

Shri Jishnu Dwivedi, Head, Industrial Accelerator Division, RRCAT informed about the challenges and timeline for the above incubation activity. According to present plan, the machine will be dispatched to incubatee site at Bengaluru by the end of November 2022 and it will be installed for testing by the end of December 2022. He also highlighted the challenges ahead for the incubation and requested the support of all team members to achieve the goal.

Shri Vikram Kalia, Director, Microtrol Sterilization Services Private Limited, Mumbai expressed his gratefulness to the Department of Atomic Energy (DAE) for supporting entrepreneurs through the process, from plant design, training of manpower to assured raw material, literally through the life cycle, “आदि से अंत तक”. He informed the house that earlier DAE extended gamma radiation technology for radiation processing applications and now they are selected for the incubation of e-beam radiation processing technology. He further expressed those institutions, like – RRCAT will provide appropriate handholding for this growing industry for the successful deployment of these new technologies.

Dr. S. V. Nakhe and Shri Vikram Kalia signed the incubation agreement on behalf of Incubation Centre-RRCAT and Sterilization Services Private Limited, respectively. This may be noted that Linac based electron beam radiation processing offers several advantages including being environment friendly, secure, and fast (offering quick turnaround time for the processed goods). The Linac e-beam technology is extremely useful for sterilization of medical devices. It can sterilize the medical devices in their finally packed condition and leaves no harmful residue in the medical devices. This not only saves the devices from any chances of reinfection during subsequent handling, but also provides a safer alternative to the presently prevailing sterilization method based on environmentally hazardous, toxic and carcinogenic gas, like ethylene oxide, which may also leave a residue in the product. In view of its advantages, the e-beam technology is rising rapidly around the world.

Reported by:
C. P. Paul (incubation@rrcat.gov.in)

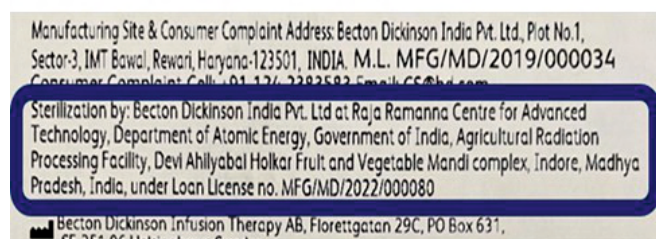
N.4: Electron beam sterilization of 630 cartons of BD Venflon Pro I.V. Cannula at ARPF, RRCAT, Indore

Incubation Centre-RRCAT received an order under incubation services for electron beam sterilization of 630 cartons (individual devices 3.15 lakhs) of Venflon™ Pro I.V. Cannula at ARPF from M/s Becton Dickinson India Pvt. Ltd., Bawal, Rewari, Haryana. The product belongs to Risk Class-B and is used for blood/fluid transfusion. M/s Becton Dickinson (BD) is one of the largest global medical technology companies in the world.

The e-beam radiation processing was carried out during October 3-7, 2022 as per standard operating procedure under the quality management system (QMS) applicable for the

regulated medical devices (ISO 11137, Medical Device Rules-2017 and ISO 13485). With this assignment, RRCAT successfully achieved the high-quality levels required for e-beam sterilization, at par with international standards, and was audited through in-depth audit by third party agencies and the quality control division of BD.

Quality control during the processing was done by keeping the machine parameters within permissible tolerance bands, continuous logging, and verification of process data. In addition, reference dosimeters (alanine pellets) were used, which were independently read and confirmed.



BD IV cannula Venflon.™

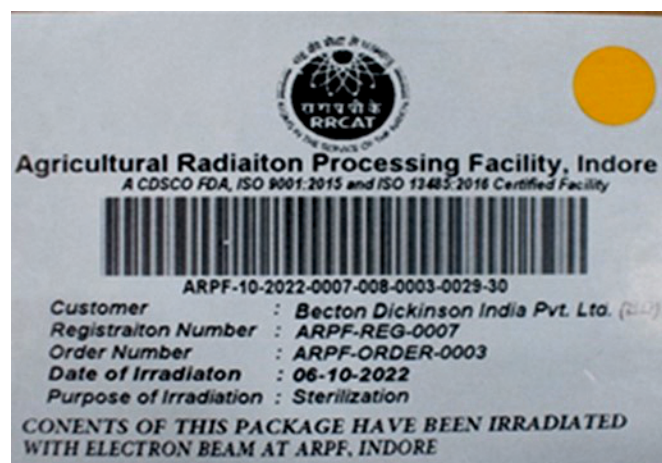


Designated storage area for BD cartons at ARPF.

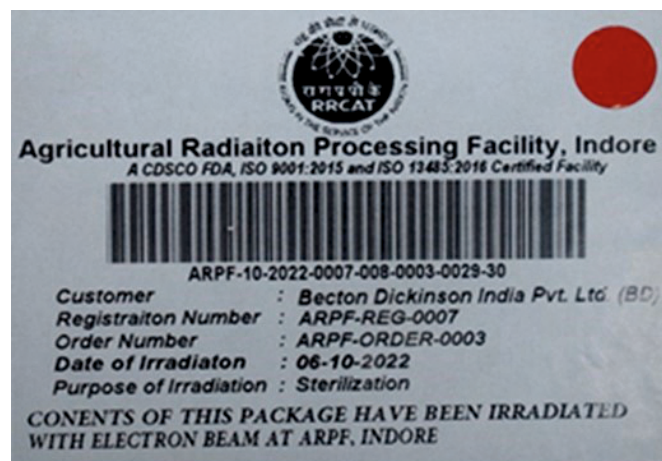
After successful inventory QC checks as per ARPF QMS requirements, the complete consignment was divided into 20

batches (32 cartons in each batch) and the traceability of each carton inside the facility was established by unique bar-code system. The non-irradiated and irradiated cartons have been stored in different, designated storage areas, and identified using irreversible radiation indicator (turned red after irradiation from yellow before irradiation).

The Linac was operated at 9.3 MeV, 6 kW beam power (effective irradiation time 22 hrs.). The average minimum dose and maximum dose delivered to the cartons were 29.5 kGy and 52.0 kGy, which is within the specified range of M/s BD (range of 25 kGy to 55 kGy). Performance qualification (PQ) for the product was done earlier this year at ARPF.



(a)



(b)

Carton barcode- (a) non-irradiated, and (b) irradiated.

The consignment has been dispatched to the customer after irradiation on 20th October 2022. The role of Incubation Centre-RRCAT was to work as a commercial wing, while whole beam processing was carried out by Industrial Accelerator Division. The above work is a milestone in the RRCAT history declaring indigenous accelerator technology irradiating medical devices at industrial scale.

Reported by:
C. P. Paul (incubation@rrcat.gov.in)

N.5: Chinese patent on portable refrigeration system based on liquid nitrogen for transporting refrigerated goods

This invention relates to a liquid nitrogen based refrigeration system for storage and transportation of perishable goods/food, at controlled temperature and humidity levels. The invention provides means for storage and transport of goods requiring controlled temperatures in the range of -40 °C to +20 °C maintained inside vacuum insulated container. The system maintains temperature and humidity levels inside container with the help of specially designed heat exchanger for cooling the air inside the storage container. The system also includes a LN₂ storage container, circulation pumps/fans, control system and batteries. The container is designed such that it can be supported on truck, trolley, railway wagons, ships or as a standalone stationary system.

Inventors of the patent are S. C. Patidar, Deepak Arzare, Rupul Ghosh, Lakshman Singh, A. Lakshminarayanan, Haribhai Vora, Piyush Saxena, Abhishek Jain, Ankit Tiwari, Hemant Patel, Shailesh Gilankar, P. K. Kush and Prashant Khare. The Chinese Patent No. is ZL201810504018.3 and patent grant date is October 25, 2022.

The technology has been commercialized and transferred to M/s Tata Motors under incubation mode.

