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A Voice for Nurses. A Vision for Health Care.

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January 15, 2019

Department of Industrial Relations
Division of Occupational Safety and Health
1515 Clay Street, Suite 1901
Oakland, CA 94612
Attn: Ms. Grace Delizo, Senior Safety Engineer; Ms. Amalia Neidhardt, Senior Safety Engineer
VIA ELECTRONIC MAIL to: RS@dir.ca.gov

RE: Discussion Draft – Occupational Exposure to Surgical Plume

Dear Ms. Delizo and Ms. Neidhardt;

The California Nurses Association/National Nurses United (CNA/NNU), representing more than 100,000 registered nurses, appreciates the opportunity to comment on the discussion draft "§51XX Occupational Exposure to Surgical Plume" developed by the California Division of Occupational Health and Safety (Cal/OSHA, hereinafter "Division"). We would also like to thank the Division staff for the comprehensive and informative Advisory Meeting held on this issue on November 8, 2018 and for their work in putting together the discussion draft. We very much appreciate that there has been recognition of the occupational hazard posed by surgical plume to nurses and other healthcare workers and that work towards a much-needed standard has begun.

Surgical plume poses a significant health hazard to nurse and other healthcare workers who may be exposed. The evidence that surgical plume exposure poses a health hazard is well-substantiated. In Petition 567, CNA/NNU provided a comprehensive overview and reference list. We recognize that the Division must substantiate the health impact on workers in order to develop an enforceable standard. To support that work, we have attached an updated review of the literature which is contained in Attachment 2.

As an initial matter, CNA/NNU would like to reiterate a point brought up by our Petition 567: that in developing a standard the Division should consider and use as benchmarks the International Standards Organization's 16571:2014(E) *Systems for evacuation of plume generation by medical devices* (hereinafter "ISO Surgical Plume Standard") and the Canadian Standards Association's *Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings* (Z305.13.13, hereinafter "CSA Surgical Plume Standard") for protecting workers from occupational exposure to surgical plume and smoke. We are not aware of any federal guidance or standards from the U.S. Occupational Safety and Health Administration (OSHA) or the U.S.

National Institute for Occupational Safety and Health (NIOSH) that are as comprehensively designed or that are more protective of healthcare workers.

In response to the Division's request for comments on the discussion draft, CNA/NNU offers the following comments as well as suggested language which is contained in the attached mock-up (Attachment 1):

Comment #1: Definitions

The Division's discussion draft contains many important and well-crafted definitions. CNA/NNU offers the following suggestions on edits and additional definitions that, in our experience, will make the discussion draft a clearer, and thus more protective, standard.

Comment #1a: Remove the Descriptor "Medical" from "Medical Device"

We suggest removing the descriptor "medical" from "medical device" in all definitions in subsection (b) of the discussion draft. The use of "medical device" instead of "device" is unnecessary and potentially limiting. Surgical plume is generated by many energy-based devices used for surgical and other purposes. Surgical purposes are often held separate from medical purposes. The Oxford Dictionary defines "medical" as:

> 1. Relating to the science or practice of medicine.
> 1.1. Relating to medicine as distinguished from surgery, psychiatry, etc.[1]

Inclusion of the descriptor "medical" is confusing in the context of surgical plume, which is most often generated during a surgical procedure. Thus we recommend the use of "device" in the definitions of "electrocautery device," "electrosurgical device," "energy-based device," and "surgical plume." The CSA Surgical Plume Standard uses the term "energy-based devices." While the ISO Surgical Plume Standard uses the term "medical device," that standard also includes a very expansive definition of "medical device"—a definition that goes beyond the common understanding of the term. That being said, CNA/NNU suggests that the Division follow the example of the CSA Surgical Plume Standard and use the terms "electrocautery device," "electrosurgical device," and "energy-based devices" for clarity and simplicity in definitions.

Comment #1b: Add a Definition of "Capture device"

[1] https://en.oxforddictionaries.com/definition/medical.

We recommend adding a definition of a "capture device" to the discussion draft in subsection (b). The ISO Surgical Plume Standard defines a capture device as "hose, tube, funnel, or other accessory that provides the inlet to the plume evacuation system at the site of plume generation," (ISO 16571:2014(E) Section 3.2). For many plume scavenging systems the capture device is separate from the plume evacuator itself. The capture device must be located as close as possible to the generation site in order to capture the plume effectively. But the plume scavenging system itself may be located farther away from the generation site due to size, noise, or other considerations. In this case, the capture device would be connected to the plume scavenging system by hoses and/or filters. Addition of this definition facilitates compliance and enforcement and ensures a higher level of protection in the standard. See Comment #3a for more details on adding "capture device" to the discussion draft.

Comment #1c: Clarification of the Definition of "Plume Scavenging System"

The definition of "plume scavenging system" in the discussion draft needs to be clarified. First, the definition should state that plume scavenging systems must both capture and filter surgical plume. Simply capturing surgical plume does not protect nurses and other healthcare workers unless the plume is filtered or otherwise neutralized. Both the ISO and CSA Surgical Plume Standards include similar language:

> CSA: "Plume scavenging system—a portable, mobile, or fixed device for capturing and neutralizing plume."
>
> ISO: "Plume evacuation system—device for capturing, transporting, and filtering plume and exhausting the filtered product."

We recommend using the term "filter" because it is more specific and accurate to how plume scavenging systems operate.

Additionally, the list of types of scavenging systems included in the definition includes both general and specific categories. All examples listed are different types of local exhaust ventilators. Also, importantly, we recommend using the conjunction "or" not "and" in this list of examples to allow for additional types of plume scavenging systems to be used if they effectively capture surgical plume but do not necessarily fall into one of the listed categories. And, by allowing for technology that effectively captures and filters surgical plume regardless of its specific category, this should address the concern raised at the Advisory Meeting about how

future technology development may fit into the discussion draft. We suggest the following changes to clarify the definition:

> (6) "Plume scavenging system" means local exhaust ventilators including smoke evacuators, laser plume evacuators, plume scavengers, ~~and local exhaust ventilators~~ or other devices, that capture and filter surgical plume at the site-of-origin and before plume can contact the eyes or respiratory tract of employees.

Comment #1d: Definition of "Surgical Plume" Should Include All Possible Contaminants

The definition of "surgical plume" should include all possible airborne contaminants. We suggest adding "particulates" and "infectious matter" to the list in the discussion draft. Additionally, we strongly recommend using the conjunction "or" instead of "and." Use of "and" could be interpreted to mean that surgical plume only occurs when all items in the list are present. This would not be protective because surgical plume is a mix of contaminants, dependent on the energy-based device used, the type of tissue, and other factors.[2]

> (9) "Surgical Plume" means airborne contaminants ~~(~~ including dusts, fumes, mists, vapors ~~and~~ gases, particulates, or infectious matter~~)~~ generated during the use of energy-based ~~medical~~ devices, electrosurgical devices, electrocautery devices, or powered mechanical tools during surgical, diagnostic, or therapeutic procedures.

Comment #2: Requirements for Written Procedures Are Important and Should be Detailed to be Effective and Protective

CNA is supportive of the requirement in the discussion draft that employers create written procedures, or "plans," as detailed below. As CNA/NNU nurses indicated when they testified at the November 8th Advisory Meeting, most employers do not have written procedures, plans, or protocols in place regarding surgical plume or the use of plume scavenging systems.

Comment #2a: Language Changes to Provide Clarity

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[2] Krones et al. "Chemical composition of surgical smoke produced by electrocautery, harmonic scalpel, and argon beaming- a short study," European Surgery 2007, 39, 2, 118-121; Radge et al. "Characterisation of Exposure to Ultrafine Particles from Surgical Smoke by Use of a Fast Mobility Particle Sizer," Annals of Occupational Hygiene 2016, 60(7): 860; Sahaf et al. "Chemical composition of smoke produced by high-frequency electrosurgery," Irish J of Medical Science, 2007, 176(3): 229.

As detailed in our attached mock-up, CNA/NNU recommends that this section be changed to "Written *Plan*" rather than "Written *Procedures*." A "plan" makes clear that employers should be thinking about how to comprehensively control employee exposure to surgical plume. That is, they should have a plan in place. We also suggest that employers be required to not only develop the plan but also actually implement and maintain it. A written plan is not protective unless implemented and maintained.

Additionally, we suggest that the discussion draft should require employers to create plans to control, not simply minimize, employee exposure to surgical plume. Other Title 8 standards enforced by the Division contain similar language. For example, Section 3342 Prevention of Workplace Violence in Health requires employers to "correct workplace violence hazards," (8 CCR §3342(c)(11)). Section 5120 Healthcare Worker Back and Musculoskeletal Injury Prevention requires employers to develop "procedures for correcting hazards related to patient handling" (8 CCR §5120(c)(7)), and Section 5155 "establishes requirements for controlling employee exposure to airborne contaminants…" (8 CCR §5155(a)(1)).

Comment #2b: Additional Requirements for Written Plans to be Effective and Protective

Written plans should be clear and understandable, and they should be available to employees for reference at all times. CNA/NNU strongly supports the Division's inclusion of a requirement in subsection (f)(3) of the discussion draft that the written plans should be available to employees at all times. CNA/NNU recommends changes to subsection (c) of the discussion draft that would make clear that the plans identify the individual or individuals responsible for implementing the plan. It is important that employers identify the point of contact so that employees can raise questions or issues effectively.

In addition, before employers know where to implement plume evacuation systems, they must identify all places where plume may be generated. More specifically, they must identify all places where energy-based devices are or may be used. The Division has addressed similar issues in other standards by requiring that the written plan include a list of job classifications with exposure. For example, Section 5193 Bloodborne Pathogen Standard requires employers with employees who have occupational exposure as defined to develop an Exposure Determination that must include "1. a list of all job classifications in which all employees in those job classifications have occupational exposure; 2. A list of job classifications in which some employees have occupational exposure..." (8 CCR §5193(C)(3)(A)1. and 2.). Also, Section 5199 Aerosol Transmissible Diseases Standard requires employers to include in the written Aerosol Transmissible Diseases Exposure Control Plan "a list of all job classifications in

which employees have occupational exposure," (8 CCR §5199(d)(2)(B)). CNA/NNU recommends that the Division add such a requirement to the draft standard.

Comment #2c: Annual Plan Review Requirement is Important But Needs Additional Elements

Furthermore, employers' written plans should be reviewed and updated at least annually to ensure they remain effective. The Division importantly recognizes this in the discussion draft. CNA/NNU suggests that the review include evaluating any exposures that might have occurred, why they happened, and how to fix the problems so that those exposures do not happen again. As discussed in more specificity in Comment #5 and detailed in our mock-up, CNA/NNU advocates strongly for the addition of an exposure records requirement. Such documentation is important for the annual review of the prevention plan to be thorough and effective.

Also, changes in workplace conditions might necessitate an update in the written plan or protection measures for surgical plume in between annual reviews. These changes could include the purchase of a new surgical device or introduction of a new surgical procedure or even changes in consensus standards. As a result, CNA/NNU recommends the written plans be updated to reflect these changes and any different or updated protections needed. This addition would address the concern raised at the Advisory Meeting that new developments in technology may not be adequately addressed by the discussion draft. Such a requirement is similar to other Title 8 Standards enforced by the Division. For example, Section 3342 Workplace Violence Prevention in Health Care Standard requires that employers review and update the plan "to reflect new or modified tasks and procedures which may affect how the Plan is implemented…" (8 CCR §3342 (e)(5)(A)), among other requirements, and Section 5193 Bloodborne Pathogens Standard requires employers to review and update the Exposure Control Plan at least annually and "to reflect new or modified tasks and procedures which affect occupational exposure…" (8 CCR §5193(c)(1)(D)1.), among other requirements. Adding such requirements to the annual review would ensure that the plan remains up-to-date and maintains the most current, safest protections for employees.

Comment #2d: Employee Involvement is Vital

Finally, CNA/NNU believes strongly that employees must be involved in creating the written plans and reviewing them. Employees have a nuanced understanding of how the workplace is set up, how procedures work, how smoke evacuators will fit into the operating room, and how they will work with other equipment. Such input is necessary to developing an effective exposure prevention plan and associated procedures. As a result, employees should also be involved in choosing the best plume scavenging system for the setting. Our members'

experience has been that important practical considerations are often neglected when the direct care employees who will be using the equipment are not involved in selecting it. Sometimes, this can mean it is impossible to use the equipment because administrators and non-direct care employees are not aware of incompatibility issues or other problems.

Such requirements for employers to engage employees' input and involvement in creating, implementing, and reviewing prevention plans are also included in several other Title 8 standards enforced by the Division. For example, Section 5193 Bloodborne Pathogens Standard, Section 5199 Aerosol Transmissible Diseases Standard, Section 5120 Healthcare Worker Back and Musculoskeletal Injury Prevention Standard, Section 3342 Workplace Violence Prevention in Health Care Standard, and others.

Comment #3: Control Measures

CNA/NNU suggests that the Division reorganize and make additions to subsection (d) in the discussion draft to make the hierarchy of controls clearer and more explicit. For the engineering controls subsection, we recommend several language changes and additions that would make the standard more protective.

Comment #3a: Clarify Plume Scavenging Systems Requirements

First, we suggest that the Division specify that plume scavenging systems be in operation continually during the use of energy-based devices. As written, the discussion draft could be interpreted to mean that plume scavenging systems must be running continually whether or not energy-based devices are being used.

Second, as discussed in Comment #1b, we suggest that the Division specify that the capture device be located as close as possible to the site of origin of the surgical plume. The plume scavenging system itself may need to be located farther away from the site of generation due to space, noise, or other considerations. The capture device is often connected to the plume scavenging system by tubing or hosing and can be located as close as possible to the site of origin of the surgical plume. Consensus standards offer examples for how the Division may craft this requirement. The CSA Surgical Plume Standard states in Section 4.3.1.d), "When a device with a plume evacuator nozzle is used, the nozzle shall be kept as close as possible to the operative site," and in Section 6.1, "A dedicated portable/mobile PSS shall include the following elements, a) an intake that can be effectively positioned at or near the operative site…." The Association of peri-Operative Registered Nurses (AORN) Guidelines state in Section II.b., "The capture device (eg, wand, tubing) of a smoke evacuation system should be positioned as close to

the surgical site as necessary to effectively collected all traces of surgical smoke [2: High Evidence]." We have also offered our suggestion in the attached mock-up.

Additionally, it is important to change the requirement that plume scavenging systems, or capture devices with CNA/NNU's suggested edits, be used "whenever surgical plume is generated," as the discussion draft currently requires. CNA/NNU suggests the requirement instead be that plume scavenging systems be in use "whenever energy-based devices are in use." This is a requirement that is more protective for workers and clearer for compliance and enforcement. If the Division were to keep the current language in the discussion draft, employers may choose not to require use of a plume scavenging system when plume is not visibly created. Dr. Bradley King's presentation at the Advisory Meeting, however, cited evidence demonstrating that not all surgical plume is visible.[3] The current discussion draft language therefore creates a situation where employers could comply with the standard but still expose employees to hazardous surgical plume. As a result, a requirement that plume scavenging systems be used whenever energy-based devices are used is more accurate and protective language and more easily enforced.

CNA/NNU suggests that the Division include a requirement that specifies minimum standards for the design and function of plume scavenging systems. We suggest that the Division incorporate by reference the appropriate section from the ISO Surgical Plume Standard Section 8.3.2. This section of the ISO Surgical Plume Standard is important to ensuring that the plume scavenging systems operate in a manner that is protective of employees' and patients' health.

Importantly, CNA/NNU advocates that the Division should add a requirement that all disposable accessories related to the plume scavenging system, such as hosing or filters, be considered biohazardous material. The Division should require that such biohazardous material be handled and disposed of safely. Blood, bacteria, cancer cells, and viruses have been found in surgical plume.[4] After use to evacuate surgical plume, the hosing, filters, capture devices, and other

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[3] Dr. King's presentation is available at https://www.dir.ca.gov/dosh/doshreg/Surgical-Plume-and-Smoke/Cal-OSHA-King-surgical-smoke-FINAL.pdf. The study that is referenced in the presentation is de Boorder, et al. "The visualization of surgical smoke produced by energy delivery devices: significance and effectiveness of evacuation systems." SPIE 6440, Available at https://www.buffalofilter.com/files/4614/1409/4386/The_visualisation_of_surgical_smoke_produced_by_energy_delivery.pdf (Accessed Jan 4, 2019).

[4] Baggish et al. "Presence of Human Immunodeficiency Virus DNA in Laser Smoke," Lasers in Surgery and Medicine 1991, 11: 197; Capizzi et al. "Microbiologic Activity in Laser Resurfacing Plume and Debris." Lasers in Surgery and Medicine 1998 23: 172; Fletcher et al. "Dissemination of melanoma cells within electrocautery plume," Am J Surg 1999; 178(1): 57-59; Garden et al. "Papillomavirus in the vapor of carbon dioxide laser-treated verrucae," JAMA 1988, 259: 1199; In et al. "Experimental Study of the potential hazards of surgical smoke from powered instruments," BJS 2015 102(12):1581; Kashima et al. "Polymerase chain reaction identification of human papillomavirus DNA in CO2 laser plume from recurrent respiratory papillomatosis," Otolaryngol Head Neck Surg

elements may become contaminated with the same particulates, infectious matter, hazardous chemicals, or other substances that pose a health hazard in the surgical plume. The Division already enforces similar safe handling and disposal requirements in the Bloodborne Pathogens Standard in subsection (d)(3)(E), which deals with regulated waste (8 CCR §5193(d)(3)(E)). CNA/NNU suggests that the Division add language to the discussion draft specifying that disposable accessories for plume scavenging systems be classified as "regulated waste" under Section 5193 Bloodborne Pathogen Standard and incorporate by reference the applicable subsection.

Finally, CNA/NNU suggests that the Division incorporate the note that plume scavenging systems must also comply with Section 5143 General Requirements of Mechanical Ventilation Systems Standard as a full requirement of the standard (8 CCR §5143). This is an important point, and CNA/NNU appreciates the Division's recognition that engineering controls must be consistently inspected and maintained over time in order to provide effective protection to employees. But for this to be a protection for employees in reality, the Division must be able to enforce the requirement. Including the reference to Section 5143 as a note is not as clear and enforceable as including the requirement as a subsection. As detailed in our attached mock-up, CNA/NNU thus suggests that the note be made a subsection.

Comment #3b: Remove the Exception for Plume Scavenging Systems Being Located Farther Away from the Site of Origin

CNA/NNU strongly advocates that the Division remove the exception in subsection (d) of the discussion draft. There seemed to be a general consensus at the Advisory Meeting on this point. The exception as written in the discussion draft allows for a single health care provider to decide not to use the plume scavenging system. In our members' experiences, it has been up to each surgeon whether they use the plume scavenging systems or not. Often the reason cited by surgeons for not using the protective equipment is that it is inconvenient to learn or to use with their current tools. That means that these individuals make the decision that their convenience outweighs the health of several employees, in addition to the patient. It is vital that the Division maintains the requirement that plume scavenging systems be in operation each time an energy-based device is used. Thus, we strongly encourage the Division to remove the exception.

Comment #3c: Remove the Visible Trigger Requirement for Administrative Controls and Personal Protective Equipment

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1991 Feb 104(2): 191; Sood et al. "Human papillomavirus DNA in LEEP plume," Infect Dis Obstet Gynecol 1994 2(3): 167.

As written, the discussion draft requires administrative controls and personal protective equipment (PPE) to be used only when "plume scavenging systems do not prevent visible surgical plume from contacting the eyes or respiratory tract of employees." As noted above in Comment #3a, CNA/NNU respectfully points to slide #3 of Dr. Bradley King's presentation at the Advisory Meeting. There, Dr. King shared a study with a new technique to look at plume that demonstrated that plume may not always be visible.[5] Thus a visible trigger for additional protections is not protective given the available evidence. We have suggested language that is more protective in our mock-up.

Comment #3d: Personal Protective Equipment Requirements Should be Clarified

We suggest that the Division create a separate subsection for the PPE requirements to underscore the requirement that employers follow the hierarchy of controls when controlling employee exposure to surgical plume. Additionally, we recommend adding a requirement that employers address the potential for appropriate surgical plume eye protection not conflict with other PPE, such as respirators or laser eye protection.

Comment #4: Training

As our members testified at the November 8th Advisory Meeting, many employers do not offer training on surgical plume and its hazards to employees. In fact, some nurses had not even realized that surgical plume was hazardous until recently despite being operating room nurses for several years. In other instances, nurses have had to go out on their own in order to obtain training to better understand surgical plume hazards and how to protect themselves. This is not right. Employers should be required to communicate with their employees about the hazards of surgical plume. Regular training on surgical plume is important because it helps employees to understand the plans and equipment that employers have provided to prevent exposure. CNA/NNU also believes employees should receive refresher training every year, and we therefore support the Division's requirement for annual training. Additional training should also be provided when there are changes and the employer needs to update the plan. This would ensure that employees are up-to-date as well.

In addition, CNA/NNU strongly recommends that training should be in person. Unfortunately, we have found that it is not enough to require "an opportunity for interactive questions and answers." This simply results in emailed questions and answers. In-person training is important

[5] King, *supra* note 3.

because employees can hear questions their co-workers ask which may very well trigger other questions. Moreover, employees are able to learn from their co-workers' experiences.

CNA/NNU is supportive of the discussion draft's list of required content for employers' training programs. The list is comprehensive and contains many important elements. Many employers do not provide any kind of training on the hazard of surgical plume, and it is important for employers to communicate information about potential exposures and protections the employer has put in place to protect employees. Employees need training regarding the employer's procedures and equipment so that they may understand how it works and how to know when it is not working effectively or correctly.

We would also recommend that the Division include two additional elements in the list of required training topics:

1) *An explanation of the importance of reporting exposures and symptoms of exposures to surgical plume.* As described in more detail below, CNA/NNU strongly recommends requiring employers to keep records of all employee exposures in order to better understand an employee's exposure history and possible work-relatedness of future health conditions. Training which emphasizes the importance of reporting exposures and symptoms goes hand-in-hand with such an exposure-record requirement.

2) *How employees can request additional training.* Employees should also be able to request additional training when they need it. With new equipment or new work practices, some employees may want or need additional training.

Comment #5: Recordkeeping Requirements Need to be Strengthened

CNA/NNU suggests that the Division include more robust recordkeeping requirements. Recordkeeping can be important to ensuring that the employer updates and maintains the prevention plan, which should include evaluating any previous incidents and examining any patterns in injuries or employee symptoms. But to do this, employers must keep records of all exposure incidents and injuries or health issues related to surgical plume. To this point, CNA/NNU strongly recommends that the Division add a requirement that employers create and maintain employee exposure records for surgical plume.

A standard on surgical plume should require prevention of exposure first and foremost, but it is also important to keep records of any exposures that do occur. Ensuring appropriate and prompt treatment for employees who are exposed is an important element of occupational health and safety. Our members' experience is that, in general, employers do not consider surgical plume to be a health hazard and thus they do not keep exposure records or monitor employee symptoms related to surgical plume exposure. But preservation of this kind of information is important to know whether the employer's prevention plan is functioning.

Maintenance of such exposure records is also important to establishing chronic health impacts of surgical plume. Employer representatives argued at the Advisory Meeting that there is insufficient evidence to substantiate the health impacts of surgical plume. We disagree—the best available evidence indicates that there is substantial health harm related to surgical plume exposure. We also maintain that if employers kept better records we would have an even better understanding of the health impacts caused by surgical plume exposure. Such records would also allow for employees to have better access to workers compensation coverage if a consistent exposure history were available. CNA/NNU has made suggestions on the information that should be captured as part of the employee exposure records in our attached mock-up.

Additionally, CNA/NNU advocates that the Division add a requirement that records of the employer's annual review be created and maintained. Such records would likely be important to the Division's enforcement actions. If the Division did not require such records, the Division's enforcement officers would not be able to determine whether or not employers had actually completed the annual review required by the discussion draft. Records of the employer's annual review would also be important information for employees to have access to in order to understand their employer's actions on surgical plume protections.

Finally and importantly, CNA/NNU urges the Division to add a requirement that employers make all records required by the standard available, upon request, to employees and their representatives in addition to the Division. This is similar to requirements in other Title 8 standards enforced by the Division.

Comment #6: Additional Information on Feasibility and Costs is Forthcoming

Finally, in addition to the above comments on the discussion draft, CNA/NNU will be submitting additional information concerning feasibility and costs, as requested by the Division staff at the November 8, 2018 meeting. We expect to have this information to Division staff in early February.

Conclusion

The evidence that surgical plume exposure causes harm to nurses' and other healthcare workers' health is solid. The controls for surgical plume exposure are feasible and, in many cases, are already present in operating rooms in California hospitals. CNA/NNU strongly advocates that the Division take the next step in creating this standard to protect employees from the significant health hazard of surgical plume. Thank you for your consideration of CNA/NNU's comments on these important issues. Please contact Saskia Kim at (916) 491-3204 with any questions.

Sincerely,

CALIFORNIA NURSES ASSOCIATION/
NATIONAL NURSES UNITED

Stephanie Roberson
Director, Government Relations

Attachment 1: CNA/NNU's Mockup of the Division's Discussion Draft "§51XX. Occupational Exposure to Surgical Plume"
Attachment 2: CNA/NNU's Updated Review of the Literature Substantiating the Health Impact of Surgical Plume Exposure

Attachment 1: CNA/NNU's Mockup of the Division's Discussion Draft "§51XX. Occupational Exposure to Surgical Plume"

Please note: CNA/NNU suggested additions in underline; deletions in strikeout

Discussion Draft November 8, 2018 Advisory Meeting:
Occupational Exposure to Surgical Plume

Add new Section 51XX to read:

§ 51XX. Occupational Exposure to Surgical Plume

(a) Scope and Application. This section applies to occupational exposure to surgical plume in general acute care hospitals, acute psychiatric hospitals, and special hospitals.

NOTE: This section does not preclude the application of sections 3203, 5141, 5143, 5193, 5199 or other title 8 safety orders to occupational exposure to surgical plume.

(b) Definitions.

(1) "Acute psychiatric hospital" means a health facility as defined in Health and Safety Code section 1250(b) and all services within the hospital's license to operate issued by the California Department of Public Health (CDPH).

(2) "Capture device" is a hose, tube, funnel, or other accessory that provides the inlet to the plume scavenging system at the site-of-origin.

~~(2)~~ (3) "Electrocautery device" means a ~~medical~~ device that is electrically heated to cut, ablate, or coagulate tissue.

~~(3)~~ (4) "Electrosurgical device" means a ~~medical~~ device that uses a radiofrequency electric current that passes through the patient to cut, ablate, or coagulate tissue.

~~(4)~~ (5)"Energy-based ~~medical~~ device" means a ~~medical~~ device that transmits energy (light and other forms of electromagnetic radiation, electrical, ultrasound, and mechanical) to tissue with enough energy to alter the structure of the tissue. Examples of energy-based devices include lasers, electrosurgical generators, broadband light sources, ultrasonic instruments, plasma generators, bone saws, reamers, and drills.

~~(5)~~ (6)"General acute care hospital" means a health facility as defined in Health and Safety Code section 1250(a) and all services within the hospital's license to operate issued by CDPH.

~~(6)~~ (7)"Plume scavenging system" means local exhaust ventilators including smoke evacuators, laser plume evacuators, plume scavengers, ~~and local exhaust ventilators~~ or other devices that

capture and filter surgical plume at the site-of-origin and before plume can contact the eyes or respiratory tract of employees.

~~(7)~~(8) "Site-of-origin" means the location where tissue is being altered, worked on or destroyed by a ~~medical~~ device or devices.

~~(8)~~(9) "Special hospital" means a health facility as defined in Health and Safety Code section 1250(f) and all services within the hospital's license to operate issued by CDPH.

~~(9)~~ (10)"Surgical Plume" means airborne contaminants ~~(~~ including dusts, fumes, mists, vapors ~~and~~ gases, particulates, or infectious matter ~~)~~ generated during the use of energy-based ~~medical~~ devices, electrosurgical devices, electrocautery devices, or powered mechanical tools during surgical, diagnostic, or therapeutic procedures.

(c) Written ~~Procedures~~ Plan.
Employers shall develop, implement, and maintain written plans ~~procedures that provide clear instructions for the effective use of plume scavenging systems~~ to ~~minimize~~ control employee exposure to surgical plume. The written plans shall include:

(1) The name(s) or title(s) of the person(s) responsible for implementing the plan.

(2) A list of all job classifications which have occupational exposure to surgical plume.
~~(1)~~ (3) Procedures to control employee exposure to surgical plume. The procedures shall be implemented whenever ~~surgical plume is generated~~ energy-based devices are in use.

(4) Procedures the employer will use to evaluate each employee exposure to surgical plume, to determine the cause, and to revise existing procedures to prevent future incidents.

~~(2)~~ (5) Procedures to review the effectiveness of the plan and to update the plan. Review of the plan should include a review of all exposure records. Review and update of the plan shall be conducted as follows: ~~The procedures shall be reviewed and evaluated~~

(i) At least annually~~,~~;
(ii) When work practices change; and ~~updated~~
(iii) As necessary~~,~~ to ensure that ~~they~~ the plan reflects current, safe work practices.

(6) Procedures to obtain the active involvement of employees and their representatives in creating, implementing, maintaining, and reviewing the plan and in evaluating and selecting plume scavenging systems.

(d) Control Measures.
Employers shall implement control measures according to the following hierarchy of controls to prevent employee exposure to surgical plume:

Attachment 1: CNA/NNU's Mockup of the Division's Discussion Draft "§51XX. Occupational Exposure to Surgical Plume"

(1) Engineering Controls.

(A) Plume Scavenging Systems. Exposure to surgical plume shall be prevented by plume scavenging systems to the greatest extent feasible.

(i) Plume scavenging systems shall be in operation continually during use of energy-based devices.

(ii) Capture devices shall be ~~and~~ located as close as possible to the site-of-origin whenever ~~surgical plume is generated~~ energy-based devices are in use.

(iii) Plume scavenging systems shall meet the requirements of Section 8.3.2 of ISO Standard 16571:2014(E), Systems for evacuation of plume generated by medical devices, incorporated herein by this reference.

(iv) All disposable accessories, including filters, hosing, or capture devices, shall be considered biohazardous material and shall be handled and disposed of safely as regulated waste required by Title 8 Section 5193 (d)(3)(E).

~~Exception: Plume scavenging systems may be located farther away from the site-oforigin if a licensed healthcare professional directly involved in a patient's care determines, in the reasonable exercise of clinical judgement, that the location of the engineering controls will jeopardize the patient's safety or jeopardize the success of the medical procedure.~~

(v) ~~NOTE:~~ The use, construction, installation, inspection, testing, and maintenance of exhaust ventilation systems must comply with section 5143.

(B) General Ventilation. General room ventilation of 20 air exchanges per hour shall be used in addition to plume scavenging systems and other local exhaust ventilation systems.

(2) Administrative Controls, including work practices, shall be used when plume scavenging systems do not prevent employee exposure. ~~are not placed as close as possible to the site of origin as allowed by the exception to subsection (d)(1), or when plume scavenging systems do not prevent visible surgical plume from contacting the eyes or respiratory tract of employees.~~ Administrative controls shall be used to minimize employee exposure to surgical plume to the greatest extent feasible.

(3) Personal protective equipment.

~~(3)~~ (A) Respiratory protective equipment, in accordance with section 5144, shall be used when the engineering controls and administrative controls do not prevent ~~visible~~ surgical plume from contacting the eyes or respiratory tract of employees.

NOTE: Surgical masks are not approved respiratory protective equipment pursuant to section 5144.

~~(4)~~ (B) The employer shall provide and ensure employees use appropriate eye protection that does not conflict with other personal protective equipment where ~~visible~~ plume may contact the eyes of an employee.

~~(e)~~ (f) Training. The employer shall provide effective training to all employees that have occupational exposure to surgical plume and to those employees' supervisors.

(1) ~~The i~~Initial training shall be provided when the written procedures are first established or at the time of initial assignment to tasks where occupational exposure may occur.

(2) Refresher training shall be provided ~~and~~ at least annually thereafter.

(3) Additional training shall also be provided when changes occur, such as the introduction of new devices, controls, procedures, or other changes that may affect the employee's occupational exposure or the employer's control measures.

(4) Training shall be in person.

(5) Training shall include at least the following elements as applicable to the employee's assignment:

~~(1)~~(A) The contents of plume.

~~(2)~~ (B) Procedures, diagnostics and techniques used at the worksite that generate surgical plume.

~~(3)~~(C) The health hazards associated with exposure to surgical plume.

~~(4)~~(D) The appropriate use of the plume scavenging systems utilized by the employer, including the employer's written procedures required by subsection (c).

~~(5)~~(E) The employer's procedures to ensure proper use, inspection, and maintenance of engineering controls and personal protective equipment, as applicable.

~~(6)~~(F) Administrative controls to minimize exposure to surgical plume, as applicable.

(G) An explanation of the importance of reporting exposures and symptoms of exposure to surgical plume.

~~(7)~~(H) An opportunity for interactive questions and answers with a person knowledgeable about occupational exposure to surgical plume and the specific controls utilized by the employer.

(I) How the employee can request additional training.

~~(f)~~ (h) Recordkeeping.

(1) Training records shall be maintained in accordance with section 3203.

(2) Records of testing of plume scavenging systems shall be maintained in accordance with section 5143.

(3) Records of implementation of the written plan.

(A) Records of annual review of the written plan as required by subsection (c)(3) shall include the name(s) of the person(s) conducting the review, the dates the review was conducted and completed, the name(s) and work area(s) of employees involved in the review, a summary of

the conclusions, and a plan for correcting any problems identified during the review. The record shall be maintained for three years.

(B) Records of each employee exposure to surgical plume shall be retained and made available as employee exposure records in accordance with Section 3204. These records shall include:

(1) The date and location of the exposure incident;
(2) The names, and any other employee identifiers used in the workplace, of employees who were included in the exposure evaluation;
(3) The type of energy-based device used;
(4) The type of procedure being performed;
(5) The length of time the employee was exposed;
(6) Any symptoms experienced by employee(s);
(7) An explanation of why the plume scavenging system was not in use or effectively capturing all surgical plume.

(3) The written operating procedures required by subsection (c) shall be available to affected employees and their representatives at the worksite at all times.

(4) The employer must make all records maintained as a requirement of this standard available for examination and copying to the Chief, the Director, each employee, and each employee's representative(s) in accordance with Section 3204.

Appendix A (Non-Mandatory)

The following are examples of professional occupational safety guidelines for the protection of health care workers exposed to surgical plume:
2017 AORN Guideline for Surgical Smoke Safety.
CSA Z305.1313, Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings.
ISO 16571:2014(E), Systems for evacuation of plume generated by medical devices.

Note: Authority cited: Sections 142.3 and 144.6, Labor Code. Reference: Section 142.3, 144.6 and 6308, Labor Code

Attachment 2: CNA/NNU's Updated Review of the Literature Substantiating the Health Impact of Surgical Plume Exposure

12/1/2017, Updated 1/7/2019

Author	Title	Journal citation	Study design	Results	Limitations	Notes/ Conclusions
Andreasson et al.	Peritonectomy with high voltage electrocautery generates higher levels of ultrafine smoke particles	European J of Surgical Oncology 2009; 35(7): 780	Evaluated amount of airborne and ultrafine particles generated during 14 consecutive peritonectomies, measured UFP 2-3 cm from surgeon's breathing zone, 3 m from smoke generation and compared to 11 standard colon and rectal cancer surgeries	Cumulative level of UFP in breathing zone and in stationary sample higher for peritonectomies than standard surgery		UFP levels measured in breathing zone of surgeon and in stationary sample
Baggish et al.	Protection of the Rat Lung From the Harmful Effects of Laser Smoke	Lasers in Surgery and Medicine 1988 8: 243	Exposed rats to surgical smoke from lasers filtered through commercially available smoke-evacuator systems, unfiltered smoke, smoke filtered with ultra-low penetration air filter, and control group	Animals exposed to smoke filtered through smoke-evacuator system and unfiltered smoke showed significant pulmonary lesions while the control group and group exposed to smoke filtered through ULPA filter showed no lesions		Significant lung damage in animal model after exposure to surgical smoke except when filtered using ULPA filter
Baggish et al.	Presence of	Lasers in Surgery	Cultured smoke	HIV DNA found in	In vitro	HIV transmission

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	Human Immunodeficiency Virus DNA in Laser Smoke	and Medicine 1991, 11: 197	isolates from laser surgery of concentrated tissue culture pellets infected with HIV	sample collected immediately and 14 day cultured material		possible in surgical smoke
Brace et al.	The air that we breath: assessment of laser and electrosurgical dissection devices on operating theater air quality	J of Otolaryngolgy-Head and Neck Surgery 2014, 43, 1	Air monitoring in OR, hallway outside OR, and rooftop of hospital for 6 months	Laser surgery associated with increase in concentration of PM2.5, fine and coarse particulate counts, electro cautery associated with significantly increased UFP levels		Increase in PM2.5 concentration, fine and coarse particulate counts, significant UFP levels
Bruske-Hohlfeld et al.	Surgical smoke and ultrafine particles	J of Occup Medicine and Toxicology 2008	Measured the amount of ultrafine particles in surgical smoke generated during different surgical procedures, near surgeon's breathing zone	Short-term very high exposures to ultrafine particles in surgeon and operating personnel breathing zone alternating with longer periods of low exposure		Very high exposures to UFP for surgeon and OR personnel, measured in breathing zone
Capizzi et al.	Microbiologic Activity in Laser Resurfacing Plume and Debris	Lasers in Surgery and Medicine 1998 23: 172	Smoke captured from laser resurfacing of 13 consecutive patients	5 samples cultured Staphylococcus, 1 also had growth of Cornyebacterium and 1 had growth of Neisseria		Bacterial transmission possible in surgical smoke
Cheng et al.	Pilot Studies of VOC Exposure	Annals of Work Exposures and	Breath samples collected before	VOCs at higher levels in surgery	Small sample size- pilot	

	Profiles during Surgical Operations	Health, 2018, 1-11	and after surgery to measure internal VOC exposures for operating room personnel. Area samples collected during surgery. Surgical plume sample contents examined with GC-mass spectrometry	area included benzene, toluene, ethylbenzene, and m/p-xylene. Average concentrations of VOCs in breath samples that were significantly higher after surgery than before: sevoflurane, dimethyl sulfide, and methyl methacrylate.	study. Unclear whether the procedures studied were the first procedures performed that shift (would make the before-after comparison less significant if previous exposure).	
Edwards and Reiman	Results of a Survey on Current Surgical Smoke Control Practices	AORN Journal 2008; 87(4): 739-749	Survey regarding surgical smoke control practices, respondents from all 50 US states and Canada, 86% perioperative RNs, 76% in general surgery, most at hospitals	Smoke evacuators and wall suction used for some procedures more than others, many respondents reported devices not used		Smoke evacuators not commonly used in US and Canada
Elmashae et al.	Surgical smoke simulation study: Physical characterization and respiratory protection	Aerosol Science and Technology 2017, 1	Electrocautery of lamb muscle tissue in simulated surgical suite, measurement of aerosol size and	Concentration of particles generated during simulated surgical procedure three times higher than background	Consideration only for respirators, not for engineering controls	High levels of particles generated during electrocautery

			concentration in plume	levels	(hierarchy of controls)	
Eshleman et al.	Occupational exposures and determinants of ultrafine particle concentrations during laser hair removal procedures	Environmental Health 2017; 16(30)	12 laser hair removal procedures sampled over 4 days, measured airborne particles 10 nm to 1 um in procedure rooms	UFP concentrations increased rapidly in procedure room during tx, peaked at end of procedure, declined steadily after procedure but not to pre-tx levels		High UFP concentrations during laser surgery procedures
Fletcher et al.	Dissemination of melanoma cells within electrocautery plume	Am J Surg 1999; 178(1): 57-59	10 aerosol samples of cauterized melanoma compared to control sample examined for viability immediately, at 5 and 7 days after cauterization	Viable cells from smoke present up to 1 week after collection	In vitro study	Viable cancer cells present in surgical smoke samples for up to 1 week
Freitag et al.	Laser smoke effect on the bronchial system	Lasers in Surgery and Medicine 1987 7(3): 283	Measured effects on sheep of exposure to surgical plume created by laser-vaporizing bronchial tissue	Smoke inhalation decreased arterial PO2 with little change in airway mechanics, significant depression of mucociliary clearance (dose-dependent), severe inflammation of inflammatory cells,	Animal study	Physiological changes in animals after exposure to surgical smoke

				neutrophils increased, percent macrophages decreased		
Gatti et al.	The mutagenicity of electrocautery smoke	Plast Reconstr Surg 1992; 89(5): 781-784	Air samples from two breast reduction surgeries compared to control air, Ames test for mutagenicity	Extracts from surgical smoke were mutagenic	Ames test	Surgical smoke is mutagenic
Garden et al.	Papillomavirus in the vapor of carbon dioxide laser-treated verrucae	JAMA 1988, 259: 1199	Captured plume emitted during in vitro laser surgery of bovine fibropapillomas and in vivo laser surgery of human papillomavirus-infected verrucae, analyzed for DNA content	Intact papillomavirus DNA was present in vapor of 2 of 7 patients		Viral transmission in surgical plume
Garden et al.	Viral disease transmitted by laser-generated plume (aerosol)	Arch Dermatol 2002;138(10):1303 -1307	Plume collected from cauterized bovine papilloma virus and reinoculated onto skin of calves	2 of 3 calves developed lesions with DNA identical to original lesions, viral transmission is possible in plume	Animal study	Papillomavirus (bovine) from surgical smoke was infectious
Hallmo and Naess	Laryngeal papillomatosis with human papillomavirus DNA	Eur Arch Otorhinolaryngol 1991, 248: 425	Case report of surgeon with papillomavirus with only occupational			Occupational papillomavirus transmission documented from surgical smoke

	contracted by a laser surgeon		exposure			exposure
Hill et al.	Surgical smoke- A health hazard in the operating theatre: A study to quantify exposure and a survey o the use of smoke extractor systems in UK plastic surgery units	J of Plastic, Reconstructive, and Aesthetic Surgery 2012, 65(7): 911	Recorded duration of diathermy use in full-time elective plastic surgery theater over 2 month period; measured the amounts of tissue destroyed through electrocautery ablation using pig tissue and some human tissue samples	Over 44 days of surgery, total cutting and coagulation time of 9 h, 19 min, 19 s plus bipolar function activated 2 h, 45 min, 52 s Mass of electrocautery tissue ablation following 5 min of continuous cutting was 2.4132 g and for continuous coagulation was 1.5817 g for human tissue	Elective surgery only	Quantified amount of tissue ablated, average time cautery devices used at elective surgery theater
Hui and Yan	Effect of electrosurgery in the operating room on surgeons' blood indices: a simulation model and experiment on rabbits	J of International Medical Research 2018, 46(12): 5245056.	Measured carbon monoxide content at certain positions in the operating room during electrosurgery. Animal model study to measure the effect of surgical smoke exposure on carboxyhemoglobin levels. Rabbits	Carbon monoxide levels near where the surgeon would stand ranged from 50 to 200 ppm. Exposure to high or low surgical smoke affected all blood indices (pH, carboxyhemoglobin , oxygen saturation, and oxygen content).	Animal model	

			were exposed to gas containing carbon dioxide, carbon monoxide, oxygen, and nitrogen that simulated surgical smoke exposure.			
Ilce et al.	The examination of problems experienced by nurses and doctors with exposure to surgical smoke and the necessary precautions	J of Clinical Nursing 2017; 26: 1555	Survey of nurses and doctors at a hospital in Turkey	Symptoms reported by more than 25% of nurse and doctor respondents after exposure to surgical plumes: headache, watery eyes, cough, throat burning, smell of hair, nausea Report low usage of central smoke evacuation system (13.3% nurses 0% doctors) and high usage of surgical masks (91.1% nurses 86.1% doctors)	Voluntary survey, recall bias	Symptoms of surgical plume exposure in nurses and doctors
In et al.	Experimental Study of the potential hazards of surgical smoke from powered	BJS 2015 102(12):1581	Evaluated viability of cells captured in surgical plume generated by electrocautery, radiofrequency	Viable cancer cells found in smoke from ultrasonic scalpels, viable cells implanted in mice grew in 16 of		Viable cancer cells isolated from surgical smoke

	instruments		ablation and ultrasonic scalpels of various cancers	40 injection sites; cancer cells isolated from plume were identical to cauterized tissue		
Kalil et al.	Analysis of electrocautery generated smoke by chromatographic mass spectrometry	Revista do Colegio Brasileiro de Cirurgioes 2016	Surgical smoke samples collected at site of generation using electrocautery device on pig subcutaneous tissue, muscle, and liver samples	Substances found in common between tissue types: decanal, hexanal, phenol, toluene, limonene, nonanal	In vitro study, chemicals identified but concentrations not measured	Hazardous chemicals in surgical smoke identified
Kashima et al.	Polymerase chain reaction identification of human papillomavirus DNA in CO2 laser plume from recurrent respiratory papillomatosis	Otolaryngol Head Neck Surg 1991 Feb 104(2): 191	Plume collected from laser vaporization of respiratory tract papillomata	HPV DNA identified in 17 of 27 plume specimens, same HPV type as in corresponding tissue specimen		HPV DNA identified in surgical smoke in majority of samples
Kim et al.	Comparison of surgical plume among laparoscopic ultrasonic dissectors using a real-time digital quantitative	Surgical Endoscopy 2012; 26(12): 3408-3412	Characterization of plume behavior	Different amounts and types of plume generated by different devices		Characterization of plume behavior

	technology					
Kocher et al.	Surgical smoke: still an underestimated health hazard in the operating theatre	European Journal of Cardio-Thoracic Surgery 2018, 0:1-6.	In vitro study measuring surgical plume generated by electocautery on porcine tissue (liver and muscle). Characterization of content of surgical plume generated.	Nin main toxic and/or carcinogenic substances identified as compounds of surgical smoke: acetylene, hydrogen cyanide, 1,3-butadiene, benzene, toluene, furfural, styrene, ethyl benzene. Surgical masks did not reduce inhaled concentration of 3 main toxic compounds (1,3-butadiene, benzene, and furfural). Chemical compounds were also found in the exhaust of the smoke evacuation system in high levels.	Small number of investigated samples. Limited identification of chemicals.	
Krones et al.	Chemical composition of surgical smoke produced by electrocautery, harmonic	European Surgery 2007, 39, 2, 118-121	Cauterized pig tissue using different cautery devices and types of tissue and analyzed contents	Varying levels and types of chemicals present in plumes from different sources; most contained	In vitro	Levels and types of chemicals measured with different cautery devices

	scalpel, and argon beaming- a short study		of plume	acrylamide, benzene, toluene, ethyl benzene, styrene at detectable levels		
Le Moual et al.	Are operating room nurses at higher risk of severe persistent asthma?: The Nurses' Health Study	J Occup Environ Med 2013, 55(8): 973-77.	Survey of operating room nurses compared to administrative nurses- Nurses' Health Study	Significant association between OR nursing and severe persistent asthma (adjusted odds ratio 2.48, 95%CI 1.06-5.77)		
Lee et al.	Surgical smoke control with local exhaust ventilation: Experimental study	JOEH 2018, 15(4): 341-50	Measures volatile organic compounds and particulates from surgical plume created during electrocautery of human tissue. Measurements taken without local exhaust ventilation, with wall irrigation, and with a smoke evacuation system.	Particulate counts reported in paper. Significant less particles were measured when smoke evacuation system was used. Surgical plume contained ethanol, isopropyl alcohol, benzene, o-xylene, styrene, acetaldehyde, acetone, acetonitrile, t		
Lin et al.	A Novel Inspection Protocol to Detect Volatile Compounds in	J of the Formosan Medical Association 2010, 109, 7, 511	Determination of certain chemicals in smoke generated during mammoplasty with	Minimum toluene production measures was 2252 ug, VOC levels depend on type and		Toluene and other volatile organic compounds found in surgical smoke, levels measured

	Breast Surgery Electrocautery Smoke		electrocautery	length of surgery		
Lopez et al.	Application of a two-zone model to estimate medical laser-generated particulate matter exposures	J of Occ and Environ Hygiene 2015	Established model for exposures to particulate matter for medical laser procedures			Model to estimate exposures to surgical smoke
Moot et al.	Composition of volatile organic compounds in diathermy plume as detected by selected ion flow tube mass spectrometry	ANZ J Surg 2007; 77(1-2):20-23	Organic compounds in surgical smoke obtained during abdominal laparotomy procedure analyzed vs control air, including monitoring at surgeon's headlight	Organic compounds identified consistently in all scans: HCN, acetylene, 1,3-butadiene, ammonia, formaldehyde Chemical composition of collected plume: 1,3-butadiene 0.15-0.70 ppm, 1-decene 0.3-1.4 ppm, 2-furancarbox aldehyde 0.1-0.4 ppm, propane nitrile 0.02-0.037 ppm, HCN 3-51 ppm, acetylene 2-8 ppm	Limited details about type of surgery and how many samples	Levels of volatile organic compounds in surgical smoke

				Chemical composition at surgeon's headlight (range): HCN 21-97 ppb, acetylene 2-40 ppb, 1,3-butadiene 0-2 ppb, 2-furancarbox aldehyde 10-21 ppb, 1-decene 7-17 ppb, propane nitrile 6-12 ppb		
Pillinger et al.	Randomized clinical trial of suction versus standard clearance of the diathermy plume	BJS 2003, 90(9): 1068-1071	Randomized trial where 30 patients underwent thyroid/parathyroid surgery, half of the surgeries used standard diathermy equipment, and the other have employed a smoke evacuation system; amount of smoke reaching operator's mask was measured	Mean amount of smoke at operator's mask without suction was 0.137 mg/m3 and with suction was 0.012 mg/m3 statistically significant difference ($p<0.001$); max amount without suction 2.411 mg/3 and with suction was 0.255 mg/m3		Exposure assessment of amount of plume at operator's mask- significantly higher levels without suction vs with suction
Plappert et al.	Laser pyrolysis products—genotoxic, clastogenic, and mutagenic effects of the	Mutation Research 1999, 441: 29	Evaluated cytotoxic, genotoxic, clastogenic, mutagenic properties of	Pyrolysis products strongly cytotoxic, genotoxic, mutagenic		Surgical smoke was strongly cytotoxic, genotoxic, and mutagenic

	particulate aerosol fractions		plumes generated by laser ablation of pig tissue (SCE test, micronucleus test, HPRT test)			
Ragde et al.	Characterisation of Exposure to Ultrafine Particles from Surgical Smoke by Use of a Fast Mobility Particle Sizer	Annals of Occupational Hygiene 2016 60(7): 860	Personal exposure monitoring for ultrafine particles for surgeon, assistant surgeon, surgical nurse, and anesthetic nurse during five different surgical procedures	Different job groups had similar levels of exposure during same types of surgeries Exposure levels and size distribution of particles different for different types of surgeries		Exposure monitoring for OR personnel showed similar levels of exposure to particulate matter from surgical smoke
Rioux et al.	HPV positive tonsillar cancer in two laser surgeons: case reports	J Otolaryngol Head Neck Surg 2013: 42: 54	Case report of two surgeons with only occupational exposure to HPV presenting with tonsillar squamous cell carcinoma and HPV 16 positive base of tongue cancer			Occupational HPV transmission documented from surgical smoke exposure
Romano et al.	Electrosurgical Smoke: Ultrafine Particle Measurements and Work Environment	Int J of Environ Research and PH 2017, 14, 2, 137	Ultrafine particulate levels measured during 10 real surgeries (liver resection most common)	Large distributions in UFP concentrations through the operating theater		Distribution of UFP throughout operating theater (not localized). High concentrations

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	Quality in Different Operating Theatres					
Sagar et al.	Chemical composition and potential hazards of electrocautery smoke	Br J Surg 1996, 83: 1792	Smoke plume generated by electrocautery in 6 actual surgeries was collected and tested for certain chemicals	Smoke contained significant levels of benzene (71 ug/m3), ethyl benzene (36 ug/m3), styrene (21 ug/m3), carbon disulphide (1.5 ug/m3), and toluene (460 ug/m3)	No measurement of variables (length of electrocautery , type of tissue)	Hazardous chemicals found in surgical smoke, levels measured
Sahaf et al.	Chemical composition of smoke produced by high-frequency electrosurgery	Irish J of Medical Science 2007, 176(3): 229	Evaluated chemical composition of surgical smoke collected during variety of surgical procedures	Different surgeries produced different levels of toxic chemicals, all types of surgery contained some toxic chemicals		Type of surgery may matter for types and levels of chemicals in plume
Sisler et al.	In vitro toxicological evaluation of surgical smoke from human tissue	Journal of Occupational Medicine and Toxicology 208, 13:12.	Collected surgical smoke in a cell culture media to measure the cytotoxicity, sample volatile organic compounds, particle concentrations, and	Reported particle size distributions, higher concentrations of VOCs found in surgical smoke than background (list in article). Surgical smoke caused statistically	In vitro study	

			other measurements	significant cell death compared to background and field blanks.		
Sood et al.	Human papillomavirus DNA in LEEP plume	Infect Dis Obstet Gynecol 1994 2(3): 167	Plumes collected from 49 consecutive patients undergoing laser surgery	80% of tissue samples were positive for HPV DNA, HPV DNA detected in 37% of plume collection samples		HPV DNA identified in 37% of surgical smoke samples
Zhao et al.	Comparative Safety Analysis of Surgical Smoke From Transurethral Resection of the Bladder Tumors and Transurethral Resection of the Prostate	Urology 2013; 82(3): 744	Composition of 36 smoke samples collected during transurethral resection of the prostate and transurethral resection of the bladder was determined	Differences in types of gas generated by different procedures; electrosurgery of malignant tissue may be more hazardous than benign tissue		Identification of gas generated during electrosurgery. Plumes from malignant tissues may be more hazardous than benign.

Ziegler et al.	Generation of Infectious Retrovirus Aerosol Through Medical Laser Irradiation	Lasers in Surgery and Medicine 1998, 22: 37-41	Cell line producing recombinant retroviruses carrying a marker gene were exposed to laser beam and aerosols collected. Susceptible indicator cell line used to investigate infectiousness of collected surgical plume aerosols.	Viral marker gene was detected in 16% to 59% of wells. Presence of infectious viruses was deted in 3% to 20% of the wells. "Surgical plume can contain infectious viruses, viral genes, or viable cells and may promote the spread of infections or tumor cell dissemination."		