New OSHA Rules for Recording Occupational Hearing Loss

By Ted K. Madison, M.A., CCC-A

Ted Madison is a certified audiologist with the 3M OH&ESD Laboratory. He is also the President-Elect of the National Hearing Conservation Association (NHCA).

Introduction

Revised Occupational Safety and Health Administration (OSHA) recordkeeping criteria may result in an increase in occupational hearing loss cases beginning in 2003. These new rules went into effect January 1, 2003. They are part of the revised OSHA recordkeeping rule, 29 CFR 1904, Occupational Injury and Illness Recording and Reporting Requirements. The most significant change to the hearing loss provisions contained 1904.10 is the elimination of the 25 dB hearing threshold shift as the criterion for recording hearing loss. In its place is a new requirement that employers record cases in which both of two criteria are met: 1) There has been a 10 dB shift in hearing threshold, known as a Standard Threshold Shift (STS), and 2) The STS case also reflects a total hearing level of at least 25 dB from audiometric zero.

In a statement on December 17, 2002, OSHA acknowledged that, "Employers will experience an increase in recorded hearing loss cases in 2003 and future years. Caution must be used when comparing the 2003 and future data to prior years, when the 25 dB criteria for recordkeeping was used. OSHA recognizes this increase, and will take the changes in the recordkeeping rule into account when evaluating an employer's injury and illness experience."

It should be noted that there has been no change to the OSHA Occupational Noise Exposure regulation, 29 CFR 1910.95. The noise exposure limits, action levels, and hearing conservation program requirements contained in 1910.95 remain the same.

Employers in any OSHA-regulated industry must record work-related hearing losses according to the rules in 1904.10 if those employers provide hearing tests for employees. This includes employers in general industry who fall under the hearing conservation provisions of OSHA 1910.95. It also includes employers in OSHA-regulated industries that are not covered under 1910.95 such as construction, agriculture, and oil and gas drilling. Table 1 summarizes the previous and revised requirements.

New Recording Criteria

Prior to 2003, OSHA required employers to record hearing loss cases when the average hearing level on the current hearing test (audiogram) had shifted 25 dB or more in either or both ears when compared with the employee's baseline audiogram.

Beginning in 2003, OSHA-regulated employers must use a new 2-part criterion. According to 1904.10 (a) the employer must record a work-related hearing loss if the employee has both an STS and a hearing level of 25 dB or higher.

(continued on page 2)
Definitions

Audiogram: A chart, graph, or table resulting from a hearing test showing an individual's hearing threshold levels as a function of frequency.

Audiometric zero: 0 dB Hearing Level (HL) on an audiogram. Corresponds to the average hearing threshold level of young adults with no history of hearing loss or aural pathology.

Standard Threshold Shift (STS): defined in the OSHA noise standard 1910.95(g)(10)(i) as a change in hearing threshold relative to the baseline audiogram of an average of 10 dB or more at 2000, 3000, and 4000 Hz in either ear. (3)

Total hearing level: defined in 1904.10(b)(2)(ii) as the average hearing level at 2000, 3000, and 4000 Hz on the employee's current audiogram.

Implementation

Baseline Audiogram

The method for evaluating the current audiogram to determine whether an STS has occurred is described in 1904.10(b)(2)(i). In a clarification dated December 17, 2002, OSHA explained that the STS computation is to be made in accordance with the Occupational Noise Exposure Standard 1910.95(2). Under 1910.95, the employee’s current audiogram is compared to the employee’s baseline audiogram. The baseline audiogram may be the original audiogram taken when the employee was first placed in a hearing conservation program, or the revised baseline audiogram allowed by the Occupational Noise Exposure standard. Paragraph 1910.95(g)(9) of the noise rule allows employers to substitute the current annual audiogram for the baseline audiogram when, in the judgment of the audiologist, otolaryngologist, or physician who is evaluating the audiogram:

(i) The standard threshold shift revealed by the audiogram is persistent, or

(ii) The hearing threshold shown in the annual audiogram indicates significant improvement over the baseline audiogram. Using a revised baseline audiogram in the years after a recordable hearing shift occurs makes it easier for employers to identify any additional hearing loss that may occur in the future and to assist the employee to help prevent further hearing loss.

Work-Relatedness

To determine if a hearing loss is work-related, the rules in 1904.5 require the employer to consider each case individually. Work-relatedness cannot be presumed solely on the basis of occupational noise exposure. A hearing loss must be considered work-related, according to
Hearing Loss
(continued from page 2)

1904.10(b)(5), if, "an event or exposure in the work environment either caused or contributed to the hearing loss, or significantly aggravated a pre-existing hearing loss." The audiologist, physician or other licensed health care professional who reviews the hearing test results can help the employer determine work-relatedness.

30 Day Retest Option
OSHA allows employers to repeat the hearing test within 30 days of the first hearing test in order to confirm recordable STS cases. If the retest confirms that a recordable STS has occurred in either or both ears, the employer must record the hearing loss on the OSHA 300 log within 7 calendar days following retset date. If the retest fails to confirm a recordable STS, the employer does not need to record hearing loss on the OSHA 300 log.

Age Correction of Audiograms
When determining whether an STS has occurred, employers may adjust the employee's current audiogram to account for age-related hearing loss. This is done by using Tables F-1 or F-2, as appropriate, in Appendix F of the OSHA noise regulation 1910.95. Employers may not use age correction when determining if the employee's total hearing level is 25 dB or more above audiometric zero.

Recording Hearing Loss
If an employer identifies a recordable hearing loss in either or both ears and does not plan to repeat the hearing test, the employer must record the hearing loss on the OSHA 300 log within 7 calendar days following the test date. During 2003, employers must record cases of occupational hearing loss on the OSHA 300 log as an "injury" (single event acoustic trauma) or "other illness" (long term noise exposure), as appropriate. A new column specifically for hearing loss will be added to the OSHA 300 log in 2004. OSHA's web site provides detailed instructions on how to fill out the 300 log and associated forms at: http://www.osha.gov/recordkeeping/OSHArecordkeepingforms.pdf.

States' Recording Criteria
OSHA no longer allows states that operate their own safety and health enforcement programs to use more stringent hearing loss recording rules than Federal OSHA. The 26 "State Plan" states and territories were required to adopt a regulation comparable to OSHA 1904.10 before January 1, 2003. Employers in those states and territories may not see as large an increase or even experience a decrease in recordable hearing loss cases in 2003 and future years, depending on the previous recording criteria used in that state.

Learn More
For more information on the hearing loss recording provisions of 29 CFR 1904, visit the OSHA web site at: http://www.osha.gov/recordkeeping/index.html. Information is also available at 3M Occupational Health and Environmental Safety web site: http://www.3m.com/occupsafety. For guidelines on audiometric baseline revision, see the National Hearing Conservation Association (NHCA) web site at: http://www.hearingconservation.org/nhca/pos_audiometric.html.

Fit testing as a requirement of NIOSH respirator certification

By Thomas J. Nelson, CIH

Tom Nelson is a consultant specializing in respiratory protection. He was secretary of the Z88.10 committee from 1995-2000.

Introduction

The previous respirator certification regulation, 30 CFR Part 11, required particulate respirator facepiece fit tests. The test used isomyl acetate, an organic vapor, as the test agent. The test was required for high efficiency (HEPA) and dust, fume, and mist (DFM) respirators, but not dust/mist (DM) respirators. Since filtering facepiece respirators are not designed to remove organic vapors, these respirators required the addition of an activated charcoal layer for the required fit test. This charcoal layer was necessary so that isomyl acetate would not pass through the filter.

The National Institute for Occupational Safety and Health (NIOSH) is the respirator approval authority in the U.S. NIOSH noted in the revised certification regulation 42 CFR Part 84, that successful fit testing in the certification process provides no assurance that the respirator will properly fit an individual when used in the workplace. The only method available to assess the fit achieved on the worker is a respirator-to-face fit test conducted on that individual with the chosen respirator.

During review of 42 CFR Part 84, both the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) have adopted the NIOSH certification regulation. NIOSH's certification regulation includes the requirements to test respirators for particulate and organic vapor hazards.

(continued on page 4)
Administration (MSHA) favored inclusion of fit testing and fit checking procedures as part of the revised NIOSH respirator certification requirements for particulate filters. Both agencies accepted the determination by NIOSH that these issues could not be properly addressed in the first module. They therefore urged NIOSH to develop a face fit module to include respiratory fit testing and fit checking procedures for all respirators.

The original purpose of face fit testing in the certification program was to assure that respirators have generally good fitting characteristics. However, there are no studies that define the effectiveness of any accepted fit test to predict workplace protection. NIOSH is presently conducting research to relate respirator "fit" with performance.

Some of the research NIOSH has started includes:

- Updating the fit test panel
- Comparing fit factors with laboratory performance
- Comparing fit factors with workplace performance
- Analyzing the effect of "fit" on performance

Fit testing as part of certification uses a panel of people to represent the likely population of respirator users. The current panel is based on face size; the distribution of sizes in the panel is based on face size measurements from 1972. The current population of respirator users may or may not be well represented by this panel. NIOSH is gathering information on the face sizes of the population of respirator users to update the makeup of the panel.

Other research NIOSH has completed involves the measurement of simulated workplace performance and comparing that data to fit test results. NIOSH also is planning to do similar work in the field. A recent article attempted to demonstrate that improved fitting characteristics improved subsequent workplace performance. (See "A critical review of respiratory protection as a function of respirator fitting characteristics and fit-test accuracy" in JobHealth Highlights Volume 20 Number 1).

To require fit testing as a part of certification NIOSH needs to demonstrate that any test developed:

- Provides reproducible data;
- Discriminates between "poor" and "good" respirators; and
- Predicts workplace performance.

It is obvious that respiratory fit is going to vary by the size and shape of a face. Those who have done a lot of fit testing can confirm that some people have faces that are unusual and do not conform to "normal" fit characteristics. Thus, it makes most sense to perform the fit test on each individual as now required.

The issue facing NIOSH is whether it can demonstrate that a small panel of people will have fitting characteristics that can be reproduced by others using different people in their panel. The issue is not to find a panel that has a face size range that mimics the United States population, but whether the fitting characteristics represent respirator wearers. No one has shown that a small group of people can represent the fit of a large group, even if face sizes are similar.

Another issue is the determination of "passing" and "failing" fits. What criteria will be used to determine if a particular respirator has satisfactory fitting characteristics? Will a respirator be required to fit each person on the panel, or some percentage of the panel? What will be the minimum required fit factor? What fit test method will be used?

These serious questions need to be addressed. Some respirator models are designed to fit certain types of faces (e.g., small). It is not expected that this respirator would fit each person on a panel. There is no basis to set criteria that describe the members of a panel that fit a particular size respirator.

NIOSH has been conducting research on the fit testing of N95 respirators. Filtering facepieces that are not class 100 must be tested with a method that does not include filter penetration. One test NIOSH has suggested using involves subtracting filter leakage from total leakage. Filter leakage is measured using a "clamp", a hollow chamber that is fitted on the filter and allows a sample of air that flows through the filter to be withdrawn. One evaluation of the clamp method concluded that the clamp's measurements have little value.

Fit testing as part of certification assumes that the fit test itself is accurate. Aerosol quantitative fit tests may not accurately measure fit: sampling errors from 20 to 80% have been demonstrated. This makes it difficult to for different groups to reproduce results.

A larger issue facing NIOSH in this endeavor is the fact that fit factors have not been shown to correlate directly with workplace performance. Several researchers have examined the results of fit tests and workplace protection factor measurements and have not seen a good correlation. In other words, workers with higher fit factors do not necessarily achieve higher workplace protection factors. So even if "better" fitting respirators can be identified, we have no assurance that their performance in the workplace will be better than any other respirator.

The underlying reason NIOSH is trying to put fit testing in certification is to improve the chance that an individual assigned a respirator without fit testing will have respiratory performance above the assigned.
Certification

(continued from page 4)

5.

(1999).

Ind. Hyg. Assoc. J. 60:618-624

filtering facepiece respirators. Am. 

performance evaluation of N95 

Z. Zhuang:

4.


Fitting Characteristics and Fit-Test 

Protection as a Function of Respirator 

and S. W. Lenhart:

3.


Care Environment: Part II-Method 

of Exposure in a Simulated Health 

Methods with an Actual Measurement 

Comparison of Six Respirator Fit-Test 

Zhuang and W. R. Myers:

2.

30336-30404.

Respiratory Protective Devices; 

Final Rules and Notice," Federal 


30336-30404.

1.

"Respiratory Protective Devices; 

people who are trained, fitted and 

properly use a respirator achieve an 

adequate level of respiratory 

protection.(10) Rather than expend 

resources on research that will likely 

not lead to the desired end result, 

more effort should be directed toward 

helping people implement and 

manage respirator programs that 

emphasize fit testing, training and 

proper use.

We do know that in well run 

respiratory protection programs, 

styles, lessening the chance that a 

person with an unusual face will 

achieve a “good” fit.

References

1. "Respiratory Protective Devices; 

Final Rules and Notice," Federal 


30336-30404.

2. Coffey, C. C., D. L. Campbell, Z. 

Zhuang and W. R. Myers: 

Comparison of Six Respirator Fit-Test 

Methods with an Actual Measurement 

of Exposure in a Simulated Health 

Care Environment: Part II-Method 


3. Campbell, D. L., C. C. Coffey 

and S. W. Lenhart: Respiratory 

Protection as a Function of Respirator 

Fitting Characteristics and Fit-Test 


4. Coffey, C. C., D.L. Campbell and 

Z. Zhuang: Simulated workplace 

performance evaluation of N95 

filtering facepiece respirators. Am. 

Ind. Hyg. Assoc. J. 60:618-624 

(1999).

5. Janssen, L.L., M.D. Luinenburg,

H.E. Mullins, S.G. Danisch, and T.J. 

Nelson: Evaluation of a Quantitative 

Fit Testing Method for N95 Filtering 

Facepiece Respirators. Am. Ind. Hyg. 

Assoc. J. 63 (in press).

6. Myers, W. R., J. Allender, R. 

Plummer, and T. Stobbe: Parameters 

that Bias the Measurement of 

Airborne Concentration Within a 


47:106-114 (1986).

7 Dixon, S.W. and T. J. Nelson: 

Workplace Protection Factors for 

Negative Pressure Half Mask 

Facepiece Respirators. J. Int. Soc. 


8. Lenhart, S.W. and D. L. 

Campbell: Assigned Protection 

Factors for Two Respirator Types 

Based Upon Workplace Performance 


S. Friar: Workplace Protection Factor 

Evaluation of Respiratory Protective 

Equipment in a Primary Aluminum 


Protection Factor of 10 for Half-mask 

Respirators. Am. Ind. Hyg. Assoc. J. 


study was to assess how well the 

results of three popular fit tests agree 

with one another. Another objective 

was to determine if the performance 

of a fit test under evaluation would 

appear to vary if it were compared 

with different "reference methods." 

(Continued on page 6)
draws air from within the facepiece until a fixed negative pressure (typically -15 millimeters water column) is obtained. Maintaining this fixed negative pressure, the volumetric rate at which air leaks through the facepiece-to-face seal is measured. A fit factor is calculated by dividing an assumed minute volume (typically 53.8 liters) by the measured leak rate.

The Bitrex QLFT method requires the test subject to detect the taste of a Bitrex solution aerosol to indicate unacceptable face seal leakage. In order to assure adequate taste sensitivity, each test subject must be screened with a sensitivity solution. The sensitivity solution is approximately 1/100th as strong as the test solution in terms of the taste response elicited. The three fit test systems were designated CNC, CNP, and Bitrex, respectively.

Twenty-five people were fit tested three times with all three methods using two different brands of respirator. Each time a respirator was donned, all three tests were conducted without removing or disturbing the fit of the respirator. This is necessary in a fit test evaluation so each method will assess the "same fit." Also, because a fit test must be able to identify both acceptable and unacceptable fits, some subjects were given respirators that were not expected to fit. A poor fit was defined as a fit factor below 100 for CNC and CNP, and a positive taste response in the Bitrex test. These are the same criteria used in the Occupational Safety and Health Administration (OSHA) respiratory protection regulation.(3)

The test results were analyzed using, in turn, each fit test as the reference method and calculating the sensitivities of the other two methods.

**Results and Discussion**

The CNC, CNP, and Bitrex methods identified 15, 24, and 22 inadequate fits, respectively. The sensitivities calculated for each method are shown in Table I.

<table>
<thead>
<tr>
<th>Reference Method</th>
<th>Bitrex Sensitivity</th>
<th>CNC Sensitivity</th>
<th>CNP Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bitrex</td>
<td>---</td>
<td>0.50</td>
<td>0.82</td>
</tr>
<tr>
<td>CNC</td>
<td>0.79</td>
<td>---</td>
<td>0.87</td>
</tr>
<tr>
<td>CNP</td>
<td>0.75</td>
<td>0.54</td>
<td>---</td>
</tr>
</tbody>
</table>

A summary of the comparability of the pass/fail results of the three test methods is given in Table II. None of the fit tests met the suggested sensitivity criterion of 0.95 when compared with the other tests. As shown in Table II, the three methods did not always agree on whether the same fit was acceptable. All three methods agreed that a particular fit was a pass or a fail approximately 75% of the time ([56  75]100). Conversely, there was disagreement among the methods approximately 25% of the time.

<table>
<thead>
<tr>
<th>Reference Method</th>
<th>Number of Tests</th>
<th>Number of Tests Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>By All Three Methods</td>
<td>46</td>
<td>10</td>
</tr>
<tr>
<td>By CNC only</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>By CNP only</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>By Bitrex only</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

These results are not surprising because the three fit tests are fundamentally different. Table III summarizes important differences among the tests. While CNC and Bitrex are designed to detect face seal leakage during the entire exercise period, CNP takes short duration samples after each exercise period. Thus, dynamic leaks that may occur during an exercise would potentially be detected by CNC and Bitrex but not by CNP. CNC and CNP integrate leak measurements over their sampling period of 30 seconds or 8 seconds and calculate a harmonic mean leakage for the entire fit test. An instantaneous leak or relatively high leakage during a single exercise can be offset by longer periods of lower leakage, resulting in an overall passing fit factor. In contrast, the Bitrex test is such that any leakage sufficient to evoke a taste response, regardless of its duration, results in test failure. CNC measurements are also subject to sampling biases such as lung deposition and particles streamlining directly from a face seal leak into the breathing zone. The sampling probe may not detect these particles. Failure to measure all the aerosol leakage into the facepiece results in overstated fit factors and possible misclassification of inadequate fit. The "aerosol detector" in the Bitrex test is located in the subject's respiratory tract. Any leakage that reaches the respiratory tract will be detected. Since CNP directly measures the volume of air that enters the facepiece through face seal leaks independent of their location, there is no concern for sample bias with this method.

Because these fundamental differences exist among the three fit tests, a fit factor of 100 measured with CNC does not appear to be the same as a fit factor of 100 measured with CNP, nor the same as passing the

(Continued on page 7)
Bitrex test. Nonetheless, workplace testing in facilities with good respiratory protection programs appears to indicate that current fit tests adequately screen for poor fits. Several studies in facilities whose programs did not include fit testing showed significantly lower levels of respirator performance.\(^{(4, 5)}\)

A workplace protection factor (WPF) represents the level of protection provided in the workplace, under the conditions of that workplace, by a properly selected, fit tested and functioning respirator correctly worn and used.\(^{(2)}\) WPF measurements equal to or greater than the respirator's APF verify that the respirator is providing its expected level of protection. Nelson summarized the results of a number of WPF studies of half-facepiece in the studies included in the analysis, geometric mean WPFs ranged from 47 to 3360; the 5th percentile of all the data was 13 with a lower 95% confidence limit of 10. In other words, 95% of workers would be respirators.\(^{(6)}\) Studies that used CNC or saccharin (for which Bitrex sensitivity of 0.98 has been shown) were included in Nelson's summary. expected to achieve WPFs greater than 10. Since Nelson's analysis, a WPF study of three models of filtering facepiece respirator was conducted.\(^{(7)}\) Subjects in this study were fit tested with Bitrex. Geometric mean WPFs of 673 to 955 were found for the three models, and 5th percentile values ranged from 73 to 169. Clearly, these WPF studies support the APF of 10 for half-facepiece respirators. Since one element of tight-fitting respirator performance is adequate fit, it appears the fit tests used in these studies effectively screen for adequately fitting respirators.

### Conclusions

The performance of the CNC, CNP, and Bitrex fit testing methods was compared in this study. The procedures used for comparison were similar to those recommended by ANSI Z88.10. None of the methods met the ANSI sensitivity criterion of 0.95 when compared with either of the other two methods. All three methods agreed that a particular fit was a pass or a fail only 75% of the time. Based on the number of inadequate fits identified, CNP was the most conservative fit test, followed by Bitrex.

These results demonstrate that the reference method used to evaluate a fit test affects the apparent performance of that test. Until the reasons for this are completely understood and accounted for, a single fit test method should be used as the reference for evaluating new tests. Because the generated aerosol method has been used as the reference for all other existing fit tests, its use for this purpose should continue.

It is also apparent that fit is not an absolute quantity that can be precisely measured. Rather, all of the fit tests evaluated in this study provide an index of acceptable fit. Less emphasis should be placed on respirator users achieving specific fit factors with QNFT. Passing any fit test validated using generated aerosol QNFT as the reference assures that an acceptable fit is achieved under actual use conditions. Currently, fit test protocols using CNC, CNP, Bitrex, saccharin and isomyl acetate meet the criteria for an acceptable fit test.


### References


3M OH&ESD offers respiratory protection training courses

Since 1995, 3M has offered two professional development courses that provide valuable information to individuals involved in respiratory protection programs. The courses are based on the technical and regulatory aspects of a sound respirator program rather than specific products. A large equipment display from a number of respirator manufacturers is used to supplement the classroom and workshop presentations. These courses emphasize the important practical aspects of a successful program, including selection principles, cartridge change schedules, and testing breathing air quality. Both courses carry CEUs, American Board of Industrial Hygiene Certification Maintenance points, and other professional development credits.

Respiratory Protection is a comprehensive 4 ½ day course intended for anyone involved with managing all or part of a respiratory protection program. All respirator types and each element of a respirator program are thoroughly discussed. Workshop sessions are used extensively to reinforce the course material.

Current Topics in Respiratory Protection is a two day course designed to provide the latest in technical and regulatory information to experienced program managers.

The 2003/2004 schedule of course locations and dates is listed here. To find out more about these courses, please do one of the following:

• Contact your 3M Sales Representative;
• 1-800-659-0151, ext. 275;
• Visit our Web site at www.3M.com/occsafety;
• 3M Fax On Demand system at 1-800-646-1655.

3M OH&ESD offers respiratory protection training courses

Since 1995, 3M has offered two professional development courses that provide valuable information to individuals involved in respiratory protection programs. The courses are based on the technical and regulatory aspects of a sound respirator program rather than specific products. A large equipment display from a number of respirator manufacturers is used to supplement the classroom and workshop presentations. These courses emphasize the important practical aspects of a successful program, including selection principles, cartridge change schedules, and testing breathing air quality. Both courses carry CEUs, American Board of Industrial Hygiene Certification Maintenance points, and other professional development credits.

Respiratory Protection is a comprehensive 4 ½ day course intended for anyone involved with managing all or part of a respiratory protection program. All respirator types and each element of a respirator program are thoroughly discussed. Workshop sessions are used extensively to reinforce the course material.

Current Topics in Respiratory Protection is a two day course designed to provide the latest in technical and regulatory information to experienced program managers.

The 2003/2004 schedule of course locations and dates is listed here. To find out more about these courses, please do one of the following:

• Contact your 3M Sales Representative;
• 1-800-659-0151, ext. 275;
• Visit our Web site at www.3M.com/occsafety;
• 3M Fax On Demand system at 1-800-646-1655.

Subscribe

If you would like to be notified by e-mail when each new issue of JHH becomes available, register at www.3M.com/occsafety/subscribe.

Tech line

To reach 3M’s Technical Service staff with questions regarding our products, you can call 1-800-243-4630. If you wish to contact your local sales representative, you can leave a message by calling 1-800-896-4223.

3M Occupational Health and Environmental Safety Division
3M Center, Building 235-2W-70
St. Paul, MN 55144-1000
© 3M May 2003