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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.

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.30 on Cardiovascular Standards.

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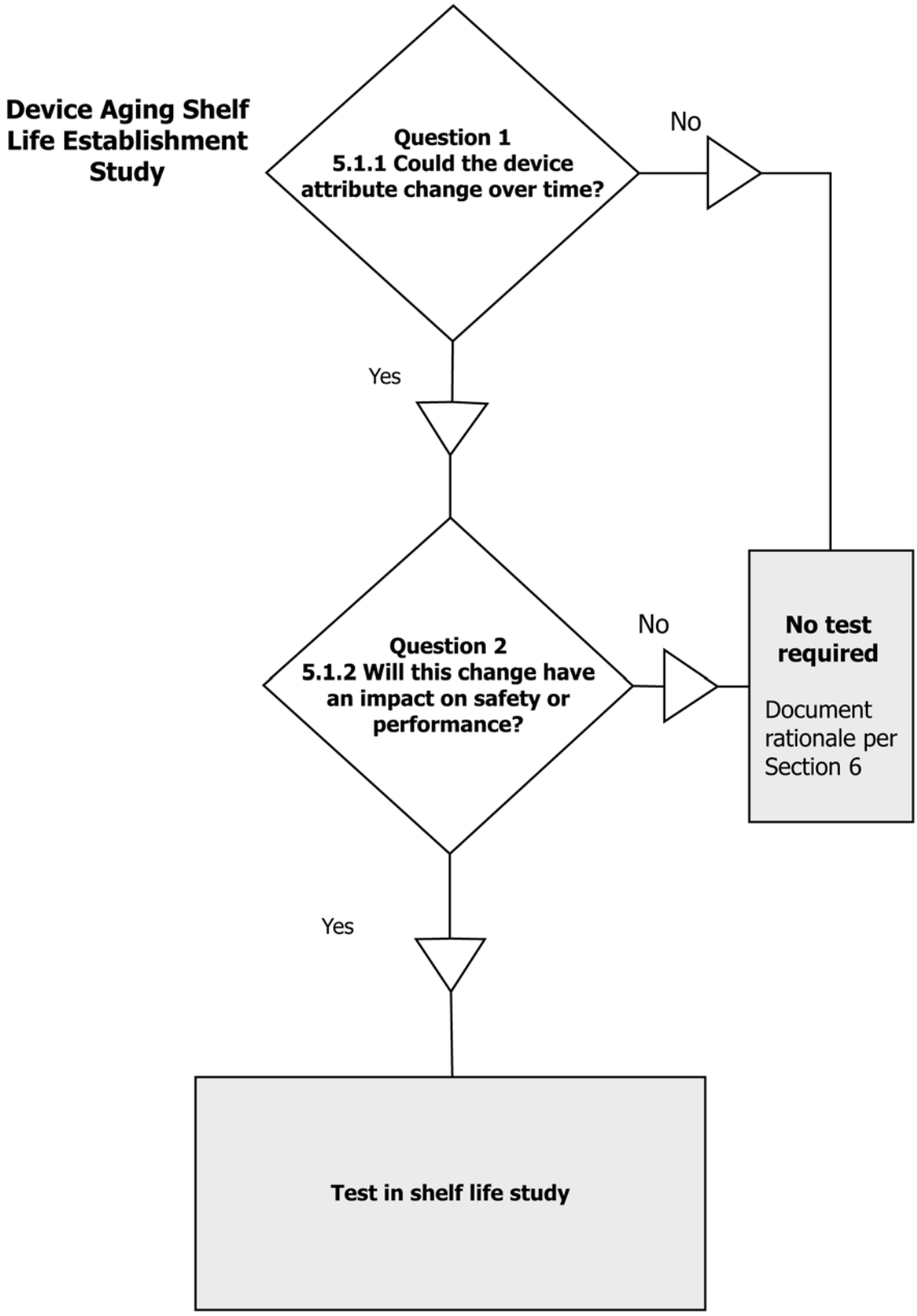

FIG. 1 Device Aging Shelf-life Establishment Flow Chart