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Standard Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices[1]

This standard is issued under the fixed designation F3293; 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 provides methods and considerations for simulated soiling of reusable medical devices for the purpose of validating cleaning instructions. Techniques for application of soil, as well as incorporation of soil by various means (e.g., actuation of devices) will be described in order to assure worst-case contamination of the surface geometry of medical devices.

1.2 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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. Referenced Documents

2.1 *ASTM Standards:*[2]

D1193 Specification for Reagent Water

D7225 Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors

F2809 Terminology Relating to Medical and Surgical Materials and Devices

F3208 Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices

2.2 *AAMI Standards:*[3]

AAMI TIR30 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

2.3 *ISO Standard:*[4]

ISO 10993-12 Biological evaluation of medical devices—Part 12: Sample preparation and reference materials

2.4 *Other References:*

ANSI/ASHRAE/ASHE Standard 170-2013 Ventilation of health care facilities; Atlanta: ASHRAE, 2013b[5]

Guidance for Industry and FDA Staff, Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2015[6]

3. Terminology

3.1 For definitions of terms in this Guide relating to the use of test soils for cleaning validation, refer to the Terminology Section of ASTM F3208.

4. Summary of Practice

4.1 The standard provides details on the application (inoculation) of the test soil for testing, evaluation, and validation of cleaning procedures. It includes:

4.2 The methods for soiling a medical device.

4.3 The selection of the appropriate method(s) for soiling a device based upon clinical use of the device.

4.4 Identification of area(s) of the device to soil based upon worst-case clinical use and device design.

4.5 Establishing the dwell time for the soiled device, prior to beginning cleaning procedures, based upon worst-case clinical conditions/practice.

[1] This practice/guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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

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

[5] https://www.ashrae.org/resources-publications/bookstore/health-care-facilities-resources

[6] www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

4.6 Identification of other worst-case clinical use conditions that represent a worst-case challenge to cleaning the device. These conditions could include the length of the procedure, condition of the patient, and/or extraordinary uses of the device (in compliance with the intended use of the device as established by the medical device manufacturer).

5. Significance and Use

5.1 This standard guide may be used by medical device manufacturers as part of their design plan and implementation of the validation of the cleaning instructions of their reusable medical devices.

5.2 It may help medical device manufacturers identify the most inaccessible locations on their device for inoculation with clinically relevant, simulated-use test soil (see ASTM F3208), thereby allowing testing to evaluate whether or not the medical device can be adequately cleaned.

5.3 Methods described include pipetting, brushing, immersing, spraying, handling, and other techniques for applying soil.

5.4 Guidance is given as to how to identify the clinically relevant areas of the device to soil, the time allowed for the soil to dry, and other conditioning considerations based upon assessment of worst-case clinical conditions.

6. Determining the Volume to Soil Each Device

6.1 The volume of test soil applied to a device should reflect worst-case clinical conditions.

6.2 ISO 10993-12 provides formulas for calculating the surface-to-area to volume ratios.

6.3 AAMI TIR30 provides formulas for calculating the surface area and volume of the internal channel of a device.

6.4 Special attention should be paid to the volume of the key soil markers (see ASTM F3208 for selection of test soil and soil markers) applied. This should not only reflect worst-case conditions, but also take into account expected recovery efficiency and the level of detection of the test method.

6.5 The method of application of soil (see Section 9) will also be a factor in the volume of test soil. For instance, if the entire device is to be immersed in the test soil (section 9.6), adequate volume of soil to accomplish this will be required. Another example is that if soiling involves perfusing internal channels of the device with test soil, the volume of soil to accomplish this must be calculated.

6.6 Other considerations include the physical characteristics of the test soil as it simulates clinical soiling (see ASTM F3208) including: Adhesion, Viscosity, and Solubility.

7. Determining the Most Difficult Areas to Soil

7.1 Special consideration should be given to ensure inoculation of the most difficult locations on the medical device to clean (i.e. worst-case location) such as crevices, narrow dead-end lumens, stopcocks, etc. (see AAMI TIR30:2011 Section 4.2 for list of difficult areas to clean).

7.2 Locations on the device that could potentially be contaminated during use should be considered for inoculation.

8. Determining Clinically Relevant Worst-Case Drying Time

8.1 *General Considerations:*

8.1.1 Duration of time for the application of test soil: A period of time should be established for the duration of the application of soil. The length of time that the test device is subjected to soiling should reflect worst-case clinical use to ensure that there is sufficient time to allow contaminants to adhere to and penetrate the device, thereby implementing worst-case soiling to the greatest degree practical.

8.1.2 If after clinical use of the device, drying of soil might occur and cleaning might not be performed immediately after use (such as with loaner devices that will be shipped without adequate reprocessing), the validation methods should allow soils to dry for a length of time that simulates worst-case (longest) duration.

8.1.3 To minimize variability of soiling, consider removing excess soil after soiling and before drying.

8.1.4 The drying phase could be performed in a number of ways. The most common approach is to dry the devices at room temperature (20-25°C) until the devices are not only visually dry, but to the touch using a gloved hand. Alternative methods to test the dryness of the soil include use of a dry cotton swab, toothpick, or similar tools.

8.1.5 If flaking of soil occurs during drying an alternative test soil or drying method should be used.

8.1.6 Accelerated drying processes generally do not reflect conditions of normal use and should be avoided. Methods to accelerate the drying process (elevated temperature, low humidity) may be considered, but may also alter the test soil, rendering it easier to remove.

8.2 *Temperature and Humidity*—The test soil should remain on the device/component and be allowed to dry in a temperature and humidity range that is similar to that found in healthcare facilities.

8.3 Current published guidelines (ASHRAE 170) for environmental conditions in areas where a soiled device will dwell include the operating theater, the operating room and procedure room.

8.4 The length of time allowed for drying should reflect the worst-case elapse of time that takes into consideration the time between patient use of the device (including the time during the clinical procedure when the device is no longer in-use) and reprocessing.

8.4.1 In busy healthcare facilities, the limitations of equipment and personnel can mean that hours elapse before cleaning procedures begin.

8.4.2 Reduced staffing on weekends can mean that cleaning procedures are delayed by 24 or 48 hours.

8.5 *Point of Use Treatment*—In general, worst-case soiling and conditioning for validating cleaning should exclude point of use pretreatment of a device.

8.6 *Repeated Soiling*—Simulated use conditions for the validation studies should be considered, especially for devices with features at risk for the accumulation of soil with repeated use. In such cases, validation studies should use devices that