Audiometric Data Analysis Tools and Methods to Prevent Noise-Induced Hearing Loss

OSHA-NIOSH Noise Safety Challenge
September 28, 2016

Summary

Our proprietary technology allows employers to efficiently utilize and analyze their workplace audiometry results **quickly, easily, and consistently**. The technology comprises two related components:

1. **dBw**™, a **numerical summary metric** that is analyzed with standard statistical tests to accurately quantify the magnitude and direction by which audiometric results in individuals and similarly exposed groups of workers trend toward a noise-induced hearing loss (NIHL) pattern.
2. **webOSCAR** ™**,** an **information management system** configurable to each organization (company, facility or other employer entity) to **streamline and automate the process** of managing audiometric data, from scheduling and collection to analysis, reporting and documentation.

With this 'real world' technology, employers have the capability to **automatically** analyze individual and aggregate audiometric trends to **identify** early hearing loss in workers, **measure** the impact of interventions to prevent irreversible NIHL, and **objectively evaluate** the performance and outcomes of their hearing conservation programs (HCPs). These outcomes **can be applied to create a benchmark** for organizations in each industry.

dBw™

Our proprietary **method** mathematically **transforms** raw data from serial (e.g., annual) audiograms into the dBw summary **metric**. The statistical **process** analyzes individual and aggregate dBw data for year-to-year variability, trends and progression toward a noise-induced hearing loss audiogram pattern. The outcomes are **interpreted** and reported as **actionable data**.

- The dBw **quantifies** how closely an audiogram hearing loss pattern matches known or typical patterns for early to moderate noise-induced hearing loss (NIHL).
- The magnitude and direction of the trends (changes) in dBw over time are **tested for statistical significance** for **individual** employees, and **comparatively** among similar exposure groups (SEGs) of employees or **duration of employment** (exposure) within an employer organization.
- **Acceptability criteria** are established based on statistical outcomes for various analyses.
- The results and acceptability outcomes are **reported in easy-to-read formats**, including graphs, histograms, and control charts.

Table 1 summarizes the robust features of the dBw metric, including how it significantly differs from the Standard Threshold Shift (STS) and other audiometric data analysis methods unsuccessfully proposed over the past 25 years.

Table 1 dBw: Metric for Audiometric Data

dBw Metric
Expressed in same units (dB) as audiogram data
Not reliant on arbitrary hearing threshold cutoffs, e.g., Standard Threshold Shift (STS)
Normalized to fit any set of data
Not affected by abnormal baseline tests
Test-to-test variability (signal-to-noise ratio) is minimized
Does not require control data
Can distinguish NIHL pattern from other hearing loss conditions
Can measure significant changes in either or both ears
Effective with small numbers of employees and variable numbers of serial audiograms
Does not require minimum number of tests or assume normal distribution of data
Age-adjusted audiometric data can be optionally used
Adaptable to a particular types of NIHL, such as 6000 Hz notch

Figure 1 illustrates the "raw" audiometric data pattern and progression of noise-induced hearing loss (NIHL), and a comparative pattern and progression for presbycusis (age-related high hearing loss. The graph beneath demonstrates how efficiently the dBw metric can differentiate them from one another at the earliest and later stages: the specific correlation for NIHL remains very close to 1 (100%), vs. a low correlation for presbycusis that declines over time to under 0.5 (50%).

Figure 1 Comparison of Audiogram Patterns and dBw Metric to Distinguish NIHL and Presbycusis

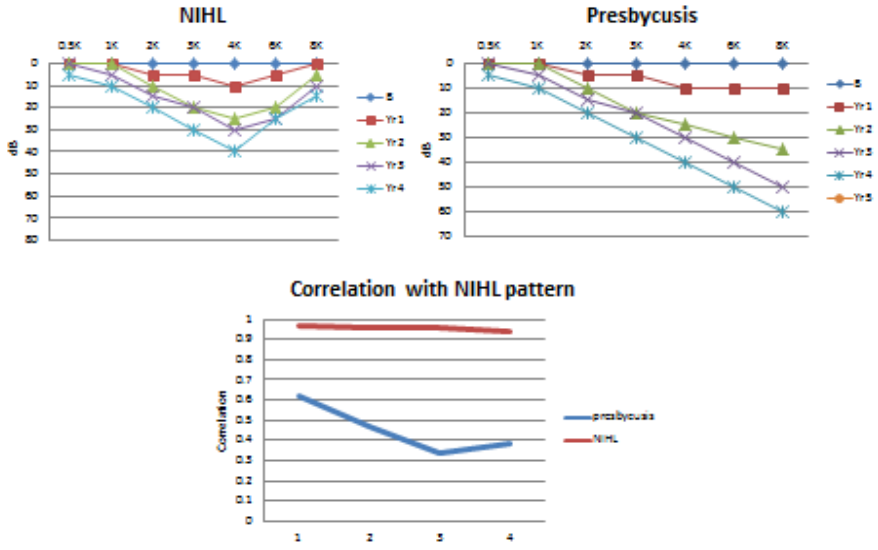


Figure 2 is a plot of correlations illustrating the sensitivity and specificity of the dBw metric for detecting early NIHL and significantly differentiating it from other prevalent hearing loss conditions (many with negative correlations) and normal hearing are substantially higher than the STS or other methods.

Figure 2 Correlation of dBw Values for Audiograms of NIHL, Normal, and Other Prevalent Conditions

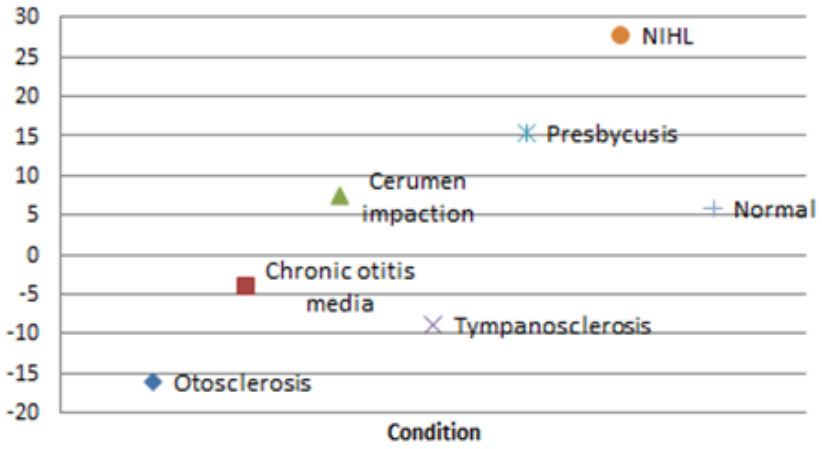


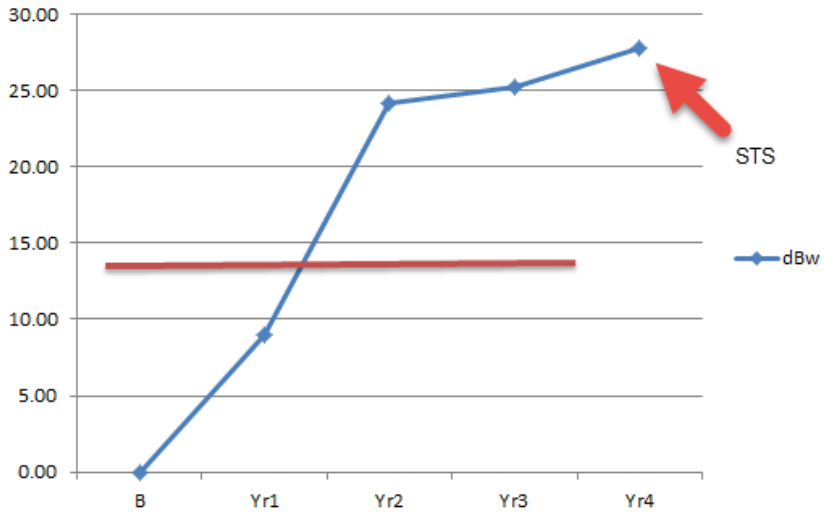
Table 2 summarizes the key features of the standardized statistical methods to analyze and report the outcomes.

Table 2 Standardized Statistical Methods

Statistical Methods
Minimizes the effect of outliers
Does not require assumption of a normal ("bell curve") distribution
Not invalidated by missing values or small numbers of subjects
Tests of statistical significance (*p* values) are applied to standardize rules for interpretation
Sensitivity and specificity analyses (i.e., receiver-operator curves) determine "acceptability"
Standard control charts to graphically report individual and aggregate dBw changes
Summary statistics can be compared to and reported along with conventional OSHA STS values
Conforms to meet the data requirements recommended by ANSI S12.13

Figure 3 illustrates how a dBw threshold (cutoff) can be applied to automatically detect an individual employee's earliest indication of audiogram progression toward NIHL, long before the "recordable" Standard Threshold Shift (STS) is reported per OSHA Noise Standard requirements.

Figure 3 dBw Cutoff to Detect Earliest Audiometric Changes of NIHL



webOSCAR™

webOSCAR (www.webOSCAR.com) is a configurable, real-time system that manages scheduling, tracking, collecting and organizing compliance activities, data, documents and tasks; and analyzes, reports, and distributes individual *and* aggregate results, outcomes and performance for myriad health and safety programs. This technology is specifically designed to manage health and safety data as an essential business process. It is alternative to time-consuming, error-prone desktop software tools like Outlook, Excel, and Access—or manual paper files, folders, post-it notes, and checklists.

"Proof of concept" has already been achieved with ten (10) small- to medium-sized company customers in hazardous, highly regulated industries. The dBw metrics and analyses will be integrated into this system for seamless management of audiometric data to prevent NIHL and measure hearing conservation program effectiveness, AND all other health and safety compliance programs.

Table 3 summarizes how **webOSCAR is differentiated** from other health and safety software systems and applications, including those utilized solely for audiometry data by audiology services, or third party or in-house software systems designed primarily for very large corporations and organizations.

Table 3 webOSCAR Key Features for Health & Safety Information Management

Feature	Description
Robust	Integrates audiometry data with other health, safety ,environmental compliance data and applications (e.g., employee training, medical surveillance, biological monitoring, respiratory, injury reporting, industrial hygiene, human resources)
Accurate	Business rules and logic eliminate errors, oversights, omissions, duplications, and loss of data
Configurable	Settings configure each specific organization's departments, jobs, shifts and compliance requirements.
Real-Time	Data, dashboards and reports are dynamically generated and updated as information changes
Secure	All data are encrypted data and protected with HIPAA-compliant access and security
Expert-Designed	Any assigned manager or clerical personnel can use it; safety expertise or professional HCP supervisor is not required.
Affordable	Software-as-service subscription costs a small fraction of what companies already spend on compliance and employee benefits
Easy and Fast	Set up and learn in 1 day; no need for on-site training or reading manuals
Integration	Capable of importing data from human resources and other applications, eliminating redundant data entry

Detailed information and screenshots about webOSCAR's key features are available. The Compliance Risk Challenge test identifies common challenges and vulnerabilities employers face in effectively managing the information requirements of compliance programs such as Noise. The following graphics illustrate some of webOSCAR's Audiogram-specific Noise module capabilities (existing and under development).

Figure 4 displays the webOSCAR Dashboard for a facility, with the Audiometric program summary metrics, and how a **single mouse click** displays real-time audiometric metrics, such as the Noise Standard-required STS, in useful tabular and graphical formats.

Figure 4 webOSCAR Dashboard with Audiometry Summary Metrics and Real-Time Analytics

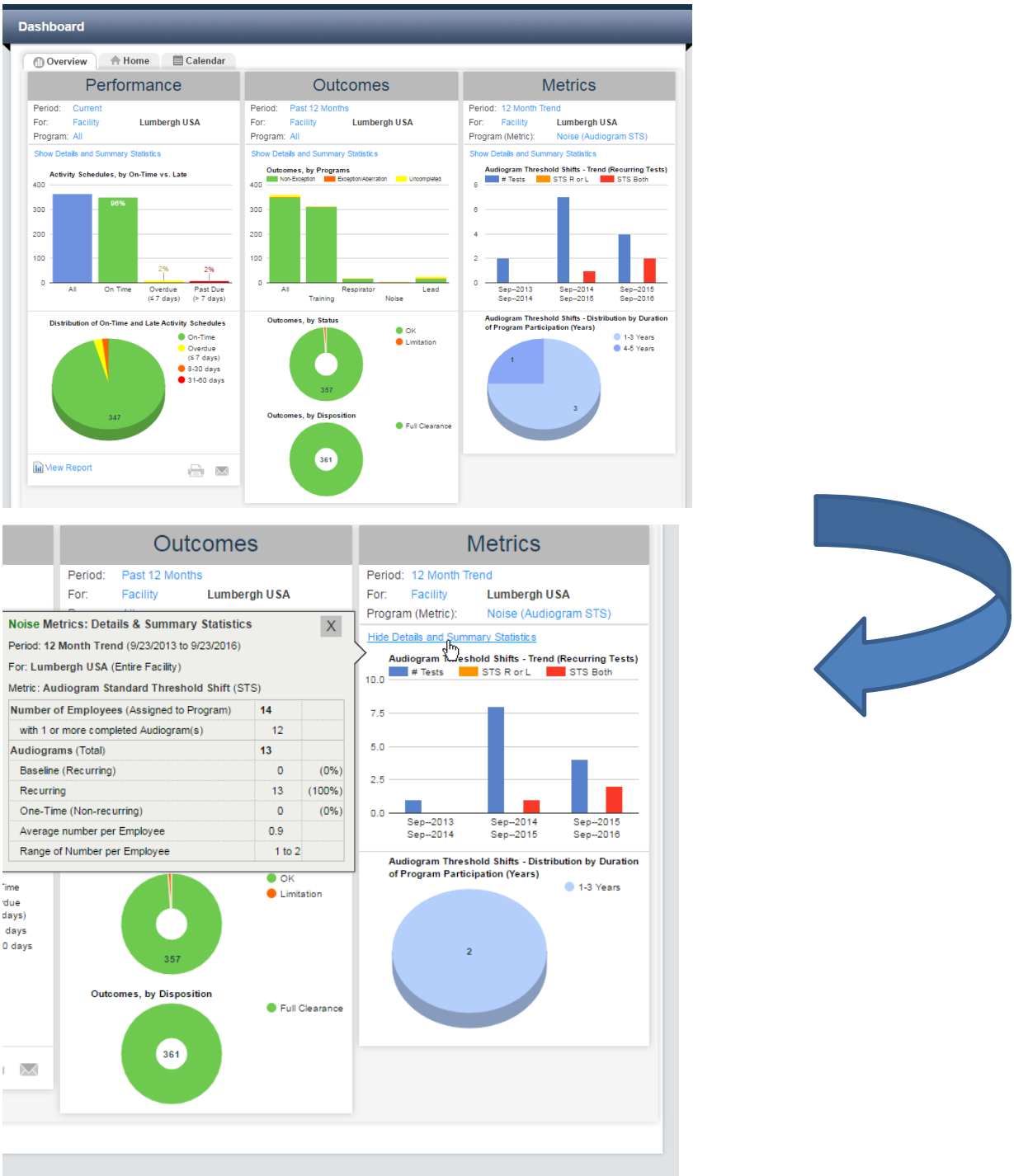


Figure 5 illustrates how webOSCAR is configured to each company (facility or organization).

- Employees' schedules for Activities such as audiograms are easily filtered and sorted.
- Activity due dates can be mass-added or mass-modified with a single mouse click.
- Automatically tracks and displays due dates and intervals.
- Flags overdue or past due schedules.
- Tracks follow-up tasks and attention items.
- Links directly to entry of activity data and documents.

Figure 5 webOSCAR Scheduling Screen for Audiogram Activities

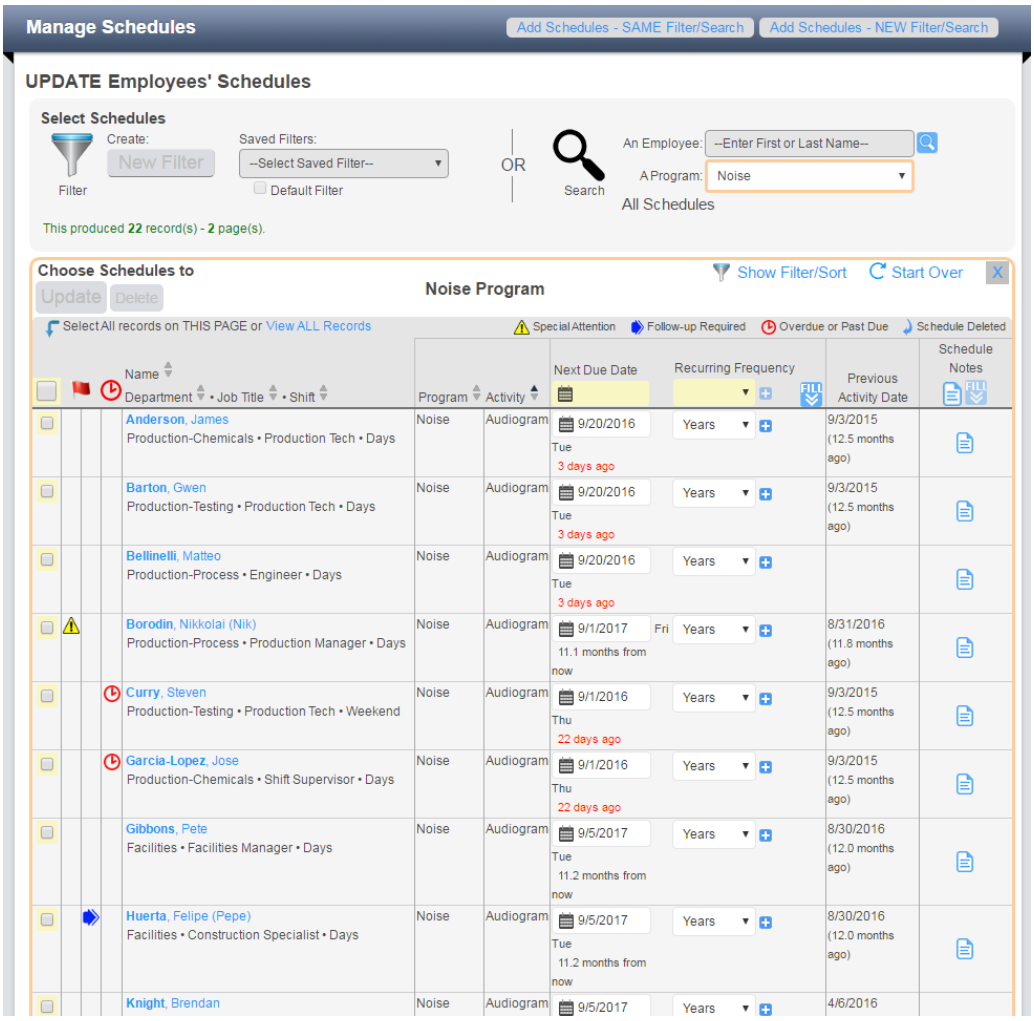
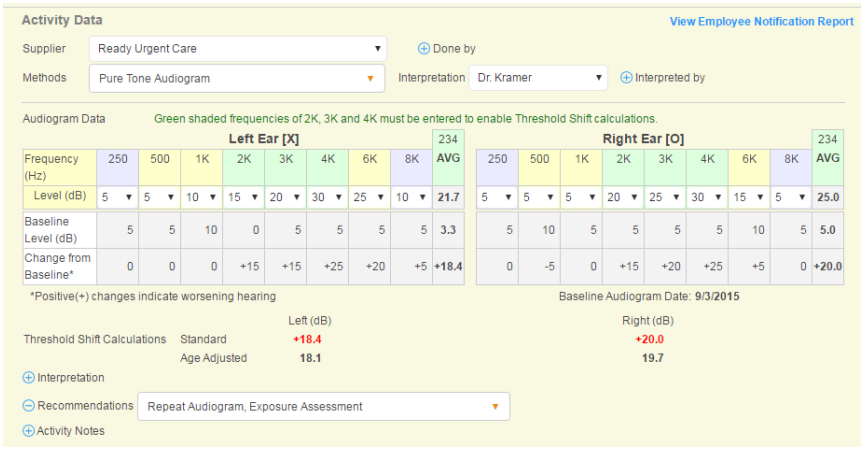


Figure 6 illustrates key built-in, configurable tools, rules and reports specific for audiograms.

- Automatically calculates of compliance outcomes, including STS and (optional) age adjustments.
- Automatically identifies and sorts non-exception results from exception results which can be flagged, tracked and documented for follow-up until they are cured or resolved.
- Dynamically generated individual and aggregate reports (automatically distributed via email).

Figure 6 Audiogram Activity Data screen and Individual Notification Report



Activity Data — View Employee Notification Report

Supplier: Ready Urgent Care — Done by

Methods: Pure Tone Audiogram — Interpretation: Dr. Kramer — Interpreted by

Audiogram Data — Green shaded frequencies of 2K, 3K and 4K must be entered to enable Threshold Shift calculations.

	Left Ear [X]									Right Ear [O]								
Frequency (Hz)	250	500	1K	2K	3K	4K	6K	8K	234 AVG	250	500	1K	2K	3K	4K	6K	8K	234 AVG
Level (dB)	5	5	10	15	20	30	25	10	21.7	5	5	5	20	25	30	15	5	25.0
Baseline Level (dB)	5	5	10	0	5	5	5	5	3.3	5	10	5	5	5	5	10	5	5.0
Change from Baseline*	0	0	0	+15	+15	+25	+20	+5	+18.4	0	-5	0	+15	+20	+25	+5	0	+20.0

*Positive(+) changes indicate worsening hearing

Baseline Audiogram Date: 9/3/2015

Threshold Shift Calculations		Left (dB)	Right (dB)
	Standard	+18.4	+20.0
	Age Adjusted	18.1	19.7

Interpretation

Recommendations: Repeat Audiogram, Exposure Assessment

Activity Notes

Lumbergh USA — Powered By webOSCAR

Employee Audiogram Notification

Report generated on: 9/28/2016

Employee: [redacted]

Date of Birth: 7/18/1957 (Age 59 years) — Department: Production-Process

Employee ID: — Job Title: Production Manager

Gender: Male — Shift: Days

Primary Language: English — Hire Date (Duration employed): 4/22/2008 (8.4 years)

Test Information:

Performed By: **Ready Urgent Care** — Interpreted By:

Results:	LEFT EAR (X) decibels (dB)								234	RIGHT EAR (O) decibels (dB)								234
Test Date [#]	250	500	1000	2000	3000	4000	6000	8000	Avg	250	500	1000	2000	3000	4000	6000	8000	Avg
9/16/2012 (1)	5	5	5	5	10	5	5	5	+5.6	5	5	10	5	5	5	5	5	+5.6
9/16/2012 [B]	5	5	5	5	10	5	5	5	+5.6	5	5	10	5	5	5	5	5	+5.6
Change vs [B]	+0	+0	+0	+0	+0	+0	+0	+0	0.0	+0	+0	+0	+0	+0	+0	+0	+0	0.0
9/4/2016 (2)	5	5	10	15	20	30	25	10	+15.0	5	5	5	20	25	30	15	5	+13.8
Change vs (2)	+0	+0	-5	-10	-10	-25	-20	-5	+9.4	+0	+0	+5	-15	-20	-25	-10	+0	+9.4
Interpretation: Threshold Shift (STS)	NO									NO								

Positive change (+) = Hearing Loss. Negative (-) change = Hearing Improved. 0 = No change. C = Current (most recent) test. B = Baseline test. P = Previous test.

234Av = Average (mean) of hearing thresholds at 2000, 3000, and 4000 Hz.

Recommendations:

Remarks (for Employee):

Activity	Most Recent	Due Date	(Interval from Today)	Recurring Frequency
Audiogram	9/16/2012	9/5/2017	11.0 mo.	12 months
Training	9/28/2015	10/1/2017	368 days	12 months