Advanced Sterilization Products

Creating a Culture of Safety:

Joint Commission Preparedness for Sterile Processing

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Key Points

- The Joint Commission (TJC) is zooming in on Sterilization Departments, spearheading an initiative to ensure Sterile Processing Departments (SPDs) are up to par with hospital needs.
- A recent TJC spotlight report has thrown into sharp relief that nearly 50% of hospitals and critical access hospitals have been flagged with a citation, prompting the Commission to outline specific improvement areas for Sterilization Departments.[12]
- Quality and environmental safety in SPDs are gauged using a meticulous "Element of Performance" method by the TJC. [12]
- Gearing up for an audit is a marathon, not a sprint; it's about embedding a culture of ongoing process enhancement.
- The application of continuous improvement ideas from other industries can enhance preparedness and, more crucially, daily performance and quality.
- Explore the inner workings of the Sterilization Department through first-hand accounts from Virginia Commonwealth University Health's experiences.

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Establishing a "Culture of Safety" within healthcare, particularly in Sterile Processing Departments (SPDs), is crucial for minimizing errors and improving patient outcomes.

Accreditation by The Joint Commission (TJC) serves as a vital marker of compliance with industry standards, affirming an organization's dedication to quality care. By prioritizing adherence to TJC standards and continuous quality improvement, healthcare facilities can enhance patient safety, bolster community confidence, and ensure long-term success.

INTRODUCTION

The fundamental objective behind fostering a **Culture of Safety** is to mitigate errors and enhance overall quality.[18] Nowhere is this more imperative than within SPDs, entrusted with the meticulous processing of instruments and intricate medical devices. Precision across multiple steps is crucial in preventing adverse patient outcomes, such as surgical site infections.[7, 27]

To realize favorable patient safety outcomes, SPDs must diligently implement a continuous quality improvement initiative that aligns with established standards, guidelines, and regulations. The TJC, a leading accreditation body, plays a pivotal role by providing standards and accreditation programs that help SPDs in ensuring compliance and drive ongoing improvement efforts.

Joint Commission audit readiness doesn't begin with a checklist, it ends with one. Lessons learned from other industries show that the highest performers have a Quality-First Mindset. Drawing insights from other industries, it's evident that top performers prioritize continuous improvement. Concepts from renowned systems like the Toyota Production System, Danaher Business System, and Fortive Business System can be effectively integrated through systematic approaches.[1, 8, 10, 17]

The Toyota Production System prioritizes the fundamental principles of 'Continuous Improvement' and 'Respect for People' as core elements.[14] Additionally, companies such as Toyota, Danaher, and Fortive, renowned for their robust improvement frameworks, assert that this philosophy is ingrained in their organizational DNA. This parallels TJC's dedication to advancing high reliability in healthcare, exemplified by its focus on fostering a 'safety culture' to enhance patient care quality.[19]

BACKGROUND

Accreditation's Role in Validating Compliance

The Joint Commission is a nonprofit organization that accredits and certifies healthcare organizations and programs in the United States. Founded in 1951, it evaluates and accredits over 22,000 healthcare organizations and programs in the country, including hospitals, nursing homes, laboratories, ambulatory care facilities, behavioral health organizations, and home care organizations. The commission's accreditation process involves rigorous evaluation of various aspects of healthcare delivery, including patient care, safety, organizational leadership, and compliance with industry standards and regulations. **Achieving accreditation from TJC is widely recognized as a mark of quality and safety in healthcare**.[13]

Accreditation serves as a cornerstone for validating the compliance of daily operations within the SPD.[7, 12] Beyond a mere checkbox exercise, accreditation processes, such as those conducted by the TJC and recognized by the Centers for Medicare and Medicaid Services, provide a holistic evaluation of the SPD's adherence to established standards.[6, 11, 25] The validation of compliance is not just a regulatory requirement but a testament to an organization's commitment to delivering quality patient care.

The Joint Commission's Approach

SPD professionals require a thorough understanding of the accreditation process to successfully navigate the complex regulatory environment. [6-7, 22] Operating within a regulatory framework that spans federal, state, and local levels, the SPD encounters varying degrees of stringency, with local regulations often imposing heightened expectations. [7] Accrediting agencies diligently monitor legislative updates, regulatory shifts, and evolving standards, drawing insights from media reports and historical survey data. Surveyors undergo extensive training to adeptly navigate these intricacies.

Employing a standardized survey approach, TJC emphasizes adherence to rules, manufacturer's instructions, evidence-based guidelines, and organizational policies.[11-12, 24] Inadequate preparation may result in citations or even immediate jeopardy of status.[5]

TJC has introduced enhanced evaluations in their on-site surveys, focusing on five key areas deemed to pose significant risks to patient safety:[22]

1. High-level disinfection and Sterilization
2. Medication Errors
3. Suicide prevention
4. Interior Clinical Space Safety for care, treatment and services
5. Environmental Airborne Contamination

Hierarchical Approach to Infection Control Standards, TJC[25]

* For organizations that use Joint Commission accreditation for deemed status purposes or that are required by state regulation or directive. Conditions of Participation (CoPs) and/or Conditions for Coverage (CfCs) should be reviewed for applicable mandatory requirements.

The most challenging requirements for hospitals through the TJC lens: [26]

Implementation of infection prevention protocols for disinfection and sterilization of medical equipment, devices and supplies - to reduce the risk of healthcare acquired infections.

Assessing physical environments to look for objects that could be used during suicide attempts and following written policies to identify at risk patients.

Ensuring medications are safely administered.

Taking steps to ensure interior spaces in the hospital are safe so patients can be treated and services can be provided.

Making sure airborne contaminants are properly controlled in critical areas using appropriate ventilation systems.

In *"The Joint Commission Guide to Reprocessing Reusable Medical Devices"*, TJC underscores the critical importance of adhering to standards and Elements of Performance concerning the cleaning, disinfection, and sterilization of reusable medical devices. These areas have persistently ranked among the top five cited non-compliance findings over the past decade, indicating systemic challenges in healthcare facilities.[12] Deficiencies in medical device reprocessing are not just frequently cited but also considered among the most hazardous, warranting the designation of 'Immediate Threat to Health or Safety (ITHS),' highlighting the urgent need for corrective action to address these deficiencies promptly.[5, 12]

Observing the following helps ensure proper instrument cleaning occurs:[12]

- Are manufacturer Instructions for Use (IFU) available to staff performing reprocessing and has staff been trained on these instructions?
- Are users removing soil and keeping instruments moist as indicated in each instrument's IFU?
- Is terminal cleaning completed as soon as possible after use?
  Or, are instruments sitting for extended periods before being cleaned?
- Are cleaning chemicals being diluted appropriately?
  Are cleaning solutions maintained at the correct temperature?
- Is the instrument inspection process before packaging occurring in a well-lit location with magnification?

Preparing for TJC Review

The Joint Commission surveys routinely identify breaks in processes that may increase the likelihood of ineffective instrument cleaning.

Is the Instrument Safe to Use on a Patient?[12]

SURGICAL INSTRUMENTS

Should be inspected and evaluated for cleanliness and correct working order after decontamination. Items that are not cleaned or do not function correctly can put a patient at risk for injury or a surgical site infection (SSI).

DAMAGED INSTRUMENTS

Damaged instruments may not function properly. The impact of instrument damage on the provision of care needs to be assessed and may result in the decision to completely remove and instrument for a tray until it can be repaired or replaced.

IMPROPERLY APPLIED INSTRUMENT TAPE

Instrument tape, when used properly, is a way of identifying specific instruments. Instruments with identification tape that is peeling, cracked, or has evidence of corrosion could potentially flake particles into an open wound during surgery and result in a foreign body being left in a wound.

REPROCESSING SINGLE-USE DEVICES (SUDS)

When a healthcare organization reprocesses an SUD, it is subjecting itself to medical device requirements and is subject to the regulatory requirements applicable to the original device manufacturer should the device fail.

Benefits of a Joint Commission Accreditation and Continued Compliance

Joint Commission Accreditation provides a wide array of benefits that go beyond simply meeting standards. It plays a crucial role in enhancing patient safety efforts and elevating the quality of care. Research shows that adhering to The Joint Commission standards for device reprocessing improves the effectiveness of cleaning instruments and reusable medical devices, ultimately leading to higher job satisfaction among medical staff and fewer adverse events.[29]

Achieving accreditation instills confidence in the community about the organization's dedication to delivering top-notch services, fostering trust and loyalty.[28] Additionally, it serves as a driving force for risk management and reduction, promoting advanced strategies for improving performance and enhancing patient safety.[4, 28]

Accreditation may result in reduced liability insurance costs and improved access to comprehensive insurance coverage, thereby easing financial burdens on healthcare organizations.[28] By taking a comprehensive approach to organizational improvement, Joint Commission Accreditation addresses staff education, regulatory compliance, and performance excellence, aiding in recruitment efforts and ensuring alignment with industry standards.[4]

The Risk of Non-Compliance

In its recent report, nearly half of hospitals surveyed had some form of non-compliance.[12]

If a Healthcare organization (HCO) seeking accreditation receives a finding at the Immediate Threat to Health and Safety (ITHS) level, their status is altered to Preliminary Denial of Accreditation. This crucial change triggers notification to the Centers for Medicare and Medicaid Services, and state agencies may also require notification, jeopardizing the organization's eligibility for Medicare and Medicaid reimbursement.[6-7, 12]

Beyond the potential loss of federal and state reimbursement, there exists a direct threat to patient safety. For instance, failure by an HCO to properly reprocess reusable medical devices in accordance with the manufacturers' Instructions for Use (IFUs) may lead to the release of non-sterile medical equipment containing blood, tissue, and other debris. This oversight can lead to Healthcare Associated Infections (HAIs), putting patients and, in some cases, healthcare practitioners at risk of infection.[5, 12]

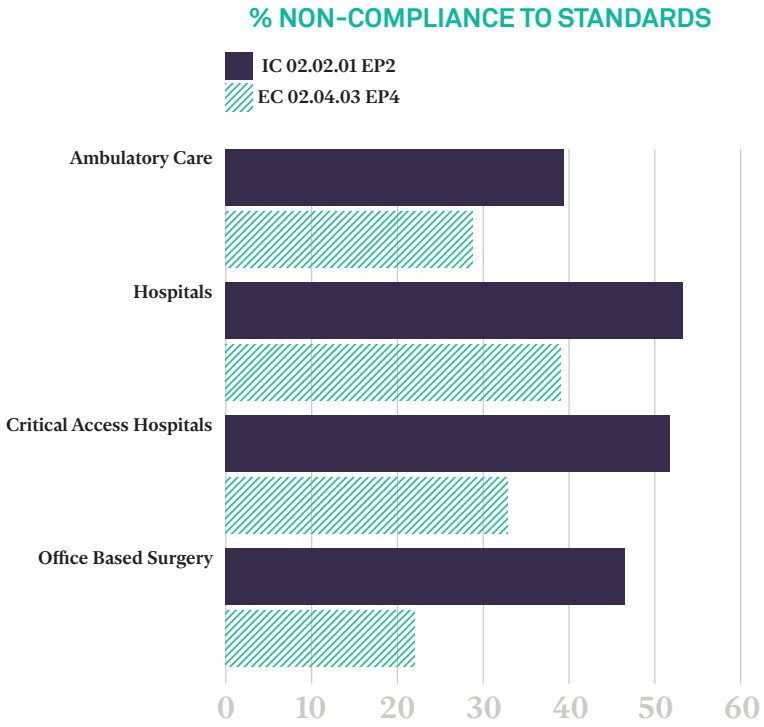


Figure 1: TJC Compliance Statistics [12] pg. 2-3

Key Joint Commission Terminology[12]

- **JC AND JCI STANDARDS**

  The Joint Commission addresses medical device cleaning, disinfection, and sterilization under two key standards.

- **IC 02.02.01 – INFECTION PREVENTION AND CONTROL (IC) STANDARD**

  The hospital inspects, tests, and maintains medical equipment.

- **EC 02.04.03 – ENVIRONMENT OF CARE (EC) STANDARD**

  The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.

- **IMMEDIATE THREAT TO HEALTH OR SAFETY (ITHS)**

  Deficiencies that are not simply citations but also pertain to hazard. A potential ITHS finding may result in a call to the central office for further review.

- **JOINT COMMISSION INTERNATIONAL (JCI)**

  Covers cleaning, disinfecting, and sterilizing medical devices under two Prevention and Control of Infections (PCI) standards.

- **ELEMENTS OF PERFORMANCE (EP)**

  Statements that detail specific performance expectations and/or the structures or processes that will be in place for an organization to provide high-quality care, treatment, and services.

- **PRELIMINARY DENIAL OF ACCREDITATION (PDA)**

  Justification to deny accreditation to a health care organization when there is significant noncompliance with Joint Commission standards.

The Risk of Non-Compliance (Continued)

Recent articles have highlighted concerning compliance issues regarding disinfection and sterilization, which have been described as "a serious breakdown in sterilization protocols".[9, 16, 20-21] These lapses in safety protocols have led facilities to suspend surgical operations, resulting in the cancellation of surgeries for several weeks while safety gaps were addressed. Notable findings that prompted surgical shutdowns include instances where instrument trays were improperly sterilized, resulting in canceled procedures[16, 21] Additionally, protective instrument tray covers were discovered to have holes upon delivery to the Operating Room (OR), further compromising safety protocols.[21] Patients have also been affected, with some having to stay overnight for what should have been same-day surgeries due to delays in instrument sterilization.[21]

Bone particles were found on two sets of instruments, and instruments opened in the OR were found to have "blood and tissue" residue from previous cases.[16, 21]

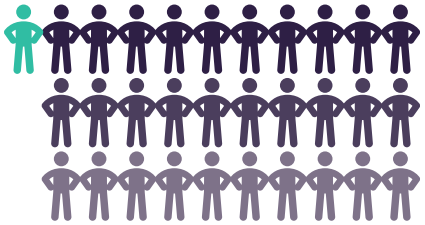
> **"I've not been able to go to work. I've not been able to do things I plan to do waiting on what's going to happen and when."** – *Patient awaiting knee replacement surgery*

One patient, a 71-year-old awaiting heart surgery, shared his experience of receiving a cancellation call the night before his scheduled surgery and being rescheduled almost a month later. Despite his disappointment, he expressed gratitude for being informed of the issue before entering the operating room.[16] Another patient, who had her knee replacement surgery canceled twice, described the impact on her life, stating, "I've not been able to go to work. I've not been able to do things I plan to do waiting on what's going to happen and when".[9]

Such breakdowns in disinfection and sterilization protocols can lead to surgical site infections (SSIs).[5, 12] Alarmingly, SSIs afflict approximately 0.5% to 3% of patients undergoing surgery, constituting a significant portion, at 20%, of all HAIs.[15] SSIs correlate with a 2-to 11-fold escalation in the risk of mortality, with a staggering 75% of SSI-associated deaths directly attributed to the infection.[15]

Not only does SSI pose substantial human toll, but it also exacts a considerable economic burden, representing the most financially burdensome HAI type with an estimated annual cost of $3.3 billion.[15] Furthermore, SSIs extend hospital stays by an average of 9.7 days and inflate the cost of hospitalization by over $20,000 per admission.[23, 27]

1 in 31 Patients



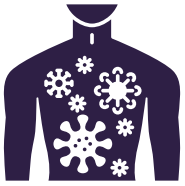
will get an HAI

(an infection while being treated in a medical facility) [2]

$28.4 Billion

Annual direct medical costs for HAIs in U.S. Hospitals [24, 29]

75,000 Deaths



each year as a result of acquiring an HAI [2]

Joint Commission SPD Readiness

Excellence in Motion:
Uniting Toyota Way and Fortive Business System for Continuous Healthcare Improvement [1, 10, 13, 17]

A foundational principle in audit readiness is that preparation does not begin weeks before the visit. Readiness is part of an ongoing, continuous improvement program that never ends—a concept pioneered by Toyota and embraced by Fortive Business Solutions. Readiness stems from **cultivating a quality mindset** complemented by **measured processes** that cater to the needs of patients and support healthcare professionals.

Quality is established at a foundational level and seamlessly extends throughout all processes from start to finish. Getting quality right the first time is crucial for maintaining higher standards. Management should immerse themselves in front-line experiences to sharpen problem-solving skills, while staff are empowered to proactively identify potential issues, fostering a culture of collaboration and trust in leadership.

Above all, **prioritizing people** is paramount. Treating individuals with respect is integral, alongside developing processes that facilitate their success and well-being.

Explore how Lean Six Sigma adopted the Toyota Production System, providing these guiding principles:

14 Principles of the Toyota Production System:[1]

A Comprehensive Guide, 2024

1. **Base Management Decisions on Long-Term Philosophy**
2. **Create Continuous Process Flows**
3. **Use Pull Systems**
4. **Level Out the Workload (Heijunka)**
5. **Build a Culture of Quality**
6. **Standardized Tasks**
7. **Use Visual Controls**
8. **Use Reliable Technology**
9. **Grow Leaders from Within**
10. **Develop Exceptional People**
11. **Respect Partners and Suppliers**
12. **Go and See for Yourself (Genchi Genbutsu)**
13. **Make Decisions by Consensus (Nemawashi)**
14. **Continuously Solve Root Problems (Hansei)**

Efficiency, as highlighted by both Toyota and a Department of Energy study, holds immense importance in averting undue strain on individuals. Standardizing work plays a pivotal role in alleviating this burden. It's crucial to recognize that human error traps are prevalent across industries, underscoring the need for safety measures or what is commonly referred to as a "Margin of Safety."[3]

- Time Pressure
- Distractive Environment
- High Workload
- First Time Task
- First Working Day After > 4 Days Off
- One-Half Hour After Wake-Up or Meal
- Vague or Incorrect Guidance
- Overconfidence
- Imprecise Communication
- Work Stress

Notable Practices:[1, 8, 10, 17]

- Invest in employee training and retraining. Let them understand what they are doing and why it is important.
- Design ergonomic workspaces.
- Use principles of flow in designing workspaces. This reduces errors and promotes efficiency.
- Work to minimize process variability. Variability introduces risk and that's when lapses happen.
- Document and track performance of employees as well as process indicators.
- Invest time in having someone oversee IFUs:
  - Are they easy to understand?
  - Up to date?
  - Easy to review summary material?
- Invest time in designing processes that support mitigating human error.
- Invest in systems that provide Margin of Safety.
- Collect and track data that allows continuous performance improvement.
- What are Key Performance Metrics?
- Plan for service line growth.

Virginia Commonwealth University

Joint Commission SPD Readiness in the Real World

Alignment Through Education

Sponsorship from Hospital Administration is enabled once they see examples of continuous improvement. The root of most problems or concerns can be related to education in the department. Education is vital to all technicians within the department to properly perform the tasks of cleaning, disinfection, and sterilization. It can help when something happens within the processes or procedures requiring different attention to send out for repair or keep the medical device continuing through the process. However, education is intended for other departments that use medical devices. Education allows us to obtain access to resources from senior leadership in the C-suites.

At VCU, a direct and continuous line of communication exists with perioperative/periprocedural management and the C-Suite. By viewing the SPD through a quality-focused lens as an essential component of the perioperative loop, hospital management can identify benefits for both patient's safety and hospital's efficiency.

VCU Health is a 820 bed health system that perform 29,880 operations and procedures per year. It has a main campus and 72 satellite facilities. The hospital runs a 6 day regular operating schedule including state of the art robotic procedures and advanced endoscopy. There are over 60,345 instruments as part of assets and 203 loads per day are processed. The shear breadth, speed, and complexity of procedures requires a Quality-Mindset as outlined.

Standardization & Centralization at the VCU Health SPD

Repeatability and consistency are the foundations of efficacy. Quality systems can be evaluated from the top down, looking for management endorsement and resource support, and then at the detail level, assessing broken instruments. Education, training, review, and quality testing provide a comprehensive framework to support these ideals. Proper staff training and knowledge of complex Instructions for Use are vital to achieving this aim.

Standardization and measurement of quality metrics drive positive SPD outcomes. If there are multiple processing sites, there should be central oversight to adherence of guidelines and IFUs. Many lapses in processes can occur if this is not appreciated. When resources are available, economies of scale can improve productivity.

VCU Health has established a centralized department specifically dedicated to overseeing high-level disinfection, effectively managing all hospital requirements. All clinics now submit their flexible scopes

Virginia Commonwealth University - Joint Commission SPD Readiness in the Real World (Continued)

and probes to this department for reprocessing and subsequent return. By consolidating all medical equipment processing activities, a single team manages manual cleaning, high-level disinfection, drying, and tracking processes in compliance with relevant standards and regulations. Previously, each of the twenty-eight departments independently handled these responsibilities. However, this fragmented approach often led to inconsistencies in procedures due to competing patient-related tasks within departments. Centralizing these tasks at VCU has allowed caregivers to prioritize patient care while SPD personnel focus solely on instrument processing.

The implementation of a dedicated staff for high-level disinfection ensures uniformity throughout the process and ensures the accurate execution of all necessary steps. This approach has also facilitated enhancements in departmental inventories, eliminating the issue of medical devices gathering dust, and improving patient traceability. Furthermore, centralizing medical instruments enables the team to ensure adherence to all instructions for use (IFUs) and adequately prepare patients for procedures.

Virginia Commonwealth University Builds on the Key Tenets of Continuous Quality Improvement and People First as follows:

Embracing **continuous quality improvement**, the department has implemented standardization through the utilization of uniform machines and supplies. This initiative has led to enhanced efficiency in turnover times and cost savings achieved through waste reduction and bulk purchasing. Moreover, this approach has not only resulted in fewer errors but has also facilitated consistent training for subject matter experts and enabled cross-training for all staff.

Regular maintenance checks for sterilizers and equipment ensure **operational reliability**, with ongoing inspection and maintenance conducted by staff in collaboration with manufacturer service representatives. Documentation of process control is crucial for auditability, with audit trails encompassing sterilizer identification, serial number, service date, type of action taken (preventative or corrective), and evidence of qualification testing before reuse.

A People First approach is deeply ingrained in the SPD culture at VCU. The department recognizes the significance of retaining skilled staff, leading to the creation of a career ladder aimed at motivating and compensating technicians. Through comprehensive training, technicians are equipped to demonstrate competency with each device without feeling overwhelmed, thereby fostering their retention and progression into leadership roles within the department. Collaborative problem-solving is encouraged among technicians, with VCU offering an eight-month training program designed to accommodate individual learning paces and ensure knowledge retention. Despite the eight-month investment, the assurance is of a fully trained individual capable of fulfilling any role within the department.

Conclusion

In conclusion, fostering a culture of safety within the Sterile Processing Department (SPD) is paramount for **ensuring the highest standards of patient care** and **minimizing adverse outcomes**. The Joint Commission (TJC) accreditation plays a pivotal role in this endeavor by providing a structured framework for organizing and fortifying patient safety efforts. Through rigorous evaluation and adherence to TJC standards, healthcare organizations can **enhance the quality of care, instill community confidence, and gain a competitive edge** in the marketplace.

TJC's approach to accreditation emphasizes continuous improvement and risk management, addressing key areas such as device reprocessing to mitigate the risk of adverse events. Failure to comply with accreditation standards not only jeopardizes federal and state reimbursement but also poses direct threats to patient safety. Surgical site infections (SSIs) are just one example of the serious consequences that can result from improper device reprocessing, underscoring the urgency of maintaining compliance with TJC standards.

The benefits of Joint Commission accreditation extend beyond regulatory compliance. It fosters a culture of excellence, enhances staff satisfaction, and reduces liability insurance costs. By investing in accreditation and ongoing compliance efforts, healthcare organizations can demonstrate their commitment to quality care, improve patient outcomes, and position themselves for long-term success in an ever-evolving healthcare landscape.

CHECK YOUR READINESS

Precision Pathways: Navigating SPD Joint Commission Standards

CHALLENGES FOR GENERAL KNOWLEDGE

- ☐ SPD processes aligned with the Spaulding Classification
- ☐ Drive reprocessing safety for instruments and personnel
- ☐ Training and Verification that IFU Instructions are followed correctly while looking for potential IFU discrepancies.
- ☐ Thorough SPD education in place
- ☐ Understanding and using Evidence based Guidelines
- ☐ Realizing that HLD is a minimum level of reprocessing for semi-critical instruments. "In some cases sterilization may be a better option." (Garcia-Houchins, 2023)
- ☐ Understanding potential causes of Outbreaks related to disinfection
- ☐ Environmental safety both for airborne contamination as well as droplet spread
- ☐ Understanding the use of Material Safety Data Sheets (MSDS)
- ☐ Correct use of PPE
- ☐ Presence of adequate ventilation
- ☐ Material Compatibility fully understood

CHALLENGES IN ENDOSCOPE REPROCESSING:

- ☐ Protocols in place to assess Decontamination & Transport
- ☐ Containment of the Decontamination area
- ☐ Up to date knowledge of IFU and changes in IFU
- ☐ Processes in place for every scope type
- ☐ Knowledge of # of lumens and length with the IFU (e.g. need for boosters, other limitations)
- ☐ Understanding Terminology: Manufacturers use varied terminology (Working Length, etc.)
- ☐ Instrument diagrams fully understood
- ☐ Inspection for surface integrity and leak testing
- ☐ Borescope Examination
- ☐ Contaminant Testing
- ☐ Automated Endoscope Reprocessing Hospital Process Integrity & Material Compatibility
- ☐ Thorough cleaning processes
- ☐ Thorough rinsing processes
- ☐ Thorough drying processes
- ☐ Storage protocols in place

CHALLENGES FOR SURFACE AND ENDOCAVITY ULTRASOUND TRANSDUCERS

- ☐ Point of Use Protocols in place
- ☐ Consider High Level Disinfection or Sterilization per IFU
- ☐ Containment and Transportation
- ☐ Electrical Leak testing if indicated (e.g. Transesophageal Echocardiography Transducers)
- ☐ Cleaning/Handling protocols in place
- ☐ Drying protocols in place
- ☐ Visual inspection of surface integrity
- ☐ Storage protocols in place

CHALLENGES FOR STERILIZATION

- ☐ Point of Use Protocols in place
- ☐ Transport of dirty instruments to decontamination
- ☐ Not letting biologic contamination dry
- ☐ Thorough disassembly processes
- ☐ Thorough cleaning processes
- ☐ Thorough rinsing processes
- ☐ Thorough drying processes
- ☐ Inspection & Lubrication
- ☐ Thorough Packaging process:
  - ☐ Properly Sized Peel Pouches
  - ☐ Easy Identification of Sterilization Status
  - ☐ Assurance that Sterilant can reach all surfaces

CHALLENGES FOR STEAM STERILIZATION

- ☐ Cycle Selection
- ☐ Process Control
- ☐ Physical Indicators
- ☐ Biological Indicators
- ☐ Point of Use Processes Clearly Understood

CHALLENGES FOR LOW TEMPERATURE STERILIZATION

- Assurance of Readiness:
  - ☐ Thorough cleaning processes
    - ☐ Protein ☐ Hard Water Salts
- ☐ Lack of water in load
- ☐ Need for booster if necessary (not available in all regions)
- ☐ Process Control
- ☐ Physical Indicators
- ☐ Biological Indicators
- ☐ Cycle selection fully understood

CHALLENGES FOR MAINTENANCE

- ☐ Record keeping / logs of service
- ☐ Continual Observation of Unit Performance and Indicators
- ☐ Auditability of stopping "failed loads" from reaching the patient
- ☐ Regular Preventive Maintenance

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