STATEMENT

OF THE

ANSI AD HOC RESPIRATOR TEST AND APPROVAL SUBCOMMITTEE

AT THE

NIOSH PUBLIC MEETING

ON

RESPIRATOR TESTING AND APPROVAL

28-30 JULY 1980

STATEMENT OF THE ANSI AD HOC RESPIRATOR TEST AND APPROVAL SUBCOMMITTEE AT THE NIOSH PUBLIC MEETING ON RESPIRATOR TESTING AND APPROVAL HELD ON 28-30 JULY 1980.

I am William H. Revoir, Chairman of the Ad Hoc Respirator Test and Approval Subcommittee of the American National Standard Institute's Z88 Committee on Respiratory Protection. I am here today, 28 July 1980, to present a statement concerning the administrative aspects of a respirator test and approval program on behalf of the mentioned Subcommittee.

Introduction

The American National Standards Institute has established an Ad Hoc Subcommittee of the Institute's Z88 Committee on Respiratory Protection for the purpose of reviewing the current respirator test and approval program being carried out by NIOSH and MSHA and for the purpose of offering suggestions for the improvement of this program.

The membership of this Ad Hoc Subcommittee has been limited to persons who have had considerable experience in respiratory protection and who are recognized to have expertise in respiratory protection by industrial hygienists, safety engineers, and other professionals in occupational health and safety. Members of the Ad Hoc Subcommittee are persons employed by government agencies involved in occupational health and safety other than NIOSH and MSHA, research institutions engaged in respirator research, consultants on respiratory protection, industrial firms which provide respirators to workers, and respirator manufacturers. The Ad Hoc Subcommittee has twenty-two members: six are employed by government agencies; three are employed by research institutions; five are consultants; three are employed by industrial users of respirators; one is employed by a respirator distributor; and four are employed by respirator manufacturers.

On 18 June 1980, NIOSH published a notice in the Federal Register which announced a public hearing to be held on 28-30 July 1980 for the purpose of discussing a respirator test and approval program. This notice stated that the issues and topics to be discussed at the public meeting are intended for use in restructuring the respirator test and approval program to increase the level of confidence of respirator users that approved respirators provide adequate protection. Inasmuch as the discussion subjects listed in the mentioned notice concern administrative aspects of a respirator test and approval program, the recommendations which I shall present today on behalf of the ANSI Ad Hoc Respirator Test and Approval Subcommittee shall be limited to various administrative aspects of a respirator test and approval program.

The members of the ANSI Ad Hoc Subcommittee deplore the very short time period of only five weeks from the date of the published meeting notice until the date of the start of the meeting to permit persons to prepare to participate in the meeting. This very short time period, especially since it occurs during the summer, has made it extremely difficult for an organization concerned with respiratory protection to get its members together to develop statements for presentation at the meeting which represent the consensus of opinion of the members. Undoubtedly, if NIOSH had allowed more time for persons to prepare for this meeting, many more organizations than those listed who are to appear at this meeting would be participating in this meeting.

Because of the very short period of time available to prepare for the public meeting and because the twenty-two members of the ANSI Ad Hoc Subcommittee are located in thirteen different states and Canada ranging from the east coast to the west coast, a comprehensive questionnaire pertaining to the administrative aspects of a respirator test and approval program was prepared by the Chairman of the Subcommittee for use in soliciting the viewpoints of the members of the Subcommittee. Copies of the questionnaire were sent to the members of the Subcommittee. The completed copies of the questionnaire were reviewed and analyzed by the Chairman of the Subcommittee to determine the consensus of opinion of the members of the Subcommittee.

A meeting of the members of the Subcommittee was held on Sunday, 27 July 1980, at the Sheraton Potomac Inn in Rockville, Maryland. This meeting ran from morning until evening. The results of the analysis of the completed questionnaires were discussed by the attendees at this meeting. After listening to the discussions of various administrative matters concerning a respirator test and approval program, some members of the Subcommittee changed their ideas on several matters. The attendees at the meeting directed the Chairman of the Subcommittee to prepare a statement which represents the consensus of opinion of the members of the Subcommittee and to present this statement at the public meeting on Monday, 28 July 1980.

While some individual members of the ANSI Ad Hoc Subcommittee may disagree with some of the recommendations, the following recommendations on various administrative matters of a respirator test and approval program represent the consensus of opinion of the majority of the members of the Subcommittee.

Responsibility and Authority for Establishing Respirator Performance Criteria, for Establishing Respirator Test Procedures, for Carrying Out Approval Testing of Respirators, and for Granting of Respirator Approvals

NIOSH alone should be given the responsibility and authority for establishing respirator performance criteria and for establishing respirator test procedures. Also, NIOSH alone should be given the responsiblity and authority for carrying out the testing of respirators submitted to NIOSH by manufacturers to determine whether or not the respirators meet the established performance requirements. In addition, NIOSH alone should be given the responsibility and authority to grant approvals to manufacturers for respirators which have been tested and found to meet the established performance criteria. However, certain federal mine safety and health statutes will require that MSHA jointly with NIOSH grant approvals for respirators that are for use in mining operations.

The governmental respirator test and approval regulation should include a provision for the establishment of a government steering committee which would develop a policy for the respirator test and approval program and which would oversee the operation of this program by NIOSH. Members of this government steering committee would be persons from government agencies concerned with respiratory protection. This government steering committee would make use of respirator experts in the private sector for advice on technical matters.

Time for Testing Respirators

NIOSH should carry out tests on particular respirators in the order that they are submitted to NIOSH by respirator manufacturers.

Modification of Appoved Respirators

The respirator test and approval program should require a respirator manufacturer to obtain a new approval for any modification of an approved respirator that affects "form, fit, or function" of the respirator and the manufacturer would not be allowed to market the respirator containing the modification until NIOSH grants the manufacturer a new approval. The designation number of the new approval would be different from the old designation number for the previous approval. This system would permit NIOSH, any government agencies having responsibility for the health and life of workers wearing respirators, employers who purchase respirators for use by employees, and employees who must wear respirators to differentiate between approved respirators of a specific make and model that are different in regard to "form, fit, or function".

The respirator test and approval program should permit a respirator manufacturer to manufacture and market an approved respirator containing a modification that does not affect "form, fit, or function" of the respirator without requiring that the manufacturer obtain a new approval for the respirator. However, the manufacturer would be required to notify NIOSH of this type of modification.

Product Documentation

The respirator test and approval program should require that respirator manufacturers submit copies of product documentation (bills of materials, drawings, specifications) to NIOSH for each respirator to be tested for approval. Also, respirator manufacturers should be required to submit copies of revised product documentation to NIOSH whenever approved respirators are modified. However, NIOSH should not be required to review, analyze, and approve the copies of product documentation, but NIOSH should be allowed to file these copies for reference whenever the results of tests and examinations of specimens of a respirator submitted for approval or the results of tests and examinations of specimens of a respirator obtained from the field indicate that a performance problem may exist.

Quality Control

The NIOSH respirator test and approval document should list detailed requirements for a quality control program to be carried out by respirator manufacturers. However, a respirator manufacturer should not be required to submit copies of detailed quality control plans for each respirator to be tested for approval by NIOSH. Instead, the respirator manufacturer should be required to certify to NIOSH that an effective quality control program which meets the requirements listed in the respirator test and approval document will be implemented for the respirator submitted for testing and approval when said respirator is manufactured and marketed.

Design Analysis

NIOSH has indicated in the notice published in the Federal Register on 18 June 1980 that a respirator manufacturer should be required to prepare an engineering design analysis for each respirator submitted to NIOSH for approval and that the results of this analysis would be given to NIOSH only if testing of specimens of a submitted respirator or testing of specimens of an approved respirator obtained from the field indicates that a respirator design problem exists. While many members of the ANSI Ad Hoc Respirator Test and Approval Subcommittee favor such a requirement, they feel that NIOSH has not explained adequately what an engineering design analysis should consist of and they want more information on this matter from NIOSH.

Respirator Specimens for Approval Testing

NIOSH should be permitted to test for approval specimens of a respirator fabricated with prototype tooling but containing materials which will be used in the respirator to be manufactured and marketed. However, the approval for the respirator should not be granted by NIOSH until NIOSH has examined specimens of the respirator made with the use of production tools, production methods, and production personnel and this examination determines that there is no need for testing of specimens of the respirator manufactured with production tools, production methods, and production personnel. However, if this examination indicates that testing of specimens of the respirator made with production tools, production methods, and production personnel should be carried out, then NIOSH shall not grant the approval until such testing has been carried out and the tested specimens are found to meet the performance criteria.

Service of Testing Prototypes

NIOSH should be permitted to provide a service to respirator manufacturers which involves the testing of specimens of prototype respirator to determine if the designs of prototype respirator have potential to result in production specimens of respirators which would meet the appropriate performance criteria. However, NIOSH only should test specimens of such a prototype respirator provided that the manufacturer submits test data to NIOSH which indicates that the prototype respirator may have potential to result in production specimens which would meet the appropriate performance criteria, and provided that the manufacturer pays fees to NIOSH to cover the cost of testing, and provided that this testing does not delay approval testing of other respirators.

Assistance to Respirator Manufacturers in Establishing Test Equipment and/or Test Procedures

NIOSH should assist a respirator manufacturer in establishing satisfactory test equipment and/or satisfactory test procedures by providing the manufacturer with copies of sketches and engineering drawings of test equipment, copies of calibration procedures for test equipment, and/or copies of detailed procedures for carrying out tests. When necessary, NIOSH should provide the manufacturer with demonstrations of the operation, and/or calibration of test equipment, and/or demonstrations of test procedures.

Duration of Approval

The duration of an approval for a respirator granted by NIOSH should not extend beyond the time when new performance criteria for the particular type of respirator becomes effective. At that time, the respirator manufacturer would be required to submit the respirator to NIOSH for approval under the provisions of the new performance criteria. However, the respirator test and approval program should allow suitable "grandfathering" of respirators approved under the provisions of the previous performance criteria to permit an orderly conversion of respirators by users.

Witnessing of Approval Testing

NIOSH should allow a respirator manufacturer to have a representative(s) present to witness the testing of a respirator submitted for approval.

Appeals Procedure

The respirator test and approval program should include provisions for an appeals procedure which would permit a respirator manufacturer to appeal a decision made by NIOSH. Appeals would cover a decision by NIOSH not to accept an application from a manufacturer for testing and approving a respirator, a decision by NIOSH not to approve a respirator after it has been tested, a disagreement by a manufacturer that testing by NIOSH was performed properly, a disagreement by a manufacturer that NIOSH has interpreted test results properly, and other disagreements between a manufacturer and NIOSH. The appeals procedure would concern matters involving the approving of respirators, the auditing of approved respirators obtained from the field, and stop sale/recall requests.

Arbitration of an appeal should be carried out by a panel of senior experienced scientists and engineers. An arbitrator could be a person employed by NIOSH in a division not involved in testing and approving respirators, a person employed by another government agency, and a person employed in the private sector.

Field Audit

NIOSH should carry out a continuing field audit of approved respirators in the market place and the work place. NIOSH should procure specimens of both unused and used respirators from the market place and the work place.

NIOSH should examine and test these specimens to determine if they meet appropriate performance criteria. If specimens of an approved respirator fail to meet appropriate performance criteria, then NIOSH should attempt to determine the causes(s) of failure.

The results of the field audit should be reported to the respirator manufacturer by NIOSH if the specimens of the approved respirators fail to meet the appropriate performance criteria and also if the specimens of the approved respirators meet the appropriate performance criteria. NIOSH should report the results to the manufacturer immediately after completion of testing the specimens of the respirator.

Investigation of Reports of Alleged Failure of Approved Respirators to Provide Proper Protection in the Field

NIOSH should investigate a report received from the field that an approved respirator may not provide adequate protection. NIOSH immediately should notify the respirator manufacturers that such an investigation is to be carried out. NIOSH should report the results of the investigation to the party that notified NIOSH of the possible failure of the approved respirator and should report the results of the investigation to the respirator manufacturer.

Stop Sale and Recall

NIOSH should have the authority to require a manufacturer to stop sale of an approved respirator if the results of a field audit of an approved respirator or the results of an investigation of a report from the field of alleged failure of an approved respirator to provide adequate protection show that the respirator manufacturer is marketing specimens of an approved respirator which fail to meet performance criteria or specimens of an approved respirator which contain a characteristic(s) that prevents them from providing adequate protection. However, NIOSH should not be permitted to mandate the stop sale order until NIOSH has proven to the respirator manufacturer that the results of the field audit or the results of the investigation of the report from the field are valid. NIOSH should have the authority to prohibit the respirator manufacturer from selling the respirator until such time that the manufacturer has proven to NIOSH that the cause(s) of the failure of the respirator to meet performance criteria has been eliminated or the characteristic(s) of the respirator that prevents it from providing adequate protection has been eliminated. Also, NIOSH should have the authority to require the respirator manufacturer to recall the specimens of an approved respirator from the field which do not meet performance criteria or which contain a characteristic(s) that prevents them from providing adequate protection. However, NIOSH should not be permitted to mandate the recall until NIOSH has proven to the respirator manufacturer that specimens of the approved respirator in the field do not meet performance criteria or that specimens of the approved respirator in the field contain characteristic(s) which prevents them from providing adequate protection.

Stop Sale and Recall Procedures

Whenever a respirator manufacturer submits a respirator to NIOSH for approval, the manufacturer should be required to certify that a detailed plan of procedures for stop sale and recall of respirator from the field exists. NIOSH should have the authority to require the respirator manufacturer to submit this plan to NIOSH for examination and approval whenever NIOSH requires the manufacturer to carry out a stop sale and recall action.

Publicity of Stop Sale and Recall of Respirators

NIOSH should publicize all orders to respirator manufacturers concerning stop sale and recall of respirators.

Revocation of Approvals

NIOSH should have the authority to revoke the approval for a respirator if the respirator manufacturer violates the requirements of the respirator test and approval program. However, NIOSH should be required to notify the manufacturer of the impending revocation of the approval and NIOSH should be required to give the manufacturer a reasonable amount of time to remedy the situation. If the manufacturer refuses to eliminate the problem in a reasonable time period or if the manufacturer is unable to eliminate the problem in a reasonable time period, then NIOSH should take action to revoke the approval. NIOSH should publicize each approval revocation.

Publication of Test Data

NIOSH should not be permitted to publish test data obtained during approval testing of a respirator. NIOSH should report this test data only to the manufacturer who submitted the respirator to NIOSH for testing and approval.

NIOSH should be allowed to publish test data obtained during a field audit of an approved respirator or obtained during an investigation of an approved respirator carried out as a result of a report from the field. However, NIOSH should be allowed to publish this data only if the test data shows that specimens of the respirator fail to meet performance criteria or that specimens of the respirator contain a characteristic(s) that prevent them from providing adequate protection and only if the respirator manufacturer refuses to carry out a stop sale/recall action, if the manufacturer delays in carrying out the stop sale/recall action, or if the stop sale/recall action carried out by the manufacturer is ineffective.

Respirator Use and Maintenance Manual

NIOSH should require a manufacturer of an approved respirator to furnish with each specimen of the respirator a copy of a manual which lists the application(s) of the respirator, describes the construction of the respirator, explains the operation of the respirator, lists the limitations of the respirator, provides instructions for donning and taking off the respirator, gives instructions for wearing the respirator, lists requirements for inspecting the respirator, gives methods for testing the fit of the respirator, provides instructions for proper maintenance and repair of the respirator, gives methods for proper storage of the respirator, and gives warning of improper uses of the respirator. NIOSH should require a respirator manufacturer to submit a copy of the manual to NIOSH for examination and approval when the manufacturer submits a respirator to NIOSH for testing and approval. Also, NIOSH should require the manufacturer to submit a copy of a revised manual to NIOSH for examination and approval whenever a manual is changed.

NIOSH Systems Manual

NIOSH should develop and make available to the public a systems manual that defines the responsibilities and authorities of NIOSH concerning a respirator test and approval program. This systems manual also should give the operating procedures for testing and approving respirators, the respirator performance criteria and the respirator test procedures in effect, methods for handling applications for respirator testing and approval, methods of issuing approvals for respirators, methods for denying approvals for respirators, procedures for field auditing of approved respirators, procedures for investigating reports from the field pertaining to alleged problems involving approved respirators, provisions for ordering manufacturers of approved respirators to stop the sale of respirators and to recall respirators from the field, and procedures from revocating approvals for respirators.

Research

NIOSH should carry out research to develop new and improved respirator test equipment, new and improved respirator test procedures, and new and improved respirator performance criteria. THis research should be aimed at improving the state-of-the-art of approved respirators.

NIOSH should perform research to develop test equipment, test procedures, and performance criteria for respirators for use by persons for protection against respiratory hazards covered by existing occupational exposure standards being revised by various government agencies or for protection against respiratory hazards to be covered by new occupational exposure standards to be promulgated by various government agencies.

NIOSH should carry out research to determine if existing approved respirators offer adequate protection against respiratory hazards covered by existing occupational exposure standards, respiratory hazards covered by existing occupational exposure standards being revised, and new respiratory hazards to be covered by new occupational exposure standards to be promulgated.

NIOSH should not perform research to develop new or improved types of respirators for protection against existing or new respiratory hazards. This type of research should be carried out by the private sector.

Future of NIOSH in Testing and Approving Respirators

If NIOSH fails to devote sufficient resources of manpower and equipment to develop meaningful respirator performance criteria and test procedures, to implement an effective program of testing and approving respirators, and to carry out a continuous program of auditing the performance of approved respirators in the field, then the ANSI Ad Hoc Respirator Test and Approval Subcommittee recommends that NIOSH relinquish its responsibility and authority to operate a respirator test and approval program.

Record of Public Meeting

The ANSI Ad Hoc Respirator Test and Approval Subcommittee recommends that the record for this public meeting concerning the administrative aspects of a respirator test and approval program remain open for at least 90 days to permit persons to submit additional comments and suggestions to NIOSH. The Subcommittee feels that NIOSH has not allowed sufficient time for persons to study the administrative aspects of a respirator test and approval program and to prepare comments and suggestions concerning this matter.