TMC
TOTAL MEDICAL COMPLIANCE

888-862-6742
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THE ADVISOR
MONTHLY COMPLIANCE COMMUNICATOR

How Clean Are Your Instruments? Manual vs Automated Cleaners

Cleaning medical and dental instruments and devices is the first critical step towards disinfection and sterilization. Cleaning is defined as the removal of foreign material from instruments and items used in any healthcare facility. Meticulous cleaning of instruments is required before high-level disinfection and sterilization can occur. Materials, either inorganic or organic, that are left on instruments impede the effectiveness of these processes. In addition, if materials become dried on the items, the removal process becomes more difficult. This in turn will make the sterilization/disinfection processes ineffective.

Cleaning medical devices can be done either manually or automatically. It should be done as soon as possible after the items have been used to prevent drying of materials on the devices. When cleaning is not done immediately, a holding solution may be used to keep debris moist to facilitate cleaning later. A holding solution is not needed when instruments are cleaned soon after use and after being transported to the reprocessing area. If a holding solution is utilized, remember to use an enzymatic detergent or solution deemed a holding solution. Never use a high-level disinfectant for a holding solution.

Manufacturers' instructions for use must be followed when utilizing cleaning agents to ensure compatibility with the instruments and effective cleaning. An important factor to consider when cleaning instruments is the nature of the object. When hinges, crevices, lumens, or complex moving parts are present, these require special attention to cleaning. Disassembling and opening the hinges may be necessary to properly clean the device.

Newsletter Content

Manual cleaning is done in areas without automated cleaners present. Manual cleaning is also done when the instruments or items are fragile or have difficult-to-clean areas. When performing manual or utilizing automated cleaning it is imperative that the appropriate personal protective equipment (PPE) be worn. Cleaning of instruments requires the use of detergents and water. Never use a high-level disinfectant for cleaning.

There are two components of manual cleaning: friction and fluidics. Friction is accomplished by rubbing/scrubbing the soiled instruments with a long-handled brush. Fluidics means fluids under pressure, and it is used to remove debris from the internal aspects of a device after cleaning. This occurs when a brush cannot pass through the internal components of a device.

When manual cleaning is performed:

- Use work practice controls to reduce the chance of injury from sharp objects
- Clean only two or three instruments at a time
- Never reach into trays or containers holding sharp instruments that cannot be seen
- Scrub instruments low in the sink under running water and use a long-handled brush to keep the scrubbing hand away from sharp instruments
- Wear appropriate PPE, including puncture-resistant, heavy-duty gloves
- Inspect all instruments for any remaining debris
- Dry instruments by allowing them to airdry or by carefully patting (not rubbing) with several thicknesses of towels.

After cleaning, instruments should be rinsed with water to remove chemical detergent residue, taking care to minimize splashing. Clean instruments are not sterile. Clean simply means all debris has been removed. Sterilization or high-level disinfection must occur after cleaning.

The preferred method of cleaning instruments is utilizing an automated or mechanical cleaner. The most common types of mechanical cleaning are ultrasonics and washer-decontaminators/ disinfector. All equipment used for cleaning must be FDA approved. Household dishwashers are not FDA approved to clean medical/dental instruments.

Ultrasonic cleaners use cavitation to remove debris from the instruments. Important things to consider when utilizing an ultrasonic cleaner:

- Always follow the manufacturers' instruction for use (IFU) on solutions used, test recommendations, and maintenance needed. The amount of solution and cycle times for loose instruments versus cassettes is found in these instructions.
- Test cleaning solution for effectiveness. Testing can occur by utilizing the aluminum foil test or by utilizing commercially available test vials. The foil test is the most common method used. This is done by immersing a strip of foil at least 2" wide and 3" long in the cleaner for 20 seconds. When you remove the foil, if evenly distributed dents are present, the cleaner is working. If they are not present, the cleaner would need to be serviced. Testing must be done at least monthly or more often following IFU.
- Don't overload the tank! The instruments should be placed loosely in the basket, submerged completely in the solution. The lid of the ultrasonic must be in place while running to reduce aerosols.
- Use the appropriate solution for the ultrasonic. Never use disinfectants- these may create the potential for hazardous fumes being released. Follow IFUs for solution types for the cleaner.
- Rinse instruments after the cycle. If the instruments were in a holding solution prior to the ultrasonic, rinse the instruments prior to placing them in the ultrasonic cleaner.
- Inspect instruments to ensure debris has been removed.
- Once the cycle and rinsing are complete, allow the instruments to dry. Dried instruments will reduce rusting or wicking when packaged.
- Best practice is to empty the ultrasonic daily or when IFU states a frequency.

A washer-disinfector/washer-decontaminator is another automated device used in healthcare settings to clean, decontaminate and disinfect heat-resistant and heat-sensitive items. These are FDA-regulated devices and work like a household dishwasher. They use a combination of water temperature, detergent, and spray technology to remove bioburden, ensuring instruments are safe for handling and sterilization. It is commonly used for rigid endoscopes, utensils, basins, and anesthesia equipment. Maintenance of the device is done by checking, cleaning, and ensuring proper function for optimal disinfection.

Once this critical step of cleaning to remove all debris from instruments and devices used in healthcare is complete, the instruments will be ready for packaging and sterilization. So, I ask you: how clean are your instruments prior to sterilization? What processes do you have in place to ensure cleaning is appropriately completed?

If you need help with this or any sterilization/disinfection processes, reach out to us and inquire about our Infection Control-Sterilization/Disinfection program. We are here for you!

A Reality Check on Recent HIPAA Updates

If you work anywhere near healthcare compliance right now, it probably feels like HIPAA is changing every five minutes. Vendors are blasting emails. Consultants are posting urgent LinkedIn takes. Webinars are promising to explain “major HIPAA updates” before it’s “too late.”
Let’s slow this way down and separate fact from hype.

The NPP Changes Are About Part 2, Not Everyone

One of the loudest sources of confusion right now is the update to the Notice of Privacy Practices (NPP). Many organizations are being told they must update their NPP immediately or they’ll be out of compliance.

Here’s the truth: **the recent NPP changes are tied to 42 CFR Part 2,** which governs substance use disorder (SUD) records.

If your organization **creates, receives, maintains, or transmits Part 2 data**, then yes, the NPP changes matter to you. You should be reviewing your notice and coordinating with legal and compliance to make sure it reflects the new alignment between HIPAA and Part 2.

If your organization **does not handle Part 2 data**, then nothing has changed for you. There is no new HIPAA-wide requirement forcing everyone to rewrite their NPP. No secret deadline. No hidden enforcement wave.

This distinction keeps getting glossed over, and that’s creating unnecessary panic for organizations that simply aren’t impacted.

The Security Rule NPRM Has Not Passed

The second big source of noise is the proposed update to the HIPAA Security Rule.
Yes, there *is* a Notice of Proposed Rulemaking (NPRM).
No, it has *not* been finalized.
And no, it is *not* law.

An NPRM is exactly what it sounds like, a proposal. It's the government saying, "Here's what we're thinking, and we want public input." Until a final rule is issued and an effective date is set, **covered entities and business associates are not required to comply with the proposed changes.**

Despite that, many vendors and consultants are already acting as if the Security Rule changes are a done deal. Some are marketing new tools, services, or "gap assessments" framed around requirements that don't yet exist.

That doesn't mean organizations shouldn't pay attention. The proposed changes give us insight into where OCR is heading and what regulators care about. But preparing thoughtfully is very different from being told you're suddenly noncompliant.

Scare Tactics Help No One

A lot of the current messaging relies on fear:

- "You're out of compliance."
- "You must act now."
- "OCR is about to crack down."

That kind of language doesn't improve compliance. In fact, it often does the opposite by overwhelming already stretched compliance, privacy, and IT teams.

Good compliance work is risk-based, thoughtful, and grounded in what is actually required today, not what might happen someday.

What Organizations Should Be Doing Right Now

Here's the reasonable, responsible approach:

- **Confirm whether Part 2 applies to you.** If it does, review your NPP. If it doesn't, document that determination and move on.
- **Track the Security Rule NPRM**, but don't treat it as final. Use it as a planning tool, not a compliance checklist.
- **Focus on existing HIPAA requirements.** Many organizations still struggle with basics like risk analyses, access controls, and workforce training, all of which are already enforceable.
- **Be skeptical of urgency without context.** Ask: "Is this final?" "Who does this actually apply to?" "What's the enforcement date?"

A Little Less Noise, A Little More Clarity

HIPAA compliance is complex enough without adding manufactured urgency and half-truths. Not every proposed change applies to everyone. Not every proposal is law. And not every email with "urgent" in the subject line reflects reality.

Clear thinking, accurate information, and steady leadership will always beat panic-driven compliance.

Sometimes the most compliant thing you can do is take a breath and read the fine print.

OSHA is Reshaping Workplace Safety in 2026

Over the past several months, OSHA efforts have accelerated in areas such as heat exposure, ergonomics, workplace violence prevention, and inspection procedures. These developments offer important insight into where workplace safety regulation and enforcement are heading.

Heat Safety

Heat illness has emerged as a regulatory priority. Its inclusion in rulemaking agendas signals the early stages of broader regulatory and enforcement action. Historically, this type of agenda placement has preceded the adoption of new standards and guidance.

Several state OSHA plans are intensifying their focus on heat-related hazards, with Federal OSHA guidance calling for written heat illness prevention plans and protective measures, including access to water, rest, shade, acclimatization protocols, and employee training. While these initiatives are currently only for guidance, enforcement activity increasingly reflects expectations that employers treat heat exposure as a structured program rather than an informal safety concern.

Ergonomics Return!

Ergonomics is reemerging as a priority area through phased regulatory strategies. Instead of broad, one-size-fits-all requirements, some state plans are developing ergonomics rules industry by industry. Early advisory materials emphasize how employers assess ergonomic risks, apply performance-based requirements, and implement program elements across different work environments.

These initiatives use structured timelines with distant deadlines, giving employers visibility into what is coming so they can properly plan.

Workplace Violence Prevention Becoming a Formalized Program

Workplace Violence Prevention is rapidly shifting from high-level mandates to detailed regulatory frameworks. Proposed standards increasingly resemble full compliance programs, with defined requirements for written plans, hazard assessments, employee involvement, incident response, investigations, training, and recordkeeping. At the same time, enforcement agencies are refining penalty structures, inspection strategies, and employee complaint and reporting mechanisms that trigger inspections and investigations.

Enforcement Tools Are Evolving

In addition to adding new safety requirements, many state plans are also changing how safety rules are enforced. These changes include setting clearer deadlines for issuing citations, treating minor paperwork or administrative issues as low-level violations, adjusting the time frame regulators can look back when deciding whether a violation is “repeat,” and tightening the evidence required to support a citation. Together, these updates can affect how inspections are conducted, how cases are challenged, and the overall risk employers face.

What This Means for Employers

Workplace risks such as heat exposure, ergonomics, and workplace violence are being translated into formal requirements with clear expectations for documentation, training, and accountability. At the same time, enforcement frameworks are being refined to cover inspections, citations, and penalties.

For employers, the challenge is no longer just keeping up with changes. It now means understanding how these initiatives affect enforcement priorities, inspections, and potential liability—and adjusting safety programs accordingly. TMC helps employers navigate this complexity by translating regulatory developments into practical guidance and defensible safety strategies.

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Instructions

Print and post newsletter in office for staff review. Each member should sign this form when completed. Keep on file as proof of training on these topics.

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Need to contact us? Scan the QR code for all the ways to get in touch!