



Industrial Safety Equipment Association

June 23, 1994

Specific Issues Regarding the National Institute of Occupational Safety and Health's Proposed Certification Requirements for Respiratory Protective Devices (42 CFR 84) that will be Addressed by the Industrial Safety Equipment Association

A. Grandfathering Provisions

i. NIOSH will continue to accept submittals in accordance with the criteria of 30 CFR 11 for 30 days after 42 CFR 84 is published as a final rule.

- ISEA supports the NIOSH proposal that new submittals in accordance with the criteria of 30 CFR 11 continue to be accepted for 30 days after publication of 42 CFR 84 as a final rule.
- Thirty days is a reasonable time to continue to allow new submittals in accordance with the criteria of 30 CFR 11 after publication of 42 CFR 84 as a final rule.

ii. Two years after publication of 42 CFR 84 as final, manufacturers may no longer sell or distribute respirators certified to the criteria of 30 CFR 11 as NIOSH-approved or NIOSH-certified respirators.

- ISEA recommends that manufacturers be permitted to sell and ship products certified to the 30 CFR 11 criteria as NIOSH-approved or NIOSH-certified respirators for four years after the date of publication of the final rule.

- Valid reasons support this ISEA request, including:
 - the experience in Europe that three or more years are required to develop respirators that meet the updated criteria;
 - The five year transition period NIOSH proposed in 1987;
 - The limited resources NIOSH has to approve respirators within the proposed time frame;
 - the experience of the Bureau of Mines when it transferred certification authority to NIOSH and MSHA demonstrated a need for sufficient time to make such an effort;
 - the lack of available filter media in all filter categories will slow manufacturers' efforts to develop respirators meeting the new criteria.

iii. Two years after publication of 42 CFR 84 as final, manufacturers may no longer sell or distribute respirators certified to the criteria of 30 CFR 11 as NIOSH-approved or NIOSH-certified respirators.

- ISEA recommends that NIOSH limit application of the grandfather period to respirators that remain under the manufacturers' control.
- Manufacturers have limited control over respirators once they enter the distribution channels.

iv. The proposed rule does not address extensions of existing product approvals involving changes in filter media or filter specifications that affect filter performance.

- ISEA recommends that for changes to filter media or filter specifications that would affect filter performance, submittals for extensions of existing product approvals be accepted for two years after the rule becomes final.
- The proposed rule must account for changes that affect filter performance that would not normally need to proceed through the entire certification process.

v. The proposed rule does not address extensions of existing product approvals involving non-substantial changes to respirators that do not affect filter performance.

- ISEA recommends that for manufacturer's making non-substantial changes to respirators that do not affect filter performance, extensions should be granted for existing product approvals for four years after the rule becomes final.
- The proposed rule must account for non-substantial changes that do not affect filter performance that would not normally need to proceed through the entire certification process.

vi. The proposed rule does not address clearly whether distributors or users who receive respirators that are certified under 30 CFR 11 prior to the proposed sales deadline will be able to continue to sell or use these products as NIOSH-certified after the deadline passes.

- ISEA recommends that NIOSH confirm that products approved under 30 CFR 11 criteria do not lose their certified status after the proposed sales deadline for manufacturers passes.
- If products previously certified by NIOSH lose their certified status after the proposed sales deadline passes, it will needlessly confuse end users and create a costly logistical nightmare for manufacturers and distributors.

B. Testing Parameters

i. Section 84.184 currently is titled "Particulate instantaneous penetration filter test"

- ISEA recommends that §84.184 be renamed "Particulate filter penetration characteristics test"
- The proposed title is an inaccurate reflection of the objective of the test.

ii. The proposed rule does not identify the proper method of aerosol generation.

- ISEA recommends that NIOSH work with respirator community to identify an appropriate method of aerosol generation.
- For electrostatic filter media, different results are reached when using thermally generated (hot) DOP or cold nebulized (cold) DOP.

iii. Limited testing has shown that the proposed test equipment does not produce consistent, reproducible results.

- ISEA recommends that NIOSH work with respirator community to develop and define test parameters that produce consistent, reproducible results.
- Testing conducted by ISEA members using the same filter media on different machines at different test sites produced considerably different results.

iv. The humidity preconditioning requirements of the rule state that "filters shall be sealed in a gas-tight container," but does not specify:

- uniform preconditioning requirements;
 - size of the container;
 - the "allowable time after conditioning" at which filter media must be placed within the container; or
 - the allowable time for the filter to remain within the container until tested.
- ISEA recommends that the rule specify:
 - a circulation air chamber and a means of filter separation to provide uniform conditioning of filtering elements;
 - that the gas tight container be no more than three times the volume of the product stored;
 - that filter media must be placed within the container immediately after conditioning; and
 - that the filter remain within the container for no more than 24 hours before testing.

- These recommended test parameters would help ensure uniformity in testing among different testing facilities.

v. The proposed rule requires an airflow rate of 85 liters per minute for resistance testing but does not include an allowable airflow tolerance.

- ISEA recommends that NIOSH include an allowable airflow tolerance of +/- 2% for resistance testing.
- Specifying an allowable airflow tolerance would help ensure uniformity in testing among different test facilities.

vi. The rule states that the initial inhalation resistance of a respirator must not exceed 30 mm H₂O and the initial exhalation rate must not exceed 20 mm H₂O.

- ISEA recommends that NIOSH change the resistance requirements to 35 mm H₂O inhalation resistance and 25 mm H₂O exhalation resistance.
- Higher resistance level, accompanying higher filter efficiency levels, will grant manufacturers more latitude in respirator design.

vii. The proposed rule requires that the filter penetration test be stopped once 200 mg of challenge aerosol contacts the filter.

- ISEA recommends that NIOSH reevaluate the filter loading limit.
- Industry testing indicates that filter penetration performance can vary greatly depending upon such factors as method of challenge aerosol generation, preconditioning exposures and aerosol concentration rates.

viii. The proposed rule specifies that a differential mobility particle sizer (DMPS) should be used to determine particle size distribution.

- ISEA recommends that a scanning mobility particle sizer (SMPS) or equivalent should be used to determine particle size distribution.

- The DMPS is obsolete and no longer available and has effectively been replaced by the SMPS.

C. Filter Efficiency

i. ISEA supports the filter penetration efficiency of 99.97% designated for Type A filters, but questions the filter penetration efficiencies of 99% and 95% designated for Type B and Type C filters, respectively.

- ISEA recommends that the designated filter penetration efficiencies for Type B and Type C filters be changed to 96% and 90%, respectively.
- A Type B filter penetration efficiency of 96% would create a meaningful distinction between Type A and Type B filters and would still allow a Type B respirator to have an APF of 25, while a Type C filter penetration efficiency of 90% would create a range of inexpensive respirators to be used against low toxicity particulates.

ii. NIOSH would categorize filters under the proposed rule as Types A, B and C, based upon filter efficiency rating.

- ISEA recommends that, in accordance with international standards, NIOSH reclassify Type A, B and C filters as Classes 3, 2 and 1, respectively.
- Such categorization will facilitate export of respirators manufactured in the U.S.

D. Powered Air-Purifying Respirators

i. The proposed rule should not include system tests for powered air-purifying respirators within the first module.

- ISEA recommends that NIOSH add a separate module for powered air-purifying respirators and that the PAPR module be given high priority.

- The unique aspects of PAPRs are not sufficiently addressed in the proposed filter penetration tests which are designed for negative pressure devices; the immediate need of the health care community requires the accelerated release of this PAPR module.

E. Test Statistics

i. The pass/fail criteria in the proposed rule require that filters submitted to NIOSH for certification meet a specified test statistic U , which assumes the submitted samples meet a normal distribution.

- ISEA recommends that NIOSH allow pass/fail acceptance of filters tested by NIOSH as an alternative to the statistical method proposed.
- Manufacturers should be able to request the use of an alternate method, such as sorting filters, of ensuring that they meet specific acceptance values, if they can demonstrate to NIOSH that all filters with penetration levels greater than the acceptable limit will be removed from the production line and will not be shipped.

ii. The proposed K factor of 2.22 is too high.

- ISEA recommends that the K factor be changed to 1.778.
- A K factor of 1.778 is the equivalent of what would have been proposed for 30 samples under the 1987 proposal, and would prevent the costs of particulate filters from rising significantly while the relative protection afforded remain the same.

F. Fit Testing

i. The proposed rule requires that all particulate respirators be fit tested.

- ISEA recommends that fit testing not be included as part of the certification program.
- Fit testing during certification will create a false sense of

confidence in the wearer and may discourage fit testing in the field.

ii. The proposed rule requires that all particulate respirators be fit tested with isoamyl acetate, an organic vapor; to do so would require that the particulate filtering element be replaced with an activated carbon element.

- ISEA recommends that NIOSH adopt either the Bitrex qualitative fit test aerosol using the protocol for saccharin in the OSHA lead standard or use a large particle quantitative fit test.
- In many cases, changing the particulate filter to one that removes organic vapor would result in the creation of a surrogate respirator with different fit characteristics from the respirator seeking certification.

G. Assigned Protection Factors

i. NIOSH intends to issue a Respirator Users' Notice at the same time as the final rule on testing requirements for particulate filters without providing an opportunity for public comment.

- ISEA recommends that NIOSH call a technical meeting to discuss the issue of appropriate uses for respirators under the new classification scheme of the proposed rule and to allow the public an opportunity to comment prior to publication of the rule as final, and that NIOSH adopt assigned protection factor values for new and existing respirators in ANSI Standard Z88.2 (1992) until the future module for APFs is final.
- Assigned protection factors play an important role in the development of new technology by manufacturers and in determining the practical applicability of particular respirators at the worksite.

MODULAR APPROACH

I.S.E.A supports NIOSH'S proposal for a modular
approach to rule making:

- Innovative
- Results Oriented
- Measurable

MODULAR APPROACH

Previous attempts toward complete rule revision created difficulties:

- Inaccurate reflection of current science and technology
- Overly burdensome
- Limited user benefit

MODULAR APPROACH

Incremental approach feasibility:

- Steps rather than overwhelming regulation
- Enhanced workable rule making process
- Manufacturing time to develop technology

MODULAR APPROACH

Benefits to interested parties:

- More efficient rule making process
- Measurable progress
- Increased motivation within NIOSH
- Enhanced external relationships with regulated community
 - Positive results
 - Progressive results

MODULAR APPROACH

Focus:

- Modules more easily understood
- Expedited rule making process
- Focus resources
- Cooperative development

MODULAR APPROACH

Key elements to success:

- Sequence
 - Support Sequence
 - Add
 - PAPR
 - Gas/Vapor/Particulate
 - Airline/Combination Respirators
- Timing
 - Five year period
 - NIOSH project manager

MODULAR APPROACH

Module ambiguities:

- Module interrelations
- Module overlap/resources
- R&D costs
- Retooling cost
- Grandfathering relationships

MODULAR APPROACH

Future module development:

- Open communications
- R&D costs
- Laboratory costs
- Unrealistic or ambiguous requirements
- Focus R&D
- Expedite advancements
- Minimize cost impact

INTERAGENCY COORDINATION

NIOSH interagency leadership role:

- Respirator standards
 - OSHA
 - MSHA

INTERAGENCY COORDINATION

Agency Coordination:

- OSHA
- MSHA
- EPA
- NRC
- FDA
- DOE
- CPSC
- Agriculture

INTERAGENCY COORDINATION

Performance Standards and APF's:

- Link performance standards to face seal leakage requirements and APF's
- NIOSH evaluate performance in workplace
- NIOSH determine APF's for respirator classes
 - User input
 - Manufacturer input
- ISEA workplace studies '91
- Recommend ANSI Z88.2 (1992)
- Coordinate throughout agencies

USER'S GUIDE

Need for user's guide:

- Inform regulated community
- Minimize confusion

Indication relative to new classes:

- Users
- Application
- Selection

Input from all concerned:

- Worker
- Academia
- Manufacturer
- Regulator

USER'S GUIDE (Cont.)

Review prior to publication:

- Avoid incorrect interpretation
- Ensure user focus
- Ensure ease of understanding
- Guidance to manufacturers
- Cross reference guide

INTERNATIONAL HARMONIZATION

Globalization Goal:

- Lower non-tariff trade barriers
- Enhance global understanding

Certification and use standards:

- Module Development

Quality Programs:

- ISO 9000

Nomenclature

- Numbers
- Class

INDUSTRY EMPOWERMENT

NIOSH program elements:

- 1) Certifying respirators
- 2) Assuring quality
- 3) Investigating field complaints
- 4) Providing technical assistance
- 5) Developing standards

INDUSTRY EMPOWERMENT

ISEA supports NIOSH's vision:

- Continuous improvement
- Industry empowerment
- Matrix management
- Goal champions

INDUSTRY EMPOWERMENT

Industry empowerment:

- Expand resources and expertise
 - Create partnerships with private sector
- Free federal funds
 - Other workplace health and safety improvement projects

INDUSTRY EMPOWERMENT

Empowerment Opportunities:

- Consensus standards
(OMB Circular A-119)
- Scientific studies
 - Peer review process
- Qualified lab performance testing
- ISO - certified quality auditors

GRANDFATHERING

Proposal: 30 day limit on 30 CFR11
submittals

Recommendation: Support limit for new submittals

Rationale: 30 days is reasonable

GRANDFATHERING

Proposal: Two year limit on sale and distribution

Recommendation: Four year limit on manufacturer sale and shipment

- Rationale:
- European experience of three-plus year required
 - NIOSH proposed five year in 1987
 - NIOSH has limited resources to approve respirators
 - Experience with Bureau of Mines transfer of certification
 - Filter media limitations
 - Ensure workplace supply

GRANDFATHERING

Proposal: NIOSH will process 30CFR11 applications previously submitted for six months. No reference made for extensions.

Recommendation: Two year limitation on extensions affecting filter media.

Rationale:

- Media supply changes
- Time

Recommendation: Four year limitation on extensions not affecting filter performance.

Rationale:

- Change color, headband, gas/vapor addition, valve material.
- Workplace enhancements
- Time

GRANDFATHERING

Proposal: Two year sales and distribution deadline.

Recommendation:

- Distributor may distribute
- Users may use

Rationale:

- Certification doesn't expire
- Distribution not controlled by manufacturer
- Costly returns
- Maintain workplace supply
- Market will demand

ECONOMIC IMPACT

Underestimated:

- Limited information previously
- Estimated excess of \$100 million
 - Member survey
 - Current information
 - Estimated R&D
 - Estimated plant retooling
 - Estimated material

ECONOMIC IMPACT

Recommendation:

- Closer working relationship
 - Focus resources
 - Cost effective rule making

- Open efficiency ratings
 - Larger range of user requirements
 - Reduce cost impact