

SPECIFICATION

Synthesis Module

for automatic labelling with beta-emitting isotopes including but not limited to Ga-68

1. SCOPE

This Specification describes the requirements for the supply, delivery, installation and acceptance testing of a synthesis module for automatic labelling with beta-emitting isotopes including but not limited to Ga⁶⁸. The System is required at the Brunei Cancer Centre, Jerudong Park, Bandar Seri Begawan BG3122, BRUNEI DARUSSALAM (hereinafter referred to as the “End-User”). The delivery of the System is under the IAEA Technical Cooperation project number BRU6003 “*Strengthening the Nuclear Medicine Department at the Brunei Cancer Centre*”.

2. DEFINITIONS, ACRONYMS, AND ABBREVIATIONS

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

Synthesis module for performing automated “labelling” procedures with beta-emitting radioisotopes = the System

Ga⁶⁸ = Gallium-68

Ge⁶⁸ = Germanium-68

GMP = Good Manufacturing Practice

Site = Brunei Cancer Centre

3. REQUIREMENTS

3.1. FUNCTIONAL AND PERFORMANCE REQUIREMENTS

The System shall meet the following functional and performance requirements:

- 3.1.1. The System shall allow performing automatic “labelling” procedures with beta-emitting isotopes including, but not limited to, Ga-68.
- 3.1.2. Labelling procedures shall result in radiopharmaceuticals complying with Good Manufacturing Practice (GMP) standards.
- 3.1.3. External dimensions and weight shall allow housing of the System inside a lead-shielded hot cell at the Site.
- 3.1.4. For Ga-68 labelling, the validated automated synthesis protocol shall be compatible with the use of standard Ga-68 generators currently available on the market
- 3.1.5. The System configuration shall allow labelling to be carried out also with the radionuclides Y-90, Lu-177 and In-111

- 3.1.6. The System shall be either modular or cassette-based system for the synthesis of Ga-68, but shall always allow conducting labelling also when a dedicated cassette system is not available
- 3.1.7. The System shall include a programmable logic controller with:
 - 3.1.7.1. Electronic device for on-and-off-control functions
 - 3.1.7.2. Network compatibility, error analysis and online-remote support-functionality
 - 3.1.7.3. Electrical cabinet extension for additional modules
- 3.1.8. The System configuration shall guarantee absolute absence of cross contamination risk among the successive batches.
- 3.1.9. The System shall have a heating and cooling system for different types of vials/reactors

3.2. ACCESSORIES AND SUPPLIES

- 3.2.1. The System shall be provided with all accessories and supplies to allow immediate operation of the System:
- 3.2.2. 10 unit: cassette for Ga68, Pre-Purification method,
- 3.2.3. 10 unit: Cassette for Elution of Ge/Ga68 Generator
- 3.2.4. 10 unit: Cassette for pressure test
- 3.2.5. Complete set of cables for interconnection of all electronic units must be included.

4. WARRANTY

- 4.1.1. The System and all components (including software) shall be covered by one (1) year warranty, starting as of the date of successful onsite acceptance as per Section 8 below.
- 4.1.2. The warranty shall include all necessary spare parts, shipment to the site, cost of replacement (work and parts), and disposal of faulty parts of the System.

5. MARKING

The System shall have all safety markings in English.

6. PACKING AND SHIPPING

The System shall be packed and shipped in accordance with international standards that are applicable for the shipment by air of this kind of equipment.

7. QUALITY REQUIREMENTS

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

8. TESTING AND ACCEPTANCE

8.1. Factory Acceptance Test

The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein. Copy of the testing results shall be provided to IAEA.

8.2. Site Acceptance Test

The System, after installation at the Site, 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

8.3. 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.

9. INSTALLATION AND TRAINING

9.1. The Contractor shall install the System at the Site. The installation shall be coordinated with the End-User's representative. No Installation activities shall start at the Site unless agreed with the End-User.

9.2. The Contractor shall provide at least one (1) day on-site training in the operation and maintenance of the System immediately after the installation of the System.

9.3. The training shall be in English.

10. DELIVERABLE DATA ITEMS

10.1. The Contractor shall provide to the End-User two (2) complete sets of operation and servicing manuals and technical drawings in the English.
