Disinfection and Sterilization: Dispelling the Myths

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October 30, 2018

The Joint Commission

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Objectives

- Describe the approach for ensuring compliance with Joint Commission Infection Control Standards.
- Review key standards related to reprocessing of items undergoing sterilization and high level disinfection regardless of the setting.
- Review minimum monitoring practices that should be followed during reprocessing and related documentation.

Standardized Approach to Infection Control Related Standards

The Joint Commission

- Regulation
- CMS
- Manufacturer Instructions
- Evidence based standards or guidelines
- Consensus documents or position statements
- Incorporate into facility based risk assessment and policy

Regulation

Regulations

- Local, state, federal
- Common sources of infection control related regulation
  - Occupational Safety and Health administration (OSHA)
  - Food and Drug Administration (FDA)
  - US Department of Transportation (DOT)
  - Local or state health authority

Regulations

The Joint Commission

Must know your state requirements

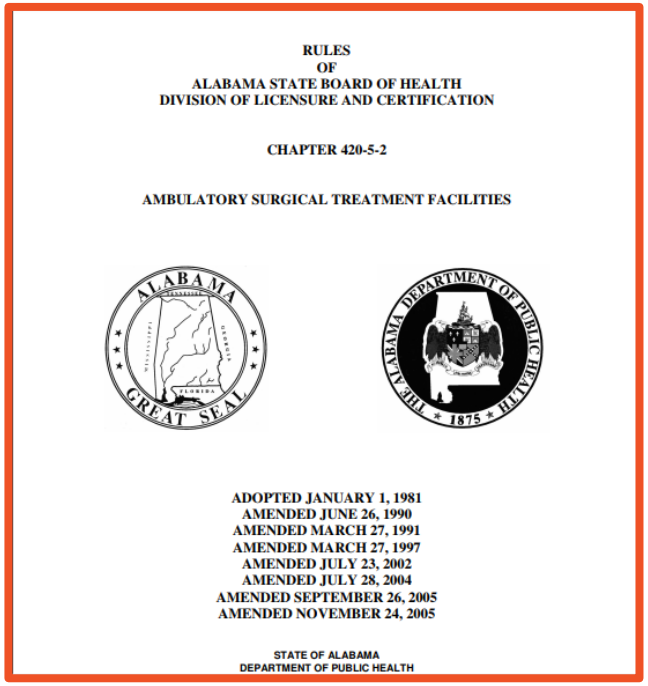
For Example: Alabama Ambulatory Surgery

Sterilization…procedures must include…

3. A prohibition against reuse of one-time-use (disposable) items, unless the items have been reprocessed in accordance with federal law.

4. Temperature, time and pressure for steam sterilization.

5. Proper methods of preparation of items for sterilization (cleaning, wrapping and dating).



RULES
OF
ALABAMA STATE BOARD OF HEALTH
DIVISION OF LICENSURE AND CERTIFICATION

CHAPTER 420-5-2

AMBULATORY SURGICAL TREATMENT FACILITIES

ADOPTED JANUARY 1, 1981
AMENDED JUNE 26, 1990
AMENDED MARCH 27, 1991
AMENDED MARCH 27, 1997
AMENDED JULY 23, 2002
AMENDED JULY 28, 2004
AMENDED SEPTEMBER 26, 2005
AMENDED NOVEMBER 24, 2005

STATE OF ALABAMA
DEPARTMENT OF PUBLIC HEALTH

Regulations

The Joint Commission

Must know your state requirements

For Example: New Jersey Hospital

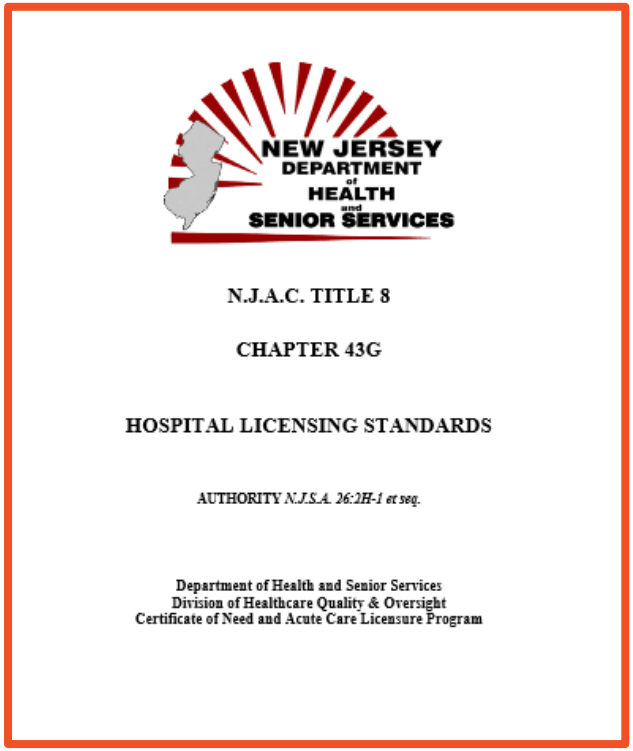
§ 8:43G-8.1 Central service policies and procedures

(d) Manufacturers' written recommendations…shall be readily available in central service and in the department where the equipment is used.

(e) Methods for processing reusable medical devices shall conform with the following publications, incorporated herein by reference…

Sterilization, Part 1: Sterilization in Health Care Facilities, 2017 Edition. The Association for the Advancement of Medical Instrumentation (AAMI)…

Society of Gastroenterology Nurses and Associates. "Standard of Infection Prevention in the Gastroenterology Setting" (2015)…


NEW JERSEY DEPARTMENT of HEALTH and SENIOR SERVICES

N.J.A.C. TITLE 8

CHAPTER 43G

HOSPITAL LICENSING STANDARDS

AUTHORITY *N.J.S.A. 26:2H-1 et seq.*

Department of Health and Senior Services
Division of Healthcare Quality & Oversight
Certificate of Need and Acute Care Licensure Program

Center for Medicare & Medicaid Services (CMS)

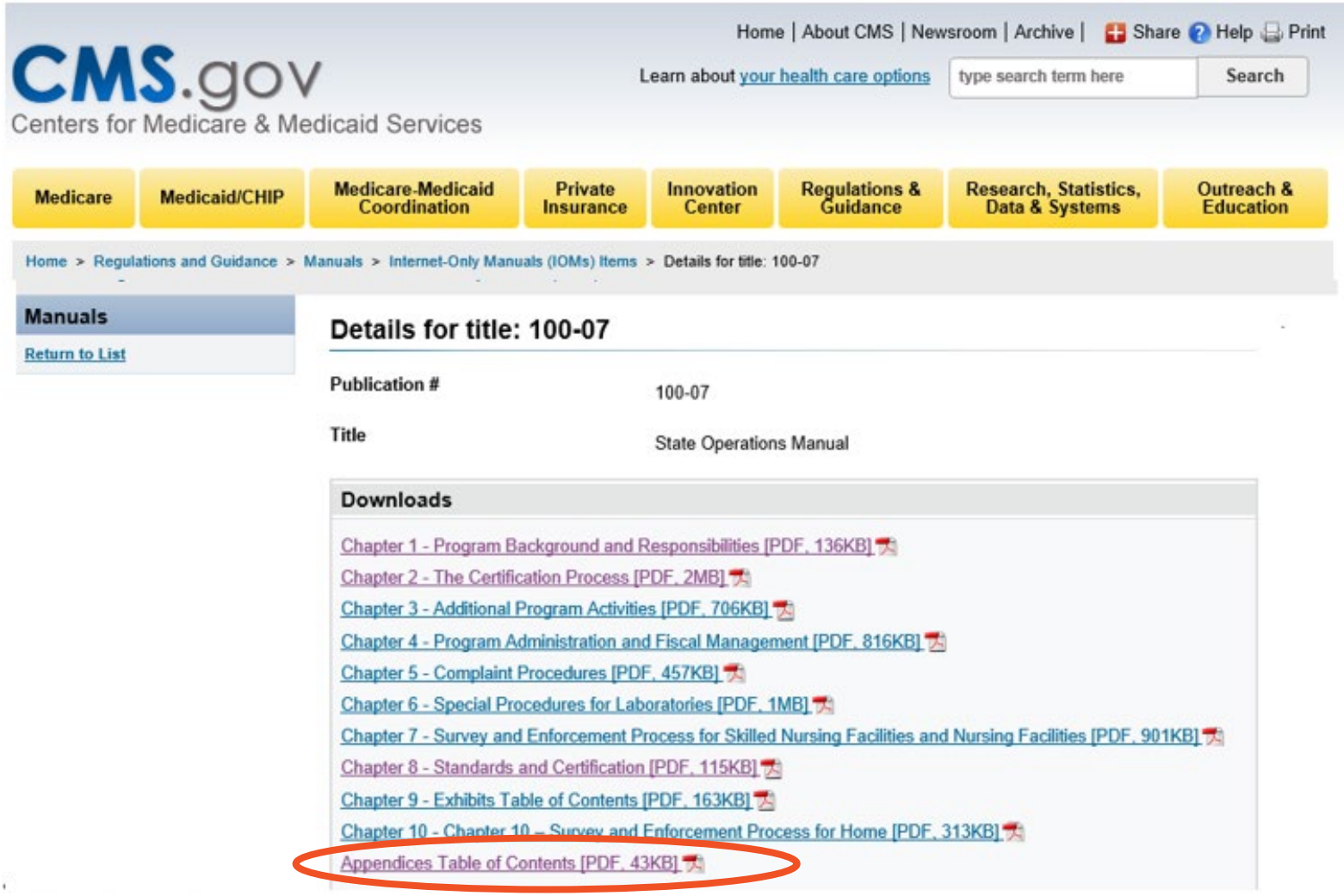
CMS

- Health care entities who participate must comply with
  - Requirements for nursing facilities (NFs) and skilled nursing facilities (SNFs)
  - Conditions of Participation (CoPs): providers
  - Conditions for Coverage (CfCs): institutional suppliers

- State agencies or deemed organizations carry out surveys

State Operations Manual

The Joint Commission



https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html?DLPage=1&DLSort=0&DLSortDir=ascending

Program Specific State Operations Manual

The Joint Commission

Click on the Appendix Letter for Your Program Specific Manual

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)

Program Specific
State Operations Manual

The Joint Commission

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

Program Specific
State Operations Manual

The Joint Commission

Example: Long Term Care Facilities

F880 (Rev. 173, Issued: 11-22-17, Effective: 11-28-17, Implementation: 11-28-17)

Regulation

§483.80 Infection Control

The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

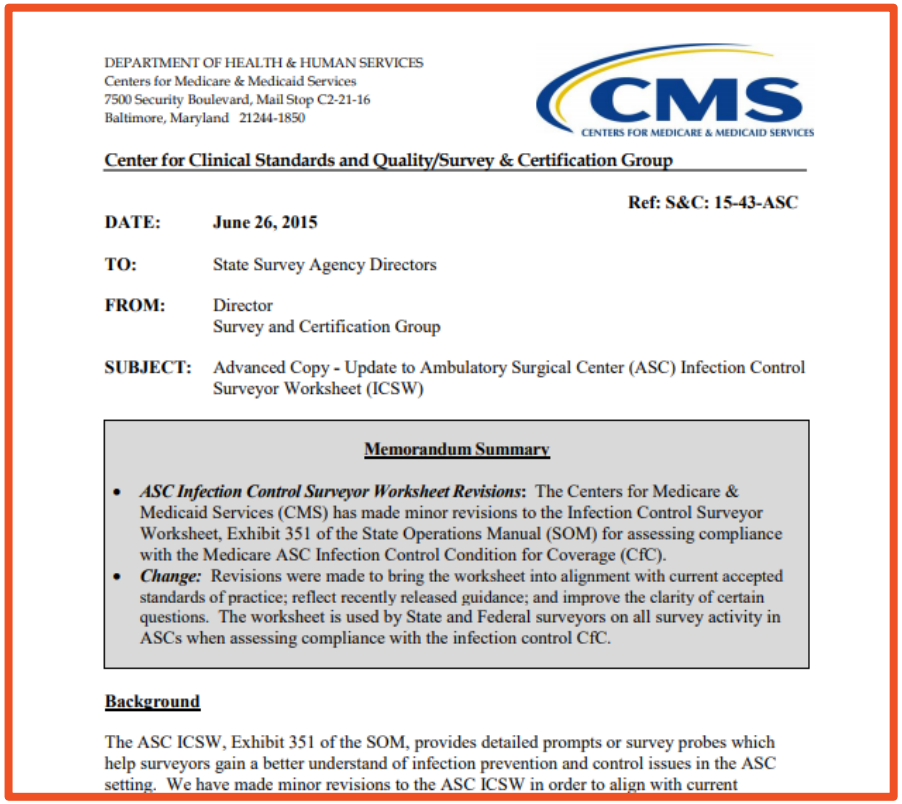
Interpretive Guidelines

The facility must identify the decontamination method based upon the risk of infection to the resident coming into contact with equipment or medical devices…The CDC has adopted the Spaulding classification system that identifies three risk levels associated with medical and surgical instruments:…Semi-critical items (e.g., dental, podiatry equipment, electric razors) contact mucous membranes or non-intact skin. Such items require meticulous cleaning followed by high-level disinfection treatment using a Food and Drug Administration (FDA)- approved high-level chemical disinfectant, or they may be sterilized.

Survey and Certification Memos

The Joint Commission

- Infection Control Worksheets for ASC and Hospitals include requirements related to disinfection and sterilization



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-43-ASC

DATE: **June 26, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)

Memorandum Summary

- ***ASC Infection Control Surveyor Worksheet Revisions*:** The Centers for Medicare & Medicaid Services (CMS) has made minor revisions to the Infection Control Surveyor Worksheet, Exhibit 351 of the State Operations Manual (SOM) for assessing compliance with the Medicare ASC Infection Control Condition for Coverage (CfC).
- ***Change:*** Revisions were made to bring the worksheet into alignment with current accepted standards of practice; reflect recently released guidance; and improve the clarity of certain questions. The worksheet is used by State and Federal surveyors on all survey activity in ASCs when assessing compliance with the infection control CfC.

Background

The ASC ICSW, Exhibit 351 of the SOM, provides detailed prompts or survey probes which help surveyors gain a better understand of infection prevention and control issues in the ASC setting. We have made minor revisions to the ASC ICSW in order to align with current

Exhibit 351

ASC INFECTION CONTROL SURVEYOR WORKSHEET

(Rev.)

Name of State Agency or AO (please specify) _____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (*e.g.*, the staff person responsible for sterilization should answer the sterilization questions). A minimum of one surgical procedure must be observed during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases. When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.

PART 1 – ASC CHARACTERISTICS

1. ASC Name _____

2. Address, State and Zip Code _____ Address _____ City State Zip

3. 10-digit CMS Certification Number

4. What year did the ASC open for operation? y y y y

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

Survey and Certification Memos

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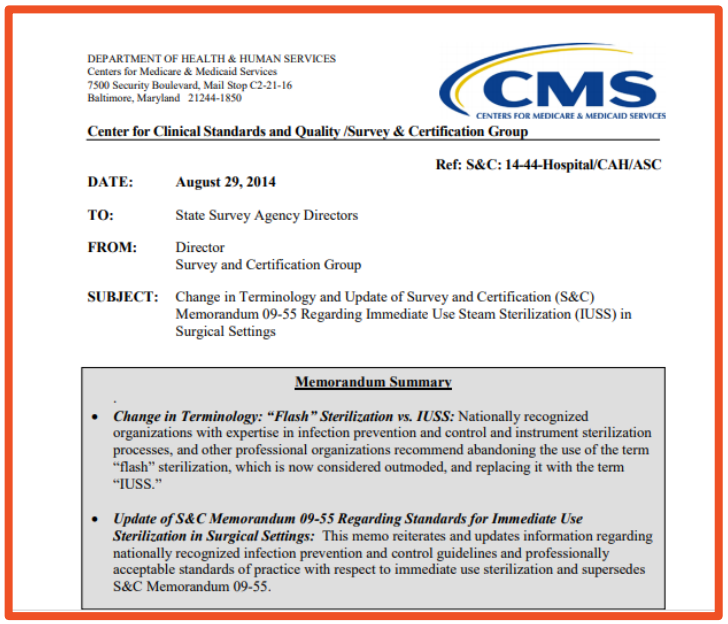
S&C Memo 14-44: Immediate Use Steam Sterilization



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-44-Hospital/CAH/ASC

DATE: August 29, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings

Memorandum Summary

- ***Change in Terminology: "Flash" Sterilization vs. IUSS:*** Nationally recognized organizations with expertise in infection prevention and control and instrument sterilization processes, and other professional organizations recommend abandoning the use of the term "flash" sterilization, which is now considered outmoded, and replacing it with the term "IUSS."
- ***Update of S&C Memorandum 09-55 Regarding Standards for Immediate Use Sterilization in Surgical Settings:*** This memo reiterates and updates information regarding nationally recognized infection prevention and control guidelines and professionally acceptable standards of practice with respect to immediate use sterilization and supersedes S&C Memorandum 09-55.

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-44.pdf

Survey Procedures

An infection prevention and control program to prevent the transmission of infectious disease and protect the health and safety of patients as required under the CoPs/CfCs will be consistent with the national standards of practice. If there is evidence to establish that the answer to any of the following questions is "no" or the provider or supplier is using IUSS in a manner that places its patients at risk for infection, a citation under the appropriate infection control CoP/CfC is warranted.

- Is IUSS reserved for immediate use needs (e.g., used only emergently), when a needed instrument has been contaminated and there is no sterile replacement available, or for a patient care item that cannot be packaged, sterilized and stored before use)?
- Is there a process in place to ensure IUSS is not used for implants (in most circumstances, as described above); instruments used on patients with known or suspected CJD or similar disorders; devices or loads not validated with the specific cycle; and single-use devices?
- Are instrument(s) to undergo IUSS first cleaned and disinfected following the manufacturer's IFU?
- Is there evidence that all of the personnel who perform IUSS:
  - Have the necessary time, equipment, supplies and facilities readily available;
  - Have been trained and are able to correctly follow the manufacturer's IFU(s) regarding IUSS with respect to each instrument, , sterilizer(s), and container(s) and cleaning supplies they are using for IUSS; and
  - Have had their competency initially verified before they undertake IUSS, and periodically thereafter?
- Can personnel provide evidence that the sterilizer cycle being used for IUSS is indicated in the device manufacturer's IFU?
- Are physical monitors used documented to record that cycle parameters are met for each load?
- Is there evidence that the sterilizer is being maintained as required by the manufacturer's IFU?
- Is the rigid sterilization container/packaging, or tray used in a particular cycle consistent with how it is labeled by the manufacturer?
- Is the rigid sterilization container being used for the load consistent with its manufacturer's recommendations for IUSS (e.g. load weight, configuration of instruments)?
- Are the CIs used labeled for use in this cycle by their manufacturer?
- Is a Class 1 CI placed outside each sterilization container/package unless the internal Class 4, 5 or 6 CI used inside each package is visible?

Crosswalk Between CMS CoPs and Joint Commission Standards

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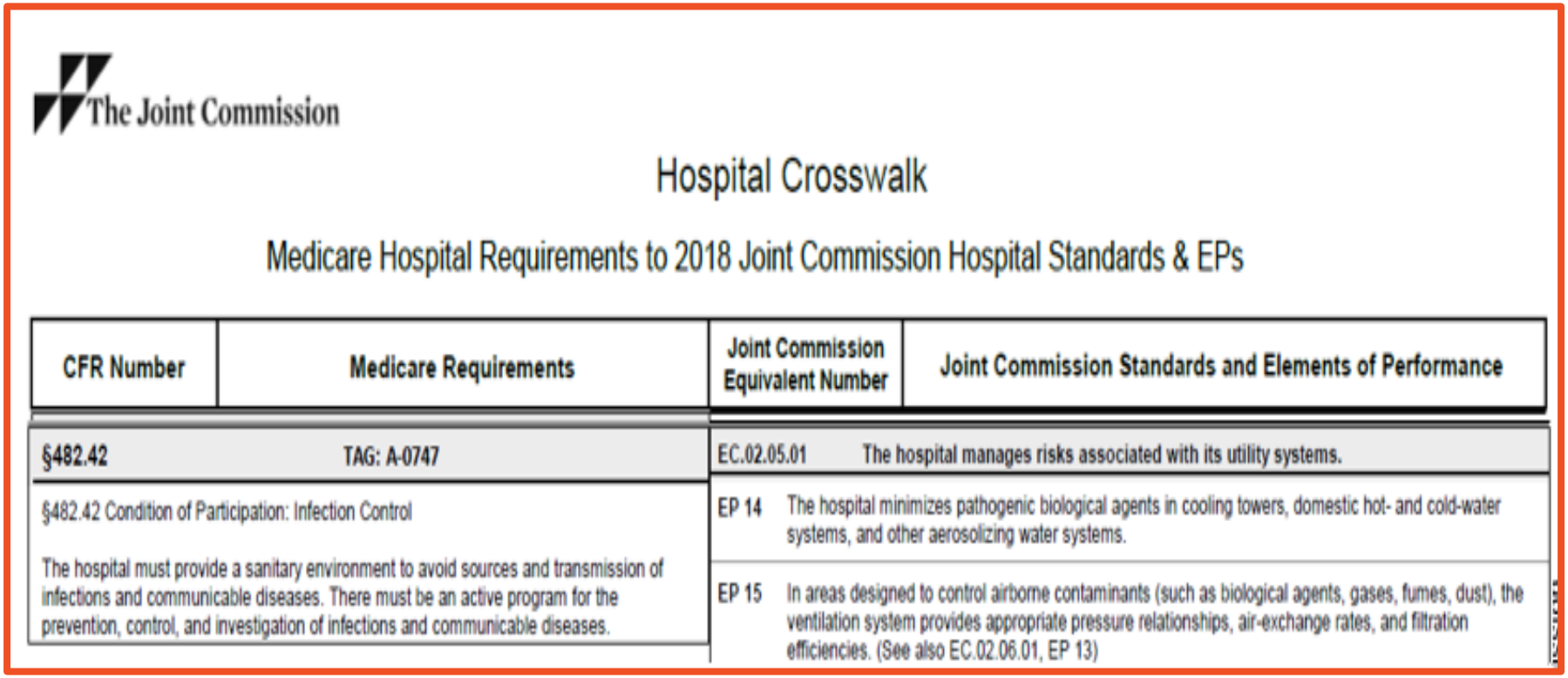

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Hospital Crosswalk

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)

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

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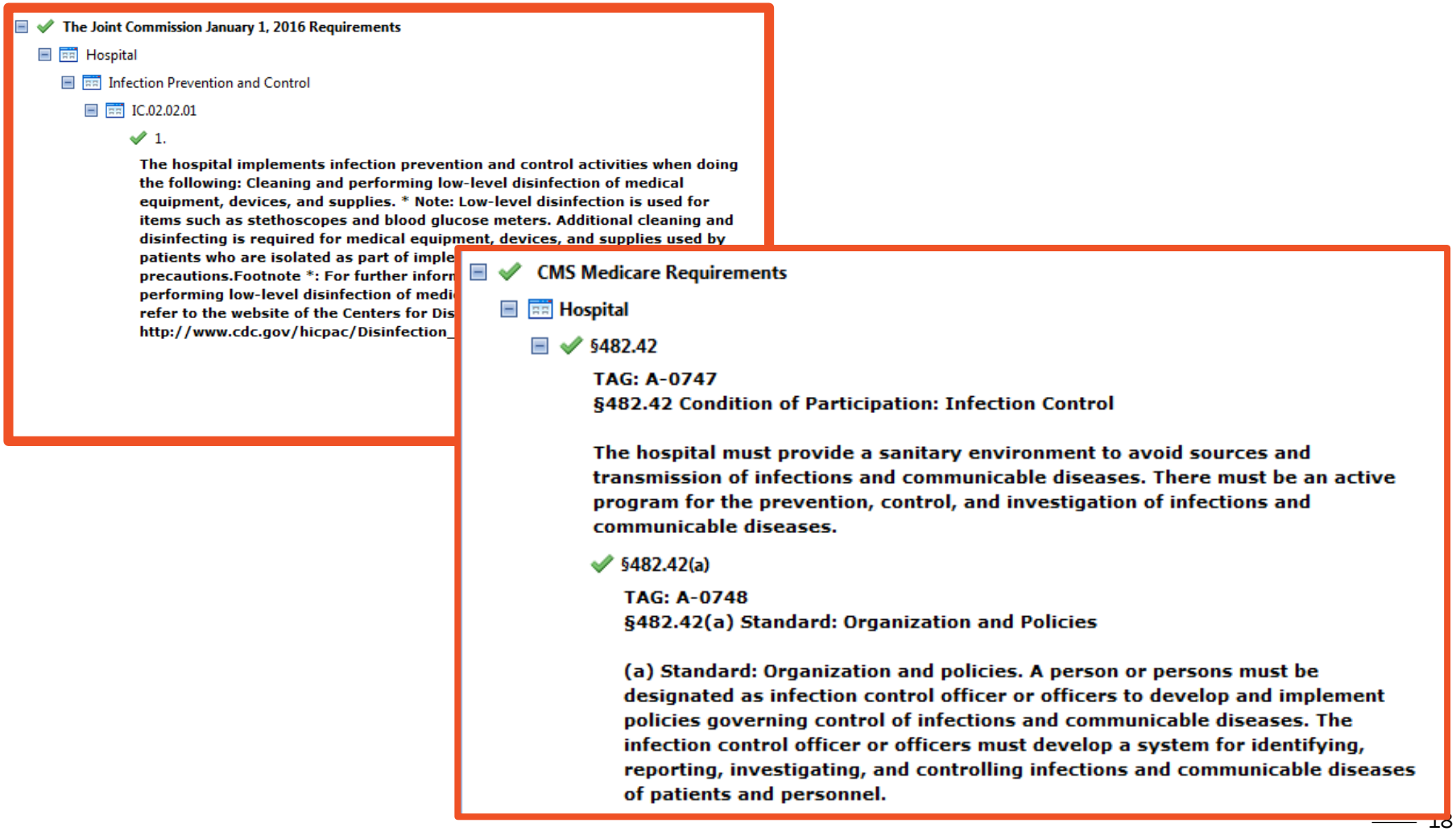


Manufacturer Instructions

Manufacturer Instructions

- Must know how the item will be used
- Must have access to instructions
- When conflicts are identified, facility must resolve
  - Contact equipment manufacturer
  - Contact product manufacturer(s)

Background: Spaulding Classification

The Joint Commission

Level	Risk of Infection	Description	Examples of Items	Reprocessing Methods
Critical	High	Item comes in contact with or enters sterile tissue, sterile body cavity, or the vascular system	Surgical and dental instruments, some endoscopes, inner surfaces of hemodialyzers, urinary catheters, biopsy forceps, implants, and needles	Sterilization
Semi-Critical	Moderate	Item comes in contact with mucous membrane or non-intact skin	Respiratory therapy and anesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, vaginal ultrasound probes and specula, and diaphragm fitting rings	Minimum: High Level Disinfection (sterilization may be needed in certain cases*)
Non-critical	Low	Item comes in contact with skin	Patient care Items: bedpans, blood pressure cuffs, crutches, incubators Environmental Surfaces: bed rails, bedside tables, patient furniture, counters, and floor	Clean or disinfect

Manufacturer Instructions

The Joint Commission

READ CAREFULLY; must identify minimum level of reprocessing required based on Spaulding classification and products that can be used

Cleaning

Rinse:	Immediately upon removal from patient's eye, thoroughly rinse in cool or tepid water.
Wash:	Place a few drops of mild soap on a moistened cotton ball. Gently clean with a circular motion.
Rinse:	Thoroughly rinse in cool or tepid water, then dry carefully with a *non-linting* tissue.
Then:	Proceed with either disinfection or sterilization instructions.

Touches eye – requires high level disinfection

Disinfection

	GLUTARALDEHYDE	OR	BLEACH
Soak In:	2% or 3.4% aqueous solution		10% solution mixed at: 1 part bleach to 9 parts cool tepid water
	Temperature per manufacturer instructions		
	Minimum exposure time = 20 minutes		Recommended exposure time = 10 minutes
	Caution *To avoid damage to the lens,* do not *exceed recommended exposure time.*		
Then:	Rinse lens *thoroughly* to remove disinfection solution. 3 cycles of 1 minute, with cool or tepid water is recommended.		
	Dry carefully and place in a dry storage case.		
NOTE	This lens is known to be compatible with: Asepti-Wipe, Cavi-cide, Cidex, Cidex OPA, DisCide Wipe, Enviro-cide, H_2O_2 - 3%, and Opti-Cide		
Caution	***If used on an ulcerated cornea, lens must be STERILIZED before next procedure.***		

Only FDA approved High Level Disinfectants

Manufacturer Instructions

The Joint Commission

Instructions from other products listed as compatible

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.

Manufacturer Instructions

The Joint Commission

May lead to a different process based on product choice

Enzymatic Detergent A: Dispense gel over surgical tray of instruments to ensure soils are evenly covered. (No instruction to reapply)

Enzymatic Detergent B: Place items in clearly marked decontamination area. Thoroughly spray directly onto instruments…reapply as needed to keep instruments moist.

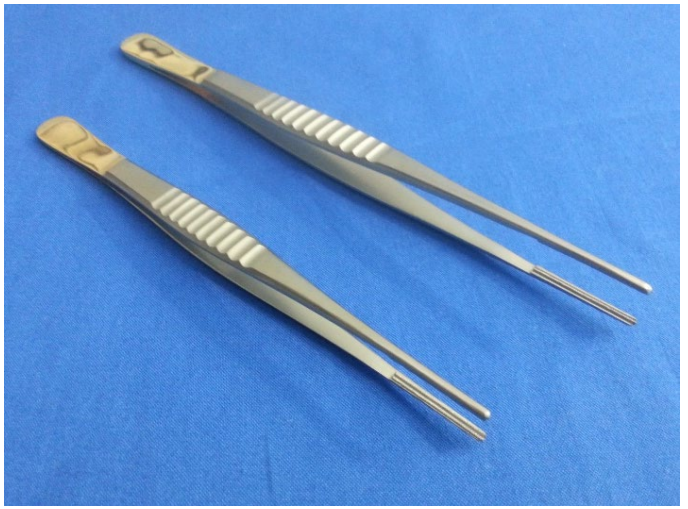
Enzymatic Detergent C: Spray directly on soiled instruments immediately after use. Allow foam to stay on instruments and scopes until ready for cleaning. Apply more as needed to keep moist.

Manufacturer Instruction

The Joint Commission

May need to seek guidance from evidence based guideline

- **Manufacturer A:** Do not allow blood, debris or bodily fluids to dry on instruments. For best results … reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner ..
- **Manufacturer B:** At point of use remove coarse contamination …and keep …moist for transit to the processing site.
- **Manufacturer C:** Immediately after procedure…cover with towel moistened with sterile distilled water…foam, spray, gel products are available…
- **Manufacturer D:** No instructions for point of use



Evidence Based Guidelines and National Standards (EBG)

Evidence Based Guidelines and National Standards (EBG)

The Joint Commission

- 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)

Evidence Based Guidelines and National Standards (EBG)

The Joint Commission

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.

Evidence Based Guidelines and National Standards (EBG)

The Joint Commission

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.

Facility Policy and Procedure

Facility Policy and Procedure

- 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

Storage of Semi-Critical Items: Endocavity Probe at ASC in Wyoming

The Joint Commission

Using the standardized approach

Regulation

State of Wyoming, Department of Health, Chapter 12, Rules and Regulations for Licensure of Hospitals http://health.wyo.gov/wp-content/uploads/2016/11/HLS-Rule-Ch-12-Hospitals.pdf

(e) All equipment and supplies shall be **protected from contamination.**

Conditions of Participation

CMS IC Infection Control Worksheet for ASC Page 15, " Following high level disinfection, items are placed in a designated clean area in a manner to **prevent contamination**"

Manufacturers Instructions

Store the transducer so that it **hangs freely and vertically**, and observe the following precautions…**Do not store the transducer in closed containers or where condensation may occur.**

Impact of Facility Policies

EXAMPLE A:
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.

EXAMPLE B:
During operative procedures, instruments should be wiped with a gauze moistened with water and lumens should be flushed, as needed. Used instruments should be kept moist until they are cleaned in Decontamination. Moisture should be maintained by

- Placing a towel moistened with water (not saline) over the instrument
- Placing items inside a package designed to maintain humid conditions
- Applying a product designed for pretreatment

Impact of Facility Policies

The Joint Commission

EXAMPLE A:

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.

Surveyor will expect:

- Same process be followed in all locations
- No blood or tissue left on instruments
- Product applied at point of use
- No dry instruments

Impact of Facility Policies

The Joint Commission

EXAMPLE B:

During operative procedures, instruments should be wiped with a gauze moistened with water and lumens should be flushed, as needed. Used instruments should be kept moist until they are cleaned in Decontamination. Moisture should be maintained by

- Placing a towel moistened with water (not saline) over the instrument
- Placing items inside a package designed to maintain humid conditions
- Applying a product designed for pretreatment

Surveyor will expect

- Variation in how process is implemented depending on situation and location

Truth or Myth

The Joint Commission

- All visible blood or tissue must be removed form instr

  Myth: Terminal cleaning of instruments should be done in a decontamination area with appropriate facilities, PPE, and equipment to protect staff from potential injury or exposure

- Facilities must use an enzymatic spray to keep instr

  Myth: Facilities must develop and implement a process to keep instruments moist if immediate terminal cleaning is not possible

- Instruments must be opened or disassembled befo

  Myth: Instruments must be opened or disassembled in accordance with IFUs during the terminal cleaning process

- Endoscopes must be pre-cleaned immediately after rem

  Truth: Drying of organic matter on surfaces and in the channels could lead to disinfection failure

room

Key Standards and Required Monitoring

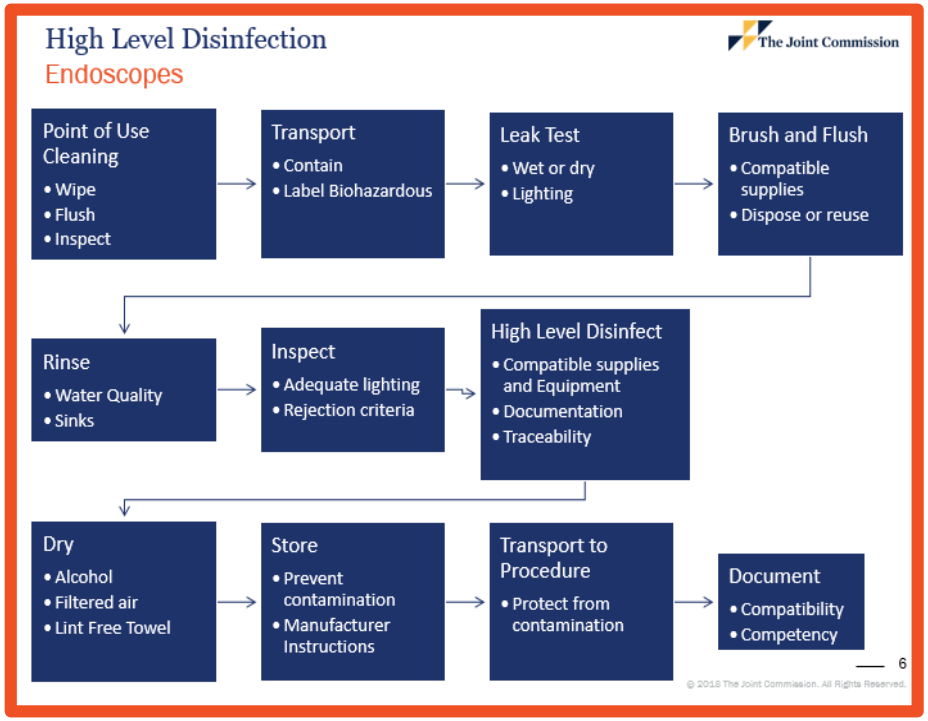
Disinfection an Sterilization

Separate Functions & Processes

The Joint Commission

Sterilization

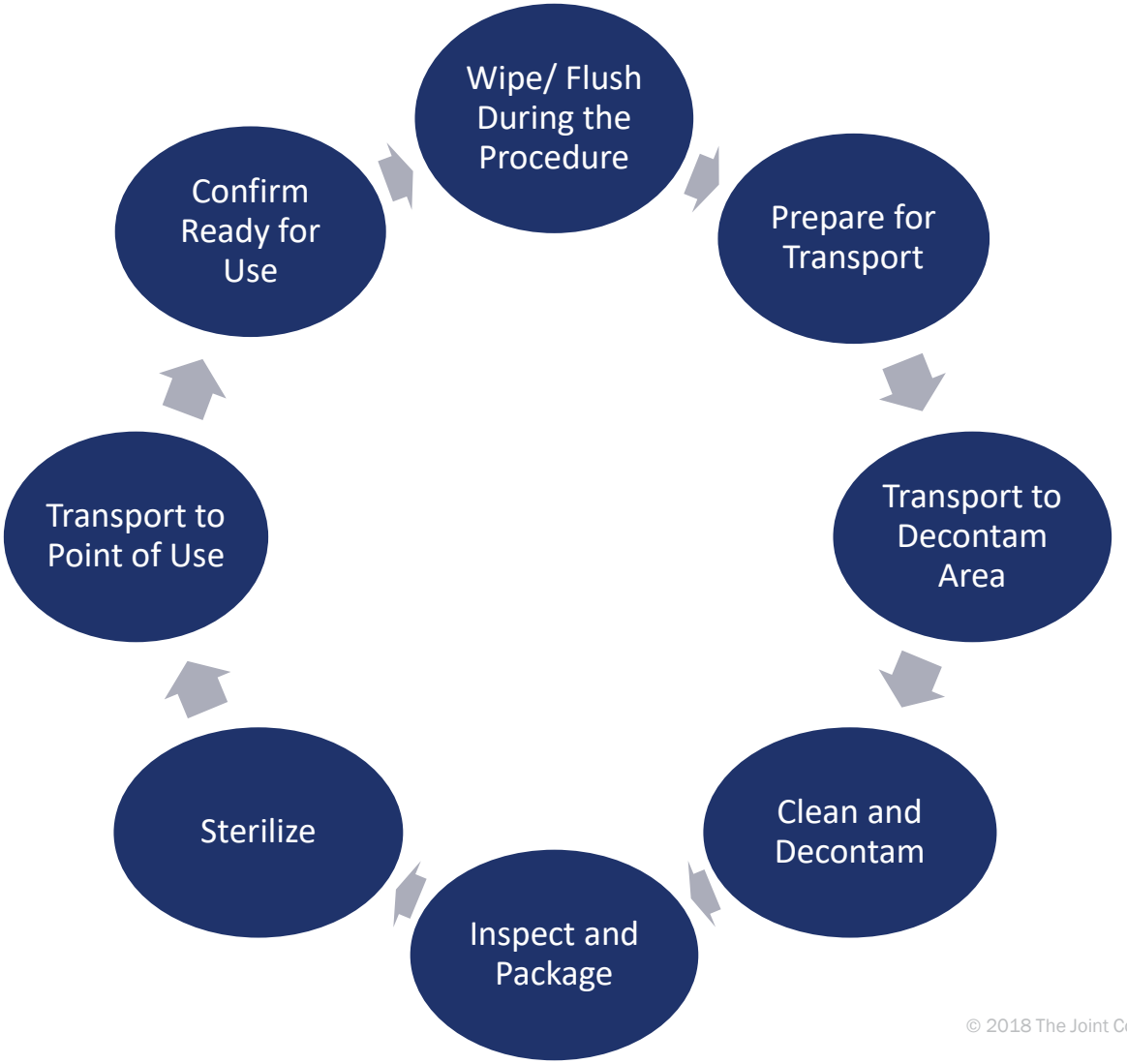
High Level Disinfection



The Sterilization Cycle

The Joint Commission

Use for Critical Instruments and Equipment



Key Standards Related to Sterilization

The Joint Commission

- Association for the Advancement of Medical Instrumentation (AAMI):
  - ST79 (Steam sterilization)
  - ST58 (Chemical sterilization)
  - 11135 (Ethylene oxide sterilization)
- Association for periOperative Registered Nurses (AORN)
  - Cleaning and care of surgical instruments
  - Selection and use of packaging
  - Sterilization
- Centers for Disease Control and Prevention (CDC)
  - Disinfection and Sterilization in Healthcare Facilities

Key Sterilization Requirements

The Joint Commission

- Critical items must be sterilized
- Single use sterile items can only be re-sterilized by an FDA monitored third party vender
- If done, Immediate Use Steam Sterilization (IUSS) must be done in a manner that complies with all CMS S&C 14-44 requirements

Key Sterilization Requirements

- Confirm sterility before introduction to the sterile field.
- Maintain sterile field under constant visual surveillance.
- Wipe and flush during the procedure as clinically indicated.

Key Sterilization Requirements

- Instruments kept moist until terminal cleaning can begin
- Soiled instruments contained for transport from point of use to decontamination in a manner that is OSHA compliant and will not result in exposure or injury
- Manufacturer instructions for use (IFU) available and followed (e.g., dilutions, open/ disassemble during cleaning, packaging, sterilization parameters)

Key Sterilization Requirements

The Joint Commission

- Selection and use of appropriate personal protective equipment

- Cleaning performed in an area that maintains separation of clean and dirty and has staff, equipment, cleaning agents, tools (e.g. brushes), water quality and availability of information needed to follow the medical device IFU

- Instruments inspected for cleanliness prior to preparation and packaging

Key Sterilization Requirements

The Joint Commission

- Quality monitoring and preventative maintenance of all reprocessing equipment must be performed

- Sterile items stored in a manner that protects them from damage or contamination.

- Staff releasing or using sterile products able to differentiate sterile from non-sterile products (e.g., required indicators not present, open, torn, wet, water staining, ratcheted instruments, folded internal pouches, writing on paper side of peel pouches)

Minimum Monitoring

The Joint Commission

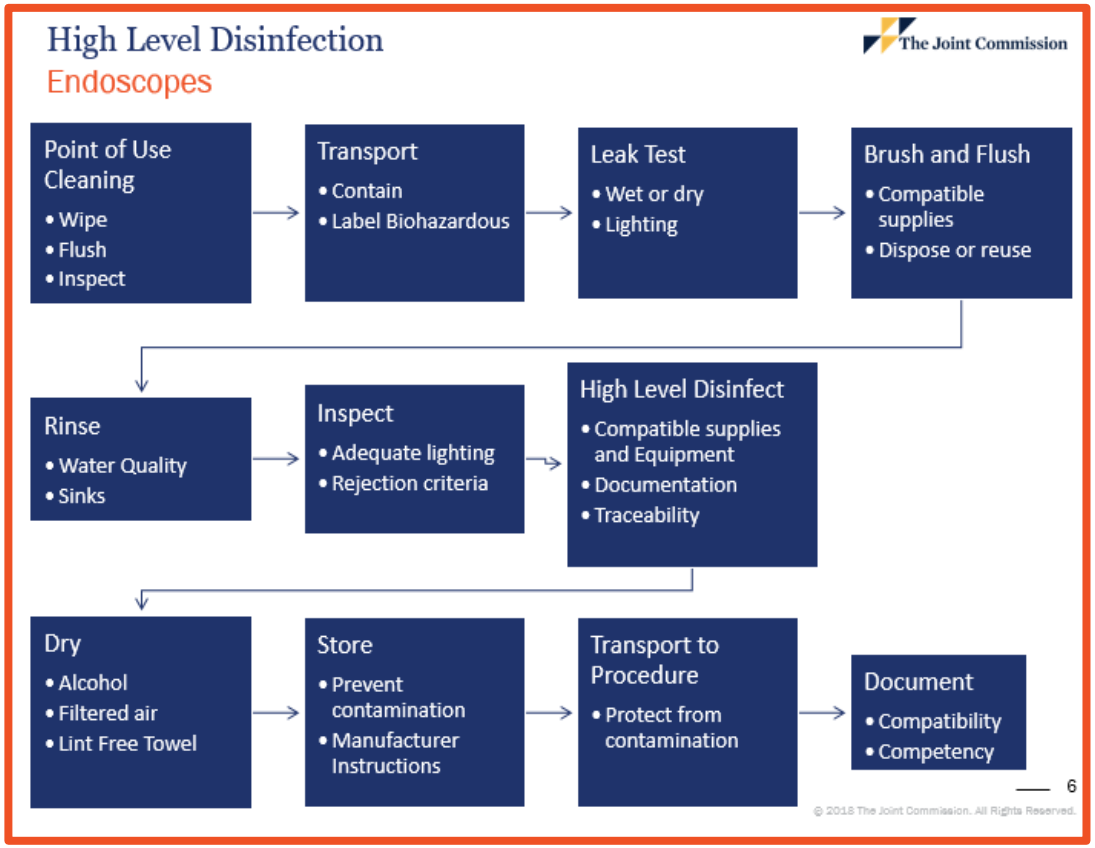
- Quality control and preventative maintenance of equipment and process
  - Physical Cycle: time, temperature and pressure
  - Biologic: consistent with regulation and IFU
  - Chemical: functional testing (e.g., bowie dick, soil challenge test), internal indicator (external if internal not visible) in every pack
- Documentation: legible and complete
- Competent Supervision: Infection Control and Leadership

High Level Disinfection

The Joint Commission

Use for semi-critical devices

- Flexible and Semi-Rigid Endoscopes
- Rigid Endocavity Probes
- Other Items that touch mucous membranes



Key Standards Related to High Level Disinfection

The Joint Commission

- Association for the Advancement of Medical Instrumentation (AAMI):
  - ST91 (Flexible and semi-rigid endoscopes)
  - ST58 (High level disinfection)
- Association for periOperative Registered Nurses (AORN)
  - Processing flexible endoscopes
  - Manual chemical high level disinfection
- Centers for Disease Control and Prevention (CDC)
  - Essential Elements of a Reprocessing Program for Flexible Endoscopes

Key High-level Disinfection Requirements

The Joint Commission

- Items that touch mucous membranes must be high level disinfected prior to reuse (acceptable alternative is sterilization)
- Probes and transducers must be protected from contamination with probe cover **during use** in accordance with manufacturer instruction and EBG
- Immediate cleaning and inspection for damage should be done at point of use as recommended by manufacturer

Key High-level Disinfection Requirements

The Joint Commission

- Appropriate personal protective equipment available and used
- Soiled equipment contained for transport from point of use to decontamination in a manner that is OSHA compliant and will not result in exposure or injury
- IFU for reprocessing each piece of equipment must be followed (e.g., for endoscope- leak testing, if applicable, brushing/flushing, rinsing, inspection, high-level disinfect, rinse, dry)

Key High-level Disinfection Requirements

The Joint Commission

- IFU for products and supplies available and followed (e.g., dilutions, exposure time, test strips)
- Cleaning performed in an area that maintains separation of clean and dirty, one way flow and has staff, equipment, cleaning agents, tools (e.g. brushes), sinks and availability of information needed to follow the medical device IFU
- Must clean equipment before high level disinfection regardless of manner for disinfection - manual or automated

Key High-level Disinfection Requirements

The Joint Commission

- If used, automated endoscope reprocessor compatible and used in accordance with IFUs
- Must rinse and dry in accordance with all product manufacturer instructions
- Quality control and preventative maintenance of all equipment performed in accordance with IFU

SAFETY ALERT: Do not use OPA (ortho-phthalaldehyde) to process any urological instrumentation used to treat patients with a history of bladder cancer due to risk of anaphylaxis

Minimum Monitoring

The Joint Commission

- Cleaning verification
- Quality control and preventative maintenance of equipment and process
  - Physical monitors: temperature of products, exposure time, cycle parameters, etc.
  - Testing of minimal effective concentration
- Traceable from patient through reprocessing
- Documentation: legible and complete
- Competent Supervision: Infection Control and Leadership

Refining and Clarifying the Survey Process

The Joint Commission

Joint Commission Online

Sept. 5, 2018

Accreditation and Certification

4-1-1 on Survey Enhancements: New scoring revisions for IC.02.02.01 now in effect

4-1-1 on Survey Enhancements

Infection Control (IC) standard IC.02.02.01 — which requires hospitals to reduce the risk of infections associated with medical equipment, devices and supplies — continues to be one of the most commonly cited standards listed as noncompliant. In 2017, 72 percent of surveyed hospitals and critical access hospitals were found to be noncompliant with this standard.

After a careful evaluation of high-level disinfection (HLD) and sterilization process steps, The Joint Commission has refined its scoring to focus on the process steps that pose the highest risk to patients if they fail.

In this issue

These revisions are the focus of the latest 4-1-1 on Survey Enhancements — a series that takes a deeper look at four high-risk areas that are evaluated by Joint Commission surveyors. The first 4-1-1 was on sterile medication compounding, this 4-1-1 focuses on HLD and sterilization, and the remaining 4-1-1s will focus on suicide prevention and hemodialysis.

These Infection Control scoring revisions (see table below) are intended to help hospitals hone in on the highest-risk process steps to become more compliant with IC.02.02.01, and they went into effect Sept. 1, 2018.

The Joint Commission will continue to score IC.02.02.01 as noncompliant whenever manufacturer instructions are not followed. Over the next several months, The Joint Commission will closely monitor the revisions to ensure consistent scoring.

Please note: IC.02.02.01 findings recorded before Sept. 1, 2018 will not be removed. Hospitals that are in the clarification window or that are preparing their Evidence of Standards Compliance (ESC) report should document compliance based upon the refined scoring guidelines. If your organization received an adverse decision and received only one finding from one of the seven areas, please contact the Standards Interpretation Group. (Contact: Sylvia Garcia-Houchins, sgarcia-houchins@jointcommission.org)

Effective immediately: New scoring revisions for IC.02.02.01

Previously Scored	New Scoring
Visible bioburden and dried blood found on instruments	• Wiping / flushing of soiled instruments is not observed during a case in the operating room or procedure room and it is clinically appropriate • Item that is ready for use on a patient is visibly soiled
Enzymatic solution was not applied to maintain moisture on instruments	• There is no process for keeping used instruments moist • Manufacturer instructions for products used to keep instruments moist were not followed • The facility policy for keeping instruments moist was not followed
Instruments were not transported from the point of use in a leak-proof puncture-	• Sharps are being transported in a manner that violates OSHA requirements (e.g., sharps not placed in puncture-resistant container that is red or labeled biohazardous)

The Joint Commission

https://www.jointcommission.org/assets/1/23/JC_Online_Sept_5.pdf

Have a question? Check Joint Commission FAQs

The Joint Commission