

NATIONAL INSTITUTE FOR  
OCCUPATIONAL SAFETY AND HEALTH

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Testing and Certification Program

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Statement of:

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My name is John B. Moran. I appreciate the opportunity to appear before you today to offer my views on the important issue of testing and certification of respiratory protective equipment. I offer these views both as a member of the Mine Health Research Advisory Committee, a Committee established pursuant to the Federal Mine Safety and Health Act of 1977 which also contains the statutory authority upon which the NIOSH/MSHA Respirator Certification Program (30CFR11) is based, and as an individual with specific personal experience in all of the primary segments which relate to the subject of this meeting: i.e., as a past director of the certification program, as a user of respiratory protective equipment, as a consultant to private industry regarding respiratory protective equipment, and as a past executive with one of the major U. S. respirator manufacturers.

My comments will cover four primary areas:

- The adequacy of the existing NIOSH/MSHA Certification Regulations embodied within 30CFR11.
- The "real world" of respiratory protective equipment application and use.
- General comments specific to the issues outlined in the meeting notice published in the Federal Register on June 18, 1980.
- Recommendations which NIOSH may wish to consider which are beyond those issues covered in the Federal Register Notice.

#### 30CFR11 Adequacy:

30CFR11, as it exists today, can most politely be characterized as a many times repaired, patched, and modified antique which is totally inadequate to meet today's needs. The direct result is and has been problems and frustrations for all involved, including the certifiers, the manufacturers, the purchasers, the users, and the occupational health regulators. The often held view that the certification process is primarily one which seeks to serve the respirator manufacturer community is one which is understandable when one recognizes that the certification program is one which grew into a regulatory program out of a voluntary process which began early in this century. Most of the problems with 30CFR11 are a result of a slow transition from the voluntary certification process to a mandatory process rather than there being a clear, sharp transition triggered by major revisions to the old certification procedures.

A joint NIOSH/OSHA/MSHA public meeting in November, 1977, sought to address this issue and to seek input and recommendations with regard to revisions to 30CFR11. Thousands of pages of testimony were received, including extensive comments from myself. To review all of the comments presented at that meeting, today, would require far too much time. It's sufficient to say that substantial information regarding the inadequacies of 30CFR11 has been available to NIOSH as a result of that meeting, and that such has resulted in no discernable change or improvement in 30CFR11 to date.

But a few examples regarding major 30CFR11 deficiencies are:

- Test criteria employed have no published technical basis. For example, asbestos certifications are routinely issued to manufacturers on the basis of tests, none of which involve exposure of the product to fibers and respirators are certified for protection against pesticides, yet are not tested with any pesticide.
- Many "special tests" are employed in the certification process which have not had public review and for which the need and resulting potential for design trade-offs are unknown to the user and occupational health regulatory community.
- Current Quality Assurance plan approvals are keyed, not to a desired, overall product quality goal, but rather to the size and sophistication of the individual manufacturer -- resulting in a wide range of manufacturer quality achievement.
- The extension of approval process for product changes is so ill-defined and broadly interpreted that some manufacturers make important changes in product without testing and approval by NIOSH/MSHA, while others have dozens of such extensions applicable to a single product.
- Manufacturers must only comply with minimum performance criteria. The results of certification testing are not published and indeed are not marketed. Many trade-offs, often complex in nature, are required in the design of any respirator. As there is no benefit attributable to superior performance, manufacturers seek nothing but achievement of the minimums required.

#### The "Real World":

This meeting, previous public meetings, and more formal hearings regarding respirator certifications have continued to focus upon the criteria and procedures for certification of respirators. With the sole exception of the Nation's firefighters, I have heard nothing which addresses that which, in fact, is the real issue: the adequacy of respiratory protective equipment in the protection of the worker who is wearing such equipment.

As a consultant, having reviewed the respirator programs of hundreds of private companies, I can state that I have not, with the exception of the Nation's very largest corporations, ever observed the proper and adequate use of respirators in the occupational setting. Why, one must ask, is that so? There are a number of reasons, none of which seem ever to be addressed in meetings such as this one.

Respirator "reality" is, in my view, as follows:

- Most employers do not know what a 29CFR1910 is, let alone the requirements embodied with 29CFR1910.134.
- Respirator salesmen, traditionally deal with purchasing agents, not industrial hygienists or occupational physicians. Purchasing agents are interested only in price and program cost.
- Respirator salesmen are rewarded by sales volume, not "correct" respirator sales.
- Purchasing agents, safety directors, industrial hygienists, and occupational physicians have no basis other than certification, for respirator selection as superior performance is not marketable.
- At least 90% of the Nation's employers are incapable of selecting the proper respirator for the hazard. Such employers do not have exposure data and most often do not know the exact material to which their employees are exposed. They trust respirator selection to the salesman who makes such selections in the absence of the needed data.
- Employees are poorly trained with regard to respirator use, maintenance, etc. Improper use, improper maintenance, improper cartridge change frequencies are the rule, not the exception.
- All respirators marketed to the industrial sector are not, as is often believed, certified by NIOSH/MSHA. Price, the salesman, and 30CFR11 inadequacies are reasons for this.
- OSHA regulations, keyed as they are to the use of protective equipment as a last resort, are often inadequate. For example, the recent OSHA Lead Standard fails to address the issue of proper respiratory equipment selection when leaded paints are used in a spray finishing operation.

I am suggesting, Mr. Chairman, that the proper use of existing respirators is as important an issue as is the issue of a "better" certification program and, further, that both NIOSH, OSHA, and MSHA have responsibilities in both matters which they should seek to address.

#### Federal Register Issues:

##### Viable Alternatives:

Before addressing the four alternatives presented, it is important to note that any of the alternatives chosen would require substantial time, easily in excess of a year, to implement due to the requirements of the Administrative Procedures Act. It is vital that a viable certification program exist in the interim, an issue which does not appear to have been addressed by NIOSH in the Federal Register Notice.

Option 1 appears to be the one most easily implemented as NIOSH/MSHA have substantial information, in hand, and clear statutory authority exists under the Mining Act.

Option 2 offers substantial impediments in that the statutory authority does not, so far as I am aware, exist within HHS. Further, MSHA has respirator certification needs also. How would these be met? This option appears to suggest that NIOSH would more fully focus on OSHA needs, clearly an important one which also offers the opportunity to meet the firefighters' needs pursuant to the planned OSHA revisions to the Fire Brigade Standards.

Option 3 does not, in my opinion, offer a viable option if private laboratories are permitted to, in any way, act or appear to function as certifiers. Certifications must, in my view, be issued by NIOSH or NIOSH/MSHA or NIOSH/OSHA.

Option 4 would appear to be viable only if NIOSH established and properly funded an extensive audit program which was required to issue reports of findings and had specific authority to issue recall notices, impose fines, etc., for non-compliance.

Germane to all options, of course, are the performance standards against which respirators would be tested. If little improvement over the existing 30CFR11 criteria results, little real change in respirators will occur, regardless of the option pursued. The primary objective, therefore, should be the performance standards, not the method necessarily by which such would be enforced.

#### Quality Control:

I fully concur with the NIOSH position in this matter, but suggest that administrative procedures be developed relative to the testing of in-use respirators which assures that the manufacturer becomes involved in a defect or flaw analysis process prior to stop-sale, recall, or revocation procedures.

#### Engineering Drawings and Dimensional Tolerances:

I fully concur with NIOSH's position.

#### Changes to Approved Devices:

While I concur with the intent of the NIOSH position on this issue, past experience suggests that a clear, precise, and fully understandable definition of changes which effect form, fit, or function would be an absolute necessity.

#### Witnessing of Approval Tests:

I disagree with the NIOSH position on this issue. For any NIOSH certification program to be effective, it must be able to stand the scrutiny of peers and not be conducted behind closed doors. Additionally, NIOSH could, relative to this issue, assist the manufacturers in assuring that their test equipment is equivalent to that in the NIOSH reference laboratory in both specifications and performances through the development of more detailed witnessing procedures.

#### Duration of Approval:

Much of the "problem" noted in the NIOSH position on this issue relates to extension of approvals. Should NIOSH issue a new approval number for any change involving form, fit, or function, the duration of approval issue would become essentially a non-issue.

#### Product Quality Requirements:

While I concur with the NIOSH approach, the APD's specified should be carefully considered to reflect the potential for health impact to the user.

#### Unpublished Test Requirements:

I fully concur with the NIOSH position.

#### Testing of Prototype Respirators:

I generally concur with the NIOSH position with the exception that I believe NIOSH should discuss the results with the applicant. I agree that direct assistance should not be provided, but NIOSH serves two purposes, the user's needs and the development of new products, in providing technically based discussions with the applicant. A "closed" NIOSH certification environment will serve to impede respirator development and, in the long run, result in the development of certification technical staff which are out of touch with either the manufacturers world or the user's world.

#### Approval Tests:

While I concur with the basis behind the NIOSH position, I am not aware of major discrepancies between prototype respirators and production respirators which would not be captured in the audit process. Perhaps NIOSH should consider modifying their position on this issue to require that the manufacturer submit his certification test data to NIOSH on the production product. This would serve to require the manufacturer to conduct such testing and would provide an incentive to fix any problem which developed prior to sale.

#### Group Testing:

My views expressed above on test witnessing preclude, perhaps, this option.

### Manuals:

I concur with the NIOSH position on this issue.

### NIOSH Systems Manual:

While I fully concur with and agree that such is needed, issuance of changes to all recipients appears to require attention. Unless that issue is addressed, this important document will be outdated within a short time.

### Publication of Test Data:

This is perhaps the single most important matter in the interest of enhancing effective respirator use, selection, purchase, and innovation. I fully support the NIOSH position and encourage NIOSH to develop a dissemination mechanism which assures that as many employers as possible receive this publication. Further, NIOSH should encourage respirator manufacturers to employ such data in their respective sales aids, brochures, and advertizing.

### Additional Recommendations:

I recommend that NIOSH consider the following additional matters with regard to respirator certification:

#### Qualitative Fit Testing:

Manufacturers should be required to submit quantitative fit test data, based upon NIOSH specified criteria, with each application. This data would assure that each respirator certified meets or exceeds minimum protection factor standards. Such data should also be published by NIOSH and should be an additional evaluation factor in the audit process.

#### Charcoal Leakage:

Air purifying sorbant containing respirator cartridges and resin impregnated felts do evidence particulate leakage. NIOSH should establish maximum leak rates keyed to the cartridge type and the material therein. Obvious categories include: organic vapor, amines, acid gases, and particulate filter felts. Compliance with these criteria should be a requisite to certification.

#### Human Use Certification:

Respirators are used by humans and, as a requisite to proper function, come into close contact with the skin and respiratory system. A requisite to certification should be a statement by the manufacturer that, as a minimum, primary skin irritancy tests have been performed and passed for all components which contact the skin. Further, Material Safety Data Sheets should be required as part of the applicants submission for all respirator materials which could be inhaled, such as electrostatic felt resins.

Electrostatic Felts:

Over long periods of time or under high humidity conditions, electrostatic felts lose their charge and, as a result, their ability to filter particulates efficiently. NIOSH performance criteria should consider the requirement to meet special minimum penetration performance criteria for electrostatic felts when tested under "discharged" conditions.

Information Center:

NIOSH might give consideration to establishing a National Respirator/Protective Equipment Information Center whereby selection information could be provided over the phone or in response to written requests to employers or employees. At least two major respirator manufacturers offer such a service at the present time. Such an information center could be publicized by the required inclusion of an address and phone number on respirator approval labels, thus assuring wide dissemination.

This concludes my formal comments. I will be pleased to respond to any questions which you might have.