

Consideration of Material Effects in Electron Beam Sterilization

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More extensive application of electron beam (E-beam) radiation technology in sterilizing single use medical devices has been hindered by the lack of data on material effects of E-beam exposure relative to those of the more commonly used ethylene oxide and gamma radiation technologies. Led by the Pacific Northwest National Laboratory and including device manufacturers, university researchers, and contract sterilizers, the National Nuclear Security Administration – sponsored Team Nablo seeks to lower barriers to broader use of E-beam in device and biopharmaceutical equipment sterilization. We have investigated the effects of E-beam dose, dose rate, temperature, atmosphere, and energy on material properties of a range of medical polymers following E-beam processing at sterilization-relevant conditions. Resultant data is being made freely available to the industry to encourage manufacturers currently using cobalt-60 gamma irradiation or ethylene oxide gas for sterilization to consider E-beam as a preferred alternative for current and future products. Findings to date have supported the conclusion that the effects of E-beam radiation on medical polymers are like those of gamma radiation and E-beam is a viable option for single use device sterilization.