

Memo from

13  
CA DUPRAZ

To Participants in the NIOSH Public Hearing  
Date July 29, 1980  
Subject Comments on Proposed Changes in NIOSH Testing/Certification

Thank you for this opportunity to share my views on some of the proposals put forth by NIOSH on the subject of testing and certification. First I'd like to offer some general comments.

The June 18 notice of this public hearing outlines four possible roles for NIOSH in the testing and certification of personal protective equipment and hazard monitoring instrumentation. However, selection of either a single option or combination of alternative approaches requires consideration of several factors:

- (1) the size and type of effort needed to provide occupational health and safety equipment users a higher level of confidence in the performance of these products
- (2) identification of the personnel and facilities needed to accomplish this objective within an acceptable time frame
- (3) development of an efficient operating system which utilizes all available resources to advantage

Although the issues and topics on which this hearing is focusing relate specifically to the respirator approval system, the Consultants' Report recommended that testing and certification activities be restructured to include all personal protective equipment and hazard monitoring instrumentation. As devices of integrated design emerge, this broader scope is increasingly desirable. Most of the elements of a restructured respirator testing and certification program should therefore be broadly applicable to all PPE and HMI.

Three major components of the proposed testing and certification program - performance specification revision, new product testing and approval and field audit assessment of in-service product performance - can be examined with this broader program scope in mind:

#### Performance Specification Revision and Development

Because parts of 30 CFR 11 have long been recognized as technological anachronisms there have been repeated attempts to upgrade existing procedures or develop new ones by NIOSH itself, through contract work at IASL, by consensus standards organizations and other technical groups. These activities have entailed extensive laboratory testing and data analysis. The situation has been much the same in developing performance test methodology in other product areas, i.e., flammable fabrics. There is no reason to believe that this will not be the case with respect to occupational health and safety products. Indeed, one of the most wanting characteristics in current performance test methods is demonstrated interlaboratory reproducibility of data.

Consequently an increase in the number of testing facilities available for participation - in at least the final stages of test method development - should be encouraged. Effective management of in-house, purchased and contributed technical effort will also be necessary to assure

that revisions and new procedures are technically sound, up-to-date and become available in a timely fashion. Use of qualified independent testing laboratories as well as NIOSH and manufacturers' in-house facilities may be essential to handling this key program element.

The proposal by NIOSH to establish new or revised performance specifications by the rulemaking process should be examined closely in view of the agency's history of previously unsuccessful attempts to change even uncontroversial material in 30 CFR 11. Alternative approaches for establishing updated performance specifications appear to be needed.

### New Product Approvals

NIOSH proposes discontinuing certain review procedures which are now part of the testing/certification system but would continue certifying new products and publish results of approval testing conducted by NIOSH. The Consultants' Report emphasized the need to assure users of product reliability in service. New product approvals would better meet this goal if certification were based, at least in part, on the results of field audits of product performance after an initial or trial use period. This could be achieved if manufacturers' were to stipulate that products met minimum standard performance specifications and provided the initial product performance test data on which this claim was based. Some mechanism for verifying manufacturers' claims might be needed so that users could confirm that new products can be expected to perform adequately during the trial period between product introduction and successful completion of an in-service field audit.

This approach would utilize NIOSH and manufacturer in-house testing facilities and personnel somewhat more efficiently than the present system by eliminating duplication of initial performance testing of new products. If necessary these resources could be augmented by the services of qualified independent testing facilities.

### Field Audit Assessment of In-Service Product Performance

An effective field audit program would go a long way towards providing a higher level of confidence to users of occupational health and safety equipment. Performance data would be particularly meaningful if the audit program involved testing multiple units of a specific product, both as purchased and after the product was placed in service, against standard performance specifications and perhaps against proposed new performance requirements. Analysis of the type and frequency of functional product deficiencies found in field audits would assist in setting priorities for tightening and/or redirecting manufacturer in-house quality control, developing new product designs or performance criteria.

A well-organized and completely detailed field audit protocol should be developed, offered for public comment and revised as necessary prior to adoption as an operating plan. This protocol should include product sampling procedures, complete, by type of product description of specification and performance test methods on which the audit will be based, mechanisms for identifying in-service product performance inadequacies due to misuse, abuse or improper maintenance, description of the process for publishing results of field audit, provisions for verifying contested field audit data, options for including proposed or tentative

test methods as part of the performance audit, procedures for assuring removal from service of unreliable or technically unsound products.

While the extent to which the services of qualified laboratories other than in-house NIOSH and manufacturers facilities would be needed in conjunction with the field audit program is uncertain at this point in time, restructuring of testing/certification activities should not preclude either their existence nor ignore their usefulness.

I would like to point out here that the Consultants' Report suggests that the Consumer Product Safety Commission operating system be examined for applicability to testing and certification of occupational health and safety products, as many of its features closely parallel those needed here.

I have only a few additional comments, which relate more directly to specific issues raised by NIOSH in connection with current practices in its operation of the respirator testing and certification program.

#### Unpublished Test Requirements

NIOSH is proposing to discontinue the current practice of accommodating new equipment designs by basing approvals on special unpublished test requirements, which have not had the benefit of public scrutiny. This recommendation highlights the need for an operating plan which encourages innovation while retaining the safeguarding provisions of uniform performance evaluation. Perhaps this can be achieved by including in the restructured testing and certification program provision for "conditional" or "temporary" approvals. These could be based on the results of both non-standard or tentative test procedures and limited scale field evaluations. Complete details of testing, field trial protocol and data analysis on which any approval is based would be published as a condition of approval. At this point the performance specification development process could be relied upon to upgrade tentative test procedures and criteria to full acceptance. Successful field audit would remain a requirement for final approval.

#### Witnessing of Approval Tests

NIOSH has proposed that applicants no longer be allowed to witness approval testing of their products because testing personnel feel pressured by the presence of witnesses. Test methods so subjective in conduct or so highly variable in results that the presence of witnesses can materially influence the outcome should be eliminated in the process of revising performance specifications. In addition testing of multiple units of the same product should dilute possible observer interference to a negligible level. Until the wide latitude in test conditions and high number of unspecified variables which exist in current certification procedures have been eliminated, the provision permitting applicants to witness product approval tests should be retained.

#### Duration of Approvals

As a practical matter the duration of final approvals, reapprovals and temporary or conditional approvals may have to be governed by the availability of product testing and data publishing resources.

However, all approvals should be limited in duration. Approval duration might be tied to the extent upon which the product is depended for survival, health or safety protection - the greater the reliance, the shorter the approval duration.

### Group Testing of Respirators

This has been proposed by NIOSH in an attempt to organize the testing work load and to accelerate product approvals. Testing of the same types of products in a group would offer the additional advantages of off-setting within-lab variations in test conditions and placing product testing on a more comparative basis. However, use of an approval testing application "time window" could result in

- (1) inadvertently controlling, in the short term, the type and number of new products available to users
- (2) unintentionally excluding, solely on the basis of timing, competing products from the approval testing schedule for a significant period of time
- (3) unwittingly frustrating occupational health and safety enforcement timetables by delaying approvals of needed or especially desirable products, particularly if only a single facility can provide the needed service.

### In Conclusion

One last comment. Since the restructuring of occupational health and safety products testing and certification is so complex I recommend that specific procedural options be developed for each key program element and the transition phase from current to restructured operation and that these be offered for public comment. Each option should be presented with an analysis of its probable effectiveness in meeting the objectives of testing/certification and an estimate of the personnel and facilities resources required to carry it out. NIOSH might recommend adoption of one of these options, but should also provide an explanation of its reasoning in making the selection.

Thank you.