A.4: ARPF starts commercial sterilization of medical devices

The electron beam (e-beam) radiation processing facility (ARPF) has reached to a matured level of operation to provide e-beam irradiation service to regulated medical devices and other industrial products on commercial basis. The medical device manufacturers, pharma industry and gem industry are using the facility for a variety of applications. It is pertinent to note that ARPF is based on the RRCAT developed Linac technology and two Linacs each having beam power of 6 kW and nominal beam energy of 10 MeV are installed in the facility (Figure A.4.1). The facility has been designed, developed, commissioned and is being operated by RRCAT to provide industrial scale irradiation services. The facility is also being used to explore the potential of electron beam in various societal applications. To meet the dose requirements of wide range of applications, facility operation can be tuned to deliver doses in the range of few Gray (Gy) to several Mega Gray (MGy).

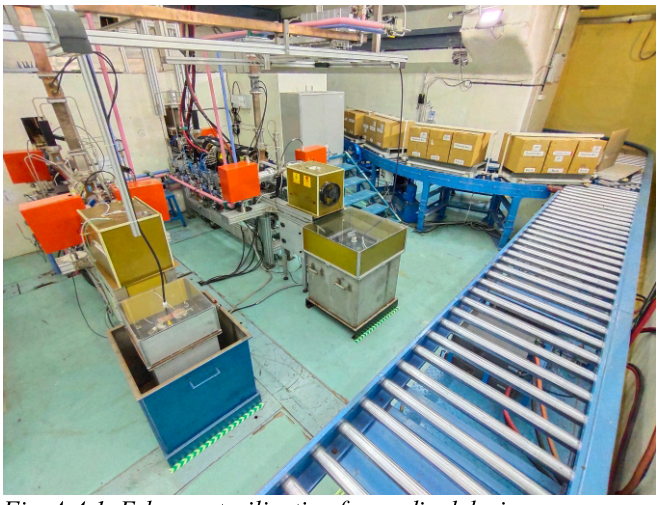

Fig. A.4.1: E-beam sterilization for medical devices.

The facility is licensed by Atomic Energy Regulatory Board (AERB) and Food and Drugs Administration (FDA) MP state. The facility has also been awarded ISO 9001:2015 and ISO 13485:2016 certifications for providing electron beam processing service for sterilization of medical devices as per the ISO 11137. ARPF is the first Linac based e-beam facility in the country providing commercial sterilization service to the regulated medical devices.

Regulatory framework for e-beam sterilization in India: In our country, Medical Device Rules (MDR) 2017 regulates manufacturing of the medical devices and sterilization of the devices is considered as an integral part of device manufacturing. Hence, stringent Quality Management System (QMS) requirements conforming to MDR-2017 are to be followed in order to provide e-beam sterilization services. The Pharmacopoeia Government of India (Volume-1, 2018) approved electron beam technology for sterilization of medical devices in year 2018. The international standard ISO 11137 specifies the requirements for development, validation and routine control of e-beam sterilization process for medical devices and being practiced worldwide. Central Drug Standards and Control Organization (CDSCO) together with State Licensing Authority (SLA) inspect and audit the facility for regulatory compliance. Recently, CDSCO "Notified Body" audited ARPF and found overall plant operation, infrastructure and the QMS system complying regulatory requirements and subsequently granted the license for sterilization of Risk Class-B medical devices.

Process development and validation for e-beam sterilization of many medical devices such as syringes, IV cannulas, catheters, surgical gloves, etc. have been established (Figure A.4.2). Loan licensing and irradiation agreement has been signed with a multinational company to provide bulk sterilization service to their products.

Fig. A.4.2: E-beam process validated medical devices.

The control system & software for plant operation has been upgraded and validated. Interface between the central control system and conveyor control system has been developed for online conveyor speed measurement and centralized process resumption. The critical process parameters are continuously monitored and at the end of process, a process summary report is generated to facilitate release of sterilized products from the facility. Apart from medical device sterilization, irradiation service has also been provided to industries for colour modification of gemstones and diamonds.

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