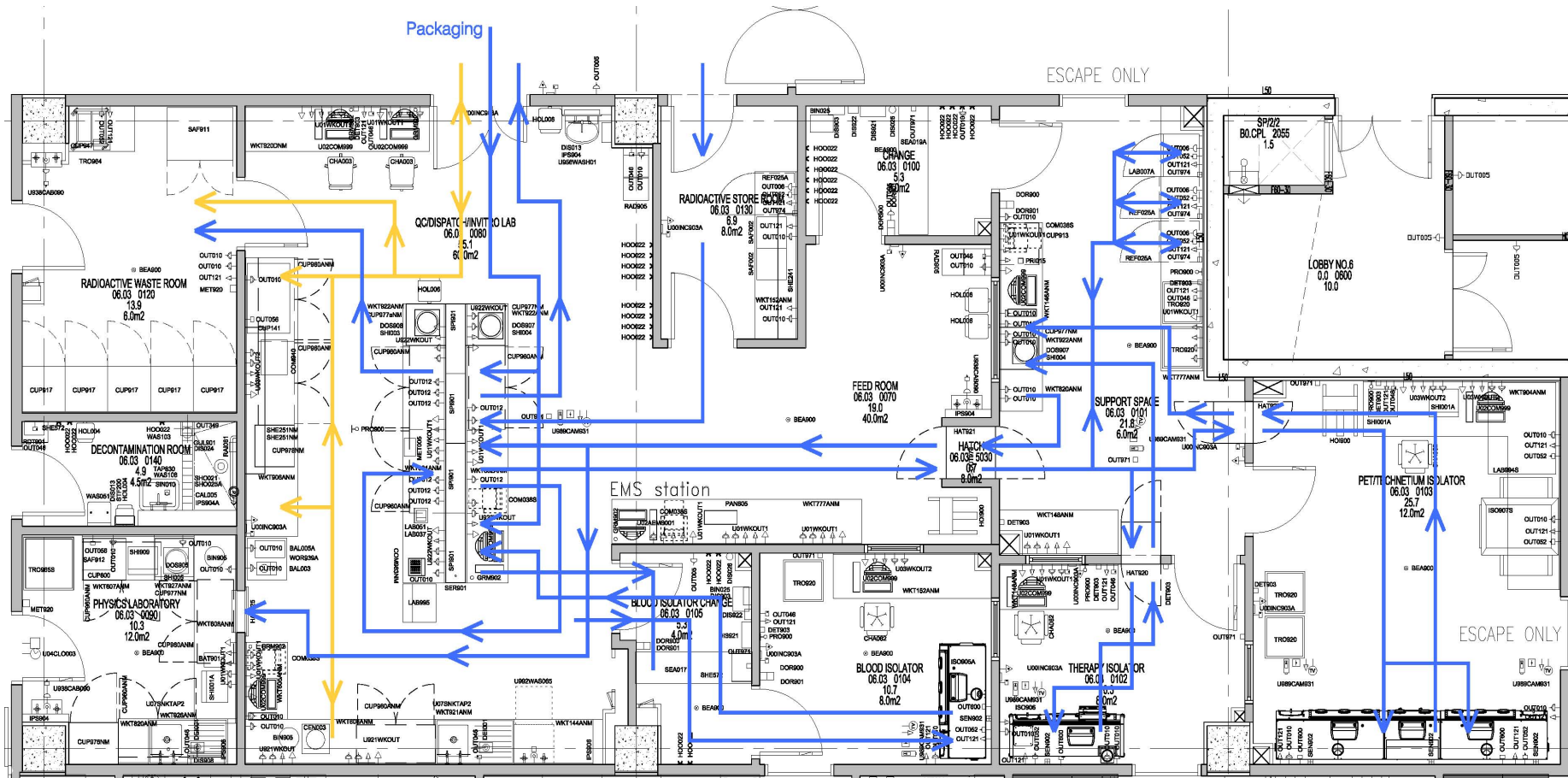
# Process Flows

As part of the Functional design specification process, flows were drawn up to verify the workability of the design. The following diagrams were drawn up identifying

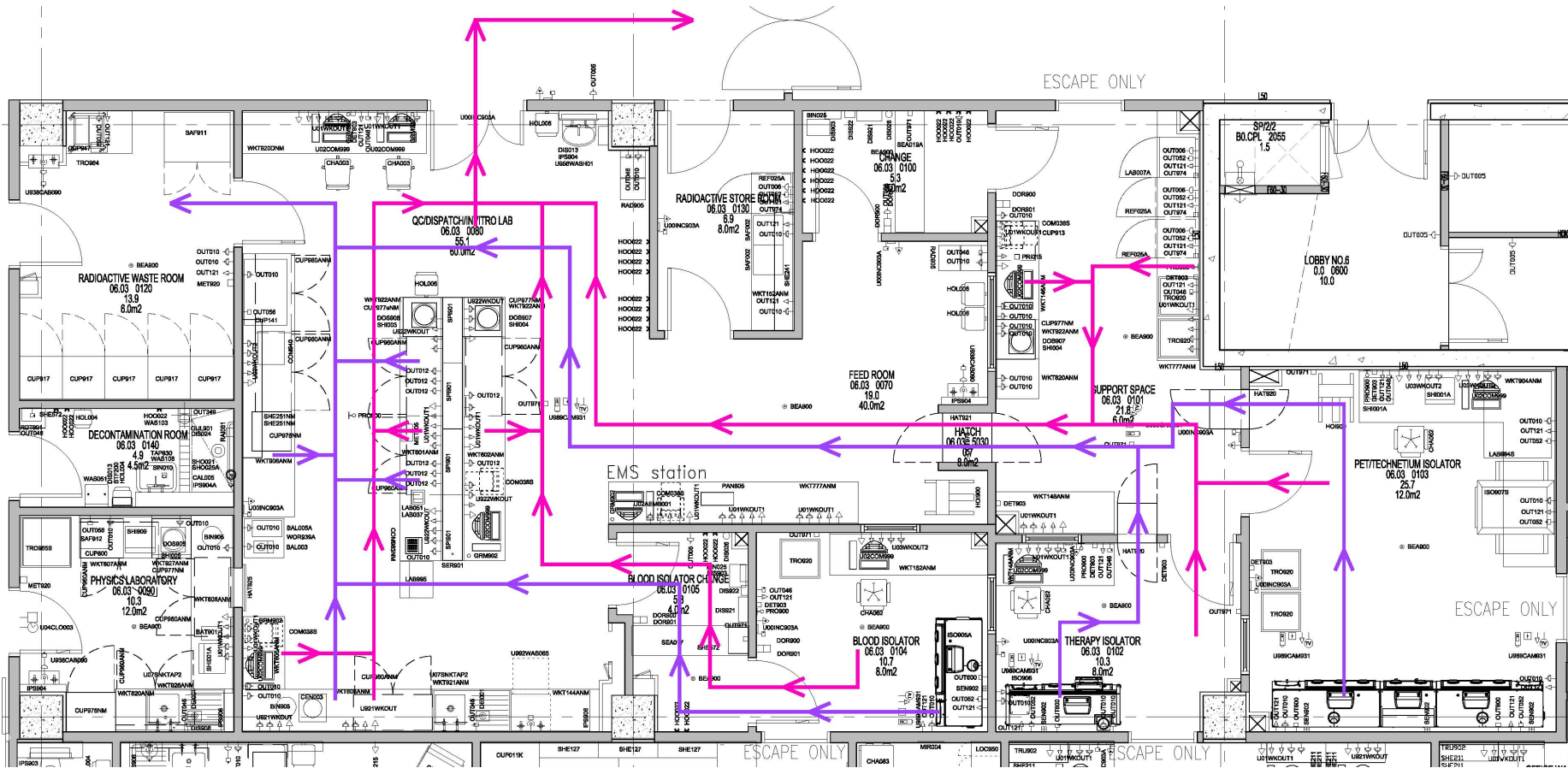
- 1) Personnel flows for the following:
  - Morning production (6am to 10am)
  - Blood labelling (10am to 2.00pm)
  - Therapy Preparation (10am to 6pm)
  - Non-Radiopharmacy Staff (9am to 5pm)
  - Deliveries



# Process Flows – Materials: Radiopharmacy & Nuclear Medicine Invitro work



# 3) Process Flows – Waste: Radioactive and paper waste

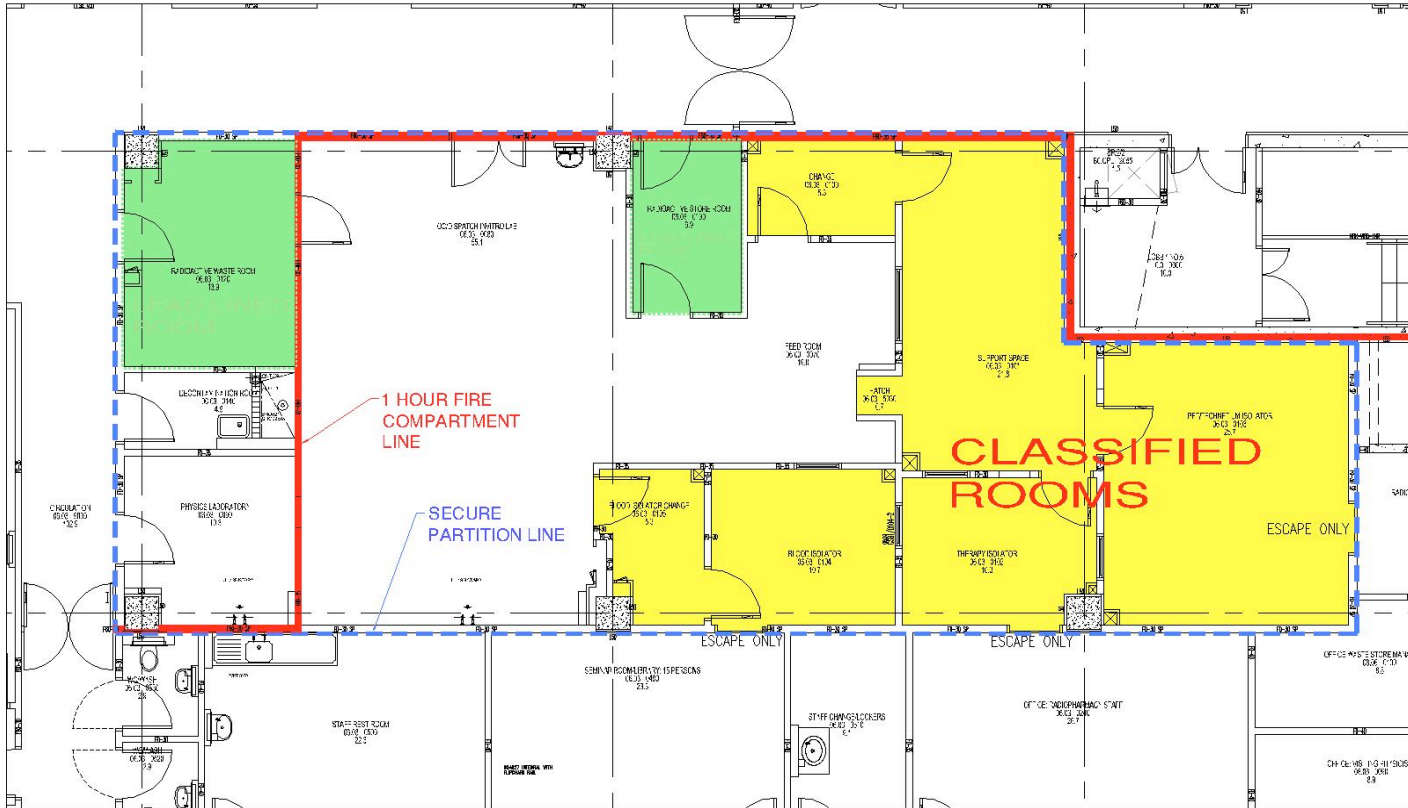


# Design Constraints

- Fire compartmentation: 1 hour fire rated construction in line with the overall Fire strategy for the building
- Security zone: Secure construction to meet the requirements of the Counter Terrorism Security Advisor
- Radiation shielding: to meet the Ionising Radiation Regulations and as stipulated by the Radiation Protection Advisor



# Design Constraints



ST BARTHOLEMEW'S HOSPITAL  
RADIOPHARMACY DEPARTMENT



## Functional Design Specification - Architectural

Clean room construction requires floors, walls & ceilings to be finished in vinyl so the surfaces can be cleaned, and to ensure the room is sealed to help maintain air pressures and a clean working environment

- Floors: Concrete floors. Finished with 2mm thick sheet vinyl with hot welded joints. The vinyl to be self-formed over coveformer to all edges laid to a reducing strip to the wall, to provide a smooth ledge-free finish.
- Walls & Ceilings: formed from 12.5mm thick Gypsum plasterboard, fixed to 70mm proprietary steel studding. 2mm thick sheet vinyl is installed to the walls and ceilings of all rooms. The internal corners will be formed over coveformer and all joints hot welded and trimmed flat and smooth.

# Vinyl finishes



# Functional Design specification – Vinyl finishes

HOMOGENEOUS



LRV 61.8

NCS S 1505-Y40R

Silver Mist 1430 w/r 1430



LRV 50.3

NCS S 2002-B

Quartz 1400 w/r 9340



LRV 55.2

NCS S 1505-Y30R

Satinwood 1370 w/r 8320



LRV 54.9

NCS S 2020-Y30R

Shoreline 1460 w/r 1460



LRV 37.3

NCS S 2020-G40Y

Asparagus 1320 w/r 8360



LRV 43.6

NCS S 2020-B90G

Wild Mint 1230 w/r 1230



LRV 47.0

NCS S 2005-B80G

Pale Slate 1200 w/r 1200



LRV 52.4

NCS S 1030-Y10R

Cornbrook 1240 w/r 1240

# Functional Design Specification – Architectural

## Doors:

- Clean room doors:
  - The Clean Room doors are constructed from GRP, with stainless steel hinges and door furniture. The frames will be anodised aluminium for all non fire rated doors and stainless steel for fire rated doors.
  - The doors are electrically interlocked to ensure differential air pressures between rooms is maintained.
- Security doors:
  - Required to all openings on the Secure wall line including in front of Breakout panels. To be constructed as LPS1175 rating 3 security doors, and lead lined where necessary. The doors and frames will be fabricated in steel with a polyester powder coated finish. Vision panels to be provided as required.

# Functional Design Specification – Architectural

GRP Clean room door





# Functional Design Specification – Architectural

## Viewing panels

Internal viewing panels are formed using 2mm thick steel subframes, stainless steel flanges and reveal liners, with 6mm Toughened glass on each side, giving an acoustic rating of 25dB



## Functional Design Specification – Architectural Pass Through Hatches

The pass-through hatches are constructed generally from Stainless steel and are fitted with two glazed, hinged doors, with electro-mechanical interlocks. Each hatch has two opposite handed doors, i.e. one left-hand and one right-hand.



# Functional Design Specification – Architectural

## Escape panels

These are provided as an emergency exit from each of the isolator clean rooms. They are sealed into openings in the walls, and constructed with stainless steel architraves and 5mm acrylic break-out panel. The panel is held in by a removable rubber strip attached to a stainless steel handle.





# Functional Design Specification – Architectural

## Furniture:

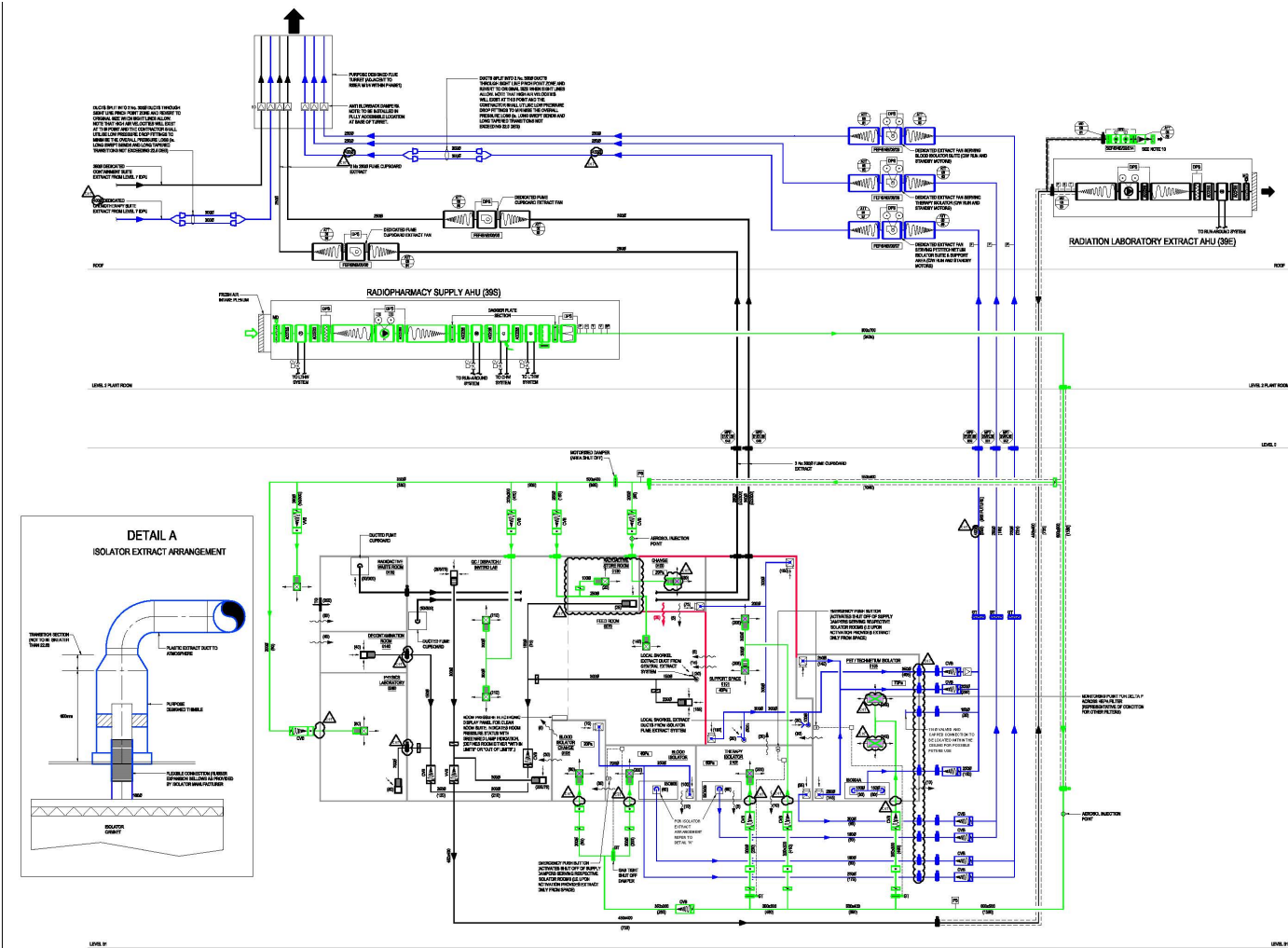
- Workbenches:
  - These are formed using Corian (man-made material giving a stone-like appearance) on a laminated timber substrate and supported on powder coated steel frames. Apertures are formed to accommodate dose calibrators.
  
- Cabinetry:
  - Mobile Units are constructed using grade 304 stainless steel
  - Other cupboards are constructed using melamine faced MDF

# Functional Design specification — Ventilation system

The design of a dedicated mechanical ventilation system for Radiopharmacy is included in the Functional Design specification allowing for supply & extract of all the rooms, and extract for the fume cupboards and isolators.

Detailed explanation of the system will be given in a separate presentation.

# Airflow schematic





## Functional Design specification - Sprinkler system

In order to comply with the Fire strategy which requires the whole hospital building to be covered by a sprinkler system.

All rooms in the Radiopharmacy are served with a Pre-action sprinkler system with concealed heads. This is designed for to prevent sprinkler pipework from being constantly under pressure, and hence reduce the risk of accidental flooding.

# Functional Design Specification - Electrical services

## Mains Supply:

- The Radio-pharmacy suite electrical lighting and power requirements are served from two lighting and power Distribution boards
- These distribution boards form part of the low voltage distribution scheme ,wherein each of the distribution boards are fed from three transformers with two standby generators providing emergency cover in the event of loss of supply .

# Functional Design Specification - Electrical services

## Lighting

- The lighting design Lux levels are specified in the room data sheets
- The luminaire's have been selected to suit the classified rooms and non classified areas.
- All luminaire's within solid ceilings will be a through access type to allow access to services above ceilings.
- The control of the luminaires is generally via local motion/ presence detectors within the room.

# Electrical Services

## General power & data:

Single phase sockets and fuse spur units, and data outlets are installed in accordance with the layout drawings

## Intercoms:

- To allow communication between rooms in the department a Stentofon intercom system has been installed in accordance compliance with the User Requirement specification.
- The system comprises a Master intercom station and individual speaker desk/ wall locations.



# Supplier led Functional Design Specs

## **Environmental Monitoring system**

The system will have the ability to monitor, record and display environmental parameters and compare the measured values against fixed alarm limits. It will provide a simple user interface showing alarm states displayed on mimic diagrams of simplified floor plan(s) of the area. Trend graphs, tabular reports and alarm reports based on the measured parameters may be accessed via password control.

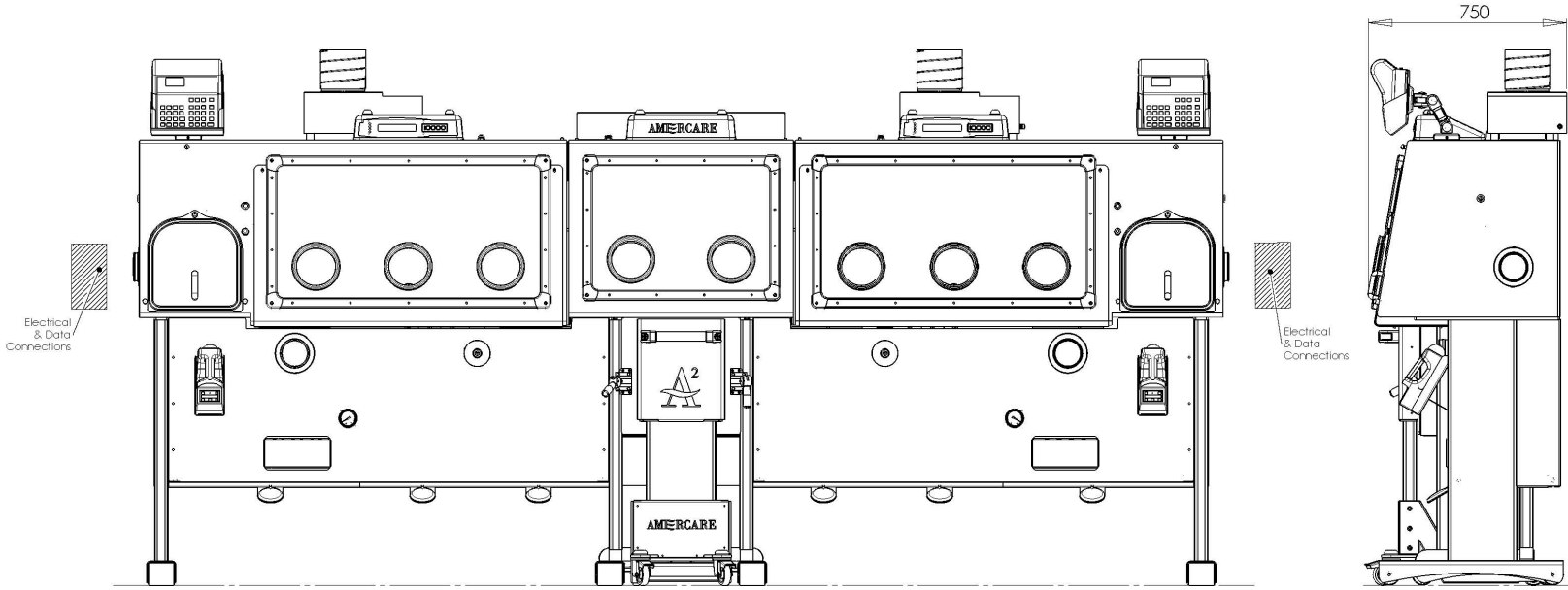
The continuous monitoring of airborne particulate levels will be achieved using Pharmagraph's (Continuous Particle Counting) particle counter subsystem. Particle counting will be configured to provide continuous monitoring of particulate levels within the specified isolators and Grade D classified rooms.

# Environmental Monitoring

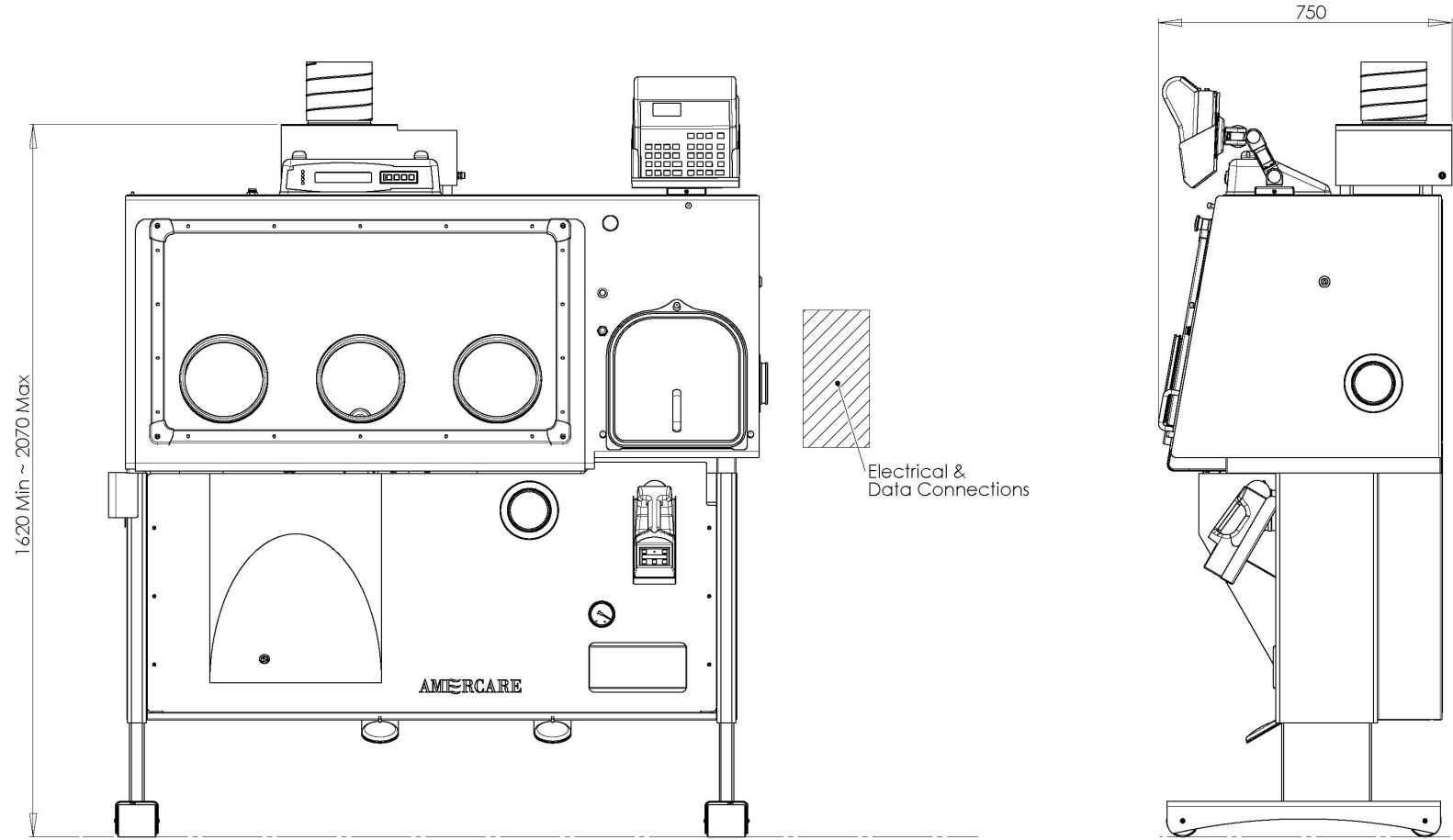
Each equipment particle counter will be located at the rear of the isolator. A stainless steel and sample tube will connect to the sample probe within the work area of the equipment.

The room particle counters will be mounted on the wall of the room to be monitored. A short sample tube will connect to the stainless steel sample probe.

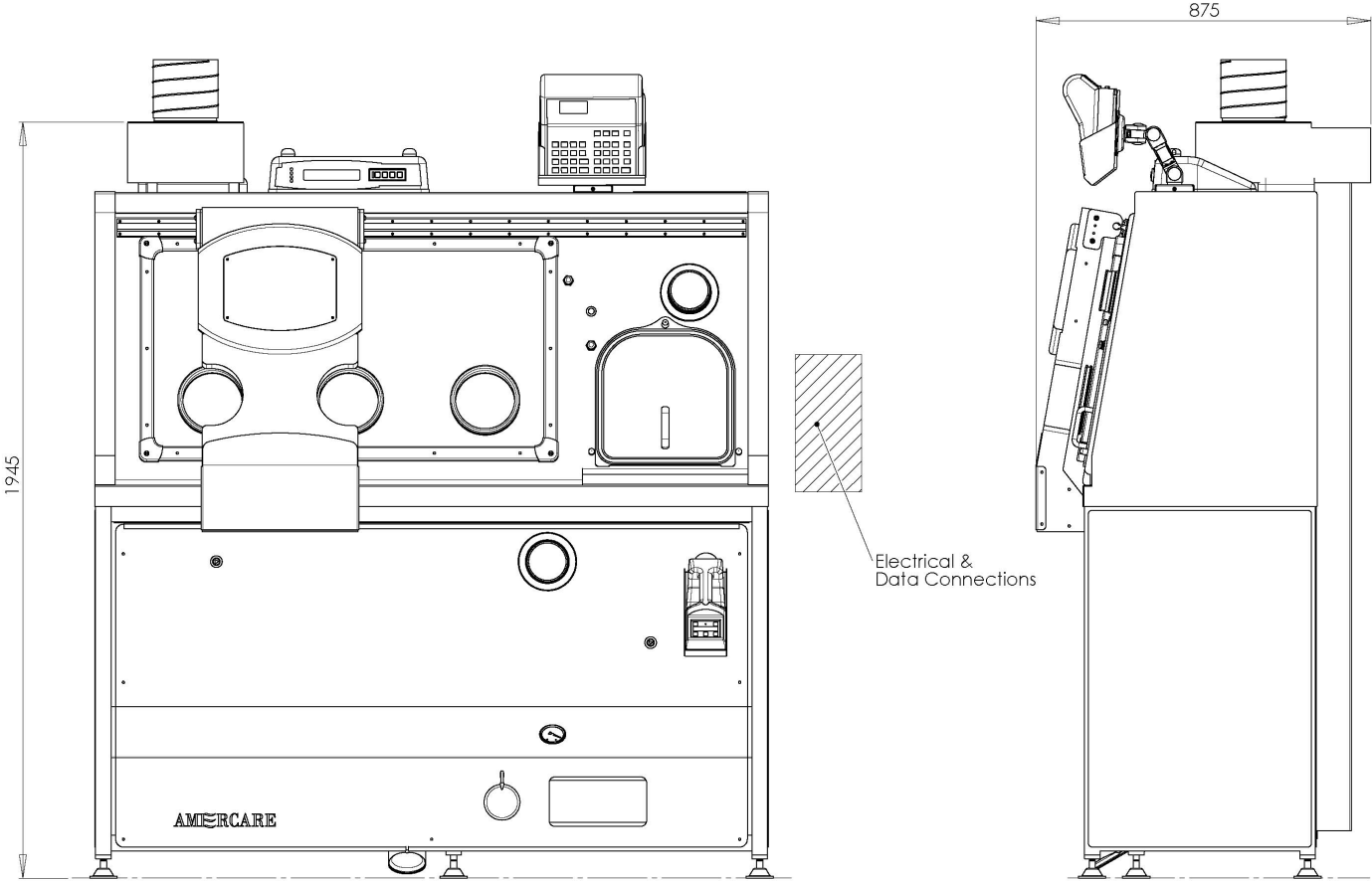
# Isolators - PET Technetium Isolator



# Isolators - Therapy Isolator



# Isolators - Blood Isolator



# **Questions & Answers?**