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FINAL STATEMENT OF REASONS

CALIFORNIA CODE OF REGULATIONS

Title 8: Chapter 4, Subchapter 7, Article 107, Section 5155
of the General Industry Safety Orders

Airborne Contaminants

MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM THE 45-DAY PUBLIC COMMENT PERIOD

There are no modifications to the information contained in the Initial Statement of Reasons except for the following modifications that are the result of public comments and/or staff evaluation.

Based on public comment and staff recommendation, ten substances that were proposed for addition or revision were withdrawn from this proposal and the original language for those ten substances was restored. During the Occupational Safety and Health Standards Board's (Board) public meeting on December 18, 2003, Mr. Len Welsh, Acting Chief, Division of Occupational Safety and Health (Division), stated that several comments and issuance of Executive Order S-2-03 made it necessary to withdraw the following ten substances from the proposal so that additional advisory committee meetings could be conducted before considering the proposed changes in a future rulemaking notice:

acetone
beryllium and beryllium compounds
2-butoxyethanol
epichlorohydrin
glutaraldehyde
methyl methacrylate
molybdenum, soluable compounds
propylene oxide
1,3,5-triglycidyl-s-triazinetrione
vinylidene fluoride

In order to restore the original language of footnote (p), it was necessary to move the proposed footnote language for flour dust and make it a new footnote (s). This modification is a nonsubstantive editorial change.

Summary and Response to Oral and Written Comments:

I. Written Comments

Mr. Marc Kolanz, Vice President, Environmental Health and Safety, Brush Wellman Inc., by letter dated December 10, 2003.

Comment:
Mr. Kolanz asked that the following points be considered regarding the proposed change to the exposure limit for beryllium:

- Due to changes in medical technology, the definition of chronic beryllium disease (CBD) changed in the late 1980s to include sub-clinical CBD (persons having no clinical symptoms or measurable impairment). Sub-clinical CBD is not a material impairment of health or functional capacity as required under Labor Code Section 144.6 and therefore should not constitute a basis for a proposed rule change.
- The use of beryllium sensitization as a health end-point for the proposed change to the beryllium permissible exposure limit (PEL) is inappropriate because beryllium sensitization is not a health effect. Since beryllium sensitization is not a health effect, it is also not a material impairment of health or functional capacity and is therefore contrary to Labor Code Section 144.6.
- The data from studies identified in the Initial Statement of Reasons do not appropriately support the proposed change to the PEL.
- Brush Wellman finds unsupportable the Initial Statement of Reasons position that the cost to comply with a new beryllium PEL is estimated to be insignificant to none. Brush Wellman has found no written analysis of the proposed beryllium PEL to evaluate its impact on the State of California. Such analysis is required to be provided to the Board by the Division of Occupational Safety and Health in sufficient time for the Board to conduct hearings and adopt standards as required under Labor Code Section 147.1.

Mr. Kolanz concluded that Cal-OSHA's use of beryllium sensitization or sub-clinical CBD as a health basis for a proposed change in the beryllium PEL is contrary to Labor Code Section 144.6, which requires material impairment of health or functional capacity. Also, the studies identified in the Initial Statement of Reasons do not support the proposed change to the PEL. In addition, the cost of complying with the proposed beryllium PEL is significant, which is contrary to the Initial Statement of Reasons. In light of the above concerns, and the fact that the proposed PEL is not based on any consensus standard, Brush Wellman recommends the Board consider remanding Cal-OSHA's proposed beryllium PEL until U.S. OSHA has completed its detailed review of beryllium exposure health effects. Remanding the standard may avoid creating a double standard between Cal-OSHA and U.S. OSHA, which could prove to be a competitive disadvantage for industries in the State of California.

Response:
As recommended by Mr. Welsh at the December 18 2003, public meeting the Board has withdrawn the proposed change for the exposure limit for beryllium. The Division held a public

advisory meeting on March 30, 2004. Mr. Kolanz attended the meeting and provided the Division with additional information regarding the health effects of beryllium exposure.

The Board thanks Mr. Kolanz for his comments and ongoing participation in the advisory process.

Mr. Thomas Tremble, Director, Government and Regional Affairs, Advanced Medical Technology Association, by letter dated December 8, 2003.

Comment:
Mr. Tremble states that the Advanced Medical Technology Association (AdvaMed) wants to convey its concerns with the proposed reduction in the PEL for glutaraldehyde from 0.2 PPM to 0.015 PPM. They believe the matter deserves further investigation to determine the feasibility, costs and benefits of changing the current exposure limit to an appropriate level based on scientific evidence. Healthcare providers rely on glutaraldehyde to sterilize numerous medical devices, primarily those used in operating rooms such as endoscopic instruments and other surgical tools. In addition, glutaraldehyde is an integral solution in the manufacturing of implantable medical devices such as tissue heart valves. AdvaMed strongly supports measures to ensure the safety of workers who are exposed to glutaraldehyde. However, they are concerned that the feasibility and economic impact of this proposed standard were not adequately considered. Medical technology manufacturers have significant reservations about their ability to meet the new level, which could involve extensive and expensive alterations to manufacturing processes and severely disrupt operations. In addition, changes in existing operations could trigger a detailed review by the U.S. Food and Drug Administration prior to implementation. Imposing significant changes to the manufacturing process has the potential to negatively impact patient care, as well as jobs.

Response:
As recommended by Mr. Welsh at the December 18 2003, public meeting the Board has withdrawn the proposed change for the exposure limit for glutaraldehyde. The Division held public advisory meetings on February 10, 2004, and May 4, 2004, to discuss the exposure limit for gluaraldehyde. Mr. Tremble attended both meetings and along with many other participants provided the Division with their views on the health effects of exposure and potential impact of changes to the current exposure limit.

The Board thanks Mr. Tremble for his comments and ongoing participation in the advisory process.

Ms. Courtney Price, Vice President, CHEMSTAR, American Chemistry Council, by letter dated December 9, 2003.

Comment:
Ms. Price, representing the American Chemistry Council's Glycol Ethers Panel, urges the Board to follow national and international precedent and lower the permissible exposure limit (PEL) for 2-butoxyethanol from 25 ppm to 20 ppm but not to 10 ppm. The available database on 2-

butoxyethanol has recently been reviewed by the American Conference of Governmental Industrial Hygienists (ACGIH) in this country and by many nations abroad. The consensus is that an exposure limit of 20-25 ppm is appropriate. The Panel urges the Board to follow the international consensus and set a 20-ppm PEL for 2-butoxyethanol. There has not been, as far as they know, any attempt by the Board to assess what impact such lower standards --lower than have been established elsewhere in the United States and abroad -- might have on California businesses. No lower standard should be established without such an investigation.

Response:
As recommended by Mr. Welsh at the December 18 2003, public meeting the Board has withdrawn the proposed change for the exposure limit for 2-butoxyethanol. The Division held a public advisory meeting on March 30, 2004, and Dr. Richard Corley, representing the American Chemistry Council's Glycol Ethers Panel was in attendance.

The Board thanks Ms. Price for her comments and the ongoing participation of her organization in the advisory process.

Ms. Elissa Pekrul, Chair, Metallized BeO Working Group, Vacuum Electron Device Manufacturers Consortium, by letter dated December 12, 2003.

Comment:
Ms. Pekrul states that as representatives of California-based manufacturers of vacuum electron devices, they would like to present their concerns regarding the proposed revision to the permissible exposure limits for beryllium and beryllium compounds in the General Industry Safety Orders, Chapter 4, Subchapter 7, Article 107, Section 5155, Airborne Contaminants. They fully support personnel protection to prevent chronic beryllium disease (CBD), though they have not seen evidence that the Board's recommended revision will be an improvement over the currently accepted levels. However, they respectfully disagree with the Board's initial assessment on cost or business impact. The group's primary focus over the last eleven months has been to improve the national capability to supply metallized beryllium oxide ceramics for use in vacuum electron devices for both civilian and military purposes. Many of these suppliers are small businesses and many reside in California. Based on discussions with these suppliers, there will be a significant cost impact associated with additional monitoring and compliance should the proposed revision be adopted. Rising costs to California-based suppliers will result in piece-part prices that may force the industry to change to alternate sources.

Response:
As recommended by Mr. Welsh at the December 18 2003, public meeting the Board has withdrawn the proposed change for the exposure limit for beryllium. The Division held a public advisory meeting on March 30, 2004, to solicit information on several substances including beryllium. Ms. Pekrul was invited to that meeting.

The Board thanks Ms. Pekrul for her comments.

Mr. David Gollaher, Ph.D., President & CEO, California Healthcare Institute, by letter dated December 5, 2003.

Comment:
Mr. Gollaher states that on behalf of the California Healthcare Institute (CHI), whose more than 200 members include California's premier life sciences companies and academic research institutions, he encourages the Board to reconsider its proposed reduction of the glutaraldehyde exposure limit from 0.2 ppm to 0.015 ppm. CHI believes further evaluation is necessary to determine the feasibility, costs and benefits of changing the current exposure limit to an appropriate level based on scientific evidence. CHI represents the interests of California's biotechnology, medical device, diagnostics, and pharmaceutical companies, and public and private academic biomedical research organizations. Many of these companies use glutaraldehyde in the production of their products. For example, two of their members manufacture heart valve devices fabricated from animal tissues. These tissues are treated in a glutaraldehyde solution to provide fixation, and also to remove any biological components that might be harmful to patients. Naturally, the processes these manufacturers use conform to strict federal Food and Drug Administration guidelines. Should the Board proceed with lowering the exposure limit to 0.015 ppm, it is anticipated the FDA would require entirely new clinical trials to ensure such process modifications do not affect the safety or efficacy of the medical devices involved. These trials would take a number of years to conduct, cost tens of millions of dollars and deprive thousands of patients access to life-saving products until such trials are completed. Moreover, it is questionable whether glutaraldehyde can be detected at the currently proposed 0.0l5 ppm exposure limit, which raises fundamental concerns over the feasibility of this proposed change. CHI encourages the Board to reconsider its proposed glutaraldehyde exposure limit reduction in order to further evaluate the measure's feasibility and the economic impact on affected industries. The life sciences industry's first priority is public health, and CHI would support a reduced exposure limit of glutaraldehyde if it could be shown to produce a reasonable public health benefit, considering the economic impacts of compliance and the practical steps manufacturers would need to take in order to comply. Unfortunately, the current proposal does not meet those objectives and, if implemented, would add tremendous cost to manufacturing life-saving medical technologies without improving public health.

Response:
As recommended by Mr. Welsh at the December 18 2003, public meeting the Board has withdrawn the proposed change for the exposure limit for glutaraldehyde. The Division held public advisory meetings on February 10, 2004, and May 4, 2004, to discuss the exposure limit for glutaraldehyde. Ms. Barbara Morrow representing CHI attended the February 10th meeting and along with many other participants provided the Division with their views on the health effects of exposure and potential impacts of changes to the current exposure limit.

The Board thanks Mr. Gollaher for his comments and the ongoing participation of his association in the advisory process.

Ms. Karen Jenkins, by letter dated December 18, 2003.

Comment:
Ms. Jenkins states that she is writing on behalf of all the nurses and radiologic technicians who have been injured from their exposures to glutaraldehyde. She hopes that the Board will take the time to go through all the letters she has collected from a multitude of people from the US and overseas. Many employees in the nursing and radiologic field have had their lives completely torn apart because of this chemical and not enough ventilation. Ms. Jenkins implored the Board to make the changes so that there will not be so many injured workers in the future.

Response:
As recommended by Mr. Welsh during the December 18, 2003, public meeting, the Board has withdrawn the proposed change for the exposure limit for glutaraldehyde. Ms Jenkins participated in the meetings held February 10, 2004, and May 4, 2004.

The Board thanks Ms. Jenkins for her comments and ongoing participation in the advisory process.

Ms. Vicki Bermudez, RN, Regulatory Policy Specialist, California Nurses Association, by letter dated December 18, 2003.

Comment:
Ms. Bermudez wrote on behalf of the 55,000 registered nurses of the California Nurses Association who support the reduction in permissible exposure limits of substances that pose a threat to the health of California workers. Ms. Bermudez believes that elimination of hazards is the best method of protecting workers from the risks associated with exposure. The proposal to reduce worker exposure is a most reasonable approach and more effective than work practice controls and personal protective equipment. When viewed in the context of the regular exposure of healthcare workers to occupational hazards such as radiation, smoke plumes from laser and electrosurgical units, blood borne pathogens, infectious microorganisms, anesthesia gases, specimen preservatives and chemotherapeutic agents, these efforts by Cal/OSHA should be viewed as a most reasonable approach to reducing worker exposure to hazardous substances. Ms. Bermudez urged the Board to support these proposed standards to ensure a safe and healthful workplace for California workers.

Response:
As noted above, the Board has withdrawn the proposed change for the exposure limit for glutaraldehyde. Ms. Bermudez was invited to participate in the meetings held February 10, 2004, and May 4, 2004, on this topic.

The Board thanks Ms. Bermudez for her comments and ongoing participation in the advisory process.

Mr. Stephen Derman, President, Industrial Hygienist, MediSHARE, by letter dated December 18, 2003.

Comment:
As an industrial hygienist working extensively with the healthcare industry and with glutaraldehyde, Mr. Derman believes that additional review of the proposed standard could be warranted. In addition to having reviewed two abstract sources referenced in the Initial Statement of Reasons, Mr. Derman has a concern that the analytical methods utilized by at least one author, P.F. Gannon (1995), provided the most accurate portrayal of exposures to the personnel described. For approximately the past twelve years Mr. Derman has monitored workplace exposure to glutaraldehyde in approximately one hundred different healthcare settings and circumstances. Mr. Derman has collected hundreds of glutaraldehyde samples. In the course of evaluating exposure levels, interviewing employees, and reviewing worker technique, Mr. Derman states that, at the existing PEL of 0.2 ppm and above, workers were more likely to experience adverse health effects. At concentrations of the existing TLV (0.05 ppm Ceiling) workers were significantly more content and did not report any adverse upper respiratory health effects. Mr. Derman assumes that at concentrations of 0.015 ppm and below, adverse health effects would also be low, but he would strongly question whether there is enough significant data, measured appropriately, to justify lowering the PEL. Mr. Derman is requesting that this issue be further reviewed and he would be interested in participating in the advisory committee process or providing additional feedback.

Response:
As noted above, the Board has withdrawn the proposed change for the exposure limit for glutaraldehyde. Mr. Derman participated in the meetings held February 10, 2004, and May 4, 2004, on this topic.

The Board thanks Mr. Derman for his comments and ongoing participation in the advisory process.

Ms. Denise Senior, Radiologic Technologist III, L250 Lead Steward, Kaiser Permanente, by letter received December 18, 2003.

Comment:
Ms. Senior has been an employee of Kaiser Permanente for l2 years as a Radiologic Technologist. She became exposed to Glutaraldehyde when there was a spill from the x-ray processor. This caused her to become asthmatic, and to have sensitivities to chemicals such as cleaning solvents, candles that are scented, paint, smoke, perfumes and colognes, diesel fuel, pesticides, and to the chemicals that she used everyday at work. Ms. Senior only had a small exposure to the spilled glutaraldehyde, but it was enough to cause her to react to the MethaCholine Challenge test and be diagnosed with RADS. It is only because of the safety officer, who was a Radiologic Technologist for many years and had sensitivities himself, that she is able to continue to work today. Her department went through a complete remodel, her ventilation system is superior, and the biomedical technologists that work on the machines are very much aware of her sensitivities and do the work without her present. The school of Allied

Health Sciences through Kaiser has added important information about this problem in their curriculum. Ms. Senior requested the Board to lower the PEL for glutaraldehyde.

Response:
As noted above, the Board has withdrawn the proposed change for the exposure limit for glutaraldehyde. Ms. Senior participated in the meetings held February 10, 2004, and May 4, 2004, on this topic.

The Board thanks Ms. Senior for her comments and ongoing participation in the advisory process.

Ms. Judith Freyman, Director of Western Occupational Safety and Health Operations, ORC Worldwide, by letter dated December 8, 2003.

Comment:
The 45-day comment period is inadequate for employers who use the numerous substances covered in the proposed revision to conduct the complex toxicological analyses that may be necessary to determine how the revision impacts their operations. There are more than 30 hazardous substances in the revision, and each of those needs to be assessed. Despite efforts to publicize the work of the Airborne Contaminant Committee (Committee), only those employers who identify themselves as interested parties and organizations that monitor its activities get detailed information in advance of the issuance of the 45-day Notice of Proposed Rulemaking. For many employers, the Notice is their first information on this very technical subject. They need more time to determine the impact of the proposed rule, and to develop meaningful comments. ORC understands other stakeholders need more time as well. The Board should extend the public comment period an additional 45 days to encourage more stakeholder participation in this rulemaking process. The reduction in the PEL for glutaraldehyde from 0.2 ppm to 0.015 ppm in the proposed revision has raised a number of questions, issues, and concerns across the industry sectors noted above. While ORC appreciates and respects the work done by the Committee to develop the recommended PELs in this proposed revision, they think there is sufficient interest and debate surrounding the glutaraldehyde PEL to support its removal from the revision for further review.

ORC's first concern is the decision by the Committee to base its recommendation on studies by Di Stefano and Gannon. Knowledgeable scientists tell ORC that these studies are limited and flawed in a number of ways. ORC thinks there should be a more extensive search of the scientific literature on glutaraldehyde, a review of the opinions of experts on occupational asthma and sensory irritation thresholds, and consideration of the weight of evidence approach that is used by other occupational exposure level setting bodies.

The second concern involves monitoring equipment capabilities. ORC does not believe there has been a full and adequate exploration of whether monitoring equipment can detect a PEL as low as 0.015 ppm, and whether it is feasible to use such equipment in the different workplaces where glutaraldehyde exposures occur, e.g., clean rooms.

A third concern is the economic impact to the business community at a time when the business climate in California is generally considered in crisis. ORC understands there was no consideration by the Committee on this issue. Some large companies have told ORC about the significant costs they will incur to comply.

In conclusion, ORC respectfully requests that the Board extend the comment period for an additional 45 days and remove glutarladehyde from the proposed revision of Section 5155 for further review.

Response:
As noted above, the Board has withdrawn the proposed change for the exposure limit for glutaraldehyde. Ms. Freyman participated in the meetings held February 10, 2004, and May 4, 2004, on this topic.

The Board thanks Ms. Freyman for her comments and ongoing participation in the advisory process.

Mr. Gene Livingston, Attorney at Law, Livingston & Mattesich, by letter dated December 17, 2003.

Comment:
Livingston & Mattesich was recently retained by the Methacrylate Producers Association (MPA) in response to the notice of proposed changes to Section 5155. The MPA would like to make the Airborne Contaminants Advisory Committee (ACAC) aware of vital information and analysis relevant to the methyl methacrylate (MMA) PEL. This information includes:

1. Unpublished data that has been accepted by other governmental and regulatory agencies and shown to be critical in the hazard evaluation and risk assessment of MMA.

2. Industry data on the feasibility and economic impact of the PEL proposed by the ACAC.

MMA has been extensively reviewed by numerous scientific and regulatory authorities in recent years including ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals), the European Union Comprehensive Risk Assessment and the OECD Summary Initial Assessment Report. The ACAC recommendation (20 PPM) is out of step with the conclusions of these authorities.

The ACAC chose three studies, Marez (1993), Jedrychowski (1982) and Mizunuma (1993) for the foundation of its recommended PEL. Based on information apparently not available to the ACAC, the above authorities identified serious technical inadequacies in these studies that would preclude their use as a basis for setting a workplace exposure limit. The weaknesses in the lead study (Marez, 1993) are of such significance that one of the co-authors has gone on file to recommend that his study be excluded for this purpose. Given these circumstances, Livingston & Mattesich believes that the PEL for MMA should be reconsidered at the advisory level by an

ad hoc committee. MPA is available and willing to provide such a committee with technical information and expertise about MMA exposures and health effects in the workplace.

Response:
As recommended by Mr. Welsh at the December 18 2003, public meeting the Board has withdrawn the proposed change for the exposure limit for methyl methacrylate. The Division held a public advisory meeting on March 30, 2004. Mr. Livingston attended the meeting and provided the Division with additional information regarding the health effects of methyl methacrylate exposure.

The Board thanks Mr. Livingston for his comments and ongoing participation in the advisory process.

II. Oral Comments

Oral comments received at the December 18, 2003, Public Meeting in Sacramento, California.

Ms. Elizabeth Treanor, Phylmar Regulatory Roundtable

Comment:
Ms. Treanor supports the Division's decision to remove certain substances from the proposal in order to reassess scientific data and the impact on businesses. She looks forward to working with Board and Division staff on the issue.

Response:
The Board thanks Ms. Treanor for her comments and ongoing participation in the advisory process.

Mr. Gene Livingston, Attorney at Law, Livingston & Mattesich

Comment:
Mr. Livingston commented on two substances contained in the proposal. The first substance was glutaraldehyde. Mr. Livingston indicated that he had spoken to Division staff regarding establishing an advisory committee to work on the scientific and economic issues and develop a proposal for the Board to consider at a later date. The second substance was amyl acetate. Mr. Livingston asked the Division to consider removing the substance from the proposal.

Response:
The Board has removed the proposed change to glutaraldehyde as noted above. The Division and Board have considered the removal of amyl acetate from the proposal, but have not been given or found a reason for such an action. Therefore, the Board will not remove amyl acetate from the proposal.

The Board thanks Mr. Livingston for his comments and ongoing participation in the advisory process.

Ms. Judith Freyman, Director of Western Occupational Safety and Health Operations, ORC Worldwide

Comment:
Ms. Freyman thanked the Division for being responsive to the concerns of those who were not able to engage in the rulemaking process at an earlier stage. She understood that receiving comments at such a late stage of the process could possibly cause difficulties and delays. She was hopeful that the proposal brought to the Board at a later date would be one that had received and reflected numerous public comments and participation.

Response:
The Board thanks Ms. Freyman for her comments and ongoing participation in the advisory process.

Ms. Karen Jenkins, former X-ray technician

Comment:
Ms. Jenkins read a letter she wrote to the Board, regarding her personal health issues from being exposed to glutaraldehyde. She explained her situation and the situations of others like her and asked the Board to make the necessary changes to the standard before more workers are injured.

Response:
The Board response to Ms. Jenkins' oral comment is the same as stated above to her written comment.

The Board thanks Ms. Jenkins for her comments and ongoing participation in the advisory process.

Mr. Tom Tremble, Advanced Medical Technology Association

Comment:
Mr. Tremble stated that there are many uses for glutaraldehyde in the health care industry. He welcomes the thought of an advisory committee and looks forward to working with staff on the proposal.

Response:
The Board's response to Mr. Tremble's oral comment is the same as stated above to his written comment.

The Board thanks Mr. Tremble for his comments and ongoing participation in the advisory process.

Ms. Denise Senior, X-Ray technician

Comment:
Ms. Senior said she was exposed to glutaraldehyde when there was a spill from an X-Ray processor at her jobsite. As a result of the spill, she is asthmatic and has extreme sensitivity to common chemicals such as household cleaners and perfumes. Some of the symptoms Ms. Senior suffers from are difficulty breathing, rash on hands and feet, raspy voice, difficulty thinking or concentrating, dizziness, headaches that progressed into migraines, agitation and depression. She described some of the treatments she has undergone and what she is doing to help prevent others from getting sick.

Response:
The Board's response to Ms. Senior's oral comment is the same as stated above to her written comment.

The Board thanks Ms. Senior for her comments and ongoing participation in the advisory process.

Dr. Robert Harrison, Board Member

Comment:
Board Member Harrison encouraged both Board and Division staff to consider designations for sensitizers and carcinogens bringing the table of chemicals in Section 5155 at least up to a level consistent with the American Conference of Governmental Industrial Hygienists.

Response:
The Division has included this topic in several of its public advisory committee meetings. The Division agrees to convene an advisory committee on the issue and may present a proposal to implement this request in the future.

ADDITIONAL DOCUMENTS RELIED UPON

None.

ADDITIONAL DOCUMENTS INCORPORATED BY REFERENCE

None.

DETERMINATION OF MANDATE

This standard does not impose a mandate on local agencies or school districts as indicated in the Initial Statement of Reasons.

ALTERNATIVES CONSIDERED

The Board invited interested persons to present statements or arguments with respect to alternatives to the proposed standard. No alternative considered by the Board would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the adopted action.