



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

January 15, 2019

Grace Delizo
Senior Safety Engineer
DOSH Research and Standards Health Unit
Cal/OSHA
Elihu Harris State Building
1515 Clay Street
Oakland, CA 94612

Dear Ms. Delizo:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments in follow up to the verbal comments we presented at the November 8, 2018, Advisory Committee meeting, convened to evaluate the issue of surgical smoke in the workplace. California hospitals take very seriously our duty to provide a safe, healthy environment for our patients and staff, and we are pleased to participate in the Advisory Committee process.

The threshold question to be addressed is whether a standard is appropriate. We believe the Injury and Illness Prevention Program (Labor Code § 3203) already covers the issue of surgical plume in the workplace, particularly in light of the most current research on the health impacts and appropriate exposure controls. Although we believe it is premature to draft regulatory language, we will take this opportunity to comment on the draft Cal/OSHA developed.

Scope and Application

We do not believe it is appropriate to define the scope and application of any regulation by reference to a location rather than the hazard. Virtually all of the stakeholders who participated in the November 2018 Advisory Committee shared this perspective. There is no rational basis for imposing significant regulatory oversight on a procedure performed in a hospital while providing no regulatory oversight to the same activity occurring in other workplaces, especially considering that hospitals are already subject to a myriad of facility building standards and infection control regulations. Surgical plume is generated in ambulatory surgery centers, physician offices, dental clinics, veterinary clinics, laboratories, cosmetic treatment clinics, morgues, research facilities and other work locations where there is virtually no regulatory oversight of the physical workspace, such as HVAC systems.

Written Procedures

As written, the subsection (c) could be interpreted to require the use of a plume scavenging system any time plume is generated. As discussed throughout this document, identifying the appropriate control strategy depends on a myriad of factors and, as explained by Dr. King, not all surgical smoke is the same. Requiring the use of a plume scavenging system without regard to the level of risk posed — or patient care considerations — is overly broad. Even Dr. King's study revealed that, while

the plume contained formaldehyde and ethanol, the levels were under permissible exposure limits, and in some cases were similar to those found in the environment before the plume was generated. We concur with others who advocated for a risk-based approach, such as that adopted by the New South Wales Ministry of Health. According to the New South Wales Government Health Guideline on Controlling Exposure to Plume, the following factors should be taken into consideration when conducting a facility risk assessment:

- Number and type of procedures that are to be performed
- The equipment being used
- Size and layout of the procedure room or treatment area
- Available ventilation in the procedure room/treatment area, including whether it has positive or negative pressure
- Expected volume of plume
- Manufacturer's specifications related to the effectiveness of the equipment

Other possible factors include the infectivity potential of the tissue and length of procedure.

Given the fact that not all plume is the same and the risk of harm varies depending on a myriad of factors, a one-size-fits-all approach is inappropriate.

Control Measures

Consistent with our earlier comments, choosing an appropriate control measure can only occur after a hazard/risk assessment is conducted. There is no evidence justifying an arbitrary hierarchy of control measures that does not account for the various possible exposure scenarios. For example, there is no evidence to support the requirement that engineering controls must be used for all situations, and respiratory protection is only appropriate in limited circumstances — e.g, the highest level of control may not be appropriate if there is a limited amount of smoke generated, the procedure is relatively short and there is no evidence that the tissue contains infectious material.

We also have concerns about the requirement for respiratory and eye protection in addition to engineering controls. Based on our evaluation of the issue, respiratory and eye protection would rarely be necessary if engineering controls are effectively used. This is a significant issue, as requiring the use of respiratory and eye protection in the operating room regardless of the presence of a hazard has inherent drawbacks. For example, N95 masks can cause users discomfort and may complicate communication; and respirators with exhalation valves, as well as the use of a surgical mask underneath a powered air purifying respirator, are not approved for surgical applications. Similarly, only certain specialty goggles are designed to keep smoke away from an employee's eyes, and use of these goggles presents other challenges, including discomfort and decreased visibility.

With respect to subsection (d)(1)(B), the general ventilation language conflicts with existing regulatory obligations, including the California Mechanical Code and ASHRAE S170 Ventilation for Healthcare Facilities. It is unclear why it is necessary to address general room ventilation, and any location other than an operating room would not be able to meet this requirement without

significant modifications. As noted during the public comment period, plume is generated in many areas inside and outside the hospital that could not currently comply with the 20 ACH provision.

Finally, while we appreciate Cal/OSHA's effort to recognize that the use of plume scavenging systems is intertwined with patient care considerations, we agree with the comments made during the Advisory Committee that the proposed exception to subsection (d)(1)(A) is not desirable. Given that numerous licensed health care professionals may be directly involved in a patient's care, conflict is likely to arise if any of those individuals has the authority to determine that the use of engineering controls will jeopardize patient care. Setting up conflict between health care providers is not in the best interest of patient care.

Training

Appropriate training is an important component of any employee health and safety program. We agree that employees should be trained both on the use of plume scavenging systems and on the steps they can take to address their concerns about the work environment. This training is already required by 8 CCR §3203 *Injury and Illness Prevention Program*.

However, some of the elements proposed are not feasible. For example, the draft language requires that training include "the contents of plume." As discussed by Dr. King, the contents vary from situation to situation so it is unclear how this requirement could be met. Similarly, the draft language contemplates the training to include the health hazards associated with exposure to plume. Again, as Dr. King explained, there is little evidence on this point other than eye and nose irritation. CHA is unaware of any workers' compensation claims related to surgical smoke exposure.

Costs

During the Advisory Committee meeting, participants were asked to submit information about the potential cost to implement the regulation as currently drafted. We have attempted to gather this information; however, the cost varies greatly depending on each hospital and health system, as shown in these examples:

- One hospital reported that it would cost roughly \$300,000 per location to change out the air handlers to achieve the minimum 20 exchanges per hour in hospital licensed ambulatory surgery centers, as there is no current requirement that they meet that standard.
- One hospital reported that it would cost approximately \$2,000-\$3,000 for each evacuation pen and associated tubing, etc. The total cost to the hospital/health system would depend on how many locations generate surgical smoke.

Other Concerns

Finally, as discussed during the Advisory Committee meeting, most California hospitals are not permitted to employ physicians/surgeons. Rather, the physicians/surgeons are independent contractors (this is referred to as the "corporate practice of medicine" doctrine). As such, the hospital does not have the authority to dictate what equipment a surgeon or physician will use. We have initiated discussions with the California Medical Association on this issue to understand the physician perspective but have not yet received a response.

Conclusion

Surgical plume is present in a wide variety of work places and carries different levels of risk depending on a myriad of factors. Thus, if the Standards Board determines that a specific regulation on this topic is appropriate, we believe it should be risk based, not location based and tailored to the risk — not one-size-fits-all. California's hospitals and health systems are committed to creating and maintaining a safe work environment and look forward to continuing to work with Cal/OSHA and other stakeholders to achieve that goal.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail Blanchard-Saiger". The signature is stylized and cursive.

Gail Blanchard-Saiger,
Vice President & Counsel, Labor and Employment