(51) EB

Bob Schutz (1)

ISEA Industrial Safety Equipment Association

January 30, 1978

Regulations Assistant
National Institutes of Occupational
Safety and Health - Room 8-11
5600 Fishers Lane
Rockville, MD 20857

Gentlemen:

This is in reply to your request for information for new and improved performance requirements for respiratory protective devices for future revisions of 30 CFR Part 11, as requested in the Federal Register of October 28, 1977.

The enclosed document is presented on behalf of the Respiratory Protection Group of the Industrial Safety Equipment Association. This material includes the data we presented at the public meeting conducted by NIOSH and MESA on November 29 - December 1, as well as detailed comments and modifications of our major issues which we have been able to develop since that date. We are also taking the liberty of responding at this time to the proposals for new testing requirements presented by NIOSH at the November 29th Hearing.

We appreciate the opportunity to submit this important information and would like to invite your representatives to meet in the near future with a committee of our Respiratory Protection Group to discuss these comments.

Sincerely,

Frank E. Wilcher, Jr.

Frank E. Wilcher, Jr.
Executive Director

FEW:af

Enclosures

cc: E. J. Baier - NIOSH
J. A. Oppold - NIOSH
R. H. Schutz - NIOSH
E. Kloos - MESA
Eula Bingham - OSHA
Ching Tsen Bien - OSHA

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

RECOMMENDED CHANGES TO 30 CFR PART 11

SUBMITTED BY

Respiratory Protection Group
INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION
1901 North Moore Street
Arlington, Virginia 22209

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION

RECOMMENDED CHANGES TO 30 CFR PART 11

MAJOR ISSUES - TECHNICAL PERFORMANCE

(1) ESTABLISHMENT OF MINIMUM PROTECTION FACTORS FOR ALL TYPES OF RESPIRATORS BY MEANS OF QUANTITATIVE FIT TESTS.

We recommend that 30 CFR Part 11 be amended to provide for the establishment of panels of human subjects having appropriate anthropometric characteristics representing at least 95% of adult working population to carry out quantitative respirator fit tests;

That human subjects, both male and female, wearing respirators in test atmospheres should carry out exercises which simulate movements in work operations, and the penetration of test agents into the respiratory inlet coverings of the respirators should be measured by appropriate instruments during the exercises;

That to determine whether or not a given make or model respirator achieves the protection factor established for the type of respirator it is, at least three series of respirator quantitative fit tests should be carried out by the panel of human subjects. In order to be approved, the given make and model respirator must achieve protection factors equal to or greater than the established minimum protection factor for the type of respirator;

That consideration should be given to the proper selection of test subjects, so as to be compatible with varying dimensional sizing of respiratory inlet coverings; and

That an applicant shall be permitted to submit for an approval a respirator which fits a specific portion of the panel referenced in the first paragraph above.

The information currently available shows unacceptable variations of protection factors when one facepiece is tested several times on one individual. The data to explain this variation is insufficient to enable a reasonable conclusion to be drawn. We feel that further work should be done to produce reproducible test results, or to show that these variations are logically explicable.

We feel that work should be done to show the effect of lung retention of the aerosol on the test results.

We feel that the temperature of the test chamber should be low enough to prevent the perspiration of the test subject, which may be generated during the exercises, from affecting the facepiece fit. Perspiration may cause the facepiece to slip on the face during head movement exercises.

Although we agree that a quantitative facepiece fit test is of great value to approval testing, we feel that this information cannot be used as a method for assuming the fit of an individual worker. Individual worker fit should be performed before any protection factor can be assumed, and is indeed required by 1910.134 and implemented in OSHA's Program Directive #300-9.

(2) PERMIT APPROVAL OF ALL TYPES OF RESPIRATORS ABLE TO MEET PERFORMANCE REQUIREMENTS FOR ANY TYPE OF RESPIRATORY HAZARD.

We recommend that 30 CFR Part 11 be amended to provide that respirators should not be limited by design requirement from receiving an Approval for any type of respiratory hazard if the device is capable of meeting all the performance requirements as published.

(3) CLARIFY CLASSIFICATION AND DESCRIPTION OF PARTICULATE FILTER RESPIRATORS AND CLARIFY CLASSIFICATION AND DESCRIPTION OF CHEMICAL CARTRIDGE RESPIRATORS.

The ISEA believes that the classification and description of the types of particulate filter respirators and chemical cartridge respirators which can be approved under the provisions of 30 CFR 11 is confusing to respirator users, government officials having jurisdiction over respirator programs, respirator manufacturers, and the general public. Therefore, Subparts K, L. M, and N of 30 CFR 11 should be amended to clairfy the classification and description of particulate filter respirators and chemical cartridge respirators.

(4) DYNAMIC LEAK TESTING OF EXHALATION VALVES.

We recommend that 30 CFR Part 11 be amended to require that when leakage tests of exhalation valves are required they shall be tested under dynamic conditions and the permitted leakage shall be appropriate to the Respirator Protection Factor.

(5) BREATHING MACHINE TESTS.

We recommend that 30 CFR Part 11 be amended so that any air purifying respirator which permits exhaled air to contact the air purifying element shall be tested with a breathing machine with the exhaled air having a temperature and humidity equivalent to body conditions.

(6) BREATHING RESISTANCE REQUIREMENTS.

We recommend that all breathing resistance requirements should be reviewed and the established values should be based on physiological limitations.

(7) CLARIFY APPROVAL OF AIR PURIFYING RESPIRATORS FOR PROTECTION AGAINST GASES AND VAPORS HAVING POOR WARNING PROPERTIES.

We recommend that Sections 11.90 (b) (Footnote 4) of Subpart I and 11.150 (Footnote 7) of Subpart L of 30 CFR 11 be amended to prohibit the use of air purifying respirators for protection of persons against vapors and gases which do not have adequate warning properties except where Federal exposure standards permit the use of air purifying respirators, provided that specific work practices listed in the standards are carried out.

(8) RESPIRATOR EYEPIECES.

We recommend that the impact requirements specified in the current edition of Federal Specification GGG-M-125, Mask, Air Line, and Respirators, Air Filtering, Industrial, be included as part of the performance requirements in 30 CFR Part 11.

(9) NOISE LEVEL MEASUREMENTS.

We recommend that any reference to noise level measurements for respirators in 30 CFR Part 11 be revised as follows: "Where applicable, noise levels generated by respirators will be measured inside the respiratory inlet covering and/or at the ear level at maximum airflow for which the device is approved, and shall not exceed 80 dBA. Measurements shall be taken in an ambient noise level not exceeding 60 dBA."

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION

RECOMMENDED CHANGES TO 30 CFR PART 11

MAJOR ISSUES - TECHNICAL PERFORMANCE AND ADMINISTRATIVE

(10) APPROVAL OF RESPIRATORS EQUIPPED WITH SUIT-TYPE RESPIRATORY INLET COVERING.

We recommend that 30 CFR Part 11 be amended to permit the approval of respirators equipped with suits.

(11) REDUCE SERVICE LIFE OF CANISTERS FOR GAS MASKS DESIGNED FOR PROTECTION AGAINST MORE THAN ONE TYPE OF GAS OR VAPOR.

We recommend that Tables 5, 6 and 7 of Section 11.102-5 of Subpart I of 30 CFR 11 be amended to state that where a gas mask is designed to protect persons against more than one type of vapor or gas, such as organic vapors and acidic gases, then the minimum vapor or gas service life of the canister shall be one-half of the listed value for each type vapor or gas.

(12) PERFORMANCE TESTING OF POWERED AIR PURIFYING RESPIRATORS.

We recommend that 30 CFR Part 11 be amended to state: "When testing the performance of a powered air purifying respirator, the respirator shall be operated in the test atmosphere at its normal air flow which shall never be less than 115 liters per minute during the test period when the device is equipped with a tight-fitting respiratory inlet covering, and 170 liters per minute during the test period when the device is equipped with a loose-fitting respiratory inlet covering. The test period shall be four hours."

MAJOR ISSUES

ADMINISTRATIVE

(1) PERMIT PUBLIC TO REVIEW AND COMMENT ON PROPOSALS TO APPROVE NEW TYPES OF RESPIRATORS AND PROPOSED TEST PROCEDURES AND CRITERIA.

We recommend that NIOSH be required to publish as proposed rulemaking in the Federal Register and thus provide adequate time for the public to review and comment on any of the following: (1) Proposed test procedures and criteria for use in approving new types of respirators; (2) Proposed test procedures and criteria for use in approving respirators against air contaminants other than those listed in 30 CFR Part 11; and (3) Any significant changes in existing test procedures and criteria.

(2) APPEALS PROCEDURE.

We recommend that 30 CFR Part 11 be amended to include a procedure by which an applicant may appeal the withdrawal or rejection of an approval. A suggested procedure has previously been submitted by ISEA to the Deputy Director of NIOSH and to the NIOSH Solicitor's office.

(3) SI UNITS

We recommend that SI units be used for all values throughout 30 CFR Part 11.

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION

RECOMMENDED CHANGES TO 30 CFR PART 11

SUBPART A - GENERAL PROVISIONS

11.3 - Definitions

We recommend that the following definitions be included in 11.3.

Abrasive Blasting Respirator

A respirator designed to protect the wearer against inhalation of, and impact and abrasion of the head and neck from particulate matter during abrasive blasting.

Air Purifying Respirator

A respirator with element(s) designed to remove contaminants from the inspired air.

Canister (Air Purifying)

A container comprising a filter and/or sorbent and/or catalyst which removes specific contaminants from the air drawn through it.

Canister (Oxygen Generating)

A container filled with a chemical which generates oxygen by chemical reaction.

Cartridge

A small canister.

Chemical Cartridge Respirator

An air purifying respirator with cartridge(s) to remove a single gas or vapor, a single class of gases or vapors, or a combination of two or more classes of gases or vapors from air where adequate oxygen is present and particulate matter is absent. This type respirator may be equipped with an additional filter to remove particulate matter. (See filter type dust, fume and mist respirator.)

Extensions

Any change in the approved respirator or any item included on the lists required by Paragraph 11.11(a) which does affect the function of the respirator. Extensions also include any additions of other configurations or options to the approved respirator requested to be approved under the same approval number.

Facepiece

A type of respiratory inlet covering designed to provide a gas-tight or particle-tight fit with the face.

SUBPART A - 11.3 (Cont'd)

Fibrosis Producing Dust

A dust which when inhaled, deposited and retained in the lungs may produce fibrous growth within the lungs which impairs lung function.

Filter

A media component used in respirators to remove particulate matter from the inspired air.

Filter, Reusable

A filter which may be used several times before the end of its useful life is reached.

Filter Type Dust, Fume and Mist Respirator

An air purifying respirator with filter(s) to remove a single type of particulate matter or any combination of particulates where adequate oxygen is present and toxic gases and vapors are absent.

Gas Mask

An air purifying respirator with canister(s) to remove a single gas or vapor, a single class of gases or vapors, or a combination of two or more classes of gases or vapors from air where adequate oxygen is present and particulate matter is absent. This type respirator may be equipped with an additional filter to remove particulate matter. (See filter type dust, fume and mist respirator.)

Gas Mask, Chin Style

A gas mask having a canister(s) which is directly attached to the respiratory inlet covering.

Gas Mask, Front-Mounted or Back-Mounted

A gas mask with the canister(s) supported on the front or back of the wearer's body.

Hazardous Atmosphere

Any atmosphere, either immediately or not immediately dangerous to life or health, which is oxygen deficient or which contains a toxic or disease producing contaminant.

High Heats of Reaction

Sorbents used in canisters may react to develop high temperatures on the surface of the canister when exposed to certain types of gases and vapors. These temperatures may be sufficiently high to cause burns on any part of the body in contact with the canister. The high heat of reaction is readily noticed by the increase in temperature of the inspired air which is a warning to the wearer that he is in a dangerously high concentration of a gas or vapor.

SUBPART A - 11.3 (Cont'd)

Hood or Helmet

A respiratory inlet covering which covers the wearer's head, or the head and neck, or the head, neck and shoulders.

Immediately Dangerous to Life or Health (IDLH)

Any atmosphere that poses an immediate hazard to life or produces irreversible debilitating effects on health.

Integral Filter

A filter which is a permanent component of the respirator.

Modifications

Any change in the approved respirator or any item included on the lists required by Paragraph 11.11(a) which does not affect the function of the respirator.

Mouthpiece/Nose Clamp

A mouthpiece/nose clamp is a type of respiratory inlet covering that is designed to provide a gas-tight seal with the wearer's lips when the mouthpiece is inserted into the mouth and the nostrils are sealed with the nose clamp.

Non-Restorable Reusable Filter

A filter which may be used repeatedly until the end of its useful life is reached and which may be used beyond a single work shift.

Oxygen Deficient Atmosphere

An atmosphere which contains less than 19.5% oxygen by volume.

Particulate Matter

A suspension of solid or liquid particles in air, such as dust, fog, fume, mist, smoke or sprays. Particulate matter suspended in air is commonly known as an aerosol.

Permissible Time Weighted Average

The standards of contaminant levels prescribed by the Secretary of Labor in accordance with the provisions of the Occupational Safety and Health Act of 1970 (Public Law 91-596; 84 Stat. 1590).

Pneumoconiosis Producing Dust

A dust which, when inhaled, deposited and retained in the lungs, may produce signs, symptoms and findings of pulmonary disease.

SUBPART A - 11.3 (Cont'd)

Poor Warning Properties

Substances which cannot be readily detected by odor, taste, or irritation at concentrations within three times the permissible exposure limit, but never to exceed the ceiling limit. Substances which cause rapid olfactory fatigue and have no other warning properties are classed as having poor warning properties.

Powered Air Purifying Respirator

A respirator having a powered blower capable of providing a continuous flow of air through air purifying elements to a respiratory inlet covering.

Remaining Service Life Indicator or Warning Device

An indicator or warning device on a respirator which warns the respirator wearer that the end of the service life of the device is approaching.

Replaceable Filter

A filter which may be removed from a respirator and replaced.

Respirable Breathing Gas

A gas which meets the minimum requirements of the latest ANSI Z86.1 Standard for Type I Grade D Gaseous Air, or Type II Grade B Liquid Air, or U.S. Pharmacopia for Medical or Breathing Oxygen, or chemically generated oxygen meeting the requirements of Military Specification MIL-E-83252 or MIL-O-15633.

Respiratory Inlet Covering

That portion of a respirator which connects the wearer's respiratory tract to an air purifying device or respirable breathing gas source or both. Examples include a facepiece, helmet, hood, suit, mouthpiece/nose clamp, or other device.

Restorable Reusable Filter

A filter which, after one or more uses, may be cleaned or otherwise reconstituted. This process may be repeated until such cleaning or reconstitution becomes ineffective.

Self-Contained Breathing Apparatus (SCBA)

A device with an independent source of respirable breathing gas carried by the wearer.

SCBA, Closed Circuit

An SCBA of the type in which the wearer's exhalation is rebreathed after the carbon dioxide has been effectively removed and a suitable oxygen concentration restored.

SUBPART A - 11.3 (Cont'd)

SCBA, Demand Type

An SCBA in which the pressure inside the respirator in relation to the immediate environment is positive during exhalation and negative during inhalation.

SCBA, Open Circuit

An SCBA of the type from which the wearer's exhalation is vented to the outside atmosphere.

SCBA, Positive Pressure

An SCBA in which the pressure inside the respirator in relation to the immediate environment is positive during exhalation and inhalation.

* Single Use Filter

A filter designed to be discarded when the end of its useful life is reached and which must not be used beyond a single work shift.

Smoke

A system which includes the products of combustion, pyrolysis, or chemical reaction, of substances in the form of visible and invisible solid and liquid particles and gaseous products in air. Smoke is usually of sufficient concentration to perceptibly obscure vision.

Spray

A liquid mechanically produced particle with sizes generally in the visible or macroscopic range.

Supplied Air Respirator

A device which provides the wearer with air from an external source such as a compressor, blower or compressed air cylinder(s).

---

* We recommend to NIOSH that the definition for single use respirators (kk) as published in the Federal Register, December 30, 1977 as final rulemaking, be dropped. Our reasoning in connection with this recommendation is that the 12/30/77 definition is inapplicable to the type of respirator it attempts to describe.

SUBPART A - 11.33 (Cont'd)

Type A Supplied Air Respirator

A respirator, whose respiratory inlet covering is supplied by a remote motor-hand driven or hand operated blower, which permits the wearer to breathe through the air supply hose from ambient air, if the blower is not operating. Commonly called a hosemask.

Type AE Supplied Air Respirator

Same as Type A but with the capability of protecting the wearer's head and neck against impact and abrasion from rebounding abrasive material and slough.

Type B Supplied Air Respirator

A respirator whose respiratory inlet covering is supplied by inspiring ambient air from a remotely located intake at the end of the air supply hose. Commonly called a hosemask without blower.

Type BE Supplied Air Respirator

Same as Type B but with the capability of protecting the wearer's head and neck against impact and abrasion from rebounding abrasive material and slough.

Type C Supplied Air Respirator

A respirator whose respiratory inlet covering is supplied from a remotely located source of compressed air. Commonly called an air line respirator.

Type CE Supplied Air Respirator

Same as Type C but with the capability of protecting the wearer's head and neck against impact and abrasion from rebounding abrasive material and slough.

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION

RECOMMENDED CHANGES TO 30 CFR PART 11

SUBPART B - APPLICATION FOR APPROVAL

11.11 - Contents of Application

Add the following sentence at the end of 11.11 (a): "Instructions for the use and maintenance of the respirators shall be included."

SUBPART D - APPROVAL AND DISAPPROVAL

11.30 - We recommend that an Appeals Procedure be incorporated as a part of Subpart D, preferably to be lettered (e) in this section. See our Major Issue #2 (Administrative).

11.35 - Change Title to read: "Changes of Approved Respirators" with the following re-wording:

(a) Each applicant must, if he desires to change an approved respirator or any item included on the lists required, inform the Institute of the details of the change and the classification of the change as a modification or an extension.

(b) Submission of Modifications: Notice of each modification must be submitted to the Institute. Such notice shall consist of the revised drawing or specification, any necessary changes to the quality control plan, and letter of explanation. Such notices, and the support documents, shall be submitted in duplicate.

(c) Approval or Rejection of Modifications: After appropriate review, if the Institute finds that the modification is not acceptable for any reason, the Institute will so notify the applicant, stating the reason(s) for rejection. The applicant shall have the right to present further clarification or evidence supporting the notice, or may withdraw the modification or upgrade it to an extension. It is not necessary for the Institute to provide the applicant with a written approval for acceptable modifications, but will promptly acknowledge receipt thereof.

(d) Submission of Extensions: Requests for approval of extensions must be made in accordance with this section.

1. Extensions shall be submitted with a request for a change of the existing certificate to cover the proposed extension.

2. The submission shall be accompanied by revised/new drawings, specifications, and quality control plans which meet the requirements of Subpart E of this part.

3. The submission for extension, together with the accompanying material, shall be examined by the Institute to determine whether testing will be required.

4. The Institute shall inform the applicant of the fee required for any additional testing and the applicant will be charged for the actual cost of any examination, inspection or test required, and such fees shall be submitted in accordance with the provisions of Subpart C of this part.

SUBPART D - APPROVAL AND DISAPPROVAL - (Cont'd)

5. If the extension meets the requirements of this part, a formal certificate of change will be issued, accompanied, where necessary, by a list of new and revised drawings and specifications covering the change(s) and reproductions of revised approval labels.

11.36 - Delivery of changed or modified respirator

Delete "certificate of modification" and substitute "certificate of change" so as to read:

"An approved respirator for which a formal certificate of change has been issued. . . . . "

SUBPART E - QUALITY CONTROL

11.41 - Quality control plans; contents

11.41 (a) - The existing paragraph should be replaced with the ISEA General Quality Assurance Guidelines. This recommendation was made to TCB in a meeting with the ISEA.

11.41 (h) - This paragraph requires large sample sizes. In many cases this is not practical and therefore we recommend a more practical sampling plan.

SUBPART F - CLASSIFICATION OF APPROVED RESPIRATORS; SCOPE OF APPROVAL; ATMOSPHERIC HAZARDS (Note: The words "Service Time" have been deleted)

The lettering in sections 11.50, 11.51, 11.52 and 11.53 should be changed from "M" to "N" wherever they occur.

11.51 - Entry and escape, or escape only; classification (We recommend the following re-wording of this section:

Respirators described in Subparts H through N of this part shall be approved for use as follows:

(a) Entry and Escape. Respirators designed and approved for use during entry into a hazardous atmosphere (i) not immediately dangerous to life or health, and for escape from a hazardous atmosphere; or (ii) immediately dangerous to life or health and escape from this atmosphere.

(b) Escape only. Respirators designed and approved for use only during escape from a hazardous atmosphere.

11.52 - Respiratory hazards; classification (We recommend the following re-wording of this section:

Respirators described in Subparts H through N of this part shall be approved for use against any or all of the following respiratory hazards:

SUBPART F - 11.52 (Cont'd)

(a) Oxygen deficiency;
(b) Gases and vapors; and
(c) Particulate matter

(Note: (d) has been dropped from the existing section in 30 CFR Part 11)

11.53 - We recommend that this section be moved to Subpart H with revised language. (This has been numbered 11.70-1 under revised Subpart H)

SUBPART G - GENERAL CONSTRUCTION AND PERFORMANCE REQUIREMENTS

The lettering in sections 11.60, 11.63, 11.64 and 11.65 should be changed from "M" to "N" wherever they occur.

11.60 - Construction and performance requirements; general

We recommend that the following be added as the last sentence to 11.60 (b):

"These additional requirements shall be published as official proposed rulemaking in the Federal Register, and that the public be allowed adequate time to review and comment on these proposals before they are used in approving respirators."

11.61 - General construction requirements

11.61 (a) - We recommend that this paragraph be revised to read as follows:

"Respirators will not be accepted by the Bureau for examination, inspection and testing, unless they are designed to provide good durability and performance, constructed of suitable materials, and evidence good workmanship."

11.62 - Component parts; minimum requirements

11.62 (a)(1) - We recommend that this sub-section be revised to read as follows:

"Complete respirator assembly shall not incorporate any design or component which may injure wearer during normal fitting or use."

11.63 - Test requirements; general

We recommend that the order of sub-sections (c) and (d) be reversed and that a new sentence be added at the end of the current (c) to read identically to our recommendation for 11.60 (b), as stated above.

11.64 - Pretesting by applicant; approval of test methods by the Bureau

11.64 (c) - We recommend that this section be revised to read as follows:

"The Bureau shall, at the written request of the applicant, supply a current description of the procedures and equipment used in testing respirators for approval. This description shall include:

SUBPART G - 11.64 (c) - (Cont'd)

(i) Drawings of the layout including any fabricated or modified parts

(ii) A list of all components, with manufacturer's name and model

(iii) Specifications which determine the selection of all components and substances used

(iv) A description of all operations necessary to achieve consistent and reproducable results, including any special skills, techniques or training of operators

Any change in equipment and procedures not described in 30 CFR Part 11 which affect method of testing or analyzing test data shall be furnished to holders of approved respirators."

11.65 - Conduct of examinations, inspections, and tests by the Bureau and the Institute; assistance by applicant; observers; recorded data; public demonstrations.

11.65 (c) - We recommend this sub-section be revised to read as follows:

"Only Bureau and Institute personnel, persons assisting the Bureau pursuant to paragraph (b) of this section, and such other persons mutually agreeable as are requested. . . . .".

11.65 (d) - We recommend that the words "test data" be added in the second line so as to read:

"The Bureau and the Institute shall hold as confidential any analyses, test data, drawings. . . . . ".

11.65 (e) - We recommend this sub-section be revised to read as follows:

"As a condition of each approval issued for any respirator, the Bureau and the Institute reserve the right, following the issuance of such approval, to conduct such public tests and demonstrations in accordance with the provisions of 30 CFR Part 11 of the approved respiratory equipment."

We recommend that all of the sections in Subparts H through M of 30 CFR Part 11 affecting performance requirements be deleted from these Subparts and moved to Subpart G. We have identified eight subjects for which we are submitting revised wording for inclusion in Subpart G. We are also referencing the relevant sections in Subparts H through M which should be deleted from 30 CFR Part 11 if our recommendations are adopted by NIOSH and MESA.

First, we are citing the relevant sections in Subparts H through M which should be deleted from 30 CFR Part 11, and following this is the new language we recommend for inclusion in Subpart G.

SUBPART G - (Cont'd)

Breathing tubes; minimum requirements

11.72	Subpart H	11.132	Subpart K
11.95	Subpart I	11.155	Subpart L
11.112	Subpart J	11.175	Subpart M

Recommended Language:

(a) Flexible breathing tubes used in conjunction with breathing apparatus shall be designed and constructed to prevent:

(1) Restriction of free head movement;
(2) Disturbance of the fit of respiratory inlet covering;
(3) Interference with the wearer's activities; and
(4) Shutoff of airflow due to kinking, or from chin or arm pressure.

Harnesses; installation and construction; minimum requirements

11.73	Subpart H	11.133	Subpart K
11.96	Subpart I	11.156	Subpart L
11.113	Subpart J	11.176	Subpart M

Recommended Language:

(a) Each Respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

(b) Harnesses shall be designed and constructed to permit easy removal and replacement of respirator parts, and, where applicable, provide for holding a respiratory inlet covering in the ready position when not in use.

Respirator Containers; minimum requirements

11.74	Subpart H	11.134	Subpart K
11.97	Subpart I	11.157	Subpart L
11.114	Subpart J	11.177	Subpart M

Recommended Language:

(a) The respirator may be equipped with a substantial, durable container bearing markings which show the applicant's name, the type and commercial designation of the respirator it contains, and all appropriate approval labels.

(b) Containers supplied by the applicant for carrying or storing self-contained breathing apparatus will be inspected, examined, and tested as components of the respirator for which approval is sought.

(c) Containers for single-use respirators may provide for storage of more than one respirator, however, such containers shall be designed and constructed to prevent contamination of respirators which are not removed, and to prevent damage to respirators during transit.

SUBPART G - (Cont'd)

Respiratory Inlet Coverings; fit; minimum requirements

11.75	Subpart H	11.135	Subpart K
11.98	Subpart I	11.158	Subpart L
11.115	Subpart J	11.178	Subpart M

Recommended Language:

(a) Respiratory inlet coverings shall be designed and constructed to fit persons with various facial shapes and sizes.

(b) Respiratory inlet coverings shall provide for optional use of corrective spectacles or lenses, where applicable, which shall not reduce the respiratory protective qualities of the respirator, and shall be designed to minimize eyepiece fogging.

(c) Mouthpiece respirators shall be equipped with noseclamps which are securely attached to the device and provide an airtight seal.

Respiratory Inlet Coverings; Eyepieces; minimum requirements

11.76	Subpart H	11.136	Subpart K
11.99	Subpart I	11.158-1	Subpart L
11.116	Subpart J	11.179	Subpart M

* Recommended Language:

(a) Respiratory inlet coverings shall be designed and constructed to provide adequate vision which is not distorted by the eyepiece.

(b) Eyepieces for respirators designed for protection against rebounding abrasive particles shall be shielded by a suitable material. The external surface of the lens shall be readily accessible for cleaning.

* We recommend that the impact requirements specified in the current edition of Federal Specification GGG-M-125, Mask, Air Line, and Respirators, Air Filtering, Industrial, be included as part of the performance requirements in 30 CFR Part 11. (See our Major Issue #8 (Technical Performance).)

Inhalation and Exhalation Valves; minimum requirements

11.77	Subpart H	11.137	Subpart K
11.100	Subpart I	11.159	Subpart L
11.117	Subpart J	11.180	Subpart M

Recommended Language:

(a) Inhalation and exhalation valves shall be provided where necessary and protected against distortion.

(b) Exhalation valves shall be protected against damage and external influence; and designed and constructed to prevent inward leakage of contaminated air.

(c) Inhalation valves shall be provided near the respiratory inlet covering of all Type A, AE, B, and BE supplied air respirators.

SUBPART G - (Cont'd)

Head Harnesses; minimum requirements

11.78	Subpart H	11.138	Subpart K
11.101	Subpart I	11.160	Subpart L
11.118	Subpart J	11.181	Subpart M

Recommended Language:

(a) Facepieces shall be equipped with head harnesses which are designed and constructed to provide adequate tension during use, and an even distribution of pressure over the entire area in contact with the face.

(b) Mouthpiece/noseclamps shall be equipped where applicable with harnesses designed and constructed to hold the mouthpiece in place.

Noise Level Measurements; minimum requirements

11.120	Subpart J
11.139	Subpart K
11.161	Subpart L
11.182	Subpart M

Recommended Language:

(a) Where applicable, noise levels generated by respirators will be measured inside the respiratory inlet covering and/or at the ear level at maximum airflow for which the device is approved, and shall not exceed 80 dBA. Measurements shall be taken in an ambient noise level not exceeding 60 dBA.

SUBPART H - SELF-CONTAINED BREATHING APPARATUS

11.70-1 - Service Time; classification (moved from Subpart F [11.53] with revised wording and the addition of a $1\frac{1}{2}$ hour service time)

(a) Respirators described in this part shall be classified, where applicable, as approved for use during the following prescribed service times:

(1) Four hours;
(2) Three hours;
(3) Two hours;
(4) One and a half hours;
(5) One hour;
(6) Forty-five minutes;
(7) Thirty minutes;
(8) Fifteen minutes;
(9) Ten minutes;
(10) Five minutes;
(11) Three minutes

(b) Other service times may be prescribed by the Bureau and the Institute.

SUBPART H - (Cont'd)

11.70 - Self-contained breathing apparatus; description

11.70 (a)(1) - We recommend adding the following wording: after (iii) - Liquid Oxygen - at the end of this sub-section to read:

"and may be of the positive pressure or demand type."

11.70 (a)(2) - We recommend revising this sub-section to read:

Open circuit apparatus. An apparatus of the following types from which exhalation is vented to the atmosphere:

(i) Demand-type apparatus
(ii) Positive pressure type apparatus

11.79 - Breathing gas; minimum requirements

We recommend that the following changes be made in this section:

11.79 (a) - to delete this paragraph in its entirety

11.79 (b) - to add the following wording at the end of this sub-section:

"and chemically generated oxygen shall meet the requirements of the latest edition of Military Specification, MIL-E-83252 or MIL-O-15633, whichever is applicable."

11.79 (c) - We recommend revising this sub-section to read:

"Compressed, gaseous breathing air shall meet the applicable minimum requirements for Type I Grade D of American National Standard Z86.1."

11.79 (d) - We recommend revising this sub-section to read:

"Compressed, liquefied breathing air shall meet the applicable minimum requirements for Type II Grade B of American National Standard Z86.1."

11.80 - Compressed breathing gas and liquefied breathing gas containers; minimum requirements

11.80 (c) - We recommend revising this sub-section to read:

"Containers normally removed from apparatus for refilling shall be equipped with an indicator showing the pressure in the container."

11.80 (b) - We recommend revising this sub-section to read:

"Breathing gas containers shall be marked in accordance with American National Standard Method of Marking Portable Compressed Gas Containers to identify the material contained: (Z48-1-1954) (R-1971); Federal Specification BB-A-1034a, June 21, 1968, Air, Compressed for Breathing Purposes; or Interim Federal Specification GG-B-00675c, October 7, 1974, Breathing Apparatus, Self-Contained."

SUBPART H - (Cont'd)

11.80 (d) - In the 8th line of this sub-section we recommend deleting "1965" and substituting it with "the latest American National Standard."

11.81 - Gas pressure gauges; minimum requirements

We recommend that the following revisions be made in this section:

(1) that the title of the section be changed to read: "Pressure indicators; minimum requirements" - and -

11.81 (a) - Recommended revised wording: "Pressure indicators employed on compressed breathing gas containers shall be calibrated in force per unit area." - and -

in sub-sections 11.81 (c)(1) and 11.81 (c)(3) substitute the words "force per unit area" for "pounds per square inch."

11.82 - Timers; elapsed time indicators; remaining service life indicator; minimum requirements

11.82 (b) - We recommend that this sub-section be revised to read:

"The timer or other indicator shall be accurately calibrated to indicate remaining service life."

11.83 - Hand-operated valves; minimum requirements

We recommend that the following revisions be made in this section:

11.83 (e) - Delete the words "Hand-operated at the beginning of the first line.

11.83 (g) - Revise to read: "The manually operated bypass system valve control shall be colored red."

11.83 (i) - Delete the word "manual" from this sub-section.

11.85-4 Weight Requirement.

11.85-4 (a) - We recommend that the first three lines of this sub-section be substituted with the following wording: "The completely assembled apparatus, charged to half of its service life shall not weigh more than 16 kg. (35 pounds); however. . . . . .".

11.85-6 Breathing resistance test; exhalation.

11.85-6 (b) - We recommend that this sub-section be revised to read: "The exhalation resistance of open-circuit demand apparatus shall not exceed 20 mm. (.8 inch) water-column height."

11.85-6 (c) - We recommend that this sub-section be revised to read: "The exhalation resistance of positive pressure apparatus shall not exceed the static pressure in the facepiece by more than 50 mm. (2 inches) water-column height for demand devices and 90 mm. (3.5 inches) water-column height for positive pressure devices."

SUBPART H - 11.85-6 (Cont'd)

11.85-6 (e) - We recommend that the following be added to the last sentence of this sub-section:

"for demand devices and 90 mm. (3.5 inches) water-column height for positive pressure devices."

On the 6th line of 11.85-6 (e) we also recommend changing "51 mm." to "50 mm."

11.85-7 Exhalation valve leakage test.

We recommend that this section be revised in accordance with our Major Issue #4 (Technical Performance) "Dynamic Leak Testing of Exhalation Valves"

11.85-8 Gas flow test; open circuit apparatus.

11.85-8 (b) - 4th line - change "51 mm." to read "50 mm."

11.85-8 (c) - 1st line - change the words "pressure demand" to "positive pressure"

11.85-9 Gas flow test; closed circuit apparatus.

11.85-9 (c) - We recommend revising this sub-section to read:

"All demand flow devices shall provide at least 115 liters per minute of oxygen when the pressure in the respiratory inlet covering is at its permissible minimum."

11.85-12 Test for carbon dioxide in inspired gas; open and closed circuit apparatus; maximum allowable limits.

We recommend adding a new sub-section to 11.85-12 to increase the CO_2 limits within the respiratory inlet covering for emergency escape breathing apparatus. We offer this recommendation in light of current Navy development work.

11.85-14 Man tests; testing conditions; general requirements.

We recommend that man tests be established to cover $1\frac{1}{2}$ hour breathing apparatus.

11.85-19 Gas tightness test; minimum requirements.

We recommend that this section be eliminated in its entirety. This recommendation is consistent with ISEA's Major Issue #1 (Technical Performance) "

SUBPART I - GAS MASKS

11.90 Gas Masks; description

11.90 (a)(1) We recommend revising this sub-section to read:

"Front mounted or back mounted gas mask. A gas mask which consists of a facepiece, mouthpiece/noseclamp, a breathing tube, a canister at the front or back, a canister harness, and associated connections."

SUBPART I - 11.90 (Cont'd)

11.90 (a)(3) We recommend revising this sub-section to read:

"Chin-style gas mask. A gas mask which consists of a facepiece, mouthpiece/noseclamp, a canister which is usually attached to the facepiece, and associated connections."

11.90 (c) We recommend that a statement be added to this sub-section to conform with our recommendations under Major Issue #1 (Administrative) "Proposed Test Procedures" and under Major Issue #7 (Technical Performance) "Poor Warning Properties"

11.90 (b) We recommend that Footnote 4 under the Maximum Use Concentration Table be amended so as to be consistent with ISEA's Major Issue #7 (Technical Performance) "Clarify Approval of Air-Purifying Respirators for Protection Against Gases and Vapors Having Poor Warning Properties."

11.91 Gas masks; required components.

11.91 (a)(1) - We recommend revising this sub-section to read:

"Facepiece or mouthpiece/noseclamp;"

11.91 (a)(4) - We recommend revising this sub-section to read:

"Inhalation valve; and"

11.102-2 Exhalation valve leakage test.

We recommend that NIOSH revise this section consistent with ISEA's Major Issue #4 (Technical Performance) "Dynamic Leak Testing of Exhalation Valves."

11.102-3 Facepiece tests; minimum requirements.

We recommend that NIOSH revise this section consistent with ISEA's Major Issue #1 (Technical Performance) "Quantitative Fit Tests."

11.102-4 Dust, fume, mist, and smoke tests; canisters containing filters; minimum requirements.

11.102-4 (b) We recommend that the first 6 lines of this sub-section be revised to read:

"Gas masks canisters designed for protection against smokes will be tested in an atmospheric concentration of 100 micrograms of monodisperse dioctyl phthalate (.3 micrometers particle size) per liter of air at continuous flow rate of 85 liters per minute, and (2). . . . . ."

11.102-5 Canister bench tests; minimum requirements.

11.102-5 (a)(1) Starting with the 4th line, we recommend this be revised to read: "50 $\pm$ 3% relative humidity and temperature 25° $\pm$ 2.5°C. to enter. . . . . ."

SUBPART I - 11.102-5 (Cont'd)

11.102-5 (a)(3) In the 3rd line, we recommend deleting the word "room", and in the 4th line revise to read: "25 ± 3% relative humidity air through them at 64 liters per minute for 6 hours."

11.102-5 (a)(4) Starting with the 4th line, we recommend deleting the word "room" and revise the balance of the sub-section to read: "temperature 25 ± 2.5% by passing 85 ± 3% relative humidity air through them at 64 liters per minute for 6 hours."

11.102-5 We recommend that NIOSH revise Tables 5, 6, and 7 so as to be consistent with ISEA's Major Issue #12 (Technical Performance) "Performance Testing of Powered Air Purifying Respirators."

SUBPART J - SUPPLIED AIR RESPIRATORS

11.111 Supplied Air Respirators; required components.

11.111 (a)(1) We recommend that the words "Facepiece, hood, or helmet:" be substituted with "Respiratory inlet covering;"

11.111 (a)(2) In the 2nd line of this sub-section change the words "pressure demand" to "positive pressure"

11.120 We recommend that the title of this section be revised to read: "Air velocity and noise levels; hoods; helmets; and suits; minimum requirements" and that the section be revised to read as follows:

"Where applicable, noise levels generated by respirators will be measured inside the respiratory inlet covering and/or at the ear level at maximum airflow for which the device is approved, and shall not exceed 80 dBA. Measurements shall be taken in an ambient noise level not exceeding 60 dBA."

(Note: The above recommended revision is in conformance with ISEA's Major Issue #9)

11.121 We recommend revising the title of this section to read: "Breathing gas; minimum user requirements"

11.124-5 We recommend revising the title of this section to read: "Type C supplied air respirators; requirements for pressures and hose lengths."

Additional suggested revisions to 11.124-5 are as follows: Take the present sub-section (b) of 11.124-6 and make this a new sub-section (d) to 11.124-5 and add the phrase "and the range of hose length for the respirator" at the end of the new 11.124-5 (d).

11.124-6 We recommend that this section be deleted in its entirety from 30 CFR Part 11.

SUBPART J - (Cont'd)

11.124-10 Airflow resistance test, Type A and Type AE supplied air respirators; minimum requirements.

11.124-10 (c) - In the 2nd line, we recommend that "25 mm. (1 inch)" be changed to "20 mm. (.8 inch)."

11.124-11 Airflow resistance test; Type B and Type BE supplied air respirators; minimum requirements.

11.124-11 (b) - Starting in the 1st line, we recommend this be revised to read: "Inhalation airflow resistance shall not exceed. . . . . .".

11.124-11 (c) - In the 2nd line, change "25 mm. (1 inch)" to "20 mm. (.8 inch)"

11.124-12 In the 2nd line, change "25 mm. (1 inch)" to "20 mm. (.8 inch)"

11.124-14 We recommend revising the title of this section to read: "Airflow resistance test; Type C supplied air respirator, positive pressure class; minimum requirements"

11.124-14 (c) - In the 5th line, change "51 mm." to read: "50 mm. (2 inches) of water-column height."

11.124-15 Exhalation valve leakage test.

This section should be revised to conform with ISEA's Major Issue #4 (Technical Performance), "Dynamic Leak Testing of Exhalation Valves."

11.124-16 through 11.124-24

ISEA recommends to NIOSH that these sections be reviewed and revised to be consistent with ISEA's Major Issue #1 (Technical Performance) "Quantitative Fit Tests."

11.124-7 Air supply line tests; minimum requirements.

ISEA offers the following recommendations in connection with Table 8 of this section:

(1) eliminate the requirement for the air to be flowing through the respirator (under "tightness" in the Table) and,

(2) that wherever the words "pressure demand" appear in the Table they be replaced with the words "positive pressure."

11.124-21 Tests for protection during abrasive blasting; Type AE, Type BE, and Type CE supplied air respirators; general performance requirements.

ISEA recommends to NIOSH that NIOSH develop a more realistic, rigorous, abrasive test with objective criteria.

SUBPART K - PARTICULATE FILTER RESPIRATORS

11.130 Particulate filter respirators; description.

(a) Particulate filter respirators are defined as respirators equipped with one or more filters designed to remove a single type of particulate matter or a combination of two or more types of particulate matter from ambient air prior to inhalation by the respirator wearer.

(b) Particulate filter respirators are designed for use as respiratory protection during entry into and escape from hazardous, particulate-containing atmospheres which have a minimum oxygen concentration of 19.5 percent by volume.

11.131 Particulate filter respirators; classification.

(a) Particulate filter respirators are classified according to the following characteristcs:

(1) Respirator type

(i) Non-powered air purifying respirators
(ii) Powered air purifying respirators

(2) Protection Class

(i) Respirators designed for use against particulates having a time-weighted average (TWA) not less than 0.05 milligrams per cubic meter, or 2 mppcf.
(ii) Respirators designed for use against particulates having a time-weighted average (TWA) less than 0.05 milligrams per cubic meter, or 2 mppcf.

(3) Type of particulate hazard.

(i) Dusts
(ii) Mists
(iii) Fumes
(iv) Radionuclides

(4) Filter efficiency

(i) Standard efficiency filters which can achieve a minimum efficiency of 99 percent against the appropriate test aerosol.
(ii) High efficiency filters which can achieve a minimum efficiency of 99.97 percent against the appropriate test aerosol.

SUBPART K - (Cont'd)

11.132 Particulate filter respirators; components.

(a) The components of each particulate filter respirator shall meet the minimum construction requirements set forth in Subpart G of this part.

11.133 Particulate filter respirators; performance requirements, general.

(a) Particulate filter respirators and the individual components of each such device shall, as appropriate, meet the requirements for performance and protection specified in the tests described in paragraphs 11.135 through 11.138.

11.135 Particulate filter respirators; airflow resistance testing, minimum requirements.

(a) Resistance to airflow will be measured in the respiratory inlet covering of a particulate filter respirator mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute, both before and after each test conducted in accordance with paragraphs 11.136 through 11.136-3.

(b) Maximum initial inhalation resistance shall be three millibar (30 millimeter water column height).

(c) Maximum final inhalation resistance shall be five millibar (50 millimeter water column height).

(d) Maximum exhalation resistance (both initial and final) shall be two millibar (20 millimeter water column height).

11.136 Particulate filter tests, general; airflow requirements.

(a) Particulate filter respirators equipped with exhalation and inhalation valves to prevent exhaled breath from contacting the filter element shall be tested against the appropriate aerosols by drawing a continuous airflow of 32 liters per minute through the filtration element.

(b) Particulate filter respirators which allow the exhaled breath to contact the filter element shall be tested against the appropriate aerosols using a cyclical airflow rate.

(i) Air shall be cycled through the respirator at the rate of 24 respirations per minute with a minute volume of 40 liters.
(ii) A breathing machine cam having a work rate of 622 kilogram-meters squared per minute shall be used.
(iii) Air exhaled through the respirator shall be conditioned to 35° ± 2°Centigrade and 94% ± 3% relative humidity.

(c) Powered air purifying respirators equipped with tight fitting respiratory inlet coverings shall be evaluated against the appropriate aerosols while in the normal operational mode.

SUBPART K - 11.136 (Cont'd)

(c) (i) A minimum airflow rate of 115 liters per minute, both before and after each applicable aerosol test, shall be required.
(ii) Airflow rates shall be measured with the respirator mounted on a suitable headform.

(d) Powered air purifying respirators equipped with loose fitting respiratory inlet coverings shall be evaluated against the appropriate aerosols while in the normal operational mode.

(i) A minimum airflow rate of 170 liters per minute, both before and after each applicable aerosol test, shall be required.
(ii) Airflow rates shall be measured with the respirator mounted on a suitable mannequin.

11.136-1 Silica dust test; minimum requirements.

(a) Three respirators will be evaluated.

(i) Non-powered air purifying respirators will be exposed to the test aerosol for a period of 90 minutes.
(ii) Powered air purifying respirators will be exposed to the test aerosol for a period of four hours.

(b) The test aerosol in the chamber will consist of 55 $\pm$ 5 milligrams per cubic meter flint (99+ percent free silica).

(c) The particle size distribution of the test aerosol will have a geometric mean diameter of 0.4 to 0.6 micrometer, and the standard geometric deviation will be 1.8 $\pm$ 0.2.

(d) Chamber concentration shall not fluctuate more than plus or minus ten percent during the performance of any test.

(e) The relative humidity in the test chamber will be 45 to 55 percent, and the chamber temperature will be 23° $\pm$ 2° Centigrade.

(f) The total amount of test aerosol not retained by the respirator filter during the entire test period shall be monitored.

(i) The maximum amount of leakage for standard efficiency filters shall be as follows:

1. The total leakage shall not exceed 1.5 milligrams for non-powered air purifying respirators equipped with inhalation and exhalation valves.

2. The total leakage shall not exceed 1.8 milligrams for non-powered air purifying respirators without valves.

3. The total leakage shall not exceed 14.4 milligrams for powered air purifying respirators equipped with tight fitting respirator inlet coverings.

SUBPART K - 11.136-1 (Cont'd)

(f) (i) 4. The total leakage shall not exceed 21.3 milligrams for powered air purifying respirators equipped with loose fitting respiratory inlet coverings.

(ii) High efficiency filters approved for dusts must comply with paragraph 11.137 in addition to the silica dust tests herein specified.

11.136-2 Silica mist test; minimum requirements.

(a) Three respirators will be evaluated.

(i) Non-powered air purifying respirators will be exposed to the test aerosol for a period of 312 minutes.

(ii) Powered air purifying respirators will be exposed to the test aerosol for a period of four hours.

(b) The test aerosol in the test chamber will not be less than 20 nor more than 25 milligrams per cubic meter of air when dried and weighed as silica dust.

(c) Mist will be produced by spraying an aqueous suspension of flint (99+ percent free silica), and the flint shall be ground to pass 99 percent through a 325-mesh sieve (U.S. Series).

(d) Chamber concentration shall not fluctuate more than plus or minus ten percent during the performance of any test.

(e) The chamber temperature will be maintained at 23° ± 2°Centigrade.

(f) The total amount of test aerosol, weighed as silica dust, not retained by the respirator filter during the entire test period shall be monitored.

(i) The maximum amount of leakage for standard efficiency filters shall be as follows:

1. The total leakage shall not exceed 2.5 milligrams for non-powered air purifying respirators equipped with inhalation and exhalation valves.

2. The total leakage shall not exceed 3.0 milligrams for non-powered air purifying respirators without valves.

3. The total leakage shall not exceed 6.9 milligrams for powered air purifying respirators equipped with tight fitting respiratory inlet coverings.

4. The total leakage shall not exceed 10.2 milligrams for powered air purifying respirators equipped with loose fitting respiratory inlet coverings.

(ii) High efficiency filters approved for mists must comply with paragraph 11.137 in addition to the silica mist tests herein specified.

SUBPART K - (Cont'd)

11.136-3 Lead fume test, minimum requirements.

(a) Three respirators will be evaluated.

(i) Non-powered air purifying respirators will be exposed to the test aerosol for a period of 312 minutes.
(ii) Powered air purifying respirators will be exposed to the test aerosol for a period of four hours.

(b) The test aerosol in the test chamber will not be less than 15 nor more than 20 milligrams of freshly generated lead-oxide fume, calculated as lead, per cubic meter of air.

(c) The fume will be generated by impinging an oxygen-gas flame on molten lead.

(d) Chamber concentration shall not fluctuate more than plus or minus ten percent during the performance of any test.

(e) The relative humidity in the test chamber will be 40 to 60 percent, and the room temperature will be 23° ± 2°Centigrade.

(f) The total amount of test aerosol, which is analyzed and calculated as lead, not retained by the respirator filter during the entire test period shall be monitored.

(i) The maximum amount of leakage for standard efficiency filters shall be as follows:

1. The total leakage shall not exceed 1.5 milligrams for non-powered air purifying respirators equipped with inhalation and exhalation valves.

2. The total leakage shall not exceed 1.8 milligrams for non-powered air purifying respirators without valves.

3. The total leakage shall not exceed 4.2 milligrams for powered air purifying respirators equipped with tight fitting respiratory inlet coverings.

4. The total leakage shall not exceed 6.2 milligrams for powered air purifying respirators equipped with loose fitting respiratory inlet coverings.

(ii) High efficiency filters approved for fumes must comply with paragraph 11.137 in addition to the lead fume tests herein specified.

11.137 DOP filter test; respirators designed as respiratory protection against particulates having a time-weighted average (TWA) less than 0.05 milligrams per cubic meter, and radionuclides; minimum requirements.

(a) All single air-purifying respirator filter elements will be tested against an 0.3 micrometer mono-dispersed, thermally-generated aerosol of DOP having a concentration of 90 to 110 micrograms per liter of air.

SUBPART K - 11.137 (Cont'd)

(b) Filter elements shall be evaluated at the following flowrates:

(i) Where the respirator design employs a single filter element, a continuous flowrate of 85 liters per minute will be used.
(ii) Where the respirator design employs filter elements in pairs, a flowrate will be 42.5 liters per minute through each filter.

(c) Filters will be evaluated for a time period of five to ten seconds.

(d) The total leakage for the filter shall not exceed 0.03 percent of the ambient DOP concentration at the flowrate.

11.138 Tests for respirators designed for respiratory protection against more than one type of particulate; minimum requirements.

(a) Respirators designed as respiratory protection against more than one type of particulate hazard (dust, fume, mist, etc.) shall comply with all the requirements of this part, with respect to each of the specific hazards involved.

(b) Filter tests required for approval. See Table ____.

We have not proposed changes to sections 11.134, 11.134-1, 11.134-2, 11.134-3 and 11.134-4, all dealing with Quantitative Fit Testing, for the following reasons:

The information currently available shows unacceptable variations of protection factors when one facepiece is tested several times on one individual. The data to explain this variation is insufficient to enable a reasonable conclusion to be drawn. We feel that further work should be done to produce reproducible test results, or to show that these variations are logically explicable.

We feel that work should be done to show the effect of lung retention of the aerosol on the test results.

We feel that the temperature of the test chamber should be low enough to prevent the perspiration of the test subject, which may be generated during the exercises, from affecting the facepiece fit. Perspiration may cause the facepiece to slip on the face during head movement exercises.

Although we agree that a quantitative facepiece fit test is of great value to approval testing, we feel that this information cannot be used as a method for assuming the fit of an individual worker. Individual worker fit should be performed before any protection factor can be assumed, and is indeed required by 1910.134 and implemented in OSHA's Program Directive #300-9.

We feel this subject is of such vital importance that we have included the above statements in our Major Issue #1 (Technical Performance) which is an earlier part of this entire submission.

SUBPART K

11.138 (b) - Filter Tests Required For Approval.

TABLE ____. REQUIRED TESTS FOR APPROVAL.

Particulate Filter Respirators	11.136-1	11.136-2	11.136-3	11.137
Dust - Standard Efficiency	x			
Dust - High Efficiency	x (1)			x
Mist - Standard Efficiency		x		
Mist - High Efficiency	x (1)			x
Fume - Standard Efficiency			x	
Fume - High Efficiency	x (1)			x

(1) If filter is tested with DOP aerosol, then fume and mist tests are not required. Silica dust test will be required for loading.

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION - RECOMMENDED CHANGES TO 30 CFR PART 11

SUBPART L - CHEMICAL CARTRIDGE RESPIRATORS

We offer the following proposed revisions to Subpart L:

11.150 Chemical cartridge respirators; description.

A chemical cartridge respirator is an air-purifying respirator equipped with a cartridge(s) to remove a single vapor or gas, a single class of vapors or gases, two or more vapors or gases or two or more classes of vapors or gases from the ambient air before the air is inspired. The chemical cartridge respirator may be equipped with a filter(s) in addition to the cartridge(s) to remove particulate matter from the ambient air before the air is inspired. A chemical cartridge respirator is designed for use as respiratory protection during entry into and escape from a hazardous atmosphere not immediately dangerous to life or health and which contains adequate oxygen to support life. Chemical cartridge respirators may be classified as follows:

(a) Non-powered. The respirator wearer inhales through a cartridge(s) which removes vapors and gases from the ambient air (if the respirator also contains a filter(s), particulate matter will be removed from the ambient air).

(b) Powered. A blower, carried by the respirator wearer or remotely located, passes ambient air through a cartridge(s) which removes vapors and gases from the air and provides the purified air to the respiratory inlet covering (if the respirator also contains a filter(s), particulate matter will be removed from the ambient air).

Chemical cartridge respirators shall be further described according to the vapors and gases against which they are designed to provide respiratory protection, as follows: Ammonia, Chlorine, Hydrogen chloride, Methyl amine, Organic vapor, Sulfur dioxide, and Vinyl chloride.

Chemical cartridge respirators may be designed to provide protection of persons against inhalation of any single or combination of vapors and gases and in addition against any single or combination of various types of particulate matter. Chemical cartridge respirators will not be approved for use as respiratory protection against vapors and gases that lack adequate warning properties except where Federal standards permit.

NOTE: Chemical cartridge respirators for respiratory protection against vapors and gases which have not been listed above may be approved. The applicant shall submit a request for approval to the Institute, listing the vapor or gas and suggest test procedures and test criteria. The Institute and the Mining Enforcement and Safety Administration will consider the application and propose to accept the application or reject the application on the basis of effect on the respirator wearer's health and safety and any field experience in the use of chemical cartridge respirators for such exposures. If the Institute and the Mining Enforcement and Safety Administration propose to accept the application, these Agencies shall publish in the Federal Register the proposed test procedures

SUBPART L - 11.150 (Cont'd)

and test criteria and the public shall be allowed adequate time to review and comment on the proposals. After the Institute and the Mining Enforcement and Safety Administration have considered any comments and suggestions received from the public, and these Agencies have agreed upon the proposed or modified test procedures and test criteria, they shall publish the acceptable test procedures and test criteria in the Federal Register as an official rulemaking before they make use of the new test procedures and test criteria in the approval of respirators.

11.151 Chemical cartridge respirators; required components.

11.151 (a)(1) - Change to read: "Respiratory inlet coverings;"

11.153 Cartridges; color and markings; requirements.

Change entire section to read: "The color and markings of all cartridges or labels shall conform with the requirements of American National Standard K13.1-1973, 'Identification of Air Purifying Respirator Canisters and Cartridges'."

11.154 Change the title of this section to read: "Filters and chemical cartridges; minimum requirements."

11.154 (a) - Revise this entire section to read:

"Respirators submitted for approval for particulate matter and gases or vapors, shall meet the performance requirements of the appropriate paragraphs of Subparts K and L."

11.155 Breathing Tubes; minimum requirements.

11.155 (a)(2) - Revise to read: "Disturbance of fit of respiratory inlet coverings;"

11.156 Harnesses; installation and construction; minimum requirements.

11.156 (b) - Change "full facepiece" to "respiratory inlet covering" in the 5th line of this sub-section.

11.158 Revise the title of this section to read: "Respiratory inlet coverings; fit; minimum requirements."

11.158 (a) and (b) - Reference is made to ISEA's Major Issue #1 (Technical Performance) "Quantitative Fit Tests": We recommend combining 11.158 (a) and (b) to read:

"A respiratory inlet covering shall be designed and constructed to fit a panel of human subjects having appropriate anthropometric characteristics representing at least 95% of the adult working population, both males and females. An applicant shall be permitted to submit for approval a respirator having a respiratory inlet covering which fits a specific portion of the panel."

11.158 (c) - Change "noseclips" to "noseclamps" in the 2nd line of this sub-section.

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION - RECOMMENDED CHANGES TO 30 CFR PART 11

SUBPART L - 11.158 (Cont'd)

11.158 (d) and (e) - Combine these two sub-sections and revise to read as follows:

"A respiratory inlet covering shall provide for optional use of corrective spectacles or lenses, where applicable, which shall not reduce the respiratory protective qualities of the respirator, and shall be designed to minimize eyepiece fogging."

11.158-1 - In the title change the words "Facepieces, hoods, and helmets" to "respiratory inlet coverings" and make this paragraph (a) of 11.158-1. Add as a new paragraph (b) of 11.158-1 the following:

"Where applicable, eyepieces shall be designed and constructed to meet the penetration requirements of the current edition of Federal Specification GGG-M-125, Mask, Airline, and Respirator, Air Filtering, Industrial."

11.160 Head Harnesses; minimum requirements

11.160 (a) - In the last line of this sub-section change "in contact with the face" to "of the face in contact with the facepiece."

11.160 (b) - Starting in the third line of this sub-section delete the words "and replaceable" and revise this entire sub-section to read:

"Mouthpieces shall be equipped where applicable, with an adjustable harness designed and constructed to hold the mouthpiece in place in the wearer's mouth."

11.161 - Revise the title of this section to read: "Powered chemical cartridge respirators; air velocity and noise levels; minimum requirements."

Revise the section to read:

"The noise level generated by a powered chemical cartridge respirator will be measured inside the respiratory inlet covering and/or at the ear level at maximum airflow for which the device is approved, and shall not exceed 80 dBA. Measurements shall be taken in an ambient noise level not exceeding 60 dBA."

11.162-1 Breathing resistance test; minimum requirements

11.162-1 (a) Starting on the second line, change "facepiece, mouthpiece, hood, or helmet" to "respiratory inlet covering"

11.162-1 (b) We recommend that the Table in this sub-section be revised to conform with ISEA's Major Issue #6 (Technical Performance) "Breathing Resistance Requirements"

Also in connection with 11.162-1, the ISEA requests that NIOSH rescind the final rulemaking on this section as published in the Federal Register, December 30, 1977.

SUBPART L - (Cont'd)

11.162-2 - Exhalation valve leakage test; minimum requirements.

ISEA requests that NIOSH revise this section to conform with our Major Issue #4 (Technical Performance) "Dynamic Leak Testing of Exhalation Valves" and include powered and non-powered respirators in the re-write of this section.

11.162-3 Facepiece test; minimum requirements.

We recommend that NIOSH revise this section in accordance with ISEA's Major Issue #1 (Technical Performance), "Quantitative Fit Tests."

11.162-4, 11.162-5, 11.162-6 - With reference to these three sections, ISEA offers the following comments:

The lacquer and enamel aerosol tests need much improvement. It is almost impossible to obtain the lacquer and enamel materials listed in 11.162-5 and 11.162-6 respectively. As these lacquer and enamel materials age, the characteristics of the aerosols generates change and this greatly affects the test results.

Substitution of other lacquer and enamel materials for those listed in 11.162-5 and 11.162-6 respectively results in the generation of aerosols of widely varying characteristics which affect test results. It is strongly recommended that a study be made of the lacquer and enamel aerosol tests with the aim of improving these tests.

11.162-8 Bench tests; gas and vapor tests; minimum requirements; general.

This section lists an air flow rate of 115 liters per minute for high humidity and low humidity equilibration of chemical cartridge used in powered chemical cartridge respirators equipped with tight-fitting respiratory inlet coverings and lists an air flow rate of 170 liters per minute for high humidity and low humidity equilibration of chemical cartridges used in powered chemical cartridge respirators equipped with loose fitting respiratory inlet coverings. Instead, 11.162-8 should state that the powered chemical cartridge respirator should be operated at its normal air flow rate which shall never be less than 115 liters per minute during the test period if the respirator is equipped with a tight-fitting respiratory inlet covering and which shall never be less than 170 liters per minute during the test period if the respirator is equipped with a loose-fitting respiratory inlet covering.

Table 11 in 11.162-8 indicates that chemical cartridges used in powered chemical cartridge respirators are given vapor and gas service life tests at the low air flow rates of 64 liters per minute and 32 liters per minute which are the air flow rates for use in testing chemical cartridges of non-powered chemical cartridge respirators designed to prevent exhaled air from contacting the chemical cartridges. This is wrong. The vapor and gas service life tests of chemical cartridges used in powered chemical cartridge respirators should be carried

SUBPART L - 11.162-8 (Cont'd)

out with the respirator being operated at its normal air flow rate which shall never be less than 115 liters per minute during the test period if the respirator is equipped with a tight-fitting respiratory inlet covering and which shall never be less than 170 liters per minute during the test period if the respirator is equipped with a loose-fitting respiratory inlet covering.

Table 11 in 11.162-8 indicates that the minimum vapor and gas service life values for chemical cartridges used in powered chemical cartridge respirators shall be the same as for chemical cartridges used in non-powered chemical cartridge respirators designed to prevent exhaled air from contacting the chemical cartridges. This is wrong. It is reasonable to expect that a powered chemical cartridge respirator should provide adequate respiratory protection for half a normal work shift which is 240 minutes. Thus, Table 11 in 11.162-8 should be corrected to list 240 minutes as the minimum service life for cartridges used in powered chemical cartridge respirators as received.

The equilibrated chemical cartridge respirators used in powered air purifying respirators shall be tested for a period of 120 minutes.

SUBPART M - PESTICIDE RESPIRATORS

In connection with Subpart M, the ISEA recommends to NIOSH that Subpart M should be reviewed and the performance requirements made more reflective of pesticide use.

SUBPART N - SPECIAL USE RESPIRATORS

11.203 Chemical cartridge respirators; requirements and tests.

In connection with the December 30, 1977 final rulemaking published in the Federal Register, the ISEA offers the following comments and recommendations with respect to 11.203:

11.203 (a) - We recommend this sub-section be revised to read:

"Except for the tests prescribed in sections 11.162-4 through 11.162-8, the minimum requirements and performance tests for chemical cartridge respirators prescribed in Subpart L of this part are applicable to vinyl chloride chemical cartridge respirators with and without valves."

11.203 (b)(3)- Revise this sub-section to read:

"The equilibrated cartridges will be resealed, kept in an upright position at room temperature, and tested according to paragraphs (b)(4) and (b)(5) for valved respirators or according to paragraphs (b)(6) and (b)(7) for valveless respirators within 18 hours."

SUBPART N - 11.203 (Cont'd)

11.203 (b)(4) - Revise this sub-section to read:

"The cartridges or pairs of cartridges for valved respirators, equilibrated and stored as described in paragraphs (b)(1), (b)(2), and (b)(3) of this section, will be tested on an apparatus that allows the test. . . . . ."

11.203 (b)(5) - Revise this sub-section to read:

"The maximum allowable penetration after 90 minutes testing of cartridges or pairs of cartridges for valved respirators, according to paragraph (b)(4) of this section, shall not exceed 1 ppm vinyl chloride."

11.203 (b)(6) - Delete the words "single use" from the 1st line so as to read:

"The valveless respirators, ..."

11.204 Powered air purifying respirators; requirements and tests.

The ISEA recommends that this section be revised to conform with our Major Issue #12 (Technical Performance) "Performance Testing of Powered Air Purifying Respirators."

* * * * * * * *

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION

COMMENTS TO NIOSH AND MESA ON MODIFICATIONS TO 30 CFR PART 11
PROVIDING FOR ADDITIONAL REQUIREMENTS AND TESTS
AS PRESENTED BY NIOSH AT PUBLIC HEARING - NOVEMBER 29, 1977

Item #4 NIOSH Proposal: To assure adequate protection to the wearer, MESA and NIOSH require that the pressure in the wearer's breathing zone of an approved powered air-purifying respirator shall not fall below ambient atmospheric pressure during silica dust testing in accordance with 11.140-4 a. and f. This is determined while the respirator is mounted on a test head and is operating under test conditions.

ISEA Response: Our position is that for a powered air purifying respirator this test should be run with a breathing machine at the end of the particulate filter loading test. We request that NIOSH and MESA furnish ISEA with more specific details regarding this test.

Item #7 NIOSH Proposal: To assure that adequate but not excessive by-pass airflow is maintained under all conditions of use of an approved self-contained breathing apparatus incorporating that feature as specified in 11.83 (e), MESA and NIOSH require a flow rate of 80 liters per minute minimum and 115 liters per minute maximum in constant flow apparatus and 130 liters per minute minimum in demand or pressure demand flow apparatus, with variable control.

ISEA Response: We request clarification from NIOSH regarding the above requirement.

Item #8 NIOSH Proposal: MESA and NIOSH have increased the severity of the gas tightness test for approval of all self-contained breathing apparatus, over that specified in 11.85-19, to assure safe operation of such apparatus, particularly those incorporating hoods and helmets. The test time specified in 11.85-19 (b) is increased to 4 minutes or until the service life is complete and the following exercises are performed for 1 minute each while wearing the apparatus: Nodding and turning head; calisthenic arm movements; running in place; and pumping with a tire pump.

ISEA Response: See ISEA's recommendations under Major Issue #1 (Technical Performance), "Quantitative Fit Tests"

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION

COMMENTS TO NIOSH AND MESA ON MODIFICATIONS TO 30 CFR PART 11
PROVIDING FOR ADDITIONAL REQUIREMENTS AND TESTS
AS PRESENTED BY NIOSH AT PUBLIC HEARING - NOVEMBER 29, 1977

Item #9 NIOSH Proposal: To assure ruggedness, all approved escape self-contained breathing apparatus are required to operate satisfactorily during applicable man tests, after having been vibrated at 150 cycles per minute at a force of 15 ± 1 G for 40 hours. This test is performed on one or more samples, as required.

ISEA Response: We would like to know what the criteria is for this test.

Item #10 NIOSH Proposal: In place of the tests for protection during abrasive blasting, for approval of Type AE, BE, and CE supplied air respirators, specified in 11.124-21 through 11.124-24, MESA and NIOSH test such respirators in an atmosphere of 15 ± 2.5 mg/M^3 sodium chloride aerosol having a mass median aerodynamic diameter of 0.6 ± 0.12 micrometers and a geometric standard deviation of 2.2 ± 0.2. The test chamber relative humidity is controlled to 50 ± 10 percent and the temperature to 25 ± 2.5° C. The maximum allowable leakage during a ten minute man test on each of three subjects is 1 percent of the test concentration. The man test consists of 5 minutes walking in place, turning head, dipping chin and 5 minutes turning body at waist and bending forward and sideward.

ISEA Response: We do not believe this test makes any sense and it does not provide adequate protection for abrasive blasting.

Item #11 NIOSH Proposal: To provide for MESA and NIOSH approval of reusable respirators without exhalation valves, such devices are tested at intermittent flow, against silica dust, using the same test conditions as 11.140-5. Each respirator is tested three times; cleaned after the first and second uses; and shall meet all applicable requirements of 11.140-4 for reusable filter respirators, except the allowable leakage is 1.8 mg.

ISEA Response: We believe these tests are unnecessary. See our recommendations under Subpart K.

Item #12 NIOSH Proposal: To provide resistance requirements for MESA and NIOSH approval of powered air-purifying dust, fume, and mist respirators, such devices are tested as specified in 11.140-4, 11.140-6, 11.140-7. It is required that the inhalation resistance shall not exceed 50 mm water-column height when blower is off and when tested for resistance at an airflow of 85 liters per minute.

ISEA Response: We believe this recommendation should apply only for tight fitting devices to be approved for entry into IDLH atmospheres.

INDUSTRIAL SAFETY EQUIPMENT ASSOCIATION

COMMENTS TO NIOSH AND MESA ON MODIFICATIONS TO 30 CFR PART 11

PROVIDING FOR ADDITIONAL REQUIREMENTS AND TESTS

AS PRESENTED BY NIOSH AT PUBLIC HEARING - NOVEMBER 29, 1977

Item #13 NIOSH Proposal: To provide resistance requirements for MESA and NIOSH approval of combination gas, vapor, or gas and vapor chemical cartridge and asbestos-containing dust and mist respirators, such devices are tested as specified in 11.140-4, 11.140-7, and 11.162-8. It is required that the initial inhalation resistance not exceed 35 mm water-column height, the final inhalation resistance shall not exceed 50 mm water-column height, and the exhalation resistance shall not exceed 15 mm water-column height, when tested for resistance as specified in 11.162-1.

ISEA Response: We request your justification of the resistance values -- Why are they different from the Table in 11.144? -- See ISEA's recommendations under Major Issue #6 (Technical Performance), "Breathing Resistance Requirements."

Item #14 NIOSH Proposal: To provide requirements for MESA and NIOSH approval of paint spray respirators with valve(s), in which the airflow is so routed that exhalation passes entirely through the particulate filtering device, such devices are tested against aerosols as specified in 11.162-5 and 11.162-6, except that airflow through the respirator is as prescribed in 11.140-5. The maximum allowable leakages are 6.25 milligrams for lacquer mist and 1.8 milligrams for enamel mist.

ISEA Response: See ISEA's comments under Subpart L - 11.162-4, 11.162-5 and 11.162-6.

Item #16 NIOSH Proposal: In section 11.85-6 Breathing Resistance Test; exhalation resistance, a maximum static pressure of 1.5 inches water-column height and an additional maximum pressure of 2 inches exhalation resistance is permitted for pressure-demand units. If the total exhalation resistance does not exceed 3.0 inches of water, then the static pressure may be increased by 0.5 inch or to a maximum of 2.0 inches of water-column height.

ISEA Response: See ISEA's comments under Major Issue #6 (Technical Performance), "Breathing Resistance Requirements."