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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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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.

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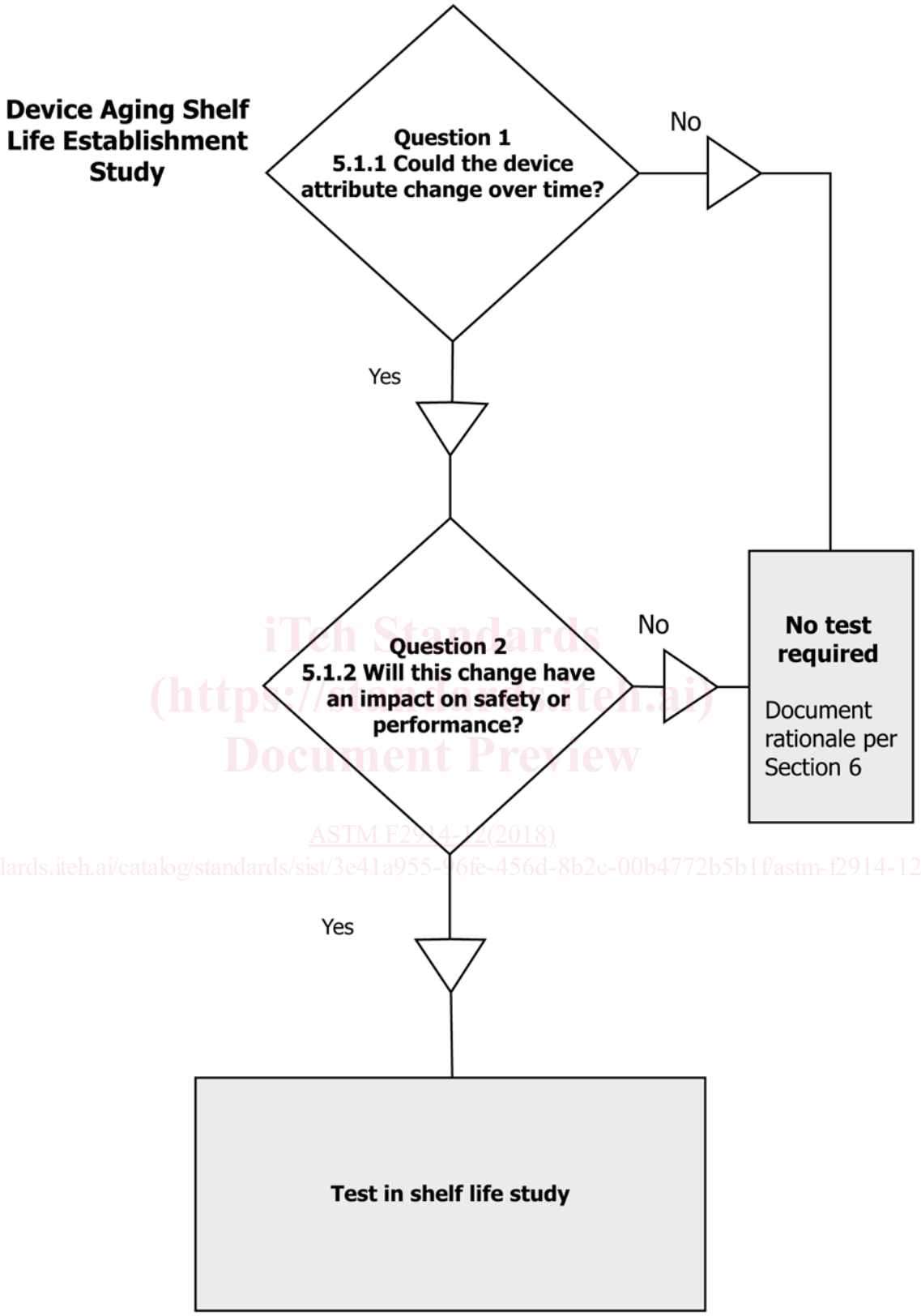

FIG. 1 Device Aging Shelf-life Establishment Flow Chart

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 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.