



Personal Protective Equipment

Respirator Certification Regulations

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To cite this article: John B. Moran (1988) Personal Protective Equipment, Applied Industrial Hygiene, 3:5, R-8-R-9, DOI: [10.1080/08828032.1988.10388554](https://doi.org/10.1080/08828032.1988.10388554)

To link to this article: <https://doi.org/10.1080/08828032.1988.10388554>



Published online: 25 Feb 2011.



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Respirator Certification Regulations

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The subject of this month's column is respirators. The first rounds of the major efforts by the National Institute of Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) to revise both the respirator certification regulations, currently known as 30 CFR 11, and the respirator use regulations under 29 CFR 1910.134 have begun. These emerging regulatory issues have been previously addressed in this column and in my article published in *Applied Industrial Hygiene* 2(6):F-20; 1987. This month's column attempts to provide an overview of the NIOSH efforts to revise the certification regulations at a time representing the conclusion of informal public hearings held by NIOSH.

NIOSH announced its long-awaited proposed revisions to the respirator certification regulations in the *Federal Register* on August 27, 1987 (52 FR 32402). On the basis of requests from the public, the close of the public written comment period was extended from October 26, 1987, to December 28, 1987; informal public meetings were scheduled in San Francisco for January 20, 1988, and Washington, DC, for January 27-28, 1988, with written comments to the informal public hearing record permitted until February 28, 1988. In addition, the proposed rule docket office location was changed from the respirator certification and research laboratories in Morgantown, West Virginia, to Atlanta, Georgia, where NIOSH headquarters offices are located.

The major feature of NIOSH's proposed revisions are as follows:

- Elimination of the present joint approval process by NIOSH and the Mine Safety and Health Administration (MSHA) under 30 CFR 11 and creation of a new certification regulation under 42 CFR 84 which would be the sole responsibility of NIOSH.
- Inclusion of minimum respirator protection factors which vary, of course, by respirator type.
- Inclusion of an option permitting respirator manufacturers to obtain certification at protection factors superior to the required minimums.
- Required conduct of workplace or simulated workplace testing as a basis for determining compliance with the protection factor requirements.
- Revisions to many of the laboratory test requirements such as filter penetration and the organic vapor cartridge service life test.

In the course of preparing the proposed revisions for review, approval, and release to the public, a contractual effort was funded by NIOSH to develop an estimate of the economic impact of the proposed revisions. The analysis indicated that the cost impact would be less than \$100 million, thus not constituting a "major rulemaking."

On the order of 100 written comments were received by the NIOSH Docket Office on or before December 28, 1987. NIOSH presented an opening statement at both the San Francisco and Washington informal public meetings, while three parties provided comment at the San Francisco meeting and about 24 parties provided comment at the Washington meeting. Notably absent were public comments from organized labor, the American Industrial Hygiene Association Respirator Committee, and a similar committee from the American National Standards Institute (ANSI) which has nearly concluded a major revision to the ANSI respirator consensus standard.

The principal issues raised by commenters were the following:

- The economic impact will greatly exceed \$100 million with estimates as high as \$900 million presented. (Note that as a consequence of this concern, expressed well before the public meetings, the Office of Management and Budget (OMB) has designated the proposal as a "major rule" under Executive Order 12291 and has directed NIOSH to develop a Regulatory Impact Analysis.)
- NIOSH did not provide a workplace or simulated workplace testing protocol or procedure with the proposed rule; thus, constructive public comment and more accurate economic impact analysis were not possible.
- The proposed regulation focuses solely

on "mines and mining," thus requiring workplace testing in mines and precluding the development of respirators for non-mining environments.

- The proposed rule constitutes self-certification by the manufacturers, an approach not supported by the manufacturers.
- Proposed revisions to the laboratory test requirements for organic vapor cartridges and filters would eliminate many filters in use today and require a large increase in the size, weight (and cost) of organic vapor cartridges while the need for such changes is not obvious.

NIOSH's opening statement addressed these issues as follows:

- The basis for the economic impact analysis was reviewed and the recent OMB requirement to expand such as a "major rule" was noted. A far more detailed economic analysis will be conducted by NIOSH.
- Lack of a workplace or simulated workplace testing protocol in the proposal was based upon a desire by NIOSH to afford manufacturers maximum flexibility in developing and utilizing such methodology. However, a performance-based guidance will be issued by NIOSH for public comment prior to final rulemaking.
- NIOSH indicated that the "mines and mining" issue relates to the legislative authority for respirator certification which is the Mine Safety and Health Act of 1977 and indeed the mining basis of all previous respirator certification and, prior to 1972, approvals by the Bureau of Mines back to 1919. NIOSH attempted to clarify this issue and express its view that workplace testing, for example, is not viewed as being required to be conducted in mines and that, with one exception, respirators currently certified under 30 CFR 11 are widely used in all industries, not just mines.
- Self-certification by the manufacturers will not occur as NIOSH, under the proposed rule, can repeat any or all (as now occurs under 30 CFR 11) labora-

tory tests supported by the manufacturer in an application for certification. NIOSH emphasized that it will be the sole "certifier" of respirators meeting the requirements of the final rule.

- With regard to revised laboratory tests for organic vapor cartridges and filters, NIOSH presented the view that such changes are needed in the workplace, that such can be achieved, and that the five-year "grandfather" period affords sufficient time to address these requirements.

NIOSH will, no doubt, review the public comments received after the record closed on February 28 and, on the basis of the review, decide upon a future course of action on the proposed regulations. Independent of that effort, however, an expanded economic impact analysis and release of a performance-based workplace testing guidance will occur.

OSHA and OMB are discussing 29 CFR 1910.134.

A final respirator note. In April 1986, NIOSH and the Environmental Protection Agency (EPA) published "A Guide to Respiratory Protection for the Asbestos Abatement Industry." Subsequently, the Industrial Safety Equipment Association (ISEA), *et al.*, filed suit in the United States District Court for the District of Columbia against EPA and NIOSH. The District Court dismissed the suit. ISEA, *et al.*, appealed to the United States Court of Appeals for the District of Columbia. The Appellate Court upheld the earlier dismissal of the complaint by the District Court on January 19, 1988. The Conclusion of the Appellate Court is important:

"The Guide was designed to advise and recommend to industry employers how to provide maximum asbestos protection to workers. It had no binding legal effect on either buyers or purchasers of certified respirators. Nor was it contemplated that the recommendations would be implemented in the context of future agency proceedings. Finally, appellants did not charge that the recommendations were false. Under these circumstances, the Guide did not amount to a rule reviewable as agency action or requiring APA (Administrative Procedures Act) rulemaking proceedings; nor did its issuance constitute a deprivation of property interests under the fifth amendment. The district court was correct in dismissing the complaint." ♦

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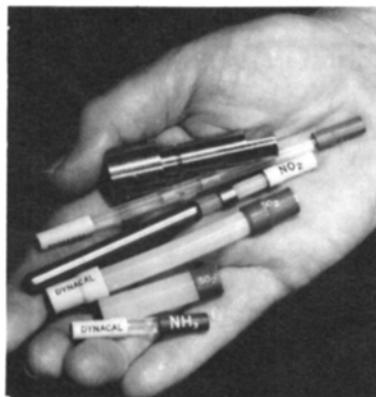
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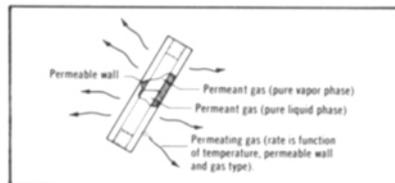
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