Minutes from the
Cal/OSHA Advisory Committee Meeting
Occupational Exposure to Surgical Plume
November 8, 2018
10:00 am – 3:00 pm
Oakland, California

Meeting Chairs: Grace Delizo, Amalia Neidhardt, Chris Kirkham, Eric Berg, Willie Nguyen
Notetakers: Valerie Royo, Patricia Coyle

Meeting Attendees

Name	Affiliation
Hamid Arabzadeh	HRA Environmental Consultants Inc.
Christina Armatas	California Department of Public Health
Gayle Batiste	SEIU Local 121 RN
Vicki Bermudez	none provided
Gail Blanchard-Saiger	California Hospital Association
Lisa Carroll	Los Angeles County RN
Steve Derman	Medishare, CIHC
Susan Eckhardt	Cal/OSHA
Kristy Elton	University of California, Office of the President
Nick Filipp	BSI
Lena Marie Gigliotti	California Nurses Association
Danielle Glover	Association of Perioperative Registered Nurses
D Gold	none provided
Michael Harris	San Francisco General Hospital
Brenda Horsley-Kuffel	Kaiser
Katherine Hughes	SEIU
Phyllis Johnson	Surgery ABSMC
Rachel Karolski	Buffalo Filter
Garrett Keating	Cal/OSHA
Saskia Kim	California Nurses Association
Bradley King	NIOSH
Martha Kuhl	California Nurses Association/NNU
Ronda Mananquil	California Nurses Association
Mike Manieri	Occupational Safety & Health Standards Board
John Martinelli	FACS
Denise Mavrogianis	CNA
Jennifer McNary	California Department of Public Health
Mark Mendoza	SEIU California State Council
Natalie Montoya	UCI, California Nurses Association
Tim Moreno	California Nurses Association

Amber Novey	LIUNA
Mary Ogg	Association of Perioperative Registered Nurses
Alexis Parker	UCSF
Doug Parker	Worksafe
Glenda Paterson	California Nurses Association
Nicole Robinson	Rad Analyst
Veronica Rojas Munoz	none provided
Sam Rowan	Stryker
Hector Sanchez	CNA, Arrowhead Regional Medical Center
Penny Smalley	International Council on Surgical Plume
Mitch Steiger	California Labor Federation
Marisa Szeps	SEIU Local 721
Jane Thomason	California Nurses Association, NNU
Lystia Villanueva	SEIU
Lisa Wilson	LA County UCLA Harbor Medical Center

Below are detailed notes of the advisory meeting. These notes do not represent a transcript of the meeting, and are simply a summary of the notes taken by the people conducting the meeting.

Welcome and Introductions

Eric Berg, Research & Standards, Cal/OSHA, introduced himself as Deputy Chief of Research & Standards, and explained that Research & Standards is a branch of Cal/OSHA that develops occupational health regulations on behalf of the Standards Board. The Occupational Health and Safety Standards Board requested that Cal/OSHA convene an advisory committee meeting to consider workplace hazards of surgical plume and to consider developing a rulemaking proposal. The Standards Board made the request to convene in response to Petition 567 from the California Nurses Association and National Nurses United. E. Berg stated that the purpose of the meeting is to seek advice from the public, employers, associations, manufacturers, workers unions, and experts, on how to proceed forward on Petition 567 that was granted by Standards Board. Input from all parties is important, and E. Berg stated that Cal/OSHA values all comments. E. Berg asked for everyone to please be respectful to comments, and reminded, due to a limited amount of time, to keep comments as succinct as possible so that everyone has a chance to speak and go through the entire discussion draft. E. Berg said that there aren't hard time limits, but if speaking goes too long, time limits may be set. E. Berg asked for attendees to sign in to receive emails on proposal updates posted on the website. The webpage already had several documents including the discussion draft, the petition, evaluations from Research and Standards and the Standards Board staff, and the decision by the Standards Board. Also posted were the law requiring surgical plume evacuation systems in hospitals and free-standing ambulatory surgical clinics in Rhode Island. There were also several technical documents on surgical plume and the control of surgical plume. E. Berg introduced the panel: Willie Nguyen,

Attorney with Cal/OSHA, and Cal/OSHA Research & Standards staff - Chris Kirkham, Principal Safety Engineer; Grace Delizo, Senior Safety Engineer; Amalia Neidhardt, Senior Safety Engineer; Valerie Royo, Analyst; and Patricia Coyle, Associate Safety Engineer.

Grace Delizo, Research and Standards, Cal/OSHA, stated that postings are on the website, and that Cal/OSHA was fortunate to have permission from AORN to post their guidelines for the purpose of this meeting, but the guidelines will be taken down on Friday. G. Delizo asked that if anyone was interested in those guidelines, to please download them by today. Cal/OSHA also got permission [from the Laser Institute of America through the ICSP and CNA/NNU] with no time limits to post ANSI standard (ANSI Z136.3-2018), Section 7.4 Laser Generated Airborne Contaminants (LGAC); Plume and Airborne Contaminants (PAC). G. Delizo stated that this is a really good reference and can be found on the webpage.

Background, the advisory meeting process, purpose and review of handouts

Chris Kirkham, Research & Standards, Cal/OSHA, stated that Cal/OSHA is audio recording the whole meeting. C. Kirkham explained that Valerie and Patricia are taking minutes and will use audio recordings to help with typed minutes. C. Kirkham asked that when making comments to please speak clearly and be cognizant that staff are taking notes and will be going through the audio recordings. C. Kirkham asked that speakers also state their names and affiliations each time. C. Kirkham pointed to two handouts for discussion. The one titled Regular Rulemaking is a flowchart from the Office of Administrative Law (OAL) website. It is a very succinct summary of the rulemaking process. C. Kirkham stated that Cal/OSHA is at the very beginning phase at the top where it says "State Agency" near the little drawing of the building, with a box to the right that says "Regulation Development." C. Kirkham clarified that this is not emergency rulemaking, and will follow the regular system, starting with the pre-rulemaking phase. There will be a formal rulemaking phase if it is decided that Cal/OSHA will propose a standard to the Standards Board. That is embodied in the flowchart – everything below the drawing of the building is a description of the formal rulemaking process. C. Kirkham stated that there are opportunities to comment both verbally and in writing in the current pre-rulemaking phase. If Cal/OSHA goes into in formal rulemaking, there will be opportunities to comment verbally and in writing, too. There is a fairly strict schedule, and Cal/OSHA will have to respond in writing to the comments.

Rulemaking process – see http://www.dir.ca.gov/dosh/steps-to-develop-an-ohs.html

C. Kirkham then pointed to the other document: Steps to Develop an Occupational Health Standard. It goes through 20 or so steps that Cal/OSHA will go through to develop a regulation if that is the decision. C. Kirkham stated that formal rulemaking is around step 9, and there are many steps to make a regulation. Cal/OSHA develops and proposes health regulations to the Standards Board for their consideration.

Presentation by Dr. Bradley King, Western States Division, NIOSH/CDC

Amalia Neidhardt, Research & Standards, Cal/OSHA, introduced guest presenter, Dr. Bradley King, a certified industrial hygienist from the National Institute for Occupational Safety and Health (NIOSH). Dr. King holds an MPH in Environmental and Occupational Health from St. Louis University and a Ph.D. in Environmental Health Science from John Hopkins University. Dr. King joined NIOSH in 1999 in the Health Hazard Evaluation program in Cincinnati, Ohio, and responded to requests from workers, employers, and union officials to evaluate occupational exposures at worksites across the country. Since 2013, Dr. King has worked at NIOSH Western States Division in Denver, Colorado, and current research interests include evaluating occupational exposures in the upstream oil and gas industry. Dr. King has extensive experience in surgical plume. N Neidhardt added that after the presentation, there will be a few minutes to ask questions.

Presentation by Dr. Bradley King, Western States Division, NIOSH/CDC

Please see "Presentation by Dr. Bradley King, CDC/NIOSH Western States Division" at https://www.dir.ca.gov/dosh/doshreg/Surgical-Plume-and-Smoke/.

A. Neidhardt asked if there were questions on the presentation, and reminded attendees to state their name and affiliation.

Dr. King mentioned availability via email for any questions or individual conversations. Dr. King wanted to present a historical review of data and NIOSH recommendations on this issue.

Mitch Steiger, California Labor Federation, asked Dr. King to talk more about one slide that showed the particle concentrations at different parts of the room that seemed to rise and fall at the same rate, but other slides showed concentrations themselves were very different at the point of surgery versus point of breathing versus other places of the room. Dr. King replied that some of the data presented showed differences expected at the surgical table very close to the procedure and the other areas of the room, and suspected that might be the effect of the type of ventilation in the room at the time. Dr. King mentioned in that particular operating room, there were similar concentrations at the surgical table and close to the periphery of wall. The ventilation within that operating room, despite the recommendation for positive pressure, was negative pressure. There was more ventilation being exhausted through the exhaust ventilation than what was being provided. For that particular graph, where the periphery of the room near the exhaust vents and the surgical table were mirroring one another, airflow was from above the table towards exhaust ventilation. In a positive pressure environment, there may be more

airflow from the top of the surgical table with more air being introduced into the room than being exhausted by the exhaust vent. It could indicate that the air flowed from the surgical table towards the door and towards the adjacent room. Some data showed that the circulating room desks were higher than what was at the exhaust vents. What might be found in the different areas of the surgical suite could be reflective of the individual characteristics provided in the operating room. More research could be done to show the differences in exposures between what is experienced at the surgical table versus what may be experienced at the circulating nurses' desk. M. Steiger asked if it was accurate or inaccurate to say that when engaging in an activity that generates surgical plume, the less visible particulate matter would travel much faster than the visible smoke that rises out of it? Dr. King was not sure if there was enough data to suggest that different sized particles travel differently. They collected ultrafine particles, and didn't know if there was a difference in larger particle travel versus smaller particle travel.

Natalie Montoya, UCI Medical Center Nurse and CNA member, asked if an argon beam for cautery was included in the studies? Dr. King answered that they did not, and do not have information on that. N. Montoya followed up with a question on the difference between open surgery versus laparoscopic surgery, and if the studies included any of that. Dr. King responded that they did not look at laparoscopic procedures compared to open surgeries. A vast majority of what was looked at was typically open procedure. N. Montoya asked if there was any interest in looking at the comparisons between laparoscopic and open surgeries, and Dr. King responded that there could be, and that they can respond to requests for investigations to look at particular issues that haven't been looked at before. N. Montoya asked if the cautery units were limited to the ones mentioned in the studies (bovie and harmonic), and Dr. King confirmed that yes, the studies were specifically on those devices, and would have loved to have included additional instrumentation that generated plume. Dr. King was not familiar with the argon beam and asked if there have been reports that it creates a greater quantity of plume. N. Montoya confirmed that the argon beam is used for massive bleeding and bleeding control and plume is seen when that device is used.

Steve Derman, Medishare Environmental Health and Safety Services, past chair of the AIHA Healthcare Working Group, Team Leader with Hazard Evaluation and Control with the AIHA, and representing the California Industrial Hygiene Council, asked Dr. King to describe the characterization of the particles that were analyzed at the time, and what was done with that. He asked for the particle counting, if types of particles were characterized, and what they were. Dr. King replied that they did not and relied on the direct reading instrumentation that were generating the data just for the concentrations, so they did not do an analysis of particle composition. However, in both of the recent papers mentioned, there were some of those

compositional analyses. They collected surgical smoke on filters and did a scanning electron microscopy analysis looking at the particles to do a general characterization. That is in the literature. S. Derman stated in past experiences, at times there might have been some formaldehyde normally in the air, and asked if baselines were taken? Dr. King responded that in the HHEs, in addition to conducting sampling within the operating room environments where the surgical procedures were, they also typically collected samples in an operating room that was not being used in which no operation was being conducted or no surgical plume was being generated. There were some of the same compounds in the air that they were finding and reporting in surgical plume, so they did find some ethanol, formaldehyde, and toluene that was present in an empty room environment. That could be attributed to indoor air quality. In the rooms where samples were being collected during surgical procedures, there were higher levels of those compounds, but those compounds were also found in empty rooms.

Glenda Paterson, Operating Room Nurse in San Francisco and California Nurses Association, commented that most cases presented were in plastics, and asked about whether there were plans to do analysis in different types of surgeries (oncology surgeries, orthopedic surgeries, etc.).There may be certain tissues that would have different particles that are actually emitted based on surgeries. Dr. King was not aware of any forthcoming investigations specifically looking at different operating room environments or procedures. There is some indication in some scientific literature that different tissue types has a significant impact in terms of the amount of plume that is being generated. It could be that the tissues looked at in plastics may be different types of exposures and/or different in amount that is being generated compared to other types of operations. Dr. King commented that it is clearly a source that needs more research, but there aren't any forthcoming. However, requests for that type of study to look at those types of procedures can be made to NIOSH. G. Patterson asked how requests are made, and Dr. King replied that one can be made on the NIOSH website by searching for "health hazard evaluation," and not only will a description of the program come up, but also an online web application that asks for basic contact information, issues, and health effects being reported. Dr. King could provide the link, if needed.

Hector Sanchez, Arrowhead Regional Medical Center and California Nurses Association, asked how OELs are established, and if multiple exposures and chronicity are taken into consideration when looking at determining what those levels are. Dr. King responded that NIOSH has recommended exposure limits (RELs) for different types of individual compounds, and there is a large process to undergo, such as doing a risk assessment for individual compounds, including looking at what the toxicological studies and real work studies are, to create what is called a current intelligence bulletin. Often times the RELs are based on more current science than OSHA permissible exposure limits. Typically when doing a specific REL, it only takes into account

the exposure to that one individual, and is not a comprehensive multi-compound exposure limit. It is individually focused.

Nick Filipp, BSI Services and Solutions, asked in regards to the recommendation of creating procedures for smoke control, are there any guidelines for that? Is it recommended for staff to use particle counters to determine the best position for LEV, or the type of LEV? Could one just go by visuals? Dr. King responded that there aren't guidelines on what the best approach would be. The studies relied on particle counters to get a general sense of reductions that were being generated, which is from an industrial hygiene approach. Dr. King stated that there are times when particles are present but not visible, so the approach taken in the study was to help evaluate how well the local exhaust ventilation was being conducted. N. Filipp commented that there are varying reductions and particle concentrations, and asked if there is a point where there isn't enough of a reduction where respiratory protection would be recommended? Dr. King replied that he could only report on what was found, and could not really comment on that specifically. Work practices should include training on proper use, and LEV should be as close as possible at the point of generation because LEV effectiveness drops rapidly the further away from the source of particle generation. There is no clear-cut guide, and they haven't developed anything like that.

John Martinelli, Forensic Analytical Consulting Services, commented when looking at particle size in the studies, it was cut at 0.3 micron, and Dr. King commented that for the first HHEs done in the early 90s with the instrumentation, it was about that size. J. Martinelli then said that later, ultrafine was mentioned and asked if that was smaller and if particle counts were being looked at for those smaller particles, and Dr. King confirmed yes to both. J. Martinelli then asked if that data was in in the study, and Dr. King responded that the data won't be in the study because anything below 0.3 microns was not looked, but in the report that will be out soon, it will delineate what those particle numbers are for everything down. They looked at particle size distribution, and particle numbers down to 0.03 or about 30 nanometers. The instrumentation being used for the particle number count might have even gone down to 10 nanometers, so the numbers were getting down into the ultrafine particle range. J. Martinelli commented that that was important because smaller particles seem to linger more with LEV, and Dr. King agreed and stated that ultrafine particles may also have pathological importance.

Mike Harris, Industrial Hygienist at San Francisco General Hospital, commented that differing amounts of general exhaust ventilation was mentioned, such as looking at a medical office versus a surgical suite, and asked if the number of air changes were evaluated during the studies? Dr. King replied that yes, at minimum, there was one at 19 air changes per hour, but

typically, it was 20-23 per hour. There is a plain language report from data in the dissertation study that will be generated. Requests for a copy can be sent via email.

A. Neidhardt thanked Dr. King and stated that the presentation slides will be posted, along with the latest report.

Outline of discussion draft items for meeting discussion

Willie Nguyen, Staff Counsel, Cal/OSHA Legal Unit, stated that the draft is just for discussion purposes, and is not an indication that Cal/OSHA has determined to move forward with formal rulemaking on a surgical plume regulation, nor is the draft as written set in stone. It is intended to provide a skeletal structure to discuss what may or may not be needed to address this issue. W. Nguyen said the draft mirrors the elements in other Cal/OSHA regulations on scope, application, possible definitions, possible training requirements, etc. W. Nguyen stated that the draft is something concrete to talk about and provides a structure to organize thoughts on possible rulemaking. If Cal/OSHA moves forward, Cal/OSHA will go through a formal rulemaking process, but the draft is to present issues for input. From comments or information provided to Cal/OSHA by January 15, Cal/OSHA will take a look at what is received and will determine how to move forward. If the determination is to go through formal rulemaking, there will be additional opportunities for the public to weigh in and to provide comments.

Scope and application

E. Berg asked for comments on subsection (a) that covers the scope of the regulation. This discussion draft right now is defined only to hospitals; there are three types of hospitals in California. E. Berg stated that it differs from the Rhode Island law which also applies to free-standing ambulatory clinics, and this draft does not have that. E. Berg mentioned that Dr. King pointed out that some of the higher exposures can be outside of hospitals.

Gail Blanchard-Saiger, California Hospital Association, stated that before commenting on scope and application, they will submit detailed written comments about whether regulations are appropriate at this time, given the lack of evidence and studies. G. Blanchard-Saiger expressed appreciation for the presentation, but the last slide captured that there is a lot more research that needs to be done. Regarding the scope, one of CHA's major concerns about this approach in a larger sense is that this document is location-based and not risk-based. As the presentation indicated, there could be higher risk to healthcare workers that can be quantified in medical office buildings or other areas where there are plume generating procedures happening. Some of the language is borrowed from other regulations, and within an acute care hospital, for anything that falls under the hospital's license, there is a regulation that treats everything the same. In an acute care hospital, plume generation could be very different

depending on procedures, where it is happening, and what the ventilation in the room is. The scope that is being proposed has no rational basis, and that is one major concern. G. Blanchard-Saiger also stated that another major concern, which was also an issue identified in the presentation, is that in California, hospitals cannot employ physicians. Private hospitals cannot employ physicians, so to put an obligation on the hospital employer when a physician is the one deciding which tool to use is a huge gap there to be cognizant of. G. Blanchard-Saiger states that the hospital doesn't have control over how a physician decides to do procedures because they're not employees.

Lena Gigliotti, Long Beach Memorial and California Nurses Association, echoed colleagues' comments and thanked division staff for working to get to this point in developing these important protections. L. Gigliotti has worked in the medical field since 18 years of age, first as a medic in the Army, and has seen many surgeries with cautery and no protections available. L. Gigliotti has also worked in labor & delivery, and has been an operating room nurse for one year. Although L. Gigliotti has seen contraptions to evacuate smoke, doctors don't want to use them because they're cumbersome. In L&D, cautery is used for surgical cesarean section incisions. Also, in an OBGYN clinic, doctors used cautery to treat genital warts, but because there were no plume evacuators used, one doctor developed HPV on her face above her mask and below her glasses. L. Gigliotti asked about it and was shocked that the doctor just accepted it. L. Gigliotti states that as healthcare providers, they accept risks, but they should be protected as they protect the public. L. Gigliotti stated support for the division's draft scope, including general acute care hospitals, psychiatric hospitals, and special hospitals, including all services and any clinics on the hospital's licenses. L. Gigliotti thanked the panel for allowing to share comments.

N. Montoya has been a registered nurse since 1993 with over 20 years in the operating room, and is currently at UCI Medical Center operating room as a nurse coordinator for vascular and trauma surgery. N. Montoya thanked division staff for putting together the meeting and the discussion draft, and expressed appreciation that the hazard and impact of surgical plume and smoke are being recognized. N. Montoya stated that she is a smoker, not of cigarettes or cigars, but of surgical plume 5 days a week, an amount equivalent to 40 unfiltered cigarettes at a modest estimate. N. Montoya stated that the longer she inhales surgical plume, the greater risk to her health, her coworkers', and anyone in the operating room, including patients. Patients in the hospital setting are sick and have resistant viral and bacterial illnesses. N. Montoya stated that nurses take universal precautions using PPE, like masks, gloves, and gowns, but what about surgical plume? N. Montoya said that surgical plume in the operating room continues to spread, and it is in the atmosphere after tissue is cauterized. N. Montoya stated that the terms "surgical plume" and "surgical smoke" don't express what they are – toxic, carcinogenic elements. One

gram of cauterized tissue is equal to seven unfiltered cigarettes. This is what she read in the literature. The weight of a light paperclip, the amount of cauterized tissue, is equal to seven unfiltered cigarettes. In the operating room, an exploratory laparotomy, kidney transplants, breast mastectomies, and gall bladder laparoscopic or open surgeries would create far more plume than the amount just explained. N. Montoya stated that she and her coworkers know the health effects of surgical plume well: eye irritation, respiratory irritation, as well as asthma. The Nurses' Health Study reported that operating room nurses were at a significantly higher risk for severe persistent asthma, a 2.5 times higher risk when compared to administrative nurses. N. Montoya stated that a significant concern is the impact of chronic exposure to surgical plume over the period of a career. Because surgical plume contains many substances that are known to be carcinogenic, mutagenic, or otherwise hazardous, there are long-term health impacts, like cancer or heart disease. N. Montoya also read a study that women over the age of 50 are significantly more likely to have heart disease when being exposed to surgical plume. N. Montoya said that because she is over 50 and has worked in the operating room for a long time, it is extremely concerning especially for women over the age of 50 who continue to work in the hospital setting. Simple control measures can be put into place to easily and quickly remove surgical plume, but employers have inconsistently and inadequately implemented these protective measures. N. Montoya said that her employer has plume scavenging systems available, but they are rarely used during procedures. Employers are legally and morally obligated to protect employees from hazardous exposures, and yet many have not implemented protection for surgical plume. A standard is needed to protect workers from surgical plume exposure. N. Montoya commended division staff for their work and said she was looking forward to engaging in this process.

Gayle Batiste, a registered nurse and president of SEIU Local 121 RN, stated that she is a perioperative nurse working at Dignity Northridge Hospital in Northridge, California. G. Batiste has experienced the same things that the study has shown, as well as her colleagues who have spoken about surgical plume. G. Batiste disagreed with G. Blanchard-Saiger from the California Hospital Association and stated that there is a need to be proactive instead of reactive. Last week, G. Batiste was on a case for a laparoscopic cholecystectomy, and the abdominal cavity filled with smoke and the surgeon had to release that smoke to visualize the organs. When released out of the abdomen, it spreads out into the room, and if unfiltered (which this was), the whole room is filled with surgical smoke. If one has not been in an operating room and has not smelled the smoke, has not seen the smoke or breathed it in, a surgical mask does not matter. A mask is not filtering particulates that are coming out because they are not designed for that. An N95 would do the trick, but nurses can't walk around wearing that all day long. A regulation is needed, and there is regulation, like bloodborne pathogens, through Cal/OSHA that regulates physicians that have to use certain things if they are out on the market. That

would apply to physicians for surgical plume regardless if the physicians are private or hired by the facility. That argument doesn't fly if this becomes a regulation. Evacuation equipment must be used, and hospitals have to get the kind that surgeons feel comfortable with because it is about their health, the staff's, and the patient's who are at risk. G. Batiste stated that an evacuation system is needed, which they do in their facility (three different types), but no one has been educated on how to use it. They have a standalone suction that has a smoke evacuator on it, but G. Batiste has only seen it used for cauterizing warts. It is not helpful if not used 100% of the time. Plume is being exposed and released into to the air with particulates. A plasma knife generates smaller particles than the electrosurgical as well as the carbon dioxide. G. Batiste has used all three plus the argon beam in her facility. Controls are needed that can be used to protect nurses and patients.

Hamid Arabzadeh, certified industrial hygienist and consultant, stated that he, along with Dr. King and others in the room, as an industrial hygienist, are exposure assessment scientists. H. Arabzadeh also stated that the most important matter for everyone is the protection of employees, and nurses have done so much. 30-40 years ago before proper active scavenging systems, nurses literally gave their lives because of the teratogenic effects of anesthetic gases. This is a real issue that needs to be studied, looked at, and H. Arabzadeh stated he is glad NIOSH is doing this. Skin protection and N95s are both important as a first measure, but a few more things need to be done, such as first characterize three aspects: the particulates, the chemicals, and bio-organisms present at the breathing zones. H. Arabzadeh stated it is difficult to come up with an exposure limit, and the most important part when having an engineering control is that it is feasible. The concern is there may be solutions presented that may not be effective. Having a local exhaust ventilation not intertwined with the HVAC system is not effective and cannot be effective. H. Arabzadeh recommended that Cal/OSHA take the lead, and this is very complex, and there is need to study it. H. Arabzadeh recommends engineering controls before recommendations are made, and will share experiences he has had with this. H. Arabzadeh expressed appreciation for nurses and the good presentation by NIOSH.

Katherine Hughes, registered nurse with SEIU, stated that the scope can be as broad as it needs it to be, and doesn't need to be limited to acute care hospitals, acute psychiatric hospitals, and special hospitals. Bloodborne pathogens and ATD standards apply to more than just those facilities. K. Hughes suggested to look wherever plume is generated, and look at different levels of controls depending on the hazard. K Hughes said that the regulation doesn't have to be cookie cutter, and that doctors follow the regulations on bloodborne pathogens and workplace violence prevention in healthcare that was just implemented, so doctors should follow this, regardless if they are employed by the hospital or not.

Danielle Glover, Association of Perioperative Registered Nurses, stated that nurses and surgical personnel should be protected no matter what type of facilities they are working in, and they encouraged the scope to go beyond the facilities listed to include ambulatory surgical centers, similar to Rhode Island's legislation.

Definitions

A. Neidhardt asked for input on definitions in subsection (b), and wanted any input, comments, or suggestions on any devices that may have been missed, any definitions that may be confusing, or any definitions that may be missing.

G. Blanchard-Saiger had a more general statement of concern that technologies are developing, and this is a snapshot in time, so there is not flexibility in respect to definitions. G. Blanchard-Saiger stated that there are new technologies coming, so there is concern about listing things out and the impacts of that. A. Neidhardt asked that when CHA submits comments, to be sure to include suggestions on future devices, and that would be greatly appreciated.

Penny Smalley, International Council on Surgical Plume, stated, following the previous comment, energy-based devices are used in many locations outside of hospitals, and there are registered nurses working in private facilities, dermatology offices, everywhere, that are also exposed to this hazard, and encouraged to broaden the definition to include wherever nurses/workers are. P. Smalley stated that throughout the document, the term "medical device" is language from other types of standards, but for energy-based devices, some are medical and some are surgical. Surgical ones create plume while there are medical energy-based devices, such as photobiomodulation devices (cold-lasers), that don't create any plume. IPLs, BBLs, and broadband light sources are also medical devices, not surgical, so P. Smalley recommended changing definitions to refer to surgical or energy-based devices so as to eliminate confusion with other types of technologies. P. Smalley also recommended adding filters to the definition for plume scavenging systems because without filters, there isn't a system, and the definition needs to include the type of filter specified in every national and him international standard for plume that exists. P. Smalley recommended ULPA filtration at 0.1 or 0.12 microns at 99.999% efficiency rating. P. Smalley stated that this is the specification in the ISO standard 16571, which is also harmonized with the European Norm 1882-1. They all specify ULPA filtration. P. Smalley stated that manufacturers don't make HEPA filters for medical systems anymore, so they are no longer sold and cannot be obtained. FDA requires all of the manufactures to verify their claims of filtration down to that level. If HEPA filters are specified in this document or any document related to it, it's something that people won't be able to purchase. Industry standard is ULPA filter of at least 0.1 at 99.999%. P. Smalley also suggested

for the definition of airborne contaminants to include potentially infectious matter and particulates. Most standards quote the ISO definition as "live and dead cellular particulates." That would include the potentially infectious material as well. That added to the definition of surgical plume would be helpful and would make it much more harmonized with the other standards that exist. P. Smalley stated that there was a comment made that there are no national standards for plume. However, there is the ANSI Z136.3, which is for the safe use of lasers in healthcare. In that section where this subject is discussed, there is also a note that relates back to the use of electrosurgical devices, which produce similar material and should be handled the same way. It could not be dealt with as a "shall" in the standard because electro surgery is outside of the scope of a laser standard but it was referenced in a note in that section.

D. Glover stated that, to build on the previous comment, "energy-based device" is preferred and not "medical device." Under #7 when looking at "Site of origin means the location where tissue is being altered, worked on or destroyed by a medical device," D. Glover would prefer to see "energy-based device" used there as well for consistency's sake. Also, under the definition for "surgical plume" at #9, – there are electrocautery devices, electrosurgical devices, energy-based devices, but then also power mechanical tools, which would be covered under energy-based devices. D. Glover suggested that power mechanical tools could be removed because it is covered by energy-based devices.

G. Blanchard-Saiger commented that in reference to the ISO standard, it is still under revision, so when looking at what's out in the universe as guidance, it's all still being developed. G. Blanchard-Saiger stated they want to be sure that what is being looked at is available and the most recent. G. Blanchard-Saiger also commented that when looking at ISO or ANSI standards, these are guidance. With other employee safety regulations, taking a guidance and putting it into a Cal/OSHA standard has not always been a good fit. When taking recommendations and then putting that into enforcement, every element has to be met. This was experienced in some respect during the workplace violence prevention in healthcare process. G. Blanchard-Saiger stated concern about this when evaluating and looking at what is available, but putting guidance into a standard can be problematic. G. Blanchard-Saiger also clarified a previous comment with respect to physicians, that if any regulation is a requirement for a hospital to comply as the employer in order to protect employee safety, hospitals need the ability to control and make decisions within its sphere of influence. With the example of workplace violence prevention, yes, the hospital employer has to have a plan and a policy and has to train its employees, and has to make sure that employees of others are trained when coming onsite. G. Blanchard-Saiger articulates that this is a different situation because it is the physican that decides how to do a procedure, what equipment to use, and whether or not to use at site of

origin plume scavenging equipment. G. Blanchard-Saiger emphasized that they cannot tell a physician what equipment to use or how to perform a procedure if they don't employ them. That is the challenge and reality for hospitals.

LUNCH BREAK

G. Delizo asked for further comments on definitions before moving on to other sections of the discussion draft.

J. Martinelli suggested that Cal/OSHA consider defining "administrative controls." It appears in subsection (d) but is not defined.

Written procedures

G. Delizo introduced subsection (c) on written procedures and asked for comments. Subsection (c) states that employers shall develop written procedures that provide clear instructions for the effective use of plume scavenging systems to minimize employee exposure to surgical plume. Subsection (c)(1) states the procedures shall be implemented whenever surgical plume is generated. Subsection (c)(2) states the procedures shall be reviewed and evaluated at least annually, and updated as necessary, to ensure that they reflect current, safe work practices.

G. Paterson briefly described her 25-year experience as an OR nurse. She stated that as far as she knew her facility did not have any written procedures regarding using an LEV device. She said that they use a suction device that has the capability to evacuate smoke plume but that they don't use the electrocautery pencils that would enable them to do that. Sometimes they just use the regular suction with a tip on the end of it. She commented that it was very important to have the written recommendations so that they can actually use this device and the surgeons and the facilities would make this available to protect both the patients and the staff. The Association of the Perioperative Nurses standards are discussed in the operating room; they throw that around all the time, but as far as evacuating electrocautery plume that is not consistent. They use an evacuation device for specific cases, pretty consistently for HPV warts. There is written documentation for that but for the rest of the uses there isn't. She expressed appreciation for the draft because she feels it's one way to advance use of evacuation devices to all surgery cases in which there is plume. She commented that it's really important to have Cal/OSHA standards because hospitals respect them and will adhere to them out of the fear of being cited. She added that, unfortunately, that's what it takes to get things done to protect people.

Tim Moreno, California Nurses Association, thanked DOSH for putting together the discussion draft to identify important issues and protections that will protect him and his coworkers from the harmful effects of surgical plume. He commented specifically on the requirement for employers to develop written procedures on surgical plume protections. He believes it's critical that employers have plans in place, which they then must follow and maintain in order to prevent employee exposure to surgical plume. These written plans should be clear and understandable. He added that it is important that the plans be available to employees for reference at all times. Employees need to be able to check what the employer has put in place for their protection to know whether it is working properly or if it's missing. He appreciated that the division recognizes this and included such a requirement in the draft. He thinks the division should add a requirement that employer's plans identify the individual(s) who are responsible for the plan. It is important the employers identify the point of contact so that the employees can raise questions or issues effectively.

Mark Mendoza, SEIU, had a couple of comments on subsection (c). SEIU believes that instead of the word "procedure," DOSH should be using "program." SEIU believes it is more robust and detailed vs. a procedure, which directs employees to simply comply with these guidelines. He added that SEIU believes that workers should be a part of the process described in subsection (c)(2) requiring review and evaluation of the procedures at least annually. SEIU also thinks that workers should be part of the equipment purchasing process. Finally, he said that Cal/OSHA should add a section that during regular Cal/OSHA inspections the inspectors should review the program and speak with workers aside from management.

H. Sanchez stated that before employers can know where to implement plume evacuation systems they need to identify all the areas where plume can be generated, and more specifically, they must identify all the areas in which energy-based devices are being used, not just the operating room. Energy-based devices can be used in clinics, doctor's offices, etc. He remarked that one of the ways that Cal/OSHA has done this in the past with other standards is to require a written plan to list the job classifications that are being exposed and CNA recommends that Cal/OSHA add that requirement to the draft plume standard. Additionally, employers should have a written plan in place that is reviewed and updated at least annually to be effective. Part of that review should include looking at exposures that might have occurred, when and why they happened, how to fix the problems so those exposures do not occur again. CNA strongly advocates for the addition of an exposure record requirement. He also made a couple of other points concerning the review of the plan. Techniques and procedures evolve almost monthly in a hospital and CNA thinks that the panel should take into consideration updating procedures as they evolve and including them in the annual review. Along with the changes in procedures, changes in the technology itself should also be looked at so as new

devices are introduced into the marketplace those technologies should be included in the annual review. He added that employers needed to update the procedures to reflect these changes and add different protections as needed. CNA recommends adding such a requirement. He commented that the requirement is similar to other Cal/OSHA standards, such as the workplace violence standard and bloodborne pathogen standard.

N. Montoya stated that employees must be involved in creating the plans and reviewing them. She and her co-workers have a nuanced understanding of how the workplace is set up, how procedures work, how smoke evacuators will fit into the operating room and work with other equipment. To that point, workers must also be involved in choosing the best plume salvaging systems for their setting. Their experience is that important practical considerations are neglected when the direct care employees who will be using the equipment are not involved in selecting it. Sometimes this means it is impossible to use equipment because of incompatibility issues or other problems that administrators and non-direct care employees have no knowledge of.

L. Gigliotti addressed the personal protective equipment section of the division's draft. She stated that the division has appropriately recognized the importance of having plume evacuations systems at all times when plume is generated and it is very important that the Division maintain this explicit requirement. However, there need to be other precautions in place if, for whatever reason, those evacuations systems are not fully effective for preventing exposure. CNA supports the division's use of the hierarchy of controls. In some hospitals, surgical masks are the only PPE provided to nurses and other health care workers in the OR. Respirators may only be used for patients with known active TB or other cases where aerosolized virus is a concern. She commented that the division draft goes a long way to fixing these problems and ensuring that employees are protected. CNA strongly supports the division's recognition that surgical masks are not respirators and offer no protection from plume. An important additional consideration is for the division to make clear that eye protection should not conflict with other protection, such as laser protection eyewear or splashguards.

K. Hughes stated that one of the things SEIU thought was missing was a hazard assessment. SEIU thinks there should be a hazard assessment for energy-based devices that create plume exposure. It should be carried out in consultation with the workers in the area where plume is generated that may be affected by the hazards. Their union representatives, if any, should be included as well. The assessment should include health and safety practitioners, infection control practitioners, technical experts who can assist in identifying the appropriate control measures, and clinicians. The following should also be taken into consideration when

conducting a risk assessment at a facility: number and type of procedures that are to be performed, the equipment being used, the size and layout of the procedure room or treatment area, available ventilation in the procedure/treatment area, including whether it is positive or negative pressure, expected volume of plume, and the manufacturer's specifications related to the effectiveness of the equipment.

Doug Parker, Worksafe, expressed appreciation for Cal/OSHA taking on this issue and the work that Cal/OSHA had done in preparing the discussion draft. Worksafe concurs with comments that this should be framed as a program or a plan that would include employee involvement. Worksafe also wants to make sure that a copy of the plan is available to employees. This is an issue they currently have to address with IIPPs. That should be clarified or perhaps piggybacked with whatever regulation comes with the current IIPP work that's happening at the Standards Board. With respect to the annual review, Worksafe thinks that review should also occur whenever there is a material change in the work environment. If there is new technology or new procedures that have been implemented, the plan should be reviewed, at least with respect to how that technology or procedure might change the factors of work protection. Finally under subsection (c)(1), it says that the procedure shall be implemented whenever surgical plume is generated, which literally would mean that the procedure would only apply once there's surgical plume. He suggested that the wording be changed to something along the lines of, "implemented or applied when there is a risk of exposure to surgical plume."

Lisa Wilson, is a RN operating room nurse at LA County UCLA Harbor Medical Center. She shared the effects surgical plume has had on her health after three to four years in the operating room. She stated that she wholeheartedly believes that it should be mandatory to use instrumentation to help decrease the inhalation of surgical plume by operating room staff. She commented that while smoking during pregnancy is unacceptable, there is no regulation regarding surgical plume. During her pregnancy, she had exposure to surgical plume. Use of smoke evacuators is preference-based at her hospital. She said her health should not be determined by the preference of a surgeon or because holding a smoke evacuator is an inconvenience. She added that written procedures are needed for smoke evacuators and training. Finally, she expressed the opinion that the people who are opposed today are the prime example of why a regulation is needed. She commented that they are opposed due to the cost. She feels that the regulation is needed to mandate that they make their employees' health a priority.

G. Blanchard-Saiger said she agreed with K. Hughes that the hazard assessment is missing. One size does not fit all. There are different amounts of smoke, different particulates, different contaminants. One of her concerns is that, as she reads it, surgical plume scavenging

equipment would have to be used any time there is surgical plume, regardless of the amount of plume or other factors as mentioned by the NIOSH presenter. She appreciated having a written program or policy for using plume scavenging systems if they are being used – there should be procedures and training, etc. – but a requirement that plume scavenging equipment be used any time a plume is generated ignores the hazard assessment process.

Control measures

E. Berg, Cal/OSHA introduced the control measures section – engineering controls, including the exception, administrative controls, and respiratory and eye protection – and asked for comments.

T. Moreno emphasized the importance of having control measures in place at all times to prevent exposures to surgical plume. His employers have smoke evacuators but they are not consistently used. It is up to each surgeon to use them or not. His experience is that surgeons only use evacuators during laparoscopic procedures in order to remove smoke so that it does not obstruct the camera inside the patient. Evacuators are hardly ever used when basic debridement procedures are performed. Even when surgeons have pens with a built in evacuation device they still choose not to use these devices. There needs to be protections for employees whenever energy based devices are used. He urged Cal/OSHA to remove the exception from the draft. He appreciated that Cal/OSHA recognized the importance of capturing the plume as soon as it has been generated. In order to make sure that this is as clear as possible, he recommended adding a definition of capturing device. He commented that the capture device is distinct from the evacuator itself. The capture device should be located as close as possible to where the plume is being generated so that plume can be effectively removed before nurses and other health care workers are exposed. Finally, he referenced the CNA petition to the Standards Board, and noted that surgical plume and smoke contains toxic aerosols, vapor, and fumes as well as gases such as benzene, hydrogen cyanide, formaldehyde and aerosolized blood and bloodborne pathogens. He stated that, as a result, they believe all disposable accessories, such as filters, hosing, or capture devices that interact with and contain the surgical plume, should be considered biohazardous material and be disposed of safely. He recommends adding a requirement that references the protections in the bloodborne pathogen standard.

M. Steiger thanked Cal/OSHA for the discussion draft. The California Labor Federation believes the control measures section is the heart of the standard and will do the most to protect workers from this hazard, but there are a few ways to strengthen it. First, he stated that the exception language should be deleted. Section (d)(1)(A) already contains language – “to the greatest extent feasible,” “as close as possible” – that allows health care professionals to

exercise judgment so that the scavenging system is located as close as it needs to be but not in way that jeopardizes anyone's health. He further stated that the language could be strengthened since different individuals will have different interpretations of what "as close as possible" means, for example. He commented that the exception could create dynamics between different health care professionals that would not be helpful. He shared, as an example, a nurse might feel pressured by a physician not to use plume scavenging equipment even if the nurse felt it was needed since the physician could have the power to directly or indirectly discipline or terminate the nurse. He commented that no one will want to have that debate right then in front of the patient. The prioritization of patient safety combined with a relationship in which one health care professional may have authority over another health care worker could create confusing dynamics at an important time and in some cases could undo a central part of standard. He stated that the exception language was not necessary and could be deleted as the previous language already allows judgment.

M. Harris commented that requiring 20 air changes per hour (ACH) per (d)(1)(B) would create significant challenges in upgrading their facilities to meet that requirement since they operate facilities dating from 1915 up to 2016. He also commented that he found the administrative controls section confusing because the requirement is based just on the presence or absence of visual plume making it to the employees face area. He said he was not sure how you could implement administrative controls because you cannot do worker rotation based on that, compared to a regulation based on an exposure level. Finally, he said that if Cal/OSHA had specific administrative control measures in mind, adding those to the regulation would provide some clarity.

N. Montoya stated that there wasn't a question that plume is hazardous and because we can't measure that with every surgical case, we need to be preventative. As an example, she said that when you drive a car you wear your seatbelt although it's unlikely that you'll get in an accident every time. She supported her colleagues comments that plume scavenging devices should be used whenever energy-based devices are used. She said that she supported Cal/OSHA's recognition that general ventilation does not provide adequate protection. Even 20 ACH would not prevent employee exposure to plume. She commented that the exception language that allows a single health care provider to decide not to use the evacuation equipment is problematic. She shared her experience of requesting that a device be used during a mastectomy but was told "no." The physician commented that he had tried it, found it inconvenient, and therefore just didn't use it. She commented that this individual made a decision that his convenience outweighed the health of several employees and the patient. She said it's vital that Cal/OSHA maintain the requirement that plume evacuation equipment be used every time energy-based devices are used. She further stated that it should never be up to

one individual to decide the impact on her or her colleagues' health and therefore Cal/OSHA should remove the exception language. If the exception language remains, practices will not change very much from current practices. Further, it would give surgeons a way to refuse arbitrarily to use the evacuator, whether it's inconvenient or personal. She stated that this is personal to her because this is her work environment and she deserves protection.

H. Sanchez spoke to the importance of using plume evacuators on every case. He stated that this requirement was important because the availability and use of evacuation devices is often lacking. His employer runs eight to ten operating rooms daily and up until two years ago, they only had one smoke evacuator available, used primarily for laser plume cases. Now they have five but that is not enough to cover the eight to ten rooms they run daily. He stated that if they're not using an evacuator, they're relying on wall suction and air room exchanges, but they know it's not sufficient because the secretaries sitting about 200-300 feet away behind three sets of closed doors can smell the smoke from the operating rooms. He added that it is not a local phenomenon. This is spreading to other employees for whom exposure to the risk is not required. He said that they believe plume scavenging systems must be used every time an energy-based device is in use with no exception. Therefore, they would like the exception language removed.

P. Smalley also spoke in support of removing the exception for the reason that one person should not be allowed to put others in an at-risk environment. She would like to point out that in her 35 years of experience working with smoke evacuation equipment – when they used shop vacuums and charcoal from the fish stores to get rid of the smoke because it didn't smell very good, long before they knew it was hazardous - there has been no evidence of any impact on patient safety or the completion of a medical procedure. It is often one person's opinion, one person's decision, based on what is frequently referred to as "unexplained emotional response." She stated she would be happy to hear if there is a reason why this would impact patient safety, but she doesn't know what that would be. She commented that the exception almost defeats the purpose of document. Allowing one person to make the decision that they don't want to use the equipment would be going back to the beginning and the requirement would become ineffective. She also added that under (d)(1)(B), 20 ACH may or may not be suitable for operating rooms, but these energy-based devices are used in many settings outside of operating rooms including clinics and other areas where there are no requirements for that type of air exchange and this language doesn't address that. Finally, she stated that the trigger for items (d)(2), (3), and (4) is when visible plume is present. Since plume is not always visible, omitting that from the document needs to be considered. Wherever surgical plume is being generated by the use of an energy-based device is a lot more appropriate as it will take into account all the types of plume that may or may not be present.

C. Kirkham asked for input on feasibility and cost of controls, or putting procedures in writing.

Mary Ogg, AORN, stated that concerning HVAC settings, her organization's (Association of Perioperative Registered Nurses) guidelines agree with the ASHRAE/ASHE guidelines that say you should have 20 ACH in the operating room but the HVAC system should be set to the standard it was designed for at the time. This should address the earlier speaker's comments about older hospitals with older HVAC systems that might not be able to reach that standard. She commented that bloodborne pathogen exposure is in their guidelines and they consider any used tubing and filters of these devices a bloodborne pathogen hazard that should be disposed of according to standard precautions. Concerning risk and hazard assessment, she urged everyone to go to their guidelines; the first recommendation is that you do a risk assessment and a hazard assessment. She further commented that any amount of smoke is not acceptable. Referring to other speakers comparing surgical smoke to cigarette smoke, she remarked that a study published in the British Medical Journal earlier this year found that people who smoked only one or two cigarettes a day still had 50% of the chance of cardiovascular disease of people who smoked a whole pack. She added that this tells us that even a small amount of smoke is bad. Finally, she stated that the determination should not be made on how much smoke is there; all smoke should be evacuated.

D. Parker expressed concern about the enforceability of the exception. As written, it would require that Cal/OSHA have a medical expert to testify on the standard of care in order to enforce a violation because it is left up to the medical provider to make the call. It's not feasible or enforceable. Concerning ventilation, he stated that he would like Cal/OSHA to consider carefully the interplay between 5143 and the air exchange language to make sure that the air exchange language is not a safe harbor that would allow an employer not to be responsible for complying with 5143. There could also be other unintended consequences with respect to airflow. He said he did not feel qualified to speak to these consequences, but other comments have alluded to them. Finally, he stated that, as written, there would have to be an exposure before implementation of administrative controls would be required, so that needs to be changed. Further, he stated that he concurred with others that the trigger being visible plume making contact with the eyes or respiratory tract is not consistent with health and safety principles. The risk needs to be eliminated.

S. Derman stated that the California Department of Public Health, the administrative agency for healthcare facilities, has adopted the current ASHRAE 170 code, which says 20 ACH. That would take into consideration the notation in (1)(A) with regard to how the building and HVAC systems are maintained. He commented that the administrative control section needed

clarification to more specifically discuss whatever types of administrative controls are adopted. Related to respiratory protection, he said that we know that surgical masks are not necessarily providing any type of protection from particulates or chemical vapors. So if Cal/OSHA wants to state, and he specified that he was not telling Cal/OSHA to do so, that at a minimum N-95s were going to be used, or under what conditions they should be used, then that should be explicitly described.

G. Blanchard-Saiger commented that the expectation that whenever there is plume there will be a plume scavenging system is a concern to the extent that it was the intent of the language. There should be hazard assessment to determine the appropriate engineering, administrative, or respiratory controls; there needs to be a match between the risk and the controls. She agrees that the exception doesn't work. They are concerned about what would happen in the operating room if people don't agree; it's not good for patient care or harmonious relationships in the operating room. However, it is important to continue to recognize patient safety. She stated that she thinks that was what Cal/OSHA was trying to get to. She added that whenever we talk about healthcare, hospitals, and healthcare workers, we are talking about patient care in addition to employee safety. They care about both and they're trying to find the right balance so it's important to continue to work through the patient care considerations. Finally, she said that "the greatest extent feasible" language gives some flexibility but it also creates a challenge for compliance since it's not clear what that means. She added that we're going to have to work through those concerns. She also shared her concern about subsection (d)(1)(B) having to do with general ventilation. She stated that 20 ACH may be the current requirement but that won't work for many buildings and for settings outside the hospital environment (she noted that she had advocated that this be risk-based and not location-based) and the cost considerations to meet that requirement for any building this could potentially touch, would be pretty significant.

J. Martinelli addressed the retrofitting of HVAC systems and stated that there are additional cost considerations. A hospital that makes modifications to an existing HVAC system will then need to bring all the other spaces served by that system up to the current code so the costs will extend beyond those costs just for retrofitting that one room.

Training

A. Neidhardt next asked for comments on the training section and for any information on costs and length of time needed for training.

Ronda Mananquil, **CNA** and **AORN**, certified operating room nurse at Kaiser Permanente South San Francisco Medical Center, spoke in support of the list of required content for employer

training programs stating that it was comprehensive and contained many of the important elements. She said that many employers do not provide any training on the hazard of surgical plume. She added that it is important for employers to communicate information to employees about potential exposures and the protections the employer has put in place. Training on the employer's procedures and equipment is important so that employees understand how it works and how to know when it's not working effectively. She thinks it would be important for Cal/OSHA to add another element to the required training topics. She commented that her colleagues had already described the importance of adding a requirement that employers keep records of all employee exposures. It is important that Cal/OSHA add a requirement that training include an explanation of why reporting exposures and symptoms of exposure is important.

Lystia Villanueva, SEIU, described that when she started as a surgical nurse 23 years ago she did not receive any warning or advice on the hazards of surgical plume from the unit's nurse educator, the nurse manager, or fellow nurses. There were no policies, procedures, or education in those days and there is still very little to none today. She first realized the danger a few years after becoming an OR nurse when OR coworkers were forced to leave work due to respiratory illnesses or to retire early. She also described her current experience and stated that the evacuators used in her facility do not work or the surgeons do not want to use them. She added that surgical plume could remain suspended in the room for an extended period even after the surgeon has stopped using the electrosurgical device. She can't stand the smell of the smoke anymore and, as a circulating nurse, can step out of the room but her coworkers cannot. After many years of exposure, she has developed an extremely sensitive airway and respiratory irritation and has become sensitive to scented candles, personal care products, etc. She said she prides herself on her healthy lifestyle but every day she goes to work and is in the OR with an electrosurgical device she's smoking more than six unfiltered cigarettes per 1 gram of cauterized tissue. She stated that had she known that she would be putting her life at risk 23 years ago when she started as an OR nurse, she would have chosen a different path. She asked that Cal/OSHA implement the hierarchy of controls, and set standards, policies, and procedures in creating a smoke-free environment for all those that work in the surgical suite and most importantly mandatory training for all health care workers on the health hazards of surgical plume, how it's created, and how it can be eliminated or minimized, including the proper use of plume scavenging systems.

T. Moreno reported that the two facilities that he has worked at have never provided him with any training on surgical plume and he only recently learned that it is a hazard. He said that employers should be required to communicate with employees about the hazards of surgical plume. He further remarked that annual training on surgical plume is important because it

helps him understand the plans and equipment his employer has provided to prevent exposure. He/they support Cal/OSHA's annual training requirement. In addition, he believes that additional training should be provided when something changes and the employer needs to update the plan. This would ensure that employees are up-to-date.

H. Sanchez addressed training requirements. He reported that in his 33 years at Arrowhead he had not received a single day of training regarding smoke plume and its hazards. The only reason he knows about the hazards of surgical plume is that he chose to educate himself. He remarked that it's not right to hire people, expose them to a hazardous material, and never provide them with the education or training that something is hazardous to their health. He added that the education should be in person, should take place regularly, whenever changes occur, whenever a new device is introduced, new procedures are implemented, when there's a change in the technology or in the physical exposures to the employee. He remarked that, for example, they have to be fitted every year for an N-95 mask. If someone gains ten pounds or grows a beard, they shouldn't be wearing their same mask. Those same conditions should apply to this. He believes that employees should be able to request and receive additional training. For example, if technology has evolved and no one has addressed it then that additional training should be provided on demand.

G. Batiste commented that there should be annual, in-person training. Their training systems are all online now so they do not get the one-on-one education that they should. She added that with online training, you have to call a number to ask a question and if the person is not available when you call, or it's after hours, you have to wait until the next day or whenever they're available to get an answer. She also commented that her risk could extend beyond eight hours to 12, 14 or 16 hours depending on the days she's on call. Further, she circulates in the OR. She can be exposed at the field but also at the desk in the OR depending on where the particulate falls. It is a health hazard that must be addressed but someone who has never been in the operating room will never know that and would be surprised at the exposures they have, not just the smoke but the bloodborne pathogens. She remarked that their health and safety needed to be addressed as well as their patients. She wanted to make sure that Cal/OSHA understood that the training must be in person because employers will put it online. Online training does not work.

D. Parker commented that, as written, training is required for all employees that have occupational exposure to surgical plume. He was concerned that may not cover employees that perform duties under (e)(5) in maintaining engineering controls, for example. He wanted to make sure that this is written so that anyone who is potentially exposed to contaminants is receiving proper training about handling them. He said that there needed to be a substantive

requirement that the engineering controls and equipment are maintained properly. He suggested as potentially appropriate language, “Maintained in accordance with manufacturer’s specifications,” but that should be looked at more closely. Finally he commented that not only is that a guidepost for proper training, but air filtration systems are only as good as the maintenance performed on them and can be harmful in many cases if not maintained properly.

M. Mendoza wanted to add to the comments made by Ms. Batiste, specifically, that this be paid training during working hours. He would also like to see something in the standard that requires verification of competency and documentation that team members understand the hazards of surgical plume, evacuation methods, and proper equipment usage and disposal of used tubing and filters. He added that there should be additional language that mirrors AORN guidelines on surgical smoke safety, which is in the AORN document on page 487.

N. Montoya said that she would also like to advocate for in-person training. She commented that it is not enough to require an opportunity for interactive questions and answers, which simply results in emailed questions and answers. She added that in-person training is important because workers can hear questions that co-workers ask, which can trigger other questions. Further, you can learn from your co-workers’ experiences. Finally, employees should also be able to request additional training when they need it. With new equipment and new practices some employees may want, and need, more training.

G. Paterson pointed out that in the training section (e)(7) it says “an opportunity for interactive questions.” She commented that as others who spoke previously had emphasized, it shouldn’t be an *opportunity*. It should mandatory that it is in person. A lot of their training is online now and many times they do not have anyone available to answer questions. She expressed concern about new employees and staff that may not feel empowered to ask questions. She added that all personnel who actually touch the equipment should have training because their environmental services and housekeeping staff don’t always understand the alerts that pop up on some of these devices. She’s had to explain that they might want to have someone come to look at the device because it said the filter needed to be changed and they didn’t know whom to contact about that. She remarked that when you talk about maintenance, it’s not just about OR staff; it needs to include any staff that either touches or maintains the actual equipment.

K. Hughes returned to subsection (c), written procedures. She said that she would be using the word “program” because they find the word “procedures” in “written procedures” problematic. She commented that part of review of the program should include an assessment of compliance, the barriers to compliance, and solutions to those barriers. She added that a requirement that the individual responsible for the written program be identified was missing

from the draft. In reference to personal protective equipment, when you're talking about N-95s, Cal/OSHA could also look into other more protective NIOSH-approved respirators. She wanted to reiterate SEIU's stance that the employee and their representative(s) should be a part of all the phases – hazard assessment, developing or writing a program, reviewing that program, and training. She remarked that real employee involvement is needed. Nobody knows better than the people who work in the OR what is going on and what is needed there.

A. Neihardt reminded attendees that Cal/OSHA is looking for information on length and cost of possible training.

Sam Rowan, Stryker, said in response to A. Neidhardt's request that Stryker offers free courses available to the hospital facility. They're accredited by ACCME and give nurses CEUs. He proposed an amendment to subsection (e) that instead of "employees" use "all healthcare personnel" because, as has been detailed previously, physicians are not always employees of the facility and it's important that they're receiving the same training that the nurses are getting.

A. Neihardt asked whether the Stryker training he referred to was in-person training.

S. Rowan responded that they can lead those trainings in person. He believes they're also available online through ACCME but most of the time they're done in person.

G. Delizo asked whether Stryker would be willing to share their information on the cost of their equipment and explained the need for this information to complete the required economic impact statements. Cal/OSHA has to estimate the cost of equipment.

S. Rowan responded that cost depended on the facility and what the policy said as well. He added that the verbiage saying, "the greatest extent capable" varied by facility depending on the cases they're doing. For some facilities, for capital costs, they already have the equipment in there. Stryker's surgical suction machines, called the Neptune machine, already have surgical smoke evacuation built into them so it would just be a matter of pushing a button on the screen to turn it on to be used in conjunction with a Bovie smoke pen.

W. Nguyen asked if Cal/OSHA could follow up with him at later time with questions about costs and S. Rowan said absolutely.

Rachel Karolski, Buffalo Filters, said that Buffalo Filters offers free CE education. They do in-person training at the facility and usually stay and offer training through the day. If not, they

also offer online training. The companies continually educate on their products. She added that not all nurses are there all the time, for example, some nurses work per diem, so you can't catch everybody but you do make yourself available to provide the education. She added, concerning products, every facility is different and it depends on whether they're on contract and the costs varies by procedure. She offered to provide additional cost information if Cal/OSHA wanted that.

C. Kirkham asked if R. Karolski would be able to share their training curriculum and set of materials.

R. Karolski responded that they worked with AORN on the Pfiedler continuing education available on line. She added that they just expand on that in their in-person training. They are required to do the set continuing education where you're following the exact program in the booklet so that they can get their full CE contact hours. As far as further education, they do in-services on the product. As far as further education on the hazards, they provide the articles, the research out there. The in-services come along with the continuing education on products but they can't talk products until after the continuing education. She offered to give Cal/OSHA a training booklet.

S. Derman said he wanted to reiterate that many of the training components, as well as the programmatic and administrative types of items, should already be covered as part of employer's injury and illness prevention program. If they don't have those, that would be specific, for example to the OR, there's a violation, or series of violations, which is citable. He added that if people are trained and they don't get it, or don't do anything, there's a potential violation because the training was inadequate since people weren't doing what they were supposed to be.

D. Glover said that as the professional association for all perioperative nurses, AORN provides training on surgical smoke, which includes everything from a gap analysis to webinars, to in-person conversations. She added that one of the things they do is training the trainers so, not only does AORN have the online program you can follow, there's often a person appointed by the facility that can be the lead. AORN works with them to make sure that they are trained so they can go on to train other employees if there's the need for in-person training. She added that Pfiedler is an organization that works with all the different vendors. Many different industry members work with them to create their own training programs so that is an option for the industry to train within those ORs. She remarked that AORN's program is not affiliated with any industry members.

A. Neidhardt asked how long the AORN program lasted.

D. Glover responded that it varied. Their program called "Go Clear," to help people go smoke-free, has a minimum of 90 days to go through the entire process but that's not just the training. It includes an evaluation in the OR of the surgical smoke that is being produced and the type of products they might need, so it's not just an hour-long or weeklong training. She said that she would be happy to provide Cal/OSHA access to all their training materials including their competency verification tool that is for both RNs and non-RNs. She agrees with others that it's important for everyone to be educated on the hazards of surgical smoke and prevention techniques, etc. She added that there might need to be slightly different training programs for people depending on their jobs, but specifically the people in the OR that are handling the smoke evacuators during those procedures.

R. Mananquil wanted to address the issue of cost and reported that in her hospital they have three different kinds of smoke evacuators. They have eight of them but only a few surgeons use them. So, it's just a matter of implementing those measures because the equipment is already there.

P. Smalley shared that the International Council on Surgical Plume (ICSP) also provides education and continual oversight programs. They help hospitals through consulting, telephone calls and onsite work to develop and monitor their programs. She is happy to provide Cal/OSHA with a brochure. She commented that the length of training has to do with who the audience is and how many staff need training. She added that ICSP believes in doing all training in person because they want to be able to assess whether there are questions, whether people understand the material, and to provide additional resources. Members have access on their website to a comprehensive library of resources – all the standards, all the white papers, all the position statements from all over the world as well as the current literature. She added that AORN is a member and all the manufacturers in the industry are supporting members of the organization so they have access to all the companies, which allows a bit of market objectivity. They would never recommend a particular company, but first do a risk assessment based a lot on the Canadian standards for how to conduct a good risk assessment for this particular subject. She said that was another resource available to Cal/OSHA and would be happy to provide any information along those lines.

L. Wilson described a recent 30-minute work training she had in which they learned how to hook up the Buffalo filters to the smoke evacuator. She commented that the training was in-depth but they were trained only because they were going to trial the equipment for a week to see if the doctors liked it. She added that if the doctors didn't like it, it "went away," and you'd

trained all the OR nurses. That's why it should be mandated for every room. She said it shouldn't depend on whether the doctors like it or it's inconvenient. She believes training the nurses and doctors would not be a big issue. The issue is making them have to use it.

G. Patterson commented that no physicians had spoken at the meeting and her concern is that some of the usage of the smoke evacuation devices is physician-driven, which is a problem because this is about safety for everyone, not just their comfort level. She added that regarding training, there are times that physicians get out of training because they don't think it's important for them or they figure they don't use the device, "like plug it in." She thinks they need to have some training on the importance of smoke plume and she hoped that Cal/OSHA would add that; it's not just nursing staff or OR staff, it's medical staff because sometimes they get pushback. Because they don't have as much understanding of safety concerns their priorities are elsewhere as far as their surgeries are concerned. She added that if it's seen as an inconvenience and they don't have a true understanding of the safety issues they will give them more pushback and impede compliance.

Recordkeeping

G. Delizo introduced subsection (f) Recordkeeping. Subsection (f)(1) requires that training records be maintained in accordance with section 3203, injury and illness prevention program. Subsection (f)(2) requires that records of testing of plume scavenging systems be maintained in accordance with section 5143. Subsection (f)(3) requires the written operating procedures required by subsection (c) be available to affected employees and their representatives at the worksite at all times. She then asked for comments on any of the record keeping requirements.

L. Gigliotti said that she strongly agreed with the requirement that employees and their representatives should be able to access the employer's written plan on surgical plume at all times at the worksite. She commented that they needed to be able to reference their employer's procedures to ensure that they are sufficiently protected from the harmful effects of surgical plume. Because work practices change, new devices are purchased, or new procedures are introduced they need to be able to see their employer's most up-to-date plan on surgical plume. She added that the requirement that plans be reviewed annually should also be supported by a requirement that records be kept of the name of the person conducting the review, the dates the review occurred, the names and work areas of the employees involved in the review, a summary of conclusions, and a plan for correcting any identified issues. Plan review should also include a review of all exposure records and identified employee symptoms. She added that with these additions the written plan would ensure that the employers implement protections adequately and consistently. She remarked that employers should make all these records available to employees and their representatives because as employees they

need to be able to see that their employer is doing what they're supposed to in order to protect them. She further added that they needed to be able to request exposure records to document their exposures and ensure that the employer is updating the plan to prevent future exposures. She commented that hospital management would pretend that problems didn't exist, perhaps because it's so expensive to change to training, purchase equipment, or it could also be that they don't know how to address and correct the problems. She added that management listens to OSHA and you should see them scramble when OSHA is on the floor. She finished by saying that if Cal/OSHA tells them what is expected, they will comply because "nobody messes around with OSHA."

Brenda Horsley read H. Sanchez's statement because Mr. Sanchez had to leave. In his statement, H. Sanchez reported that he had recently learned of a coworker's lung cancer diagnosis. He had no risk factors other than being in the OR for 15 years exposed to surgical plume nearly every day. His coworker has no idea the extent of his exposure to surgical plume since no one keeps exposure records. He added that had he been required to keep a record of his exposures, including every time they did not use an evacuation system at the site of origin, perhaps he would have a better understanding of his exposure. Exposure records could also include the type of energy-based device used, the type of procedure being performed, the length of time the employee was exposed, any symptoms experienced by the employee, and an explanation of why the plume scavenging system was not in use or effectively capturing all surgical plume. All this information is necessary for establishing an employee's exposure history for work-relatedness of future health conditions. His statement also strongly supported the requirement that the employer's written procedures be available to the affected employees and their representatives at the worksite at all times. It is important that employees be able to reference the written plan and be able to determine whether the plan is being followed.

P. Smalley wanted to clarify that there are two types of exposure records when talking about surgical plume. One is the employer record where the administrator/employer documents what has happened to the employee. She added that one of the things they have found that has been very successful in helping to track exposures is similar to what they used to call a communications log – a book basically that's kept in each OR. When a nurse or a technician in an OR begins to experience unanticipated symptoms – someone who is not ill when they came to work and had no symptoms, such as headache, runny eyes, at the start begins to experience these symptoms during a case – they can open the book and jot that down. ICSP has 10 different items on a suggested exposure record that they have been distributing to all the hospitals they work with. The items include: which room were you working in, what type of procedure was going on, what energy-based device was in use, how long was your exposure, during the case when did your symptoms become noticeable, did your symptoms affect your

productivity, for example, if a nurse is coughing and can't control it and someone has to come to take her place, did the symptoms resolve when you left the room or did you still feel like you were coming down with the flu, who did you report that to, was it health and safety, your manager, or no one at all, what LEV was in place, and if there was none, what was the reason, if you did not report your symptoms to anyone, why not. This internal tracking tool that can be reviewed over time to look for a relationship between symptomatic employees and the specific room, type of procedure, a particular surgeon's techniques, or whatever. Those variables can then be prioritized for eliminating or mitigating the hazard in that room. It's part of an ongoing risk assessment that is non-threatening for the staff – they're happy to do that, they can discuss that in a huddle or in their turnover time where they have internal discussions and it doesn't become something that can be used against them rather than something that helps people identify what is actually going on in real time in the rooms. She added that this is a different type of exposure log than what had been discussed and wanted to bring it to Cal/OSHA's attention.

K. Hughes stated that there should be language related to how to communicate and report concerns without fear of retaliation. She said they loved the idea of exposure records. They are also looking at procedures for reporting symptoms of exposure, who to report that to without fear of retaliation. This should include some kind of medical surveillance so that you're looking at long-term effects. For example, if you don't have a risk factor for lung cancer and you develop lung cancer that's a problem. She added that in health care they don't have any assumed health risks, unlike firefighters for whom certain cancers are assumed to be work-related. She reported that SEIU had tried to introduce legislation related to assumed work-relatedness of HIV infection for health care workers. Medical surveillance might help with that. An employee could walk out of the room and feel better but there could be long-term effects that wouldn't be apparent until much later. She commented that if we don't have data for that it's because no one has been tracking it. They have never correlated that the OR nurse didn't smoke for 30 years but they worked in the OR for 30 years and that's why they got lung cancer. That's tragic and it's wrong. She concluded that's why we're here, to prevent that kind of thing.

N. Montoya commented that her institution has Neptunes and have the smoke evacuator equipment available, the tubing costs $9.12 but they rarely use it. That's what their costs would be because they already have the equipment.

G. Paterson suggested adding to existing electronic health records whether evacuation devices were used. They already document use of certain AESUs and use of lasers. She added that her institution has rigorous electronic recordkeeping and if workers have health issues they could

use those records to track the cases to see what they've been exposed to over a period of time. Whether the LEV has been activated could be added to the record.

Appendix A

G. Delizo described Appendix A – AORN guidelines, Canadian guidelines, and the ISO standard referenced by CNA in their petition. She then asked that participants bring to Cal/OSHA's attention any elements not identified in the discussion draft or already raised at the meeting.

M. Harris suggested that it would be helpful to have a set of basic design requirements for the local exhaust ventilation added to the appendix. There are many different brands of local exhaust systems for devices that generate plume but with no existing regulation, he's sure they're built to different specifications. He commented that it would be good to have one set of specifications as a design minimum to make sure that the LEV systems they have are effective.

G. Paterson asked the meaning of "special hospitals" referred to in the scope.

Patricia Coyle, Cal/OSHA, responded that they are a special category of hospitals that are either dental hospitals or maternity hospitals. Currently there are no licensed special hospitals in California.

G. Paterson asked whether freestanding surgical centers were covered by the Scope.

E. Berg responded that freestanding surgical centers were not covered by the discussion draft as written.

G. Paterson said that Cal/OSHA needed to add them because that is the wave of the future. They're doing a lot of same-day surgeries, for example, knee arthroscopies, hernia and cataract surgeries. She added that the model of having your surgery done at an acute care hospital is drastically changing. Surgical plume is generated in orthopedic surgery but the move is to do more orthopedic surgeries, including total hip replacements, in surgical centers rather than acute care hospitals. Surgical centers definitely need to be dealt with.

E. Berg responded that the Rhode Island law included ambulatory surgical centers.

G. Paterson said that, depending on your institution, many things are being done in a clinic setting. She added that "all your little lumps and bumps" are handled in a clinic where you're getting a local anesthetic not in an OR. Cautery may be used there as well. She reiterated that this is the wave of the future to have fewer procedures done in acute care hospital settings. In

response to a question from A. Neidhardt, she responded that a surgical center may be at the same footprint as the hospital but it's in a separate setting, it's not inside the hospital, but rather in a separate center.

C. Kirkham asked whether these facilities were licensed as surgery centers.

G. Paterson responded that she did not know how surgical centers were licensed. Some are affiliated with hospitals and some are freestanding. Plastic surgeries, including facelifts, may be done in settings outside the hospital. She added that the days of having everything done at an acute care hospital have passed.

S. Derman wanted to clarify the licensing of surgery centers. He said that technically the license is for an ambulatory surgical center, or ASC for short. Sometimes they're known as outpatient surgery centers. He added that they do have separate licenses typically and the accreditation requirements are different but as far as ventilation is concerned there is in some cases a similar type of ventilation requirement for those facilities and their operating rooms.

D. Glover also wanted to clarify that ambulatory surgical centers are sometimes known as surgery centers. And then there are outpatient facilities often associated with a hospital and can be located on the same campus. The California Department of Health licenses those ASCs but there are also surgery centers owned solely by MDs; those are regulated by the Medical Board of California.

G. Blanchard-Saiger commented that this was illuminating the point she was making earlier about regulating location vs. regulating the risk or the procedure. She mentioned the variety of settings in which surgical procedures might occur - licensed surgery centers, medical offices that might be licensed by the Medical Board, the dentist office. Some settings are licensed and some are not licensed. She will provide written comments with more detail but that was the point she was making at the outset about focusing on general acute care hospitals.

Feasibility, cost and additional issues to consider

C. Kirkham introduced the next agenda item, feasibility and cost, and asked attendees for any additional information. He mentioned that participants had commented that some of these local exhaust systems already exist and asked if there was any more information on that related to cost, or if they were aware of any studies that have been done.

G. Blanchard-Saiger said that costs could vary dramatically depending on the location, for example a physician's office compared to an acute care hospital. Talking about acute care

hospitals, they have equipment now but if Cal/OSHA requires something else, like 20 air exchanges, and they're not meeting that part of the regulation, that's a whole HVAC issue. She commented that, as mentioned by a previous speaker, it's not just the HVAC; you'd be touching every part of the hospital that's served by that system. She commented that it would be hard to quantify this. She added that she might have a follow-up conversation with Cal/OSHA about what additional guidance Cal/OSHA could provide those in the room about what Cal/OSHA is looking for. She remarked that she couldn't say for a hospital it would cost X amount, because it depends on a whole host of factors. In addition, for medical office buildings, it would be another issue because they probably don't have equipment and whatever their HVAC needs are. She finished by saying it was complicated and they might need a follow up conversation about the most efficient way to do a monumental task.

C. Kirkham said risk assessments had been mentioned and asked if anyone had examples of risk assessments had been conducted or written policies on the use of surgical plume control systems.

P. Smalley said that they could provide Cal/OSHA two examples. One she believes Cal/OSHA already has in the Canadian standard. She submitted another example, from New South Wales in Australia, to Cal/OSHA, but it was probably too late to have gotten in for the meeting. The document was published by Worksafe, which is part of administrative health there, so it's a legal document that applies to all the hospitals in New South Wales. She remarked that they have a clinically relevant, easy-to-follow, system for risk assessment for plume and technology assessment, which is the other piece that is usually not addressed. Instead of a situation in which a vendor comes in and the hospital buys everything the vendor has because they need equipment but haven't assessed what they need, there are many ways to obtain equipment. A number of companies will give the hospitals the hardware, the actual smoke evacuators systems, on disposable contracts so there are many ways to get equipment in without a big outlay for capital costs. There are variables beyond what type of cases you're doing, what sort of approach, and what vendor. However, the basis for the risk assessment is already available. She added that she would leave Cal/OSHA a copy.

Recap, next steps and adjourn

C. Kirkham asked for any other comments on cost or feasibility. No further comments were offered. He reiterated that Cal/OSHA is at the beginning of the process, the pre-rulemaking phase. He asked attendees to submit written comments to RS@dir.ca.gov subject line "Surgical Plume Comments" by January 15, 2019 or earlier. He assured attendees that Cal/OSHA would consider all comments. He said that the rulemaking process is lengthy and depends on a number of factors, including the number of times Cal/OSHA posts a revised discussion draft and

solicits comments. He added it was not possible at this point to say how many times Cal/OSHA might do that, but it is possible that Cal/OSHA would revise the draft for further comment. In addition, Cal/OSHA may or may not hold another advisory meeting. Cal/OSHA will keep people posted on these events by emailing those on the sign-in sheet. He also recommended that attendees pay attention to the Cal/OSHA website where Cal/OSHA will publish information on the rulemaking process. If Cal/OSHA goes into formal rulemaking, there will be additional opportunities to make verbal and written comments that Cal/OSHA would respond to. The minutes from this meeting will be publically available on the Cal/OSHA website and Cal/OSHA will notify attendees who signed in when they're ready. He added that it would likely be a couple of months before Cal/OSHA posts the minutes. He thanked participants for coming and said that Cal/OSHA valued their input and hoped that they would stay engaged in the advisory process.