26

FILE COPY

STATEMENT

of the

Industrial Safety Equipment Association

to the

NIOSH Public Meeting

on

Testing and Certification

July 28-30, 1980

Industrial Safety Equipment Association

1901 N. Moore Street, Arlington, VA 22209 (703) 525-1695

STATEMENT OF THE INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION
TO THE
NIOSH PUBLIC MEETING ON TESTING AND CERTIFICATION
July 28-30, 1980

It is a pleasure for the Industrial Safety Equipment Association to participate in this public meeting which NIOSH has convened to discuss the role of this agency in testing and certifying personal protective equipment and hazard measuring instruments. I am Frank E. Wilcher, Jr., Executive Director of the Association.

While I am here today representing our Respiratory Protection Group which is made up of most of the United States manufacturers of respiratory protection equipment, I should also point out that ISEA is an Association of 80 manufacturers representing a broad spectrum of industrial safety equipment. Our organization comprising 12 different Product Groups has been interested in the role NIOSH plans to take with regard to testing and certification of all personal protective equipment.

I would also like to point out at the outset that the Industrial Safety Equipment Association for the past five years has been urging NIOSH to adopt more modern performance standards and implement a certification program for all personal protective equipment. In addition to encouraging NIOSH in this direction, our Association has also gone on record in writing with the Occupational Safety and Health Administration that we would be in favor of having OSHA make it mandatory in their regulations that personal protective equipment be certified by NIOSH. For one reason or another, NIOSH has not been able to move forward in this direction, and, therefore, we are going to suggest today a different approach to testing and certification of personal protective equipment.

Certainly no issue is more critical than the protection of America's working men and women. We believe that an important part of accomplishing this objective is through an effective testing and certification program based on realistic performance standards. However, because NIOSH through lack of funding or for whatever reason has not been able to effectively expand its testing and certification program at Morgantown, we would like to recommend today that NIOSH adopt a variation of the fourth alternative listed in the Federal Register notice of June 18, 1980.

The Industrial Safety Equipment Association feels that the users of respiratory protection equipment, and other personal protective equipment, in the long run are going to be better off if NIOSH concentrates its efforts in establishing recommended performance standards, and allows the Industry to establish a certification program. Specifically, we recommend that a third party certification program using independent private laboratories be implemented for the testing and certifying of respiratory protection equipment. We recommend that the performance standards used by these laboratories be specified by NIOSH and that NIOSH continue its field audit testing programs which we will comment upon later as we address the specific issues which have been raised by the Agency.

Both NIOSH and ISEA have a common goal in our mutual desire to provide the best possible on-the-job protection to American workers be they engaged in industrial pursuits, mining or public service. The provisions of 30 CFR Part 11 were issued with this goal in mind as far as respiratory protection devices go, but unfortunately have not worked effectively from the point of view of either NIOSH or the manufacturers. The reasons are varied. At the outset, it must be recognized that the testing and certification procedures were developed for underground mining applications and consequently do not adequately cover

other common applications of these types of devices. As frequently is the case with government regulations, the provisions are too rigid to be applied widely in a cost efficient manner. In addition, we feel that NIOSH's Testing and Certification Branch has been hampered with constant turnover of staff, as well as lacking personnel with sufficient expertise in the field to handle the program effectively, fairly and in a timely manner. Delays in obtaining approvals on new devices and extensions of approval on modified devices is excessive to the extreme.

The resources of NIOSH could be more effectively utilized if the Agency concentrates its activities on the development of performance standards based on adequate and suitable research. The actual certification of involved products would be conducted by the Industry itself based on a suitable test criteria which they would develop. Under a third party certification program, NIOSH would develop performance standards that are realistic, and as technologically advanced as the state of the art will permit. To assure users that Industry Certification of this type of equipment is valid, NIOSH would, on a regular basis, purchase new off-the-shelf random samples of approved equipment of each manufacturer and test this equipment either in their own laboratory or subcontract testing to a qualified laboratory.

During the transition from the current certification system to the one proposed today by ISEA, a device approved under the existing performance standards established by NIOSH would continue to be "approved" until such time as the applicable performance standard was revised. Subsequent thereto, involved products would have to be approved under the revised updated standard with suitable grandfathering being permitted for orderly manufacturing transition from one design to another, and for the continued use of approved equipment in the field for a reasonable time to relieve the economic impact on employers.

Where testing of off-the-shelf equipment by NIOSH indicates a serious deficiency involving reasonable potential for harm to the wearer; suitable enforcement action or approval revocation action would be taken in line with the seriousness of the problem indicated following the pursuit of a fair Appeals Procedure.

Such a program would relieve NIOSH of the responsibility of the testing and certification, and at the same time enable the Agency to assure the users of such equipment that it was fit for use in terms of the current, applicable Performance Standards.

We believe a program of this nature would be beneficial to the American workers using personal protective equipment and hazard measuring instruments, would be beneficial to NIOSH in their role of assuring the American worker safety in the work place, and to the manufacturer in providing reliable, fit for use equipment.

In light of this proposal which ISEA is making today, we respond to the 18 questions from the Consultants' Report entitled "Evaluation of the NIOSH Certification Program, Division of Safety Research, Testing and Certification Branch", NIOSH Publication #80-113, as follows:

1. NIOSH should develop Performance Standards for HMI and PPE, and in doing so should cooperate with ANSI and other groups of stature writing voluntary standards. The ISEA recommends that NIOSH's priority for the development of such criteria be as follows: Head Protection, Hearing Protection, Protective Eyewear, Instruments, Fall Protection, Machine Guards, Emergency Eyewash and Shower Equipment, and Safety Clothing.
2. As you know, it is the preference of ISEA that NIOSH restrict its activities to the development of Performance Standards

for product approval, and leave the development of test criteria to the Industry Certification Program. However, should NIOSH decide to continue in the testing and certification of PPE, we favor their publishing detailed test criteria. Some tests currently in existence should be retained while others need to be modified. If desired, we would be pleased to elaborate further on this issue.

3. As explained in our response to question #2, we feel NIOSH should publish only performance criteria, and leave the development of appropriate detailed performance tests to the Industry Certification Program.

4. Recognizing the contribution of the voluntary standards development groups to technological progress, and the goals of the regulatory system, the Office of Management and Budget has endorsed active participation by the Federal Government Agencies in voluntary concensus standards activities. This policy is clearly set forth in the OMB Circular - A119. Beyond any question, NIOSH should participate on concensus standard making committees, preferably as a voting member, but at least as a participating guest. These committees are composed of members representing government agencies, technological societies, research institutes, universities, labor organizations, and trade associations, which afford a much broader expertise in occupational health and safety than what is available to NIOSH acting alone. Clearly, NIOSH cannot establish meaningful performance standards which cannot be achieved by the present state of the art. The health and safety of the American worker will benefit through NIOSH's participation in the voluntary standards development activities.

5. Except for rare occasions, NIOSH should not offer manufacturers on a fee for service basis, the testing of devices on a continuing basis or just prior to approval application. In no case should NIOSH approve or certify a device when being tested on an informal basis.

6. ISEA favors NIOSH placing the responsibility for performance testing according to NIOSH-developed Performance Standards upon the manufacturer. Neither NIOSH nor OSHA need monitor manufacturer adherence to Performance Test Protocol; proof of performance should be determined by the Field Audit Testing Program.

7. ISEA favors a NIOSH developed system of random sampling for the evaluation of Certification Reliability. We consider this to be the essence of the Field Audit Testing Program, and it should be based on identical tests as are involved in the Certification Procedure. Inasmuch as the experience of many manufacturers indicates that tests conducted by NIOSH personnel at the Testing and Certification Branch in Morgantown have frequently been improperly conducted or improperly interpreted, we are opposed to the publication of any test results from the Field Audit Testing Program until after they have been confirmed by consultation with the manufacturer, and the implementation of effective administrative controls. It is the position of ISEA that NIOSH test results, like Bar Examination test results, should be announced on a pass/fail basis. The statutory mandate of NIOSH does not extend to the publishing of comparative test results. If a product meets the Standard, it meets it; and if it fails, it fails. Our suggested procedures for handling publication of test data appear in our Exhibit 2.

8. In as much as OSHA is in the process of establishing a Laboratory Accreditation Program, ISEA believes it would be preferable for NIOSH to contract for services as described in Questions 6 and 7 with OSHA Accredited Laboratories, rather than undertake such accreditation themselves.

9. Re-certification of approved products should be required only when a new or more stringent Performance Standard is established. There is no regulatory need for any time limit on a certification of an approved product that continues to meet the current Performance Standards. When a new Standard is established, suitable "grandfathering" must be provided to permit an orderly conversion both by users and by manufacturers.

10. As indicated in our response to Question 8, ISEA sees no need for NIOSH to certify private laboratories for the testing of PPE inasmuch as OSHA is already well along in the development of a suitable Laboratory Accreditation Program.

11. When manufacturers need assistance in developing suitable facilities for conducting tests to achieve certification under NIOSH's promulgated Performance Standards, NIOSH should continue to offer such assistance. NIOSH should not continue tests for manufacturers in lieu of the manufacturers establishing such facilities in their plants. Further, NIOSH should not evaluate the test set-ups in manufacturers' facilities.

12. There should be no Field Incident Reporting System because the use of unverified Field Incident Reports as a basis for alerting the public is irresponsible. See the recent Supreme Court Opinion in Consumer Product Safety Commission v GTE Sylvania, No 79-521-(Decided 6/9/80), halting disclosure of unverified accident reports which would both injure manufacturers and mislead consumers.

13. As we indicated earlier in our response to Question 7, NIOSH could undertake to publicize the results of tests randomly sampled from the marketplace, provided the following conditions apply: (a) There has been prior consultation with the manufacturer, and appropriate Administrative Procedures including an appeal have been followed; (b) Tests are conducted on similar products of all manufacturers at the same time; and (c) only pass/fail results are published without any specific test data or an attempt at ranking of products. (See Exhibit 2.)

14. Under the system of third party certification favored by the Industrial Safety Equipment Association, NIOSH would not be certifying products and, therefore, would not need to be burdened with any change information. Even under a system where NIOSH certifies, it should require manufacturers to submit changes to approved products only where such changes materially affect the fitness for use of such products. Records relative to changes or alterations not affecting fitness for use should be retained by the manufacturer for a reasonable time.

15. NIOSH should request "stop sale" or "recall" where a fair determination has established that the discovered defect or product design is either "Critical" or "Major A" as those terms are presently defined in 30CFR 11.41(d), and the manufacturer refuses to implement its own "stop sale" or "recall" program. We have suggested a procedure for handling defects and departures from approved designs and/or quality control plans that includes

provision for a hearing where the manufacturer questions the need for a recall, and provides an opportunity for an expedited appeal. Rescission of "stop sale" and "recall" should occur when the recall has been completed, and the manufacturer has obtained an extension of approval or has returned to the approved design or quality control plan. (See Exhibit 1.)

16. The public notification mechanism to be implemented upon discovery of defective devices in the field should be similar to that utilized by the Food and Drug Administration as in 21 CFR 7.50, adapted to suit the different nature of the products covered. As part of our comments still to follow on the NIOSH Federal Register proposal published June 18, 1980, we are proposing a specific voluntary recall procedure based on the Food and Drug Administration 21 CFR, Part 7, Subpart C which includes an appropriate public notification mechanism. This proposal is attached as Appendix A to Exhibit 1 of this presentation.

17. ISEA believes that NIOSH should restrict its research efforts to the development of realistic, practical Performance Standards and leave the research related to product development to meet those Standards to the manufacturers of such equipment.

18. Again, ISEA believes that NIOSH should restrict its research role within its own laboratories or through contracts placed with outside laboratories to the development of Performance Standards. The manufacturers of Personal Protective Equipment have always developed products promptly to meet new Performance Standards or to meet new market applications as they occur. There is no need

whatsoever for NIOSH to become involved in product development in order to have suitable devices available to the American worker.

That completes our response to the questions raised in the Consultants' Report. We appreciate the fact that the ISEA proposal for a Third Party Certification Program is a substantial departure from current NIOSH thinking, and that its assessment by the respective Government Agencies involved will take a considerable amount of time. We recognize, therefore, in the interim NIOSH is most likely to adopt its own alternative to these recommendations or some variation thereof, and accordingly what follows is the ISEA position on the 14 issues on which comment was requested in the June 18, 1980 Federal Register.

Performance Specifications

ISEA concurs that the tests to be performed in the certification process need to be replaced with test specifications that are realistic and as technologically advanced as the state of the art will permit. Obviously, research by NIOSH to this end is indicated.

Quality Control

ISEA favors the elimination of the procedure for NIOSH approval and surveillance of Quality Control Plans as presently specified in 30 CFR Part 11. Requirements that the manufacturer of such equipment certifies that an effective Quality Control Plan is in place supplemented by continuous NIOSH Field Audits should be adequate. However, NIOSH's Field Audit Program should provide for only the testing of unused equipment and under no circumstances should used equipment be tested. No tests under this program should be conducted on used equipment because there is no way to ascertain whether improper

maintenance or abuse has damaged such equipment. Stop sale, recall and approval revocation resulting from the Field Audit Program should follow an agreed upon procedure such as set forth in Exhibit 1 attached to this presentation. This procedure provides the necessary due process in the determination of the need for such enforcement action and provides effective mechanisms for the protection of interests of the user, NIOSH, and the manufacturer. The recall procedure in Exhibit 1 is modeled after the Food and Drug Administration Program set forth in 21 CFR 7.40(c).

Engineering Drawings with Dimensional Tolerances

Engineering drawings with dimensional tolerance should not be a condition of application for NIOSH approval; rather, NIOSH should rely on the requirement for sound engineering design based on accepted scientific principles, construction of suitable materials, and evidence of good workmanship. Before ISEA can accept the potential requirement for a failure mode analyses, NIOSH will have to provide more details on this proposal.

Changes to Approved Devices

The present Program that any and all changes made to respiratory protective devices must be submitted to and approved by NIOSH prior to being incorporated is impractical. Therefore, ISEA concurs completely with the current proposal by NIOSH for handling changes to approved devices.

Witnessing of Approval Tests

Inasmuch as the experience of many manufacturers indicates tests conducted by NIOSH personnel at the Testing and Certification Branch at Morgantown have frequently been improperly conducted, and improperly interpreted, we believe it is essential that manufacturers have the right to witness tests on their equipment only. NIOSH agrees with this position as reflected in their Appeals Procedure Policy which was made effective July 1, 1980. ISEA recommends

that this new Policy be made more broadly applicable and equitable as reflected in Exhibit 2, attached hereto.

Duration of Approval

As indicated earlier, an approval should continue in effect until new Performance Standards are implemented at which time re-certification to the newer and higher standard should be required with applicable "grandfathering" permitted to allow an orderly conversion by both manufacturers and users. The contention by NIOSH that continuous approval "creates a confusing and potentially dangerous situation" is without any factual basis. There is no regulatory need for any time limit on a certification of an approved product that continues to meet the current Performance Standards.

Product Quality Requirements

ISEA believes that because product quality levels expressed in terms of AQL's, which are well established, conversion to a percentage defective would be time consuming as well as costly, and serve no useful purpose.

Unpublished Test Requirements

ISEA agrees with NIOSH that no special unpublished test requirements should be permitted. Rather, NIOSH should only rely on test requirements that have been tested, proven and subjected to public scrutiny.

Testing of Prototype Respirators and Approval Tests

ISEA feels that NIOSH should not be expected to test prototype devices in the design stage as a research and design service for manufacturers. NIOSH should accept for testing and approval items, the design of which has been finalized, but some components of which may have been run from temporary tooling, subject to later confirmation with products run on production tooling. Obviously, it is not practical for a manufacturer to buy expensive tooling prior to ascertaining from NIOSH that the device as designed will meet their

approval test requirements.

Group Testing of Respirators

ISEA protests the group testing of respirators in that it will delay the release to the market of new and improved products which are ready for tests and approval well in advance of the next designated acceptance period. Further, group testing will preclude witnessing of tests, which as noted above ISEA considers to be essential (See Exhibit 2).

User and Maintenance Manuals

ISEA agrees with the requirement that User and Maintenance Manuals be submitted with applications for approval. Only major Manual revisions and updates should require submission to NIOSH. It is desirable that NIOSH develop and issue Guidelines relative to the content of such Manuals.

NIOSH Systems Manual

ISEA agrees fully with NIOSH's suggestion that it develop a Systems Manual relative to the procedure for Testing and Certification of PPE and HMI, and that the Manual would be made available to interested parties on request. This Systems Manual should contain complete descriptions of acceptable procedures for (1) receiving notice of approval testing, (2) witnessing tests, (3) witnessing retests of failures on audit testing, (4) appealing test failures on an expedited basis, and (5) prohibiting publication or release of test data other than on a pass/fail basis. As previously indicated, these administrative procedures are set forth in Exhibit 2. Similarly, fair procedures for handling defects and departures from approved products and requesting stop sales, and recalls need to be included along the lines set forth in Exhibit 1. We believe that the FDA procedures for recalls should be adopted in principle by NIOSH (See Appendix A to Exhibit 1). Provisions should be made to supply information when requested by manufacturers relative to the status of their Applications for Approval or Extensions of Approval. Also to be included in this

Manual is the stipulation that Test Procedures and Values cannot be changed without prior notification to manufacturers. Once NIOSH has established Procedures, Rules and Policies via their Systems Manual, all NIOSH personnel should consistently abide by them.

Publication of Test Data

ISEA opposes the publication of any test data from Approval Tests except as an indication that a particular respirator may have passed such tests. ISEA strongly believes that the publication of Failure Test Data from Approval Tests for the purposes of injuring a manufacturer's reputation as a means of reaching some internal NIOSH administrative objective, is irresponsible and not worthy of further comment. An effective mechanism for assuring better Pre-Approval Submission Tests would be to increase Approval Test Fees. Experience has shown that many tests conducted by NIOSH personnel have frequently been improperly conducted and improperly interpreted. Therefore, no publicity should be issued with regard to Field Audit Tests performed except after prior consultation with the manufacturer, and the exhaustion of an appropriate Appeals Procedure (See Exhibit 2). ISEA reiterates that it is strongly opposed to the publication of any information relative to Field Audit Testings other than pass/fail information and that no specific test data or information relative to ranking be published by NIOSH.

We appreciate the opportunity to participate in this public meeting, and would like to summarize by reiterating that we feel it would be in the best interests of the American worker, the Department of Health and Human Services, and ISEA for NIOSH to abandon its present role as the Testing and Certification Agency for Personal Protective Equipment, and restrict its activities solely to the development of effective, realistic Performance Standards leaving

the actual testing and certification responsibility to Industry through a Third Party Certification Program.

Thank you very much.

/mc

PROCEDURE FOR HANDLING DEFECTS OR DEPARTURES FROM APPROVED DESIGNS AND/OR QUALITY CONTROL PLANS

A. The severity of the defect(s) or departure(s) from the approved design and/or quality control plan will be assessed by NIOSH and classified by its potential effect on the user as: 1) Critical, 2) Major A, 3) Major B, or 4) Minor, as defined by 30 CFR 11.41(d).

B. In the case of Minor defects or departures, no action will be taken by NIOSH provided the manufacturer updates the documentation on file with NIOSH to reflect the revision or corrects the defect within 90 days.

C. In the case of Major B defects or departures, no action will be taken by NIOSH provided the manufacturer either:

1. applies for and receives an extension of approval for the change(s) made to the affected products, or
2. returns to approved design, production, and quality control methods.

D. In the case of Critical or Major A defects or departures, a stop sale, and (when appropriate) a recall pursuant to Appendix A, of all affected products may be recommended by the DSR Staff. In the event that the manufacturer questions the need for a stop sale, or recall, or questions the level of recall, the Director, DSR will convene a hearing on these issues. The DSR Staff and the manufacturer shall make written and/or oral presentations in support of their respective positions, the burden being on DSR Staff to prove its position by a preponderance of the evidence. On the basis of the presentations, the Director, DSR will decide whether a stop sale, a recall or a particular level of recall will be

requested. In the event that the manufacturer is not satisfied with the decision of the Director, DSR, the manufacturer may request reconsideration by the Director of the Institute, who shall confirm, modify or reverse the Director, DSR's decision.

E. Stop sale and recall requests will not be rescinded until such time as the recall procedure (Appendix A) has been completed and the manufacturer has either:

1. received an extension of approval for the change(s) made to the affected products, or
2. returned to approved design, production, and quality control methods.

F. A proceeding to withdraw certification of the affected products may be initiated if:

1. the manufacturer fails to comply with the stop sale request, or
2. the manufacturer fails to use reasonable efforts to implement and complete the agreed upon recall procedure.

/mc

7/80

APPENDIX A

PROPOSED PROCEDURE FOR NIOSH RE: RECALLS

(Excerpted from FDA Procedure Published as 21CFR Part 7, Subpart C --Recalls (Including Product Corrections) -- Guidelines on Policy, Procedures, and Industry responsibilities)

1. Recall policy.

Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the health and safety of workers from products that present a risk of injury. These sections recognize the voluntary nature of recall by providing guidelines so that responsible firms may effectively discharge their recall responsibilities. These sections also set forth specific recall procedures for NIOSH to monitor recalls and assess the adequacy of a firm's efforts in recall (FDA:21CFR 7,40)

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of NIOSH. A request by NIOSH that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

1. Health hazard evaluation and recall classification.

(a) An evaluation of the health/safety hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of NIOSH scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a workplace situation that could expose workers to a health/safety hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individuals(s) making the health/safety hazard determination.

(3) Assessment of hazard to various segments of the worker population, who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health/safety to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, NIOSH will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health/safety hazard of the product being recalled or considered for recall. (FDA: 21CFR 7.41)

3. Recall Strategy

(a) General. (1) A recall strategy that takes into account the following factors will be developed by the agency for a NIOSH requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.

(ii) Ease in identifying the product.

(iii) Degree to which the product's deficiency is obvious to the user.

(iv) Degree to which the product remains unused in the marketplace.

(v) Continued availability of essential products.

(2) NIOSH will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) Elements of a recall strategy. A recall strategy will address the following elements regarding the conduct of the reall:

(1) Depth of recall. Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) User level, which may vary with product, including any intermediate

wholesale or retail level; or

(ii) Retail level, including any intermediate wholesale level; or

(iii) Wholesale level.

(2) Public warning. The purpose of a public warning is to alert users and their employers that a product being recalled presents a serious hazard to health/safety. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. NIOSH in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by NIOSH. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as municipal fire departments, trade associations, labor organizations etc.

(3) Effectiveness checks. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that

describes the use of these different methods is available upon request from the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but NIOSH will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

(i) Level A--100 percent of the total number of consignees to be contacted;

(ii) Level B--Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater that 10 percent and less than 100 percent of the total number of consignees;

(iii) Level C--10 percent of the total number of consignees to be contacted;

(iv) Level D--2 percent of the total number of consignees to be contacted; or

(v) Level E--No effectiveness checks. (FDA: 21CFR 7.42)

4. NIOSH Requested Recall

(a) The Director DSR may request a firm to initiate a recall when the following determinations have been made:

(1) That a product that has been distributed has been determined to have a defect, or departure from approved design which is critical or Major A as defined in 30CFR11.41 (d).

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the health and safety of workers.

(b) The Director DSR will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of NIOSH with formal, written confirmation from the Director DSR afterward. The notification will specify the violation, the health/safety hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.

(c) Upon receipt of a request to recall, the firm may be asked to provide NIOSH any or all of the information listed in par. 5. The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's determination of the need for the recall or how the recall should be conducted. (FDA: 21CFR 7.45)

5. Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be defective is requested to notify NIOSH DSR immediately. In such cases, the firm will be asked to provide NIOSH the following information:

(1) Identity of the product involved.

(2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.

(3) Evaluation of the risk associated with the deficiency or possible deficiency.

(4) Total amount of such products produced and/or the timespan of the production.

(5) Total amount of such products estimated to be in distribution channels.

(6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.

(7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.

(8) Proposed strategy for conducting the recall.

(9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) NIOSH will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall. Pending this review, the firm need not delay initiation of its product removal or correction

(c) A firm may decide to recall a product when informed by NIOSH that the agency recommends that a recall be instituted, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.

(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with NIOSH when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, NIOSH will assist the firm in determining the exact nature of the problem. (FDA: 21 CFR 7.46)

6. Recall communications.

(a) General. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

(1) That the product in question is subject to a recall.

(2) That further distribution or use of any remaining product should cease immediately.

(3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.

(4) Instructions regarding what to do with the product.

(b) Implementation. A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "Respirator Recall (or Correction)". The letter and the envelope should be also marked: "URGENT" for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) Contents. (1) A recall communication should be written in accordance with the following guidelines:

(i) Be brief and to the point;

(ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;

(iii) Explain concisely the reason for the recall and the hazard involved, if any;

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, followup communications should be sent to those who fail to respond to the initial recall communication

(d) Responsibility of recipient. Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section. (FDA: 21CFR7.49)

7. Public notification of recall.

NIOSH will promptly make available to the public a descriptive listing of each new recall according to its classification, whether it was NIOSH requested or firm-initiated, and the specific action being taken by the recalling firm. NIOSH will consult with the recalling firm on the text prior to publication. NIOSH will intentionally delay public notification of recalls of certain products where the agency determines that public notification may cause unnecessary and harmful anxiety in users. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. (FDA: 21CFR7.50).

8. Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to NIOSH so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by NIOSH in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

(1) Number of consignees notified of the recall, and date and method of notification.

(2) Number of consignees responding to the recall communication and qualtity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by NIOSH)

(4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.

(5) Number and results of effectiveness checks that were made.

(6) Estimated time frames for completion of the recall.

(c) Recall status reports are to be discontinued when the recall is terminated by NIOSH. (FDA: 21CFR7.53)

9. Termination of a recall.

(a) A recall will be terminated when NIOSH determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by NIOSH to the recalling firm.

(b) A recalling firm may request termination of its recall by submitting a written request to NIOSH stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a desciption of the disposition of the recalled product. (FDA: 21 CFR 7.55)

10. General industry guidance

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take

in advance to minimize this disruptive effect. The following is provided by NIOSH as guidance for a firm's consideration:

(a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with Pars 1 through 6, 8, and 9.

(b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all affected lots.

(c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention. (FDA: 21 CFR 7.59)

# # #

ADMINISTRATIVE PROCEDURES

Purpose: The purpose of this procedure is to provide due process to companies subject to 30 CFR 11 who wish to question NIOSH decisions on the testing of respirators for compliance with 30 CFR 11.

Scope: This procedure applies to all tests performed pursuant to 30 CFR 11 for certification approvals, extensions of approval, and field audits.

Procedure:

1. Upon written request, the applicant seeking certification approval or an extension of approval will be informed of the test date(s) pertaining to the applicant's equipment. NIOSH will provide the applicant with a minimum of five working days (i.e., excluding Saturdays and Sundays) advance notice of the scheduled test date(s);
2. Applicant will be permitted to witness the test(s) but will not be allowed to interfere with or otherwise interrupt the test(s);
3. In the event that the equipment fails any test:
   a. NIOSH will notify the applicant orally if present at the test, or if not present at the test, and in the case of an audited company, orally by telephone; and
   b. Provided that the applicant or the audited company has test data which demonstrates that the equipment tested has passed this test previously, NIOSH, at the request of applicant or the audited company, will retest this equipment pursuant to these procedures.
4. In the event the equipment fails to pass any test, applicant or the audited company may appeal the test results based on one or more of the following three reasons:
   a. NIOSH conducted the wrong test.
   b. NIOSH performed the right test incorrectly.
   c. NIOSH misinterpreted the test results;

5. a. A written intent to appeal must be submitted to the Director, Division of Safety Research (DSR), within five working days of receipt of the test results pursuant to 3a above.

   b. Documents supporting the appeal must be submitted to Director of DSR within 10 days after the receipt of the test results;

6. When an appeal is received, the Director, DSR, will designate a senior, experienced engineer or scientist employed by the National Bureau of Standards to serve as an appeal arbiter;

7. An informal hearing will be held within 7 working days of receipt of the appeal documents (5b above). The appeal arbiter will provide the Director, DSR. with a written decision within five working days of the hearing. The hearing arbiter will either uphold the test results, reverse the test results, or order retesting.

8. Except as provided below, NIOSH shall not publish or release any specific test data or notice of failure concerning any equipment undergoing tests for approval, extension of approval or field audit testing. For equipment undergoing field audit testing, NIOSH may publish or release a notice of failure only after the appeals procedure is exhausted or the audited company does not appeal. Such notice shall state only that the product failed to meet the applicable performance standard. In no event shall NIOSH publish or release specific test data on equipment, whether passing or failing, or any purported ranking of products based on such tests.