Sharps safety

What OSHA says about safety scalpels

An interview with OSHA on sharps safety.

Dionne Williams, a senior industrial hygienist in the Occupational Safety and Health Administration’s (OSHA) Office of Health Enforcement, answered OR Manager’s questions about the bloodborne pathogens regulation.

Q Do you have statistics on how many OSHA inspections of hospitals in the past year have been random versus based on an employee complaint?

Williams. For the states covered by federal OSHA, which is about half of the states, in fiscal year 2004, we had a total of 195 inspections. Of those, 94 (48%) were strictly from complaints. A total of 84 were planned inspections. Those resulted either from a regional-level or an area office-level special emphasis on needlesticks/bloodborne pathogens exposure in the health care industry. The remaining inspections were of other types, such as referrals from other agencies.

Q Were more inspections conducted in some areas than others?

Williams. The regions with special-emphasis programs generally conducted more inspections than those that did not have special emphasis. There currently are 3 regions with local emphasis programs related to bloodborne pathogens and needlesticks (sidebar).

Q Would you please comment on OSHA’s expectations regarding use of safer devices in the OR? Our readers say they have conducted trials on safer types of scalpels, such as those with retractable blades. But their surgeons will not always accept them. They document this fact, as OSHA requires. But some hospitals have been cited for failing to implement these safer scalps even though their surgeons have rejected them. Is it mandatory to use these kinds of devices? How much discretion do OSHA inspectors have in determining whether a hospital is cited for this?

Williams. That’s tough to say categorically. The findings for each inspection are on a case-by-case basis. We determine the outcome of every case based on the merits of that particular case. In some hospitals, surgeons are independent contractors. OSHA considers it a multi-employer worksite when a contractor works in a facility where that person may be exposing employees. The hospital may have employees who are being exposed, such as nurses and surgical techs who assist in surgical procedures. So an inspection may result in a citation to the surgeon as well as to the hospital because both share the responsibility of safety for the exposed workers.

Q Do you have any statistics on how many surgeons have been cited for this?

Williams. No, I don’t.
Some OR directors say they’re caught in the middle between OSHA and the surgeons. They are trying to comply with the bloodborne pathogens regulation, yet some surgeons say, “We are the ones who do the surgery, and we don’t want to change to a device we’re not comfortable using.” What should OR directors do?

Williams. That’s something they need to document. If the hospital has done an evaluation and determined some of these newer devices are appropriate for certain situations—obviously, no one device is going to be appropriate for every situation, particularly for surgery—you’re going to have some delicate situations where a surgeon feels comfortable using one particular type of device, and that comfort may make a difference in whether the surgery is successful or not. Those situations have to be weighed. If it’s a situation where the surgeon has determined he or she does not want to use the safer device because of a concern about patient safety, we certainly don’t expect the patient’s safety to be jeopardized. Those situations need to be documented. In cases where we might have issued citations, it’s because that documentation hasn’t been represented in the Exposure Control Plan. So it’s not just a discussion to have with the surgeons, it has to be written.

Is there any form this documentation needs to take? Must there be documentation for every kind of surgical procedure for which the surgeons will not use a safety scalpel?

Williams. It might come down to that because you might have some procedures where it’s accepted across the board that a safety device is appropriate and feasible to implement. In cases where they can’t use safety devices, they need to explore other measures also, such as a neutral zone for passing sharps. The bloodborne pathogens standard calls for the use of engineering controls as well as administrative controls, so it’s a combination. There are also some scalpel-free procedures that could be used in certain cases that would eliminate the scalpel altogether. They need to explore all the possibilities and include as much documentation as possible.

Would you please elaborate on the documentation OSHA expects? We have talked to one facility that was cited even though it had documentation to this effect.

Williams. In a lot of cases, the documentation just says the surgeons don’t want to use the safer devices. The documentation must show a real reason why surgeons aren’t using them. There needs to be more than just a blanket statement that the surgeons will not use them. That sounds like a preference as opposed to a concern about the safety of patients. There are surgeons who will not use safer devices no matter what the procedure is. That’s the kind of situation we’re trying to avoid because there’s no way we’re going to get these types of devices to become commonplace unless people actually use them when they can. Also, manufacturers will stall on advancing technology if they find surgeons are not using these devices and hospitals are accepting that fact.

Is there a specific form to use for documenting exceptions for surgeons who say they cannot use safety scalpels?

Williams. There is no exemption form. Each facility is required to perform an evaluation of its individual circumstances and determine whether safety scalpels (or any other safety equipment) are appropriate and/or feasible.

It is not appropriate for a facility to use a blanket exemption for safety devices (ie, scalpels for all operations). If a facility is using patient safety as a reason for not using a safety scalpel for certain procedures, it must document this in the Exposure Control Plan, not on a blanket exemption form. No doubt there will be some cases where use is appropriate and others where it is not, especially given the fact that some newer safety scalpels are metal; they look and feel almost exactly like traditional scalpels except for the safety feature that shields the blade after use.
Regarding blade-removal devices that are mounted on the wall, it is not always possible to use these during a procedure because they are located away from the sterile field. Will you please comment on this?

**Williams.** We hear mixed things. In some cases, it might be feasible to mount the blade removal device on the tray used as a neutral zone for passing sharp devices. If a blade must be removed, it is easier and safer to have removal as close to the area of use as possible.

Our readers have questions about the neutral zone, or no-pass zone, for sharps. A no-pass zone isn’t always feasible. Surgeons may not be able to take their eyes away from the sterile field to pick up the instrument. In some cases, they may be wearing loupes for magnification. How can facilities meet the OSHA requirements and still meet the needs of the surgeon?

**Williams.** The requirement is to use engineering controls and administrative controls together. In cases where use of the neutral zone is feasible and will reduce the likelihood of injuries, we will look to see that it is being used. Situations where surgeons are unable to look away from the sterile field present concerns for the safety of assistants as well as the surgeon. This is a difficult situation, and hospitals should involve surgeons in discussions of ways to prevent injuries to workers in the OR. We do not think it’s acceptable to pass contaminated devices blindly to workers who are being stuck. Surgeons should be aware of the facility’s protocols and should be in agreement with adhering to protocols set up to avoid employee injuries. It cannot just be a policy of the hospital without the doctors being involved.

What role do a facility’s statistics on injury rates play? If a facility tracks sharps injuries and finds injuries have not been documented from passing of sharp instruments, does that affect the decision about whether to use a neutral zone?

**Williams.** Safety measures are there to prevent injuries. Even if a facility has a low number of injuries, it doesn’t mean it is exempt from using safety devices. As an example, facilities are expected to use safety syringes regardless of the number of needlesticks during use of syringes. We do not expect employers to rely on the low numbers of injuries to determine whether they are going to implement use of safety devices.

Does this mean OSHA expects ORs to implement a neutral zone even if they have a low injury rate from passing sharps?

**Williams.** That’s correct. Again, not every situation is the same. We look at it on a case-by-case basis. Feasibility is an important factor in implementing any safety measure. If it is not at all feasible, that’s one thing. But if there’s a feasible method of reducing injuries, we expect they will consider implementing that.

How often does a facility need to revisit these decisions?

**Williams.** Facilities must evaluate devices annually and must document the annual evaluation. Technology is continually advancing. Employers may find something new and better on subsequent evaluations. In cases where no new devices are selected after the annual review, employers need to document the fact that they looked at available devices and found the device they currently use to be most appropriate.

OSHA has an interpretation on use of safety scalpels on its web site at www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=25090
Where is OSHA focusing?

OSHA has local-emphasis programs for bloodborne pathogens and needlesticks in 3 regions:

Region 2
New York, New Jersey, Puerto Rico, Virgin Islands

Region 3
Pennsylvania, Delaware, District of Columbia, Maryland, West Virginia, Virginia

Region 8
Colorado, Utah, Wyoming, North Dakota, South Dakota, Montana