Updates and Challenges Regarding Reprocessing Validations For Reusable Medical Devices

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Recent updates regarding standards that govern reprocessing validations for reusable medical devices.

Upcoming changes to cleaning validations for reusable medical devices?

What reprocessing validations requirements are needed for capital equipment?

What is happening in the endoscope industry?
• **DIN EN ISO 17664:2018**: Processing of health care products – Information to be provided by the medical device manufacturer for the processing medical devices was published. ISO 17664 was originally published in 2017.

• **ISO 17664-2**: Processing of health care products – Information to be provided by the medical device manufacturer for the processing medical devices – Part 2: Medical devices not intended for direct patient contact. The second draft was discussed during the September ISO meeting. The document is still under development.

• **ISO 15883-1**: Washer-disinfectors – Part 1: General requirements, terms and definitions and tests was just published in January 2019.

• **ISO 15883-5**: Washer-disinfectors – Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy is under revision to add new acceptance criteria for cleaning validations. This should be published in the next couple months.
**AAMI ST98**: Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices. This is a new standard replacing AAMI TIR30. The first draft has gone through comments will go for comments for the spring meeting. Estimated time completion of the standard is fall 2020.

**AAMI ST91**: Flexible and semi-rigid endoscope processing is still under revision. There was a meeting the first week of January covered 192 comments. A total of 846 comments were received.

**AAMI TIR99**: Dilator and Ultrasound Probes Processing in Health Care Facilities is a new technical information report. This document is in draft format.

**AAMI TIR12**: Instructions for Reusable Device Reprocessing is being rewritten to include more consistent cleaning instructions and updating the sterilization validation processes to include full cycle validations.
Standard Updates – ASTM F04 – Medical and Surgical Materials and Devices

- **ASTM F3293-18**: Application of Test Soil for the Validation Testing of Device Reprocessing Instructions is a new standard.

- **WK60064** – Standard guide for methods of Extraction of test soil for the validation of cleaning methods for Reusable Medical devices.

- **WK63284** - Detection and Quantification of Cleaning Markers (Analytes) for the Validation of Cleaning Methods for Reusable Medical Devices

- **WK60639** – New Guide for Designing Medical Devices for Cleanability

- **WK59761** - New Standard — Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)
<table>
<thead>
<tr>
<th>Analyte</th>
<th>Recommended Level</th>
<th>ISO 15883-5 DRAFT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protein</strong></td>
<td>≤ 6.4 µg/cm²</td>
<td><strong>Protein</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>≤ 3 µg/cm² ≤ 6.4 µg/cm²</td>
</tr>
<tr>
<td><strong>Hemoglobin</strong></td>
<td>≤ 2.2 µg/cm²</td>
<td><strong>Hemoglobin</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>≤ 1.0 µg/cm² ≤ 2.2 µg/cm²</td>
</tr>
<tr>
<td><strong>Carbohydrate</strong></td>
<td>≤ 1.8 µg/cm²</td>
<td><strong>Carbohydrate</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>NA ≤ 1.8 µg/cm²</td>
</tr>
<tr>
<td><strong>Endotoxin</strong></td>
<td>≤ 2.2 EU/cm²</td>
<td><strong>Endotoxin</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>≤ 2.2 EU/cm² ≤ 20 EU/cm²</td>
</tr>
</tbody>
</table>

**ISO 10993-5**

Detergent Residuals (MEM) - reactivity grade of ≤ 2 - Qualitative method

ISO 10993-5

Detergent Residuals (MEM) - reactivity grade of ≤ 2 - Qualitative method
Cleaning validation acceptance criteria update

• German Guideline (Zentral Steril 2013; 21:212-215- acceptance criteria for < 3 µg protein /cm² in Germany
  o They tested 3780 surgical instruments, 786 MIS instruments and 288 ophthalmological instruments = 4854 devices tested

• Hygiene Requirements for the Reprocessing of Medical Devices
  o German Document - Robert Koch Institute (RKI)
  o Suggests theoretical considerations for protein to be 100 µg/instrument (Table 3)
1. Ransomware and Cybersecurity Threats Can Endanger Patients

2. Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk

3. Mattresses and Covers May Be Infected by Body Fluids and Microbiological Contaminants

4. Missed Alarms May Result from Inappropriately Configured Secondary Notification Devices and Systems

5. Improper Cleaning May Cause Device Malfunctions, Equipment Failures, and Potential for Patient Injury

ECRI Institute is an independent nonprofit organization that researches approaches to improving patient care.
Human factor considerations play a main role in the reusable medical device industry because sterile processing personnel are the front line people performing these tasks.

Training, competency, documentation are necessary.
IFU – Human Factors

• Regulatory agencies are asking for:
  – human factor testing data and documentation
  – Number of participants involved
  – Who were the participants (users? Third party? Self?)
  – Feed back documentation from users
  – Any improvements to IFU documented
Disassembly Instructions

1. Depress button and remove sleeve

2. Depress button and remove shaft
Processing for Used Condition Devices

Repeat Processing

- Manipulation
- Lubrication
- Inspection
- Pictures

Contamination

- Sterilizer

Automated Washer

Manual Cleaning

6x
Selecting Test Soil

Clinical Relevancy
- ISO 15883-5
- ASTM F3208

Blood Soil
- Coagulated Blood
- Defibrinated blood soil

Mucous Soil (British Soil)

?
### Test soils: Clinical Relevancy

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Why Clinically Relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole sheep blood, 3.8% citrated</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Rabbit blood in citrate</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Defibrinated sheep  blood</td>
<td>Hemoglobin</td>
</tr>
<tr>
<td>Bovine calf serum</td>
<td>Protein</td>
</tr>
<tr>
<td>Physiological saline</td>
<td>Isotonic equivalence to Human tissue and blood</td>
</tr>
<tr>
<td>Calcium chloride</td>
<td>Coagulation of blood</td>
</tr>
<tr>
<td>Fresh Egg yolk</td>
<td>Carbohydrates and Protein, lipids</td>
</tr>
<tr>
<td>Dehydrated Hog Mucin</td>
<td>Carbon Source, protein, viscosity properties</td>
</tr>
<tr>
<td>Dry milk powder</td>
<td>Protein, Carbohydrates, Carbon Source</td>
</tr>
</tbody>
</table>
Perform visual inspection

- Naked eye
- Boroscope
- Magnification 10X

Lumens

Hinges and crevices
### Comparison chart: IFU Vs. Validation Parameters

<table>
<thead>
<tr>
<th>IFU</th>
<th>Validation Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare detergent per manufacturer recommendations (¼,½,1oz/gal)</td>
<td>Prepare detergent using (¼oz/gal)</td>
</tr>
<tr>
<td>Soak the devices in detergent for 2-5 minutes</td>
<td>Soak the devices in detergent for 2 or less minutes</td>
</tr>
<tr>
<td>Flush the lumen with 60mL of prepared detergent</td>
<td>Flush the lumen 55mL of prepared detergent</td>
</tr>
<tr>
<td>Clean the devices in an enzymatic detergent at 45 ± 5°C</td>
<td>Clean the devices in an enzymatic detergent at 40°C</td>
</tr>
<tr>
<td>Cleaning Validation Information Needed</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Description of accessories required</td>
<td></td>
</tr>
<tr>
<td>Techniques used including rinsing</td>
<td></td>
</tr>
<tr>
<td>Water quality for each process</td>
<td></td>
</tr>
<tr>
<td>Concentration and type of chemicals</td>
<td></td>
</tr>
<tr>
<td>Exposure time and temperature of each step</td>
<td></td>
</tr>
</tbody>
</table>
Is End of Life Testing Needed?

Surgical suction device cut in half was found to be packed with debris.

Image courtesy of University of Michigan Health System
Disinfection Validations – High Level Disinfection

ENDOSCOPES

- Disinfectant to be diluted to MEC using hard water
- Test soil prepared using hard water
- Performing an extra positive control – LLP
- Neutralization methods include whole volume

OTHER REUSABLE MEDICAL DEVICES

- Full concentration disinfectant to be used
- Test soil prepared with sterile water
- Only 1 positive control required
- Neutralization methods include testing aliquots

THERMAL DISINFECTION
Capital Equipment - Validations
Valiation Parameters

Cleaning Validation

Patient contacting
- Protein, Hemoglobin, TOC

Non-Patient Contacting
- Visual Inspection

Intermediate level
- 6 log reduction of bacteria, 3 log reduction of M. terrae

Low level
- 6 log reduction of bacteria
Main Points discussed during the comments emphasized on:

- Surveillance/Cleaning verification tests- frequency, results?
- Drying methods – criteria
- Spaulding classification for endoscopes – where they belong
- Sterilization of endoscopes
- Design flow of endoscope reprocessing/cleaning rooms
NEXT STEPS:

- Consider/categorize what scope would fall in the “critical” device classification
  - Determine what scopes fall under the “Gray zone”
  - Prepare a Gap assessment

- Determine what sterilization modality will be applicable for your endoscopes

- How will drying be qualified – validation/verification plans

- Training programs for reprocessing staff for HCF

- Increasing Inspection program for HCF
  - Training for determining what a failure is

- Considerations for adding to validation
  - Use of simethicone
  - Use of double pouches for sterilization validations
  - Assessing using used filters for AER validations
Thank You!

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