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Human Resources Policy

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BY HAND

The Docket Office
Docket No. H-409
U.S. Department of Labor
Occupational Safety & Health Administration
Room N-2625
200 Constitution Avenue, Room N2625
Washington, DC 20210

COMM
DOCT
DATE 4/14/95

Re: Docket H-049, Respiratory Protection, 29 C.F.R. § 1910.134

Dear Docket Officer:

The National Association of Manufacturers (NAM) is pleased to submit its views and comments on the proposed revisions to the Occupational Safety and Health Administration's (OSHA) respiratory protection standard. The NAM supports the revision of OSHA standards when there is a demonstrated need, and where the changes eliminate unwieldy specification standards in favor of standards expressed "in terms of the performance desired based on objective criteria." OSHA's proposed revisions to the respirator standard meet this criterion in some ways, but in many others retreat to specifying -- and thereby limiting employer flexibility -- the details of a singular compliance program for respiratory protection.

I. NAM MEMBERS ARE AFFECTED BY THE PROPOSED RESPIRATOR STANDARD.

The National Association of Manufacturers (NAM) is a voluntary business association of more than 13,000 member companies and subsidiaries, large and small, located in every state. Members range in size from the very large to the more than 9,000 smaller manufacturing firms, each with fewer than 500 employees. The NAM member companies employ 85 percent of all workers in manufacturing and produce more than 80 percent of the nation's manufactured goods. The NAM is affiliated with an additional 185,000 businesses through its Associations Council and the National Industrial Council.

Many of NAM's members use respirators in the course of their daily operations, both to protect employees from exposure to air contaminants which cannot be controlled by engineering or administrative controls, as well as for purposes related to comfort and convenience. The NAM members are concerned about the application of a mandatory

standard that is overly rigid and specific. In addition, the NAM members maintain that regulations should be based upon sound scientific knowledge, methods, and practices.

II. THE PROPOSED STANDARD IS NOT A PERFORMANCE-ORIENTED STANDARD, AND SHOULD BE REVISED TO ESTABLISH OBJECTIVE CRITERIA IN TERMS OF THE PERFORMANCE DESIRED.

OSHA has proposed revising the respirator standard by specifying in far greater detail what is necessary to comply with the OSH Act. The requirements of the standard should be as flexible as possible and should be limited to that which is necessary for each employer to have an effective respiratory protection program. An effective program is one which eliminates the significant risks to employees exposed to airborne hazardous substances in the most cost-effective manner. For example, OSHA specifies the frequency of training, fit testing, cleaning and disinfection, and other precise actions an employer is obligated to take. It appears that OSHA has abandoned the performance-oriented mandated approach mandated under Section (6)(b)(5) of the statute.¹ This provision requires that OSHA adopt standards which describe the "performance desired in terms of objective criteria" where practicable. OSHA asserts in the proposed rule that the provisions are performance-oriented. However, many proposed requirements are set forth in specification language when objective, performance-based criteria would be adequate, and would allow employers the flexibility needed to ensure cost-effective compliance and to avoid stifling innovation.

Examples of this unnecessary and counter-productive specificity abound. OSHA proposes in paragraph (d)(2) to require that employers provide at least three different face pieces from at least two manufacturers during fit testing when elastomeric face pieces are used. OSHA believes -- *incorrectly in our opinion* -- that

nothing in the course of respirator use is more important than achieving the best possible fitting respirator and that this is only possible where an adequate selection is available. Availability of different sizes and types of respirators during retesting is especially critical where the employee's physical conditions may have changed as the result of a modest weight change or changed facial configuration due to surgery or dental work, which may affect respirator fit. [Emphasis added].

The OSHA's assertion that the "best possible fit" is required is simply incorrect. OSHA ascribes too much accuracy and precision to what is more art than science. The objective of fit testing is to obtain an adequate fit, one that can be repeatedly obtained and can be verified by a fit check when donning and periodically when wearing the respirator.

¹ 59 Fed. Reg. 58886, November 15, 1994.

First, fit cannot be measured with a degree of precision that warrants distinguishing between face pieces from different manufacturers for individual wearers. Only gross differences, as measured by failure in the fit test, can be detected. Thus, it becomes more a question of comfort for the individual user rather than of optimum fit, and arguably, the fit testing data presented by OSHA in the preamble do not distinguish between comfortable respirators providing optimal fit in contrast to uncomfortable respirators providing an inadequate fit.

Second, the present approach to selecting the assigned protection factor for a particular class of respirators incorporates a substantial margin of safety. Basically, the method used is to test, under a fixed, known set of conditions, a large group of respirator users. The testing is designed to measure the quantitative reduction in concentration that a particular respirator provides to a particular user. The data are then ranked according to the measured protection factor, and a value is selected to be assigned to that particular class of respirator. The value selected is that which assures that only a small proportion of users will not be able to routinely achieve a degree of protection equal to the assigned protection factor. Most researchers suggest that the 95th or 90th percentile be the cut off for selecting the assigned protection (*i.e.*, fit) factors for a particular type of respirator. That is, most of the time 90 or 95% of tested users will have a measured protection factor of at least the value assigned to the class.

This provides a large margin of safety for the vast majority of users. Assuming that the distribution of fit factors is normally distributed in a given population, and that the mean and standard deviation of fit factors measured for the group are, for example, 75 and 25 respectively, half of users will achieve protection factors in excess of 75, and 80% will exceed protection factors of approximately 25. If the respirator is given an assigned protection factor of 10, as in the case of half-mask air purifying respirators, a large percentage of workers will have substantially more protection than indicated by the assigned protection factor. If the fit test adequately identifies those who do not achieve an adequate fit, then those individuals will also be protected. In other words, most users will receive a fit that reduces exposure during use far below the so-called hazardous exposure level, *i.e.*, that which is necessary to protect the user's health.

A. Fit Test Methods

With regard to fit test methods, OSHA has commendably asked for comments on the performance criteria that should be used to evaluate new fit test methods. Appendix A lists the specific fit test methods that are acceptable and the criteria that will be used to submit future fit test methods to notice and comment rulemaking. Rulemaking on new fit test methods is unnecessary. OSHA should publish the criteria for acceptability of fit test methods and include a provision in the standard that the employer must demonstrate that his fit test method is equivalent.

There is no need for OSHA to go through even an informal rulemaking to adopt as "equivalent" any particular fit test method, nor would there necessarily be any person other than the proponent of the new method that would have any factual information on the efficacy of a particular fit test method. Publication of the data in a peer-reviewed journal should be *prima facie* evidence that the method has been validated, and if OSHA publishes the criteria used to judge the validity of the methods, employers will be able to adopt -- and, more importantly, demonstrate the validity of -- new fit test methods without the cumbersome and unnecessary process of rulemaking envisioned by the proposal.

These two examples simply illustrate the fact that the proposal does not meet the statutory requirement requiring performance oriented language and objective criteria. OSHA should redraft the proposal to eliminate to a much more significant degree the specification requirements and repropose a standard that meets its statutory mandate.

III. THE STATED PREFERENCE FOR ENGINEERING CONTROLS SHOULD NOT BE INCLUDED IN THE RESPIRATOR STANDARD.

OSHA has retained the so-called hierarchy of controls language in paragraph (a) which describes the scope of the proposed standard. With respect to that language, OSHA has stated that

[t]his provision of the standard is not a subject of this rulemaking; only issues relevant to the content of a respirator use program are to be addressed at this time. OSHA is reviewing § 1910.134(a)(1) and similar hierarchy of controls provisions contained in § 1910.1000 in a separate rulemaking.

However, NAM has significant concerns about the continued inclusion of this provision, coupled with the proposed definition of the term, "hazardous exposure level." NAM is concerned that the respiratory protection provisions could be used to create an enforceable standard out of employer-established voluntary exposure criteria. Implicit in this provision is the requirement that engineering controls would have to be used to reduce airborne concentrations of substances which do not now have Permissible Exposure Limits (PELs). This provision should be deleted from the respiratory protection standard unless interested parties have the opportunity to comment on it and OSHA demonstrates that it should be retained by satisfying the applicable legal criteria under Sections 3(8) and 6(b) of the OSH Act.

IV. ANNUAL MEDICAL EVALUATIONS SHOULD BE LIMITED TO THOSE RESPIRATOR USERS WHOSE EQUIPMENT CREATES A HEALTH RISK DUE TO BREATHING RESISTANCE OR INCREASED METABOLIC LOAD.

In regard to paragraph (e) on medical evaluation, OSHA asked for comment on whether and what kind of medical evaluations should be provided to respirator users. NAM

believes that the current standard adequately describes the obligations of the employer in this regard. Both the frequency and content of medical examinations are the responsibility of the employer. Although OSHA asserts the need for annual evaluations, OSHA has cited no data, other than "compliance experience," to show what the frequency should be. One conclusion that can be drawn from the experience of the health care industry over the last 20 to 30 years is that requirements for periodic medical services increases costs, and that, without a specific demonstrable need -- expressed in terms of a specific risk factor or pre-disposing condition -- such expenditures do not provide a commensurate benefit.

Before OSHA imposes a blanket requirement for annual medical evaluations for all or any subgroup of respirator users, it should be able to point to specific cases or conditions where the lack of such surveillance led to injury or illnesses due to the use of the particular type of respirator. In other words, to be reasonably necessary, the provisions for medical evaluation (and any other provision) must be directed at preventing a real risk to health, not a hypothetical possibility based on unsupported "expert" opinion and anecdotal testimony; the provisions should be based on scientific evidence. And scientific evidence should be judged by government agencies as to its relevance and reliability on the same basis as courts require.

A. The Type and Degree of Medical Evaluation Should Be Left To The Discretion of The Physician.

Detailed specifications for medical evaluations stifle developments in medical evaluation, management, and treatment. OSHA is not qualified to delimit medical practice in this fashion. What constitutes the generally accepted standard of care in any given period changes as medical science advances. OSHA's rulemaking process is too cumbersome and slow for such details to be specified in a standard. The standard will rapidly become outdated and could, if the standard of care changed rapidly enough, become a source of medical malpractice litigation.

Physicians are subject to other pressures to assure that they take appropriate steps to protect the respirator users in their care. Legal liability for medical malpractice has been driving the practice of medicine steadily for more than thirty years. There is no reason to believe that physicians engaged in occupational health practice are any more immune from these pressures than other physicians and medical personnel. Physicians have obligations to keep abreast of the technology and standards of medical practice in a way that no amount of regulatory oversight can impose. Thus, physicians are far better situated to decide what the appropriate content and frequency of medical evaluation of respirator users should be at any given time, in the context of the prevailing medical opinion of occupational health practitioners.

OSHA should, therefore, leave the frequency and content of medical evaluations of respirator users to the discretion of the physician. OSHA can enforce this requirement by

simply requiring that the employer obtain the physician's certification of the frequency and content of the evaluations along with a certification that the physician has based his or her opinion on the contaminants to which the employee is exposed, the type of respirator to be used, the frequency and duration of use, and the work to be performed while wearing the respirator as well as any other personal protective equipment.

Before a requirement for an annual physical can be shown by OSHA to be appropriate, OSHA must be able to conclude from the evidence in the record that an annual medical evaluation is required and that a physical examination is an essential component of that evaluation -- *i.e.*, that it is necessary to mitigate the anticipated risk. Hypothetical risks reduced by some unknown but hypothetical amount or degree do not satisfy OSHA's statutory criteria.

V. THE COSTS FOR THE PROPOSAL ARE SIGNIFICANTLY UNDERESTIMATED OVER CURRENT PRACTICE.

OSHA estimates that the annualized incremental costs for compliance with the proposed revised provisions of the respirator standard will be \$106.8 million with benefits totalling \$79 million. NAM believes that OSHA grossly underestimates the cost of compliance. Data from some members suggests that the employee time required to comply with the requirements for daily cleaning and inspection (after daily use), training, and annual fit testing would be approximately 127 hours per year for each employee (30 minutes per day for cleaning, disinfection, and inspection, one hour annual fit testing and training, and one hour annual medical examination). Costs associated with maintaining a supply of multiple respiration brands and sizes are estimated to be \$50 per employee per year, while the costs for medical evaluation alternatives 1 and 2 are estimated to exceed \$100 per employee per year.

OSHA's own estimates show that the training and qualitative fit testing requirements constitute over half the annual cost. Costs associated with requiring multiple face pieces for selection of respirators increases the proportion attributable to these three provisions to nearly 85% of the total estimated cost.

Using OSHA's estimate of 1.1 million affected employees who wear respirators "routinely," and an average direct and indirect hourly labor cost of \$20, and assuming "routinely" means "daily," NAM estimates that the costs associated with daily cleaning and inspection, training, and annual fit testing would total \$2,540 per employee, or \$2.7 billion. The costs for employees who wear respirators occasionally, assuming that on average these employees wear respirators 2 times per week, are expected to total \$1,040 per employee (\$20 * 50 hours maintenance + 2 hours for the annual medical evaluation, training and fit testing). Based on OSHA's estimate of 1.9 million occasional users, the annual costs for the proposed provisions would be \$1.98 billion. Costs for stocking multiple respirator brands would total \$180 million. Finally, the costs of the proposed medical evaluations would total

\$360 million. Assuming that OSHA's estimate of the number of employees is correct, and even assuming, for the sake of argument, that the previously-discussed time estimates for cleaning and inspection provided by our members are not representative of all industries, and overestimate the time needed to perform those tasks by a factor of 2 or even 10, it is clear that the costs estimated by OSHA in its Regulatory Flexibility Analysis are, at best, inadequate. OSHA should reexamine its estimates and produce a more realistic cost picture to determine the economic impacts of this proposed rule.

VI. THE RECORDKEEPING REQUIREMENTS ARE NOT REASONABLY NECESSARY OR APPROPRIATE.

OSHA's proposal would require employers to maintain detailed records of medical evaluations, training, and OSHA is considering requiring detailed records for fit testing for each covered employee. These records and costs are not necessary for compliance purposes. OSHA has made significant use of employer certifications in recent standards to reduce the costs of complying with recordkeeping provisions. See the recent rulemakings on Personal Protective Equipment (PPE), Fall Protection in Construction, and Logging. While we believe that these types of certifications are a form of recordkeeping under the Paperwork Reduction Act, the burden of compliance is substantially less than the burden associated with a full-blown recordkeeping system requiring documentation of each and every required action of the employer. The Agency's mission is to provide employers with the information necessary to establish an effective respiratory protection system and not to create compliance obligations whose sole purpose is to make it easy for the Agency to identify and bring successful enforcement actions against employers who are wholly out of compliance. A certification requirement in the respirator proposal would be adequate and satisfy OSHA's administrative need for a written record to demonstrate compliance, while limiting the burden on employers to that which is reasonably necessary. OSHA should adopt a certification provision similar to those in the fall protection and logging standards. The certification should require an employer to keep a written certification which includes the name of the covered employee, the date of the certified event, the nature of the obligation covered, and the signature or initials of the person making the certification. Such certifications shall be made available to the Assistant Secretary of Labor on request. The certification requirement should contain an appropriate "grandfather" provision and should allow for an alternative to initials or signatures where electronic records are used.

Indeed, it could be argued that OSHA is obligated to limit the recordkeeping requirements to these certifications, for it has already determined that such certifications are adequate for other kinds of personal protective equipment. In accordance with presidential policies regarding new regulatory initiatives and review of existing regulations, NAM believes that OSHA must adopt the most cost-effective approach to recordkeeping and require only that necessary to accomplish its regulatory mandate. Section 8(d) of the OSH Act imposes some limitations on the recordkeeping requirements the Secretary of Labor adopts. A certification system, appropriately approved by the Office of Management and Budget

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under the Paperwork Reduction Act, would, in NAM's view, more than adequately satisfy OSHA's needs, and limit the impact on employers.

No other requirements are necessary for OSHA to ascertain the compliance status of an employer. Verification of the certification can be accomplished by the same methods OSHA now uses to verify hazard communication training and similar requirements. The respirator standard should be rewritten to adopt this same approach.

VII. SUMMARY

NAM generally supports standards which contain objective measures of compliance while providing flexibility in the means of achieving the standards' goals. The proposed respirator standard unfortunately does not meet this criterion, which Congress imposed on the Agency in its grant of legislative authority to adopt health standards. OSHA should revise the proposal to remove the specifications that limit innovation and cost effective compliance, and should repropose the standard for public comment.

We trust you will find that these comments are constructive and assist OSHA in developing an appropriate and effective respirator standard. Should any of OSHA's reviewers have any questions, or if we can be of assistance in any other way, please do not hesitate to contact us.

Sincerely,



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