NUCLEAR MEDICINE MANUFACTURING PROGRAM

Nuclear Medicine Technology Demonstration (NMTD)

Facility Functional Description

File Number: NMTD-0080-SP-0001

Table of Contents

Records					
Document Location	P:\Radiopharmaceutical Facility\55 Technology Demonstration\5530 Design\6030.01 Technology Demonstration URS				
Revision History					
Revision	Date	Summary of Change	Author	Review	Approved
A0	05.12.23	First Issue	SIVERIO GONZALEZ, Alejandra	Amy Le Leena Burgess Russell Thiering	Mark Moore
A1	29/11/2024	Revised document incorporating detailed design changes and revised facility operational limits	Jude Perera	Moshiul Alam Leena Burgess Russell Thiering	Mark Moore

1. Purpose

The purpose of this document is to provide a functional description of the Nuclear Medicine Technology Demonstration (NMTD). More specifically, it will provide a description of the following aspects of this demonstration facility:

- Description of the Facility including:
    - Building specifications
    - Building intent
    - Spatial organization including major equipment installed.
    - Operational limits
    - Hot cells
    - Material movement
    - Personnel movement
- Process overview.
    - Molybdenum-99/Technetium-99m (Mo-99/Tc-99m)
    - Lutetium-177 (Lu-177)
    - Iodine-131 (I-131)
- Active Ventilation System and HVAC
- Waste Management
- Security

This document is a live document and must be reviewed and updated during the development of each design stage of the project.

2. Scope

2.1. In scope:

The scope of this document covers the following areas of the Nuclear Medicine Technology Demonstration Facility:

- Secondary Containment
- Plant Room (internal and external)
- Transition Zone
- Wet Chemical Lab

2.2. Out of scope

All other aspects of Building 22 such as amenities, existing laboratories etc.

3. Site

ANSTO has endorsed the Nuclear Medicine Technology Demonstration (NMTD) Facility to be constructed at the Institute of Environmental Research, "STAR ACCELERATOR", located in Building 22 on the Lucas Heights campus.

Building 22 provides the required footprint for the construction of the NMTD with minimum impact to the existing tenants and operations. The NMTD takes advantage of the existing amenities, truck bay access, services and utilities including Electricity, Compressed Air, Communications, Potable Water, Trade waste, and Radioactive waste.

The NMTD will be constructed in rooms 8 & 9 (refer to Figure 1) as a secondary containment in existing building number 22. Existing rooms no.24 & 25 will house NMTD plant room that includes the AVS, a new external area to house HVAC system, room no.23 will be utilised for the Wet Lab, existing toilets, rooms no. 26 & 27 will be refurbished and a new comms room will be established in the area that is currently used as locker room in the women's bathroom, room 26. A new comms rack will be installed next to existing racks in room 16.

Hazardous material surveys were undertaken, and pre-demolition register updated [Ref: (1), (2), (3), (4), (5) (6), (7) and (8)]. Due to presence of hazardous materials in the trenches, remediation works will be carried out by ANSTO Hazmat Team and completed prior to commencement of principal contractor works. Hazardous materials found in other areas will be remediated and removed by the principal contractor prior to commencement of works.

Figure 1- Existing Ground Floor Plan

4. Facility Description

4.1. Building specifications

The Nuclear Medicine Technology Demonstration footprint is approximately 500 m^2 inside building 22 (refer to Figure 2), which includes:

- Secondary containment structure housing the laboratory area and change room, approximately 220m2.
- Internal Plant Room for HVAC, approximately 70m2
- External Plant Room for HVAC, approximately 47m2
- Chemical laboratory, approximately 27m2; and
- The remaining, approximately 180m2 area includes corridors and truck bay area.

The total area does not include refurbishment of existing bathrooms.

4.2. Building Intent

The primary function of the NMTD is to provide the physical workspace and testing equipment to support the NMMF program by:

- Undertake the GEP test plans.
- Supplying training facilities to production staff, quality technicians and maintenance staff in anticipation of validation activities,
- Physically mock-up hot cell containment areas and manufacturing line equipment,
- Demonstrating safe operation and maintenance of the equipment.
- Assisting in the engagement with regulators,
- Assisting in the definition of operational limits and waste characterisation,
- Validating modular and automation equipment (where permitted).

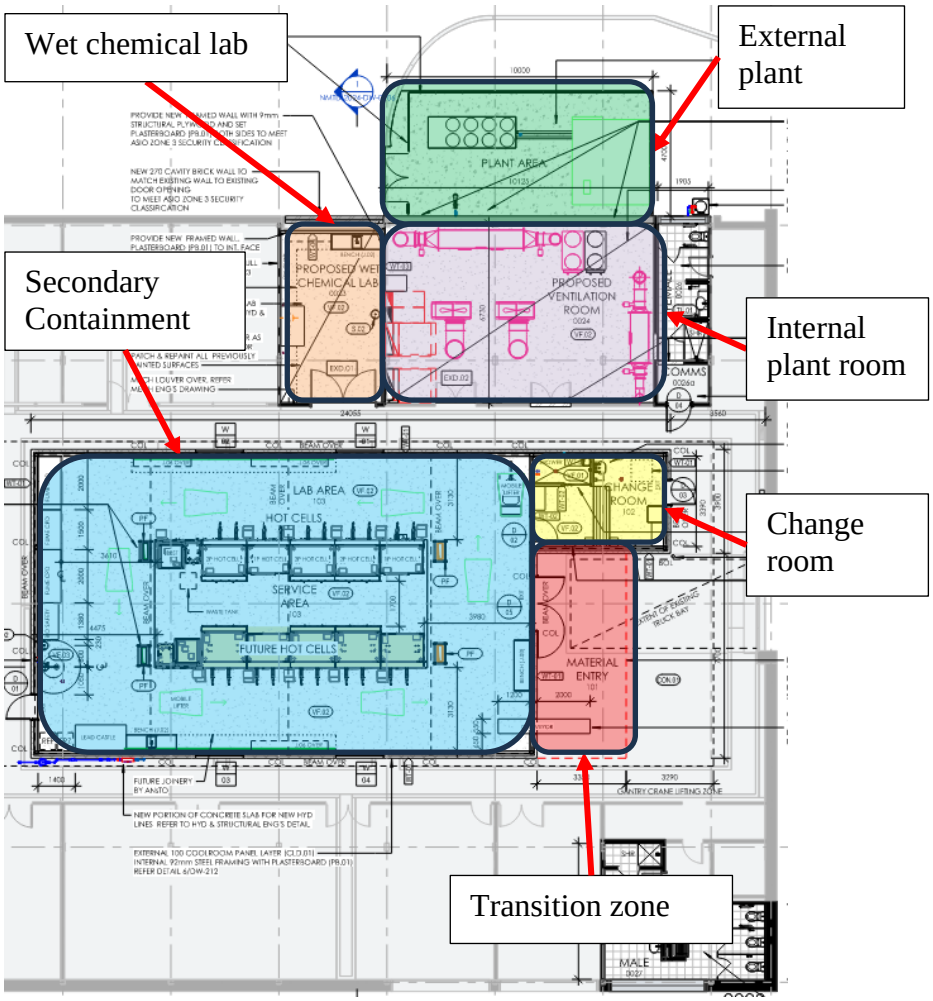


Figure 2: NMTD Facility floor plan

4.3. Spatial Organisation

The spatial organisation of the facility is driven by operational and material flows, as well as room functions. The NMTD total footprint is divided into four (4) main rooms or areas:

1. Secondary Containment (Blue Rad. / Blue Contam. Zone)
2. Wet Chemical Lab (no radioactive work conducted, therefore no classification required.)
3. Transition Zone (White Rad. / White Contam. Zone)
4. Internal Plant Room (White Rad. / White Contam. Zone with temporary change to a Blue Rad. / Blue Contam. zone during filter change out).
5. Change Room (White Rad. / Blue Contam. Zone)
6. External plant (no radioactive work conducted, therefore no classification required).

Refer to Appendix A (Containment Classification and Rationale).

4.4. Secondary Containment

The following activities are conducted within the secondary containment:

- Receipting of the radioactive isotopes via the conveyor system. The radioactive isotopes will be brough in via B(U) containers or Type A containers.
- Testing and processing of the radioisotopes in the hot cells.
- QC testing in the shielded fume cupboards.
- Non-radioactive and/or tracer level testing in the bio-safety cabinet.
- Non-radioactive and/or tracer level testing on benchtops.
- Storage of radioactive waste for decay.

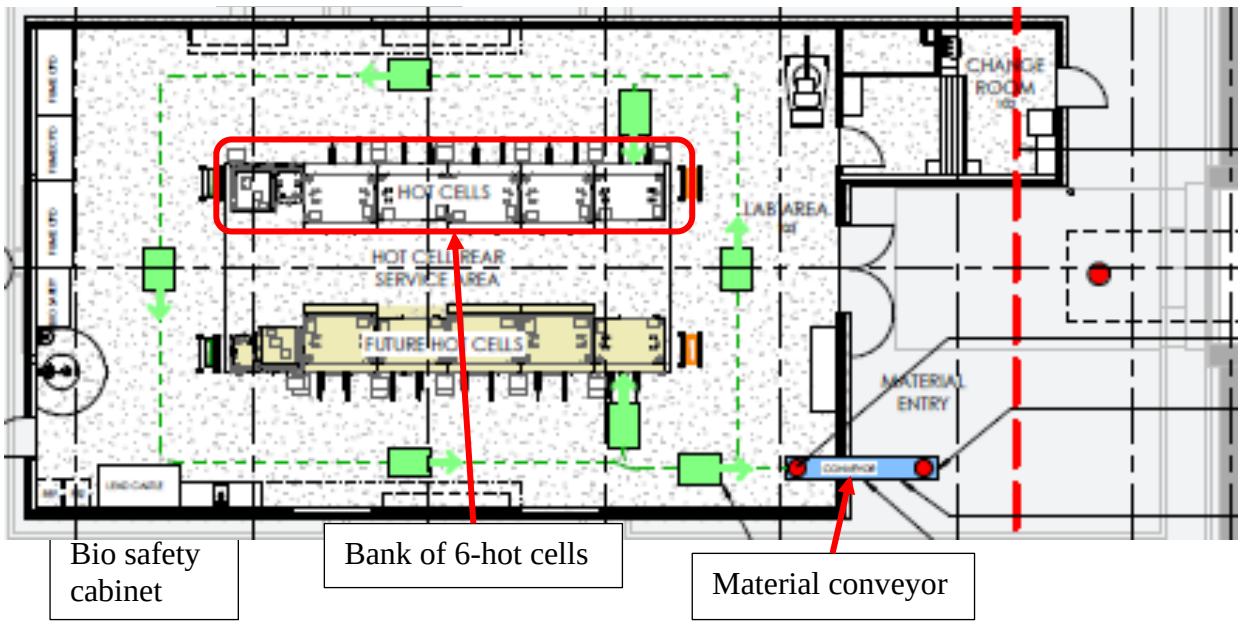


Figure 3: Layout of the Secondary Containment with proposed location of equipment.

The Secondary Containment allows for the testing of the following radioisotopes:

- Lutetium 177 (Lu-177)
- Iodine 131 (I-131)

- Molybdenum-99/Technetium 99m (Mo-99/Tc-99m)

The Table 1 below contains the major radioactive process/storage equipment used within the Secondary Containment:

Description	Make	Model	Comments
Hot cell	Comecer	MIP1-2P	**I-131 processing hot cell.** Personnel access via the front and rear sliding doors. Capable of fume hood mode. Refer section 6.1 for description of various modes of operation of these hot cells.
Hot cell	Comecer	MIP1-2P	**Mo-99/Tc-99m processing hot cell.** Personnel access via the front and rear sliding doors. Capable of fume hood mode. Refer section 6.1 for description of various modes of operation of these hot cells.
Hot cell	Comecer	MIP1-2P	**Lu-177 processing hot cell.** Personnel access via the front and rear sliding doors. Capable of fume hood mode. Refer section 6.1 for description of various modes of operation of these hot cells.
Hot cell	Comecer	MIP1 1P 1390	**Receiving hot cell.** Can only be accessed from the front via sliding door. This hot cell will receive radioactive targets in D(U) container. An electric hoist will be installed in the hot cell to enable extraction of Inner Product Container (IPC).
Hot cell	Comecer	MIP1 1P 1390	**Waste hot cell.** This hot cell will be used to store any remote handled solid waste which requires further decay in a hot cell. As result, this cell will not be accessible by personnel. Refer to Waste Management Strategy [Ref: (9)] for further information for remote handled solid waste.
Hot cell	Comecer	BBST PC	**Dispensing Hot cell.** This hot cell will be used to dispense Iodine produced in the Iodine hot cell, for further testing and experimentation. This hot cell contains a pre-chamber where reagents and chemicals can be stored and passed through internally via an existing internal transfer hatch.
Shielded fume cupboards (3 off)	Dynaflow	2000GRP x2 1500GRP x1	The shielded fume cupboards will be used for QC testing of radioisotopes produced in the 2P hot cells (lu-177, I-131 and Mo-99/Tc-99m).
Bio Safety Cabinet	Euroclone	Safe Mate Eco 1.2	This bio safety cabinet will be used for non-radioactive and/or tracer level testing.
Waste management equipment	N/A	N/A	**Liquid waste.** Bottles/tanks to store remote handled liquid waste generated from activity conducted in Secondary Containment. Location within Secondary Containment to be confirmed. **Solid waste.** Lead castle to store solid waste generated from activity conducted within Secondary Containment. Location within Secondary Containment to be confirmed
Chemical storage cabinets	Various	Various	There are three chemical storage cabinets installed in the Secondary Containment: 1. Storage cabinet for acids. 2. Storage cabinet for bases. 3. Storage cabinet for flammable/dangerous goods.
Tele manipulators	TBC	TBC	5 pairs of tele manipulators (manips) will be installed one for each of the following hot cells: - 3x MIP1-2P hot cells - 2x MIP1 1P 1390 hot cells. NOTE: no manips will be installed for the BBST PC hot cell.

Table 1 Major equipment used within the Secondary Containment

4.5. Wet Chemical Lab

The Wet Chemical Lab is a non-radioactive (white) zone which is primarily used for preparation (decanting, dilution etc.) of reagents and chemicals to be used within the Secondary Containment. This lab will be located in Room 23 of Building 22. The Wet Chemical Lab will contain the following major equipment:

Description	Make	Model	Comments
Unshielded fume cupboard (1 off)	Dynflow	1200GRP	The fume cupboard is located in the Wet Chemical Lab and is not used for handling or storing of any radioisotopes.
Chemical storage cabinets	Various	Various	There are three chemical storage cabinets installed in the wet chemical lab: 1. Storage cabinet for acids. 2. Storage cabinet for bases. 3. Storage cabinet for flammable/dangerous goods.

Table 2 Wet Chemical Lab

4.6. Transition Zone

The transition zone is a non-radioactive (white zone). The primary purpose of this space is for the receipt of radioactive radioisotopes in B(U) or Type A containers, staging of empty (no radioisotopes) B(U) or Type A containers to be returned, and storage of any lifting aids (i.e. straps, slings etc.).

The process of receipting containers is as follows:

1. Delivery vehicle enters via the truck bay located to the east of the building. The truck bay door is closed prior to removing any straps securing the load on to the vehicle. Once the door is closed, remove any straps securing the load to the vehicle.
2. **For type B(U) containers:** move the building gantry crane and lower the hook into position. Sling the load to the gantry crane hook using the lifting aids. Move the container onto the conveyor at the transition zone. Remove all straps/slings from the gantry crane hook and the container and move the container inside the secondary containment.
   NOTE: ensure all WHS/OH&S protocols are followed during the movement of the load from the delivery vehicle to the conveyor.
3. **For type A containers:** manually lift the container from the delivery vehicle and load on to the conveyor.

The process of returning empty B(U) and Druce Pot containers is as follows:

Transfer the cleared container out of the secondary containment via the conveyor.

1. **For type B(U) container:**
   a. Use the building overhead gantry crane to lift the container off the conveyor and place on the floor of the transition zone until the incoming container is transferred into the secondary containment.
2. Lift the container onto the delivery vehicle and secure with straps.
3. **For type A container:**
   a. Manually lift the container from the conveyor and place on the delivery vehicle.
4. Open the truck bay door and allow the vehicle to exit before closing the truck bay door.

4.7. Internal Plant room

The plant room contains Active Ventilation System (AVS) filters (HEPA and Carbon Filters) along with exhaust fans. In normal operation, this room is classified as a white zone (that is, no radioactive contamination) and is classified as a blue zone during routine filter changes and during any other maintenance activity that would potentially generate radioactive contamination. This plant room will be located in Rooms 24 and 25 of Building 22.

4.8. Change Room

All personnel movement to the Secondary Containment (entering and exiting) is via the Change Room. Refer to Section 4.8 for further information.

4.9. External Plant room

The external plant room contains equipment that is used to supply conditioned outside air into the Secondary Containment. This includes the following equipment:

- Air Handling Unit (AHU)
  - Pre and final filters
  - Supply fans
  - Heating and cooling coils
- Heat pump
  - Supply heating and cooling to the coils in the AHU.

5. Operational Limits

Table 3 below shows the max radioactivity design limit for this facility.

Radioisotope	Description	Max Radioactivity (GBq)
Mo-99	Supplied by Building 88	500GBq
Lu-177	1.25g High Flux Target, repackaged and supplied by Building 23*	1500GBq (EOI* + 48 hours)
I-131	85g Target repackaged and supplied by B23**	400GBq (EOI* + 48 hours)

Table 3 Max target radioactivity limit for NMTD

* EOI – End of Irradiation

Table 4 below defines the operational limits in terms of frequency and radioactivity level for this facility for targets brought in via Type B(U) containers. It is assumed this facility will operate 40 weeks per year.

Table 4: Operational limits and frequencies for targets received from Type B(U) container.

Radioisotope	Activity (GBq)	Frequency
Mo-99/Tc-99m	500	5 weeks per year
	300	35 weeks per year
Lu-177	1500*	5 weeks per year
	200	10 weeks per year
	100	25 weeks per year
I-131	397*	10 weeks per year
	200	20 weeks per year
	100	10 weeks per year

Table 5: Operational limits and frequencies for targets received from Type A containers.

Radioisotope	Activity	Pot	Volume	Frequency (annual)
Lu-177	10-80GBq*	12mm Medi-Ray pot in cimpatible box	0.5mL	20 times per year
I-131	≤185GBq* @ calibration	Druce Pot in a compatible transport container	~8mL	20 times per year (may replace the delivery of a tellurium targets – table 4)
I-131	≤16GBq @ calibration	12mm or 19mm Medi-Ray Pot in a compatible box	~8mL	20 times per year
I-131	≤16 GBq	12mm or 19mm Medi-Ray Pot in a compatible box	variable – up to 8 mL (23 GBq/mL)	20 times per year
I-131 capsule	3 – 6 GBq	19mm Medi-Ray Pot in a compatible box	60 - 120 µL (approx. 50 GBq/mL) in a capsule	20 times per year
I-131 capsule	401 MBq – 2.99 GBq	12mm Medi-Ray Pot in a compatible box	80 - 100 µL (approx. 5 GBq/mL) or 20 - 60 µL (approx. 50 GBq/mL In a capsule	20 times per year
I-131	≤400 MBq	6 mm lead pot in bucket	Approx. 20 - 80 µL (approx. 5 GBq/mL) in a capsule	20 times per year

* Work involving Lu-177 @80GBq or I-131 @185GBq will not occur simultaneously with work involving Lu-177 @1500GBq or I-131 @397GBq.

Note:

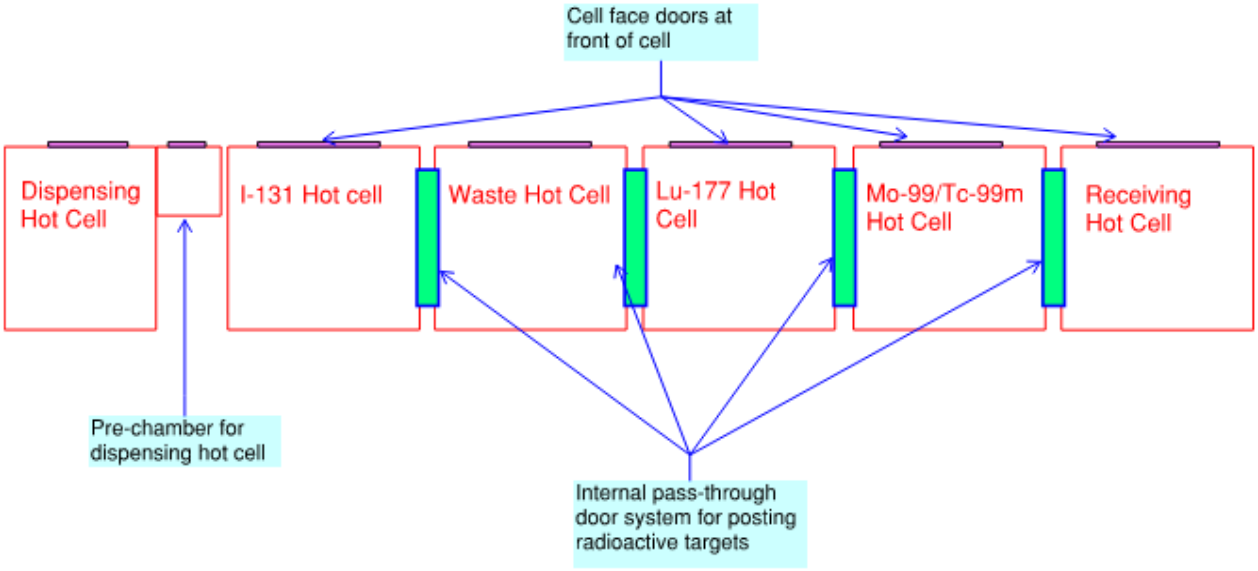
- It is expected that no more than one radioactive target packed in B(U) type container for each radioisotope, will be received and processed each week. However, the various radioisotopes (Mo/Tc-99m, Lu-177, I-131 and [^{131}I]MIBG) can be expected to be in the facility at the same time. It is also possible that smaller amounts of Lu-177 or I-131 may be received in a type A container in the same week as a larger B(U) package. However, total levels of radioacitivity will not exceed those listed in table 4 in any given week.

6. Hot Cells

One (1) bank of 6 hot cells will be installed in this facility (refer to Table 1 for information on the hot cells to be installed). The hot cells will be organised as follows:

- Receiving hot cell
- Mo-99/Tc-99m hot cell
- Lu-177 hot cell
- Waste hot cell.
- I-131 hot cell
- Dispensing hot cell

See Figure 4 and Figure 5 below for the layout of these hot cells including a cut-away view of the internal transfer hatch feature.



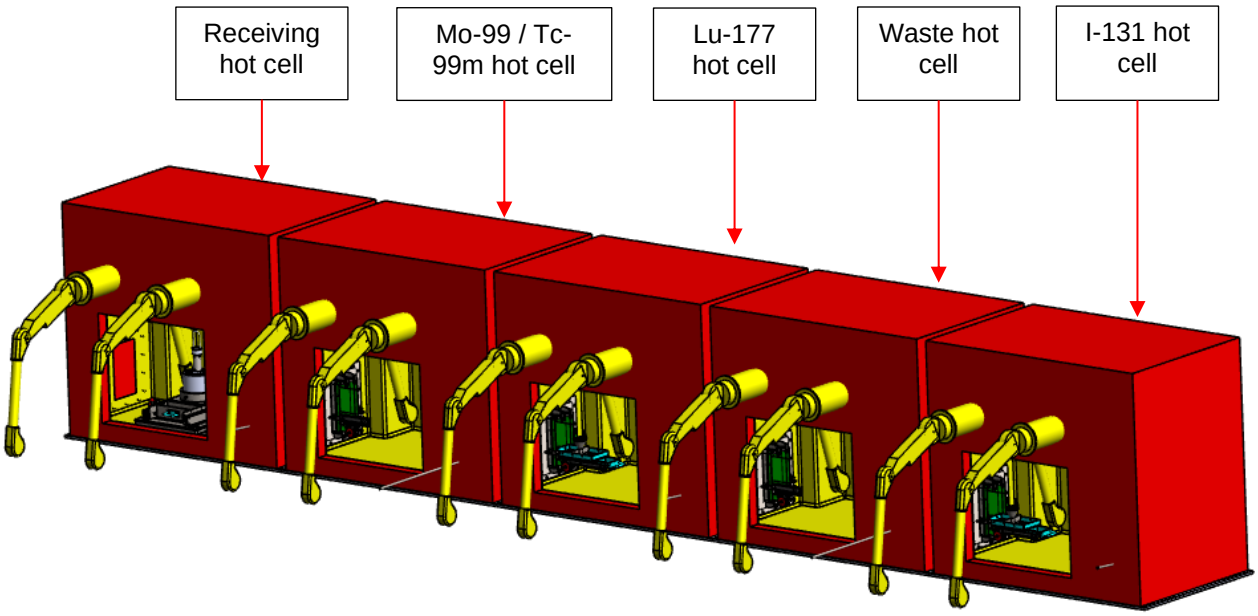


Figure 4: Cell layout and schematic.

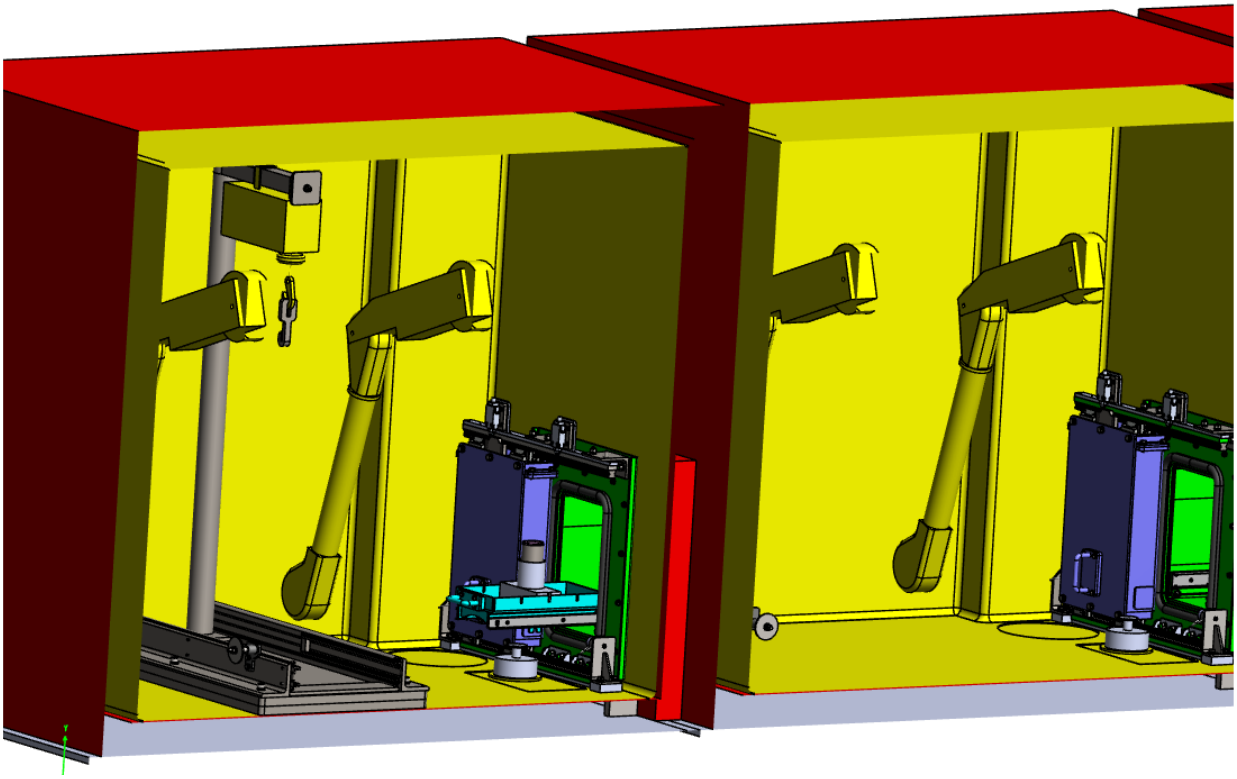


Figure 5: A cut-away view showing the internal transfer hatch feature of the receiving hot cell

6.1. Hot cell modes of operation

The following modes of operation are available to these hot cells:

1. MIP1-2P
    a. Normal Operation
        i. This mode of operation is when the hot cell is operating as an isolator (i.e. low exhaust flow rate and high differential pressure).
    b. Fume Hood Operation
        i. This mode enables the hot cell to operate as a fume cupboard (i.e. maintaining 0.5m/s face velocity). In this mode of operation, there will be a high exhaust flow rate with a minimal (negligible) differential pressure between the hot cell and surrounding.
2. MIP1 1P 1390
    a. Normal Operation
        i. Similar to the Normal Operation mode in MIP1-2P
3. BBST PC
    a. Normal Operation
        i. Similar to the Normal Operation mode in MIP1-2P

For further information, please refer to Hot Cell Functional Description (NMTD-1520-SP-0001)

7. Material Movement

The Table 6 below shows all material movement into and out of the Secondary Containment:

Description	Entry location
Material movement *into* the Secondary Containment	
Radioactive targets: - High level radioactive targets are brought in B(U) container*. - Low level radioactive targets are brought in Type A container: ○ [^{177}Lu] Lutetium Chloride (10-80 GBq) – 12mm Medi-Ray Pot in a compatible box. ○ [^{131}I] Stabilised and Unstabilised Solution (up to 185 GBq @ calibration) – Druce Pot in a compatible transport container. ○ [^{131}I] Stabilised and Unstabilised Solution (up to 16 GBq @ calibration) - 19mm Medi-Ray Pot in a compatible box. (12 mm Medi-Ray for ≤2.99 GBq, 6 mm Medi-Ray pot for ≤400 MBq). ○ [^{131}I] Capsules: ▪ Up to 400 MBq: 6mm lead pot in a bucket (inner and outer packaging as per ANSTO/082). ▪ 401 MBq – 2.99 GBq: 12mm Medi-Ray Pot in a compatible box. ▪ 3 - 6 GBq: 19mm Medi-Ray Pot in a compatible box.	Entry via the conveyor.
Chemicals and Reagents	Entry via the material entry doors.
Laboratory Consumables (i.e. pipettes, syringes etc.)	Entry via the material entry doors.
PPE (gloves, safety glasses etc.)	Change Room
Clean Laundry	Change Room
New laboratory equipment/spare parts (i.e. bench top scale, radiation monitor etc.)	Change Room (for smaller equipment) or Material entry doors (for larger equipment)
Material movement *out of* the Secondary Containment	
Empty target containers: - B(U) containers - Type A containers (Druce Pot)	Exit via the conveyor
Waste: - Radioactive waste - Non-radioactive waste - Used Laundry - Other non-typical waste (i.e. broken equipment, used equipment spares etc.)	Refer to Waste Management Strategy (NMTD-0010-PM-0010) [Ref (9)] for more information

Table 6 Material movement for Secondary Containment

*** NOTE:** All Mo-99/Tc-99m targets (high scale and low scale targets) will be delivered by Type B(U) container.

Note: All material movement into and out of the Wet Chemical Lab is considered non-critical, since all material are non-radioactive. Material movement into and out of the Wet Chemical Lab is via the main entry into the Wet Chemical Lab.

All non-radioactive material movements (all material except radioactive targets and their containers) into the Secondary Containment are considered non-critical and can be transported using following good WHS and OH&S practice on suitable trolleys.

Refer to Process Flow Diagrams:

- NMTD-1524-DW-0001 for I-131 [Ref (11)].
- NMTD-1524-DW-0002 Lu-177 [Ref (12)].
- NMTD-1524-DW-0003 Mo-99/Tc-99m [Ref (13)].

Radioactive material movement within the secondary containment can either be using B(U) containers or Type A container.

7.1. Movement Using B(U) Container

Following the movement of B(U) into the secondary containment, (refer to Section 4.6), the following procedure will be used:

1. Remove the lid from the B(U) container and extract the D(U) container using the mobile crane.
2. Lift the D(U), using the mobile crane and transfer it into the Receiving Hot Cell.
3. Open the front of the hot cell and manually retrieve the sliding tray.
4. Lift the D(U) container and carefully load the D(U) container onto the tray.
5. With the tray extended out, loosen and remove all bolts from the D(U) container lid, while keeping the lid on the D(U).
6. Twist the lid of the D(U) to ensure the hoist can safely lift the lid.
7. Attach the lifting aid onto the D(U) lid.
8. Slide the tray into the hot cell and close the front door. Lower the hoist hook and, using the manipulators, latch the hook to the D(U) lid.
9. Lift the lid sufficiently using the manipulator. and using the manips and the electromagnetic tool in the hot cell, extract the Inner Product Container (IPC) from the D(U) container. Place the IPC in the correct slot of the internal transfer tray.
10. Using the controls outside, unlock and open the sliding door. Slide the tray with the IPC to the adjacent cell. Close the door once the tray has cleared the internal transfer hatch. [Ref (10)] Refer to Hot Cell Functional Description document NMTD-1520-SP-0001 for further information.

7.2. Movement Using Type A Container

Following the movement of Type (A) container into the secondary containment, (refer to Section 4.6), the following procedure will be used:

1. Open the outer container (i.e. box, bucket, pail etc.) and extract the lead pot manually. This lead pot will then be transferred by the Operator to the Target Receiving Hot Cell.
2. Once at the Receiving Hot Cell, operator will place the lead pot in the sliding tray of the cell. The operator will open the lead pot prior to sliding the tray back into the cell and close the cell door.
3. Use the manips to lift the inner container and place on the inner transfer tray. Once on the transfer tray, transfer this inner container as per normal.
4. If the radioactive target (QC sample) inside the Type A container is less than target concentrations listed in Table 12, these could be introduced directly inside the Shielded Fume cupboard. Note radioisotopes: Tc-99m and Mo-99 will never go directly into shielded fume cupboards even if the target inside the Type A container is less than the concentrations outlined in Table 12 for these radioisotopes.

7.3. Liquid transfer between Iodine and Dispensing Hot Cell

Only liquid is expected to be transferred between Iodine Hot Cell and the dispensing hot cell. For this purpose, a simple liquid transfer pipe is available between the two hot cells (2P Iodine hot cell and the BBST dispensing hot cell). Manual flow control valves will be provided at each end of the liquid transfer line to control the flow rate.

The valves are expected to be operated using the telemanipulators installed in the hot cells.

7.4. Movement of Targets Out of Facility

Procedure for movement of radioactive targets *out of* the facility is as follows:

7.4.1. Retrieving IPC/D(U) Containers from the Receiving Hot Cell

1. Prior to retrieving container from the Receiving Hot Cell (i.e. Medi-Ray Pots, Druce Pots, GenTec generators D(U) containers etc.), remotely swab the exterior of the container and verify the container is free from contamination.
2. Unlock and open the inner transfer door of the receiving hot cell and retrieve the IPC.

   Note: If the IPC contained a Molly Product Bottle (MPB), ensure this MPB is in the IPC it arrived in, prior to transferring the IPC to the receiving hot cell. For the other two radioisotopes (i.e. Lu-177 and I-131), there is no MPB and only IPC is retrieved. It is important that the MPB is placed in the IPC that it arrived in as these two containers are tracked together.
3. Using the manipulators and the electromagnetic tool, retrieve the IPC from the transfer tray and place in the D(U) container.
4. Lower the lid of the D(U) on to the D(U) container. Disconnect the hoist and lift out of the way prior to opening the front of the hot cell.
5. With the receiving hot cell door open, retrieve the tray, swab the lid using reaching tools to check for contamination on the lid, if free of contamination twist close the lid closed, fasten all bolts to the lid and remove the lifting aid.
6. Using the mobile crane, lift the D(U) container out of the tray and transfer to the bench at the conveyor.
7. Carefully place the D(U) in the B(U) container including all the inserts and fasten all the bolts of the B(U) container.
   NOTE: Similar to the IPC and MPB pairing, the ensure the correct D(U) is placed in the correct B(U) as these two containers are tracked together.
8. Ensure that all inner containers are inside the B(U):
   a. For B(U) container this involves:
      i. Product vial (only applicable for Mo-99/Tc-99m)
      ii. Inner Product Container (IPC)
      iii. D(U)
      iv. B(U) outer container
9. Contact Health Physics Surveyor to survey and verify the B(U) container is free from contamination. After clearance has been granted for the B(U), place the B(U) container in the conveyor and transfer to the Transition zone outside the Secondary Containment.
10. Refer to Section 4.3 for material movement out of the Secondary Containment.

7.4.2. Retrieving Medi-Ray Pots and Druce Pots from The Receiving Hot Cell

1. Ensure that all inner containers are inside the Type A container:
    a. For Type A containers, this involves:
        i. Lead pots (6 mm, Medi-Ray Pot, 12mm Medi-Ray Pot, 19mm Medi-Ray Pots) OR Druce Pots.
        ii. Druce pots to be transported in approved outer containers.
2. Operator to open the Receiving Hot Cell and do a swipe test to check for contamination prior to retrieving the Medi-Ray or Druce pot from the tray.
3. Once confirmed the pot is free of contamination, place the pot on the trolley and fasten the lid.
4. Transfer the pot to the storage rack for re-use for Medi-Ray pots. For Druce pots, place in the approved transport container.
5. Contact Health Physics Surveyor to survey and verify the outer container is free from contamination. After clearance has been granted, place the container with the empty Druce Pot in the conveyor and transfer to the Transition zone outside the Secondary Containment.
6. Refer to Section 4.3 for material movement out of the Secondary Containment.

7.4.3. Procedure For Retrieving Gentec Generators Out of The Facility

The procedure for retrieving Gentec Generators out of the of the receiving hot cell is described in Figure 6.

Once all testing has been completed, Gentec generators will be placed in the designated storage area for decay.

Once the generators have been decayed, remove the Core Unit (Generator Core Unit) from the decayed generator and placed in the shielded waste bin. The generator casing and the shielding will remain in the Secondary Containment to be used again. The Core Unit will be discarded in one of the shielded waste bins. Refer to Waste Management Strategy (NMTD-0010-PM-0010).

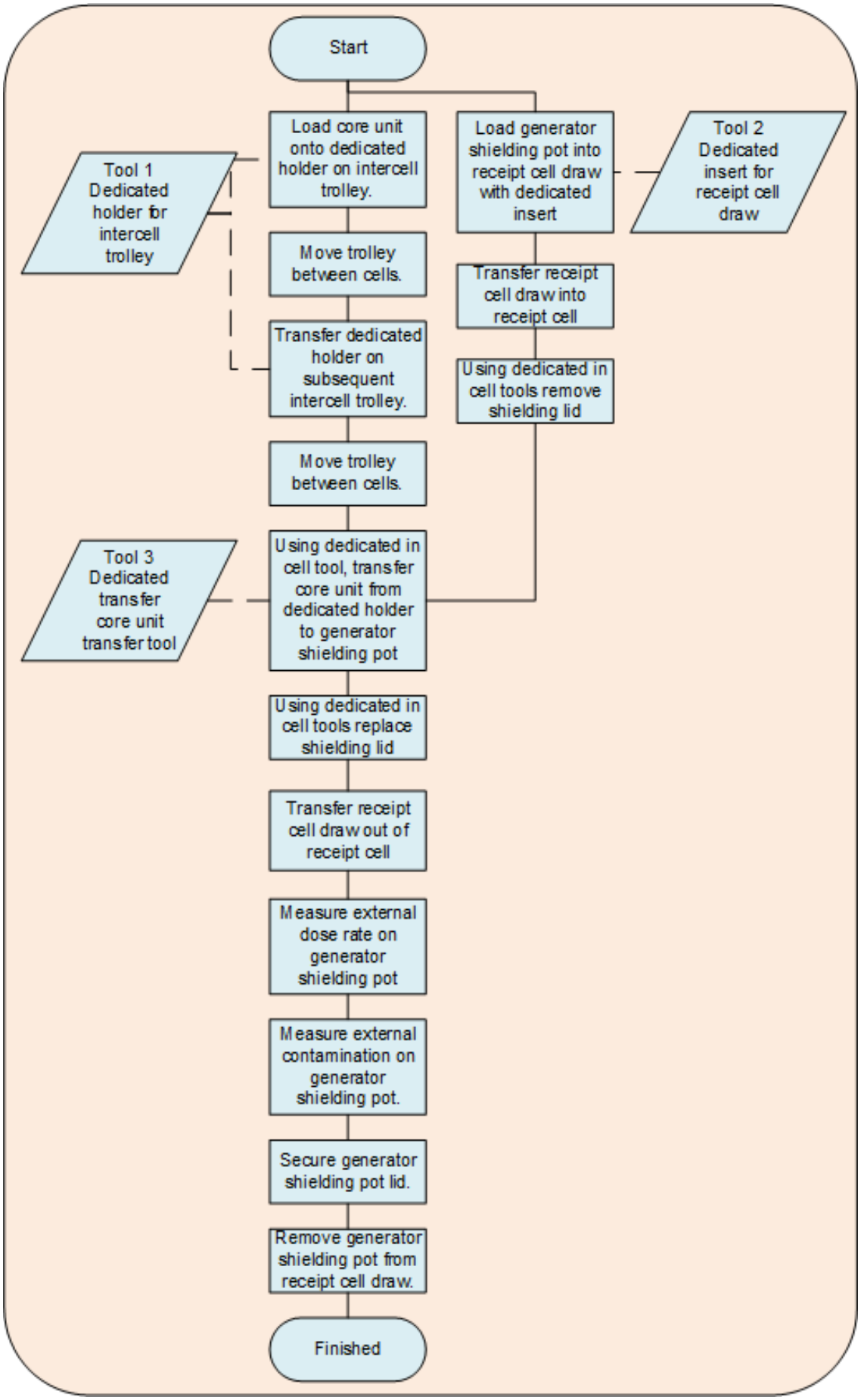


Figure 6: Flow chart for retrieval of the Gentec generators.

8. Personnel movement

Entry and exit from the Secondary Containment is via the Change Room provide. This change room contains the following:

- 2x sinks, one in the white zone (non-contaminated side of the change room) and one sink in the blue zone (contaminated side of the change room).
- Decontamination shower in the blue side of the change room
- Hand and foot monitor in the white zone of the change room.
- 2x frisking monitors one in the white zone and one in the blue zone of the change room.
- Bins for used laundry, storage space for clean laundry and space for laundry that is currently being used.
- Storage space for PPE (i.e. safety glasses) along with hair nets and beard masks.

Personnel and material entry into the Wet Chemical Lab is via the main door to the Wet Chemical Lab. This lab will contain space to hold in-use lab coats and for appropriate PPE (i.e. safety glasses).

9. Hot Cell Entry via Front Door of Cell

Following hot cells are considered critical due to potential contamination and radioactivity present as a result of the activity conducted within the hot cell:

- I-131 hot cell
- Mo-99/Tc-99m hot cell
- Lu-177 hot cell
- Dispensing hot cell

Following Hot Cell Entry protocol is to be followed when opening front or rear doors of the hot cells mentioned above:

1. Remove Radioactive Sources: Transfer any radioactive sources out of the hot cell, either to the waste hot cell, lead castle, or waste operations.
2. Surface Cleaning: Use manipulators to clean the surfaces of the cell, which may involve lint-free cloths or paper towels and water or other solvent. Contaminated materials should be placed in a solid waste container, such as a paint can.
3. Dose Rate Check: Use a dose rate meter to verify if the dose within the hot cell is low enough to allow the lead door to be lowered, leaving the Perspex window with gloves exposed (contamination remains contained). The acceptable dose rate should be 5µSv/hr or less prior to lowering the shield.
4. Contamination Monitoring: Place a contamination monitor in a glove and check for areas of maximum radioactive contamination within the cell.
5. Further Cleaning: Use gloves to continue cleaning areas of gross decontamination, disposing of cloths, paper towels, or other waste in solid waste containers.
6. Recheck Contamination Levels: Measure the dose rate via the gloves again or insert a probe into the hot cell to check contamination levels.
7. Repeat Cleaning: Continue the cleanup process until the contamination risk is deemed reasonable (specific criteria for this determination need to be established).
8. Final Steps: Once contamination is reduced to an acceptable level, the Perspex shield can be safely removed. Repeat steps 3 –7 above for proper understanding of beta-contamination (e,g, Lu-177) and further remote decontamination.

The processing hot cells (I-131, Lu-177 and Mo-99/Tc-99m hot cells) and dispensing hot cell entry will only be to reconfigure experimentation setup only. It is expected that frequency of hot cell entry via front/rear door for the hot cells mentioned above will be no more than 9 times a year.

9. Process Overview

This demonstration facility is used to test the following radioisotopes:

- Iodine 131 (I-131)
- Technetium 99 (TC-99m) generators
- Lutetium 177 (Lu-177)
- Iodine-131 meta-iodo-benzyl-guanidine ([^{131}I]MIBG)

Table 3 and **Error! Reference source not found.** indicate the maximum radioactivity per radioisotope and the operational limits for the facility.

It is expected that all these operations will be carried out by 2 – 3 individuals per process to mitigate operator fatigue, facilitate note taking and data collection, and where necessary to share radiation dose.

9.1. Technetium-99m Generators Process

Tc-99m is produced in a generator through the radioactive decay of its precursor, Mo-99. At ANSTO's OPAL reactor, Mo-99 is generated by irradiating U-235 targets, later processed at ANSTO's ANM facility to extract the Mo-99.

The generator employs an alumina column where Mo-99 adsorbs. As this parent isotope undergoes decay, it transforms into Tc-99m, which is extracted from the column using a saline solution, leaving the Mo-99 behind. This selective separation is achieved due to the different affinities of these metals for the alumina solid phase.

ANSTO is undertaking a redesign of its Tc-99m generator, introducing significant modifications to the materials used and method of assembly. These changes include engaging an external provider to pack alumina into a column body with rigid fluidic lines, known as the Core Unit. This unit will be sterilised by the provider before delivery to ANSTO. In contrast, the current process at ANSTO involves packing alumina into glass column bodies and utilising flexible plastic lines.

The revamped approach aims to enhance elution efficiency and alleviate Mo-99 and alumina break through from the column as well as allow for safe, rapid, and automated production of the generator in the NMMF.

These changes need to be tested for various aspects of performance and it is this testing, along with other process and equipment parameters, that will be tested in NMTD.

There are two general scenarios to capture the frequency and radioactivity levels for these operations:

- Lower scale radioactive work: Using less than 300 GBq per week to load an average of 10 FCUs per week (approximately 30 GBq per FCU). This will require enough generator housings to permit at least three weeks of storage and elution (i.e., a minimum of 30 generator housings).
- Higher scale radioactive work: Using up to 500 GBq per week to load up to one FCU.

Chemical Name [CAS number]	GHS Classifications	DG Class	Approx. Volume Stored	Volume Used (weekly)	Storage Location
Nitric acid (14 M) [7697-37-2]	Oxidizing Liquids: Cat 3 Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage/Eye Irritation: Cat 1 Acute Toxicity: Inhalation: Cat 3	8 (Acid)	5 L	1 L	Wet Chem Lab
Nitric acid (0.001 M, 2 M) [7697-37-2]	Oxidizing Liquids: Cat 3 Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage/Eye Irritation: Cat 1 Acute Toxicity: Inhalation: Cat 3	8 (Acid)	5 L	2.5 L	Secondary Containment

Chemical Name [CAS number]	GHS Classifications	DG Class	Approx. Volume Stored	Volume Used (weekly)	Storage Location
Sodium hydroxide (solid) [1310-73-2]	Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Base)	1 kg	0.1 kg	Wet Chem Lab
Sodium hydroxide (1 M) [1310-73-2]	Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Base)	2 L	0.5 L	Secondary Containment
Ethanol (96 - 100 %) [64-17-5]	Flammable Liquids: Cat 2 Serious Eye Damage / Eye Irritation: Cat 2A Specific Target Organ Toxicity (Single Exposure): Cat 2	3 (Flammable)	5 L	2 L	Secondary Containment
Isopropanol [67-63-0]	Flammable Liquids: Cat 2 Serious Eye Damage / Eye Irritation: Cat 2A Specific Target Organ Toxicity (Single Exposure): Cat 3 (Narcotic Effects)	3 (Flammable)	5 L	2 L	Secondary Containment
Hydrogen peroxide, 50 % [7722-84-1]	Acute toxicity, Oral: Cat 4 Skin corrosion/irritation: Cat 2 Serious eye damage/eye Irritation: Cat 1 Specific target organ toxicity (Single Exposure): Cat 3 (Respiratory system)	5 (Oxidising)	2.5 L	0.2 L	Secondary Containment
Sodium chloride (solid) [7647-14-5]	None	No class	5 kg	0.5 kg	Secondary Containment
Saline (0.9 %) [7647-14-5]	None	No class	10 L	5 L	Secondary Containment
Sodium molybdate (solid) [7631-95-0]	None	No class	0.5 kg	0.05 kg	Secondary Containment
Quaternary ammonium salts [Various]	Various	No class	1 kg	0.1 kg	Secondary Containment

Table 7 Chemicals used in the Tc-99m Generator process

9.1.1. Target containers

Mo-99 will arrive as sodium molybdate, via Type B(U) container (for all target sizes). The B(U) will be received into the Secondary Containment via the conveyor, and D(U) will be received into the Target Receiving hot cell. The MPB ('Molly Product Bottle') will be transferred using the pass-through system to the Mo-99/Tc-99m hot cell.

9.1.2. Tc-99m process overview

1. The FCUs, generator housing and reagents will be moved into the Mo-99/Tc-99m hot cell in preparation for loading. A specially designed remote filling module will be employed to condition the FCU/s with nitric acid.
2. The consumables, reagents, and other single use materials (maximum size 2 L) are loaded into the receiving hot cell and then transferred to the Mo-99/Tc-99m hot cell through the internal doors with sliding trays using tele-manipulators.
3. The MPB will be opened in Mo-99/Tc-99m hot cell using in-cell tools. The solution will then be sucked into another vessel for pH adjustment.
4. The remote filling module will be employed to extract the now acidic Mo-99 solution, either through a needle or a dip tube, and load it onto the preconditioned FCUs.
5. The remote filling module will be used to wash the FCU with up to 200 mL of 0.9 % saline. After the wash, the FCU will be disconnected from the filling module and safely removed in a fully shielded generator (18kg). Refer to Figure 6 above for safe removal of the generator from the Receiving hot cell.
6. The generator will subsequently be relocated either to the shielded fume hood within the NMTD or, preferably, to the building 76 for ongoing generator elution testing.
7. Samples (10mL) will be collected in glass vials and transferred through the hot cell drawing system into Tungsten pots. These samples will then be transferred to either the NMTD shielded fume hood or the lead castle. Depending on the needs, these samples may be utilised as is or repackaged into other lead pots (Type A container), allowing for the reuse of Tungsten pots.
8. Type A container will be used for the movement of QC samples across site for analysis such as gamma spectrometry, ICPMS, particle counting, etc.

9.1.3. Waste

On average, it is expected that 75% of the radioactivity from the radiochemical solution (Mo-99/Tc-99m solution) will be from the generators and 25% radioactive will be form the liquid waste.

Liquid Waste: It is expected that the loading of each FCU will generate up to 200 mL of liquid waste. This waste is expected to be radioactive and mildly acidic (primarily saline and dilute nitric acid.)

The liquid waste is transferred from the Mo-99/Tc-99m hot cell into a 40L capacity tank. Once at capacity, this tank is decayed for a period of time and transferred to Waste Management Services. Refer to Waste Management Strategy (NMTD-0010-PM-0010) [Ref (9)] for more information.

Solid waste: will consist of absorbent materials, vials, plastic films and more (TBD) and will be collected in 2L tins before being closed and moved to the waste hot cell for decay.

The Tc-99m generators (including the radioactive Core Unit) assembled during testing will be left to decay within the lead castle provided. Once the generators are sufficiently decayed, the generators will be transferred to Building 23 to be recycled. Refer to Waste Management Strategy (NMTD-0010-PM-0010) [Ref (9)] for more information.

9.2. Lutetium-177 process

The production of specific high activity Lu-177 at ANSTO involves a series of steps. It commences with the irradiation of an enriched stable [176Yb] Ytterbium Oxide target. The target material is weighed into a silica ampoule which is then sealed and encased in aluminium foil. This tube is then arranged into a series of cans, ready for the subsequent irradiation in ANSTO's OPAL reactor.

During irradiation, Yb-176 captures neutrons forming Yb-177, which undergoes beta decay, to give Lu-177. Post-irradiation, the target is transported to building 23 for de-canning and repackaging.

The final step involves the use of a chromatographic separation of Lu-177 from the irradiated target material and other isotopes generated during the process.

The maximum radioactivity level expected to be used in the process is approximately 1.5 TBq. It is expected that $LuCl_3$ solution will be used no more than 20 times a year and no more than once per week.

Chemical Name [CAS number]	GHS Classifications	DG Class	Approx. Volume Stored	Volume Used (weekly)	Storage Location
α-hydroxyisobutyric acid (HIBA) 0.1M [594-61-6]	Skin Corrosion/Irritation: Cat 2 Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Acid)	10 L	10 L	Secondary Containment
α-hydroxyisobutyric acid (HIBA) 1M [594-61-6]	Skin Corrosion/Irritation: Cat 2 Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Acid)	10 L	10 L	Secondary Containment
α-hydroxyisobutyric acid (HIBA) (solid) [594-61-6]	Skin Corrosion/Irritation: Cat 2 Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Acid)	20 kg	1 kg	Wet Chem Lab
Hydrochloric acid (10 – 12 M) [7647-01-0]	Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Acid)	5 L	1 L	Wet Chem Lab
Hydrochloric acid (2 M) [7647-01-0]	Corrosive to Metals: Cat Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Acid)	1 L	1 L	Secondary Containment
Hydrochloric acid (0.4 M) [7647-01-0]	Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Acid)	0.5 L	0.5 L	Secondary Containment
Nitric acid (14 M) [7697-37-2]	Oxidizing Liquids: Cat 3 Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage/Eye Irritation: Cat 1 Acute Toxicity: Inhalation: Cat 3	8 (Acid)	1 L	0.25 L	Wet Chem Lab

Chemical Name [CAS number]	GHS Classifications	DG Class	Approx. Volume Stored	Volume Used (weekly)	Storage Location
Nitric acid (10 M) [7697-37-2]	Oxidizing Liquids: Cat 3 Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage/Eye Irritation: Cat 1 Acute Toxicity: Inhalation: Cat 3	8 (Acid)	1 L	0.5 L	Secondary Containment
Methanol (99 %) [67-56-1]	Flammable Liquids: Cat 2 Acute Toxicity: Oral: Cat 3 Acute Toxicity: Skin: Cat 3 Acute Toxicity: Inhalation: Cat 3 Specific Target Organ Toxicity (Single Exposure): Cat 1	3 (Flammable)	5 L	0.25 L	Wet Chem Lab
Ethanol (96 - 100 %) [64-17-5]	Flammable Liquids: Cat 2 Serious Eye Damage / Eye Irritation: Cat 2A Specific Target Organ Toxicity (Single Exposure): Cat 2	3 (Flammable)	5 L	1 L	Wet Chem Lab
Sodium hydroxide [1310-73-2]	Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3(Respiratory Irritation)	8 (Base)	1 kg	0.1 kg	Wet Chem Lab
Ytterbium oxide [1314-37-0]	None	No class	50 g	1g	Wet Chem Lab
Lutetium oxide [12032-20-1]	None	No class	50 g	1g	Wet Chem Lab
Ammonium chloride (0.1 M) [12125-02-9]	Acute Toxicity: Oral: Cat 4 Serious Eye Damage / Eye Irritation: Cat 2A	No class	0	0	Secondary Containment

Table 8 Chemicals used in the Lutetium process

9.2.1. Target Containers

The irradiated target material (up to approximately 1g) will be transported using a type B(U) container. This is used for higher scale work (i.e. > 100GBq)

For lower scale work (up to 100GBq), $LuCl_3$ solution will be used. This solution will be transported to Technology Demonstration Facility in existing approved type A container (ANSTO/073 container).

9.2.2. Lutetium process overview

1. Upon arrival at the Lu-177 hot cell, specialized manipulators and/or tools (TBD) will be utilised to open the internal container holding the irradiated ampoule (still wrapped in aluminium foil). The contents will be carefully poured into a 50 mL falcon tube, followed by the addition of 4 M HCl to fully immerse the ampoule. Once the aluminium foil dissolves, the HCl solution will be carefully transferred to a separate vessel, potentially allowing for a QC sample collection at this stage.

2. The consumables, reagents, and other single use materials are loaded into the receiving hot cell and then transferred to the Lu-177 hot cell through the internal doors with sliding trays using tele-manipulators. Acidic solutions are pumped from outside the hot cell for column purification, elution and washing.
3. Subsequently, the ampoule undergoes a thorough cleansing process involving multiple washes: water, 1 M NaOH, water, 3 M HCl, water, and finally methanol, before being left to air-dry. The dried ampoule is then moved into a purpose-built ampoule crushing device.
4. The ampoule crushing device will be a robust plastic tube, carefully designed to accommodate the ampoule's size. It will be sealed with friction-fitted filters at both ends to secure the ampoule inside. This setup will be connected to fluidic lines linked to a peristaltic pump.
5. Once properly secured, the tube will undergo compression using a vice to crush the ampoule. Once the vice is released the passage of 10 M nitric acid through the fluidic lines and over the mixture of crushed ampoule and powder (ytterbium/lutetium oxide) will initiate dissolution. The resulting solution will be carefully transferred to a ~100 mL Schott bottle leaving the crushed ampoule in the tube. Subsequently, the tube and lines will be thoroughly cleansed by repeating the process.
6. To finalise the transformation, the solution containing the dissolved components will be subjected to heat to convert the lutetium into the nitrate salt form in preparation for chromatographic separation.
7. The purification of Lu-177 from the target material and other radionuclides will be achieved via the use of chromatographic separation. The digested target will be pumped, using an HPLC pump, over 1 – 3 columns containing a strong cationic exchange resin. The elution of the product will be controlled by varying concentrations of HIBA, with the final stage elution requiring dilute HCl.
8. The volumes of HIBA required will be too large to have these inside the cell so it is anticipated that both HIBA and HCl will be pumped from a pumping station outside of the hot cell. The fluidic lines will be fitted with non-return valves to prevent radioactive liquids coming out of the hot cell.
9. QC samples (approximately 10 GBq or less) are likely to be taken from following steps:
    a. The foil dissolution solution and washings (4 M HCl + radionuclides form by foil irradiation)
    b. The digested target (10 M nitric acid + Lu-177 and ytterbium oxide)
    c. A sample of the elution from the 3-4 columns (HIBA, or dilute HCl)
    d. Washing of the column (1 M HCl)
10. QC analysis will be performed in the secondary containment shielded fume cupboards and/or in another facilities on site.
11. Samples will be collected in 10 mL glass vials and transferred through the hot cell drawing system into tungsten pots. These samples will then be transferred to either the NMTD shielded fume hood or the lead castle. Depending on the needs, these samples may be utilised as is or repackaged into other lead pots, allowing for the reuse of tungsten pots.
12. The exact number of QC samples will vary depending on the factors being tested in each experiment but is likely to range from 5 – 10 samples in total per run.
13. Type A containers will be used for the movement of QC samples across site for analysis such as gamma spectrometry, ICPMS, etc)

9.2.3. Waste

On average, it is expected that 75% of the radioactivity from Lu-177 dispensed into glass vials will be decayed in the lead castle and transferred to Waste Management Services. The remainder of the activity (25% from the Lu-177 dispensed into the glass vial) will be transferred to Liquid Waste on-site (inside the Secondary Containment) and transferred to Waste Management Services after decay.

The Lu-177 purification process will produce four types of waste:

- Liquid waste from general acidic production

- Nitric acid waste
- Solid Waste
- Ytterbium waste.

Acidic liquid waste and Ytterbium are collected in separate containers in Lu 177 hot cell and may be sampled for QC.

It is expected that up to 13 L of liquid waste (acidic waste) will be generated per run and that this will be collected into a 40L capacity shielded tank. Once at capacity, this tank is collected by Waste Management Services team.

The Ytterbium waste (approximately 850mL) is collected separately in liquid waste system. This liquid waste is allowed to be decayed sufficiently prior to transferring to B2 for recycling.

Solid waste: will be collected in a 2L tin container. When full, the container is closed and transferred to the waste hot cell for decay.

It is expected that the empty inner vials containing Lu-177 ampules will be treated as solid waste and decayed in the waste hot cell. Once sufficiently decayed, these will be transferred to Waste Management Services [Ref (9)] .

9.3. Iodine-131 process

At ANSTO, the production of I-131 involves the activation of a stable tellurium ingot through neutron bombardment. This process initiates when tellurium-130 absorbs a neutron, converting into tellurium 131, which subsequently decays into I-131.

The separation of I-131 from tellurium occurs through sublimation, where iodine is transformed from a solid directly into a gas without passing through a liquid phase. This method is employed due to the lower sublimation temperature of iodine relative to tellurium.

Under an inert atmosphere of nitrogen gas, the I-131 is directed into a sodium hydroxide solution, trapping it. This solution is recognised as "unstabilised I-131." To generate "stabilised I-131," sodium thiosulphate is added, reducing the volatility of iodine in the solution.

Iodine capsules are crafted by dispensing a measured quantity of stabilised I-131 into gelatine capsules and sealing them securely.

It is anticipated that the processing of tellurium ingots (maximum activity 397 GBq) will take place no more than once per week and no more than 10 times per year.

It is expected that [^{131}I]NaI solution will typically be performed with up to 185 GBq of I-131 and are expected to take place no more twice a week and not more than 40 weeks of the year.

Chemical Name [CAS number]	GHS Classifications	DG Class	Approx. Volume Stored	Volume Used (weekly)	Storage Location
Tellurium dioxide (solid) [2025820]	Skin Sensitisation: Cat 1B Acute Toxicity: Inhalation: Cat 4 Toxic to Reproduction: Cat 1B Toxic to Reproduction: Lactation effects Aquatic Toxicity (Chronic): Cat 2	9 miscellaneous	10 kg	0.1 kg	Wet Chem Lab
Sodium hydroxide (solid) [1310-73-2]	Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Base)	1 kg	0.1 kg	Wet Chem Lab

Chemical Name [CAS number]	GHS Classifications	DG Class	Approx. Volume Stored	Volume Used (weekly)	Storage Location
Sodium hydroxide 0.02 M [1310-73-2]	Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Base)	2 L	0.5 L	Secondary Containment
Sodium hydroxide 0.1 M [1310-73-2]	Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Base)	2 L	0.5 L	Secondary Containment
Sodium hydroxide 1.0 M [1310-73-2]	Corrosive to Metals: Cat 1 Skin Corrosion/Irritation: Cat 1A Serious Eye Damage / Eye Irritation: Cat 1 Specific Target Organ Toxicity (Single Exposure): Cat 3 (Respiratory Irritation)	8 (Base)	2 L	0.2 L	Secondary Containment
Sodium bicarbonate (solid) [144-55-8]	None	Not regulated	1 kg	0.5L	Wet Chem Lab
Sodium bicarbonate 0.02 M [144-55-8]	None	Not regulated	2 L	0.5 L	Secondary Containment
Sodium phosphate dibasic (solid) [7558-79-4]	None	Not regulated	1 kg	0.1 kg	Wet Chem Lab & Secondary Containment
Sodium thiosulphate (solid) [7772-98-7]	None	Not regulated	1 kg	0.1 kg	Wet Chem Lab & Secondary Containment

Table 9 Chemicals used in the I-131 process

9.3.1. Target Containers

An irradiated tellurium ingot (29 mm x 25 mm, approx. 90 g) will be received in a B(U) type container. This is used for higher scale work.

For lower scale work Iodine-131 in various forms will be delivered to the facility in the lead containers specified in Table 6.

9.3.2. I-131 process overview

Iodine-131 testing in the NMTD will be grouped into categories:

- Sublimation and collection

- The sublimation system comprises three vessels, the interconnections between these vessels and the required services. The three vessels are the furnace, the trap and the scrubber. The services supplied to the system are nitrogen gas, which is used to provide an inert atmosphere for the sublimation process, and compressed air which is used to drive the in-cell valves and the air ejector (which is used for the creation of a system vacuum).

- Stabilisation
  - Stabilisation testing will be conducted using I-131 generated in NMTD or in the form of stabilised and un-stabilised [^{131}I]NaI solution from Building 23 (max activity 185GBq). If received from B23 it will be delivered in a Type A Druce pot (ANSTO/097).
- Encapsulation and stability
  - Encapsulation testing will involve testing capsule dispensing equipment and the subsequent stability of these capsules. This process will use either stabilised I-131 generated in NMTD or [^{131}I]NaI stabilised or and unstabilised solution received from building 23 (max activity 16 GBq). If received from B23 it will be delivered in Medi-ray lockable lead pot (ANSTO/073).

1. The consumables, reagents, and other single use materials (maximum size 2 L) (TBC) are loaded into the receiving hot cell and then transferred to the I-131 hot cell through the internal doors with sliding trays using tele-manipulators.
2. The sublimation and collection studies with I-131 can be summarised as follows.
3. During sublimation, the system will be sealed, and leak tested before the process begins. After ensuring the system is leak tight the follow of nitrogen is initiated, a vacuum applied, and the temperature increased. Testing temperatures are likely to range from 600 – 900°C.
4. The I-131 will be trapped in a preprepared solution of NaOH.
5. Stabilisation studies will involve dispensing un-stabilised I-131 into vessels with a variety of stabilising agents. This will be achieved using either an automated dispensing system or manipulators/other tools (TBD).
6. QC samples will be dispensed into 10 mL glass vials within the I-131 hot cell and removed via the drawing system of the hot cell into a tungsten pot.
7. These samples will then be transferred to either the NMTD shielded fume hood or the lead castle. Depending on the needs, these samples may be utilised as is or repackaged into other lead pots, allowing for the reuse of tungsten pots.
8. It is expected that approximately 5-10 QC samples will be generated per run.

9.3.3. Iodine-131 meta-iodo-benzyl-guanidine ([131I] MIBG) process overview

1. [^{131}I]MIBG is a noradrenaline analogue used in the imaging and therapy of neuroendocrine tumours.
2. This radiopharmaceutical was formerly produced at ANSTO via manual radiochemical synthesis techniques. Production using this method has now ceased and Australian patients now rely on international sources for this product.
3. An automated production methodology for [^{131}I]MIBG will be established at ANSTO with a view to recommence production in the newly commissioned NMF facility.
4. The majority of automated [^{131}I]MIBG research and development will take place in ANSTO's building 76 radiochemistry laboratories. [^{131}I]MIBG will only be moved to the NMTD once a full procedure has been developed. Then the focus will shift to equipment testing/IQ, process limit testing and optimisation, and staff training.
5. Each run is expected to require less than 20 GBq of I-131.
6. The final product is expected to be dispensed into a 10 mL glass vial in the BBST dispensing hot cell. A liquid transfer hose will facilitate this transfer.

7. QC samples may be taken from the I-131 hot cell in 10 mL glass vials via the drawing system.
8. In the later operational years of the NMTD, the process may be carried out up to once per week and up to 20 times per year.
9. Liquid and solid waste will be generated and captured in a 1 L bottle and a 2L solid waste tin container, respectively and moved to the waste hot cell via the internal doors system.

9.4. Waste

Solid waste: will consist of absorbent materials, vials, plastic tubing and other single used materials and will be collected in a 2L tin containers before being closed and moved to the waste hot cell for decay.

It is expected that the empty ampoule containers will be moved, via the internal doors and sliding trays, to the waste hot cell for decay.

It is expected that all liquid waste generated during the Iodine process will be transferred to a shielded liquid waste tank external to the hot cell. The liquid waste will be decayed in this tank and once this liquid waste has been sufficiently decayed, it will be transferred to Waste Management Services [Ref (9)] .

10. Active Ventilation System and HVAC

An Active Ventilation System (AVS) will be installed to service the following areas:

- Secondary containment
  - Shielded fume hoods
  - Hot cells
- Plant room during filter change

The AVS system will be designed, installed and commissioned as per ANSTO Active Ventilation Manual (AG-2906).

A Building Management and Control System (BMCS) will be installed and will monitor and control the HVAC and the AVS system. This system will be used to monitor hot cell status which includes the following:

- Differential pressure between the hot cell and the secondary containment.
- Status of the interlock of the internal transfer hatch.
- Status of the liquid waste system.
- Status of doors of the Secondary Containment.

Table below lists the design and drawings for the AVS and HVAC system:

Drawing number	Title
NMTD-2200-DW-0203	HVAC P&ID
NMTD-2200-DW-0204	HVAC GENERAL ARRANGEMENT - OVERALL LAYOUT
NMTD-2200-DW-0205	HVAC GENERAL ARRANGEMENT - ROOF LAYOUT
NMTD-2200-DW-0206	HVAC AIR SCHEMATIC
NMTD-2200-DW-0207	HVAC WATER SCHEMATIC
NMTD-2200-SP-0201	MECHANICAL SPECIFICATION
NMTD-2210-DW-0202	HVAC INLET SYSTEM EXTERNAL PLANT AREA

Table 10 Drawing list for AVS and HVAC

10.1. Source term for AVS

The table below outline the radioactivity release values from processing I-131 and Tc-99m processing in the hot cell. These values are for information only. Refer to emissions licence for detailed list of isotopes and their corresponding radioactivity.

Isotope	Normal Expected Release (Bq)	Accidental Release (Bq)
Activity per Iodine Ingot Processing*		
I – 131	2.25E+08	4.00E+11
Emissions from the Dispensing Hot Cell		
I-131	2.25E+08**	
Activity per 2TBq Mo-99/Tc-99m batch***		
Tc-99m	2.77E+07	4.73E+07

Table 11 Normal and accidental release radioactivity levels for I-131 and Tc-99m process

* for I-131 process, this is the full activity from the sublimation process of largest batch.

** assumed all the radioactivity from the sublimation to be transferred to dispensing hot cells

*** for Tc-99m process, this is the 0.01% breakthrough for release.

NOTE: Lutetium-177 isotope is not considered volatile. Therefore, it is not shown in the table above. Lutetium emissions are filtered by the built-in HEPA filter in the cell (in-cell HEPA filter).

The above radioactivity release values have been based on the following design assumptions:

- For the Iodine Ingot process, isotopes emitted with activity levels below 1.00E+10 Bq are not shown in the emissions table above. Filter sizing for Iodine will be based on the isotope emitted with the largest activity, which is I-131 with an activity level of 1.70E+12.
- For the Mo-99/Tc-99m, a breakthrough of 0.0001% has been assumed to determine the accidental release emissions value.
- For Mo-99/Tc-99m, the normal release value has been calculated based on a 2-stage filtration process with following filter efficiencies:
    - 1st stage filtration: 95% efficiency filter (HEPA/Carbon)
    - 2nd stage filtration: 99.9% efficiency filter (HEPA/Carbon)
- Accidental emissions from the dispensing hot cell (due to spillages etc.) is assumed to be 1% of the accidental release of Iodine ingot processing.
- The table below shows max radioactivity concentration to be used in shielded fume cupboards installed in the Secondary Containment.

Isotope	Radioactivity levels
Tc-99m	370 GBq in 10 mL
Lu-177	10 GBq in 0.5 mL
Mo-99	1 GBq in 5 mL
I-131 (stabilised and un-stabilised)	200 MBq in 0.2 mL

Table 12 Max radioactivity concentration in fume cupboards

10.2. Emissions monitoring

Ventilation exhaust from this facility will be exhausted via a stack, to be located outside Building 22, in close proximity to the ventilation room. This exhaust air is monitored for I-131.

ANSTO standard emissions sample instruments for offline monitoring will be used to monitor the exhaust (i.e. TC-45 by HI-Q). The location for sampling will be appropriately selected based on the following:

- Safe and accessible to retrieve sampling cartridges.
- Sampling point is well mixed and at a location that is representative of the airflow (i.e. middle of the exhaust duct).
- Sampling point will be located prior to dilution.

11. Waste Management

Waste generated in this Technology Demonstration Facility can be classified into the following categories:

- Solid Waste
    - Contact handled solid waste
    - Remote handled solid waste
    - Non-radioactive solid waste
- Liquid Waste
    - Contact handled liquid waste
    - Remote handled liquid waste
    - Non-radioactive liquid waste (trade waste water)

11.1. Solid Waste

11.1.1. Non-radioactive waste generated in the Secondary Containment

Non-radioactive waste generated in the Secondary Containment is segregated as follow in separate bins. The waste is packaged and arranged for inspection and collection from the Changeroom Area (TBC):

- General waste (paper, gloves, plastic syringes etc., produced from work in non-active areas or procedures not employing radioactivity).
- Glass Waste (glass pipettes, glass vials which is not contaminated by radioactive material)
- Hazardous chemical waste (flammable solvents (HPLC analysis), corrosives, and solutions of organic acids).
- Sharps waste.
- Recyclables (recyclable packaging, non-radioactive contaminated cardboard etc.)

11.1.2. Contact handled solid waste.

Contact handled solid waste is (gamma dose <2 mSv/hr or beta dose <8 mSv/hr on contact) is segregated in shielded containers with clear plastic liner/bin bag as follows:

- General waste (Paper, plastic, gloves, pipette tips, tubing, lids, used Solid Phase Extraction (SPE) cartridges and other consumables, hair nets etc.)
- Glass (Reaction and reagent vials, test tubes, culture tubes, etc.).
- Sharps (Disposable needles, razor and scalpel blades etc; excluding broken glass).

The containers are arranged for inspection and collection. Large or bulky items are packaged with a second bag to minimise radiological hazards.

11.1.3. Remote Handled Solid Waste

Remote Handled Solid Waste is generated primarily from hot cell operations, if the waste is less than 2 mSv/hr this can be removed to and stored in the lead castle for further decay, if the waste has a dose rate greater than 2 mSv/h at contact, the waste is either left in cell to decay or transferred between cells internally to the waste cell for further decay.

Once decayed to an acceptable level is then arranged for collection by the Waste Operations team for further processing. The solid and liquid waste management to be detailed within the waste management strategy document.

11.2. Liquid Waste

11.2.1. Contact Handled Liquid Waste

Contact handled wastewater comes from radioactive drains in the QC bench preparation area and emergency safety shower within the Secondary Containment. The radioactive wastewater is drained into the site's B-line.

The limit of activity for disposal via the B-line is 1 MBq/day/laboratory of beta/gamma emitters and 50 KBq/day/laboratory for alpha emitters.

11.2.2. Trade Wastewaters (Non-radioactive)

Trade wastewater is generated from non-radioactive operations and stored in B22 chemical waste storage area for collection.

11.2.3. Remote Handled Liquid Waste

Remote Handled Liquid Waste is generated primarily from hot cell operations and has a dose rate greater than 2 mSv/h at contact.

The remote handled liquid waste is stored in a local shielded waste tanks for further decay and then arranged for collection by Waste Operations for further processing. The solid and liquid waste management to be detailed within the waste management strategy document.

Refer to Waste Management Strategy [Ref (9)].

12. Security Arrangements

The detailed description of the security arrangements that are in place for this facility are outlined in the Engineering Requirements Specifications (NMTD-2860-SP-0002) and NMTD Security Plan as outlined in Plans and Arrangement (NMTD-0410-PM-0001) Facility Security Plan (FSP) (NMTD-0410-PM-0001). The FSP is to implement local security control of all nuclear material and/or radiological sources in line with their regulatory requirements, interfacing with enterprise security arrangements, systems, and functions. The plan addresses the material, sources, layout, activities, and security risk controls of this facility, relying on the implementation of the ANSTO Security Plan (AG-5534) to control security risks at the enterprise level.

13. Definitions

Term	Definition
ANM	ANSTO Nuclear Medicine
ANSTO	Australian Nuclear Science and Technology Organisation
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
AVS	Active Ventilation System
BMS	Building Management System
BSC	Biological Safety Cabinet
B(U)	Beatrice Transport Container
D(U)	Depleted uranium pot (fits within a Beatrice transport container)
FSP	Facility Security Plan
GBq	Giga-becquerel
HAZID	Hazard Identification
HIBA	α-hydroxyisobutyric acid
HCl	Hydrochloric acid
I-131	Iodine-131
ICPMS	Inductively coupled plasma mass spectrometry
IPC	Inner product container
IQ	Installation qualification
Lu-177	Lutetium-177
MBq	Mega-becquerel
Mo-99	Molybdenum-99
MPB	Molybdenum-99 product bottle
NaOH	Sodium hydroxide
NMF	Nuclear Medicine Facility
NMTD	Nuclear Medicine Technology Demonstration
QC	Quality Control
Tc-99m	Technetium-99m

Term	Definition
TBC	‘To be Confirmed’
TBD	‘To be Determined’
TBq	Tera-becquerel
Te-130	Tellurium-130
Yb-176	Ytterbium-176
Yb-177	Ytterbium-177
U-235	Uranium-235

14. Applicable Standards and Licences

In preparing their tender response and proposed provision of the Services, tenderers should consider ANSTO's applicable standards and relevant specification requirements, and the latest relevant Australian Standards, Codes and Legislation. Tenderers must satisfy themselves all requirements at law are complied with.

The following standards, Codes and Legislations are identified as applicable but is not an exhaustive list:

14.1. Australian Standards, Codes and Legislation

Engineering Discipline	Relevant Australian Standards and Codes
Architectural and Structural	Australian Building Codes - https://www.abcb.gov.au/ AS/NZS 1170:2002 Load Combinations AS 4100 Steel Structures Design
Crane	AS1418 / AS 2550 – Crane, hoist, winches
Environmental	AS/NZS ISO 14000 including: Australian Safety and Compensation Council, Asbestos Code of Practice for the Management and Control of Asbestos in the Workplace
Environmental	Environmental Protection – Codes and Standards according to the Australian EPBC Act and Regulations
Gas	Storage and handling of cylinders, AS 4332 Copper tubes for plumbing, gas fittings and drainage applications, AS 1432 Identification of the contents of pipes, conduits and ducts, AS 1345
General - Quality	Accredited Quality Management System: Equivalent to AS/NZS ISO 9001:2000
Geotechnical	Civil and Site Analysis ISO/IEC 17025 Geotechnical investigation of proposed site
Hydraulic	Water, Sewer, Stormwater, B Line and C Line Liquid Waste Installation of Fire Hose Reels, AS 2441 National Plumbing and Drainage Code (all parts), AS 3500 Air and Water systems for Buildings - Microbial Control, AS 3666
Mechanical	Ventilation and Air-conditioning in Buildings, AS/NZS 1668 Refrigerating Systems, AS/NZS 1677 Fixed Platforms, Walkways, Stairs and Ladders, AS1657
Pressure Equipment	Pressure Equipment – Hazard Levels, AS4343
Process Piping	Pressure Piping, AS 4041
Regulatory Compliance	Australian Radiation Protection and Nuclear Safety – Codes and Standards https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards
Regulatory Compliance	Air Transport Safety (CASA) https://www.casa.gov.au/aircraft/cabin-safety/cabin-safety-regulatory-reference-index

Engineering Discipline	Relevant Australian Standards and Codes
Safety	Chemical and Radiation Safety in Laboratories, AS 2243 Series Laboratory Design and Construction, AS 2982 Dangerous Goods, AS 3780
Radiation Safety	ARPANSA Regulations 2018, RPS F-1, RPS C-1, IAEA Basic Safety Standards (GSR Part 3)
Safety	Electrical Installations AS 3000 SAA Wiring Rules; AS 3008 Selection of Cables
Safety	I&C - Safety Instrumented Systems AS/NZS 61508 Functional safety of electrical/electronic/programmable electronic safety related systems AS/NZS 61511 Functional safety - Safety instrumented systems for the process industry sector
Safety	NSW Fire Brigade & Rescue requirements Building Code of Australia
Safety	Transport of Packages, Dangerous Goods AS 1418 Cranes, Hoists and Winches IAEA Transport Guidelines as applicable
Safety	Work Cover Authority (Workplace Health and Safety) requirements, including Safety in Design standards
Security (OT)	ANSTO Security (Operational Technology) Guidelines, including: ANSTO Cyber Security Strategy 2020-2022, AG-2732
Security (Physical)	Australian Federal Police (AFP) As a minimum, the following will apply: Australian Government Protective Security Policy Framework (PSPF); AS 3555 Building Elements – Testing and Rating for Intruder Resistance
Waste	ANSTO Non-radioactive Waste Guidelines, AG-2985 ANSTO Safe Management of Radioactive Waste, AG-2517
Welding	AS/NZS 1554.1 Structural steel welding, Part 1 Welding of steel structures AS/NZS 1554.2 - Structural steel welding, Part 2 Stud welding (steel studs to steel) AS/NZS 1554.3 - Structural steel welding, Part 3 Welding of reinforcing steel AS/NZS 1554.5 - Structural steel welding, Part 5 Welding of steel structures subject to high levels of fatigue loading AS/NZS 1554.6 - Structural steel welding, Part 6 Welding of stainless steels for structural purposes AS 1579 - Arc-welded steel pipes and fittings for water and wastewater AS/NZS 1665 - Welding of aluminium structures

14.2. International Standards

Acts of Parliament	Relevant International Standards
Active Ventilation	ISO 17873 Nuclear Facilities – Criteria for the design and operation of ventilation systems for nuclear installations other nuclear reactors.

14.3. ANSTO's Information Documents

Engineering Discipline	Relevant ANSTO Standards and specification requirements
Architectural and Structural	AS 3219 ANSTO Building Code
Mechanical	AG 2906 Active Ventilation System Manual
Environmental	AG-5400 Project Environmental Protection Requirements
Radioactive Waste	AG-2517 Safe Management of Radioactive Waste
Radioactive Materials movement	AG-2515 Safe Movement & Transport of Radioactive Materials
Security Plan	AG-5534 ANSTO Security Plan
General	G-3376 Abbreviations and Acronyms used at ANSTO
Storage	AG-2441 Storage of Chemicals
URS	NMMP-0010-SP-0003 (Demo Project) Demonstration Facility - User Requirements Specification [Ref (14)]
Layout	Preliminary Hot Cells Layout Sketch
Document Management Plan	NMMP-0010-PM-0013 Document Management Plan [Ref (15)] **(This document is currently being reviewed)**

15. References

1. ***Hazardous Materials Pre-Demolition Register.*** **NMTD-1610-RT-0002.**
2. *Hazardous Materials Pre-Demolition Register.* NMTD-1610-RT-0006.
3. *Targeted Sampling Report.* NMTD-1610-RT-0003.
4. *Airborne Fibre Monitoring Report.* NMTD-1610-RT-0004.
5. *Shift Log Report.* NMTD-1610-RT-0005.
6. *Asbestos Management Register.* NMTD-1610-RT-0008.
7. *Targeted Sampling Report.* NMTD-1610-RT-0007.
8. *Hazardous Materials Pre- Demolition Register.* NMTD-1610-RT-0009.
9. Waste Management Strategy. NMTD-0010-PM-0010_NMTD.
10. *Facility Functional Description.* NMTD-1520-SP-0001.
11. *Iodine-131 Process Flow Chart.* NMTD-1524-DW-0001.
12. *Lutetium-177 Process Flow Chart.* NMTD-1524-DW-0002.
13. *Mo-99/Tc-99m Process Flow Chart.* NMTD-1524-DW-0003.
14. *Technology Demonstration Facility URS.* NMMP-0010-SP-0003.
15. *Document Management Plan.* NMMP-0010-PM-0013.
16. *Process Descriptive Report - Technetium-99m.* NMMP-4020-RT-0002.
17. *Process Descriptive Report - Lutetium-177.* NMMP-5020-RT-0001.
18. *Process Descriptive Report - Aseptic Product and Development Zones.* NMMP-7000-RT-0001.
19. *Process Description Report - Active Material Handling.* NMMP-3020-RT-0002.
20. *Process Descriptive Report - Quality Control and Microbiology.* NMMP-3100-RT-0001.
21. *Waste Management Plan.* NMMP-0750-PM-0001.
22. *Facility Site Location Report.* NMMP-1100-RT-0003.
23. *Process and Equipment List.* NMMP-2026-SC-0104.
24. *Pre-Concept Facility Description.* NMMP-0030-RT-0002.
25. *Process Descriptive Report - Active Receipt.* NMMP-3320-RT-0101.
26. *Process Descriptive Report - Iodine 131 Products.* NMMP-6020-RT-0002.
27. *Technology Demonstration Facility Scope of Works.* NMTD-0030-SW-0001-00.
28. *ERS - Protective Security Overlay.* NMTD-2860-SP-0002.
29. *Security Vulnerability Assessment.* NMTD-2860-SP-0001.

Appendix A: Containment Classification and Rationale

Section	Classification	Rationale
Secondary Containment	Blue Radiation (Controlled R2) Blue Contamination (Controlled C2)	For radiation classification: Low risk of operator exposure to radiation (1-2 mSv per year). For contamination classification: There is a low risk of spreading radioactive contamination outside of radioactive containment
Change Room	White Radiation (Supervised R0) Blue Contamination (Supervised C1)	For radiation classification: Change room is designated as an area where there are no sources of ionising radiation and therefore there is no reasonable potential for occupational radiation exposure. For contamination classification: The change room is a buffer area for monitoring of persons from a radioactive contamination-controlled area.
Transition area	White Radiation (Supervised R0) White Contamination (Supervised C0)	For radiation classification: Transition area is designated as an area where there are normally no sources of ionising radiation and therefore there is no reasonable potential for occupational radiation exposure. For contamination classification: The containers in which targets are delivered are surveyed and have been cleared for contamination prior to arrival to this facility. Therefore, there should be no risk of contamination in this transition zone.
Internal Plant Room	During filter change: Blue Radiation (Controlled R2) Blue Contamination (Supervised C1) All other times: White Contamination (Supervised R0) White Contamination (Supervised R0)	For radiation classification during filter change: Low risk of operator exposure to radiation (1-2 mSv per year) during filter change. For contamination classification: There is a low risk of spreading radioactive contamination outside of the internal plant room.
Wet Chemical Lab	N/A	No radioactive work conducted in this laboratory.
External Plant	N/A	The plant equipment supplies conditioned outside air into the lab space. Therefore, no classification required.

Table 1: Containment Classification Rationale