STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY
PETE WILSON, Governor

DEPARTMENT OF HEALTH SERVICES
2151 BERKELEY WAY
BERKELEY, CALIFORNIA 94704

94-360

July 29, 1994

Linda Rosenstock, MD, Director
c/o NIOSH Docket Office
Robert A. Taft Laboratories
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Dear Dr. Rosenstock:

On behalf of the California Department of Health Services (CDHS) Occupational Health Branch, I wish to comment on the National Institute of Occupational Health and Safety (NIOSH) proposal to improve respirator testing and certification methods through the adoption of 42 CFR part 84 (Federal register Vol. 59 N. 99 pp. 26850-26889 on May 24, 1994).

Your proposal to change the test methods and classification system for respiratory protection devices for particulates from contaminant specific (ie: dust/mist/fume) to Types A, B and C is a welcome simplification which should facilitate respirator selection. Certifying particulate filters according to their ability to prevent the penetration of relatively small particles, prior to filter loading, also represents an increase in scientific validity. Although ideally, filter penetration test conditions would emulate a "worst case" scenario for each respirator, the data you propose to collect will generally predict how effectively a filter performs.

We appreciate the dilemma NIOSH faces in trying to design a laboratory-based respirator fit test for what is inherently a field performance factor. However, as proposed in sections 84.181 and 84. 182 of the proposed regulation, the isoamyl acetate test methods for respirator fit do not yet provide a meaningful and reproducible measure of fit. For example, the number of persons tested, the size and shape of their faces, their ability to detect isoamyl acetate and other factors expected to influence the outcome and interpretation of fit test results are not specified. The pass/fail criterion needs further definition. What percentage of persons are permitted to detect isoamyl acetate in order for the respirator to fail the test?

We do not support setting different performance criteria for single-use ("filtering facepiece") particulate respirators compared to elastomeric halfmask respirators with replaceable filters. This difference is, in essence, the assignment of protection factors (APFs) for these two types of respirators. Clearly, how well a

respirator fits is a determining factor in its ability to reduce exposures to airborne particulates. In recognition of the linkage between APFs and fit testing, the details of the testing protocol must be explicitly stated so that they can be reproduced. Because APFs are quantitative measures of respirator performance, a quantitative tightness/fit test protocol should be implemented. In addition, NIOSH should require that appropriate information about fit testing and checking be included with each respirator. This could be accomplished either by NIOSH approving a manufacturer's materials or by NIOSH developing its own fit testing/checking materials for dissemination.

It is our interpretation that the use of the U statistic to analyze particle instantaneous-penetration filter test results conducted under section 84.184 would allow five percent of the filters tested to fall short of the performance criteria. On page 26859, the proposed rule states that 7 million workers use respirators at some time each year, and employers purchase an estimated 110 million disposable respirators annually. Given the magnitude of these numbers, a failure rate of five percent represents an unacceptably high number of workers placed at risk due to a failure of quality control. We urge NIOSH to strengthen this criterion to one percent or less.

Filter type identification requirements in section 84.180 specify a color for Type A/L&S filters only. For many users, the letter designations may not be as reliable or as user friendly as a system of color coding. We recommend that NIOSH designate color coding as well as letter designations for each of the other five filter types.

We support NIOSH in taking a modular approach to rule making. This approach will provide an on-going mechanism for scientific and technologic advances to be incorporated into regulations in a timely way. Evaluation of the data collected in the testing and certification program could encourage innovation and lead to improvements in respirator design and enhance exposure assessment and control efforts. Therefore, we suggest that it will be of utmost importance for NIOSH to critically review the data and to place all test data collected in the certification process in the public domain.

On page 26851, NIOSH states its intent in changing the particulate filter testing and certification methodology is to ... "enable users to easily discern the levels of protection that can be expected when using a particulate respirator". By this logic, NIOSH would establish the particle size efficiency rating of the filter. This information would be linked to knowledge of the particle size distribution, toxicity, exposure levels and allowable risk for a specific contaminant and a respirator selected accordingly. This approach is consistent with 1987 *Respirator Decision Logic* which specifies consideration of airborne concentration level of a chemical toxicant, its exposure limit (which is by definition a statement of toxicity and allowable risk), and the minimum respirator protection factor

needed to reduce the inspired concentration to the exposure limit. We fully support this widely accepted, scientifically-based approach.

We are therefore very concerned that the proposed endorsement of contaminant-specific criteria for respiratory protection for *Mycobacterium tuberculosis* (TB) in this regulation would appear to undermine this approach to respirator selection decision making. In the proposed rule on page 26852 NIOSH states ... "Modifications to the current requirements in this proposed rule were *not developed specifically to certify respirators against biological agents* (emphasis added). However, the provisions of this rule will address an important public health need regarding the transmission of TB .... CDC (U. S. Centers for Disease Control and Prevention) has *determined* that these four criteria are necessary (emphasis added) ... all six classes of air purifying particulate respirators to be certified would meet or exceed the recommendations contained in the CDC document .... the other classes are less expensive.... consequently the rule should promote a substantial increase in respiratory protection." We believe that NIOSH's endorsement of CDC criteria in this regulation will in effect be certifying respirators for use against biological agents (TB) without adequate consideration of the issues which are routinely incorporated into respirator decision logic.

In the 1992 *NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health Care Facilities Potentially Exposed to Tuberculosis* , NIOSH considered the nature of the TB hazard to workers and potential respirator leakage (face seal and filter ). After consideration of the issues associated with the nature of the hazard, NIOSH concluded, "any tuberculosis infection in a health care facility worker due to occupational transmission should be considered unacceptable. Infection of health care facility workers with tuberculosis, whether with or without clinical disease, constitutes a preventable impairment of the health of these workers. Additionally, chemoprophylaxis of tuberculosis infected workers with isoniazid (INH) poses further significant risks due to isoniazid-related hepatitis and other potential side effects."[1] However, the underlying assumptions of CDC's determination of their criteria have not been articulated. CDC states only that its criteria ..."are based on estimated characteristics of respirators which were used in conjunction with administrative and engineering controls in outbreak settings where transmission to health care workers and patients appeared to cease". [2] CDC makes no reference to the extensive rationale set forth in NIOSH's 1992 *Recommended Guidelines*. Without an understanding of the assumptions of acceptable risk inherent in the CDC criteria, decisions regarding respirator selection cannot be made according to the

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[1] National Institute for Occupational Safety and Health. *NIOSH recommended guidelines for personal respiratory protection of workers in health care facilities potentially exposed to tuberculosis*.. pp. 16-17. September 14, 1992

[2] U.S. Centers for Disease Control and Prevention. Guidelines for the prevention of tuberculosis transmission in health care facilities. Federal Register Vol. 58. No. 195. October 12, 1993 page 52843.

logic NIOSH has previously promoted. Such a change in NIOSH policy would set a worrisome precedent.

Therefore, it is our position that the prevention of occupationally acquired TB would be better served if NIOSH published its new recommendations for respiratory protection for TB in the format of your September 14, 1992 guidelines, including the decision logic and assumptions of the analysis, rather than by incorporating these changes into the proposed regulation. We recognize that decisions about what constitutes adequate respiratory protection against biological agents in the workplace are plagued by a lack of information regarding what constitutes an infectious dose and exposure concentration levels. Moreover, there exists no public consensus or regulatory statement of what constitutes an acceptable risk for occupational exposure to TB [3]. A decision regarding exposure to biological agents has implications well beyond a discussion of respirator criteria for TB. Drug resistant strains of biological agents are becoming an increasing public health problem and pose additional occupational risks for health care workers. These risks are of even greater concern for the immunocompromised health care worker and deserve careful consideration. Endorsement of the CDC criteria into this regulation may generate a false sense of security and forestall the research needed to resolve these questions.

In summary, e believe that the changes in testing and certification methods for particulate respirators will improve the nature and quality of the data collected about filter performance and will provide a sound basis for making decisions regarding respirator selection. The regulations could be further improved if NIOSH were to adopt these recommendations:

- Substantially improve the fit testing requirements (84.181/84.182) to establish a quantitative, reproducible test explicitly linked to APF. Require respirators to include information regarding fit testing and checking which has been either developed or approved by NIOSH;

- Increase the target value for respirator performance set forth in 84.184 to at least 99%;

- Additionally require color coding for all six classes of filters (84.180);

- Place all data collected in the testing and certification process in the public domain;

- Delete all references to criteria for respiratory protection for *Mycobacterium tuberculosis* from this regulation. Publish new recommendations for

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[3] M.Nicas, JE Sprinson, SE Royce, RJ Harrison and JM Macher (1993): "Editorial - Isolation Rooms for Tuberculosis Control," *Infect. Control Hospital Epidemiol.* 14:619-622.

respiratory protection for TB in the format of NIOSH's September 14, 1992 guidelines, including the decision logic and assumptions of the analysis. Promote research and educational efforts regarding the nature of particulate hazards, including biological agents, to facilitate the linkage between filter performance data and hazard reduction.

We appreciate your consideration of these comments. If you have any questions please contact Patrice Sutton at (510) 849-5115.

Yours truly,

Frank Mycroft

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