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84-270

3M

FEDERAL EXPRESS

March 25, 1988

Dr. Nelson A. Leidel
Docket Officer
NIOSH Docket Office
Mail Stop D-37
Building 1 Room 3120
1600 Clifton Road N.E.
Atlanta, GA 30333

Re: Post Hearing Comments to 42 CFR 84

Dear Dr. Leidel:

Pursuant to the notice published in the Federal Register on Thursday, February 25, 1988 extending the period to submit Post Hearing Comments with respect to the hearings held by NIOSH on the proposed rule 42 CFR 84, please find attached the Post Hearing Comments of the Minnesota Mining and Manufacturing Company with respect thereto. If any further information or assistance is needed please do not hesitate to contact the undersigned at your convenience.

Very truly yours,

Nelson E. Schmidt

NES:dlg

Attachment

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84-270

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY

AND HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:

PROPOSED REVISION OF TESTS AND REQUIREMENTS FOR CERTIFICATION OF PERMISSIBILITY OF RESPIRATORY PROTECTIVE DEVICES USED IN MINES AND MINING	))))	42 CFR PART 84

POST HEARING COMMENT OF
MINNESOTA MINING AND MANUFACTURING COMPANY

Pursuant to the notice published by the National Institute for Occupational Safety and Health (NIOSH), on February 25, 1988 (53 Fed. Reg. 5595), extending the period for submitting post-hearing comments on issues raised at the public meetings on the proposed rule regulating the certification of respirators used in mines and mining held on January 20, 1988 in San Francisco and January 27 and 28 in Washington, D.C., the Minnesota Mining and Manufacturing Company (3M) hereby submits its comments with respect thereto.

INTRODUCTION

As a manufacturer of many respiratory devices which are currently certified by NIOSH, 3M is directly affected by any revisions to the requirements for certification of respirators and is concerned that the promulgation of new certification requirements properly reflect feasible and sufficiently rigorous tests that will help predict a minimum level of respirator performance.

A change to these requirements, however, should not be made merely for the sake of change, but be based on need and well reasoned decisions. To this end, 3M submits this post hearing comment to assist NIOSH in its efforts to issue a meaningful and feasible revised regulation for the certification of respiratory protection devices.

COMMENTS

In overall terms, the proposed revision to 32 CFR 11 issued by NIOSH on August 27, 1987 (52 Fed. Reg. 32401 et. seq.) was noticeably deficient in its failure to contain any field test protocols to evaluate respirator performance, which by NIOSH's own words was the most significant of the proposed changes, and in its failure to explain why changes from 32 CFR 11 were being proposed (the preamble to this major amendment to the certification rules was only three pages long). These deficiencies were so extensive that submitting meaningful comments on the proposed 42 CFR 84 was virtually impossible. Because of this, 3M and virtually all commenters suggested that NIOSH withdraw the proposal until these glaring gaps could be filled. Based on the comments submitted, 3M again contends that NIOSH not proceed to a final rule at this time. Rather, it is recommended that NIOSH immediately embark on a rulemaking process that encourages and solicits a meaningful exchange between all affected parties. This rulemaking could follow a negotiated rulemaking format or one that relies primarily on a consensus standard developed by affected parties.

The following remarks are directed to specific areas of the proposal and the accompanying comments.

1) Workplace Testing Protocol

NIOSH's submission for the record states at page 6 that:

> "NIOSH is currently preparing a document to provide performance-based guidance for field testing....NIOSH intends to afford the manufacturers maximum flexibility in developing and utilizing workplace or simulated workplace testing methodology....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 Test Procedures for Respirators.'"

3M has three main points to impress upon NIOSH regarding the above claims about flexibility and innovation. First, the argument that innovation will be encouraged by not specifying a protocol for workplace testing is blatantly specious in that each product will first need to meet several laboratory test requirements that will have very detailed test procedures, exactly as exists today in the NIOSH Test Procedures for Respirators. As a consequence, products will have to be designed to meet those detailed test requirements before they ever proceed to workplace testing.

Second, comments by several participants revealed that field testing in this context cannot yield meaningful results. Quotes

from several commenters focus specifically on the issue of data collection and consistent repeatable test results. For example, OSHA and MSHA jointly commented: "The results of workplace testing are dependent on the specific contaminant present, particle size, concentration, and on the working conditions in the workplace and workload performed during testing. The environmental conditions during testing can also affect test results. These variables must be controlled so that comparable results can be obtained." (84-094). The American Optical Corporation testified: "Analytical methods do not have sensitivity sufficient to make meaningful measurements of performance, especially with those respirators having high assigned protection factors (APF)." (84-136).

OSHA and MSHA further commented on the problem of interpreting highly variable test results as follows: "The methodology involved in workplace testing is currently in the research stage, and therefore is not appropriate for regulatory action." (84-094). Similarly, Neoterik Company commented: "The field tests will introduce large elements of variability, subjectivity and lack of control into the certification process. In other words, the lucky ones will get approved." (84-14). Several other representatives from the manufacturers and several representatives from industry expressed the same sentiment (84-137, 126, 192, 131, 191, 080, 130, 079, 073, 075).

Moreover, many commenters claimed that workplace testing is technically infeasible. In anticipation of this viewpoint, NIOSH stated at page 7 of its submission that: "Field testing of

respirators is not a new or untried idea." Uses of workplace testing data in the past, however, were most often simply to determine that for a particular use situation workers were not being overexposed. Only in very recent years has the technology and equipment been developed to permit the use of field studies as a basis for determining the limits of a respirator's performance, and then only in very special applications. There are many practical difficulties to be addressed but even when these are resolved, the limitations to the value of field testing for the certification of respirators will remain. As stated by 3M in its comments to the record: 'Workplace testing may be extremely valuable to a respirator manufacturer in determining how a respirator performs on the job, but with the inherently high variability associated with workplace testing, such results are poorly suited for a certification requirement. Few would disagree that any test requirement which is a tenet for certification must provide reliable, reproducible results.' (84-126)

Third, and last, 3M submits that NIOSH is greatly mistaken about their claim that detailed procedures on how to perform a test inhibits innovation. Once a requirement is chosen, product design and performance must move to meet that requirement. The key then, is to develop an appropriate performance based requirement and leave the innovation to the manufacturers. Lack of detailed "how to" guidelines merely blurs the target, in effect setting a much higher standard than is apparent to account for the spectrum of possible interpretations. The affront over the lack of a detailed protocol for field testing was practically unanimous

among those commenting and testifying. The sole exception was the Building and Construction Trades Department of the AFL-CIO (84-195).

2) Focus on Mines and Mining

Users, manufacturers and OSHA unanimously expressed concern over NIOSH's proposal to limit certification of respirators to mines and mining applications only. Sixty-seven parties commented or testified as to the undesirability of this limitation. No one supported it, even the American Mining Congress commented that "...42 CFR Part 84 should be modified to address broad industry concerns..." (84-081). The matters expressed centered around two main points. First, the sudden shift to a mines and mining approach to certification was interpreted as meaning NIOSH had no intention of addressing the respirator needs facing users in non-mining workplaces. Second, that the specific requirement for testing respirators in mines or mining applications would make the requirement for workplace testing which is already impracticable and for most applications infeasible, even more so.

Although NIOSH's comments on these issues attempt to minimize the fear that the focus on "mines and mining" represents no change in policy since 1919 by emphasizing that even though 95% of all certified respirators sold are for non-mining uses, all certified respirators (except vinyl chloride respirators) are used in mines and that routine contaminant exposures in mines are identical to the type of exposures in general industry, the plain reality is that no one has been appeased or satisfied by this explanation.

If it is all so obvious to NIOSH, then 3M submits that the proposal be clearly amended to reflect that NIOSH will continue to certify respirators for general industry use and that the worksites for testing respirators need not be limited to mines or mining applications but can include any appropriate worksite application where the respirator will be used.

3) Economic Impact of the Regulation

In the preamble to the proposal (52 Fed. Reg. 32404), NIOSH concluded that in accordance with Executive Order 12291, 42 CFR 84 did not constitute a "major rule" since the estimated cost of compliance to industry was substantially less than $100 million. Nevertheless, while OMB has now designated 42 CFR 84 as a "major rule", 3M has elected to retain this section in these comments as a "lessons learned" scenario to show that this issue is merely symptomatic of the need for NIOSH to be more aware of and accountable to the respirator community regarding their position on 42 CFR 84 before proceeding to final rulemaking.

NIOSH's effort to collect accurate cost information from manufacturers on the proposal was at best half hearted. For example, the questionnaire employed was written so ambiguously it was impossible to respond intelligently. No effort was made to validate responses or to survey nonrespondents. Moreover, arriving at realistic cost estimates was doomed from the outset since the single largest factor constituting costs would stem from the workplace evaluation testing, for which no protocols had yet been established. Thus, a determination that the economic impact

of the new rule would be less than $100 million amounted to nothing more than pure speculation since it was not known what the scope of this testing would entail.

Inspite of this, when the manufacturers submitted detailed comments on costs based on a known research field evaluation research protocol and some clearly stated assumptions, NIOSH dismissed them by misreading the assumptions. In particular, the manufacturers stated that their costs for workplace testing was based on three tests per respirator (84-043). For reasons that are without explanation, however, NIOSH's testimony asserts that the manufacturers based their estimates on testing each product against hundreds of substances, thus, NIOSH claims, falsely inflating the costs associated with field testing. The comments unequivocally show, however, that NIOSH's conclusion is without substance and is in fact inaccurate.

In addition, NIOSH failed to address whether the rule would have a disproportionate impact on small businesses as required by the Regulatory Flexibility Act of 1980. Neoterik Company testified that the requirement for workplace testing is..."devastatingly unfair to small business." (84-140). Likewise, another company testified workplace testing in particular "...could put small companies such as Moldex out of business."

It appears that NIOSH similarly overlooked the cost of the proposed changes on respirator users. Many users expressed concern over having to purchase respiratory equipment they believed would cost more if certified under the proposed rule

(84-131, 079, 080, 129, 104, 100, 099, 098, 092, 068, 076, 096). Users also commented on increased costs to refit workers on new respirators (84-104, 068) and to change other affiliated aspects of their respirator programs such as changing their maintenance programs, training programs and written procedures (84-085, 098, 104, 129, 110, 128).

4) Much More Stringent Requirements

An analysis of the record shows users are satisfied with the performance of currently approved respiratory equipment (84-092, 098, 099, 100, 068). Not surprisingly, many commenters questioned what deficiency the proposed changes were attempting to rectify. As an example, Norfolk Southern Company stated: "NIOSH should provide documentation describing the identity of the complaints, the exact nature of the problems, and how NIOSH verified that problems did indeed exist. They should substantiate that the regulations need revision." And later in addressing NIOSH's claim that the changes will result in greater safety and reliability: "NIOSH should provide documentation in regard to reaching this conclusion." (84-096). Several other respirator users also challenged NIOSH to document deficiencies in respirators certified under the current system and show how the proposed changes will remedy those deficiencies (84-091, 098, 099, 100, 093, 080, 128).

In addition to questioning the need for more stringent performance requirements many users expressed concerns over the impact of the changes on the acceptability of the product to their employees. Nucor Steel-Nebraska Corporation commented: "Nucor's

primary concern with the Proposed Rules is that its employees who use respirators are ambulatory and any change in a respirator that serves to make it additionally uncomfortable (e.g., increase in weight, bulk, in- or exhalation resistance, heat or perspiration) will, in all likelihood be unwelcomed, perhaps to the point that workers will refuse to wear them." (84-076). Norfolk Southern Company commented: "If respirators become bulkier due to modifications, workers may be less inclined to wear them regularly. A perfect respirator offers zero protection if it is not worn." (84-096). An industrial hygienist stated: "From my experience user acceptance of a respirator is still the single most important factor in providing the user respiratory protection." (84-102).

The American Iron and Steel Institute commented: "Hazard Communication programs have heightened awareness relative to chemical substances health effects. Consequently, employees are requesting respirators to reduce workplace exposures. Because this proposed rule would make respirators more cumbersome, more costly, and less acceptable to wear it would undermine progress in prevention of occupational disease, threaten the health and safety of millions of workers who use respiratory protection to prevent exposure to chemical agents." (84-098).

Many other industry users of equipment also expressed concerns over onerous design changes that would be induced by compliance with the proposed changes (84-100, 092, 068, 091, 131, 088).

Organic Vapor Cartridges: The proposed changes for the certification of organic vapor cartridges are, in addition to being without justification, so stringent that no cartridge currently certified will pass. In fact, it is estimated that cartridges will need to be made 3-4 times larger to pass the proposed certification requirements which will increase the relative humidity and double the airflow rates. NIOSH proposed this change for organic vapor cartridges even though users have not expressed performance deficiencies in current product nor a need for longer filter service lives. In this regard, Boehringer Ingelheim Pharmaceuticals commented "Are these proposed requirements for chemical cartridge respirators consistent with the needs of industry? In our industry, which is mainly indoors, we rarely have a relative humidity over 50%." (84-068).

Not unpredictably, NIOSH dismissed the manufacturer's claim that the proposed change to the test requirements for organic vapor cartridges would necessitate enlarging cartridges by 3-4 times on the basis that NIOSH is unaware of published technical data to substantiate the manufacturer's claim. 3M submits that this position gives fibrance and truth to the underlying problem that NIOSH's state of unawares is the very crux of the disastrous reception for their proposed rule. Clearly, that the change being proposed would have a negative effect on the service life of organic vapor cartridges is very well known and the list of technical publications supporting this position would fill several pages. Literally hundreds of technical papers and presentations have been given and published on this subject. More telling is

the fact that one of NIOSH's own researchers is in the forefront of the work being done in this area today. If this isn't enough, it is queried, who is in a better position to analyze this issue (or even to try it out before proposing it) than NIOSH, the only establishment in the government that routinely evaluates all respiratory products sold in this country.

Likewise, NIOSH's perplexity that manufacturers' and users' comments on cartridge size were only directed at organic vapor type cartridges and not other types of cartridges is similarly remarkable. It is again common knowledge and routinely witnessed through the day-to-day business of respirator testing at Morgantown, that increasing the humidity during testing does not have a detrimental effect on other types of cartridges, and in fact enhances the service life for some cartridges, such as those used for acid gases. The inescapable conclusion is that NIOSH adhered to a casual and unsystematic effort in gathering background information on which to base their proposed changes and by so doing apparently did not even consult or draw on the knowledge and experience of their own personnel before issuing the proposed changes. As if now wedded to the tradition of "going it alone", NIOSH technical personnel were again overlooked in reviewing and analyzing the manufacturers' comments regarding the impact of the proposed changes.

Finally, NIOSH also mistakenly implies that this proposed change would improve worker protection. The record shows, however, that this is not true. The only non-negative effect of the change is that the cartridges would last longer. They would

not protect the user any better. For many applications, NIOSH has in effect decided for the user that it is automatically better to carry a day's worth or perhaps several days worth of sorbent around with them instead of changing the cartridges as needed.

Requirements for Testing Filters

NIOSH is proposing that particulate filters must now pass both a solid and liquid oil mist test. To successfully pass the challenge of both a solid and oil mist aerosol would require significant modifications to current products which would not be beneficial for filters used against solid particulates. Since the presence of oil mists in a workplace alone or in conjunction with other contaminants is not common and where it does exist is easily ascertained, the detrimental effects of this proposed requirement tips the scales against its adoption. Notwithstanding this evidence, NIOSH opined in its submission to the record that the detrimental effects of oil mists have been demonstrated and thus for "public health reasons" it will require all filters to pass both a solid and oil mist test.

This position is without support and does not reflect the needs of the users. Norfolk Southern Company specifically questioned the need for any test for filters that is more severe than currently required. "NIOSH's suggestion that the sodium chloride aerosol test is more severe does not indicate why a more severe test is necessary or relevant for protection from silica and lead." (84-096). Boehringer Ingelheim Pharmaceuticals questioned the value of the oil mist loading tests by stating:

"Should oil mist loading tests be required for all respirators? Our company has many applications where we have only solid aerosol contaminants and I would prefer a more comfortable respirator for employees.... Again, should there be two different standards? (84-068).

In the final analysis, NIOSH's concern for exposure to oil mists is easily solved by testing and certifying respirators for use against such contaminants. Further, since oil mists are readily detectable, proper selection and use of an appropriate respirator poses no problem. This presents a feasible solution while concomitantly avoiding the problem of requiring solid particulate filters to pass both the solid and oil mist aerosol challenge.

As 3M previously stated, the rules for certifying respirators are in need of updating, but this change must not create and impose insurmountable burdens on respirator manufacturers and users. To do so serves no one except those who possess no knowledge of reality nor any understanding of the benefits to worker safety and health that can be and are being derived from effective respiratory protection devices. 3M contends that transforming the proposal to one which is feasible can be accomplished and offers its assistance and expertise to NIOSH in reading this goal.

CONCLUSION

In summary, 3M submits that while the information exchange to date represents a start at what is needed to arrive at an

acceptable respirator certification program, to stop here would be a great disservice to the respirator community. We urge NIOSH to begin a process of negotiated rulemaking regarding the proposed sections of 42 CFR 84 as well as in establishing and developing appropriate uses of feasible workplace testing protocols, for only in this manner can the myriad of values and impacts of proposed changes to the certification program be distilled and the changes tempered so that they are the most beneficial to all.

Respectfully submitted,

Minnesota Mining and
Manufacturing Company