Add new Section 51XX to read: – draft revisions 4/06/26 compared to 8/29/25

§ 51XX. Occupational Exposure to Plume in Health Care

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

(1) Exposures to plume in other health care settings and exposures to similar smoke, particulates, vapors, and gases in other settings are covered under Title 8, Group 16—Control of Hazardous Substances, and other applicable substance-specific standards.

(2) This section does not preclude the application of sections 3203, 5141, 5143, 5144, 5155, 5193, 5199 or other title 8 safety orders to occupational exposure to plume.

(b) Definitions.

(1) "Administrative control" means a method to limit exposure to a hazard by adjustment of work procedures, practices, or schedules.

(2) "Ambulatory surgical center or ASC" means any surgical clinic as defined in the California Health and Safety Code Section 1204, subdivision (b)(1), any ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. SEC. 1395 et seq.) of the federal Social Security Act, or any surgical clinic accredited by an accrediting agency as approved by the Licensing Division of the Medical Board of California pursuant to Health and Safety Code Sections 1248.15 and 1248.4 to use anesthesia, except local anesthesia or peripheral nerve blocks, or both, in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes.

(3) "Authorized employee representative" for purposes of this section only, means a labor organization which has a collective bargaining relationship with an employer and which represents affected employees or an employee organization which has been formally acknowledged by a public agency as an employee organization that represents employees of the public agency. ~~an organization that has a collective bargaining relationship with an employer or an organization acknowledged by a public agency as representing its employees.~~

(4) "Capture device" means an accessory of a plume ~~evacuation~~control system that captures the plume near the site-of-origin ~~and passes it into the transfer tubing~~. A capture device can be single use or reusable.

(5~~4~~) "Designated employee representative" for purposes of this section only, means any individual or organization to whom an employee gives written authorization to exercise a right of access. A recognized or certified collective bargaining agent shall

Commented [DG1]: We have deleted the only use of the term Capture Device. One suggestion is just to delete the words "and passes it into the transfer tubing". Then the only use of the Capture Device term can stay in as-is?

be treated automatically as a designated employee representative for the purpose of access to employee exposure records and analyses using exposure or medical records, but access to an employee's medical records requires the employee's written consent. ~~their right to access records required by this section.~~

(6~~5~~) "Electrocautery device" means a device that is electrically heated to cut, ablate, or coagulate human tissue.

(7~~6~~) "Electrosurgical device" means a device that uses a radio frequency electric current that passes through human tissue to cut, ablate, or coagulate.

(8~~7~~) "Energy-based device" means a device that uses energy to ablate, cauterize, or mechanically manipulate human tissue, including lasers, electrosurgical generators, broadband light sources, ultrasonic instruments, plasma generators, bone saws, and drills.

(9~~8~~) "Gas phase filter" (e.g., activated carbon filter) means a filter that effectively removes gaseous air contaminants, which are too small to be filtered by particulate filters, through adsorption, absorption, or other chemical reaction.

(10~~9~~) "General acute care hospital" means a hospital licensed by the California Department of Public Health as such meeting the definition provided in Health and Safety Code Section 1250(a) or California Code of Regulations, Title 22, Section 70005, and all services within the hospital's license.

(11~~10~~) "High efficiency particulate air (HEPA) filter" means a filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter.

(12) "Medical-surgical vacuum" means a method used to provide a source of drainage, aspiration, and suction in order to remove body fluids from patients.

(13~~11~~) "Plume" means airborne contaminants and smoke generated from the use of energy-based devices, electrosurgical devices, electrocautery devices, ~~or~~ mechanical tools, or high-speed powered instruments during surgical, diagnostic, or therapeutic procedures. Plume can include visible or invisible aerosol particles, smoke, toxic gases, and vapors such as benzene, hydrogen cyanide, formaldehyde, bioaerosols, and dead and live cellular material including blood fragments and viruses.

(14~~12~~) "Plume ~~evacuation~~ control system (PC~~E~~S)" means any system, device, or technology ~~smoke evacuators, laser plume evacuators, plume scavengers, and local exhaust ventilators~~ that, when used in concert with other engineering controls and equipment, and to the extent technologically feasible, effectively captures, ~~and~~ removes, or neutralizes plume at the ~~site of origin~~ site-of-origin and before plume can make contact with the eyes or contact with the respiratory tract. The system can be portable, mobile, or fixed. Such systems may include smoke evacuators, laser plume evacuators, plume scavengers, local exhaust ventilators, electrostatic precipitators, or other FDA-cleared or ISO/CSA-validated technologies.

(15) "Qualified person" for the purposes of this section, means a person designated by the employer, and who by extensive instruction, knowledge, training, and experience, has demonstrated their ability to effectively identify, evaluate, and control the hazards of occupational exposure to plume. The qualified person shall be knowledgeable in this standard and shall be competent in industrial hygiene practice. A Certified Industrial Hygienist as codified in California's Business and Professions Code sections 20700-20705 is considered competent in industrial hygiene practice.

(16~~13~~) "Site-of-origin" means the location where tissue is being altered, worked on, or destroyed by a medical device or devices.

(17~~14~~) "Ultra-low particulate air (ULPA) filter" means a filter that removes particles as small as 0.12 micrometers with a filtration efficiency of not less than 99.999%.

(c) Written Exposure Control Plan.

(1) Employers shall establish, implement, and maintain a written exposure control plan that provides clear instructions for the effective use of plume ~~evacuation~~ control systems to minimize employee exposure to plume and that contains all the elements in subsection (c)(2). The plan shall be developed under the guidance of a qualified person.

(2) The plan shall contain all of the following elements:

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

(B) A list of all job classifications that have occupational exposure to plume.

(C) Effective procedures for identifying and evaluating occupational hazards associated with ~~exposure to~~ plume to include identifying unsafe conditions, work practices, and potential exposures in accordance with Section 3203(a)(4).

(D) Effective procedures to control employee exposure to plume. The procedures shall contain clear instructions for whenever energy-based devices, electrosurgical devices, electrocautery devices, ~~or~~ mechanical tools, or high-speed powered instruments are in use.

(E) Effective procedures for reviewing, at least annually, the effectiveness of the plan.

(F) Effective procedures for obtaining the active involvement of employees and authorized employee representatives in all elements of the exposure control plan including, but not limited to:

1. Identifying and evaluating exposures to plume;
2. Controlling exposures to plume including administrative controls, and selection and use of plume ~~evacuation~~control systems;
3. Selection and use of personal protective equipment;

4. Selection and use of respirators;
5. Reviewing and updating the plan; and
6. Training.

(3~~2~~) The exposure control plan shall be reviewed, evaluated, and updated:

(A) At least annually,
(B) When new processes, procedures, and equipment are introduced to the workplace, and
(C) Whenever a new or previously unrecognized hazard is identified.

(d) Control Measures.

(1) Engineering Controls.

(A) Plume ~~Evacuation~~Control Systems. Exposure to plume shall be prevented by plume ~~evacuation~~control systems to the greatest extent feasible. Medical-surgical vacuums (e.g., wall suction units, portable suction units) are not considered plume ~~evacuation~~control systems. Plume ~~evacuation~~control systems shall:

1. Be in operation continually whenever plume is present, generated, or whenever plume generating devices are in use.

2. ~~Be~~ Have the inlet of the capture device that is designed, located, or otherwise configured to effectively capture, remove, or neutralize plume at or near ~~as close as possible to~~ the site-of-origin, consistent with the technology's mode of action; and.

3. Plume control systems shall either:

i. When relying on exhaust or filtration:

Exhaust in accordance with section 5143 and by one or a combination of the following:

i. Directly outdoors at least 25 feet from any doors, window, air intakes, other openings in buildings, or places where persons ~~are~~ may be present; and/or

ii. Indoors through an ULPA filter and gas phase filter~~.~~ and have sufficient capacity to handle the anticipated level of plume for all procedures within its expected application.

4. Be ~~used,~~ constructed, set up or installed, inspected, tested, used and maintained in accordance with section 5143 and in accordance with the manufacturer's instructions.

ii. When relying on another FDA-cleared or ISO/CSA-validated mode of action: Demonstrate that the system, when installed, operated, and maintained in

accordance with the manufacturer's instructions, provides effective reduction of plume consistent with its mode of action and in accordance with recognized performance benchmarks as applicable (e.g., ISO 16571, CSA Z305.13-13), such that worker protection is at least equivalent in effectiveness to conventional smoke evacuation methods in controlling particulate plume.

(B) General Ventilation. The minimum total air exchange rate for the room or area where ~~surgical~~ plume is generated shall be at least 20 air changes per hour and shall be used in addition to plume ~~evacuation~~control systems ~~and other local exhaust ventilation systems~~. The room air shall be exhausted directly to the outdoors or returned to the air circulation system through a HEPA filter.

(2) Administrative controls shall be used to minimize employee exposure to plume to the greatest extent feasible.

(3) Respirators that provide protection against particulates and organic vapors shall be used in accordance with section 5144 when the engineering controls and administrative controls do not prevent plume from contacting the respiratory tract of employees.

(A) Surgical masks are not respirators pursuant to section 5144.

~~NOTE: Surgical masks are not respirators pursuant to section 5144.~~

(4) The employer shall provide and ensure employees use appropriate eye protection where plume may be reasonably anticipated to contact the eyes of an employee.

(e) Training. The employer shall provide effective training to all employees who have occupational exposure to plume, including new employees and to exposed employees' supervisors. The initial training shall be provided when the written procedures are first established and annually thereafter. Training shall include at least the following elements ~~as applicable to the employee's assignment~~:

(1) General education on the contents of plume;

(2) The circumstances in which plume is generated;

(3) Procedures, diagnostics, and techniques used at the worksite that generate plume;

(4) The safety and health hazards associated with exposure to plume;

(5) The appropriate use of the plume ~~evacuation~~control systems utilized by the employer, including the employer's written exposure control plan and procedures required by subsection (c);

(6) The employer's procedures to ensure proper use, inspection, and maintenance of engineering controls and personal protective equipment, as applicable;

(7) Administrative controls to minimize exposure to plume, as applicable;

(8) An opportunity for interactive questions and answers with a person knowledgeable about occupational exposure to plume and the specific equipment utilized to scavenge plume; ~~and;~~

(9)(~~8~~) How the employee can request additional training; and;

(10)(~~9~~) The contents of this section.

(f) Recordkeeping. The employer shall make available for examination and provide copies of records required by this subsection to employees, authorized employee representatives, and designated employee representatives within five business days upon request.~~;~~ These records shall also be made available to ~~and~~ representatives of the Division upon request.

(1) The written exposure control plan required by subsection (c) shall be available at the worksite at all times.

(2) Training records. These records shall be maintained for at least three years.

(A) Training records shall include the following information:

1. The date(s) of the training session(s);
2. The contents or a summary of the training session(s);
3. The names and qualifications of people conducting the training or who are designated to respond to interactive questions; and
4. The names and job titles of all persons attending the training sessions.

(3) Plume ~~evacuation~~control systems.

(A) The employer shall maintain records that the plume ~~evacuation~~control system conforms to the minimum requirements in section (d)(1)(A) and which demonstrate that it is constructed, set up, or installed, operated, and maintained in accordance with the manufacturer's instructions. These records shall be retained for at least ~~5~~ five years.

(B) For systems that rely on exhaust or filtration, ~~R~~records of testing of plume ~~evacuation~~control systems shall be maintained in accordance with section 5143. For other validated technologies, the employer shall maintain documentation showing that the system is installed, operated, and maintained in accordance with manufacturer's instructions and provides effective protection consistent with this section. Records of the testing shall be retained for at least ~~5~~ five years.

(4) Records of the annual review of the exposure control plan to identify unsafe conditions and work practices, including person(s) conducting the inspection, the unsafe conditions and work practices that have been identified and action taken to correct the identified unsafe conditions and work practices shall be maintained 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 plume. This appendix is non-exhaustive. Employers may also rely on FDA authorizations, ISO/CSA benchmarks, and other validated evidence to demonstrate compliance, provided the technology achieves equivalent or superior worker protection.

2022 AORN Guideline for Surgical Smoke Safety.

CSA Z305.1313, (reaffirmed 2020) *Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings*.

CSA Z7001:24 National Standard of Canada. *Safe use of energy-based medical and surgical devices in health care*.

ISO 16571: Second edition 2024-03, *Systems for evacuation of plume generated by medical devices*.

NIOSH Control of Smoke from Laser/Electric Surgical Procedures, DHHS (NIOSH) Publication No. 96-128

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