

# Challenges in the US Approach to Disinfection and Sterilization

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# Objectives

- Discuss the challenges of communication between instrument manufacturers and end users (specifically orthopedic instruments)
- Review the controversy surrounding “flash” sterilization
- Identify challenges to providing education, certification and recommended practice standards to healthcare facilities

# The Challenge of Loaner Instrumentation



# The Current System

- Medical devices designed with little or no consideration for cleaning, disinfection and sterilization
- Although required, cleaning and sterilization instructions are often not provided
- Many instrument sets require extended sterilization time

# What We Did At Anderson Hospital

- Established policies/procedures regarding loaner instrumentation
- Met with vendors to explain our expectations
- Improved communication between CSSD and Surgery by huddling and having a “go to” staff member

# What is IAHCSSMM Doing?

- IAHCSSMM established an *Orthopedic Council*
  - Members include CSSD professionals, container manufacturers, orthopedic instrumentation manufacturers, sterilization testing facilities, orthopedic surgeon, educators

# Council Goals

- Develop a collaboration between IAHCSSM, Association for the Advancement of Medical Instrumentation (AAMI) and Orthopedic Specialty Manufacturer's Association (OSMA)
- Provide education to OSMA members
- Collaboratively develop standards regarding packaging and sterilization of loaner instrumentation

# The Challenge of “Flash” Sterilization



# What is “Flash” Sterilization?

- Performed in the OR for JIT delivery of instruments
- No dry time added to cycle
- Challenges
  - Improper cleaning of instruments
  - Improper cycle selection
  - Aseptic delivery to sterile field

# The Joint Commission Position

- Updated position paper presented  
15 June 2009
  - Identified “issues” with the process such as terminology used to describe the process, the choice of the proper cycle for item(s) sterilized and lack of proper cleaning, C/Is and aseptic transport to the sterile field
  - Cleaning and decontamination, sterilization and storage or return to the field were identified as the **Three Critical Steps of Reprocessing**

# Current Practice

- Joint Commission surveys of CSSD are surveyor dependant and inconsistent
- Inconsistent adherence to Best Practice Standards from hospital to hospital
- These practices make the process of “flash” sterilization inconsistent

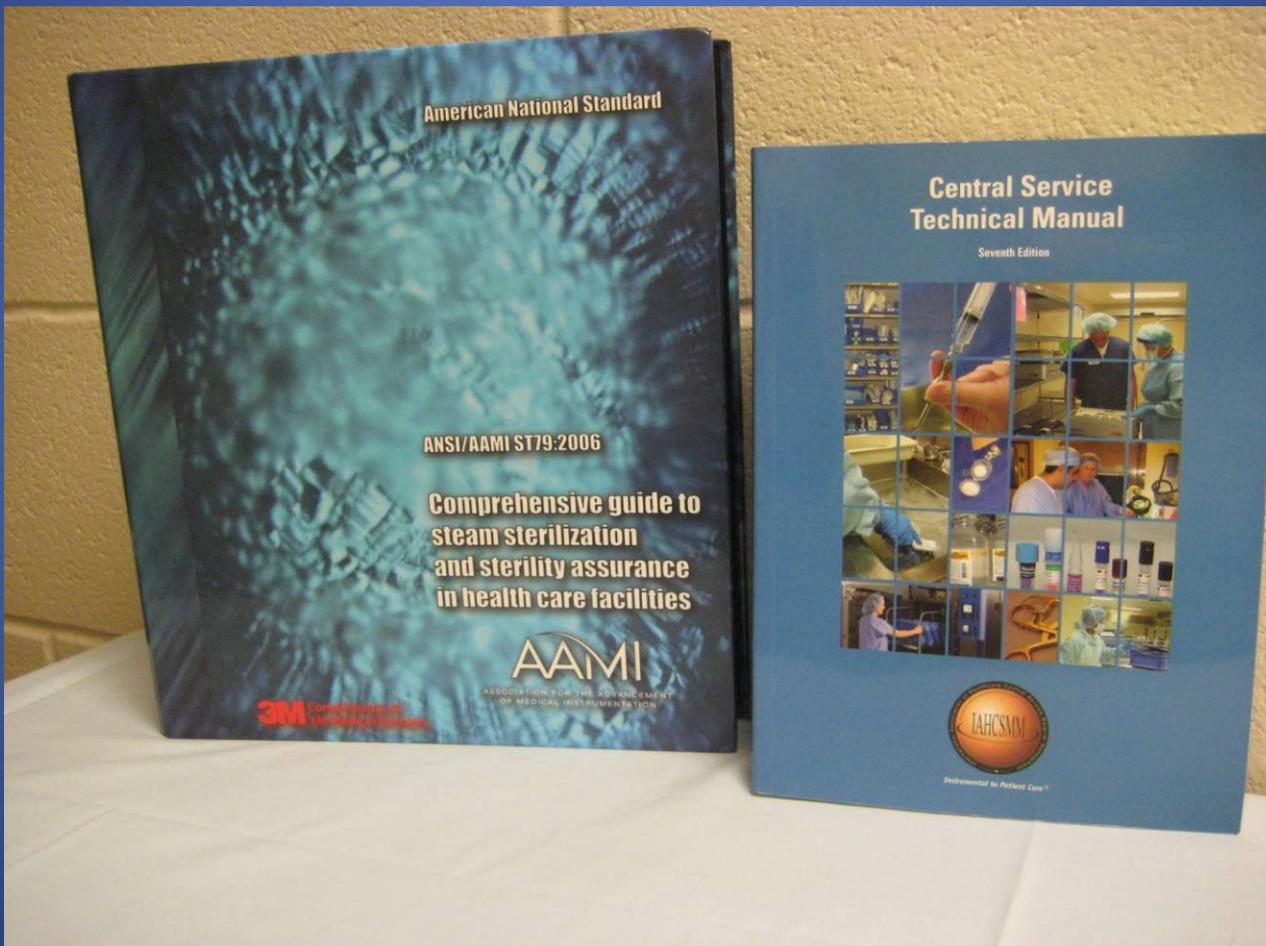
# Summit on the sterilization process formerly known as “Flash”

- Associations and Agencies represented
  - Association of Perioperative Registered Nurses
  - The Joint Commission
  - American Dental Association
  - Centers for Medicare and Medicaid Services
  - US Food and Drug Administration
  - Association for the Advancement of Medical Instrumentation
  - Centers for Disease Control and Prevention
  - Others...

# Points agreed upon...

- Cycles with no dry time can be effective
- Adequate cleaning, decontamination and rinsing are critical
- Aseptic transfer is critical
- Device manufacturer's written instructions must be followed
- Personnel involved in reprocessing must be adequately educated and trained

# Challenges to providing Education and Certification in CSSD



# Current Status

- New Jersey is the only US state that requires certification for CSSD technicians or that CSSD follows best practice standards
- Actively seeking Mandatory Certification legislation in New York, Ohio, California, Arizona, others...
- Adherence to best practice standards is “voluntary”

# What is AAMI

- The Association for the Advancement of Medical Instrumentation
- Founded in 1967
- 6000+ members – clinical & biomedical engineers and technicians, researchers, manufacturers, physicians, RNs, educators, CSSD professionals, other healthcare professionals

# Why do we need AAMI?

- Recommended Practice implies a consensus of those substantially concerned with its scope and provisions
- It is not the law – it is the standard of practice that “should” be followed in the US
- The standards are recommendations for optimum performance levels in the reprocessing of reusable medical devices in a healthcare setting

# How should the AAMI Standards be used?

- They should be used as the basis for establishing policies and procedures in CSSD
- They are used to answer questions regarding cleaning, decontamination, sterilization, transport and storage, etc.

# AAMI Standards for Everyone!

- All IAHCSSMM educational materials based on AAMI standards
- IAHCSSMM provides AAMI education at meetings, in Communiqué, etc.
- AAMI Standards available at ½ price to IAHCSSMM members
- AAMI Webinar series provided information to CSSD professionals

# Summary

- Under the leadership of the professional association, challenges are being identified and addressed
- Change is slow but sure
- Patient safety remains the primary focus

# References

- AAMI ST79:2009
- The Joint Commission
- Central Service Technical Manual, 7<sup>th</sup> ed.

Thank you