ISO 10993-7:2026 VS ISO 10993-7:2008A1:2022

BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 7: ETHYLENE OXIDE STERILIZATION RESIDUALS

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REVISION;01

Report Description	ISO 10993-7:2026 VS ISO 10993-7:2008A1:2022
Industry Type	Medical device
Document Type	Pre-audit record
Summary of changes	2026 edition introduces **quantitative formulae, expanded categorization logic, and explicit tolerable intake (TI) and allowable limit (AL) calculations** for ethylene oxide (EO) and ethylene chlorohydrin (ECH). The changes emphasize **risk-based assessment, patient population specificity, and structured calculation protocols**, moving beyond the descriptive toxicological focus of the 2008/A1 edition.

1.0. Comparison Table: below describes the alignment clause-by-clause between the two versions of the standard. Status is **Full** / **Part** / **Not**.

2026 Clause	Requirement	2022 Clause	Requirement	Alignment	Remarks
4 Requirements **4.1** General	The 2026 text frames EO and ECH residual limits as part of a refined toxicological safeguard. It emphasizes that allowable limits are designed to protect against both local irritation and systemic effects, while requiring alignment with ISO 10993-1. Devices already tested under earlier editions are not forced into retesting unless changes trigger new biological risk assessments, reinforcing continuity with prior standards. The toxicological values remain consistent with earlier limits, signaling stability in regulatory expectations. Flowcharts, annexes, and NIST rounding rules are introduced to strengthen transparency, reproducibility, and confidence in conformity assessments.	**4** Requirements **4.1** General	The 2008 text establishes EO, ECH, and EG residual limits within a patient-safety framework, stressing that EO sterilization must minimize residual exposure. It incorporates tolerable contact limits for EO and ECH, while EG is treated differently—acknowledged as a potential risk in hyperosmolar conditions but considered unlikely in device sterilization. The clause reflects regulators' intent to balance practicality with toxicological caution, anchoring evaluations in ISO 10993-1 and related parts, with systemic effects as a key concern. Annexes provide the scientific derivation of limits and testing methods, reinforcing transparency and reproducibility.	Part	2026 (4.1) clarifies maximum allowable limits (ALs) for EO and ECH, references ISO 10993-1:2025, and exempts devices tested to the previous edition unless ISO 10993-1:2025 Clause 10 issues arise. 2022 (4.1) required ISO 10993-3 ISO 10993-10, and EG risk assessment, omitted in 2026. 2026 adds an Annex A flowchart and rounding rules; 2022 detailed EG and TCL annexes.
4.2 Categorization of devices	The 2026 text frames EO and ECH dose limits around exposure duration, introducing categories of limited, prolonged, and long-term contact. It stresses that when devices fall into multiple categories, the stricter evaluation applies, and cumulative exposure from repeated use must be considered. Examples like dialyzer cartridges illustrate how short individual uses can still add up to long-term exposure. Brief-contact devices such as lancets may justify exemption, but coatings or lubricants that persist after removal demand deeper biological evaluation. Overall, the clause reflects regulators' intent to balance practicality with cumulative risk awareness, ensuring exposure assessments remain biologically meaningful.	**4.2** Categorization of devices	The 2008 text frames EO and ECH dose limits around exposure duration, introducing categories of limited, prolonged, and permanent contact. It emphasizes that cumulative exposure must be considered, with stricter evaluation applied if devices overlap categories. The example of dialyzer cartridges illustrates how repeated use can shift classification into higher-risk categories. Overall, the clause reflects regulators' intent to tie dose limits directly to practical timelines of patient contact, ensuring cumulative risks are not overlooked.	Part	2026 (4.2) updates exposure category terminology, replacing 2022's 'permanent exposure' wi 'long-term exposure', omitting 2022 (4.2)'s explicit cumulative contact time thresholds (24 h, 3(d), expanding repeated-use devi requirements, and adding provisions for very brief contact and residual materials, now requiring detailed biological evaluation.
4.3 Allowable limits **4.3.1** General	The 2026 text presents EO and ECH exposure limits through a more formula-driven framework, tying allowable limits (ALs) to tolerable intake, body mass, and concomitant	**4.3** Allowable limits **4.3.1** General	The 2008 text sets EO and ECH dose limits by exposure category, with added constraints for prolonged and permanent contact devices during early exposure	Part	2026 (4.3.1) introduces explicit EO/ECH exposure formulae (TE TI × mb × CEF; AL = TE × (D/N)), mandates lowest patient population mass, allows risk-based alternative limits, clarifies non-device-based exposure

2026 Clause	Requirement	2022 Clause	Requirement	Alignment	Remarks
	exposure factors. It introduces additional constraints for prolonged and long-term devices, particularly during early exposure periods, reflecting heightened concern for initial patient risk. The clause also allows flexibility through risk-based alternative limits, while requiring documentation of intended patient populations and justification for body mass assumptions. Overall, regulators signal a shift toward quantitative rigor and transparency, ensuring exposure assessments remain adaptable yet scientifically grounded.		periods. It highlights regulators' concern for the first 24 hours and first 30 days, where patient risk is most acute. The clause also introduces proportional adjustments when multiple devices are used simultaneously or intermittently, referencing CEF and PEF factors from ISO 10993-17. The default CEF of 0.2 for five devices illustrates how regulators sought to balance practicality with cumulative exposure control, ensuring patient safety across varied device use scenarios.		(liquids, powders), and requires intended population documentation. 2022 (4.3.1) onl referenced max doses by exposu category, suggested but did not require CEF/PEF or formulae, an lacked these specifics.
4.3.2 Limited exposure devices	The 2026 text introduces a formula-based approach for calculating allowable limits (ALs) of EO and ECH in limited-exposure devices. It anchors values in tolerable intake (0.3 mg/kg/d for EO, 0.64 mg/kg/d for ECH) combined with body mass and a default concomitant exposure factor of 0.2. By requiring simulated-use or exhaustive extraction comparisons, regulators emphasize realistic exposure modeling. At the same time, the clause allows risk-based flexibility, enabling alternative calculations tailored to specific devices and patient populations. This reflects a shift toward quantitative precision and clinical relevance, supported by worked examples in Annex K.	**4.3.4** Limited exposure devices	The 2008 text anchors EO and ECH limits in default adult assumptions—70 kg body mass with CEF and PEF factors applied—yielding daily dose caps of 4 mg for EO and 9 mg for ECH. Regulators also highlight the need to adjust limits for special populations, such as neonates or children, by recalculating based on lower body masses and tolerable intake values. This reflects a pragmatic balance: standardized defaults for general use, but flexibility to ensure vulnerable groups are not overlooked.	Part	2026 (4.3.2) introduces formula for AL of EO and ECH using TI (0 mg/kg/d EO, 0.64 mg/kg/d ECH body mass, default CEF 0.2, and exposure duration, replacing 20 (4.3.4)'s fixed adult limits (4 mg EO, 9 mg ECH) and PEF referenc 2026 permits risk-based adjustment by device-specific exposure and clinical context; 2022 required body mass justification for special populations but no formulae.
4.3.3 Prolonged exposure devices	The 2026 text applies a formula-based framework to prolonged exposure devices, anchoring EO and ECH limits in tolerable intake values (0.3 mg/kg/d for EO, 0.27 mg/kg/d for ECH), patient body mass, and a default concomitant exposure factor of 0.2. It requires cumulative exposure estimates from simulated-use or exhaustive extraction to be	**4.3.3** Prolonged exposure devices	The 2008 text defines EO exposure limits for adults using default assumptions—70 kg body mass with CEF and PEF factors—resulting in a daily cap of 2 mg, plus stricter thresholds of 4 mg in the first 24 hours and 60 mg in the first 30 days. Regulators also emphasize adjusting limits for special populations, such as neonates or children, by recalculating	Part	2026 (4.3.3) introduces explicit formulae for AL for EO (TI 0.3 mg/kg/d) and ECH (TI 0.27 mg/kg/d), using body mass, default CEF 0.2, for any exposure up to 30 days. 2022 (4.3.3) specified fixed EO doses (4 mg/2 h, 60 mg/30 d, 2.0 mg/d adults), referencing TI only for special populations. 2026 requires meeting limited exposure AL fro 4.3.2 in first 24 h; 2022 set fixed mg limit.