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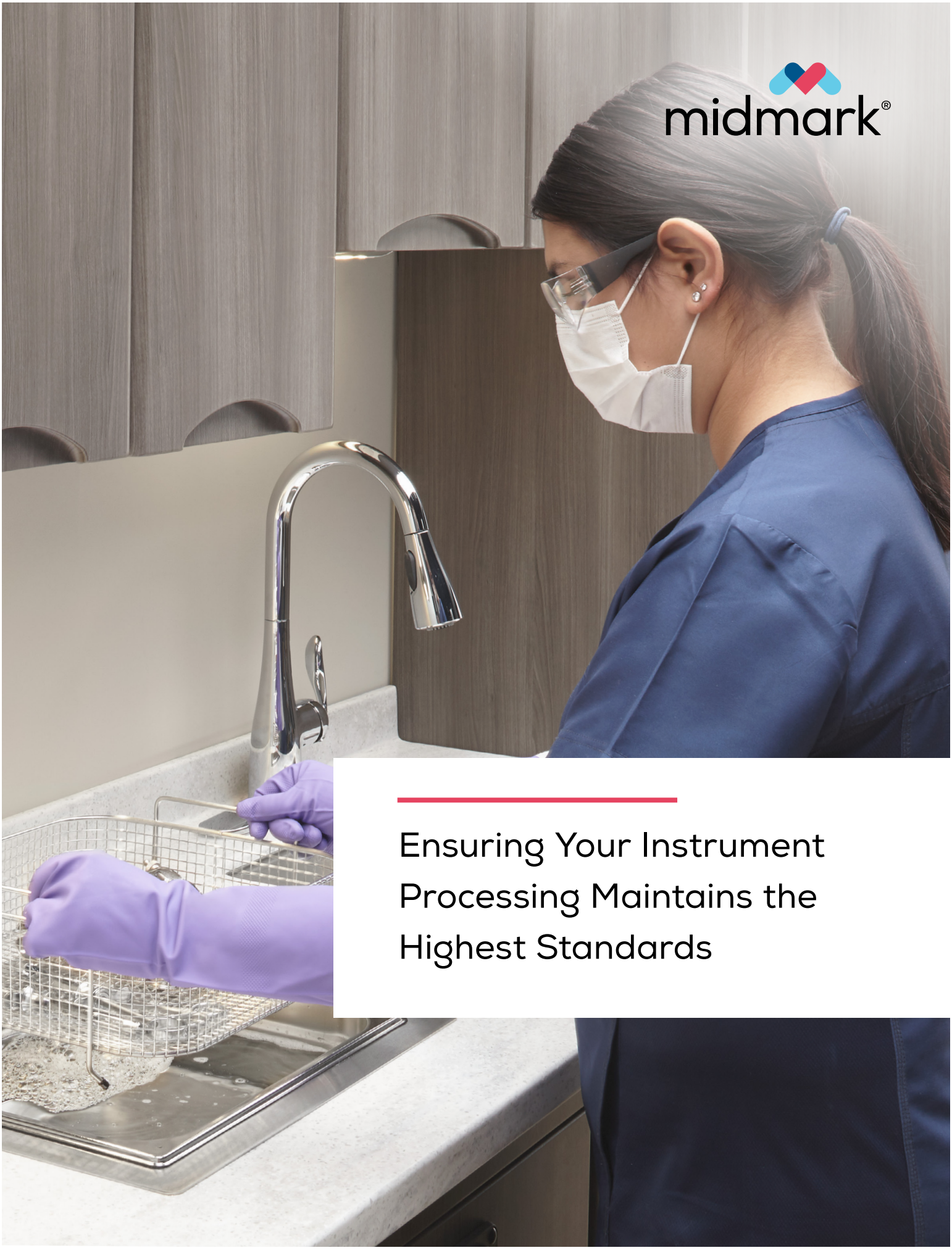


Ensuring Your Instrument Processing Maintains the Highest Standards

The lessons of the COVID-19 pandemic and the ongoing migration of procedures from inpatient healthcare settings to outpatient settings has brought a new urgency to infection prevention in non-acute environments. Patients are now seeking assurances that necessary precautions are taken to ensure a safer healthcare experience, while clinicians and staff want the peace of mind a safe working environment can provide.

To that end, more healthcare organizations are seeking accreditation. The most well-known accrediting organization is The Joint Commission. This voluntary action requires healthcare organizations remain compliant with a number of regulations and standards to become and remain accredited.

In this white paper, we provide a high-level overview of The Joint Commission's approach to standards compliance for sterile processing and offer a few tips on how you can strengthen your instrument processing area to help successfully complete the accreditation process and continually enhance your infection prevention efforts.

Becoming and Remaining Compliant

According to The Joint Commission website, the independent, not-for-profit organization is the nation's oldest and largest standards-setting and accrediting body in healthcare. It accredits and certifies over 21,000 healthcare organizations and programs in the US, visiting accreditation applicants a minimum of once every 39 months to evaluate compliance. These visits are usually unannounced.

There are a number of key players, guidelines and regulations when it comes to compliance for your instrument processing area. There are regulations from organizations such as the Food and Drug Administration (FDA) and Occupational Health and Safety Administration (OSHA), standards from accreditation organizations like The Joint Commission, and evidence-based guides that include standards and best practices from the Association for the Advancement of Medical Instrumentation (AAMI) and the Centers for Disease Control and Prevention (CDC). It can become pretty overwhelming and confusing at times.

Keep in mind that accrediting organizations are enforcing a consensus of all the relevant regulations, standards and recommended best practices, expecting participating healthcare organizations to show adherence by practice and in their standard operating procedure (SOP).

The Joint Commission developed a hierarchy guide to help organizations comply with the regulations and standards:

1. **Rules and Regulations** (e.g., FDA, EPA, OSHA, local and state health authorities)
2. **The Centers for Medicare & Medicaid Services (CMS) Requirements** (e.g., conditions of participation, conditions for coverage)
3. **Manufacturer's Instructions for Use (IFU)** (e.g., intended use Spaulding Classifications, validating cleaning, disinfection and sterilization)
4. **Evidence-Based Guidelines and National Standards** (e.g., AAMI ST79, CDC, World Health Organization)
5. **Consensus Documents** (e.g., professional organizations, expert panels)
6. **Organization's SOP** (e.g., explain how your organization came to this conclusion within the context of the hierarchical approach)

You should have a good understanding of this hierarchy approach and be able to present a strong rationale for the processes and procedures you have in place for your instrument processing space.

For instance, during a typical accreditation survey, a Joint Commission surveyor will run a tracer where they will follow the healthcare path for a patient visit. This will likely lead into the sterile processing area or department where they will observe the technicians and ask them questions about the process. They may ask why technicians have elected to carry out their processes and procedures in the manner they are currently. This is where the manufacturer's IFUs and SOPs usually come into play.

The surveyors want to ensure the processes and practices align with the manufacturer's IFUs and the evidence-based guidelines adopted by the facility. If they do not, the facility could be cited and would need to submit corrective action plans to receive accreditation. If the surveyors determine there is an immediate threat to life, they may force the facility to temporarily close.

Strengthening Your Infection Prevention Program

As you look to gain or renew accreditation for your facility, it is important you assess the current state of your entire infection prevention program. The following are important steps you can take to evolve your program and better position your instrument processing space for a successful survey visit.

Holistic Approach to Infection Prevention

A fragmented or inconsistent approach to infection prevention is inadequate when applied to today's evolving point of care ecosystem that includes new technology, equipment and best practices. Rather than a disjointed approach that lends itself to simply checking boxes, a broader, more encompassing approach is more effective.

Taking a holistic approach to infection prevention helps ensure all your bases are covered. It also allows you to create and maintain a consistent and sustained focus that is instrumental in identifying often overlooked threats and opportunities for successfully dealing with them.

This holistic approach should focus on five key components of your non-acute facility: facility design, equipment design, data analytics, the instrument processing area and sterilizers. Successfully adopting this approach can strengthen your entire infection prevention program and better position your organization to keep patients and staff safe.

Sterilizers

Often considered the focal point of any infection prevention program and instrument processing area, sterilizers are part of a front-line defense in keeping patients safe from contaminants, especially as more procedures move to the non-acute space. Having the right sterilizer is also a vital tool for your successful survey visit.

It is important to have the right size, type and number of sterilizers that fit the needs of each practice or facility. They should be FDA-cleared and certified to the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code by a third-party, licensed inspector. Your sterilizers should also have the capability to record, store and print documentation of the physical and mechanical performance of every sterilization cycle, including time, temperature and pressure.

This audit-ready recordkeeping ensures the necessary data is automatically loaded, backed up and organized for safe transfer and easy access, allowing you to streamline and simplify the audit to help you maintain compliance.

In fact, the CDC recommends that for each sterilization cycle, you should record the type of sterilizer and cycle used; the load identification number; the load contents; the exposure parameters (e.g., time and temperature); the operator's name or initials; and the results of mechanical, chemical and biological monitoring.

Instrument Processing Workflow

Instrument processing is a critical part of infection prevention—and even with a designated area for instrument processing, there's a chance the workflow design may not be compliant.

Regardless of the size and shape of your instrument processing area, there are five critical steps, based on guidelines from the CDC, that can help standardize your instrument processing workflow. By utilizing these five steps to standardize your instrument processing workflow, you can make it easier to manage the process so it may be properly reproduced by all your staff.

1. **Receiving, Cleaning + Decontamination**
   Reusable instruments, supplies and equipment should be placed in appropriate containers at the point of use to prevent percutaneous exposure incidents (PEIs) during transportation to the instrument processing area. All items should be received, sorted, cleaned and decontaminated of both macro- and microscopic debris in one section of the processing area.

2. **Preparation + Packaging**
   This area should contain a sink where the cleaned instruments and other supplies can be rinsed and then dried thoroughly. Items should then be inspected, assembled into sets or trays and wrapped or packaged to maintain sterility.

3. **Sterilization**
   The sterilization area should include the sterilizer and related supplies with adequate space for loading, unloading and cooling down of instruments and other supplies. Thought should be given to the size and type of sterilizer(s) that will need to fit into the configuration of your instrument processing space.

4. **Monitoring/Sterility Assurance**
   This area needs to be configured to support the documentation and recording of mechanical, chemical and/or biological monitoring utilized to help ensure the effectiveness of the sterilization process. Monitoring results and records need to be stored long enough to comply with federal, state and local regulations.

5. **Storage**
   The storage area should be covered and contain space for both sterile and disposable items. Supplies and instruments should not be stored under sinks or in other locations where they might become wet or damaged, or the packaging could be compromised.

Clinical Education Programs

Having the right approach, equipment and instrument processing workflow in place is only effective if your clinicians and staff are educated appropriately. They need to understand how to properly use and maintain the equipment and workflow to help ensure benefits are maximized and compliance is maintained.

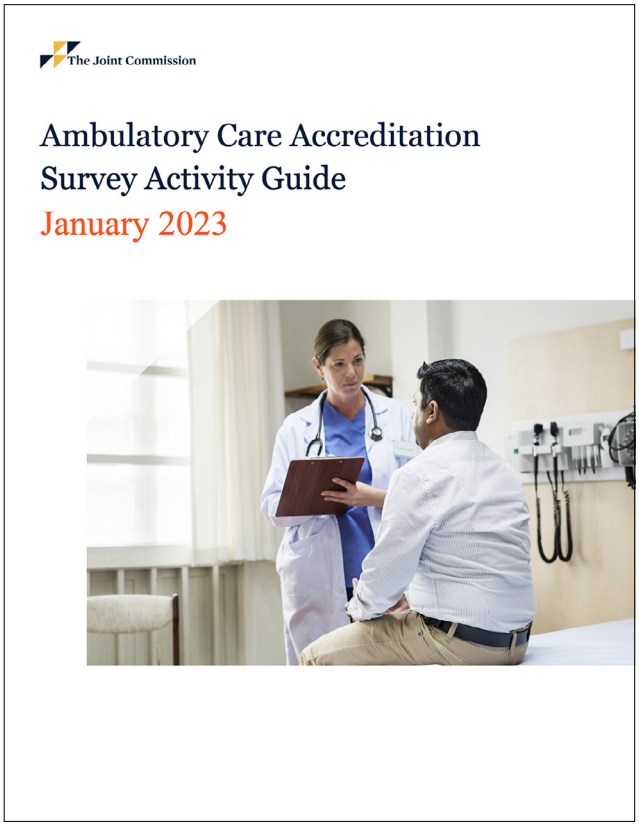
This type of education is becoming even more important with the steady migration of procedures and care from inpatient healthcare settings to outpatient settings. To address this growing demand, some companies, such as Midmark, are establishing clinical education programs to share their expertise and knowledge more easily. For example, Midmark offers an on-demand training module that focuses on the basics of the instrument processing workflow, IP area design principles and sterilizer technology.

Make sure you choose an education program that has flexible and scalable options specialized to meet the needs of your everchanging clinical environment. This should include offering onsite training, virtual education sessions and on-demand education options. The program should also be led by professional clinical educators who specialize in proper device use, workflow efficiency and infection prevention compliance.

Preparation and Planning

Finally, to help ensure a successful survey visit, it is essential you have a plan and timeline in place for all preparation activities and the necessary staff and participants are fully briefed on the process. Ensure everyone is familiar with the standards and understands where your instrument processing is compliant and where work still needs to be done before a survey. If you are going through the process for the first time, peers who have participated in survey visits can be a great resource.

The Joint Commission also offers a Survey Activity Guide that includes a variety of information to help prepare you for the visit. This includes a description of the onsite survey events, a sample survey agenda outlining what you should expect and a list of documents, information and participants you will need for the visit.



Conclusion

As the spotlight continues to shine on infection prevention in non-acute environments, many healthcare organizations are securing accreditation for their facility. When embarking on this path, it is important that you assess the current state of your entire infection prevention efforts and take the necessary steps to evolve your program. This will better position your facility for accreditation and reaffirm your commitment to help safeguard the well-being of patients and staff.

Contact us to learn how Midmark can help you strengthen your infection prevention program.

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