The Evolution of Device Cleaning Standards and the Conversion of TIR30 to ST98

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This article describes key milestones in the evolution of cleaning guidance for medical devices, with a particular focus on the conversion of the technical information report (TIR), AAMI TIR30:2011/(R)2016,[1] to the forthcoming standard, AAMI ST98, *Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices.*

Historical Background: Cleaning Guidance Strikes Back

A long time ago in a galaxy far, far away, standards organizations accomplished the impossible: They established powerful and comprehensive sterilization standards that were meaningful for both the medical device industry and healthcare facility users, as well as recognized by the Food and Drug Administration (FDA) as consensus standards.

However, this was not the case for comprehensive cleaning standards for medical devices.

Sterilization standards for medical devices were built on more than a century of science related to steam sterilization (and more than half a century of evidence related to ethylene oxide). The development of standards was aided by a relatively early adoption of a definition for "sterile" (i.e., a sterility assurance level of 10–6) and relatively limited parameters (e.g., time and temperature), and it likely was accelerated by the limited number of recognized sterilization agents. None of this could be said about cleaning: No clear definition for "clean" existed, there were a large number of possible cleaning agents, and the number of potential cleaning parameters was limited only by the imagination.

Progress began to occur in 1996, when the FDA's Office of Device Evaluation published *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance.*[2] It established guidance based on available scientific knowledge and the known complexity of medical devices. In 2003, AAMI published the first edition of TIR30, which was the first comprehensive presentation and extensive review of medical device cleaning processes to appear in the literature. With Congress's passage of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the FDA assumed enhanced regulatory oversight of the emerging concerns in the largely unregulated field of reprocessing single-use devices (SUDs) in January 2004.

After MDUFMA was passed, the FDA provided guidance prior to the submission, and throughout the regulatory review, of reprocessed SUD applications. Such guidance emphasized the importance of ensuring that the design of cleaning validations addressed assessment of soil accumulation over a product's life cycle, as well as the evaluation of multiple markers to more comprehensively assess cleaning effectiveness. In addition, special emphasis was given to the qualification of cleaning test method validation, as this was not within the scope of the original 1996 guidance document.

Over the years, cleaning science continued to evolve, as did medical device complexity. As the body of interactive guidance provided to the SUD reprocessing industry grew, the value of offering this information to the reusable medical device industry became apparent. A revision of the 1996 FDA guidance document on reusable medical device labeling was soon underway.

Key Takeaways

- The technical information report (TIR), AAMI TIR30:2011/(R)2016, is being converted into the forthcoming standard, AAMI ST98, *Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices.*
- TIR30 applies to reusable medical devices only, while ST98 will apply to all medical devices that require cleaning prior to clinical use.
- TIR30 provides guidance to device manufacturers regarding which test methods may be applicable for their cleaning validation, while ST98 provides guidance to medical device manufacturers regarding cleaning validation requirements.

The earliest drafts of this document included guidance on overall test method design and validation. New sections presented the expanded guidance recently shared with the SUD reprocessing industry (i.e., the value of assessing the accumulation of soil over time and incorporation of testing for multiple markers).

A draft of this guidance was released for public comment in 2011. Upon publication, the FDA received nearly 600 comments from industry and users, each of which was considered by the agency when developing the final guidance. These comments and knowledge gleaned through Medical Device Reporting; recalls; periodic outbreaks of microbial transmission or patient infections reported in the literature or media; reports provided by the Centers for Disease Control and Prevention, Department of Veterans Affairs, and other healthcare settings; and manufacturer-initiated surveillance studies enabled the FDA to publish a comprehensive guidance document in 2015.[3] Appendix E of that document identified a subset of medical devices that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately processed.

Section 3059 of the 21st Century Cures Act (P.L. 114-255) required the FDA to publish a list of reusable medical devices for which validated processing instructions and the validation data for processing of the reusable device must be included in a 510(k) submission. This section also gives the FDA authority to determine that a 510(k) submission for reusable devices is not substantially equivalent to a predicate device if the validated instructions for use (IFUs) and processing validation data submitted as part of the 510(k) are inadequate. As required under section 3059 of the 21st Century Cures Act, a list of these reusable devices—categorized specifically by regulation and product code or by design features for certain device types that will require validated IFUs and validation data in their premarket notifications—was published in the *Federal Register* (82 FR 26807) in June 2017 and Appendix E was updated to reflect consistency between the device lists.

Converting TIR30 to ST98

In 2017, the AAMI Cleaning of Reusable Medical Devices Working Group (ST/WG 93) met to review updates to AAMI TIR30, with the release of the FDA's new guidance documents in mind. Based on the review, ST/WG 93 decided that, rather than revising the TIR, converting a new standard for cleaning validations would better serve the community. A new work item proposal (NWIP) was completed and presented to the AAMI Standards Board in early 2018. This NWIP was approved, and ST/WG 93 has been reviewing working drafts of ST98.

Two key differences exist between TIR30 and ST98: (1) scope of medical devices and (2) layout of the document.

According to the scope of TIR30, it applies to reusable medical devices only. ST98 will apply to all medical devices that require cleaning prior to clinical use. The scope of ST98 excludes single-use devices that are provided sterile and ready for patient use, textiles used for draping or clothing, and devices that might have been exposed to prions that cause Creutzfeldt-Jakob disease. Thus, ST98 applies not only to critical and semicritical medical devices but also to noncritical devices (based on the Spaulding classification). Further, ST98 is being written to include methods and practices that may be used for the validation of SUD reprocessing.

ST98 applies not only to critical and semicritical medical devices but also to noncritical devices (based on the Spaulding classification). Further, ST98 is being written to include methods and practices that may be used for the validation of single-use device reprocessing.

ST98 has been approved to be an American National Standard; therefore, its layout will differ from that of a TIR. TIR30 provides guidance to medical device manufacturers regarding which test methods may be applicable for their cleaning validation, while ST98 provides guidance to device manufacturers regarding cleaning validation requirements.

These requirements are organized in different sections of ST98: product definition, process definition, design of validation methods, validation of processes, and endpoints.

- Product definition: requires identification of the product and any applicable product family evaluation
- Process definition: requires identification of the cleaning process
- Design of validation methods: requires a review of the clinical use of the

product and rationale for determining the test soil, simulated use method(s), applicable test methods, and samples and controls required for a cleaning validation
- Validation of processes: requires an evaluation of the process with establishment of worst-case conditions and use, as well as identification of possible sources of interference during a cleaning validation
- Endpoints: provides an overview of the Spaulding classification and appropriate acceptance criteria for each device category

In addition, the informative section of ST98 provides further guidance on the normative section; the relevant test methods listed in TIR30 are part of that informative section.

ST/WG 93 will vote on the first draft of the committee draft during its August meeting. (Note: This article was written before that meeting occurred.) Submitted comments will be reviewed during the October AAMI Sterilization Standards Week meeting.

The FDA guidance documents described here, TIR30, and the forthcoming ST98 are part of the voyage toward a no-longer-far-far-away galaxy for device cleaning standards.

References

1. AAMI TIR30:2011/(R)2016. *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*. Arlington, VA: Association for the Advancement of Medical Instrumentation.
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3. Food and Drug Administration. *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling—Guidance for Industry and Food and Drug Administration Staff*. Available at: www.fda.gov/media/80265/download. Accessed Aug. 8, 2019.