



Reply to the attention of:

DEC 22 2005

Dr. Michael Sinnott, MBBS, FACEM, FRACP  
PO Box 5677  
West End QLD 4101  
Australia

Dear Dr. Sinnott:

Thank you for your July 16, 2005 letter to the United States Occupational Safety and Health Administration's (OSHA's) Directorate of Enforcement Programs (DEP). You have concerns about the use of safety-engineered scalpels in surgery. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence. For clarification, your specific questions are paraphrased below, followed by OSHA's responses. We apologize for the delay in addressing your concerns.

**Question 1 :** In situations where a surgeon chooses to use a scalpel with a reusable metal handle, from which the used blade is removed, instead of a plastic disposable scalpel, would the use of a single-handed scalpel blade remover meet the requirements of OSHA's bloodborne pathogens standard (29 CFR 1910.1030)?

**Reply 1:** As you know, OSHA's bloodborne pathogens standard at 29 CFR 1910.1030(c)(1)(iv)(B) requires employers to first evaluate the efficacy of the use of safer medical devices as a means of meeting their responsibility under 29 CFR 1910.1030(d)(2)(i) to eliminate or minimize employee exposure to blood or other potentially infectious materials (OPIM). Surgical practitioners must base their evaluation and selection of scalpels and other medical sharps on the impact a device will have on achieving the necessary balance between employee safety and the delivery of optimal healthcare to patients. If appropriate commercially available and effective safety scalpels are feasible for a particular procedure and do not compromise patient safety, then the surgeon must use them. However, if the use of a safety engineered scalpel compromises patient safety or is in some other way infeasible for use in a particular procedure, the employer must then determine what other engineering and work practice controls would effectively minimize employee exposure and implement their use.

In general, the bending, recapping or removal of a contaminated needle or other contaminated sharp is prohibited. However, the standard provides an exception where an "employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure." [29 CFR 1910.1030(d)(2)(vii)(A)]. In situations where an employer has demonstrated that the use of a scalpel with a reusable handle is required by a specific medical or dental procedure or that no alternative is feasible, the blade removal must be accomplished

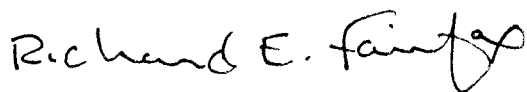
through the use of a mechanical device or a one-handed technique [29 CFR 1910.1030(d)(2)(vii)(B)]. The use of a single-handed scalpel blade remover meets these criteria.

**Question:** Is it correct that the use of a passing tray is considered to be “standard procedure” in operating rooms in the United States? Is it also considered to comply with OSHA standards?

**Reply:** Yes to both questions. The professional literature reflects that a no-hands-pass procedure, such as the use of a passing tray, is a frequently used work practice control for the prevention of sharps injuries in operating rooms across the United States. It complies with the bloodborne pathogens standard. OSHA’s Compliance Directive, *Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens*, CPL 02-02-069 states: “Preventing exposures requires a comprehensive program, including the use of engineering controls (e.g., needless devices, shielded needle devices, and plastic capillary tubes) and proper work practices (e.g., no-hands procedures in handling contaminated sharps, eliminating hand-to-hand instrument passing in the operating room).”

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA requirements are set by statute, standards, and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at <http://www.osha.gov>. If you have any further questions, please feel free to contact the Office of Health Enforcement at 202-693-2190.

Sincerely,



Richard E. Fairfax, Director  
Directorate of Enforcement Programs