Leading the Way to Zero™
Through Infection Prevention

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Field Surveyor, The Joint Commission

Spring 2019

The Joint Commission

Conflict of Interest Disclosure

The speaker is an employee of The Joint Commission.

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Committing to Zero Patient Harm

- Make a personal commitment
- Establish a culture of safety and collaboration
- Deploy highly effective process improvement models

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Approach to IC Related Standards

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- Regulation
- Conditions of Participation (if deemed)
- Manufacturer Instructions
- Evidence based standards or guidelines
- Consensus documents or position statements
- Incorporate into facility based risk assessment and policy

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Program Specific State Operations Manual

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Medicare State Operations Manual

Appendix

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. **Click on the corresponding letter in the "Appendix Letter" column to see any available file in PDF.**
- To return to this page after opening a PDF file on your desktop use the browser "back" button. This is because closing the file usually will also close most browsers

Appendix Letter	Description
A	Hospitals
AA	Psychiatric Hospitals
B	Home Health Agencies
C	Laboratories and Laboratory Services
D	Portable X-Ray Service
E	Outpatient Physical Therapy or Speech PathologyServices-Interpretive Guidelines
F	Physical Therapists in Independent Practice - **Deleted**
G	Rural Health Clinics (RHCs)

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Program Specific
State Operations Manual

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State Operations Manual
Appendix A - Survey Protocol,
Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev. 176, 12-29-17)

§482.42 Condition of Participation: Infection Control

Infection Control is integrated throughout- do not limit search to one section

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How Do Joint Commission Standards Tie into CMS Standards E-dition: IC.02.02.01

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Nbr	Elements of Performance (EPs)	CMS
1	The hospital implements infection prevention and control activities when doing the following: Cleaning and performing low-level disinfection of medical equipment, devices, and supplies. * Note: Low-level disinfection is used for items such as stethoscopes and blood glucose meters. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions. Footnote *: For further information regarding cleaning and performing low-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html.	§482.42 §482.51 §482.51(b)...
2	The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. * (See also EC.02.04.03, EP 4) Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes. Footnote *: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention	§482.42 §482.51 §482.51(b)...

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Blue Links in E-dition Tie to CMS TAGs and CoPs

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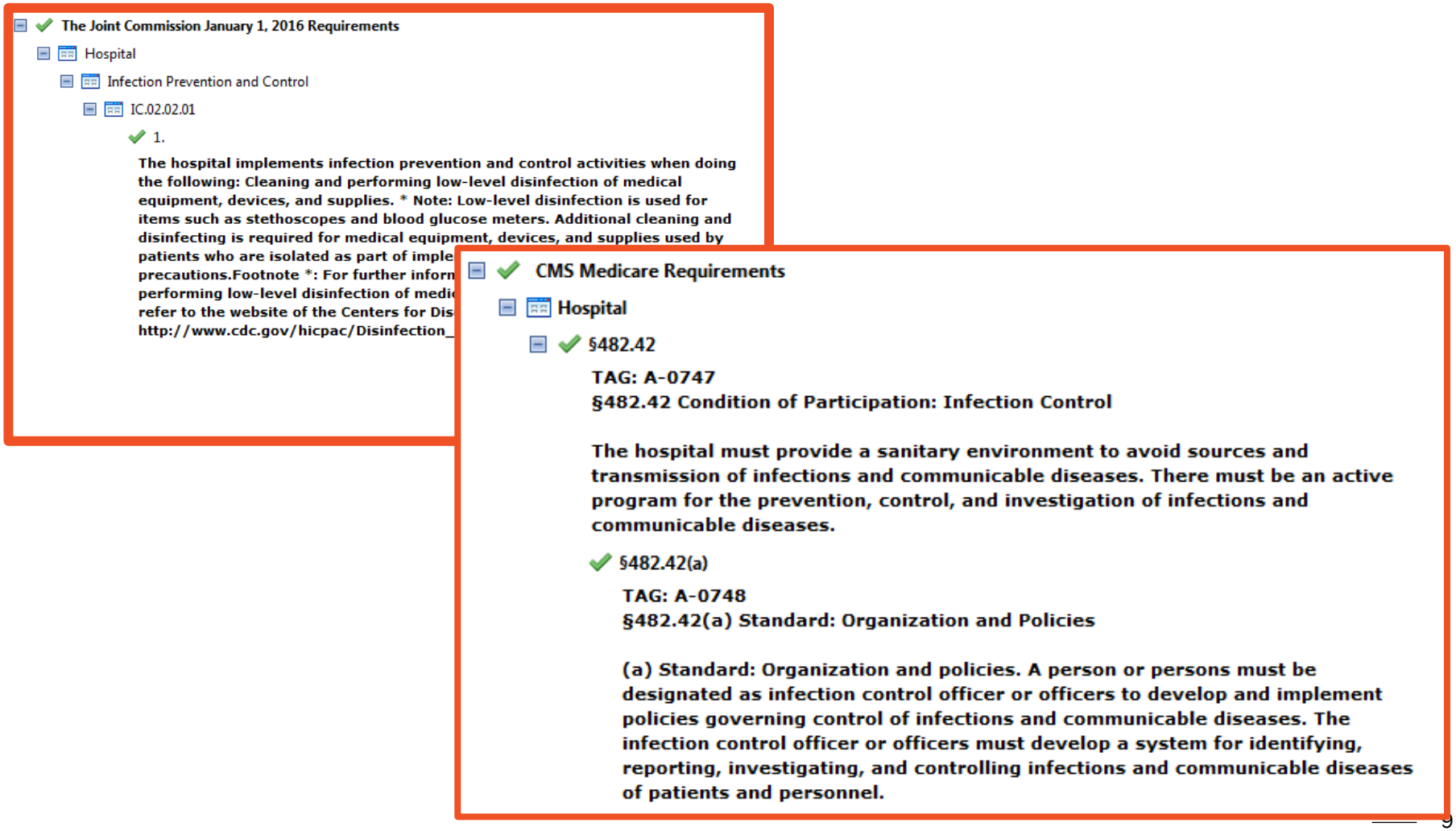

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Crosswalk Between CMS CoPs and Joint Commission Standards

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Hospital Crosswalk

Medicare Hospital Requirements to 2018 Joint Commission Hospital Standards & EPs

CFR Number	Medicare Requirements	Joint Commission Equivalent Number	Joint Commission Standards and Elements of Performance
§482.42	TAG: A-0747	EC.02.05.01	The hospital manages risks associated with its utility systems.
§482.42 Condition of Participation: Infection Control The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.		EP 14	The hospital minimizes pathogenic biological agents in cooling towers, domestic hot- and cold-water systems, and other aerosolizing water systems.
		EP 15	In areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, and filtration efficiencies. (See also EC.02.06.01, EP 13)

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Manufacturer Instructions

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- Organization must know how the item will be used
- Staff must have access to instructions
- When conflicts are identified, organization must resolve
  - Contact equipment manufacturer
  - Contact product manufacturer(s)
  - If organization still cannot resolve issue, recommend contacting FDA Division of Industry and Consumer Education (DICE) at 800 638 2041 or DICE@fda.hhs.gov

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Manufacturer Instructions

- Medical Device Manufacturers
  - experts on their own devices
  - responsible for validating the specific cleaning, disinfection and sterilization methods
- Biologic compatibility does not mean a disinfectant or process is chemically or functionally compatible

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Manufacturer Instruction

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May need to seek guidance from evidence based guideline when directed by manufacturer or if no guidance provided

Recommended Steam Sterilization Monitoring Program

Physical monitors (temperature and pressure measuring devices) can be used to help detect failures in sterilizer function. The sterilizer notifies the user if sterilization conditions fall outside of established limits. It is recommended that the Printer Accessory be used to create a record of each load's actual cycle time, temperature, and pressure.

Process monitors, such as biological indicators and chemical indicators, should be included in each sterilization cycle. The process monitors detect whether the cycle parameters were delivered. Process monitors cannot establish that a processed item is actually sterile. If the monitors detect a failure, the user must determine the source of the failure. Failures could result from improper packaging, loading, or sterilizer malfunction. Follow the process monitor manufacturer's instructions for proper selection, storage, use, and interpretation of their devices.

Follow the appropriate agency (state dental or medical board) for sterilization monitoring guidelines for your office. Additional information can also be obtained from CDC, AAMI, OSAP, and ADA regarding monitoring programs or other sterilization issues.

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Evidence Based Guidelines and National Standards (EBG)

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Evidence Based Guidelines and National Standards (EBG)

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- Facilities must use evidence based guidelines and standards (EBG) when developing infection prevention and control activities (IC.01.05.01)

- Facilities should be able to articulate the source of their IC practices if they are based on multiple EBG, for example a facility might choose:
  - AORN for dress code and aseptic practices in the OR
  - AAMI for reprocessing of sterile instruments and endoscopes
  - CDC for isolation practices in oncology clinics

- EBG should be available (IC.01.02.01 EP 1)

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Evidence Based Guidelines and National Standards (EBG)

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Your Choice Guides Your Practices

AMMI (ST91 2015) states

10 Storage of reprocessed endoscopes

10.1 General Considerations

The endoscope should be hung vertically with the distal tip hanging freely in a well-ventilated, clean area, following the endoscope manufacturer's written IFU for storage…Store endoscopes in a manner that will protect them from damage or contamination…Special storage cupboards or cabinets…are commercially available…Regardless of whether a special cabinet is used, the temperature and humidity in the area where the scopes are stored should be monitored.

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Evidence Based Guidelines and National Standards (EBG)

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Your Choice Guides Your Practices

AORN (Effective February 1, 2016) Guideline for Processing Flexible Endoscopes states

IX. Flexible endoscopes and endoscope accessories should be stored in a manner that minimizes contamination and protects the device or item from damage

IX.b. Flexible endoscopes should be stored in accordance with the endoscope and storage cabinet manufacturers' IFU.

IX.b.1. Flexible endoscopes should be stored in a drying cabinet

IX.b.2. If a drying cabinet is not available, flexible endoscopes may be stored in a closed cabinet with HEPA-filtered air that provides positive pressure and allows air circulation around the flexible endoscopes.

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Evidence Based Guidelines and National Standards (EBG)

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- Some EBGs are required by regulation or Joint Commission standards
  - Transmission based precautions
  - Standard Precautions
  - Hand Hygiene

- Chosen EBGs cannot be less strict than regulation, CoPs, or IFUs

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CDC Core Practices

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Standard Precautions

- Hand hygiene
- Environmental cleaning and disinfection
- Injection and medication safety
- Appropriate use of personal protective equipment
- Minimizing potential exposures
- Reprocessing of reusable medical equipment between each patient and when soiled

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Consensus and Position Statements

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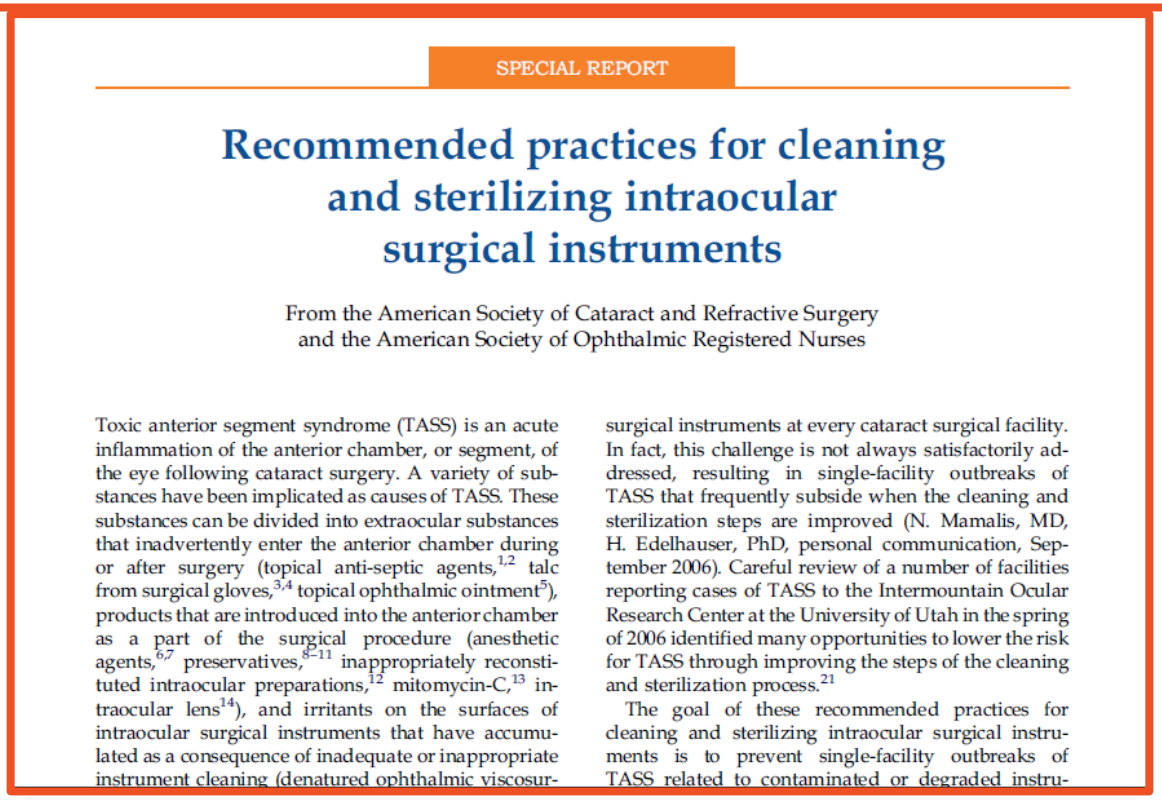
Recommendations for Ophthalmic Surgery Centers

Ophthalmic surgery centers under the purview of the Joint Commission should be familiar with the Position Statement on Steam Sterilization as well as the Centers for Disease Control/Hospital Infection Control Practices Advisory Committee Guideline for Disinfection and Sterilization in Healthcare Facilities.



SPECIAL REPORT

Recommended practices for cleaning and sterilizing intraocular surgical instruments

From the American Society of Cataract and Refractive Surgery and the American Society of Ophthalmic Registered Nurses

Toxic anterior segment syndrome (TASS) is an acute inflammation of the anterior chamber, or segment, of the eye following cataract surgery. A variety of substances have been implicated as causes of TASS. These substances can be divided into extraocular substances that inadvertently enter the anterior chamber during or after surgery (topical anti-septic agents,[1,2] talc from surgical gloves,[3,4] topical ophthalmic ointment[5]), products that are introduced into the anterior chamber as a part of the surgical procedure (anesthetic agents,[6,7] preservatives,[8–11] inappropriately reconstituted intraocular preparations,[12] mitomycin-C,[13] intraocular lens[14]), and irritants on the surfaces of intraocular surgical instruments that have accumulated as a consequence of inadequate or inappropriate instrument cleaning (denatured ophthalmic viscosur-

surgical instruments at every cataract surgical facility. In fact, this challenge is not always satisfactorily addressed, resulting in single-facility outbreaks of TASS that frequently subside when the cleaning and sterilization steps are improved (N. Mamalis, MD, H. Edelhauser, PhD, personal communication, September 2006). Careful review of a number of facilities reporting cases of TASS to the Intermountain Ocular Research Center at the University of Utah in the spring of 2006 identified many opportunities to lower the risk for TASS through improving the steps of the cleaning and sterilization process.[21]

The goal of these recommended practices for cleaning and sterilizing intraocular surgical instruments is to prevent single-facility outbreaks of TASS related to contaminated or degraded instru-

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Facility Policy and Procedure

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- Facilities should use the recommended approach to develop IC related policies and procedures
- Care should be taken to address the unique aspects of the organization
  - Care settings
  - Equipment, products and supplies
  - Physical space
  - Staffing
  - Facilities in multiple states

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Facility Based Risk Assessment

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There are somethings that cannot be “risk-assessed.” Do NOT write a policy that conflicts with

- Regulations
- CoPs– look at interpretive guidelines or seek clarification from CMS (HospitalSCG@cms.hhs.gov)
- Manufacturer instructions for use – must resolve conflicts

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Impact of Facility Policies on Survey

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Facility Policy: Care at Point of Use

All instruments should have bioburden removed at point of use and should be sprayed with an enzymatic detergent. Enzymatic detergent A should be reapplied to maintain moisture as needed.

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Implementing IC Plan

- Take care that policies use the standard approach and are realistic
- Take the time to resolve conflicts and issues
- Involve staff in the process of developing policies

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Problem Areas

- Disinfection and Sterilization
- WaterManagement Programs
- MoldPrevention (e.g.maintiningbarriersduringmaintenance, renovation orconstruction)
- Medication compounding
- Food safety and sanitation
- Hand Hygiene
  - Not providing hand sanitizer, soap or lotion
  - Use of artificial fingernails
- Care of dialysis patients
- Aseptic technique

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Separate Functions & Processes

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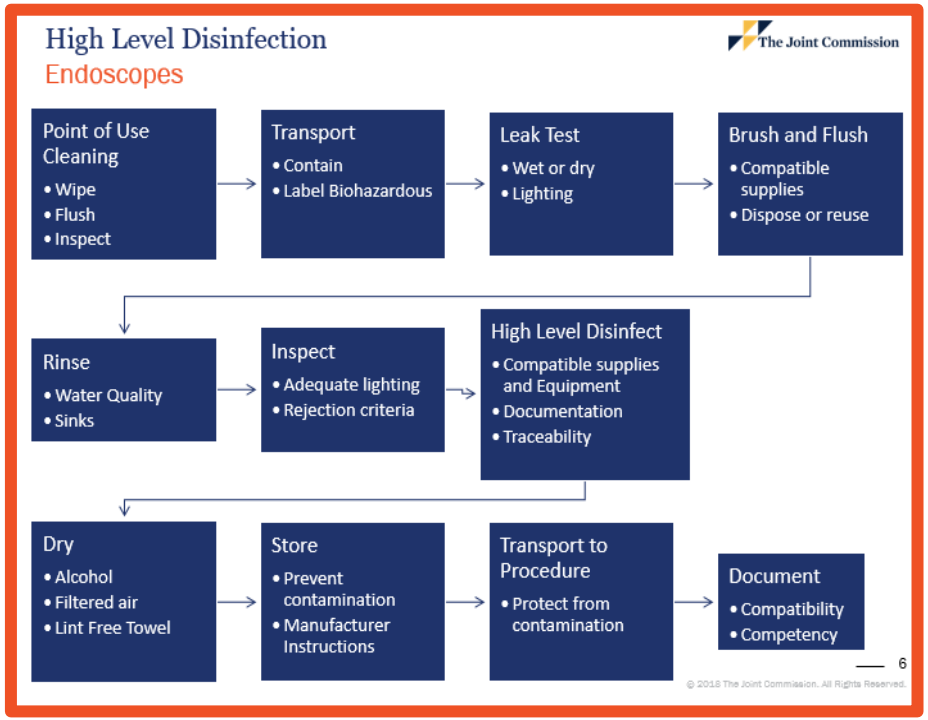
Sterilization

High Level Disinfection



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Key Risks for Sterilization Failure

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- Sterilant cannot reach all surfaces
  - Disassembly, cleaning and decontamination process
  - Inspection and packaging
  - Correct sterilization cycle
- Failure of the cleaning and sterilizing equipment
  - User error
  - Monitoring
  - Maintenance

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Key Risks for Sterilization Failure

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- Non-Sterile Product Availability
  - Load release
    - Verification of exposure to process
  - Prior to Use of Item
    - Verification of exposure to the process and package integrity

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High Level Disinfection

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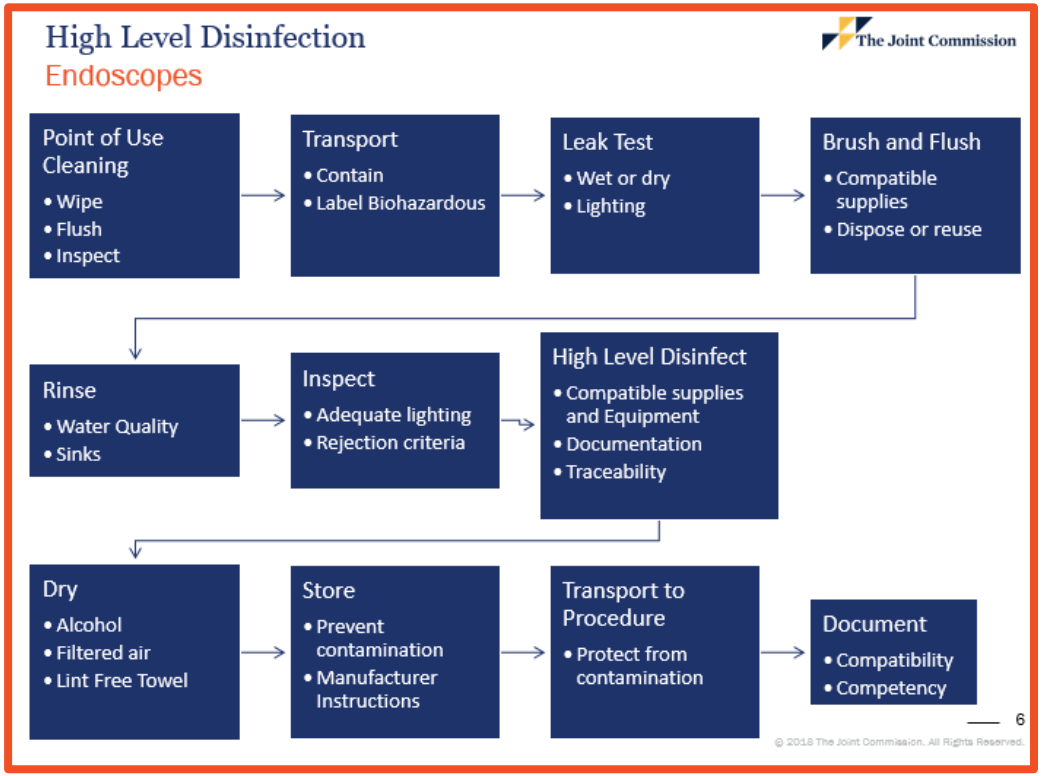
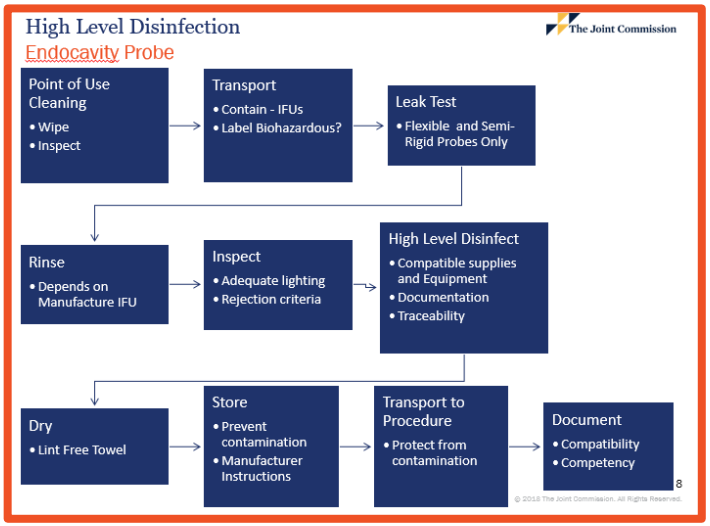
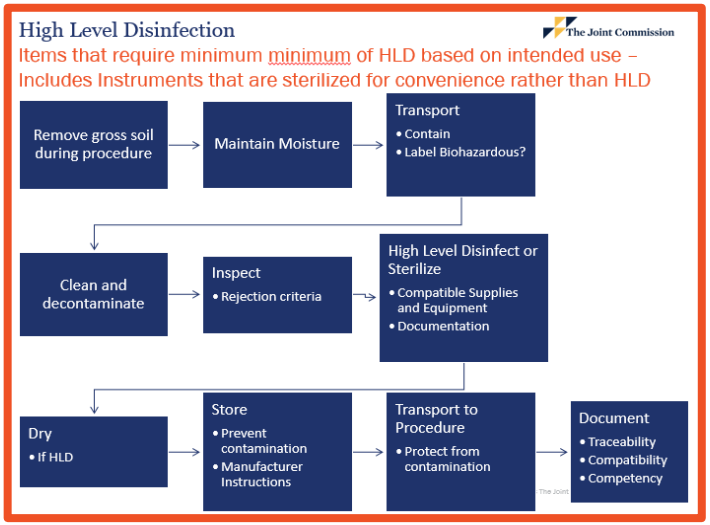
- Level of risk associated with complexity of equipment







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Key Risks for High Level Disinfection Failure

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Not following manufacturer's instructions for use

- Improper or inadequate pre-cleaning/ cleaning procedures
- Inappropriate use or choice of detergent or disinfectant
- Lack of inspection/ quality control
- Use of a untreated or contaminated water supply
- Failure to completely dry channels
- Lack of routine maintenance

Flaws in the mechanical design

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Training and Competency

- Hands on versus oversight
- Knowledge and skills to perform job
- Facility defines competency and frequency
  - Regulations, EBGs, IFUs

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Provide Resources to Make it Easier for Your Employee

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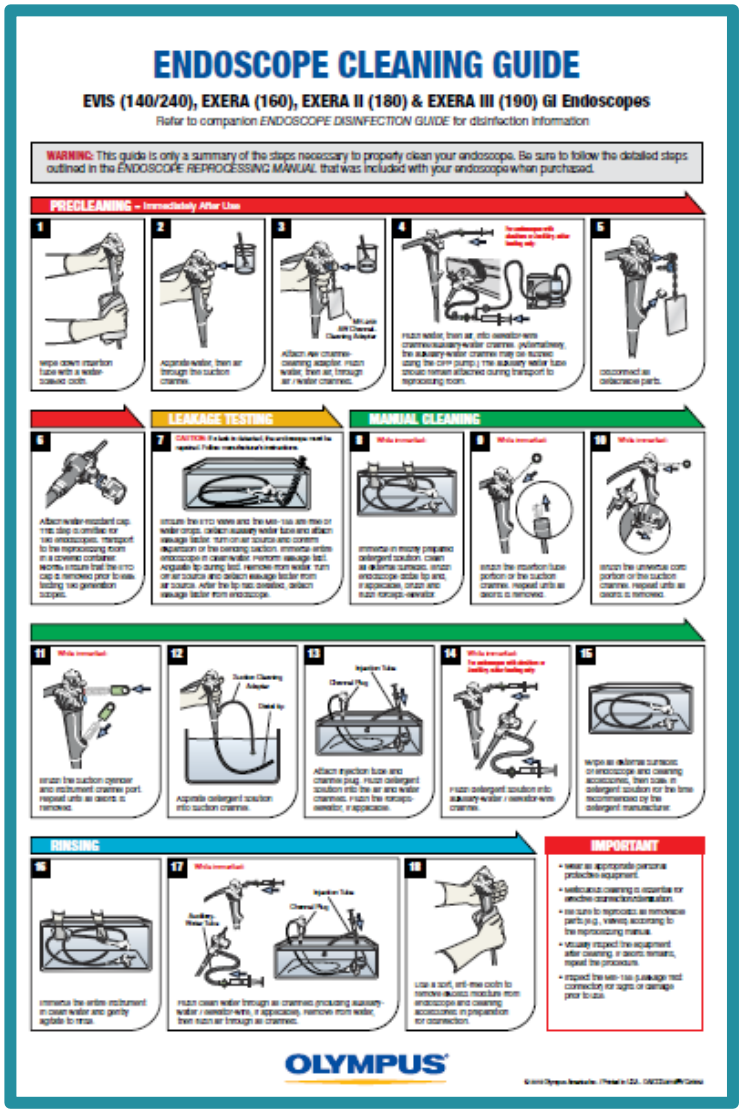

ENDOSCOPE CLEANING GUIDE

EVIS (140/240), EXERA (160), EXERA II (180) & EXERA III (190) GI Endoscopes

Refer to companion *ENDOSCOPE DISINFECTION GUIDE* for disinfection information

WARNING: This guide is only a summary of the steps necessary to properly clean your endoscope. Be sure to follow the detailed steps outlined in the *ENDOSCOPE REPROCESSING MANUAL* that was included with your endoscope when purchased.

PRECLEANING – Immediately After Use

LEAKAGE TESTING

MANUAL CLEANING

RINSING

IMPORTANT

- wear an appropriate personal protective equipment.
- use brush to clean all accessible channels.
- be sure to reprocess all removable parts (e.g., valves) according to the reprocessing manual.
- visually inspect the equipment after cleaning. If stains remain, repeat the procedure.
- inspect the insertion tube connection for signs of damage prior to use.

OLYMPUS

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High Level Disinfection

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- MUST follow instructions
- Perform pre-cleaning immediately after use
- Do NOT allow soiled items to sit for extended period of time
- Perform EVERY step
- Use compatible brushes and other supplies
- Verify cleaning
- Follow all high level disinfectant instructions
- Use an automated reprocessor that has been validated, if applicable
- Perform all preventative maintenance

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Common Findings

- Improper use of High Level Disinfectants (HLD)
  - Temperature
  - Soak time
  - Rinsing
  - Quality Control
- Use of an automated reprocessor that has not been validated
- SHOULD have clear rejection criteria for staff
- When should a scope be sent for repair?

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During Survey

- Issue resolution session
  - Present all written documentation
- Collaborative call with Central Office

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After Survey

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"After a survey event, organizations have the opportunity to submit clarifying ESC if they believe that their organization was in compliance with a particular standard at the time of Survey."

ACC-60

Majority of Health Care Organizations DO NOT Seek to Clarify

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Clarification

- Can submit information as to why a finding should be removed during the clarification period
- Can clarify
  - Survey process errors
  - Findings that have been made in error
- Cannot clarify items that were document- related
  - All documentation related to compliance must be presented during survey

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