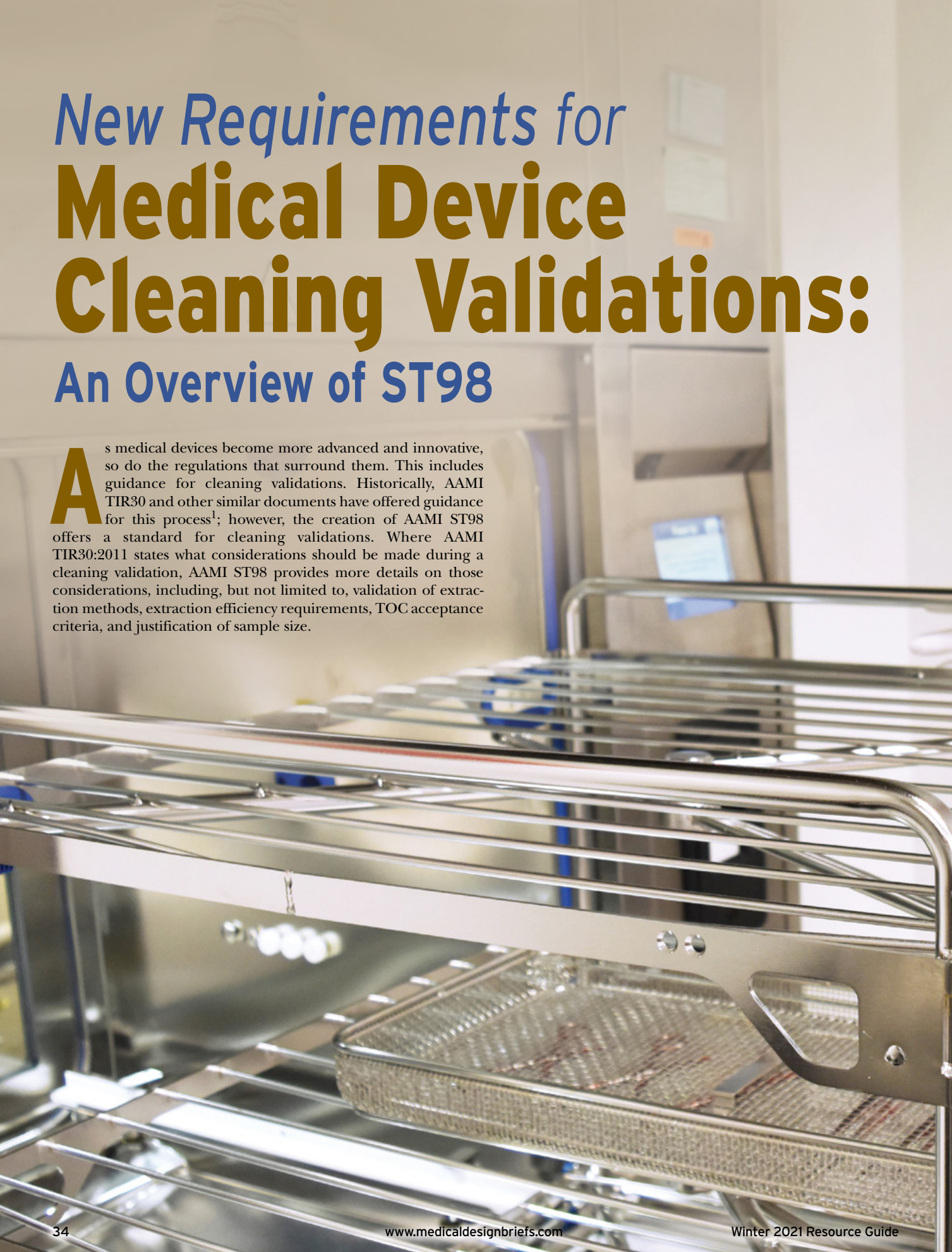
New Requirements for Medical Device Cleaning Validations:

An Overview of ST98

As medical devices become more advanced and innovative, so do the regulations that surround them. This includes guidance for cleaning validations. Historically, AAMI TIR30 and other similar documents have offered guidance for this process[1]; however, the creation of AAMI ST98 offers a standard for cleaning validations. Where AAMI TIR30:2011 states what considerations should be made during a cleaning validation, AAMI ST98 provides more details on those considerations, including, but not limited to, validation of extraction methods, extraction efficiency requirements, TOC acceptance criteria, and justification of sample size.



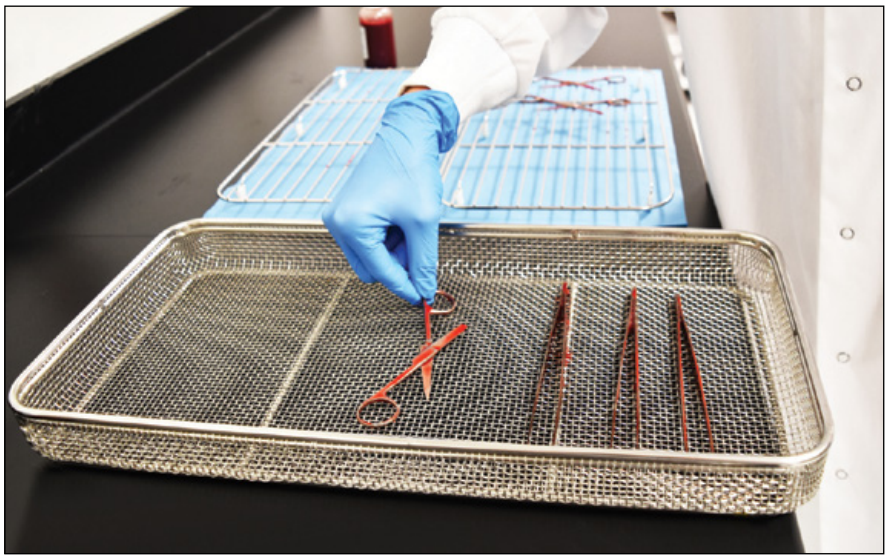
Validation of Extraction Methods

One of the new requirements in AAMI ST98 is that cleaning extraction methods should be validated. AAMI TIR30:2011 presents different methods for performing an extraction; however, it does not mention that the methods need to be validated or how to perform the validation. Per the new standard, ST98, two possible approaches for validating an extraction method are *spike recovery* and *exhaustive extraction*.

The use of spike recovery for validating an extraction method involves soiling a medical device with a known amount of soil. The soils used for spiking are the same soils that are tested in the endpoint testing. Using this method, the extraction efficiency is a comparison between the amounts of soil recovered to the amount of soil added.

The use of exhaustive extraction for validating an extraction method involves performing extractions several times on the same soiled device. The amount of

Preparation of medical devices for the automated washing process. (Credit: Eurofins)



Soiling of medical devices for reprocessing cleaning validations. (Credit: Eurofins)

soil recovered is determined for each extraction. The extraction efficiency compares the testing result of the first extraction to the sum of all testing results for all extractions performed.

Extraction Efficiency Requirements

In addition to the need to validate the extraction method, ST98 states that the extraction efficiency from the validation of the method should be greater than 70 percent. When validating using spike recovery, the ratio of the amount of soil recovered to the amount of soil added should be greater than 70 percent. If validating using exhaustive extraction, the ratio between the testing result of the first extraction and the sum of all testing results for all extractions performed should be greater than 70 percent.

A higher extraction efficiency equates to a better extraction method. ST98 allows for the use of an extraction method that yields a lower efficiency; however, its use must be justified.

The lab performing the cleaning validation must ensure that this new consideration is documented in the validation. The lab must establish controls that will provide the reproducibility needed for a seamless submission.

Total Organic Carbon Acceptance Criteria

AAMI TIR30:2011 offers some, but not all, acceptance criteria for endpoint tests. Total organic carbon (TOC) is not included. Currently, TOC acceptance criteria for cleaning validations derives from various studies on cleaning validations. The new AAMI ST98 includes a list of all currently relevant acceptance criteria for endpoint tests, including TOC. ST98 defines the acceptance criteria for TOC as ≤12 µg/cm^2.

Justification of Sample Size

When performing a cleaning validation study, the number of devices tested and the number of results generated are an important factor in showing that the device is clean. AAMI ST98 states that the number of devices tested is to be justified within the cleaning validation. The new standard also provides guidance on the conditions to be achieved in order to prove that the number of devices tested was sufficient. These conditions include:

1. A minimum of three data points are generated per each endpoint test.
2. All data points must be within the stated acceptance criteria, within ST98, for that endpoint test.
3. The variation of data points between samples must be determined.

The acceptability of the variation is determined by calculating the standard deviation of the set of data points. This value is then added to the highest data point; the result must not exceed the acceptance criteria for that endpoint test. If this value exceeds the acceptance criteria, the number of devices tested was not sufficient.

It is important to ensure that this new consideration is documented within the validation. The lab performing this should document all results and offer justification for the sample size to ensure that there are no regulatory delays.

Considerations for Manufacturers and Test Labs for Cleaning Validation Studies

When planning a cleaning validation study, the testing laboratory chosen to perform the study should be knowledgeable in the regulations surrounding the study. It is important that the lab understands all current and upcoming regulations, so that the device being validated is tested appropriately. Additionally, the lab should have testing equipment similar to what is used in a clinical or hospital setting. The end users of the device must be able to replicate the cleaning process when using the device.

Finally, the lab should be agile and competent to troubleshoot any obstacles as they arise. A team of scientists that have a myriad of experience performing cleaning validations on all types and categories of medical devices will help keep the validation on track and completed in an efficient manner. A global network of resources is advantageous when performing cleaning validations on any categories of devices, but it is also beneficial if the device will be used in different countries.

The upcoming AAMI ST98 standard will help medical device manufacturers and scientists in developing and testing devices that will undergo cleaning validations. The detail provided in ST98 on validation of extraction methods, extraction efficiency requirements, TOC acceptance criteria, and justification of sample size helps to ensure that the cleaning validation meets regulatory requirements. AAMI ST98, along with the aforementioned considerations for test labs, will help the continuity of the cleaning validation against any setbacks and ensure that it is completed successfully. The considerations detailed in ST98 are critical to a successful cleaning validation and confirm the cleaning protocols on medical devices to help ensure patient safety.

Reference

1. AAMI TIR30:2011 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

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