A.5: One million medical devices sterilized at ARPF with 10 MeV electron beam

Electron Beam Radiation Processing Facility (named ARPF) has reached a new milestone in providing commercial services for electron beam sterilization of medical devices. More than 1.2 million regulated medical devices have been successfully sterilized using 10 MeV, 6 kW electron linac at ARPF. The facility is being operated in conformance with Medical Device Rules (MDR) 2017 under license from Food & Drugs Administration (FDA), MP state up to risk class-B medical devices. The sterilization is carried out as per quality requirements of ISO 11137. The quality management system of the facility has been audited by Central Drugs Standard Control Organisation (CDSCO) notified body and the facility has ISO 13485:2016 with ISO 9001:2015 certifications.

Commercial electron beam sterilization services started at ARPF in October 2022 with signing of MoU between M/s Becton Dickinson (BD), one of the largest global medical devices manufacturing company and RRCAT. The first consignment of IV cannula (used for blood/fluid transfusion), containing 640 cartons, were sterilized at ARPF and dispatched on 20th October 2022. Dr. S. V. Nakhe, Director, RRCAT flagged off the first consignment in presence of senior Becton Dickinson officials. The flagging off ceremony was attended by Shri Abhay K. Jain, Plant Management Head, Sourabha N., BD India-South Asia Business Director, team members from BD, and Shri Tushar Puntambekar, Director, EAG, Shri G. Mundra Director, TDSG, Shri Jishnu Dwivedi, Project Coordinator & Facility In-charge and other colleagues form RRCAT (Figure A.5.1).

Fig. A.5.1: Flag off ceremony and dispatch of the first consignment from ARPF.

The IV cannulas, which are used for blood/fluid transfusion comes in direct contact with patient blood stream, therefore ensuring sterility assurance level (SAL) of 10^{-6} is a key requirement for device sterilization. It is mandatory to perform the volumetric dose measurement in the process load to optimize the process specification and deliver the dose within specified limit of minimum and maximum dose. IV cannula, which is a heterogeneous medical device, poses special challenges in obtaining uniform dose distribution within process load.

The performance qualification for the IV cannula boxes was performed by conducting product depth dose profile, 3-dimensional volumetric dose mapping to identify the minimum & maximum dose region and relation of min./max. dose to the dose at a reference location on box surface. Alanine EPR dosimetry system, traceable to National Dosimetry Laboratory, BARC has been used for dose mapping study.

Expert teams from BD visited ARPF on several occasions and critically audited the various SOPs, process and procedures implemented to meet the regulatory requirements of Schedule IV & V of MDR-2017 and ISO 13485. The BD team found ARPF facility to have required technical capabilities and process control for electron beam sterilization while maintaining the integrity of the irradiation process. The IV cannula being CE ("Conformité Européenne") mark product has additional requirement of CE auditing. A CE certified auditor critically audited QMS & the facility and certified them to CE standards.

Fig. A.5.2: A batch of IV cannula cartons stored at ARPF for radiation sterilization.

ARPF is providing sterilization service to M/s BD on regular basis (Figure A.5.2) and 2535 cartons containing more than 1.2 million devices have been sterilized in six batches. Figure A.5.3 shows the cumulative growth in the number of medical devices sterilized at ARPF. ARPF is ready to provide sterilization services to wider customer base and is inviting medical device industry to make use of this modern facility.

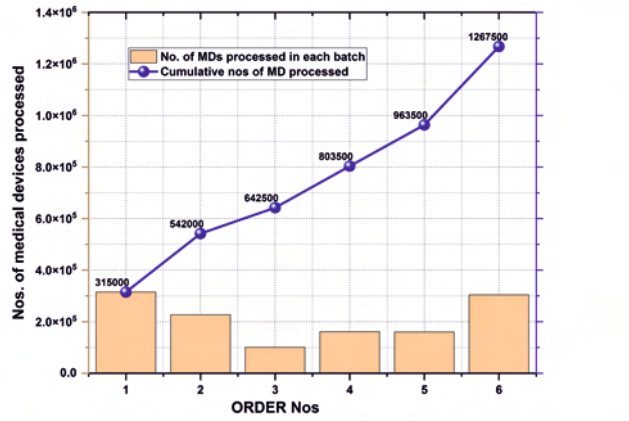

Fig. A.5.3: Cumulative growth in the number of sterilized medical devices.

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