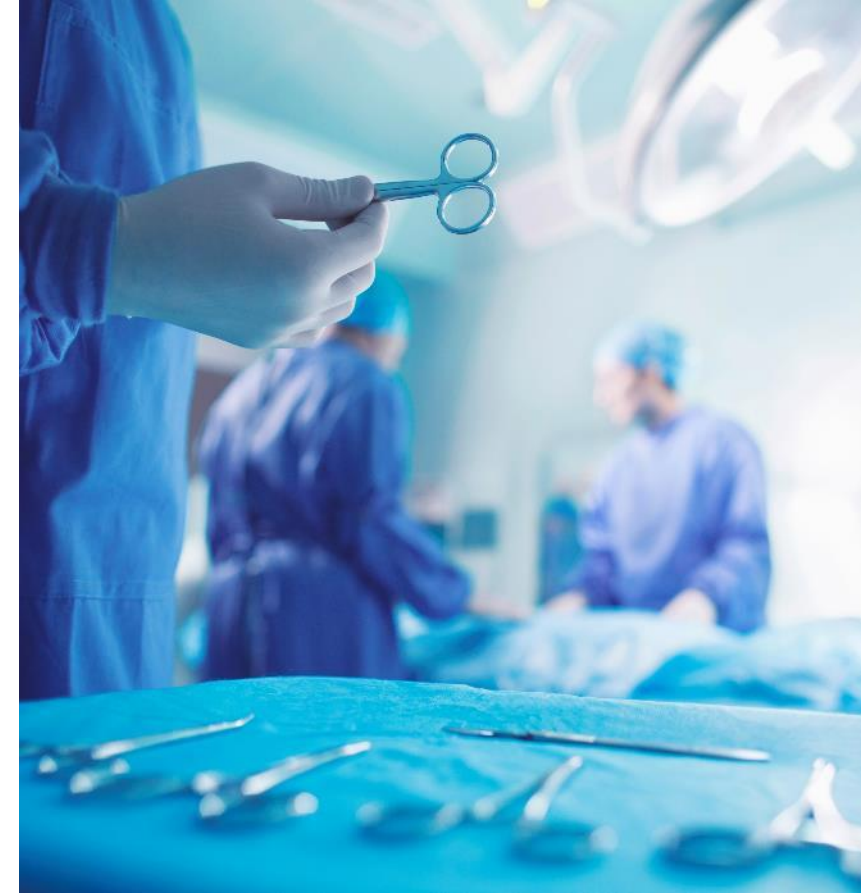


Engineers of Confidence.



Regulations, Standards, and Guidelines, Oh My!

A deeper look into regulatory agencies for the CSSD professional.

Randalyn Harreld,
Clinical Education Manager

Belimed
Infection Control

Today's Presenters



Randalyn Harreld

*National Clinical
Education Manager*



Educating the Sterile Processing Industry one topic at a time. I am Randalyn, I have joined the Belimed team in January 2022, working towards developing new innovative educational tools and resources that will help support the CSSD, and safe patient outcomes.

Session Objectives

- 1. Identifying Agencies & Organizations that are supporting us**
- 2. Recognizing what resources are available to use**
- 3. Standards, Regulations and Guidelines related to CSSD**
- 4. The most influential standards for our industry**
- 5. Regulations to abide by**
- 6. Building purposeful policies, procedures and incorporating the guidelines into your work**

Regulations, Standards, and Guidelines - Oh My!

And other useful resources to help guide you

- ✓ **Occupational Safety and Health Administration**
- ✓ **US Food and Drug Administration**
- ✓ **Environmental Protection Agency**
- ✓ **State and Local Licensure Agencies**
- ✓ **AAMI (ST79, ST92, TIR34)**
- ✓ **AORN (Peri-op Guidelines)**
- ✓ **CDC (Disinfection & Sterilization Guidelines)**
- ✓ **SGNA (Standards for Infection Control)**
- ✓ **APIC (Guidelines for Infection Control)**
- ✓ **WHO (Decontamination and reprocessing guidelines)**



Which are the most forceful?

Have the backing of Law and Legal Influences



Statute - a written law adopted by a legislative body that governs a city, county or state



Regulations - rules issued by administrative agencies that have the force of law



Regulatory Standard - a comparison benchmark that is mandated by a governing agency. Noncompliance may lead to citations and legal penalties

Which are the ones we “Should” follow?

Not forced by law, but highly recommended



Standard - A uniform method of defining basic parameters for processes, products, services or measurements



Voluntary Standard - Guidelines or recommendations to provide better patient care. Developed by industry, nonprofit organizations or associations.



Best Practices - A method or technique that has consistently shown results superior to those achieved by other means

The Food and Drug Administration

Regulatory Agencies

Classification

- Class I Device- low risk (handheld instruments)
- Class II Device- Sterilization Equipment, indicators
- Class III Device- Heart valves, pacemakers

Recalls & Reporting

- MedWatch program for reporting of device related problems
- Safe Medical Devices Act of 1990
- Management of single use devices and enforcements

IFU's

- Supporting reprocessing instructions, care & Handling
- Medical Device requirements, such as labeling and use
- 510(k) and Premarket approvals, and validations

The FDA Recall Process

Three Categories of the recall

Class I - High Risk

Reasonable chance it could cause serious health problems

Class II - Less Serious Risk

Possibility cause adverse problem, of remote chance of serious problems

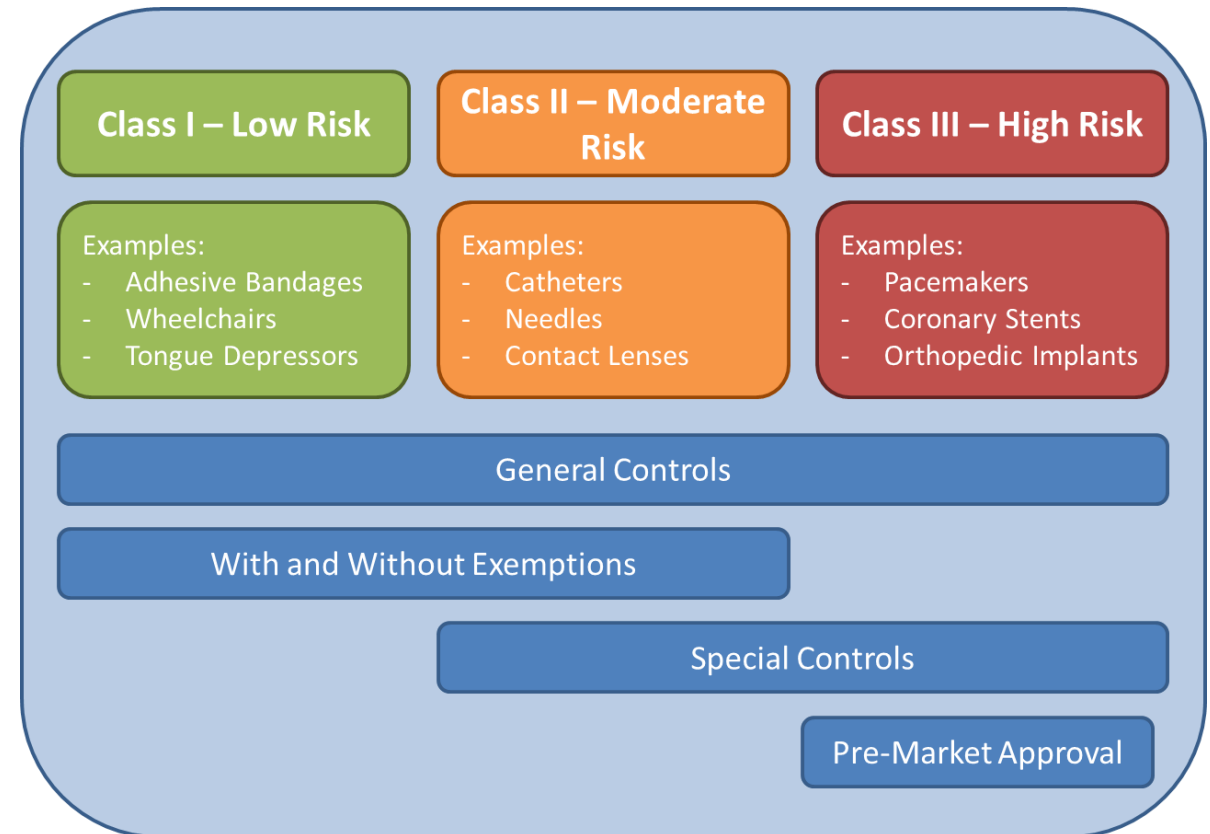
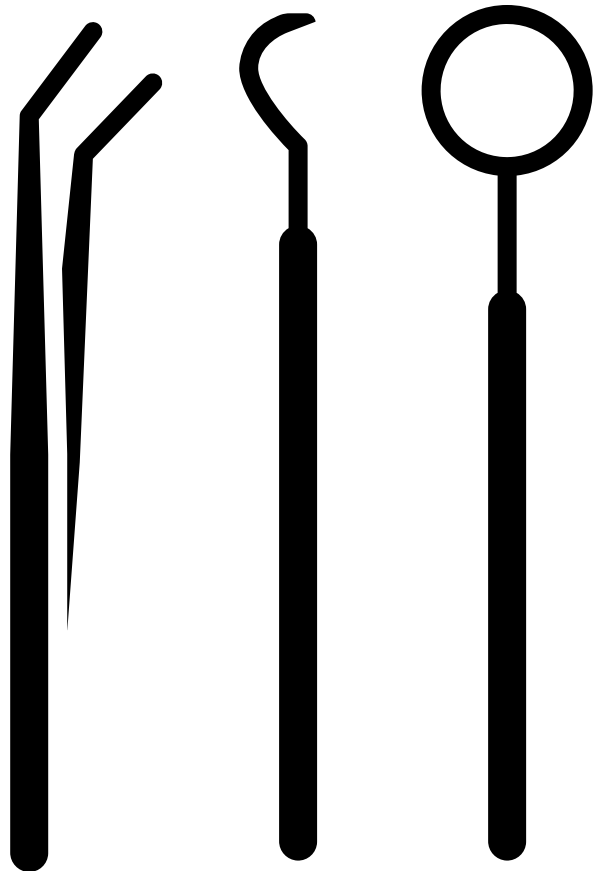
Class III - Low Risk

Not likely to cause adverse health problems or reactions



Pre and Post Market Requirements

Understanding the FDA's role



The Centers for Disease Control and Prevention

Regulatory Agencies

Guidelines

- Disinfection and Sterilization
- Isolation Technique
- Infection Control Guidelines

Department of Health

- Works to promote health and quality of life
- Responding to health emergencies

Disease Control

- Controlling disease
- Controlling disability
- Controlling injury and illness

The U.S Environmental Protection Agency

Regulatory Agencies

Regulations

- Minimizing Greenhouse gases
- Controlling toxic emissions
- Regulating the reuse of waste, air pollution, pesticides

Acts & Amendments

- Federal Insecticide, Fungicide and Rodenticide (FIFRA)
- 1990 Clean Air Act
- Ethylene oxide (EtO) Sterilant
- NESHAP, HCFC

Product Approval

- Antimicrobial Products
- Labeling management of products

Centers for Medicare and Medicaid Services

Regulatory Agencies

Standards

- Health Insurance Portability and Accountability Act (HIPAA)

Reimbursement

- HAI's monitoring and loss of funding
- Acquired list of infections for hospitals

Insurance

- Federal medical insurance program for those aged 65 or older
- Covered medical expenses for low income
- Children's health insurance program

Occupational Safety and Health Administration

Occupational Safety and Health Administration

Regulations

- Free from death, serious physical harm
- Whistle Blower Program
- Reduce high hazards targets

Guidelines & Standards

- Bloodborne Pathogens Exposure
- Ethylene Oxide Sterilization

Acts

- General Duty Clause of Safety and health
- Protecting workers, safety, labor injuries

Hazard Communication Standard

OSHA enacted the HCS- to protect employers and workers against chemical source injuries and illnesses by providing information to anticipate, recognize and control chemical hazards.



Professional Associations

Association for the Advancement of Medical Instrumentation (AAMI)

- I. **Standards from AAMI** - Voluntary guidelines representing a consensus of AAMI members that are intended for use by healthcare facilities to ensure that medical devices are safe for patient use and reprocessing properly
- II. **Technical Information Reports (TIR)** - Reports developed by experts in the field that contain valuable information
 - ✓ They have not undergone the formal approval system that standards are submitted
 - ✓ May require further evaluation and trial runs by experts
 - ✓ They can be revised or withdrawn at any time



Standards related to sterile processing

AAMI ST 79 Comprehensive Guide to Steam Sterilization

- ✓ Cleaning
- ✓ Disinfecting
- ✓ Packaging
- ✓ Indicators
- ✓ Product verification
- ✓ Education requirements
- ✓ Departmental workflow
- ✓ Departmental design
- ✓ Sterilization
- ✓ Safety, Hazards & Attire



ANSI / AAMI Library for CSSD professionals

- ✓ **ST 79** - *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities*
- ✓ **ST 91** - *flexible and semi rigid endoscope processing*
- ✓ **ST 58** - *Chemical sterilization and high-level disinfection*
- ✓ **ST 90** - *Processing health care products- quality management systems for processing in healthcare facilities*
- ✓ **ST 41** - *Ethylene oxide sterilization in healthcare facilities*
- ✓ **TIR 34** - *Water for reprocessing medical devices*
- ✓ **TIR 63** - *Management of loaned critical and semi critical medical devices that requires sterilization or high-level disinfection*
- ✓ **TIR 68** - *Low and intermediate level disinfection in healthcare settings for medical devices and patient care equipment and sterile processing environmental surfaces*
- ✓ **TIR 67** - *Promoting safe practices pertaining to the use of sterilant and disinfectant chemicals*



Professional Associations

American National Standards Institute

- I. **Enhance Global competitiveness** of the U.S business and America quality of life by promoting and facilitating voluntary standards
- II. **Represents the interests** of more than 125,000 companies and 3,500,000 individuals
 - ✓ Standards development
 - ✓ Standards review and approval
 - ✓ Sole representative to the ISO organization



Professional Associations

Association of perioperative Registered Nurses

- I. **Professional organization** consisting of nurses and others who provide optimal care to the surgical patient
- II. **Members and allied association members** who develop the nationally recognized, evidence-based standards and guidelines
 - ✓ Several Sections
 - ✓ Different topics for perioperative setting
 - ✓ Reprinted annually, and are on a five-year review cycle
 - ✓ Not regulatory but officials will look for compliance
 - ✓ Reprocessing guidelines are built within the topics



Perioperative AORN Guidelines

- ✓ Environmental Cleaning
- ✓ Hand Hygiene
- ✓ Flexible Endoscopes
- ✓ Instrument Cleaning
- ✓ Minimally Invasive Surgery
- ✓ Packaging Systems
- ✓ Product Evaluation
- ✓ Sharps Safety
- ✓ Sterile Technique
- ✓ Sterilization
- ✓ Surgical Attire
- ✓ Team Communication



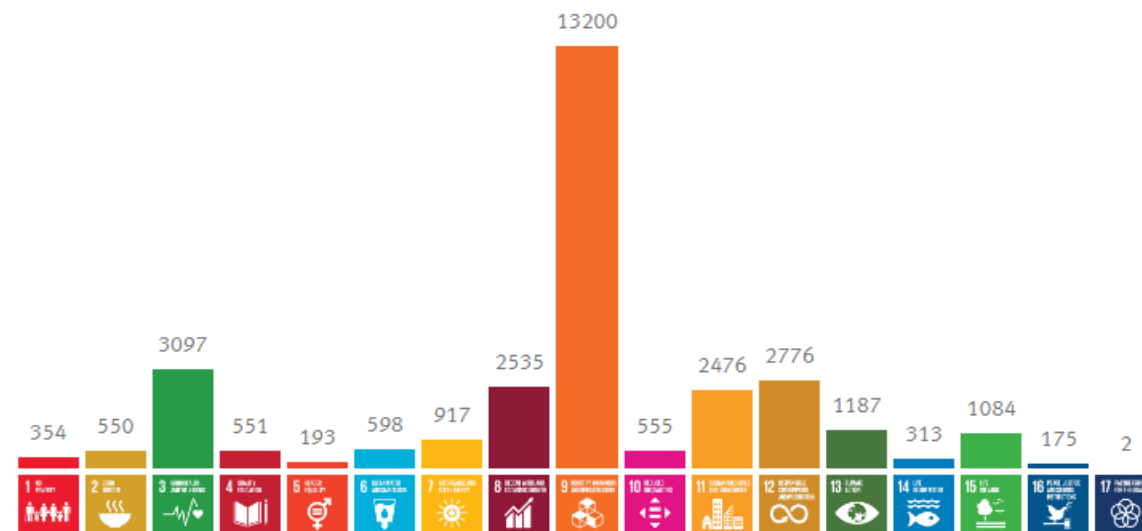
Professional Associations

International Standards Organization

- I. **Nongovernment organization** with a network of national standards institutes representing 163 countries
- II. **International standards** give state of the art specifications for products
 - ✓ Standards are voluntary and the organization has no legal enforcement of authority
 - ✓ ISO standards have been adopted by some countries into jurisdictions and legislation
 - ✓ Survey is like CMS and ISO is more focused on results



Here you can see the number of ISO standards that apply to each Goal.



Professional Associations

The Joint Commission

- I. **Private, independent and nonprofit organization** that develops standards for healthcare facilities
- II. **Evaluate the organization and programs** in the U.S by conducting onsite surveys as least every 3 years
 - ✓ Unannounced visits
 - ✓ Accredited facilities are recognized
 - ✓ Loss of accreditation is when failure to comply with standards
 - ✓ May result in forfeiture of dollars



How can accreditation help your organization

National Recognition

Insurance Company Recognition

Improvement in customer satisfaction ratings

Continuous Quality improvement efforts

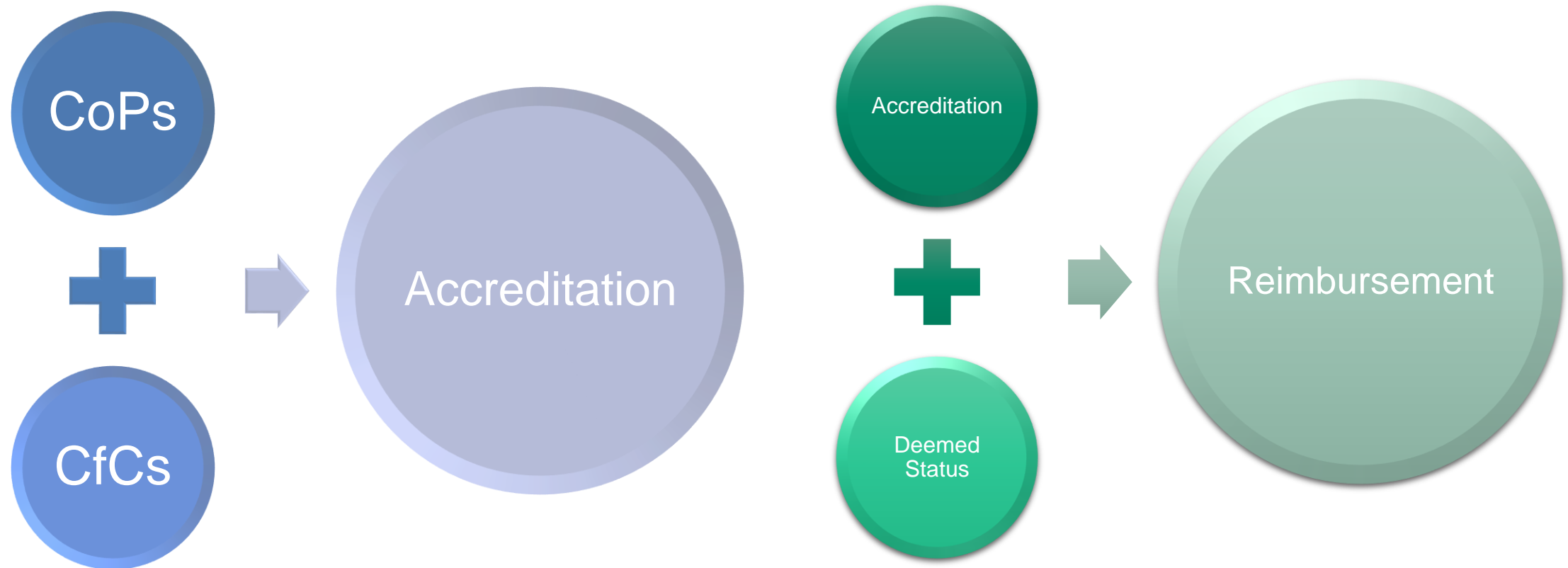
Improved Risk Management and Risk Reduction

Fulfillment of State regulatory requirements

Reduce Liability insurance costs

First, why are they here?

What does the accreditation survey really do?



The purpose of the survey process is to validate compliance of the work you are doing everyday.

State Regulatory Agencies

Here are the most common examples;

DHS

- Department of Health Services

DOT

- Department of Transportation

OSHA

- 26 states maintain OSHA offices

The Instructions for Use

The Manufacturer's Responsibility

- Supporting the claim of reuse with adequate labeling
- Ensuring the labeling has sufficient instructions on how to prepare the device for the next patient
- The validation of tests
- The documentation of tests
- Instructions are adequate and can be reasonably executed

The Users Responsibility

- Confirming they have the facilities and equipment to execute the instructions
- The verification of manufacturer's instructions and ensuring they are followed

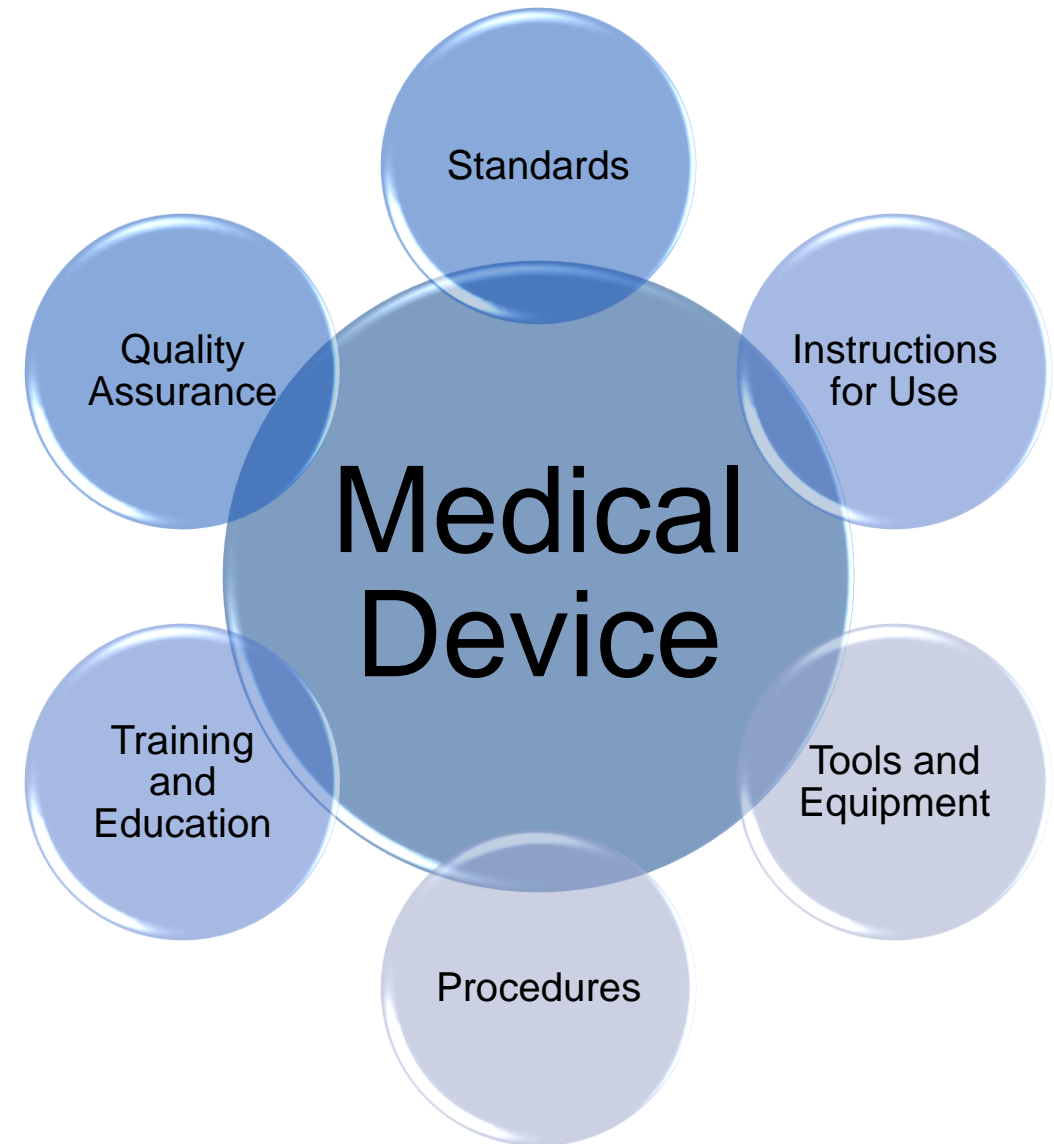


Can sterile processing process everything?



Best Practices for SPD

- ✓ Using recognized best practices makes it easier to justify the work
 - ✓ Using recognized best practices can bolster the credibility of an organization
 - ✓ Can make it easier to get funding
- ✓ Removes a lot of the guess work from planning
- ✓ Most Important and obvious, we know that best practices work
 - ✓ Using an existing method or program that's been tested and found to be successful saves a lot of the work along the way



Policies, Procedures and Protocols



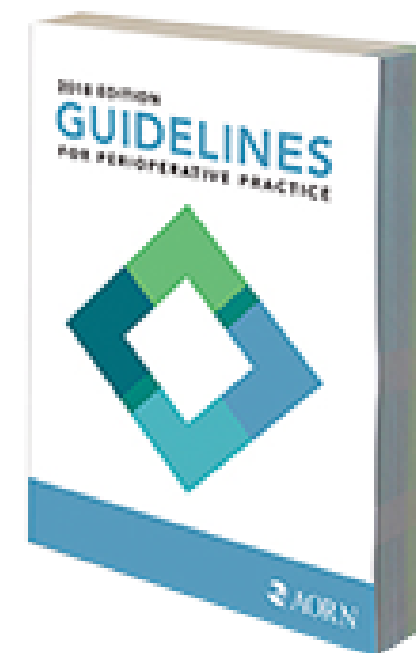


Do you feel
comfortable today
in reading and
using AAMI
Standards?

*Do you know if
your department
has policies and if
so, how many?*



Resources



Questions?

Continuous Educational Credit

- ✓ You will be provided with a certificate of completion that is approved for credit.
- ✓ All certificates will be provided to the email address used at registration.
- ✓ Please allow for up to 5 business days to receive your certificate.
- ✓ Credit is approved for 2 years



Contact

Belimed Inc. is a leading supplier of medical and surgical instrument sterilization, disinfection, and cleaning products and services.

With 10 Belimed companies throughout Europe, North America and China, Belimed is represented worldwide by a strong network in over 80 countries.

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