

M e m o r a n d u m

To: ALL STANDARDS BOARD MEMBERS

Date: June 8, 2004



From: Department of Industrial Relations
Division of Occupational Safety & Health
Len Welsh, Acting Chief

Subject: Section 5147, Respiratory Protection for M. Tuberculosis Amendments

At the May 20, 2004, Public Hearing, the Occupational Safety and Standards Board considered repealing California Code of Regulations, Title 8, General Industry Safety Orders, Chapter 4, Subchapter 4, Article 4, section 5147, Respiratory Protection for M. Tuberculosis. This standard is substantially the same as the federal standard that was revoked in December 2003.

Labor Code section 142.3(a)(3) exempts the Board from providing a comment period when adopting a standard substantially the same as a federal standard. However, as indicated in the Notice and Informative Digest, the Board still provided a comment period for the purpose of identifying only issues related to the following three areas: 1) any clear and compelling reasons for California to deviate from the federal standards; 2) any issues unique to California related to this proposal which should be addressed in this rulemaking and/or subsequent rulemaking; and 3) solicit comments on the proposed effective date.

In response to a comment by Mr. Myers, Ms. Prickitt and Mr. Richter, the proposal was modified to delay the implementation date by ninety days. A ninety-day implementation period is necessary to allow employers sufficient time to implement the provisions of section 5144 and is consistent with the amount of time given to allow other employers to comply when section 5144 was initially adopted in 1998. No other modifications were made to the proposal and informative digest in response to comments.

SUMMARY OF WRITTEN AND ORAL COMMENTS

List of Commenters:

John Mehring, Health and Safety Educator, Service Employees International Union
Written and oral comments received on May 20, 2004.

Gayle Valverde, SEIU Local 250
Written and oral comments received on May 20, 2004.

Mark Nicas, PhD, MPH, CIH, Adjunct Associate Professor, Industrial Hygiene Program
Director University of California, Berkeley
Written and oral comments received on May 20, 2004.

Kenneth Smith, CIH, Chief, Environmental Health & Safety, Facilities Management Section, California Department of Health Services, Richmond Facility
Written comments received on May 26, 2004.

Jennifer McNary, MPH, CIH, Associate Industrial Hygienist, Facilities Management Section, California Department of Health Services, Richmond Facility
Written comments received on May 26, 2004.

Frank Edward Myers III, MA, CIC, CPHQ, President, California Association for Professionals in Infection Control and Epidemiology Coordinating Council (CACC)
Written and oral comments received on May 20, 2004 and May 28, 2004.

Sandra Prickitt, RN, FNP, COHN-S AOHP, Executive Vice President, GAC Chair
Written and oral comments received on May 20, 2004 and May 28, 2004.

Numerous emails and letters (50+) supporting or duplicating the May 20th comments of Mr. Myers.

Comment #1:

Mr. John Mehring, Service Employees International Union, in written and oral comments urges the adoption of the proposal. The U.S. Department of Labor Occupational Safety and Health Administration (OSHA) repealed their standard on the basis of a national decline in the number of Mycobacterium Tuberculosis (TB) cases, but California was the state with the highest number of TB cases in 2003. Annual fit testing should be performed in order to provide health care employees with protection equivalent to respirator users in other industries.

Response:

The Board thanks Mr. Mehring for his support of the proposal and for the information regarding the presence of TB in California.

Comment #2:

Ms. Gayle Valverde, Local 250, SEIU supports the proposal. The rate of TB in California is higher than the national average. TB is spread by inhalable droplets that are filtered out by N95 respirators more effectively than surgical masks that were originally issued for protection. N95 respirators are also issued against Severe Acute Respiratory Syndrome (SARS). The protection conferred by N95 respirators is only as good as the fit of the respirator to the user and annual fit testing provides an effective approach to assuring that the equipment works properly. The annual test also reinforces the importance of using the respirator for the user.

Response:

The Board thanks Ms. Valverde for the support of the proposal and concurs that respirators are being used for other respiratory hazards besides TB in health care settings. The Board is aware that the use of respirators is expanding in response to emerging diseases such as SARS and the implementation of emergency preparedness programs as established by the U.S. Department of Homeland Security and the California Office of Emergency Services. The Board notes that the use of respirators for these and other health care issues is currently within the scope of section 5144 and subject to the requirement of annual fit testing. TB respirator use was not included because OSHA planned to promulgate a comprehensive standard for TB. The Board also

acknowledges the importance of training and other methods for reinforcing the importance of properly utilizing respiratory protective equipment.

Comment #3:

Dr. Mark Nicas, in oral and written comments, supports the proposal to rescind section 5147 and provides comments that the general industry respirator standard is applicable to TB transmission because TB bacilli are carried on airborne particles that behave just like other airborne particles of comparable size. Health care facilities do not have to measure these airborne particles to assess the potential for exposure since the Center for Disease Control (CDC) has established such methods. Further, individual susceptibility is not unique to infection, but can be seen with exposures to chemicals, and does not negate the importance of providing respiratory protection. Finally, unlike an exposure to most chemicals, an infected health care employee can infect other employees with TB.

Response:

The Board thanks Dr. Nicas for his support of this proposal and these factual comments and concurs that section 5144 can be applied to the reduction of TB transmission as well as similarly transmitted diseases.

Comment #4:

Dr. Nicas notes that the declining number of cases of TB does not mean that occupational infections have been eliminated. The January 2004, "Report on Tuberculosis in California" from the Tuberculosis Control Branch of the California Department of Health Services suggests that the decline in TB is leveling off.

Response:

The Board thanks Dr. Nicas for his analysis of the data, notes that it is consistent with Comment #1, and concurs that TB still poses an occupational hazard in California.

Comment #5:

Dr. Nicas reports that a recent National Institute for Occupational Safety and Health (NIOSH) study showed that respirator users who passed a fit test tended to have higher simulated workplace protection factors than those who do not which supports the efficacy of fit testing. He also notes that actual research to compare exposures to TB for respirator users with and without fit testing would be unethical.

Response:

The Board thanks Dr. Nicas for this information and explanation for the seeming lack of data on the efficacy of fit testing.

Comment #6:

Dr. Nicas, in written and oral comments, provides information supporting the need for fit testing by citing information provided in the OSHA preamble in the Federal Register, Volume 63, January 8, 1998, pages 1223-1224. OSHA received comments and data from employers that showed that by one year after passing a fit test, a small percentage could no longer pass the fit test with the same respirator, and after two years, more than 5 percent could not pass the test. The importance of fit testing is especially critical for the health care worker who is attending a

pulmonary TB patient in close proximity since the respirator usually provides “the first line of defense.”

Response:

The Board thanks Dr. Nicas for this data and concurs that whenever respirators are critical in providing protection against a respiratory hazard, it is critical to assure that the respirator has been properly selected and fits the user.

Comment #7:

Kenneth Smith and Jennifer McNary support the proposal. They report that respiratory protection is provided for TB research at their facility for emergencies. Although not required, they conduct annual fit testing because it is a necessity in minimizing face seal leakage. The test also provides an opportunity for refresher training for proper use of the respirator. They also cite NIOSH research, cited by other commenters, that shows that individuals who pass a fit test tend to have higher simulated workplace protection values than individuals who fail the test.

Response:

The Board thanks Mr. Smith and Ms. McNary for their support of the proposal and demonstration of an employer conducting annual fit testing. The Board notes that this research was also discussed by Dr. Nicas in comment #5.

Comment #8:

Frank E. Myers III, Sandra Prickitt, and Roger Richter (as well as numerous other individuals providing similar written comments) oppose the proposal on the basis of the high cost of conducting fit testing. Fit testing was “one of the most burdensome requirements” in the proposed TB regulation from OSHA. When fit testing is conducted for nursing staff, California mandatory nursing ratios require additional staffing and increased operating expenses. The figure for the fiscal impact of the proposal was below the actual costs that are being experienced by California health care facilities. The money should be spent to enhance early patient identification and primary precautions. Mr. Myers and Ms. Prickitt also supplied additional cost-related information to the Board on May 28th at the request of Board Member Robert Harrison, M.D. Within this correspondence, information that a survey done by CHA of 194 acute care facilities reported only three tuberculin skin test conversions since personnel began using respirators. The cost to California facilities is between 1.6 and 18.5 million dollars, and 40 hospitals in the high-risk areas for TB in the state had operating losses.

Response:

The Board thanks Mr. Myers and Ms. Prickitt for the specific and detailed data on costs that have been provided and acknowledges that the Division’s projection of cost, based on the OSHA estimates, did not include this information. However, as noted in the response to Ms. Valverde, the use of respirators within health care facilities and auxiliary services extends to procedures for other diseases such as SARS, and other hazards created by a natural, accidental, or criminal catastrophic event. Therefore, the cost of using respirators cannot be attributed to compliance with section 5147 alone. Further, the Board acknowledges that studies have shown that certain counties have high rates of TB cases compared to others but concludes that the solution to the fiscal problems at these facilities should not be derived from providing lessened employee protection. The Board also notes that the few cases of TB found in the CHA survey can be

interpreted as evidence of the effectiveness of respirators in minimizing infections among the users.

Comment #9:

Frank E. Myers III and Sandra Prickitt *et al* believe that there is no scientific proof that fit testing on an annual basis confers added protection against TB for several reasons. First, there is little likelihood that there will be exposure to TB since, as OSHA stated, the rate of TB is declining. Secondly, respirators have not been proven to have prevented any cases of TB. Third, the fit of a respirator can be assured by retesting when a user is aware of facial structure changes, weight fluctuations and other criteria. Mr. Myers also cites correspondence from APIC to OSHA that states that fit testing results vary with different methods, and if the respirator has inherently good fit characteristics, the benefit of fit testing is minimal. Within the additional comments provided to the Board on May 28th, Mr. Myers and Ms. Prickitt note that the Institute of Medicine publication, Tuberculosis in the Workplace, and research conducted by NIOSH researcher, Christopher C. Coffee, indicate that the primary respirators used to protect against TB, classified by NIOSH as the N95, vary in their ability to pass fit tests. This is partly due to the fact that NIOSH tests the filtration rather than the fit of respirator models. This shows that N95 respirators have questionable efficacy.

Response:

The Board acknowledges that OSHA reports a national decline in the overall number of TB cases over the last few years. However, as reported by Mr. Mehring and Dr. Nicas, CDC data also show that California has the highest number of TB cases in the nation. The Board acknowledges that respirators made by various manufacturers will not be equally protective in terms of its overall performance nor is one respirator made by one manufacturer likely to properly fit and protect every person. For this reason, section 5144 requires the employer to provide respirators of different modes and sizes. Fit testing is intended, in part, to assure that an employee will be issued with a type of respirator that provides the best protection by providing an “inherently good fit” for that individual. Section 5144 provides specific testing methodologies. The May 16, 2004, CDC publication, Mortality and Morbidity Weekly Report, reports that a study of health care workers in Toronto who became infected with SARS, indicated that 6 of 11 infected workers wore personal protective equipment, including respirators, but did not have a fit testing program. In a letter of interpretation to the Chief of Infection Control Service at Walter Reed Army Medical Center, OSHA affirmed that the use of respirators for SARS, Smallpox, and Monkeypox has been included in the scope of the respirator standard. Also, OSHA discusses NIOSH Health Hazard Evaluations that showed improved respiratory protection with annual fit testing in the preamble to the respirator standard in 1998. OSHA also received data from employers showing that annual fit testing resulted in a fit test failure rate that was half the rate of a program that was done biannually or on the basis of reported facial changes (please see Comment #6). On consideration of these factors, the Board respectfully declines to deny the proposal on the basis of these statements.

Comment #10:

Frank E. Myers III, Sandra Prickitt, and Roger Richter note that section 5144 does not include TB protections such as PPD testing of employees, treatment of TB infection at work, training employees about TB, or the use of negative pressure for certain procedures for TB patients.

Response:

The Board acknowledges that section 5144 does not include specific TB protections since it applies only to the use of respirators. The Board does not concur with the suggestion that these protections, inherent within the CDC guidelines and other sections of the General Industry Safety Orders, would be removed by the repeal of section 5147, which applies solely to the use of respirators for occupational exposure to TB.

Comment #11:

Frank E. Myers III, Sandra Prickitt, and Roger Richter request a delay in adopting the proposal on the basis of comments #8 and #9. In addition, they believe that an alternative to the implementation of the proposal could be developed within the rulemaking process.

Response:

The Board acknowledges that the changes to respiratory protection programs that would be required by the proposal may require significant effort to implement and will provide an implementation date of 90 days following adoption of the proposal. Since 90 days was provided for other employers to implement section 5144 in 1998, it would be appropriate for this proposal as well. The Board further recommends that the interested parties meet with the Division during the extended implementation period to discuss alternative measures.

Comment #12:

Sandra Prickitt expresses concern at the abrupt nature of the OSHA decision to rescind the Federal TB interim standard which precluded affected organizations from making comments.

Response:

The Board acknowledges that OSHA did not provide significant public notice of the repeal of their standard, but OSHA has a separate process from this Board. Concerns regarding the manner or content of the changes promulgated by OSHA should be directed to that agency.

DETERMINATION OF MANDATE

This regulation does not impose a mandate on local agencies or school districts as indicated in the Staff Development Memorandum.