Auditing Endoscope Processing Areas for Compliance with ST91

MARY ANN DROSNOCK

DHSC (ABD), FAPIC, CIC, CFER, FAPIC, AAMIF

HEALTHMARK INDUSTRIES

DIRECTOR OF CLINICAL AFFAIRS

FORMER CO-CHAIR OF WG84

Disclosure

- Mary Ann Drosnock is an employee of Healthmark Industries Fraser, Michigan, which manufactures and distributes medical products for healthcare.

- All opinions are those of the presenter
- This presentation reflects the techniques, approaches, and opinions of the individual presenter. This sponsored presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings, and precautions, and steps for the use of the device(s).

Objectives

1. Identify existing guidelines and recommendations that guide HLD best practice
2. Review existing toolkits to help build individualized rounding tools
3. Review samples of rounding tools for auditing:
    - Endoscopy areas
    - Areas with Trophon
    - Areas with Cidex/GUS

Audit – what is it?

- Reviewing processing practices for compliance with standards, guidelines, and best practices as designated by the facility.
- Also known as:
  - practice review,
  - mock audit,
  - survey,
  - tracer,
  - rounding

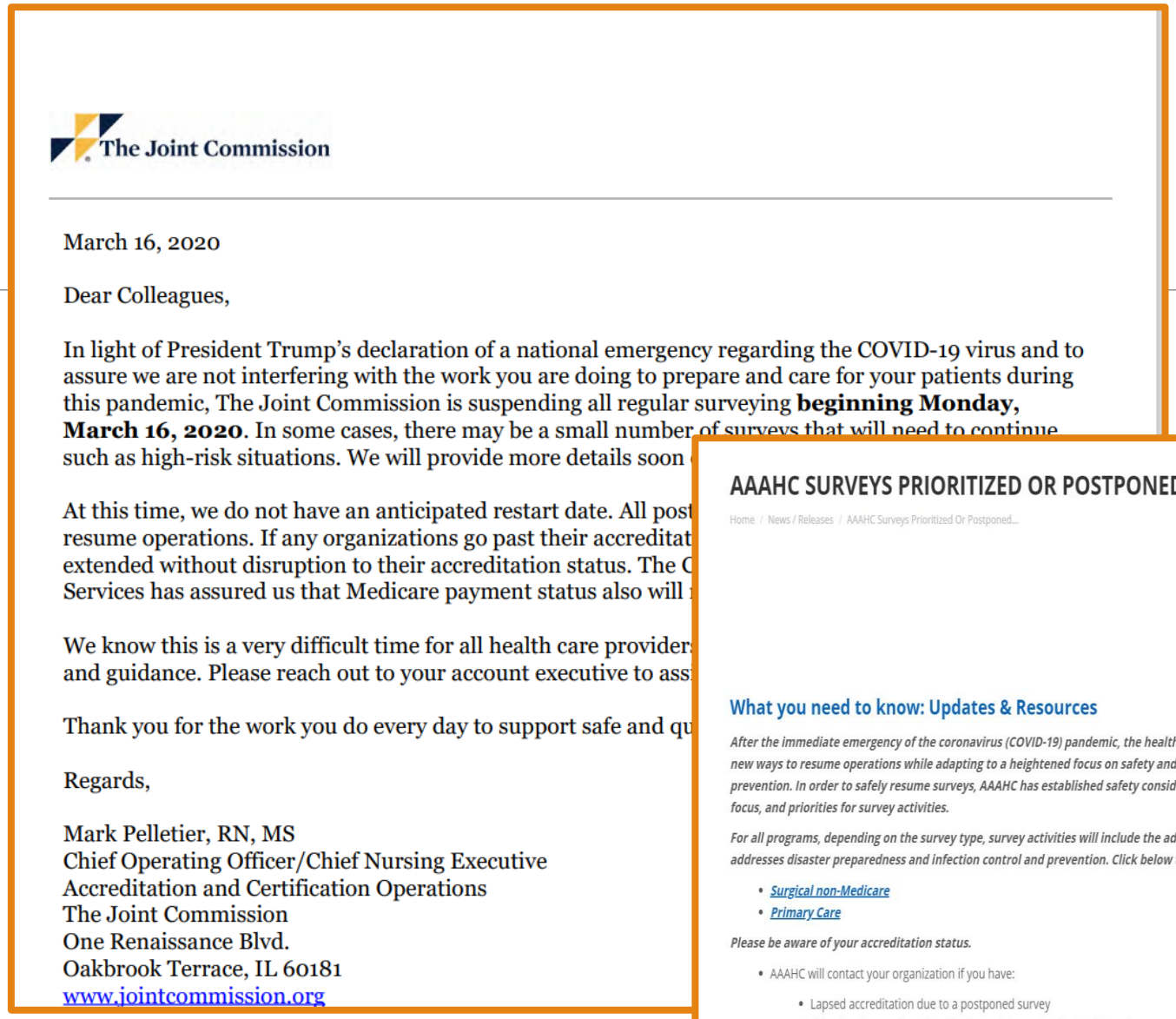
Audit – Why do we do it?

- Requirement of the standards (ST91, CDC, TJC, etc.)
- To gain knowledge of compliance with a given standard
- To determine the current state of affairs
- To see if previously made changes are still in effect
- To determine if your current practices are “in control”
  - Audits conducted of facilities have found widespread lapses in infection prevention and control practices and non in accordance with standards and guidelines (ST91)

REGULATORY READINESS

HISTORICALLY, THE “OUTSIDE LOOKING IN” PERSPECTIVE

2020 - Temporary suspension of accreditation surveys



The Joint Commission

March 16, 2020

Dear Colleagues,

In light of President Trump's declaration of a national emergency regarding the COVID-19 virus and to assure we are not interfering with the work you are doing to prepare and care for your patients during this pandemic, The Joint Commission is suspending all regular surveying **beginning Monday, March 16, 2020**. In some cases, there may be a small number of surveys that will need to continue such as high-risk situations. We will provide more details soon

At this time, we do not have an anticipated restart date. All post
resume operations. If any organizations go past their accreditat
extended without disruption to their accreditation status. The C
Services has assured us that Medicare payment status also will

We know this is a very difficult time for all health care provider
and guidance. Please reach out to your account executive to ass

Thank you for the work you do every day to support safe and qu

Regards,

Mark Pelletier, RN, MS
Chief Operating Officer/Chief Nursing Executive
Accreditation and Certification Operations
The Joint Commission
One Renaissance Blvd.
Oakbrook Terrace, IL 60181
www.jointcommission.org

AAAHC SURVEYS PRIORITIZED OR POSTPONED AND COVID-19 RESOURCES

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What you need to know: Updates & Resources

After the immediate emergency of the coronavirus (COVID-19) pandemic, the health care industry is finding new ways to resume operations while adapting to a heightened focus on safety and infection control and prevention. In order to safely resume surveys, AAAHC has established safety considerations, survey areas of focus, and priorities for survey activities.

For all programs, depending on the survey type, survey activities will include the addition of a worksheet that addresses disaster preparedness and infection control and prevention. Click below to download worksheets.

- *Surgical non-Medicare*
- *Primary Care*

Please be aware of your accreditation status.

- AAAHC will contact your organization if you have:
  - Lapsed accreditation due to a postponed survey
  - Submitted a completed application and accreditation has lapsed
  - Submitted a completed application, scheduled survey was postponed, and accreditation has not

Latest Releases

AAAHC Announces Kershner Winners
September 17, 2020

New AAAHC Accreditation Handbook Enhances Medicare Deemed Status Standards
September 1, 2020

AAAHC Drives 1095 Strong, Quality Every Day Philosophy with Inaugural Virtual Conference
August 18, 2020

Press Release Archives

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Press Release Archives

WE'RE BACK!

Survey Process

- We will NOT enter an at risk or confirmed COVID-19 room.
- We will avoid visiting a unit/area with any confirmed COVID-19 patients when possible.
- Limit physical review of high risk and aerosol generating procedures
- Consider using a simulation and/or distant review of certain activities/procedures
- Practice social/physical distancing during the survey
- Follow "PPE" and risk reduction strategies as established by the CDC
- Limit attendance at group sessions (e.g., opening, briefings, system tracers)
- Limit observers or scribes to avoid additional exposure during the survey

The Joint Commission

https://pages.jointcommission.org/rs/433-HWV-508/images/FINAL%20COVID%20QA%20Ambulatory%20Health%20Care%20Accreditation%20November%2019%20webinar.pdf?mkt_tok=eyJpIjoiTWpsaFpqWXlNV0V5WXpoaSIsInQiOiIwRmh1WVJYbWd4WGxpK3VpYTNzOTduY2VpcFRTUE9nbXBZTlNFUHpya0wrdzgxdnZKSGM3eG5GenJQcWNhN1B4Qm1yWTBtTXkwNXdtNlwvUFF4enRZZGJkYVBabFhOVVJUN2FuOHN1TEljXC9uREZFQTdTUExHZk5HT1dsYVNmSHhUIn0%3D

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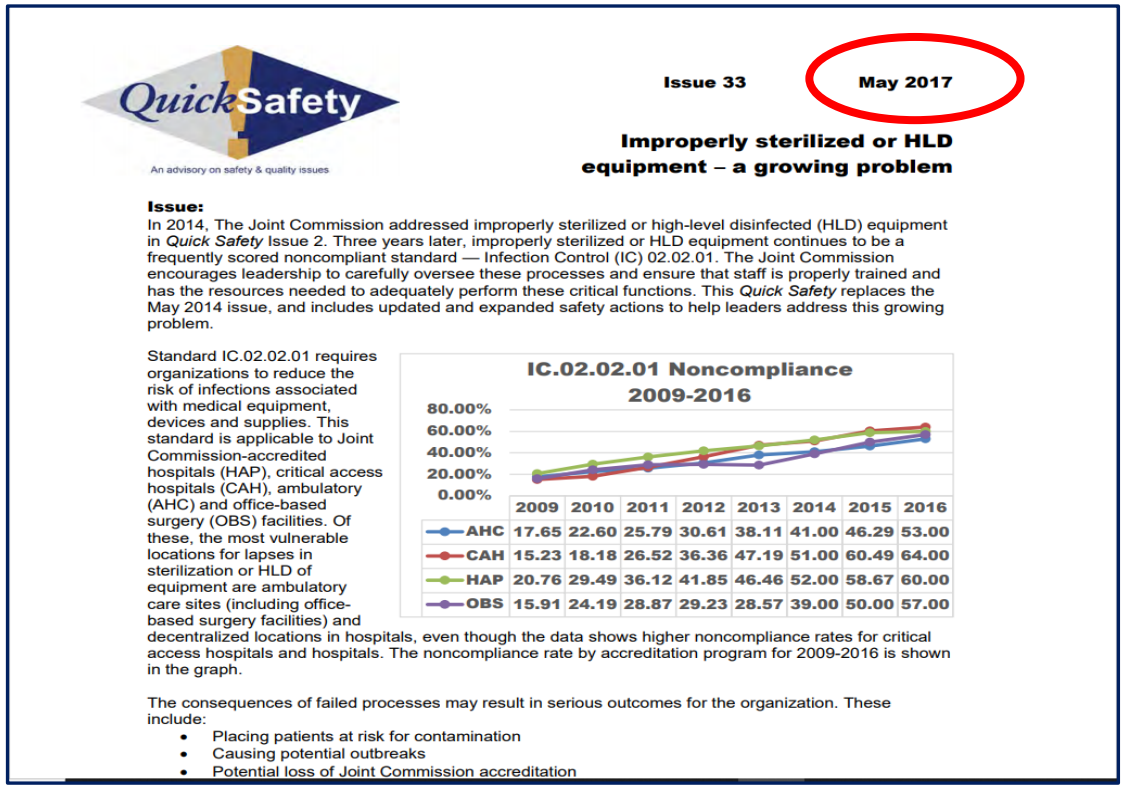

QuickSafety

An advisory on safety & quality issues

Issue 33 May 2017

Improperly sterilized or HLD equipment – a growing problem

Issue:

In 2014, The Joint Commission addressed improperly sterilized or high-level disinfected (HLD) equipment in *Quick Safety* Issue 2. Three years later, improperly sterilized or HLD equipment continues to be a frequently scored noncompliant standard — Infection Control (IC) 02.02.01. The Joint Commission encourages leadership to carefully oversee these processes and ensure that staff is properly trained and has the resources needed to adequately perform these critical functions. This *Quick Safety* replaces the May 2014 issue, and includes updated and expanded safety actions to help leaders address this growing problem.

Standard IC.02.02.01 requires organizations to reduce the risk of infections associated with medical equipment, devices and supplies. This standard is applicable to Joint Commission-accredited hospitals (HAP), critical access hospitals (CAH), ambulatory (AHC) and office-based surgery (OBS) facilities. Of these, the most vulnerable locations for lapses in sterilization or HLD of equipment are ambulatory care sites (including office-based surgery facilities) and decentralized locations in hospitals, even though the data shows higher noncompliance rates for critical access hospitals and hospitals. The noncompliance rate by accreditation program for 2009-2016 is shown in the graph.

IC.02.02.01 Noncompliance 2009-2016

	2009	2010	2011	2012	2013	2014	2015	2016
AHC	17.65	22.60	25.79	30.61	38.11	41.00	46.29	53.00
CAH	15.23	18.18	26.52	36.36	47.19	51.00	60.49	64.00
HAP	20.76	29.49	36.12	41.85	46.46	52.00	58.67	60.00
OBS	15.91	24.19	28.87	29.23	28.57	39.00	50.00	57.00

The consequences of failed processes may result in serious outcomes for the organization. These include:

- Placing patients at risk for contamination
- Causing potential outbreaks
- Potential loss of Joint Commission accreditation

https://www.jointcommission.org/-/media/tjc/documents/newsletters/qs_33a_2017pdf.pdf

"from 2013-2016, immediate threat to life (ITL) declarations directly related to improperly sterilized or HLD equipment increased significantly. In 2016, 74 percent of all ITLs were related to improperly sterilized or HLD equipment."

"In many instances, the problem is long-standing at an organization, and the true scope of the problem isn't known until there is an outbreak…"

"… the data shows higher noncompliance rates for critical access hospitals and hospitals"

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.

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.

In this issue

- 4-1-1 on Survey Enhancements: New scoring revisions for IC.02.02.01 now in effect
- Comment on proposed pain standards revisions for behavioral health organizations
- Don't miss out: Plan to attend Sept. 18 Pioneers in Quality Proven Practices webinar
- September Journal: Study on intensive rapid response system treatment in end-of-life care
- Up in the blogosphere with The Joint Commission

https://www.jointcommission.org/-/media/tjc/newsletters/jc_online_sept_5pdf.pdf?db=web&hash=9773ACEC5B74D6C48C5AE7D6D0BEB74B

"…72 percent of surveyed hospitals and critical access hospitals were found to be noncompliant with this standard."

"The Joint Commission has refined its scoring to focus on the process steps that pose the highest risk to patients if they fail."

Joint Commission Online 09-05-2018

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-resistant container with the biohazard symbol or color red	• 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) • Non-sharps are transported in a way that could lead to contamination of staff or other people
Instruments in the closed position	• Packaged instruments awaiting sterilization are in the closed/ratcheted position • Items that have just undergone sterilization are on the trolley or in the sterilizer in the closed/ ratcheted position • Items in preparation and packaging that have come through the washer or pass-through window have not been disassembled in accordance with manufacturer instructions
Instruments are released prior to the biologic indicator being read	• Routine sterilizer monitoring with a biologic indicator required by the state or per evidence-based guideline is not followed and recorded • Non-implant load is released without physical monitoring of cycle and external and internal chemical indicators • Implant loads are released without routine sterilizer monitoring, a biologic indicator and a type 5 integrating indicator (aka integrator) • Biologic indicator not read before implant release (unless allowed in emergent situations by facility policy and policy was followed)
Items in the high level-disinfected area that are stored in drawers	• Container or location of storage is visibly soiled or staff are observed contaminating other high level-disinfected products • Storage is not consistent with the items intended use (e.g., items that require minimum of high-level disinfection may be stored in a way that protects from contamination even if they were sterilized) • Item is not stored in accordance with manufacturer instructions for use (IFU) • Item is not stored in accordance with facility risk assessment / policy if no guidance was provided by the item's manufacturer IFU
Stored scopes exceeded the hang time	• Facility is not following manufacturer IFU for drying • Facility is not following manufacturer IFU for frequency of reprocessing Will NOT score any finding related to hang time under IC standards

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AAMI/ANSI ST91:2021

- Has recommendations to monitor quality processes of endoscope reprocessing through performing regular periodic audits
- Has recommendations to create a multidisciplinary team to look at a variety of practices within endoscope processing

ST91 on Auditing

- The facility should determine the length of storage for endoscopes before they must be processed again.
  - “Compliance should be audited to determine if changes to storage time need to be made.”
- Quality Control:
  - Audit and document the introduction and withdrawal from use of all endoscopes, accessories, and AERs.

ST91 on Auditing

- Quality Process Improvements:
  - A root cause analysis should be completed for any problem related to endoscope processing that could pose a risk to patients or personnel.
  - There should be a planned, systemic and ongoing process to verify compliance with procedures.
  - This process is enhanced with regularly conducted audits.
  - The info learned during audits should be summarized and made available to designated individuals or groups.

ST91 on Auditing

- Quality Process Improvements:
  - Audits are measurements of process performance that allow processing to be monitored against a predetermined level of quality.
  - Evaluating findings provides a way to identify problems or shifts in activities.
  - Allows for informed decision-making on policies and procedures.
  - On-going audits provide data essential to assessing the effectiveness of the process and making improvements in performance.

ST91 on Auditing

- Quality Process Improvements:
  - Point of use treatment – Ongoing auditing provides data essential to assessing the effectiveness of processes and making improvements in performance.
  - Root cause analysis should be completed when a patient safety event occurs that results in death, permanent harm, or severe temporary harm (per Joint Commission, 2015).

ST91 on Auditing

- Quality Process Improvements:
  - Decontamination: Auditing results should be routinely summarized and submitted to infection prevention and control personnel to review.
  - Ongoing auditing provides data that can be used to assess the effectiveness of the process and make ongoing improvements in performance.
  - Measurements of process performance allow the system to be monitored and the results compared with a predetermined level of quality.

ST91 on Auditing

- Processing policies and procedures:
  - Evaluating and monitoring the effectiveness of processing should be an ongoing effort and is critical to maintaining control over products and processes.
    - Review records
    - Review quality control procedures for monitoring and evaluating the process
    - Review written procedures and current practices for compliance with a continuous quality improvement (CQI) program

ST91 on Auditing

- Areas of the CQI program to review:
  - Training, CEs, and Competency Verification
  - Product Identification and Traceability
  - Monitoring Cleaning Effectiveness
  - Monitoring Manual and Automated HLD usage
  - Monitoring Sterilization Practices
  - Product Testing
  - Product Recalls
  - Workplace Safety Training

ST91 on Auditing

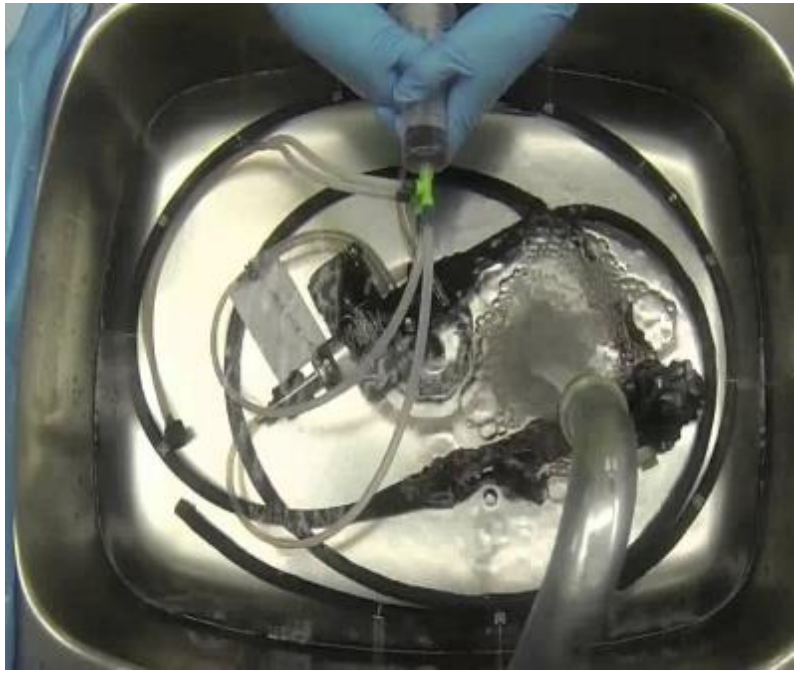
- Product Usage:
  - Internal evaluations can be used to audit the quality of finished products.
    - Examples
      - Instruments can be checked for functionality, packaging, and delivery.
      - Decontamination - evaluated by visually examining instruments for contamination
      - Product recalls – review records or actions following process failures
      - Periodic product monitoring can be evaluated on the basis of loads or cycles tested and the actions taken as a result of failures.

ST91 on Auditing

- Drying Verification
  - Using a borescope as part of a routine audit program is a practical approach to be used as part of a routine audit program that involves a thorough visual inspection of an endoscope.
  - A fully processed endoscope including drying can be inspected for visible signs of moisture retention.
  - Borescopes are a highly useful toll for inspection of endoscope channels during assessment for suspected damage, repeated positive cultures, or in studies of drying parameters.

ST91 on Auditing - Topics to review

- Policies and procedures should be reviewed by a multidisciplinary group and updated at regular intervals established by the facility and local regulations:
  - The group should be made up of:
    - Personnel Representing GI
    - Sterile Processing
    - Operating Poom
    - Infection Prevention and Control
    - Risk Management
    - As applicable to the facility



Multidisciplinary Teams should review:

- Alcohol flush to dry endoscopes
- Length of storage for processed endoscopes
- All quality control and monitoring documentation
- The method to detect clusters of infections, outbreaks, and suspected infections related to endoscopy
- Recall policies
- Create an action plan for culture positive results
- Previous audit results
- Records of processing endoscopes

Multidisciplinary Quality Teams should review:

- Repair documentation
- Competency testing results
- Make recommendations based on trending
- Maintain a perpetual inventory of scopes
- Evaluate new equipment before ordering looking at purchase considerations
- Help in IFU conflict management
- Create gap analysis and auditing tools
- Review new standards and guidelines
- Perform risk assessments

Common Lapses to Look For When Auditing Endoscope Processing

Basic steps for any reusable medical device that requires HLD/sterilization processing

01

Point of use treatment/ precleaning

02

Soiled transport

03

Manual/ automated cleaning then rinse

04

Post-cleaning inspection - includes cleaning verification

05

Packaging (sterilization)

06

HLD or sterilization

07

Post HLD rinsing and drying

08

Clean transport

09

Storage

POINT OF USE TREATMENT (PRECLEANING)

- Always performed
- At the point of use – exam/procedure room.
- Wipe externally
- Flush all channels
- Suction deteregent
  - May involve prepackaged kits – e.g. with enzymatic detergent.
- May use foaming sprays
- Use A/W Channel Cleaning Adapter
- Note the time point of use treatment occurs
  - Convey to processing staff
  - Use tag, label, electronic record, etc.

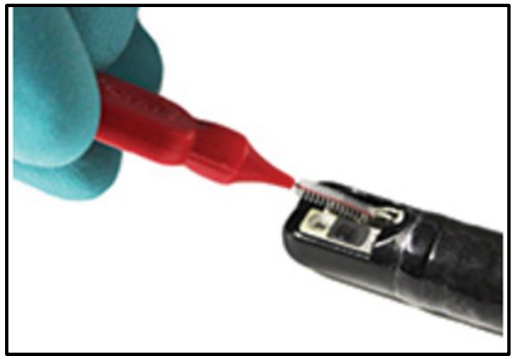
SOILED TRANSPORT

- Containment – commonly solid, leakproof, puncture-resistant containers or transport carts
- Appropriate size transport container
- Labeling as contaminated (biohazard), NOT patient ready
- Meets OSHA hazardous transport guidelines
- For OFFSITE transport in U.S., needs to meet D.O.T., state, local regulations.
- Containers must be processed
- Not hand carried

Leak Testing

- **Should** not use endoscopes that can not be leak tested
- Should regularly calibrate automated leak testers to verify the correct pressure output
- Should inspect manual and hand-held units for damage, leakage and correct pressure output
- Should verify each type of tester each day that endoscopes are used
  - Document results
- Wet leak testing – minimum observation of 60 seconds (not 30)
- Only water in the sink (no detergent)

MANUAL CLEANING



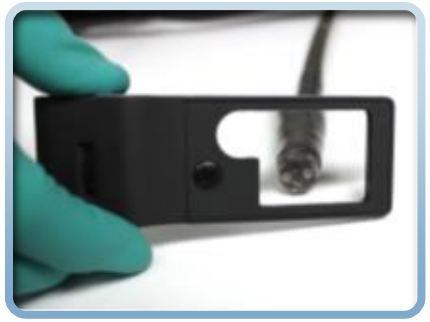
- Appropriate brushes – made for cleaning medical devices
  - Preferred single use
  - If not, processed in between each use
- Negative pressure air flow – DOORS REMAIN SHUT
- Dirty-to-clean workflow
- 4 ft. separation between sink and AER **AND** a barrier that extends 4 ft. above the sink if not 2 rooms
- All required cleaning adapters are used
- Monitor temperature of detergent solution
- Check dilution of detergent to water per the bottle

MANUAL CLEANING

- Limited access space.
- Separate hand hygiene space.
- Eye wash available within 10 seconds.
- Complete and appropriate PPE.
- Compatible automated processes.
- No clean supply storage.

INSPECTION POST CLEANING

- Every endoscopes is inspected
- Minimally gross visual inspection with unaided eye
- Recommended to use enhanced visual inspection (lighted magnification)
  - Allows items to be returned for additional cleaning if needed
  - Allows damaged items to be removed from service
- Do they inspect internally with a borescope?



Identifying High Risk Endoscopes

- Have an inventory of all endoscopes in the department
- Have high-risk scopes identified from that list

- High-risk = those associated with infectious outbreaks that are difficult to process and have increased risk Or those with complex design
- Duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes and as determined by the facility

Cleaning Verification Testing

- Make sure it's being done
- Ask what is the frequency?
- ST91:
  - Monitored all high-risk scopes with a cleaning verification test after each cleaning.
  - Monitor all non-high-risk endoscopes when new endoscopes are purchased and at established intervals (e.g., at a statistically significant frequency based on the number of procedures performed).
    - See Annex F, for statistical frequency determination.
    - Consider other factors: endoscope type, technician competency, procedural characteristics (e.g., duration, complexity, and heavy soiling), or delayed reprocessing.

HLD

- Is Manual Disinfection still being performed? (not recommended)
- Check the Process monitoring:
  - HLD soak time
  - Minimum effective concentration (test strips) for each cycle
  - Temperature
- Complete rinsing critical
- What water quality is being used
- Check filter changes
- Look at workflow and separation of space

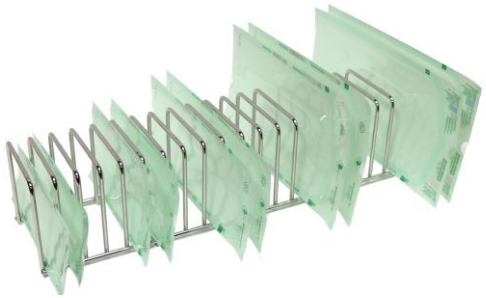
POST-HLD RINSING AND DRYING

- PPE used for cleaning was removed and hand hygiene took place.
- Complete rinsing – as per mfr. IFUs.
- Pay attention to IFU re: quality of rinse water.
- Drying area and beyond is dedicated clean space
- Is drying being performed post HLD?
- Is the drying process verified periodically?
- Post-HLD visual cues (i.e., tag on scopes in cabinet)
- Are single-use non-linting clothes used for drying?

CLEAN/STERILE TRANSPORT

- Containment intended to protect the device and minimize the chance of contamination
- Trays and carts
- Avoid excessive handling
- Anything dropping to the floor is considered contaminated
- Containers processed between uses?
- Gloves used for handling scopes?
- Are containers labeled clean?

Sterilization



- Automated process monitoring
- Physical, chemical, and biological indicators
- Complete documentation of sterilization cycle
- Check logs – Look for blanks
- Look at sterilizer printout – check temperatures and pressure

Class 5 Chemical Indicators

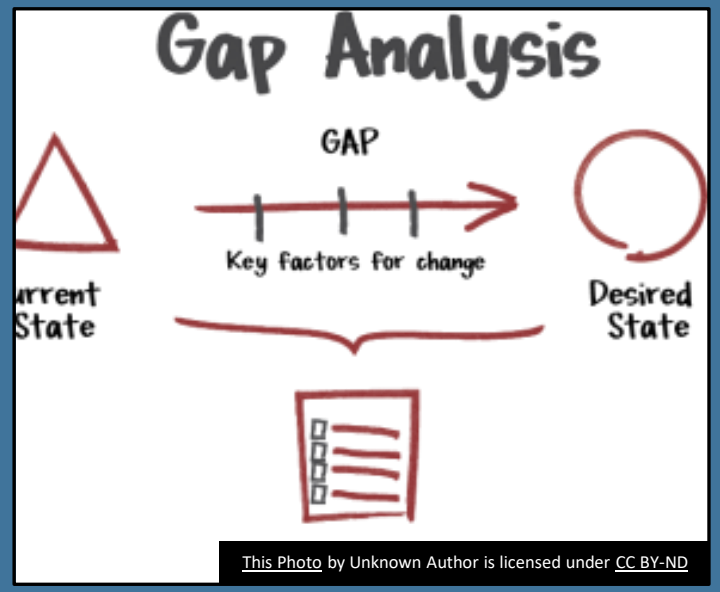
STORAGE

- POSITIVE pressure space – doors remain closed.
- Clean, protected (e.g. endoscope storage cabinets).
- Temperature/humidity controlled.
- Not randomly kept amongst equipment. and office supplies.
- No food or drink.
- Visual cues for items post-HLD.

What to do Next?

Develop Gap Analysis Audit Tool and Timelines

- Can use or modify available templates.
- Needs to pointedly be reflective of institution's written policies/procedures.
- "Basics" address P & P and assessment of:
  - Reprocessing steps
  - Reprocessing staff
  - Reprocessing equipment and supplies
  - Reprocessing OEM IFU readily available and followed
  - Adequate physical space and HVAC
  - Appropriate storage
  - Documentation
  - Traceability
  - AER validation
  - Frequency of Gap Analysis



What to use to Create Your Program: Audit Tools, Documents and Safety Alerts to Consider

CDC HICPAC: Essential Elements Document

- Perform periodic audits of facility reprocessing protocols and the completeness of documentation to monitor compliance. Gap analyses and risk assessments should be conducted periodically and whenever new endoscopes are purchased, manufacturer's IFUs change, and when changes occur in guidance from professional and regulatory organizations.

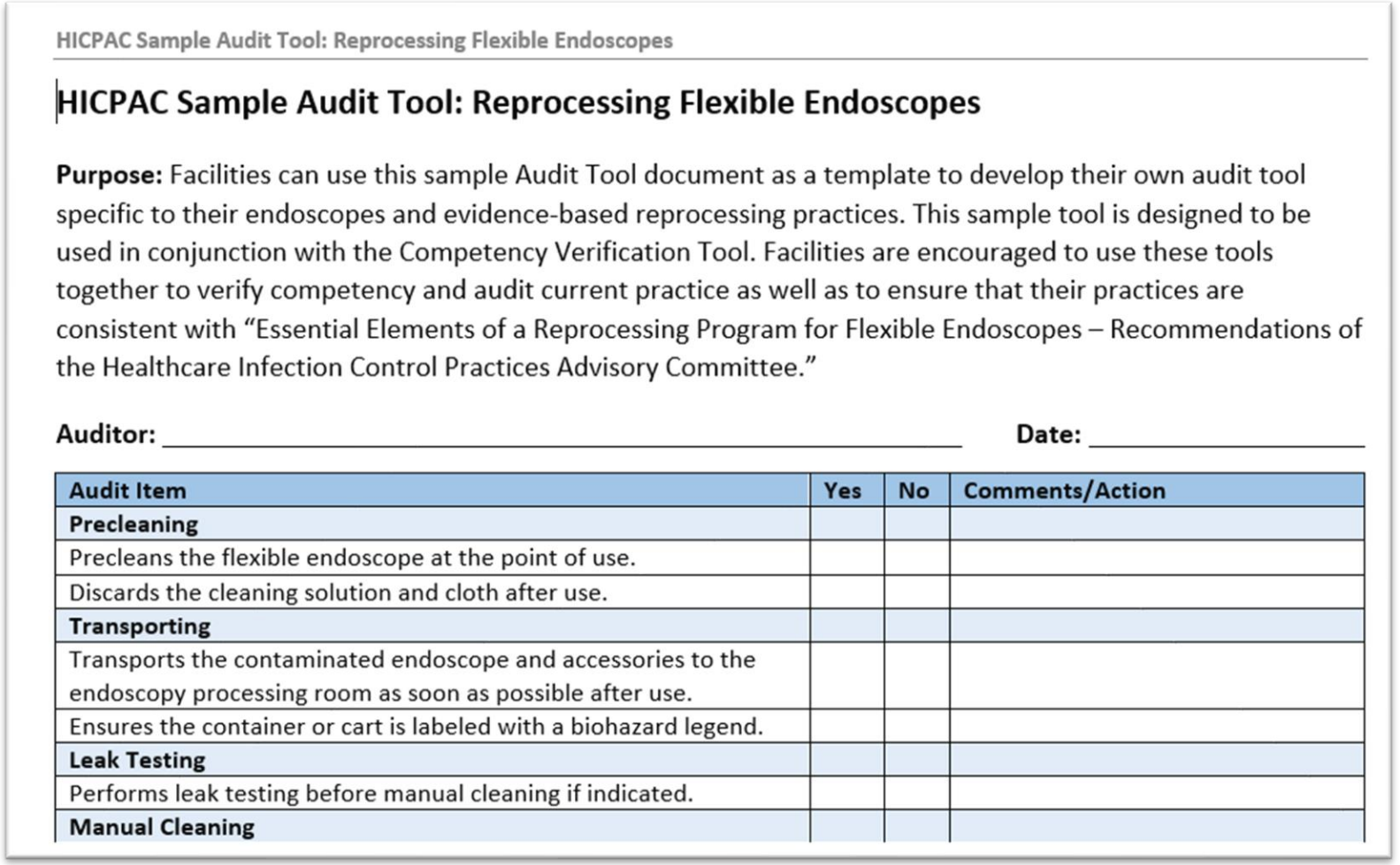
https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html

- Tools available:

  - Policy Template [DOC – 43 KB]
  - Audit Tool [DOC – 39 KB]
  - Competency Verification Tool [DOC – 68 KB]
  - Inventory and Repair and Maintenance Log [XLS – 53 KB]
  - Gap Analysis Tool [DOC – 48 KB]
  - Root Cause Analysis Template [DOC – 28 KB]

CDC HICPAC: Essential Elements Document – Audit Tool

- Audit tool:
  - https://www.cdc.gov/hicpac/pdf/FlexEndoReprocessing-AuditTool.docx



HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

Purpose: Facilities can use this sample Audit Tool document as a template to develop their own audit tool specific to their endoscopes and evidence-based reprocessing practices. This sample tool is designed to be used in conjunction with the Competency Verification Tool. Facilities are encouraged to use these tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee."

Auditor: _____ **Date:** _____

Audit Item	Yes	No	Comments/Action
Precleaning			
Precleans the flexible endoscope at the point of use.			
Discards the cleaning solution and cloth after use.			
Transporting			
Transports the contaminated endoscope and accessories to the endoscopy processing room as soon as possible after use.			
Ensures the container or cart is labeled with a biohazard legend.			
Leak Testing			
Performs leak testing before manual cleaning if indicated.			
Manual Cleaning			

AORN Audit Tool

- https://www.google.com/search?q=audit+endoscope+processing&rlz=1C1GCEU_enUS990US990&oq=audit+endoscope+processing&aqs=chrome..69i57j69i61.4188j1j15&sourceid=chrome&ie=UTF-8
- Word file that can be configured for your facility.

AORN Guideline Audit Tool: Processing Flexible Endoscopes

[Insert facility name or a header]

Audit Item	Yes	No	Comments/Action
Precleaning			
Precleans the flexible endoscope at the point of use.			
Uses a fresh cleaning solution.			
Washes the exterior surface of the endoscope with the cleaning solution and a soft, lint-free cloth or sponge.			
Places the distal end of the endoscope in the cleaning solution and suctions the cleaning solution through the endoscope.			
Suctions the cleaning solution through the suction and biopsy channels.			
Flushes the air, water, and other channels of the endoscope alternately with the cleaning solution and air, finishing with air.			
Discards the cleaning solution and cloth or sponge after use.			
Transporting			

Infection Control Assessment & Response (ICAR)

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has policies and procedures to ensure that reusable medical devices are cleaned and reprocessed appropriately prior to use on another patient. *Note: This includes clear delineation of responsibility among HCP for cleaning and disinfection of equipment including, non-critical equipment, mobile devices, and other electronics (e.g., point-of-care devices) that might not be reprocessed in a centralized reprocessing area.*	○ Yes ○ No	
B. The individual(s) in charge of infection prevention at the facility is consulted whenever new devices or products will be purchased or introduced to ensure implementation of appropriate reprocessing policies and procedures.	○ Yes ○ No	
C. HCP responsible for reprocessing reusable medical devices receive hands-on training on proper selection and use of PPE and recommended steps for reprocessing assigned devices: i. Upon hire, prior to being allowed to reprocess devices ii. Annually iii. When new devices are introduced or policies/procedures change. *Note: If device reprocessing is performed by contract personnel, facility should verify this is provided by contracting company.*	○ Yes ○ No ○ Yes ○ No ○ Yes ○ No	
D. HCP are required to demonstrate competency with reprocessing procedures (i.e., correct technique is observed by trainer) following each training.	○ Yes ○ No	

Tool intended to assist in the assessment of IC programs

https://www.cdc.gov/infectioncontrol/pdf/icar/outpatient.pdf

IPAC - Canada

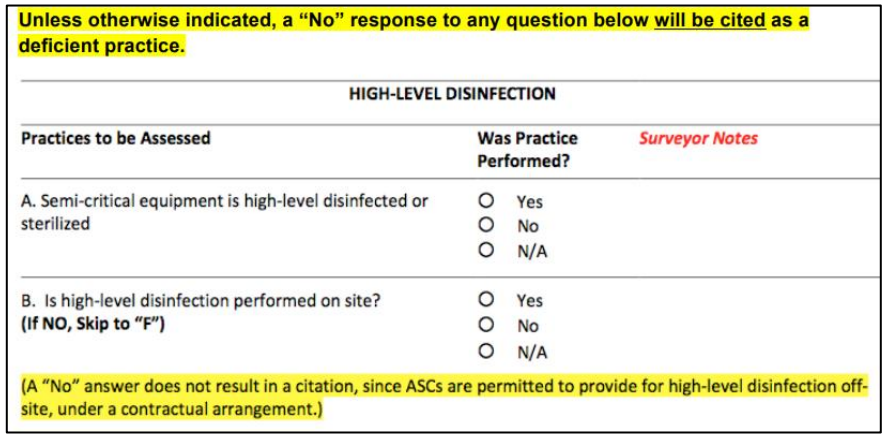
- Infection Prevention and Control Audit Form
- https://ipac-canada.org/photos/custom/OldSite/AuditToolkit/Tools/tools_Endoscopy.pdf
- This audit tool may be used by those who do Endoscopy, endoscope reprocessing or Infection Prevention and Control (IP&C), or as a joint tool by those in Endoscopy and IP&C.

INFECTION PREVENTION AND CONTROL AUDIT for Endoscopy

NOTE: See the **Table of Contents** for additional audit tools that expand on individual elements of these audit tools (e.g., Hand Hygiene, PPE, Routine Practices, Environmental Cleaning)

Element		Compliance			Deficiency Noted
		Yes	No	N/A	
1.0	**Policies and Procedures**				
1.1	The department maintains written infection prevention and control (IP&C) policies and procedures and reviews them at least annually				
1.2	Written procedures and instructions are readily available to reprocessing staff				
1.3	There are policies and procedures regarding the use of single-use medical equipment/devices				
1.4	There is a policy that prohibits the purchase of endoscopes that cannot be cleaned and reprocessed according to recommended standards				

ASQ Quality Collaboration



Unless otherwise indicated, a "No" response to any question below will be cited as a deficient practice.

HIGH-LEVEL DISINFECTION

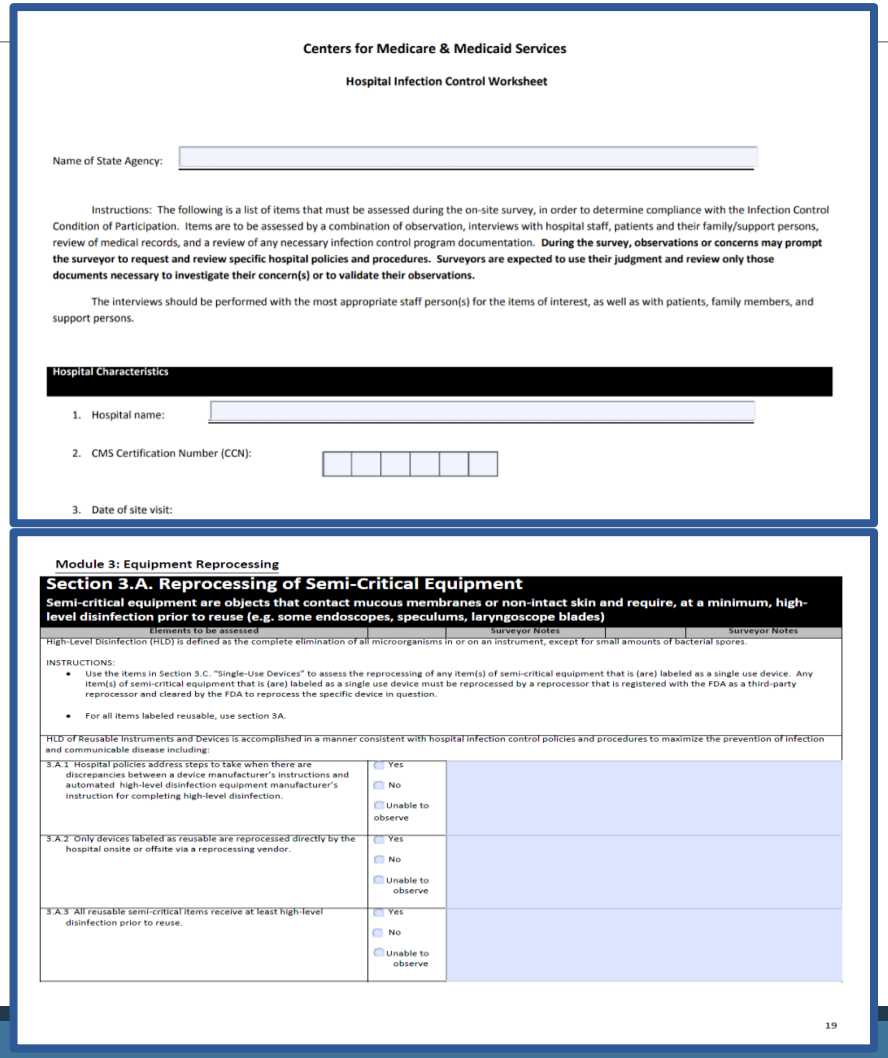
Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
A. Semi-critical equipment is high-level disinfected or sterilized	○ Yes ○ No ○ N/A	
B. Is high-level disinfection performed on site? **(If NO, Skip to "F")**	○ Yes ○ No ○ N/A	

(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.)

- **Endoscope Reprocessing: What CMS Surveyors Are Looking For**
- CMS surveyors use a worksheet to assess infection control practices during ASC surveys. The section of the worksheet used to assess practices surrounding the reprocessing of endoscopes is reproduced below. Because this is the SAME TOOL a CMS surveyor will use to assess practices associated with the reprocessing of endoscopes and accessories, it is also a useful SELFASSESSMENT tool for an ASC.

- https://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/1b34f1a1-0180-4005-9507-902fdf8f242e/UploadedImages/ASC_Quality_Collaboration/Documents/Endoscope_Reprocessing_-_What_CMS_Surveyors_Are_Looking_For.pdf

Consider converting existing Guidelines/Recommendations/Audits into your own Yes/No Document



Centers for Medicare & Medicaid Services

Hospital Infection Control Worksheet

Name of State Agency:

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 of Participation. Items are to be assessed by a combination of observation, interviews with hospital staff, patients and their family/support persons, review of medical records, and a review of any necessary infection control program documentation. **During the survey, observations or concerns may prompt the surveyor to request and review specific hospital policies and procedures. Surveyors are expected to use their judgment and review only those documents necessary to investigate their concern(s) or to validate their observations.**

The interviews should be performed with the most appropriate staff person(s) for the items of interest, as well as with patients, family members, and support persons.

Hospital Characteristics

1. Hospital name:
2. CMS Certification Number (CCN):
3. Date of site visit:

Module 3: Equipment Reprocessing

Section 3.A. Reprocessing of Semi-Critical Equipment

Semi-critical equipment are objects that contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse (e.g. some endoscopes, speculums, laryngoscope blades)

Elements to be assessed		Surveyor Notes	Surveyor Notes
High-Level Disinfection (HLD) is defined as the complete elimination of all microorganisms in or on an instrument, except for small amounts of bacterial spores. INSTRUCTIONS: • Use the items in Section 3.C. "Single-Use Devices" to assess the reprocessing of any item(s) of semi-critical equipment that is (are) labeled as a single use device. Any item(s) of semi-critical equipment that is (are) labeled as a single use device must be reprocessed by a reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. • For all items labeled reusable, use section 3A.			
HLD of Reusable Instruments and Devices is accomplished in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including:			
3.A.1 Hospital policies address steps to take when there are discrepancies between a device manufacturer's instructions and automated high-level disinfection equipment manufacturer's instruction for completing high-level disinfection.	☐ Yes ☐ No ☐ Unable to observe		
3.A.2 Only devices labeled as reusable are reprocessed directly by the hospital onsite or offsite via a reprocessing vendor.	☐ Yes ☐ No ☐ Unable to observe		
3.A.3 All reusable semi-critical items receive at least high-level disinfection prior to reuse.	☐ Yes ☐ No ☐ Unable to observe		

19

CMS.gov
Centers for Medicare & Medicaid Services

CMS Hospital Infection Control Worksheet – https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf

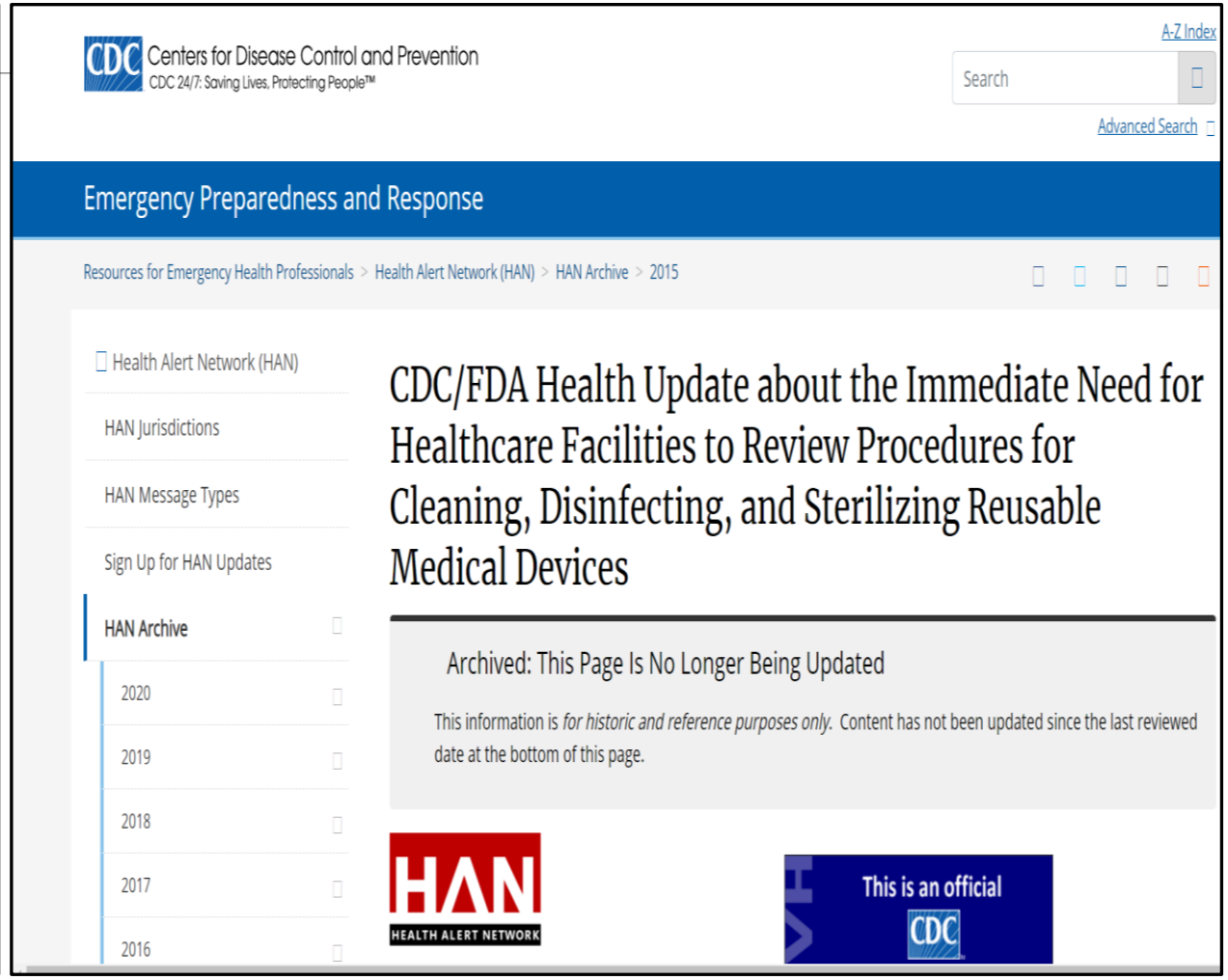
APIC recommendations

XIII - The health care organization's quality management program should evaluate the processing of flexible endoscopes.

- A multidisciplinary team that includes facility engineers, endoscopy processing personnel, infection preventionists, and other involved personnel should establish a policy to determine processes for monitoring and **auditing** facility water quality to ensure compliance with requirements for endoscope processing as specified in the endoscope, processing equipment, and processing products manufacturers' IFU.
- Water quality and water filtration systems should be assessed at established intervals and after major maintenance to the water supply system.

https://apic.org/Resource_/TinyMceFileManager/Implementation_Guides/10_AORNGuidelineProcessingFlexibleEndoscopes.pdf

This is, and has been, a dynamic process – stay connected and up-to-date



Infections Associated with Reprocessed Urological Endoscopes - Letter to Health Care Providers

Letters to Health Care Providers

April 1, 2021

The U.S. Food and Drug Administration (FDA) wants to raise awareness among health care providers, including those working in reprocessing units in health care facilities, about the risk of infections associated with reprocessed urological endoscopes, including cystoscopes, ureteroscopes, and cystourethroscopes, used for viewing and accessing the urinary tract. The FDA has received numerous Medical Device Reports (MDRs) which describe patient infections post procedure or other possible contamination issues associated with reprocessing these devices.

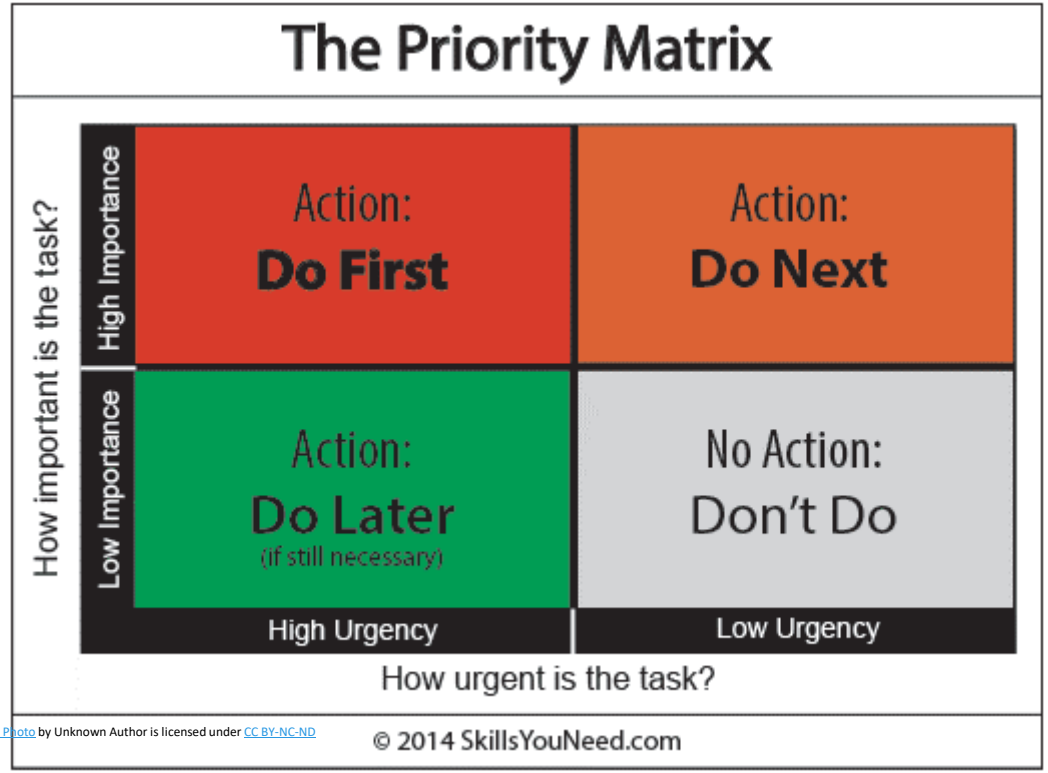
The FDA is currently investigating the potential causes and contributing factors associated with the reported infections and contamination issues. While some reports indicate

Content current as of:
04/01/2021

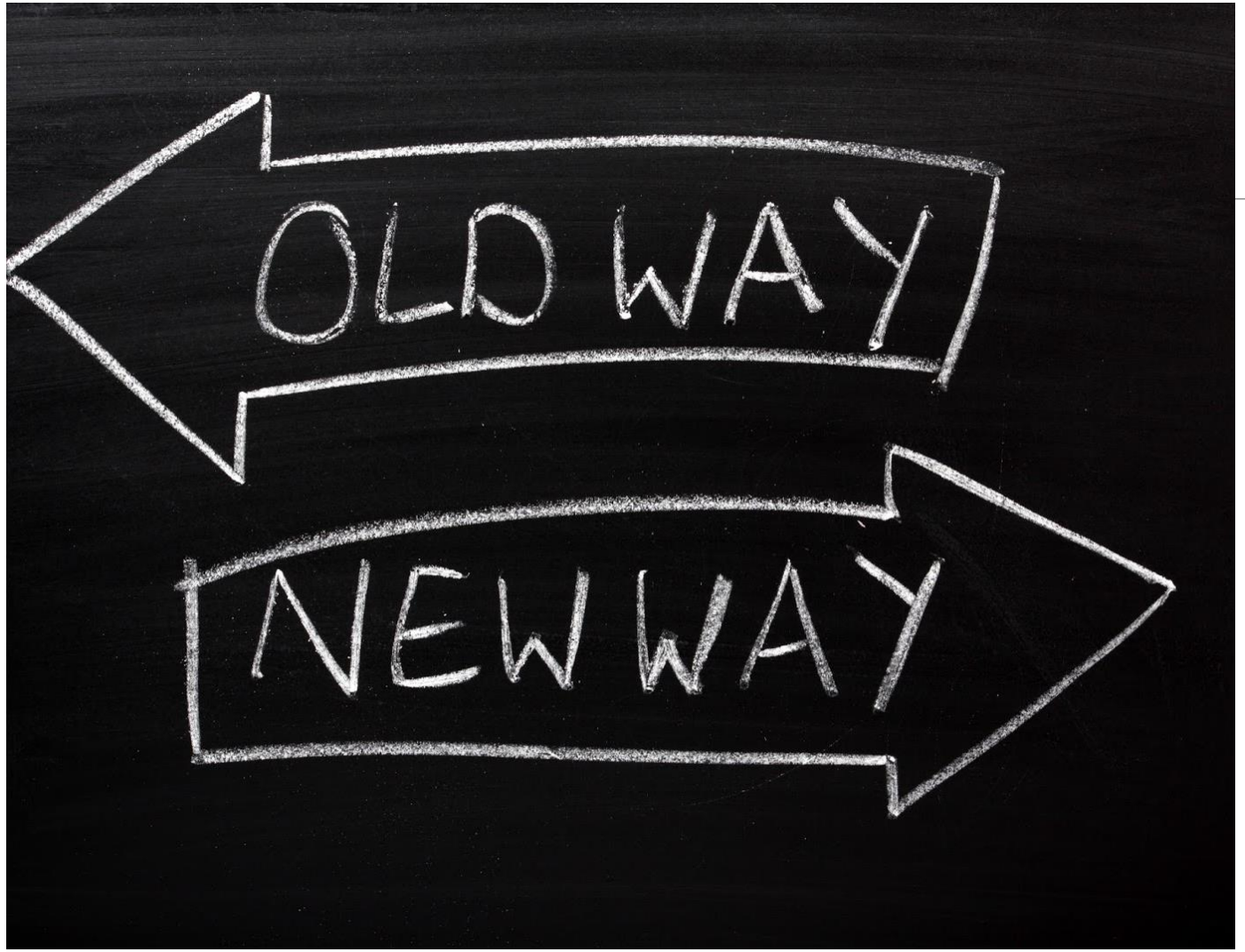
Regulated Product(s)
Medical Devices

Conducting Mock Tracers / Gap Analyses

Have	Hit	Identify	Ensure
Have multiple disciplines tour together.	Hit all areas that process reusable devices. • Common: CSPD, GI Endo., ORs, Respiratory, ICU, ED, Anesthesia, Urology, ENT, OB/GYN	Identify deficiencies in practice as compared to policies.	Ensure compliance with all current federal and local regulatory requirements, as well as applicable accrediting organizations.

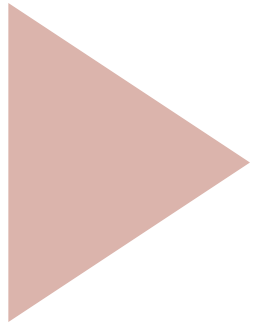


- Present and Analyze Results
  - Need ongoing relationship with and support of administration!
- Prioritize Issues
  - Can't/shouldn't do it all at once.



- Change/modify practices where needed
  - On the spot
  - Through policies
  - Through education
- Follow up Improvement Plans
  - Don’t assume changes are sustained.

Evaluate Actions



Conduct Regular Risk Assessments, Mock Tracers, Gap/Risk Analyses

AAMI ST90

Processing of health care products— Quality management systems for reprocessing

- This standard specifies the minimum requirements for a quality management system that can be used by healthcare organizations that process medical devices.

- It was developed to help healthcare professionals more effectively, efficiently, and consistently reprocess reusable medical devices in order to prevent infections, pyrogenic reactions, or other adverse events.

References

AAMI ST91: 2021

FDA MAUDE database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

And as noted on slides

Questions

Thank you!

MARY ANN DROSNOCK

DIRECTOR OF CLINICAL AFFAIRS

HEALTHMARK INDUSTRIES

MDROSNOCK@HMARK.COM