

94-319

SERVICE EMPLOYEES



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To the attention of the NIOSH Docket Officer:

The Service Employees International Union, AFL-CIO, CLC (SEIU) is providing the following comments and review of the draft document entitled, NIOSH Proposed Rule for Respiratory Protective Devices 42 CFR Part 84 published in the May 24th, 1994 Federal Register.

SEIU will only address the sections of the document that refer to respiratory protection for the control of tuberculosis in healthcare facilities. While we recognize that this document is much broader in scope, as the largest union of healthcare workers in the United States, the issue of proper respiratory protection is of major importance to the workers we represent.

SEIU believes that engineering controls are the first line of defense to eliminate or reduce the hazard at its source. When it is not possible to reduce or eliminate the hazard at its source then other measures such as, administrative controls and work practice controls should be used. Personal protective equipment, such as respiratory protection falls last in the order of hierarchy controls to protect the employee. We believe that respiratory protection, as a part of the hierarchy of controls, is an important component of a comprehensive TB control program.

Although the new proposed rule provides adequate protection against chemical contaminants with an accepted threshold limit, we do not believe that the recommendations in the NIOSH proposed guidelines will effectively protect health care workers from infectious droplet nuclei containing Mycobacterium tuberculosis, the causative agent of TB. We believe it is inappropriate for NIOSH to determine that the proposed respirator certification process will provide

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adequate respiratory protection for TB exposure. Specifically, we cite the following concerns:

1. **There is no safe level of exposure to TB.** According to the CDC guidance document entitled "Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, Second Edition" (draft #13, August 4, 1993), the probability that a susceptible person will become infected with Mycobacterium tuberculosis (TB) depends primarily on the concentration of infectious droplet nuclei in the air and the duration of exposure. However, it has not been demonstrated that there is a safe threshold level of exposure whereby a worker can be repeatedly exposed to infectious droplet nuclei and not become infected. Therefore protection of workers should be accomplished through the use of the best available technology.

2. **The proposed rule would result in a reduction in protection against TB exposure.** Common practice in the hospital and health care industries has been to provide workers exposed to aerosolized droplet nuclei via high-hazard procedures with respiratory protection because exposure may not be completely eliminated even with full implementation of the recommended administrative and engineering controls. Currently, the CDC recommends the use of the best particulate filtration available for respirators, i.e., single-use or reusable air-purifying respirators with high-efficiency particulate respirators (HEPAs). HEPA particulate filters are capable of removing at least 99.97% of particles 0.3 microns in diameter. The use of the proposed Type B/L&S particulate filters, capable of a 99% filtering efficiency, and the Type C/L&S particulate filters, capable of a 95% filtering efficiency, represents a reduction in protection for exposure to TB for health care workers from current practice.

3. **The proposed rule fails to account for differences in intensity of risk and exposure.** Importantly, both the CDC and NIOSH have failed to account for differences in intensity of risk and exposure among health care workers in the determination of appropriate respiratory protection. It is inappropriate to advocate the use of the proposed Type B/L&S and Type C/L&S particulate filters to all workers, some of whom may have dramatically different exposures. A worker who is engaged in a high risk procedure such as a sputum induction should be afforded the highest level of respiratory protection available.

Moreover, NIOSH/CDC has failed to consider the working lifetime risk of TB infection to a healthcare worker. NIOSH has used the CDC's calculations of an annual rate of TB infection to a healthcare worker. By adopting CDC's calculation of this annual rate of infection, NIOSH has seriously underestimated the real risk of exposure to an individual healthcare worker.

In their draft #13 guideline, CDC assumes that all health care workers have a uniform risk of TB exposure. While CDC's reliance on a 2% risk rate for TB infection may be a reasonable assumption for health care workers overall, it fails to account for the greater risk of exposure among health care workers performing certain jobs, i.e., working on a TB isolation room, performing sputum inductions and working in an emergency room. Further, CDC's guideline permits a respiratory penetration of 14% from a combination of face seal and filter medium. Assuming CDC's questionably derived 2% rate of risk and given a 14% rate of respiratory penetration, health care workers as a whole would suffer a 0.28% annual rate of TB infection. However, when an annual rate of 0.28 percent is applied to a forty-five year working lifetime risk of exposure, an individual worker has a 12% working lifetime risk of exposure. A calculation for a lifetime risk of TB infection provides a truer picture of risk--and a 12% rate of risk is wholly unacceptable.

4. A filter efficiency of 95% has not been proven to adequately protect workers against exposure to TB. For chemicals with a threshold limit value, the use of respirators with a minimum of 95% filter efficiency in removing particulate contaminants can be applied in the typical industrial setting. For such chemical contaminants, one can measure the worker's exposure and then predict contaminant dose using various levels of respiratory protection. For example, for a worker who is exposed to 10 milligrams per cubic meter (mg/M³) of welding fume, a respirator that removes contaminants with a filtering efficiency of 95% or better will reduce the worker's exposure to 50 micrograms per cubic meter (ug/M³) or even less. Such a reduction in turn reduces the worker's body burden of welding fume. A toxicological effect can then be predicted. Since one can neither measure concentrations of TB in the air nor demonstrate a safe level of exposure one cannot apply the industrial hygienist's rationale to protect workers against TB. A comparison can be made to the rationale for protecting workers against carcinogens. For all carcinogenic particulates (for example, asbestos), general practice in the industry has been to use air-purifying respirators with HEPA filters as a minimum level of protection.

5. The proposed rule will not certify respirators against biological agents such as TB. In the second paragraph on page 26852 of the preamble of the proposed rule, the authors indicate that the proposed rules were not developed to certify respirators against biological agents (e.g. M. tb). As stated, all particulate respirators certified under the proposed rule's performance criteria will meet the CDC respiratory performance criteria in the CDC draft #13. There is no scientific evidence presented anywhere in the CDC document to support the 95% filter

efficiency as a threshold against TB infection.

6. HEPA filters are currently used in ventilation systems. In draft #13 document, the CDC specifies the use of HEPA filters in a number of ventilation designs to eliminate infectious droplet nuclei from room air. Again, this demonstrates the use of the best available technology to reduce or eliminate infectious droplet nuclei.

7. Faceseal Leakage. The document does not address the issue of face seal, a critical component of respiratory protection. Penetration of aerosolized particles can occur through the filter medium and faceseal leakage. In its draft #13 guidelines, CDC addresses both filtration efficiency and face seal. While we believe it was correct for the CDC to address both filtration efficiency and face seal, we question whether there is adequate scientific evidence to conclude that a respirator with a filtration efficiency of 95% for one micron particles, and with a faceseal leakage value of 10%, is adequate for protection against M.tb. The CDC failed to support this determination with adequate scientific evidence.

Even though NIOSH states they will be address the issue of face seal in a subsequent module, we believe that in order to achieve adequate respiratory protection for healthcare workers from exposure to M.tb, the discussion of faceseal leakage cannot be separated from the discussion of filtration efficiency.

Further, HEPA filter respirators provide a better fit and will insure less penetration. HEPA filter respirators are available in more than one size. This feature is particularly desirable for female healthcare workers who usually have smaller faces than men, for whom respirators are typically designed.

It is also critical for NIOSH and CDC to determine an acceptable level of face seal leakage, especially when taking into consideration the fact that when using a disposable HEPA filter the face seal leakage is less than 10%. By contrast a DM or DMF face seal leakage is 10% to 20% under optimum conditions.

8. Fit-Testing. We believe the fit-testing protocol described in the proposed rule is related to the certification of the respirator and is not necessarily related to the employer's responsibility for fit-testing workers under OSHA's respiratory protection standard. Isoamyl acetate (banana oil) is preferred over irritant smoke due to the potential for the generation of acid gas contaminant concentrations above OSHA's Ceiling limit.

If you would like to discuss these comments further, please contact Laura Kenny at (212) 947-1944 or Jamie Cohen at (202) 898-3434.

Sincerely,

Laura Kenny (jc)

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