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Strategies for Optimizing Compliance with Manufacturers' Instructions for Use

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LEARNING OBJECTIVES

1. Discuss the importance of following manufacturers' instructions for use
2. Explore methods to help ensure compliance with instructions for use
3. Review how leveraging technology can ensure compliance with instructions for use

When surveyors visit Sterile Processing departments (SPDs), they inspect the processes to ensure team members are following manufacturers' instructions for use (IFU). Often, when team members are decontaminating instruments, the surveyor will quiz the technician on their knowledge. Sterile Processing (SP) leaders have trained their staff to go online and pull up IFU to show the surveyor and to demonstrate compliance with the IFU. Decontamination and assembly area walls are often covered in posters and signage that outlines steps for difficult-to-process instruments. Technicians may ask why so much focus and attention are placed on IFU, and why they matter.

SP professionals should ensure that IFU are being consistently followed every day and not just something when a surveyor is in the building. This lesson will address how IFU can be operationalized into SPDs to ensure instruments are processed safely and properly to ensure a clean functioning instrument for every patient.

Objective 1: Discuss the importance of following manufacturers' instructions for use

The US Food and Drug Administration (FDA) requires devices intended to be sterilized by the user before use to be properly labeled – with adequate information for a suitable method of sterilization and precautions or safeguards to be followed. This includes special cleaning methods required; changes in physical characteristics of the device that may result from reprocessing, which affect its safety, effectiveness or performance; and limits on the number of times resterilization and reuse can be done without affecting the safety or effectiveness of the device. The FDA requires manufactures of reusable medical devices to have labeling that bears adequate directions for use, including instructions on preparing a device for use. The labeling should include materials and equipment and parameters to adequately process devices. Device manufacturers must perform testing to demonstrate that the reprocessing instructions are validated,

complete and understandable, and can reasonably be implemented by the user.

AAMI TIR12, *Designing, testing and labeling reusable medical devices for reprocessing in healthcare settings: A guide for medical device manufactures*, AAMI TIR30, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*, and AAMI/ANSI ST81, *Sterilization of medical devices – Information to be provided by the manufacture for the processing of resterilizable medical devices*, are excellent references for additional information on what manufacturers are required by the FDA to provide to the end users in labeling and IFU.

According to the FDA, end users (SP technicians) are responsible for following the validated reprocessing instructions in the device labeling. End users are required to ensure they have the needed facilities and equipment, and easy access to manufacturer-specified cleaning and disinfection agents, and sterilization methods to implement the instructions. End users must also ensure that the instructions are followed.

Over the past several years, innovation has exponentially exploded in the surgical field. Devices are becoming highly complex in design and more difficult to process. This innovation growth has outpaced SPDs in terms of volume, competency, and process innovation. This disconnect has led to several device failures, surgical site infections (SSIs) and significant regulatory compliance issues nationwide. According to the Joint Commission, "each patient care item has its own IFU for cleaning and disinfection and the expectation is that the organization will follow these instructions. Failure to follow such instructions for use creates significant risk to safe, quality care." SPDs are being surveyed thoroughly to ensure surgical instruments are safe to use and are expected by regulatory agencies to follow manufacturers' IFU. Unfortunately, departments continue to struggle with compliance and need to implement processes and educational systems to ensure IFU and processes are consistently followed to safety process instruments every day.

Failing to process instruments in accordance with the methods that the device manufacture validated (and the FDA approved) puts patients at risk for device failure and infections from improperly-cleaned devices. Failure to follow IFU causes patient harm.

Objective 2: Explore methods to help ensure compliance with instructions for use

Many organizations have moved to online database repositories to hold their manufacturers' IFU. These repositories can serve as a safety net when a surveyor asks SP professionals to show the IFU. Technicians can quickly pull the IFU from the database, provide it to the surveyor, and then demonstrate that they are following the indicated steps, as listed in the document.

Instrument specialists should periodically perform self-audits to help ensure proficiency. Self-audits should include questions such as:

- Do you typically perform all the steps listed?
- Do you time your soaking, brushing, flushing and sonication steps as required by most device manufacturers?
- Are your decontamination chemicals approved by the device manufacturer?
- Do your washer parameters match those listed in the document?
- Are your instruments lubricated with the proper lubricant or not lubricated as required?
- Are all the inspection steps completed in the assembly area, including insulation testing or other inspection steps defined by the device manufacturer?
- Do all the instruments on your tray have the same cleaning steps and sterilization parameters?
- Do your sterilization parameters meet the requirements from the device manufacturer?
- Does the device manufacturer limit the number of uses or reprocessing cycles? If so, are you tracking the utilization?

Although database repository systems provide easy access to IFU, they are not the final solution. IFU must be available but they also must be operationalized. In day-to-day reprocessing, technicians must be able to follow the instructions from every device manufacturer for every instrument, every time. This is a daunting expectation given the complexity of instruments and sheer volume of different manufacturers and devices in a typical SPD.

Some common tactics for operationalizing IFU include using wall charts, flip books and competencies. For highly complex, difficult-to-process, specialized instrumentation, the device manufacturer will often provide a wipeable wallchart to position over the reprocessing area. Flexible endoscopes, robotic instrumentation, and power equipment are excellent examples of when these wall charts can be useful. Wall charts with step-by-step reprocessing instructions can be located over the sinks and assembly workstations, giving the technician a direct view of the process, step by step, to improve compliance with the reprocessing instructions. In organizations with computers at sinks and workstations, the wall charts can be added to the instrument tracking system to display when the tray is scanned or pulled up from a search bar. It's important to note that in large

departments, technicians can process thousands of types of instrumentations. There is not enough wall space for all the IFU to be displayed. Large amounts of wall charts quickly become overwhelming and ineffective.

For complex, difficult-to-process instruments like flexible endoscopes, robotic instruments, power equipment, vendor trays, and laparoscopic instruments, to name a few, organizations will typically provide staff training and competencies to ensure employees are trained and validated to process the instruments. This process typically has multiple modalities of training and competency verification. For example, an educator from the device manufacturer educates the SP staff on how to clean, inspect and sterilize the instruments following the IFU. After training, the team is given a copy of the IFU to read and a quiz to verify that they understood the process. After the knowledge-based competency is completed, an SP educator or subject matter expert (SME) will complete a direct observation competency for each technician to confirm they are able to operationalize the process effectively. This process is followed for new instruments before they are put into service, and for complex instruments, either biannually or annually. This is an effective system for elevating the knowledge and abilities of SP technicians; however, it does not solve the problem of how to operationalize IFU.

SPDs process thousands of types of instruments and they typically are unable to complete effective inservicing, training and competencies on each type of instrument. Competency validation alone does not ensure SP technicians are able to memorize the steps and follow the steps precisely every time. Process drift often occurs, and processes become further and further from the validated, safe and effective methods of instrument processing. Organizations may mitigate the risk of failing to follow IFU by implementing online database repositories, wall charts and training systems; however, these systems are not 100% effective because of process drift and the pure volume and complexity of instruments coming through the SPD. These systems may help pass a survey successfully and are good systems to put in place, but they are not enough to ensure that instruments are functional and safe to use on every patient. More can be done.

Objective 3: Review how leveraging technology can ensure compliance with instructions for use

Manufacturers' IFU can change over time. Devices can come to market with a validated process, but because of manufacturing changes or new information identified by the manufacturer or the FDA, manufacturers may conduct new validation testing and update the manufacturer's IFU. What this means for SP professionals is that they must not only implement the process when the new device comes into the organization but also have a process in place for updating the process if the IFU changes. If the organization uses an online database repository for IFU maintained by a third-party vendor, the SPD should ensure the database stays current. The department should have a policy in place to check IFU for updates, and a process to ensure the IFU changes are operationalized.

Manufacturers' IFU should be current and easily accessible at the point of processing. IFU should be available at decontamination sinks to ensure all cleaning processes are timed and followed exactly as required. IFU should also be at the assembly workstations to ensure all inspection steps and approved packaging methods are followed. Additionally, manufacturers' IFU should be accessible at sterilization and high-level disinfection (HLD) locations to ensure all weight restrictions and parameters are validated and approved to ensure HLD or sterilization are achieved as required by the device manufacture. By leveraging technology, the IFU can be operationalized every time.

Instrument tracking systems have the capability to integrate with IFU. The instructions can be manually uploaded or integrated to ensure they are tied to each device in the system. Timers can be set for each IFU in the tracking system to trigger the department to check for updates to the IFU. Instrument tracking systems are capable of having workflows built into the system to follow the IFU exactly. When an instrument tray is scanned in the decontamination area, the workflow can take the technician through all the steps required by the device manufacture and ensure all the steps are documented. On the assembly side, a workflow can trigger a borescope inspection or insulation test, if required by the device manufacture. Instruments and trays can be set with only the validated sterilization parameters allowed to ensure instruments are always sterilized on the appropriate cycle and with a biological indicator, if required. Weight limits can be added to sterilization cycles to match the sterilizer manufacturer's IFU. Advanced systems can integrate IFU with the tracking system to create an automated workflow, matching the IFU precisely.

Leveraging instrument tracking systems to operationalize IFU can build the path to compliance and reduce the risk of patient harm; however, a competency process and audit process are still needed to ensure technicians are not drifting from the proper processes. Instrument tracking systems can be set

with competencies for instruments. If an employee attempts to process a tray for which they have not completed a competency, the system will not allow them to proceed. The system will trigger an SME to complete a direct observation competency and approve them to process the instrument. The system can require multiple direct observations or a repeat of the direct observation at a time interval for the SP technician to continue to process the instrument. For example, for a flexible endoscope, a new employee may have to process it five times with an SME's direct observation before being able to process it on their own. Then the system can be set to require a SME's direct observation every six months to ensure competency is maintained and the process stays consistent.

An effective routine auditing process will ensure there is no process drift. Instrument specialists can and should self-audit routinely; however, proactive auditing should be performed routinely on high-risk instrumentation. For example, shavers should be routinely audited to ensure the channels are being cleaned in strict accordance with the device manufacturer's requirements and the borescope inspection is completed, if required. Instrument tracking systems can be leveraged to set up routine audits. A high-risk tray can be set to trigger a check after each processing cycle in extreme cases or after every five reprocessing cycles, for example. The organization will have to evaluate the risk and set a frequency. The audits should be used as a routine process monitoring system to ensure there is no process drift and to quickly implement remedial interventions if manufacturers' IFU are not being followed.

Conclusion

By leveraging technology, it becomes possible to effectively operationalize IFU. An effective system can ensure current IFU are built into operational workflows. Competencies can be integrated into the system to ensure all staff are trained and current on the required processes. Proactive auditing can also be integrated to ensure the implemented process continues to be consistently followed.

RESOURCES

1. US Food and Drug Administration. Labeling-Regulatory Requirements for Medical Devices (FDA 89-4203) https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling.

2. US Food and Drug Administration. Final Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling https://www.fda.gov/media/80265/download.

3. Association for the Advancement of Medical Instrumentation. AAMI TIR12, *Designing, testing and labeling reusable medical devices for reprocessing in healthcare settings: A guide for medical device manufacturers.*

4. Association for the Advancement of Medical Instrumentation. AAMI TIR30, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical device*s.

5. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST81, *Sterilization of medical devices* – Information to be provided by the manufacturer for the processing of resterilizable medical devices.

6. The Joint Commission. *Manufacturer Instructions for Use – Expectations Regarding Access to IFU for Medical Instruments and Devices.*

CIS Self-Study Lesson Plan Quiz - Strategies for Optimizing Compliance with Manufacturers' Instructions for Use

Lesson No. CIS 282 (Instrument Continuing Education - ICE) • Lesson expires November 2023

1. Which regulatory agency requires device manufacturers to provide instructions for use?
   a. US Food and Drug Administration
   b. Association for the Advancement of Medical Instrumentation
   c. US Environmental Protection Agency
   d. Centers for Disease Control and Prevention

2. Which of the following are required by the US Food and Drug Administration to be provided on a manufacturer's instructions for use?
   a. Special cleaning methods required
   b. Changes in physical characteristics of the device that may result from reprocessing, which affect its safety, effectiveness or performance
   c. Limits on the number of times resterilization and reuse can be performed without affecting the safety or effectiveness of the device
   d. All the above

3. Device manufacturers are responsible for following the validated reprocessing instructions in the device labeling.
   a. True
   b. False

4. A Sterile Processing department's failure to follow manufacturers' instructions for use creates:
   a. Risk to quality care
   b. An increased risk for infection
   c. An increased risk for device failure
   d. All the above

5. When implementing new devices, organizations should ensure:
   a. All required processing equipment is available
   b. Access to the US Food and Drug Administration labeling document
   c. Access to AAMI TIR12
   d. All the above

6. Manufacturer instructions for use are provided when a new device is purchased. Once the device is in place – with the instructions for use operationalized – the instructions should be updated:
   a. Every six months
   b. After a device failure
   c. Per facility policy
   d. The instructions for use do not need updating

7. Online database repositories are sufficient in and of themselves to:
   a. Provide instructions for use for every device approved by the US Food and Drug Administration
   b. Help ensure compliance with reprocessing steps for complex devices
   c. Ensure technical competency
   d. All the above

8. An effective system for operationalizing instructions for use should contain which of the following characteristics?
   a. Accessibility at the point of processing
   b. System for updating instructions for use
   c. Competency process
   d. All the above

9. By integrating instructions for use into instrument tracking workflows, departments can improve compliance with operationalizing the instructions.
   a. True
   b. False

10. Sterile Processing technicians are responsible for following the validated reprocessing instructions in the device labeling.
   a. True
   b. False

11. Direct observation competency should be performed to:
   a. Ensure the appropriate equipment is available
   b. Verify the third-party vendor has the appropriate instructions for use
   c. Ensure technicians can perform the process correctly
   d. Avoid the use of wall charts

12. AAMI TIR12 is:
   a. A guideline for the medical device manufacturer
   b. A standard that healthcare facilities should follow
   c. A resource for healthcare facilities that resterilize single-use devices
   d. None of the above

13. Leveraging tracking systems to operationalize instructions for use:
   a. Shortens the processing time
   b. Will alert the technician if a process is performed incorrectly
   c. Can reduce the risk of patient harm
   d. All the above

14. Performing routine audits:
   a. Ensures compliance with surveying agencies
   b. Is unnecessary if observational competencies are performed
   c. Is a requirement of the US Food and Drug Administration
   d. Helps ensure there is no process drift

15. According to the Joint Commission, each item has its own validated instructions for use for cleaning and disinfecting. These instructions:
   a. Should be posted in a centralized location
   b. Should be the basis of competencies that are performed at least annually
   c. Should be consistently followed by every organization
   d. All the above

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