

Self-shielded X-ray Blood Irradiator	 IAEA International Atomic Energy Agency	IAEA Specification Dated 2018-10-14
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SPECIFICATION

Self-shielded X-ray Blood Irradiator

1 Scope

This specification describes the requirements for a production model of a self-shielded X-ray blood irradiator (hereinafter referred to as the “System”). The System will be installed in the Insect Pest Control Laboratory of the International Atomic Energy Agency (IAEA), Seibersdorf, Austria.

2 Applicable Documents

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

- 2.1 Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards – General Safety Requirements Part 3, No. GSR Part 3. IAEA, 2014.
- 2.2 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements, IEC 61010-1:2010+AMD1:2016 CSV (Consolidated version)

OR

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, IEC 60601-1

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

3.1 Functional and Performance Requirements:

The System shall meet the following functional and performance requirements:

- 3.1.1 Be a standard production model. Equipment prototypes will not be considered, however it is understood that minor changes to a standard model, such as software modifications or limitations on the standard irradiation volume to meet the requirements in this Specification may be required and as such, those will be considered.
- 3.1.2 Be capable of irradiating a volume not less than 1.5 litres.
- 3.1.3 Be capable of delivering a central dose rate of at least 7 Gy.min⁻¹.
- 3.1.4 Have an overall dose uniformity ratio (DUR) of 1.5 or less in the irradiation volume.

Self-shielded X-ray Blood Irradiator	 IAEA International Atomic Energy Agency	IAEA Specification Dated 2018-10-14
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3.1.5 Be capable of operating continuously during a standard 8 hour working day.

3.1.6 Have an operational availability greater than 90%.

3.2 Technical Requirements

The System shall meet the following technical requirements:

3.2.1 Operate at an anode voltage between 150 kV and 225 kV.

3.2.2 Require no utility other than electricity and cooling water to operate.

3.2.3 Operate on a power supply of 230V 1 ph/400V 3ph 50 Hz.

3.2.4 Conform to the standard IEC 61010 or 60601 and the requirements for CE marking.

3.2.5 Incorporate suitable devices to protect the system from power fluctuation or loss.

3.2.6 Have an external dose rate not exceeding $3 \mu\text{Sv.hr}^{-1}$ at any point 10 cm from the external surface when the System is operating at its maximum rated output.

3.2.7 Be provided with two sets of removable canisters with locking lids to fit the irradiation volume(s) made of durable, washable radio-transparent material.

3.2.8 Incorporate twin vertically opposed X-ray tubes.

3.2.9 Operate in the temperature range 10 – 30 °C and in the relative humidity range 20 - 75%.

3.2.10 Incorporate a supervision and control system, including a timer, for the visualisation, control, recording and storage of operating parameters with provision to set the anode current and voltage and run time to provide any dose in the range 0 – 200 Gy.

3.2.11 Incorporate the necessary features to allow for checking and calibration of the radiation field produced and calibration of a suitable dosimetry system, including a pass-through port for measurement instrument cables and a system for reproducibly positioning an ion chamber or alanine dosimeters at the geometric centre of (one of) the irradiation canisters.

3.2.12 Have any covers either secured with key locks or removable using suitable tools to allow access for maintenance.

4 Additional items

The contractor shall include, as an option at the IAEA discretion, one replacement X-ray tube for the irradiator

Self-shielded X-ray Blood Irradiator	 IAEA International Atomic Energy Agency	IAEA Specification Dated 2018-10-14
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5 Delivery time

The System should be available and delivered within 26 weeks after issuance of a purchase order (due to readiness for installation at the IAEA premises, the delivery shall occur in July 2019).

6 Warranty

6.1 A Warranty period shall be in accordance with the IAEA General Conditions of contract.

6.2 The Contractor shall, as an option, upon the IAEA's request provide an on-site maintenance and service contract for four (4) additional years beyond the warranty period.

The Contractor shall warrant that it will make every reasonable effort to resolve any defect or non-compliant part in a timely manner and that any warranty or corrective maintenance claim requiring the Contractor's presence at the IAEA site will be addressed at the site within fifteen (15) working days of the Contractor's receipt of the claim.

7 Marking

The System shall have a name plate with manufacturer's name, model, serial number and compliance to manufacturing or quality standard in English. All safety warnings shall be in English.

The System as well as the transportation packing shall bear all mandatory markings in English.

8 Packing

For shipment the System shall be packed in accordance with international standards that are applicable for the shipment by air/sea of this kind of equipment.

9 Quality Requirements

For the design, manufacturing, preparation for shipment and for after-sales activities, the Contractor shall comply with the requirements of the ISO 9001:2008 standard.

10 Testing and Acceptance

10.1 Factory testing before shipment:

10.1.1 A factory test report shall be submitted to the IAEA for approval prior to the shipment of the System to the IAEA. The factory tests shall be carried out on the System according to a pre-established protocol that shall have been reviewed and approved by IAEA. If required, the Contractor shall authorize the IAEA's designated technical officer to inspect and test the System prior to shipment.

Self-shielded X-ray Blood Irradiator	 IAEA International Atomic Energy Agency	IAEA Specification Dated 2018-10-14
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Validation and testing after installation at the IAEA:

10.2 Installation qualification:

10.2.1 The Contractor shall provide an installation qualification report which shall provide documented evidence that the System was provided and installed in accordance with the specifications and that it functions within the pre-determined limits. The tests shall also cover any software and ancillary equipment.

10.3 Operational qualification:

10.3.1 The Contractor shall demonstrate that the System, as installed, is capable of operating and delivering appropriate doses and dose rates as defined in 3.1 and 3.2. This shall be mainly based on a series of dosimetry exercises that will be performed by staff having been properly trained in dosimetry and only after all instruments have been calibrated.

10.4 The operational qualification report shall include the following information:

10.4.1 The dose rate at one or more reference positions using a dosimetry system calibrated with traceability to a national or international primary or secondary standard.

10.4.2 The dose distribution pattern within the full usable volume (dose mapping) for homogeneous organic material with a density between 0.40 and 0.50 g.cm⁻³ at a resolution not less than 2 × 2 mm.

10.4.3 The uncertainty on the doses and dose rates.

10.4.4 The calibration certificates of all instruments.

10.4.5 The training certificates of the staff having performed the dosimetry exercises for the operational qualification.

10.4.6 The System, after installation, shall be tested by the Contractor together with the IAEA to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified herein as determined by the IAEA. The results of the testing of the System, as per the Specification requirements, shall be documented by the Contractor in an acceptance protocol that shall be signed by the IAEA.

11 Installation and Training:

11.1 The Contractor shall install the System at the IAEA Seibersdorf facility.

11.2 The Contractor shall provide one day of training for up to three IAEA staff in the operation and maintenance of the System at the IAEA installation location immediately after the installation of the System. The training shall be documented and assessed.

Self-shielded X-ray Blood Irradiator	 IAEA International Atomic Energy Agency	IAEA Specification Dated 2018-10-14
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11.3 The IAEA will make available at least one its staff member who has been trained in the dosimetry system(s) that will be used during the Operational qualification testing. This staff member(s) will be involved in the Operational Qualification.

12 Deliverable Data Items

The Contractor shall provide:

12.1 A protocol for the factory acceptance test prior to shipment.

12.2 The factory test report prior to shipment.

12.3 Two complete sets of operation and servicing manuals and technical drawings in the English language.

12.4 The Installation Report.

12.5 The calibration certificates of all instruments.

12.6 The training certificates of Contractor's staff performing the dosimetry exercises.

12.7 The report on the training received by the IAEA staff to operate the System (programme, contents, participants, duration, assessment).

12.8 The Operational testing/qualification report.

13 Additional obligations of the Contractor

13.1 The Contractor shall provide information on the reliability of the system including, but not limited to, mean time between failures and operational availability.

13.2 The Contractor shall provide all necessary tools for the maintenance of the irradiator and any special equipment required for installation or connection of the System to the mains (e.g. special rating circuit breakers).

13.3 The Contractor shall provide the spare parts and consumables that are required during one year of normal operation of the System.