DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute for
Occupational Safety and Health
Centers for Disease Control
Atlanta GA 30333

National Institute for Occupational Safety
and Health

Statement for the Record

January 27, 1988

Informal Hearings

Notice of Proposed Rulemaking
42 CFR Part 84

Revision of Tests and Requirements for Certification
of Respiratory Protective Devices

We are here today to solicit public comments on the proposal by the National Institute for Occupational Safety and Health (NIOSH) to revise tests and requirements used in certifying respiratory protective devices. The current regulation under which NIOSH tests and certifies respirators (30 CFR Part 11) was originally promulgated in 1972. During the last decade, there has been a growing consensus among respirator manufacturers and user communities that these requirements should be revised. NIOSH has, therefore, developed the current proposal (52 FR 32402) to reflect technical advances in the field and the more complex environments of today's workplaces. Most importantly, the proposal will provide respirators that are safer and more reliable. It will also permit innovation in respirator design since it is a performance-based rather than a specification-based standard.

In order to facilitate useful input at these hearings, NIOSH has conducted a preliminary review of the written comments received on the Notice of Proposed Rulemaking (NPRM). NIOSH would like to highlight several areas of apparent misinterpretation of the proposal which have been reflected in the comments received to date. This overview is intended to be helpful for those providing comments for the record. While these issues are not an inclusive listing of all the concerns raised, it would appear that some clarification by NIOSH would be helpful with respect to the following six issues:

1. **The Focus on "Mines" and "Mining"**

   The fundamental NIOSH regulatory authority for certifying respirators is derived from legislative mandates in the Mine Safety and Health Act of 1977 (30 USC 842(h), 844, and 957). Both the current certification regulation (a joint regulation between NIOSH and the Mine Safety and Health Administration [MSHA] under 30 CFR Part 11) and the prior **certification procedure (used before 1972 under the Bureau of Mines [BOM]) have as their basis the testing and approval--which began in 1919--of** respirators used in mining. Over the years, respirators approved by the BOM and the current NIOSH/MSHA procedure have gained wide acceptance and use outside the mining environment. They have been required by such regulatory agencies as the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), and the Nuclear Regulatory Commission (NRC). Although more than 95 percent of all respirators sold (certified by the present system) are not used in mines or mining, <u>all</u> the respirator models currently certified <u>are</u> used in mines and mining (with the sole exception of devices sold for protection against vinyl chloride).

The terms "mines" and "mining" are not limited to underground mines. Mining activities vary as widely in nature and scope as do other industrial activities. Routine exposures to gases, vapors, dusts, fumes and mists, and emergency exposures to fires, explosions, and oxygen deficiency are as possible in general industry as in mining. Industrial worksites could, therefore, be equally appropriate test sites for the required workplace testing. The alternative simulated workplace testing described in Section 84.32 could be based on these equivalent activities. **Thus, the argument that a "mines and mining" focus in the proposed regulation would result in respirators that are not suitable for other uses is no more true now than it has been since 1919. Indeed, a respirator intended for mining use is not particularly unique unless it is a respirator such as a powered air purifier that contains electrical components.** In the current regulation, these latter devices require additional approval from MSHA before use in underground mines is permitted because electrical components may ignite methane and cause explosions.

2. **Economic Impact of the Regulation**

In accordance with established regulatory procedures, NIOSH contracted for a study of costs associated with the proposed Part 84 regulations. A report, "Economic Overview of the Respirator Industry" (developed in Phase I of a two-phase project) was delivered to NIOSH in March 1982 and was circulated to all respirator manufacturers for review and comment. No comments were received. Phase II involved the development of questionnaires designed to assess the cost impact--as estimated by the respirator manufacturers--of each major provision in the proposed rule.

Questionnaires were sent to all manufacturers for their response. Although all did not respond, NIOSH received enough information to make an informed estimate of the costs associated with the proposed rule. The estimated cost was substantially less than $100 million.

To ensure that all relevant economic impact information is considered, last month the Office of Management and Budget designated this rule as a "major rule" under Executive Order No. 12291 and has directed NIOSH to submit a Regulatory Impact Analysis (RIA) with the final rule.

As reflected in the docket, some comments estimate that it will cost $700-$900 million to comply with this regulation. Based on information submitted to the docket, it appears that these estimates are based on two critical, but incorrect, assumptions. First, all workplace testing must be performed "in mines;" and second, each exposure agent for which the respirator would provide protection (e.g., hundreds of organic vapor compounds) must be tested individually. Section 84.31 in the proposed rule, Guidelines for Workplace or Simulated Workplace Testing, makes no mention of mines or mining. The section requires that testing be done under conditions "reasonably representative of those in which the applicant anticipates the respirator will be used" [84.31(b)]. Subsequent sections, 84.32 and 84.33, are consistent with this statement.

The term "reasonably representative" also has bearing on the incorrect assumption that each agent of potential exposure must be tested. It is not the intent of the proposed rule to require manufacturers to conduct workplace or simulated workplace testing for every contaminant for which

this device may be used. Rather, it is proposed that the respirator manufacturer, who is in the best position to know the product and its marketplace application, conduct appropriate workplace or simulated workplace testing to properly reflect the intended use of the product. This is consistent with present requirements of 30 CFR Part 11, where a few representative challenge gases, vapors, and aerosols are used as laboratory test agents; for example, if an applicant wishes to obtain dust approval under the current 30 CFR Part 11, NIOSH tests using only a silica dust as a challenge aerosal.

3. **"Self-Certification" Concerns**

Concern has also been expressed that the proposed regulation will, in essence, permit self-certification. It is alleged that respirator manufacturers will conduct the required tests and certify their own products as complying with the regulation. An example would be the present self-certification by manufacturers of most other personal protective equipment, such as safety glasses. To the contrary, the proposed regulation clearly states--in Section 84.30 and in the preamble under a discussion of Section 84.30--that NIOSH will require manufacturers to conduct and report the results of tests (as currently required under 30 CFR Part 11.11(d)). NIOSH will have the option to repeat any or all such tests of the applicant's device in its own laboratories. Under the current regulation, NIOSH must repeat all tests, even test procedures for which no failure has occurred for many years. The proposed Part 84 thus permits NIOSH to focus its resources for verification testing on the most critical performance issues. This will improve respirator reliability and

reduce both the costs and the time required to process applications. It is evident throughout the proposed rule that NIOSH will be the sole "certifier" of respirators that meet the requirements of 42 CFR Part 84.

4. The "Workplace Testing Protocol"

Another concern reflected in comments to the Docket is that NIOSH has not issued a "Workplace Testing Protocol," thus preventing the manufacturers from effectively responding to the proposed rule. NIOSH is currently preparing a document to provide performance-based guidance for field testing. Comments will be solicited on this draft guidance and will be made a part of the record prior to final rulemaking.

NIOSH intends to afford the manufacturers maximum flexibility in developing and utilizing workplace or simulated workplace testing methodology. We intend to permit any scientifically valid methodology that will appropriately reflect the "work conditions that are reasonably representative of the places and conditions in which it is anticipated the respirator will be used (Section 84.32(b))." This flexibility in a workplace testing protocol is important, and even critical, for permitting and encouraging innovation in the respirator industry. Currently, this flexibility is severely restricted by the detailed test procedures described in the "NIOSH Laboratory Test Procedures for Respirators."

The proposed rule also contains provisions that will permit a manufacturer to obtain certification for a higher level of performance. Thus, for the first time, a manufacturer has an incentive to develop a truly superior

product and has the potential to obtain a marketing advantage with the superior device. This provides a marketplace incentive totally absent in today's respirator market and not possible under the current regulation. NIOSH is concerned that a NIOSH-specified protocol could limit flexibility and chill innovation in the development of improved products.

Field testing of respirators is not a new, or untried idea. Over the past 15 or more years, substantial field testing of respirators has occurred in the respirator community both in the United States and internationally.

Concerns about NIOSH acceptance or possible rejection of a manufacturer's workplace or simulated workplace study are addressed in Section 84.32(c)(2). As detailed in Section 84.80, a manufacturer is permitted to appeal if NIOSH deems any tests to be inadequate.

5. "Organic Vapor Cartridges"

There are comments in the Docket which indicate that the required humidity conditioning and testing requirements proposed for organic-vapor cartridges would necessitate a cartridge four times larger than the cartridges presently certified under 30 CFR Part 11. NIOSH is unaware of any published technical data to substantiate this claim nor has it been received. In addition, the same humidity conditioning and testing are required in the proposed rule for other sorbent cartridges, such as for acid gases; yet no similar comments have been made for any cartridge other than organic-vapors.

NIOSH recognizes that respirators fitted with organic-vapor cartridges are often stored and used by workers in high-humidity environments. However, current regulations fail to adequately address the performance of these devices in high-humidity environments. More and more frequently, these cartridges and canisters are being used for protection against organic vapors that have poor warning properties (such as smell, irritation, etc.). These public health considerations place a burden on the certification process to assure the proper and adequate function for respirator users. **By necessity, the revised high-humidity test requirement is more stringent than under the current regulation. No advancement in sorbent technology has occurred in this application in decades. We believe that the five-year "grandfather" period proposed in the new rule in Section 84.2(b)(1) allows ample time to address this** requirement, particularly in light of ongoing research by manufacturers and others on this problem.

6. **"Filter Technology"**

Comments have also been made that certain filter devices presently in use will not meet the revised test requirements. Over the past 4-5 years, research has shown that filters that pass the present certification criteria--in which penetration of specified aerosols is averaged over the full duration of the test--may mislead respirator users. For example, filter penetration is dependent on particle and aerosol size, filter loading, and the condition of the filter as affected by humidity during storage. In addition, initial penetration of a new filter may be very high compared with total penetration averaged over a long test period.

Although advances have occurred in filtration technology for other applications, this has not been true for respirator filters (except for reductions in the breathing resistance of some high efficiency filters).

The adverse effects on filter efficiency due to humidity and other contaminants, such as oil mists, in the workplace are very real and have been amply demonstrated (Mitchell, A.N. et al., AIHAJ, June 1971, and Ackley, World Filtration Congress III Proceedings). Thus for public health reasons, NIOSH has incorporated a liquid, as well as a solid, aerosol test into the requirements for all filter types.

NIOSH considers this proceeding as an important part of its efforts to develop the final rule. It should be noted that the comment period will remain open for thirty (30) days following tomorrow's hearing; therefore closing COB, February 28, 1988. Your participation and contributions to the public record are greatly appreciated and will provide additional important information on which the final rule will be based.