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AMENDMENT 2
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Sterilization of health care products — Radiation —

Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

AMENDMENT 2: Revision to 4.3.4 and 11.2

Stérilisation des produits de santé — Irradiation —

Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux

AMENDEMENT 2: Révision de 4.3.4 et de 11.2

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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4.3.4

Add the following sentence to the end of the clause:

Detailed guidance on dosimetry and associated measurement uncertainty is given in ISO 11137-3.

11.2

Replace the second sentence with the following:

The procedure(s) shall define the requirements (see 9.4.3 or 9.4.4 as appropriate) for designating a sterilization process as conforming.

ICS 11.080.01
Price based on 1 page