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Final Report

Role of Workplace Testing of Respirators as a Condition of Certification for the Federally Mandated NIOSH Respiratory Protective Equipment Certification Program

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I. Executive Summary/Abstract:

The practicality and advisability of incorporating workplace field testing, as part of the formal NIOSH Respirator Certification process, has been evaluated. Conclusions are based on a review of previous publications and prior rulemaking information; presentations at a January 7-9, 1991 NIOSH sponsored meeting; and the authors professional judgement. Based on this information it is recommended that field testing not be used in the formal respirator certification process. Several other recommendations relating to certification and: respirator field testing, chamber simulated workplace testing, and supplemental unresolved questions are also identified.

II. Scope of Review Requested by NIOSH

Guidance provided by NIOSH requested that development of recommendations concerning the role of workplace testing relative to respirator certification should consider the following information:

a) The August 27, 1987 NPRM describing a new respirator certification procedure (42 CFR 84).

b) Comments to the August 27, 1987 NPRM which address the subject of workplace or simulated workplace testing as part of the certification process (84.31/.32/.34).

c) The confidential draft of a second NPRM on this subject dated September 18, 1989.

d) Material presented at a January 7-9, 1991 meeting sponsored by NIOSH and announced in the October 19, 1990 Federal Register.

All this information has been considered and is discussed in this report. In addition, I actively participated in the questions and discussions at the January 7-9 meeting, and reviewed the entire transcript of presentations/discussions at the meeting. I also reviewed over 20 manuscripts provided by NIOSH (many of which only represent presentations) on the subject of workplace respirator testing.

III. Perception of NIOSH Management Philosophy

To put some perspective on the question under consideration it is necessary to identify recent (following publication of the 1987 NPRM) statements by NIOSH management. While these statements can change over time, they provide a setting for perceptions of attendees at the January 7-9 meeting. The following four statements cover the period from November 1988 to January 1991.

a) A November 22, 1988 letter from the Director of NIOSH to the President of ISEA states: "However it remains our conviction that NIOSH Certification testing in the future must eventually rest primarily on workplace-testing or simulated workplace-testing so as to provide the most reliable information for predicting the actual performance to be expected from a product."

b) The October 19, 1990 Federal Register notice announcing the January 7-9, 1991 meeting states: "Therefore, NIOSH believes that federal certification requirements must include workplace or validated simulated-workplace testing."

c) The transcript of the January 7-9 meeting includes the following statement by the Deputy Director of NIOSH, "However, NIOSH still feels strongly that assessments of workplace performance of respirators needs to be done in order for us to feel confident that certified respirators provide workers with adequate levels of protection."

At this same meeting the NIOSH Director of Safety Research stated that: "Yet there is evidence that these laboratory tests may not always reflect how these respirators, when actually used in the workplace, will perform in protecting workers."

The above quotes indicate that simulated workplace testing, with the development of experimental data relating workplace tests to laboratory tests, might satisfy NIOSH objectives. However, primary emphasis appears to be directed at workplace field testing. A time frame for implementing such testing is not clearly defined. However, inclusion of a requirement for such testing in the 1987 NPRM strongly suggests that NIOSH management believes that workplace testing is a well developed technical procedure.

IV. Introduction and Background

a) August 27, 1987 NPRM (42 CFR 84) and Resulting Comments

Statements in this NPRM identify the goals that workplace testing or simulated workplace testing should satisfy to achieve NIOSH objectives. These statements also identify two major problems associated with achieving these objectives. Sections 84.31 and 84.32 state that tests will be reasonably representative of the places and conditions in which it is anticipated the respirators will be used.

Section 84.34 states that NIOSH will make available for public review the protocols utilized in tests conducted under provisions of this part. The preamble to the NPRM implies that model protocols would be available shortly. However, the ability to define representative workplaces is questionable, and a standard protocol has not yet been published.

Review of the comments (October 1987-1988) following publication of the NPRM indicated almost unanimous opposition to the concept of field testing as part of the certification process. This includes comments from respirator manufacturers, industry respirator users, trade associations and OSHA. Some support for the concept of field testing was provided by the Nuclear Regulatory Commission and the United Mine Workers America. However, both qualified their support due to the absence of published field test protocols.

b) Confidential Draft of Second NPRM (September 18, 1989)

This draft indicates that Sections 84.31/.32 have been deleted from the August 27, 1987 NPRM.

c) Relevant Publications

Review of the more than 20 manuscripts provided by NIOSH indicates a situation which relates to the development and transfer of quality technical information on the subject of concern. There is only one NIOSH publication in the open peer reviewed literature dated 1987 or later. This publications is dated March 1987 and is only concerned with disposable respirators. While there are at least seven post-1987 non-NIOSH manuscripts, almost all of these are from presentations.

None of these have undergone the peer review process which is critical to assure the adequacy of the conclusions developed. Limited discussions with some of the investigators (from manufacturers) indicated that they did not have the time/motivation to go through a typical peer review process.

One "potential publication" which should be mentioned is the draft NIOSH report by Barry Pallay and John Gamble (Revised August 31, 1990). While this is an extensive report, with considerable detail, its Sampling Strategy Section only represents what the authors did, and will not immediately permit development of a model test protocol which can be widely used. The Conclusion Section of this report also identifies another problem associated with including workplace testing as part of the certification process. This Section starts with the statement that "The below conclusions apply for the two lead-sulfuric acid battery manufacturing facilities studied, when WPF measurements are made using polystyrene sampling cassettes and polycarbonate filters to measure lead particulate." Clearly the authors did not see their results as being immediately extrapolated to a wide variety of respirator use situations.

It appears that to make progress in this area, NIOSH must more promptly disseminate the information it develops. This will require the commitment of adequate NIOSH resources so that such publications can be prepared and disseminated promptly. In addition, NIOSH should consider approaches which will help disseminate information developed by others, through a modified peer review process, which assures the scientific adequacy of the information. This may present an implementation problem, but it would permit NIOSH and industry to move forward regarding the problem of how to do workplace testing. In

addition, it will allow NIOSH to make better use of the extensive data that can/will be developed by industry and manufacturers.

V. Major Discussion Points at January 7-9 Meeting

Attendees at the January 7-9 Meeting represented a broad spectrum of organizations. This included individuals from NIOSH who provided technical presentations, and individuals from respirator manufacturers, academia, national laboratories, and consultants who provided both technical and policy presentations. A brief discussion of some of the highlights is provided to put a perspective on the current state of the art/science regarding field testing.

a) NIOSH Studies

A study of firefighter use of SCBAs identified some of the problems associated with field testing. This study (initiated in 1987) had to become a Program Protection Factor (PPF) study because of operational constraints. This study had not yet defined specific fit factors. The authors believe that there will be differences in the PPF for different chemicals.

Another study (initiated in 1987) in two lead-acid battery manufacturing facilities is probably the most comprehensive study I am aware of. The report provides extensive detail, but as noted in Section IV of this report, does not provide a model test protocol which can be widely used. This presentation identified intra-subject WPF variability, and similar results were identified by other speakers later in the program. The presentation also indicated, that the WPF was a function of the contaminant measured, possibly due to differences in particle

size. This variable was also identified by other speakers, and raises the question of how to measure/define WPFs when several contaminants are measured in a field study.

The effect of lung deposition on the measured WPF was scientifically interesting, but it is not clear that the magnitude of the correction noted is significant compared to other test variables of concern.

b) Presentations by Non-NIOSH Organizations

Some of the major technical points and identified problems discussed during these presentations include the following:

1) While there have been several field studies: test protocols are different in most cases; environmental test conditions are poorly defined; the number of test subjects and usable data is limited for any single study; particle size is not always measured even though particle size and contaminant of concern seems to influence the measured WPF. This raises questions regarding the interpretation of any single study and the comparison of different studies.

2) There has been no evaluation of the effect of performing the field test on the measured WPF (i.e., worker response to being monitored). The potential for this type of effect was noted by several meeting attendees. This raises questions regarding extrapolation of the results of any field study, to general use situations of concern when considering certification.

3) It is not clear that test results can be extrapolated between different work situations.

4) There is no well defined test methodology for evaluating gas/vapor situations.

5) Test results indicate that the measured WPF is dependent (up to a point) on the mass of material collected on the sample obtained outside the mask. The measurable WPF is also constrained by the limit of detection and background for the sample obtained inside the mask.

6) Most test data indicates that the measured WPF exceeds the Assigned Protection Faction (APF) for the class of respirator being tested.

Based on these technical problems the overwhelming opinion of meeting attendees was negative regarding the use of field testing as part of the certification process. They believed that:

a) It was not possible to identify a representative workplace.

b) There was no standard test protocol.

c) Field testing would introduce: uncontrollable test conditions; a high level of uncertainty; and a large number of poorly defined variables.

d) There was insufficient information to implement a test procedure of this type into a formal certification program.

e) Field testing to determine WPF was in a research stage of development.

VI. Conclusions and Primary Recommendation

Evaluation of the information previously summarized in this report, together with my past experience in operational industrial hygiene, aerosol research and respirator research provides the basis for the conclusions which follow. To help focus these conclusions I have used the nomenclature used by Dr. Donald Campbell, NIOSH, at the January 7-9 meeting. That is, what should be the role of WPF in the "following regulations," and in the "distant future" regulations? The answer to this question partly depends on the NIOSH timetable, which is determined by Agency policy and priorities. In light of typical regulatory schedules for occupational health and safety regulations it seems appropriate to only consider the "following regulations" aspect, assuming that such an NPRM would be published before the end of 1995 (i.e., within 4 years). This permits use of reasonable estimates of available technology, resources, and priorities.

It is also necessary to more clearly define the objectives of the NIOSH Respirator Certification process. This represents Agency policy, but a generic starting point would be the accepted definition of the verb "certify." This is:

> To confirm formally as true, accurate or genuine; testify to or vouch for in writing; to guarantee as meeting a standard; attest.

If we apply this definition to the requirement to be reasonably representative of the places and conditions in which the respirator will be used, a field test should not be used in a formal respirator certification process for the following reasons:

a) Definition of a single (or a few) representative facility(ies) is probably impractical.

b) Impact of doing a field test will have some not yet defined effect on the measured WPF.

c) Lack of controls in the field will make testing reproducibility and variability unsatisfactory for use as a direct formal certification test. Experimental variability under laboratory test conditions are not fully controlled at the present time.

d) The slow rate of progress by NIOSH in developing a standard field test protocol suggests that standardization represents a potential problem. This constraint might be solvable in a reasonable time frame, if this is addressed as a priority need. However, to fully solve this problem will also require attention to situations where gases/vapors are the contaminant of concern.

Certification must represent an indication of performance under controlled, reproducible, and verifiable test conditions, and these requirements cannot be satisfied at the present time.

VII. Additional Recommendations

In light of these conclusions the question remains regarding the role of WPF relative to worker protection. As stated by James L. Weeks (United Mine Workers America) in his comments regarding the August 27, 1987 NPRM, "Our members, and all other workers, do not wear respirators under laboratory conditions; they wear them at work."

Two parallel approaches are recommended to complement certification laboratory test procedures. Both these efforts must be actively pursued to develop a complete evaluation of respirator performance.

First, NIOSH, with input from industry and manufacturers, needs to develop a standard test protocol so that WPF can be determined under a variety of work situations using comparable test methods. Without this benchmark, data collected is of questionable value. While the problems noted in items VI a/b/c of this report will still be present, test results obtained using a standard procedure, and organized into a NIOSH data base, will help identify the limits of respirator performance when used in actual work situations. This can be provided as guidance to respirator users. The standard protocol must address a wide variety of test variables which must be measured during testing. The standard test protocol should initially be focused on particulate contaminants. The need for a separate standard protocol for gas/vapor situations should also be evaluated.

As a supplemental condition for certification, manufacturers should be required to perform, (or have an established research organization perform) some field testing which satisfies the previously published and agreed to test protocol. These protocols would be designed for the data base development objectives noted, rather than for formal respirator certification. This might simplify the test procedures and data gathering requirements.

As part of this field test program, NIOSH should evaluate the possibility of developing a simplified report review procedure which will allow all interested parties to have greater confidence in the adequacy of field test data. At present such data are only presented at the American Industrial Hygiene Conference. This is not adequate.

In parallel to these efforts addressing field study needs, NIOSH should make a major commitment towards developing chamber test procedures which represent simulated workplace testing. Preliminary (and limited) work of this type has been done in the past at Los Alamos National Laboratory (Report LA 11236) and Lawrence Livermore National Laboratory. Such tests should incorporate environmental variables (temperature and humidity), different physiological work rates, aerosol characteristics (particle size and concentration) and other test parameters which are necessary to simulate work situations of interest. Defining those work situations of interest will require considerable development. In the long term (i.e., "distant future") these chamber tests might be related to information developed in the field tests previously described, as a supplemental condition for certification.

In addition, to these priority broad objectives, NIOSH must also look at a variety of other problems which have been identified. These include:

a) Development of gas/vapor test methods for field application.

b) Evaluation of the effect of field testing on the measured WPF (i.e., worker reaction to being monitored).

c) Evaluation of the relative magnitude of intra- and inter-subject variability under laboratory test conditions and field test conditions.

d) Evaluation of why some data indicates dependence of measured WPF on mass collected outside the respirator.

e) Develop a rationale for defining a WPF when a single test yields different results for different test substances.

f) Promptly publish the results of NIOSH studies.

As a final note it is worth commenting on the statement that field testing is in a research phase. Clearly there are still many unanswered questions. Some of these have been discussed in this report and others (i.e., probe location, anthropometric criteria for test subjects, etc.) are not discussed. However, it is my opinion that the knowledge base is well beyond the research stage, and well into the development and application stages. It is now necessary to complete the demonstration, testing and evaluation/analysis phases.

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16. Abstract (Limit: 200 words) This evaluation considered the practicality and advisability of incorporating workplace field testing as part of the formal NIOSH Respirator Certification process. According to the author, there is a need to more clearly define the objectives of the NIOSH Respirator Certification process, specifically to define more clearly the term certify. The author concludes that the definition of a single or a few representative facilities is likely to be impractical, that the impact of doing a field test will have some not yet defined effect on the measured workplace protection factors (WPF), that the lack of controls in the field will make testing reproducibility and variability unsatisfactory for use as a direct formal certification test, and that the slow rate of progress being made in developing a standard field test protocol suggests that standardization represents a potential problem. The author recommends two parallel approaches to complement certification laboratory test procedures. The first calls for NIOSH, with input from industry and manufacturers to develop a standard test protocol so that WPF can be determined under a variety of work situations using comparable test methods. Secondly, manufacturers should be required to perform some field testing which satisfies the previously published and agreed to test protocol.

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