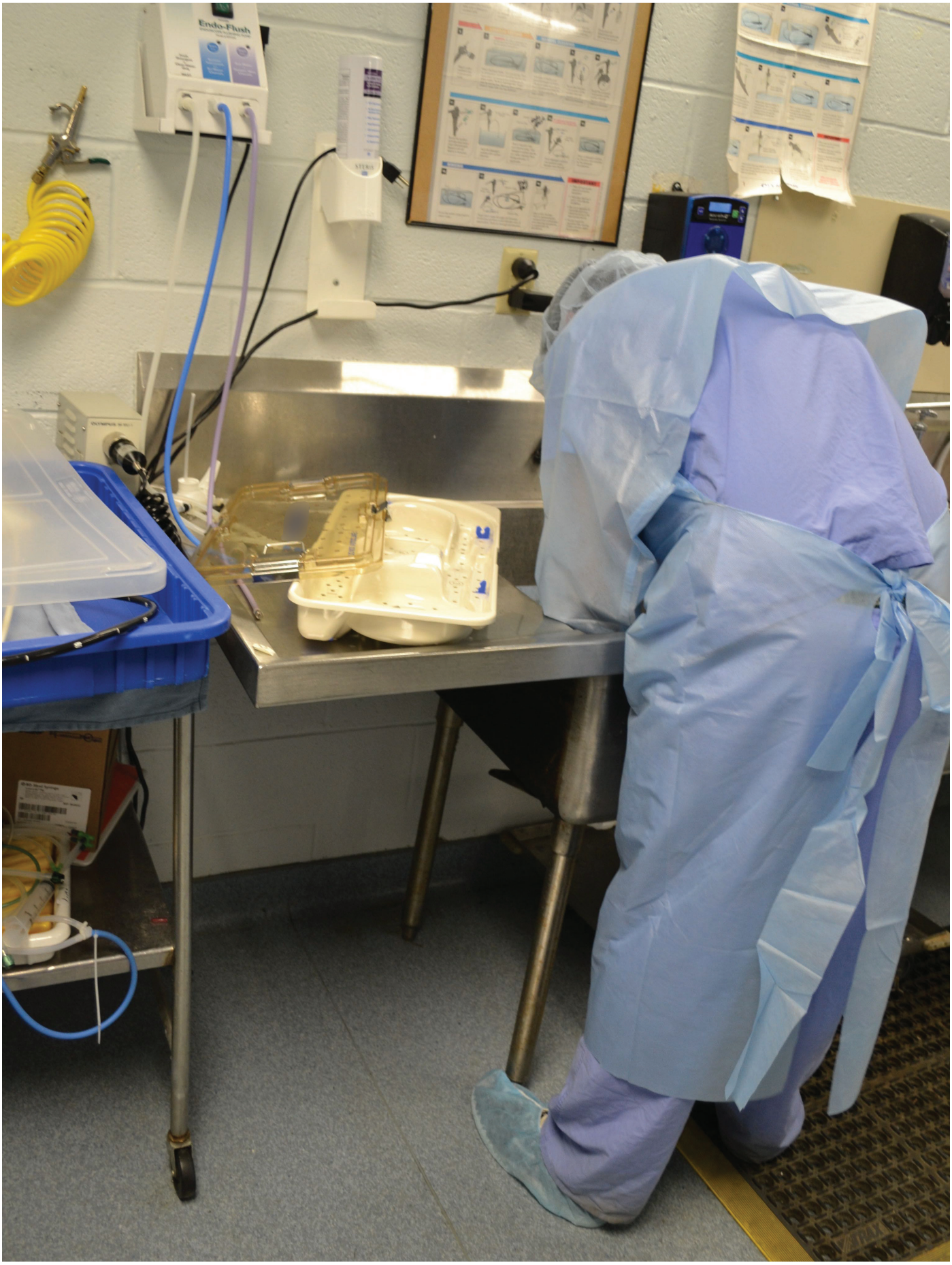
Endo-Flush

ANSI/AAMI ST98:

Requirements for Validating Cleaning Instructions Have Arrived

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LEARNING OBJECTIVES

1. Understand the cleaning challenges for today's more complex medical devices and the requirements for validating cleaning instructions in ANSI/AAMI ST98
2. Explore ANSI/AAMI ST98's key recommendations
3. Identify medical device designs that present the greatest challenge to cleaning and highlight the expected improvements in cleaning and cleaning instructions as a result of adopting ANSI/AAMI ST98

In the May/June 2021 issue of *PROCESS*, the CER lesson, "Raising the Bar: New Standards for IFU Development," reviewed newly adopted Association for the Advancement of Medical Instrumentation (AAMI) standards that significantly increased the requirement on cleaning instructions for medical devices supplied by the medical device manufacturer. Those documents included ANSI/AAMI/ISO 17664:2017 *Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices* and AAMI TIR12:2020 *Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers*. The documents focused on the instructions for use (IFU) for processing medical devices to make them patient ready but did not provide requirements for or information about how medical device manufacturers needed to validate those instructions. Standards exist related to sterilization validations; however, no global standard did the same for cleaning. Filling that critical void is ANSI/AAMI ST98:2022 *Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices.*

Objective 1: Understand the cleaning challenges for today's more complex medical devices and the requirements for validating cleaning instructions in ANSI/AAMI ST98

Developing and validating the IFU for processing (cleaning, disinfecting and/or sterilizing) medical devices by a healthcare facility is a major responsibility of medical device manufacturers. The U.S. Food and Drug Administration (FDA) requires

that these instructions are validated for efficacy and that the healthcare facility can implement the instructions in a practical way.

When it comes to cleaning, the challenges have only increased in recent decades. Such challenges include:

- Many devices, particularly the newest and most innovative ones, are highly complex with designs that are challenging to not only clean but also to confirm that each device is indeed clean.
- The sheer diversity of devices (many different designs, material construction, etc.) increases the difficulty of implementing IFU as written for each device.
- While medical devices cleared by the FDA since 2015 have had to meet the higher standard for validation of cleaning, there are still thousands of medical devices in use that were cleared before 2015.

Before ANSI/AAMI ST98, there was a often-referenced AAMI technical information report (TIR), AAMI TIR30:2011/(R)2016 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.* In fact, ST98 has replaced TIR30. While TIR30 provided valuable information to medical device manufacturers regarding validation testing of cleaning instructions, it provided information, as the name implies, not requirements. ST98, therefore, is a significant step forward from the document that preceded it.

ST98 has two sections. The first, the normative section, lays out the requirements for medical device manufacturers to validate their cleaning processes. The second, an informative annex, guides device manufacturers on meeting the requirements in the normative section.

ST98 Acceptance Criteria for Endpoints	
Clinically relevant soil components	Acceptance level
Protein	≤ 6.4 µg/cm2
Total organic carbon	≤ 12 µg/cm2
Carbohydrate	≤ 1.8 µg/cm2
Hemoglobin	≤ 2.2 µg/cm2
ATP	≤ 22 femtomoles

Figure 1

Objective 2: Explore ANSI/AAMI ST98's key recommendations

ST98's key recommendations include the following, which are addressed in greater detail later in this objective:

- Setting maximum acceptable limits for analytes that are tested to measure the removal of test soil(s) from the medical device after cleaning.
- Ensuring that both test soil formulations and analytes tested are clinically relevant.
- Testing to include the actual or a representative medical device.
- Following clinically relevant, worst-case conditions.
- Setting parameters for cleaning that also reflect worst-case conditions.
- Ensuring that the application of test soil reflects soiling during clinical use (e.g., manipulations of the medical device that are likely to occur during use and contribute to soiling of the device, including areas of the device that are most difficult to clean). This also includes repeated cycles of soiling and processing to determine if repeated use and processing of the device leads to degradation or impacts cleaning efficacy.
- Ensuring that the validated cleaning instructions are in the final IFU.

For years, the industry often referred to analytes as "markers." Consensus, however, is that the term marker could be misunderstood; therefore, the more precisely defined term analyte was adopted. Analyte is defined as "a chemical substance that is the subject of chemical analysis." This closely aligns with the testing that is done to measure how clean a medical device is after the cleaning steps are performed. Analytes are detected and measured with a quantitative validated test method. One of the great questions that pertains to cleaning is: *How clean is clean?* ST98 answers this by providing the maximum acceptable levels for the measured analyte(s). (See **Figure 1**)

To be clear, values below these could be set as the maximum acceptable level for a given device. Still, ST98 provides absolute maximum acceptance criteria for the industry. It is important to point out that these same values can be found in the International Organization for Standardization's recently published ISO 15883-5:2021 *Washer-disinfectors—Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*, which provides requirements for validating the cleaning effectiveness of washer-disinfectors. For critical and semi-critical devices, ST98 recommends that at least two analytes be tested. Also, the medical device should be visibly clean. These requirements align with the FDA guidance document. *Note: For non-critical devices, only visual cleanliness may be an acceptable endpoint.*

A test soil is necessary to limit the variability and have controls during testing, and this is true for several

reasons. Depending upon the medical device, the device may be a new product and not yet ready for clinical use (or even clinical trial). In this circumstance, a clinically soiled device's level and composition are unknown. The use of a test soil means that the device can be soiled to a known level and composition. ST98 requires the use of a clinically relevant test soil; that is, a test soil that reflects the expected composition of soil during clinical use, including the soil components, adhesion properties, viscosity and other characteristics. It is essential that the test has components and properties that represent the greatest challenge to cleaning. Similarly, ST98 requires the use of analytes that are clinically relevant. The most common (but not only) analytes are protein, hemoglobin and total organic carbon (TOC).

To demonstrate that the device manufacturer's cleaning instructions will sufficiently clean the medical device, ST98 recommends that the device or a surrogate be used to perform the testing. This is logical. After all, how else could the medical device manufacturer prove their cleaning steps render a clean device that is ready for the next step in processing? Surrogates can be used in the cleaning program's development, but the final step for validation has to be with the device itself. Surrogates, such as a polytetrafluoroethylene (PTFE) tube, can help develop the cleaning process. In addition, they may be beneficial when trying to determine whether a step (or steps) will be effective for certain design features that might be difficult to tease out in the finished device. Again, the final validation testing needs to be determined with the actual medical device.

Using clinically relevant, worse-case testing can be one of the more challenging and confusing requirements for validation testing. The worst case should be based on intended clinical use (not misuse) and anticipated use errors. In the case of cleaning parameters, it is somewhat easier to understand. Say a cleaning agent has a stated minimum and maximum concentration; the use of the minimum concentration is the worst case. The same is true with water temperature; typically, using a cleaning agent at the coldest acceptable temperature will be the worst case. By testing under the most challenging conditions, the validation testing should prove the device can be rendered clean. This can prove confusing for medical device manufacturers and those responsible for processing devices because, typically, the IFU will not recommend worst-case parameters for cleaning. On the contrary, the IFU is more likely to reflect the recommended, best case or optimal conditions to achieve cleaning.

Application of a test soil often means more than just inoculating a device with the test soil. According to ST98, it means ensuring that the soil is in the areas of the device that are the most challenging to clean (crevices, lumens, etc.). Depending on the device's design and function, this may also mean simulating manipulations (e.g., actuation) of the device expected to occur during clinical use. This is necessary because mechanical actions can direct the test soil into areas that are difficult to clean and that otherwise would not be easy to directly inoculate. Another part of this is allowing the test soil to dry. Extended dry time can make organic soils more difficult to remove. While an IFU may recommend beginning cleaning within a specified time, often this is not possible in the real world. Validation testing should reflect practical and realistic scenarios.

The medical device manufacturer is required to demonstrate that the steps in the IFU do indeed render a clean medical device. Importantly, additional steps or conditions should not be part of the validation unless they are included in the IFU.

Objective 3: Identify medical device designs that present the greatest challenge to cleaning and highlight the expected improvements in cleaning and cleaning instructions as a result of adopting ANSI/AAMI ST98

In the informative annex, ST98 identifies medical device designs that are challenging to clean. Medical device manufacturers are encouraged to avoid these designs when possible. If not possible, manufacturers are encouraged to take steps to make their devices easier to clean (take apart, ported, etc.).

These designs include:

- Lumens
- Valves
- Crevices
- Fittings with very close tolerances
- Clamps that cannot be fully opened
- Small internal parts
- Rough, irregular and discontinuous surfaces
- Hinges, depressions, joints with gaps, overlapping or butted joints
- Capillary gaps
- Luer locks
- Porous materials
- Junctions and activating mechanisms
- Dead-end chambers
- Powered instruments
- Instruments with internal moveable devices, such as cables

What might the future look like because of the influence of ST98? The hope is that cleanability will be a key consideration for medical devices at the beginning of the design process. Further, ensuring the latest cleaning instructions are provided to Sterile Processing (SP) professionals will not only help result in clean devices but

will also be simpler to implement and achieve the desired outcome: medical devices that are safe and patient ready.

Conclusion

ANSI/AAMI ST98 is part of a larger focus on advancing medical device cleaning validations. The future is brighter with the availability of this guidance document. Medical device manufacturers, SP professionals, testing labs, regulators and standards organizations must collaborate effectively to improve cleaning. It is encouraging to look back and take stock of the progress made in recent years, and there is no better example of this than the development of ST98.