LEARNING OBJECTIVES
1. Explain the importance of a successful accreditation survey and why Central Service is an important part of that process
2. Discuss The Joint Commission’s accreditation process and identify helpful resources for survey preparation
3. Define The Joint Commission’s National Patient Safety Goals
4. Identify published standards and guidelines for safe and effective reprocessing of reusable medical devices
5. Discuss strategies for developing a plan for continuous accreditation survey readiness relating to sterilization and high-level disinfection

ACCREDITATION SURVEYS
PROCESS IMPROVEMENT AND ENHANCED QUALITY CARE ARE THE heart and soul of any healthcare accreditation process. Successfully passing an accreditation survey process helps demonstrate that the facility provides quality patient care by following the most current standards. Now, more than ever, accreditation surveyors will be looking for evidence of process improvements relating to high-level disinfection (HLD) and sterilization during the onsite survey process.

OBJECTIVE 1: EXPLAIN THE IMPORTANCE OF A SUCCESSFUL ACCREDITATION SURVEY AND WHY CENTRAL SERVICE IS AN IMPORTANT PART OF THAT PROCESS
Healthcare providers must be accredited and receive certification from an approved national accreditation organization (AO) in order to receive payment from the Centers for Medicare and Medicaid Services (CMS). AOs, such as The Joint Commission (TJC) or the American Association for Accreditation of Ambulatory Surgery Facilities (AAASF), are granted deeming authority from CMS as an accreditation provider if they can demonstrate their ability to meet or exceed the CMS conditions of participation/coverage, as cited in the Code of Federal Regulations. Accreditation is a very important factor for the healthcare facilities’ bottom line because the accreditation and certification are tied to reimbursements. CMS wants all surveyors to assess HLD and sterilization issues during an onsite accreditation survey; therefore, reprocessing professionals can be sure that the next accrediting survey visit will include an in-depth review of the CS department, as well as any area where HLD and sterilization are being performed. Surveyors also want to ensure the Infection Preventionist (IP)
can provide evidence that the facility has developed general infection control policies and procedures that are based on nationally-recognized guidelines and applicable state and federal law. Consequently, the surveyor will want to see that the organization’s policies related to HLD and sterilization are developed and written according to current published standards and recommendations by professional organizations, such as the Association of periOperative Registered Nurses (AORN), the Association for the Advancement of Medical Instrumentation (AAMI) and the Centers for Disease Control and Prevention (CDC).3

During live presentations, CS and Operating Room (OR) professionals and IPs were asked how long TJC surveyors spent in CS and/or the gastrointestinal (GI) lab; the majority of these professionals in attendance stated three to four hours. They noted that a physician or a nurse surveyor reviewed their sterilization and HLD processes, and wanted to see current, relevant competencies that are documented. An engineer surveyor was also part of the TJC surveyor team, they noted, and this surveyor evaluated facility design. This facility design focus included the temperature, humidity and directional airflow in various processing areas.

**OBJECTIVE 2: DISCUSS THE JOINT COMMISSION’S ACCREDITATION PROCESS AND IDENTIFY HELPFUL RESOURCES FOR SURVEY PREPARATION**

TJC uses standards, rationale statements and elements of performance (EP) to provide guidance about what to expect when a survey is conducted. The standards are the performance objectives and each objective has rationale statements to describe the importance of those objectives. Each standard also has at least one, but often multiple, applicable EPs that specify how the standard or objective should be met. The EP scores play a critical role as surveyors determine the overall compliance with the standard. Facilities must score at least a 90% on every EP on the survey or they may be cited.4

For hospitals, TJC standards are grouped into the following chapters:
- Environment of Care (EC);
- Emergency Management (EM);
- Human Resources (HR);
- Infection Prevention and Control (IC);
- Information Management (IM);
- Leadership (LD);
- Life Safety (LS);
- Medication Management (MM);
- Medical Staff (MS);
- National Patient Safety Goals (NPSG);
- Nursing (NR);
- Provision of Care, Treatment and Services (PC);
- Performance Improvement (PI);
- Record of Care, Treatment and Services (RC);
- Rights and Responsibilities of the Individual (RI);
- Transplant Safety (TS); and
- Waived Testing (WT).4

The standards that most affect CS departments are in the EC, HR, IC, LD and PI chapters. Each TJC standard has at least one, but often many, very specific EPs that the surveyor reviews. For example, consider standard HR.01.06.01: “Staff are competent to perform their responsibilities.” This standard has numerous EPs that impact sterile processing, such as:

**EP 1.** The hospital defines the competencies it requires of its staff who provide patient care, treatment or services.
EP 2. The hospital uses assessment methods to determine the individual’s competence in the skills being assessed. Note: Methods may include test taking, return demonstration or the use of simulation.

EP 3. An individual with the educational background, experience or knowledge related to the skills being reviewed assesses competence.5

Surveyors may look for three types of staff competencies: demonstration, certification and involvement with professional associations. They want to see job descriptions that match responsibilities, documented skill checklists, and training based on annual evaluations forms.

Another example of a standard directly applicable to CS is LD.04.01.11: “The hospital makes space and equipment available as needed for the provision of care, treatment and services.”5

EP 2. The arrangement and allocation of space supports safe, efficient and effective care, treatment and services.

EP 5. The leaders provide for equipment, supplies and other resources.5

Sterilization is a complex process that requires environmental controls (e.g., for controlled air changes, exhaust ventilation, temperature and humidity); appropriate equipment and supplies; adequate space; qualified, competent personnel who are provided with ongoing training and personal protective equipment (PPE); and monitoring for quality assurance.

TJC has created several standards BoosterPaks. These are searchable documents that provide specific information about TJC standards associated with a high volume of non-compliance scores in the healthcare field. The BoosterPaks were created for accredited organizations and staff within TJC to improve the understanding and consistency of standards interpretation. BoosterPaks are available to TJC-accredited and -certified organizations on the secure Joint Commission Connect Extranet.6

In December 2015, TJC released its newest BoosterPak, High-Level Disinfection (HLD) and Sterilization. This resource is directed toward hospitals, ambulatory services and office-based surgery practices as they prepare for an accreditation survey. The goal of the BoosterPak is “to ensure work practices are carried out following regulatory standards and evidence-based guidelines for HLD and sterilization in order to minimize potential risk of infection transmission to patients.”6

During accreditation surveys, TJC continues to cite facilities for serious noncompliance with the Infection Prevention and Control standards. This document was created to help facilities improve patient safety and compliance for a successful accreditation process. The BoosterPak highlights the related TJC standards and their requirements, and provides links to references and training sites. It also lists “Important Takeaways” and “Important Things to Know” regarding leadership, risk assessment, sterilization, environment of care, human resources, competency and training.6

The BoosterPak describes the concept of performing a risk assessment to refine HLD and sterilization processes, and the importance of using multidisciplinary teams to perform these assessments. When conducting a risk assessment, TJC states it is important to create teams that involve key stakeholders, including:

- Infection Prevention;
- Environmental Services;
- Facilities/Engineering;
- Managers/Supervisors;
- Frontline staff; and
- Directors.6

It is suggested that a senior leadership champion be identified to help implement best practices and supervise the development and activities around these procedures. Senior leadership can be very helpful when making a case for the necessary improvement projects as they compete with other priorities within the healthcare facility.

The BoosterPak includes an appendix that lists standards relating to HLD and/or sterilization processes that may be addressed during a survey for healthcare facilities that reprocess reusable medical devices.

Another helpful resource is the AAMI guidance document, Sterile Processing in Healthcare Facilities: Preparing for Accreditation Surveys, which helps healthcare professionals prepare for an accrediting agency survey as it relates to reprocessing. This document contains valuable tools, such as a step-by-step guide to prepare for a survey, guidelines on risk reduction, and self-auditing tools to help maintain compliance with accreditation standards.2

OBJECTIVE 3: DEFINE THE JOINT COMMISSION’S NATIONAL PATIENT SAFETY GOALS

In 2002, TJC established the National Patient Safety Goals (NPSG) which are targeted goals healthcare professionals may address regarding areas known to create significant challenges. The NPSG that is most important for CS is NPSG.07.05.01: Implement evidence-based practices for preventing surgical site infections (SSIs).7

There are two priority EPs that this NPSG addresses:
EP 3: Implement policies and practices aimed at reducing the risk of SSIs. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines (e.g., the CDC and/or professional organization guidelines).7

Surveyors will want to determine whether the facility is following current published national and local standards.

EP 4: As part of the effort to reduce SSIs, healthcare facilities should:
• Conduct periodic risk assessments for SSIs;
• Select SSI measures using best practices or evidence-based guidelines;
• Routinely monitor compliance with current best practices or evidence-based guidelines; and
• Evaluate the effectiveness of prevention efforts.7

TJC surveyors consider CS leaders to be the subject matter experts who set the reprocessing standards for the facility (this includes processing that may take place in other areas of the facility, such as endoscopy suites or labor and delivery). These standards, which include policies, procedures and recordkeeping, should be the same in all areas where processing is performed within the organization.

OBJECTIVE 5: DEVELOP A PLAN FOR CONTINUOUS ACCREDITATION SURVEY READINESS RELATING TO STERILIZATION AND HIGH-LEVEL DISINFECTON

The majority of healthcare surveys are now unannounced, so it is particularly important that organizations be in a constant state of accreditation readiness. Preparing for an accrediting agency survey related to reprocessing is no small feat, especially if the cleaning, HLD and sterilization activities take place in several areas.

AORN creates guidelines that are intended to illustrate best practices for patients undergoing surgery and invasive procedures to support the safety of patients and healthcare workers. Sterile processing is considered part of the perioperative function. The AORN Guidelines and Tools for the Sterile Processing Team is an eBook that contains CS-applicable guidelines taken from the AORN Guidelines for Perioperative Practice. A set of customizable Microsoft Word documents is also included. This resource includes editable documents (e.g., policy and procedure templates, competency verification tools and job descriptions), as well as an AORN to AAMI crosswalk tool.9

AORN Guidelines for the CS team include:
• Guideline for Environmental Cleaning;
• Guideline for Hand Hygiene;
• Guideline for Surgical Attire;
• Guideline for Processing Flexible Endoscopes;
• Guideline for High-Level Disinfection;
• Guideline for Cleaning and Care of Surgical Instruments;
• Guideline for Selection and Use of Packaging Systems for Sterilization; and
• Guideline for Sterilization.9

OBJECTIVE 4: IDENTIFY PUBLISHED STANDARDS AND GUIDELINES FOR SAFE AND EFFECTIVE REPROCESSING OF REUSABLE MEDICAL DEVICES

During an accreditation site visit, surveyors will assess the facility’s conformance to HLD and sterilization current best practices and adherence to the organization’s written policies and procedures. During a survey, frontline employees will be expected to know and follow the most current published standards, recommended practices and guidelines. The organization should conduct routine audits with feedback to help ensure the facility policies and procedures are consistently being followed.

Referencing current professional guidelines, standards and/or recommendations used to develop the policies is one way to demonstrate to surveyors that the facility uses the most updated published resources.

AAMI develops standards (ST) and technical information reports (TIR) related to medical instrumentation. They are intended to promote HLD or sterility assurance and guide healthcare personnel in the proper use of processing equipment. Some of the current AAMI documents relating to the reprocessing of medical devices include:
• ST41:2008/(R)2012 Ethylene oxide sterilization in health care facilities;
• ST58:2013 Chemical sterilization and high-level disinfection in health care facilities;
• ST91:2015 Flexible and semi-rigid endoscope processing in health care facilities;
• ST65:2013 Processing of reusable surgical textiles for use in health care facilities;
• ST40: 2004/(R)2010 Table-top dry heat (heated air) sterilization and sterility assurance;
• ST77:2013 Containment devices for reusable medical device sterilization;
• TIR63:2014 Management of medical devices used in health care facilities that are not owned by the facility;
• TIR34:2014 Water for reprocessing of medical devices; and
• TIR55:2014 Human factors engineering for processing medical devices.8

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Published standards and guidelines
relating to sterilization and HLD guidelines are consistently being updated as new evidence is revealed. On September 11, 2015, the CDC and the U.S. Food and Drug Administration (FDA) issued a Reprocessing Alert that strongly recommended each healthcare organization have at least one sterilization/HLD subject matter expert (SME) who is well versed on the accreditation standards, as well as current professional guidelines and recommendations. TJC standards state that it is the responsibility of the organization’s leadership to provide resources to support the SME and ensure the staff are competent. The following are a couple specific TJC standards that address these issues:

**LD.04.01.11:** The hospital makes space and equipment available, as needed, for the provision of care, treatment and services.
- **EP 2.** The arrangement and allocation of space supports safe, efficient and effective care, treatment and services.
- **EP 5.** The leaders provide for equipment, supplies and other resources.

**HR.01.06.01:** Staff are competent to perform their responsibilities.
- **EP 3.** An individual with the educational background, experience or knowledge related to the skills being reviewed assesses competence.

A multidisciplinary reprocessing preparation accreditation committee (RPAC) should be developed to examine all issues associated with reprocessing reusable medical devices. The RPAC should include, but not be limited to, representatives from CS, OR, IPC, clinical/biomedical engineering, endoscopy, risk management, quality, safety, education, administration and materials management. The RPAC should have access to all appropriate documents and standards from their accreditation organization and ensure they have the most current editions of the relevant published guidelines and recommended practices, as well as any pertinent local, state and federal regulations.

The RPAC should ensure:
- The organization has a cleaning, sterilization and HLD (also known as reprocessing) SME to review all locations where processes related to sterilization and/or HLD are performed, and help ensure staff are adhering to policies and current guidelines;
- They have centralized all reprocessing activities to the extent possible to make the process of standardization more practical;
- Staff can articulate the current guideline used to create the policies and procedures;
- Reprocessing activities are only assigned to staff who have documented competencies;
- Staff wear the required attire and PPE (e.g., scrubs provided by and donned at the facility, fluid-resistant face mask and eye protection, etc.);
- Instructions for use (IFU) for instruments, monitoring devices, equipment, and cleaning and disinfectant solutions are followed;
- Temperature, humidity and airflow are within standards and are recorded daily for each area; and
- Equipment is maintained according to the manufacturers’ IFU.

TJC’s survey process includes tracer methodology, a whereby surveyors select a patient and use his or her record as a roadmap to evaluate the facility’s compliance with specific standards. The objectives of a tracer are to assemble proof of compliance with policies and procedures, identify process problems, and establish accountability by observing and talking to staff. HLD will be high on the radar screen for all surveyors due to publicized outbreaks related to endoscopes.

The RPAC should conduct unannounced mock surveys routinely (e.g., annually) to help evaluate compliance with best practices and current policies and procedures, and identify opportunities for process improvements. If the facility reprocesses endoscopes, the RPAC mock tracer should be conducted to ensure:
- Staff documents the quality control test when opening new bottles of HLD test strips, if required in the manufacturer’s IFU;
- The facility observes the HLD test strip expiration date;
- Scope storage cabinets are properly ventilated and tall enough to hang scopes without looping or touching the bottom of the cabinet;
- All staff who perform HLD have a current documented competency;
- There is adequate separation of...
clean and dirty activities in the scope processing area;
- The specific manufacturer’s advice on brushes are used in scope cleaning (e.g., disposing single-use brushes after use or cleaning the reusable brushes in accordance with IFU); and
- There is proper negative pressure in the scope decontamination area.²

To conduct a mock tracer for surgical instrument processing, the RPAC should select a specific instrument set and trace it through all the reprocessing steps while looking for compliance with every applicable policy and procedure. This self audit should also include equipment monitoring and objectively evaluate the facility’s physical spaces, such as sterile storage and clean and decontamination areas, to ensure they comply with recommended design standards.²

A tracer related to surgical instruments should include an evaluation of issues, such as:
- How were the instruments packaged?
- How were the instruments sterilized?
- If there were implants, were they quarantined until the results of the biological indicator were available?
- How were the instruments stored?
- How was the sterile instrument set transported to the OR?
- How were the instruments decontaminated after their use?
- Are these steps spelled out in the facility’s policies and procedures?
- Are the manufacturers’ written IFU available?
- Is documentation for specific competencies and orientation, training, education and other activities that enable CS personnel to consistently perform to the required standards demonstrated during the mock tracer?
- Are equipment maintenance records available and up to date?
- Is the department clean?
- Can each instrument be traced to the patient selected for the mock survey?²

CONCLUSION
To help ensure a successful unannounced accreditation survey, organizations should stay in a constant state of readiness. Facilities should have a reprocessing subject matter expert and a multidisciplinary team that ensures policies and procedures relating to sterilization and/or high-level disinfection are written based on the most current evidence-based guidelines/recommendations and then standardized throughout the healthcare organization.

The number one thing for healthcare professionals to remember as they prepare for their next survey is that risk reduction and process improvement are the foundation of any accreditation surveys. Patient safety is the top priority. ☛

REFERENCES