List of Titles

Technical Information Report

AAMI TIR19/A1:1999

Guidance for ANSI/AAMI/ISO 10993-7:1995, Biological evaluation of medical deices—Part 7: Ethylene oxide sterilization residuals

Amendment

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

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Amendment 1 to AAMI TIR19:1998,
Guidance for ANSI/AAMI/ISO 10993-7:1996,
Biological evaluation of medical devices—
Part 7: Ethylene oxide

Background

Following the publications of ANSI/AAMI/ISO 10993-7:1995 and AAMI TIR19:1998, the U.S. Food and Drug Administration's Center for Biological Evaluation and Review (CBER) contacted the AAMI Sterilization Residuals Working Group and noted that certain devices used in donor and patient apheresis procedures would be considered to be in the same device category as blood oxygenators and blood separators. The limits for this category in ANSI/AAMI/ISO 10993-7:1995 were established based on blood oxygenators, which are large devices used once in a lifetime in life-saving situations. The apheresis devices that CBER was concerned about, however, were relatively small devices that are sometimes used frequently by donors, and some users of such devices which have been ethylene oxide sterilized have reportedly become sensitized to ethylene oxide.

After reviewing the information provided, the AAMI Sterilization Residuals Working Group agreed that a new category for such devices should be established and agreed to recommend that the allowable limit for ethylene oxide on devices in this category be set at 15 mg per device to protect users from being sensitized to ethylene oxide. This 15 mg limit, expressed as a dose-to-patient dose, retains essentially the same limit provided in the 1978 FDA proposed rule on ethylene oxide sterilization residuals. The working group agreed to incorporate this recommendation into AAMI TIR19 by amendment and to forward this recommendation to the International Organization for Standardization for consideration when ISO 10993-7:1995 is revised.

This amendment is being issued because the AAMI Sterilization Residuals Working Group believes that the procedures for amending or revising ANSI/AAMI/ISO 10993-7:1995 would unduly delay the promulgation of information needed by the industry. In accordance with AAMI's policies and procedures, the recommendations contained in this amendment will be reviewed and either converted to an amendment to AAMI/ANSI/ISO 10993-7, incorporated into a revision of the standard, or discontinued within 3 years.

The modifications to AAMI TIR19:1998 are given in I, II, and III, IV, and V, following. Additions are indicated by underlined text (example). Deletions are indicated by strike-out text (~~example~~). The flow chart provided in this amendment replaces the flow chart appearing in TIR19:1998.

I. Change clause 4 as follows:

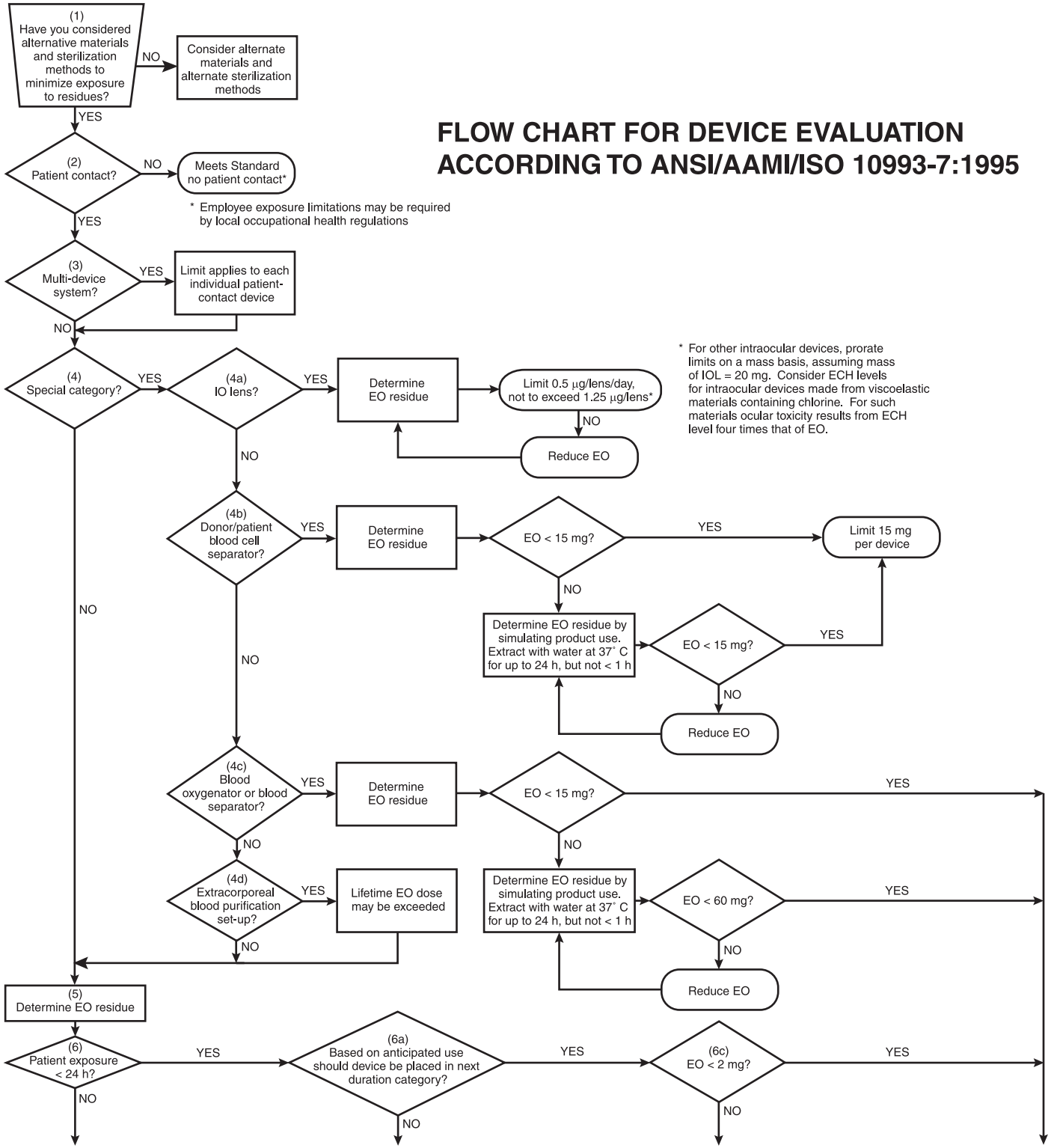
4 If the device is in a special category:

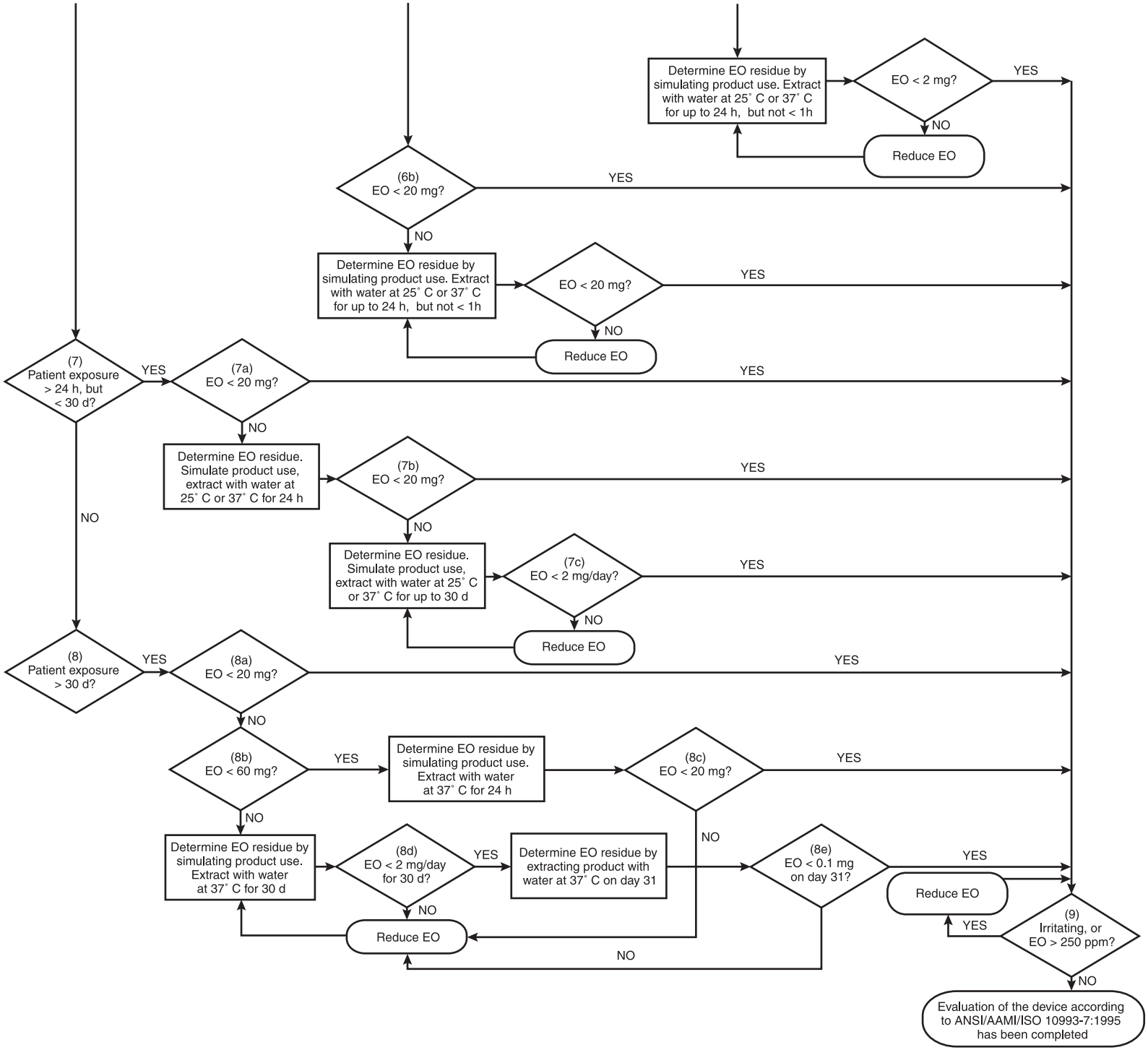
4.a. If the device is an intraocular lens, the limits are 0.5 micrograms/lens/day, not to exceed 1.25 micrograms total.[3] Limits for other intraocular devices can be prorated on the basis of the mass of the device, with the mass of an intraocular lens taken as 20 mg. When EO residues are controlled as specified here for intraocular devices, it is unlikely that significant amounts of ECH will be present. This may not be true for intraocular devices made from viscoelastic materials that contain chlorine. In such cases, the literature (references 25, 71, 72, and 73 from annex F of ANSI/AAMI/ISO 10993-7) indicates the level of ECH that results in ocular toxicity is about four times greater than the corresponding EO level. This should be taken into consideration when evaluating the acceptability of ECH levels associated with these devices.

4.b. If the device is a blood cell separator used in donor and patient blood collection, determine EO residues. The maximum allowable limit for EO shall not exceed 15 mg per device. If it does, determine EO residues by simulating product use by extracting the device at 37° C for up to 24 h, but not less than 1 h (see annex A). If EO from simulating product use exceeds 15 mg, reduce EO; otherwise, the EO residue requirement for this device is met, provided the requirements noted in footnote 11 on page 5 have been addressed.

[3] An exhaustive extraction procedure as specified in table D.1, annex D, and defined in clause 3.2 of ISO 10993-7 is required to determine EO residues for these permanent contact devices. The analyst shall verify and document the procedure used.

FLOW CHART FOR DEVICE EVALUATION ACCORDING TO ANSI/AAMI/ISO 10993-7:1995





Meeting the biological testing requirements for each individually designed medical device as indicated in ANSI/AAMI/ISO 10993-1, combined with the EO-sterilization process residual limits, form the justification that an EO-sterilized device is acceptable for use with regard to its biological evaluation.

4.~~b~~c. If the device is a blood oxygenator or blood separator, determine EO residues,[4] the average daily dose shall not exceed 60 mg per device. If it does, determine EO residues by simulating product use by extracting the device at 37º C for up to 24 h, but not less than 1 h (see annex A). If the daily dose from simulation of product use exceeds 60 mg, reduce EO. Otherwise, if the daily EO dose is less than 60 mg, go to 9.

These devices are used in severe operations such as open-heart surgery. The limit takes into consideration the acute need of the patient during such procedures while still allowing over an 80-fold safety factor. Under such circumstances, this relaxation is warranted.

4.~~c~~d. If the device is a blood purification set-up, the limited (daily) and prolonged (monthly) duration category dose requirements shall be met, but the lifetime dose may be exceeded.

II. Replace flowchart with the flowchart provided in this amendment.

III. *Editorial correction:* In the original published text of AAMI TIR19:1998, page 4, paragraph 6.c., the footnote number should read “9” instead of “6.”

IV. Add subclause 7.c. as follows, so that the text matches the revised flowchart:

7.c. If the measured EO dose from simulated use is less than 2 mg/day, go to 9, otherwise reduce EO.

V. Change the text of subclause A.6 as follows to clarify the meaning:

A.6 Device kits and trays

Initially determine residues for each EO-absorbing patient-contact device in kits and trays, and use these data to establish the worst-case device ~~established~~. Additional data can then be collected using the worst-case device. Document the rationale for the selection.

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Association for the Advancement of Medical Instrumentation

[4] An exhaustive extraction procedure may be impractical for these products, in which case proceed directly to the simulated-use procedure.

