

MEETING RECORD

Cal/OSHA Glutaraldehyde Advisory Meeting

Thursday October 14, 2004
1515 Clay Street
Oakland, CA

Attendees

Karen Jenkins, injured worker
Denise Senior, SEIU Local 250
Barry Foose, Kaiser Permanente
Joe Ascenzi, Advanced Sterilization Products
Kathy Krol, Center for Endoscopy
Rich Shumway, Edwards Lifescience
John Mehring, SEIU
Dan Leacox, Livingston & Mattesich
Stephen Derman, MediShare
Erica Stewart, Kaiser Permanente
Mitch Cohen, Kaiser Permanente
Deepak Plaha, Medtronic
Tom Tremble, Advanced Medical Device Association
Dennis Shoji, Edwards Lifesciences
Cheryl Christenson, Edwards Lifesciences
Janice Prudhomme, California Department of Health Services
Judi Freyman, ORC Worldwide
Liz Brott, Kaiser Permanente
Paul Brownson, Dow Chemical
Pam Spencer, Dow Chemical
Greg Gorden, Technology Sciences Group
Artie Lawyer, Technology Sciences Group
Roger Richter, California Healthcare Association
Julia Klees, BASF
Susan Ripple, DOW Chemical

Steve Smith, DOSH, meeting chair
Bob Barish, DOSH
Tom Mithchell, Cal/OSHA Standards Board

MINUTES

The meeting was opened by Steve Smith, Supervising Industrial Hygienist, DOSH. Steve gave a brief update on progress since the last meeting in May with respect to developing language for a footnote to supplement whatever PEL was agreed to. Steve noted his understanding that industry representatives felt that a PEL of 0.05 ppm ceiling limit was reachable, but not without some concerns that might be addressed by a delayed implementation after adoption. Steve said that the meeting today would include discussion of supplemental protections such as medical monitoring, in light of the fact that the Division's PEL committee had recommended a PEL of 0.015 ppm ceiling.

Dan Leacox noted absence from the minutes of the May meeting of a comment made by Mike Cooper that differences of the magnitude of 0.015 and 0.05 were not usually considered by the Air Contaminants Advisory Committee that he had participated in.

Steve Smith briefly reviewed the history and status of the current round of PEL amendments.

Tom Tremble said that his recollection was that there was agreement at the last meeting in May for a PEL of 0.05 as a Ceiling Limit. Steve Derman agreed with Tom Tremble's recollection. Artie Lawyer agreed with Tom and Steve and said that today's meeting was intended to address supplemental elements that would compensate for the compromise from the 0.015 ppm level proposed by the Air Contaminants Advisory Committee based on health effects only. John Mehring said that SEIU would like to see the Ceiling Limit be 0.015 ppm, but in the interest of consensus SEIU could accept 0.05 ppm ceiling if it was coupled with a footnote to address communication issues associated with safe use. Steve Smith said that a possible medical monitoring element for glutaraldehyde might look like that from the federal OSHA formaldehyde standard which focuses on asthma. Artie Lawyer suggested that what was generally agreed was that a statement would be made about medical monitoring but that it would not be a new requirement. Artie Lawyer also said that recognizing the sensitizing effects of glutaraldehyde, a footnote should be included in Table AC-1 of section 5155 to address employee training and education. He suggested that this could be an interim measure until the Sensitizer Advisory Meeting (SAM) being organized by the Division developed a more comprehensive approach.

Steve Smith noted that many glutaraldehyde users already had medical monitoring programs in place and that what was proposed was not a new medical monitoring requirement but rather direction for existing programs. John Mehring said that the basis of SEIU's support for the footnote on training and education and acceptance of lowering the Ceiling Limit to 0.05 ppm rather than 0.015 ppm was that the SAM would be looking at medical monitoring requirements for sensitizers. Artie Lawyer and Mitch Cohen agreed that medical monitoring should be part of the SAM discussion.

Judi Freyman wanted to know if the SAM was a follow-on to the present meeting on glutaraldehyde, or independent, and in either case, had a charge for it been developed. Janice Prudhomme asked if the SAM would address only 5155 substances or even substances that are not chemicals. Julia Klees wanted to know what the definition of sensitization was for the purpose of the SAM. Steve noted that there are some substances in 5155 such as wood dust that are not chemicals. He noted that his vision was to limit the SAM's initial charge to substances in section 5155 and that the question of a definition of "sensitization" would be a subject of discussion at that meeting.

Returning to discussion of the education and training footnote, Steve noted that it was intended to be temporary until the SAM developed a more comprehensive approach. Artie Lawyer said that he believed

that the proposed footnote passed out by Steve did accurately reflect the results of the two sub-group meetings that had taken place. He thought that Steve’s addition of references to specific Title 8 sections was helpful.

The draft proposal for both the PEL and footnote that was passed out at the meeting read as follows:

§5155. Airborne Contaminants.

* * * *

**TABLE AC-1
PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS**

Chemical Abstracts Registry Number ^(a)	Skin ^(b)	Name ^(c)	PEL ^(d)		Ceiling ^(e)	STEL ^(f)	
			ppm ^(e)	mg/M ^{3(f)}		ppm ^(e)	mg/M ^{3(f)}
111308		Glutaraldehyde	0.2 <u>0.05</u>	0.82 <u>0.2</u>	C		

Footnotes:

* * * *

s) Glutaraldehyde can cause occupational asthma and skin sensitization responses such as contact dermatitis. Potential symptoms include shortness of breath, chest tightness, wheeze, cough, skin rash, hives, and irritation of the nose, throat, skin or eye. Hazard communication training required by sections 5191 or 5194 shall address these health hazards and symptoms along with the measures taken by the employer to evaluate and control exposures such as medical evaluations, exposure monitoring, ventilation systems, work practices, and personal protective equipment. The communication system required by section 3203 shall encourage employees to report possible symptoms and questions about the evaluation and control measures.

Paul Brownson suggested modifying the second sentence of the footnote to state that “*Exposure related symptoms may include....*” This was done. In sentence 3 Artie Lawyer suggested the phrase “*which can include*” rather than “*such as.*” This change was made. Judi Freyman suggested that sentence 4 should include reference to “*sources of information and contacts for information on evaluation and control measures.*” This suggestion led to an extended discussion. The footnote wording agreed to by those in attendance was:

s) Glutaraldehyde can cause occupational asthma and skin sensitization responses such as contact dermatitis. Exposure related symptoms may include one or more of the following: shortness of breath, chest tightness, wheeze, cough, skin rash, hives, and irritation of the nose, throat, skin or eye. Hazard communication training required by sections 5191 or 5194 shall address these health hazards and symptoms along with the measures taken by the employer to evaluate and control exposures that can include medical evaluations, exposure monitoring, ventilation systems, work practices, and personal protective equipment. The communication

system required by section 3203 shall inform employees where to report possible health symptoms and where to ask questions, report concerns, and receive information about the employer's evaluation and control measures.

Steve Derman asked if this footnote would apply only to glutaraldehyde. Steve Smith replied that it was a temporary measure specific to glutaraldehyde and that the planned SAM would take up the possibility of a more generally applicable statement. Steve Derman expressed concern that the footnote could be viewed as suggesting that other substances might be excluded from the requirements stated. Steve Smith acknowledged this as a possible concern. Steve Derman suggested that this issue should be reviewed by the Division's Legal Unit to address this concern. Steve Smith acknowledged that internally there may be a concern with this potential issue. Artie Lawyer said that applying the footnote developed for glutaraldehyde to other substances in section 5155 would be likely to result in opposition from other sources, for example those interested in isocyanates.

After lunch, Steve Smith opened the discussion of requests for an extended effective date for an amended Ceiling Limit. Steve said that the effective dates of standards and amendments are shown in the "History" notes found at the end of each Title 8 standard. Steve said that usually, and unless requested otherwise, Title 8 standards take effect 30 days after their filing with the Secretary of State in Sacramento.

Artie Lawyer proposed a footnote indicating an implementation timeframe for an amended Ceiling Limit to 0.05 ppm of 30 days or when "technically feasible" but not longer than 2 years. He noted that while a 30-day period might be feasible for some employers and operations, some operations would require extensive modifications to achieve the proposed Ceiling Limit.

Tom Tremble asked about the timeframe for promulgation of a revised Ceiling Limit. Steve Smith said that with the usual timeframes of the rulemaking process the earliest an amended standard would be likely to be adopted would be summer 2005.

Roger Richter said that with their special requirements for design review, hospitals cannot modify ventilation systems in under two years.

Steve Smith noted that a revised Ceiling Limit would not have to be initially achieved by engineering controls. He noted that Title 8 section 5141 provides that control by means of respirators is acceptable during the time necessary to install or implement feasible engineering controls. Barry Foose of Kaiser said that respirators could be problematic, especially if employees and their unions objected to their use. Deepak Plaha noted that his company continues to make modifications to their processes in order to achieve the Ceiling Limit of 0.05 ppm or less, but the use of respiratory protection in some job tasks is not an option, i.e. microscope work. Therefore, the use of respiratory protection on an interim basis would not be feasible and a 2-year implementation period would be necessary to incorporate adequate engineering controls. Mitch Cohen said that Kaiser would not be able to control all exposures to a Ceiling Limit of 0.05 ppm until 2007. Erica Stewart said that substituting ortho-phthalaldehyde (OPA) was not a good solution as it was at least a skin sensitizer. Tom Tremble said that engineering controls, not respirators, were the way that exposures should be controlled. Judi Freyman said that if a Ceiling Limit of 0.05 ppm was adopted it would be important to provide time for affected employers to come into compliance.

Dennis Shoji suggested that a requirement for a "compliance plan" coupled with the 2-year timeframe for compliance could address concerns over the longer than usual time allowed to achieve the new PEL. Steve Smith noted that Division compliance personnel already have a requirement to assess feasibility

before issuing a citation. He also noted that employers with particular difficulty achieving compliance in the time allowed could pursue a temporary variance. Artie Lawyer asked how long that process can take. Steve said that it can happen quickly as it does not go through the formal process with the Standards Board required for permanent variances. John Mehring suggested that the question of the effective date was more appropriately addressed by the Standards Board. Steve Smith said that in most cases regulatory proposals made to the Standards Board don't address the effective date. Steve said that it is an item on the Form 400 submitted along with the rulemaking package to the Office of Administrative Law, and that justification was required if a timeframe other than 30 days is requested. Artie Lawyer suggested amending the Ceiling Limit and providing a variable effective date. Judi Freyman said that if the effective date was not addressed in the proposal but only left up to the Standards Board then employers would oppose the reduction of the Ceiling Limit to 0.05 ppm.

Mitch Cohen supported the idea of requiring a "compliance plan" as an alternative to a 30-day compliance requirement.

Steve Smith suggested a possible approach for allowing the time requested for compliance while also generating immediate workplace improvement: retention for 2 years of the existing Ceiling Limit of 0.2 ppm with adoption of a PEL-TWA of 0.05 ppm which would convert to a Ceiling Limit at the end of the 2 years. There was general agreement from employer and manufacturing representatives that this approach would be acceptable and employee and union participants at the meeting did not express objection.

Steve Smith stated he would send draft language and these minutes to the members for one last review before developing the proposed rulemaking package. When the proposal is sent to the Standards Board for public hearing the members will be included in the mailing list for that process. Mr. Smith thanked the members for their attendance and working to develop a consensus proposal.

END – No attachments