Instrument Reprocessing Update: What’s New?

Objectives

Upon completion, participants will be able to...

1. Explain various national accreditation organizations along with their new survey methods,
2. Identify recent updates in HLD and sterilization national standards,
3. Discuss manufacturer’s IFUs and national Standards for steam chemical indicators,
4. List ten (10) common practices versus best practices for instrument reprocessing.

All the national accreditation organizations, including CMS now survey hospitals and surgery centers for strict compliance with standards, guidelines, and MFG’s IFUs regarding instrument reprocessing.

AAAHC - The Accreditation Association for Ambulatory Healthcare recently added an infection control chapter to their standards handbook.

Infection control highlights included:

“Adhering to standards, guidelines, and manufacturer’s instructions for cleaning, disinfection, and sterilization of instruments, equipment, supplies, and implants.”

Reference:
OR Manager Magazine, Volume 26, Number 2, 2010

The Centers for Medicare & Medicaid Services (CMS) recently revised their Survey and Certification document to include more stringent audits in the areas of infection control and sterilization.

Areas of emphasis, include:

- Compliance with nationally recognized standards/documents.
• Formal training in areas of infection control and sterilization.
• Compliant cleaning, sterilization and monitoring procedures.
• Established criteria for flash sterilization.

Reference:

New "tray tracer" survey method includes:
• Observe instruments from point of use transportation through each of the reprocessing steps.
• Ask HCWs to provide the MFG’s' 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. Rinsing is rarely enough to properly remove soil from instruments; meticulous cleaning is needed.

• Verify that staff members are wearing appropriate personal protective equipment.
• Observe the sterilization process. The surveyor will ask for the manufacturer’s instructions for the following items: the sterilizer, wrapping or packing, and the instruments.
• Review sterilization logs. Surveyors will ask about physical, chemical and biological indicators.
• Observe the return of instruments to the sterile field and verify that they are being protected from recontamination.

Why the new emphasis on Instrument Reprocessing?
Mostly, due to unwanted media attention, hospitals and surgery centers are seeing much stricter surveys from these accreditation organizations.

7,000 patients of Dr. W. Scott Harrington, of Tulsa, have been advised to get tested for hepatitis B and C and HIV after health officials discovered that instruments may have been improperly cleaned and shared among patients, some who carried infectious diseases.

Health officials opened their investigation after a patient with no known risk factors tested positive for both hepatitis C and HIV, the virus that causes AIDS. After determining the "index patient" had had a dental procedure done about the likely time of exposure, investigators visited Harrington's office and found a number of unsafe practices.

I believe that instrument reprocessing errors can be eliminated with formal training and education of
health care personnel to comply with “best practices” all of the time.

**Instrument Reprocessing**

**Best Practices**

**Point of Use**
- pre-clean to prevent soil from drying and to transport properly to the reprocessing area.

**Reprocessing Area**
- clean & disinfect in Decontamination area,
- inspect & assemble in Prep & Pack area,
- package & sterilize in Sterilization area,
- maintain sterility in Sterile Storage area.

**Quality Assurance**
- documentation & record keeping.

**Best Practices**

In the U.S., instrument reprocessing “best practices” are detailed in AAMI Standards and CDC Guidelines. As you know, the dental Guidelines are being updated this year, while the following AAMI standards were updated in 2013.

**Chemical Sterilization & HLD**

**Steam Sterilization**

AAMI ST79 A4:2013

Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Considered the bible of sterilization, this comprehensive guide to steam sterilization in healthcare facilities covers all aspects of facility design, personnel and instrument reprocessing procedures.

*The referee for what’s "best practice" versus what’s "common practice".*

Both of these recently updated national standards stress the importance of having and following device MFR’s validated IFU when reprocessing reusable medical devices.

**Where Do You Get IFUs?**

Many healthcare facilities rely on the local Sales Rep to provide IFUs; however, I recommend you contact the Corporate office and speak directly with Quality Control
or Regulatory Affairs of the device manufacturer.

Quality Control and/or Regulatory Affairs personnel are the ones most familiar with these documents and should be eager to provide them to you.

**For Patient Safety...**

It is critical you follow the device MFR’s validated cleaning IFU with regards to water temperature, water type, brush, detergent and specific cleaning procedures.

It is also critical to follow the device MFR’s validated sterilization IFU with regards to which process and specified parameters.

**Why Are IFUs Important?**

"If manufacturer’s instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the ASC’s practice should be cited as a violation of 42 CFR 416.44(b)(5).” CMS, 2009

So, let’s take a look at some DENTAL MFG’s IFUs to see what dental instrument reprocessing personnel are dealing with...

**Instrument Reprocessing**

As you can see, there is a wide variance in MFR’s IFUs. However, for patient safety, compliance with standards, and to stay out of the national media; you must have and must follow each device MFR’s validated IFU.

**AAMI/FDA Medical Device Reprocessing Summit**

**10 Things Your Organization Can Do Now to Improve Reprocessing**

1) The basics: Cleaning and disinfection/sterilization of reusable devices are separate, equally important processes and must be performed before each patient use according to the device manufacturer’s written instructions for use (IFU).

**10 Things Your Organization Can Do Now to Improve Reprocessing**

2) The right tools:
Have the IFU as well as all cleaning implements and equipment required by the IFU readily available in all the reprocessing areas.

10 Things Your Organization Can Do Now to Improve Reprocessing

3) Create a multidisciplinary committee to review the priority issues and set a plan for solving them throughout the organization.

The following areas should be represented: OR, infection prevention and control, health care technology management (biomed), endoscopy, risk management, quality, safety, education, and materials management.

10 Things Your Organization Can Do Now to Improve Reprocessing

4) Share lessons learned:
Remind senior management and safety officers that it costs a lot less to “do it right the first time.” Share lessons learned from other health care organizations that have had to inform patients of patients of exposure to inadequately reprocessed reusable devices.

10 Things Your Organization Can Do Now to Improve Reprocessing

5) Written procedures:
Establish a formal program for reprocessing, including written standardized policies and procedures that include a chain of accountability. Expert guidance can be obtained from industry experts in order to resolve conflicts between the IFU and facility policies. Written procedures should also be developed and implemented for central sterile processing reporting of inadequate instructions, equipment problems, and in-service issues to the manufacturer and, when applicable, to the FDA’s MedWatch program.

10 Things Your Organization Can Do Now to Improve Reprocessing

6) Standards matter:
Know the current standards, recommended practices, and IFUs.
7) Purchasing:
Sterile processing should be included in purchasing decisions for reusable devices, to provide input on whether the device can be reprocessed appropriately and with the facility's existing resources.

8) Separate and standardize functions and locations:
Separate central service (warehouse, stocking, etc.) from reprocessing; create standardized job descriptions and functions.

9) Training:
Train and retrain. Ideas include: assess staff competencies; negotiate for training budget with cost/ benefit analysis to prove value; partner with vendors for education; create a list of available continuing education units (CEUs) for easy access by staff; work with human resources to create career ladders for certification and promotion; promote the importance of certification. Note: In-service for loaner or new instruments should include reprocessing in-service areas that are separate from (or in) central sterile processing.

10) Assessment:
Conduct an audit of compliance with standards and regulations, using any number of available tools and resources.

For more information regarding the AAMI/FDA Summit go to:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252941.htm

Now, let’s switch gears and discuss Chemical Indicators
ANSI/AAMI ST79 10.5.2.2.2
An internal CI should be used within each package, tray, or rigid container system to be sterilized. This internal CI may be a single-variable indicator (Class 3 CI), multi-variable indicator (Class 4 CI), integrating indicator (Class 5 CI), or emulating indicator (Class 6 CI). It should be noted that Class 6 emulating indicators are cycle-specific; that is, they should be used only in the specific cycles for which they are labeled.
Multi-parameter internal chemical indicators are designed to react to >2 parameters (e.g. time and temperature, or time, temperature, and the presence of steam) and can provide more reliable indication that sterilization conditions have been met.

**Chemical Indicators**

ANSI/AAMI ST79 10.5.2.1

A Class 5 integrating CI within a PCD (that also contains a BI) should be used to monitor each load containing implants and may be used as a basis for early load release in documented emergency situations only; however, loads containing implants should always be biologically monitored.

AORN Standards and Recommended Practices, VII.c.3.

A class 5 chemical integrating indicator or a class 6 indicator should be used within each sterilization container or tray used for IUSS. Class 6 indicators are cycle specific and should be used only in the specific cycles for which they are labeled.

**Class 5 Integrators**

AAMI definition

Class 5 (integrating indicators): chemical indicators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs.

**Finally, allow me to share with you 10 common practices I see in dentistry that are not “Best Practices”**

1. Transport – common practice after the procedure, is to transport soiled instruments to the reprocessing area on an open tray, whereas best practice is to transport soiled instruments in a sealed container identified with a biohazard symbol.

2. Manual cleaning – common practice is to use a standard procedure for cleaning all instruments, whereas best practice is to have and follow each device manufacturer’s cleaning IFU regarding water type, water temperature, detergent and brush type.

3. Ultrasonic cleaning – common practice is to run the sonic for a short amount of time, e.g. 2 - 5 min, whereas best practice is to follow each device manufacturer’s IFU regarding length of time.

4. Packaging – common practice is to use a single layer of disposable wrap, whereas best practice is to use two layers per the wrap MFR’s clearance and IFU to ensure items remain sterile until point of use.
5. Packaging—common practice is to place sterilization pouches flat in the sterilizer tray paper side up or plastic side up, whereas best practice is to place pouches on edge facing the same direction to allow for sterilant penetration and complete drying.

6. Sterilization—common practice is to run the shortest programed cycle on the sterilizer, whereas best practice is to have and follow each device manufacturer’s IFU regarding sterilizer type and cycle parameters.

7. Sterilization—common practice is to remove packaging from the sterilizer at cycle’s end even if it is wet, whereas best practice is to reprocess packages that are visibly wet ensuring the sterilizer is not overloaded and that the proper drying time is being used.

8. Sterile Storage—common practice is to store sterile packages near sinks and/or in high traffic areas, whereas best practice is to place sterile packages in a separate, environmentally controlled area away from sinks, floors, walls and ceiling to reduce the potential for contamination.

9. Quality Assurance—common practice is to run a BI test once a month, whereas best practice is to run the BI test weekly, with any load that contains an implant and 3 consecutive times after a failure.

10. Quality Assurance—common practice is to run the BI test in an empty sterilizer, whereas best practice is to run the BI test in the center of a load that is representative of what is being routinely processed.

Conclusion

It is important to know that accreditation organizations, State Health departments and Dental boards, as well as the national media, are all looking for compliance with infection control "Best Practices".

And, my take home message to each of you, is to never forget that behind every instrument, is a PATIENT!

References & Resources

Association for the Advancement of Medical Instrumentation
1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795
703-525-4890  Fax: 703-276-0793   www.aami.org

Accreditation Association for Ambulatory Health Care (AAAHC)
5250 Old Orchard Road, Suite 200  ·  Skokie, IL 60007  www.aaahc.org

Centers for Disease Control and Prevention
1600 Clifton Road  Atlanta, GA 30333
800-232-4636  www.cdc.gov
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard · Baltimore, MD 21244
www.cms.gov

The Joint Commission (TJC)
One Renaissance Boulevard · Oakbrook Terrace, IL 60181
www.jointcommission.org