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AMENDMENT 1
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Biological evaluation of medical devices —

Part 7: Ethylene oxide sterilization residuals

AMENDMENT 1: Applicability of allowable limits for neonates and infants

Reference number
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This document was prepared by Technical Committee ISO/TC 194, *Biological and clinical evaluation of medical devices*.

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Biological evaluation of medical devices —

Part 7:
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AMENDMENT 1: Applicability of allowable limits for neonates and infants

Normative references

Replace the reference to ISO 10993-1:— (including the footnote) with the following:

> ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

4.2, second paragraph

Replace the reference "ISO 10993-1:—, 5.3:" with "ISO 10993-1:2018, 5.3:".

4.2, a) to c)

Replace the text with the following:

a) Limited exposure (A) – medical devices whose cumulative sum of single, multiple or repeated duration of contact is up to 24 h.

b) Prolonged exposure (B) – medical devices whose cumulative sum of single, multiple or repeated contact time is likely to exceed 24 h but not exceed 30 d.

c) Permanent exposure (C) – medical devices whose cumulative sum of single, multiple or repeated contact time exceeds 30 d.

4.3.1, second paragraph

Replace the paragraph with the following:

> The limits for permanent contact and prolonged exposure devices are expressed as maximum average daily doses. These limits carry additional constraints for the first 24 h of the exposure period and, in the case of the permanent contact devices, for the first 30 days, whichever extraction method is used. These constraints place limitations on the amount of EO and ECH that can be delivered to the patient during these early time periods.

4.3.1, third paragraph

Add a new paragraph:

If data are available, consideration should be given for proportioning the limits downward if multiple devices with the residue of concern are used at one time, e.g. multi-device systems, convenience kits, or proportioning the limits upward when device use is only for a part of the exposure period of concern. These concomitant exposure factors (CEF) and proportional exposure factors (PEF) are given in ISO 10993-17. A default value of 0,2 for CEF have been given for 5 medical devices used and contributing to the patient residues daily exposure.

4.3.2, first paragraph

Replace the paragraph with the following:

In the case of a device used in an adult of body mass m_b = 70 kg, and with CEF = 0,2 and PEF = 1,0 (default factors), the average daily dose of EO to patient shall not exceed 0,1 mg/d. In addition, the maximum EO dose shall not exceed:

4.3.2, last paragraph

Replace the paragraph with the following:

When the device is intended to be used in special populations, the appropriate patient body mass shall be used for the derivation of the allowable limits. For example, if the device is intended to be used in premature neonates, neonates or children, the allowable limits shall be derived using the TI value of 0,02 mg/kg/day for EO and 0,029 mg/kg/day for ECH as established in G.6.4 and H.4.1.3, respectively. The appropriate default body mass used for each category of special patient population shall be justified and documented.

4.3.3, first paragraph

Replace the paragraph with the following:

In the case of a device used in an adult of body mass m_b = 70 kg, and with CEF = 0,2 and PEF = 1,0 (default factors), the average daily dose of EO to patient shall not exceed 2,0 mg/d. In addition, the maximum EO dose shall not exceed:

4.3.3, last paragraph

Replace the paragraph with the following:

When the device is intended to be used in special populations, the appropriate patient body mass shall be used for the derivation of the allowable limits. For example, if the device is intended to be used in premature neonates, neonates or children, the allowable limits shall be derived using the TI value of 0,3 mg/kg/day for EO and 0,27 mg/kg/day for ECH as established in G.6.3 and H.4.1.2, respectively. The appropriate default body mass used for each category of special patient population shall be justified and documented.

4.3.4

Replace the text with the following:

In the case of a device used in an adult of body mass m_b = 70 kg, and with CEF = 0,2 and PEF = 1,0 (default factors), the average daily dose of EO to patient shall not exceed 4 mg. The average daily dose of ECH to patient shall not exceed 9 mg.