

Technical Information Report

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Sterilization of health care
products—
Radiation sterilization—
Product adoption and
alternative sampling
plans for verification
dose experiments and
sterilization dose audits

Sterilization of health care products— Radiation sterilization— Product adoption and alternative sampling plans for verification dose experiments and sterilization dose audits

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Abstract: Describes approaches to the selection and auditing of a sterilization dose that may reduce the number of product items required while maintaining assurance of attaining the desired sterility assurance level (SAL). This approach addresses sampling plans for verification dose experiments and sterilization dose audits. In addition the approaches to adopting a product into an established product family are defined.

Keywords: sterility, bioburden, radiation, health care products, dose, audits, product adoption, design verification, procedures

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