The importance of IFU for sterile processing quality management

by Michele McKinley, LVN, CRCST and Richard Schule, MBA, BS, CST, CRCST, CHMMC, FCS

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NSI/ASQ/ISO 9001:2008 provides a model for quality management that has been used in dozens of healthcare facilities and departments across North America. Facilities that have implemented a quality model such as ISO 9001 have gained many advantages, including a better understanding of what to do and how to do it and an ability to assure that their work meets requirements. Applying this model has also provided the ability to react faster and to adjust processes when results are not meeting specified requirements, and the ability to develop and acquire resources to help solve problems. From an organizational perspective, the ISO 9001 model has also yielded an understanding of how to communicate problems in a nonthreatening way by focusing on process issues, and has provided a nurturing working environment in which staff is not blamed for issues that can only be resolved by management.

Under this model, there are eight quality management elements that can help to guide your organization toward improved performance: customer focus; leadership; involvement of staff; process approach; system approach to management; continual improvement; factual approach to decision-making; and mutually beneficial supplier relationships.

As an integral part of the staff involvement, process approach and continual improvement elements, a sound quality management system also requires the collecting and archiving of product instructions for use (IFU) and the use of IFU for educating staff and auditing departmental processes. Unlike the user’s manual for your television or coffee maker, these documents are extremely thorough and detailed because they have a direct impact on the health of human beings.

Collecting, reviewing and archiving IFU

The U.S. Food and Drug Administration’s 510(k) and pre-market approval (PMA) guidance documents for medical devices require manufacturers to document re-processing instructions for the user. The requirement includes:

- Detailed cleaning instructions, including disassembly
- Detailed disinfection and sterilization instructions with specific sterilization parameters
- Expected end of life and how this can be determined by the user
- Roles and responsibilities
- 21CFR 820.30 Design Controls
- 21CFR 820.70 Production and Process Controls
- 21 CFR 820.75 Process Validation

Manufacturers of products must provide cleared labeling for all medical devices intended for patient care. These documents should include, but not be limited to IFU, cleaning, sterilization, and preventative maintenance instructions. (Figure 1)

IFU are typically packed with new items and should be removed from the packaging and saved in some type of archive or file for staff reference. They may be needed in the future to provide the necessary information for training on the device, equipment repairs, or for purchasing replacement parts, for example.

Methods of storage should be organized for easy access. For example, IFU can be stored in a system of filing such as a three-ring binder with tabs indicating the location where the device resides. They can also be filed in hanging folders in a filing cabinet and alphabetized and/or color coded by location. The point here is the physical collection and control of documented information for future use.

If IFU are brought to the facility on a per-case basis with loaner instrument sets, the facility should require the instrument manufacturer to provide the IFUs before the instruments are cleaned and sterilized. If the facility owns medical devices that are missing their IFU, the manufacturer should be contacted to send a set to the facility.

Once the manufacturers’ IFU are obtained, they need to be reviewed for each device’s required processes. This is especially important for instruments that...
require special handling, such as disassembly, channel flushing, and any special sterilization processes or parameters.

Next, the IFU must be shared with the staff that will be performing the processes. It is important to have a systematic process for providing this information to the staff, to ensure that everyone understands and is able to provide resources the staff can use when they need to confirm any of the processes. If there is a computer system in the sterile processing department, a database can be created that includes an area for special instructions and alerts. Any item that requires special handling should be identified in the database, along with any special package labeling. If there is no computer system for archiving this information, a process flow sheet should be in place that enables supervisors/managers to disseminate the information in a manner that will ensure staff compliance (Figure 2).

In addition, a form that lists pertinent information can be a useful tool (Figure 3). Once the information is provided to the staff, having them sign or initial an acknowledgement will also enable supervisors/managers to hold them accountable for each process.

Once the information has been reviewed with the staff, it is helpful to post the new instrument form in a central area for a designated period of time as a resource. After the designated period, the forms should be removed and placed in a binder as a permanent resource.

It is very important to obtain, store, and be able to provide IFU to inspectors when asked, but it's also critical that staff understand and follow AAMI guidelines or sterilizer manufacturer’s guidelines... If this is the case, it is the facility’s responsibility to contact the manufacturer for clarification when developing their process.

The ramifications of not following IFU

Manufacturers are required to validate cleaning processes for reusable medical devices. The validation testing should address not only cleaning and sterilization efficacy, but also the process’ compatibility with the component materials of the device. The validation documents confirm that the devices continue to function safely and effectively after many cleaning/disinfection/sterilization cycles. The cleaning process must see SELF-STUDY on page 46.
Changes in the type of packaging or wrapper material.

When the IFU supersedes current standards and recommended practice
If there is a discrepancy between the two, IFU will override professional standards and recommended practice, as long as a patient’s safety is not in jeopardy. Typically, standards and recommended practices are developed by professional bodies and consortiums to help guide policy and safe practice within their respective specialties. This guidance is more general in scope and is developed through evidence-based practice.

In contrast, medical device IFU are validated for a specific device and are included in that device’s regulatory registrations. However, advances in device development or medicine can sometimes create a situation in which a practice becomes necessary even though an IFU may not include that practice. For example, consider what often happens in sterile processing departments. Medical device and steam sterilizer manufacturers create thorough IFU documents detailing sterilization parameters, but the instructions for sterilizing a particular medical device may not exactly match those for the sterilizer. The question becomes; which IFU should be followed?

In situations like these, the healthcare facility must apply scientific judgment to make the best medical decision that promotes the safety of patients. The analysis should be documented and the practice justified. Justification may include a review of scientific literature, internal or contracted testing, or communication with manufacturers. The documentation package is essential in demonstrating that the decision to not follow an IFU is sound and reasonable.

IFU as education/auditing tools
As surgical procedures continue to evolve at a rapid pace, so too, do surgical instruments. What was once a one-size-fits-all type of cleaning and sterilization for basic stainless steel tools has had to change. Devices are now motorized, cabled, robotic and very complex technologies, many with a host of accessories or components made of a mix of substrates. Cleaning and sterilization methods and guidelines have had to evolve with each new item, and be validated by the manufacturer for each specific device to assure effective disinfection.

The key to successful cleaning and sterilization of these complex instruments is to study the IFU and learn the manufacturer’s validated reprocessing method for each device. This should happen automatically when a device is new to the department, but it is also important that managers utilize IFUs as ongoing in-service resources and for annual competency assessments. In addition, IFUs should be used to conduct regular process audits to keep the department in a continual state of readiness. Quality audits can be performed by reviewing the IFU for a particular instrument and then observing that the staff is compliant to the manufacturer’s instructions. The audits should be documented and used as criteria for additional education and process improvement plans.

As a part of measurement, analysis and continual improvement, the audit or survey process should include the review of IFU. The audit should identify the facility’s system for organizing these documents and more importantly, assess how these documents support the daily work performed in the departments or locations where these devices are used. IFU should be used to develop a linear progression; a step-by-step process for performing a task, such as the introduction of a new surgical/medical device for reprocessing.

IFU are a rich resource for sterile processing department managers. Once a complete IFU library is in place, it will provide much of the information needed to run the department’s equipment and process all necessary medical devices in compliance with manufacturers’ instructions. But the library itself must also...
become part of the department’s quality systems process; it is a living archive that must be updated regularly, as new devices are introduced or removed from service.

References:

Richard Schule, MBA, BS, CST, CRCST, CHMMC, FCS is the director of clinical education at STERIS Corporation, and is responsible for customer education, clinical support, troubleshooting, and issues concerning sterilization and infection control. Schule has been in healthcare for 30 years, and was a site manager, interim manager and consultant with STERIS Corporation’s SteriITek process improvement team for eight years. She is a licensed vocational nurse and has also been trained as an operating room technician. She has worked as a materials coordinator for the operating room (OR) and was responsible for OR purchasing, inventory control, capital budget, charge master, maintenance and clean-up of OR supply inventory lists, instrument tray lists and preference cards. Schule has led effective team building and process improvement efforts in total CS reorganization and improvement and has supervised specific areas of Joint Commission and state mandated inspections, flash sterilization reduction, loaner tray programs and tray reorganization.

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Circle the one correct answer:

1. If instructions for use are not clear, what is the facility’s responsibility?
   A. Process the items like you do everything else
   B. Contact the manufacturer for clarification
   C. Ask the sales rep
   D. Ask for clarification in writing

2. Instructions for use should be obtained for:
   A. Every item you process
   B. Only the new items
   C. Everything but loaners
   D. Specialty items

3. If the vendor delivers an item for processing without IFU, what do you do?
   A. Ask your coworker if they know how to process
   B. Stick it in the washer
   C. Request the instructions for use in writing from the vendor
   D. Leave it for the next shift

4. Which government agency requires the manufacturer of medical devices to document reprocessing instructions?
   A. OSHA
   B. CMS
   C. FDA
   D. CDC

5. When do IFUs not supersede current standards and recommended practice?
   A. When patient safety is at risk
   B. When AAMI, AORN and CDC say so
   C. When CMS states this is not a measurable event
   D. None of the above

6. Which element is not found in the ISO 9001 model?
   A. Customer focus
   B. Continual improvement
   C. Leadership
   D. Avoid changes
   E. Factual approach to decision-making

7. Which organization recommends periodic quality testing of routinely processed items?
   A. FDA
   B. AORN
   C. AAMI
   D. APIC
   E. Both b and c

8. When should instructions for use be utilized?
   A. Teaching tool for staff
   B. A part of annual competencies
   C. Quality audits
   D. As part of a checklist
   E. All of the above

9. What is included in the cleared labeling for all medical devices?
   A. Cleaning specifications
   B. Sterilization parameters
   C. IFU
   D. Preventive maintenance instructions
   E. All of the above

10. When is the healthcare facility accepting liability for patient safety?
    A. The sterile processing department is following instructions for use
    B. The sterile processing department is using a practice not listed in the manufacturer’s instructions for use
    C. The sterile processing department is inspecting the surgical device according to the manufacturer’s instructions for use
    D. All of the above

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