AUTHORS: Ward WD, Glorig A:

DATE: 1975

TITLE: Protocol of inter-industry noise study.

SOURCE: JOM 17:760-770

MAIN SUBJECT HEADING:

AN
ANALYTICS

HU
HUMAN EFFECTS

AT
ANIMAL TOXICITY

IH
WORKPLACE PRACTICES-
ENGINEERING CONTROLS

M
MISCELLANEOUS

SECONDARY SUBJECT HEADINGS:

AN
Physical/Chemical Properties

HU
Animal Toxicology

AT
Non-occupational Human Exposure

IH
Occupational Exposure

M
Epidemiology

AN
Standards

HU
Manufacturing

AT
Uses

IH
Reactions

M

Sampling/Analytical Methods

Reported Ambient Levels

Measured Methods

Work Practices

Engineering Controls

Biological Monitoring

Methods of Analysis

Treatment

Transportation/Handling/
Storage/Labelling

Not Referent
Protocol of Inter-Industry Noise Study

Authorized for Publication by:
Raymond A. Yerg, M.D., Chairman,
Steering Committee I.I.N.S.

The federal government and Secretary of Labor's Noise Standard Advisory Committee encountered considerable difficulty in arriving at definite standards for occupational noise exposures. This is primarily because there is dispute as to the reliability and adequacy of scientific data. Estimates have varied from 70 dBA to 92 dBA as to the level above which long-term occupational exposure to noise causes loss of hearing. The reasons for lack of data are chiefly that all previous investigations have been unable to overcome certain serious difficulties which are:

(1) Obtaining accurate audiograms neither affected by temporary hearing loss nor masked by environmental noise in the test room.

(2) Finding occupational environments in which employees are exposed to continuous noise that lasts all day and is steady in that it does not fluctuate more than three to five decibels throughout the day.

(3) Getting an accurate history of the duration of the exposure to the specific steady-state noise levels. In most industries, the noises fluctuate extensively; and the men move between areas having different noise levels.

(4) Interpretation of audiograms so as to exclude those employees having hearing losses that are caused by factors other than their occupational exposure.

(5) Other problems, such as calibration of audiometers and sound measuring devices, interpretations of results, and use of suitable controls.

The Inter-Industry Noise Study is a national study which is being performed and monitored by recognized experts and scientists who have competence in the noise and hearing field. One group of these experts is doing the actual work. Another group acts as the Scientific Advisory Committee. This latter group is composed of experts representing a diversity of viewpoints within the scientific community. These individuals are affiliated with such outstanding organizations as: National Research Council, Acoustical Society of America, American National Standards Institute, American Industrial Hygiene Association, American Council of Otolaryngology, American Speech and Hearing Association, and the federal government, among others.

The steering committee consists of outstanding leaders from industry, labor, government, and science who monitor the overall investigation.

The objective is to insure that the present investigation is as accurate and reliable as possible. The results will be carefully analyzed and scrutinized before being published in scientific literature.

It is believed that the resulting data will provide a sound and valid basis for general agreement on a national occupational noise exposure standard which will protect employees from occupational hearing loss without requiring wasteful or unnecessary expenditures.

The study is financed by individual companies and national industry associations, and has been budgeted at $100,000 per year for a period of three years.

Background

In consideration of the need for reliable scientific data on noise-induced hearing loss, we are immediately aware of the present inability to compare the results of one study with another. This is not surprising when one considers the many known variables which affect the total scene. Physical, physiological, psychological, and methodological aspects contribute to the introduction of nonuniform influences on recorded results.

Our primary concern, therefore, in this protocol is not only to state a series of conditions which prevail for the purposes of this study, but also to set forth a set of guidelines which are acceptable to the various disciplines of the scientific members of this study, plus all communities of scientists who may conduct future studies.

Thus, we conclude, we are deavoring to set forth governing parameters for all those who follow in the quest for scientifically valid evidence of the effects of noise on hearing loss. Whether the future investigators are American, European, or others; whether their concern is singular to an industry, an area, an ethnic population or whatever, we gain much in our collective analyses if direct comparisons are possible. Authorship characteristics become secondary to the weight of evidence in forming conclusions. This is not too much for which to hope. This is a vital necessity.

The acceptance of 90 dBA by federal agencies as the criterion for implementing hearing conservation programs in industry is based in part on reports of the Interindustry Committee on Guidelines for Noise Exposure Control. In effect, the guidelines indicated that at 90 dBA, approximately 10% more of the 50- to 59-year-old exposed populations will have hearing impairment than a similarly aged non-noise exposed popu-
lution. Some of the data used for these compilations have been challenged, especially since personnel with conductive deafness and non-noise induced deafness were not excluded from the studies. During 1968 to 1971, the National Institute for Occupational Safety and Health (NIOSH) undertook its own studies and handled their data much differently from the Inter-society Committee. They concluded that 85 dBA should be the criteria for implementing hearing conservation programs with a risk of 15% in the 55- to 70-year-old group. Their research data have not been published fully or made available for scientific evaluation. The relation of hearing to noise exposure in the range between 82 dBA and 92 dBA needs more explicit clarification. Reliable scientific data are simply not available at this time. (See "A Critique of Exhibit 1.")

An assessment of the hearing loss literature reveals that in practically all field studies and many laboratory studies at least one of the following shortcomings is a source of controversy: (1) Noise measurements were not sufficiently accurate. (2) Histories of duration of exposure were inadequate. (3) Otological examinations and histories were conducted by inexperienced persons. (4) Audiometry was done in an area of high background noise level. (5) Instrument calibration and audiometric technique were not identified or reported. (6) Temporary threshold shift due to recent noise exposure was not excluded. (7) Statistics and interpretations of results were questionable. (8) Proper controls were not used. (9) Employees with hearing losses due to infection, otosclerosis, and other non-noise-induced causes were not excluded from the study. (10) Noise exposures were not continuous or steady state and rarely were subjects exposed to steady-state noise in a narrow band within the broad range of 82 dBA to 92 dBA.

Objectives of the Study

The accurate determination of the extent and degree of hearing loss is basic to the establishment of valid damage risk criteria. It is not possible in the laboratory to carry out large-scale experiments in which irreversible hearing loss is produced in human subjects. Consequently, information on the production of permanent hearing loss in employees from noise exposure can only be obtained from a study of actual industrial exposure conditions.

For an accurate, detailed research study relating hearing loss to continuous exposure to intense noise, rigid requirements have been set. (1) The spectral and temporal characteristics of the noise exposure have to be clearly defined. (2) The duration and extent of the noise exposure have to be specified. (3) The individual whose audiogram is used in the study must have a record of no other exposure to intense noises.

The primary concern is to limit the research study to "continuous" exposure, that is, to exposure during the whole of the working day, every day of the working year, in a range of 82 dBA to 92 dBA, with no more than a five dBA range. Also, (insofar as practical industrial operation permits) the noise is limited to steady noise with a relatively smooth spectrum, that is, to noise with no sharp peak of sound pressure in any narrow frequency band. In this way, the complications that accompany intermittent exposures, impulsive noises, etc., are avoided. The subjects, both experimental and control, selected for study include men and women of all ages. If any of these men and women have had previous exposure to intense noise, both the noise and the exposure are being documented as well as possible.

Undoubtedly, the greatest cause for the lack of valid experimental conclusions relating industrial noise to hearing damage is the failure of the investigator to appreciate the limitations and problems that arise in industrial audiometry, such as: (a) Physical Variables — Improper placement of earphones. Ambient noise levels in test room. Equipment variables, such as accuracy of attenuator steps, type of earphone cushions, hum, noise, etc. (b) Physiological Variables — Age and Sex. Pathology of the auditory organs. General health of subject. Temporary threshold shift. Tinnitus and other head noise. (c) Psychological Variables — Motivation of subject. Momentary fluctuations of attention. Attitude toward the test situation. Personality attributes. Intellectual factors: Comprehension of instructions and experience in test taking of any sort. Response conditions: Type of response required of subject: i.e., button pressing, finger raising, verbal response, etc. (d) Methodological variables — Testing technique used. Time interval between successive tests. Instructions to subjects. Order of presentation of frequencies. Interpretation of thresholds if self-recording audiometry is used.

This investigation is designed to set up appropriate safeguards to avoid these and other pitfalls. There have been located, especially in the paper and textile industries, among others, jobs where workers are exposed all day to steady noise levels that vary no more than 5 dBA (± cross-sectional about 2.5 dBA) and fall within the range of 82 dBA to 92 dBA. It is expected to include in this study about 500 experimental test subjects who have been working in these constant noise levels a minimum of three years, and also include approximately the same number of control subjects who are not exposed to occupational noise greater than 75 dBA. All hearing testing, noise measurement, otologic examinations, histories, and data handling will be done by the research team in a standardized manner. Test and control subjects both are given two independent audiometric tests at each visit by the study team. This dual test approach is basically intended to produce a more reliable threshold as subjects become more sophisticated in test responses. The three visits at each test site provide six audiograms for cross-sectional analysis.

1. These factors have been demonstrated to influence audiometric measurements. Not all of these factors are of concern in the industrial hearing conservation program. The list is presented to illustrate the potential complexity of audiometry. (This information is adapted from "Guide for Conservation of Hearing in Noise" published by the Committee on Conservation of Hearing of the American Academy of Ophthalmology and Otalaryngology, 15 Second Street, Southwest, Rochester, Minnesota 55901.)

The final report will include an offer to make the original raw data available to serious investigators upon request. These include: audiograms, noise measurements, medical and work history questionnaires, and statistical management.

In-Plant Procedures

Subject Interview Procedure

Before the interview, an employee who
meets the criteria for the study is given an outline of the study procedure. He is given a summary of questions to be asked during the interview and told that all answers are voluntary and will be kept confidential. The subject is then asked to volunteer for the project.

The interviewer asks the questions as they appear on the form, and the responses are recorded. (See Questionnaire Exhibit 2.)

Additional information, including a whole life work history, use of hearing protection, any part-time employment is included. An otoscopic examination is included.

After completing the interview, the subject is asked if he can think of anything else which may have affected his hearing. Responses are recorded.

Equipment. — (1) Audiometers manufactured and calibrated to A.N.S.I. S-3.6, 1969, specifications for audiometers: Beltone 10-D and 12-D audiometers are used.

(2) Calibrators — Daily electro-acoustic calibration checks before and after testing of subjects are performed using a NBS type 9A coupler with a standard SLM; frequency checks are performed weekly. If calibration checks show that an audiometer does not meet A.N.S.I. specifications, the instrument is sent to a qualified laboratory for adjustment.

Sound level meters conform to the requirements of A.N.S.I. S-1.4, Type 1. An acoustical calibrator accurate to within ± 1 dBA is used to verify the before and after calibration of the sound measuring instrument. (2) Audiometric test rooms meet the A.N.S.I. S-3.1, 1960, (R. 1971) requirement for audiometric testing environments. (3) Records of Calibration. — (a) Records of all electro-acoustic calibration procedures are maintained. These include the date of the calibration procedure, the make, model, and serial number of the instrument being calibrated, the actual meter readings of the instrument being calibrated, and the calibrating technician. (b) Records of calibrating instruments are also maintained. Make, model, serial number, and calibrating procedures are recorded and dated. (c) In addition to electro-acoustic calibration records, listening and visual checks of the audiometer are made. These records include the date, audiometer serial number, make and model, jacks seated properly, earphone cords not frayed or broken, headband tension satisfactory, earphone cushion O.K., dials secure, tone presenter audible, no static, no crosstalk, volume increases and decreases, pitch O.K., and the name and signature of the examiner. (d) Records of noise levels in audiometric test rooms are maintained. Measurements are taken in the test area under conditions similar to those obtained during the actual experimental study. Test booth noise levels are measured daily.

Audiometric Technicians. — All technicians have as a minimum, a certificate obtained from a course approved by the Council for Accreditation in Occupational Hearing Conservation (CAOHC). These courses have as a minimum, the standards specified by the Intersociety Committee on Audiometric Technician Training. Audiologists have a certificate of clinical competence (CC) in audiology as awarded by the American Speech and Hearing Association (ASHA).

Audiometric Technique. — All technicians use the audiometric technique approved by CAOHC and described below:

1. Instructions to the Subject. — “Have you had your hearing checked before?” “Yes.”

“Tha’t’s fine — let me remind you what we’re going to do. You will be listening for some tones.

Each time you hear a tone, raise your finger (demonstrate) and lower it when the tone goes away. (demonstrate)

No matter how faint the tone, raise your finger when you hear it (demonstrate) and lower it when the tone goes away. (demonstrate) Do you hear better in one ear than the other?” “No”.

“Then we will check your right ear first.” If there is a difference, check the better ear first and advise the subject as such.

2. Determining Threshold. — The subject is seated in the booth in a profile position. Earphone selector switch set properly, frequency dial at 1KHz.

Present the tone and roll the hearing level dial slowly upward from 0 dBA until the subject responds. Release the tone.

Present the tone again at this level to confirm the initial response. If subject responds, interrupt the tone and decrease the intensity by 10 dB. Present the tone.

Generally there should be no response to this 10 dB reduction in intensity.

If no response, interrupt the tone, increase intensity 5 dB and present the tone.

If subject responds to this 5 dB increase, interrupt the tone and decrease by 5 dB.

If no response, interrupt the tone, increase by 5 dB and present the tone.

If subject responds, record as threshold.

The object is to obtain at least two “no”, and two “yes” responses always ending on a “yes” response. This technique is used to determine threshold at the following frequencies in the order listed:

First Ear. — 1000, 2000, 3000, 4000, 6000, 8000, 1000, 500 Second Ear. — 1000, 2000, 3000, 4000, 6000, 8000, 500

Note that two threshold readings are obtained at 1000 Hz in the first ear tested.

3. Two complete air-conduction audiograms are taken for each subject. See Audiogram Form: Exhibit 3. When time permits, these audiograms are performed five to ten minutes apart. On some occasions, time is limited, and the second audiogram is taken almost immediately after the first. In no instance does the examiner have visual access to previous audiograms for the subject being tested. After both audiograms are completed, the examiner compares the two audiograms. If a greater than ± 5 dBA difference is noted at any frequency, threshold for that frequency is checked again and recorded.

To eliminate TTS, experimental subjects are tested prior to the work shift, at least 14 to 16 hours after exposure to occupational noise. Additional questioning is provided to establish any interim noise exposure possibilities.

4. Control Subjects. — They are tested at any time during their work shift. TTS is not considered since by definition control subjects are not exposed to noise greater than 75 dBA.

5. Bone Conduction Testing. — If a hearing loss of 15 dB or more is noted at 500, 1000 or 2000 Hz, masked bone-conduction thresholds are obtained at those frequencies. This is performed only once on the ear(s) showing the above hearing loss. The subject is instructed to respond to the tone as before and to ignore the masking noise. The oscillator is placed on the mastoid, and the masking earphone is placed on the opposite ear. Sixty to 65 dBA white noise, masking, is used, if the nontest ear shows hearing
loss less than 20 dB. Seventy-five dB masking is used if the hearing loss in the lowest test ear is 25 dB or greater. Bone conduction thresholds are obtained using the procedure outlined for air conduction testing.

2. Audiogram Recording. — The following is recorded on each audiogram: subject number; plant number; experimental or control subject; age; sex; date of test; time of test; audiometer number; standard reference; exposure level; and signature of audiometrist.

3. Noise Measurement

1. Equipment: — SLM B & K 2209 Microphone B & K 4145 Octave filter set B & K 1613 Pistonphone B & K 4220 Environmental noise classifier B & K 166-B Calibrator B & K 4230

2. The sound level meter is calibrated before and after measurement. Date, time, department, and researcher's names are recorded. If noise levels meet the study criteria (82-92 dBA with no greater than 5 dBA range for experiments; 75 dBA or less for controls), then employees, area supervisors, and appropriate management personnel are consulted to determine if the noise levels have been present as measured for at least three years. This includes questions concerning movement of equipment into or out of the area, noise abatement, and changes in production speeds or processes. Adjacent areas which may affect sound levels in the study area are also checked. Work habits of potential experimental subjects are investigated to determine if their noise exposure is six or more hours per day. Work habits of the potential control subjects are investigated to insure that the noise levels to which they are exposed do not exceed 75 dBA during a work day.

3. Documentation of Sound Levels. — A block diagram of the study area is drawn showing noise sources and work positions. Noise measurements are made at representative operator positions and their locations plotted on the diagram. Batteries are checked, and the meter is calibrated before and after each set of noise measurements. Date, time, plant code, number, department, and researcher's names are recorded. All measurements are made at operator's ear level while operator is not there and include "A" scale: slow response and linear: slow response. Octave band analyses, 31.5 Hz through 16 KHz are made at the same positions as "A" scale and linear measurements, but are performed at every fourth or fifth measurement point. "A" scale and linear readings are obtained in break and lunch areas, high noise areas used by subjects in transit, and other areas subjects may visit during a work day. Three continuous sets of noise measurements are made on each shift from which subjects are taken. Measurements are made on different days and at different times. Throughout the documentation of sound levels, extreme caution is taken to establish that the entire study area does not exceed the specified criterion of no more than a 5 dBA range.

4. Environmental noise is used to further record noise levels. The instrument is positioned at a representative workstation, operator's ear level, and operates until the end of the shift. The unit is calibrated at the site before and after measurement.

5. During the process of noise measurement and on subsequent visits to the work area, subject movement within and without the area is studied. Conversation with subjects at these times is often helpful in describing actual time spent in the noise area. This information augments that obtained through the subject's formal interview and interviews with supervisors and management personnel.

6. Subject interviews and, when possible, reviews of personnel records, provide in-plant work histories. "A" scale and linear noise measurements are made in departments where subjects have previously worked. If the department in question has been moved or eliminated, an estimate of noise level is made.

7. A chronological history of work experience outside the study plant is obtained during the subject's interview. Since sound levels cannot be measured at these locations, estimates of noise levels are made on the basis of experience with similar industries, in an effort to determine that there has been no greater past exposure.

8. All available information for each subject is then gathered together and a chronology of noise exposure is developed.

Note. — The sound measurement procedure will be amended to include the use of a flexible extension rod, B & K part UA 0196, mounted on the sound level meter. Revisits to plants where measurements were made without the extension rod, measurements will be made both with and without the extension. Differences, if any, will be noted. The use of the extension provides increased accuracy of high frequency sound measurements.

Revisits to Study Plants

Revisits to plants are made between 10 and 12 months after the previous visit. Notes are reviewed and additional information is obtained as required from the personnel. Technicians do not have visual access to previous audiograms.

1. Audiometry. — Adherence to the previously described method is maintained. Two audiograms are taken on each subject. Experimental subjects are tested before their work shift. Control subjects are tested at any time during the work day.

2. Interviews. — Prior to the hearing test, each subject is interviewed briefly to determine if: (1) He has worked on the same job since the last test. (2) He has had any changes in duties. (3) Any machinery in his work area has been modified, moved, eliminated, or added. (4) He has experienced any middle ear disease during the past year.

An otoscopic examination is performed after the hearing test.

Management and supervisory personnel are questioned concerning any changes in the work environment, duties, or work habits of subjects.

3. Noise Measurements. — Noise measurements are made using the previously described procedure at points identified on earlier visits. Noise levels are measured only in the experimental or control areas where subjects are currently working, not in those areas where subjects may have worked before employment in study areas.

One set of noise measurements is made on each shift from which subjects were taken. Measurements agree within +3 dBA of the earlier measurements, the noise is considered to have remained stable over the past year. If a greater than +3 dBA variation is noted at one or more points, two additional sets of noise measurements are made at the points in question. Possible reasons for the difference are noted.

Statistical Analysis

Prior to the complete analysis of the data, the audiometric data will not be available to anyone except those who will analyze the data.

Exclusions. — All information collected for the study will be included and available for analysis. Exclusions of certain items will be made only for the purpose of conducting special studies. However, the results of every analysis will be included in the report; and all of the raw data will be presented. (See Exhibit 4)

Types of Analyses. — It is not possible to specify a single type of analysis for all the data collected in the study because the data will be used for different purposes to achieve a variety of objectives.

In general, parametric and nonparametric analyses will be considered. Where parametric analyses can be done (i.e., where the variables are approximately normally distributed), a stepwise regression analysis will be undertaken. The hearing threshold level will be the dependent variable; and the independent variables will be age, intensity of exposure in the current job, duration of exposure in the current job, and where possible, intensity and duration of exposure in previous jobs.

Separate analyses will be done for each test frequency and for males and females.

If the distributions of hearing threshold levels are so badly skewed as to preclude parametric analysis, nonparametric analysis will be done. Categories will be established for each of the independent variables, and median hearing levels calculated for each category.

It may also be possible to perform a discriminant function analysis, where the dichotomy will be the presence or absence of hearing impairment.

Special Problems. — 1. Selection of the Audiogram. — At least two audiograms are taken on each subject at each of three visits. Since the second or subsequent audiograms are taken after the subject has become familiar with the test, the last audiogram is probably the most reliable. Therefore, it will be used in the analysis. However, if comparisons are to be made with audiograms taken in audiogram will be used because in that the U.S. National Health Survey, the first survey only one audiogram was taken.

2. Otologic Criteria for Screening. — It is well established in otolaryngology that excessive steady-state noise exposure is well established in otolaryngology that excessive steady-state noise exposure over long periods of time produces only sensorineural deafness and not conductive deafness. It is also known that damage is initial and more severe in the higher frequencies than in the lower frequencies. Otologists also agree that severe unilateral deafness in all frequencies, with normal hearing in the opposite ear, is not produced by long-term steady-state free field noise exposure.

The following criteria will be used to screen out those individuals in both the control and experimental groups whose audiograms show the following characteristics: (a) Bilateral nerve deafness greater than 70 dB in all test frequencies in both ears. (b) Individuals with ascending hearing losses in which the lower frequency thresholds at 500, 1000, and 2000 Hz are 40 dB or more, while the higher frequencies show thresholds of less than 15 dB. (c) Individuals with normal hearing in one ear and 60 dB thresholds or more at 500, 1000, and 2000 in the opposite ear. (d) Individuals who have over 20 dB hearing levels at 500, 1000, and 2000 cycles and who show an air-bone gap of at least 15 dB at all these frequencies.

In addition, on the basis of history, individuals will be eliminated from both the control and experimental groups who have the following findings: (a) Individuals with perforated eardrums. (b) Individuals with evidence of mastoid surgery such as postauricular or endaural scars or absent eardrums. (c) Individuals with previous histories of stapes surgery or fenestration surgery. (d) Individuals with a history of mumps or head injuries followed by unilateral deafness. (e) Individuals with severe sudden unilateral deafness over 40 dB in all frequencies.

3. In all instances, the audiograms and history will be screened without identification as to whether the individual was in the experimental or control group.

In the event that there is any question as to whether an individual should be excluded from the study, a board of five otologists and audiologists will evaluate each audiogram without knowledge of whether it be in the experimental or control group, and the majority will prevail.

All cases from both groups that are excluded from this investigation will be described in the report, and the reason for exclusion will be identified. Analyses will be made including and excluding these cases to determine effect, if any.

4. Noise Level Ranges. — It is not possible to get subjects whose exposure to noise does not vary during the course of a working day. Therefore, the data will be analyzed according to the range of the noise level.

First, analyses will be restricted to subjects whose noise exposure ranges from 2 dB to 9 dB. Then analyses will be made where the range is 2-3 dB, 4-5 dB, and 6-7 dB. If no analyses will be made where the range was larger than 8 dB.

For each pass, data will be analyzed as if the intensity was at the low, middle, and high points.

5. Selection of the Ear. — Data will be analyzed separately for the right and left ears, and for unprotected ears and ears with protective devices. Data will be analyzed separately for the right ear, better ear, worse ear, the average of both ears, and for various definitions of hearing impairment.

The analyses will be done separately for each test frequency.

6. Analyses by Site. — Data will be analyzed for each site individually. Controls and experimental groups will be compared among sites to determine if the pooling of data from various sites is feasible.

7. Other Considerations. — All analyses will be separate for males and females. The same kinds of analyses will be applied to both the experimental and control groups.

References


Monitoring Committees
Inter-Industry Noise Study
Steering Committee
Edward J. Baier
Deputy Director
National Institute for Occupational Safety and Health
Daniel C. Braun, M.D.
President
Industrial Health Foundation
Wayne T. Brooks
Director
Occupational Safety and Health Services
Organization Resources Counselors, Inc.
Angelo J. Cefalo
Assistant to the President
International Association of Machinists, AFL-CIO
James P. Dunn, M.D.
Assistant General Medical Director
Western Electric Company
F. Sadier Love
Secretary-Treasurer
American Textile Manufacturers Institute, Inc.
John P. Markey
Coordinator, OSHA Activities
Industrial Relations Division
Edison Electric Institute
Vernon McDougall
Industrial Hygienist
United Paperworks International Union
Burk E. McGarahan
Corporate Safety Manager
Mead Corporation
George D. Melex
Manager, Washington Corporate Office
Ingersoll-Rand
Frank F. Murtha
Assistant, Employee Relations Counsel
American Can Company
Joseph Satloff, M.D.
L.T. Savory
Technical Advisor
Penzoil Company
William D. Schaeffer
Director
Environmental Conservation Board
Graphics Communications Industries, Inc.
Geoffrey M. Stein
Director of Safety & Industrial Relations Services
Forging Industry Association
Charles N. Sumwalt, Jr.
President
Hearing Conservation Noise Control, Inc.
Leo Teplow
Special Consultant
Organization Resources Counselors, Inc.
Robert P. Timmerman
President
Grantsville Company
Royd A. Van Atta, Ph.D.
Occupational Safety & Health Administration
U.S. Department of Labor
Michael World
International Representative
International Brotherhood of Boilermakers, Iron Shipbuilders, Blacksmiths, Forgers & Helpers
Raymond A. Yerg, M.D.
Director
Medicine, Health & Safety
American Can Company

Steering Committee. — This committee meets quarterly and has the following functions: (1) Insure that Study is oriented properly. (2) Insure that funds are wisely used and accounted for. (3) Receive and evaluate periodic reports. (4) Establish and maintain liaison with participating companies. (5) Recommend changes in the program. (6) Facilitate the conduct of the research. (7) Disseminate the results. (8) Publicize the Study. (9) Verify union-management cooperation and understanding. (10) Maintain liaison with the scientific advisory committee.

Scientific Advisory Committee
Members
Sidney Pell, Ph.D.
E. I. du Pont de Nemours & Company
Employee Relations Department
Medical Division
Wilmington, Del.
Rudolph Gosztonyi, M.D.
Ingersoll Rand Company
Phillipsburg, N.J.
Harold Imbus, M.D.
Burlington Industries
Greensboro, N.C.
Robert Benson, Ph.D.
Boniton, Inc.
633 Thompson Lane
Nashville, Tenn.
George Diehl, Ph.D.
Ingersoll Rand Company
Phillipsburg, N.J.
Terry Henderson, Ph.D.
Department of Health and Welfare
Bureau of Occupational Safety & Health
Cincinnati, Ohio
Royd Van Atta, Ph.D.
Bureau of Labor Standards
U.S. Department of Labor
Washington, D.C.
Leo Doerfler, Ph.D.
Eye & Ear Hospital of Pittsburgh
230 Lathrop St.
Pittsburgh, Pa.
Mansfield F. W. Smith, M.D.
American Council of Otolaryngology
751 South Bascom Ave.
San Jose, Calif.
Hymen Menduke, Ph.D.
Thomas Jefferson University
Sixteenth and Walnut Streets
W. Dixon Ward, Ph.D.
2630 University Avenue, S.E.
Minneapolis, Minn.
Joseph Huntley
A. T. M. I.
1501 Johnson Building
Charlotte, N.C.
John Fletcher, Ph.D.
5505 North Clover Drive
Memphis, Tenn.
Vaughn Hill, Ph.D.
E. I. du Pont de Nemours & Company
Wilmington, Del.
C. A. Wold
C. A. Wold & Associates
P.O. Box 8202
Boise, Idaho
James Botterford
Howard Engineering Company
P.O. Box 3164
Bethlehem, Pa.
Karl Kyrer
Bilt, Barenk & Newman
50 Molton St.
Cambridge, Mass.

Scientific Advisory Committee. — These members from Scientific communities have the following functions: (1) Establish criteria on all scientific and medical aspects, including subject selection. (2) Audit plant sites by spot visits to certify technique and rigid adherence to specifications. (3) Establish statistical analysis and management procedures. (4) Establish in-plant procedures including subject interview testing, questionnaire design, noise measurement techniques. (5) Provide on-going review of all procedures and recommend changes where indicated. (6) Critique past noise induced hearing loss studies. (7) Edit final results before publication. (8) Establish procedure for orderly handling of public requests for raw data; and (9) Maintain liaison with steering committee.
Exhibit 1
A. Critique of Research Data Relating Hearing Level to Exposure to Noise Below 90 dBA

W. Dixon Ward, Ph.D. and Aram Glorig, M.D.

The Department of Labor is proposing a noise exposure standard for American industry. This standard specifies basically that for steady-state noise exposure above 90 dBA for an eight-hour work day, every industry must institute feasible noise control measures and that above 85 dBA for an eight-hour day a hearing conservation program must be maintained. Vigorous exception to this standard has been taken by the Environmental Protection Agency (EPA), apparently on the basis of their so-called "levels" document (EPA 550/9-74-004, March 1974). The levels document, prepared to meet one of the tasks mandated by congress in the Noise Control Act of 1972, contends that an 8-hour exposure level of 75 dBA should not be exceeded if any measurable change in hearing (no more than 5 dBA at the most sensitive frequency) is to be avoided in 90% of the workers exposed for ten years or more. The EPA is therefore promoting the adoption of levels lower than those proposed by the Department of Labor. The ultimate goal of the EPA — to protect everyone against everything — is of course commendable. However, the justification for a lower level, in view of the costs of implementing it, can be seriously questioned. Clearly, the effects of noise levels between 75 and 90 dBA should be subjected to close scrutiny.

Unfortunately, however, few studies of industrial hearing loss have concentrated on noise levels in this range, and even these have serious shortcomings that make their results ambiguous. The purpose of this note is to itemize some shortcomings in the two studies that formed the primary basis for current proposal, those of Baughn (1973) and of Burns and Robinson (1970), in order to emphasize that additional data must be gathered before the hazard to hearing of an 8-hour exposure to noise levels below 90 dBA can be adequately assessed.

The Baughn study is an analysis of 8,835 audiograms from "employees of a midwestern industrial plant producing automobile parts" (p. 2). This represents, it is said, "a little more than one third of all audiograms taken from this population . . . from 1960 through 1965." (The remainder) were eliminated from the study because the subjects had significant unknown or mixed "exposures" (p. 1). These 8,835 audiograms (presumably from 8,835 different workers, although the point is never made explicit) were assigned to groups called "78 dBA", "86 dBA" and "92 dBA" depending on which of these noise levels the particular worker's average exposure seemed to be closest to. Now, the noise environments found in automobile manufacturing plants are not those usually considered to be really steady-state; as Baughn states, "the 86 dBA noises tend to be principally associated with light assembly operations on thin metal, plastic, wood and glass. The 92 dBA exposure arise largely from press operations, grinding and heavier assembly operations." The range of variability is illustrated by this description: "the group assigned 86 dBA spent 65% of their work time at 96 plus or minus 3 dBA, 80% at 86 dBA plus or minus 5 dBA, and not more than 2% at above 92 and below 78 dBA combined." To draw conclusions about the effect of steady noise exposure on hearing on the basis of these rather variable noise environments, contaminated heavily with impact-noise components, and to use these conclusions as the basis for a national noise standard is questionable.

Most of the Baughn report is devoted to statistical manipulation, smoothing of curves, and extrapolation to 115 dBA (1) of the "risk" expected; details of the audiometric procedure are only briefly mentioned. However, in an earlier letter to Dr. H. O. Parrack (a letter that is otherwise substantially the same as the report under discussion), Baughn included a sample data sheet, this data sheet, with names of individuals eliminated, is shown in Figure A. This data sheet permits two important deductions about the audiometry of the audiometric environment was not good enough to measure normal hearing. Notice that in this entire group of 26 ears of 13 workers, no ear indicated a Hearing Level (HL) of better than +5 at 500 or 1000 Hz, although several values of -5 and even -10 would normally be found. The presence of masking is indeed admitted by Baughn (p. 27). Somewhat more serious is the inference that the audiometrician responsible for this data was not familiar with the equipment used or with standard recording procedures. Note the entry for the right ear of worker No. 5 for 8000 Hz: viz., "below 100." At 8000 Hz, on the audiometer used (Maico H-1), correct values of HL can be measured only up to 80 dB. This fact should have been known to the audiometrician; that it apparently was not raises doubt about other aspects of the audiometry as well.

However, masking noise and tester naivete will presumably act approximately equally on all three of the exposure groups. So although masking will of course tend to inflate considerably the number of persons that appear to have "handicapping" loss, even average HL in excess of 25 dB (ISO at 500, 1000, and 2000 Hz) — this would not explain why the 852 workers in "78 dBA" indicated less average hearing loss, and the 833 in "92 dBA" indicated more,
more than 5 dB, it is clear that Baughn's data do not prove that 92 dB produces any more permanent hearing loss than 78 dB. We contend that the combined shortcomings of non-steady-state exposures, auditory fatigue, test-room masking and inadequate training of technicians render this data essentially meaningless in regard to auditory hazard.

The second study, that of Burns and Robinson, is much more sophisticated. After all the averaging and smoothing, the data of Burns and Robinson's final idealized curves imply that a lifetime of daily exposure to 80 dB will produce an increase in the hearing threshold that will produce no change whatever in regard to auditory levels of less than 90 dB. A large fraction had exposures that cannot be considered "steady".

After all the averaging and smoothing, the data of Burns and Robinson's final idealized curves imply that a lifetime of daily exposure to 80 dB is the highest that will produce no change whatever (their Figure 10.1, p. 108). However, if one inspects what little they show us of the original unmanipulated data, then the alleged hazard associated with levels below 90 dB is seen to be anything but firmly established. For example, their Figure 10.22, p. 140, indicates that there is less than a 1-decibel difference between the hearing levels of men exposed to noise in which "Lw" (the noise level exceeded only 2% of the time) was 80-89 dB and those for whom this level was 90-94 dB, although those exposed to 95-99 dB showed considerably more
Exhibit 2
INTER-INDUSTRY NOISE STUDY
QUESTIONNAIRE

Identification Code No. ________________________ Dept. ______ Place of Birth ____________ Sex ____________

Demographics: Birth Date/Age ____________ Hire Date ____________

A. Military
1. Were you ever in the Military service? No _____ Yes _____ Branch _________ Years _________
   Did you have more than one job? Yes _____ No _____
2. Did you have basic training? No _____ Yes _____ How long? ____________
   Were you ever on the practice firing range? No _____ Yes _____ How many times? ________
   Approximately how many rounds did you fire? None ________ Exact number ________
   If you do not know, was it: Few (less than 50) ________ Many (more than 50) ________
3. Were you in combat? No _____ Yes _____ How long? ____________
   What firearms did you use? None ________ Small arms ________ Machine guns ________ Artillery ________
4. Were you assigned to heavy equipment? No _____ Yes _____

B. Work History (Occupational Noise-exposure)
1. Before your present employment, did you work in any noisy jobs? No _____ Yes _____
   How long were you in this noise? Years ________ Months ________
2. How long have you worked in your present job? More than 3 years? No _____ Yes _____
   If yes, estimate the number of hours per day you are at or near your machine ________
3. Is the noise where you work equally loud all the time? No _____ Yes _____
   If no, are the changes in loudness large (easily noticeable)? No _____ Yes _____
   If yes, are the changes frequent or infrequent ________
   If frequent, how many times do the changes occur? ________
4. Do you work more than eight hours a day? No _____ Yes _____
   If yes, is the overtime spent at your usual job? No _____ Yes _____
   If no, is your overtime spent in a job that is noisy? No _____ Yes _____
   If yes, is it less noisy ________ or more noisy ________ than your usual job?
5. How much overtime do you work per day? Hours ________

C. Non-Occupational (Non-Military) Noise Exposure History
1. Do any of your non-occupational activities involve, or have they involved, noise-exposure? No _____ Yes _____
   If yes, which of the following:

<table>
<thead>
<tr>
<th>Activity</th>
<th>No. of Yrs.</th>
<th>Caliber of Guns</th>
<th>No. Rounds/Yr.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hunting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skeet Shooting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rifle Shooting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pistol Shooting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flying</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   | Flying: No _____ Yes _____
   | If yes, how much flying do you do? Five or more hours per month ________ Less than five hours per month ________
   | If five or more how much in hours per month? ________
   | What kind of plane do you fly? Piston engine ________ Turbo jet ________ Jet ________
   | How long have you been flying regularly? Years ________
2. Do you have any hobbies? No _____ Yes _____
   Activity Years of Use Hours/Month Activity Years of Use Hours/Month
   Wood Working          Motor Boats
   Metal Working         Chain Saws
   Model Airplanes       Grinders
   Go-Carts              Riveters
   Motorcycles           Air-driven Tools
   Drag Racing           Explosive-driven Tools
   Auto Racing           Powered Wood Working Tools

3. Any other noisy non-occupational, non-military pursuits subject has knowledge of? No _____ Yes _____
   If yes, what is noise due to? ________
   How long? Total time involved in years Total time per month ________

D. Otological History
1. Does anyone in your family have a hearing loss? No _____ Yes _____
   If yes, who? Mother ________ Father ________ Brother ________ Sister ________ Other ________
2. How old was (were) the relative (relatives) when the hearing loss started or was complained of? ________
   If age is not known was the person over 40 ________ under 40 ________
3. Did the hearing loss occur suddenly ________ or gradually ________
4. Do you think your hearing is: Good ________ Fair ________ Poor ________
5. Do you think you have a hearing loss in one ear only? No _____ Yes _____
   If yes, Right ________ Left ________
6. If not good, do you have difficulty understanding ________ hearing in noisy situations ________ hearing in movies or church
   at home ________ on the job ________
7. When did you first notice difficulty ________ continues on following page

Protocol of Inter-Industry Noise Study/

9. Have you had your hearing tested before? No. Yes. 
   How? With an audiometer (Machine)? By spoken voice? 
   With tuning forks? Other.

    If yes, did you receive treatment? No. Yes. 

11. Have you ever had:

<table>
<thead>
<tr>
<th>Symptom</th>
<th>R</th>
<th>L</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earaches</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ringing in ears</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Age of onset: 
How long did it last? Years: Months: Any treatment? No. Yes.

E. Otoscopic Examination

1. Is external ear and canal normal? No. Yes.
   If no, answer the following:
   Ear flap: very small
   wrong shape
   parts missing
   absent
   other
   Ear canal: very small
   very large
   normal opening
   slit like opening
   closed
   drumhead not seen

2. Is wax present? No. R. L. Yes. R. L.
   If yes, is drumhead visible? No. R. L. Yes. R. L.
   If yes, does drumhead look normal? No. R. L. Yes. R. L.
   If no, is cone of light seen? No. R. L. Yes. R. L.
   is drumhead perforated? No. R. L. Yes. R. L.
   is drumhead scarred? No. R. L. Yes. R. L.
   is drumhead reddish in color? No. R. L. Yes. R. L.
   is drumhead yellow? No. R. L. Yes. R. L.
   is drumhead grayish? No. R. L. Yes. R. L.

F. General Health

1. Do you know of any general health problems you have? No. Yes.
   If yes, which of the following:
   High blood pressure
   Diabetes:
   Allergy
   Thorax problem:
   Sinusitis:
   Sinusitis, Mild
   Sinusitis, Moderate
   Sinusitis, Severe
   Dizzy spells, Occasional (once or twice a year)
   Frequent (once or twice a month)
   Very Frequent (once or twice a week)
   Other


G. General Health History

1. Have you ever been knocked unconscious? No. Yes.
   If yes, how many times?
   How long were you unconscious each time: a few minutes? a few days?

2. Have you ever been hospitalized? No. Yes.
   If yes, how many times?
   Total time in hospital: Days Weeks Months
   Reason for surgery?
   Non-surgical illness?
   Examination only?

3. Did you have a normal birth? Yes. No.
   If no, was it: long labor? illness in your mother? premature birth? other?

4. Have you ever had very high fever (over 103°) for more than a day or two? No. Yes.
   If yes, how old were you? Years Months

5. How long did it last? days.

6. Have you ever had any of the following:
   • Bed sores
   • Tonsils removed
   • Mouth breathing
   • Mumps
   • Frequent colds
   • Meningitis
   • Encephalitis
   • Streptomycin
   • Neomycin
   • Kanomycin
   • Quinine
   • Large amounts of aspirin

Yes. No.
In short, a significant loss to be produced only when the level exceeds 95 dBA. What this means in terms of the average or median exposure level (Lₐₐ) can only be surmised, since they publish no comparable data using Lₐₐ, and merely compute that "the difference (Lₐₐ-Lₐₐ) ranged generally from 0 to 10 dB" (p. 97). If one assumes an average difference of 5 dB, then an Lₐₐ of 95 dBA would correspond to an Lₐₐ of 90 dBA, which is precisely the figure in the Department of Labor's proposed standard.

There are other possible sources of error in Burns and Robinson's study. For example, all tests were on a voluntary basis, so that self-selection factors could operate. Furthermore, one of their requirements for inclusion in the study as "otologically normal" was that the audiogram be "compatible with clinical findings" (p. 90), which would seem to permit rejecting audiograms from analysis if they showed a severe loss for which no plausible explanation could be found in the individual's history (although the principles used for exclusion are never stated specifically and unequivocally). However, even if these are unimportant, it is clear that we are still in doubt about the level at which a daily industrial noise exposure begins to have a measurable effect. We feel that the verdict must await further evidence; even if economic considerations were completely ignored, lowering the 8-hour standard from 90 down to 85 dBA at this time would be premature and ill considered.

### References

---

### Exhibit 3

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Last</th>
<th>First</th>
<th>Middle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service Date</td>
<td>Right Ear</td>
<td>Left Ear</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>500</td>
<td>1000</td>
<td>1500</td>
</tr>
<tr>
<td>Date</td>
<td>500</td>
<td>1000</td>
<td>1500</td>
</tr>
</tbody>
</table>

**HISTORY:** Anyone in your family have hearing loss? Is your hearing—Good? Fair? Poor?

Ever had previous measurement? Where? Been in military service?

Exposed to any gunfire or loud noises? Ever had infections (running ear)?

Ever had surgery on either ear? Explain.

What antibiotics or other drugs have you taken? What contagious diseases have you had?

Ever worked at a very noisy job? If yes, where, type job, length of time.

Ever had resonant? What type, when does it occur?

Have you ever had noises in your ears? What does it sound like?

Do you have any noisy hobbies? Do you have a second job?

---

### Exhibit 4

The methodology of all data collection was reviewed by Hymen Menduke, PhD, Statistical Consultant and member of the Scientific Advisory Committee. His conclusions are:

For each subject, we do have the plant identification number, the status of the subject as either experimental or control (and, if control, whether office or production worker), the subject identification number, the age and the sex. Each subject is also identified as having either no visible abnormality, definite abnormality or questionable abnormality. For each subject, we have noise level in current job with months of exposure and noise level in previous job with months of exposure. These noise levels are necessary sometimes ranges rather than exact single numbers.

I am impressed with the obvious care taken by Mr. Loyborg and staff and I see no reason for concern with respect to completeness or quality of data.

Protocol of Inter-Industry Noise Study/