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Technical Information Report

AAMI TIR19:1998
& AAMI TIR19:1998/A1:1999

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

AAMI
Association for the Advancement of Medical Instrumentation

AAMI TIR No.19—1998

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

Approved 30 January 1998

Abstract: This AAMI Technical Information Report (TIR) provides guidance to augment ANSI/AAMI/ISO 10993-7, *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals.* This TIR is intended to assist those individuals using ANSI/AAMI/ISO 10993-7 in understanding the steps necessary to evaluate an ethylene oxide-sterilized device according to the standard and to help those individuals choose appropriate actions where alternatives are given. This TIR also provides limited guidance for the application of other parts of the ANSI/AAMI/ISO 10993 series of standards to the biological evaluation of ethylene oxide-sterilized medical devices.

Keywords: EO, EtO, allowable limits, ethylene chlorohydrin, ECH, ethylene glycol, EG, simulated-use extraction procedure

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

FOREWORD

This technical information report (TIR) was developed by the Task Group on Ethylene Oxide Sterilization Residuals of the AAMI Sterilization Residuals Working Group, under the auspices of the AAMI Sterilization Standards Committee. The Task Group has the following members:

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In Memoriam

The Sterilization Standards Committee and the Sterilization Residuals Working Group would like to gratefully acknowledge the contributions of the late Barbara Whittaker, PhD, Becton Dickinson, whose input and assistance contributed to the writing of this document.

Comments on this technical information report are invited and should be sent to AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201–4598

GUIDANCE FOR ANSI/AAMI/ISO 10993-7: 1995, BIOLOGICAL EVALUATION OF MEDICAL DEVICES—PART 7: ETHYLENE OXIDE STERILIZATION RESIDUALS

Introduction

This AAMI TIR provides guidance on the application of parts of the ANSI/AAMI/ISO 10993 series of standards to the biological evaluation of medical devices that have been sterilized with ethylene oxide (EO). This TIR primarily addresses evaluation of devices according to ANSI/AAMI/ISO 10993-7:1995, *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals*, but limited guidance is also given for other parts of the ANSI/AAMI/ISO 10993 series.

ANSI/AAMI/ISO 10993-7 specifies the requirements for establishing allowable limits for EO residues and analytical methods to show that an EO-sterilized device is in compliance with the allowable limits. Maximum allowable residues for ethylene chlorohydrin (ECH) when ECH has been found to be present in medical devices sterilized with EO are also specified. No exposure limits are set for ethylene glycol (EG) because risk assessment indicates that when EO residues are controlled, it is unlikely that biologically significant residues of EG would be present. Dose to patient is the basis for establishing the allowable limits and the reference method for showing compliance with this standard. The introduction to ANSI/AAMI/ISO 10993-7 also notes that alternative materials and sterilization methods should have been considered during product development and design to minimize exposure to EO residues

In addition to meeting the requirements of ANSI/AAMI/ISO 10993-7, an EO-sterilized device must meet the biological testing requirements of the other parts of the ANSI/AAMI/ISO 10993 series of standards. While this TIR does provide limited guidance relating to other parts of this series (particularly to ANSI/AAMI/ISO 10993-10, *Biological evaluation of medical devices—Part 10: Tests for irritation and sensitization)*, it is not a complete guide for the biological evaluation of EO-sterilized devices. The requirements of the other parts of the ANSI/AAMI/ISO 10993 series should also be considered.

There are certain circumstances (e.g., major surgery) where the lifesaving nature of the therapy significantly alters the risk-benefit analysis of the use of an EO-sterilized medical device. The exposure limits given in ANSI/AAMI/ISO 10993-7 are based on risks and benefits associated with less critical circumstances. In consequence, there is scope for relaxation of the proposed limits in life-threatening situations where it is not possible to meet the specified limits.

The TIR includes a flow chart that is intended to assist a user in understanding the steps necessary to apply the standard. The TIR shows the decision points and provides guidance for choosing the appropriate actions where alternatives are given in the standard. Some of the guidance represents a practical means to apply the standard to different products based on factors such as: nature of exposure, duration of exposure, frequency of use, special situations of use (e.g., as cited in clause 4.3.4 of the standard), and product size. The flow chart is supplemented by more detailed text.

Clause 4.4 of the standard (ANSI/AAMI/ISO 10993-7:1995) gives the requirements for determining EO and ECH residues, and analytical procedures are described in normative annex B. Extraction conditions for the determination of residual EO are given in informative annex D. Guidance on developing an appropriate simulated-use extraction procedure is given in annex A to this TIR. This enables users to develop and document the rationale for an appropriate simulated-use extraction procedure for their EO-sterilized products.

This text should be used in conjunction with the flow chart appended as figure 1. The flow chart is annotated and the text here describes the basis for the decision taken from the standard.

NOTE—Where the statement *Reduce EO* is made in this TIR, accomplish this reduction by additional aeration of the medical device.

Guidance

1 Use of alternate materials and sterilization methods should have been considered during product development and design with the aim of minimizing exposure to residues. The rationale and basis for the decision made should be documented.

2 If the device has no patient contact,[1] the standard is met.[2]

3 If this is a multidevice system, the limits apply to each individual patient-contact device.

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.

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[1] Examples include *in vitro* diagnostic devices, back table covers, Mayo stand covers, light handles, etc.

[2] Employee exposure limitations may be required by local occupational health regulations.

[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. The analyst shall verify and document the procedure used.

4.b. 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.

4.c. 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.

5 Determine total EO residues:[5]

6 For limited exposure devices (those contacting the patient for up to 24 hours):

6.a. Multiple or neonatal use—If consideration of the cumulative effects of multiple use[6] or of neonatal use of the device results in a decision to move the device to the next exposure category, document the rationale for the decision and use the allowable daily dose limit for the prolonged exposure category (24 hours up to 30 days) of 2 mg/day for this limited exposure category device and go to 6.c. If it is concluded that it is not necessary to move the device to the next category, document the rationale for the decision and continue at 6.b.

6.b. No change in category—If the measured EO residue is less than 20 mg, go to 9; otherwise, use appropriate temperatures (either 37º C [body temperature] or 25º C [room temperature]) and times (based on anticipated use time, but with a minimum of 1 hour), with water as the extracting medium to simulate product use.[7, 8] If the measured EO dose from simulated-use is less than 20 mg, go to 9; otherwise, reduce EO.

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

[5] 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. The analyst shall verify and document the procedure used. For very large products, an exhaustive extraction procedure may be impractical. In such cases, continue at 6 and follow the requirement to employ a simulated-use procedure for the appropriate device category.

[6] Frequently used devices are those used more than one hundred (100) times on the average person in a lifetime. (Appendix D in: *Ethylene oxide residues on sterilized medical devices.* HIMA report 88-6, prepared by ENVIRON Corporation, published by the Health Industry Manufacturers Association, Washington, D.C., 1988.)

[7] See annex A.

[8] In certain exceptional situations where simulated-use extraction may be neither feasible nor practical (e.g., for large, surface-contacting devices such as gowns or drapes), the dose of EO transferred to the patient may be estimated on a weight- or surface area-proportional basis using, for example, the transfer reduction factor approach described in the section *Exposure per use* in: *Data requirements for assessment of device risks: J.V. Rodricks and S.L. Brown; J. Am. Coll. Toxicol. 7, 509–518, 1988.*

6.c. Change in category—If the measured EO for these devices is less than 2 mg, go to 9; otherwise, use appropriate temperatures (either 37º C [body temperature] or 25º C [room temperature]) and times (based on anticipated use time, but with a minimum of 1 hour), with water as the extracting medium to simulate product use.[6] If the measured EO dose from simulated-use is less than 2 mg, go to 9; otherwise, reduce EO.

7 For prolonged exposure devices (those contacting the patient for more than 24 hours up to 30 days):

7.a. If the measured EO for these devices is < 20 mg—Go to 9. Otherwise use appropriate temperatures (either 37º C [body temperature] or 25º C [room temperature]) and extract the device for 24 h with water as the extracting medium to simulate product use.[9] If the measured EO dose from simulated-use for the first 24 h is less than 20 mg, go to 7.b; otherwise reduce EO.

7.b. If the measured EO is > 20 mg but < 60 mg—Simulate use of the device by using appropriate temperatures (either 37º C [body temperature] or 25º C [room temperature]) and times (based on anticipated use time), extracting with water.[9] If the measured EO dose from simulated-use is less than 2 mg/day, go to 9; otherwise reduce EO.

8 For permanent exposure devices (those contacting the patient from 30 days to lifetime):

8.a. If the measured EO is < 20 mg—Go to 9; otherwise go to 8.b. or 8.d.

8.b. If the measured EO is < 2 mg/day for 30 days (i.e., <60 mg)—Extract the device using water at 37º C for 24 hours and go to 8.c; otherwise reduce EO.

8.c. If the measured EO dose for the first 24 hours from simulated-use is < 20 mg—Go to 9; otherwise reduce EO.

8.d. If the measured EO is > 60 mg—Extract the device at 37º C for 24 h. If the measured EO dose for the first 24 hours from simulated-use exceeds 20 mg reduce EO, otherwise extract at 37º C for 30 days and go to 8.e.

[9] See Annex A.

8.e. If the measured EO dose for the first 30 days from simulated-use is > 2 mg/day (i.e., > 60 mg)—Reduce EO. Otherwise extract the same device on day 31 at 37º C for 24 hours.[10] If the measured EO dose exceeds 0.1 mg, reduce EO; otherwise, go to 9.

9 The device shall not be irritating with the amount of EO to be allowed on the device at release when tested following the appropriate procedures described in ANSI/AAMI/ISO 10993-10, *Biological evaluation of medical devices—Part 10: Tests for irritation and sensitization*, paying particular attention to A.2.7. The AAMI Sterilization Residues Working Group has evaluated available data and has determined that medical devices might not meet the requirements of Part 10 if the EO residue concentration exceeds 250 ppm. Therefore, if the device is irritating or the EO residue exceeds 250 ppm, reduce EO. Otherwise, the evaluation of the device according to ANSI/AAMI/ISO 10993-7 has been completed.[11]

[10] The dose to patient shall not exceed 0.1 mg/day from day 31 for devices in the permanent exposure category, and this specific test is to confirm that this requirement is met.

[11] 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.

Annex A

Simulated-use extraction procedure

A.1 Extraction fluid

Water should be used for simulated-use extraction of EO residues (Ref: Kroes, R., Bock, B., and Martis, L. *Ethylene oxide extraction and stability in water and blood.* Personal communication to the AAMI committee, Jan. 1985).

A.2 Extraction temperature

Extract devices wholly or in part in contact with the body during use at 37º C (body temperature). Extract devices having no immediate body contact during use (e.g., hypodermic syringes) at 25º C (room temperature). When devices are extracted at 37º C, evaluate the conversion of EO to ethylene glycol (EG).

A.3 Extraction time

Consider the expected reasonable worst case range of times over which the device use is recommended or anticipated when establishing extraction times. In addition, it may be useful to collect data to establish the extraction rate for EO from the device at the use temperature established by reference to clause A.2 (10993-7:1995 clause 4.4.6.1.1). Evaluate these data or other pertinent information to determine an extraction time appropriate for the device that takes into account the available data. The minimum extraction time is one (1) hour.

A.4 Extraction of device

Where pretreatment of the device is required prior to use, perform this pretreatment before the device is extracted. Where the device is filled for extraction, do this in a manner that eliminates entrained air pockets. Extract the device with water at the temperature and for the time established. Where use of the device involves circulation of fluids (e.g., blood, dialyzer fluid), extract the device using water to simulate the fluids circulating in a manner consistent with product use. Note that where blood is returned from the device to the patient, it must be assumed that any EO will stay in the body. Hence, fluids simulating blood passing from a device into a patient should not be recirculated. Document the rationale for the conditions established.

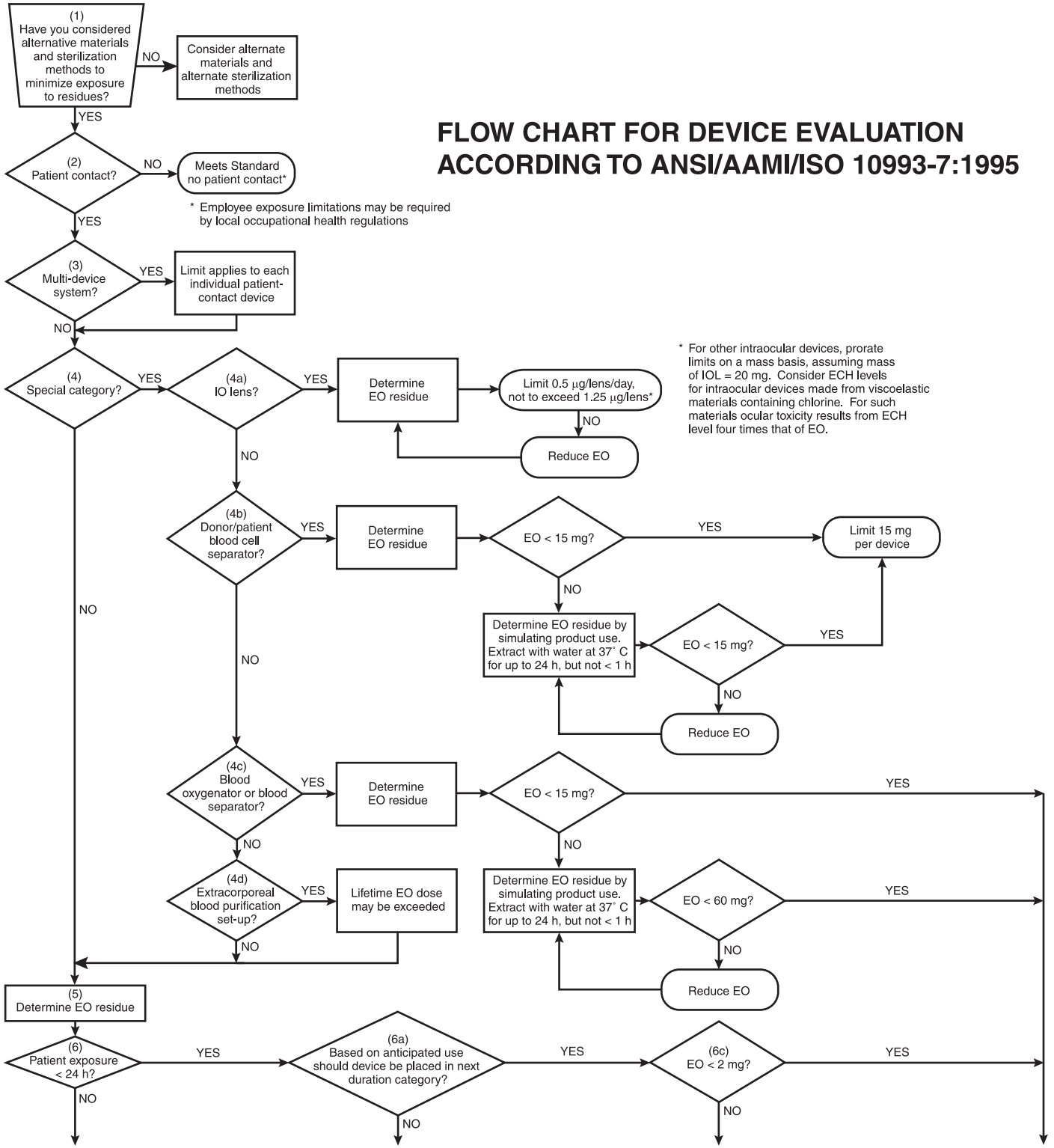
A.5 Grouping of devices

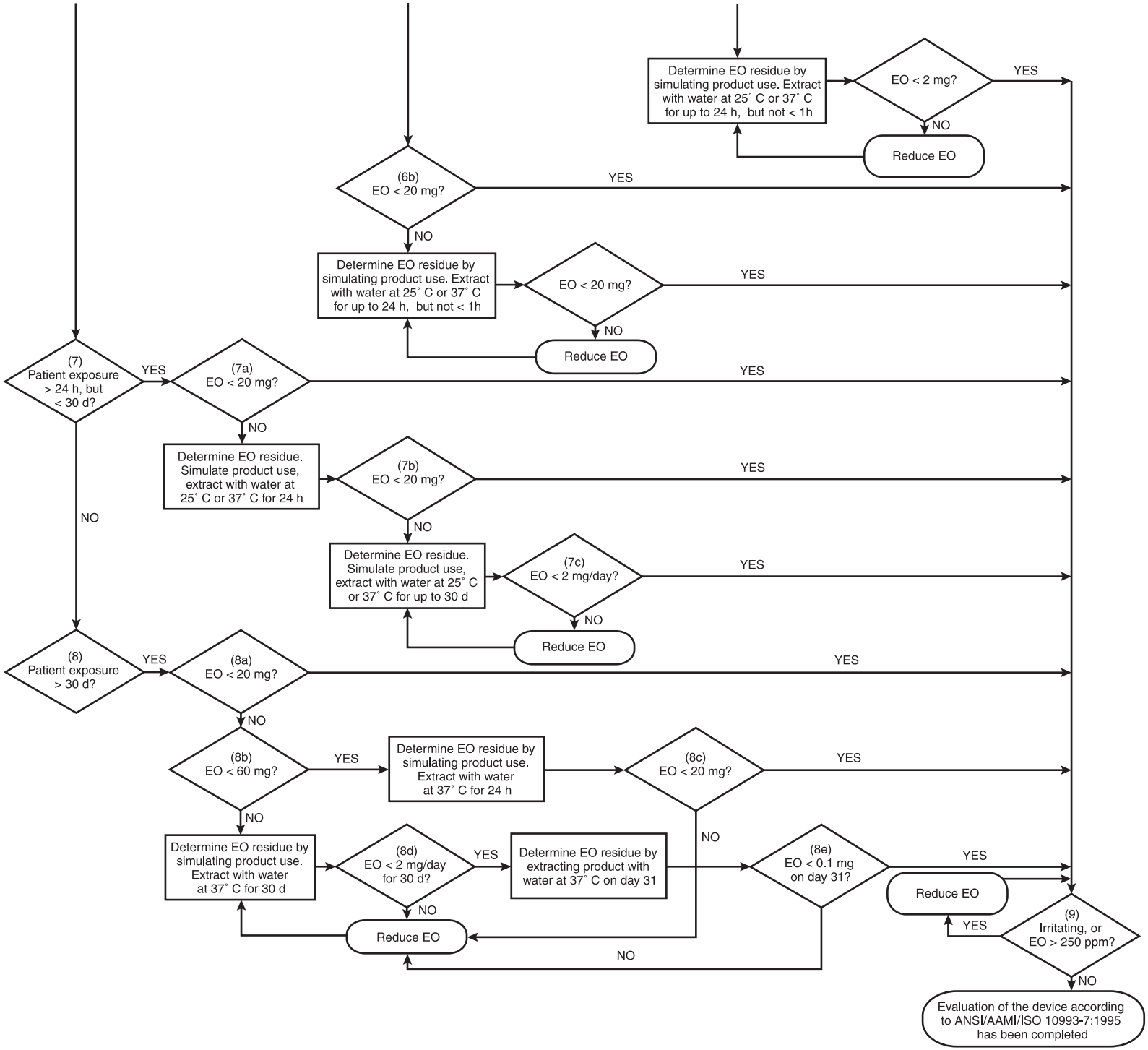
Devices of similar design but different sizes may be grouped and the worst-case selected for testing as representative of the group. Document the rationale for this decision.

A.6 Device kits and trays

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

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.

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:

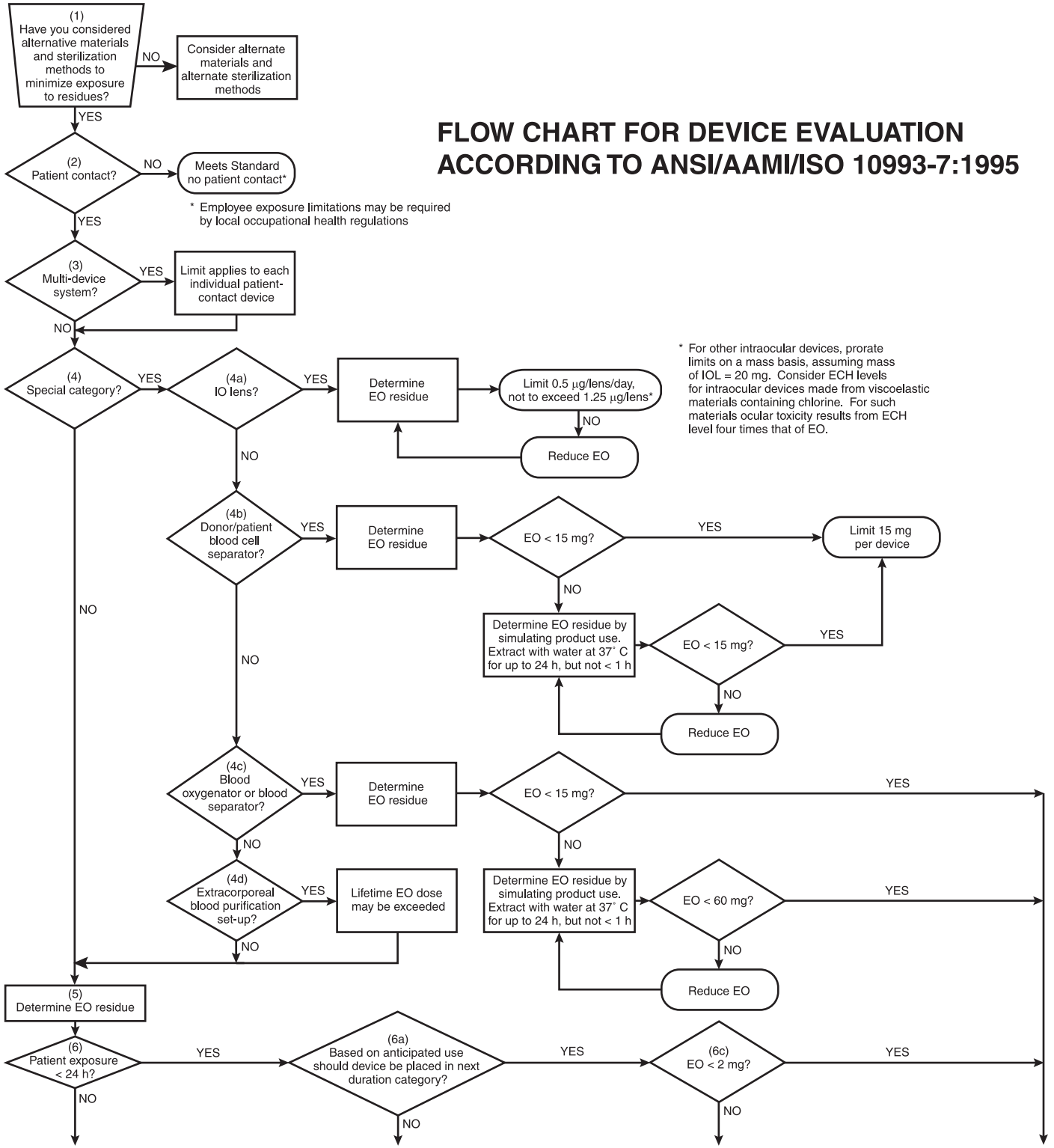
4 If the device is in a special category:

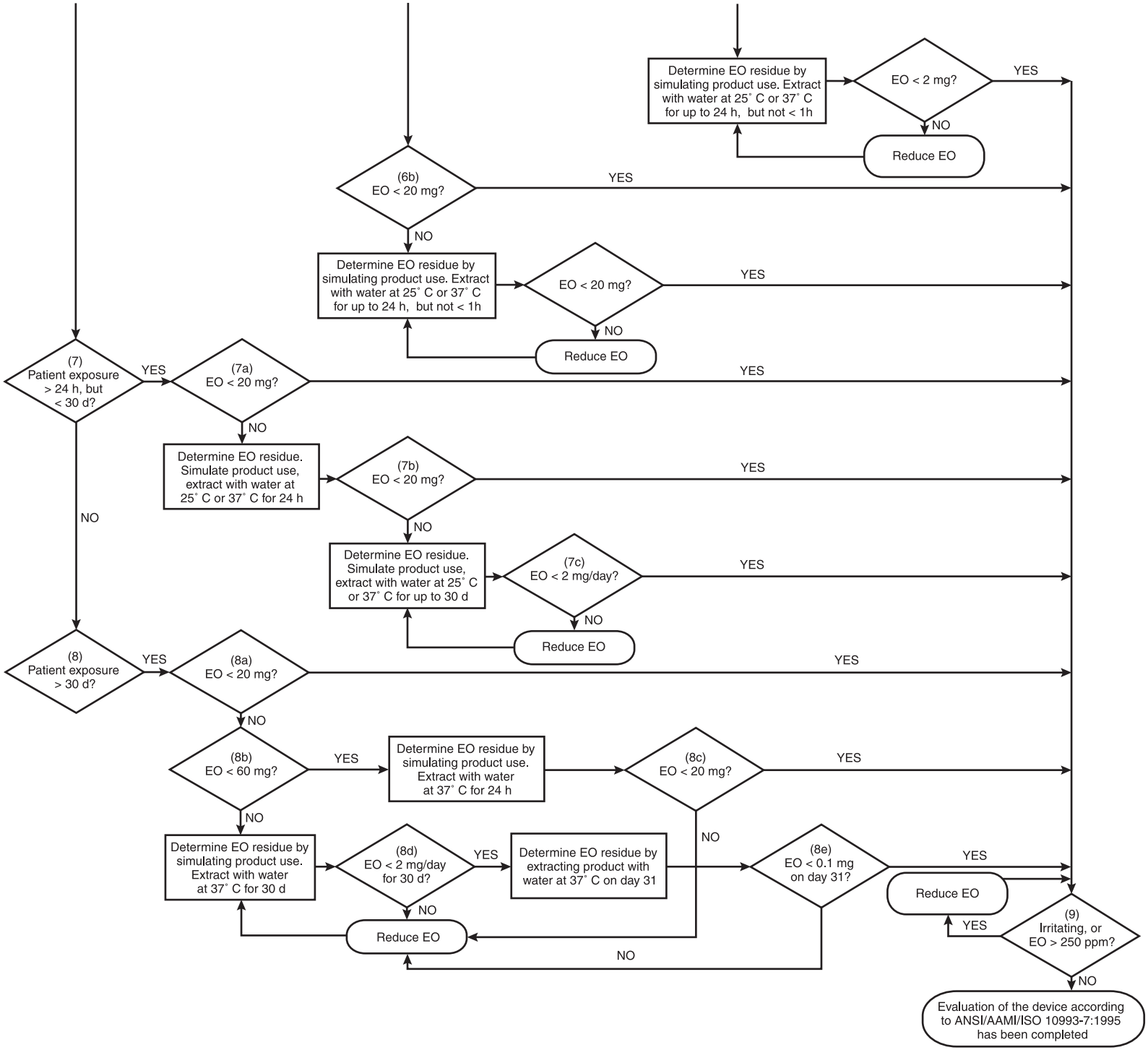
4.a. If the device is an intraocular lens, the limits are 0.5 micrograms/lens/day, not to exceed 1.25 micrograms total.[3] Limits for other intraocular devices can be prorated on the basis of the mass of the device, with the mass of an intraocular lens taken as 20 mg. When EO residues are controlled 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.

Approved 15 March 1999 by
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[4] An exhaustive extraction procedure may be impractical for these products, in which case proceed directly to the simulated-use procedure.

