



Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices¹

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1. Scope

1.1 This guide provides information for developing accelerated aging protocols to rapidly determine the effects, if any, due to the passage of time on the sterile integrity of the sterile barrier system (SBS), as defined in ANSI/AAMI/ISO 11607–1:2006 and the physical properties of their component packaging materials.

1.2 Information obtained using this guide may be used to support expiration date claims for medical device sterile barrier systems.

1.3 The accelerated aging guideline addresses the sterile barrier systems in whole with or without devices. The sterile barrier system material and device interaction compatibility that may be required for new product development or the resulting evaluation is not addressed in this guide.

1.4 Real-time aging protocols are not addressed in this guide; however, it is essential that real-time aging studies be performed to confirm the accelerated aging test results using the same methods of evaluation.

1.5 Methods used for sterile barrier system validation, which include the machine process, the effects of the sterilization process, environmental challenge, distribution, handling, and shipping events, are beyond the scope of this guide.

1.6 This guide does not address environmental challenging that stimulates extreme climactic conditions that may exist in the shipping and handling environment. Refer to Practice [D4332](#) for standard conditions that may be used to challenge the sterile barrier system to realistic extremes in temperature and humidity conditions. See Terminology [F1327](#) for a definition of “environmental challenging.”

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appro-*

priate safety and health practices and determine the applicability of regulatory limitations prior to use.

2. Referenced Documents

2.1 ASTM Standards:²

[D4332](#) Practice for Conditioning Containers, Packages, or Packaging Components for Testing

[E337](#) Test Method for Measuring Humidity with a Psychrometer (the Measurement of Wet- and Dry-Bulb Temperatures)

[F17](#) Terminology Relating to Flexible Barrier Packaging

[F1327](#) Terminology Relating to Barrier Materials for Medical Packaging (Withdrawn 2007)³

[F2097](#) Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products

2.2 AAMI Standards:

[ANSI/AAMI/ISO 11607–1: 2006](#), Packaging for Terminally Sterilized Medical Devices⁴

[AAMI TIR 22–2007](#), Guidance for ANSI/AAMI/ISO 11607, Packaging for Terminally Sterilized Medical Devices⁴

3. Terminology

3.1 *Definitions*—For general definitions of packaging for medical devices, see ANSI/AAMI/ISO 11607. For terminology related to barrier materials for medical packaging see Terminology [F17](#).

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *accelerated aging (AA)*, *n*—storage of samples at an elevated temperature (T_{AA}) in order to simulate real time aging in a reduced amount of time.

3.2.2 *accelerated aging factor (AAF)*, *n*—an estimated or calculated ratio of the time to achieve the same level of physical property change as a sterile barrier system stored at real time (RT) conditions.

¹ This guide is under the jurisdiction of ASTM Committee [F02](#) on Primary Barrier Packaging and is the direct responsibility of Subcommittee [F02.50](#) on Package Design and Development.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ The last approved version of this historical standard is referenced on www.astm.org.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.