A.3: Expansion of commercial E-beam irradiation services at ARPF

Electron Beam Radiation Processing Facility (ARPF) began its commercial operation in second half of 2022 and made its first shipment of electron beam sterilized Risk Class-B medical devices in October 2022. The E-beam irradiation services at ARPF are being provided as per the process control requirements of ISO 11137 and Quality Management System (QMS) requirements of Medical Device Rules (MDR) 2017, ISO 13485:2016 and ISO 9001:2015 certifications.

Sterilization of the IV cannula (used for transfusion of blood or liquids in patient body) manufactured by M/s Becton Dickinson (BD) is being carried out on regular basis after signing of irradiation agreement between RRCAT Incubation Centre and Becton Dickinson in 2022. Figure 3.1 shows progressive growth in the sterilization of medical devices (IV cannula) at ARPF till June 2023.

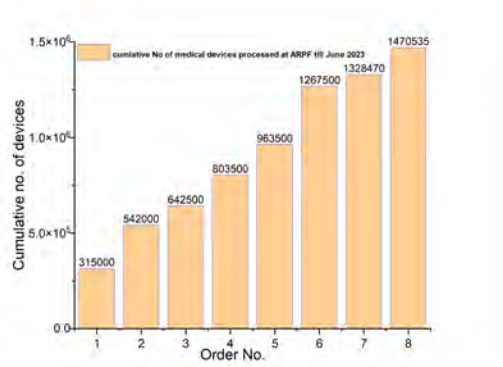

Fig. 3.1: Cumulative sterilization of medical devices at ARPF.

To expand the user base for electron beam applications, outreach activities were carried out through e-mails/ presentation and webinar. As a result, a large number of medical device manufacturers from across the country have started exploring, qualifying and validating the electron beam facility for electron beam sterilization process development and to generate the baseline data for radiation compatibility of various products. Some of the products irradiated with electron beam are listed in Table 3.1 and shown in Figure 3.2.

Table 3.1: Products irradiated with electron beam.

Product name	Usage	Dose (kGy)
Silvasorb	Wounds dressing	18 - 28
IV blood bags	Filling of drug and blood	25 - 45
Skin Temp AG	Burn healing	27 -32
Butyl rubber stopper	Drug packaging	25 – 40
Blood collection tubes	Blood sample collection	7 – 9
EPDM sheet	Crosslinking	120 - 145

Making improvements in the process performance, the conveyor control system has been upgraded for reliable and efficient process operations. Firmware of PLC and drives have been updated. New PLC, HMI and SCADA programs for "Batch mode" "Performance Qualification (PQ) mode", "Manual mode" has been developed.

Blood collection tubes

Blood transfusion bags

Antimicrobial dressing

Butyl rubber stopper

Fig. 3.2: Medical devices irradiated for process development.

These modes can be operated for one as well as two sets of trolley trains. In case of two sets of trolley trains, empty trolleys can be transferred from unloading station to loading station while irradiation process of one batch is going on. This permits loading of next batch of products on the second trolley train while first batch is being irradiated. Thus, irradiation of next batch can be started immediately after process completion of the previous batch. A customized system for process speed measurement, irradiation pass counting, box identification (in case of process trip) and jamming detection has been developed and implemented. The PLC based conveyor control system has been integrated with main control system (MCS) in such a way that all the operations can be executed from main control system, data of critical parameters (process speed, number of pass and location of box at trip time) is transferred for data logging. Figure 3.3 shows the mimic of conveyor control panel for two sets of trollies.

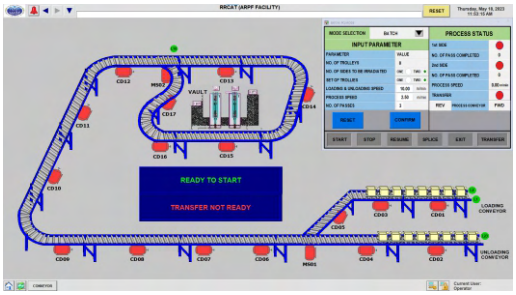

Fig. 3.3: Mimic control panel for upgraded conveyor.

Additionally, gem industry is availing ARPF services for color modification of their products.

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