Changing from Gamma to IMPELA®

ISO11137 ANNEX A GUIDANCE – 8.4.1

"the higher the dose rate, the lower the unwanted effects upon product.

A product qualified at a low dose rate (gamma or x-rays) will typically require minimal qualification to demonstrate material compatibility at a higher dose rate (electron-beam)."

Changing from Gamma Irradiation to IMPELA® Electron Beam Processing requires two simple steps for most products. The first is a product dose map and the second, dose verification. The dose verification can be completed as a normal quarterly dose audit.

- **PER ISO 11137 SECTION 8.4.1;**
  In transferring a maximum acceptable dose to a radiation source different from that on which the dose was originally established, an assessment shall be made demonstrating that differences in irradiation conditions of the two radiation sources do not affect the validity of the doses. The Assessment shall be documented and the outcome shall be recorded.

  and;

- *Transference of a verification dose or a sterilization dose to a radiation source different from that on which the dose was originally established shall not be permitted unless: a) data are available to demonstrate that differences in operating conditions of the two radiation sources have no effect on microbicidal effectiveness.*

Put the Power of IMPELA® to Work for You

Essentially, this means that Iotron will perform a dose mapping study to confirm the original validated sterilization dose can be adequately delivered by the IMPELA® throughout the product. During the dose map, Iotron will also verify that the delivered dose will be within the parameters for maximum dose. The Customer will then evaluate the product for functional requirements after treatment on the IMPELA® and confirm the continued validity of the maximum acceptable dose. This analysis is required when changing between gamma facilities as well.

Second, a dose verification is performed. The dose verification can be performed at any time and is essentially the same tests performed during the quarterly dose audit. In fact, to save costs, it can be performed in replacement of and as the quarterly dose audit. Routinely manufactured product often has a consistent bioburden history and by simply running a routine quarterly dose check with the initial lot, confirmation that microbial inactivation is similar between gamma and IMPELA® can be achieved.

Conversion from Gamma to Electron Beam typically ranges from 10-15 days and includes the timeline for the routine lab work as well as concurrent dose map and processing activities. One or many products can be processed within this window. In general, the process described above is applicable to most routine products with few exceptions

Contact Iotron Industries today to put the Power of IMPELA® to work for you.

IOTRON ELECTRON-BEAM FACILITY

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