LEGAL IMPLICATIONS
OF STANDARDS AND
RECOMMENDED PRACTICES
FOR CS DEPARTMENTS
LEARNING OBJECTIVES

1. Describe applicable terms and how they apply to the CS profession
2. Discuss methods to incorporate standards and recommended practices into a comprehensive policies and procedures manual
3. Explain the consequences of failing to incorporate standards and recommended practices within the CS Department

Managers and their central service (CS) employees are confronted with significant challenges as they reprocess complex instruments and medical devices. They must be concerned about patient safety, and they have a duty to perform their tasks accurately and within professional and industry standards and guidelines. At the same time, they must also comply with all of the federal, state, and local laws, codes, and ordinances that govern our profession.

CS managers and staff must be well-versed in the standards and recommended practices that are used as guidelines for the safe practice and handling of instrumentation and medical devices. With the ever-changing healthcare workplace, new challenges constantly emerge that directly impact patient and staff safety and the environment, and strain the limited resources allocated to successfully complete tasks.

What are the legal concerns that affect CS personnel as they successfully incorporate the various Standards and Recommended Practices into the day-to-day operation of their department? What do the various legal terms mean? These issues are addressed in this Self-Study lesson.

OBJECTIVE 1: DEFINE APPLICABLE TERMS AND PROVIDE EXAMPLES OF HOW THEY APPLY TO THE CS PROFESSION

A recommended practice contains guidelines for the use, care or processing of a medical device or system. A recommended practice does not address device performance per se, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained. A guideline is an official recommendation indicating how something should be done or what sort of action should be taken in a particular circumstance.

The Association for the Advancement of Medical Instrumentation (AAMI) recommended practices are created by healthcare professionals, in cooperation with medical device and equipment manufacturers, to develop recommendations for optimum performance in the processing of reusable medical devices.1 AAMI states that, in many cases, their recommendations might not be achievable right away. However, the recommendations should be used to guide personnel toward advantageous performance objectives, and applied using critical thinking, sound professional judgment and experience.2

The Association of periOperative Registered Nurses (AORN) states that “Recommended Practices are intended as achievable recommendations representing what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented.”

Let's take a look at one of the most commonly referred to standards for reprocessing, ANSI/AAMI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. ST79 incorporates several previous standards and recommended practices into one document.1 It details the rationale for the method that should be used to provide the appropriate care and handling of contaminated items. This is important to reprocessing professionals because contaminated items pose a health risk to the staff who are handling the devices and to the patient during the next use.
All reprocessing staff handles contaminated items and procedures and policies must be developed to guide staff in their handling. ST79 details the separation of waste material from reusable items, the care and handling of the items at point of use, material containment, and transport protocols. ST79 also details the off-site transport of contaminated items between healthcare facilities and states that certain “non-waste” products are considered to be “infectious substances” by the U.S. Department of Transportation (DOT).

Regulations are “a rule of order having the force of law, prescribed by a superior or competent authority, relating to the actions of those under the authority’s control”. Regulations are issued by various federal government departments and agencies to carry out the intent of legislation enacted by Congress. Rules created by these agencies are considered regulations and are designed to guide the activity of those regulated by the agency and their employees. Regulations are created to ensure consistent application of the law. Regulations are not voluntary and, typically, several agencies may have responsibility for enforcement.

In the example above, a failure to properly educate staff in the care, packaging, separation, and transport of contaminated surgical instruments from an off-site surgical center to a decontamination room could open a healthcare facility to a state or federal inspection and subsequent fines for any regulation violations. For example, a spill of improperly containerized contaminated instruments during transport could expose a driver to hazardous material. The Occupational Safety and Health Administration (OSHA) requires that measures be in place to limit exposure(s) and to facilitate the safe clean-up of any spills. An exposure plan and staff safety training relating to exposures are requirements of all healthcare facilities and are detailed in applicable regulations. It would be prudent to have these safety measures in place before implementing off-site transport of contaminated surgical instruments.

Safety procedures must be developed and incorporated into the policy and procedure (P&P) manual of every facility. Then initial training for new staff and ongoing training for all reprocessing personnel are required to ensure that appropriate procedures are consistently followed.

A policy is a set of ideas or a plan of what to do in particular situations that has been agreed officially by a group of people, a business organization, a government, or a political party. Each healthcare facility should have a detailed manual of procedures detailing the actions that a prudent professional should take in a given situation. Policies must meet a variety of facility, federal, state, and local requirements and incorporate professional best practices based upon the standards and recommendations from a body of experts. In litigation, facility policies will be considered the “floor” of proper conduct. This means, at minimum, employees must follow their facility’s own policies.

The concept of best practice is a term used in the business world to describe the process of developing and following a standard way of doing things that multiple organizations can use for management or policy. Reprocessing professionals should be well versed in ways to measure and objectively determine the best method for implementing strategies that help achieve desired results. One way to measure best practices is a management tool called benchmarking. Benchmarking is the process of comparing one’s business processes and performance metrics to industry bests and/or best practices from other industries. Dimensions typically measured are quality, time and cost. Improvements accomplished from analyzing the data and changing the necessary processes means doing things better, faster and cheaper.

In a court of law, you may be challenged to measure your policies and procedures against what is considered to be an industry “best practice.” How your facility’s processes compare to best practice determines whether the course of action taken was reasonable, as we will discuss below.

ST79, for example, states that “instruments with lumens should be brushed using a brush that is of the correct size (diameter and length), and bristle type and material for the lumen, then rinsed”1 If a facility has a policy that does not address this cleaning step, a sterilization failure as a result of potential residual biological burden could result. In a civil case where a patient was alleged to have been injured due to contaminated instruments, the facility’s P&P manual will be examined by the expert witnesses presented by the attorney of the plaintiff (the party bringing the court action) as to whether the failure to adopt the industry best practice of cleaning lumens with a brush helped to cause the patient’s injury.

The defendant’s (healthcare facility’s) attorney would likely note the “voluntary” nature of the application and use of the AAMI Standard cited previously. However, unless your facility can offer a detailed study or manufacturer’s guideline that indicates that the brushing of lumen is not required for a particular instrument, your actions would be judged against the body of evidence as presented in ST79.

Your actions, policies and procedures will also be evaluated against what is known as a “Standard of Care.” This refers to the amount of attentiveness, caution...
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and prudence that a reasonable person in the same circumstances would exercise. Failure to meet the standard is negligence, and the person who fails to meet the standard is liable for any damages caused by the negligence. The standard is not subject to a precise definition and must be judged on a case-by-case basis. Again, healthcare facilities will be compared to reasonable care and actions taken by reprocessing professionals and to the standards of care as defined by the CS profession. Would a reasonable reprocessing technician brush out a contaminated lumen? According to the AAMI ST79, the answer is “yes.”

**OBJECTIVE 2: REVIEW METHODS TO INCORPORATE STANDARDS AND RECOMMENDED PRACTICES INTO A COMPREHENSIVE POLICIES AND PROCEDURES MANUAL**

How should the various standards and recommended practices be incorporated into a comprehensive P&P manual? Some companies offer “cookie cutter” or “off the shelf” approaches to the development and writing of CS policies. Several claim their template material is based upon standards and recommended practices developed by AAMI and AORN. Purchasers just add unique details to make the policies relevant to their facility. Potential purchasers must conduct the necessary research to determine if this is a viable alternative. Departments with a restricted budget may not be able to invest in this process and, instead, will choose a different method.

Most healthcare facilities write their own P&P manuals based upon a template selected by the facility. The typical document has a header containing information about:

- The name of the healthcare facility
- Document title; example: Steam Sterilization
- Policy statement
- The target audience of the document (“All Central Services staff”)
- Procedure
- Dates that the document was written, reviewed and revised
- Document’s author
- References/recommended practice

The policy statement will be followed by a concise procedure containing the following information:

- The name of the healthcare facility
- Procedure

The policy statement typically describes its purpose or goal. In the case of a steam sterilization policy, the policy should clearly address the use of immediate use steam sterilization (IUSS) by operating room and/or obstetrical staff. The P&P should describe the policy’s scope, including all personnel who perform the procedures.

Because ST79 describes the preparation of instruments for sterilization and their loading and off-loading, sterilizer testing, and sterilization parameters, the writer should consult and reference the document for guidance about how to handle the various device operations as recommended by the body of experts that contributed to ST79.

It is important to include the original equipment manufacturers’ written Instructions for Use (IFU) when researching and referencing source material for the P&P. These guidelines typically include a major segment with information about the safe and intended operation of the device(s). The writer could reference selected portions of ST79 to detail the importance of performing each operating step correctly and in compliance with the standards. Illustrations, pictures and diagrams could help the reader and provide additional details about the safe loading and off-loading of steam sterilizer racks. As well, use of the IFU manual will provide additional and equipment-specific information.

Education and training inservice sessions, skills checklists, and hands-on
skills labs are good opportunities for CS managers and technicians to review policies and procedures. As they do so, they will gain confidence in the safe handling of instruments, medical devices and the many complex machines used in the profession. ST79 explains that training must be provided on new procedures, and that the department should be staffed with able and competent employees. The use of a well-written P&P manual is the foundation for achieving that goal. It is the responsibility of all personnel to familiarize themselves with the various standards, guidelines, recommendations, and regulations that influence/impact the operation of the department.

ST79 recommends that individuals assigned to sterile reprocessing are those who have "demonstrated competence in all aspects of sterile reprocessing: decontamination, preparation, packaging, sterile storage, and distribution of sterile medical devices." It also discusses orientation, training and verification of staff competence, and the importance of continuous education. Further, it is recommended that only certified personnel perform reprocessing duties and that, at minimum, all newly-employed personnel successfully complete a certification examination within two years as a requirement of their employment. The reason: only a skilled and certified workforce can meet the ongoing challenges regarding advancements in technology and work processes.

OBJECTIVE 3: EXPLAIN THE CONSEQUENCES OF FAILING TO INCORPORATE STANDARDS AND RECOMMENDED PRACTICES WITHIN THE CENTRAL SERVICE DEPARTMENT

What are the potential consequences of not addressing reprocessing standards and recommended practices? Failure within the scope of the professional practice in the healthcare setting can lead to potentially negative outcomes for both the patients and the facility. The facility and its reprocessing team will be expected to meet the standards of care practiced by all individuals working in similar departments and performing similar tasks. A complete examination of the skills, training, and policies and procedures will occur whenever a patient is potentially harmed. It will be a difficult position to defend if the written policy fails to follow national industry standards. A civil lawsuit argued by a plaintiff’s attorney will explore these standards in an effort to show causation and to place blame for negative outcomes because of a failure to follow these guidelines.

Recently, the Centers for Medicare & Medicaid Services (CMS) implemented several new policy mandates regarding healthcare institution reimbursement. Patients who develop a hospital-acquired infection (such as a surgical site infection) due, for example, to a failure to properly clean and sterilize an instrument may not have their medical expenses reimbursed to the facility that provided the service. This revenue loss will impact the ability of healthcare facilities to render service, pay expenses, and hire and retain employees.

IN CONCLUSION

Efforts should be made to reduce the potential risk to patients and to enhance the abilities of skilled technical staff to effectively process instruments and medical devices. The incorporation of standard practices will help to reduce cleaning and sterilization errors, and reduce the potential for harm to the patients.

REFERENCES


ROSE SEAVEY is President/CEO of Seavey Healthcare Consulting and formerly the Director of the Sterile Processing Department at The Children’s Hospital of Denver. She served on the AORN Board in 2008-2010. She received AORN’s award for Mentorship in 2012 and Outstanding Nurse Education in 2001. Seavey is a past President of ASHCSPI. She was one of the Who’s Who in Infection Prevention in 2006 by Infection Control Today, and received the IAHCSMM Award of Honor in 2013. Seavey is the author of the book Sterile Processing In Healthcare Facilities: Preparing for Accreditations Surveys, published by AAMI, and she serves on several AAMI committees writing standards.