January 9, 2019

Grace Delizo
Senior Safety Engineer
Division of Occupational Safety and Health

Amalia Neidhardt
Senior Safety Engineer
Division of Occupational Safety and Health

AIHA Comments on Cal/OSHA Discussion Draft on Occupational Exposure to Surgical Plume

Dear Ms. Delizo and Ms. Neidhardt:

The American Industrial Hygiene Association ® (AIHA) appreciates the opportunity to comment upon Cal/OSHA petition 567, §51xx *Occupational Exposure to Surgical Plume*. As you review our comments and contemplate how we might be of service, please keep in mind that AIHA and our members have a reach that extends to millions of people, with solid credibility that is built from 79 years of service to the occupational and environmental health and safety community. Specifically, AIHA has 8,500 members who represent a cross-section of industry, private business, labor, government, and academia. We maintain 68 active US Local Sections, more than 50 volunteer groups, and have partnership agreements with governmental and nongovernmental organizations representing the full spectrum of worker health and safety vocations. Finally, we have several award-winning publications, a strong social media presence, and host conferences where thought leaders from a variety of industries gather to share new information and answer practical questions on specialized health and safety topics.

General Comment on the need for the Standard:
The science is not settled as to the health risks of exposure to surgical plume. Research on occupational exposure to the components of surgical smoke has not shown levels to exceed established exposure limits. Therefore, it is unclear that a standard is necessary over and above what is required by a comprehensive injury and illness prevention program. Surgical plume exposures are intermittent and the plume itself is considered an irritant. The generation of surgical plume is dependent upon several factors including the surgical procedure, skill and technique of the surgeon, the tissue being operated on, the room characteristics (including ventilation), and the proximity of individuals to the surgical site.

In the final paragraph of *Operating Room Nursing and Lung Cancer Risk in a Cohort of Female Registered Nurses* (Gates MA, Feskanich D, Speizer FE, Hankinson SE, *Scand J Work Environ Health* 2007;33(2):140-147 doi:10.5271/sjweh.1117), the authors state, *"According to the results*

of this prospective analysis, long-term operating room employment and the resulting exposure to surgical smoke does not appear to increase the risk of lung cancer. However, surgical smoke exposure may increase the risk of chronic pulmonary conditions other than lung cancer, such as asthma or pneumonia, and additional research is needed on the association between exposure to surgical smoke and these outcomes [emphasis added]*. Given the composition of surgical smoke and its mutagenic and inflammatory potential demonstrated in animal and laboratory studies, prudent practice dictates that precautions be taken to minimize the exposure of both surgical personnel and patients to surgical smoke."*

The Standard should be based on an assessment of risk to the employee of exposure to smoke and infectious aerosols. A risk assessment is critical to identify the potential for harm to staff, physicians and patients, instead of having the standard apply to a broad application of electrosurgical, electrocautery and energy-based surgery procedures in hospital settings.

Recommendation 1: The scope of the standard should be based on the risk of exposure to smoke and infectious aerosols.

As currently written, in section (a) Scope and Application, the Standard applies to general acute care, acute psychiatric and special hospitals. Not all smoke plumes are generated in an in-patient perioperative setting; a variety of procedures are performed in out-patient settings that generate smoke plume from electrocautery, electrosurgical and energy-based devices. It would make more sense to have the standard apply to settings where smoke plume is generated in appreciable amounts from procedures using those devices rather than to hospitals alone. In addition, it is unlikely that any psychiatric hospital would perform such procedures, as outlined in the current draft of the Standard.

The Canadian Standard Z305.13-13, "Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings" addresses plume hazard in healthcare workers. This standard has an expanded scope that applies to "systems and equipment used to capture and evacuate plume and applies to all settings where such systems and equipment are used, including but not limited to, the following:

a. Surgical facilities
b. Dental clinics
c. Medical offices
d. Veterinary facilities
e. Laboratories and other research and testing facilities
f. Cosmetic treatment facilities
g. Teaching facilities
h. Manufacturing facilities
i. Professional exhibitions and trade shows.

It is recommended that the draft Standard be amended to apply to all settings where occupational exposures to surgical plumes may occur including, but not necessarily limited to: surgical facilities; dental clinics; medical offices; veterinary facilities; laboratories and other research and testing facilities; cosmetic treatment facilities; teaching facilities; manufacturing facilities; and professional exhibitions and trade shows.

It is also recommended that the application of the Standard should not only be location-based but also based on the activities performed where occupational exposures to surgical plumes may occur. Some procedures, such as in ophthalmology, generate only a small amount of plume and the tissue does not contain infectious pathogens that would be a concern of being inhaled by clinical personnel. Procedures in dermatology would more likely generate an appreciable amount of plume, even if the tissue is also not likely to contain infectious pathogens; and those in gynecology would generate both plume and infectious aerosols, as has been documented in the literature. (Gardner, J.M., O'Banion, K., Backus, A.D., Olson, C., *Viral disease transmitted by laser-generated plume (aerosol)*. *Arch Dermatol* 2002: 138(10): 1303-7)

Recommendation 2: Provide a methodology for documenting clinical judgment justifications when plume scavenging systems are not used.

Section (d)(1)(A) of the proposed Standard requires that scavenging devices shall be used as close as possible to the site-of-origin to the greatest extent feasible whenever surgical plume is generated, except if a licensed healthcare professional directly involved with the patient's care determines that such use will jeopardize the patient's safety or success of the medical procedure. If implemented as worded, language explaining the process for determining how an investigator would determine if the surgeon's decision to ensure patient safety or the integrity of the procedure by removing the evacuator would need to be included.

It is important to note that the literature describes barriers to compliance for smoke evacuation practices. Among these non-compliance reasons are surgeons' resistance or refusal to use the device all together, excessive noise, and physician preference. (AORN *Management of Surgical Smoke Toolkit*) Noise of the scavenging device has been found to be a barrier to use and could have additional occupational health implications. The Canadian standard CAN Z305.13-13 indicates that plume scavenging systems should operate at a noise level of 65 dBA or less. If a plume scavenging system is too loud, this has been noted as a barrier to compliance for smoke evacuation practices (Ball K., *Compliance with surgical smoke evacuation guidelines: implications for practice*. AORN J. 2010;92(2):142-149). In a recent study by Siepp et al., smoke evacuation system sound levels ranged between 51-69 dBA (Hans-Martin Seipp, Thomas Steffens, Janine Weigold, et al. (2018) *Efficiencies and noise levels of portable surgical smoke evacuation systems*, Journal of Occupational and Environmental Hygiene, 15:11, 773-781, DOI: 10.1080/15459624.2018.1513134). In addition to these barriers, providers could conceivably argue that the scavenging device interferes with their field of view of the surgical wound site to continue avoiding use of the device, even when safe, feasible and practical with a modification of surgical technique.

Along with this recommendation, it is also suggested that an exposure determination element should be conducted as a part of the standard. This exposure determination would be similar to that which is completed under the Bloodborne Pathogens standard (29 CFR 1910.1030 (OSHA) / 8 CCR § 5193 *Bloodborne Pathogens* (Cal/OSHA)). It is recommended to define what an occupational exposure would be to surgical smoke plume. From there, an exposure determination should be developed containing a list of (1) all job classifications in which all employees in those job classifications have occupational exposure, (2) a list of job classifications in which some employees have occupational exposure, and (3) a list of all tasks and procedures or groups of closely-related tasks and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in category 2 above.

Recommendation 3: The Standard should require that smoke evacuators be tested and certified as meeting a third-party standard.

Nowhere does the draft Standard state how efficient the scavenging equipment must be in capturing plume. The Standard should require that smoke evacuators be tested and certified as meeting a third-party standard, such as ISO 16571:2014, and not just include the reference in a non-mandatory appendix.

In addition to setting capture efficiency standards, smoke evacuator manufacturers should provide facilities with validation methods used to ensure reproducible conditions of their device and information on the frequency of device maintenance standards. Validation methods should set reproducible conditions of testing with standardized power settings on the generation device, the flesh to be operated on, and the distance from the surgical site that the evacuator is being assessed. Maintenance programs should include frequency of filter changes and tubing installation and disposal.

Recommendation 4: Revise the need for the use of general ventilation of 20 air exchanges per hour based on current building design standards.

Section (d)(1)(B) of the proposed standard requires general room ventilation of 20 air exchanges (ACHs). It appears that this requirement is adopting the 20 ACH prescribed for operating rooms in ASHRAE Standard 170, *Ventilation of Health Care Facilities*. It is important to realize that the prescribed ventilation rate (and HVAC design) for operating rooms is based upon a primary design objective of maintaining a sterile surgical field. However, it is feasible that surgical smoke could be generated during minor treatment procedures that would not ordinarily occur within an operating room. Absent the sterile surgical field requirement, the 20 ACH dilution ventilation is a costly over-prescription that will provide limited benefits in regard to occupational exposure protection. If a risk assessment for a particular treatment activity determines that the surgical smoke is an occupational exposure concern, then given the proximity between the source and

the healthcare workers, the prudent approach to controlling the exposure should be through the use of local exhaust ventilation (i.e. smoke evacuators).

It is recommended that Section (d)(1)(B) be modified to require ventilation systems be designed to ASHRAE Standard 170 ventilation requirements or applicable design standards as specified by the authority having jurisdiction, such as the California Mechanical Code (Title 24 Chapter 4 2016). In addition, if the occupational exposure risk assessment for a specific treatment activity identifies a potential hazardous exposure resulting through the generation of surgical plume smoke, then the use of local exhaust ventilation systems (consistent with recommendation #3 above) that capture and remove the smoke prior to occupational exposure is required.

Recommendation 5: The use of personal protective equipment should be based on risk assessment and not on qualitative measures such as "visible" surgical plume.

Sections (d)(3) and (d)(4) of the Standard require that any amount of "visible" surgical plume would require respiratory and eye protection to prevent plume from contacting the eyes and/or the respiratory tract.

The need for respiratory protection should be based on an established, quantifiable exposure level, based on sound epidemiological and toxicological science, not on whether smoke is visible. Plume visibility is a subjective condition that is not defined in the standard. If a smoke evacuator is used, and it is effective at removing smoke plume at the point-of-origin, requiring respiratory protection with eye protection is excessive and unnecessary and could interfere with the surgical procedure.

If the plume cannot be analyzed to identify one or more toxins with established Permissible Exposure Limits (PEL), then more likely than not, the plume would be categorized as a nuisance, e.g. odor or Particulates Not Otherwise Regulated, respirable fraction. The PEL listed in Table AC-1 of 8 CCR § 5155 for respirable particulates not otherwise regulated is 5 mg/m3. To address nuisance odors perhaps single-use filtering facepiece respirator/surgical mask impregnated with activated charcoal would adequately eliminate the nuisance odors.

In addition, smoke plume from electrocautery, electrosurgical and energy-based devices can include high concentrations of ultrafine particles that may not be visible under any conditions. However, the performance of particulate respirators has never been evaluated in field conditions against ultrafine particles. One study stated that, "*Findings in the published literature indicate that N95 filtering facepiece respirators may not provide desirable 95% protection for most categories of ultrafine particles…"* (Excerpted from: *Field Evaluation of N95 Filtering Facepiece Respirators on Construction Jobsites for Protection against Airborne Ultrafine Particles*.Adhikari, Mitra , Rashidi , Ekpo , Schwartz , Doehling. Int J Environ Res Public Health. 2018 Sep 7:15(9). pii: E1958. doi: 10.3390/ijerph15091958.)

Another study stated that, "*peak inhalation flows and breathing frequency could potentially raise the particle penetration through N95 filtering facepiece respirators."* (Excerpted from: *Efficiency Evaluation of N95 FFRs under Cyclic and Constant Flows*, Institut de recherche Robert-Sauvé en santé et en sécurité du travail, June 2016)

It is recommended that the Standard base requirements for the use of personal protective equipment on known health risks, efficacy of the equipment required to be used and patient safety factors. The use of eye protection where chemicals may be present is likely to require the use of either a full face respirator (which is not allowed in the surgical setting) or chemical protective goggles which may have an impact of the user's ability to perform the surgical tasks, and therefore should be included in the risk assessment to determine impact to the integrity of the sterile field in surgical settings and impact to patient safety.

Recommendation 6: Training on this proposed Standard should be included as part of existing comprehensive hazard communication programs and injury and illness prevention plans.

Requiring training annually appears to be excessive given the hazards present. Training should be addressed as part of a comprehensive hazard communication program and injury and illness prevention plan. In addition, if the contents of the plume and their health hazards are unknown and the feasibility of administrative controls being used has not been assessed, it would appear that requiring this of the employer would put this requirement in the category of regulatory-mandated research.

Next Steps

AIHA thanks you for the opportunity to comment on §51xx *Occupational Exposure to Surgical Plume* and looks forward to working with you to help protect the health and safety of workers in California. Please feel free to contact me at mames@aiha.org or 703-846-0730.

Sincerely,

Mark Ames
Director of Government Relations
AIHA