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July 21, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
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RE: PROPOSED RULE: RESPIRATORY PROTECTIVE DEVICES, 42 CFR 84, AS PUBLISHED IN FEDERAL REGISTER FOR TUESDAY, 24 MAY 1994, VOL. 59, NO.99.

Since 1977, I have participated in the revision of the MSHA/NIOSH respirator testing and certification regulations. I was a member of the first NIOSH/OSHA team to develop a draft proposal on air-purifying respirators and I was also a member of the ANSI Z88 Ad Hoc Subcommittee on Respirator Test and Approval whose recommendations have been adopted by NIOSH to develop the 1987 proposal.

I am very pleased that NIOSH has published the revised proposal for the filter module and would like to congratulate NIOSH for taking a more active role in upgrading the respirator test and approval regulations. I am enclosing my comments on the proposed regulation for your consideration.

I would like to thank you for the opportunity to comment and also to offer clarification or amplification of any comments if it might be helpful.

Sincerely,

Ching-tsen Bien, PE, CIH

Enclosure

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Ching-tsen Bien July 21, 1994

COMMENTS ON PROPOSED REVISION OF 42 CFR 84

A. **General.**

1. There is no timetable for proposed rule on supplied air respirators (SAR).

2. It is not clear whether the assigned protection factor module includes faceseal leakage test.

3. Since filter penetration, faceseal leakage, and simulated workplace protection factor tests are interrelated, they should be proposed as a single module. Without knowledge of the requirements of other modules, it is difficult for the manufacturer to design a respirator to meet the requirements of the proposed revision.

4. NIOSH has sent a draft test method on particulate filters to respirator manufacturers for comments. It is understandable since respirator manufacturers have a strong interest in the proposed revision. However, NIOSH should not give preferential treatment to any one specific group. NIOSH should provide relevant documents to all interested parties, and NIOSH should make meeting minutes of discussions with any special interest group available in the docket for public review.

5. In general, OSHA's regular rulemaking on standards follows three stages: advanced notice of proposed rulemaking (ANPR), notice of proposed rulemaking (NPRM), and final rule. Questions related to the proposed rule are asked on the ANPR. Comments relating to these questions are used as a basis for developing the PR. Information such as health effects, risk assessment, regulatory and environmental impact analyses and a summary of explanation of the proposed rule are included in the proposed rulemaking. A hearing is generally convened after the proposed rule is published. During the hearing, cross examination is permitted between the participants and the witness who made the presentation. A post hearing comment period of 30 to 60 days is set to allow additional comments. The final standard includes a preamble with analysis of comments received. Discussions are provided concerning whether the comment was accepted or rejected. NIOSH should consider using the OSHA rulemaking format on future rulemaking.

B. **Filter Test.**

1. Grandfather Clause.

The grandfather clause setting the expiration date for currently approved particulate filtering respirators is stated in the preamble. In general, any language listed in the preamble is not an enforceable part of the regulation. This requirement should be listed in the regulatory text of the final rule.

2. The "Worse Case" Test Aerosol.

Based on the data presented by the respirator manufacturers at the informal hearing, there is a significant increase in penetration when the electro-static (including electret) type filter medium is exposed to the monodisperse (hot) DOP aerosol compared to when the filter is exposed to the polydisperse (cold) DOP aerosol. The difference can mean that an electrostatic filter may pass the cold DOP test but fail the hot DOP test. The tests which NIOSH[1] conducted on approved electret type HEPA filters also indicated that these filters will degrade upon exposure to the hot DOP aerosol. The hot DOP aerosol appears to be a "worse case" test aerosol which should replace the cold DOP aerosol in the certification test.

3. Neutralization of Filter Charges.

At this time, the permanently charged (electret) fibrous filters may be the only available filter media that would meet the proposed requirements of Type B and Type C filters. The main advantage of the electret type filters media is its relatively low breathing resistance due to filtration enhancement by electrical charges. Studies conducted by the ANSI ad hoc Subcommittee for Respirator Test and Approval[2], Lawrence Livermore National Laboratory (LLNL)[3], Willeke[4], Cheng[5] (both NIOSH sponsored), Brown[6] and NIOSH's own study[1] indicated that charges built up on the electret type filters may be neutralized by many agents. Once the filter is neutralized, there is a substantial reduction in filter efficiency. The conclusions of the LLNL study[3] is a very good assessment on the electret filter media "*Since the filter discharging problem is due to charged aerosols or reactive chemicals, field applications will have to avoid these agents. Thus, permanently charged filters will be ideally suited for filtering neutral or low charged aerosols as may occur in filtering atmospheric aerosols in building ventilation systems. These filters will not perform well in controlling particulate emissions from various industrial processes since the aerosols are generally highly charged*". It is likely that filters approved under 42 CFR 84 will be more

expensive than the current ones. The filter replacement period would be increased for this reason. The longer use time would greatly increase the possibility for these charged filter media to degrade during use.

In order to provide adequate protection to the respirator user, NIOSH should conduct additional tests on electrostatic filters or other degradable media under neutralized state[3,4] to determine whether there is a significant increase in filter penetration (i.e. more than 10% change). The degradable filter media should be certified as the Type C filter with solid approval only. The manufacturer must attach a warning label to the filter stating the environments for which the filter is acceptable to use. This approach has been used in NIOSH's regulation for the end-of-service-life indicators[7]. It is understandable that NIOSH is sensitive to the cost of filters, however, worker protection should not be compromised by permitting unrestricted use of degradable filters.

4. Filter Classifications.

There are only three classes of filter approvals in the 1987 proposal, which required that each class of filter pass both the solid and liquid aerosol tests. In the current proposal, three classes of solid aerosol test only have been added and the manufacturer has the option to request approval in any of the six classes. There is no explanation in the preamble why these three classes of solid approval have been added. Based on the round robin DOP penetration tests submitted by the manufacturers at the informal hearing, it is likely that a filter may receive a Type A solid approval but may fail the Type B hot DOP test. Since the average user may not understand the difference between a solid or liquid aerosol test, users may assume that a Type A filter with the solid only approval may provide the same degree of liquid protection as well. Since price is the determining factor in procurement decision and filters that receive the solid approval are always cheaper than the filters with solid/liquid approval, most employers will purchase filters with solid approval only. Filters with solid/liquid approval may become an endangered species.

In order to assure that filters with solid/liquid approvals are available, NIOSH should accept the solid only approval for only Type C filters. Since the performance of filter receives solid/liquid approval is better than solid approval alone, NIOSH should establish a rating system and classify the filters as the following:

Class A: Type A filter with solid/liquid approval.
Class B: Type B filter with solid/liquid approval.

Class C: Type C filter with solid/liquid approval.
Class D: Type C filter with solid approval.

If NIOSH desires to maintain the proposed six types of filter certification, the filter rating system should be classified as:

Class A: Type A filter with solid/liquid approval.
Class B: Type B filter with solid/liquid approval.
Class C: Type C filter with solid/liquid approval.
Class D: Type A filter with solid approval.
Class E: Type B filter with solid approval.
Class F: Type C filter with solid approval.

This rating system will assist regulatory agencies such as OSHA, EPA, DOE or NRC in assigning filter classes, and it will also assist safety and health professional in selecting appropriate filters for worker protection.

5. Very High Particulate Challenge Concentration.

The proposal permits the use of a very high aerosol challenge concentration of 200 mg/m^3 for evaluating filter penetration. This requirement was based on a recommendation of the ANSI Ad Hoc Respirator Test and Approval Subcommittee made in 1982. However, the 8 July 1981 ANSI Z88 Ad Hoc Respirator Test and Approval Subcommittee report stated that 0.2 μm size solid sodium chloride aerosol particles at a concentration of 30 mg/m^3 was selected for filter testing. The 1982 Z88 ANSI Ad Hoc Subcommittee final report had not included the results of testing respirator particulate-filtering elements with either a solid or liquid aerosol particles at such high concentration. Contact with the person who was the Chairman of the ANSI Z88 Ad Hoc Respirator Test and Approval Subcommittee in 1982 failed to uncover any report of the results of testing respirator particulate-filtering elements by either solid or liquid aerosol particles at the very high concentration of 200 mg/m^3. Since such a high concentration does not exist in the workplace, the filter test should be conducted at a maximum concentration of 30 mg/m^3.

6. Final Inhalation Resistance.

The proposal requires a maximum initial inhalation resistance and a maximum initial exhalation resistance of the respirator filter. However, the current 30 CFR 11 filter test requirement prescribes both initial and final inhalation resistance. Eliminating the maximum final inhalation resistance after completion of an aerosol

test of the respirator means that the particulate filter(s) will be allowed to plug rapidly by the retained particulate matter. A rapid increase in the resistance offered to breathing by the filter may increase the fatigue of respirator wearers if the wearers fail to replace respirator filters when they should. In order to encourage manufacturers to design a filter with lower breathing resistance, a requirement for final inhalation resistance should be added. It should not exceed the value permitted in 30 CFR 11.

7. Measurement of Instantaneous Filter Penetration.

The proposal requires that instantaneous filter penetration be measured. However, it did no specify when the first reading must be taken and the time intervals for subsequent measurements. These terms should be defined.

8. Filter Preconditioning.

Previous work carried out in the 1970s by the Los Alamos National Laboratory (LANL)[8,9] demonstrated that conditioning respirator filters passively by merely keeping them in an atmosphere at an elevated temperature and humidity for even a week (7 days) was inadequate to have much effect on the performance of dust/mist filters composed of electrostatic felt. These tests carried out by the LANL also demonstrated that a relative humidity of 80% was too low for conditioning respirator filters prior to testing the performance of the filters for removing particulate matter from air. The conditioning of respirator filters at an elevated temperature and humidity is supposed to replicate storage of respirator filters under summertime conditions in the sunbelt area. Conditioning of the respirator filters for 30 days at a minimum temperature of 38°C and a minimum relative humidity of 90% would be satisfactory. An accelerated preconditioning test by passing hot humid air through the filter may replace the regular test to shorten the filter preconditioning time.

9. Fit Testing.

Several respirator manufacturers raised the objection that a surrogate mask would not provide the same fit as the original. Since the Bitrex qualitative fit testing method has not been independently validated and shown its equivalency to the isoamyl acetate method prescribed in the proposal, it should not be used for performing fit testing. NIOSH has conducted quantitative fit testing (QNFT) for filtering facepieces equipped with a high-efficiency particulate air (HEPA) filtering element as a part of the certification test. NIOSH should conducted the same

QNFT for filtering facepieces using the same pass or fail criteria for the current approved HEPA filtering facepiece. If the filtering facepiece fails the QNFT, it may not be approved under the proposed APF module.

10. Number of test samples.

The proposal requires that 20 samples of filters be tested while the current regulation only requires three samples. Since the users only interest is whether his/her respirator provides the same performance as the one on which NIOSH conducts certification test, the testing of 20 filters does not generate more user confidence. The only way which NIOSH can inspire user confidence is using more stringent quality control procedures to ensure product quality. Five samples may be a good compromise for conducting filter testing.

11. Mechanical Tests.

Test methods should be developed to determine whether the cartridge is still securely attached to the facepiece after mechanical impact. For filter element without a protective enclosure, tests should be developed to determine its stability and resistance to mechanical forces such as cut or abrasion.

12. Combination Respirators.

There are many types of combination respirators such as the combination particulate filter and gas or vapor cartridges or canister, combination particulate and gas or vapor canisters for the powered air-purifying respirators and the combination of supplied air respirator equipped with a back up particulate filter. Should the particulate filter for the combination respirators be tested alone or should it be tested in the combination use mode? Since the combination cartridges or canister are often used in the presence of gaseous and particulate contaminants, and it is likely these air contaminants may reduce the efficiency of the particulate filter media, test methods should be developed to test the particulate filter in the presence of the approved gas or vapor.

13. Applicability of Testing Methods.

NIOSH has not released any data concerning whether the proposed test methods has been proven for evaluating filter performance. For example, Racal has commented that the test statistics are too stringent and will lead to overdesign and development of bulky filters. Under the current monodisperse DOP penetration test prescribed in 30 CFR 11, many manufacturers have set the

passing criteria at 0.02% (the requirement is 0.03%) to take account the variability of testing instruments and operators. Does NIOSH have data to indicate whether HEPA filters that pass the current DOP test prescribed in 30 CFR 11 will also pass the proposed statistical requirement even when every one of the 20 filters has met the hot DOP test requirement of the proposal? Does NIOSH have data to indicate the variability among testing instruments and operators? Has NIOSH conducted tests on the available filter media to ensure that low cost filter media that will meet the requirements of the Type C filter will be available? If the data is available, NIOSH should release it to the public.

14. Filter Cartridge Color Coding.

There is no mention of the color of filter cartridges. In order to prevent the sale of the filters approved under 30 CFR 11, new colors should be designated for filter cartridges approved under 42 CFR 84. Different colors should be designated for solid only and solid & liquid approvals. For the same approval class (solid or solid & liquid), a filter with lower penetration value should be more intense in color than one with a higher penetration value.

C. **PAPRs**

1. Certifying the PAPRs as a Positive Pressure Device.

Based on the test results of an OSHA sponsored simulated workplace study conducted by the Los Alamos National Laboratory (LANL)[10], the tight fitting half-mask PAPR would provide the same degree of protection as a full facepiece pressure demand SAR under high temperature and humidity. Another OSHA sponsored simulated workplace study on PAPRs conducted by the Lawrence Livermore National Laboratory (LLNL)[11] indicated that for a tight fitting PAPR, a positive facepiece pressure can only be maintained at an air flow of 170 lpm (proposed air flow is 115 lpm) when the test subject performed heavy work at 80% of the maximum cardiac capacity on a treadmill. However, for the loose fitting facepiece PAPRs, these devices cannot maintain a positive pressure inside the inlet covering even when the air flow was 252 lpm (the required air flow is 170 lpm). It is obvious that there is a clear distinction in performance between the tight and loose fitting facepiece PAPRs.

John Stephenson of Ontario Hydro made inexpensive modifications to the Racal AH-3 and the device demonstrated positive pressure. Since PAPRs sells at much higher price than a negative pressure air-purifying respirator, NIOSH should only

certify the PAPR as a positive pressure device. This can be achieved by testing the device on a treadmill with the test protocol developed by LLNL.

One respirator manufacturer has a proto type pressure demand (PD) PAPR available. The blower speed varies with the work rate of the wearer. The PDPAPR may not be able to meet the certification requirement since its air flow under normal use may not meet the current required flow rate. In order to remove all design restrictions, the PAPR should be certified with any enclosure and at any normal flow rate as long as the inlet covering pressure of the PAPR remain positive under the test protocols developed by LLNL and LANL. If NIOSH does not intend to take this approach, the minimum air flow requirement for PAPRs should be raised to reflect the physiological requirements of the worker.

2. Low Inlet Covering Pressure Warning Device.

There is no requirement for a low air flow or low inlet covering pressure warning for the PAPRs. Several PAPR manufacturers have already incorporated warning devices to their devices. Requirements for PAPR warning devices should be incorporated into the revision. Requiring a low inlet covering pressure warning device is preferred over a low air flow warning since the approved air flow rates for PAPRs are inadequate for higher work rates.

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