

National Place, Suite 911  
 1331 Pennsylvania Avenue, N.W.  
 Washington, D.C. 20004  
 202-737-6330

RECEIVED  
 1987 DEC 28 AM 10: 15

NIOSH



Organization Resources  
 Counselors, Inc.

December 15, 1987

Director  
 Division of Safety Research  
 NIOSH  
 944 Chestnut Ridge Road  
 Morgantown, West Virginia 26505

Dear Sir:

Organization Resources Counselors, Inc., (ORC) is pleased to submit comments to the National Institute for Occupational Safety and Health and Centers for Disease Control (CDC) Public Health Service, on the Notice of Proposed Rulemaking for Revision of Tests and Requirements for Certification of Permissibility of Respiratory Protective Devices, published in the Federal Register (52 FR 32402).

Organization Resources Counselors Inc. sponsors an Occupational Safety and Health Group which is comprised of more than 75 companies from a wide range of industries and with employment size ranging from medium to large. All of these companies have a strong commitment to employee safety and health. The members of this Group work with ORC on OSHA rulemaking activities and other aspects of employee safety and health. This statement is, however, solely the responsibility of ORC and may differ from comments submitted by member companies.

ORC supports a strong and active role for the Federal government in the testing and certification of respiratory protective devices used by all sectors of the American working population. Respirators are an important source of protection for those individuals who may, in the course of their employment, be exposed to potentially toxic airborne substances. It is vital that the respiratory protective devices used by all workers be as safe and effective as modern science can make them. An effective testing and certification program for respirators, run by an agency of the Federal government, can give assurance to employers and workers alike that their respirators have, at the least, passed certain minimum standards for quality and performance.

ORC believes that respirators should not be the first or only means of worker protection considered, but rather should be one part of an integrated and comprehensive safety and health program.

RECEIVED  
 87 DEC 18 PM 1:40  
 OD, DSR, NIOSH



In any evaluation of ways to deal with potential workplace hazards, engineering controls should always be the first consideration. Every workplace is, however, unique, and often engineering controls are not feasible or practical. When this is the case, work practice controls, the use of respirators and administrative controls, all have an important role to play in reducing employee exposure to health and safety hazards in the workplace.

Most employers are neither large nor sophisticated, and their understanding of potential health and safety problems in the workplace is as limited as the resources available to deal with them. For this less sophisticated employer, respirators are often the most important protection for employees potentially exposed to airborne toxic substances. For these employers, the availability of reliable, effective, properly tested and certified respirators is especially important. Large corporations often have the resources to properly evaluate the available respirators and choose those appropriate to their need. For employers with fewer resources, the selection of an appropriate respirator can be a difficult task.

Therefore, ORC believes it is imperative that those in the Federal government with responsibility for managing the nations health and safety resources take seriously the task of assuring that safe and effective respirators are available to all employers and employees. ORC and its member companies have worked for many years to encourage and assist the development of effective testing and certification programs by agencies of the Federal government.

We believe it is unacceptable for NIOSH to abandon the testing and certifying of respirators for general industry. NIOSH has a responsibility to this nations working men and women, and what it is proposing to do is an abdication of its responsibility.

The following comments address some of the specific issues raised by NIOSH's Notice of Proposed Rulemaking on the testing and certification of respirators.

#### **Limiting Testing and Certification Activities To Only Those Respirators Used In Mines and Mining.**

ORC believes that limiting the testing and certification of respirators to only those used in mines and mining, as stated in the proposed revision of 30 CFR 11, is irresponsible and an abdication of NIOSH's duty to protect the safety and health of workers. The great majority of respirator users in this country are found outside of the mining industry. These individuals deserve to have available respirators that have been adequately tested and certified, **under conditions related to those they will experience in their own workplace.**



Given the importance of an effective respirator testing and certification program to this nation's working population, ORC requests that NIOSH withdraw its Notice of Proposed Rulemaking and, in cooperation with the Occupational Safety and Health Administration and the Mine Safety and Health Administrations, reconsider its approach.

### **Economic Impact of This Proposed Regulation**

The economic impact of this regulation on employers will almost certainly be greater than \$ 100 million dollars for the following reasons:

- \* When present certifications run out, virtually no respirator in service will meet the proposed requirements. This will force many employers to purchase all new equipment and restructure their training and maintenance programs; all at great additional expense.
- \* The new requirements for certification have the potential to eliminate all but the very largest respirator manufacturers from the business. This lowered competition can quickly lead to increased prices for respirators of all kinds.
- \* The procedures outlined by the proposed rule are complex and difficult and will result in increased costs to those manufacturers which survive. These costs will in turn be passed on to the end user, sharply increasing the costs of every respirator program.
- \* NIOSH's proposed rule requires that all workplace testing be done in mines or mining operations. At the present time there are relatively few mines operating in this country. If all respirators being certified must undergo field testing in working mines, it would impose a heavy burden on existing mines.
- \* Because of the inability to purchase certified respirators designed to protect against the hazards found in workplaces in general industry, the legal liability incurred by the employer could greatly increase. Increased legal liability can quickly translate into increased costs, not the least of which would be insurance. The end of the certification process as we know it today may eliminate the ability to employ respiratory protection at all, leaving as the only option, the use of engineering controls.



\* Lacking incentive to produce respirators designed to protect against specific problems found in general industry, some manufacturers will greatly reduce the range of respirators produced. Many employers will be forced to use respiratory protective equipment supplying less than optimum performance. This practice could result in an eventual increase in worker exposure and ultimately, illness. This could result in significant cost increases to the nations employers, not to mention pain and suffering to many workers.

#### **Requirement to Comply with HHS Policy for Protection of Human Research Subjects.**

This proposal requires that any testing carried out under these proposed regulations must meet the requirements of the Department of Health and Human Services for Protection of Human Research Subjects as discussed in 45 CFR Part 46, Subpart A. This is an extremely involved and complex regulation, and to comply with its many requirements would result in a large paperwork burden. This in turn would delay the certification process, increase costs to the manufacturer, and ultimately the user.

This procedure was developed for the testing of new drugs, vaccines and medical procedures that entail unknown and potentially large risks. The kind of testing that NIOSH proposes to require industry to perform entails little if any additional risk to the field test subject beyond that associated with the individual's normal employment. Respirator fit testing involves virtually zero incremental risk for the individual. It could be argued that the potential for improved respirator performance associated with fit testing actually results in an incremental decrease in the risk associated with an individuals normal employment.

ORC recommends that if NIOSH believes that the tests that it proposes to require of industry are in fact dangerous, it should itself submit its field and fit test procedures to HHS for approval.


#### **Self Certification Provisions**

For a respirator certification process to have any ultimate utility, it must be trusted by those using the respirators. Historically, workers have demonstrated a greater trust in the regulatory activities of the Federal government than in the self-regulation of industry. ORC believes that industry must not be directly involved in the certification process for respirators if it is to have the requisite trust of the ultimate end user, the worker who must wear the respirator.



There are other effective approaches that can work to solve this problem. NIOSH, OSHA, the respirator manufacturers, and the American National Standards Institute should work together to develop effective protocols for the testing and certifying of respirators that can retain the trust of employers and employees alike.

Sincerely

A handwritten signature in blue ink that reads "Richard F. Boggs". The signature is written in a cursive style with a large, looped "B" at the end.

Richard F. Boggs, Ph.D.  
Vice President

RFB3:lgs