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Memorandum

OCCUPATIONAL SAFETY AND HEALTH
STANDARDS BOARD

To: Marley Hart, Executive Officer
Occupational Safety and Health Standards Board
2520 Venture Oaks Way, Suite 350
Sacramento, CA 95833

Date: January 18, 2018

From: Juliann Sum, Chief
Division of Occupational Safety and Health



Subject: Evaluation of Petition 567 from Donald. W. Nielsen

1.0 Introduction

On October 11, 2017, the Division of Occupational Safety and Health (Cal/OSHA) received a petition from Donald W. Nielsen, Director of Government Relations, California Nurses Association (CNA)/National Nurses United (NNU). The petitioner requests a new regulation be added to the California Code of Regulations title 8 to protect health care workers from exposure to surgical plume generated during medical procedures.

Labor Code Section 142.2 permits interested persons to propose new or revised standards concerning occupational safety and health, and requires the Occupational Safety and Health Standards Board (Standards Board) to consider such proposals, and render a decision no later than six months following receipt. Further, as required by Labor Code Section 147, any proposed occupational safety or health standard received by the Board from a source other than Cal/OSHA must be referred to Cal/OSHA for evaluation, and the Division has 60 days after receipt to submit a report on the proposal.

In addition to the petition, Cal/OSHA received, reviewed and considered the following information¹ regarding the petition:

1. Letter from Leonard Schultz, M.D., Nascent Surgical, LLC, November 1, 2017,
2. Email from Gail M. Blanchard-Saiger, California Hospital Association on November 15, 2017 with a link to the following article: Lee McFarling, Usha; *Blowing smoke: Profit motive — and scant evidence — propel dire warnings about surgical fumes.*
3. Letter from the California Medical Association, December 19, 2017.

Please see Appendix A for a copy of the above correspondence received by Cal/OSHA regarding petition 567.

¹ The documents received are not peer reviewed scientific publications.

2.0 Actions Requested by the Petitioner

The petitioner requests that the Standards Board promulgate a standard to protect healthcare workers from exposure to surgical plume/smoke. More specifically, the petitioner asks for a regulation that addresses the following:

1. At a minimum, covers all healthcare workers employed by general acute care, acute psychiatric and special hospitals licensed pursuant to the Health and Safety Code section 1250, and all units, including inpatient and outpatient settings and clinics on the license of the hospital;
2. Considers and uses as benchmarks the International Organization for Standardization's (ISO) *Systems for evacuation of plume generated by medical devices* (ISO 16571:2014), and the Canadian Standards Association's (CSA Group) *Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings* (CSA Z305.13-13); and
3. If the Board determines that there are more protective federal or international standards, that they be used as additional benchmarks for consideration.

3.0 Potential Hazards and Control of Surgical Plume/Smoke.

During surgical procedures that use a laser or electrosurgical unit, the thermal destruction of human tissue creates a plume. The plume normally contains toxic gases, toxic aerosols, respirable particulates, as well as aerosolized blood, blood fragments, viable bacteria, biological aerosols, viruses and bloodborne pathogens.^{2,3}

Approximately 150 volatile compounds have been identified in surgical smoke⁴ with approximately 600 additional compounds that still need to be identified.⁵ The identified compounds consist of many toxic substances including, but not limited to the following: acetaldehyde, acrolein, acetonitrile, benzene, carbon monoxide, dioxins, formaldehyde, hydrogen cyanide, polycyclic aromatic hydrocarbons, styrene, toluene, and xylene.^{6,7,8} Benzene and formaldehyde are regulated carcinogens in Title 8.

Respirable particulate matter smaller than 2.5 micrometers in aerodynamic diameter can reach "very unhealthy" or "hazardous" air quality index levels⁹ in employee breathing zones during electrocautery surgeries in less than 5 seconds.¹⁰

² <https://www.cdc.gov/niosh/topics/healthcarehsps/smoke.html>

³ Heinsohn P, Jewett DL. Exposure to blood-containing aerosols in the operating room: a preliminary study. *Am Ind Hyg Assoc J*. 1993 Aug;54(8):446-53.

⁴ Francke, W., O. Fleck, D.L. Mihalache, and W. Woellmer: Identification of volatile compounds released from biological tissue during CO2 laser treatment. SPIE 1994 September 6-9, 1994; Lille, France 1995.

⁵ Hoglan M, (1995). Potential hazards from electrosurgical plume. *Canadian Operating Room Nursing Journal*, 13, 10-16

⁶ Barrett WL1, Garber SM. Surgical smoke: a review of the literature. Is this just a lot of hot air? *Surgical Endoscopy*. 2003 Jun;17(6):979-87.

⁷ Tseng HS, Liu SP, Uang SN, Yang LR, Lee SC, Liu YJ, Chen DR. Cancer risk of incremental exposure to polycyclic aromatic hydrocarbons in electrocautery smoke for mastectomy personnel. *World J Surg Oncol*. 2014 Feb 4;12:31. doi: 10.1186/1477-7819-12-31.

⁸ Dobrogowski M, Wesolowski W, Kucharska M, Padászyńska K, Dworzyńska A, Szymczak W, Sapota A, Pomorski L. Health risk to medical personnel of surgical smoke produced during laparoscopic surgery. *Int J Occup Med Environ Health*. 2015;28(5):831-40.

⁹ The air quality index for very unhealthy and hazardous is determined by the U.S EPA. Title 8 section 5155 does not contain exposure limits for particulate matter smaller than 2.5 micrometers in aerodynamic diameter.

¹⁰ Tseng HS, Liu SP, Uang SN, Yang LR, Lee SC, Liu YJ, Chen DR. Cancer risk of incremental exposure to polycyclic aromatic hydrocarbons in electrocautery smoke for mastectomy personnel. *World J Surg Oncol*. 2014 Feb 4;12:31.

Additionally, transmission of the papilloma virus through surgical plume from lasers has been documented.^{11,12} Two gynecologists with long term exposure to laser plume and no other known risk factors for human papilloma virus infection were diagnosed with human papillomavirus positive squamous cell carcinoma.¹³

The National Institute of Occupational Safety and Health (NIOSH) determined that exposure to surgical smoke can cause both acute and chronic health effects ranging from eye, nose and throat irritation to emphysema, asthma or chronic bronchitis.¹⁴

Research conducted by the National Institute of Occupational Safety and Health (NIOSH) shows that airborne contaminants from surgical plume can be effectively controlled with commercially-available portable smoke evacuators. The hazards and methods to control smoke plumes when using lasers or electrosurgical units during surgery are described in their publication, *Control of Smoke from Laser/Electric Surgical Procedures*, NIOSH Publication No. 96-128 (Hazard Controls 11), (1996).

NIOSH also conducted the following Health Hazard Evaluation and Technical Assistance Reports regarding surgical plume.

1. Bryn Mawr Hospital: On the basis of the mutagenicity of the airborne compounds collected during this evaluation, and the acute health effects reported by operating room personnel, NIOSH investigators determined that there is a potential hazard from exposure to smoke generated by electrocautery knives during reduction mammoplasty surgical procedures. NIOSH recommended the use of engineering ventilation controls (smoke evacuation units) to reduce exposures among operating room personnel to minimize the acute health effects, reduce the potential for any chronic health effects, and to eliminate the emissions that can impair the surgeon's vision. HETA 85-126-1932 (1988) <https://www.cdc.gov/niosh/hhe/reports/pdfs/85-126-1932.pdf>
2. University of Utah, Health Sciences Center: Based on the data obtained during this investigation, NIOSH determined that exposure to the constituents of the smoke generated during laser surgery presents a potential health hazard. NIOSH recommended the use of smoke evacuators to reduce exposures. HETA 88-101-2008 (1990) <https://www.cdc.gov/niosh/hhe/reports/pdfs/1988-0101-2008.pdf>
3. Inova Fairfax Hospital Falls Church, Virginia: Based on air sampling, employee surveys and previous research, NIOSH recommended that surgical smoke exposure be controlled using a combination of local exhaust ventilation placed as close as possible to the point of smoke production and general room ventilation. HETA #2000-0402-3021(2006) <https://www.cdc.gov/niosh/hhe/reports/pdfs/2000-0402-3021.pdf>

¹¹ Hallmo P, Naess O.[1991] [Laryngeal papillomatosis with human papillomavirus contracted by laser surgery](#). Eur Arch Otorhinolaryngol. 248:425-427.

¹² Garden JM, O'Banion MK, Bakus AD, Olson C. Viral disease transmitted by laser-generated plume (aerosol). Arch Dermatol. 2002 Oct;138(10):1303-7.

¹³ Rioux M, Garland A, Webster D, Reardon E. HPV positive tonsillar cancer in two laser surgeons: case reports. J Otolaryngol Head Neck Surg. 2013 Nov 18;42:54.

¹⁴ NIOSH Study Finds Healthcare Workers' Exposure to Surgical Smoke Still Common. November 3, 2015. <https://www.cdc.gov/niosh/updates/upd-11-03-15.html>

4.0 Existing Title 8 Requirements

Title 8 section 5155 establishes exposure limits for specific airborne contaminants.

§ 5155. Airborne Contaminants.

(a) Scope and Application.

(1) This section establishes requirements for controlling employee exposure to airborne contaminants...

* * * * *

Note: Table AC-1 of this section presents concentration limits for airborne contaminants to which nearly all workers may be exposed daily during a 40-hour workweek for a working lifetime without adverse effect.

... The division recognizes the need for almost continuous review of these concentration limits and also anticipates the need for including new or additional substances. Harmful exposure to any substances not listed in this section shall be controlled in accordance with section 5141.

* * * * *

(c) Exposure Limits.

(1) Permissible Exposure Limits (PELs).

(A) An employee exposure to an airborne contaminant in a workday, expressed as an 8-hour TWA concentration, shall not exceed the PEL specified for the substance in Table AC-1.

* * * * *

Title 8 section 5193 requires employers to protect employees from bloodborne pathogens.

§ 5193. Bloodborne Pathogens.

(a) Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by subsection (b) of this section.

* * * * *

(b) Definitions. For purposes of this section, the following shall apply:

* * * * *

“Blood” means human blood, human blood components, and products made from human blood.

* * * * *

“Other Potentially Infectious Materials” means:

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as emergency response;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:

(A) Cell, tissue, or organ cultures from humans or experimental animals;

(B) Blood, organs, or other tissues from experimental animals; or

(C) Culture medium or other solutions.

* * * * *

Title 8 section 5199 requires employers to protect employees from airborne infectious diseases and airborne infectious pathogens.

§5199. Aerosol Transmissible Diseases.

(a) Scope and Application.

(1) Scope. This section applies to work in the following facilities, service categories, or operations:

(A) Each of the following health care facilities, services, or operations:

1. Hospitals

* * * * *

(b) Definitions.

* * * * *

Aerosol transmissible disease (ATD) or aerosol transmissible pathogen (ATP). A disease or pathogen for which droplet or airborne precautions are required, as listed in Appendix A.

* * * * *

Airborne infectious disease (AirID). 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 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.

Airborne infectious pathogen (AirIP). Either: (1) an aerosol transmissible pathogen transmitted through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the infectious agent, and for which the CDC or CDPH recommends AII, as listed in Appendix A, or (2) a novel or unknown pathogen for which there is no evidence to rule out with reasonable certainty the possibility that it is transmissible through dissemination of airborne droplet nuclei, small particle aerosols, or dust particles containing the novel or unknown pathogen.

* * * * *

(e) Engineering and Work Practice Controls, and Personal Protective Equipment.

(1) General. Employers shall use feasible engineering and work practice controls to minimize employee exposures to ATPs. Where engineering and work practice controls do not provide sufficient protection (e.g., when an employee enters an AII room or area) the employer shall provide, and ensure that employees use, personal protective equipment, and shall provide respiratory protection in accordance with subsection (g) to control exposures to AirIPs.

* * * * *

§5199. Appendix A.

Appendix A - Aerosol Transmissible Diseases/Pathogens (Mandatory)

This appendix contains a list of diseases and pathogens which are to be considered aerosol transmissible pathogens or diseases for the purpose of Section 5199. Employers are required to provide the protections required by Section 5199 according to whether the disease or pathogen requires airborne infection isolation or droplet precautions as indicated by the two lists below.

Diseases/Pathogens Requiring Airborne Infection Isolation

Aerosolizable spore-containing powder or other substance that is capable of causing serious human disease, e.g. Anthrax/*Bacillus anthracis*

Avian influenza/Avian influenza A viruses (strains capable of causing serious disease in humans)

Varicella disease (chickenpox, shingles)/Varicella zoster and Herpes zoster viruses, disseminated disease in any patient. Localized disease in immunocompromised patient until disseminated infection ruled out

Measles (rubeola)/Measles virus

Monkeypox/Monkeypox virus

Novel or unknown pathogens

Severe acute respiratory syndrome (SARS)
Smallpox (variola)/Variola virus
Tuberculosis (TB)/*Mycobacterium tuberculosis* -- Extrapulmonary, draining lesion;
Pulmonary or laryngeal disease, confirmed; Pulmonary or laryngeal disease, suspected
Any other disease for which public health guidelines recommend airborne infection
isolation

Diseases/Pathogens Requiring Droplet Precautions

Diphtheria pharyngeal
Epiglottitis, due to *Haemophilus influenzae* type b
Haemophilus influenzae Serotype b (Hib) disease/*Haemophilus influenzae* serotype b --
Infants and children
Influenza, human (typical seasonal variations)/influenza viruses
Meningitis
Haemophilus influenzae, type b known or suspected
Neisseria meningitidis (meningococcal) known or suspected
Meningococcal disease sepsis, pneumonia (see also meningitis)
Mumps (infectious parotitis)/Mumps virus
Mycoplasmal pneumonia
Parvovirus B19 infection (erythema infectiosum)
Pertussis (whooping cough)
Pharyngitis in infants and young children/Adenovirus, Orthomyxoviridae, Epstein-Barr
virus, Herpes simplex virus,
Pneumonia
Adenovirus
Haemophilus influenzae Serotype b, infants and children
Meningococcal
Mycoplasma, primary atypical
Streptococcus Group A
Pneumonic plague/*Yersinia pestis*
Rubella virus infection (German measles)/Rubella virus
Severe acute respiratory syndrome (SARS)
Streptococcal disease (group A streptococcus)
Skin, wound or burn, Major
Pharyngitis in infants and young children
Pneumonia
Scarlet fever in infants and young children
Serious invasive disease

Viral hemorrhagic fevers due to Lassa, Ebola, Marburg, Crimean-Congo fever viruses
(airborne infection isolation and respirator use may be required for aerosol-generating
procedures)

Any other disease for which public health guidelines recommend droplet precautions

* * * * *

5.0 Other Laws, Regulations and Standards

5.1 Federal OSHA

There is no federal Occupational Safety and Health Administration (OSHA) regulation that specifically addresses laser/electrosurgery plume hazards. OSHA published a Hazard Information Bulletin, *Hazard of*

*Laser Surgery Smoke*¹⁵, April 11, 1988, that associates potential airborne biological hazards with the use of lasers during surgery. Federal OSHA states in the document:

...when performing laser therapy on patients infected with viruses such as hepatitis or the human immunodeficiency virus, the smoke plume should be assumed to be infectious and appropriate precautions, such as a well maintained vacuum apparatus should be observed.

5.2 American National Standards Institute (ANSI)

The most recent version of the ANSI Z136.3 (2011) consensus standard, *American National Standard for Safe Use of Lasers in Health Care* requires airborne contaminants from laser surgery be controlled. ANSI Z136.3 also states that other electrosurgical devices produce the same type of airborne contaminants as lasers.

5.3 Denmark

In Denmark, the Working Environment Act of 2010, requires local exhaust ventilation for all smoke generating processes, including surgical smoke. Smoke and harmful air contaminants must be removed as close to the source as possible.

Danish Ministry of Labor
Executive Order on the Conditions at Permanent Places of Work
Part 8 - Ventilation
* * * * *

35.

(1) If the generation of gasses, dust or similar substances that are damaging to health or explosive or the generation of smoke, micro-organisms, aerosols, foul odors or other unpleasant air contamination cannot be prevented, an extraction system must be established that removes the contamination as far as possible at the site where it is generated. At the same time, fresh replacement air must be supplied at the appropriate temperature.¹⁶
* * * * *

6.0 Petitioner's Basis for a New Regulation

The petitioner requests a new regulation to protect employees from surgical plume, due to the hazardous chemical and biological components (described in part 3.0 above) in the plume. The petitioner states that a regulation is needed because few precautionary steps have been taken by employers to protect employees. Additionally, the petitioner notes that federal OSHA stated that the bloodborne pathogen regulation does not apply to surgical plume even though research indicates that diseases can be transmitted through surgical plume.¹⁷

7.0 Analysis

Abundant evidence shows that surgical plume is potentially harmful to employees, as discussed in part 3 above. In addition, employees are not protected from surgical plume under existing title 8 regulations, as

¹⁵ https://www.osha.gov/dts/hib/hib_data/hib19880411.html

¹⁶ <http://engelsk.arbejdstilsynet.dk/en/regulations/executive-orders/96-faste-arbejdssteders-indretning>

¹⁷ https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=23461

discussed in parts 7.1 through 7.3 below. Furthermore, some employers are not voluntarily implementing engineering controls to protect employees from surgical plume, as discussed in part 7.4 below.

7.1 Section 5155. Airborne Contaminants.

Title 8 section 5155 establishes permissible exposure limits (PELs) for individual substances. Employee exposure to any substance above a PEL is a violation of section 5155. For exposures consisting of multiple substances, like surgical plume, section 5155 requires employers to calculate the additive effects¹⁸ of multiple chemical exposures to employees using the formulas below:

First, the 8-hour time-weighted average (TWA) of each individual substance must be calculated for a workday:

$$\text{TWA} = (C_1 * T_1 + C_2 * T_2 + \dots C_n * T_n) / 8, \text{ where}$$

- T is the duration in hours of each procedure in a workday where an employee is exposed to surgical plume.
- n is the number of surgical procedures in a workday where an employee is exposed to surgical plumes.
- C is concentration of a toxic substance in the air. C is determined through personal air sampling using equipment worn by employees followed by laboratory analysis of the sample.
- Throughout the workday, hospital employees may be exposed to surgical plume during multiple procedures. The TWA for the entire workday must be determined for each substance.

Once the time-weighted average of each substance is calculated, the additive effect of the substances must be calculated:

$$D = (\text{TWA}_1 / \text{PEL}_1 + \text{TWA}_2 / \text{PEL}_2 + \dots \text{TWA}_n / \text{PEL}_n), \text{ where}$$

- D is the fraction of the allowable daily exposure allowed.
- PEL is the corresponding permissible exposure limit for that substance as specified by Table AC-1 of section 5155.
- n is the number of substances in the plume.

If D is greater than 1, then the employee is overexposed and the employer is in violation of section 5155.

Exposure determinations, as described above, may vary from day to day if employees do not perform the same procedures on a daily basis. Exposures will vary from procedure to procedure, depending on the type of

¹⁸ Section 5155 assumes that multiple chemicals have additive effects, unless information shows the contrary.

tools used and extent of the surgical work. Therefore, employers must conduct sampling on multiple workdays under different conditions to determine if employees may be overexposed.

Air sampling, laboratory analysis, and computation of exposure to surgical plume consisting of 150 or more substances using the process described above is complex and expensive. It would be burdensome for employers (or Cal/OSHA) to use the methods required by section 5155 to determine if employees are overexposed to the toxic components of surgical smoke.

Furthermore, section 5155 does not include quantitative exposure limits for airborne viruses and bacteria.

7.2 Section 5193. Bloodborne Pathogens.

Section 5193 applies when employees are exposed to blood or “Other Potentially Infectious Materials” (OPIM).

Although surgical plume may contain blood or OPIM, the blood or OPIM would be present as microscopic droplets that are invisible to the naked eye. To determine if a surgical plume contains blood or OPIM, employers would need to conduct specialized air sampling and laboratory analysis. The blood and OPIM content for surgical plume may vary from procedure to procedure, depending on the type of tools used and extent of the surgical work. Therefore, employers would need to conduct sampling on a variety of procedures to determine which procedures involve employee exposure to blood or OPIM. The procedures that do not result in exposure to blood or OPIM would not be covered by section 5193.

7.3 Section 5199. Aerosol Transmissible Diseases.

Section 5199 protects employees from the pathogens listed in Appendix A of section 5199. Most of those pathogens are transmitted from person to person through the air. Section 5199 does not protect employees from pathogens like the papilloma virus (see part 3.0 above) that are transmitted through surgical plume but not transmitted from person to person through the air. Section 5199 is applicable to surgical plume only where the tissue receiving treatment is known to be infected with a pathogen listed in Appendix A of section 5199.

7.4 Some employers are not voluntarily implementing engineering controls to protect employees from surgical plume

Surveys of surgical smoke control practices found that fewer than half of the medical facilities surveyed used engineering controls to reduce surgical smoke during procedures.^{19, 20, 21} In addition, many employees do not receive training on the potential hazards of surgical plume.²²

¹⁹ Edwards, B.E. and R.E Reiman: Results of a survey on current surgical smoke control practices. *AORN*; 87(4): 739-749 (2008).

²⁰ Steege, A.L., J. M. Boiano, M.H. Sweeney: Secondhand smoke in the operating room? Precautionary practices lacking for surgical smoke. *American Journal of Industrial Medicine* 59: 1020-1031 (2016).

²¹ Ball K. Compliance with surgical smoke evacuation guidelines: implications for practice. *ORNAC J.* 2012;30(1):14-16, 18-19, 35-37.

²² Steege AL, Boiano JM, Sweeney MH. NIOSH health and safety practices survey of healthcare workers: training and awareness of employer safety procedures. *Am J Ind Med.* 2014;57(6): 640-652.

7.5 A new regulation may be needed

The development of an occupational health regulation, specific to surgical plume, would protect employees from surgical plume without requiring employers to conduct costly, resource-intensive, time-consuming air sampling and laboratory analysis on a case-by-case basis.

8.0 Conclusion

Cal/OSHA recommends that Petition 567 be granted to the extent that the Standards Board requests Cal/OSHA to convene an advisory committee representing stakeholders to consider and discuss the suggestions and requests provided in Petition No. 567.

Cal/OSHA also recommends that the petitioner and stakeholders be invited to provide further scientific data and information on the methods of prevention identified in Petition No. 567. This information would be reviewed and considered prior to the advisory committee meeting and included with the materials to be discussed during the meeting.

cc: Grace Delizo
Eric Berg

NASCENT SURGICAL, LLC™

David Thomas, Board Chair
Occupational Safety and Health
Standards Board
2520 Venture Oaks Way, Ste. # 350
Sacramento, CA 95833
Re: Petition File # 567

1 November 2017

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OCCUPATIONAL SAFETY AND HEALTH
STANDARDS BOARD

Dear Chairman Thomas,

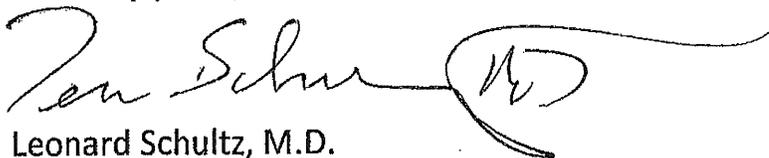
My name is Leonard Schultz and I am writing to you as a retired general surgeon with a long-standing interest in removal of smoke from the operating room of surgical facilities.

The first attempt to do so was to help develop a central vacuum system at Abbott Northwestern Hospital in Minneapolis to capture the voluminous smoke caused by laser surgery. The second was the development of the first laparoscopic filter to remove smoke from the abdomen that obscured the laparoscopic camera lens. More recently, since I retired, we commercialized another invention to capture smoke that is produced during open surgeries such as done for heart valve, hip and knee replacement. My current company is called, Nascent Surgical, LLC which was founded in 2010 and makes a surgical smoke and bioaerosol capture device called, "miniSquair®."

I believe it is important for me to be transparent so that you realize that I am a member of the smoke evacuation industry but that we play a miniscule part in it as compared to companies such as Medtronic, Stryker, Conmed, etc. Their competitive product is generically referred to as the "electrosurgical unit 'pencil'" and each company has its own variant of the "pencil."

I respectfully request that you consider the content of the enclosed white paper that I wrote based on my continuing perspective on the topic of surgical smoke.

Sincerely yours,



Leonard Schultz, M.D.

Nascent Surgical, LLC
6585 Edenvale Blvd. Suite #150
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NASCENT SURGICAL, LLC™

The California OSHA Standard's Board is being asked to consider the question, "Should surgical plume be removed from the operating room?" The corollary question, "Is chronic inhalation of surgical plume harmful to the health of the perioperative team?" must also be asked.

To answer these questions, one must first consider if surgical plume, the result of burning/coagulating human tissue, is any different from other forms of burnt organic materials, recognizing that human tissue is just as "organic" (carbon atom-based) as tobacco leaf, timber or animal droppings^{1,2}? When burned, they all release the same particulates and toxic chemicals³ minus nicotine which is exclusive to tobacco leaf.⁴

The difference with surgical smoke is that it uniquely can also transport living bacteria⁵, viruses⁶ and cancer cells⁷, depending upon whether electrocautery, laser, orthopedic drills/saws and harmonic/ultrasound instruments are used.

Let's consider the above while separating tobacco leaf since it uniquely contains nicotine which has been shown to cause adverse vascular maladies in the human body. The leaf, however, also contains particulates and chemicals which are identical to those given off by burnt human tissue⁸. It is these particulates that are important to the operating room staff and have nothing to do with nicotine; hence, the confusion when inhalation of surgical smoke is equated to a number of smoked cigarettes. It is the equally deleterious effects of these particulates that we will consider and not nicotine content.

As mentioned earlier, human tissue is no different from other organic or carbon-based material. When burnt, the toxic gases and particulates released from tissue, gasoline, timber, etc., all contain the same chemicals albeit in varying amounts. Consider the amounts emitted in the operating room compared to that released in forest fires as recently witnessed in Northern California. One is tolerable, the other overwhelming. Both are bad to inhale but the comparison points out that the harmful effects are, in part, the result of dose and duration of

exposure to which we must add a person's genetic predisposition and pre-existing illnesses⁹. Certainly, you must agree that all of these elements are unknown for any individual; that is, their sensitivity to smoke exposure is unknown although we will admit that an employee with asthma will be more sensitive to smoke exposure than a non-asthmatic. From this discussion, it should be obvious that smoke evacuation from the operating room must be universal and not selective in order to protect workers from the associated ill effects that result from chronic inhalation.

And just what are the associated health effects of unprotected inhalation of surgical smoke, burnt gasoline vapors or animal droppings used for fuel in third world countries which accounts for three (3) million deaths a year¹⁰? Are the results comparable? The answer is, "Yes," because organic smoke is the same no matter what the source. This simple truth is the basis for why the operating room team must be universally protected from chronic inhalation of surgical smoke.

Now let us consider the scientific evidence to support that premise and we will drill down to the components of organic smoke. Little known is the fact that 80% of organic smoke consists of nanoparticles¹¹ which are very tiny particles that are referred to in the medical literature as "ultrafine particles"¹². They include viruses but are 4-5x's smaller than bacteria. Most of the air we breathe contains nanoparticles which we inhale into our lungs where they are neutralized by cells called macrophages¹³ and expelled as phlegm which exits the body in our stool¹⁴.

Unfortunately, certain nanoparticles are not so easily removed and can accumulate in our lungs in great enough amounts that they can pass through the lung's capillaries (the process is called, "translocation"¹⁵) and enter our vascular and lymphatic systems and travel to all organs in our bodies¹⁶.

These nanoparticles can also travel via nerves directly to our brains without entering the lungs as an initial step¹⁷. It is this process of inhalation and translocation to other sites that is responsible, over time, and again, inclusive of dose/duration of exposure, genetics and pre-existing illnesses, for various serious systemic diseases. They include: neurodegenerative diseases like Parkinsonism and Alzheimer's Disease¹⁸, cardiac arrhythmias and coronary artery disease¹⁹,

collagen diseases (lupus erythematosus and rheumatoid arthritis²⁰) and cancers²¹ (breast, prostate and pancreas). Note that lung cancer is not included in this list since the nanoparticles do their damage after they leave the lungs, primarily by causing “oxidative stress” which leads to mitochondrial death in the cell²². Thus, it is an error to assume that because these nanoparticles are inhaled, that their damage is limited to the lungs although we know they do promote a higher incidence of respiratory illnesses²³.

In addition, cutting/coagulation devices can release bacteria and viruses from the body into the smoke that will, if unrestrained by capture devices, disperse throughout the operating room suite²⁴. Thus, the need to decontaminate all surfaces with the use of disinfectants²⁵ and, more recently, ultraviolet light machines²⁶. These pathogens, like tuberculosis bacillus, human papilloma virus and Staphylococcus bacteria can be transmitted via surgical smoke which then serves as the source of transmitted disease. The CDC has shown that a single inhaled tuberculosis particle can cause a new case of tuberculosis²⁷. Further, as a former practicing general surgeon who continues to visit operating rooms, it often is the case where one of the nurses will relate a case of nasopharyngeal or tonsillar cancer in a gynecologist or colon and rectal surgeon who has been removing genital warts with cautery over a lengthy career. These cases may be “anecdotal” but knowledge of causality has definitely increased reportability.

To return to the scientific evidence for the relationship between nanoparticles present in organic smoke and the development of diseases, please read the monograph by Christian Buzea, et. al. entitled, “Nanomaterials and nanoparticles: Source and toxicity”, 2007; *Biointerphases* 2(4): MR 17-MR 172. It cites over 250 peer-reviewed references on this topic.

Up until now, we have discussed that:

1. Surgical smoke has the same components as found in other organic materials that are burned.
2. Human sensitivity to its inhalation reflects multiple variables that prevent predictability and therefore requires universal removal for adequate protection.

3. Chronic exposure in susceptible employees can result in any of a number of serious systemic illnesses.

What we now need to consider is:

1. Is there a way to effectively clear the operating room air of such a hazard?
2. What can we use as a reasonable standard for "effective smoke capture?"

The answer to both questions is, "Yes." The definition of "effective" capture has been determined and published as an ISO standard²⁸ while the current technology does allow for highly effective smoke evacuation. To date, industry has developed various capture devices which are all dependent on a suction machine ("smoke evacuator") that is strong enough to gather smoke to the device. Once captured, the smoke is carried via a tube to a filter which removes particulates and neutralizes the chemical odors²⁹. Once this is done, the "purified" air is then returned to the operating room for rebreathing by personnel. These devices, in order of appearance, were first a plastic tube of a little less than 1" in internal diameter (I.D.). Its opening was placed close to the source of smoke and an assistant held it and chased after the plume as it was produced. Not efficient use of personnel and largely abandoned today. This was followed by a 3/8" I.D. wide flexible tube whose opening was placed close to the end of the electrode tip which carried the electricity to the tissue. The tube was embedded as part of the electrode "pencil" but the tube's opening was often too close to the tip and obscured the surgeon's vision while the small caliber tubing limited the smoke capture efficiency of the device. More recently, a product was introduced that was placed close to the wound, had a wide-bore tubing (1 1/4" I.D.) allowing for greater air flow and suction capability with a 98.5% efficiency. In fact, it functioned like the smoke vent over your stovetop³⁰.

Thus, industry responded to need with improved technology, not only in functionality but also with quieter turbines needed for suction which were less of a distraction to the surgeon. The standard for such technology, however, was left to a world-wide panel of experts who met in Australia in 2014 and developed the first standard for such technology. The result of their efforts was entitled, "Systems for evacuation of plume generated by medical devices" and can be

referenced as ISO 16571:2014 (E). The committees of the Organization responsible for the standard were the Anesthetic and Respiratory Equipment and the Medical Gas System Committees. In Section 4 of that standard, entitled, "General requirements," it states, "PES's (Plume Evacuation Systems) shall, when used in accordance with the manufacturer's instructions, the efficiency of plume removal shall be at least 90%...and ...evidence shall be provided by the manufacturer." That 90% minimum requirement is reasonable in view of our earlier discussion on the need for a universal approach. The adoption of this standard will hopefully be accepted by the California Standard's Board.

Lastly, one needs to consider the potential economic cost of not protecting the operating room staff from the hazard of inhaling surgical smoke. Studies indicate that poor air quality results in increased absenteeism and decreased productivity. Alternatively, efforts to improve air quality can decrease absenteeism as much as 60%³¹ and productivity by 17%³². In a 2010 report, absenteeism in Canadian nurses which was due to illness, often respiratory (25%), was as high as 9% among public sector nurses. This resulted in an overtime rate of 17.3% at a total annual cost of \$660,300,000³³. Case law has already established that the healthcare system employer is responsible for providing a safe working environment for their employees³⁴. There is little doubt that perioperative personnel will learn of the causal effect of chronic inhalation of nanoparticles within surgical plume and their illnesses. Without a program of continuous employee protection, workman compensation claims will balloon making the cost of mesothelioma and asbestos inhalation³⁵ seem minimal in contrast to the financial risk to self-insuring healthcare systems responsible for such claims. Should insurance be handled by a third party, then each claim could potentially cost three times the amount of the medical costs in premiums over three years because of the impact on the "experience modification factor."

Your decision must consider if it is less expensive for on-going protection or to compensate the effected. Is a penny of prevention really worth more than a pound of cure?

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STAT

Blowing smoke: Profit motive — and scant evidence — propel dire warnings about surgical fumes

By Usha Lee McFarling @ushamefarling

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Dom Smith/STAT

The claims sound terrifying:

Just breathing the air in an operating room where hot surgical tools are being used to slice and cauterize tissue — emitting puffs of caustic smoke in the process — is said to be the equivalent of smoking up to 30 unfiltered cigarettes a day. The smoke contains an array of carcinogenic toxins. And nurses regularly exposed to it report they are twice as likely as the general public to suffer congestion, coughing, and asthma.

Citing such data, health care workers have launched national campaigns to push hospitals to require the use of devices that suction up surgical smoke as it's produced. Laws to mandate such devices in operating rooms are already making their way through state Legislatures in California and Rhode Island, with vocal backing from nurses. But the warnings of health risks are based on scant evidence — and, at least in some cases, propelled by profit motives.

A STAT analysis of scientific literature has found that the most frightening claims about the dangers of surgical smoke are mostly drawn from small studies of dubious quality and scattered anecdotal reports. Activists generally fail to highlight more reputable studies that find little danger in exposure to plumes.

What's more, the public campaigns warning about risks are largely funded by companies that sell devices to capture surgical smoke. A global nonprofit working on the issue, for instance, is sponsored by several companies in the field — and run by a former sales and marketing executive for a leading manufacturer of smoke evacuation devices.

Related Story: ¹

One man's desperate quest for a brutal surgery ¹

Those devices, with names like “Smoke Shark II,” “PlumeSafe Turbo,” and “StrykeVac,” can cost anywhere from a few hundred to a few thousand dollars, depending on size and complexity. They used to be bulky, noisy, and hard to operate, but newer models are considerably more nimble and much cheaper. Global sales are projected to hit² \$180 million a year by 2020.

And manufacturers are doing their best to grow the market: They're putting out white papers³ on the risks of surgical plume, sponsoring awards⁴ for hospitals that improve operating room air quality, and hosting “continuing education”⁵ workshops for health care professionals to raise concerns about surgical smoke.

“Do you know the hidden danger of surgical smoke?” a trade group for surgical nurses asks on its website, in a campaign sponsored by medical device maker Medtronic.

Perhaps the most dramatic promotional pitch about the perils of smoke comes from Dr. Tony Hedley, an orthopedic surgeon in Phoenix. In 2014, Hedley received a double transplant to replace lungs so scarred by pulmonary fibrosis he could scarcely breathe. He hadn't smoked for 40 years. But he had spent more than 30,000 hours in the operating room.

While he does have a family history of weak lungs, he's convinced his problems stem from the voluminous smoke he inhaled while performing thousands of joint replacements over his decades-long career.

Hedley, 72, has been working with public relations professionals to promote his story in media interviews and with a [video](#)⁶. Those efforts are being paid for by Stryker, a global medical device company that makes several smoke evacuation products, including a lightweight surgical tool that can evacuate smoke as it cauterizes tissue.

[Related Story:](#)⁷

[Raising an alarm, doctors fight to yank hospital ICUs into the modern era](#)⁷

Stryker has also paid Hedley nearly \$3 million in recent years, largely to license innovations he developed for hip and knee surgeries. But Hedley said he does not stand to profit personally from Stryker's sales of smoke evacuating devices. “They contacted me because I'm on the team, so to speak,” he said, adding that his push for stronger smoke protections in the OR comes out of concern for his colleagues' health.

Stryker's director of marketing, Nate Miersma, said his company's interest in the area — it helps sponsor the interest group⁸ highlighting the issue of surgical smoke — is partly about boosting its share of the market. But he said Stryker also wants to protect OR doctors and nurses. “Obviously we benefit from sales, but we want to be seen as partners and leaders in health care safety,” Miersma said.

That's a compelling pitch. But it appears to be based on very weak data. The health risks of surgical plumes have been little studied — other than by those worried about those risks.

Those who are less worried — including many surgeons, who are often closest to the smoke as they operate — said they are hesitant to publicly question the health risk research for fear of coming across as uncaring to hospital staff. But the handful of experts with no ties to industry who have looked deeply into the matter in recent years are not convinced that health risks truly exist.

A group of surgeons and researchers who examined 20 of the strongest papers in their 2013 review “Is Surgical Smoke Harmful to Theater Staff?”⁹ found that while toxins were present in smoke, “the risk presented to the theater staff remains unproven.” They concluded that “no existing literature establishes a direct link between the components of smoke and the transmission of disease.”

An in-depth review of 30 years of literature¹⁰ on surgical smoke conducted by the British government's workplace safety arm in 2012 found most published research studies on the issue were either biased,

filled with confounding factors, poorly designed — so much so that authors could not conclude that smoke causes any short- or long-term health risk.

“High quality papers,” the authors wrote, “were in short supply.”

Behind dire warnings, flimsy science

There's no doubt that smoke from surgical tools is highly unpleasant and irritating. It smells terrible, often stings the eyes and throats of those in the operating theater, and can lead to headaches and chest tightening.

More worrisome, the smoke has been shown¹¹ — conclusively — to contain numerous toxins, carcinogens, and particles small enough to slip through regular surgical masks and embed in alveoli, the tiny air sacs in the lungs. The smoke can even carry viruses and bacteria that are dislodged when surgical tools tear through tissue. Some think the smoke might harm patients by slowing healing if it collects in large amounts in abdominal cavities during laparoscopic surgeries.

“OR smoke is not ordinary smoke,” Hedley said, reading off dozens of chemicals found in surgical smoke — formaldehyde, benzene, and hydrogen cyanide among them — from a list he carries. “It's scary.”

That's why the California Nurses Association is pushing a bill¹² that would require the state to adopt stricter smoke evacuation regulations. The Legislature is expected to vote later this month. (A similar bill was passed last year, but Governor Jerry Brown vetoed it, saying the issue should be up to the state occupational safety board. This year's version will allow that board to set the specific regulations.)

“Our members wanted to know, why aren't hospitals doing something to mitigate this harm?” said Stephanie Roberson, a legislative advocate for the association. Roberson said her group had accepted no funding from manufacturers. “We are strictly doing this to protect our nurses and our patients,” she said.

STAT's close look at the research, however, raised doubts about the level of threats. Consider the claim that breathing surgical plumes for a day is equivalent to smoking more than two dozen unfiltered cigarettes. It's become something of a rallying cry⁴ for advocates.

But it does not appear to be grounded in solid science.

That statistic was extrapolated from a single obscure paper¹⁴ — which involved analyzing fumes emitted when the researchers used surgical tools to burn 1 gram of dog tongue in a small box. A direct comparison doesn't take into account that when you smoke cigarettes, you inhale the chemicals directly into your lungs. The paper's authors even stated in their conclusion that based on experience at their hospital, they felt exposure to smoke in an OR was “rather limited” compared to cigarette smoke.

A separate, three-month study¹⁵ of operating room air found that while surgical tools did indeed create airborne particles, OR air was actually cleaner than air outside the hospital: It contained fewer small and

potentially irritating particles, likely because of routine HEPA filtering. (The study also noted that OR air was much drier than outdoor air, a factor which could contribute to airway irritation.)

Related Story: ¹⁶

Choked, punched, bitten: Nurses recount attacks by patients ¹⁶

And while mutagenic compounds have been detected in trace amounts in surgical smoke, exposure to the smoke has never been proven to cause cancer. A 2007 analysis of health records ¹⁷ of more than 86,000 nurses found no increase in lung cancer risk for those who had spent their careers in operating rooms.

As for the statistic that OR nurses are twice as likely to have respiratory ailments, that comes from a web survey ¹⁸ of nearly 800 nurses but does not account for other reasons — like drier air or more exposure to disease — that OR nurses could become sick. Nor does it account for the fact that people with respiratory issues might be more interested in taking the survey.

'No clear signal of disease'

One of the most frightening claims about surgical plume is that it may transmit genital warts, or human papillomavirus, to medical staff who are working to ablate a patient's warts.

Those pushing for smoke restrictions repeatedly cite two decades-old published case reports, one involving a surgeon from Norway ¹⁹, another nurse from Germany ²⁰; both were diagnosed with genital warts in their throats after taking part in laser surgeries. There are other anecdotal case reports involving surgeons with warts in uncommon areas: their eyes and at the edges of their noses, and one 2013 study reporting that two laser surgeons suffered HPV-positive tonsillar cancer ²¹ despite having few risk factors.

But an analysis of laser surgeons ²² showed that those who treated warts — even those with long careers — were no more likely to suffer warts than the general public. What's more, those who took precautions in the OR, including using laser masks and smoke evacuators, suffered warts as commonly as those who did not.

The one lab study ²³ often cited by advocates as proof that surgical smoke can cause viral disease is not all that relevant to real-life conditions in a hospital. Researchers captured smoke emitted while using lasers on cow tissue infected with bovine papilloma — and then injected bits of viral DNA from the smoke directly into calves. They got sick. But it is not typical of OR nurses to inject themselves with particulates found in surgical smoke.

In 2013, a panel that advises the Centers for Disease Control and Prevention on infection control said there was no evidence of disease transmission during laser surgery on patients with HPV. "We've had 20 years of these exposures happening and no clear signal of disease," Dr. David Kumar, a CDC medical officer, said at the time.

For its part, the National Institute for Occupational Safety and Health has been recommending ²⁴ the use of smoke evacuators within 2 inches of a surgical site since 1996, but has shown little urgency in mandating action. The Occupational Safety and Health Administration's website estimates some 500,000

hospital workers²⁵ are exposed to surgical smoke annually and says “employers should be aware of this emerging problem” — but states there have been no documented cases of disease transmission.

Related Story: ²⁶

‘Something wasn’t right’: When an infection after surgery isn’t what it seems²⁶

One surgeon who’s long been skeptical about the hype over surgical smoke is popular medical blogger²⁷ and tweeter @skepticscalpel²⁸. He’s inhaled his share of smoke in the OR over decades of general surgery — “It’s not pleasant,” he said — but said he’s searched in vain for concrete evidence that it’s dangerous. (He requested anonymity for this article so he can continue to speak freely on controversial medical issues.)

The blogger estimated that equipping every OR and outpatient clinic in the country, even as prices of the devices decline, could cost tens of millions of dollars.

“Is this really worth spending all this money on?” he asked. “I just can’t see how it’s a real problem when there are so many real problems out there.”



Orthopedic surgeon Dr. Tony Hedley is convinced his lung problems stem from the voluminous smoke he inhaled while performing thousands of joint replacements over his decades-long career. *Igor Nedvaluke/Pinkston Group*

Nurses rally for stricter controls on smoke

Those pushing for new rules say they are critical to protect worker health — and complain that stingy hospital administrators won’t invest in smoke evacuators unless they are forced to by law.

The push is being made largely by OR nurses, who, like scrub technicians and anesthesiologists, are considered to be at higher risk than surgeons because of the longer hours they often spend in operating

rooms. Many feel this issue has been overlooked because it has not been important to surgeons.

Last year, the Association of periOperative Registered Nurses launched a three-year campaign, called “Go Clear,”⁴ to encourage hospitals to reduce their surgical smoke. The program is supported by Medtronic, which sells a number of smoke evacuation devices and systems.

Related Story:²⁹

Surgeons who are rude to patients also have higher rates of OR problems²⁹

The International Council on Surgical Plume Inc.³⁰ launched two years ago to support education and expert consulting on surgical smoke and to generate funding for new studies. The council’s sponsors, prominently displayed on its website, include by Stryker, Buffalo Filter, Megadyne and Medtronic — all sellers of smoke evacuation devices.

Among the council’s recommendations: Nurses should consider refusing to work with any surgeon who doesn’t use smoke evacuation equipment. “That would take some guts, but it would send a powerful message,” said an article in the council’s most recent newsletter³¹. It also recommended that nurses demand safety audits of their operating theaters: “Doing nothing is not an option.”

The council was created and is led by Daniel Palmerton, who spent 20 years working in sales and marketing for Buffalo Filter, a New York company that’s widely considered the world leader in smoke evacuation devices.

Palmerton said his group’s connections with the corporations are not a conflict of interest, noting that many nonprofit medical organizations rely on funding from related industries. His corporate sponsors, he said, have no vote or say in council matters.

Palmerton said he started the council because in his decades in the field he heard from countless nurses who were upset and worried about surgical smoke and couldn’t find anyone to listen. “These people have been beating their heads against the wall for years,” he said. “Nurses would plead with me, ‘We can’t get our facility to do anything about this.’”

Despite the lack of gold-standard studies showing harm, Palmerton said it’s a threat worth taking seriously: “We’re not saying the sky is falling,” he said. “We are just saying there are people in the OR every day that don’t want to be breathing ablated human tissue.”

The campaigns, however, can have a sky-is-falling feel to them.

In its official guidelines, available to members, the Association of periOperative Registered Nurses offers an exhaustive review of the scientific literature and is careful to caution that many potential health risks have not been conclusively proved.

But its public website leaves out any ambiguity: It states point-blank that smoke does pose a health risk and asserts that a day in the OR is as hazardous⁴ as 27 to 30 unfiltered cigarettes.

Dr. Mark Talamonti, a general surgeon at NorthShore University HealthSystem in Chicago, acknowledges the lack of gold-standard studies to back up such claims. Yet he says he knows from personal experience how bad plumes can be: He attributes the sarcoidosis in his lungs to years of inhaling smoke from oncology surgery. He said he's had far fewer symptoms and discomfort since he's started using smoke eliminating devices.

Another side benefit: happier colleagues. Nurses tell him they love working in the clearer air of his OR, said Talamonti, who is a board member with the International Council on Surgical Plumes.

As for Hedley, the orthopedic surgeon in Arizona, he's now back to full health and a full operating schedule. But he will no longer replace a hip or a knee without a small suction device attached to his surgical tool to evacuate the smoke.

He estimated the disposable tool might add, at most, a few hundred dollars to a surgery — a fraction of the cost of most of his procedures.

“They are routine in my OR,” he said. “And definitely worth it.”

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December 19, 2017

Marley Hart, Executive Officer
Occupational Safety and Health Standards Boards
2520 Venture Oaks Way, Suite 350
Sacramento, CA 95833

Re: Petition No. 567 – Adoption of a Standard Protecting Healthcare Personnel from Exposure to Surgical Plume/Smoke Generated During Medical Procedures

Dear Ms. Hart:

On behalf of more than 42,000 physicians and medical students in the State, the California Medical Association (CMA) thanks you for the opportunity to comment on the Petition for Adoption of a Standard Protecting Healthcare Personnel from Exposure to Surgical Plume/Smoke Generated During Medical Procedures, submitted to the Occupational Safety and Health Standards Board (OSHSB) on October 10, 2017. We believe that additional standards regarding the evacuation of plume/surgical smoke generated during a medical procedure are unnecessary because there are already standards in place to require that any smoke in the operating room be continuously removed.

We also have questions about the research currently available discussing the risks of exposure to plume smoke. After reviewing the available research on the risks of exposure to plume and consulting with our physician members, we do not believe that sufficient research evidence exists to support the development of further regulations at this time. While we support standards that have a basis in scientific evidence, the research is very limited on the risks of plume and surgical smoke. Electrocautery and laser units have been in use for many years, and the benefits of requiring additional equipment in the operating room have not been demonstrated. The use of evacuators with fresh tubing for each and every case in which electrocautery or laser units are being used will add greatly to the cost of procedures, generate excessive waste, and is unnecessary as long as sterile technique is maintained. While certain types of lasers may generate enough smoke to require smoke evacuation, this will vary on a case by case basis.

Additionally, accrediting organizations already require the use of safety measures for plume smoke generated by certain procedures. For example, the Institute for Medical Quality (IMQ) accredits ambulatory and office-based surgery practices. IMQ standards require an entire exchange of air between 12-20 times per hour in operating and procedure rooms (IMQ Standard 7.3.2). Additionally, the IMQ standards call for these facilities to implement policies and procedures for the “[u]tilization of smoke evacuators, appropriate devices to control tissue debris or high filtration masks and/or wall suction with filters to minimize laser plume inhalation” (IMQ Standard 7.6.6). Similarly, the Accreditation Association for Ambulatory Health Care (AAAHC) requires the use of smoke evacuators and/or wall suction when appropriate. Facilities already employ methods to minimize plume smoke when needed to comply with these existing standards. Both IMQ and the AAAHC recognize that certain equipment may

or may not be appropriate based on different circumstances, and that outpatient facilities should have the discretion to implement standards that reflect a physician's determination of the best standard of care for each patient.

We recommend that the Board continue to monitor this issue and assess the need to promulgate new regulations on this issue after additional research becomes available.

We appreciate the opportunity to comment and look forward to discussing this further. If you have questions, please contact me at jrubenstein@cmanet.org or at 916-551-2554.

Sincerely,



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