3M JobHealth HIGHLIGHTS

Technical Information for Occupational Health and Safety Professionals

New OSHA Rules for Recording Occupational Hearing Loss

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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.(1) 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.(2)

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.

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Table 1. Summary of Hearing Loss Recording provisions from 29 CFR 1904 Occupational Injury and Illness Recording and Reporting Requirements.

	PREVIOUS REQUREMENTS	REQUIREMENTS STARTING JANUARY 1, 2003
Criteria for recording hearing loss in either or both ears	**25 dB Threshold Shift** Average hearing threshold shift at 2000, 3000, & 4000 Hz is 25 dB or more relative to the employee's baseline hearing test (audiogram)	**10 dB Standard Threshold Shift (STS)** Average hearing threshold shift at 2000, 3000, & 4000 Hz is 10 dB or more relative to the employee's baseline audiogram **AND** **25 dB Hearing Level** Average hearing level at the same 3 frequencies is 25 dB or higher relative to 0 dB Hearing Level (HL)
Form to be used for recording	OSHA form 200 (prior to 2002) OSHA form 300 (started in 2002)	OSHA form 300
Hearing Loss Column on 300 Log	No	Delayed until January 2004
How soon hearing loss must be recorded?	Within 6 working days	Within 7 calendar days of determination
Retesting allowed	Within 30 days from test date	Within 30 days from test date
Age correction allowed	Yes	Yes, for STS criterion No, for 25 dB hearing level criterion
Different criteria allowed for State Plan states	Yes	No

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

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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 retest 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/occsafety
For guidelines on audiometric baseline revision, see the National Hearing Conservation Association (NHCA) web site at:http://www.hearingconservation.org/nhea/pos_audiometric.html

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2. "Occupational Injury and Illness Recordkeeping and Reporting Requirements; Final Amendments Supplementary Information," Occupational Safety and Health Administration, Federal Register, Vol. 67, No. 242, pp. 77165-77170, December 17, 2002.
3. "Occupational Noise Exposure," Code of Federal Regulations, Title 29, part 1910.95.

Fit testing as a requirement of NIOSH respirator certification

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Introduction

The previous respirator certification regulation, 30 CFR Part 11, required particulate respirator facepiece fit tests. The test used isoamyl 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 isoamyl 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.(1) 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

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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 respirator 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 labora tory performance
- Comparing fit factors with work place 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.[2] NIOSH also is planning do to similar work in the field. A recent article attempted to demonstrate that improved fitting characteristics improved subsequent workplace performance.[3] (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 respirator 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.[4] 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.[5]

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.[6] 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 be 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. [7-9] 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 respirator performance above the assigned

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protection factor. This is noble goal, but it may lead to undesirable results. For example, fitting all respirators to the same panel will likely require similar shapes of facepieces. If fit testing is made a part of certification, the design of facepieces is likely to vary less among manufacturers. This may lead to less diversity in facepiece styles, lessening the chance that a person with an unusual face will achieve a “good” fit.

We do know that in well run respiratory protection programs, 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.

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Research supports current fit testing methods

Introduction

A recently published study provides new perspective on the similarities and differences of three commonly used fit testing methods.[1] The study illustrates that while the three methods measure fit differently, each is effective in identifying acceptable fits. The primary objective of the 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." (In a fit test method evaluation, the reference method is the fit test that is believed to correctly identify acceptable and unacceptable fits).

Methods

The procedures used were similar to those recommended for evaluating new fit tests in American National Standards Institute (ANSI) standard Z88.10-2001.[2] These recommendations suggest that a new fit test should have a sensitivity of 0.95. In other words, the test under evaluation should identify 95% of the same poor fits identified by a quantitative fit test (QNFT) reference method. This means the QNFT results are considered to be correct. The ANSI recommendations permit any of the following QNFT methods to serve as the reference method: 1) generated aerosol; 2) ambient aerosol (the Portacount®; and 3) controlled negative pressure (FitTester 3000).

This study compared the performance of the Portacount, the FitTester 3000 and the Bitrex™ qualitative fit test (QLFT). All three of these fit tests have been validated against the generated aerosol QNFT. The Portacount is a QNFT instrument that counts submicrometer particles known as condensation nuclei outside and inside the test subject's facepiece. The outside particle count is divided by the inside count to calculate a fit factor.

The FitTester 3000 is a QNFT device that requires the subject's respirator to be sealed with special manifolds while the subject holds his/hers breath. The instrument then

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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 faceseal 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 I. Test Sensitivity as a Function of Reference Method

Reference Method	Bitrex Sensitivity	CNC Sensitivity	CNP Sensitivity
Bitrex	---	0.50	0.82
CNC	0.79	---	0.87
CNP	0.75	0.54	---

Table II. Comparability of Pass/Fail Results

	Number of Tests	Number of Tests Failed
By All Three Methods	46	10
By CNC only	8	1
By CNP only	1	3
By Bitrex only	3	3

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.

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 faceseal 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 faceseal 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 faceseal 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

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Table III. Fundamental Differences Among the Fit Test Methods

	Measurement Period	Measurement Type	Failure Response	Sampling Issue
CNC	30 seconds	Dynamic	Integrated	Potential bias
CNP	~8 seconds	Static	Integrated	No bias
Bitrex	30 seconds	Dynamic	Instantaneous	No Bias

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 isoamyl acetate meet the criteria for an acceptable fit test.

More detailed information about this study can be found at: http://www.mmm.com/market/safety/ohes2/html/reprints.html.

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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.

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