



Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization

TECHNICAL CORRIGENDUM 1

Stérilisation des dispositifs médicaux — Prescriptions pour la validation et le contrôle de routine — Stérilisation par irradiation

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to International Standard ISO 11137:1995 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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B.3.4.2.2.3 Stage 3: Perform verification dose experiment

(For Method 2A) Replace the last two sentences of the first paragraph with the following text:

“The actual dose may vary from the D* kGy dose by + 1,0 kGy or + 10 %, whichever is greater. If the delivered dose is less than 90 % of the D* kGy dose, the verification dose experiment may be repeated.”

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B.3.4.2.4.3 Stage 3: Perform verification dose experiment

(For Method 2B) Replace the last two sentences of the first paragraph with the following text.

“The actual dose may vary from the D* kGy dose by + 1,0 kGy or + 10 %, whichever is greater. If the delivered dose is less than 90 % of the D* kGy dose, the verification dose experiment may be repeated.”

ICS 11.080

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Descriptors: health care products, medical equipment, sterilization, radiation, gamma radiation, electron beams, specifications, validation, routine control.

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