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# OR Manager

The monthly publication for OR decision makers

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## Regulations

### CMS expects greater scrutiny from Joint Commission surveyors

The start of a new year includes OR Manager's annual updates on Joint Commission standards—an effort to help OR leaders ensure their facilities are in compliance. With increasingly stringent expectations from the Centers for Medicare & Medicaid Services (CMS), the Joint Commission and other accreditation organizations are under pressure to conduct more thorough surveys.

In recent years, when CMS has done a validation or follow-up survey on an ac-

credited organization, which under a pilot program happens concurrently with 5% of Joint Commission surveys, CMS typically has identified 30% to 40% more findings than the Joint Commission.

"CMS is not happy about this disparity rate, obviously, because they expect the surveyors to also catch these deficiencies," says John R. Rosing, MHA, FACHE, executive vice president and principal, Patton Healthcare Consulting,

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## Patient safety

### Is your staff ready to manage malignant hyperthermia?

Malignant hyperthermia (MH) is a rare but life-threatening surgical complication that seems to turn the effects of general anesthesia upside down. Instead of relaxing, muscles become rigid, releasing large amounts of acid and potassium into the blood. Instead of a normal slowing of breathing, respirations quicken, and end-tidal CO<sub>2</sub> rises. Other signs include tachycardia and a spike in body temperature that can reach over 110 °F. Without rapid treatment, MH can lead to cardiac arrest and death.

Fortunately, MH crisis is rare, occurring in only one in about 100,000

adult procedures and one in about 30,000 pediatric procedures, according to the Malignant Hyperthermia Association of the United States (MHAUS, <https://www.mhaus.org/faqs/>). However, when MH does strike, it requires rapid response by highly trained staff.

So how do you keep your staff's skills sharp enough to treat this potentially catastrophic condition, which many healthcare professionals have never seen? OR Manager spoke with nurse leaders at three US healthcare facilities who have found that drills are

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## Joint Commission

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Naperville, Illinois. This is contributing to the greater scrutiny seen on surveys this year. A single observation of a deficiency will cause a requirement for improvement.

Astute organizations that aim for zero defects welcome this level of scrutiny, says Rosing. “It’s not about ramping up to prepare for a survey; it’s about doing the right thing each day, without fail.”

### New scoring process lowers infection control findings



**John R. Rosing,**  
MHA, FACHE

In September 2018, the Joint Commission updated and clarified requirements and surveyor scoring instructions for a particularly troublesome standard, IC.02.02.01, says Rosing. The second element of performance (EP 2) under this infection control standard—Hospitals perform high-level disinfection and sterilization capably—had been responsible for the most high- and medium-level risk findings on the SAFER Matrix, he says.

The SAFER (Survey Analysis for Evaluating Risk) Matrix uses an algorithm to score a finding as low, moderate, or high, depending on its likelihood to harm a patient, visitor, or staff and whether the occurrence was limited, a pattern, or widespread ([https://www.jointcommission.org/topics/safer\\_matrix\\_resources.aspx](https://www.jointcommission.org/topics/safer_matrix_resources.aspx)).

Since the surveyors started the new scoring process, the percentage of hospitals that receive an infection control finding has dropped from 83% to 70%.

In addition to training surveyors to score differently, the Joint Commission updated its Frequently Asked Questions for this standard. The new emphasis is on following a hierarchy of requirements

beginning with CMS Conditions of Participation (interpretive guidelines and worksheets), followed by the manufacturer’s instructions for use (MIFU), evidence-based guidelines, and consensus statements. If an issue isn’t addressed by any of these, a facility’s own policies and procedures are the ruling document. “This new emphasis changes a few things,” Rosing notes.

**Precleaning at point of use.** Surveyors used to score as deficient visible bioburden observed on instruments in a holding area or when entering decontamination.

Now they will score for not wiping dirty instruments during a procedure if it is clinically appropriate to do so, or if an item that is in storage ready for use (ie, an instrument in a sterilized tray or peel package) is still visibly soiled (ie, indicating a failure at some point in the process). This puts a greater focus on items ready for use rather than those awaiting decontamination.

The Joint Commission is shifting away from expecting staff to physically, mechanically scrub an instrument in the OR or procedure room in order to remove all blood and bioburden, which presents a possibility of sharps injuries to employees who are not wearing the correct heavy-duty gloves, gowns, or eye protection. But surveyors do expect instruments to be disassembled and precleaned by staff at the point of use in accordance with the MIFU and in accordance with evidence-based guidelines and consensus statements from organizations like AORN and the Association for the Advancement of Medical Instrumentation (AAMI).

Therefore, “gross soil” should be removed at the point of use, says Rosing. “When a surgical tech is handed a bloody instrument from the sterile field, and he knows the surgeon is going to need it again, he will wipe it off before handing it back to the surgeon. That is commonplace and acceptable,” he says. “Now, surveyors will cite you only

if the tech doesn’t wipe it off before handing it back, but they would have to be in the room to see it happen, which is why this is a very rare finding.”

They will also score when an instrument that’s already sterilized and in a peel pack or tray has visible soil on it. This would mean that the instrument had not been properly processed. “This also would be a rare finding,” he notes, “because it would be like looking for a ‘needle in a haystack’ in all of the trays and peel packs in central sterile and other areas where instruments are kept, such as the emergency department [ED], OB, or ICU.”

**Keeping instruments moist.** Coupled with the revised precleaning at point of use expectations, surveyors have modified their approach to judging if instruments are kept moist between the point of use and the decontamination process in sterile processing.

Now they will score if:

- The instrument MIFU are not followed.
- The organization’s policy is not followed.
- There is no process for keeping instruments moist (note: the wetting agent need not contain an enzyme).

“Your policy and procedure should be very specific to guide staff on what you want done, when, and where,” says Rosing.

Rosing advises that OR managers think about the entire organization and all locations where instruments are used when they write their policies and procedures. They should also include footnotes that point back to a specific guideline (ie, AAMI or AORN) on which the procedure is based. One suggestion is to include a statement such as, “point of use is defined as an operating room, procedure room, exam room, treatment room, or nearby soiled utility room,” he says.

This statement provides options. For example, the wound care exam room might not be a good place to spray the

# Regulations

instruments with a wetting agent. They can be carefully contained, labeled as biohazardous, and transported immediately to a nearby soiled utility room and sprayed there. In the OR, on the other hand, the process could entail soaking instruments in a basin of sterile water.

"You want to have these different options spelled out in your policy, so the surveyor can determine if you are following your policy, which should be based on the MIFU for the instruments and the spray as well as AORN and AAMI guidelines," Rosing says. "For example, AAMI ST79 states simply that instruments may be kept moist by covering with a wet towel or by applying a wetting agent. We recommend parroting this language into your policy," he says.

## **Transport of dirty instruments.**

"Surveyors used to score if instruments were not transported in a leak-proof, puncture-proof container with a lid and biohazard sticker," says Rosing.

Now they will score if Occupational Safety and Health Administration (OSHA) requirements are not followed when transporting sharps, or if non-sharps are not transported in a way that prevents staff or others from being exposed to contaminated items.

"This gives you a little wiggle room in some situations, such as an open case cart rolling down the hall with dirty instruments," he says. "The instruments don't need to be contained if there are no sharps. Sharps, however, need to be in containers that are puncture-resistant, labeled, or color-coded with a biohazard label, and leak-proof on the sides and bottom."

Rosing notes that both AAMI and OSHA guidelines can be used when writing a policy and procedure for transport of dirty instruments.

## **Instruments in closed position.**

Surveyors used to score instruments observed in a closed position prior to or any time after sterilization.

Now they will score:

- ratcheted or hinged instruments that



## Containment and Transport

Source: John R. Rosing. Used with permission.

were washed in a locked or closed position

- instruments in sterile processing that were washed but not disassembled per the MIFU
- packaged, ratcheted instruments awaiting sterilization that are locked
- packaged, ratcheted instruments after sterilization or in storage that are locked.

"'Prior to' is the key point here," says Rosing. "For example, in the past, if surveyors were in a wound care clinic looking in a basin and the scissors were closed, they would score it. Now, they are going back to what AAMI says, which is: 'Any hinged instrument, including ratcheting instruments, are open when they go through the decontamination process to include the washer, sanitizer.'"

Furthermore, AAMI ST79 says the ratchet on a ratcheted instrument has to be unlocked when going through the sterilizer and when stored. "Formerly, surveyors were scoring anytime any hinged instrument, ratcheted or not, at any point in the process was observed to be 'closed.' The new scoring approach is more objective and consistent with AAMI language," he says.

Therefore, if a hinged instrument, such as a scissor, is closed in a peel pack, they won't score that because

they are acknowledging that the scissor could have closed as it was being transported to where it was being stored.

"These are subtle differences, but they have led to less scoring," he says.

**Instruments released prior to the biological indicator (BI).** Surveyors used to score if instruments were released for use prior to the biological indicator being read.

Now they will score for:

- not following the MIFU when running the BI in the sterilizer
- failing to document the results of the BI
- failure to check the external and internal chemical indicators for a non-implant load
- failing to check the physical monitor (check the autoclave or sterilizer strip) for a non-implant load
- failure to check the strip, BI and type 5 integrator, or the BI prior to release of an implant load.

"One of the things that is new here is that OR managers will want to prepare their staffs as well as staffs in the ED, OB, ICU, and wound care departments that use sterile instruments to answer the question: 'How do you know this instrument is sterile?' Telling a surveyor that it's sterile because it came from central sterile is not the right an-

- Separate or label broken instruments or instruments in need of repair
- Discard disposable sharps
- For sharps they need to:
  - Be covered
  - Be leak proof
  - Be puncture proof
  - Have a biohazard label

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swer,” says Rosing. OR managers must teach their staffs:

- to examine instruments for visible blood or bioburden and rusted or pitted areas
- to make sure there are no rips in the sterile package or peel pouch or stains or wet marks on the peel pouches
- which external and internal indicators are appropriate for which sterile items and how to check and document the results.

## Changes for storage of sterilized semi-critical devices

Several changes have been made to IC.02.02.01 EP 4: Storage of sterilized semi-critical devices.

**Peel packs for semi-critical devices.** Individual peel packs are no longer necessary for instruments that touch mucous membranes (ie, semi-critical devices).

“A big change is that you can now remove semi-critical devices from their peel packs or containers they are sterilized in, and store them unpackaged in a clean drawer,” says Rosing.

This change is due in large part to the lobbying of the ear, nose, and throat (ENT) physicians. They pointed out that, for example, when they have a speculum in the nose of a patient in the ENT exam room, it is very cumbersome for them to have to open peel packs of other instruments they need during a procedure with the other hand. They had always been accustomed to having sterilized instruments loose in a drawer until the Joint Commission began to score this practice.

The Joint Commission now says it will accept having instruments out of peel packs for the convenience of the physician as long as they are in a clean drawer and they are put into and removed from the drawer using aseptic technique. The same holds true for vagi-

## Storage of Sterilized Semi-Critical Devices IC.02.02.01 EP 4

- Individual peel pack no longer necessary for instruments that touch mucous membranes (semi critical)
  - Can remove semi critical devices from peel pack or individual bag and store in a clean drawer. Need clean hands. Big change.
- Based on hospital policy
- Be careful on this point; don't give up ground you've gained



*Source: John R. Rosing. Used with permission.*

nal speculums and oral airways on the anesthesia cart.

Rosing notes that this changed interpretation surprised many, and he recommends that OR managers proceed cautiously before adopting this more liberal position.

**Endoscope hang time.** Hang time for endoscopes is now based on the MIFU as well as the facility's written process, if the process defines a hang time.

The Joint Commission used to follow the Society of Gastroenterology Nurses and Associates' (SGNA) recommendation of a 7-day hang time, meaning facilities had to reprocess an endoscope that had hung for more than 7 days.

The Joint Commission will no longer score based on the SGNA recommended hang time. However, a facility that is not following the endoscope manufacturer's mandated hang time or its own policy will be scored.

Rosing recommends that facilities consider modifying their policies and procedures to only have a hang time if the endoscope manufacturer mandates a hang time.

The Joint Commission also requires that facilities follow the MIFU for cleaning and storage, and that fresh gloves be used when handling and transporting clean endoscopes.

## Surgical and sterile processing attire

The updated AORN recommended practices on surgical attire, which were released July 1, 2019, say:

- Fresh attire daily, hospital-accredited laundry, change into attire on site
- No recommendation for the style of head covers worn in the semi-restricted and restricted areas (though cloth hats must be laundered daily in a hospital-grade laundry)
- No recommendation about covering the ears in the semi-restricted and restricted areas
- No recommendation about long sleeves in semi-restricted or restricted areas, or when performing the preoperative skin prep (“may” wear long sleeves during the skin prep)
- Beard covers must be worn in restricted areas and during preparation and packaging of items in the clean area of sterile processing.

Sterile processing attire must be donned at the hospital and changed daily, and no one can cross the red line without proper attire. No artificial nails, nail polish, jewelry, or watches are allowed.

AORN says that head and facial hair must be covered at all times “during preparation and packaging of items in



the clean assembly section of the sterile processing department.” AORN’s revised standard in July backed away from the ears being covered, implying that skull caps would be acceptable.

In decontamination, liquid-resistant category 4 gowns, heavy-duty gloves, eye protection, and an eyewash station within 10 seconds’ travel time are required.

One thing that often gets cited is the surgical mask dangling around the neck, says Rosing. He notes that there has been some controversy over whether the mask is intended to protect the patient or the person wearing the mask. Rosing says it’s both.

“The bottom line is, no matter whose protection you think it’s for, or no matter what you read into what AORN says, if surveyors see a mask around the neck outside a restricted area, they are going to cite it,” he says.

## Timeouts scored for not paying attention

“Timeouts are scored and scored often when the surveyor asks to stand in the corner of the OR or procedure room and watch the timeout,” says Rosing. “If they see someone doing something other than paying attention, it will result in a finding.”

It can be something subtle, such as an anesthesiologist who turns to a monitor or adjusts the tubing or airway while the timeout proceeds. The surveyor would accept if, for clinical reasons, the anesthesiologist had to adjust the airway on the patient during the timeout, but the timeout should be paused for the adjustment and then started again.

Active participation in the timeout and no multitasking needs to happen every day, in every case, in order to avoid a never event in real life or a pratfall in a survey. “You can’t possibly suddenly do it right the moment the surveyor is in the corner of the room if you are not doing it right each and every day. In order for the timeout to be real, and to truly be a tool

**Timeouts may lead to a finding if any inattention from staff is observed.**

to prevent a wrong site, wrong patient, wrong procedure error, undivided attention has to be your mantra all the time, and you must call people out if they are violating it,” he says.

## Removing alcohol solution-soaked prep material from the OR

In recent years, CMS and the Joint Commission have been enforcing the National Fire Protection Association 2012 Life Safety Code (LSC), which calls for alcohol solution-soaked items to be removed from the OR prior to the start of a case involving electrosurgery, cautery, or a laser.

Because of feedback that removing any materials from the OR runs contrary to AORN recommended practices, the CMS and Joint Commission have changed their interpretation of the LSC from “removed from the operating room” to “removed from the vicinity of the patient.”

## USP Chapter <797> standards

The revised USP Chapter <797> standards, effective as of December 2019, give more leeway to medications drawn up in the OR, Rosing says.

“In the past, once a medication was drawn into a syringe, you had to begin using it within an hour, which correlates with the definition of ‘immediate use,’” he says. “The new USP that’s out now and effective December 1 gives you 4 hours, but it still requires that you date and time the syringe when it is drawn up, and it has to be discarded at 4 hours.”

If an organization receives Medicare or Medicaid funding, it must follow USP regulations for compounding.

## Information management standards

After extensive discussion, the Joint Commission determined that text messaging cannot be used to communicate patient care orders.

However, a secure text messaging platform can be used to communicate patient health information.

Key features include:

- secure sign-on process
- encrypted messaging
- delivery and read receipts
- date and time stamp
- customized message retention time frames.

In addition, organizations must assess compliance with texting policies and procedures, do risk assessments, and train staff.

## Pain management standards

The Joint Commission’s new pain management standards, issued more than a year ago, call for a more conservative approach.

Some standards developed in the early 2000s have now been deleted:

- Educating licensed independent practitioners about pain assessment and managing pain (MS: Medical Staff)
- The right to pain management (RI: Rights and Responsibilities of Individuals)
- The comprehensive pain assessment and criteria for reassessment stand-alone elements of practice (PC: Provision of Care Treatment and Services)
- The response to pain elements of practice (PC: Provision of Care Treatment and Services).

CMS also got involved with a requirement in 2014 that called for better post-operative monitoring, and in 2018 issued a Medicare Part D payment memorandum aimed directly at the prescribing of opioids. “It was a 231-page document for Medicare Advantage patients, but one sentence was the sum and substance of it: ‘Medicare will only pay for a

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7-day supply of opioids,” says Rosing.

CMS also changed its Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scoring, which used to ask patients to grade hospitals on whether they were happy with their pain management. CMS no longer considers pain management scores when determining value-based purchasing reimbursement, he says.

The Joint Commission has added new standards under the leadership chapter that require having a process to implement safe opioid prescribing along with performance monitoring and improvement activities. The standards also talk about having alternatives to pharmacologic pain treatment and having educational resources available for providers and nurses.

“These are all structural things the Joint Commission wanted hospitals to begin working on,” says Rosing.

In addition, there is now a prescription drug monitoring program database in every state, where, for instance, ED staff can look up patients to see if they have a history of drug abuse or are potential abusers.

Because medical staff are involved in the whole program, there is a Medical Staff standard on establishing protocols and quality metrics as well as reviewing ongoing process improvement data.

A Provision of Care standard introduces language about minimizing risk associated with treatment, and incorporating criteria to screen, assess, and reassess pain. Though not totally new, some new wording has been added to this standard, and pain and management policies and procedures should be updated to say treatment “strategies must include nonpharmacologic, pharmacologic, or a combination.”

The Provision of Care standard also talks about developing realistic expectations with patients.

“This should be a key area of focus,” says Rosing, “so that throughout the patients’ episode of care, you are talking about what they should expect and the fact that they may or may not be comfortable at certain times.”

Rosing adds that “in the past, we said, ‘we’re going to make you comfortable. You have a right to be comfortable.’ The idea now is to be more realistic with them on the amount of pain they may have.” ♦

—Judith M. Mathias, MA, RN

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