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Upgrading NIOSH's Respirator Approval Requirements—A Public Health Necessity

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Introduction

It has been over 16 years since the federal government last issued substantial revisions to the federal certification requirements for industrial respirators.[1] These requirements are contained in the federal regulation designated as 30 CFR 11 (i.e., Part 11 of Title 30, *Code of Federal Regulations*). The regulation specifies the performance tests and approval criteria for industrial respirators that must be met before a respirator can receive an approval certification from the National Institute for Occupational Safety and Health (NIOSH) and the Mine Safety and Health Administration (MSHA).[2] Since 1972, NIOSH and MSHA have jointly issued approvals for several thousand makes and models of industrial respirators that are worn by millions of workers to protect themselves from hazardous workplace atmospheres.

Why Revise the Respirator Approval Requirements?

Over the last 16 years, NIOSH and MSHA have made only minor amendments to the certification requirements. NIOSH has always recognized that a major upgrade of the approval requirements is a public health necessity. The respirator manufacturers have shared the Institute's feelings about the inadequacy of the present certification regulation. They have been quite vocal regarding the inadequacies of the present test requirements. For example, in 1980, Mr. Einar Horne of the 3M Company stated that the present regulation:

> "... includes tests that are not accurate, not reproducible or adequately defined. These tests have been established without a determined test variation, and are designed for 1930–1940 era instrumentation. Under the present system of testing and approvals, manufacturers are forced to submit products that will pass tests that may or may not guarantee protection to the user. It is possible that existing NIOSH testing does more harm than good based on the fact the tests have little, if any, correlation to actual field conditions."[3]

However, NIOSH recognized that a comprehensive regulatory revision would require a substantial base of research data that did not exist in 1972. Thus, for over 15 years, NIOSH has conducted or contracted for the necessary respirator research studies. Over a year ago, NIOSH initiated a complex rulemaking process by proposing a sweeping revision to 30 CFR 11[4] and recodifying it as 42 CFR 84 (the Public Health Service part of the *Code of Federal Regulations*). The 1987 proposal has four major advances compared to the present approval requirements

- A sweeping technical upgrade of the laboratory performance tests.
- Addition of quantitative fit performance testing in the laboratory on 25-person panels for all negative pressure respirators.
- Addition of workplace or simulated workplace performance testing to demonstrate the safety and efficacy of every NIOSH-approved respirator.
- Providing respirator manufacturers with the maximum opportunity to market innovative new respirators by replacing current approval tests that are design- or application-specific with tests that are performance-based.

Before NIOSH grants an approval certification, the Institute must have sufficient evidence of safety and adequate performance. Without the test data required in the proposed 42 CFR 84, NIOSH will be unable to adequately evaluate respirator safety and efficacy. The current certification test criteria provide insufficient evidence to NIOSH to reliably approve industrial respirators. The present regulatory criteria cannot assure the safety and performance of these devices.

NIOSH recognized that the process of revising the approval test requirements would involve a complex tapestry of interested parties, including manufacturers of respirators, the businesses who purchase respirators, and the workers themselves whose lives may depend on using an effective respirator. The Institute initiated formal rulemaking procedures in the belief that the process would best provide all parties an open opportunity to exchange opinions and contribute their technical expertise. NIOSH is committed to a certification program that assures one thing—respirators that will work, to protect the health of workers. Dr. J. Donald Millar, Director of NIOSH, has stated that "every buyer and user of NIOSH-certified respirators needs to be able to see the NIOSH name on a product and feel that it means something, namely, that it protects."

The most important consideration in the regulatory revision is to improve the test procedures by incorporating technical advances in respirator devices and test methods. The proposed regulatory revision places increased responsibility on the private sector to manufacture safe and effective respirators. In exchange for this increased responsibility, the proposal contains substantially more performance-based certification tests. Thus, the respirator industry will have greater opportunity and motivation to develop innovative personal respiratory protection for workers. The proposal provides a substantially expanded role in the certification process for the respirator manufacturers. It permits ample flexibility for them to expand their role even further.

Who Did NIOSH Listen to?

During the formulative stages of the proposal over the past decade, NIOSH solicited and received extensive comments regarding necessary changes to the existing regulation. Voluminous public comments were received at two public meetings held by NIOSH in 1977 and 1980. The Institute received 327 pages of comments at the 1977 public meeting[5] on new and improved performance requirements for future revisions of 30 CFR 11. There were 740 pages of comments received at the 1980 public meeting[6] on the NIOSH Testing and Certification Program.

Five months after publication of the proposed rule, NIOSH held two informal public meetings to provide the public with further opportunity to comment on the proposal. The first meeting was held in San Francisco, California[7] on January 20, 1988, and the second was held in Washington, DC[8] on January 27 and 28, 1988. The NIOSH Docket on the proposed 42 CFR 84 was held open for seven months to receive public comments on the proposal. The Docket closed on March 28, 1988, two months after the public hearings.

Affected parties such as respirator manufacturers, respirator purchasers, labor groups, other end users, professional associations, and other governmental agencies had ample opportunity to contribute their technical expertise and other constructive comments during the lengthy seven-month comment period. NIOSH received a total of 271 written comments on the proposed rule. However, essentially all comments on the proposal have been received from the respirator manufacturers or resulted from information distributed by the manufacturers. Chris O'Leary of A.D. Little, Inc., observed:

> "Perhaps the most curious aspect of the public response to the proposed NIOSH respirator certification procedures at 42 84) has been the virtual absence of comment from respirator users. The most logical source of such comment, the American Industrial Hygiene Association, has been curiously silent. Other professional societies and trade associations, which traditionally have been active participants in the public debate in this area, have had little or nothing to say."[9]

Controversial Issues

The most controversial part of the proposed revision has been the new provisions requiring workplace or simulated workplace testing of respirators (§§ 84.32 and 84.33) in order to obtain a NIOSH approval. These test requirements were included so that both NIOSH and the respirator user will have substantial evidence of respirator safety and effectiveness in the actual environment in which the device is supposed to work—the workplace. Workplace or simulated workplace testing enables a respirator manufacturer to provide evidence that a respirator performs as expected in at least one workplace or simulated workplace. This testing also helps to demonstrate that a respirator is free from defects or characteristics which may make it unsafe for its intended use in the workplace.

There is ample precedent for requiring workplace testing for respirators. For the past 12 years, a manufacturer of a medical device regulated by the Food and Drug Administration (FDA) under the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act has had to demonstrate both the safety and efficacy (i.e., adequate performance) of the device in order to receive the necessary government approval before marketing. Demonstrating efficacy means that there must be appropriate testing to indicate that the device actually does what the manufacturer says it will. FDA premarket approval for a Class III device (e.g., one that is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health)[10] depends on the manufacturer conducting clinical studies showing the safety and efficacy of the device.

The 1976 FDA Medical Device Amendments protect consumers from medical devices for which the complexity of the technology prohibits consumers from personally assessing the safety and efficacy of the products used to prevent their illnesses. In a similar manner, the nature and technology of industrial respirators prohibit users from assessing the safety and efficacy of the devices they wear to protect themselves from hazardous atmospheres—usually as an involuntary condition of employment. Thus, NIOSH strongly believes that workplace testing requirements for respirators are necessary to protect the health and safety of respirator users.

Under the current regulation, NIOSH must repeat all certification tests that a respirator manufacturer has to conduct before applying for certification. Institute testing resources that are badly needed for performance standard research must be used to conduct routine certification tests. Under the proposal, NIOSH will continue to require manufacturers to conduct and report the results of laboratory certification tests. However, NIOSH will have the option of repeating any of the certification tests and verifying the manufacturer's test results. This will enable the Institute to focus its testing resources on the most critical performance issues.

What Should Industrial Hygienists Do?

First, call NIOSH at (513) 533-8287 and obtain a copy of the proposed regulation (42 CFR 84) with the new respirator approval requirements. Read it and send your comments to NIOSH (c/o Dr. J. Donald Millar, Director, NIOSH, 1600 Clifton Road, NE, Atlanta, Georgia 30333).

Second, recognize the limitations of the certification tests and approval criteria that underlie the current NIOSH approvals. Purchase, use, or recommend the use of NIOSH-approved respirators only after you consider the limitations of the NIOSH approvals.

Third, recognize that the use of NIOSH-approved respirators is only one part of an adequate respiratory protection program. Obtain and read a copy of the recent *NIOSH Respirator Decision Logic*[11]; call (513) 533-8287 for a free copy. Note the NIOSH Cautionary Statements on pages 2 to 4 regarding the limitations and deficiencies of these key respirator program elements:

- assigned protection factors for respirator selection
- fit testing procedures
- QNFT fit factor screening levels
- "adequate" warning properties
- service life information
- determining the protection factor levels required for adequate protection

Fourth, request answers to the following questions from your respirator distributor(s) and manufacturer(s) before you purchase, use, or recommend the use of particular makes and models of respirators:

- What workplace testing has been performed on the respirator makes and models I am considering for use? What are the test results including the necessary allowance for statistical uncertainty due to variability of results and small sample sizes?
- What fit tests are recommended and approved by the respirator manufacturer for use with the manufacturer's respirators?
- Against which chemicals will the respirators provide adequate protection?

For air-purifying cartridge and canister respirators, which chemicals have adequate warning properties?

- What are the expected service lives for the respirators? For what use conditions are the data valid? What are the limitations and uncertainties of the information?

References

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Respirator Fit and Facial Hair —Regulators' Dilemma

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Introduction

The question of whether an employee who might be required to use a respirator must be clean shaven for respirator fit is not specifically addressed in the Ontario Occupational Health and Safety Act or its related regulations. A mention is made in the regulations that respirators must be fitted so that there is an effective seal between the respirator and the worker's face. The employers have interpreted this to mean that all employees who may be required to use or wear respirators, at some point in their employment, should be clean shaven as a growth of beard may interfere with the seal. The workers' representatives have protested with respect to the application of this policy on the grounds of individual freedom and have asked the Ontario Government to arbitrate the matter.

In order to resolve this matter, other regulatory agencies were contacted in regards to their policies on facial hair. In addition, the National Institute for Occupational Safety and Health (NIOSH) was contacted for an expert opinion on the necessity of being clean shaven for all types of respirators, including powered air purifying respirators and pressure demand Self Contained Breathing Apparatus (SCBA).

Historical Background of Ontario Legislation Related to Respirators

In order to properly understand the dilemma facing the Ontario regulators regarding respirator fit and facial hair, it is important to understand the fundamental principles upon which the Occupational Health and Safety Act of Ontario, 1978 is structured and some of the key provisions of the Act itself.

First of all, it is important to understand that the Act incorporates what we refer to as the "internal responsibility system" (IRS). The Act places obligations essentially on the employer, the managers who represent the employer, and the workers to work in a safe and healthy manner. The IRS is designed to make it possible for employers and their managers to work with workers to ensure that their workplaces are both safe and healthy. In a sense then, the inspectorate of the division are essentially auditors and arbitrators if the IRS fails to work.

The Act requires the employer to ensure that every precaution reasonable in the circumstances for the protection of the worker is taken. In addition to this general duty of the employer, the Act imposes duties that only come into effect when regulations are made under the Act.

Since 1978, several regulations for specific substances have been put in place. These regulations are referred to as Designated Substance Regulations (DSRs) and include regulations respecting lead, mercury, benzene, acrylonitrile, asbestos, vinyl chloride, coke oven emissions, isocyanates, silica, ethylene oxide and arsenic. In addition, there is a separate asbestos regulation for construction projects, buildings, and repair operations. Several other DSRs are in the process of being enacted.

When respiratory equipment for designated substances is provided and used, it must comply with or exceed the requirements set out in the code for respiratory equipment. The employer is also required to provide training and instruction to the worker using the respirator in the proper care and use of that respirator.

The DSRs respirator code delineates the requirements of different types of respirators based on the protection factors (PF) and general requirements for the use of respirators. The general requirements (up to 14 in number) include: