

**OCCUPATIONAL SAFETY
AND HEALTH STANDARDS BOARD**

2520 Venture Oaks Way, Suite 350
Sacramento, CA 95833
(916) 274-5721
FAX (916) 274-5743
Website address www.dir.ca.gov/oshsb



November 6, 2017

Leonard Shultz, M.D.
Nascent Surgical, LLC
6585 Edenvale Blvd. Suite #150
Eden Prairie, MN 55346-2505

Dear Dr. Shultz,

We are in receipt of your letter dated November 1, 2017 and attached white paper concerning surgical smoke sent on behalf of Nascent Surgical LLC. You requested the Occupational Safety and Health Standards Board (Board) to consider the content of the white paper concerning the hazards of surgical smoke and the importance of smoke removal during surgical procedures.

As you may be aware, presently the Board is considering a Petition, File No. 567 received on October 10, 2017 from a representative of the California Nurses Association/National Nurses United, requesting amendment of Title 8, Occupational Safety and Health Standards, to add standards addressing the removal of surgical smoke.

In accordance with the California Labor Code (LC) Section 142.2, any interested person may propose new or revised standards to the Board, and the Board is required to consider such proposed standards and report its decision no later than six months following receipt of such proposal. As required by LC Section 147, Petition 567 has been referred to the Division of Occupational Safety and Health (Division) for evaluation and report.

A copy of your letter and white paper will be sent to the Division for their evaluation. The information contained in your white paper will also be considered by Board staff as part of staff's evaluation of Petition File No. 567.

Should you have any questions regarding this matter, please do not hesitate to contact me or Ms. Elisa Koski, CIH, Senior Safety Engineer of my staff.

Sincerely,

A handwritten signature in black ink that reads "Marley Hart". The signature is written in a cursive, flowing style.

Marley Hart
Executive Officer

Attachment

cc: All Standards Board Members
Christine Baker, Director, Department of Industrial Relations
Juliann Sum, Chief, Division
Eric Berg, Deputy Chief for Health
Michael Manieri, Principal Safety Engineer
Elisa Koski, CIH, Senior Safety Engineer
Kevin Thompson, Editor, Cal-OSHA Reporter
Petition 567 file

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

RECEIVED

NOV 02 2017

OCCUPATIONAL SAFETY AND HEALTH
STANDARDS BOARD

Dear Chairman Thomas,

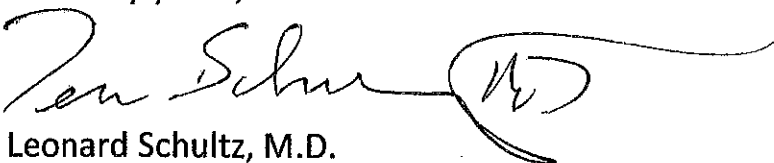
My name is Leonard Schultz and I am writing to you as a retired general surgeon with a long-standing interest in removal of smoke from the operating room of surgical facilities.

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
Eden Prairie, MN 55346-2505
Phone: 952-345-1112 Fax: 952-345-1114

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 ¼” 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?

REFERENCE LIST

1. "Natural organic matter," Green Facts. 22 April 2007. Available at <http://www.greenfacts.org/glossary/mno/natural-organic-matter-NOM.htm>
2. Gould S.E. "Why are humans made of carbon? Chemist points to electrons, molecular bonds. Available at http://www.huffingtonpost.com/2012/11/13/humans-carbon-chemist-molecular-bonds_n_2119037.html
3. Saager PM, Meagher A., Sobczak S, Wolft BG. Chemical composition and potential hazards of electrocautery smoke. *Brit. J. Surg.* 1996; 83(6): 1792-1799.
4. Chemical notes: surgical smoke. Available at http://www.surgin.com/PDF%20articles/whitepaper_surgin.clearflow.pdf
5. Schultz L. Can efficient smoke evacuation limit aerosolization of bacteria? *AORN J.* 2015; 102(1): 7-14.
6. Ferenczy A, Bergeron C, Richart RM. Human papilloma virus DNA in CO₂ laser-generated plume of smoke and its consequences to the surgeon. *Ob & Gyn.* 2004; 75(1): 114-118.
7. Laparoscopic surgery. Does smoke transport cells? Available at researchgate.net/publication/13923167_laparoscopic_surgery_does_smoke_transport_cells.
8. Donaldson K, Tran L, Jimenez LH, Duffin R, Newby DE, Mills N et. al. Combustion-derived nanoparticles: a review of their toxicology following inhalation exposure. *Fibre toxicol.* 2005; 2(1): 10-16.
9. Buzea C, Ivan IPB, Robbie K. Nanomaterials and nanoparticles: sources and toxicity. *Biointerphases* 2007; 2(4): MR 17-MR 172.
10. See SW, Balasubramanian R. Risk assessment of exposure to indoor aerosols associated with Chinese cooking. *Environ. Res.* 2006; 102(1): 197-204.
11. Hoet PHM, Bruske-Hohlfeld I, Salata OV. Nanoparticles- known and unknown health risks. *J. Nanobiotechnol.* 2004; 2(1): 12-27.
12. Bruske-Hohlfeld I, Preissler G, Jauch K-W, Pitz M, Nowak D, Peters A, Wichmann HE. Surgical smoke and ultrafine particles. *J. Occup. Med. & Toxic.* 2008; 3(3): 230-235.

13. Aderem A, Underhill DM. Mechanisms of phagocytosis in macrophages. *Ann. Rev. Immunol.* 1999; 17(3): 593-623.
14. *Ibid.* Ref. # 9.
15. Gatti AM, Montanaro S, Monari E, Gamberelli A, Capitani F, Panssini B. detection of micro- and nano-sized biocompatible particles in the blood. *J. Mater. Sci. Mater. Med.* 2004; 15(4): 469-472.
16. Nemmar A, Hoet PHM, Vanquickenborne B. Passage of inhaled particles into the blood circulation in humans. *Circulation* 2002; 105(2): 411-414.
17. Itzhaki RF, Wozniak MA, Appelt DM, Balin BJ. Infiltration of the brain by pathogens causes Alzheimer's disease. *Neurobiol. Aging.* 2004; 25(6): 619-627.
18. Brown RC, Lockwood AH, Sonowana BR. Neurodegenerative diseases; an overview of environmental risk factors. *Environ. Hlth Perspect.* 2005; 113(4): 934-946.
19. Delfino RJ, Sioutas C, Malik S. Potential role of ultrafine particles in association between airborne particle mass and cardiovascular health. *Environ. Hlth, Perspect.* 2005; 113(8): 1250-1256.
20. Iwai K, Mizumo S, Miyasaka Y, Mori T. correlation between suspended particles in the environment and causes of disease among inhabitants; cross-sectional studies using the vital statistics and air pollution data in Japan. *Environ. Res.* 2005; 99(1): 106-117.
21. *Ibid.* Ref. # 20.
22. Li N, Sioutas C, Cho A, Schmitz D, Misra C, Sempf J, Wang M. Ultrafine particulate pollutants induce oxidative stress and mitochondrial damage. *Environ. Hlth. Perspect.* 2003; 111(2): 455-460.
23. Ball K. Surgical smoke evacuation guidelines; compliance among perioperative nurses. *AORN J.* 2010; 92(2): 1-23.
24. Sonnergren H, Potessie S, Strombeck L, Aldenborg F, Johansson B, Faegemann J. Bacterial aerosol spread and wound bacteria reduction with different methods for wound debridement in an animal model. *Acta Berm. Venereal.* 2014; 32(6): 630-634.
25. Allen G. Implementing AORN recommended practices for environmental cleansing. *AORN J.* 2014; 99(5): 571-579.

26. Ritter MA, Olberding EM, Malinzak RA. Ultraviolet lighting during orthopedic surgery and the rate of infection. *J. Bone & Joint Dis.* 2007; 89(9): 1936-1940.
27. Center for Disease Control and Prevention. "Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings." *MMWR* 2005 (No. RR-17).
28. "System for evacuation of plume generated by medical devices." ISO 16571:2014. Published March 15, 2014. Geneva, Switzerland.
29. Haghghat F, Bahloul A, Jamie L. Performance of mechanical filters and respirators capturing nanoparticles- limitations and future directions. *Ind. Health* 2010; 48(3): 296-304.
30. Schultz L. An analysis of surgical smoke, plume components, capture and evacuation. *AORN J.* 2014; 99(2): 289-298.
31. Gilliland FD, Behane K, Rappaport FB. The effects of ambient air pollution on school absenteeism due to respiratory illnesses. *Epidemiol.* 2001; 112(1): 43-54.
32. "Indoor air quality and school performance" in EPA Series 402-K-03-006, revised August, 2003.
33. "Trends in our illness or disability-related absenteeism and overtime in publicly-employed registered nurses" in Quick Facts prepared for the Canadian Federation of Nurses Unions. Informetrica Limited, June, 2011.
34. Gretchen P. Maglisch, Commissioner, Department of Labor and Industry, State of Minnesota versus Miller-Dwan Medical Center, Duluth, April, 1999.
35. Dunnigan J. Linking Chrysotile asbestos with mesothelioma. *Ann. Indust. Med.* 1988; 14(1): 205-209.

Submitted by:

Leonard Schultz, M.D.

Founder and Chairman

Nascent Surgical, LLC

6595 Edenvale Blvd. Suite # 140

Eden Prairie, MN 55346

lschultz@nascentsurgical.com

952-345-1112