TESTIMONY OF
ORGANIZATION RESOURCES COUNSELORS INC.

At The NIOSH Public Meeting
On Proposed 42 CFR Part 84

January 28, 1988
Washington, D.C.

I am Richard F. Boggs, Vice President, Organization Resources Counselors Inc. This testimony supplements the written comments submitted to the NIOSH Director, Division of Safety Research, on December 15, 1987.

Organization Resources Counselors, Inc., (ORC) is pleased to present this testimony to the National Institute for Occupational Safety and Health regarding 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., (ORC) sponsors an Occupational Safety and Health Group which is comprised of more than 75 companies from a wide range of industries and with employment sizes 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 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 individual 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 be exposed, in the course of their employment, 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 passed at least 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.
In any evaluation of ways to deal with potential workplace hazards, engineering controls should always be the first consideration. Every workplace is unique, however, 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 usually have the resources to properly evaluate the available respirators and to choose those appropriate to their needs. 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 who have responsibility for managing the Nation’s 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. For NIOSH to abandon the testing and certifying of respirators for general industry is unacceptable. NIOSH has a responsibility to this Nation’s 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 a basic 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 respirators that have been adequately tested and certified under conditions related to those they will experience in their own workplaces.
Given the importance of an effective respirator testing and certification program to this Nation's working population, ORC requests that NIOSH repurpose its Notice of Proposed Rulemaking and, in cooperation with the Occupational Safety and Health Administration and the Mine Safety and Health Administration, reconsider its approach.

ORC is pleased to note that NIOSH, as evidenced by its Statements for the Record, issued on January 20 and 27, 1988, has decided that it is inappropriate to limit 42 CFR Part 84 only to those respirators used in mines and mining. However, when NIOSH refers to comments expressing concern with its narrow focus on mines and mining as being an "apparent misinterpretation of the proposal..." (page 2, para. 1), ORC must disagree with NIOSH.

ORC believes that NIOSH, in its Federal Register notice (52 FR 32402) of Thursday, August 27, 1987, has been very clear and consistent in its narrow focus on mines and mining. To understand some of the reasons why ORC believes 42 CFR Part 84 was, and is, directed toward mines and mining, it is useful to examine the exact language in 42 CFR Part 84 (52 FR 32402).

Page 32402, Summary, middle of column one:

"REQUIREMENTS AND TESTS ARE INCLUDED FOR NEW TYPES OF RESPIRATORS USED IN MINES AND MINING; NEW AND REVISED REQUIREMENTS AND TESTS ARE INCORPORATED WHICH MORE COMPLETELY ADDRESS MINE AND MINING CONDITIONS AND THEIR EFFECTS ON RESPIRATORS; AND ADMINISTRATIVE CHANGES ARE INCLUDED WHICH WILL GENERALLY IMPROVE THE RESPIRATOR TESTING AND CERTIFICATION PROGRAM"

Page 32402, Supplementary Information, bottom of column two:

"IN ACCORDANCE WITH THE MINE SAFETY AND HEALTH AMENDMENTS ACT OF 1977 (30 U.S.C. 842(h) AND 957) WHICH HAS BEEN ENACTED FOR THE PURPOSE, IN PART, OF DEVELOPING AND PROMULGATING IMPROVED MANDATORY HEALTH OR SAFETY STANDARDS TO PROTECT THE HEALTH AND SAFETY OF THE NATION'S COAL OR OTHER MINERS, THE ISSUANCE OF CERTIFICATES OF APPROVAL FOR RESPIRATORS IS LIMITED TO ONLY THOSE RESPIRATORS USED IN COAL OR OTHER MINES."

Page 32405, Subpart A-General Provisions, Section 84.1 Purpose:

"THE PURPOSE OF THIS PART IS TO PRESCRIBE PROCEDURES AND REQUIREMENTS FOR THE CERTIFICATION OF RESPIRATORS FOR USE IN MINES AND MINING."
Page 32406, Section 84.3 Definitions:

"RESPIRATOR" MEANS ANY DEVICE WORN BY AN INDIVIDUAL ENGAGED IN MINING AND DESIGNED TO PROVIDE THE WEARER WITH RESPIRATORY PROTECTION AGAINST INHALATION OF A HAZARDOUS ATMOSPHERE."

"SIMULATED WORKPLACE" MEANS A SIMULATED ENVIRONMENT THAT IS A REASONABLE REPRESENTATION OF MINES OR MINING WORK SITES WITH REGARD TO CONTAMINANT EXPOSURES FOR [sic] WHICH A RESPIRATOR IS INTENDED TO PROTECT."

"WORKPLACE" MEANS ANY MINE OR MINING WORK SITE WITH REGARD TO CONTAMINANT EXPOSURES FOR WHICH A RESPIRATOR IS INTENDED TO PROVIDE PROTECTION."

ORC believes that the evidence of NIOSH's own words as published in the Federal Register is clear: NIOSH intended 42 CFR Part 84 to apply only to respirators used in mines and mining.

On page 3 of its January 20 and 27 Statements for the Record, NIOSH states [emphasis added]: "The terms "mines" and "mining" are not limited to underground mines" and further that "industrial worksites COULD therefore be equally appropriate test sites for the required workplace testing," and finally that "the alternative simulated workplace testing described in Section 84.32 COULD be based on these equivalent activities."

ORC has always understood that the purpose of a Notice of Proposed Rulemaking was to make clear the intent of the proposing agency. To assert, however, that a proposed regulation could mean, or could be interpreted to mean, something other than what it says, is to purposefully obscure the intent.

ORC believes that NIOSH's respirator testing and certification program should address the needs of general industry as well as the mining industry. Toward that end, ORC urges NIOSH to repurpose 42 CFR Part 84 and, in cooperation with OSHA and MSHA, to specifically address the needs of general industry for adequate respirator testing and certification programs.

Economic Impact of This Proposed Regulation

The economic impact of this regulation on the nations 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 reduced competition can lead quickly 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 who survive. These costs, in turn, will 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 the use of engineering controls as the only option.

* 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, increased incidence of illness. This could result in significant cost increases to the Nation's employers, not to mention increases in pain and suffering among 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 regulation 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 individual's normal employment.

**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. ORC recommends that NIOSH work with OSHA to explore the possibility of OSHA taking responsibility for the testing and certifying of respiratory protective equipment. Alternatively, NIOSH, the respirator manufacturers, and the American National Standards Institute can work together to develop effective protocols for the testing and certifying of respirators that can retain the trust of employers and employees alike.

In closing, ORC would like to recommend that NIOSH repose 42 CFR Part 84. In its repose, NIOSH should modify its narrow focus on mines and mining to specifically include the needs of general industry for an effective respirator testing and certification program, and respond positively to the many excellent recommendations it has received. In its modifications to 42 CFR Part 84, NIOSH should also make provisions for a three month comment period prior to the closing of the record.

It has taken more than ten years to reach this point on the revision of 30 CFR Part 11. It would be a great waste if through a lack of cooperation and communication, this opportunity to craft a superior respirator testing and certification regulation were to be lost.