PLAINTIFF'S EXHIBIT

IHF-515

INDUSTRIAL HYGIENE FOUNDATION OF AMERICA, Inc.

Engineering Series, Bulletin No. 5



International Audiometric Zero

4400 Fifth Avenue
Pittsburgh, Pennsylvania
1963

01 132 1912

INTRODUCTION

The purpose of this Bulletin is to provide Industrial Hygiene Foundation member companies with timely and accurate advice concerning a matter currently under deliberation in the American Standards Association Committee S3.

The Foundation expresses appreciation to American Industrial Hygiene Association for its cooperation in supplying the detailed information on which this report is based.

01 132 1913

The pure tone audiometer, used exclusively in industrial hearing conservation programs, is an electro-acoustic device designed for measuring an individual's hearing acuity. It introduces tones of discrete frequencies into the ear in order to determine the faintest sounds an individual can hear. These thresholds of audibility, expressed relative to an established normal, are used for numerically rating hearing ability. Various formulas have been devised for converting these threshold values into a single number intended to rate hearing impairment.

The American Standards Association (ASA) has adopted standard specifications for the type of audiometers that are commonly used in industrial audiometry.[1,2] The standards are intended to make sure that an audiometer will accurately perform the job that is expected of it. Among the specifications in these standards are the reference hearing threshold levels. These are the intensity levels, at each test frequency, that are considered as the normal threshold of hearing. New reference levels have been proposed by the International Standards Organization (ISO) and these new values are now being proposed by the ASA for inclusion in the revised standard for audiometers.

In the present ASA Audiometer Standards (Z24.5-1951 and Z24.12-1952), the normal threshold of hearing is defined as follows:

> "The normal threshold of audibility for air conduction at a given frequency is the modal value of the minimum sound pressures at the entrance to the ear canal which produces a pitch sensation in a large number of normal ears of individuals between 18 and 30 years of age. The threshold values accepted for the purpose of this specification shall be those determined by the National Health Survey 1935-36."

01 132 1914

In the cited health survey[4] some 8310 subjects ranging in age from 8 to 90 years were examined. From this number, a smaller group was selected as those having normal hearing. This smaller group consisted of less than 15% of the 8310 persons studied. None had a clinical history of speech impairment and no audiogram showed variations of more than 20 db for each of the frequencies tested from 64 to 8192 cps. The ASA reference levels based on the USPHS survey are shown in Table I.

Table I -- A Comparison of ASA-1951 and ISO-1963 Reference Hearing Threshold Levels

Frequency, cps	Reference Threshold Level, db		
	ASA-1951*	ISO-1963	Difference
125	54.5	45.5	9.0
250	39.5	24.5	15.0
500	25.0	11.0	14.0
1000	16.5	6.5	10.0
1500	(16.5)	6.5	10.0
2000	17.0	8.5	8.5
3000	(16.0)	7.5	8.5
4000	15.0	9.0	6.0
6000	(17.5)	8.0	9.5
8000	21.0	9.5	11.5

* The figures in parentheses are interpolations.

Present day audiometers vary the intensity of each tone in five decibel steps above and below the reference levels. For each measurement, the reference threshold level at each frequency is subtracted from the measured threshold of audibility in order to determine an individual's characteristic "hearing loss". Subtraction of the reference level from the level introduced to the ear is done automatically by appropriately marking the intensity control knob.

01 132 1915

For several years, the ASA Committee on Bio-acoustics (S3) has been engaged in revision of the current specifications of audiometers. From the start of their work, it apparently was understood that their standard would include the reference levels agreed upon by the ISO. Subsequently, Group S3-W-35 prepared the ASA Specifications for Audiometers S3.6/60 intended to supersede all of the present audiometer standards. Among the changes, and of principal interest here, was the adoption of the ISO recommended standard reference levels. Because some objections were expressed about the new reference levels during balloting, Committee S3 voted to resubmit the entire document to another letter ballot. This was intended to give all interested parties an opportunity to reconsider the document since it was known that the procedure would take about a year to complete.

What are the values that prompted the objections and where did they come from? The values came from the ISO Technical Committee 43 (Acoustics). One of its concerns was the establishment of an international reference zero for the calibration of pure tone audiometers. An ISO document[5] has been circulated for approval as an ISO Recommendation and its approval seems almost certain. The reference levels recommended in this document, as shown in Table I, represent greater hearing acuity than the older ASA levels and range from 6-15 db below them.

The proposed values have a solid foundation and are not the product of whims and fancies.[3,6] The ISO has had audiometer reference threshold levels under consideration since 1955. Their recommended levels are based on fifteen different studies, more than half of them American, made between 1950 and 1961. In the preparation of these values, the national standardizing laboratories of five countries were involved

01 132 1916

It is intended that the new reference levels represent a truer picture of normal hearing thresholds. One important reason for the ISO's desire to change the ASA-1951 reference levels was the recent studies' indication that the older values were distorted as regards frequency. The variations are shown in the "Differences" column of Table I. The ISO group felt that these distorted values have led to erroneous generalizations about human hearing.

There has also been the feeling expressed that the present standard "condones laxity (and) defers (at the expense of the patient's well-being) initiation of therapy."(3) This point is open to question.

There is no doubt that there are justifications for changing the reference threshold levels. However, there are disadvantages as well as advantages involved and both must be considered. Changing ASA-1951 to conform with the ISO recommendations will also produce widespread deleterious effects in this country.

The vast majority of audiometers used today are in the United States. As such, almost all of them will be calibrated according to ASA-1951. Therefore, if the American users (approximately 30,000) are to conform to a revised standard, they must recalibrate or replace their existing instruments or correct their readings accordingly. It must be realized that many of these audiometer users, for one reason or another, alter neither their equipment nor their readings. Therefore, it seems clear that with a change there will be a considerable time during which there will be an intermixing of audiometric values, those based on the new and those on the old zero references. Much confusion is likely during the transition period.

01 132 1917

All formulas currently being used to determine hearing impairment will have to be revised to take into account new normal hearing threshold levels. All of these formulas, based on the present ASA Standard, convert hearing threshold levels at several frequencies into a single figure that represents the percentage of hearing impairment. Therefore, unless the ISO-based threshold values are adjusted, the resulting impairment figure will be incorrect.

In order to calculate percentage of hearing impairment, the American Medical Association recommends that the hearing threshold levels at 500, 1000, and 2000 cps be averaged.[7] Impairment is assessed at the rate of 1 1/2% for each decibel that the threshold level is above 15 db. The 15 db "low fence" is used because it is felt that there is no impairment below this value. An ISO-calibrated audiometer would increase the average of the 500, 1000, and 2000 cps readings by about 11 db above that which would be obtained by an ASA-calibrated instrument. Therefore, in order than an impairment figure, based on readings from an ISO-calibrated audiometer, be correct, it would be necessary to increase the "low fence" to 26 db. If the deduction were not increased to 26 db, the percentage impairment values, as calculated by the present method and using ISO values, will be increased by 16.5%

Several states have adopted by legislative action or administrative ruling, formulas to be used for determining hearing disability. They all rely on audiometric values. Therefore, any change in audiometer zero will affect the determinations of disability the same way that they affect those of impairment. The rulings and laws must be changed if the existing concepts of rating hearing disability are to be maintained. Otherwise,

01 132 1918

hearing disability rating procedures will probably be upset by a seemingly innocent change in the standard. Although conversion of figures based on one reference to those of another is a simple matter for technical people, it must be remembered that non-technical people process hearing loss claims. The non-technical viewpoints of these persons may cause them to discount the need for conversion in order to obtain a true estimate of impairment.

Related standards will also be affected by reference level changes in the audiometer standard. For example, ASA Z24.22-1957, for evaluating ear protector performance, states that listeners should have no more than 10 db hearing loss in either ear at any frequency. Therefore, a change in audiometer zero will result in more stringent requirements for the listeners.

Also, the standard for allowable background noise in audiometer rooms will be affected.[9] It is conceivable that permissible ambient noise levels might be lowered by as much as 15 db in order to permit measurement of hearing acuity at the ISO zero levels. Such a revision would require further quieting of the testing environments. In industry, even now it is sometimes difficult to get below the present maximum permissible levels, especially at low frequencies. Current users of audiometers have purchased their instruments and testing rooms that conform with present standards. Thousands of audiograms have been collected. If the proposed standard is adopted, the users must modify or replace their audiometers, or apply a calibration correction to all of their figures. Audiometer test booths meeting ASA standards usually cost in excess of $1000. To reach the new standards, cost of such booths would increase several orders of magnitude.

01 132 1919

It seems appropriate at this point to inject a plea for stable reference levels. At this time, ASA Committee S3 must decide whether or not it is of sufficient importance to change the existing audiometric reference levels to conform more closely with current concepts of "normal" hearing thresholds. Although some groups may find it more convenient if the proposed changes are made, others will not. It is not essential that such changes be made because it is always a simple matter to express the latest "normals" in terms of any reference level.

Changing reference levels must not be a casual procedure. If future studies show that neither the ISO nor the ASA zeros are realistic, this should not be sufficient justification for attempting another change. We are making frivolous use of reference levels if we change them every time we obtain new norms. There is no reason to believe that we will always be satisfied with a norm selected at any given time. If reference levels must always be made to match closely the "normal" levels, we will forever be changing our standards. As has been pointed out above, such changes cause problems and confusion. We should regard a proposal that the audiometric reference levels be changed just as seriously as we would regard a proposal that the decibel reference pressure be changed on the basis that 0.0002 microbar were not a realistic figure.

From the above discussion, it is clear that there are advantages and disadvantages to be obtained by changing the audiometer zero. Some of the disadvantages no doubt could be avoided to some extent by including appropriate statements in a new standard. On the other hand, it seems obvious that real and serious problems are unavoidable and will follow from

01 132 1920

its adoption. Since the change in zero is not essential and since the United States is not bound to ISO standards, the fundamental question remains: Are the ultimate advantages of the proposed changes in audiometer reference levels worth the immediate and subsequent disadvantages that will result?

References:

1. American Standard Specification for Audiometers for General Diagnostic Purposes, Z24.5-1951, American Standards Association, New York.

2. American Standard Specification for Pure Tone Audiometers for Screening Purposes, Z24.12-1952, American Standards Association, New York.

3. J. D. Harris: Steps Toward an International Audiometric Zero. J. Speech & Hearing Disorders, Monograph Supplement No. 9, 63-68, Sept. 1961.

4. Normal Hearing by Air and Bone Conduction, Hearing Study Series, Bulletin 4, National Institutes of Health, U.S. Public Health Service, Washington, D.C.

5. Normal Threshold, WG43-1, ISO Document 43 (Secretariat - 175) 295, circulated for approval as an ISO recommendation, with balloting to be completed by June 18, 1963.

6. H. Davis: For an International Audiometric Zero. Asha 1:47-49, Oct. 1959.

7. Guides to Evaluation of Impairment, Ear, Nose, Throat and Related Structures, AMA Committee on Medical Rating of Physical Impairment. J. Am. Med. Assoc. 177:489-501, Aug. 19, 1961.

8. American Standard Method for the Measurement of the Real-Ear Attenuation of Ear Protectors at Threshold, Z24.22-1957, American Standards Association, New York.

9. American Standard Criteria for Background Noise in Audiometer Rooms, S1.3-1960, American Standards Association, New York.

01 132 1921