Designation: F3321 – 19

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

This standard is issued under the fixed designation F3321; 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 extracting test soil(s) from reusable medical device(s) that occurs during simulated use validation, clinical use of the device(s) and after the device(s) have been through a cleaning process.

1.2 This is a part of a series of ASTM guides for validating cleaning instructions. The scope of the first guide in the series is regarding selecting appropriate test soils (Guide F3208). The second in the series (Guide F3293) describes methods that are used to inoculate medical devices with simulated-use test soil(s). This third in the series describes methods for extracting test soils in order to measure residual soil remaining on medical devices after the performance of cleaning procedures.

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

1.4 *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.*

1.5 *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]

E1097 Guide for Determination of Various Elements by Direct Current Plasma Atomic Emission Spectrometry

E2314 Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)

E2520 Practice for Measuring and Scoring Performance of Trace Explosive Chemical Detectors

F619 Practice for Extraction of Medical Plastics

F2459 Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis

F3127 Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices

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

F3293 Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices

2.2 *AAMI Documents:*[3]

AAMI TIR17 Compatibility of materials subject to sterilization

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

ANSI/AAMI/ISO 15883-1 Washer-disinfectors – Part 1: General requirements, terms and definitions and tests

2.3 *FDA Document:*

FDA Guidance for Industry and FDA Staff, Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, June 6, 2017[4]

2.4 *Other Documents:*

EPA, SW-846 Test Method 3540C Soxhlet Extraction[5]

Evotech® endoscope cleaner and reprocessor (ECR) simulated use and clinical use evaluation of cleaning efficacy, BMC Infectious Diseases 201010:200, Alfa, M.J., DeGagne, P., Olson, N, Fatima, I . 2010

3. Terminology

3.1 *Definitions:*

[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 F04.15 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] https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

[5] https://www.epa.gov/hw-sw846/sw-846-test-method-3540c-soxhlet-extraction

3.1.1 *extraction, n*—procedure for sampling a medical device to recover residuals that will then be used for quantitative testing for cleaning markers such as protein, hemoglobin, etc.

3.1.2 *limit of detection (LOD), n*—lowest quantity of a substance that can be distinguished from the absence of that substance within a stated confidence limit (Practice E2520-15). LOD is also generally defined as 3 times the standard deviation of the blank (Guide F3127-16).

3.1.3 *limit of quantification (LOQ), n*—lowest concentration at which an instrument can measure reliably with a defined error and confidence level (Guide E1097-17). LOQ is also generally defined as 10 times the standard deviation of the blank (Guide F3127-16).

3.1.4 *test soil, n*—single substance or a mixture of substances that reflect the contaminants likely to be encountered during the use of the device for its intended clinical procedure (Guide F3208).

4. Summary of Guide

4.1 This guide describes techniques for extracting residuals from soiled medical devices during validation testing of the instructions for medical device reprocessing by a healthcare facility.

4.2 This guide describes method(s) for validating the extraction method, including use of positive and negative controls.

4.3 This guide also describes methods for extracting samples from clinically used medical devices as a means of determining the clinical relevance of the simulated-use testing.

5. Significance and Use

5.1 This 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 This guide helps medical device manufacturers to identify the best method(s) for extracting simulated-use test soil (see Guide F3208), thereby evaluating whether the medical device can be adequately cleaned.

5.3 Methods describing various techniques for extracting soil are given.

5.4 Guidance is further given as to how to validate the method(s) for extraction.

6. General Considerations

6.1 Medical device manufacturers, as part of their validation testing, need to:

6.1.1 Use a validated extraction method(s). Extraction method(s) that are effective at removing constitutes of the test soil, including key markers (protein, etc.) to be measured, need to be validated. Exhaustive extraction or equivalent methods are to be used to validate the efficiency of the extraction method. Ensure that the extraction method(s) used to determine the residuals after the cleaning process will allow for a quantitative method to be used for measuring residual soil (with the chosen marker(s) to be used). One limitation of exhaustive extraction is that a significant fraction of soil may still remain even after exhaustive recovery ceases to yield measurable results. Steps should be taken to determine if this is indeed the case. The inspection or testing used to verify that soil is removed by extraction should be capable of detecting very low surface concentrations of soil remaining at levels that would significantly change the extraction efficiency calculations. This could be a step during validation of the extraction method (Section 6.3).

6.1.2 Establish any potential interference effects between the extraction media and the test methods, to ensure that the extraction method accurately represents the measurement of what is being tested. The correct use of extraction volumes should be assessed as part of the validation to avoid diluting the sample and reporting inaccurate results. The extraction volume used to remove the test soil for the test method used to detect the test marker should not be compromised as this could lead to a false negative (FDA, Reprocessing, 2017, Section A.3.c).

6.2 For all testing, choose a justifiable number of replicate samples to support the validity of any instructions based on the tests being performed (FDA, Reprocessing, 2017 Section VIII Part A). Consider performing a preliminary experiment to establish the number of test articles needed to support the validation of cleaning instructions.

6.2.1 There are two types of positive controls that are performed during a cleaning validation, one that uses a contaminated test article to determine the baseline for the test articles before processing, referred to as a positive device control. The other control is one that serves to assure that the chemical assays used to evaluate the cleanliness of the test articles are capable of detecting trace amounts of the test soils used for the validation, referred as a positive sample control. The positive device control utilizes an unprocessed contaminated test article that is extracted and tested for residuals. To conduct the positive sample control, the amount of soil markers in the test soil should be determined. The positive sample control should then be spiked with a small, known amount of test soil and undergo the same extraction conditions as the test samples. This control assesses whether extraction conditions (e.g., duration of testing, temperature, plastic ware) causes a decrease in the amount of measured soil in the sample. If the amount of soil measured in the positive sample control is significantly decreased relative to the amount of soil that was added, consider revising the extraction conditions to minimize sample loss. For validation, the positive control is extracted multiple times through an exhaustive extraction to establish an extraction efficiency.

6.2.2 It is recommended to perform at least one (1) positive control for a study. Multiple positive controls can be tested if testing occurs over multiple days. However, it is not necessary to perform an exhaustive extraction every day of the study.

6.2.3 Test articles are contaminated, cleaned, and subjected to only one extraction. Exhaustive extraction is not necessary for cleaned devices as levels of residuals would be expected to be below or at the LOD of the residual being evaluated.

6.3 The medical device manufacturer must validate the extraction method, (FDA Reprocessing, 2017, Section VIII. A. 3.c) including determining the level of recovery efficiency. A