

-
-
-
-
-
-
-
-
-

Central Sterile Reprocessing



The U.S.A. Perspective

Jacqueline Daley HBSC, MLT, CIC, CSPDS
Director Infection Prevention and Control
Sinai Hospital of Baltimore

July 25, 2008

-
-
-

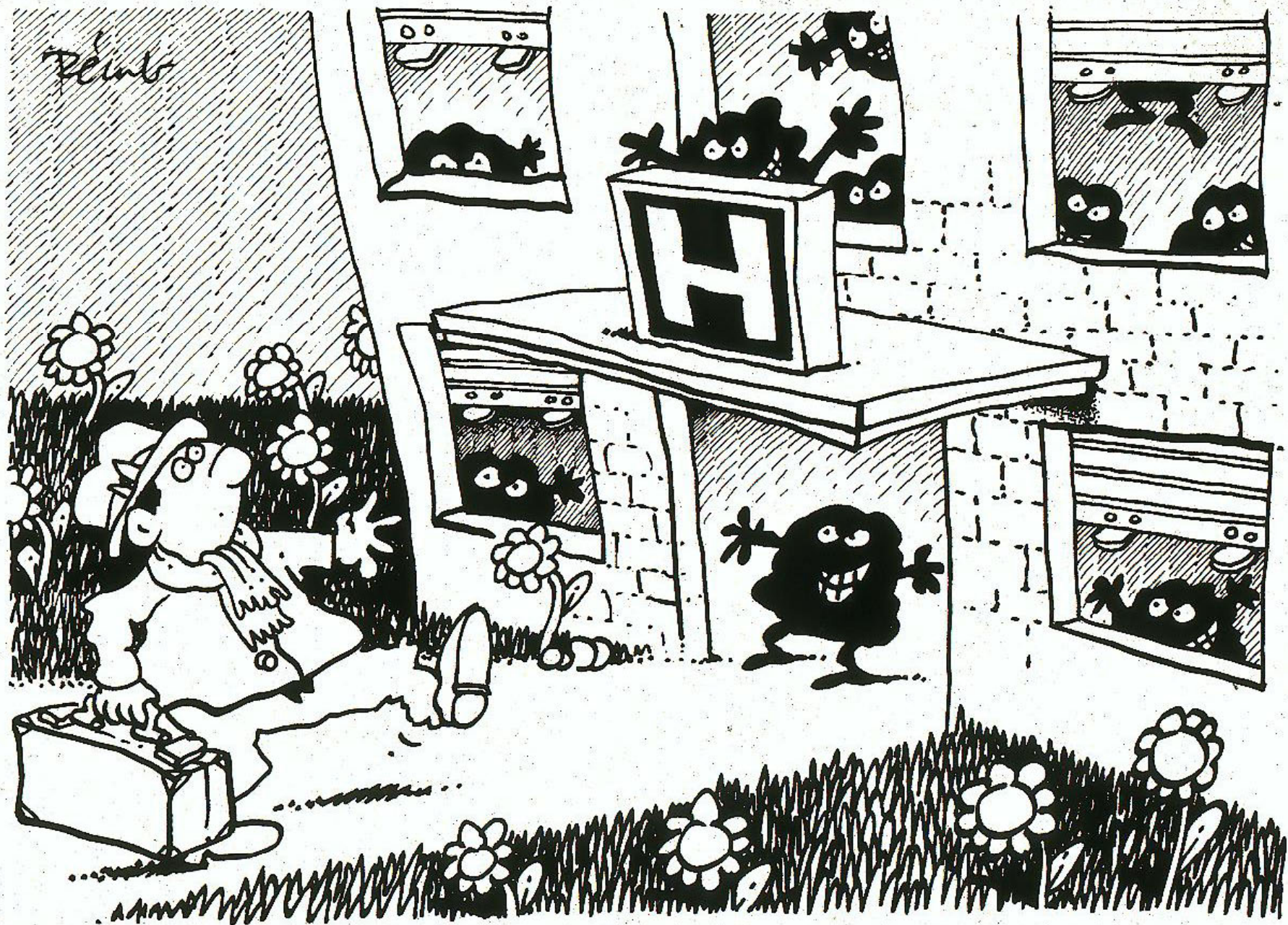
Sinai Hospital of Baltimore



•
•
•

Objectives

- Describe the central sterile department in the United States
- List the organizations that influence the Central Sterile Department
- List requirements for the Central Sterile Professional
- Identify requirements to be addressed in policies and procedures



-
-
-



-
-
-

Central Sterile Department

- Referred to as CSSD, CSPD, CSD, SPD, CPD, CSRD
- Major role in the prevention of healthcare-associated infections (HAIs)
 - improperly reprocessed reusable medical devices, increases the risk for infections
- Reprocessing activities are centralized to
 - increase efficiency of operation,
 - be more economical and
 - to maintain high quality, controlled standards

-
-
-

Central Sterile Department

- Primary Function
 - cleaning, preparing, processing, storing, and distributing medical and surgical supplies and equipment both sterile and non-sterile required for diagnosis of disease and treatment and care of patients

•
•
•

Central Sterile Department

- Reporting structure
 - Operating Room
 - Infection Prevention and Control
 - Materials Management
- Committee Participation
 - Operating Room Committee
 - Infection Prevention and Control Committee
 - Performance Improvement Committee
 - Product Evaluation Committee

•
•
•



Certification

- Certification Board for Sterile Processing and Distribution (CBSPD)
- International Association of Healthcare Central Service Materiel Management (IAHCSMM)
- Certification is mandatory in one state since 2004 and other states are looking at mandating certification
- Recommended by AAMI and supported by AORN

•
•
•

Levels of Certification

- CBSPD - Six levels of certification
 - *Technician, Surgical Instrument Processor, Flexible Endoscope Reprocessor, Ambulatory Surgery Technician, Supervisor, and Manager*
- IAHCMM
 - Certified Central Service Technician (CRST)
 - Certified Instrument Specialist (CIS)
 - Certification in Healthcare Leadership (CHL)
 - Certification in Materials Management Concepts (CHMMC)
 - Fellowship in Central Services (FCS)

•
•
•

Certification Eligibility

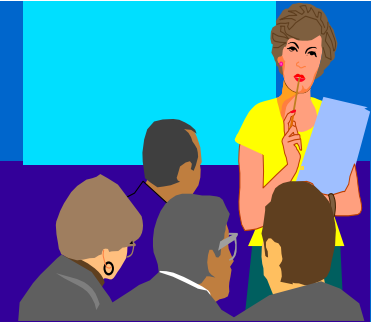
- Relevant experience
 - full-time employment or equivalent part-time hours performing SPD activities
- Successful completion of a Central Service/SPD Training Course with a passing grade

•
•
•

Certification is proof ...

- Competence in all aspects of central sterile processes and materials management
- Achievement of a minimum level of knowledge and skills
- Professionalism and commitment to personal development
- Accountability for the sterile processing and distribution of instrumentation and equipment
- Commitment to patient safety to ensure a safe and effective level of practice
- Eligibility for financial recognition

Education is a must ...



- Supervisors
 - Competent qualified persons with experience and education
 - Certification a must through CBSPD or IAHCSMM
 - Demonstrate current knowledge and adequate relevant experience in hospital related work
 - Participate in continuing education courses
 - Demonstrate knowledge of state and federal regulations
 - Participate in education programs
 - Expertise by participating in committees in the healthcare facility

Education is a must ...



- Sterile Processing Personnel (CRCST)
 - Qualified for the job with demonstrated and ongoing competency
 - Initial and on the job education and training
 - Continuing education to ensure current knowledge with changing practices and new technologies
 - AAMI recommendation that all personnel performing sterile processing activities be certified as a condition of employment
 - Determines initial competency if present on employment
 - Documentation and continuing education required by the Joint commission

•
•
•

Regulatory Agencies

- Occupational Safety and Health Administration (OSHA)
- Center for Medicare Medicaid (CMS)
- Food and Drug Administration (FDA)
- Center for Disease Control and Prevention (CDC)
- Environmental Protection Agency (EPA)
- Department of Transportation (DOT)

•
•
•

Professional Organizations

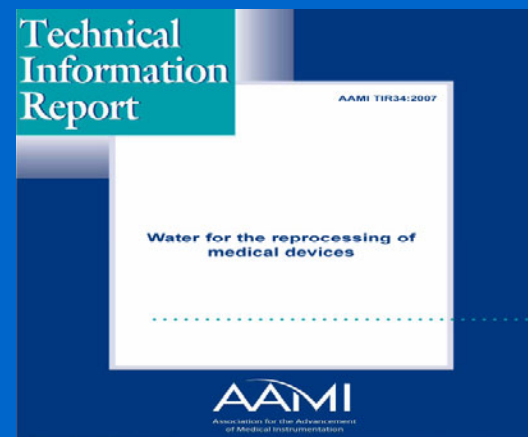
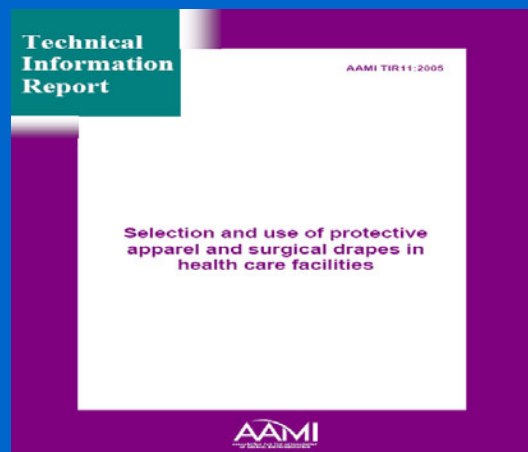
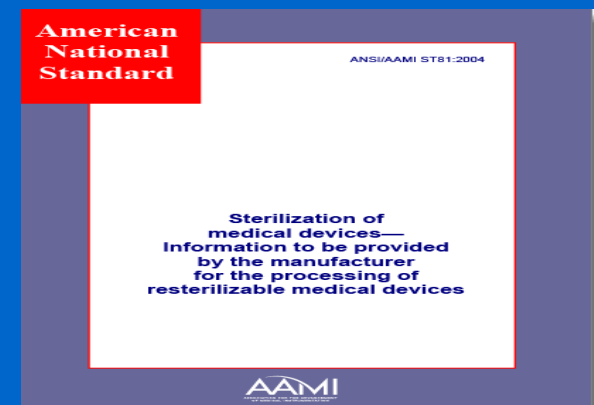
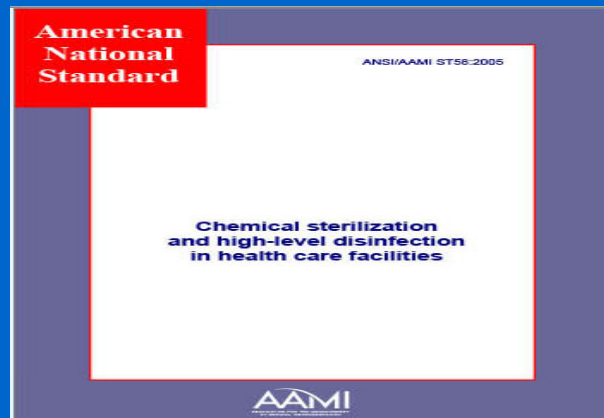
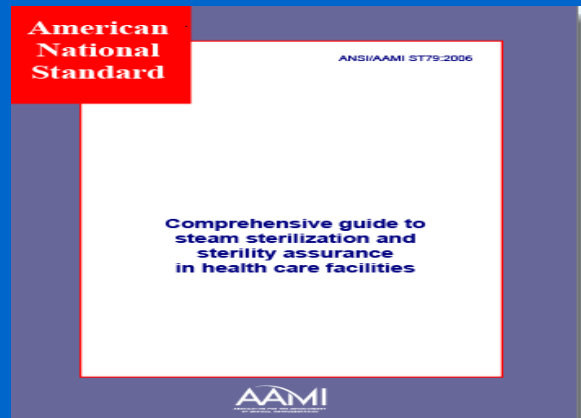
- Association of periOperative Registered Nurses (AORN)
- American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI)
- Associations for Professionals in Infection Control and Epidemiology (APIC)
- International Organization for Standardization (ISO)
- The Joint Commission
- National Fire Protection Association (NFPA)
- Society of Gastroenterology Nurses and Associates (SGNA)

•
•
•

Rule Makers

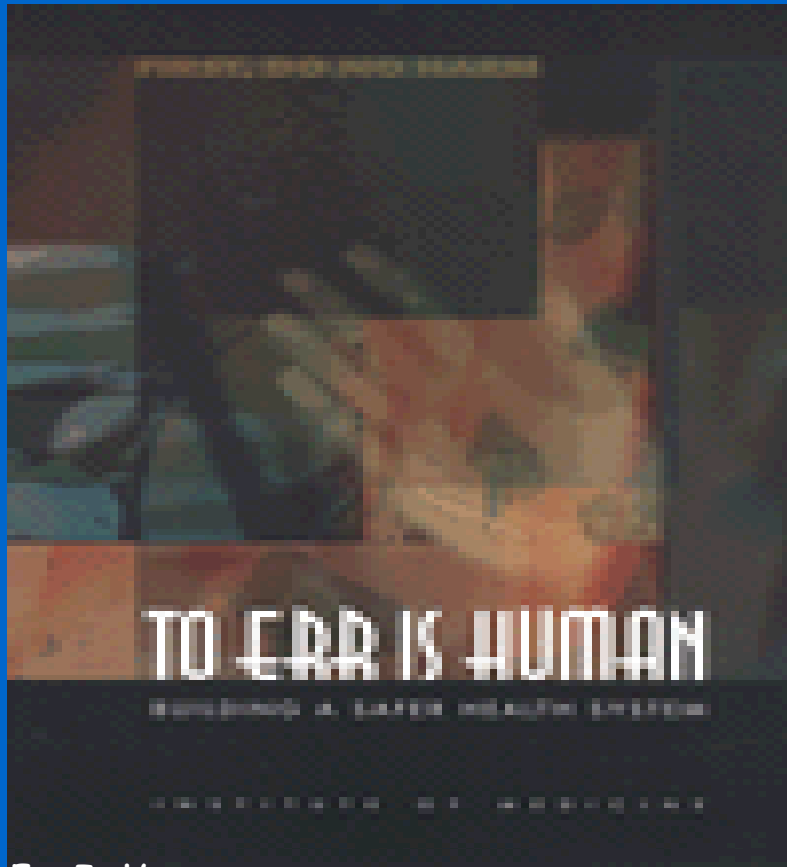
- OSHA Regulations – 29 CFR 1910.1030
 - Bloodborne Pathogens (BBP) Standard
- Environmental Protection Agency (EPA)
 - 40 CFR Part 63 National Emission Standards for Hospital Ethylene Oxide – Final Rule
 - Emissions standards for new and existing hospital sterilizers that emit hazardous air pollutants and are sources of within the meaning of Clean Air Act section

AAMI Standards

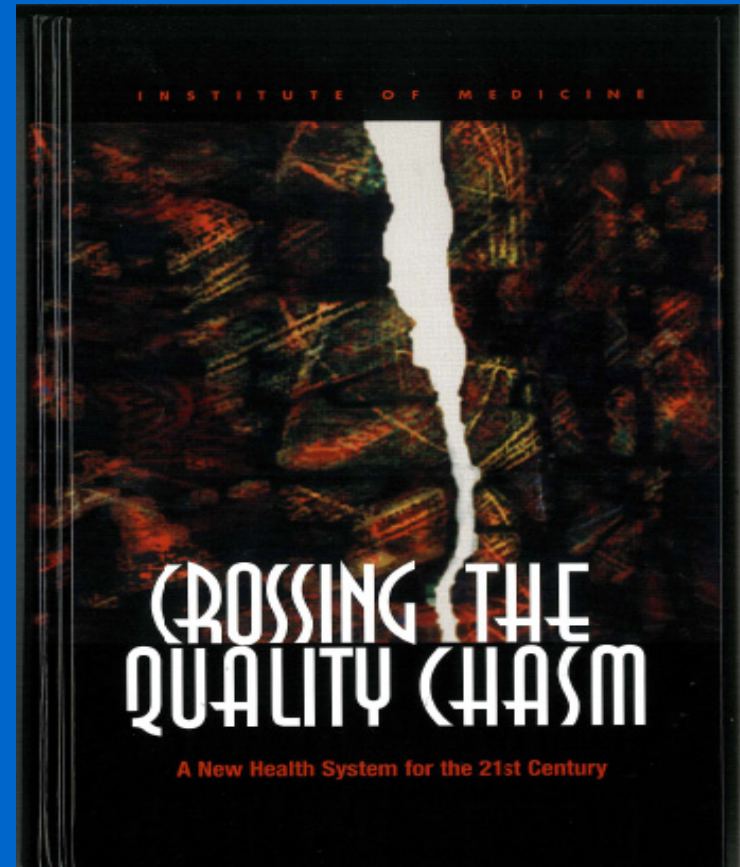


-
-
-

Institute of Medicine (IOM) Reports



To Err Is Human
Building a Safer Health System
Published November 1999



Crossing the Quality Chasm, 2001

•
•
•

Joint Commission

- Unannounced Survey
- Tracer Methodology
- Sentinel Events
- Patient Safety Goals
- Policies and procedures should be based on the most stringent:
 - Accepted practice guidelines
 - Laws and regulations
 - Current scientific knowledge
 - Consistent throughout the health care facility

2008 Joint Commission National Patient Safety Goals

- Reduce the risk of health care-associated infections.
 - Compliance with hand hygiene guidelines
 - Report sentinel events
- Future Phase In - January 1, 2010
 - MDRO (MRSA, VRE, ESBL, and C. diff)
 - Central Line-Associated Bloodstream Infection (CLABSI)
 - Best practices to prevent surgical site infections

•
•
•

Critical Focus Areas

Patient assessment

Communication

Credentialing

Equipment use

Infection control

Information
management

Medication use

Organizational structure

*Staff orientation and
training*

Rights and ethics

Physical environment

*Quality improvement
expertise and
activities*

Safety engineering

Staffing

-
-
-

- Copyright 2008 – Association for Professionals in Infection Control and Epidemiology, Inc.
Please contact communications@apic.org for preprint permission and update requests.
Last updated 6/4/2008

Centers for Medicare-Medicaid (CMS)

- Final Rule-October 1, 2008
- Never, Never Event List - 8 conditions
 - Catheter-associated UTI's,
 - selected surgical site infections, e.g. Mediastinitis,
 - Decubitus Ulcers,
 - Vascular Catheter associated infections,
 - Objects left in surgery,
 - Air Embolism,
 - Blood Incompatibility
 - Falls and trauma

•
•
•

Keys to Department Function

- Collaboration with Infection Prevention and Control, Operating Room and Risk Management/Performance Improvement
- Team work and mutual respect
- Implement evidenced-based best practices
- Open honest communication encouraged



-
-
-
-
-
-
-
-
-
-

Policies and Procedures



If you write... you must follow!

•
•
•

Spaulding Classification

- **Critical Items** - enters sterile tissue or the vascular space
 - sterilization recommended - implants, surgical instruments, etc.
- **Semi-critical Items** - come into contact with mucous membranes or non-intact skin
 - high-level disinfection (e.g. glutaraldehyde, orthophthalaldehyde-OPA - flexible endoscopes, laryngoscope, endotracheal tube)
- **Non-critical** - items touch intact skin
 - intermediate/low-level disinfection (disinfectant with tuberculocidal claim - quats,) - stethoscopes, BP cuffs

•
•
•

Policies and Procedures

- Written policies and procedures are required for all aspects of reprocessing, storage and distribution
 - specifies methods for monitoring disinfection and sterilization to ensure continued sterility of both hospital sterilized and commercially prepared sterile items

-
-
-

Policies and Procedures

- Personnel Qualification
- Education and training/competency evaluation with timelines
- Minimum criteria for personnel health including reporting of exposures, hygiene and attire - clearly defined and practical
- Workflow including traffic patterns/restriction - to prevent cross-contamination
- Handling and transportation of contaminated waste

-
-
-

Policies and Procedures

- Environment - HVAC/humidity/temperature
- Decontamination including difficult to clean devices
- Single use devices
- Packaging and wrapping
- Sterilization procedures/monitoring/process failures/recall
- Verification of sterilization processes with new products/packaging
- Instrument weight/loaner instrumentation
- Record Keeping

•
•
•

Department Design

- Four separate functional areas
 - soiled receiving and decontamination
 - preparation and packaging (Prep 'n Pack)
 - Sterilization
 - Sterile supply storage

-
-
-

Processes

- Manual and mechanical cleaning
- chemical disinfection processes
 - high-level disinfection
 - intermediate-level disinfection
 - low-level disinfection
 - follow manufacturers instructions

⋮
Do not take shortcuts!!



What are you doing to save time?

-
-
-

Manual Cleaning



Ultrasonic Cleaner



Washer-Disinfector



-
-
-
-
-
-
-
-

•
•
•

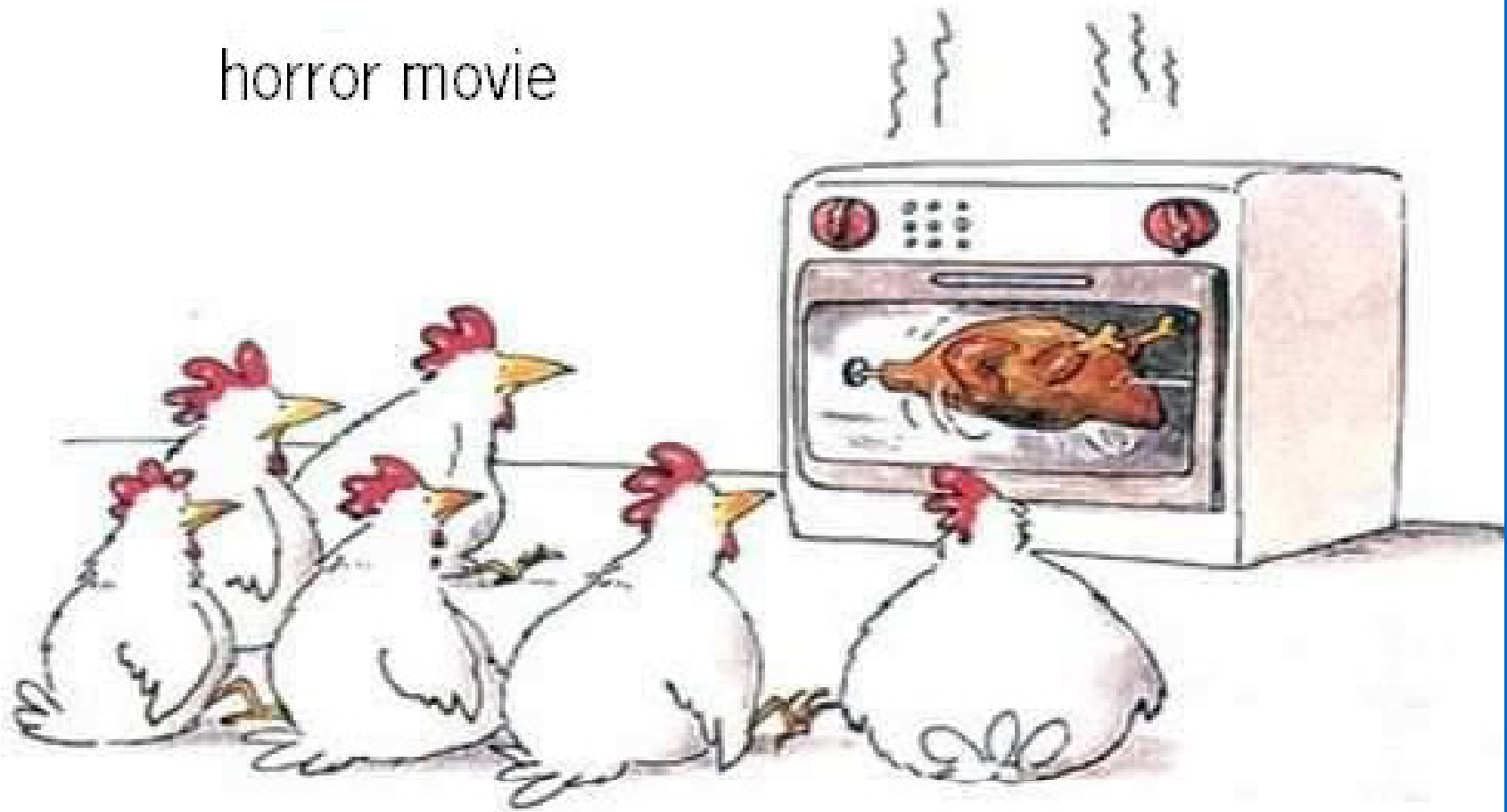
Assembly and Packaging



- Disposable wraps
- Peel pouches
- Container systems
- Open trays
- weight of container and contents cannot exceed 25 pounds (11.36 kilos)

Sterilization

horror movie



Sterilizer Types

- Dry Heat Sterilizers
- Moist Heat (Steam) Sterilizers
 - Gravity-displacement
 - Flash
 - Dynamic-air-removal
 - Vacuum assisted or steam-flush-pressure-pulse
- Low Temperature Sterilizers
 - Ethylene Oxide (EO)
 - Vaporized hydrogen peroxide gas plasma
 - Ozone
 - Liquid Peracetic acid



•
•
•

Ensure Process Monitoring

- Verify that parameters for sterilization has been met
- Physical Monitoring
 - printouts, graphs, gauges for immediate sterilizer failure
 - record cycle parameters - time/temperature
- Chemical/Biological Monitoring
 - monitors sterilizer efficacy

•
•
•

Tools of the trade

- Physical monitors
 - gauges, printouts
 - Review and initial each cycle
 - Document
- Chemical
 - Class 1, 2, 3, 4, 5 and 6
- Biological indicators (BI's)
 - enzyme-based early readout or rapid action biological monitoring device or indicator
 - products utilizing spore outgrowth

-
-
-

Documentation

- Record Keeping
 - Computerized or electronic record keeping systems are an asset to accuracy
 - kept for preventive maintenance of the sterilizers and performance verification
 - Allows for recall and tracking of sterilized supplies

Exception Form for Early Release - ANSI/AAMI ST79:2006

Exception Form for Premature Release of Implantable Device/Tray

NOTE—In a documented emergency situation, implantable devices will be released from quarantine in Central Service without the biological monitor result. This form should accompany the implant to the Operating Room. Operating Room personnel should complete this form and return it to Central Service within 24 hours.

PLEASE COMPLETE ALL INFORMATION:

DATE: _____ SHIFT: _____ TIME: _____ AM PM

PERSON COMPLETING THIS REPORT IN CENTRAL SERVICE: _____

The following implantable devices/trays were prematurely released to the Operating Room:

NAME OF OR PERSON REQUESTING PREMATURE RELEASE OF DEVICES:

OPERATING ROOM REPORT:

PATIENT NAME: _____

SURGEON NAME: _____

TIME OF PROCEDURE: _____ AM PM DATE: _____

REASON PREMATURE RELEASE WAS NEEDED: _____

WHAT COULD HAVE PREVENTED PREMATURE RELEASE OF THIS DEVICE? TRAY? _____

NAME OF OR PERSON COMPLETING THIS REPORT: _____

DATE REPORT COMPLETED: _____ FORM RETURNED TO CENTRAL SERVICE ON: _____

Figure L.2—Exception form for premature release of implantable device/tray

-
-
-

Challenges ...

- New technologies/minimally invasive surgery
- Device construction and complexity and cleaning issues
- Extended sterilization cycles
- Inventory issues/Instrument shortages
 - Loaner instrumentation
- Time pressures/constraints
 - Surgical through-put/turnaround time
- Various manufacturer's instructions/processing requirements

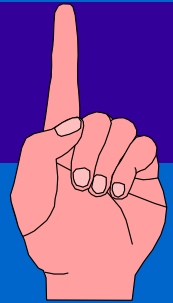
-
-
-

Challenges ...

- Outsourcing of services
- Bioterrorism/Emergency Preparedness
- Shortages of qualified staff/aging workforce
- Employee satisfaction
 - Salaries
 - Certification
- Budget Management - costs reduction/labor costs
 - Temporary workers
- Packaging requirements/limitations
- Improving patient Safety is in the spotlight
- Construction and renovation of central sterile and OR

•
•
•

Quality is Priority #1



- Processes - efficiency
- Service - avoid delays, customer service focus
- Products - sterile and in good working conditions
- Work Life - continuing education; maintaining health

•
•
•

Best Practices Encouraged ...

- Written continuous quality improvement program
- Do not flash sterilize implants
- Document when done in an emergency
 - implant exception form
- Biological monitoring of every load with an implant
- Event related shelf life
- Creating and focusing on development of a culture of safety
- Open and honest communication
- Sterile processing is a part of the surgical team

•
•
•

It Start's with Central Sterile!

- Engage staff of their role in patient safety
- Move from punitive culture to an open and collaborative one
 - move from policing to coaching
 - move from buy-in to ownership
- Be vigilant; Be prepared
- Hire motivated and educated staff

•
•
•

It Start's with Central Sterile!

- Do not just get staff to do their work, but to do their best
- Address barriers to cooperation and collaboration
- Job shadowing, mentoring, education and open communication
- Follow recommended practices and guidelines

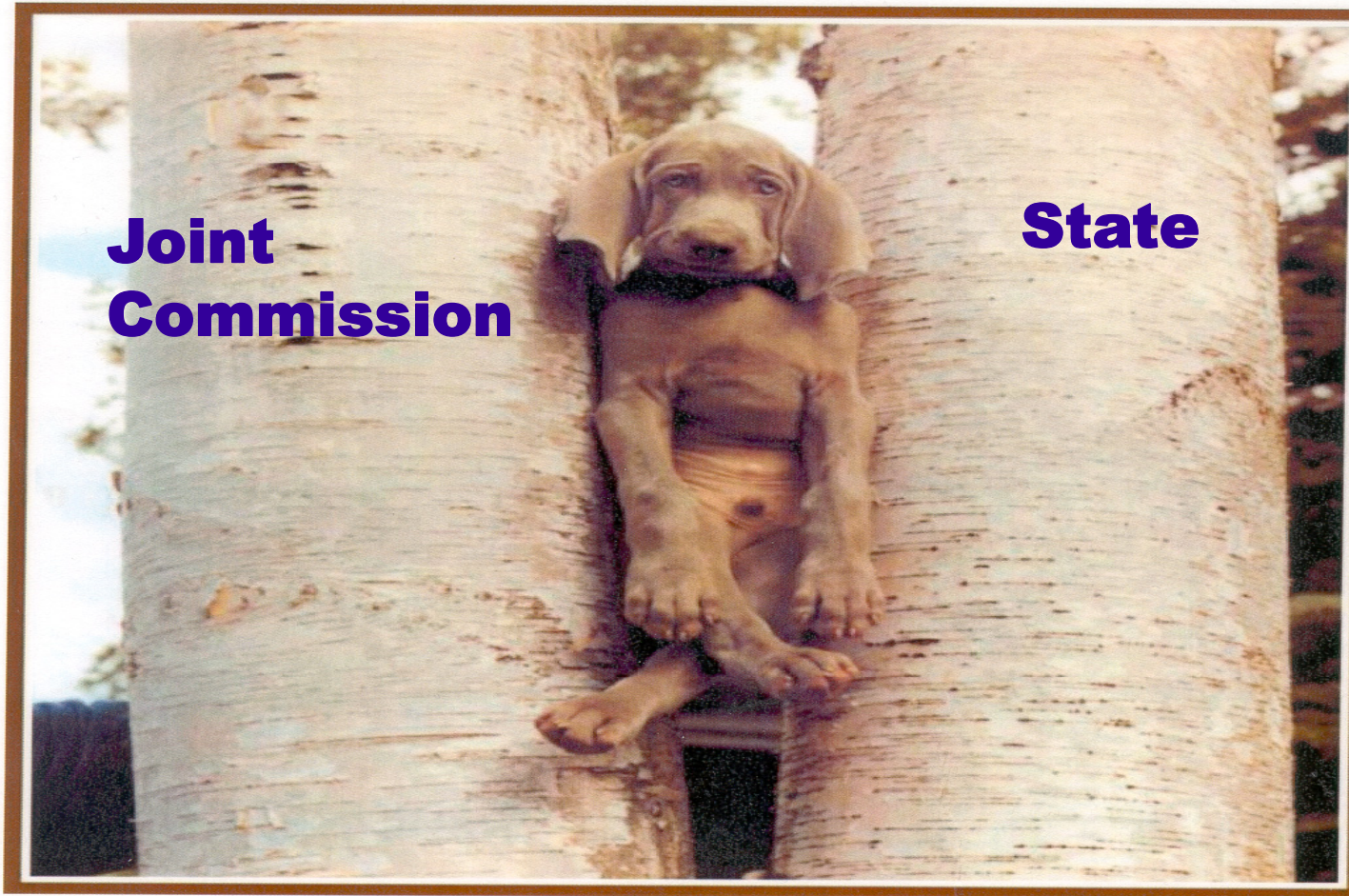
-
-
-

“Knowing is not enough; we must
apply. Willing is not enough; we
must do.”

- Goethe

**Joint
Commission**

State



Some days we just get stuck, and bogged down.
Some days all you can do is smile and wait for someone to kindly
remove your butt from the hole you find it wedged into.

-
-
-

Resources

- The Joint Commission - www.jointcommission.org
- International Association of Healthcare Central Service Materiel Management (IAHCSMM) - www.iahcsmm.com
- Association for periOperative Registered Nurses
www.aorn.org
- Association for the Advancement of Medical Instrumentation
- www.aami.com
- Center for Disease Control and Prevention - www.cdc.gov
- Occupational Health and Safety Administration -
www.osha.gov
- Food and Drug Administration - www.fda.gov
- Certification Board for Sterile Processing and Distribution (CBSPD) - www.sterileprocessing.org
- Environmental Protection Agency - www.epa.gov

-
-
-

References

- Pugliese, Gina and Hubbard, Cynthia A. Central Services, Linens and Laundry. Hospital Infections 4th ed. Edited by John V. Bennett and Philip S. Brachman, 1998, pages 325-3321
- ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- Occupational Safety and Health Administration. Occupational exposure to blood-borne pathogens. Code of Federal Regulations, Title 29, 1910.1030
- Association of periOperative Registered Nurses. PeriOperative Standards and Recommended Practices 2008 ed.
- Environmental Protection Agency 40 CFR Part 63 National Emission Standards for Hospital Ethylene Oxide Sterilizers. Federal Register Vol. 72, No. 248, December 28, 2007/Rules and Regulations