



CMS ASC Surveyor's Infection Control Worksheet (ICWS)

Updated 7/17/15

Marcia Patrick, MSN, RN ,CIC
Consultant and Educator
Surveyor, AAAHC

Objectives

- Understand the elements of infection prevention and control in the ambulatory settings surveyed by CMS.
- Identify common problems, gaps and practice deficiencies related to infection prevention detected via the ICWS.

Disclaimer

References to specific brands of products and supplies are for illustration only and do not represent an endorsement of the product the speaker



Locating the ICWS on the CMS Web Site

- CMS Home www.cms.gov
- Search "CMS ASC Infection Control Surveyor's Worksheet"
- Exhibit 351
- State Operations Manual

CMS Survey Outcomes



- No Deficiency
- Standard Level Deficiency
- Condition Level Deficiency
- Immediate Jeopardy

Terminology used in CMS ICWS

Includes instructions to surveyors regarding when/at what level to cite specific deficiencies

Updated Worksheet 7/17/15

- Primarily clarifies safe injection and multidose vial practices
- Clarifies cleaning, disinfection and sterilization practices and IUSS
- Adds environmental cleaning with an EPA-registered product
- It specifically **prohibits** false nails, extenders, etc. for those who touch patients

ICWS Part 1 – General Information

- Facility Name
- Location
- CMS Certification Number
- Year opened for operation
- Date of most recent federal survey
- Does ASC participate in Medicare via accredited “deemed” status?
- By: AAAHC; AAAASF; AOA; TJC

You will need to provide some of these details to the surveyor.

How are Your Services Provided?

	Contract	Employee	Other
Anesthesia			
Env Cleaning			
Linen			
Nursing			
Pharmacy			
Sterilization/ Reprocessing			
Waste Mgmt			

Infection Control Program: ICWS Required Elements

- Written IC program plan
- Qualified, licensed professional to direct the program
- Selection of nationally recognized guidelines
- Evidence of compliance with selected guidelines
- Surveillance system, including notifiable disease reporting per State requirements
- Staff education & training

National Guidelines

- Guideline for Isolation Precautions (CDC)
- Guideline for Hand Hygiene (CDC or WHO)
- Disinfection & Sterilization in Healthcare Settings (CDC, AORN)
- Environmental Infection Control in Healthcare Settings (CDC)
- Guidelines for Perioperative Practice (AORN)
- Specialty Guidelines (SGNA*, Ortho, etc.)
- Other (eye, pain, etc.)

Reminder: staff must have easy access to any guidelines you use and reference in the description of your facility program.

*Society of Gastroenterology Nurses and Assistants - sгна.org

How Many IC Hours per Week?

- On average, how many IC hours per week?
- Note: §416.51(b)(1) does **not** specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends **sufficient time on-site** directing the program, taking into consideration the size of the ASC and the volume of its surgical activity

What is Your System to Identify and Track Infections? What is Your Surveillance Method?

- ASC sends emails or survey forms to patient home post procedure
- ASC follows-up with primary care provider
- Physician/surgeon obtains infection information at post-op visit and notifies ASC
- ASC call patients post-op
- Others?
- Supporting documentation required



ICWS: Infection Control Staff Education



- **Frequently Asked Questions**
 - Does everyone need training?
 - How often must I provide education/in-services?
 - Who can I use for education program and product support? Are web-based programs acceptable?
 - Is it OK if I train my own employees even if I'm not an IP or experienced in infection control?
 - Does CMS approve programs?

Infection Control Education: CMS Documentation Requirement



- Is training documented?
- If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency **must** be cited in relation to 42 CFR 416.51(b) and (b)(3).
- If training is **completely absent**, then consideration should be given to **condition-level citation**, particularly when the ASC's practices fail to comply with infection control standards of practice

ICWS Part 2: Infection Control Practices

Surveyors are expected, as much as possible, to base their findings on observation. Staff interview and documentation review will also be included.

- Hand hygiene (including glove use)
- Proper use of PPE (bloodborne pathogens)
- Safe injection practices (including use of medication vials)
- Disinfection and sterilization
- Environmental infection control
- Safe use and handling of POC testing devices

Surveyor Observations

- The surveyor is required to examine more than just ASC documentation
- How many procedures were observed?
- Can the ASC refuse to allow the surveyor to observe in the OR?

ICWS: Hand Hygiene

What is the compliance in your ASC?



- Measured by observation, interview, both
- Soap, water and **ABHR readily accessible in appropriate locations**
- ABHR installed correctly 42 CFR 416.44(b)(5)
- Ongoing monitoring of hh compliance
- **Need more information on installation?**
- **See NFPA Life Safety Code®**



Gloves: Some Common Mistakes Seen in CMS Surveys

- Failure to clean hands before donning and after removing gloves
- Moving from patient to patient without changing gloves and cleaning hands
- Using ABHR on gloves (rather than changing gloves and using ABHR)
- Thinking double gloving protects against puncture injury
- Not having gloves accessible in locations where they are needed/used

ICWS: Safe Injection Practices are a Survey Priority!



- The surveyor will inspect injectable medications, saline, other infusates to make sure that:
 - Needles are used for only one patient
 - Syringes are used for only one patient
 - Medication vials are always entered with new needle and syringe
 - MDV labeled with expiration date 28 days after opening or mfr expiration date, whichever first

Injection Practices

The Surveyor Will Also Check:



- Single use vials used on only one patient
- Manufacturer pre-filled syringes used only on one patient
- Bags of IV solution used on only one patient- **not as a source of flush solution for multiple pts.**
- Medication administration tubing and connectors used on only one patient
- Med vials & IV ports swabbed prior to each entry, **even if unopened**

Reminder: if the product or device is labeled "single use" it CANNOT be used again

A Persistent Misconception – and Dangerous Practice!

- ➔ The lack of a needle does NOT make a syringe reusable. A safety syringe with a blunt cannula (tip) or a luer connector must be used only once
- ➔ A syringe is never protected against contamination by changing the needle or by using needleless systems

A Frequently Asked Question . . .

DO CMS & CDC Permit Incremental Dosing? Yes, *but only when . . .*

- Same syringe, same drug
- Required intraoperatively
- No opportunity to reuse with another patient
- Most common scenario: anesthesia, dentistry



Labeling Requirements are Strictly Enforced!

- ICWS: Medications that are pre-drawn are labeled with the time of draw, initials of the person drawing, medication name, strength and beyond use date and time (2015)



Reminder: There are NO acceptable “work arounds” or substitute practices to avoid using a label

ICWS: Inspection of Multi Dose Vials

- Multidose vials used on > 1 patient
 - Vial septum disinfected with alcohol before each entry
 - New needle and syringe used for each access
 - Vials are dated when first penetrated and discarded in 28 days or manufacturer’s expiration date, whichever comes first
 - Vials are not stored or accessed in immediate vicinity of the patient- if so, discard after use
 - **This includes OR and anesthesia carts (2015)**

Reminder: single dose and multi dose vials are not interchangeable. Drug cost/availability does not justify doing so

Surveyors Will Look in More Than One Place for Injection Safety Deficiencies

Important Reminders

- Per CDC, medications should be drawn up as close to the time of use as possible (USP 797: 1 hour)
- Do not “carry over” pre drawn syringes from one day to the next; discard at the end of the day
- Do not spike & prime IV bags & sets the day before they will be used (USP 797: 1 hour)
- NEVER use a bag of saline for flush solution on multiple patients
- NEVER combine the “leftover” contents in partially used vials

Sharps Disposal

- Sharps disposed of in puncture-resistant sharps containers
- Containers are replaced when fill line is reached
- NIOSH/OSHA: Mounted 52-56" from floor to slot for standing use
- Biohazard labeled
- Located at point of use



• <http://www.cdc.gov/niosh/docs/97-111/>

A Problem Prone Area in Many ASC Surveys!

ICWS: Disinfection and Sterilization

- Surveyors will observe CDS practices
- Precleaning must always be performed
- Surgical instruments (entering normally sterile sites or vascular system) must be sterilized
- High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as flexible endoscopes, laryngoscope blades, vaginal specula, etc.)

ICWS: Sterilized Items

- Appropriately maintained and handled throughout the process
- Stored in designated clean areas
- Temp and humidity monitored
- Packages inspected for integrity, reprocessed if not intact
- No "wet packs"



ICWS Precleaning: Often Incomplete or Incorrect

- Instruments are precleaned per manufacturer's or evidence-based guidelines
- Enzymatic cleaners often used
- Devices and instruments are inspected for residual soil and re-cleaned as necessary
- Proper cleaning tools are available, in good repair, e.g. scope brushes
- Appropriate PPE worn

Reminder: precleaning is essential because you cannot sterilize organic matter, debris or dirt!

When Instruments are Rinsed, is the Process Adequate?

- Adequate rinsing is NOT a “bird bath” technique! Use copious amounts of running water



Surveyors know the difference. Make sure your techs do too!

Sterilization of Instruments

Surveyors will look for documentation that shows . . .

- Each load monitored with **physical indicators** for time, temperature, pressure (printout)
- **Chemical indicator** used in each load
- **Biological indicator** run at least weekly and with each load containing implants
- **Documentation** maintained for each load for each piece of sterilizing equipment
- Equipment has routine **maintenance/preventive checks, documented**

Hint: if staff think the autoclave works more or less like a microwave, you are probably NOT ready for your next survey.

“Immediate Use” Sterilization

- **What will trigger a deficiency? What is NOT acceptable?**
 - Performed routinely
 - To avoid purchasing additional instruments
 - To minimize instrument processing times or for staff convenience
- **The surveyor will look for evidence of**
 - Performing IUS often or every load
 - Instruments are always or usually unwrapped
 - Instruments are steam sterilized in open trays or not contained/covered in any way

Reminder: an unwrapped instrument must be protected from the time it is removed from the sterilizer until it is delivered to the sterile field.

Short – Cycle Steam Sterilization

- Different from IUSS
- Sterilizer manufacturer has validated process
- Instrument manufacturer has validated process
- Container is designed and validated for process
- Mostly for small instruments
- 50% of eye facilities use short-cycle processes
- CMS is OK with this, **if** above conditions met

Eye World, March, 2015
<http://www.eyeworld.org/article-short-cycle-steam-sterilization-usage-permissible-in-ophthalmic-ascs>

Single Use Devices (SUDs)

- If reprocessed, the device is approved by FDA for reprocessing by a 3rd party
- Device is reprocessed by an FDA-approved reprocessor
- No ambulatory care facilities or ASCs have been approved by the FDA to reprocess

Reminder: if you are reprocessing any single use/ disposable items in your facility, you are not only in violation of CMS CfCs, you are violating FDA law

ICWS: High-Level Disinfection



- Semi-critical equipment is high-level disinfected
- Performed on site or via contract service
- Items are precleaned, inspected, recleaned if necessary
- Documentation (log) supports that processes are safe and accurate



ICWS: High-Level Disinfection



- HLD equipment is maintained per manufacturer's instructions
- AERs: Do NOT skip precleaning
- Make sure specific reprocessing protocols are in place for each type of scope that you use
- Documentation of preventive maintenance of AERs and scopes

Remember: ECRI* continues to rank cross-contamination from flexible endoscopes in the top 10 health technology hazards!

*Emergency Care Research Institute (ECRI)

ICWS: Chemicals in High Level Disinfection



- Prepared per manufacturer's instructions
- Tested for appropriate concentration per manufacturer's instructions (dipstick)
- Replaced according to manufacturer's instructions
- Documentation of above
- Neutralize chemical before discarding (EPA)

Remember: Adverse respiratory reactions and skin sensitivities have resulted from staff exposure to some HLD chemicals. Know the directions for use and warnings specific to the chemical you use.

High-Level Disinfection of Endoscopes

The surveyor will investigate . . .

- Scopes are soaked for length of time specified on product label
- If using AER, proper connectors are used
- Appropriate temperature is maintained
- Scopes are adequately dry before used again
- Scopes are correctly stored (per manufacturer directions)



Reminder: are **current** manufacturer instructions on file and available to staff if/when needed?

ICWS: Environmental Infection Control

- Surveyors will observe cleaning
- ORs cleaned with EPA-registered disinfectant between cases/procedures
- ORs terminally cleaned daily (includes endoscopy suites)
- Special attention to high-touch surfaces
- Procedure for cleaning gross blood spills

Reminder: if you are using a vendor for cleaning, including terminal cleaning of ORs, how do you assure that their services meet infection control standards?

Point of Care Testing Devices



- Most Common Example: **Blood Glucose Monitors**
- Labeled for multi-patient use
- New, auto-disabling lancet used each time
- Meter cleaned, disinfected after each use:
 - Follow manufacturer's instructions
 - If no instructions, cannot be used on > 1 patient
 - Disinfectant must be effective against HBV and HIV
 - Dilute bleach solution is also effective but may be too corrosive for some equipment.
- **ALCOHOL is NEVER an acceptable disinfectant in shared-use situations!**

ICWS Summary

- The ASC ICWS is an important survey tool in identifying actual and potential threats to patient safety
- Based on preliminary and recent findings, infection control practices in ASCs may be deficient and require rigorous attention and enforcement to protect ambulatory patients

References



- CDC Guideline for Sterilization & Disinfection in Healthcare Settings, 2008
 - <http://www.cdc.gov/hicpac/pubs.html>
- FDA. Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals. 8/14/2000. <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm107172.pdf>
- FDA. Reprocessing Medical Devices in Healthcare Settings: Validation Methods and Labeling Guidance for Industry and FDA Staff . March 17, 2015. <http://www.fda.gov/MedicalDevices/default.htm>

References

- FDA Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data Attachment 1. List of SUDS Known to be Reprocessed or Considered for Reprocessing <http://www.fda.gov/RegulatoryInformation/Guidances/ucm107164.htm>
- AORN Guidelines for Perioperative Practice, 2016. www.aorn.org
- Multi-society Position paper on Immediate Use Steam Sterilization at: www.apic.org

References

- Joint Commission FAQs. Laryngoscopes – Blades and Handles - How to clean, disinfect and store these devices. Oct. 11, 2013
http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=508&StandardsFAQChapterId=69
- American Academy of Ophthalmology. *Infection Prevention in Eye Care Services and Operating Areas and Operating Rooms*, Aug. 2012
 - <http://www.aao.org/clinical-statement/infection-prevention-in-eye-care-services-operating>

References

- American Society of Cataract & Refractive Surgery (ACRS)
- American Academy of Ophthalmology (AAO)
- Outpatient Ophthalmic Surgery Society (OOSS)
- Recommendations Regarding Use of Enzyme Detergent For Cleaning Intraocular Surgical Instruments

AAMI Standards for High Level Disinfection and Sterilization in Health Care Settings

- Association for the Advancement of Medical Instrumentation
- *Sterilization Pt 1: Sterilization in Health Care Facilities, 2015 ed.* - includes 14 AAMI sterilization standards & documents for health care facilities, incl. ST79.
 - ST79: ANSI/AAMI *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*
 - ST58 High-Level Disinfection
 - ST55 Desktop Sterilizers
 - ST40-2004(R 2010) Dry Heat Sterilization
 - ST91 Flexible and Semi-rigid Endoscope Processing in Health Care Facilities, 2015



Resources

- **AORN** (Association of periOperative Registered Nurses) at www.aorn.org
- **CDC HICPAC** Guidelines for Healthcare Facilities at <http://www.cdc.gov/hicpac/pubs.html>
- **APIC** Practice Guidance and Topic-Specific Infection Prevention sections at <http://www.apic.org>
- **OSAP** (Organization for Safety, Asepsis and Prevention) (Dentistry) <http://www.osap.org/>

Questions?



marcia.patrickip@gmail.com
