

MOR6026	 IAEA International Atomic Energy Agency	IAEA Specification Dated 10/06/2024
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SPECIFICATION

Hydrogen Peroxide Generator for Telstar Freeze Dryer (Iyogamma 15-3)

1. Scope

- 1.1. This Specification describes the requirements for the equipment and components (hereinafter referred to as the “System”) suitable for quality testing of both diagnostic and therapeutic radiopharmaceuticals to be installed at the ‘regulatory laboratory’ under TC project MOR6026. Radioisotope production facility, Morocco (hereinafter referred to as the “End User”) The equipment should be addressed to Ms. Bentaleb Naoual, Head division of radiopharmaceuticals production, **National Center for Nuclear Energy, Science and Technology (CNESTEN)**, Bled Dendoun- Kenitra, Morocco

2. The detailed specifications are as below

2.1. General characteristics

- Double Loop technology for optimum cycles
- Closed circuit operation – Catalytic filter in case of
- CTA failure
- Proprietary HMI color touch screen
- GAMP compliant software
- Compact and mobile design
- Easily cleanable surfaces
- Volt free contacts for external communication
- Integrated thermal printer
- Remote Start/Stop with remote screen
- Parameterization and recording of cycles
- Effective against a broad spectrum of microorganisms
- H₂O₂ sensor
- HR probe
- Decontamination capacity: 100m³*

2.2. Technical characteristics

- External materials of construction: compliant to be used in a clean room iso 5
- Temperature - Operation: 15°C to 30°C
- Power supply / Consumption: AC 220 – 240V 50 Hz (Euro), 6Amp
- Position: Vertical only
- Volume H₂O₂ Liquid: 1 Liter
- Concentration H₂O₂ Liquid: 30-60% w/w
- Control System: Siemens S7 PLC (GAMP compliant software)
- Air flow - Gassing: 25m³/h

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- Aeration: 25m³/h at 800Pa external pressure

- Pressure available at output: 1200Pa
- Output steam temperature: From 50°C to 75°C
- Liquid H₂O₂ injection rate: 2 – 8 g/min
- Refrigeration System Temperature: Approx. 2°C
- Condensate Disposal: Evaporation into the atmosphere
- Efficacité filtre HEPA d'entrée : 99.99%
- Efficacité filtre HEPA Circuit A et B : 99.99%
- Pressurisation Système débit d'air : 100 l/min (max)
- Gamme de Pressurisation Système : -70Pa à -10Pa, +10Pa à +70Pa
- Filtres Catalytiques : Charbon
- Capacité de décontamination : Jusqu'à 100m³

2.3. Accessories required

1. The portable gas leak detector
2. Adapter plate for gassing the freeze dryer chamber
3. H₂O₂ PROBE HOLDER on Bioquell L4 generator
4. Insulated pipe for gassing
5. Return pipe
6. 4 Bottle of hydrogen peroxide 35% of 1 Liter

3. Marking

- 3.1. The System shall have all safety markings (bar codes; name plates with manufacturer's name, model number, manufacturing standard, hazard or fragility warnings) in English.

4. Packing

- 4.1. The System, for the shipment by air 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.
- 4.2. The manufacturer of the system must guarantee that the equipment arrives in optimum state for its later installation.

5. Quality Requirements

- 5.1. The System shall be manufactured, shipped and installed in accordance with the Contractor's ISO quality assurance system or an equivalent quality assurance system.
- 5.2. The Contractor shall document the compliance with this quality assurance system.

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6. Testing and Acceptance

- 6.1. The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein.
- 6.2. 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.
- 6.3. 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.

7. Installation and Training

- 7.1. The Contractor shall install and integrate the system in existing freeze dryer unit at the End-User facilities. Integration of the generator in the telstar lyogamma 15-3 freeze dryer before the start of qualification
- 7.2. Installation Qualification (IQ) and Operational Qualification (QO) of the Generator. The IQ/OQ must include protocols and the execution of functionality tests according to the characteristics of the freeze dryer lyogamma 15-3 (TELSTAR).

8. Cycle Development

8.1 Identification of the parameters of the "optimum" bio-decontamination cycle (time/efficiency/H₂O₂ consumption) involving the study of the distribution of the steam, the mapping of the temperature, the quantity of H₂O₂, the contact times and aeration.

8.2 Use of biological indicators at 6log of *Geobacillus Stearothermophilus* spores to confirm the effectiveness of the process.

List of studies that should be included in the development of the cycle:

- Study 1: Pre-gassing to check surface temperature
- Study 2: Study of the distribution of steam in the enclosure corresponding to the first vaporization cycle
- Study 3: Plan for the location of biological indicators and determination from studies 1 and 2 of the most difficult to reach "worst cases" places. Note: Hot areas with poor gas distribution will be the most unfavorable areas.
- Study 4: Development of cycle time parameters by varying them in order to determine and optimize the cycle while keeping a safety margin.

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- Study 5: Confirmation of the conditioning and aeration times and entry into the device of the parameters of the final cycle.

9. Operator training in routine operation and maintenance

- Training of three operators in the operation and routine maintenance of the generator

10. Deliverable Data Items

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