Welcome!

**Topic:** Demystifying Cleaning and Decontamination

**Facilitators:**
- Diane Koch, 3M Sterilization Assurance
- Sandra Velte, 3M Technical Service
- Stephen Kovach, Director of Education, Healthmark Industries

**Housekeeping:**
- Questions
- Mute feature (*7 = unmute; *6 = mute)
- “Chat” feature
- Technical difficulties
- CE Credits
- Post session follow-up

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**Objectives**

1. Understand the nine factors of cleaning
2. Review the concepts of manual and automatic cleaning
3. Understand cleaning verification, including equipment and instrument verification
Conflict of Interest

✓ The following individuals are industry employees and report.

“I, or a member of my family, or partner, have a significant financial interest of other significant relationship with one or more companies who manufacture products used in the treatment of perioperative patients.”

Stephen Kovach, Healthmark

The Joint Commission makes a statement “...ask healthcare workers to provide the manufacturers’ instructions for instrument sterilization, and to describe and demonstrate how instruments are being cleaned and decontaminated according to those written instructions; observe the cleaning of instruments...” as reported in HPN ONLINE 6/26/09

The supply of sterile goods requires a chain of activities. All steps have to be performed well. We will be talking about one of those chains that deals with Cleaning and decontamination.
It takes just one break in the link to cause a problem.

Definitions

- Cleaning is “removal of contamination from an item to the extent necessary for further processing or for the intended use.”
  (ANSI/AAMI ST79, page 7, section 2.19)
- Decontamination “is the process by which medical devices, instruments, and equipment are rendered safe for personnel to handle”
  (ANSI/AAMI ST79, page 3)

The Power of Cleaning

- By cleaning, the population of micro-organisms residing on the materials (known as the bioburden) is reduced considerably.
- The initial contamination for a subsequent disinfection or sterilization is considerably lower and thus these processes will be more effective, as much less organisms have to be killed.
The Facts of Cleaning
Cleaning is not disinfection
- The cleaning process is not microbicidal
- Multi step process of cleaning
No two CS departments are the same
There is Standard Operating Procedure
- AAMI
- CDC
- EPA
- CSHA
- Professional Groups
  - IAHCSMM
  - AORN
  - AST
  - CBSPD
Follow manufacturer’s guidelines
- Every manufacturer must provide you with at least information on how to clean their item by manual methods

Remember to help prevent infections; all equipment (carts, instruments, IV pumps, scopes…) must be disinfected between uses according to the Spaulding classifications

Understanding the factors of cleaning
The nine factors that affect the cleaning process are:
- Type of soil to be cleaned off the item (blood, sputum, …)
- Items to be cleaned (simple or complex)
- Water quality (pH, hardness…)
- Temperature (cycles, cleaning solutions…)
- Chemical activity (cleaning solution)
- Mechanical action (manual - “arm power-scrubbing”, spray arms)
- Human factor (training…)
- Verification of the process
- Influence of the standards

It is the various combinations of these factors that determine how clean your instrument will be.
Reprocessing of Medical Devices: Who is responsible for What??

- **Manufacturers** validate that an instrument can be reliably cleaned and sterilized / disinfected and is therefore reusable.
- **Users** verify that cleaning / sterilization equipment is working and that in-hospital cleaning / sterilization methods are consistently performed.
The Ideal Manual Cleaning Process

- Everything is found in ANSI/AAMI ST79 (ANSI/AAMI ST79 3.3.7.1)
- Three sinks
- An “ideal sink”
  - 36 inches from the floor
  - 8 to 10 inches deep
  - Width and length to allow a tray or container basket for instruments to be placed flat for pretreatment or manual cleaning

The Ideal Manual Cleaning Process
Continued

Temperature in the decontamination area (ANSI/AAMI ST79 3.3.6.5)
- 60-65°C
Relative humidity (ANSI/AAMI ST79 3.3.6.6)
- 30-60%
Air exchange (ANSI/AAMI ST79 3.3.6.4)

<table>
<thead>
<tr>
<th>Functional area</th>
<th>Airflow</th>
<th>Minimum number of air exchanges per hour (ANSI/AAMI ST79)</th>
<th>Minimum number of air exchanges (area, 2001)</th>
<th>All air exhausted directly to the outdoors?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization</td>
<td>Negative (n)</td>
<td>10</td>
<td>6</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Lighting requirements
Physical separation
Nonporous material
- Floor, ceiling, work surfaces
Workflow is important
- Adequate space for activities
Ergonomic factors
- Counters and work surfaces “average height”
The Ideal Manual Cleaning Process
Continued

Space
• For everything
  ▶ Hand washing
  ▶ Body-fluid disposal systems
  ▶ Computers
  ▶ Eye wash stations
  ▶ You name it

The Ideal Manual Cleaning Process
Continued

Luke warm water and detergents
• At temperature range of 80-110°F
  ▶ Prevent coagulation and thus assist in the removal of protein substances
Temperature should be monitored and documented
• Also water hardness, pH, temperature
Thoroughly rinsed to remove debris and detergent residues

Now the Real world ........no two CS/SPD are alike...not everybody has the same equipment...not all the right information...let only certified staff...but we all have to get the job done...get it done right... and get it CLEAN.......HELP !!!!
Just as a carpenter needs special tools to do their job correctly….so does a Central Service Professional …they also need those same special tools to …Get it Clean!

Dilution get it right!
Personal protection when cleaning

Hard to hand-clean items

- Any lumened item
  - Suction
  - Reamers
  - MIS instruments
  - Power equipment

- Take-a-parts
You need the right tools to "Get it Clean"

- Spray guns
- Vertical soakers
- Proper Brushes
- Verified equipment
- Magnifying glass
- Quality Improvement Program

The hand shower can be used for an initial rinse of instruments. Use a deep basin, which will help to prevent splashing sideways. Make sure that the water pressure is not too high in order to limit splashing. Only use cold water for blood removal! Protect yourself by wearing gloves and mask, or use a splash screen.

Delicate instruments such as optics may be cleaned by soft towel or sponge.
A spray gun is essential for rinsing/flushing of hollow instruments. Various nozzles are available for a range of specific cleaning applications.

Manual Cleaning

- Everything can be manually cleaned and you must have that on file
- Have the right “tools” to do the job
- Understand your process
- Train your staff

We are focusing on Automatic Washers
Medical Automatic Washers Have Two Basic Model Design Types:

- Batch-type medical automatic washers
- Rack conveyor type medical automatic washers (tunnel washers)

Batch-type

Batch-type medical automatic washers have a closed cabinet which is linked to the water supply and drainage system. The machines are loaded with the soiled instruments / utensils and the doors locked before the cycle commences and all cycle are done in the one chamber.

Tunnel type

Rack conveyor type medical automatic washers (tunnel washers) operate on a continuous process in which the machines are loaded with the soiled instruments / utensils and the doors locked before the cycle commences and are transported from stage to stage at a fixed speed by means of a conveyor.
Medical Automatic Washer Fall Into Two Very Distinctive Categories on Theory of Operation Which Are:

High impingement washer
- Relies on high pressure coming from the spray arms

High water volume washer
- Relies on high volume of water with a lower pressure coming from the spray arms

(Impingement is a term used to describe water pressure)
Each design and theory have their own issue

Review the specific concerns
- Spray arms
- Productivity
- Coupler

Common concerns
- Delivery system
- Loading
- Staff training
- Biofilm

Spray Arm Impingement Pattern

Slide is courtesy of Tim Brooks – Yuma Regional

Missing spray arm
Automatic Cleaning

Observations of Machine Operations / Condition:
- Occlusion of spray arms
- Nozzle directions
- Freedom of movement of spinner arms
- Instrument rack coupler alignment
- Staining, scaling of inside of chamber
- Clean screens, wipe down equipment
- Make sure the light in the washer is working
- Is the cleaning solution being delivered properly
- Daily, weekly, monthly, quarterly monitoring needs to be done

Keep a record of all results / record in a log book
Document the best cycle settings / keep a copy if they change

Ultrasonic Cavitation

- Like any mechanical device, from time to time, transducers fail.
- Given the nature of ultrasonic cleaning, observation of failure is not easy.
- Also, in a series of transducers, one may be failing, while the remaining units are functioning, creating dead spots within the ultrasonic.
- Monitoring devices for detecting cavitation are now commercially available.

Verification and Standards

“For verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the automated washer (if used) and the cleanliness of specific devices after manual or automated cleaning is completed.”

(ANSI/AAMI ST79, Annex D, section D.3)
“...as with all automated equipment it is important to ensure that the reprocessing equipment is properly used and maintained." 


What can I use to test with?

- There are many types of test methods. Some are more focused in research and used specifically by manufacturers. I am focusing in on what a hospital user can use as a “just in time” type test for instruments and equipment.
- Equipment and instrument testing
  - They are different

Instrument Verification

Use to help identify cleaning issues (Hygiene monitoring)
- Stains on instruments
- Cleanliness of surfaces (OR tables, equipment, work surfaces...)
- Done mostly by swabbing the area
  - Color change over time
    - Clean / Dirty
- Commercially available products
  - ATP
  - Hemoglobin specific
  - Protein Specific
Equipment Verification

- To help ensure that equipment are performing properly
- These tests are designed to challenge the operational level of cleaning equipment.
- These tests either measure a specific parameter or challenge the cleaning efficiency of the entire system.
- Think of your sterilizer

Some Examples of Standardized Test for Efficiency of Equipment

Sonic Cleaning
- Foil test
- Ceramic disc method
- Probe
- Sonochek™

Temperature Testing
- Irreversible
- Reversible
- Thermologgers

More Examples of Standardized Test for Efficiency of Equipment

Water Quality
- Simple dip stick method
- Comprehensive water study

Test Soil
- It is important to remember that as stated in AAMI ST79 clinical soil is a substance consisting of the inorganic, organic and biological matter typically found on medical instruments after clinical use.
  - AAMI Annex D
Module 3

AORN

Standards, Recommended Practices, and Guidelines
2009 Edition

- RP VIII.c – page 617 – “...water quality assessment should be performed periodically...”
- RP X.c.14 – page 619 – “...operator should ensure that the proper cycle is being used...”
- RP XIX – page 630- ...competency, education, training...

Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, AORN:2009

AORN

Standards, Recommended Practices, and Guidelines
2009 Edition

- RP XXII.a – page 632 – “Mechanical instrument washers should be tested for proper functioning before initial use, weekly during service, and after major maintenance.”
- RP XXII.a.1 – page 632 – “...Testing washer decontaminators on a regular basis verifies that the equipment is functioning properly...”

Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, AORN:2009

Benefits continued

Meets recent standards and guidelines
Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, AORN:2009

- XXII.a.2 – page 632 – “...Protein indicators are commercially available to assist with this evaluation.”
- XXII.a.3 – page 632 – “...Visual inspection of insulation... Electrical testing can identify very small insulation failures...”
- XXII.a.4 – page 632 – “...When investigating surgical infections, documentation of the cleaning process of instruments should be reviewed...”
Key Elements of AAMI ST79
Importance of qualifications, training, continuing education of staff
Example: Section 4.3.1
“…. Personnel should receive in-service training for all new instrumentation, devices, and equipment. All orientation, on-the-job, and in-service training should be documented.”

Verification of the cleaning process
Section 7.5.5
“Rationale: Sterile processing personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of devices for patient use. Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function. A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically.”

Periodic product quality assurance testing of routinely processed items
Section 10.2 and Annex D
“…. health care personnel may perform verification tests as part of the overall quality assurance program. Methods of verification include the use of devices that directly test individual instruments for residual soils, challenge cleaning effectiveness with standardized test methods, or measure specific key parameters to evaluate the functionality of the cleaning equipment. Key performance outcomes include clean surfaces and adequate fluid flow in equipment that has adaptors for lumened devices. See Annex D.”
Other AAMI Documents

- AAMI TIR 12:2004, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI TIR 30:2003, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

The Joint Commission

Standard EC.02.04.03
The hospital inspects, tests, and maintains medical equipment.

ASTM Standard

D7225-06 Standard Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfector

This guide is based on a standardized test soil correlating to coagulated blood suitable for screening tests and the evaluation of the cleaning efficiency of washer-disinfectors used for reprocessing of surgical instruments. This guide strictly deals with cleaning and does not describe any methods that are related to disinfection.
A Quality System helps you put all of this together

- Reduce variance in the process
- A proven system that works
- Reduce your stress
- Allows you to provide the best quality product concerning cleaning
- Regulations and guidelines support a Quality System
- Remember it is more than just running a "test" - it is a combination of everything

I Leave You With These Images?

Which tray of instruments do you think will get clean?
Quality is doing the work right when nobody is looking

Henry Ford
References

- AAMI TIR12:2004
- AAMI TIR30:2003
- The Joint Commission, Hospital Accreditation Standards: 2010

Contact Information

Stephen M. Kovach
1-800-521-6224/Ext.6621
cpguy@healthmark.info
www.cpguy.net

Thank you to 3M