A.6: Electron beam sterilization of medical devices at ARPF, RRCAT

RRCAT has operationalized an electron beam radiation processing facility, called ARPF, at Indore. The electron beam (e-beam) facility is based on 10 MeV, 6 kW linacs, developed at RRCAT. E-beam processing is a rising, environment friendly and secure technology for terminal sterilization of medical devices. The facility is licensed by Atomic Energy Regulatory Board (AERB) and Food and Drugs Administration (FDA) MP, through Central Drugs Standard Control Organization (CDSCO). This facility is capable of delivering doses in the range of few gray (Gy) to several mega gray (MGy). Though the focus of e-beam services is on bulk sterilization of medical devices, the facility provides irradiation services for a range of applications including for power electronics, gem industry, mutation breeding studies to develop improved crop varieties and irradiation studies on food products.

Two linacs, each of 10 MeV, 6 kW beam power, are installed in the facility. One linac is exclusively used for sterilization of medical devices and the other is used for irradiation experiments on research samples. The product to be radiation processed is transported in front of scanned beam with a roller conveyor. The speed of conveyor and number of passes are controlled to deliver the required dose to the products.

Facility qualification, licenses and accreditation: The facility has been validated in accordance with ISO 51649:2015 standard. Detailed dosimetric measurements have been performed under installation qualification (IQ), operation qualification (OQ) and performance qualification (PQ) to characterize the facility. 3-D dose mapping in actual product, identification of positions of maximum dose, minimum dose and reference dose, optimization of product dimension, packing orientation, etc. have been carried out to deliver the required dose to various products. A quality management system (QMS) conforming to the requirements of Medical Device Rules (MDR)-2017 has been implemented to provide sterilization services to medical devices. FDA license for radiation processing of Risk Class-A medical devices has been obtained. Furthermore, conformance of implemented QMS was audited by a third party, certified by International Accreditation Forum (IAF) and the facility has been accorded ISO 9001:2015 and ISO 13485:2016 certifications for providing electron beam processing services for sterilization of medical devices complying the requirements of ISO 11137. ARPF is the first 10 MeV electron beam facility in the country having all licenses and accreditations to provide sterilization service for medical devices.

Quality assurance program at ARPF: The facility operates under stringent quality assurance program including the following elements to deliver quality irradiation services to the customer products:

a) Calibrated dosimetry system is used to ensure correct irradiation dose measurements.
b) Process monitoring dosimetry is done for each batch being irradiated.
c) Monitoring and logging of process critical parameters.
d) Implementation of process parameter control window to ensure that machine operates within the specified limits of parameters.
e) An electronic tracking system for product traceability throughout the process cycle, i.e. receiving, storage, handling, irradiation, quality control (QC) checks and release from facility.
f) Periodic maintenance, servicing and calibration of the subsystems.
g) Electronic storage of dosimetry and process parameter and QC related data of each batch traceable using a bar code system.

Recent product qualifications at ARPF: Performance qualification for various medical products such as self-standing viral transport media (VTM) tubes used for COVID-19 testing, petri-dishes, blood vacutainer, gauze pieces, and latex surgical gloves etc. has been carried-out, to achieve dose uniformity ratio (DUR) in the range of 1.4 to 1.6. Processing capacity of 6 kGy-Tons / hr is achieved for these medical devices.

A batch of 125 boxes (about a truck load) of self-standing VTM tubes and petri-dish (Figure A.6.1) was processed. The sterility test of the batch was carried out by a National Accreditation Board for testing and Calibration Laboratories (NABL) certified and CDSCO approved testing laboratory at Ahmadabad, which confirmed successful sterilization of the medical devices.

ARPF is now available to provide e-beam sterilization service for medical devices at industrial scale.

Fig. A.6.1: Bulk sterilization of medical devices with electron beam at ARPF.

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