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Standard Guide for Identification of Shelf-life Test Attributes for Endovascular Devices[1]

This standard is issued under the fixed designation F2914; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide addresses the determination of appropriate device attributes for testing as part of a shelf-life study for endovascular devices. Combination and biodegradable devices (for example drug-devices, biologic devices or drug biologics) may require additional considerations, depending on their nature.

1.2 This guide does not directly provide any test methods for conducting shelf-life testing.

1.3 *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 appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Terminology

2.1 *Definitions:*

2.1.1 *endovascular device*—device used to treat vascular disease from within the vessel.

2.1.2 *product*—final packaged and sterilized device with all included components.

2.1.3 *shelf life*—the amount of real time that a fully packaged (and sterilized, if applicable) product can be expected to remain in storage at specified conditions and maintain its critical performance properties.

3. Significance and Use

3.1 The purpose of this guide is to provide a procedure for determining the appropriate attributes to evaluate in a shelf-life study for an endovascular device.

4. Procedure

4.1 *Shelf-life Establishment Model Introduction*—The decision flow chart (Fig. 1) assists study developers in selecting and justifying risk-appropriate test protocols for medical devices to establish shelf life. The decision flowchart is intended to elicit questions and an appropriate rationale for testing or not testing a particular attribute during aging. The risk to the patient as the device ages is one of the primary drivers. It is recommended that all regulatory requirements and guidances be considered during development of the shelf-life establishment test plan. See Fig. 1.

4.2 *Question 1: "Could the device attribute change over time?":*

4.2.1 *Considerations in Evaluating Question 1*—This question must be addressed based on the device design characteristics (and also in relation to the device being packaged, sterilized, shipped and stored).

4.2.1.1 Consider attributes such as the following, for example:

(1) Material Properties/Characterization—Composition; Mechanical Properties; Corrosion Resistance

(2) Dimensional and Functional Properties—Dimensions; Surface Area; Foreshortening

(3) Deliverability and Functionality—Balloon Fatigue; Balloon Rated Burst; Bond Tensile Strength

4.2.1.2 Various sources may provide sufficient evidence to confirm that some specific attributes do not change over time for the application or that the change is not a risk to the patient.

(1) Scientific literature.

(2) Appropriate vendor publication.

(3) In-house research.

(4) Assessment of clinically accepted device.

4.2.1.3 When using such data to justify why certain attributes may not require shelf-life testing, consider all differences between the subject device and the source of those data to ensure applicability. For example, vendor literature may not represent the actual use of the material by the device manufacturer. Additionally, further processing (for example, sterilization) may change the physical or chemical attribute(s) of the material. Finally consider whether there are interactions (chemical or physical) that may impact your assessment.

4.2.1.4 In order for testing to be applicable, the testing must be conducted on articles that are representative of the final device (that is, utilizing the same sterilization method and dose, dimensions, material, processing conditions, and packaging). If

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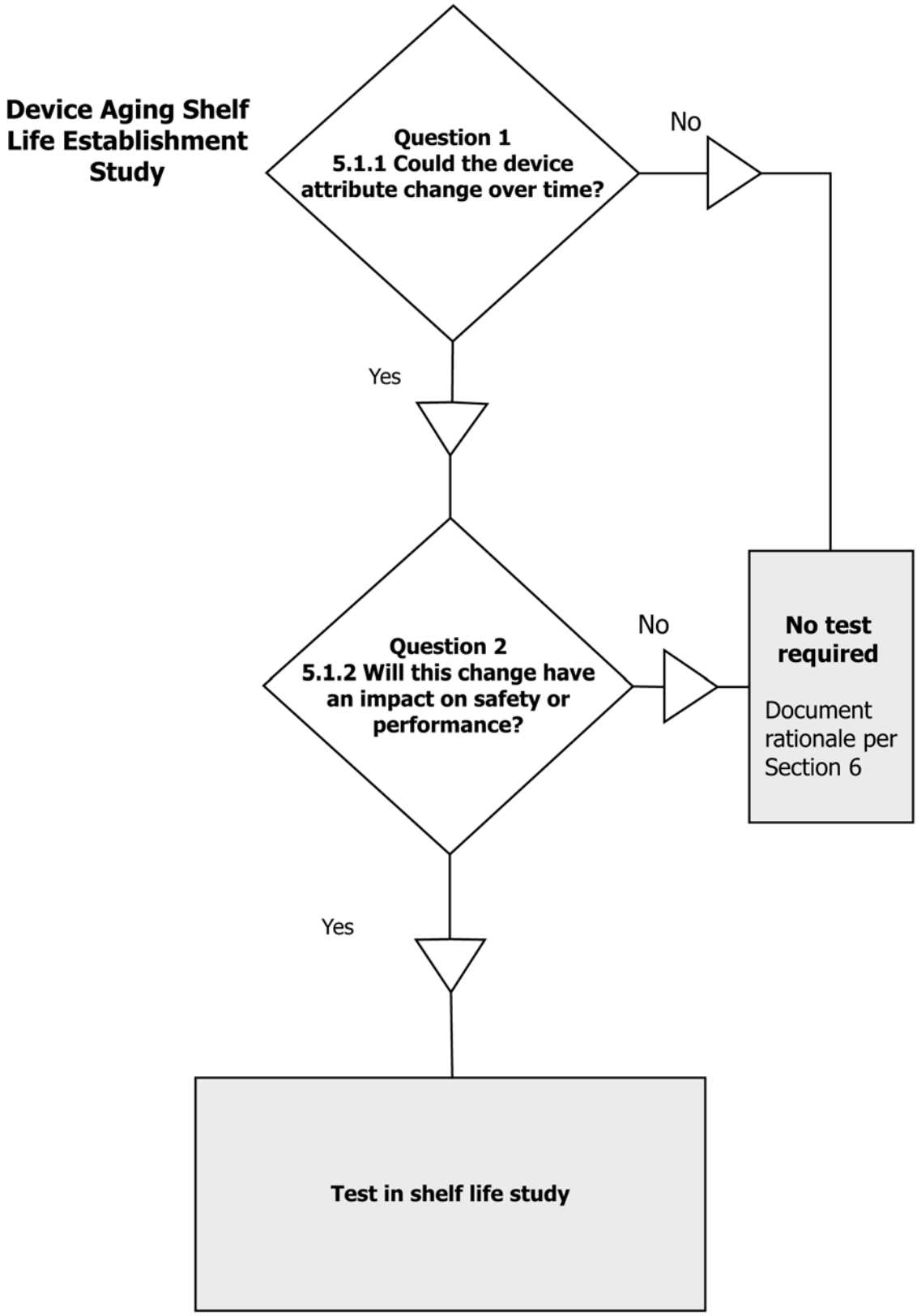


FIG. 1 Device Aging Shelf-life Establishment Flow Chart

test articles are not identical, provide appropriate justification for applicability of the testing.

4.2.2 *Justification Based upon Scientific Principles*—When one considers whether an attribute should be included in a shelf-life study, the first question is whether the attribute changes over time. There are several device attributes that may be driven by physical parameters of the device that would not change over time and therefore will not require shelf-life testing. The assessment should be conducted using universal scientific/physical principles. In cases where the assessment is based on universal scientific/physical principal, appropriate references should be provided. In cases where justifications may be less obvious, data to support the scientific/physical rationale shall be generated. Tables 1 and 2 list two groups of device attributes with accompanying scientific rationale.

4.2.3 *Justification Based upon Data*—Scientific principles for some device attributes/requirements are not readily evident. In such cases, one may generate data to support a rationale. It may be advantageous to conduct testing in a manner that allows for the data to be applicable to various size devices. In this case, it is important to translate the device attribute (such as system flexibility) into the underlying size independent scientific parameters (such as Young's modulus). Testing is then conducted to evaluate the stability of the core scientific parameter. For each device attribute, more than one scientific parameter may be necessary to demonstrate stability over the aging period. (For simplicity of the examples, only one test parameter is illustrated in Table 3.) Each device attribute should be evaluated to determine what scientific parameters may be affected by aging and the appropriate testing to mitigate each of those risks should then be conducted. The attributes evaluated must be conducted on samples that are representative of the device; and the stability evaluation must be equal or greater than the anticipated shelf life. Some hypothetical examples are printed in the remainder of this section.

4.3 *Question 2: "Will the change have an impact on safety or performance?"*—Once it has been determined that a device attribute is likely to be affected by time and storage conditions, the second question to evaluate is whether the change poses a possible risk to the patient or product performance. Another way of stating the question is: "Will a change in the device attribute, resulting from aging, pose a significant risk to the patient or clinician?" Risk analysis is an appropriate technique used to answer this question. However, since risk analysis methodologies have yet to be standardized, there is no definitive risk level that can be applied universally for all devices and parameters. It will be the responsibility of individual companies to carefully develop the threshold for acceptable risk.

4.3.1 *Basis for Risk Assessment*—The assessment of risk related to a device attribute may be conducted using clinical history (in literature or privately held) or the complaint history of a similar device used in a similar application. Additionally, a scientific/medical argument might provide adequate information to assess the risk.

4.3.2 *Risk Assessment Examples*—The following examples of risk assessment of selected attributes are for illustrative purposes only; this guide cannot claim to address all circumstances and thus these examples should not be used to overly influence a company's policies. When not expected to impact safety or performance, the scientific justification shall be documented in detail.

5. Shelf-life Establishment Report

5.1 The report shall include a complete device description, assumptions for device storage, and the device attributes considered for testing in conducting a device aging shelf-life establishment study. The decision to conduct testing or not for each device attribute shall be reported. The rationale for why testing of a specific device attribute was determined to not be necessary (answered "no" to Questions 1 or 2) shall be reported. The reported rationale shall provide sufficient detail to convince a person with adequate engineering/scientific experience. References supporting rationale to not conduct testing should be provided, as appropriate. When testing of a specific device attribute was determined to be necessary (answered "yes" to Questions 1 and 2), no rationale needs to be reported. The following template may be used to report the decisions and appropriate rationale for the development of the device aging shelf-life establishment plan. In addition, protocols and/or reports should also be provided for the individual shelf-life tests conducted which are used to justify attribute inclusion or exclusion.

6. Keywords

6.1 aging; establishment; shelf life; shelf-life; stability

TABLE 1 Example Attributes Typically Impacted by Aging

Device Attribute	Scientific Principle
Nylon polymer catheter tensile at break	Aging of polymers can result in the breaking of chemical bonds and/or a reduction in polymer chain entanglement. Therefore this dynamic process needs to be assessed after defined shelf-life testing conditions.
Balloon rated burst	Aging of polymers can result in the breaking of chemical bonds and/or a reduction in polymer chain entanglement. Therefore this dynamic process needs to be assessed after defined shelf- life conditions.
Balloon fatigue	Aging of polymers can result in the breaking of chemical bonds and/or a reduction in polymer chain entanglement. Therefore this dynamic process needs to be assessed after defined shelf-life conditions.
Stent securement	Stent securement is driven by interactions between stents and balloon surfaces. Since polymers may relax after time, the engagement of these surfaces may change. Therefore this dynamic process needs to be assessed after defined shelf-life conditions.

TABLE 2 Examples of Attributes Typically Not Impacted by Aging

Device Attribute	Scientific Principle
Stent surface area	Metals are generally stable at storage conditions. Therefore the actual dimensions and resultant calculated surface area will not change.
Stent fatigue	Metals are generally stable at storage conditions and therefore the actual dimensions will not change. Additionally, the microstructure will not change under storage conditions and therefore the fatigue performance will not change.
Dimensions of hard plastics (such as hub/manifolds)	Plastics such as polycarbonate which are sterilized by Ethylene Oxide are in their glassy state under storage conditions, and therefore the physical dimensions will not change over time.
MR compatibility	The magnetic response of an implant is driven by the magnetic properties, mass and dimensions of the metallic components. Since the composition of the metallic components is not altered under storage conditions with time the MR compatibility will not change over time.
Marker radiopacity	The absorption of X-ray radiation is driven by the thickness and composition of a marker. Since the composition of the marker band is not altered under storage conditions with time, and since the marker band is stable at storage conditions and the actual dimensions will not change with time, the marker radiopacity will not change over time.
Corrosion resistance	Corrosion resistance of a metal implant (e.g. stent or Inferior Vena Cava filter) in a known environment is determined by the surface composition of the medical device. Since the surface composition of the metallic device is not altered with time, the corrosion resistance will not change over time under storage conditions.

TABLE 3 Example of Data and Decision on Whether to Test

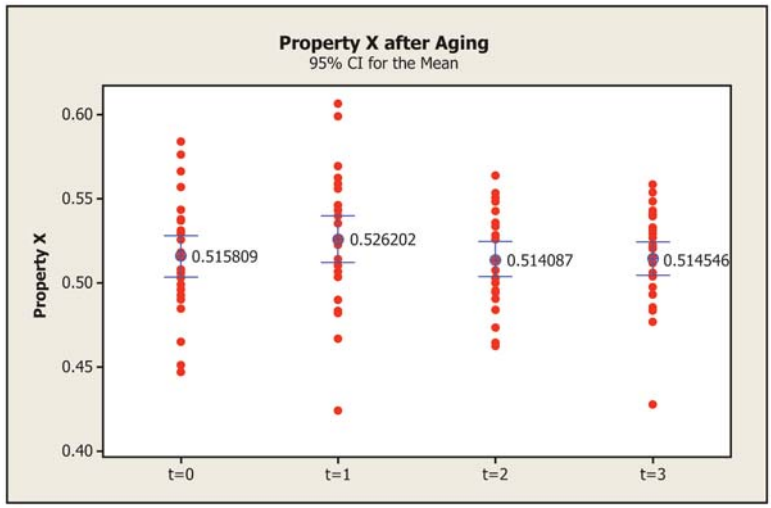
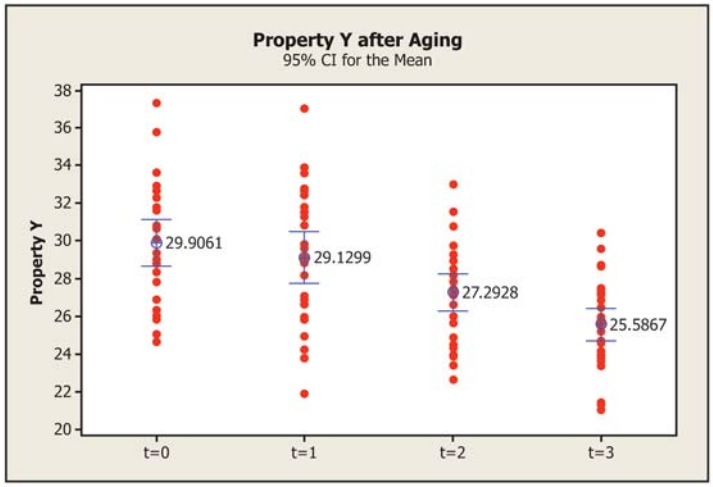
Device Attribute	Data
Polymer catheter flexibility	Catheter flexibility is driven by multiple attributes such as the bulk modulus of the individual components, tensile testing has been conducted on aged polymer tubing to demonstrate the stability of the Young's modulus. Some hypothetical results are shown below:  As seen in the above graph, the modulus does not change within the shelf-life conditions and therefore catheter flexibility does not change.
Balloon rated burst pressure	Balloon burst strength is driven by multiple attributes such as ultimate tensile strength of the balloon material, the wall thickness, and the process for bonding the balloon to the catheter shaft. Testing has been conducted on aged balloon tubes to demonstrate the stability of the material strength, dimensions. Some hypothetical results are shown below:  As seen on the above graph, the tensile strength of the balloon tubes does change within the shelf-life conditions. Therefore balloon burst strength of a catheter is likely to change and will be included in a shelf-life study.

TABLE 4 Hypothetical Example of Risk Assessment

Device Attribute	Likely to impact safety or performance?
Stent Deployment Force	Yes
Balloon Burst	Yes
Balloon Compliance	Yes
Bond Strength	Yes
Cosmetic feature of non-blood-contacting component	No—cosmetic feature has no safety or performance impact. This assumes the proper functional requirements are in place and are met.
Stylette/product mandrel hub tensile strength	No—there is never patient contact with this component.

TABLE 5 Example Report Template

Device description:				
Assumptions for storage environment:				
Device Attribute	Q1. Could the Device Attribute/Requirement Change Over Time? (Y or N)	Q2. Will this Change Have a Safety or Performance Impact? (N/A, Y or N)	Decision to Perform Aging Testing (Y or N)	Rationale for Performing No Testing (N/A or Provide Rationale) Q1: Q2:

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(2) Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, April 18, 2010[3]

(3) Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010[3]

(4) Shelf Life of Medical Devices, April 1991[3]

(5) ISO 11346 Rubber, Vulcanized or Thermoplastic—Estimation of Life-time and Maximum Temperature of Use[4]

(6) ISO 11607-1:2006 Packaging for Terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging[4]

(7) ISO 14971 Medical Devices—Application of Risk Management to Medical Devices[4]

(8) ISO 25539-1 Cardiovascular Implants—Endovascular Devices—Part 1: Endovascular Prostheses[4]

(9) ISO 25539-2 Cardiovascular Implants—Endovascular Devices Part 2: Vascular Stents[4]

(10) TIR 17:2008Compatibility of Materials Subject to Sterilization, Section 6 and Annex G—Accelerated Aging Programs[5]

[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] Available from Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, http://www.fda.gov.

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

[5] Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, http://www.aami.org.