

84-192



Industrial Safety Equipment Association

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NIOSH Docket Office
Mail Stop E-23
1600 Clifton Road, NE
Atlanta, GA 30333

Dear Sir or Madam:

ISEA appreciated the opportunity to participate in the rulemaking procedure as originally announced in 52 FR 32402. After reviewing the public testimony at the NIOSH hearings on the proposed rule and the initial written comments submitted to the record, the following conclusions are drawn.

1. The standard as proposed must be withdrawn. There is no support for the proposed rule in the record from either the testimony given at the public hearing nor in the written comments submitted to the docket.
2. NIOSH must expand the scope of its respirator certification beyond application in mines or mining operations. No one supported this limitation in the testimony or written comments submitted to the docket.
3. Complete protocols and reasoning that led to their development must be provided in the proposed rule in order for meaningful comments and economic and technical assessments to be made. No one supported NIOSH's contention that the absence of protocols would lead to greater innovation.
4. NIOSH must carefully review the justification and feasibility for its proposed technical changes in the certification process. The agency would be judged arbitrary and capricious, hence in violation of both the Due Process Clause and the Administrative Procedures Act if it did not make these assessments. Nothing in the testimony or written record supports technical changes such as the workplace test requirements, the need for a particle respirator to meet both liquid and particulate aerosol test, the new organic vapor test conditions nor the statistical method for compliance determination. Nothing in the

record supports the need for more "Stringent" test requirements nor that the changes are justified for "Public Health Reasons".

5. NIOSH must begin a dialogue with those affected by the revision. ISEA strongly recommends that NIOSH initiate a negotiated rulemaking process to arrive at a new proposed rule. The established record aptly demonstrates the current proposed rule fulfills no one's needs.

ISEA strongly urges NIOSH to adopt the above recommendations and will assist in any way possible to effect their implementation.

ISEA is also compelled to address the NIOSH comments submitted to the record on January 27 and 28, 1988.

NIOSH states in its comments that it is a misinterpretation of the proposed rule to conclude that respirators will be certified for mines and mining only. Organizational Resource Counselors in January 28, 1988 testimony stated very clearly what is also ISEA's position. Testimony is as follows:

"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 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 32405, 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 re-propose 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".

ISEA also strongly feels that the NIOSH certification system should address the needs of construction, general industry and agriculture as well as mines and mining.

ISEA is pleased that this rule was designated a "major rule" and will assist NIOSH in any way possible in preparation of the Regulatory Impact Analysis. It is critical however, that the same errors made in the original survey are not repeated. The response of the industry to that original NIOSH survey was at best confused. For example several respondents stated they would have additional costs to purchase more silica dust chambers when indeed NIOSH was proposing to eliminate the test altogether. Likewise estimating costs of the totally undefined workplace testing was impossible. Future cost estimates must clearly explain the requirements and must be conducted via personal interviews in order to assure there is no confusion.

Also on page two of the NIOSH comments it is stated that the industry cost estimate is flawed because it assumed testing must be done in mines or mining operations. The statement in the NIOSH comments is incorrect. The cost estimate, (copy attached), as defined in our written comments, is not dependent on whether the worksite is a mine or not. The issue of testing in a mine addresses the feasibility, not the cost of the proposed requirements.

Secondly, NIOSH incorrectly states that the estimate is flawed because the industry assumed that "each exposure agent for which the respirator would provide protection (e.g. hundreds of organic vapor compounds) must be tested individually".

Page twenty of the ISEA's written comments clearly states: "NIOSH states (in its draft protocol) that 3-6 substances for each type of respirator will be required. For the cost estimate, the industry selected a conservative number of three substances. For example, for a dust respirator, 3 different type dusts will be tested: for an organic vapor respirator, 3 different organic vapors, for an air line respirator 3 different substances; etc." (Emphasis added)

The NIOSH clarification, if anything, reaffirms the accuracy of the industry's cost estimate. NIOSH states that "This is consistent with present requirements of 30 CFR 11, where a few representative gases, vapors and aerosols are used as

laboratory test agents; . . .". The industry's estimate, using 3 challenge agents, falls within NIOSH's intent to require a "few".

NIOSH also addresses the issue of "self-certification" in its comments. NIOSH states that the proposal is not self-certification but that NIOSH will remain the "sole certifier of respirators". It is difficult to understand precisely what NIOSH will "certify" other than that the manufacturer has submitted the necessary paperwork to assure compliance with 42 CFR Part 84. The statement that NIOSH may perform some verification testing on some "critical performance issues" does little to assure equality among manufacturers or relieve the concern of the user that the system is really a form of self-certification.

Those requirements and tests that NIOSH considers essential for manufacturers to perform, must be verified by NIOSH. All others should be deleted.

ISEA agrees with NIOSH's intent to permit and encourage respirator innovation that will lead to devices that more fully meet the user needs. Flexibility should be encouraged and allowed in respirator design but not in respirator evaluation. Respirators should be evaluated using only established and verified test procedures. Innovation in respirator evaluation can lead to procedures that can easily produce the best results for the worst respirator. Certainly ISEA feels that provisions should be made for development of equivalent procedures where a particular design of a respirator does not allow for proper evaluation using established procedures. Today, however, it is difficult to envision a design that could not be evaluated using a single procedure.

NIOSH states in its comments that workplace testing is not a new or untried idea and that such workplace testing has been occurring for the last fifteen years. This statement is, at best, misleading. The testing that has occurred was performed as research attempting to develop methods to evaluate respirators, not for certification purposes as NIOSH implies. Most of the tests performed have been judged by respirator experts as inappropriate because of defects in the protocol. For example, many of the tests allowed the wearer to remove the respirator during testing thereby preventing the accurate measurement of respirator performance. In addition, many other problems have been identified in our written comments. NIOSH is well aware of these as evidenced by their establishment of a major research project under way to improve the efficiency and accuracy of sampling the atmosphere inside the facepiece.

NIOSH has indicated that, if under the proposed regulation, a manufacturer's workplace study is rejected by NIOSH the

manufacturer need not be concerned because of the existence of an appeals process. This again is misleading for as described in our written comments, the proposed appeals process is nothing more than the right of a manufacturer to go back and say "please" because the same agency that made the original decision is solely responsible for hearing the appeal. ISEA insists that if workplace testing is required, established and verified protocols be used, and that an appeals board as described in our written comments on 84.80 be established.

NIOSH states in its comments that it is unaware of any published data to substantiate the claim that under the proposed regulation cartridges would have to be made larger. NIOSH should consult with its own internal experts. For example, in the Journal of the International Society for Respiratory Protection, Vol. 4, issue 2, page 1, Ernest Meyer, a NIOSH expert on chemical cartridge respirators describes the effect of relative humidity on cartridges and specifically references five additional papers dealing with the adverse effect of high humidity on OV cartridge service life. The references are:

1. Balieu, E. (September 1980) "Effects of Water Vapor on the Performance of Respirator Gas and Vapor Filters" Presented at NIOSH International Respirator Research Workshop, Morgantown, WV.
2. Burrage, L. J. and A. J. Allmand (in press) "The Effect of Moisture on the Sorption of Carbon Tetrachloride from an Air Stream by Activated Charcoal". J. Soc. Chem. Ind.
3. Maggs, F. A. P. and M. E. Smith (1976) "Adsorption of Anesthetic Vapors on Charcoal Beds", Anesthesia 31:30.
4. McGinnis, N. and G. L. Fawcett (May 1976) "The Effects of the Variation of Relative Humidity Within the Specifications of 30 CFR Part 11 on the Service Life of Cartridges", Presented at AIHA Conference, New Orleans, LA.
5. Nelson, G. O., A. M. Corrcia and C. A. Harder (1976) "Respirator Cartridge Efficiency Studies: VII. Effect of Relative Humidity and temperature", Am. Ind. Hyg. Assoc. J. 37:280.

Additionally, testing done by the industry for example, indicates that two major manufacturers' cartridges lasted on the average 100 minutes and 75 minutes under the current conditions and lasted 21.8 minutes and 18.3 minutes respectively under the proposed requirements.

NIOSH is mistaken in its statement that no comments were made on the testing conditions for other than organic vapor cartridges. Pages 71-73 of the ISEA comments state that testing conditions for these cartridges should remain as currently described in 30 CFR Part 11.

The proposed requirements will offer no more protection than that for existing cartridges, but will merely provide longer service life. Respirator users have not indicated a need for longer service life. Consequently the industry fails to see how this can possibly be constructed as a Public Health Policy decision. NIOSH is correct in stating that the proposed requirements for testing organic vapor cartridges are more stringent and that respirators are used at 85% relative humidity. However, respirators are also used at 90% and 95% relative humidity which is obviously more severe with respect to service life than 85% relative humidity. Imposing more severe requirements that will add weight to the respirator and discomfort to the respirator wearer will result in poorer protection. Sorbent technology is advancing, but to push the technology beyond the feasible limit as a requirement for certification will result in high costs and less protective respirators. NIOSH will be judged arbitrary and capricious if it attempts to push technology in this manner.

ISEA supports the concept of the proposed revisions to particulate filtering respirator testing requirements but objects to two specific areas: The actual limits imposed in the regulation, and the requirement that the filters meet both solid and liquid aerosol tests.

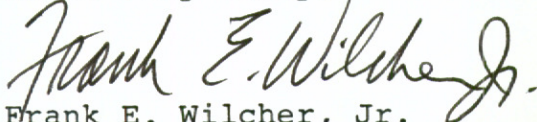
The actual limits ISEA is proposing are discussed in our written comments. The industry strongly objects to the imposition of both the solid and liquid test. Respirator filter technology has made significant advances in the last 15 years. Dust respirators are now available that have 2-3 mm H₂O breathing resistance compared to 9-15 mm H₂O fifteen years ago.

All filters have limitations. The respirator limitations should be clearly stated. For example even high efficiency filters will degrade rapidly when exposed to an atmosphere containing hydrogen fluoride (HF) which is common in many industries.

The presence of HF can easily be determined and appropriate action taken. Likewise the presence of a high concentration of oil mist is easily determined and a respirator specifically designed for oil mist can be selected. Consequently ISEA strongly recommends that separate categories for liquid and solid aerosols or both be established to allow the majority of respirator users to continue to wear respirators best suited for their needs.

In conclusion, the record for this docket confirms that this proposal is flawed, and we would like to reiterate our suggestion that all interested parties come together and develop a new program. We believe negotiated rulemaking involving experts from labor, industry, concerned regulatory agencies, and respirator manufacturers would result in a certification program that would be meaningful and would provide the best possible protection for workers.

Yours very truly,



Frank E. Wilcher, Jr.
President

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ASSUMPTIONS FOR DETERMINING COSTS
FOR WORKPLACE TESTING

Testing Costs

126 good samples per substance per industry are required. To obtain this, one needs 200 "good" tests in the field. This does not include those samples rejected in the field because of pump failure, respirator removal, etc.

	<u>People weeks</u>
35 "good" tests	5
200 "good" tests	30 (or 1,200 people hours)

Non-Testing Costs

Scouting "good site"	3
Preparing equipment for shipping	1
Cleaning equipment	1
Preparing samples	1
Tabulating results	4
Writing reports	4
Administration	3
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	17 people weeks non-testing or (680 people hours)

Total: 1,880 people hours/200 "good"
tests or 9.4 people hour/test
or 14.92 people hours per
usable data point

Other Direct Costs

\$2.50/sample for collection media, 800 needed	\$ 2,000
\$30/sample analytical costs, 600 needed	18,000
\$1,000/people week travel costs, 33 needed	33,000
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Total:	\$53,000 or \$265 per test or \$421 per usable data point

Cost of Respirators - additional direct cost

Indirect Costs

Reusable equipment \$80,000

Grand Total = 1,800 people hours + \$53,000 + indirect costs per
substance to get 126 usable data points