OCCUPATIONAL SAFETY AND HEALTH
STANDARDS BOARD

PETITION FILE NO. 567

Petitioner: Donald W. Nielsen

Director of Government Relations

California Nurses Association/National Nurses United

BOARD STAFF EVALUATION

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INTRODUCTION

Petition 567 was submitted by Donald W. Nielsen, Director of Government Relations, California Nurses Association/National Nurses United, to add a new section to General Industry Safety Orders to include control of medical plume/smoke exposure to healthcare professionals.

BACKGROUND

California Assembly bills numbered 2272 (2016) and 402 (2017) were both introduced by Assembly Member Thurmond. Both bills passed the Assembly and the Senate then were subsequently vetoed by Governor Brown. The bills contained identical language except for the dates that were set for the Division to submit a proposed regulation to the Board and the date for the Board to adopt the regulation.

In a veto message to the California State Assembly, dated October 9, 2017, Governor Brown stated that he agreed that the State should evaluate the need for a standard to address the health and safety hazards posed by plume and he suggested that the author and sponsor petition the Standards Board to initiate that process.

REQUESTED ACTION

- *Petitioner requests that the Board promulgate a surgical plume/smoke standard.*
- *Petitioner requests that the standard cover all health care workers employed by general acute care hospitals licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety code in all units, including inpatient and outpatient settings and clinics on the license of the hospital.*
- *Petitioner encourages the Board to expand protections to healthcare workers in other settings.*
- *Petitioner requests that the Board consider as benchmarks the International Standards Organization's (ISO) Systems for Evacuation of plume generation by medical devices (ISO) 16571, and the Canada Standards Association's (CSA) Plume Scavenging in surgical, diagnostic, therapeutic and aesthetic settings (Z305.13.13).*

PETITIONER ASSERTIONS

The petitioner asserts that both the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Institute for Occupational Safety and Health (NIOSH) have called for a reduction of surgical plume/smoke exposure to health care workers, but a

federal regulatory mandate is not expected to be forthcoming. The petitioner asserts that California should take the lead in developing a regulation.

The petitioner states that California does not have enforceable regulations that specifically describe the requirements for removal of surgical plume/smoke and that are protective of health care workers in surgical settings where surgical plume/smoke is generated.

The petitioner asserts that as explained by the Canadian Standards Association (CSA), procedures that rely on the ablation, cauterization, or mechanical manipulation of human tissue by lasers, electrosurgical generators, broadband light sources, ultrasonic instruments, plasma generators, bone saws, and drills generate noxious airborne contaminants as by-products from those procedures. Human tissue destroyed during these procedures generates a smoke by-product or "plume." The plume/smoke can contain toxic aerosols, vapors and fumes. Plume smoke consists of gases such as benzene, hydrogen cyanide, and formaldehyde as well as aerosolized blood and blood-borne pathogens in the form of bacteria and viruses.

The petitioner referenced a 2003 article from the journal, *Surgical Endoscopy*, "Surgical smoke, a review of the literature," which lists 39 different chemicals identified in electrosurgical smoke.

STAFF EVALUATION

Board staff reviewed relevant peer-reviewed scientific articles and met with representatives of the Hospital Association and, separately, with representatives of the California Nurses Association. Additionally, a letter was receive by Leonard Schultz, a retired general surgeon, which Board Staff determined to be a letter in support of adopting a surgical smoke regulation.

Background

Surgical plume/smoke is created when electrosurgical devices are used in medical procedures. The ablation, cauterization, or mechanical manipulation of human tissue by lasers, electrosurgical generators, broadband light sources, ultrasonic instruments, plasma generators, bone saws, and drills are capable of generating smoke as by-products. Studies have attempted to characterize the contents of the smoke generated when biological tissue is manipulated using the various devices. Studies have shown that there are many different chemicals that can be generated during the procedures, among them: benzene and formaldehyde (regulated carcinogens), hydrogen cyanide, carbon monoxide.[1,2] The smoke may contain many other chemicals as well as viruses, bacteria and ultrafine particles.[3,4] For simplicity, throughout this evaluation, the term surgical smoke will be used to refer to all types of airborne contaminants that result from the various medical procedures herein referenced.

The various devices that generate surgical smoke have been in use for decades. Local exhaust ventilation, commonly referred to as "smoke evacuators" are sometimes used, but not all of the time.

The Federal OSHA website states that an estimated 500,000 workers are exposed to laser or electro-surgical smoke each year, including surgeons, nurses, anesthesiologists, and surgical technologists and recommends the use of smoke evacuators.
https://www.osha.gov/SLTC/laserelectrosurgeryplume/index.html

Operating room staff report symptoms of exposure to surgical smoke including: headache, watery eyes, cough, sore throat, bad odors absorbed in the hair, nausea, drowsiness, dizziness, sneezing and rhinitis.[5] Additionally, studies have shown that patients are also exposed to the components of the smoke. A study testing patient urine after a procedure were higher than before the procedure for such chemicals as benzene, toluene, ethylbenzene, M-p-xylene and O-xylene.[6]

Nearly all operating room personnel wear surgical masks during procedures, but surgical masks are not effective at filtering smoke, due to their comparatively large pore size.[7]

A cursory search of the internet for "surgical smoke evacuators" revealed a number of different devices, in a wide range of prices, intended to reduce exposure to surgical plume. This preliminary search indicates that the technology exists that is intended to reduce breathing zone exposure to surgical plume. However, since no regulation presently exists which sets out the design criteria and sampling studies during actual procedures (as opposed to created procedures) are few, their effectiveness is not well documented.

Relevant Standards

Federal Standards

Federal OSHA does not have a regulation that specifically addresses the potential hazards of surgical smoke. 29 CFR 1910 Subpart Z contains the substances for which Federal OSHA has exposure limits. 29 CFR 1910.1000a states that "an employee's exposure to any substance listed in Tables Z-1, Z-2, or Z-3 of this section shall be limited in accordance with the requirements of the following paragraphs of this section." Which means, an employee would need to be exposed above one of the limits of a listed chemical in order for the regulation to apply to surgical smoke. Board Staff was not able to find a study indicating that employees were exposed above a permissible exposure limit (PEL) or other regulatory limit, such as a short term exposure limit (STEL) or a ceiling limit for a chemical listed in table Z-1, Z-2, or Z-3, therefore the requirements of 29 CFR 1910.1000a would appear not to apply.

If blood were found to be present in surgical smoke, then it would be reasonable to consider whether the Federal bloodborne pathogen regulation, 29 CFR 1910.1030, should apply to employee exposure. However, the present Federal position, as stated in a September 6, 2000, letter issued by then Director of OSHA Enforcement, Richard Fairfax, is that surgical smoke exposure does not fall within the subject scope of that regulation. Perhaps that position will change with the benefit of further research findings such as those of a 2016 peer reviewed article[3] in which Hepatitis B virus was found present in surgical plume samples taken during operations upon patients know to be Hepatitis B positive.

At the time of this review, the Federal OSHA website advised: "Local smoke evacuation systems have been recommended by consensus organizations, and may improve the quality of the

operating field. Employers should be aware of this emerging problem and advise employees of the hazards of laser smoke." https://www.osha.gov/SLTC/laserelectrosurgeryplume/index.html

California Standards

California, likewise, does not have a regulation that specifically addresses surgical smoke. However, California does have regulations beyond those of Federal OSHA which may apply to surgical smoke exposure.

Title 8 Code of California Regulations (T8CCR) Section 5141(a) Engineering Controls states: "Harmful exposures shall be prevented by engineering controls whenever feasible." Harmful exposure is defined in Section 5140: "Harmful exposure. An exposure to dusts, fumes, mists, vapors, or gases:

(a) In excess of any permissible limit prescribed by Section 5155; or

(b) Of such a nature by inhalation as to result in, or have a probability to result in, injury, illness, disease, impairment, or loss of function."

Therefore, the California Division of Occupational Safety and Health is not limited strictly by the table of hazardous substances in Title 8, in the manner that Federal OSHA is limited to its list of hazardous substances in Section 1910.1000a, so California could potentially determine that surgical smoke meets the criteria of a hazardous exposure under Section 5140(b).

Since it has been reported that surgical staff have experienced throat irritation, headaches and other symptoms following exposure to surgical smoke [5], one could make an argument that 5141 would apply.

Furthermore, as stated earlier, at least one recent study identified viable bacteria and the Hepatitis B virus in the aerosol of surgical smoke indicating that Title 8 Section 5193, bloodborne pathogens regulation may apply.

Surgeons having operated on patients positive for human papilloma virus (HPV) have been diagnosed with HPV-related cancers.[9, 10] While not definitively shown that the surgeons' cancers were caused by their occupations, a causal link was suspected.

California T8CCR Section 5199 Aerosol Transmissible Diseases regulation, for which Federal OSHA has no equivalent, could also be relevant for employee exposure to surgical smoke. The regulation lists, "Novel or unknown pathogens" and "Any other disease for which public health guidelines recommend airborne infection isolation" in its scope.

It defines Airborne infectious disease (AirID) as either:

(1) "An aerosol transmissible disease transmitted through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the disease agent for which

AII [airborne infection isolation] is recommended by the CDC or CDPH, as listed in Appendix A"; or

(2) "The disease process caused by a novel or unknown pathogen for which there is no evidence to rule out with reasonable certainty the possibility that the pathogen is transmissible through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the novel or unknown pathogen."

More generally, California's Injury and Illness Prevention Program (T8CCR Section 3203(a)(6)) requires that the employer's program: "Include methods and/or procedures for correcting unsafe or unhealthy conditions, work practices and work procedures in a timely manner based on the severity of the hazard."

Consensus Standards

The petition referenced two different consensus standards:

1. 2013 Canadian Standards Group issued, Z305.13-13, "Plum scavenging in surgical, diagnostic, therapeutic, and aesthetic settings" which also recommends the use of "plume scavenging equipment" for procedures that generate surgical smoke.
2. 2014 International Standards Organization issued ISO 16571, "Systems for evacuation of plume generated by medical devices", which recommends the use of local exhaust ventilation for surgical smoke and specifies the components and efficiency of devices.

The standards have similar specifications and requirements. The ISO standard is focused more on the requirements of the smoke capturing devices with an informative annex with information for healthcare facility policies and procedures.

The CSA standard also focuses on device specification but also has requirements for policies and procedures regarding when to use devices, training, etc., for facilities that are affected.

Other Standards, Guidelines, Codes

The National Institute for Occupational Safety and Health (NIOSH) has published two Health Hazard Evaluation reports (HETA 85-126-1932, September 1988 and HETA 88-101-2008, February 1990) related to surgical smoke exposure. Both evaluations recommended the use of local exhaust ventilation for surgical smoke.

Position of Division

The Division of Occupational Safety and Health report dated January 18, 2018, recommended that an advisory committee be convened by the Division to discuss the suggestions and requests provided in Petition No. 567.

Analysis

Based on Board Staff research of the literature it is evident that surgical smoke has the potential to contain an array of chemicals including some that are recognized human carcinogens. Also, depending on the patient, surgical smoke may contain viruses and/or bacteria that have the potential to transmit disease through inhalation.[12, 13]

Although, California has regulations that could potentially apply to the hazards of surgical smoke, Board Staff is unaware whether any formal complaints have been lodged regarding the hazards of surgical smoke to the Division of Occupational Safety and Health (Division).

STAFF RECOMMENDATION

Upon a review of the literature related to surgical smoke exposure, there is sufficient evidence to show that there is the potential for harm to employees (and patients) from uncontrolled exposure to surgical smoke.

Based on the uncertainty of whether an existing regulation could be successfully applied to surgical smoke, Board staff recommends that Petition No. 567 be granted to the extent that an advisory committee be convened by the Division to determine whether a rulemaking action should be initiated and what control measures as reflected by Title 8 standards may be necessary to address the potential hazards of surgical smoke. The Petitioner, other key stakeholders, and other subject matter experts on this issue should be invited to participate in the committee deliberations.

Board Staff suggests that the advisory committee refer to 2013 Canadian Standards Group, Z305.13-13, "Plum scavenging in surgical, diagnostic, therapeutic, and aesthetic settings" and 2014 International Standards Organization, ISO 16571, "Systems for evacuation of plume generated by medical devices", documents as guidelines for a proposed regulation.

Although, surgical staff may wear surgical masks during smoke-generating procedures, the purpose of the mask is to protect the patient and not the wearer. The temptation to resort to respiratory protection as the primary means to protect employees exposed to surgical smoke should be avoided. The hierarchy of employee protection should follow the generally accepted sequence and OSHA requirement of engineering controls first, administrative controls second, and lastly, personal protective equipment (i.e. respiratory protection, in this case).

References

The following are the references within the evaluation, however many more articles were reviewed that were not referenced.

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