A brief report on the

Electron Beam Sterilization of 3.15 lakh devices of BD Venflon Pro I.V. Cannula at ARPF, RRCAT, Indore

RRCAT received an order for electron beam sterilization of 640 cartons (2.4 ton – individual devices 3.15 lakhs – cost of product ~ Rs 36 lakhs) of Venflon^{TM} Pro I.V. Cannula at ARPF (Fig.-1) from M/s Becton Dickinson India Pvt. Ltd., Bawal, Rewari, Haryana. The devices were received on 1st Oct. 2022. The product belongs to Rick Class-B, is made of polypropylene and used for blood/fluid transfusion. M/s Becton Dickinson (BD), is one of the largest global medical technology companies in the world engaged in manufacturing of medical devices.

All process operations were carried out as per SOPs under the Quality Management System (QMS) for regulated medical devices as per ISO 11137, Medical Device Rules-2017, GOI (Sch.-IV and Sch.-V) and ISO 13485. RRCAT successfully achieved the high quality levels required, at par with international standards, for electron beam sterilization of this product and was audited through in-depth audit by third party agencies and the quality control division of M/s Becton Dickinson.

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, Fig. - 2 (a & b) and identified using irreversible radiation indicator (turned red after irradiation from yellow before irradiation), Fig.-3 (a & b). The linac was operated at 9.3 MeV, 6 kW beam power and the complete consignment has been irradiated within **three working days** (effective irradiation time 22 hr.). Fig. - 4 shows the critical process parameter during irradiation. 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 to 55 kGy). Performance Qualification (PQ) for the product was done earlier this year at ARPF.

Since this is a significant event, a formal function is proposed to flag off the dispatch of the processed material on 20th October 2022.

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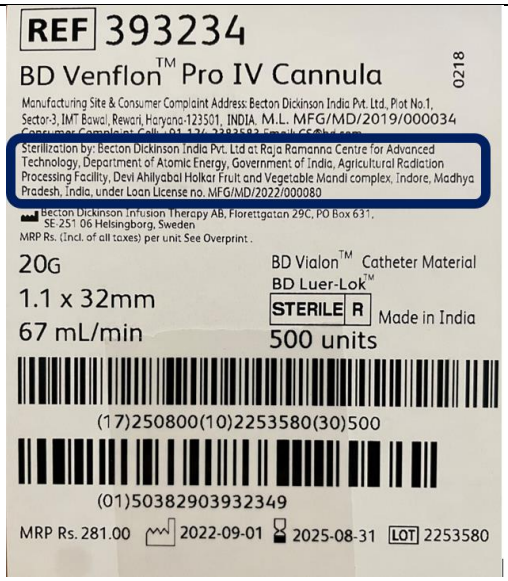

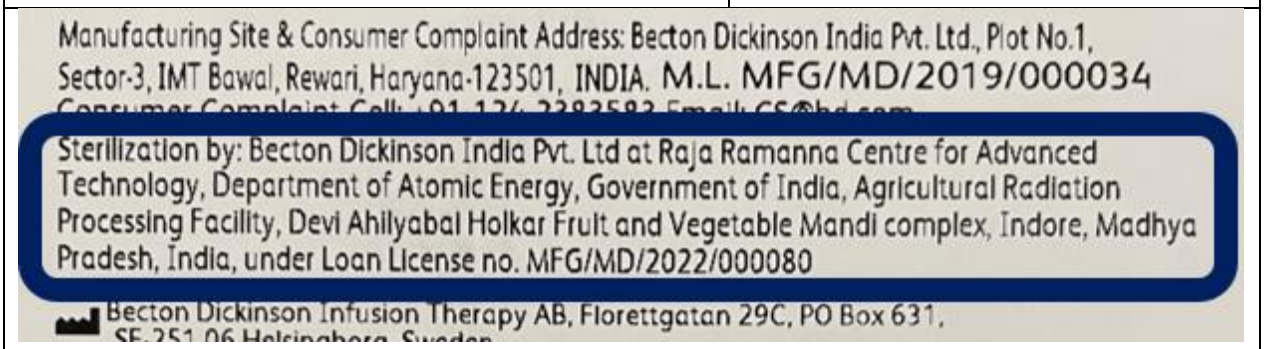

Fig.-1: BD IV cannula Venflon™

Fig.-2 (a): Non-irradiated BD cartons stored in non-irradiated product storage area of ARPF

Fig.-2 (b): Irradiated BD cartons stored in ready to dispatch product storage area of ARPF

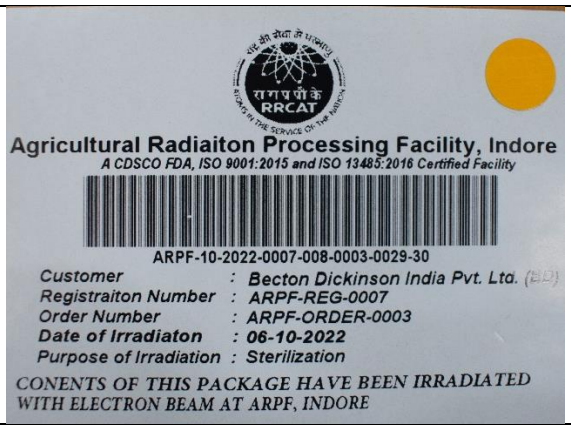

Fig.-3 (a): Non-irradiated carton barcode

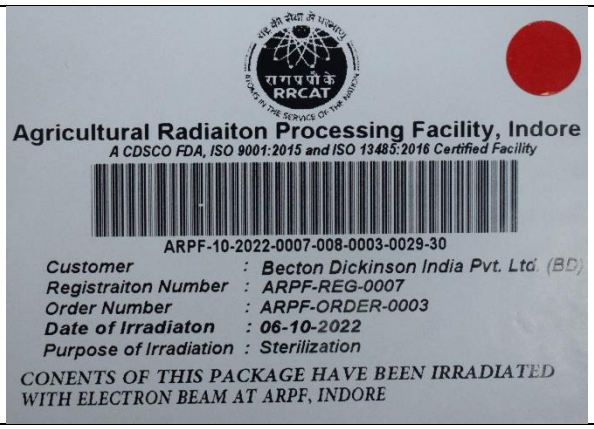

Fig.-3 (b): Irradiated carton barcode

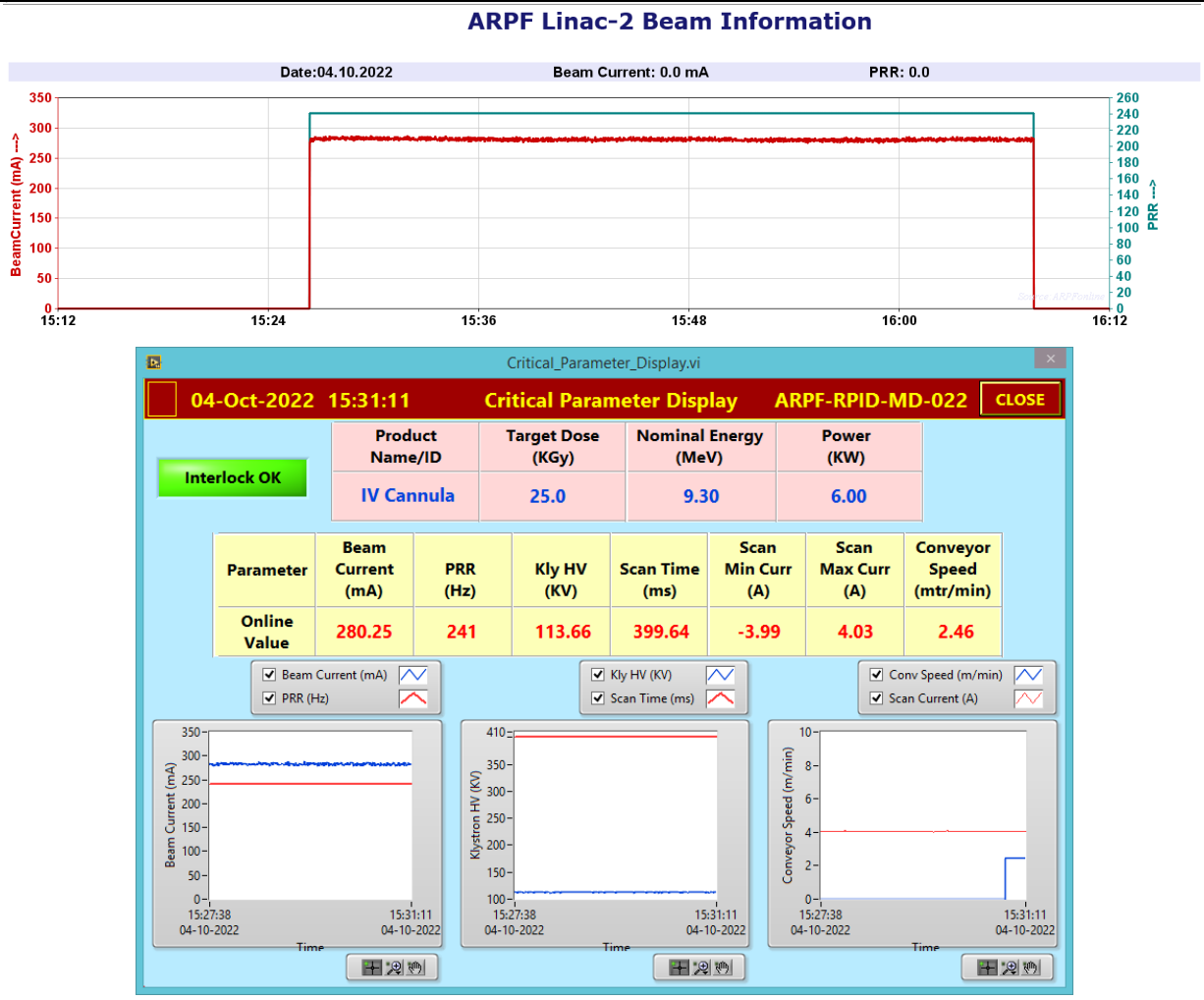

Fig.-4: Beam parameter of Linac while irradiation and critical parameter display