





# Accreditation Survey Preparedness for Sterile Processing Professionals

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#### LEARNING OBJECTIVES

1. Discuss the importance of an accreditation survey by a Centers for Medicare and Medicaid Services deemed agency for the healthcare facility
2. Identify regulatory, standards and guidelines to assist with accreditation preparedness
3. Discuss key areas of focus in preparation for an accreditation survey

The “surveyor on site” notification signals that “surveyors are here” -- and it understandably brings dread to some and nervous anticipation to others. Lack of preparation for an accreditation survey is unacceptable, especially if one’s healthcare facility has gone through accreditation surveys in the past. The purpose of the accreditation survey process is to validate compliance of the work the Sterile Processing department (SPD) does every day. It is not meant to be confrontational or an “I got you” moment, but rather to provide a meaningful assessment and to share best practices and resources that the surveyor might have observed elsewhere. The surveys are meant to be transparent, collaborative and educational. The necessary steps for becoming prepared in the SPD should be discussed in advance of the facility’s next accreditation survey.

#### **Objective 1: Discuss the importance of an accreditation survey by a Centers for Medicare and Medicaid Services deemed agency for the healthcare facility**

The Centers for Medicare and Medicaid Services (CMS) grants deemed status

to accreditation organizations with a demonstrated expertise in specific areas of healthcare (e.g., hospitals, ambulatory surgery centers, etc.). For a hospital, as an example, to participate in and receive federal payment from Medicare or Medicaid programs, it must have achieved accreditation status from a deemed accreditation agency. A healthcare organization must meet the government requirements for program participation, including a certification of compliance with the health and safety requirements called out in the Conditions of Participation (CoPs) or Conditions for Coverage (CfCs), which are set forth in federal regulations.

Accreditation, along with reimbursement, provides an opportunity to perform a critical evaluation of the organization’s patient care practices and is the impetus for change and/or improvement in these same practices. A healthcare organization that achieves accreditation through a “deemed status” survey is determined to meet or exceed Medicare and Medicaid requirements. Some state agencies will accept the accreditation survey process instead of conducting their own routine



licensure inspection and will mandate accreditation as a condition of licensure or certification.

## Objective 2: Identify regulatory, standards and guidelines to assist with accreditation preparedness

The SPD's role is driven, influenced and/or dictated by regulatory bodies from the federal level to the state and local levels (which may have stricter expectations). The accrediting agencies actively monitor these state legislative and regulatory activities, standards, guidelines and recommended best practices, media reports and past survey results; surveyors are trained to these. The agencies will expect the same from the SPD and the organization's leadership, so it is very important to be knowledgeable of the relevant standards impacting SP and infection prevention practices, regardless of the organization that accredits the facility.

As an example, the Joint Commission (TJC) takes a standardized survey process approach. They first look at rules and regulations; the COPs and CfCs, and manufacturer's instructions for use (IFU); evidence-based guidelines and national standards; consensus documents/position statements; and, finally, the organization's policies and procedures.

The surveyor will expect SPD staff to be able to speak to their role in processing instruments, medical devices and equipment, and their impact on patient safety. (*Author's note: Remember, this is the work you do every day, and no one knows it better than you.*) It is all about preparation and practice to avoid becoming anxious and tongue tied when questioned. For example, SP practices and processes fall under the TJC's infection prevention standard; however, when reviewing the accreditation standards, it is important to realize

there will be crossover with other standards such as the environment of care, leadership, human resources, and performance improvement.

Regulatory agencies to be aware of include:

1. Occupational Safety and Health Administration (OSHA) (state and federal);
2. US Food and Drug Administration (FDA);
3. Environmental Protection Agency (EPA); and
4. State and local licensure agencies.

Accreditation standards' relevant chapters as they relate to the SPD include risk assessment regarding medical equipment, devices and supplies and how the determined risk will be mitigated to the risk of infection.

The following are examples of healthcare accrediting organizations:

1. Det Norske Veritas (DNV GL);
2. The Joint Commission (TJC);
3. Accreditation Association for Ambulatory Health Care (AAAHC);
4. Accreditation Commission for Health Care Inc. (ACHC);
5. Center for Improvement in Healthcare Quality (CIHQ); and
6. Healthcare Facilities Accreditation Program (HFPA).

Standards, technical information reports, evidence-based professional guidelines and recommended practices related to processing of instruments and medical devices are developed by the following groups:

1. Association for the Advancement of Medical Instrumentation (AAMI);
2. Association of periOperative Registered Nurses (AORN);
3. Centers for Disease Control and Prevention (CDC);

4. Society of Gastrointestinal Nurses and Associates (SGNA); and
5. Professional societies such as the Association for Profession in Infection Control and Epidemiology (APIC), etc.

Other useful resources include:

1. TJC's sentinel events and safety alerts;
2. CMS interpretive guidelines (Hospital Infection Control Worksheet – Section 3. A. Reprocessing of Semi-Critical Equipment; Section 3. B. Reprocessing of Critical, Instruments and Devices: Sterilization)
3. Root cause analysis (RCA) and failure modes effect analysis (FMEA) conducted by the facility, related to the SPD;
4. Manufacturer's IFU and recall notifications;
5. Accreditation newsletters;
6. Peer-reviewed journal publications; and
7. Professional association journals and magazines.

A review of previous accreditation survey reports is also highly useful in determining whether previous findings were addressed and remain in compliance, and whether issues identified in facility environment of care rounds were reported and addressed. If the SPD had to submit action plans in the past, it is helpful to review those plans and audits to verify ongoing compliance with implemented practice changes. Lack of preparation with key areas of Sterile Processing could lead to citations that go as far as a determination of immediate jeopardy or immediate threat to life and a failed survey.



### Objective 3: Discuss key areas of focus in preparation for an accreditation survey

One of the most frequently cited standards by TJC relates to “the hospital [healthcare setting] [reducing] the risk of infections associated with medical equipment, devices and supplies.” This includes cleaning and performing low-level disinfection as well as intermediate and high-level disinfection (HLD) and sterilization.

TJC Survey Analysis for Evaluating Risk® (SAFER™) Matrix is a comprehensive visual representation of survey findings that surveyors use to organize and prioritize content plotted on the matrix (based on the likelihood to cause harm to patients, staff and visitors and how widespread the observations of specific findings are). This is tool that can be used by the SPD for ongoing accreditation preparation activities.

Preparedness for an accreditation survey is not a solo project but rather an opportunity to collaborate with a multidisciplinary team of experts within the organization (this can include representation from leadership, Quality, Risk Management, Infection Prevention, Regulatory, Surgical Services, physicians, educators, Facility engineering, Biomedical, Sterile Processing, Environmental Services, patient care and others, as appropriate). Once the team has been established, it is essential to approach preparedness in an organized and systematic manner; this helps to avoid overlooking important elements of the program. There is the option of using accreditation agencies’ consulting services (or if the facility is part of a larger system, internal regulatory staff can conduct mock surveys).

When organizing preparedness efforts, one approach is to look at structure (design and layout, utilities, people, equipment, etc.), processes (transportation, cleaning, disassembly,

disinfection, preparation and packaging, sterilization, etc.) and outcomes (quality control, quality improvement, etc.).

#### Accreditation Focus – Structure

**Resources:** Surveyor expectation is that leadership will provide the resources needed for effective, efficient functioning of the department and to maintain safe, quality care and services. This includes provisions for appropriate space and location to safely conduct decontamination, HLD, sterilization and storage. The appropriate human resources are needed to carry out the necessary functions. Job descriptions and documentation of staff education, training and competency activities should also be available. If contractors are hired to perform device reprocessing, a verification process is needed to ensure the contractor’s training program is comparable to the healthcare facility’s employee training program (this should include the specific devices used by the healthcare facility. Surveyors will request and review personnel files to validate this.

#### Centralization of Processing Activities:

Accreditation surveyors will want to know whether instrument device processing activities are centralized - and if not, they will want staff to know where the functions are taking place. During a survey is not the time to discover a location that is processing instruments and devices. It is important for SP professionals to do their homework and round as part of their readiness activities; this will allow them to identify all inpatient and outpatient locations such as procedure areas, physician offices, ambulatory clinics, dental offices, sleep labs, Emergency Department, patient care units, rehabilitation units, labor and delivery, obstetrics, and so on. In all locations that fall under the hospital license, there is to be standardization

and consistent compliance with current policies and procedures. Accreditation surveyors will determine compliance by visiting the areas where processing is performed and having conversations with the staff responsible (not management) for processing medical devices and instrumentation.

**Physical Facilities:** The determination of physical facility issues that impact instrument processing should be addressed. This includes proper space to allow for separation of clean and dirty, and workflow from clean to dirty; physical barriers in areas where processing takes place in one room such as in small clinics or physician or dental offices; heating, ventilation and air conditioning (HVAC) requirements (temperature, humidity, pressure relationships, filtration and air exchanges) *Note: Surveyors will watch for doors propped open and pass-through windows and doors left open from the decontamination area to clean areas;* availability of instrument air for drying of lumened instruments and medical devices; utility outages (water, steam or electrical) and contingency plans to address such occurrences, especially those related to airborne contaminants; chemical storage; plumbed eye wash stations where chemicals are used (eye wash stations should be checked weekly and within easy reach of staff); sinks for hand hygiene with necessary supplies; sinks for cleaning contaminated instruments and devices; and availability and wearing of appropriate personal protective equipment. Surveyors will also inquire about oversight for construction and renovation activities, and whether a water management program is in place for reviewing treatment modalities (reverse osmosis, deionization, distillation, etc.) and ensuring microbial monitoring of water is taking place.



**Environmental Services:** A key focus area for surveyors is the environment of care and ensuring the facility provides a clean/sanitary care environment. An SPD that lacks cleanliness (dust on vents and flat surfaces, the presence of tape and adhesive residues, etc.) is a red flag for surveyors. Written policies that establish cleaning schedules and responsibilities for who cleans what and when should be in place. The use of surface disinfectants should be registered by the EPA and approved by the healthcare facility for use. Those responsible for cleaning and disinfecting the environment should know the wet contact time for each surface disinfectant. It is also important to take note of what is happening behind the sterilizers. Surveyors will look to see if this area is being used for storage by Facilities engineers, EVS, contractors, etc. (not recommended) and is a source of dust, debris and contamination for processing areas.

### Accreditation Focus - Process

**Tracer Methodology and Quality Audit:** The tracer methodology is a key assessment tool used in real time by TJC. It follows a patient or a process through the healthcare facility to address compliance with standards and evidence-based guidelines. This type of audit is like pulling a string and seeing where it leads, which may not be a straight line. For example, the surveyor may do a tracer on instruments from the point of use in the procedure area, with the expectation that there is proper treatment to remove gross clinical soil and bioburden to prevent drying and biofilm formation that can interfere with cleaning. They may then trace transportation along designated routes for contaminated items to the decontamination area (even if near the procedure area) and ensure items are transported in leak- and puncture-

proof containers and labeled as “biohazardous.” Then they may examine the cleaning steps and ensure proper dilution of cleaning agents, followed by evaluating use of cleaning implements, examining disinfection and sterilization processes and sterile storage, and subsequent distribution back to the point of use.

If HLD is performed, surveyors will focus on whether the process is automated or manual and how staff are protected from exposure risks. They will also explore how specialty devices such as endoscopes and ophthalmology instruments are managed to prevent damage and residual contamination. Additionally, they will look to see how expired supplies are being monitored.

Tracer audits are necessary to ensure that the expected outcomes and compliance with policies and procedures are being maintained. If SPD management chooses to do tracers, they should engage staff in the process. As part of this process, they may wish to open sterile packages and check for bioburden/debris, wetness and odor; ensure that proper monitoring indicators are used; and ensure that proper dating of sterilized items is either time-related or event-related.

**Loaned Instruments:** It is important that SP professionals are prepared to discuss the management of loaned instrumentation, including policies and procedures that clearly outline vendor expectations (e.g., delivery, IFU, count sheets, images, etc.). Surveyors will also want to ensure that the policy is shared with vendors.

**Immediate Use Steam Sterilization (IUSS):** IUSS continues to be a focus for surveyors; they will look to see how it is being used and why. Are items containerized? Are the same items being sterilized? Are there plans to address items that repeatedly

undergo IUSS? Are there established benchmarks—and if so, what is the rate? If IUSS is used due to an emergency, how are items cooled to prevent patient burns or thermal injuries? Is IUSS used for implants? These are all questions SP professionals must be prepared to answer.

**Sterile Storage:** Surveyors will focus on storage clean and sterile items, according to the manufacturer’s instructions and intended use. They will look to see how they are they protected (paper-plastic pouches, containment devices, woven and non-woven wrap materials) to prevent ingress of contaminants in external cardboard and microorganisms, and whether they are located away from windows and exterior walls. They will also assess whether access is restricted. If sterile and cleaned equipment is stored in the same area, they will look to see that sterile items are prioritized. The sterile storage environment should be well-ventilated and provide protection against dust, moisture, insects, and temperature and humidity extremes. Endoscopes should be stored in clean, ventilated cabinets and they must not touch each other or the bottom of the cabinet. It is also important to not store clean and sterile supplies near sinks or under sinks or in any location where they could get wet.

**Pandemic Factors:** The COVID-19 pandemic is a key focus for surveyors, and they will want to see how the SPD has adapted. There will be questions on what the plans are to continue high-risk activities during the pandemic such as surgery and the need for sterilization of instrumentation and HLD of endoscopes. Surveyors will want to know the department’s involvement in the management of respirator reprocessing, and they may want to trace the process from use to return to the user. They



will also want to know the process for managing exposed staff and preventing exposure in the workplace, especially in break rooms.

#### **Accreditation Focus - Outcome**

Processing of instruments, medical devices and equipment is complex and process improvement is critical. Errors or missing steps in the process can lead to adverse patient outcomes. To provide the expected positive patient safety outcomes, a continuous quality improvement program should be in place and encompass the entire sterilization process. Quality control should be part of each instrument and device reprocessing step. This includes cleaning verification of mechanical and cart washers, ultrasonic cleaners, lumened devices and endoscopes (visual versus qualitative versus quantitative); sterilization monitoring and frequency (physical, chemical and biological indicators; running of controls); monitoring of high-level disinfectants; and documentation completed with no gaps (paper or electronic tracking system, not both), with product identification and traceability to the patient. They will look to ensure a product recall policy is in place that clearly states who is to be notified and when. They will also see whether a risk analysis is performed and whether it is included as part of the infection prevention risk assessment.

#### **Conclusion**

The journey to a state of constant accreditation survey preparedness is a long and winding road that requires perseverance and due diligence. Ongoing preparation will give SP professionals the confidence they need to know they are compliant with the accreditation standards and are able to demonstrate a commitment to

patient and healthcare worker safety. Conducting ongoing self-assessments involving the SPD staff, performing mock surveys and asking questions that surveyors may ask is important for ensuring the team is ready when surveyors enter the facility. ©



# CRCST Self-Study Lesson Plan Quiz - Improving Communication in the Work Area

Lesson No. CRCST 176 (Technical Continuing Education - TCE) • Lesson expires January 2024

1. For hospitals to participate in Medicare or Medicaid programs, they must:
  - a. Have achieved full accreditation by a Centers for Medicare and Medicaid Services deemed organization
  - b. Have a certification of compliance with the Conditions of Participation
  - c. Meet or exceed Medicare and Medicaid requirements
  - d. All the above
2. Before surveying Sterile Processing departments, accreditation agencies will review:
  - a. State legislative and regulatory activities
  - b. Standards, guidelines and recommended best practices
  - c. Past accreditation survey reports
  - d. All the above
3. The first item Joint Commission surveyors will review is:
  - a. Rules and regulations
  - b. Position statements and consensus documents
  - c. Policies and procedures
  - d. Manufacturer's instructions for use
4. Resources to assist with accreditation preparedness include:
  - a. Professional guidelines and recommended best practices
  - b. The Centers for Medicare and Medicaid Services' infection control worksheet
  - c. Association for the Advancement of Medical Instrumentation standards
  - d. All the above
5. Lack of accreditation preparation by Sterile Processing professionals can:
  - a. Lead to immediate threat to life citations and a failed survey
  - b. Cause a surveyor to recommend a negative employee review
  - c. Result in a Sterile Processing professional losing their certification
  - d. All the above
6. The Joint Commission's SAFER™ Matrix:
  - a. Spans five years of surveys
  - b. Only lists immediate jeopardy or immediate threat to life citations
  - c. Organizes and prioritizes findings by likelihood of harm and widespread observation
  - d. Is only used for facilities with a history of repeated threat to life citations
7. A multidisciplinary team for accreditation preparedness does not need to include which of the following?
  - a. Infection Prevention
  - b. Volunteer services
  - c. Operating Room
  - d. Risk management
8. During a survey, technicians should be able to discuss their role in:
  - a. Following the tracer matrix
  - b. The development of the department's policies and procedures
  - c. Past survey results
  - d. Instrument processing
9. Accreditation surveys will review Sterile Processing activities in:
  - a. Inpatient settings
  - b. Ambulatory surgery centers
  - c. Outpatient clinics and physician offices
  - d. All the above
10. Which of the following physical factors impacts the function of a Sterile Processing department?
  - a. Space for proper workflow and ventilation requirements
  - b. The number of instruments that will be processed
  - c. The distance between workstations
  - d. The distance between the Sterile Processing department and the Operating Room
11. The Joint Commission's tracer methodology is used for:
  - a. Reviewing policies and procedures
  - b. Patient care units only
  - c. Outpatient facilities only
  - d. Following a patient or a process from start to finish
12. Which of the following are areas of focus for surveyors?
  - a. Loaned instrument management
  - b. Instrument management at the point of use
  - c. Transportation to the decontamination area for processing
  - d. All the above
13. If immediate use steam sterilization is performed, which of the following is true?
  - a. A benchmark does not need to be established
  - b. Packaging of items is not required
  - c. The immediate use steam sterilization process should not be used for implants
  - d. Biological and chemical indicator use is not required
14. Quality control of the sterilization process includes:
  - a. Use of cleaning verification monitors
  - b. Use of physical monitors
  - c. Use of chemical and biological indicators
  - d. All the above
15. Surveyors will address how the Sterile Processing department has adapted to the COVID-19 pandemic as it relates to:
  - a. Management of staff exposure
  - b. High-risk activities such as processing of contaminated instruments
  - c. Reprocessing of respirators
  - d. All the above

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