Testimony presented at NIOSH hearing proposed rule 42CFR part 84 DRAFT

I am Tom Nelson , Vice Chair of the AIHA Respiratory Protection committee. ~~Our chair, Pat Paulus could not be here today because she is tied up with 2 week shut down. We~~ appreciate being given to opportunity to provide testimony regarding NIOSH's proposed rule CFR 42 part 84.

The Respiratory Protection committee is AIHA's technical committee that deals with issues of respiratory protection. The committee has 30 active members and approximately 10 former members that act as consultants to the committee. The members and consultants come from a wide variety of industries, government and academic groups, providing a broad base of knowledge and experience.

The committee supports NIOSH's efforts to update the filter testing section, subpart K for certification of filters for respirators. We also support NIOSH's proposed plan to update the entire regulation in a modular process. This process does allow NIOSH to prioritize upgrades.

The committee does have concerns with the proposal. These are in five broad categories: the modular approach, powered air purifying respirators, isoamyl acetate fit testing, the filter efficiency classifications and the grand fathering of current filters.

Modular Approach

Specifically even though we support the modular approach we are concerned that this approach has not been tried until this rulemaking. When modules are developed how will the effect on other modules be determined, will the effect on previously published modules be determined? What input will NIOSH utilize in writing modules? There are many groups with a great deal of experience such as our committee that can be used to help formulate modules.

We are also concerned that a plan be developed to address the international integration of modules. And finally we see the need for a separate modules to be added to the schedule for powered air purifying respirators, supplied air respirators, gas masks and combination respirators.

PAPR's

In reviewing the test requirements for PAPR systems, the committee found the requirements difficult to follow. This is the result of combining filter tests with system tests. We recommend that the test requirements for filters should only address filter performance, the system performance of PAPRs should be addressed in a separate module dealing specifically with those systems unique to PAPRs such as performance testing with breathing machines.

Currently NIOSH recognizes only two types of PAPRs, tight fitting and loose fitting. The ANSI Z88.2 (1992) standard on respiratory protection recognizes four types, half mask, full facepiece, loose fitting facepiece and helmets/hoods. A visual examination of the types of inlet coverings would lead one to believe that four types exist. This is also supported by the results of workplace protection factor studies that have found differing levels of protection for these types of PAPRs.

We recommend that NIOSH should add ANSI definition of loose fitting facepiece to the proposed rule and include loose fitting facepieces as a separate category of PAPRs.

Provisions for isoamyl acetate tightness testing:

In §84.181 and §84.182 NIOSH proposes a tightness test using isoamyl acetate. The purpose of this test is not given, but we believe that it is unnecessary, is not reproducible and provides no benefit.

Respirator fit is an important factor in how a respirator fits an individual, so important that ANSI requires that each person who will use a tight fitting respirator be given a fit test. OSHA in most of their substance specific standards also require that respirator users be fit tested. However the tightness test as required by NIOSH does nothing help assures adequate fits. Fit testing must be done on an individual basis, prior testing during certification will not assure that an individual receives an adequate fit.

~~Ensuring that a respirator face seal has the ability to conform to a range of facial~~ structures is critical in respirator design. Using the isoamyl acetate test as a part of certification though may restrict technical innovation.

NIOSH in the requirement has not provided a test that can be reproduced by others. No descriptions of the face sizes and qualities for a test panel have been given. Unlike the isoamyl acetate fit test (as in OSHA's lead standard), no provision is given to determine if a person participating in the test can sense the presence of isoamyl acetate that leaks into the respirator. The test conditions vary among the two tests for test time and test exercises.

Our recommendation with an understanding that fit testing is a requirement of a respiratory protection program, is that the isoamyl acetate fit test be deleted from the proposal or replaced with a more appropriate and scientifically supported test.

Filter efficiencies

Current respirators provide adequate filter efficiency as evidenced by the number of workplace protection factor studies that have found average WPFs well over a 100, and 5th percentile WPFs over 10. In changing the filter test, NIOSH is moving the least efficient respirator filter class from one that would test at 20 to 1% penetration depending on the exact manufacturer to a class with no more than 5% penetration. Since the test is so demanding, and since current respirator filters are adequate, a penetration limitation of 90% would provide for improved respirators with less of a burden on the people who must use the respirators.

To get higher filter efficiencies will require that filters have more pressure drop that may increase leakage, make them more uncomfortable and less likely to be used properly, resulting in an overall decrease in protection.

A 10% filter penetration during testing is not an unreasonable limit for a respirator filter when the test aerosol is considered. For example, the sodium chloride aerosol is specified to have a count medium diameter of between 0.06 and 0.11 with a geometric standard deviation less than 1.86. Now where will such an aerosol occur outside the laboratory, so the field performance of a filter that passes at 90% will always be more efficient than 90%.

Our recommendation is that filter efficiencies be set at 99.97%, 95% and 90%. This will provide an appropriate range of filters with enough differentiation to meet the various needs if the workplace including the healthcare setting.

Grandfathering

We are concerned with the length of time allowed for grandfathering in the proposal. The committee does not believe that a two year period is the proper amount of time.

First, requiring that new applications for approval meet the new requirements 30 days from publication provides little time for the development of products, performance testing, procurement of testing equipment. This work cannot begin until the final rule is published. Second, products already being developed that may provide a benefit to users will be cut out of the process.

A two year limit on the sale and distribution of currently certified respirators does not provide enough time for NIOSH to process applications considering that development cannot even begin until the final rule is published. Disallowing extensions on approvals certified under 30CFR part 11, will limit the supply of equipment which may cause a disruption in the workplace. Finally, no provisions have been given to the grandfathering of respirators which may be affected by changes in future modules. The committees recommendation considering the range of unknowns is to extend the time line to four years for the sale of equipment currently approved and a two year limitation for extensions of approval for 30 CFR part 11 filter respirators.

If manufacturers are able to obtain approvals under the new procedures and get those to the market place sooner than we estimate, manufacture marketing will create a swifter conversion. We also believe that current respirators are adequate and that there is no health based pressing need to make a faster conversion.

Finally, we are particularly concerned with the effect of this proposal on respirator selection and assigned protection factors. We recommend that the current assigned protection factors remain intact until the proposed module on assigned protection factors is promulgated.

We appreciate this opportunity to testify and extend to NIOSH an offer to work with us in the development of the modules such as that for assigned protection factors.

Source	Type of PAPR			
	Half Mask	Full Face	Helmet/ Hood	Loose Fitting Facepiece
ANSI	50	1000	1000	25
ANSI- DM filter	50	100	100	25
NIOSH	50	50	25	25
OSHA- asbestos	100	100	100	100
OSHA- vinyl chloride	25	25	25	25
OSHA -arsenic	1000	1000	1000	1000
OSHA lead	1000	1000	1000	1000
OSHA cadmium	50	250	25	25
OSHA benzene	—	100	—	—
OSHA coke oven	> 10	> 10	> 10	> 10
OSHA cotton dust	> 100	> 100	> 100	> 100
OSHA- MDA	—	1000	—	—