



SPECIFICATION

Shielded Radiochemistry Fume Hood with Laminar Flow and Generators Compartment

1. Scope

This Specification describes the requirements for a Shielded Laminar Flow Cabinet (hereinafter referred to as “the System”); BSC Class II Type A EN-12469, NSF/ANSI Standard 49; ISO14644-1 ECGMP Grade A (Class 100) environment for hospital radio-pharmacy.

The System shall be used for radiopharmaceutical compounding/reconstitution; for manipulations, and for aseptic dispensing of radio-pharmaceuticals in nuclear medicine departments of hospitals.

Two potential requirements have been identified. One System for South Africa (University of Pretoria; Steve Biko Academic Hospital), and one System for Paraguay (Instituto de Investigaciones en Ciencias de la Salud, Asunción (hereinafter referred to as “the End-User”)),

2. Definitions, Acronyms, and Abbreviations

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

BSC - Biosafety Cabinet

AISI - American Iron and Steel Institute

ECC - elliptic curve cryptography

GMP - Good Manufacturing Practice

HEPA - High efficiency particulate air

NSF/ ANSI - NSF International Standard/ American National Standards

Institute/ American National Standard for Biosafety Cabinetry

3. Requirements

The System shall meet the following technical requirements:

3.1. Main Characteristics

3.1.1. Working area dimensions shall be at least 1200 x 600 x 600 mm (W x D x H);

3.1.2. Lead shielding with a thickness of 5mm, except as noted elsewhere in this Specification;

3.1.3. The 5mm thick leaded shielding shall have a continuous stainless steel covering for total decontamination and is found in: the Work top; Back wall; Lateral walls; and Front protection with sliding lead glass window.

3.1.4. The work area shall be made of AISI 316L stainless steel, 3 mm thick laminar cabinet, and the working area shall be fitted with a pneumatic elevator for vial calibration, with internal door connecting to the generator area (supporting at least 2 generators), with access to the waste area, with electric sockets.

3.2. The inside of the cabinet shall include at least the following:

3.2.1. Lighting with cold-light lamps;

3.2.2. Panel with electricity sockets, with individual control through external pushbutton;

3.2.3. Calibrator lift unit;

3.2.3.1. Dose calibrator with shielding Pb40;

3.2.3.2. Waste Compartment Pb20; and

3.2.3.3. Generator Compartment Pb40.

3.3. The System shall be constructed as follows, or equivalence demonstrated:

3.3.1. External casing: Stainless steel sheet AISI 304;

3.3.2. Internal Cabinet: Stainless steel sheet AISI 316L;

3.3.3. Hood classification Class A;

3.3.4. nr.2 LAF filters Absolute filters (HEPA - H14);

Absolute filter for air outlet Absolute filters (HEPA - H14); and

Carbonfilter for air outlet active charcoal.

3.3.5. Generator Compartment (Shielding: Pb 40 mm)

3.3.5.1. This cabinet shall be provided with a lead-shielded compartment for the storage and handling of Tc99m generators;

3.3.5.2. Inside the shielded compartment, a platform shall be provided, allowing to store up to two generators, either round or square; with no need for additional changes;

3.3.5.3. A pneumatic command to allow selection of the generator. A pneumatic elevator brings the generator to the worktop for safe elution;

3.3.5.4. The access to the generator compartment shall be possible by opening a hinged shielded door (Pb. 20) provided with a static gasket; and

3.3.5.5. The system commands shall be located on the upper panel of the cabinet.

3.3.6. Waste Compartment (Shielding: Pb. 20mm)

3.3.6.1. The system shall allow storage of the waste produced inside the cabinet into an air-tight lead shielded compartment located in the lower part of the cabinet;

3.3.6.2. Waste shall be droppable through a hole provided with a shielded plug located on the worktop; and

3.3.6.3. The waste compartment shall include a container.

3.3.7. Dose Calibrator (Shielding: Pb 40 mm)

3.3.7.1. The cabinet shall be provided with a dose calibrator with an ionization chamber positioned inside the cabinet, below the worktop and separated from the measuring instrument;

3.3.7.2. The ionization chamber shall be equipped with an air-tight flange and a work top;

3.3.7.3. Measurement range up to 20 Ci (F-18);

3.3.7.4. Response time of at least 0,5 sec;

3.3.7.5. Accuracy of at least +2%;

3.3.7.6. At least two Ethernet interfaces in addition to USB; and

3.3.7.7. A pneumatic elevator shall move syringes or vials inside the ionizing chamber.

3.3.8. Air Quality – Laminar Flow

3.3.8.1. The upper shall have two HEPA absolute filters (eff. 99,995% - M) which cover the entire work area (LAF zone);

3.3.8.2. The air mass shall be moved by two ventilators that circulate the air through the HEPA absolute filters. The flow is directed downwards by vertical direction and then it returns to the ventilator through the Plenum.

3.3.8.3. The content of the particulate matter in the air shall be in conformity with the ISO14644-1 and ECGMP requisites:

3.3.8.4. For Class A (at rest) < 3520 part/m³ for particle ≥ Ø 0.5 µm;

3.3.8.5. For class ISO 5 (at rest) < 3520 part/m³ for particle ≥ Ø 0.5 µm;
< 832 part/m³ for particle ≥ Ø 1.0 µm;
< 29 part/m³ for particle ≥ Ø 5.0 µm;

3.3.8.6. The flow speed shall meet the critical area (Class A) characteristics requested by the EEC-GMP directive: 0,45 m/sec ± 20%;

3.3.8.7. The outlet air shall be filtered by an absolute filter and by a carbon filter; and

3.3.8.8. The status of filters obstruction shall be continually monitored by manometers and by a warning light located on the control panel.

4. Marking

The System shall have all safety markings in English language.



5. Packing

The System, for the shipment by air or other means to the End-User, shall be packed in accordance with international standards that are applicable for the shipment by air of this kind of equipment.

6. Quality Requirements

The System shall be manufactured, shipped and installed in accordance with the Contractor's ISO 9000 quality assurance system or an equivalent quality assurance system.

The Contractor shall document the compliance with this quality assurance system.

7. Testing and Acceptance

7.1. Factory Acceptance Test (FAT)

The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein as determined by the IAEA and the End-Users.

7.2. On site Acceptance Test (SAT)

The System, after installation, shall be tested by the Contractor 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 End-User.

A minimum of six (6) weeks prior to installation, the Contractor shall notify the IAEA, which retains the right to depute an IAEA representative to be present at the SAT.

The results of the testing of the System shall be documented by the Contractor in an acceptance protocol that shall be signed by the End-User, noting the name and position of the appropriate End-User representative.

8. Installation and Training

The Contractor shall liaise with the End User: and when site readiness is confirmed, install the System at the End-User location. The Contractor shall provide for this purpose all necessary tools and staff.

The Contractor shall provide training for up to three staff of the End-User in the operation and maintenance of the System at the End-User's location immediately after the installation of the System.

9. Deliverable Data Items

The Contractor shall provide two complete sets of operation and servicing manuals and technical drawings in English.
