

Naval Submarine Medical Research Laboratory

Memorandum Report #MR03-02 23 September 2003



**RECOMMENDATIONS REGARDING THE EFFECTS OF
AUDIOMETRIC TEST-RETEST RELIABILITY ON THE
DEVELOPMENT OF OSHA STANDARD THRESHOLD SHIFT
CRITERIA AND RECORDING OF WORK-RELATED MATERIAL
HEARING LOSS**

KEITH S. WOLGEMUTH, CDR, MSC, USN,

LYNNE MARSHALL, Ph.D., and

JUDI LAPSLEY MILLER, Ph.D.

Approved and released by:
G. A. Higgins
CAPT, MSC, USN
Commanding Officer
NAVSUBMEDRSCHLAB

Approved for public release; distribution unlimited

RECOMMENDATIONS REGARDING THE EFFECTS OF AUDIOMETRIC TEST-
RETEST RELIABILITY ON THE DEVELOPMENT OF OSHA STANDARD
THRESHOLD SHIFT CRITERIA AND RECORDING OF WORK-RELATED
MATERIAL HEARING LOSS

KEITH S. WOLGEMUTH, CDR, MSC, USN

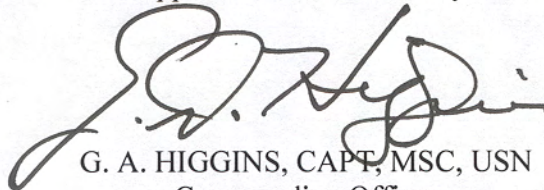
LYNNE MARSHALL, Ph.D., and

JUDI LAPSLEY MILLER, Ph.D.

Naval Submarine Medical Research Laboratory
Memorandum Report 03-02

Research Work Unit No. 50001

Approved and Released by:

A handwritten signature in dark ink, appearing to read 'G. A. Higgins', is written over the printed name.

G. A. HIGGINS, CAPT, MSC, USN
Commanding Officer
NAVSUBMEDRSCHLAB

SUMMARY PAGE

THE PROBLEM

The 3 July 2001 issue of the Federal Register contained a notice of a proposed delay of the effective date and a request for comments regarding the recording of occupational hearing loss as part of the Occupational Safety and Health Administration (OSHA) Noise Standard record keeping rule revision (OSHA, 1983). The Hearing Conservation Research Team at the Naval Submarine Medical Research Laboratory (NSMRL) prepared and submitted comments in response to this request since the team had performed work that was pertinent to two of the four issues identified in the call for comments. Based on research findings obtained by NSMRL, input was provided regarding the following two issues:

Issue 1- "What is the appropriate criterion for recording cases of occupational hearing loss? OSHA is particularly interested in comments on the advantages and disadvantages of various hearing loss levels, including 10, 15, 20, and 25 dB on alternative approaches such as the use of a sliding scale in which smaller incremental shifts would be recordable for employees with significant pre-existing hearing loss, and on the frequency of "false positive" results or other errors in audiometric measurements associated with each of these levels and approaches."

Issue 2- "What is the variability of audiometric testing equipment and how should this variability be taken into account, if at all, in the record keeping rule?"

Work performed by the NSMRL Hearing Conservation Team indicated that the question of how much hearing threshold shift in decibels (dB) should be used to define standard threshold shift (STS) and for material hearing loss recordability purposes depends on the test-retest reliability of the audiogram.

THE FINDINGS

Any criterion used to determine STS, the need for follow-up testing, temporary (TTS) and permanent threshold shift (PTS) determinations must take into account audiometric test-retest variability. Before selecting STS and recordability criteria, the test-retest variability in a group of people who are not noise-exposed must be known. These people function as a control group, in which the test-retest variability of the test procedure and environment can be determined independently of the effects of noise. Test-retest reliability can be measured using the standard error of measurement (SEmeas), a statistical procedure that can be used with a minimum of two tests per person. Further research needs to be performed with non-noise exposed control groups to obtain average test-retest reliability ranges that can be used to determine more appropriate STS criteria and to ensure the accuracy of hearing threshold levels used for recording purposes.

APPLICATION

A letter documenting NSMRL input and recommendations was mailed to the OSHA Docket Officer (Docket No. R-02A), Department of Labor, on September 4, 2001. NSMRL's recommendations were cited in the Federal Register, Vol. 67, No. 126, July 1, 2002, Rules and Regulations, Occupational Injury and Illness Recording and Reporting Requirements.

ADMINISTRATIVE INFORMATION

The work that formed the basis for these recommendations was conducted under NSMRL Work Unit No. 50001, Title: Auditory and Genetic Determinants of Susceptibility to Noise-induced Hearing Loss and was funded by the Office of Naval Research (ONR). The authors of this memo report are currently in the process of preparing a manuscript for peer reviewed publication on the importance of considering audiometric test-retest reliability in the development of hearing threshold shift criteria. The opinions or assertions contained herein are the private ones of the authors and are not to be construed as official or reflecting the views of the Department of the Navy, the Department of Defense, or the United States Government. This Memorandum Report was approved on 23 September 2003, and designated as NSMRL Memorandum Report MR#03-02.

ABSTRACT

The 3 July 2001 issue of the Federal Register provided notification of a proposed delay for the effective date regarding the recording of OSHA occupational hearing loss. OSHA requested comments on several issues related to appropriate criteria for recording cases of occupational hearing loss. The NSMRL Hearing Conservation Team had performed work pertaining to two of these issues: 1) “What is the variability of audiometric testing”; and 2) “How should variability be taken into account in the record keeping rule?” NSMRL had performed measurements of both manual and automated audiometric test-retest reliability in field settings using the standard error of measurement (SEmeas). The SEmeas is a statistical procedure that can be used with a minimum of two tests per person and can also be used to empirically develop STS and recordability criterion that will potentially reduce the number of false positive threshold shift determinations. Results from NSMRL studies showed that any criterion used to determine either significant or standard hearing threshold shift must take test-retest reliability into account as measured in non-noised exposed control groups that were in the same physical and mental state and tested in the same manner as the noise-exposed population. It was strongly recommended that further work be done in this area using representative samples of non-noise exposed control subjects, at multiple test sites. In this manner, average test-retest reliability ranges will be empirically obtained and can be used to determine more appropriate STS criteria and to ensure the accuracy of hearing threshold levels used for recording purposes. These results were provided in an NSMRL letter to OSHA in September 2001 as input regarding possible revision of the OSHA hearing loss record keeping rule. NSMRL's recommendations were cited in the July 2002 issue of the Federal Register.

Comments Submitted to OSHA Regarding Selection of STS and Occupational Hearing Loss Recordability Criteria

Background

The Hearing Conservation Research Team at the Naval Submarine Medical Research Laboratory (NSMRL), Groton, CT prepared and submitted comments in response to the July, 2001 issue of the Federal Register that requested comments regarding the recording of occupational hearing loss (See Appendix A). The team has been performing work in areas that are pertinent to some of the issues identified in the call for comments (See Appendix B). Their comments regarding two of these issues (Issues 1 and 2) are provided below.

Issue 1: “What is the appropriate criterion for recording cases of occupational hearing loss?” OSHA is particularly interested in comments on the advantages and disadvantages of various hearing loss levels, including 10, 15, 20, and 25 dB on alternative approaches such as the use of a sliding scale in which smaller incremental shifts would be recordable for employees with significant pre-existing hearing loss, and on the frequency of “false positive” results or other errors in audiometric measurements associated with each of these levels and approaches.

Comments: The question of using 10, 15, 20, or 25 decibel (dB) shifts to define standard threshold shift and for recording purposes, depends on the test-reliability of the audiogram. Before selecting a criterion, the variability in a group of people who are not noise-exposed must be known. These people function as a control group, in which the test-retest variability of the test procedure and environment can be determined independently of the effects of noise. After the test-retest variability in the control group has been established, the STS criterion can then be set so that most people in the non-noise exposed control group are not identified as having a hearing shift (false positives). Once the test-retest reliability of the audiogram is known and a criterion is set that minimizes false positive STS, STS criteria can be modified to take other factors into account (i.e., case loads, costs associated with audiological follow-up).

Issue 2: “What is the variability of audiometric testing equipment and how should this variability be taken into account, if at all, in the record keeping rule?”

Comments: Many investigators have examined the reliability of both manual and automated audiometry (Dobie, 1983; Jerivall, Dryselius, and Arlinger, 1983; Lane, Dobie, Morgan, and Crawford 1985). Unfortunately, the statistical methods used to evaluate test-retest reliability, the time interval between hearing tests, and the types of subject populations used varied widely between these studies making comparisons difficult. Some studies examined the correlation coefficients between successive audiometric tests, others used the standard error of measurement of thresholds, and others reported on the standard deviations of the test-retest score differences to examine test-retest reliability (Dobie, 1983; Lane et al., 1985). Some studies used highly trained listeners using more painstaking methodology than what is normally the case in industrial and clinical settings. Using highly trained individuals may not reflect the variability found in a group of naïve listeners who are given fewer test trials (i.e.,

industrial or military employees undergoing baseline audiogram testing who do not have much experience taking hearing tests). Other studies used noise-exposed populations to assess test-retest reliability. Using noise-exposed individuals to assess test-retest reliability defeats the purpose of measuring the reliability inherent in the audiogram itself. The control group should consist of relatively naïve listeners, with similar demographics to the noise-exposed population of interest.

It is difficult to detect noise-induced STS as these shifts in hearing level can often fall within the normal range of audiometry test-retest variability (Dobie, 1983; Lane et al., 1985). The range of this variability has not yet been firmly established. There are several variables that can influence industrial audiometric results, including earphone placement (particularly in group-testing situations where individuals place their own earphones on), earwax occlusions, ear pathology (e.g., middle ear infections), fatigue, ambient noise in the test environment, employee attention, employee motivation, tinnitus, examiner experience, the instructions given to the employee, or changes in the individual's response criterion (i.e., how intense the tone needs to be before the individual is willing to report hearing the tone). In summary, reliability of audiometric testing is a combination of test equipment, examiner, and environment. Test-retest reliability needs to be studied using control groups that are in the same physical and mental state and tested in the same manner as the noise-exposed population.

Selection of STS Criteria

Research in the area of STS criteria appears to have been focused on comparing the STS hit rates of different criteria, both single frequency, averaging across frequencies, and a combination of the two (Dobie, 1983, Royster, 1992). The main goal of these studies was to find criteria that would limit the number of “false positive” cases of STS. This is difficult because we have no way of telling which individuals in the population have a true STS and which do not. Dobie (1983) borrowed principles and techniques from both signal-detection and decision theory to examine various STS criteria. To apply these theories, the results of the test in question need to be accurately confirmed or denied by a separate, independent test, or “gold standard.” Unfortunately, a pragmatic gold standard that is able to confirm or deny noise-induced hearing loss does not yet exist. There are hearing-threshold psychophysical procedures available that have potential to be gold standards, but these are very time consuming compared to current clinical audiometric methods. Without this knowledge the best we can do is measure the test-retest reliability of the audiometric procedure in a control group, which has not been noise-exposed between tests and has no other ear pathology. If a noise-exposed person exceeds the variability seen in this type of control group, then it is likely they have had a significant change in hearing. Typically, changes in hearing levels in a control group are not considered when setting STS criteria.

Conclusions and Recommendations

Any criterion used to determine STS, the need for follow-up testing, and PTS determinations must take into account this test-retest variability. Our work, which is currently being prepared for submission to a peer-reviewed journal, will recommend using the standard error of measurement to empirically derive STS criteria. This statistical procedure can be used with a minimum of two tests per person.

We strongly recommend that further work be done in this area using a representative sample of non-noise exposed control subjects, at multiple test sites. In this manner, average test-retest reliability ranges will be obtained and can be used to determine more appropriate STS criteria and to ensure the accuracy of hearing threshold levels used for recording purposes. These studies will have costs in terms of both time and money. However, re-testing employees with false-positive STS has a high cost. Also, invalid hearing levels do defeat the purpose of measuring and recording occupational hearing loss.

References:

Dobie, R.A. (1983). Reliability and validity of industrial audiometry: Implications for hearing conservation design. *Laryngoscope*, 93, 906-927.

Jerivall, H., Dryselius, H., and Arlinger, S. (1983). Comparison of manual and computer-Controlled audiometry using identical procedures. *Scandinavian Audiology*, 12, pp. 209-213.

Lane, C.L., Dobie, R.A., Crawford, D.R., and Morgan, M.S. (1985). Standard threshold shift Criteria: An investigation of the most reliable indicator of noise-induced hearing loss. *Journal of Occupational Medicine*, 27, pp. 34-42.

Royster, J.D. (1992). Evaluation of different criteria for significant threshold shift in occupational hearing conservation programs. Available from Environmental Noise Consultants, Inc. P.O. Box 30698, Raleigh, NC 27622-0698.

Appendix A

	Three-year average ac- tual costs	Three-year percentage of volume	Average year 2002 fee
Cantor Financial Futures Exchange	\$10,990	0.0286	\$5,606
Chicago Board of Trade	199,253	39.0619	199,253
Chicago Mercantile Exchange	192,731	40.8601	192,731
NYMEX/COMEX	191,576	16.3441	158,927
New York Board of Trade	161,025	3.1319	92,612
Kansas City Board of Trade	15,396	.4047	9,262
Minneapolis Grain Exchange	12,645	.1696	6,978
Philadelphia Board of Trade	0	.0000	0
Subtotal	772,627	100.0000	665,369
National Futures Association	206,046	N/A	206,046
Total	978,673	100.0000	871,415

An example of how the fee is calculated for one exchange, the Minneapolis Grain Exchange, is set forth here:

a. Actual three-year average costs equal \$12,645.

b. The alternative computation is:

$(.5)(\$12,645) + (.5)(.001696)(\$772,627) = \$6,978.$

c. The fee is the lesser of a or b; in this case \$6,978.

As noted above, the alternative calculation based on contracts traded, is not applicable to the NFA because it is not a contract market and has no contracts traded. The Commission's average annual cost for conducting oversight review of the NFA rule enforcement program during fiscal years 1999 through 2001 was \$206,046 (one-third of \$618,139). The fee to be paid by the NFA for the current fiscal year is \$206,046.

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 USC 601, *et seq.*, requires agencies to consider the impact of rules on small business. The fees implemented in this release affect contract markets (also referred to as exchanges) and registered futures associations. The Commission has previously determined that contract markets and registered futures associations are not "small entities" for purposes of the Regulatory Flexibility Act. Accordingly, the Chairman on behalf of the Commission, certifies pursuant to 5 USC 605(b), that the fees implemented here will not have a significant economic impact on a substantial number of small entities.

Issued in Washington, DC, on June 21, 2002, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 02-16201 Filed 6-28-02; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1904

[Docket No. R-02A]

RIN 1218-AC06

Occupational Injury and Illness Recording and Reporting Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is revising the hearing loss recording provisions of the Occupational Injury and Illness Recording and Reporting Requirements rule published January 19, 2001 (66 FR 5916-6135), scheduled to take effect on January 1, 2003 (66 FR 52031-52034). This final rule revises the criteria for recording hearing loss cases in several ways, including requiring the recording of Standard Threshold Shifts (10 dB shifts in hearing acuity) that have resulted in a total 25 dB level of hearing above audiometric zero, averaged over the frequencies at 2000, 3000, and 4000 Hz, beginning in year 2003.

EFFECTIVE DATE: January 1, 2003.

FOR FURTHER INFORMATION CONTACT: Jim Maddux, Occupational Safety and Health Administration, U.S. Department of Labor, Directorate of Safety Standards Programs, Room N-3609, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In January, 2001 (66 FR 5916-6135), OSHA published revisions to its rule on recording and reporting occupational

injuries and illnesses (29 CFR parts 1904 and 1952) to take effect on January 1, 2002. On July 3, 2001, the agency proposed to delay the effective date of §§ 1904.10 *Recording criteria for cases involving occupational hearing loss*, and 1904.12 *Recording criteria for cases involving work-related musculoskeletal disorders*, until January 1, 2003 (66 FR 35113-35115). In that notice, OSHA explained that the Agency was reconsidering the requirement in § 1904.10 to record all cases involving an occupational hearing loss averaging 10 decibels (dB) or more. OSHA found that there were reasons to question the appropriateness of 10 dB as the recording criterion, and asked for comment on other approaches and criteria, including recording losses averaging 15, 20 or 25 dB. OSHA also stated that it was reconsidering the requirement in § 1904.12 that employers check the MSD column on the OSHA Log for a case involving a "musculoskeletal disorder" as defined in that section.

OSHA received a total of 77 written comments on the July 3, 2001 proposal. After considering the views of interested parties, OSHA published a final rule on October 12, 2001 (66 FR 52031-52034) delaying the effective date of §§ 1904.10(a) and 1904.12(a) and (b) until January 1, 2003, adding a new paragraph (c) to § 1904.10 establishing a 25-dB recording criterion for hearing loss cases for calendar year 2002, and modifying the regulatory note to paragraph 1904.29(b)(7)(vi) to delay the language referring to privacy case consideration for MSD cases.

This final rule contains amended hearing loss recording criteria codified at 29 CFR 1904.10(a) and 1904.10(b)(1)-(7). In a separate **Federal Register** document published today, OSHA is proposing to delay the effective date of § 1904.10(b)(7), which requires employers to check the hearing loss column on the Log for hearing loss cases

meeting the revised recording criteria, as well as the MSD provisions addressed in the October 12 final rule. Additional information about the proposal to delay the effective date of the hearing loss column is contained in the section of this rule titled *Adding a column to the 300 Log*, and in the separate **Federal Register** publication *Proposed Delay of Effective Dates; Request for Comment*, published today.

II. Recording Occupational Hearing Loss Cases

Section 1904.10 of the January 19, 2001 final recordkeeping rule required employers to record, by checking the "hearing loss" column on the OSHA 300 Log, all cases in which an employee's hearing test (audiogram) revealed that a Standard Threshold Shift (STS) in hearing acuity had occurred. An STS was defined as "a change in hearing threshold, relative to the most recent audiogram for that employee, of an average of 10 decibels or more at 2000, 3000 and 4000 Hertz (Hz) in one or both ears." The recordkeeping rule itself does not require the employer to test employee's hearing. However, OSHA's occupational noise standard (29 CFR 1910.95) requires employers in general industry to conduct periodic audiometric testing of employees when employees' noise exposures are equal to, or exceed, an 8-hour time-weighted average of 85dBA. Under the provisions of § 1910.95, if such testing reveals that an employee has sustained a hearing loss equal to an STS, the employer must take protective measures, including requiring the use of hearing protectors, to prevent further hearing loss. Employers in the construction, agriculture, oil and gas drilling and servicing, and shipbuilding industries are not covered by § 1910.95, and therefore are not required by OSHA to provide hearing tests. If employers in these industries voluntarily conduct hearing tests they are required to record hearing loss cases meeting the recording criteria set forth in the final Section 1904.10 rule.

The former recordkeeping rule, which remained in effect until January 1, 2001, contained no specific threshold for recording hearing loss cases. In 1991, OSHA issued an enforcement policy on the criteria for recording hearing loss cases, to remain in effect until new criteria were established by rulemaking. The 1991 policy stated that OSHA would cite employers for failing to record work related shifts in hearing of an average of 25 dB or more at 2000, 3000 and 4000 Hz in either ear. Subsequently, OSHA released interpretations stating that the employer

could adjust the audiogram for aging using the tables in Appendix F of the Noise Standard, and that the employer was to use the employee's original baseline audiogram as the baseline reference audiogram for determining a recordable hearing loss.

One of the major issues in the recordkeeping rulemaking was to determine the level of occupational hearing loss that constitutes a health condition serious enough to warrant recording. This was necessary because the final rule no longer requires recording of minor or insignificant health conditions that do not result in one or more of the general recording criteria such as medical treatment, restricted work, or days away from work (See, e.g., 66 FR 5931). In its 1996 **Federal Register** notice OSHA proposed a requirement to record hearing loss averaging 15 dB at 2000, 3000 and 4000 Hz in one or both ears (61 FR 4040). OSHA adopted the lower 10-dB threshold in the final rule based in part upon comments that "(a)n age-corrected STS is a large hearing change that can affect communicative competence" (66 FR 6008).

Comments on the Recording of 10-dB Shifts

Most commenters opposed the adoption of the 10-dB threshold for recording hearing loss (Exs. 3-1, 3-13, 3-14, 3-19, 3-20, 3-22, 3-25, 3-26, 3-27, 3-29, 3-34, 3-35, 3-37, 3-43, 3-45, 3-48, 3-49, 3-50, 3-54, 3-57, 3-58, 3-59, 3-61, 3-62, 3-63, 4-3, 4-5, 5-5, 5-7). A number of these commenters challenged the significance of a 10-dB shift, stating that: 10-dB shifts are not significant—only significant health conditions should be captured (Exs. 3-14, 3-26, 3-48); the level selected must amount to a significant alteration in an employee's ability to hear (Exs. 3-50, 3-54, 3-59); a 10-dB shift from audiometric zero is a virtually imperceptible loss in hearing—10-dB shifts at higher levels become more important (Ex. 3-49); the medical community and workers' compensation do not recognize a 10 dB shift as a significant hearing loss (Exs. 3-19, 3-20, 3-25, 3-35, 3-43, 3-63); a 10-dB shift is not a material impairment, so it should not be a recordable illness (Exs. 3-25, 3-26, 3-34, 3-50, 3-54, 3-59, 3-58, 3-61); and, 10 dB is an early warning mechanism that is appropriate for the hearing standard but not for injury and illness recording—the 1904 provisions are intended to collect data on serious injuries and illnesses, not potential precursors (Exs. 3-25, 3-49, 3-50, 3-54, 3-59, 3-62). Organization Resources Counselors (ORC) remarked that:

[a] 10 dB shift from audiometric zero is a virtually imperceptible loss in hearing * * * ORC understands that the finding of a Standard Threshold Shift (STS) to be a "flag" for the implementation of a series of actions required by the OSHA standard on exposure to noise. It was not intended, of and by itself, to be an indicator of illness, or impairment, but, rather, a sentinel event that triggers a series of actions that will prevent illness or impairment from occurring. As such a tool, it has been an effective indicator of employee hearing, but does not, by itself, rise to the level of recordability (Ex. 3-49).

A number of the commenters objected to recording 10-dB shifts because this recording level would result in the recording of too many "false positive" cases, either because of audiometric testing errors, because the hearing loss was temporary and not persistent, or because the case was insufficiently work-related (Exs. 3-14, 3-19, 3-20, 3-25, 3-26, 3-27, 3-29, 3-35, 3-37, 3-43, 3-45, 3-49, 3-50, 3-54, 3-56, 3-58, 3-59, 3-61, 3-62, 3-63, 4-5). The issues of audiometric error, persistence, and work-relationship are discussed in more detail below. The commenters opposed to the 10-dB shift also remarked that using 10-dB shifts will lead to overrecording (Ex. 3-37), 10 dB will result in a 5 to 10 fold increase in hearing loss recording (Ex. 3-49), too many *non-occupational* (emphasis added) cases are captured by 10 dB (See, e.g., Ex. 4-5), changing to 10 dB would make the past data useless and make it difficult to establish trends (Ex. 3-19), and that if OSHA adopts 10 dB, the states may be influenced to change their workers' compensation standards, resulting in higher workers' compensation costs (Ex. 3-34).

Some of the commenters opposed to the recording of all 10-dB shifts recognized a critical difference between the 25-dB criteria contained in the *American Medical Association (AMA) Guides to the Evaluation of Permanent Impairment* and the 25-dB level OSHA has enforced since 1991 (Exs. 3-25, 3-49, 3-50, 3-54, 3-59, 3-62). The AMA Guides measure hearing loss from a baseline of audiometric zero, which represents the statistical average hearing threshold level of young adults with no history of aural pathology (ANSI S3.6-1969). The 1991 OSHA recording level used the individual employee's original baseline audiogram taken at the time the worker was first placed in a hearing conservation program. If an individual employee has experienced some hearing loss before being hired, a 25-dB shift from the original baseline will be a larger hearing loss than the hearing impairment recognized by the AMA as a disabling condition. In a single comment submitted by both

organizations, the National Association of Manufacturers (NAM) and the Can Manufacturing Institute (CMI) stated that:

[i]t is generally accepted in the medical community that an average hearing level of more than 25 dB from audiometric zero (the hearing level of healthy young adults never exposed to high noise levels) at certain frequencies constitutes a material impairment. Accordingly, an employee with near-perfect hearing (at or near audiometric zero) might very well suffer a 10 or 15 dB shift in hearing yet continue to function within the normal range of hearing with no impairment whatsoever. Conversely, an employee with hearing on the outer edge of the normal range who experiences a 15 dB shift would likely suffer a material impairment. The NAM and CMI believe that a shift in hearing should not be recorded unless it is confirmed and it results in hearing levels in excess of 25 dB at the shift frequencies (Ex. 3-50).

Industrial Health, Inc., a mobile hearing testing vendor, added that:

[i]t is almost universally accepted in the profession that hearing impairment starts when hearing levels exceed 25 dB * * *. We believe there should be an "impairment fence" of 25 which must be crossed before a shift in hearing is required to be recorded. We recommend that to be recordable a shift must result in an average hearing level at 2000, 3000, and 4000 Hz in excess of 25 dB. This fence would not be adjusted for aging (however, the shift calculation itself should retain OSHA's allowance for aging) (Ex. 3-62).

A number of commenters urged OSHA to adopt the 10-dB threshold for recording occupational hearing loss, consistent with the January 19, 2001 **Federal Register** notice (Exs. 3-3, 3-4, 3-10, 3-11, 3-15, 3-17, 3-18, 3-21, 3-23-1, 3-24, 3-30, 3-36, 3-40, 3-47, 3-52, 3-53, 4-2, 5-2, 5-3, 5-6). Many of these commenters argued that an age-corrected 10-dB shift is a large change in hearing that can affect communication ability (Exs. 3-3, 3-21, 3-23-1, 3-53), that a persistent 10-dB shift represents a permanent and irreversible loss of hearing acuity (Ex. 3-21), that a 10-dB shift is a material impairment (Exs. 3-17, 3-23-1, 3-53), and that real and debilitating hearing loss may not be detected if a higher threshold is selected (Ex. 3-3). The remarks of the Coalition to Protect Workers Hearing are representative:

An age-corrected STS represents a significant amount of cumulative hearing change from baseline, enough to affect communicative competence, safety, and job productivity in the workplace. A confirmed, age corrected STS is not a sensitive indicator of early hearing damage; rather it reflects a very substantial permanent hearing change over time. The appropriate sensitive indicator of early hearing damage is a

temporary threshold shift (TTS), which recovers quickly as the worker is noise free. This indicator is currently used in hearing conservation programs. (Ex. 2-23-1)

Commenters also stated that use of a 10-dB shift reduces recordkeeping and data management burdens for industry (Exs. 3-3, 3-10, 3-23-1, 3-47, 3-53, 5-2), reduces confusion for industrial managers and occupational hearing conservation technicians—"a problem that occurred with OSHA's 1991 policy" (Ex. 3-23-1), that current STS rates are not sufficiently high to result in an undue or inappropriate number of recordable events (Ex. 3-3), that many of the states (Michigan, North Carolina, South Carolina, Puerto Rico and Tennessee) require the recording of 10-dB shifts with little detrimental effect on industry (Exs. 3-3, 3-4, 3-24), that a 10-dB shift is comparable to other permanent injuries that are recorded on the OSHA 300 Form, such as an amputated finger (Ex. 3-23-1) or medical removal under the lead standard (Ex. 3-47), and that the 10-dB shift is better for mobile and transient employees because the original baseline may not follow employees when they change jobs (Ex. 3-23-1).

Several of the commenters argued that recording 10-dB shifts would be more protective for workers (3-3, 3-10, 3-17, 3-18, 3-21, 3-23-1, 3-24, 3-30, 3-47, 3-53). In a representative comment, the AFL-CIO argued that: "[t]he requirement to record a 10-dB hearing loss on the Log would aid in the early detection and prevention of occupational hearing loss." It stated that "(r)ecording a 10-dB STS on Form 300 is a practical and reasonable means to assist in the early detection of a loss in hearing so that workplace intervention measures can be implemented to protect workers from the hazards of noise. Having employers continue to record shifts in hearing of an average of 25 dB * * * is too high a threshold of loss in hearing acuity to be sufficiently proactive in preventing worker hearing loss" (Ex. 3-24).

Other commenters added that by recognizing disease earlier, employers may take preventive measures to avoid potential workers' compensation cases that are sometimes triggered at the 25-dB level (Ex. 3-10), that recording triggers action on the part of employers (Ex. 3-23-1), that 10-dB shifts provide consistency for construction employers who are not required to test hearing (Ex. 3-10), and that the 10-dB recording criterion is more protective and reasonable for employers who are not covered by the OSHA noise standard (Exs. 3-10, 3-17, 3-18, 3-24).

Alternatives Offered

Most of the commenters who objected to the recording of 10-dB shifts presented alternative recording thresholds. The American Chemistry Council recommended a 15-dB shift (Ex. 5-5), the Rubber Manufacturers Association recommended a 20-dB shift (Ex. 3-27), and Abbott Laboratories recommended recording second and subsequent 10-dB shifts (Ex. 3-13). By far, the most common alternative offered was a shift of 25 dB (Exs. 3-1, 3-14, 3-19, 3-20, 3-22, 3-26, 3-29, 3-34, 3-35, 3-37, 3-43, 3-45, 3-48, 3-50, 3-57, 3-58, 3-61, 3-63, 4-3, 4-5). The commenters supporting a 25-dB shift argued that 25 dB was superior because medical and health care professionals recommend using 25 dB (Exs. 3-29, 3-50, 3-54, 3-59), 25 dB is consistent with the American Medical Association (AMA) guidelines (Exs. 3-50, 3-54, 3-59), 25 dB is used for workers' compensation (Ex. 3-13), 25 dB is protective and provides an easily identifiable measurement for determining injuries (Ex. 3-35), and OSHA adopted 25 dB in 1991 because it is widely accepted as a meaningful loss of hearing and is well documented (Exs. 3-37, 3-50, 3-54, 3-59).

The National Association of Manufacturers (Ex. 3-50), the Can Manufacturing Institute (Ex. 3-50), and Industrial Health, Inc. (Ex. 3-62) recommended a system where 15-dB shifts would be recorded, but only when the shift crossed the disability boundary of 25 dB from audiometric zero. These commenters argued that the 15-dB difference eliminated most shifts caused by audiometric error, and that by requiring them to cross the 25-dB fence, they would also clearly involve a hearing disability.

Organization Resources Counselors (ORC) urged OSHA to adopt a "sliding scale" recording criteria whereby the employer would record the first STS that exceeds 25 dB over audiometric zero, and all subsequent STS cases (Ex. 3-49). ORC argued that "[t]here is no single objective level of hearing loss that is uniformly identifiable for every employee. Different employees enter the workplace with different levels of hearing capability, and noise affects people differently" and that this concept reflects the intent of the OSH Act and the new rule in capturing significant injuries and illnesses.

The American Iron and Steel Institute (Ex. 3-54), the Society for the Plastics Industry (Ex. 3-25) and the American Forest & Paper Association (Ex. 3-59) encouraged the adoption of a similar recording criteria where shifts would be

averaged over the frequencies of 500, 1000, 2000, and 3000 Hz, and the first shift of 10 dB over the disability fence of 25 dB would be recorded. This approach also set forth thresholds for the recording of subsequent shifts when they crossed boundaries used by various organizations for delineating mild, moderate, and severe hearing disability at the 40, 55 and 70-dB levels from audiometric zero.

OSHA's Decision

Following consideration of the comments received in response to the July 3, 2001 proposal to modify the hearing loss recording criteria, OSHA has decided to require employers to record audiometric results indicating a Standard Threshold Shift (STS) only when such STS cases also reflect a total hearing level of at least 25 dB from audiometric zero. The STS calculation uses audiometric results averaged over the frequencies 2000, 3000 and 4000 Hz, using the original baseline and annual audiograms required by the OSHA noise standard § 1910.95. The rule also allows the employer to adjust the employee's audiogram results used to determine an STS to subtract hearing loss caused by aging, allows the employer to retest the workers' hearing to make sure the hearing loss is persistent, and allows the employer to seek and follow the advice of a physician or licensed health care professional in determining whether or not the hearing loss was work-related.

The approach adopted in the final rule has several advantages. By using the STS definition from the OSHA noise standard § 1910.95, the § 1904.10 regulation uses a sensitive measure of hearing loss that has occurred while the employee is employed by his or her current employer. By requiring all STSs to exceed 25 dB from audiometric zero, the regulation assures that all recorded hearing losses are significant illnesses. OSHA received no comments suggesting that a shift of 25 dB from audiometric zero was anything less than a serious hearing loss case. While there is little consensus among the commenters concerning the appropriate level that should be used to record hearing loss cases, there is widespread agreement that a 25-dB shift from audiometric zero is a serious hearing loss.

The hearing loss recording level is also compatible with the final rule's definition of injury or illness, "an abnormal condition or disorder" (§ 1904.46). Various scales used to rate hearing loss consider hearing levels less than 25 dB to be within the "normal range" (American Medical Association Guidelines to the evaluation of Material Impairment, American Academy of

Family Physicians, Audiology Awareness Campaign). The recording level is also compatible with the definition of material impairment used by OSHA and MSHA in the development of standards for occupational noise exposure (64 FR 49548, 48 FR 9738).

The hearing loss recording requirements in § 1904.10 differ from the requirements of the OSHA noise standard (§ 1910.95) because under the noise standard the employer is required to take certain actions (employee notification, providing hearing protectors or refitting of hearing protectors, etc.) for *all* 10-dB standard threshold shifts while the part 1904 rule only requires the recording of STSs that also exceed the total 25-dB level. OSHA believes that this is an appropriate policy, because 10-dB shifts in hearing at higher levels (above 25 dB) are more significant. Several commenters agreed that some shifts are more significant than others. ORC stated that "(a) 10-dB shift from audiometric zero is virtually imperceptible, while 10-dB shifts at higher levels become more important" (Ex. 3-49). The American Federation of Government Employees (Ex. 3-17) argued that "(h)earing loss is not linear, but is exponential, and changes are incrementally more serious and irreversible" and the American Federation of State, County and Municipal Employees remarked that "(a)dditional shifts are progressively more serious in nature" (Ex. 3-21)).

When audiometric testing is done, test tones are presented at various sound levels, usually increasing or decreasing in 5-dB steps. The employee is asked to respond whenever a tone is heard, with the goal being finding the lowest level at which the employee can consistently hear. The standard measurement for measuring hearing level is decibels, a logarithmic scale. For the first increase in hearing level from 0 to 10 dB, the sound intensity increases 10 fold. The next 10 dB is a 100-fold increase. By the time a person's hearing level changes from 0 to 30 dB hearing level, he or she needs 1,000 times more sound intensity to just barely hear.

Although the part 1904 recordkeeping regulation and the § 1910.95 noise standard treat the STS cases differently, this has no effect on the noise standard's requirements and does not have any effect on the requirement for employers to comply with § 1910.95. When employers detect work-related STS cases, they are required to take all of the follow-up actions required by the noise standard.

Additionally, the STS measure uses existing measurements and calculations

employers are already using to comply with the OSHA noise standard, resulting in less paperwork burden for employers covered by both rules. Employers are required to take one additional step to determine if the STS has also resulted in a total hearing level of 25 dB or more, and if so, to record it. The position taken in § 1904.10 provides a reasonable compromise between the commenters' highly polarized views on the proper recording level. The final rule's hearing loss recording provisions provide a reasonable "middle ground" solution to reconcile the differences between a highly sensitive measure of hearing loss (all 10-dB shifts) and increasingly insensitive measures (15, 20, or 25-dB shifts).

The approach used in this final rule is a newly developed alternative that was not considered in the January 2001 rulemaking because none of the commenters to the 1996 proposed rule suggested it. The approach was first suggested by Organization Resources Counselors in an unsolicited post-promulgation submission following publication of the January 2001 rule (Ex. 1-6). OSHA then solicited comment on the approach in the July 3, 2001 **Federal Register** notice requesting comment on the hearing loss recording issue (66 FR 35113-35115).

OSHA believes that the § 1904.10 requirements will improve the nation's statistics on occupational hearing loss and that more hearing loss cases will be entered on employers' OSHA 300 Logs. However, OSHA recognizes that the new requirements may not result in comprehensive statistics for occupational hearing loss. Employees may experience significant hearing loss in industries where audiometric testing is not required (construction, agriculture, oil and gas drilling and servicing, and shipbuilding industries), and is not provided voluntarily by the employer, and thus never be entered into the records. Likewise, an employee may experience gradual hearing loss while employed by several employers, but never work for the same employer long enough to allow a recordable STS to be captured. As to the effect on trend analysis, caution must be used when comparing § 1904.10 hearing loss data that span the effective date of this rule. The new hearing loss recording rule will result in the recording of additional cases of hearing loss, not as a result of a change in the number of workers who experience hearing loss, but simply because of the recordkeeping change.

OSHA finds that recording only 25-dB shifts from the employee's baseline audiogram is not an appropriate policy. If an employee had significant hearing

loss before being hired by the employer, additional hearing loss would not be recorded until well beyond the point of disability. This would not conform to the requirements of section 24 of the Act directing the Secretary to “[c]ompile accurate statistics on work injuries and illnesses which shall include *all* disabling, serious, or significant injuries and illnesses * * *” (emphasis added) (29 U.S.C. 673). The recording of 25-dB shifts in hearing acuity, measured from the employee’s original baseline audiogram would clearly understate the true incidence of work-related hearing loss. Likewise, if the part 1904 regulation were to require only the recording of 15 or 20-dB shifts, or categorically exclude the first STS case the rule would exclude many legitimate and serious hearing loss cases that should rightfully be entered into the records and the Nation’s injury and illness statistics. This approach would be especially deficient at capturing hearing loss in those employees who change employers several times during their working lives.

The Coalition to Protect Workers Hearing (Ex. 3–23) and the AFL–CIO (Ex. 3–24) specifically opposed the approach used in the final rule, which is often referred to as a “sliding scale” approach because it treats some STS cases as being more serious than others (Exs. 3–23, 3–24). These Commenters argued that a sliding scale approach was rejected in 1981 because it was too complex (Exs. 3–23, 3–24), that sliding scales are difficult to administer and do not provide uniform protection for workers (Ex. 3–24), and that “(c)ategorizing employers on the basis of hearing impairment is discriminatory. * * * Women and African Americans, both of whom tend to have better hearing sensitivity, might be placed in noise-hazardous jobs since they could develop more hearing change without crossing the line” (Exs. 3–23–1, 3–53).

OSHA does not believe that these concerns are serious impediments to the Section 1904.10 requirements. The two-part test, an STS combined with a total hearing level in excess of 25 dB from audiometric zero, is not overly complex, and is not nearly as complex as some of the sliding scale approaches that were rejected during the revision of the OSHA noise standard in 1981. In the years since 1981, computer technology has become much more commonplace and is incorporated into most, if not all, audiometric equipment. OSHA expects that most employers and contractors who administer hearing tests under the provisions of the noise standard will use computer software to make the needed calculations, so the requirements will

not be difficult to administer. OSHA has received no evidence to show that the policies in the final rule will encourage discriminatory behavior by employers. The suggestion that women or African Americans may be selected for noise exposed jobs in order to avoid a potential recordable hearing loss case is highly speculative. OSHA has seen no evidence that such discrimination has occurred either to avoid the requirements of the OSHA noise standard or to avoid workers’ compensation issues.

OSHA does not agree with the commenters who argued that because the function of the OSHA standards and regulations, including the part 1904 regulation, is to protect workers, worker protection would be compromised by any policy other than the recording of all STS cases. OSHA encourages employers and employees to use the OSHA injury and illness records to improve workplace safety and health conditions, and this is one of the functions of the Part 1904 records. However, this is not the only function of the records. They are also used to generate injury and illness statistics for the Nation and for individual workplaces. They are used by OSHA representatives to identify hazards during workplace inspections, and are collected by OSHA to target its intervention efforts to more hazardous worksites (See 66 FR 5916–5917). As stated in the 2001 rulemaking, “[n]o new protections are being provided by the recordkeeping rule”. Further, the OSH Act does not require the recording of all injuries and illnesses and specifically excludes certain minor injury and illness cases. This exclusion, which is discussed in the preamble to the January 19, 2001 final rule, applies to both injuries and illnesses, including hearing loss (See 66 FR 5931–5932). It is thus entirely appropriate for the recordkeeping rule to exclude certain minor illness cases while capturing more serious cases.

The hearing loss recording requirements of Section 1904.10 will not deprive employers and employees of information about noise hazards or diminish workers’ protection against the hazards of noise in the workplace. The occupational noise exposure standard requires that employees in general industry be tested for hearing loss when noise exposure exceeds an 8-hour time-weighted average of 85dB, and that employees be informed, in writing, if a 10-dB shift has occurred. The audiometric test records must be retained for the duration of the affected employee’s employment. (See 29 CFR 1910.95(g), (m)). The noise standard also

specifies the protective measures to be taken to prevent further hearing loss for employees who have experienced a 10-dB shift, including the use of hearing protectors and referral for audiological evaluation where appropriate. (See 29 CFR 1910.95(g)(8)). These requirements, which apply without regard to the recording criteria in the recordkeeping rule, will protect workers against the hazards of noise. The modified requirements of Section 1904.10 will therefore not deprive employers and workers of the means to detect and prevent hearing loss.

Finally, section 4(b)(4) of the OSH Act provides that “[n]othing in this Act shall be construed to supercede or in any manner affect any workmen’s compensation law or to enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment.” 29 U.S.C. 653(b)(4). Accordingly, the OSHA recordkeeping rule will have no legal effect on state workers’ compensation systems. There is no evidence that the states have modified their systems to conform to OSHA’s previous hearing loss recording policies; in fact, the states are far from uniform in their treatment of occupational hearing loss (Ex. 3–24–14). Therefore, OSHA does not expect the 1904 regulation to have any effect on state workers’ compensation in the future.

Audiometric Error

In its July 3, 2001 proposal, OSHA asked the public to comment on the variability of audiometric testing equipment and how testing variability should be taken into account, if at all, in the recordkeeping rule (66 FR 35115). Many commenters questioned the accuracy of audiograms, and some of them specifically questioned the accuracy of audiograms used to compute 10-dB shifts in hearing acuity (Exs. 3–5, 3–13, 3–14, 3–19, 3–20, 3–25, 3–26, 3–27, 3–29, 3–30, 3–35, 3–37, 3–45, 3–48, 3–49, 3–50, 3–54, 3–56, 3–58, 3–59, 3–63). These commenters argued that 10 dB is the lowest level of detection and is not reliable (Exs. 3–48, 3–63); at 10 dB the precision of the measurement becomes an issue (Ex. 3–49); 5 to 10-dB variability is common, which argues for 25 dB and against 10 dB (Ex. 3–29); 10 dB is not effective because of the testing environment, testing procedures, and error of audiometric equipment (Ex. 3–27); and that at a 10-dB shift, there is significant uncertainty in measurement, rendering

a typical audiometric reading unreliable (Exs. 3–37, 3–56). Verizon Communications, Inc., while supporting the recording of 10-dB shifts, summarized the potential recording problem as follows:

The test-retest variability inherent in properly calibrated audiometric equipment is ± 5 dB. * * * if a 10-dB recording threshold is adopted, the following scenario is possible:

Baseline audiogram—the threshold at 200 Hz is measured at 10 dB; however, the equipment is off by -5 dB, so the threshold is really 15 dB

Follow-up audiogram—the threshold at 200 Hz is measured at 20 dB; however, the equipment is off by $+5$ dB, so the threshold is still 15 dB

This employee would have a recordable 10-dB loss, yet, in reality, his/her hearing would be unchanged. This is the risk that is taken with a 10-dB threshold—too many false positives (Ex. 3–30).

The International Paper Company stated that “[a]pplying the 10-dB STS criterion for recordkeeping purposes would have the effect of recording large numbers of workers whose hearing losses may simply be due to testing variability” (Ex. 3–14). The Society for the Plastics Industry (Ex. 3–25) cited a number of articles in the scientific literature to argue that measurement error in field testing as approximately ± 10 dB and the measurement error under laboratory conditions is ± 5 dB. The Specialty Steel Industry of North America (SSINA) and the Steel Manufacturers Association (SMA), in a combined comment, used information from the National Institute for Occupational Safety and Health (NIOSH) to argue that typical audiometric testing variability is 10 dB, stating that “(e)memployers will be required to record each occurrence of an STS at 10 dB, using a test that has a 10-dB measurement variability. This will generate an overwhelming number of false positives” (Ex. 3–37).

In a single comment, the National Chicken Council and the National Turkey Federation argued that “Lacking standardization in testing methods and in testing equipment, this change will mean that employers will likely be forced to record (or fail to record) STSs that are inaccurately measured” (Ex. 3–19). The Hearing Conservation Team at the Naval Submarine Medical Research Laboratory (Ex. 3–56) reviewed the scientific literature on audiogram reliability and found that methodology used by various researchers varied widely, making study comparisons difficult. The Hearing Conservation Team recommended further research into the test-retest reliability of various

threshold levels that could then be used to set an STS criterion that would minimize false positives.

Another group of commenters argued that the accuracy of audiometric testing equipment is not a major factor (Exs. 3–15, 3–22, 3–23–1, 3–24, 3–57, 3–58, 3–61, 5–2, 5–3). In a representative comment, the AFL–CIO remarked that “The issue of audiometric test variability has been a settled matter since the hearing conservation amendment was promulgated nearly 20 years ago and is adequately addressed by the existing provisions contained in 1904.10” (Ex. 3–24). The American Textile Manufacturers Institute commented that: “Variability is a given in audiometric testing as it can never be an exact process as long as it relies on any given individual being tested to sense a signal and respond. However, variability can be minimized if there are tight quality controls on the test equipment, procedures, etc.” (Ex. 3–15).

The Coalition to Protect Workers Hearing disagreed with OSHA’s suggestion that the 10-dB recordability criterion does not allow for audiometric variability, stating that “The evaluation of work-relatedness takes calibration shifts into account, and such audiometric variability occurs infrequently. When random measurement variability does occur, retesting reduces it”, adding that “It is true that audiometric data are vulnerable to calibration differences between different audiometers. Calibration discrepancies may occur if the employer changes service providers (e.g., mobile audiometric testing, testing in an off-site clinic) or if the employer switches audiometers for in-house testing. Such change can easily affect data by 5 dB. However, calibration discrepancies can be minimized through careful procedural controls such as the use of bio-acoustic simulators and proper professional supervision of the audiometric monitoring program” (Ex. 3–23–1).

The Dow Chemical Company, which has voluntarily been using 10-dB shifts for recording loss, stated that “In Dow’s experience, following a standardized testing protocol (using 29 CFR 1910.95), and including adjustment for age and the use of a retest in 30 days, has provided accurate, consistent results” (Ex. 5–2). The National Institute for Occupational Safety and Health (NIOSH) argued that the variability of testing should not be taken into account in the recordkeeping rule because audiometric variability issues have been addressed in the OSHA Noise Standard 29 CFR 1910.95. NIOSH stated that they believe that under the OSHA Noise

Standard the expected variability due to error will be ± 5 dB (Ex. 5–3).

OSHA agrees with NIOSH that the recordkeeping rule should not take any actions to address the issues of audiometric variability, and finds that there is no need to increase the recording loss threshold to 15 or 20 dB to account for variability. The OSHA noise standard includes provisions that standardize audiometric testing protocols. The requirements in § 1910.95 (g) Audiometric Testing Program, § 1910.95 (h) Audiometric Test Requirements, Mandatory Appendix C to § 1910.95 Audiometric Measuring Instruments, Mandatory Appendix D to § 1910.95 Audiometric Test Rooms, and Mandatory Appendix E to § 1910.95 Acoustic Calibration of Audiometers, and the incorporated provisions of American Standard Specification for Audiometers S3.6–1969 provide standardized methodologies for conducting hearing tests designed to assure, as far as possible, that audiograms are accurate. As discussed in the preamble to the January 2001 final rule (66 FR 6009), following these requirements will result in audiometric test results with a variability of ± 5 dB. As the Medical Educational Development Institute argued in response to the 1996 proposal, “(t)est/re-test reliability of 5 dB is well established in hearing testing. For example, the Council on Accrediting Occupational Hearing Conservationists maintain this range of reliability in their training guidelines and this is recognized in American National Standard Method for Manual Pure-Tone Threshold Audiometry, S3.21–1978 (R1992).” At the ± 5 -dB reliability level, errors of 10 dB will be infrequent. There is a low probability that the audiometer will be incorrect by -5 dB on one test and $+5$ dB on a subsequent test because many of the variables affecting reliability will remain the same from year to year. The employer is likely to use the same audiometer, in the same room, operated by the same technician from one test to the next. When these variables are not held constant, or a 10-dB shift occurs due to residual random variability, the allowance for retesting should largely eliminate spurious shifts due to audiometric measurement errors. Additionally, the use of an average shift at three frequencies reduces the influence of random audiometric variability; this is one of the reasons that a frequency averaged shift was adopted in the § 1910.95 STS definition.

It should be noted that it is impossible to eliminate audiometric errors in their entirety. Any recording level, no matter how it is set, will be subject to some

level of false positive and false negative errors. However, OSHA believes that the audiometric testing requirements of § 1910.95, if followed, will provide reasonably accurate audiometric data for the administration of the OSHA noise standard, and for the recording of occupational hearing loss. As the Dow Chemical Company (Ex. 5-2) commented: “(f)ollowing a standardized testing protocol (using 29 CFR 1910.95), and including adjustments for age and the use of a retest in 30 days, has provided accurate, consistent results.” OSHA believes that the provisions allowing the employer to age adjust audiograms, seek advice from a physician or other licensed health care professional for determining work-relationship, retest within 30 days, and remove cases later found not to be persistent provide reasonable checks against false positive results being recorded on the 300 Log.

Age Correction

The final rule carries forward the January 19, 2001 rule's conceptual framework allowing, but not requiring, the employer to age adjust an employee's annual audiogram when determining whether or not a 10-dB shift in hearing acuity has occurred. There were no comments objecting to the age-correction of audiometric results when evaluating Standard Threshold Shifts in hearing. However, the American Iron and Steel Institute (Ex. 3-54), the Society for the Plastics Industry (Ex. 3-25) and the American Forest & Paper Association (Ex. 3-59), in support of a recording criteria similar to that adopted in the final rule, recommended that, “[b]ecause of the recognized contribution of aging to hearing loss, all hearing loss determinations would be age-adjusted in accordance with Appendix F to 29 CFR 1910.95”.

While the final rule allows the employer to age-correct the STS portion of the recording criteria, there is no allowance for age correction for determining a 25-dB hearing level. The AMA Guides specifically state that total hearing loss should not be age adjusted, and there is no recognized consensus method for age adjusting a single audiogram. The method used in Appendix F of § 1910.95 is designed to age correct STS, not absolute hearing ability. The 25-dB criteria is used to assure the existence of a serious illness, and reflects the employee's overall health condition, regardless of causation. Age correcting the STS will provide adequate safeguards against recording age corrected hearing loss. Therefore, it would be inappropriate

and unnecessary to age correct the 25-dB hearing level.

Persistence

Although OSHA did not specifically ask for comment on the topic, several commenters raised the issue of how to verify that recorded hearing loss cases are persistent. The OSHA noise standard addresses the issue of temporary hearing losses by allowing the employer to retest the employee's hearing within 30 days (1910.95(g)(7)(ii)). The 2001 rule adopted the same 30 day retest option at § 1904.10(b)(4) by allowing the employer to delay recording if a retest was going to be performed in the next 30 days.

A number of commenters stated that OSHA should record only permanent shifts in hearing (Exs. 3-23-1, 3-25, 3-26, 3-37, 3-48, 3-50, 3-58, 3-61, 3-62). In a representative comment, Industrial Health Inc. remarked that “[n]o shift, regardless of the number of dB, should be recorded unless it is found to be persistent in a second audiogram taken at a later time, which we believe should be no less than 60 days and preferably 6 months or more after the initial audiogram which revealed the shift” (Ex. 3-62).

The National Association of Manufacturers and the Can Manufacturing Institute, in a combined comment, argued that 30 days does not allow enough time to resolve transient conditions such as colds or allergies, and the retest period should be extended to one year (Ex. 3-50). The Coalition to Protect Workers Hearing recommended that “(a)t the discretion of the reviewing professional, within 15 months of the initial identification of the STS, any STSs which are not confirmed by subsequent retesting or otherwise found not to be work related, may be lined out on Form 300. Documentation justifying line outs must be provided and should be retained with the employees' records” (Ex. 3-23).

OSHA agrees with these commenters that the goal of the rule is to record only persistent hearing loss cases, and to help accomplish that goal, the Agency has carried forward the 30 day retest provision. However, OSHA has decided not to allow a longer retesting period. A longer retesting period would increase the likelihood that the employer would lose track of the case and therefore inadvertently fail to record the case. These errors would have a detrimental effect on the accuracy of the records and run counter to OSHA's goal of improving the quality of the injury and illness data. The Agency also believes that using different time periods for

retesting in the part 1904 and § 1910.95 rules would result in increased confusion for employers.

The Agency has also rejected the suggestion that all hearing loss cases must be confirmed prior to recording them. Waiting for one year or longer to record an occupational hearing loss would move the recording to a year in which the original hearing loss was not initially discovered, would be administratively more complex for employers, and would have a detrimental effect on the hearing loss data. Many legitimate hearing loss cases could go unrecorded simply because the employee did not receive a subsequent audiogram due to job changes or some other circumstance that might occur before the next annual audiogram required by the noise standard.

In order to make it clear to employers that they may remove any cases that are found to be temporary, the final rule has adopted the removal option recommended by the Coalition to Protect Workers Hearing, with three modifications. First, the final rule does not include the 15 month time limit. OSHA does not believe that a time limit is needed because any future audiogram that shows an improvement in hearing and refutes the recorded hearing loss would indicate a temporary hearing loss that should be removed from the records. Second, the regulatory text does not specify that the removal must be at the discretion of the reviewing professional. The OSHA noise standard, at § 1910.95(g)(3), requires that:

Audiometric tests shall be performed by a licensed or certified audiologist, otolaryngologist, or other physician, or by a technician who is certified by the Council of Accreditation in Occupational Hearing Conservation, or who has satisfactorily demonstrated competence in administering audiometric examinations, obtaining valid audiograms, and properly using, maintaining and checking calibration and proper functioning of the audiometers being used. A technician who operates microprocessor audiometers does not need to be certified. A technician who performs audiometric tests must be responsible to an audiologist, otolaryngologist or physician.

Because the noise standard already requires audiograms to be conducted by, or under the supervision of, a qualified professional, subsequent audiograms that may refute the persistence of a recorded hearing loss will be reviewed by the appropriate professional. The § 1904.10 simply cross-references the need for the audiograms to be obtained pursuant to the requirements of § 1910.95, so there is no need for the § 1904.10 rule to repeat the review requirement. Third, the rule does not

require the employer to maintain documentation concerning the removal of cases. Section 1910.95(m)(2) of the noise standard requires the employer to keep records of all audiometric tests that are performed, and those records will be available, should they be needed for future reference. As a result, there is no need to add a duplicative paperwork burden in the § 1904.10 rule. Therefore, § 1904.10(b)(4) states that "If subsequent audiometric testing indicates that an STS is not persistent, you may erase or line-out the recorded entry". OSHA has added this additional regulatory language to minimize the recording of temporary hearing loss cases while capturing complete data on the incidence of hearing loss disorders.

Frequencies

Some commenters urged OSHA to measure hearing loss at frequencies other than 2000, 3000 and 4000 Hz (*See, e.g.,* Exs. 3-25, 3-54, 3-57, 3-58, 3-59, 3-61). Alabama Power (Ex. 3-61) and the Southern Company (Ex. 3-58) recommended using 500, 1000, and 2000 because "these are the frequencies where most communication occurs". Another group of commenters recommended the use of 500, 1000, 2000 and 3000 Hz because these are the frequencies specified by the American Medical Association and the American Academy of Otolaryngology-Head and Neck Surgery, Inc. (Exs. 3-25, 3-54, 3-57, 3-59).

OSHA has decided to continue to use the frequencies used in the § 1910.95 OSHA noise standard (2000, 3000, and 4000 Hz). While "most" communication occurs at lower frequencies, these are clearly audible frequencies where some speech occurs, and where hearing loss can have a significant impact on workers' lives outside of verbal communication. Using these frequencies reduces the burden on employers that would be created by requiring separate calculations of audiometric results, and, as Industrial Health, Inc. stated "(w)ith regard to the early effects of noise exposure, it seems reasonable to extend the definition across the standard shift frequencies 2000, 3000, and 4000 Hz" (Ex. 3-62).

Baseline Reference and Revision of Baseline

In its July 3, 2001 **Federal Register** notice OSHA asked the public to comment on the appropriate benchmark against which to measure hearing loss, e.g., the employee's baseline audiogram, audiometric zero, or some other measure (66 FR 35115). One commenter, Eric Zaban with the State of Michigan, suggested using audiometric zero as the

appropriate benchmark (Ex. 4-1). The vast majority of the commenters who addressed this issue supported using the employee's baseline audiogram (Exs. 3-15, 3-20, 3-21, 3-22, 3-23-1, 3-24, 3-25, 3-27, 3-29, 3-30, 3-37, 3-47, 3-49, 3-50, 3-53, 3-54, 3-57, 3-58, 3-59, 3-61, 3-62, 3-63, 4-2, 4-5, 5-2, 5-3, 5-5). Alabama Power remarked that:

[T]he appropriate benchmark against which to measure hearing loss is the employee's original baseline. Using the employee's original baseline ensures that employers are not held responsible for any prior hearing loss the employee may have suffered. Comparing an employee's audiogram to audiometric zero would not take into account any previous hearing loss that may have occurred prior to employment (Ex. 3-61).

The AFL-CIO agreed, stating that "Using the original baseline takes into account any hearing loss that a worker may have experienced while employed by a previous employer" and "Using the baseline ideogram (audiogram) will assist in preventing the recording of cases of non-occupational hearing loss" (Ex. 3-24).

The two-part test for recording that is being adopted in the final rule uses the baseline audiogram as the reference point for determining whether or not the employee has had a change in hearing while employed by his or her current employer, and then uses audiometric zero as the reference point for determining the overall hearing ability of the affected employee. OSHA agrees that the employee's baseline audiogram is a superior reference point for measuring a change of hearing, a Standard Threshold Shift. Using the baseline audiogram taken upon employment reduces the effect of any prior hearing loss the employee have experienced, whether it is non-occupational hearing loss or occupational hearing loss caused by previous employment. Therefore, the final rule uses the employee's original baseline audiogram as the reference for the STS component of an initial hearing loss cases, and uses the revised baseline audiogram from that initial case as the reference for future cases.

The 25-dB total hearing level component of an OSHA recordable hearing loss uses a reference of audiometric zero. This portion of the recording criteria is used to assure that the employee's total hearing level is beyond the normal range of hearing, so it does not exclude hearing loss due to non-work causes, prior employment, or any other cause. The measurement simply reflects the employee's current hearing ability as reflected in the most recent audiogram. This comparison to audiometric zero is a simple matter,

because audiometers are designed to provide results that are referenced to audiometric zero. The hearing level at each frequency is oftentimes printed by the equipment, so there is rarely a need to perform manual calculations.

Work Relationship

The final rule published on January 19, 2001 included a presumption of work-relatedness when employees are exposed to loud noise at work, relying on the OSHA noise standards criteria of an 8-hour 85 dBA exposure level, or a total noise dose of 50 percent. The preamble discussion of the work-relatedness presumption was that:

[I]n line with the overall concept of work relationship adopted in this final rule for all conditions, an injury or illness is considered work related if it occurs in the work environment. For workers who are exposed to the noise levels that require medical surveillance under § 1910.95 (an 8-hour time-weighted average of 85 dB(A) or greater, or a total noise dose of 50 percent), it is highly likely that workplace noise is the cause of or, at a minimum, has contributed to the observed STS. It is not necessary for the workplace to be the sole cause, or even the predominant cause, of the hearing loss in order for it to be work-related (66 FR 6012).

Several commenters discussed the difficulties of determining the work-relatedness of hearing losses, and many argued that the 8-hour 85 dBA presumption was invalid (Exs. 3-2, 3-3, 3-13, 3-20, 3-23-1, 3-25, 3-27, 3-29, 3-37, 3-43, 3-48, 3-50, 3-54, 3-63, 4-3). In a representative comment, the Coalition to Protect Workers Hearing (Ex. 3-23-1) remarked that:

[W]ork relatedness should not be presumed solely on the basis of an exposure to time-weighted averages (TWAs) of 85 dBA or higher; instead it should be evaluated on a case-by-case basis. Presumption of work-relatedness based on equivalent 8-hour exposure alone is unsatisfactory because it presumes that the employer's hearing conservation program is completely ineffective and does not take into account other factors such as hearing protector fit and use compliance. Presumption of work-relatedness is a disincentive for employers to develop successful programs and to implement noise control because they receive no credit for their efforts. The audiologist or physician reviewing the audiometric record should make a determination regarding whether the OSHA STS is work-related and should do so when the 10-dB STS occurs.

Other commenters suggested that if an employer has an active and enforceable hearing conservation program in effect, then the recordkeeping rule should presume that a hearing loss case is non-work-related (Exs. 3-37, 3-50); that the rule needs to take non-work noise exposure into account (Exs. 3-29, 3-37, 3-50); and that the rule should only

consider a hearing loss to be work-related if work contributed more than 50% (Ex. 3-63). Several commenters made the same argument as the Coalition to Protect Workers Hearing, arguing that each case should be evaluated on its merits (Exs. 3-29, 3-43, 3-50, 3-63). The American Foundry Society argued that "[w]ork-relatedness should be evaluated by a health care professional with experience in occupational health. Low level occupational noise exposure or documented regular use of hearing protection devices (HPDs) in noisy areas should mitigate against the presumption of work-relatedness" (Ex. 3-63).

OSHA agrees with these commenters that it is not appropriate to include a presumption of work-relatedness for hearing loss cases to employees who are working in noisy work environments. It is possible for a worker who is exposed at or above the 8-hour 85-dBA action levels of the noise standard to experience a non-work-related hearing loss, and it is also possible for a worker to experience a work-related hearing loss and not be exposed above those levels. Therefore, the final rule states that there are no special rules for determining work-relationship and restates the rule's overall approach to determining work-relatedness—that a case is work-related if one or more events or exposures in the work environment either caused or contributed to the hearing loss, or significantly aggravated a pre-existing hearing loss.

The final rule's approach to determining work-relatedness differs from the January 2001 rule for three reasons. First, although it is likely that occupational exposure to noise in excess of 85 dBA will be a causal factor in hearing loss in some cases, a presumption of work-relatedness is not justified in all cases. Further evaluation is needed to make this determination. Second, the policy in the final rule is consistent with the general principle in § 1904.5 that work-relatedness is to be determined on a case-by-case basis. Third, the approach used in the January 2001 rule is not supported by comments to the docket. None of the commenters supported the presumption, while many opposed it.

The final rule also continues the 2001 rule's policy allowing the employer to seek the guidance of a physician or other licensed health care professional when determining the work-relatedness of hearing loss cases. Paragraph (b)(6) of the rule states that if a physician or other licensed health care professional determines that the hearing loss is not work-related or has not been

significantly aggravated by occupational noise exposure, the employer is not required to consider the case work-related, and therefore is not required to record it.

When evaluating the work relatedness of a given hearing loss case, the employer should take several factors into account. The Coalition to Protect Workers Hearing recommended that employers consider prior occupational and non-occupational noise exposure, evaluation of calibration records and the audiometric environment, investigation of related activities and personal medical conditions, and age correction before presuming that hearing loss is work related (Ex. 3-23-1). One important factor to consider is the effectiveness of the hearing protection program. When employees are exposed to high levels of noise in the workplace, and do not wear appropriate hearing protection devices, a case of hearing loss is more likely to be work-related. If an employee's hearing protection devices are not appropriate for the noise conditions, if they do not fit properly, or if they are not used properly and consistently, they may not provide enough protection to prevent workplace noise from contributing to a hearing loss case.

Adding a Column to the 300 Log

Section 1904.10(a) of the January 2001 rule required that employers check a hearing loss column on the Log when recording a hearing loss case. OSHA is issuing a separate **Federal Register** document proposing to delay the effective date of the hearing loss column requirement until January 1, 2004, and asking for comment on issues related to the hearing loss column. The 1996 proposed recordkeeping rule did not contain a hearing loss column requirement, and did not ask for comment on whether a column should be added. In the 2001 final rule, OSHA explained that it was adding a hearing loss column to the 300 Log so that BLS could produce more reliable statistics on occupational hearing loss cases (66 FR 6005). OSHA's July 3, 2001 **Federal Register** notice sought comment on alternative criteria for recording occupational hearing loss, but did not mention the hearing loss column as an issue.

OSHA does not believe that the existing record provides an adequate basis to determine the need for the hearing loss column. OSHA believes that interested parties should be allowed to comment on the issue. Accordingly, OSHA is publishing a separate **Federal Register** document today, proposing to delay the effective

date of the hearing loss requirement until January 1, 2004 while the Agency reconsiders the column requirement in light of public comment. To facilitate public comment, OSHA has separated the requirement from § 1904.10(a) and placed it in a separate paragraph at § 1904.10(b)(7), which asks "How do I complete the 300 Log for a hearing loss case?" and answers "When you enter a recordable hearing loss case on the OSHA 300 Log, you must check the 300 Log column for hearing loss illnesses." To further help assure that the public is informed about this additional rulemaking activity, OSHA is adding a regulatory note to § 1904.10(b)(7) explaining that OSHA is delaying the applicability of § 1904.10(b)(7) until further notice while the Agency reconsiders the hearing loss column.

Miscellaneous Hearing Loss Issues

OSHA received one miscellaneous comment that is worthy of discussion. The International Chemical Workers Union Council (Ex. 3-53) remarked that "[i]t is difficult for workers and their representatives to gain access to audiometric exams or summaries of those exams". Several of OSHA's rules provide access rights to audiometric data. Section 1910.95(g)(8) of the noise standard requires employers to inform employees, in writing, that they have experienced a standard threshold shift. OSHA's rule for access to employee exposure and medical records (§ 1910.1020) requires employers to provide access to medical records, exposure records, and analyses of records to employee's and their designated representatives. Finally, the part 1904 regulation requires employers to provide employee access to the OSHA injury and illness data.

Economic Analysis

Costs of the Revisions to the Hearing Loss Recording Provisions

OSHA has determined that the total cost of this action is \$1,049,650 per year and, thus, that it is not an economically significant regulatory action within the meaning of Executive Order 12866. The methodology that OSHA has used for computing costs for the new rule is presented in the next two sections.

Changes in Coverage

Under the 2002 rule, employers were required to record all hearing loss cases that involved a work-related Standard Threshold Shift (STS) of an average of 25 dB or more at 2000, 3000 and 4000 hertz (Hz) in either ear, compared to the employee's original baseline audiogram. The new rule requires recording all

hearing loss cases that involve a work-related STS of an average of 10 dB or more if the accumulated loss of hearing is at least 25 dB above audiometric zero. (The use of the tables in Appendix F of the Noise Standard to adjust for aging remains unchanged.)

OSHA estimates that approximately 40,000 hearing loss cases would have to be recorded under the 2002 rule, as opposed to approximately 145,000 hearing loss cases under the new rule. Thus, the new rule increases the number of recordable hearing loss cases by approximately 105,000. (In the Final Economic Analysis of the 2001 revisions to the rule, OSHA estimated that there would be 275,000 additional hearing loss cases (66 FR 6121), but the new rule has a narrower definition of hearing loss cases than the 2001 rule.)

Estimating the Number of Recordable Hearing Loss Cases

To estimate the number of cases that would be recorded, OSHA used the same estimation methodology as in the January 19, 2001 final rule. First, OSHA estimated the number of employees that would receive audiometric tests. OSHA's noise standard § 1910.95 requires employers to provide baseline and annual audiograms (and take other actions) when employees are exposed to certain noise levels. OSHA believes that approximately 23% of workers in the manufacturing sector are covered by the OSHA noise standard. Therefore, the number of covered manufacturing workers is 4,255,000 (18,500,000 manufacturing workers $\times$.23). OSHA estimates that an additional 10% of workers are covered in other general industry sectors (such as transportation and utilities) or receive audiograms in industries not required to perform audiometric testing under the OSHA noise standard (such as construction and agriculture). Therefore, the total number of covered workers is estimated to be approximately 4,680,500 (4,255,000 $\times$ 1.1).

OSHA then reviewed a National Institute for Occupational Safety and Health (NIOSH) database of audiograms to determine the proportion of audiograms meeting the recording criteria. 3.09% of audiograms met the final rule's criteria for recording hearing loss, and 0.83% met the 2002 recording criteria (25 dB). Applying this percentage to the number of employees receiving annual audiograms results in 144,627 (4,680,500 $\times$ 0.0309) estimated hearing loss cases under the final rule, and 38,848 (4,680,500 $\times$.0083) estimated hearing loss cases recorded under the 2002 rule.

Therefore, OSHA estimates 105,779 (144,627 – 38,848) additional cases of occupational hearing loss will be captured by the final section 1904.10 regulation, and has rounded this figure to 105,000 for cost estimation purposes.

Annual Costs of Maintaining Records

The additional hearing loss cases will require additional entries on the OSHA Form 300 Log and Summary of Occupational Injuries and Illnesses and the OSHA Form 301 Injury and Illness Incident Report. Access of employees and their representatives to the additional Form 301s will also involve costs.

OSHA estimates that employers will incur for each additional hearing loss case a cost of 15 minutes for the Log entry.

As explained in the 2001 Final Economic Analysis, based on data collected during approximately 400 recordkeeping audit inspections, OSHA estimates that 82 percent of incidents will be recorded on forms other than Form 301, such as workers' compensation forms. The remaining 18% of additional hearing loss cases will take 22 minutes for the filling out the Form 301.

Assuming that an individual with the skill level of a Personnel Training and Labor Relations Specialist will do the recordkeeping required by this rule, an hourly wage of \$30.02 is used to compute cost. (The average hourly wage for a Personnel Training and Labor Relations Specialist as reported in the Bureau of Labor Statistics Occupational Employment Statistics Survey for Year 2000 was \$21.71; benefits are computed at 38.3 percent of the hourly wage.)

Thus, employers will incur, for each additional hearing loss case, data entry costs of 15 minutes for the Log entry plus, for 18% of the cases, 22 minutes for the Form 301. The total annual cost is estimated to be \$996,064 [= (105,000 Cases) $\times$ (15 Minutes/Case) $\times$ (\$30.02/Hour) + (18,900 Cases) $\times$ (22 Minutes/Case) $\times$ (\$30.02/Hour)].

As in the Year 2001 Final Economic Analysis, OSHA assumes that (a) at one-tenth of covered establishments, one employee would request access to his or her own Form 301 (10,500 instances), and (b) at one percent of covered establishments, a union representative would request access to all Form 301s at the establishment. Using the same estimation method as the 2001 Economic Analysis, OSHA estimates union representative access will result in an additional 10,500 forms being provided by employers. OSHA assumes that, for each of the 21,000 forms being provided (10,500 + 10,500), employers

would require five minutes to pull, copy (at \$0.05), and replace the relevant Form 301.

The estimated total cost of providing access to additional hearing loss records would thus be \$47,110 [= (21,000 Forms) $\times$ (5 Minutes $\times$ (\$30.02/Hour) + \$.05/Copy)]. Thus, according to the above analysis, the total annual cost of this regulatory action is \$1,049,650.

Benefits

Hearing loss cases result in substantial disability and lead to safety accidents as well. OSHA believes that aligning the recording threshold for such cases with the STS criterion in the Agency's Noise Standard will simplify recording for many employers who are already familiar with this criterion and provide more opportunities for employers to intervene to prevent other hearing loss cases.

As explained in the 2001 Final Economic Analysis, possession of information about events and exposures will increase the ability of employers and employees to identify hazardous conditions and to take remedial action to prevent future illnesses. If this enhanced ability to identify (and thus address) hazards translates into a reduction even as small as 0.5 to 1 percent of the estimated number of additional recordable cases, it would mean the prevention of 525 to 1,050 illnesses per year [= (.005 to .01 $\times$ 105,000)].

The revisions in the rule will also make the injury and illness records more useful to OSHA, as well as to employers and employees. Improvements in the records being kept by employers would enhance OSHA's capacity to focus compliance outreach efforts on the most significant hazards; identify types or patterns of illness whose investigation might lead to regulatory changes or other types of prevention efforts, such as enforcement strategies, information and training, or technology development; and set priorities among establishments for inspection purposes.

Employers and employees both stand to benefit from the more effective use of OSHA's resources. The enhanced ability of compliance officers to identify patterns of illness will enable OSHA to focus on more serious problems. Identification of such patterns will also increase the ability of employers to control these hazards and prevent other similar illnesses. To the extent that employers take advantage of this information, the burden of OSHA inspections should be reduced in the long run. Employees clearly also will

benefit from these reductions in illnesses.

Regulatory Flexibility Certification

The 2001 revisions of the recordkeeping rule, which were much more extensive, did not have a significant impact on a substantial number of small entities (66 FR 6121). In the Final Economic Analysis for those revisions, OSHA estimated that over the entire range of SICs affected, the average cost per small firm was only \$31.63. The impacts of those revisions on sales and profits did not exceed 1 percent for small firms in any covered industry (66 FR 6108).

Even if all the additional hearing loss cases estimated to result from this year's revisions were distributed among the 541,988 small firms that keep the injury and illness records (as OSHA identified in its Year 2001 Final Economic Analysis) the average cost of the current revisions per small firm would be less than two dollars.

OSHA hereby certifies that the current revision to the hearing loss recording provisions, with an estimated annual cost of just over a million dollars, will not have a significant impact on a substantial number of small entities.

Unfunded Mandates

For the purposes of the Unfunded Mandates Reform Act of 1995, as well as Executive Order 12875, this rule does not include any Federal mandate that may result in increased expenditures by State, local, and tribal governments, or increased expenditures by the private sector of more than \$100 million in any year.

Federalism

This rule has been reviewed in accordance with Executive Order 13132 (52 FR 41685), regarding Federalism. Because this rulemaking action involves a "regulation" issued under section 8 of the OSH Act, and not a "standard" issued under section 6 of the Act, the rule does not preempt State law, see 29 U.S.C. 667(a). The effect of the rule on States is discussed in the State Plans section of this preamble.

Paperwork Reduction Act

OSHA will modify its previously approved information collection requirements prior to the January 1, 2003 effective date.

State Plans

The 26 States and territories with their own OSHA-approved occupational safety and health plans must adopt a comparable regulation within six months of the publication date of this

final regulation. These states and territories are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Connecticut, New Jersey, and New York have OSHA approved State Plans that apply to state and local government employees only.

A few commenters urged OSHA to make sure that the State Plan States have the same recording criteria as federal OSHA (see, e.g., Exs. 3-22, 3-30, 3-49, 3-55). During 2002, the State Plan States were allowed to maintain their policies for the recording of hearing loss to maintain their former requirements, while OSHA reconsidered what the appropriate recording criteria should be. In the **Federal Register** document announcing the one year delay and the interim policy for year 2002, OSHA stated that when it issues a final determination for the recording of occupational hearing loss for calendar years 2003 and beyond, the states would be required to have identical criteria (66 FR 52033). Now that OSHA has issued its final determination, the States are required to promulgate identical criteria.

Executive Order

This document has been deemed significant under Executive Order 12866 and has been reviewed by OMB.

Authority

This document was prepared under the direction of John L. Henshaw, Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. It is issued pursuant to section 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 657).

Signed at Washington, DC, this 25th day of June, 2002.

John L. Henshaw,
Assistant Secretary of Labor.

For the reasons stated in the preamble, 29 CFR part 1904 is amended as follows:

PART 1904—[AMENDED]

1. The authority citation for part 1904 continues to read as follows:

Authority: 29 U.S.C. 657, 658, 660, 666, 673, Secretary of Labor's Order No. 3-2000 (65 FR 50017), and 5 U.S.C. 533.

2. Revise § 1904.10 to read as follows:

§ 1904.10 Recording criteria for cases involving occupational hearing loss.

(a) Basic requirement. If an employee's hearing test (audiogram) reveals that the employee has experienced a work-related Standard Threshold Shift (STS) in hearing in one or both ears, and the employee's total hearing level is 25 decibels (dB) or more above audiometric zero (averaged at 2000, 3000, and 4000 Hz) in the same ear(s) as the STS, you must record the case on the OSHA 300 Log.

(b) Implementation.

(1) *What is a Standard Threshold Shift?* A Standard Threshold Shift, or STS, is defined in the occupational noise exposure standard at 29 CFR 1910.95(g)(10)(i) as a change in hearing threshold, relative to the baseline audiogram for that employee, of an average of 10 decibels (dB) or more at 2000, 3000, and 4000 hertz (Hz) in one or both ears.

(2) *How do I evaluate the current audiogram to determine whether an employee has an STS and a 25-dB hearing level?*

(i) *STS.* If the employee has never previously experienced a recordable hearing loss, you must compare the employee's current audiogram with that employee's baseline audiogram. If the employee has previously experienced a recordable hearing loss, you must compare the employee's current audiogram with the employee's revised baseline audiogram (the audiogram reflecting the employee's previous recordable hearing loss case).

(ii) *25-dB loss.* Audiometric test results reflect the employee's overall hearing ability in comparison to audiometric zero. Therefore, using the employee's current audiogram, you must use the average hearing level at 2000, 3000, and 4000 Hz to determine whether or not the employee's total hearing level is 25 dB or more.

(3) *May I adjust the current audiogram to reflect the effects of aging on hearing?*

Yes. When you are determining whether an STS has occurred, you may age adjust the employee's current audiogram results by using Tables F-1 or F-2, as appropriate, in Appendix F of 29 CFR 1910.95. You may not use an age adjustment when determining whether the employee's total hearing level is 25 dB or more above audiometric zero.

(4) *Do I have to record the hearing loss if I am going to retest the employee's hearing?*

No, if you retest the employee's hearing within 30 days of the first test, and the retest does not confirm the recordable STS, you are not required to record the hearing loss case on the

OSHA 300 Log. If the retest confirms the recordable STS, you must record the hearing loss illness within seven (7) calendar days of the retest. If subsequent audiometric testing performed under the testing requirements of the § 1910.95 noise standard indicates that an STS is not persistent, you may erase or line-out the recorded entry.

(5) *Are there any special rules for determining whether a hearing loss case is work-related?*

No. You must use the rules in § 1904.5 to determine if the hearing loss is work-related. 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, you must consider the case to be work related.

(6) *If a physician or other licensed health care professional determines the hearing loss is not work-related, do I still need to record the case?*

If a physician or other licensed health care professional determines that the hearing loss is not work-related or has not been significantly aggravated by occupational noise exposure, you are not required to consider the case work-related or to record the case on the OSHA 300 Log.

(7) *How do I complete the 300 Log for a hearing loss case?*

When you enter a recordable hearing loss case on the OSHA 300 Log, you must check the 300 Log column for hearing loss.

Note to 1904.10(b)(7): The applicability of paragraph (b)(7) is delayed until further notice.

[FR Doc. 02-16392 Filed 6-28-02; 8:45 am]

BILLING CODE 4510-26-P

DEPARTMENT OF THE TREASURY

31 CFR Part 103

RIN 1506-AA21

Financial Crimes Enforcement Network; Amendment to the Bank Secrecy Act Regulations—Requirement that Brokers or Dealers in Securities Report Suspicious Transactions

AGENCY: Financial Crimes Enforcement Network (“FinCEN”), Treasury.

ACTION: Final rule.

SUMMARY: This document contains amendments to the regulations implementing the statute generally referred to as the Bank Secrecy Act (“BSA”). The amendments require brokers or dealers in securities (“broker-dealers”) to report suspicious

transactions to the Department of the Treasury. The amendments constitute a further step in the creation of a comprehensive system for the reporting of suspicious transactions by the major categories of financial institutions operating in the United States, as a part of the counter-money laundering program of the Department of the Treasury.

DATES: *Effective Date:* July 31, 2002.

Applicability Date: December 30, 2002. See 31 CFR 103.19(h) of the final rule contained in this document.

FOR FURTHER INFORMATION CONTACT:

Peter G. Djinis, Executive Assistant Director for Regulatory Policy, FinCEN, at (703) 905-3930; Judith R. Starr, Chief Counsel, Cynthia L. Clark, Deputy Chief Counsel, and Christine L. Schuetz, Attorney-Advisor, Office of Chief Counsel, FinCEN, at (703) 905-3590.

SUPPLEMENTARY INFORMATION:

I. Statutory Provisions

The BSA, Public Law 91-508, as amended, codified at 12 U.S.C. 1829b, 12 U.S.C. 1951-1959, and 31 U.S.C. 5311-5332, authorizes the Secretary of the Treasury, *inter alia*, to issue regulations requiring financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures.¹ Regulations implementing Title II of the BSA (codified at 31 U.S.C. 5311 *et seq.*) appear at 31 CFR part 103. The authority of the Secretary to administer the BSA has been delegated to the Director of FinCEN.

The Secretary of the Treasury was granted authority in 1992, with the enactment of 31 U.S.C. 5318(g),² to require financial institutions to report

¹ Language expanding the scope of the BSA to intelligence or counter-intelligence activities to protect against international terrorism was added by section 358 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001 (the “USA Patriot Act”), Public Law 107-56.

² 31 U.S.C. 5318(g) was added to the BSA by section 1517 of the Annunzio-Wylie Anti-Money Laundering Act (the “Annunzio-Wylie Anti-Money Laundering Act”), Title XV of the Housing and Community Development Act of 1992, Public Law 102-550; it was expanded by section 403 of the Money Laundering Suppression Act of 1994 (the “Money Laundering Suppression Act”), Title IV of the Riegle Community Development and Regulatory Improvement Act of 1994, Public Law 103-325, to require designation of a single government recipient for reports of suspicious transactions.

suspicious transactions. As amended by the USA Patriot Act, subsection (g)(1) states generally:

The Secretary may require any financial institution, and any director, officer, employee, or agent of any financial institution, to report any suspicious transaction relevant to a possible violation of law or regulation.

Subsection (g)(2)(A) provides further that

If a financial institution or any director, officer, employee, or agent of any financial institution, voluntarily or pursuant to this section or any other authority, reports a suspicious transaction to a government agency—

(i) the financial institution, director, officer, employee, or agent may not notify any person involved in the transaction that the transaction has been reported; and

(ii) no officer or employee of the Federal Government or of any State, local, tribal, or territorial government within the United States, who has any knowledge that such report was made may disclose to any person involved in the transaction that the transaction has been reported, other than as necessary to fulfill the official duties of such officer or employee.

Subsection (g)(3)(A) provides that neither a financial institution, nor any director, officer, employee, or agent of any financial institution

that makes a voluntary disclosure of any possible violation of law or regulation to a government agency or makes a disclosure pursuant to this subsection or any other authority * * * shall * * * be liable to any person under any law or regulation of the United States, any constitution, law, or regulation of any State or political subdivision of any State, or under any contract or other legally enforceable agreement (including any arbitration agreement), for such disclosure or for any failure to provide notice of such disclosure to the person who is the subject of such disclosure or any other person identified in the disclosure.

Finally, subsection (g)(4) requires the Secretary of the Treasury, “to the extent practicable and appropriate,” to designate “a single officer or agency of the United States to whom such reports shall be made.”³ The designated agency is in turn responsible for referring any report of a suspicious transaction to “any appropriate law enforcement, supervisory agency, or United States intelligence agency for use in the conduct of intelligence or counterintelligence activities, including

³ This designation does not preclude the authority of supervisory agencies to require financial institutions to submit other reports to the same agency or another agency “pursuant to any other applicable provision of law.” 31 U.S.C. 5318(g)(4)(C).

Appendix B



DEPARTMENT OF THE NAVY
NAVAL SUBMARINE MEDICAL RESEARCH LABORATORY
NAVAL SUBMARINE BASE NEW LONDON
GROTON, CONNECTICUT 06349-5900

IN REPLY REFER TO:

6260

Ser 043/265

06 SEP 2001

Docket Officer
Docket No. R-02A
Occupational Safety and Health Administration
Room N-2625
U.S. Department of Labor
200 Constitution Avenue NW
Washington DC 20210

Dear Sir or Madam:

The Hearing Conservation Research Team at our facility has prepared comments in response to the July, 2001 issue of the Federal Register. That issue requested comments regarding the recording of occupational hearing loss. The team has been performing work in areas that are pertinent to some of the issues identified in the call for comments. Their comments regarding these issues (Issues 1 and 2) are provided below.

The question of using 10, 15, 20, or 25 decibel (dB) shifts to define standard threshold shift and for recording purposes, depends on the test-reliability of the audiogram. Before selecting a criterion, the variability in a group of people who are not noise-exposed must be known. These people function as a control group, in which the test-retest variability of the test procedure and environment can be determined independently of the effects of noise. After the test-retest variability in the control group has been established, the STS criterion can then be set so that most people in the non-noise exposed control group are not identified as having a hearing shift (false positives). Once the test-retest reliability of the audiogram is known and a criterion is set that minimizes false positive STS, STS criteria can be modified to take other factors into account (i.e., case loads, costs associated with audiological follow-up).

Many investigators have examined the reliability of both manual and automated audiometry (Dobie, 1983; Lane et. al, 1985). Unfortunately, the statistical methods used to evaluate test-retest reliability, the time interval between hearing tests, and the types of subject populations used varied widely between these studies making comparisons difficult. Some studies examined the correlation coefficients between successive audiometric tests, others used the standard error of measurement of thresholds, and others reported on the standard deviations of the test-retest score differences to examine test-retest reliability (Dobie, 1983; Lane et al., 1985). Some studies used highly trained listeners using more painstaking methodology than what is normally the case in industrial and clinical settings. Using highly trained individuals may not reflect the variability found in a group of naïve listeners (i.e., industrial or military employees undergoing baseline audiogram testing who do not have much experience taking hearing tests) who are given fewer test trials. Other studies used noise-exposed populations to assess test reliability. Using noise-exposed individuals to assess test-retest

reliability defeats the purpose of measuring the reliability inherent in audiogram itself. The control group should consist of relatively naïve listeners, with similar demographics to the noise-exposed population of interest.

It is difficult to detect noise-induced STS as these shifts in hearing level can often fall within the normal range of audiometry test-retest variability (reliability) (Lane et al., 1985). The range of this normal variability has not yet been firmly established. There are several variables that can influence industrial audiometric results, including earphone placement (particularly in group-testing situations where individuals place their own earphones on), earwax occlusions, ear pathology (e.g., middle ear infections), fatigue, ambient noise in the test environment, employee attention, employee motivation, tinnitus, examiner experience, the instructions given to the employee, or changes in the individual's response criterion (i.e., how strong the perception of hearing is before the individual is willing to report hearing the tone). In summary, reliability of audiometric testing is a combination of test equipment, examiner, and environment. Test-retest reliability needs to be studied using control groups that are in the same physical and mental state and tested in the same manner as the noise-exposed population.

Research in the area of STS criteria appears to have been focused on comparing the STS hit rates of different criteria, both single frequency, averaging across frequencies, and a combination of the two (Dobie, 1983, Royster, 1992). The main goal of these studies was to find criteria that would limit the number of "false positive" cases of STS. This is difficult because we have no way of telling which individuals in the population have a true STS and who do not. Dobie (1983) borrowed principles and techniques from both signal-detection and decision theory to examine various STS criteria. To apply these theories, the results of the test in question need to be accurately confirmed or denied by a separate, independent test, or "gold standard." Unfortunately, a pragmatic gold standard that is able to confirm or deny noise-induced hearing loss does not yet exist. There are hearing-threshold psychophysical procedures available that have potential to be gold standards, but these are very time consuming compared to current clinical audiometric methods. Without this knowledge the best we can do is measure the test-retest reliability of the audiometric procedure in a control group, which has not been noise-exposed between tests and has no other ear pathology. If a noise-exposed person exceeds the variability seen in this type of control group, then it is likely they have had a significant change in hearing. Typically, changes in hearing levels in a control group are not considered when setting STS criteria.

Any criterion used to determine STS, the need for follow-up testing, and PTS determinations must take into account this test-retest variability. Our work, which is currently being prepared for submission to a peer-reviewed journal, will recommend using the standard error of measurement to empirically derive STS criteria. This statistical procedure can be used with a minimum of two tests per person.

We strongly recommend that further work be done in this area using a representative sample of non-noise exposed control subjects, at multiple test sites. In this manner, average test-retest reliability ranges will be obtained and can be used to determine more appropriate STS criteria and ensure the accuracy of hearing threshold levels used for recording purposes. These studies will have costs in terms of both time and money. However, re-testing employees with false-positive STS has a high cost.

Also, invalid hearing levels do defeat the purpose of measuring and recording occupational hearing loss.

These comments were prepared by this laboratory's Hearing Conservation Research Team and consists of the following individuals:

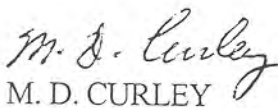
Lynne Marshall, Ph.D. (Doctorate in Speech and Hearing Science; clinical certification and state licensure in audiology; researcher in areas of hearing test methodology, inner ear assessment, and early detection of noise-induced hearing loss; Team Leader of the Hearing Conservation Research Team.).

Keith Wolgemuth, Ph.D. (Doctorate in Audiology and Speech-Language Pathology; Commander, Medical Service Corps, U.S. Navy, clinical certification and state licensure in audiology, researcher in areas of epidemiological studies of hearing conservation programs and hearing test methodology, member of Hearing Conservation Research Team.).

Judi Lapsley Miller, Ph.D. (Doctorate in psychoacoustics of human hearing, CAOHC and Navy certified occupational hearing conservationist, researcher in area of using otoacoustic emissions in hearing conservation programs)

Points of contact regarding these comments are: CDR Keith Wolgemuth, MSC, USN, who can be reached at (860)-694-4680 (e-mail: wolgemuth@nsmrl.navy.mil) or Dr. Judi Lapsley Miller, who can be reached at (860)-694-2557 (e-mail: jmiller@nsmrl.navy.mil). A list of the references is provided as Appendix A. We greatly appreciate the opportunity to provide input for the hearing loss recordability and STS issues.

Sincerely,



M. D. CURLEY

Captain, Medical Service Corps, United States Navy
Commanding Officer

APPENDIX A (LIST OF REFERENCES)

1. Dobie, R.A. (1983). Reliability and validity of industrial audiometry: Implications for hearing conservation program design. Laryngoscope, 93, 906-927.
2. Lane, C., Dobie, R., Crawford, D., and Morgan, M. (1985). Standard threshold shift criteria: An investigation of the most reliable indicator of noise-induced hearing loss. Journal of Occupational Medicine, 27, 34-42.
3. Royster, J.D. (1992). Evaluation of different criteria for significant threshold shift in occupational hearing conservation programs. Available from Environmental Noise Consultants, Inc., PO Box 30698, Raleigh, NC 27622-0698.

REPORT DOCUMENTATION PAGE				<i>Form Approved OMB No. 0704-0188</i>	
The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) ?? September 2003		2. REPORT TYPE Memorandum		3. DATES COVERED (From - To) 9/4/01-7/1/02	
4. TITLE AND SUBTITLE RECOMMENDATIONS REGARDING THE EFFECTS OF AUDIOMETRIC TEST-RETEST RELIABILITY ON THE DEVELOPMENT OF OSHA STANDARD THRESHOLD SHIFT CRITERIA AND RECORDING OF WORK-RELATED METEIRAL HEARING LOSS				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Keith S. WOLGEMUTH, Lynne MARSHALL, and Judi Lapsley MILLER				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER 50001	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Naval Submarine Medical Research Laboratory Box 900 Groton, CT 06349-5900				8. PERFORMING ORGANIZATION REPORT NUMBER MR #	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT APPROVED FOR PUBLIC RELEASE; DISTRIBUTION UNLIMITED					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The 3 July 2001 issue of the FEDERAL REGISTER provided notification of a proposed delay for the effective date regarding the recording of OSHA occupational hearing loss. OSHA requested comments on several issues related to appropriate criteria for recording cases of occupational hearing loss. The NSMRL Hearing Conservation Team had performed work pertaining to two of these issues: 1) What is the variability of audiometric testing? and 2) How should variability be taken into account in the recordkeeping rule? NSMRL had performed measurements of both manual and automated audiometric test-retest reliability in field settings using the standard error of measurement (SEmeas). The SEmeas is a statistical procedure that can be used with a minimum of two tests per person and can also be used to empirically develop STS and recordability criterion that will potentially reduce the number of false positive threshold shift determinations. Results from NSMRL studies showed that any criterion used to determine either significant or standard hearing threshold shift must take test-retest reliability into account as measured in non-noise exposed					
15. SUBJECT TERMS OSHA; Occupational Hearing Loss; standard error of measurement (SEmeas); STS; Federal Register.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Ellen M. Perkins, Publications Manager
U	U	U			19b. TELEPHONE NUMBER (Include area code) 860/DSN 694-3201

Control groups that were in the same physical and mental state and tested in the same manner as the noise-exposed population. It was strongly recommended that further work be done in this area using representative samples of non-noise exposed control subjects at multiple test sites. In this manner, average test-retest reliability ranges could be empirically obtained and could be used to determine more appropriate STS criteria and ensure the accuracy of hearing threshold levels used for recording purposes. These results were provided in an NSMRL letter to OSHA in September 2001 as input regarding possible revision of the OSHA hearing loss record keeping rule. NSMRL's recommendations were cited in the July 2002 issue of the FEDERAL REGISTER.