July 30, 2026

Department of Industrial Relations
Division of Occupational Health and Safety
1515 Clay St., Suite 1901
Oakland, California 94612

Subject: Alesi Surgical Ltd.'s Second Comment on Cal/OSHA Rulemaking to Implement AB1007 Concerning Occupational Exposure to Plume in Health Care

Dear Ms. Ali and Ms. Delizo,

Alesi Surgical Technologies Inc. ("Alesi") respectfully submits these comments on Cal/OSHA's April 24, 2026 discussion draft (the "April Draft") of the proposed regulation governing occupational exposure to plume in health care settings (proposed section 51XX), to be adopted pursuant to Assembly Bill 1007 (2023-2024) ("AB 1007"). Alesi met with Cal/OSHA staff May 16 and June 30, 2026, at which time several specific technical and regulatory questions were raised. This letter addresses those questions, supplements Alesi's initial comments submitted September 30, 2025, and sets forth Alesi's continuing positions for the administrative record.

Alesi supports Cal/OSHA's objective of protecting health care workers from the hazards of surgical plume. Alesi respectfully maintains, however, that the April Draft, as currently written, does not satisfy AB 1007's mandate for a performance-based, technology-neutral standard—a mandate reflected in section 144.9's functional definition of "plume scavenging system" and its direction to benchmark performance-based international standards, which the Legislature adopted precisely to ensure that the regulation would protect workers through validated outcomes rather than lock in a single, incumbent technology (Lab. Code, § 144.9, subds. (a)(8), (b)(2)(A), added by Stats. 2023, ch. 352, § 2).

Specifically, as detailed below, the April Draft's definition of "plume evacuation system" (PES) and its engineering controls framework improperly exclude electrostatic precipitation, an FDA-cleared technology with demonstrated surgical smoke management performance at least equivalent to—and by some measures superior to—conventional suction-based evacuators. Excluding validated technologies that achieve the same worker-protection outcome by a different mode of action is inconsistent with the Labor Code section 144.9's outcome-based structure, contradicts the Legislature's direction to "evaluate… as a benchmark" the international standards ISO 16571 and CSA Z305.13-13—standards that define smoke-management performance in terms of particulate capture, not by requiring any specific mechanism such as suction or filtration—and could deny California health care workers the benefits of technologies that may be considered better suited to certain open, laparoscopic, or robotic procedures.

The comments below address each of the issues raised during the May 16 and June 30, 2026 meetings. Alesi preserves all prior objections and all arguments identified herein for the administrative record and for any subsequent review.

I. A Performance-Based Approach to Electrostatic Precipitation Under AB 1007

Alesi's September 30, 2025, comments addressed the underlying science and FDA regulatory history for electrostatic precipitation in detail. Rather than repeat that material, this letter focuses on the specific points Cal/OSHA has asked us to address, considered against the statute's own terms.

Labor Code section 144.9, subdivision (a)(8), defines a "plume scavenging system" by the outcome it must achieve, which is "to the extent technologically feasible, captur[ing] and neutraliz[ing]" plume at the site of origin before it reaches a worker's eyes or respiratory tract, rather than by any specific mechanism (Lab. Code, § 144.9(a)(8), added by Stats. 2023, ch. 352, § 2). Subdivision (b)(2)(A) directs Cal/OSHA to benchmark ISO 16571 and CSA Z305.13-13 in developing the standard (Lab. Code, § 144.9(b)(2)(A)). Both standards are performance-based: ISO 16571 requires a minimum 90% particulate capture under specified test conditions, while CSA Z305.13-13 defines a "Plume Scavenging System (PSS)" as "[a] portable, mobile, or fixed device for capturing and neutralizing plume," with a note that "PSSs are also called smoke evacuators, laser plume evacuators, plume scavengers, and local exhaust ventilators (LEVs)." Neither standard contemplates 100% elimination of surgical plume, nor could any technology achieve that result in real-world use: all plume-management devices—regardless of mode of action—are activated selectively by the operator, operate at user-selected power or flow settings, and depend for their effectiveness on proper positioning and technique. These definitions describe plume-scavenging systems by their function—effective reduction of plume exposure consistent with recognized performance benchmarks—rather than by a particular mechanism, and the listed device types should be illustrative, not exclusive.

In Alesi's view, the CSA definition is consistent with recognition of electrostatic precipitation, which achieves the same functional outcome through a different mode of action. By framing the statutory definition in functional terms, the Legislature ensured that the standard would be adaptable to technological advances and that worker protection would depend on demonstrated performance rather than adherence to a legacy design.

We understand the April 24, 2026, discussion draft's reliance on an ULPA-filter and-gas-phase-filter architecture as one reasonable way to operationalize that outcome-based standard, and we address the questions below in that context. We respectfully submit, however, that adherence to the statute's text and legislative purpose requires and would benefit from an additional pathway recognizing technologies—such as electrostatic precipitation—that achieve the same statutory outcome through a different, independently validated mode of action.

Acknowledging the requirement of the standards, Alesi has demonstrated (internal test report MCR-007-3 Rev 1) that in simulated open surgery:

- 0.80% of surgical smoke particulates reached the simulated breathing zone using the Ultravision2 IonPencil, compared with
- 1.4%, 6.6% and 39.3% when using a representative smoke evacuator and accessory at 100%, 50% and 20% power settings; and
- 100% with no smoke management.

Using Ultravision2 therefore far exceeds the 90% requirement threshold defined by the standard and can be considered equivalent to a representative smoke evacuator device.

A. Whether the Exhaust/Filtration Requirement in Subsection (d)(1)(A)(3) Applies to Electrostatic Precipitation

Cal/OSHA has asked whether electrostatic precipitation satisfies the discussion draft's filtration requirement. We respectfully submit that subsection (d)(1)(A)(3)'s exhaust/filtration requirement is architecturally inapplicable to electrostatic precipitation and should not apply to technologies that capture and neutralize plume at the source.

The exhaust/filtration requirement in subsection (d)(1)(A)(3) presupposes a suction-based architecture: the system draws contaminated air away from the surgical site through tubing, and that air must then be either (i) exhausted outdoors or (ii) filtered through an ULPA and gas-phase filter before being released indoors. This makes sense for conventional smoke evacuators, which transport plume-laden air to a separate device for processing. But electrostatic precipitation works differently. It does not draw contaminated air into a separate device; instead, it electrically ionizes gases and charges airborne particles at the surgical site and deposits them onto a grounded surface—the patient tissue—before it can disperse into the room air. The plume is neutralized at the point of origin, not transported elsewhere for downstream treatment. This mode of action conveys performance, safety, and ergonomic differences that certain users may find best suits their needs during some or all of their surgical procedures. This includes – for example – the suction-free mode of action reducing risk of accidental damage to critical structures in operation; the lower profile design allowing better visualization of the operative site when operating in confined spaces; and the ability to both capture and deactivate enveloped and non-enveloped viruses present in surgical smoke.

Requiring electrostatic precipitation to satisfy subsection (d)(1)(A)(3) would be like requiring a self-contained appliance to vent outdoors even though it produces no exhaust. There is no contaminated air stream to filter or exhaust—the particles have already been precipitated out at the source. Applying the exhaust/filtration requirement to this technology would not add any worker protection; it would simply disqualify a validated technology for failing to match an architectural assumption that does not fit its mode of action.

We therefore propose that Cal/OSHA add a pathway to subsection (d)(1)(A) recognizing that a plume control system satisfies that subsection where it neutralizes plume at or near the site of origin through an FDA-cleared or ISO/CSA-validated mode of action other than exhaust or filtration, including electrostatic precipitation, and the manufacturer demonstrates performance at least equivalent to conventional smoke evacuation methods for the intended procedure. This approach preserves worker protection while fulfilling section 144.9's direction to evaluate

technologies on demonstrated performance. A technology-neutral equivalence pathway also preserves surgeon discretion to select the plume-management approach best suited to the specific procedure and patient—the patient, after all, sits in the middle of this—consistent with the surgeon's primary obligation to patient safety, provided the selected technology meets recognized performance benchmarks. An equivalence pathway also incentivizes innovation: manufacturers would have a clear route to compliance for next-generation technologies, rather than being forced to retrofit their designs to resemble an incumbent architecture. The Legislature could have mandated a specific technology but chose not to do so; instead, it directed Cal/OSHA to evaluate performance-based international standards (ISO 16571 and CSA Z305.13-13) as benchmarks, take into consideration recommendations from federal OSHA and NIOSH, and use ISO 16571 in developing a standard establishing how much plume shall be captured (Lab. Code, § 144.9(b)(2)(A)–(C)). This is consistent with the equivalence pathway Alesi proposed in its first comment letter, summarized in Section II below.

B. Procedural Conversion from Laparoscopic to Open Surgery

Cal/OSHA also asked how the standard should apply when a procedure converts from laparoscopic to open surgery, noting that surgical smoke can escape through the trocar or during instrument changes. Trocar-site leakage is a known, physics-based limitation of laparoscopic smoke-management technologies generally, not one specific to electrostatic precipitation (*see* Göhler et al., Performance of Intraoperative Surgical Smoke Management Technologies for Laparoscopic Surgery: A Comparative In-Vivo Pig Study, 177 J. Aerosol Sci. 106309 (2024)). Published comparative data, including a prospective in-human clinical trial in laparoscopic sleeve gastrectomy patients, indicate that electrostatic precipitation reduces this leakage more effectively than vacuum- or insufflation-based systems because surgical smoke is captured *in situ*, at the site of origin, rather than escaping as leakage (*see* Demtröder et al., Evaluating the Efficacy of Smoke Management Technologies in Laparoscopic Sleeve Gastrectomy, 16 Sci. Rep. 9722 (2026); Göhler et al., supra).

On the conversion scenario itself, the Ultravision2 IonPencil is FDA-cleared (510(k) K240868) for general surgical procedures, including open surgery, so a facility using the Ultravision2 platform retains a cleared option if a case converts intraoperatively. We also ask Cal/OSHA to confirm that the applicable standard is the one suited to the procedure actually being performed at any given time, and that a surgical team is not required to interrupt an ongoing procedure to install or exchange equipment where doing so would itself create a patient safety risk. Conversions are typically unplanned and time-sensitive; a compliance framework that could be read to require a mid-procedure equipment change, regardless of clinical circumstances, risks placing compliance in tension with patient safety. Ultravision2's cross-modal capability helps minimize this risk in practice, but the standard should make clear that patient safety governs the timing of any equipment change.

C. FDA Clearance Scope

FDA clearance of electrostatic precipitators is not specific to Alesi. FDA's authorization of the original Ultravision System established Product Code PQM ("Surgical Smoke Precipitator") as a device category, just as conventional smoke evacuators sit under Product Code FYD (*see*

FDA De Novo Summary, Ultravision Visual Field Clearing System, DEN150022 (May 26, 2015); 21 C.F.R. § 878.5050). Any manufacturer may seek clearance under PQM by showing substantial equivalence to an already-cleared precipitator, and Alesi's own clearances have expanded from the original laparoscopic indication (DEN150022) to the 2024 IonPencil clearance covering general surgical procedures, including open surgery (K240868) (FDA 510(k) Summary, Ultravision2 IonPencil, K240868 (Aug. 12, 2024)).

Notably, FDA's Office of Surgical and Infection Control reviews both smoke evacuators (FYD) and electrostatic precipitators (PQM), indicating that FDA treats the two categories as subject to the same infection-control review framework despite their different mechanisms. This mirrors the treatment of advanced insufflators, which carry a distinct product code (HIF) and a different reviewing office, yet are already recognized as compliant smoke-management systems under the discussion draft. If a different product code or reviewing office does not disqualify insufflators, the same logic should apply to electrostatic precipitators.

D. VOC and Gas Capture

On whether the device addresses volatile organic compounds and gases: surgical smoke is a complex mixture comprising solids, liquids, and gases. Electrostatic precipitation functions by imparting a transient negative charge on the gas molecules adjacent to the electrode device, causing these gases to be attracted to patient tissue. The gas molecules collide with particulate matter – which will include solids, liquids and adsorbed gas molecules – and cause it to be precipitated at the point of origin. Recognising the difference in the mode of action compared to traditional smoke evacuators Alesi assessed residual VOC release into the breathing zone via independent testing of gas samples captured in simulated-surgery testing using the EPA TO-15 method. VOC levels in the breathing zone demonstrated margins of safety of 26 to 28,000 times the short-term exposure limit and 17 to 75,000 times the time-weighted average limit (internal test report DVER-007-012 Rev 1). This places electrostatic precipitation in a unique position: no international standard—including ISO 16571—requires any smoke-management technology to demonstrate VOC-capture performance, and no FDA-cleared smoke evacuator or insufflator makes any performance claim or provides any data evidencing VOC control. If Cal/OSHA nevertheless intends to impose a VOC-capture requirement, it should apply the same test method, exposure limits, and threshold to all smoke-management technologies equally. On that basis, Ultravision2 is the only smoke-management system that has demonstrated VOC margins of safety against recognized short-term and long-term exposure limits—meaning that, under a VOC-performance standard applied equally to all technologies, Ultravision2 would be among the few, if not the only, systems currently able to demonstrate compliance.

E. California Deployment

Cal/OSHA also asked about the scope of electrostatic precipitator use in California and whether the device is used alongside a conventional evacuation system. Alesi would prefer not to identify specific client facilities or surgeons for Cal/OSHA to contact in this rulemaking. AB 1007's performance-based framework directs Cal/OSHA to evaluate a plume-scavenging technology by benchmarking ISO 16571 and CSA Z305.13-13—standards that focus on

demonstrated capture-and-neutralize performance—not by the technology's current commercial adoption (Lab. Code, § 144.9(b)(2)(A)). The Legislature chose this evidence standard for good reason: tethering regulatory recognition to market penetration would entrench incumbents, discourage entry by newer or more effective technologies, and create a regulatory asymmetry inconsistent with the statute's outcome-based structure. Identifying and interviewing individual users risks making commercial adoption, rather than demonstrated safety and efficacy, a *de facto* prerequisite for regulatory recognition.

We ask that Cal/OSHA evaluates the evidence in this letter on its merits rather than on usage volume. Alesi confirms that it sells its products in California through a distributor, and that, to its knowledge, the device is used in both ambulatory surgical centers and acute-care hospitals, across a range of surgical specialties, and as a stand-alone technology rather than alongside a conventional evacuator. Procedure types and workflows differ materially between acute care hospitals and ambulatory surgical centers, which often perform high-volume, shorter procedures with different equipment and turnover constraints; we ask that compliance requirements be tailored to, or at least not inconsistent with, that operational reality, including the practical benefit of technologies that do not require a separate portable suction unit.

Finally, we ask Cal/OSHA to confirm that the standard does not require, expressly or implicitly, concurrent use of an electrostatic precipitator with a conventional evacuator as a condition of compliance. Such a requirement would be impractical, add cost without a demonstrated protection benefit, and could make electrostatic precipitation commercially impractical, thereby excluding a validated technology from the California market for reasons unrelated to worker safety. Alesi supports the discussion draft's requirement of a minimum total air exchange rate of at least 20 air changes per hour in addition to any plume control system (proposed subsection (d)(1)(B)). This layered approach—combining mandated general room ventilation with local plume control at the surgical site—provides an additional risk control that applies equally to all smoke-management technologies. Because electrostatic precipitation has demonstrated particle-management performance at least equivalent to conventional smoke evacuators, and because the mandated room ventilation already provides a secondary control layer, there is no safety basis for requiring electrostatic precipitation to be used in tandem with a conventional evacuator. Requiring a third layer of control for electrostatic precipitation—but not for smoke evacuators—would impose an asymmetric compliance burden unsupported by the evidence.

II. Proposed Regulatory Text

In its September 30, 2025, comments, Alesi proposed replacing the definition of "plume evacuation system (PES)" with a technology-neutral "plume control system (PCS)," expanded to include electrostatic precipitators and other FDA-cleared or ISO/CSA-validated technologies, with an equivalence pathway for compliance through a validated alternative mode of action (*see* Alesi Surgical Ltd., Comments on Cal/OSHA Rulemaking to Implement AB 1007 (Sept. 30, 2025)). Cal/OSHA did not adopt this language, and the April 24, 2026 discussion draft retains the "plume evacuation system (PES)" definition without an equivalence pathway (*see* Discussion Draft § 51XX(b)(14) (Apr. 24, 2026)). We renew that request here. A

technology-neutral definition would resolve the filtration-classification and conversion issues addressed above in a single definitional change, consistent with section 144.9's own outcome-based structure and its direction to benchmark ISO 16571 and CSA Z305.13-13—standards that, as noted above, Alesi understands to define plume-scavenging systems by their function rather than by a specific filter technology (Lab. Code, § 144.9(b)(2)(A)).

Equally important, it would future proof the standard against the risk that new, validated technologies will be excluded from California's market simply because they employ a different mode of action than the incumbent architecture. The Legislature's choice to define plume-scavenging systems by their functional result, rather than by hardware, reflects an understanding that worker protection and technological innovation are complementary goals.

We also note that the discussion draft's references to an "inlet" and "capacity" in subsection (d)(1)(A) read most naturally as describing suction-based systems (*see* Discussion Draft § 51XX(d)(1)(A) (Apr. 24, 2026)); the technology-neutral definition proposed above would resolve that as well. Other stakeholders have separately urged a similarly flexible approach, including the California Hospital Association (Letter from Cal. Hosp. Ass'n to Christine Hoffman & Zohra Ali, Cal/OSHA (Sept. 30, 2025)) and the California Industrial Hygiene Council (Letter from Cal. Indus. Hygiene Council to Eric Berg, Cal/OSHA (Sept. 30, 2025)).

See **Attachment A** for Alesi's proposed revisions in redline of the April 24, 2026 discussion draft.

Alesi appreciates the opportunity to provide comments to the Division. Please let us know if there are any questions concerning the above-stated comments.

Dr. Dominic Griffiths

CEO, Alesi Surgical