RB designee

ISEA THE SAFETY EQUIPMENT ASSOCIATION

1901 North Moore Street, Arlington, Virginia 22209-1762
703-525-1695 ■ fax 703-528-2148 ■ e-mail isea@safetycentral.org
www.safetycentral.org/isea

December 6, 1999

Dr. Greg Wagner, Director
Respiratory Disease Studies Division -B101
National Institute of Occupational and Safety Health
1095 Willowdale Road
Morgantown, WV 26505

Dear Dr. Wagner:

Thank you for your letter of September 27, 1999 requesting that ISEA-The Safety Equipment Association provide additional information regarding the appropriateness of including validated approval fit tests within the Administrative/Quality Assurance module.

I mentioned in my letter of August 19, 1999 that ISEA has serious concerns about placing the highly controversial issue of validated fit tests within the Administrative/Quality Assurance module. ISEA members are certain that the inclusion of fit testing will result in significant delays in finalizing the module. NIOSH is seriously behind its own schedule of module development and it makes little sense to add to the delay by including fit test protocols especially since it has been almost 4 years since respirator users have benefited from a advances of new module.

The purpose of module development was to bite off pieces of the respirator standard (30 CFR Part 11) that were related and that could be dealt with in a timely manner. For twenty years NIOSH attempted to rewrite the entire document and could not get passage because of numerous arguments against many of the changes. Fit testing happened to be among the most highly challenged issues and continues to be. Once NIOSH adopted the modular approach it managed to win approval of the first module. This has provided benefits to both the respirator user and the manufacturers.

ISEA is as interested in the continuous improvement to the respirator standard (42CFR 84) as is NIOSH and the user community. It is vitally important that we develop improvements to the quality and administrative portions of the standard. Those issues are clear, unambiguous and of little controversy. This module can pass into a regulation in a short time. However, the addition of the fit test portion will mire this whole module down into a quagmire. Let us consider some of the issues surrounding "validated approval fit testing":

> **Issue 1**: NIOSH has to choose a quantitative fit test protocol to include in the module(QNFT). Unfortunately, there currently is no widely accepted validated fit test protocol for all types of respirators. Moreover, Dr. Warren Myers, in a June 4, 1999 letter to ISEA (attached), notes that NIOSH has assumed that quantitative fit tests have no systematic errors or biases in the measurements. He then points out that recent data in peer reviewed research indicates this assumption may not be true.
>
> What is the current state-of-the-art? Perhaps the work of NIOSH's Dr. Chris Coffey is as current as any work today. Nonetheless, *the scientific community has not yet validated his work.* We do not think it prudent to publish a regulatory requirement on the basis of internal studies alone. Dr. Coffey himself noted, "This study is only the beginning of the process to develop a laboratory test that is predictive of actual respirator performance in the workplace. Other researchers need

to corroborate the results under the same conditions. Further studies are needed to examine the relationships under different conditions and with other respirator types." [Coffey, C.C., Campbell, D.L., Myers, W.R. and Zhang, Z.: Comparison of six respirator fit-test methods with the actual measurement of exposure in simulated health care environment: Part II - Method comparison testing. Am Ind. Hyg. J. 59:862-870 (1998)]

Issue 2: A valid technique for accurate measurement of the fit of a filtering facepiece has not yet been developed. The currently accepted technique of using a Portacount instrument and the "clamp method" is fraught with problems. Many have questioned the accuracy of this method. Briefly the test is conducted as follows. Clamps are part of the fixture used to isolate a portion of the filter material of a 95 class of respirator. A Portacount instrument then draws ambient aerosol through the isolated portion of the respirator filter and the aerosol penetration of that portion of the respirator filter is determined. The filter penetration determined with the clamp method is then subtracted from the penetration determined when the respirator is worn and that remaining is assumed to be respirator fit leakage.

There are too many uncontrolled variables in this test to be used as product certification requirements. Some of these variables include: the test subject's control of his breathing rate, the ability of the clamping fixture to properly isolate a portion of the filter, the calculated area of the filter isolated, the variability of one area of the filter to another, the stability of the size of the aerosol and the stability of the concentration of the aerosol. It is our understanding that TSI, the manufacturer of the Portacount no longer recommends this method for fit testing 95 class respirators.

Issue 3: In previous comments to NIOSH rulemaking regarding fit testing, ISEA has vigorously opposed fit testing negative pressure respirators as part of certification. Our point is that even if NIOSH actually could develop a validated fit test that was acceptable to the scientific community in a few years, we maintain that fit tests for most commonly used respirators should not be conducted as a requirement within 42 CFR Part 84. ISEA believes that fit testing needs to be performed on the wearer of the actual respirator before entering the workplace. Then and only then can we all feel confident that this specific respirator can provide protection for that worker.

In Europe, the regulations (CEN) utilize a ten-person fit test panel and require the respirator to fit to a specified degree on eight of the ten test subjects as a requirement of product certification. Because of this certification requirement, European workers consider that the fit of a respirator is "certified" or guaranteed and that they need not do anything to ensure that the equipment fits them properly. Workplace protection factor studies done in Europe show unacceptably low workplace protection factors attributable to the fact that the respirator wearers believe that any respirator selected has been tested for fit during certification and therefore will fit all workers equally well without any test to check for proper fit.

ISEA suspects that this trend will occur in the US if the responsibility for ensuring fit is placed on equipment performance during the certification test and not the actual wearer. We all understand that OSHA requires fit-tests as part of 29 CFR Part 1910.134, but that requirement will be followed with less vigor once workers and employers come to believe in the benchmark NIOSH tests. In fact, the health care industry is already lobbying hard to eliminate the need to fit test at all from the TB standard. We feel that this sentiment will emanate throughout other industries if the concept of NIOSH actually putting its stamp of approval on the "fit" of every approved mask is adopted.

In summary, the assumption that all respirator models, regardless of how many sizes they may come in, will fit all faces, is flawed. ISEA believes that the fit testing on the actual wearer of the respirator is the only fit test of importance to provide worker protection.

Issue 4: NIOSH will establish what percentages of faces the respirator must fit. Whatever percentage NIOSH chooses will be arbitrary and thus open to criticism and discussion. Further, this decision may eliminate effective respirators that provide excellent protection on those workers that can achieve a good fit during the required respirator selection process. For example, respirators that are designed to fit a specific size face or particular ethnic group may be good for its purpose but never make it through the approval process. We do not believe that the loss of such innovation is NIOSH's intention.

These are but some of the issues surrounding the "validated approval fit test" controversy. This does not even cover any specifics of a NIOSH suggested fit test protocol (since we do not have this). You can imagine the number of technical questions that will develop once that is placed in the draft module and released to the public. I am sure that NIOSH technical people can point out today the weak points and thus the many questions about validation and demands for proof of technique that will occur should it be published within the Administrative/QA module. Once again I ask that NIOSH carve out the "validated fit test" requirement and establish it within its own module. In fact, ISEA has suggestions related to how and under what circumstances a fit test module can help improve the respirator standard.

Consider that the respirator user would be better served if NIOSH's resources could be utilized to develop a specific simulated workplace test (validated fit test) for hooded and helmeted supplied air and powered air purifying respirators. These respirators are not typically fit tested on the actual user and recent studies done for the Organizational Resource Council by Lawrence Livermore National Laboratories indicate some of these respirators may not perform as well as anticipated in spite of passing all the current NIOSH requirements. Since the employer does not conduct fit testing on this type of respirator, neither the wearer nor the employer would know of this inadequate protection. Acceptable simulated workplace tests have been peer reviewed and with cooperative work between NIOSH and ISEA could be firmed up into an acceptable fit test for hoods and helmets.

On behalf of the respirator manufacturers I am once again asking that you reconsider the inclusion of the "validated fit test" protocol from the Administrative/QA module. It is our goal to continue to work with NIOSH to revise certification modules that will benefit respirator users through innovative quality products. If you have any questions please don't hesitate to contact me.

Sincerely,

Janice C. Bradley

Janice Comer Bradley, *CSP*
Technical Director

enclosure

College of Engineering and Mineral Resources
West Virginia University
Department of Industrial and Management Systems Engineering

June 4, 1999

Ms. Janice Bradley
ISEA
1901 North Street
Arlington, Virginia 22209-1762

Dear Ms. Bradley,

Thank you for the FAX of the QLFT and QNFT Verification Request for Proposal. My colleagues and I at West Virginia University have a significant interest in the project. However we believe that the experimental procedure outlined in the RFP can be improved dramatically. While it is certainly possible to compare fit outcomes obtained with QLFT vs QNFT in the manner specified in the RFP, the results will be extremely questionable. Please allow us to briefly discuss our concerns with you and the ISEA.

The advantages and disadvantages of conducting qualitative fit testing (QLFT) or quantitative fit testing (QNFT) have been discussed and debated for the last half century. The issues ultimately distill down to the single question of whether the results obtained with a QLFT protocol are "as good as" or "as reliable as" the results obtained with a QNFT protocol.

Attempts in the early 1980's were made to "validate" the pass/fail decisions made with irritant smoke, isoamyl acetate and sodium saccharin QLFT protocols with the pass/fail decisions made with QNFT. As you know for example, Marsh reported on "validation" results for QLFT procedures using irritant smoke and sodium saccharin.

These validations were based on the signal detection theory (SDT) model outlined in Table I of the enclosure. That model employs a true or false conclusion for the "standard" or "actual" state versus a true or false conclusion based on the "test" state outcome.

In 1981, NIOSH used this signal detection theory (SDT) model to evaluated results of QLFT and QNFT decision pairs in response to the OSHA's rulemaking process with its lead standard. The condition of " false alarm " in the original SDT model is referred to as "Type I error" and the condition of "miss " as "Type II error" as illustrated in the Table II of the enclosure. The probabilities of committing type I and type II errors are referred to as "Alpha" and "Beta" respectively.

Applying the SDT model to evaluate QLFT pass/fail outcomes against QNFT pass/fail outcomes required NIOSH to make the very significant assumption that the QNFT test outcome was a true representation of the actual fit of the respirator. NIOSH estimated the CV (CV = std. dev./mean) for QNFT to be 0.08 based in part on estimates of CV made from QNFT data for oil mist leakage of 4.2% (CV = 0.075) and sodium chloride leakage of 5.1% (CV = 0.073) (Lowry et al 1978). In deriving power functions for QNFT, NIOSH states that "This analysis assumes there are no systematic errors or biases in the quantitative measurements".

However more recent data (Myers et al 1986, Myers et al 1988, and Myers and

Hornung 1993) indicate that NIOSH grossly underestimated the CV associated with QNFT. Furthermore, the assumption NIOSH made that QNFT had no systematic error or bias was incorrect.

Myers et al, (1986) reported CV's associated with QNFT ranging from 0.23 to 0.82 that could occur with changing probe location and depth, leak location, breathing pattern and sample rate. These CV estimates are approximately 4 to 8 times the estimate made by NIOSH. In later work, they reported on the sampling bias associated with QNFT results on five brands of half facepiece respirators. The sampling biases (mean±1 std. dev.) measured on those five devices were -25%±5.1, -17%±3.2, -41%±3.4, -24%±1.9 and -23%±2.6. Clearly the QNFT method has systematic error and bias. Furthermore the magnitude of the bias is facepiece dependent.

This later research calls into critical question the fact that NIOSH accepted QNFT results as true, unbiased measures of fit that had low measurement variability. It also calls into question the validation procedure of Marsh and other that followed the NIOSH modified SDT model and made the same set of assumptions as NIOSH.

We therefore believe with the current RFP, the ISEA will not obtain data that can stand critical review by the scientific community. As a consequence we will not be submitting a proposal in response to the RFP. However, we would be happy and are quite eager to discuss alternative protocols that can advance the state of the art in this area and ascertain the degree of correspondence between QNFT and QLFT.

Sincerely,

Warren R. Myers
Professor Industrial and Management Systems Engineering

Majid Jaraiedi
Professor Industrial and Management Systems Engineering

Wafik Iskander
Professor Industrial and Management Systems Engineering

Enclosures

Table I Signal Detection Theory Model with Decision Outcomes.

	True State	
Response	Signal	Noise
Yes	Hit	False Alarm
No	Miss	Correct Rejection

Table II Signal Detection Theory Model as Used by NIOSH in Evaluating QLFT and QNFT Fit Test Decision Outcomes.

	QLFT Test Outcome	
QNFT Test Outcome	Pass	Fail
Pass (FF>100)	Hit	Type I Error (Alpha)
Fail (FF<100)	Type II Error (Beta)	Correct Rejection