SPECIFICATION

Synthesis Module

1. Scope

This Specification describes the requirements for the supply, delivery, installation, and acceptance testing of a fully automated synthesis module (hereinafter referred to as "the System"). The System will be used for labelling of biomolecules with Ga-68, Lu-177 and Y-90. The System is required at the University Hospital Centre Zagreb, Department of Nuclear Medicine and Radiation Protection, Kispaticeva, Zagreb, Croatia (hereinafter referred to as "the End-User"). The delivery of the System is under the IAEA Technical Cooperation project number (CRO6017) "Implementing Gallium-68 Positron Emission Tomography/Computed Tomography Imaging".

2. Applicable Documents

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

European Good manufacturing practice (EU GMP) Guidelines
http://ec.europa.eu/health/documents/eudralex/vol-4_en.

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. Requirements

The System meet the following functional and performance requirements:

3.1. Be able to label biomolecules, e.g. peptides, antibodies, etc. with Ga-68, Lu-177, Y-90, and Ac-225

3.2. The System shall meet the following technical requirements:

- 3.1.1 Be supplied with all required accessories;
- 3.1.2 Be supplied with interface cables;
- 3.1.3 Be supplied with power rechargers;
- 3.1.4 Be supplied with spare kits, color-coded vials and cassette;
- 3.1.5 Power supply: 100 – 240 V AC, frequency 50/60 Hz;
- 3.1.6 Capable of GMP production (RFID Tag tracking system, detailed protocol, and real-time control);
- 3.1.7 Be able to produce Ga-68 labelled peptides in less than thirty (30) minutes including elution, purification and filter integrity test;
- 3.1.8 Have the capacity to minimize liquid waste;
- 3.1.9 Supplied with self-diagnosis software;
- 3.1.10 Have a remote support function

4 Marking

The System shall have all safety markings in English language.

5 Packing

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.

6 Quality Requirements

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

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

7 Testing and Acceptance

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

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. SAT shall be performed in the presence of a representative of the Contractor, End-User, and the IAEA.

7.3 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. This document shall be dated and accepted as the start of the System's warranty period.

8 Warranty

8.1 The System shall be covered by one (1) year warranty starting as of the date of successful onsite acceptance as per Section 7 above.

8.2 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.

9 Installation and Training

9.1 The Contractor shall install the System at the End-User's site.

9.2 The Contractor shall provide all necessary drawings and installation provisions, including photos and other useful information for site preparation. The installation shall be accepted after SAT, training and validation. The validation shall consist of three (3) runs of the installation to validate that the process meets the design specifications and GMP requirements. This step shall also be used as training of the End-User's staff.

9.3 The Contractor shall provide at least one (1) day training to the End-User's staff in the operation and application of the System immediately after the installation. The training shall be in English.

9.4 The Contractor shall document the detailed results of the installation and operation of the System. This documentation shall be signed by the End-User and provided to the IAEA.

10 Deliverable Data Items

The following data items shall be provided in English. The documentation shall include, at the minimum, the following:

10.1 Two (2) complete sets of operation, service maintenance, and user's manuals

10.2 Technical documentation

10.3 Technical drawings (electrical, mechanical, pneumatic & process schemes)

10.4 Certificates of all used materials

10.5 Signed SAT report
10.6 Recommended spare parts list
10.7 The System data sheets
10.8 Instruments calibration certificates
