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International Council on Surgical Plume, Inc.

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Subject: Discussion Draft: Occupational Exposure to Surgical Plume - Comments

Dear Dr. Berg

This letter comes to you from the International Council on Surgical Plume, representing over 150,000 healthcare professionals, in support of the timely and appropriate completion of a standard for management of exposure to the hazards of surgical plume in healthcare workplaces across California. ICSP is a non-profit clinical advocacy organization committed to eliminating surgical plume, through education, research, and support for standards and legislation. Our members include physicians, surgeons, nurses, technicians, scientists, academics, hospitals, professional organizations, veterinarians, dentists, manufacturers, regulators, standards developers, and other individuals having an interest in improving the health and safety of surgical team members and patients.

While it is true, that there are a number of standards, guidelines, and recommended professional practices currently published, they fail to have a meaningful impact on practice, due to lack of enforcement, and failure to empower staff to require compliance. There is a significant change to that situation, when standards are mandated by OSHA.

ICSP respectfully urges you to consider the following comments and suggestion for more clinically relevant language as you continue the work of completing the document.

1. (b) Definitions

(6) "Plume evacuation system" (PES) - means a device for capturing, transporting, and Filtering plume, and exhausting the filtered product.

Citation: ISO 16571 3.13

ADD: Capture Device – a hose, tube, funnel, or other accessory that provides the inlet to the Plume evacuation system at the site of plume generation

Citation: ISO 16571 3.2

(9) add to the definition: potentially infectious matter, live and dead cellular particulates

D – Control Measures Exception

We feel very strongly that this clause should be eliminated. It's intent is a clear mechanism that allows individuals to disregard this document. The reason we need to have a standard, is to remove emotional and personal responses to it's implementation ensuring universal adoption of it's requirements and a healthy and safe workplace free of the hazards of exposure to surgical plume, for every healthcare worker, every day, and in every surgical case. Further, there is no evidence that the use of a PES in any way jeopardizes patient safety or the success of a medical procedure. If anything, it improves safety, by clearing the surgical site of plume which then allows for better visibility, as well as preventing aero-digestive symptoms in staff that can decrease their ability to care for the patients. This exception negates the purpose of the standard – please omit it.

B. General ventilation – most clinical practice settings outside of hospital operating rooms do not have 20 air exchanges per hour – this cannot be a SHALL requirement. Further, with proper use of appropriate PES, it is not a concern.

2 Administrative Controls, - please omit the word VISIBLE when referring to plume. Invisible plume contains gases including benzene, toluene, carbon monoxide, etc., and the resulting odor is neutralized by adsorption into the carbon matrix in PES filters. Invisible hazardous gases cannot be separated or ignored, when referring to surgical plume.

Suggest that you include the requirement for PES filtration to meet ISO (16571:2014(E) IEC (60825:TR8) ANSI (Z136.3:2018) CSA (Z305.13-13), and all other current and developing standards. This means the use of ULPA (Ultra-low penetrating air filter) rated at 0.1micron filtration, and 99.999% efficiency rating. HEPA filters (0.3microns at 99.97%efficiency) capture only to the size of bacteria, but since viral capture and prevention of viral transmission is of critical importance in surgical practice, HEPA is not adequate, and should not be used. Further – the medical device industry does not provide HEPA filters anymore, as they do not comply with US standards.

Thank you for the opportunity to provide comment. We are readily available to you and the committee for consultation and can provide you extensive resources, references, and training materials as needed. We would also be happy to present to the committee, at a future meeting, an example of our nursing educational programs, as a way of sharing with you the type of material needed and the user focused level of material that best communicates both clinical and technical aspects of planning and implementing a plume program in a clinical facility. We hope that you will continue to keep us involved in this promising initiative, and appreciate the work you are doing.

Regards,

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Chairman, Board of Directors, ICSP
Chairman of Anesthesiology, Roswell Park Cancer Institute, NY

Daniel R. Palmerton,
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Addendum:

Regarding the contents of the exposure log I discussed at the November meeting. Our logs are completed by the person having the exposure, and not a 3rd party, and are left in a log book in each room, until they are reviewed weekly by management. The following data elements are useful:

Which room were you in
What energy based device was used
What PES was in use – if none, please explain why
What capture device was used
If no PES, what alternative procedure was followed
What surgical procedure was done
Number of people in the room
Length of case
Duration of exposure to surgical plume
How long into the exposure, did symptoms occur
What symptoms occurred
Did you experience loss of productivity, focus, or feeling of safety
Did symptoms resolve when you left the plume contaminated environment
Who did you report your exposure to – if no report, please explain why not