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> NIOSH Docket Office Mail Stop E-23 1600 Clifton Road, N.E. Atlanta, Georgia 30333

> > Comments of the Building and Construction Trades Department, AFL-CIO, on Proposed 42 CFR Part 84

Dear Sir/Madam:

Attached are the three copies of the Comments of the Building and Construction Trades Department, AFL-CIO, on Proposed 42 CFR Part 84.

Sincerely,

SHERMAN, DUNN, COHEN, LEIFER & COUNTS

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Enclosures

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COMMENTS ON PROPOSED 42 CFR PART 84

Introduction

These comments are filed on behalf of the Building and Construction Trades Department, AFL-CIO (BCTD), its sixteen national and international affiliated unions, and the more than six million employees represented by its member unions. These BCTD comments on the oral presentations delivered during the NIOSH hearings held in Washington, D.C., January 27th, 1988, are designed to refocus the discussion on the facts underlying the proposed regulations and to clear away the misconceptions that some of the manufacturers' testimony at the hearings may have created.

The BCTD strongly endorses NIOSH's current efforts to eliminate 30 CFR Part 11, the outmoded respirator regulations currently in effect, in favor of proposed 42 CFR Part 84. The BCTD shares NIOSH's basic premise: workers who must labor in an environment that contains noxious chemicals and toxins should be protected against debilitating illnesses that can be prevented. In order to accomplish this, as NIOSH has concluded, respirators must be tested and rated on the basis of performance in real or simulated workplace environments, rather than merely in the laboratory.

Current regulatory fashion favors a simplistic cost benefit analysis equation; the manufacturers argue that the employees' interest in a healthful workplace is outweighed by the employers' interest in trimming expenditures. In contrast, NIOSH's sophisticated analytical approach to these regulations

deserves commendation. NIOSH has introduced the interest in worker health, productivity, and longevity in a long needed reevaluation of the notion of "costs." Cost means not only the amount a manufacturer must spend to design a respirator to do the job it is supposed to do; "cost" also comprehends the social costs all of us must bear when an employee is needlessly disabled by job-related terminal illnesses. Accurate and complete economic analysis requires that the enterprise internalize all of the costs that it creates; if the jargon of economics is to be used at all in assessing health and safety regulations, the NIOSH approach is the only possible correct one.

In addition to contesting NIOSH's overall approach, i.e., including all of the costs imposed by manufacturers as part of its cost/benefit equation, the manufacturers have levelled detailed criticism at several aspects of the proposed regulations: timing of the issuance of the final test protocol; the requirement that the testing be conducted in actual or simulated workplaces using human subjects; and the costs and feasibility of implementing the proposed regulations. The BCTD believes these objections have little merit—were NIOSH to require less stringent testing and certification requirements, it would be unable to fulfill its statutory duty under the Occupational Safety and Health Act to ensure that every worker is provided with a safe and healthful workplace.

Costs and Benefits of Workplace Testing

NIOSH's proposed rule requires actual or simulated workplace testing of respirators under conditions reasonably representative of those in which the respirator will be used. At the Washington hearings, the manufacturers argued that workplace testing should not be required at this time, contending that it was not technologically feasible and that it would be too costly.

The primary problem with the manufacturers' costliness objection is that there is no adequate substitute for the type of testing NIOSH requires in the proposed regulations. Actual or simulated workplace testing based upon data collected from human subjects is the only reliable testing for two basic reasons. First, the human lung's filtration process is inimitable in the laboratory. As Dr. Warren R. Myers of West Virginia University noted during the external peer review of the workplace protection factor study, collecting data in an actual workplace is the only way to accurately estimate the lung retention loss that occurs with particulates, gases, and vapors. Simulated techniques are unable to mime the lung's filtration process. Therefore, during simulations, an inaccurate level of contaminants is inevitably recorded.

Equally important, as Mike Wright of the Steelworkers observed during the peer review proceedings, only workplace testing demonstrates how a respirator actually performs in the

workplace. For instance, even if a respirator is operating properly as a filtration device, only real work conditions can establish the effectiveness of a respirator's fit as it loosens, slides, and its facemask becomes foggy during hours of wear in conditions of heat and high humidity. Under these conditions, a human worker adjusts the respirator to make it more comfortable under work conditions and thereby risks exposure to the unfiltered ambient air. It is difficult, if not impossible, to approximate these factors in a test run without human subjects.

Costs cannot be an objection to the proposals; no alternative is adequate to the task, so the manufacturers' cost/benefit arguments are irrelevant.

The Mines and Mining Objection

All of the manufacturers present at the Washington hearings argued that NIOSH's proposed rule would require testing of all respirators in mines or places where mining operations occur. The manufacturers' misconception arises from their incomplete reading of the proposed regulation. The "General Provisions" section of subpart A of the regulation states, "the purpose of this part is to prescribe procedures and requirements for the certification of respirators for use in mines and mining." 52 Fed. Reg. 32,405 (August 27, 1987).

Read alone, this provision might lead the reader to believe that the testing requirements were applicable only to respirators intended for use in mines and mining. However, a reading of the full set of proposed rules makes evident NIOSH's intention that all respirators intended for use on the job meet its proposed testing requirements. The final regulation section 84.1 should be revised to clarify this regulatory intention.

However, the manufacturers' complaint is not that the "purpose" provision understates the intended coverage of the rules; their objection is that all respirators, even if not intended for use in the mines, would have to be tested under mining conditions. This objection is spurious; the proposed regulations, read as a whole, make clear that NIOSH will not require all manufacturers to test their respirators in mines or mining. The only manufacturers who may be required to perform such testing are those manufacturers who market respirators used for that purpose.

requires that "[w]orkplace or simulated workplace evaluation of respirator performance shall be conducted so as to determine the distribution of workplace protection factors or simulated workplace protection factors that are measured in workplaces or in simulated workplaces and in work conditions that are reasonably representative of the places and conditions in which it is anticipated the respirator will be used." 52 Fed. Reg. 32,408. As the manufacturers remind us, those respirators used in mines or mining comprise only about 5 percent or so of the market. Manufacturers of the remaining respirators will have no obligation to test them under mining conditions; they need only test the respirators under conditions reasonably representative of those under which the respirator is likely to be used.

Moreover, to allay any manufacturer confusion over an incomplete reading of the regulation, on January 20, 1988, NIOSH issued a clarification explaining that its intention was not to require that all respirators be tested in mines. NIOSH recognized that industrial worksites also routinely expose employees to gases, vapors, dusts, mists, explosions and oxygen deficiency and that those sites are "equally appropriate test sites for the required workplace testing," 1/2 as to respirators

^{1/}NIOSH Statement for the Record, January 20, 1988, Informal Hearings, Notice of Proposed Rulemaking, 42 C.F.R. Part 84.

not intended for use in the mining industry. In light of NIOSH's formal clarification, the respirator manufacturers' quibbles on this score are meritless.

Costs of Compliance and Noncompliance

David J. Kolander, the Marketing Director in the Health and Safety Division of 3M, the company that dominates the respirator manufacturing market, represented that he would recommend to 3M that they ultimately withdraw from the respirator market. The proposed changes, he averred, would make respirators so expensive that demand would drop precipitously, making respirator production unprofitable for 3M. He raised the specter that an adequate respirator standard would leave no American company manufacturing the necessary respirators.

Mr. Kolander's testimony ignores the plethora of health and safety regulations that require employers who engage in certain industries to provide respirators for their employees. It is unlikely that these industrial employers would choose to abandon their businesses because respirators became more expensive. Failing that, the demand for respirators is unlikely to be significantly influenced by a minor increase in price. Assuming 3M is economically rational, it will simply pass a modest cost increase on to its respirator purchasing consumers, industrial manufacturers.

Industrial employers are concerned about tort litigation brought by employees who find that they have contracted illnesses from exposure to workplace poisons, exposure that could have been prevented if the employees were properly protected. Additionally, manufacturing employers are concerned about rising workers' compensation insurance costs, costs that could be contained if the employees were using respirators that operated effectively on the site.

If manufacturing employers had the choice of spending more on fully functioning respirators instead of trying to keep up with rising insurance and litigation claims, employers would choose to buy respirators that operated properly. 3M's argument that demand would cease is economically irrational.

Finally, 3M would do well to be concerned about its own exposure to products liability claims. The proposed NIOSH regulations will help 3M to minimize these risks from its business.

Feasibility of the Assigned Protection Factor Test

The proposed rule sets the assigned protection factor so that, for example, a class of respirators with a workplace protection factor of 25 would be expected to provide workplace protection factors in excess of 25 for at least 95% of users. Sec. 84.32(b)(2), 52 Fed. Reg. 32408. 3M argues that the

proposed rule requires that, during analysis of the workplace protection factor data, "95% of the test subjects must achieve a workplace protection factor in excess of the stated assigned protection factor with 95% confidence." They argue that "there is too much variability in the test methods to require the use of confidence intervals. When the confidence interval is added to the prediction, no field test performed to date indicates any tested respirator can meet its assigned protection factor." (3M letter to Customers and Distributors, October 9, 1987)

3M misses the point of the proposed regulations. The regulations are designed to accomplish truth in advertising, so that respirators in fact will function at the safety levels for which they are advertised. Moreover, the regulations are intended to ensure that the central objective of the Occupational Safety and Health Act, that every worker be provided with a safe and healthful workplace, is met. If 3M's respirators do not meet the proposed testing standards, they will not suffice to provide the degree of safety regulators intended to provide workers in establishing respirator standards.

The proposed regulations require the manufacturer to advertise the level of protection the user may realistically expect from the respirator manufacturer's product. Suppose, for instance, the assigned protection factor of a respirator is labelled ten, but using the new criteria set forth in the

proposed regulations, the protection factor would be only six. A substantial number of employees using that respirator will be exposed to a much greater risk of harm than they or their employer have been led to expect based on the respirator ratings; the employees receive significantly less protection than the regulatory scheme was designed to provide them. Moreover, those employers who provide the respirators for their employees are presently unable to make an informed choice about the respirators they purchase and employees are unaware of the risk to which they are exposed. The proposed regulations will eliminate these problems by requiring accurate testing and certification ensure that workers and employers obtain the degree of protection they are paying for. In addition, under the proposed regulations, respirators may be certified for higher levels of protection than the regulatory minimum. Employers will then be able, as intelligent consumers, to pay a little more and assure a greater degree of protection for their workers; unions will be able to bargain with employers for the provision of protective respirators on the job.

For example, in the construction industry, workers who install asbestos-cement sheets have a current exposure level to asbestos at the rate of 2.0 Mf/m³. The respirator manufacturer claims that wearing the respirator the manufacturer has labelled as having an assigned protection factor of ten will reduce within

the mask the exposure level to a worker wearing the mask to 0.2 Mf/m³. However, according to the proposed NIOSH rule, the actual protection factor is 6. This means in reality, the worker wearing the mask is being subjected to a higher exposure level; the worker's actual exposure level would be 0.33 Mf/m³. OSHA regulations limit exposure to 0.2 Mf/m³. The advertised protection level of the respirators would leave workers within OSHA standards. The actual protection level of the respirators, however, leaves asbestos sheet workers exposed to levels above OSHA standards. Thus, 1,765 asbestos sheet workers wearing the mask would not be protected at levels deemed safe.²/

Asbestos workers are not getting the protection they believe they are. More of those workers will develop asbestosis as a result of continued exposure to a known hazard substance. They, and their employers, will foot the bill for respirator manufacturers' failure to accurately assess the effectiveness of their products. Workers in other industries—cotton dust, benzene, and lead, for example—will suffer similar harms, contracting at a greater rate irreversible neurotoxic illnesses, lung, and kidney disease.

^{2/}These statistics were derived from statistics found in Table 2.1 of the Hattis report, Health Benefits and Costs of Supplementary Measures to Improve Compliance with Workplace Exposure Limits for Asbestos in the Construction Industry, prepared by Dale Hattis, July 1984.

The current situation is actually worse than mere overstated safety claims for respirators. In point of fact, scientists have been unable to demonstrate any relationship between the laboratory fit factors and workplace performance factors. 3/ Therefore, present assigned protection factors are at best mere guesses. The NIOSH Guide to Industrial Respiratory Protection warns that at present assigned protection factors "should not be considered reliable predictors of performance levels that will be achieved during the actual use, since APF's are not based on a sufficient amount of workplace testing."4/

Since July, 1982, when NIOSH began to investigate respirator problems through audits and notifications from users and manufacturers, they have received at least 215 reports of problems with respirators. Those reports include information about 15 employees who were wearing respirators when they died. 5/As the regulations presently stand, both employees and the employers who purchase respirators are unable to make an informed choice about the reliability of the product because the testing

^{3/}Bollinger and Schultz, NIOSH Guide to Industrial Respiratory Protection, U.S. Dept. of Health and Human Services (1987), at 200.

^{4/}NIOSH Guide at 200.

^{5/}Bollinger and Schultz, NIOSH Guide to Industrial Respiratory Protection, U.S. Dept. of Health and Human Services (1987), at 128.

and certification procedures are ineffective. NIOSH must be allowed to revise those procedures in the interest of those people who bear the consequences of faulty, improper equipment—the employees who must labor in the fields, factories, and mines and suffer potential death and respiratory related diseases.

Test Protocol

The respirator manufacturers argue that they are being denied their due process right to comment because the final test protocol was not issued simultaneously with the proposed rule. They ask that the rule be withdrawn and reissued when NIOSH is prepared to issue the protocol. As the rule currently stands, however, interested parties will be given the opportunity to comment on the proposed test protocol after it has been issued.

The respirator manufacturers claim that they are unable to comment on the rule as it stands now because they are unaware of what the test protocol will require; these contentions are disingenuous at best. Respirator manufacturers' representatives, including Thomas J. Nelson, representative of DuPont and former chairman of the ANSI Z88.2 committee, and Donald Wilmes, representative of 3M and of the Industrial Safety Equipment Association, were members of the peer review panel that discussed the feasibility of NIOSH's proposed test protocol. Even if the manufacturers are unaware of every detail of specific changes in

the protocol, they are certainly aware of the parameters of the protocol and its basic aims. Furthermore, as members of the peer review panel that reviewed the NIOSH proposed test protocol, manufacturers were allowed to participate in the evolution of the protocol itself. Given their substantial input into every segment of the regulatory process, the respirator manufacturers are in a poor position to plead denial of due process.

Conclusion

The Occupational Safety and Health Act states that it is NIOSH's responsibility to carry out the purpose of the OSH Act. As stated in 29 U.S.C. § 651(b)(7), one purpose of the Act is to provide "medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience." Another purpose of the Act is to "preserve our human resources . . . by encouraging joint labor-management efforts to reduce injuries and disease arising out of employment." 29 U.S.C. § 651(b)(13).

NIOSH's proposed rule accomplishes both of those purposes. In calling for more accurate representation of the amount of protection a worker can expect to get when he or she uses a respirator, NIOSH is attempting to reduce the incidence of diminished health, life, or functional capacity. The focus on

workplace testing encourages joint labor-management efforts to reduce disease arising out of employment in industries where workers are required to wear respirators to protect them from their environment.

NIOSH's proposed rule is an improvement upon the current regulation because it focuses on actual hazards that confront the employee in the workplace, rather than hypothetical possibilities formulated in unrealistic testing environments. Current evidence is highly uncertain about correlation between current respirator testing procedures and the actual level of safety provided on the job. Under the circumstances, the NIOSH proposal is essential if the statutory mandate is to be fulfilled. The proposed rules must be made final so that respirators can be tested to assure that the fewest possible number of workers have their working lives cut short by irreversible respiratory disease.