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October 10, 2017

David Thomas, Board Chair
Occupational Safety and Health Standards Board
2520 Venture Oaks Way, Suite 350
Sacramento, CA 95833

RE: Petition for Adoption of a Standard Protecting Healthcare Personnel from Exposure to Surgical Plume/Smoke Generated During Medical Procedures

Dear Chairman Thomas:

The California Nurses Association/National Nurses United (CNA/NNU), representing more than 100,000 registered nurses (RNs) in California, submits this petition for the promulgation of a surgical plume/smoke removal standard by the Occupational Safety and Health Standards Board (OSHSB), pursuant to Section 142.2 of the California Labor Code.[1]

I. The OSHSB has Authority to Set a Surgical Plume/Smoke Removal Standard

California is one of twenty-two states and territories that administer their own occupational safety and health program covering both private and public sector workers.[2] Both the Joint Commission on Accreditation of Healthcare Organizations[3] and the National Institute for Occupational Safety and Health (NIOSH)[4] have called for the reduction of surgical plume/smoke exposure to healthcare workers, but a federal regulatory mandate is not expected to be forthcoming. California's Occupational Safety and Health Administration-approved state plan (Cal/OSHA) allows for the adoption of occupational standards without having to resort to the federal rulemaking process. California can and should, therefore, take the lead on this important issue as it has in areas such as occupational exposure to aerosol transmissible diseases, musculoskeletal disorders related to patient handling, and workplace violence.

The OSHSB is the standards-setting agency within the Cal/OSHA Program authorized to adopt, amend, or repeal occupational safety and health standards. Cal/OSHA enforces occupational

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[1] The standards that have been developed to date refer to the product of electrosurgical and laser tools as "plume," however, the terms "smoke," "aerosol," and "vapor" have all been used (*See*, Barrett WL, Garber SM. "Surgical smoke: a review of the literature," Surg Endosc 2003;17:979-987 at 980). For the purpose of consistency in describing the toxic by-products generated from the use of electrosurgical and laser tools, we will refer to these as "Surgical Plume/Smoke."

[2] *See* U.S. Department of Labor, Occupational Safety and Health Administration, "State Plans, Office of State Programs, Frequently Asked Questions," available at: https://www.osha.gov/dcsp/osp/.

[3] https://www.jointcommission.org/assets/1/18/Implementing_Hospital_RPP_2-19-15.pdf.

[4] U.S. Department of Health and Human Services, National Institute of Occupational Safety and Health, "Control of Smoke From Laser/Electric Surgical Procedures," DHHS (NIOSH) Publication Number 96-128, 1996, available at: https://www.cdc.gov/niosh/docs/hazardcontrol/hc11.html.

safety and health laws and regulations adopted by the OSHSB. We respectfully note that Cal/OSHA does not have enforceable regulations that specifically describe the requirements for removal of surgical plume/smoke and that are protective of healthcare workers in surgical settings where surgical plume/smoke is generated.

CNA/NNU was the sponsor of legislation during both the 2017-2018 and 2015-2016 legislative session which would have required the adoption of regulations by the OSHSB for the protection of healthcare workers from exposure to surgical plume/smoke (See AB 402 (Thurmond) of 2017 and AB 2272 (Thurmond) of 2016). Both of these bills were approved by the California Assembly and Senate and were sent to Governor Brown for a signature. Although Governor Brown vetoed the bills, he made clear that it was the process of using legislation to direct the OSHSB to adopt regulations that was the basis of his veto and not a disagreement with the need for such protections. The Governor specifically stated in his veto message on AB 2272, "I agree with the author and sponsor that the potentially hazardous effects of plume merits thorough review."[5] And, in his recent veto message on AB 402, the Governor stated, "I agree that the state should evaluate the need for a standard to address the health and safety hazards posed by plume and I suggest that the Author and Sponsor petition the Standards Board to initiate that process."[6]

Two OSHSB standards—the standard on workplace violence prevention in healthcare settings and the standard on safe patient handling—both started through the legislative process and both are now models for worker protection around the world. We appreciate the OSHSB's hard work in developing those regulations and hope to work with OSHSB on a surgical plume/smoke removal standard that could similarly serve as the model for enforceable standards in other states and at the federal level. CNA/NNU urges OSHSB to take the lead once again on worker exposure to surgical plume/smoke.

II. Surgical Plume/Smoke Exposure is a Serious Occupational Hazard

As explained by the Canadian Standards Association (CSA), procedures that rely on the ablation, cauterization, or mechanical manipulation of human tissue by lasers, electrosurgical generators, broadband light sources, ultrasonic instruments, plasma generators, bone saws, and drills generate noxious airborne contaminants as by-products from those procedures.[7] Human tissue destroyed during these procedures generates a smoke by-product or "plume."[8] Unfortunately, the plume/smoke can contain toxic aerosols, vapors and fumes.[9] Additionally, plume/smoke

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[5] Governor Edmund G. Brown, Jr. Veto Message, A.B. 2272 (Sept. 30, 2016), available at: http://www.leginfo.ca.gov/pub/15-16/bill/asm/ab_2251-2300/ab_2272_vt_20160930.html.
[6] Governor Edmund G. Brown, Jr. Veto Message, A.B. 402 (Oct. 9, 2017), available at: https://www.gov.ca.gov/docs/AB_402_Veto_Message_2017.pdf
[7] Canadian Standards Association, *Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings - Z305.13-13* (Dec. 2013), 6.
[8] The terms "surgical plume" and "surgical smoke" can be used interchangeably.
[9] Supra note 7 at 6.

consists of gases such as benzene, hydrogen cyanide, and formaldehyde as well as aerosolized blood and blood-borne pathogens in the form of bacteria and viruses.[10]

A 2003 article in the journal *Surgical Endoscopy*, "Surgical smoke, a review of the literature," contained a table listing the chemicals identified within electrosurgical smoke (*See* Table 1).[11] The authors note that while the potential dangers of surgical plume/ smoke had been known for two decades, at the time the article was published,[12] few precautionary steps have been taken because many of the effects are subtle and not immediate and because most effects would become apparent only after large numbers of individuals were studied over a long period of time.[13]

Table 1. Chemicals Identified Within Electrosurgical Smoke (As listed in "Surgical smoke: a review of the literature")

Acetonitrile	1-Decene (hydrocarbon)	6-Methyl indole (amine)
Acetylene	Ethane	4-Methyl phenol
Acroloin	Ethene	2-Methyl propanol (aldehyde)
Acrylonitrile	Ethylene	Methyl pyrazine
Alkyl benzene	Ethyl benzene	Phenol
Benzaldehyde	Ethynyl benzene	Propene
Benzene	Furfural (aldehyde)	2-Propylene nitrile 2,3-Dihydro indene (hydrocarbon)
Benzonitrile	Hexadecanoic acid	Pyridine
Butadiene	Hydrogen cyanide	Pyrrole (amine)
Butene	Indole (amine)	Styrene
3-Butenenitrile	Isobutene	Toluene (hydrocarbon)
Carbon monoxide	Methane	1-Undecene (hydrocarbon)
Creosol	3-Methyl butenal (aldehyde)	Xylene Formaldehyde

With respect to the chemicals found in Table 1, the 2003 article noted:

> The chemicals present in the greatest quantity in electrocautery smoke are hydrocarbons, nitriles, fatty acids, and phenols. Of these, carbon monoxide (CO) and acrylonitrile are the most concerning. Other chemicals present in smaller quantities but of significant concern include hydrogen cyanide, formaldehyde, and benzene.[14]

[10] Id.
[11] Supra note 1, Barrett.
[12] This article was published in 2003 so we are now talking about at least three decades.
[13] Supra note 1, Barrett at 985.
[14] Id. at 980.

It is noteworthy that Cal/OSHA regulations already recognize formaldehyde and benzene as regulated carcinogens under 8 CCR § 5217 and 8 CCR §5218, respectively. Additionally, summarizing the risk of benzene, the American Cancer Society explains that the link between benzene and cancer has largely focused on leukemia and other cancers of blood cells and that leukemia rates have been found to be higher for workers exposed to high levels of benzene.[15] Lab studies in rats also have demonstrated different types of tumors when benzene is inhaled or swallowed, supporting the finding of an excess risk of leukemia in humans.[16]

Peer-reviewed studies have confirmed surgical plume/smoke's mutagenic potential.[17] One study equated the mutagenic exposure of smoke condensate generated from just *one gram of tissue* destroyed by lasers to smoking *three cigarettes*, and exposure to smoke generated from just *one gram of tissue* destroyed by electrocautery procedures is equivalent to smoking *six cigarettes.*[18]

III. Surgical Plume/Smoke Contains Contaminants of Bloodborne Pathogens

Researchers have long recognized that surgical plume/smoke can cause workplace exposure to bloodborne pathogens. One study from 1993 that measured the exposure of operating room personnel to blood concluded that primary and assistant surgeons are exposed to inhalable blood containing aerosols while performing surgical procedures.[19]

Additionally, Pfiedler Enterprises, a continuing education provider approved by the California Board of Registered Nursing, offers a continuing education course for perioperative and operating room nurses, *Surgical Smoke: What We Know*.[20] This continuing education course addresses the evidence of surgical plume/smoke contamination with bloodborne pathogens:

> In 1998 Capizzi and colleagues looked at the viability of bacteria during laser resurfacing done on 13 patients. Specimens were collected and tested following the procedure. Of 13 bacterial cultures, five resulted in coagulase-negative Staphylococcus growth. Of the five, one had growth of Corynebacterium and one showed Neisseria growth. The researchers concluded there was potential for transmitting bacteria to operating room personnel, and that smoke evacuation should be used.[21]

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[15] American Cancer Society, "Benzene and Cancer Risk," (Jan. 8, 2016) available at: https://www.cancer.org/cancer/cancer-causes/benzene.html.
[16] Id. at I.
[17] Gatti, J.E., et al, "The mutagenicity of electocautery smoke," Plast Reconstr Surg. 1992; 89: 781.
[18] Hill DS, et al, "Surgical smoke - a health hazard in the operating theatre: a study to quantify exposure and a survey of the use of smoke extractor systems in UK plastic surgery units," *Journal of Plastic, Reconstructive & Aesthetic Surgery, July 2012.*
[19] 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):446-453.
[20] Pfiedler Enterprises, "*Surgical Smoke What We Know,*" available at http://www.pfiedler.com/ce/1311/files/assets/common/downloads/Surgical%20Smoke.pdf.
[20] Capizzi PJ, Clay RP, Battey MJ. "Microbiologic activity in laser resurfacing plume and

> Garden and associates studied viral disease transmission through exposure to smoke aerosols. They exposed bovine papillomavirus to carbon dioxide laser. The smoke was collected and then reinoculated onto the skin of the cows. The collected plume was tested and the presence of papillomavirus DNA was positive. They found that tumors developed at the laser-plume inoculated sites. Histology and chemical analyses revealed that the tumors were infected with the same type of virus as was in the laser smoke. The researchers concluded they had proved that laser plume could transmit disease.[22]

However, when OSHA was asked for a letter of interpretation to indicate whether surgical plume/smoke was covered under the provisions of the federal Bloodborne Pathogens Standards (BBP),[23] OSHA opined that surgical plume/smoke was neither blood nor "Other Potentially Infectious Material" (OPIM), as defined in the BBP standard. Thus, federal OSHA concluded that the provision under the BBP Standard would not apply to occupational exposure to surgical plume/smoke:

> According to the scope of the Bloodborne Pathogens Standard, "(it) applies to all occupational exposure to blood or other potentially infectious materials (OPIM)..." Blood is defined as "...human blood, blood components, and products made from blood." Subsequently, OPIM is defined by the standard as "...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 body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; any unfixed tissue or organ (other than intact skin) from a human (living or dead); and HIV-containing cell or tissue cultures, organ culture, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV." Surgical smoke would not qualify as blood or OPIM under the standard and its provisions would not apply. [24]

Importantly, OSHA was not denying the presence of bloodborne pathogens in surgical plume/smoke. OSHA was stating only that surgical plume/smoke was not covered under existing provisions. This OSHA interpretation of the BBP standard supports the need for the

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Debris," Lasers Surg Med. 1998;23(3):172-4.

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

[23] U.S. Department of Labor, Occupational Health and Safety Administration, Standard Interpretation Letter (Corrected June. 2, 2005), available at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=23461.

[24] Id.

OSHSB to adopt a specific standard for enforcement by Cal/OSHA of occupational protection of healthcare workers from exposure to surgical plume/smoke.

IV. Surgical Plume/Smoke is a Respiratory Irritant

NIOSH already recognizes that surgical plume/smoke causes ocular and upper respiratory tract irritation.[25] Furthermore, the well-known Nurses' Health Study found that operating room nurses were at significantly higher risk of severe persistent asthma as a result of occupational exposure to toxic chemicals and infectious materials.[26] The 2007 study analyzing operating room RNs participating in the Nurses' Health Study warned, "Given the composition of surgical smoke and its mutagenic and inflammatory potential . . . prudent practice dictates that precautions be taken to minimize the exposure of both surgical personnel and patients to surgical smoke."[27]

Further potential effects of surgical plume/smoke were discussed in an article from *Annals of the Royal College of Surgeons in England*, "Current attitudes and practices towards diathermy smoke," which we list here in Table 2.[28] The authors performed an Ovid Medline search and reviewed articles that included data on both laser and electrosurgical generated surgical plume/smoke to generate the information contained in Table 2.[29]

Table 2. Potential Effects of Surgical Plume/Smoke (as discussed in "Current attitudes and practices towards diathermy smoke")

Airway inflammation	Nausea/vomiting	Hepatitis
Hypoxia/dizziness	Asthma	Carcinoma
Coughing	Pulmonary congestion	AIDS
Headaches	Chronic bronchitis	
Tearing	Emphysema	

V. Scope

CNA/NNU asks that any standard developed by OSHSB should, at a minimum, cover all health care workers employed by general acute care hospitals licensed pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health and Safety Code in all units, including inpatient and

[25] U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health, "Control of Smoke From Laser/Electric Surgical Procedures," DHHS (NIOSH) Publication Number 96-128 (1996).
[26] Nicole Le Moual, PhD, et. al., "Are Operating Room Nurses At Higher Risk of Severe Persistent Asthma?," J Occup Environ Med. 2013 Aug; 55(8): 973–977.
[27] Gates, M.A., et. al, "Operating room nursing and lung cancer risk in a cohort of female registered nurses," Scand. J. Work Environ. Health, Vol. 33:2 (2007), 140-47.
[28] J. Spearman, G Tsavellas, P. Nichols, "Current attitudes and practices towards diathermy smoke," Ann R Coll Surg Engl 2007; 89: 162-165.
[29] Id. at 163.

outpatient settings and clinics on the license of the hospital. However, we are aware that the OSHSB has the authority and obligation to protect all healthcare workers from exposure to surgical plume or smoke, and we would encourage the use of this authority to expand protections to healthcare workers in other settings.

VI. Feasible Control Measures Can Abate Surgical Plume/Smoke Exposure

Feasible control measures exist that can be utilized to abate workplace exposure to surgical plume and smoke, including the use of plume scavenging systems or devices that capture and neutralize plume. According to experts in the field of occupational health, surgical plume associated risks are not eliminated by room ventilation or masks.[30] Local exhaust ventilation, also referred to as plume scavenging systems, must be placed close to where the plume or smoke is generated so that it can effectively reduce or eliminate surgical plume-associated risks.[31]

Recognizing the need for plume scavenging systems, CNA/NNU asks that in developing a standard the OSHSB consider and use as benchmarks the International Standards Organization's (ISO) *Systems for evacuation of plume generation by medical devices (ISO) 16571,* and the CSA's *Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings (Z305.13.13).* We are not aware of any NIOSH guidance or federal-OSHA standards that are as comprehensively designed or that are more protective of healthcare workers but, if the OSHSB determines that there are more protective federal or international standards, we request that these be used as additional benchmarks for consideration. As comprehensive and specific as the above referenced ISO and CSA standards are for the evacuation of plume, these standards are only recommendations. Without regulations, Cal/OSHA cannot enforce the use of plume scavenging systems in surgical settings and other settings where surgical procedures are performed.

During the aforementioned legislative process on A.B. 2272, the California Assembly Committee on Labor and Employment gathered its own information to analyze the feasibility of surgical plume control measures for a hearing held on April 20, 2016. The Committee included in its analysis NIOSH's recommendations:

> According to information published on [NIOSH] website, during surgical procedures using a laser or electrosurgical unit, the thermal destruction of tissue creates a smoke byproduct. Research studies have confirmed that this smoke

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[30] See, e.g., CSA Group, "Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings," Z305.13-13, 6 Operational Requirements at 12., Supra note 4; Int. J. Environ. Res. Public Health 2017, 14, 137; doi:10.3390/ijerph14020137, at 1.

[31] See, e.g., Smith, J.P. et al., "Factors Affecting Emission Collection by Surgical Smoke Evacuators," Lasers in Surgery and Medicine 10:244-233, p. 232. http://onlinelibrary.wiley.com/doi/10.1002/lsm.1900100303/epdf; U.S. Department of Labor, Occupational Health and Safety Administration, "Surgical Suite, Smoke Plume" Hospital eTool, available at: https://www.osha.gov/SLTC/etools/hospital/surgical/surgical.html#LaserPlume; Supra note 4; Canadian Centre for Occupational Health and Safety, "OSH Answer Fact Sheets: Laser Plumes – Health Care Facilities" Last Modified on April 4, 2017, available at: https://www.ccohs.ca/oshanswers/phys_agents/laser_plume.html.

plume can contain toxic gases and vapors such as benzene, hydrogen cyanide, and formaldehyde, bio-aerosols, dead and live cellular material (including blood fragments), and viruses. At high concentrations the smoke causes ocular and upper respiratory tract irritation in health care personnel, and creates visual problems for the surgeon. The smoke has unpleasant odors and has been shown to have mutagenic potential.

NIOSH research has shown airborne contaminants generated by these surgical devices can be effectively controlled. Two methods of control are recommended by NIOSH:

Ventilation
Recommended ventilation techniques include a combination of general room and local exhaust ventilation (LEV). General room ventilation is not by itself sufficient to capture contaminants generated at the source. The two major LEV approaches used to reduce surgical smoke levels for health care personnel are portable smoke evacuators and room suction systems.

Smoke evacuators contain a suction unit (vacuum pump), filter, hose, and an inlet nozzle. The smoke evacuator should have high efficiency in airborne particle reduction and should be used in accordance with the manufacturer's recommendations to achieve maximum efficiency. A capture velocity of about 100 to 150 feet per minute at the inlet nozzle is generally recommended. It is also important to choose a filter that is effective in collecting the contaminants. A High Efficiency Particulate Air (HEPA) filter or equivalent is recommended for trapping particulates. Various filtering and cleaning processes also exist which remove or inactivate airborne gases and vapors. The various filters and absorbers used in smoke evacuators require monitoring and replacement on a regular basis and are considered a possible biohazard requiring proper disposal.

Room suction systems can pull at a much lower rate and were designed primarily to capture liquids rather than particulate or gases. If these systems are used to capture generated smoke, users must install appropriate filters in the line ensure that the line is cleared, and that filters are disposed of properly. Generally speaking, the use of smoke evacuators is more effective than room suction systems to control the generated smoke from non-endoscopic laser/electric surgical procedures.

Work Practices
The smoke evacuator or room suction hose nozzle inlet must be kept within two inches of the surgical site to effectively capture airborne contaminants generated by these surgical devices. The smoke evacuator should be ON (activated) at all times when airborne particles are produced during all surgical or other procedures.

> At the completion of the procedure all tubing, filters, and absorbers must be considered infectious waste and be disposed appropriately. New filters and tubing should be installed on the smoke evacuator for each procedure. While there are many commercially available smoke evacuator systems to select from, all of these LEV systems must be regularly inspected and maintained to prevent possible leaks. Users shall also utilize control measures such as "universal precautions," as required by the OSHA Blood-Borne Pathogen standard.[32]

The analysis also provided federal OSHA's recommendations to address the problem of surgical plume exposure in the workplace:

> During surgical procedures that use a laser or electrosurgical unit, the thermal destruction of tissue creates a smoke byproduct. Each year, an estimated 500,000 workers, including surgeons, nurses, anesthesiologists, and surgical technologists, are exposed to laser or electrosurgical smoke. Surgical plumes have contents similar to other smoke plumes, including carbon monoxide, polyaromatic hydrocarbons, and a variety of trace toxic gases. As such, they can produce upper respiratory irritation, and have in-vitro mutagenic potential. Although there has been no documented transmission of infectious disease through surgical smoke, the potential for generating infectious viral fragments, particularly following treatment of venereal warts, exists. Local smoke evacuation systems have been recommended by consensus organizations, and may improve the quality of the operating field. Employers should be aware of this emerging problem and advise employees of the hazards of laser smoke.
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> There are currently no specific OSHA standards for laser/electrosurgery plume hazards however they make the following recommendations:
>
> - Use portable smoke evacuators and room suction systems with inline filters.
> - Keep the smoke evacuator or room suction hose nozzle inlet within two inches of the surgical site to effectively capture airborne contaminants.
> - Have a smoke evacuator available for every operating room where plume is generated.
> - Evacuate all smoke, no matter how much is generated.
> - Keep smoke evacuator "ON" (activated) at all times when airborne particles are produced during all surgical or other procedures.
> - Consider all tubing, filters, and absorbers as infectious waste and dispose of them appropriately. Use Universal Precautions as required by the OSHA Bloodborne Pathogens Standard when contaminated with blood or OPIM [29 CFR 1910.1030(d)(1)].

[32] Bill Analysis: Hearing on A.B. 2271 (as introduced on February 18, 2016) before the California Assembly Committee on Labor and Employment (April 20, 2016), 2-3, available at: http://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201520160AB2272#.

- Use new tubing before each procedure and replace the smoke evacuator filter as recommended by the manufacturer.
- Inspect smoke evacuator systems regularly to ensure proper functioning.[33]

Finally, attached hereto as Attachment 1 is a bibliography that we found useful during the legislative process and that we believe will also be useful for the OSHSB and Cal/OSHA in evaluating the need for protections of healthcare workers from exposure to surgical plume or smoke through processes that are currently available for removal of this hazardous material and that remediate its impact on healthcare workers.[34]

Thank you for giving consideration to our request for the OSHSB to consider this petition for an enforceable workplace standard to protect healthcare workers from exposure to this procedure-generated hazard.

Sincerely,

Donald W. Nielsen
Director of Government Relations
California Nurses Association/National Nurses United

cc: Marley Hart, Executive Officer, Occupational Safety and Health Standards Board

[33] *Id.* at 4.
[34] *See* Attachment 1 (Bibliography of Articles Relevant to Plume Effects and Need for Remediation).

ATTACHMENT 1

Bibliography of Relevant Articles on Smoke Plume Effects

1. CSA Z305.13-09, Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings
2. International Standard Organization, Systems for evacuation of plume generated by medical devices, ISO 16571:2014[E]
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