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Introduction

Based on data collected during surveys and reviews from January – December 31, 2014, The Joint Commission identified five areas where healthcare facilities most frequently fell out of compliance. One of those areas was the organization's **ability to reduce the risk of infections associated with medical equipment, devices, and supplies**. Here is a summary of the 2014 statistics¹:

NON-COMPLIANCE % FACILITY TYPE

52%	Hospitals
41%	Ambulatory Care
51%	Critical Access Hospitals
39%	Office Based Surgery

In an August 2014 Infection Control Today article, author Kelly M. Pyrek commented,

"When you read through that Joint Commission communication, much of it can be ascribed to lack of education. In CS, we are trained how to do things the right way and I truly believe that the errors that were made were not intentional, but due to a lack of education and training." 2

To get those non-compliance numbers down, multiple regulatory agencies consistently emphasize three recommendations that all facilities should be following. Following these recommendations will help to minimize a patient's risk of surgical site infections from improperly reprocessed surgical instruments and devices.





Recommendation 1

Adherence to Manufacturers' IFUs

Every healthcare regulatory agency recommends or requires strict adherence to a Manufacturers' Instructions for Use (IFUs), including The Joint Commission, AAMI, CDC, Centers for Medicare and Medicaid, AORN, and the FDA.

IFUs are important because:

- ♦ Improperly processed instruments have been linked to patient injury
- ♦ The manufacturer, in accordance with FDA and AAMI guidelines, is required to validate the steps necessary to prepare a device for safe patient use

The Joint Commission now requires that, during an audit, Central Sterile Supply Departments show current manufacturers' IFUs as well as how they are used. The Centers for Medicare and Medicaid also check for the presence of manufacturers' IFUs on the Infection Control Surveyor worksheet.3

Recommendation 1: Adherence to Manufacturers' IFUs

Tips for Success

- Consider designating a seasoned staff member to be responsible for managing, updating, and educating staff on changes to manufacturers' IFU documentation at the facility.
- Use an online database service of manufacturers' IFU documents such as oneSOURCE.
- Contact your device manufacturer and request additional in-servicing and training.
- ♦ Engage your facility's Infection Preventionist to help identify and champion the department's needs.

Following the manufacturers' IFUs is key to delivering a safe product for surgery and can be a big step toward improving patient safety. In order to impress this significant fact on your staff, incorporate the message into the department's culture in an ongoing manner.

"If manufacturers' instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the ASC's practices should be cited as a violation of 42 CFR 416.51(a)." - CMS, 2009 ⁴





Recommendation 2

On-Going Staff Training

Following an October 2011 FDA and AAMI Summit conference, AAMI published a report entitled, "10 Things Your Organization Can Do Now to Improve Reprocessing." Number nine on the list is staff training. The message is to train, train, and retrain. The amount of knowledge a CSSD technician needs to have to do his or her job effectively has become so overwhelming; the first job skill needed is the ability to exercise critical thinking and judgment.

Hiring competent individuals is step one. Additionally, regulatory agencies are moving in the direction of recommending CSSD technicians be board certified (although

this is not yet a requirement in most states). AAMI ST79 recommends all personnel be required to successfully complete a sterile processing certification examination within two years of employment and maintain that certification as a condition for continued employment.⁵

With the continuous technological advancements of medical devices and instruments, beyond the topic of certification, on-going staff training is a constant challenge. Making sure competencies are completed and documented annually, at a minimum, can be incredibly effective in ensuring an educated and informed staff.

Recommendation 2: On-Going Staff Training

Tips for Success

- ♦ Observe staff firsthand periodically, in addition to annual competencies
- ♦ Have a different staff member choose one competency to review for the team at every staff meeting
- ♦ Provide learning opportunities on all shifts
- ♦ If you do not have an automated instrument management system, consider implementing one that offers a competency module. Features to look for in a competency management software product include:
 - Provides a tool for managing training, certification, or competency requirements for employees
 - Restricts access within the system for a technician to perform tasks if they have not completed the required competency
 - Allows a competency requirement to be set up to control access to workflow processes for assets or asset groupings
 - Offers access to comprehensive reports including:
 - Competency Record The complete competency training record for each technician
 - Competency Warning Log A list of warnings issued to technicians who lacked a competency required to access a function

Recommendation 3

Continuous Auditing and Review

Number 10 on AAMI's report "10 Things Your Organization Can Do Now to Improve Reprocessing" is "Assessment." Successful CSSD leaders routinely check for compliance. A CDC Health Advisory issued Sept. 11, 2015 specifies the following for auditing in the CSSD area:

- Healthcare facilities should regularly audit (monitor and document) adherence to cleaning, disinfection, sterilization, and device storage procedures. Audits should assess all reprocessing steps, including:
 - Performing prompt cleaning after use, prior to disinfection or sterilization procedures
 - Using disinfectants in accordance with manufacturers' instructions (e.g., dilution, contact time, storage, shelf-life)
 - Monitoring sterilizer performance (e.g., use of chemical and biological indicators, read-outs of sterilizer cycle parameters, appropriate record keeping)
 - Monitoring automated endoscope reprocessor performance (e.g., print out of flow rate, time, and temperature, use of chemical indicators for monitoring high-level disinfectant concentration)
- ♦ Audits should be conducted in all areas of the facility where reprocessing occurs.
- ♦ Healthcare facilities should provide feedback from audits to personnel regarding their adherence to cleaning, disinfection, and sterilization procedures.⁶

Recommendation 3: Continuous Auditing and Review *Tips for Success*

Successful department leaders work to be in a constant state of readiness for regulatory agency surveys. Conducting audits to assess staff compliance to policies and procedures is a key component to being prepared for the next survey. When it comes to auditing practices, keep the following in mind:

- Stay on top of regulatory requirements—appoint a CSSD subject matter expert to stay on top of regulatory literature and communicate changes in practice to staff.
- Conduct planned but unannounced mock audits. (Make sure to audit all shifts.)
- ♦ If the department uses an automated instrument management system, use available data analytics to help pinpoint areas to audit and evaluate quality initiative results.
 - Productivity reports identify processing activity by technician and activity type
 - Out-of-Sequence Warning reports can help target possible areas of concern that may need to be assessed.
- ♦ Document quality initiative actions and outcomes in addition to audit findings.
- Seek out staff input to determine possible solutions to identified problems.

"Mock audits should be conducted routinely (e.g., annually) by a multidisciplinary team that includes OR, sterile processing, and infection prevention and control representatives." - Rose E. Seavy 7



Why Training Matters

While there is no guaranteed process for ensuring success in the sterile processing world, effective staff training still plays a critical role in infection prevention. Make on-going staff training a department priority and continue to fine-tune what tactics and approaches work best for your employees.

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