



CORE SPECIFICATION

Isolator for Cell Labelling Shielded Cabinet for Daily Production of Low Energy SPECT Radiopharmaceuticals Shielded Laminar Flow Hood for Radiopharmaceuticals

1. Scope

This Specification describes the generic requirements for Equipment, Installation, and Training required in support of the Counterpart, under an IAEA Technical Cooperation programme.

2. Applicable Documents

The following documents shall be applicable for this Specification to the extent specified hereinafter:

- 2.1. EudraLex GMP Guidelines (https://ec.europa.eu/health/documents/eudralex/vol-4_en); or USP document 21 CFR Part– 211 cGMP for finished pharmaceuticals subpart D (<https://ecfr.io/Title-21/pt21.4.211>)
- 2.2. EN12469 Microbiological Safety Cabinets – Class II standard

In the event of conflict between the documents listed above and the content of this Specification, the content of this Specification shall take precedence to the extent of the conflict.

3. Definitions, Acronyms, and Abbreviations

The following definitions, acronyms, and abbreviations shall apply throughout this Specification unless defined otherwise hereinafter:

“Site” means the location prepared by the User for Installation;

“Counterpart” means the organisation assigned by the receiving government to act on their behalf for this project.

“End-User” is the organisation that will operate the equipment. They may be the same organisation as the Counterpart.

“System” means the entire equipment and services to be provided;

“USP” means United States Pharmacopeia

“HEPA” means High-Efficiency Particulate Air

“GMP” means Good Manufacturing Practice

“SPECT” means Single Photon Emission Computed Tomography

“BSC” means Biosafety Cabinet

“HEPA” means High efficiency particulate air

“AISI” means American Iron and Steel Institute

4. Requirements

The System shall meet the requirements in the applicable Compliance Matrix

5. Marking and Packing

- 5.1. The System shall have all required safety markings in the English language.
- 5.2. The System, for the shipment by air/road to the End-User, shall be packed in accordance with international standards that are applicable for the shipment by air/road of this kind of equipment.
- 5.3. Storage may be required prior to shipment, and pending installation on Site.

6. Licenses, Permits, and Quality Assurance

- 6.1. The Supplier shall obtain and maintain all permits and licenses necessary for the supply and delivery of the System to the End-User. The Supplier shall timely provide the End-User with all information and technical support that may be needed to obtain the import licenses, permits and/or authorisations in accordance with the regulations of the appropriate regulatory authorities
- 6.2. The System shall be manufactured, shipped and installed in accordance with the Supplier's ISO quality assurance system or an equivalent quality assurance system. The Supplier shall document compliance with this quality assurance system.

7. Testing and Acceptance

- 7.1. The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein.
- 7.2. The System, after installation, shall be tested by the Supplier together with the End-User to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified herein as determined by the IAEA and the User.
- 7.3. The results of the testing of the System shall be documented by the Supplier in an acceptance protocol that shall be signed by the User.

8. Installation and Training

- 8.1. Once the Supplier has confirmation that the Site is ready, they shall in agreement with the End-User, install the System at the Site. The Supplier shall provide for this purpose all necessary tools and staff (including their travel, accommodation and subsistence as necessary) to be used during installation and to be re-exported at the end of work.
- 8.2. The Supplier shall provide appropriate training for staff of the User in the operation and maintenance of the System at the User's location, immediately after the installation of the System. The training shall be in English.
- 8.3. The Supplier shall provide on-site training for up to four (4) staff of the End-User in the operation, maintenance, proper handling and quality assurance of the System immediately after the installation of the System.

9. Warranty and Support

- 9.1. The System shall be covered by one (1) year warranty including parts and labour, starting as of the date of successful on-site acceptance, as per Testing and Acceptance above.
- 9.2. Warranty shall include all necessary spare parts, shipment to site, cost of replacement work, personnel, disposal of faulty parts, and software (patches, upgrades, and updates).

10. Deliverable Data Items

The following data items shall be provided in English.



- 10.1. Two (2) complete sets of operation and servicing manuals and technical drawings (electrical, mechanical, pneumatic, and process schemes) in the English language.
- 10.2. DQ, IQ and OQ documentation
- 10.3. Certificates of stainless steel and filters and all used materials
- 10.4. Recommended spare parts list (included in the maintenance manual)
- 10.5. Main equipment data sheets
- 10.6. Calibration certificates, for the System (and dose calibrator if applicable)

CORE SPECIFICATION

Isolator for Cell Labelling

1. Scope

- 1.1. This Specification describes the requirements for an isolator with ISO Class 5 air quality for cell labelling. The System is an enclosed, ventilated laboratory workspace for safely working with materials contaminated with (or potentially contaminated with) pathogens requiring a defined biosafety level.
- 1.2. Requests to vary from this Specification must be supplied with supporting evidence and are subject to approval of the IAEA technical officers.

2. Applicable Documents

- 2.1. Core Specification "CABRD001"

3. Requirements

3.1. Functional and Performance Requirements

The System shall be used for manipulations and aseptic dispensing of radiolabelled cells in nuclear medicine departments of hospitals.

The System shall meet the following functional and performance requirements:

- 3.1.1. It shall meet USP 797 compliance without expense to for pharmacy ventilation renovations
- 3.1.2. It shall provide a fully controlled environment with 100% HEPA filtration of supply and exhaust air from work area and antechamber
- 3.1.3. It shall maintain ISO 14644-1 Class 5 (Class 100) air quality under dynamic conditions
- 3.1.4. It shall have unidirectional airflow that showers the work zone with a continuous supply of filtered air that sweeps contaminants out through the air exhaust system

3.2. Technical Requirements

The System shall meet the following technical requirements:

- 3.2.1. It shall be equipped with a built-in centrifuge for blood cell separation (optional).
- 3.2.2. It shall have between 5-20 mm lead shielding (located in back, sides, bottom and front of work area) to protect the user while compounding sterile radiopharmaceuticals;
- 3.2.3. It shall have two (2) or three (3) anthropometrically correct glove ports;
- 3.2.4. It shall have digital pressure gauge with audible and visual low-pressure alarm
- 3.2.5. It shall be able to facilitate glove change without breaking containment
- 3.2.6. It shall include height adjustors to make the work environment ergonomic
- 3.2.7. It shall be made of durable materials (stainless steel, glass and high-performance, scratch-resistant plastics)
- 3.2.8. The System shall be easy to clean and disinfect inside and out
- 4.2.10 All necessary accessories needed for work shall be provided. Supplier shall provide a list of necessary accessories.



CORE SPECIFICATION

Shielded Cabinet for Low Energy SPECT Radiopharmaceuticals

1. Scope

- 1.1. This Specification describes the requirements for a shielded cabinet for daily production of low energy SPECT radiopharmaceuticals Tc-99m.
- 1.2. Requests to vary from this Specification must be supplied with supporting evidence and are subject to approval of the IAEA technical officers.

2. Applicable Documents

- 2.1. Core Specification "CABRD001"

3. Requirements

- 3.1. Functional and Performance Requirements.

The System shall meet the following functional and performance requirements:

- 3.1.1. The System shall be used for the daily production of low energy SPECT radiopharmaceutical doses
- 3.1.2. The System shall allow the dose production according to the accepted international standards for shielding enclosures and for handling radioactive materials.
- 3.1.3. The System shall meet the GMP requirements for enclosures for the preparation of sterile medical products.

- 3.2. Technical Requirements

The System shall meet the following technical requirements:

- 3.2.1. Accommodate Tc-99m generators, with a possibility to place the generator in a motorized lift for generator transport;
- 3.2.2. Equipped with a pneumatic lift unit (option)
- 3.2.3. One (1) dose calibrator (optional) for radiopharmaceutical dose determination with environmental shielding
- 3.2.4. Lead container for waste products storage
- 3.2.5. Lead shielding present in frontal wall, lateral walls and under the worktop, suitable for the Mo-99/Tc-99m generators elution
- 3.2.6. Lead shielded sliding glass window
- 3.2.7. Ventilation system making the working area compliant with GMP requirements (option)
- 3.2.8. Access for cleaning and maintenance
- 3.2.9. Have a sealed passage for the connection of airborne particle counter. (option)
- 3.2.10. Contain a radiation monitoring system
- 3.2.11. Fit within the room space available. Site layout will be provided
- 3.2.12. All surfaces shall be easy to clean inside according to pharmaceutical surface standards



- 3.2.13. All necessary accessories required for work shall be provided. Supplier shall provide a list of necessary accessories.



CORE SPECIFICATION

Shielded Laminar Flow Hood for Radiopharmaceuticals

1. Scope

- 1.1. This Specification describes the requirements for a shielded fume hood with laminar flow (hereinafter referred to as “the System”). The System is mainly used for radiopharmaceuticals.
- 1.2. Requests to vary from this Specification must be supplied with supporting evidence and are subject to approval of the IAEA technical officers.

2. Applicable Documents

- 2.1. **Core Specification “CABRD001”**

3. Requirements

3.1. Functional and Performance Requirements

The System shall be used for manipulations and aseptic dispensing of radiopharmaceuticals in nuclear medicine departments of hospitals.

3.2. The System shall meet the technical requirements:

- 3.2.1. Equipped with frontal sliding and laminar flow,
- 3.2.2. Supported structure and worktop made of AISI 304 stainless steel,
- 3.2.3. All the bends have the right bend radius to guarantee easy cleaning conditions,
- 3.2.4. **Shielding**
 - 3.2.4.1. the hood is shielded with 5 mm of lead, in the work top, the back wall and the lateral walls. The front sliding protection is equipped with a lead glass window, dimensions 300 x 200 mm (w x h), thickness equivalent to 5 mm of lead; and
 - 3.2.4.2. The lead shielding is mounted in a continuous stainless-steel covering for total decontamination. The 5-mm thick shielding is made using lead plates with recesses that provide continuous shielding.
- 3.2.5. Ancillary equipment
 - 3.2.5.1. lighting with cold light lamps;
 - 3.2.5.2. external panel with 4 electrical feeding sockets, with a voltage compliant to the End-user's location (220V),
 - 3.2.5.3. 1 pneumatic lift unit for vials and syringes calibration,
 - 3.2.5.4. 1 dose calibrator mounted under the worktop,
 - 3.2.5.5. 1 airtight waste compartment shielded with 20 mm of lead,
 - 3.2.5.6. 1 generator compartment (for 2 units) shielded with 40 mm of lead equipped with lifting unit,
 - 3.2.5.7. 2 manometers for filters control (inlet and resumption filters),
 - 3.2.5.8. 4 technical gas inlets connected to 4 manual shut off valves and plate for fluid identification,
 - 3.2.5.9. The flow speed meets the critical area (class A) characteristics requested by the ECC-GMP directive: 0,45 m/s \pm 20%
- 3.2.6. Accommodate Tc-99m generators, with a possibility to place the generator in a motorized lift for generator transport;
- 3.2.7. Equipped with a pneumatic lift unit (option)
- 3.2.8. One (1) dose calibrator (optional) for radiopharmaceutical dose determination with environmental shielding



- 3.2.9. Lead container for waste products storage
 - 3.2.10. Lead shielding present in frontal wall, lateral walls and under the worktop, suitable for the Mo-99/Tc-99m generators elution
 - 3.2.11. Lead shielded sliding glass window
 - 3.2.12. Ventilation system making the working area compliant with GMP requirements
 - 3.2.13. Access for cleaning and maintenance
 - 3.2.14. Have a sealed passage for the connection of airborne particle counter.
 - 3.2.15. Contain a radiation monitoring system
 - 3.2.16. Fit within the room space available. Site layout will be provided
 - 3.2.17. All surfaces shall be easy to clean inside according to pharmaceutical surface standards
 - 3.2.18. All necessary accessories required for work shall be provided. Supplier shall provide a list of necessary accessories.
-