



Radiation Sterilization: Validation and Routine Operations Handbook

By Anne F. Booth

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This comprehensive handbook is intended to provide a framework for the validation and routine operation of irradiation sterilization processes. It defines methods to assist you in the interpretation and understanding of ancillary standards and guidelines. It offers practical procedures for the validation and routine monitoring of your specific radiation sterilization process. Although the scope of the standards refers to medical devices, the requirements and guidance may be applicable to other health care products. The guidance presented complies with: • ANSI/AAMI/ISO 11137-1: 2006: Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices; • ANSI/AAMI/ISO 11137-2: 2006: Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose; • ANSI/AAMI/ISO 11137-3: 2006 - Sterilization of health care products - Radiation - Part 3: Guidance on Dosimetric aspects.

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