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PRODUCT NOISE LABELING STANDARDS

DRAFT

BACKGROUND DOCUMENT FOR THE LABELING OF HEARING PROTECTORS

APRIL 1977

U.S. Environmental Protection Agency
Office of Noise Abatement and Control
Washington, D.C. 20460

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BACKGROUND DOCUMENT
FOR THE
LABELING OF HEARING PROTECTORS

APRIL 1977

Prepared By

THE U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Noise Abatement and Control

FORDWORD

This Background Document has been prepared by the Environmental Protection Agency in support of the Proposed Noise Labeling Standards for Hearing Protectors. The proposed regulation will be promulgated under the authority of sections 8, 10, 11 and 13 of the Noise Control Act of 1972.

CONTENTS

SECTION I

STATUTORY BASIS FOR ACTION

With passage of the Noise Control Act of 1972 (86 Stat. 1234), Congress established a national policy "to promote an environment for all Americans free from noise that jeopardizes their health and welfare." Section 2 (b) states that ". . .it is the purpose of this Act. . .to provide information to the public respecting the noise emission and noise reduction characteristics of. . .products" (distributed in commerce).

The requirements and authority to fulfill this purpose are delineated in section 8 of the Act. This section is included below, in its entirety, as it appears in the Act:

LABELING

Sec. 8. (a) The Administrator shall by regulation designate any product (or class thereof)--

(1) which emits noise capable of adversely affecting the public health or welfare/ or

(2) which is sold wholly or in part on the basis of its effectiveness in reducing noise.

(b) For each project (or class thereof) designated under subsection (a) the Administrator shall by regulation require that notice be given to the prospective user of the level of the noise the product emits, or if its effectiveness in reducing noise, as the case may be. Such regulations shall specify (1) whether such notice shall be affixed to the product or to the outside of its container, or to both, at the time of its sale to the ultimate purchaser or whether such notice shall be given to the prospective user in some other manner, (2) the form of the notice, and (3) the methods and units of measurement to be used. Sections 6(c) (2) shall apply to the prescribing of any regulation under this section.

In section 10(a) (3) of the Act, entitled, "Prohibited Acts," Congress declared that it was prohibited for a manufacturer to distribute in commerce any new product manufactured after the effective date of a regulation under section 8(b) which is applicable to such product, except in conformity with such regulation." Section 10(a) (4) further prohibits "the removal by any person of any notice affixed to a product or container pursuant to regulations prescribed under section 8(b), prior to sale of the product to the ultimate purchaser."

In order to provide incentive for prompt compliance with the regulations, Congress imposed stiff penalties for willful violators. Section 11(a) states, "Any person who willfully or knowingly violates paragraph (1), (3), (5), or (6) of subsection (a) of section 10 of this Act shall be punished by a fine of not more than $25,000 per day of violation, or by imprisonment for not more than one year, or by both."

It is evident that Congress viewed "labeling" as an important means of dealing with the problem of noise pollution.

SECTION II

RATIONALE FOR THE LABELING OF HEARING PROTECTORS

Most people will agree that the ideal method of noise control is to reduce the level of noise that a source emits. However, this is often neither technically, nor economically feasible. In section 6 of the Noise Control Act, Congress provided for the regulation of the maximum levels of noise emitted by newly manufactured products. These regulations are to consider best available technology and the cost of compliance. It will take a number of years for EPA to develop these maximum noise emission regulations for all major sources of noise. Also, in many cases, technically and economically feasible noise control measures will not permit sound levels which totally eliminate detrimental effects upon health and welfare. Finally, except for interstate rail and motor carriers, these noise regulations will apply only to new products, allowing noisy in-use products to diminish by attrition.

The most expedient means of reducing our exposure to harmful and annoying noise which cannot be adequately controlled at the source is through the use of hearing protective devices. EPA believes that providing information regarding the performance of hearing protectors will assist individuals with this immediate, potentially effective, and relatively easy and inexpensive method of protection from noise. Therefore, EPA has selected hearing protective devices as the first product for which labeling will be required under section 8 of the Act.

SECTION III

METHODOLOGY OF REGULATORY DEVELOPMENT

The task of developing product labeling requirements is divided into two broad areas: (1) products which emit noise capable of adversely affecting the public health and welfare and (2) products which are sold wholly, or in part, for their effectiveness in reducing noise. As discussed above, EPA has selected hearing protective devices which fall into the second category of eligible products. The approach taken in developing these initial labeling requirements was to study labeling generally, and concurrently investigate hearing protectors, specifically. The purpose was to permit the developing of a general independent labeling philosophy, approach, and strategy; and then integrate the unique aspects of hearing protectors into this framework.

A consultant was hired to investigate the broad aspects of labeling as intended under section 8 and to relate these considerations to issues involved with hearing protectors. EPA conducted an investigation of the current state-of-the-art of hearing protectors and available rating schemes for the purpose of developing a meaningful rating of effectiveness. In addition, EPA sponsored an interagency workshop on labeling to which all Federal agencies involved in labeling were invited to discuss their experiences. The purpose of the workshop was to help the EPA in avoiding any obvious pitfalls that may previously have been encountered.

Prior to the effort outlined above, EPA published an Advance Notice of Proposed Rulemaking in the Federal Register explaining the intent to require labeling of hearing protectors and requesting knowledgeable parties to submit pertinent information. Approximately ten responses were submitted which provided only a limited amount of the information necessary to properly evaluate alternative requirements. Additional information was sought by posing a series of questions to selected companies in the hearing protector industry.

The more generalized aspects of product noise labeling mentioned above have been proposed by the Agency in a separate rulemaking action, entitled Product Noise Labeling - General Provisions. That rulemaking action creates a new Part 211 of the Code of Federal Regulations for all product noise labeling under section 8 of the Act, and establishes the general provisions of such as Subpart A. The general provisions have been utilized in the proposed labeling of hearing protectors and will be utilized in all further section 8 labeling actions. For a complete discussion of the General Provisions and their regulatory development, one should refer to the associated Notice of Proposed Rulemaking and Background Document for Product Noise Labeling - General Provisions, ________________.

SECTION IV

DESCRIPTION OF HEARING PROTECTIVE DEVICES AND THEIR PERFORMANCE CHARACTERISTICS

INTRODUCTION

Recognition of the need for hearing protection dates back to the early 1900's. Concern for the need of effective hearing protective devices appeared first in the armed forces where cotton wading inserted in the ear was used widely during World War I. In the 1940's, cotton was found to be ineffective and consequently, considerable attention was devoted to developing truly effective devices. The product of these early efforts was an earplug known as the V-51R which is probably the most widely used earplug today.

Since 1945, with the rapid growth of technology and industrialization, noise has been recognized as an occupational health hazard. Of greatest concern is the danger of noise-induced hearing loss. This has been found to be caused by permanent damage to the auditory nerve cells which cannot be corrected at present. Much research has been conducted to determine more precisely the effects of noise on humans. Significant effects in addition to hearing loss have been observed. These include headaches, nausea, hypertension, irritability and diminished work performance. Growing concern over noise and all workplace environmental hazards culminated with the passage of the Occupational Safety and Health Act of 1970. This legislation requires, among other things, Federal standards for safe noise exposure at the workplace.

With the rapid growth of urbanization and mechanization, ambient environmental noise rose to levels which created great public concern. The hazards of environmental noise to the public's health or welfare were recognized by Congress with passage of the Noise Control Act of 1972.

Thus, the effects of noise exposure have grown from a military hazard, to an industrial problem, to an insidious environmental threat to the public's health and welfare.

The Environmental Protection Agency was designated to fulfill the mandate of the Noise Control Act. The Act provides authority to carry out major responsibilities in two areas: (1) regulation of maximum noise emissions from major sources of environmental noise; and (2) providing information to the public regarding a product's noise levels or a product's effectiveness in reducing noise. In order to fulfill the latter function, the Act directs EPA to develop appropriate labeling requirements. On December 5, 1974, EPA announced that the first product to be labeled would be hearing protective devices.

DESCRIPTION OF AVAILABLE DEVICES

Over the years, a wide variety of hearing protective devices have been introduced. Indeed, virtually anything that can fit in or over the ear might fall into this category. In fact, such items as cigarette filters, dimes, pencil erasers, and cigar butts have been observed in use. Contemporary devices may be classified as 1) ear insert devices, 2) ear cap devices, 3) ear muff devices, and 4) combination devices.

EAR INSERT DEVICES

This type of device is one which is designed to fit into the ear canal. A variety of different types of insert devices have been developed. They may be conveniently discussed as a) pre-molded, b) malleable, and c) custom molded.

Pre-Molded Inserts

These devices are uniformly molded of soft, flexible rubber or plastic compounds. They are often flanged and come in various sizes to accommodate the wide range of ear canal geometry. Most pre-molded devices are designed for substantial reuse and, therefore, are washable. Some of these inserts are straight and symmetrical while others are shaped to conform more to curved ear canals. A few pre-molded devices are intended for little reuse and can be considered disposable.

Pre-molded insert devices are relatively inexpensive. The most varies considerably from devices purchased in bulk to purchase of a single pair. In bulk they may cost 10-15¢, while a single pair may cost $1.00. Often the carrying case costs more than the device itself.

These devices when properly cared for are capable of providing effective hearing protection for extended periods of time. The duration is governed primarily by the materials used which may shrink, crack, or lose their needed resiliency with time. Also, due to the small size of these devices, loss is an important consideration. Ear wax will cause some molded plugs to shrink and harden after a period of time. The wax tends to extract plasticizer from the plug material. This will vary from person to person. Normal life for reusable devices can be as los as 5-6 weeks, but for most, it is about 6 months.

Malleable Inserts

These devices are, for the most, intended to be disposable. Their use may range from 1-3 days before replacement is necessary. They are made from materials such as plastic foam, fine glass fibers, and wax-impregnated cotton. Malleable inserts are not sized but rather personally molded to conform to each individual's ear canal. This is an advantage over pre-molded devices, but due to their limited reusability they are usually more expensive for continuous use. The cost per pair ranges from 5-30 cents. Again, the price depends upon the quantity purchased. Since the material must be kneaded before inserting, proper hygiene is required to prevent the introduction if dirt into the ear canal.

Custom Molded Inserts

Insert devices which are permanently molded to the exact shape of an individual's ear are considered custom molded devices. Although the process may be somewhat complex, it basically involves first pressing a pliable material into the outer ear and ear canal. This shape is then hardened in some manner to yield a permanent custom mold. Typical materials are plastic and silicone compounds. Hardeners added to these compounds allow the material to remain pliable long enough to make the mold and then set permanently after drying. This may require a few minutes to a full day. With proper care these devices may last from 2-3 years. Costs may range from $3.00-$30.00 depending upon the materials, quantities and source of the labor. Custom molded devices are generally more comfortable, but are not necessarily more effective, than other devices. They also have the drawback of requiring greater time and skill in fitting.

EAR CAP DEVICES

These devices consist of two ear caps fastened to a head band which maintains pressure on the caps to seal the outer edges of the ear canal. The end of the cap fits slightly into the ear canal and the balance spreads around the edge of the canal. They are molded from soft rubbery material and fit a large range of ear sizes. The caps last about 12 months and may be replaced for about $2.00 a pair. The initial cost of the device is from $3.00-$5.00. Ear caps serve to bridge the gap between inserts and ear muffs, having some of the advantages and disadvantages of each. They do not seem to be in widespread use at the present time.

EAR MUFF DEVICES

These devices fit over the entire outer ear as opposed to within the ear canal. They consist of hard molded plastic cups held in place by a spring-loaded headband. The cups surround and cover the ear completely, forming a tight seal around the ear with a flexible vinyl sealing cushion filled with air, liquid or foam. Foam fillings are the most commonly found. In addition, the cups are lined with an acoustically absorbent material, usually foam sponge. The attachment of the cup to the headband is critical in that it must allow minimum leakage, while permitting a rather loose joint to accommodate varying head shapes. Many devices are designed to allow the headband to be worn over, under and behind the head to suit different personal preferences and use situations.

All parts of the ear muff that contact the skin can be washed with soap and water. The rigid ear cups require periodic inspection for cracks or other damage. The ear seals are usually the first component to deteriorate generally from perspiration. Most ear muffs have replaceable seals which can extend their useful life indefinitely.

The price of ear muffs varies in the range of $5.00 to $12.00.

COMBINATION DEVICES

There are a number of noisy areas where the need for hearing protection is compounded by other important requirements. For example, the need for concise communication, the use of hard hats and the use of welder shields require that hearing protection be compatible with other personal devices. Any of the devices mentioned above may be suitable for various circumstances. In certain instances, however, special modifications and designs are necessary to satisfy the particular needs. For example, ear muffs are fitted with communication gear, helmets are designed with built in ear muffs, hard hats have muffs fastened directly to them and headbands are shaped differently. Special care must be taken to ensure that the needed protection is being provided by these special purpose devices.

FACTORS AFFECTING SELECTION OF HEARING PROTECTIVE DEVICES

The most obvious factor to be considered in selecting the proper hearing protective device is its noise attenuating capability. However, there are a number of aspects which, in certain ways, are equally important as attenuation. It has often been quoted that "a good hearing protector is one that is used," the point being that the user acceptance to wearing the device is paramount to its effectiveness. This point of view arises from the occupational noise situation in which employers must often seek workers' acceptance of hearing protection. Of course, when a person decides to purchase a hearing protective device, he or she has most likely already accepted the need and benefits which will be derived from its use. Nonetheless, it is important to realize that attenuation is not the only factor to consider. Further, care must be taken in selecting hearing protectors because these additional considerations are either subjective or vary greatly among individuals. It is always desirable to provide a choice of hearing protective devices to suit different individual preferences, each of which is capable of providing adequate attenuation.

The factors which must be considered are: (1) attenuation capability, (2) use requirements/environment, (3) fitability, (4) comfort, (5) care requirements, (6) cost, (7) biological compatibility, and (8) durability.

ATTENUATION CAPABILITY

Since attenuation of unwanted noise is the purpose for which hearing protectors are used, special care must be taken to ensure that adequate attenuation will be realized by the user. The evaluation of attenuation capability has received considerable emphasis since early development of the devices. Virtually all tests have been conducted under strictly controlled experimental conditions. Recently there is concern that results obtained under these laboratory conditions are not truly indicative of the attenuation that is realized under field use conditions. Attempts are underway to acquire such field data in order to determine the extent of this problem. A field test procedure has been developed under a grant from the National Institute for Occupational Safety and Health.

Due to the importance of the aspect of attenuation, it will be treated separately in detail in the following section.

USE REQUIREMENTS/ENVIRONMENT

It is necessary to consider the type of use and the conditions under which hearing protectors will be needed. Such items as temperature and humidity, intermittent or continuous use, need for compatibility with other personal safety devices and work space restraints should be considered. For example, wax-impregnated cotton inserts may be unsuitable for high temperature environments due to the softening or melting of the material; ear muffs may be best for intermittent use where the individual must go in and out of noise frequently; ear muffs may not be suited to use with other equipment such as goggles or respirators; and inserts may be desirable where use is anticipated in very close quarters such as machine repair and maintenance might require.

FITABILITY

It has become evident that few devices, if any, will provide an optimum fit for everyone. The matter of proper fit is essential to realizing the attenuation potential of a device. Much of the developmental efforts for hearing protection have been directed to broadening the range of persons that a particular protector can fit properly. For example, the V51-R ear insert was originally manufactured in small, medium and large sizes. This was broadened to include extra-small and extra-large which fit up to 95% of the population. It was felt that an extra-extra large size would be necessary to obtain 98% fit. Another example is the triple-flanged insert which was first believed to fit everyone by providing three progressively larger concentric flanges. It soon became necessary to manufacture three sizes to provide an adequate range of fit. A final example is the E-A-R expandable foam insert which is squeezed to a small cylinder, inserted and allowed to expand in the ear canal. Even with this moldable device it became beneficial to reduce the original diameter of the foam cylinder to provide improved range of fit.

In addition to providing a satisfactory fit initially, the hearing protective device must be able to maintain its fit during a variety of activities such as talking, chewing, and head movement. For inserts this requires adequate depth of penetration and pressure on the ear canal. For muffs it requires flexible joints, proper ear cushions, and adequate headband tension.

Fit is less of a problem for ear muff devices, but still requires special considerations. First, it is necessary to cover the entire ear comfortably while allowing a minimum circumference for the cushion seal. This minimizes the interference of physical irregularities. Next, it is necessary to provide a loose joint between headband and earcup to accommodate the range of skull curvatures encountered. Finally, the headband must be adjustable to allow for different sized heads and ear location. This is accomplished either by an adjustable headband or a movable ear cup joint.

COMFORT

The need for satisfactory comfort is essential if hearing protectors are to be used. Obviously, if use of the device creates greater discomfort than the noise, it will be discarded. It is certain that no one device will be comfortable to everyone. Therefore, it is desirable to be able to select from different styles. It is, however, equally certain that some persons will not find any device comfortable.

The major cause of discomfort is pressure exerted either on the ear canal by inserts or the side of the head by muffs.

Unfortunately, pressure is required to create and maintain the seal so crucial to attenuation. Thus, a major design objective is to obtain and maintain the required fit, while creating the minimum pressure. This is accomplished both by use of soft, pliable materials and through various design features. For inserts the sizing is very important and in muffs the ear cushion is critical. Some inserts are hermetically sealed and others have multiple soft flanges, along with various sizes. Ear muffs use foam, air filled, and liquid filled cushions for comfort. Undue pressure may occur when straight symmetrical inserts are provided for an obliqud, asymmetrical ear canal. This emphasizes the need for a certain minimum number of devices to select from.

Another factor which is cause for discomfort is the weight of the device, thus introducing another design restraint. Since attenuation is related to mass and density, a trade off with weight and effectiveness, and weight and comfort, is required.

CARE REQUIREMENTS

It is wise to include the care requirements of a device in the purchase decision. Factors affecting care, such as the type of environment, the duration of exposure, the type of user and available facilities to provide the proper care should be considered.

For example, ear muffs may require a closed space for storage depending upon the environment. Molded inserts may need a near-by sink. If inserts are removed often, a sink may be necessary very close at hand. Provisions must be made to care for hearing protective devices in the necessary manner. The more convenient it is to provide the necessary care, the better the care will be.

COST

Hearing protective devices vary considerably in cost from a few cents to about $12.00. The cost must be considered in the light of other factors. For example, there is no need to purchase ear muffs or even pre-molded inserts for one day's use. It may not be economical to purchase disposable inserts for repeated daily use. It may be wise to maintain some choice if cost is nearly the same and other factors are satisfied. Thus, one might have the choice between purchasing one pair of ear muffs or ten ear inserts. Personal preference could then be the determining factor if all else were equal.

Cost must also be put in a perspective which considers and weights the importance of wearing the device. Thus, the lowest cost may not be the best measure, if the cost is not significant to start with. It is better to buy a $10.00 device which is used and is effective than to provide a five dollar or fifty cent device which is not used.

BIOLOGICAL COMPATIBILITY

This factor is primarily a design consideration of the manufacturer. Prior to the use of certain materials, tests are conducted to determine their compatibility with the human body. Unfortunately, it is inevitable that a portion of the population will be particularly sensitive to certain of the materials used. In such cases irritation may result, making it difficult to continue the use of the protector. Poor hygiene practice may also cause problems and it is necessary to distinguish between the possible causes.

Another problem may arise from the accumulation of ear wax which may obstruct the insertion of the device resulting in discomfort and a poor seal. The ear protector may tend to push wax inward toward the ear drum, causing additional discomfort.

Another consideration is that some individuals have a boney projection from the external auditory canal. Unless the projection is quite large there is usually not a problem since most devices do not reach that deeply into the auditory canal.

Finally, more careful consideration needs to be given to the projection found in front of the external ear called the tragus. In many individuals the tragus extends too far backwards over the ear canal opening and thereby prevents the insertion of an insert device to its intended depth. The tragus may also produce unequal pressure against the device, forcing the device backward and outward, displacing it enough to cause an acoustic leak.

DURABILITY

The ability of a device to maintain its integrity for a satisfactory period of time is an important consideration from various viewpoints, such as health protection and economics. Durability refers to the endurance of the other properties being considered in the section. It is highlighted here because when considering each of the factors of selection, attention must be given to the durability of each attribute. How long will a device provide the attenuation needed? How long will it remain confortable and maintain the proper fit? How long will it remain hygienically acceptable? These are questions which should be asked when purchasing hearing protective devices. It is known that these devices age and deteriorate to varying degrees. There is very little information found regarding the useful life of hearing protective devices. Different materials will shrink, harden or become too soiled for use depending upon the environment in which it is used and also the individual using it.

Manufacturers can give general guidance, but it is necessary for the user to be sensitive to changes in hearing protectors. At present the useful life is determined by the materials involved, the use environment, and personal experience. Various efforts are underway to develop a field test to evaluate the practical protection of these devices when in use. Such a test will permit the evaluation of reliability and could shed some light on durability.

A summary of some of the advantages and disadvantages of the currently available hearing protectors is as follows:

<u>Insert Type Devices</u>

Advantages

- small and easily carried
- can be worn conveniently and effectively with other personally worn items
- relatively comfortable to wear in hot environments
- convenient for use where the head must be maneuvered in close quarters
- the cost of pre-molded inserts is significantly less than that of others; though other inserts may be comparable to other type protectors

Disadvantages

- sized inserts require more time and skill for fitting than muffs
- the amount of attenuation provided is more variable
- proper hygiene is more difficult when devices must be removed and re-inserted

- many inserts are difficult to see from a distance; hence, it is difficult to monitor groups using inserts
- inserts can be worn only in healthy ear canals and even some healthy canals require a period of time for acceptance

Muff Type Devices

Advantages
- attenuation is less variable
- one size muff accommodates large range of head sizes and shapes
- relatively large sizes are readily visible at a distance; thus, use of these protectors by groups is easily monitored
- muffs are more convenient when use is intermittent
- muffs can be worn in spite of minor ear infections
- muffs are not lost as easily as inserts

Disadvantages
- muffs are uncomfortable in hot and/or humid environments
- muffs are not easily carried or stored
- muffs are not as compatible with other personally worn items
- headband spring force may diminish from use or from deliberate actions and reduce the protection provided
- muffs may be awkward when used in close quarters
- muffs are more expensive than most insert devices

Ear Cap Devices

These devices which attempt to seal the outer edge of the ear canal, fill the middle ground between inserts and muffs. As such, they reduce the disadvantages of each while preserving many of the advantages.

ATTENUATION/EFFECTIVENESS OF DEVICES

FACTORS AFFECTING ATTENUATION

Since hearing protective devices are used to prevent noise from entering the ear, it follows that the ability to attenuate noise is the single most important parameter. All of the factors of selection may be traded off against one another, but the amount of hearing protection required and the ability of a device to provide the necessary attenuation must be firmly established first.

Noise may reach the inner ears of persons wearing protectors by four different pathways. These are: (1) by passing through bone and tissue around the protector; (2) by causing vibration of the protector which in turn generates sound into the internal ear canal; (3) by passing through leaks in the protector; and (4) by passing through leaks around the protector. These pathways are illustrated in Figure 1. Even if the device permits no acoustical leaks through or around it, some noise will reach the inner ear by the first two of these pathways if the levels are sufficiently high. The practical limits set by the bone and tissue conduction threshold and the vibration of the protector vary considerably with the design of the device and the individual's physical make-up. However, approximate limits for inserts and muffs have been determined and are illustrated in Figure 2.

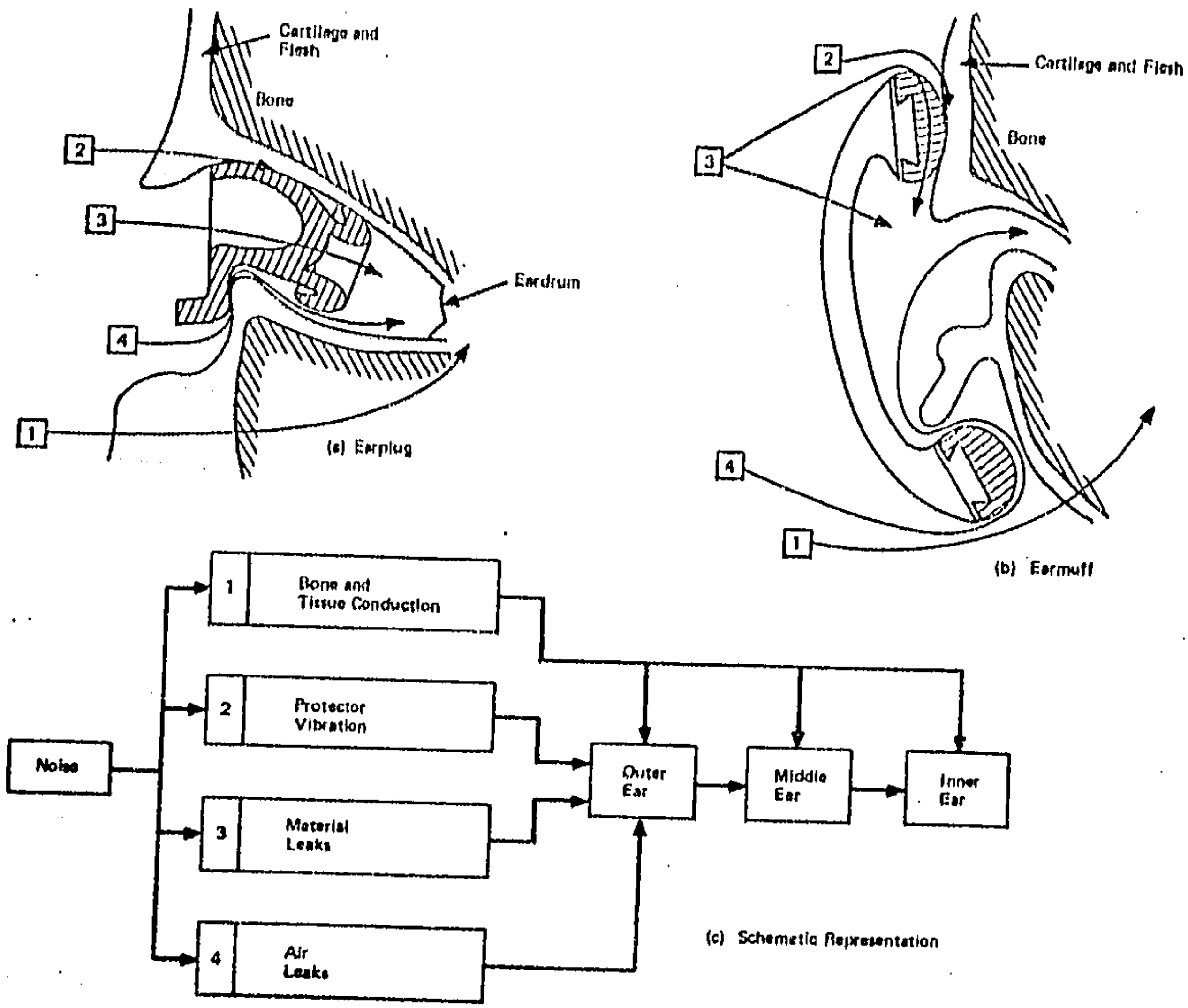

Figure 1. Noise Pathways to the Inner Ear.

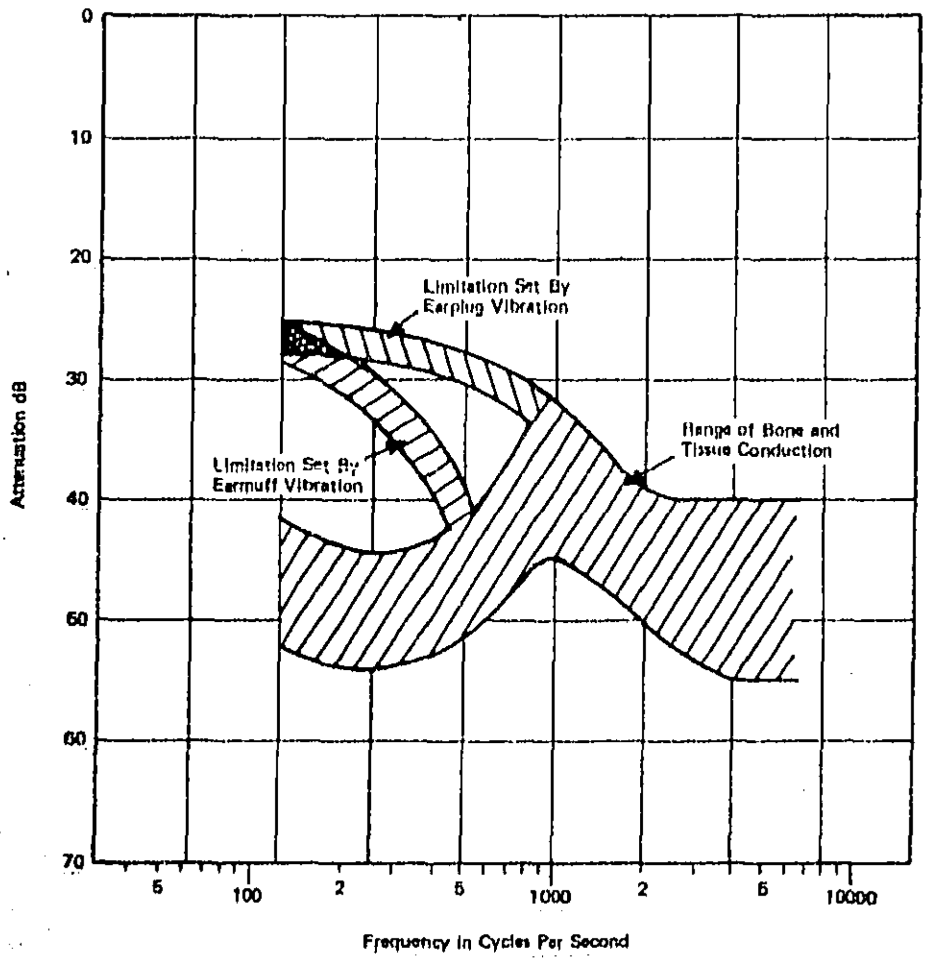

Figure 2. Practical Protection Limits for Plugs and Muffs.

In order to approach these practical limits of attenuation, the hearing protector must minimize losses due to acoustical leaks. The following design criteria should be useful in accomplishing this goal:

1. Hearing protectors should be made of imperforate material. If it is possible for air to pass freely through a material, noise will also be able to pass with little attenuation.
2. Protectors should be designed to conform readily to the head or ear canal configuration so that an efficient acoustic seal can be achieved and the device worn with reasonable comfort.
3. Protectors should have a support means or a seal compliance that will minimize protector vibration.

It is interesting to note how these design criteria have been applied to the current generation of hearing protective devices. Also of interest is the tradeoff of selection factors necessarily encountered in hearing protector design. A brief discussion of such observations follows.

Ear muffs use a stiff plastic cup to reduce transmission of sound. The greater the mass (hence weight) the greater the attenuation for a given material. Weight is a comfort factor and, therefore, a tradeoff arises. Similarly, the greater the headband tension, the better the acoustic seal with the head. Tension is also a comfort factor and again a tradeoff exists. The need to accommodate a wide range of head size has led to the use of a loose joint where the ear cup meets the headband. This permits less headband tension to obtain a satisfactory seal for more head shapes. The need to fasten the ear cups to the headband has required special attention to obtain an airtight fastening system.

A suitable material was needed for the ear cushions to allow durability, comfort, cleansibility and a good seal. All of these qualities cannot be expected to be optimized in any one material; hence, more tradeoffs. The ear cup volume necessary for good low frequency attenuation is restricted by practical size limitations of the device for comfort and maneuverability.

A similar situation exists for insert devices. Here comfort and fitability are even more sensitive. A plug must be soft and pliable for comfort and fit, yet firm and dense for good transmission loss. Materials of relatively low density have been used with good attenuation results, however, They must fit tightly to avoid vibration of the device and subsequent noise generation.

TECHNIQUES OF EVALUATING ATTENUATION

A variety of different methods have been experimented with to yield meaningful information regarding the attenuation capability of hearing protectors. These techniques may be classified as either subjective or physical. Subjective methods measure one of an individual's psycho-acoustical responses with and without the protector in place. Physical methods are those in which the sound pressure level inside and outside the protectors are measured directly. A brief discussion of various methods reported in the literature is appropriate, but closer attention will be given to the subjective method which has been widely adopted as the standard method. This method, entitled "Measurement of Real-Ear Attenuation of Ear Protectors at Threshold," has been used extensively to report the performance of most currently available devices.

Subjective Methods

The threshold shift method of evaluating attenuation determines a subject's threshold of hearing with and without a protector. This was the first psychoacoustic method used. The threshold shift is determined for both ears simultaneously using pure tones in a free or nearly free sound field. Narrow and broad band noise have also been used. Broad band stimuli were given little attention due to the frequency dependent nature of attenuations. A Japanese standard (JISB9904-1598) describes a threshold shift method testing one ear at a time. It requires the subject to press the side of his head against a foam rubber bordered hole in a loudspeaker box, in which the stimulus is presented.

A masked threshold shift method has been used. An active earphone is inserted under an earmuff and the threshold for a stimulus presented by the earphone is determined with and without high ambient noise present. The difference in the threshold provides a measure of the amount of masking noise excluded by the ear muff.

Another method called loudness balance has been reported. The procedure requires the subject to match the loudness of an auditory stimulus perceived while wearing a hearing protector with the same stimulus after removing the protector. This method has been conducted with pure tones in a free field and half-octave band noise in a diffuse field.

The difference in sound pressure level necessary to elicit action of an individual's acoustic reflex with and without hearing protectors has been measured. Also the difference in temporary threshold shift (TTS) observed with and without protectors in continuous and impulsive noise has been measured as an indicator of performance.

Articulation or intelligibility testing in quiet, with and without hearing protectors, provides an indication of the degradation of speech communication by protectors. However, it has been found that in a relatively high noise field, communication is enhanced with the use of hearing protectors. This is accounted for because the attenuation maintains nearly the same speech to noise ratio while bringing the levels out of the range of auditory distortion.

The last subjective method to be mentioned here is to simply allow an individual to wear a variety of different devices and ask him to choose the best one. Experiments of this nature have shown that unless the attenuation of the protectors differs considerably, effectiveness ranking by the subjects is not useful.

Physical Methods

Direct physical measurement of hearing protector attenuation is attractive because of the relative simplicity and objectivity as compared to subjective measures. Unfortunately, modeling and producing a test fixture which reproduces the acoustical response of a human head or ear throughout the audible frequency range is a difficult task.

At present, a standard method for ear muff measurements exists using a "dummy" head fixture. The method is intended to supplement the subjective test for such purposes as product design and quality control.

A variety of experiments have been reported using different means to simulate human conditions. These include artificial ears and heads. One experiment uses ear canals from human cadavers as test devices. Another system uses a small microphone inserted under or through an ear muff. This permits sound pressure level measurements as the protector is worn by human subjects, thus measuring the attenuation directly. This method has produced good agreement with subjective measures at mid and high frequencies, but low frequency results are 3 to 10 decibels off. One difficulty is that the placement of the monitoring microphone is crucial. Displacements as small as one millimeter may cause changes in measured sound pressure level of six decibels or more at high frequencies.

STANDARDIZATION OF ATTENUATION MEASUREMENTS

The need for a standardized methodology for determining and reporting hearing protector attenuation is apparent when the variety and sensitivity of these measurements are considered. This was first done in 1957 when the American National Standards Institute (ANSI) published standard Z24.22-1957, "American Standard Method for the Measurement of the Real-Ear Attenuation of Ear Protectors at Threshold." As mentioned in the Foreword to this standard, it was originally intended to establish psychological and physical procedures for evaluating hearing protectors. However, the scope was reduced to a specification of procedures for evaluating real-ear attenuation on the basis of auditory thresholds on human observers. It is further stated that the wirting group is aware of the simplicity of purely physical methods, but feels the questionable comparison to human subjective results is overriding. Finally, the need for continued efforts in the field and subsequent revisions to the standard are recognized and recommended.

Standardization of this methodology by ANSI indicates that at that time the subjective threshold shift method was the only technique which received sufficient unanimity of expert opinion to be standardized. The standard specified that the thresholds of at least ten randomly selected, normal hearing subjects be measured with and without the protector worn. This was to be done on no less than three separate occasions, for each individual at a minimum of nine pure-tone test frequencies (125, 250, 500, 1000, 2000, 3000, 4000, 6000, and 8000). The difference between the thresholds with and without protectors at each test frequency is reported as the protectors' attenuation characteristics.

This standard, Z24.22-1957, has been used extensively in determining and reporting attenuation performance. A number of shortcomings of this procedure have been realized and have led to the revision of this standard in 1975. Before discussing the recently published revision, it is worthwhile noting these limitations. First, pure-tone signals are not characteristic of the broad band noises which are normally encountered. Second, the use of threshold-level test tones may not accurately represent performance of protectors in high level noise. Third, test tones are introduced only from the front position. Attenuation has been observed to vary up to 10 dB with the angle of incidence. Finally, the time required to perform this test procedure is very lengthy and the test room requirements are strict.

Recognizing the impact of these factors, the U.S. Department of Health, Education and Welfare supported research which was intended to serve as a foundation for revisions to this standard. The most important conclusion of this research was that ". . . . measurement of hearing protector noise attenuation by a threshold shift technique in diffuse sound field using one-third octave bands of noise as stimuli is a desirable technique and is amenable to attenuation standardization. This technique eliminates the problems associated with pure tone stimuli and a fixed angle of incidence and also more closely approximates the noise exposure conditions in which hearing protectors are usually worn."

The revised standard, then, which is based on research performed at the Pennsylvania State University and supported by HEW, was published by the Acoustical Society of America in mid 1975. It is officially known as ASA STD 1 - 1975 " "Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs."

The primary improvements over the previous standard are the use of a diffuse sound field and one third-octave band test tones. The diffuse field eliminates the effect of angle of incidence since diffuse sound impinges randomly from all directions. The diffuse field also facilitates creation of the proper test conditions since a free field is more difficult and costly to produce. The use of third-octave band test tones is more realistic than use of pure tones and enhances reproducibility of results by reducing possible variations due to excitation of resonances in the devices. Small differences in the absolute frequency of pure tones may cause disproportionately larger differences in the measured attenuation between investigations.

In addition to these revisions to the subjective threshold methodology, a supplemental physical test for ear muff devices is included in the standard. A "dummy head" with an artificial flesh material is specified for obtaining attenuation measurements. As stated in the Foreword to the standard, "the physical measurement method is intended for production test and engineering design. . . . it is not suitable for earplug testing."

CURRENT STATE-OF-THE-ART OF HEARING PROTECTOR ATTENUATION

Most hearing protector manufacturers have determined the attenuation capability of their devices in accordance with ANSI Z22.54-1957 and report the attenuation value at each discrete test frequency. Some manufacturers have obtained data using the ASA STD 1-1975 methodology, but do not report it because the results generally indicate somewhat less attenuation than the Z22.54-1957 test. Performance testing is usually conducted by an independent testing laboratory so as to insure unbiased evaluations.

A report by the National Institute for Occupational Safety and Health, HEW Publication No. (NIOSH) 76-120, contains attenuation data compiled for a wide variety of hearing protectors. These data was collected by NIOSH in response to a letter survey of manufacturers. It does not claim to be complete nor does it endorse the data submitted by the manufacturers. The compiled data includes the standard deviation of the measurements at each frequency, thereby providing an indication of the variability in performance to be expected.

The data represents the current state-of-the-art of hearing protector attenuation. The range on attenuation at the test frequencies is indicated below.

Table 1

State of the Art of Hearing Protector
Attenuation vs. Frequency

	125	250	500	1000	2000	3000	4000	6000	8000
Maximum Attenuation (dB)	33	35	37	46	46	48	50	48	52
Minimum Attenuation (dB)	3	4	5	13	22	28	25	27	19

EFFECT OF HEARING PROTECTORS ON VERBAL COMMUNICATION

Wearing hearing protective devices will interfere with speech communication in relatively quiet environments. However, when worn in high level noise (90-199 dB(A)) hearing protectors not only do not interfere, but may actually enhance speech intelligibility for normal ears. The reason is that hearing protectors maintain approximately the same speech to noise ratios, while reducing the absolute levels. This reduces distortion due to overdriving of the auditory mechanism. This may not be the case for individuals who have hearing impairments, although no studies have been found to determine the effect of a hearing impairment. Figure 3 illustrates the effect of hearing protectors on speech intelligibility in various noise environments.

SIMPLIFIED METHODS OF EXPRESSING HEARING PROTECTOR PERFORMANCE

The attenuation data obtained from the standardized threshold shift methodology is very useful performance information, provided it is interpreted and applied correctly. However, it may be difficult for many interested individuals to relate octave band attenuation values to the commonly used A-weighted sound pressure level noise descriptor. In other words, most noise levels and current standards are expressed in A-weighted decibels, a unit which weighs each octave band empirically according to human response and then sums these values. This is the most common notation and is symbolically represented as "dB(A)."

Recognition of this difficulty in relating the standardized attenuation data to practical, everyday noise measurements, has led to the development of various techniques which provide an estimate of the dB(A) noise reduction from the

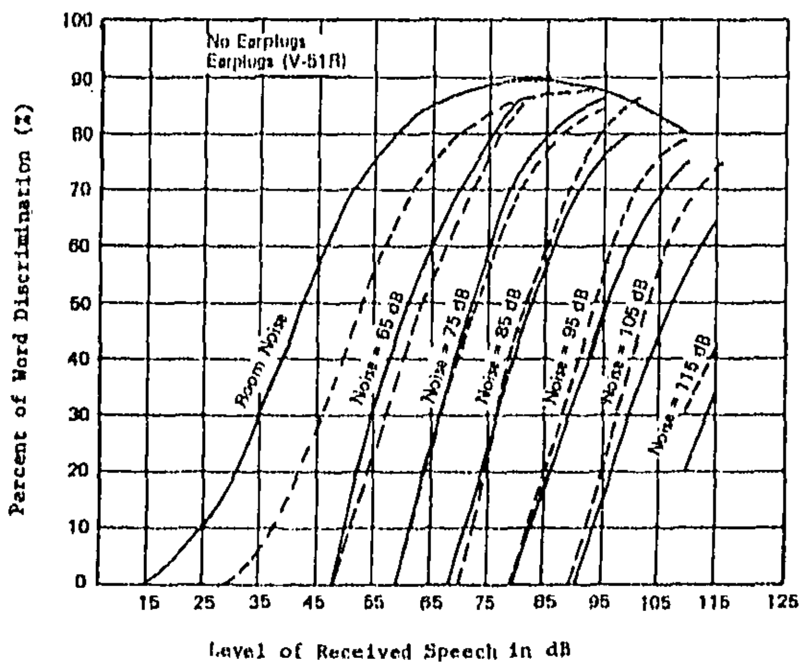

Figure 3. Relation between speech discrimination and signal (speech) level with and without earplugs (V-51R). Parameter is level of masking noise. [2]

octave band attenuation values. These techniques are similar to one another and, generally, trade off accuracy for simplicity. The primary difficulty in estimating dB(A) reduction is due to the fact that the performance of hearing protective devices depends upon the frequency spectrum of the noise. Consequently, it is common for a single device to provide substantially different amounts of attenuation for different noise fields when expressed in terms dB(A). Therefore, specifying a constant value of expected dB(A) attenuation is virtually impossible. Also, there is a significant variation in hearing protector performance observed from individual to individual. This variation is expressed statistically as the "standard deviation" calculated at each frequency from the 30 measurements required by the standard procedure.

There are three basic techniques for relating octave band attenuation to dB(A) attenuation. These are described below qualitatively by listing the major steps in the procedure. The distinction between the techniques lies in what data is required to apply the technique and the accuracy of the estimated attenuation value obtained.

<u>Method One</u>

Data Required:	Octave band noise levels at 125, 250, 500, 1000, 2000, 4000, and 800 hertz (Hz) the dB(A) noise level
	Hearing protector mean attenuation data at 125, 250, 400, 1000, 2000, 3000, 4000, 6000, 8000 Hz.
Comments:	Most precise method
	Attenuation value will vary for different noises but not for different levels of the same noise

Procedure: Apply the A-weighting to the sound pressure level at each frequency to yield A-weighted octave band data

Logarithmically sum A-weighted octave band sound levels

Adjust the hearing protector attenuation data for statistical variation by subtracting two standard deviations at each frequency

Subtract the adjusted attenuation values from the A-weighted octave band sound levels

Logarithmically sum the values from the previous step to yield the A-weighted sound level under the hearing protector

Subtract the calculated level under the protector from the A-weighted noise levels to obtain the dB(A) attenuation capability of the hearing protective device

Method Two

Data Required: A-weighted sound level of the noise

C-weighted sonnd level of the noise

Hearing protector mean attenuation data at 125, 250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz

Comments: Second most precise of the three techniques

Requires that the reduction factor be subtracted from the C-weighted sound level to obtain A-weighted sound level entering the ear

Reduction factor is constant although C-weighted sound level values change with differing noise spectrums

Procedure:	Apply A-weighting to an assumed "pink" noise spectrum of 100 dB in each octave
	Adjust heaing protector mean attenuation data for statistical variation by subtracting two standard deviations at each frequency
	Subtract the adjusted attenuation values from the A-weighted octave band sound levels
	Logarithmically sum the values from the previous step to obtain the A-weighted sound level under the hearing protector
	Add 3 dB(A) to the level under the protector to correct for actual noise spectrum variations
	Subtract this value from the C-weighted value of the pink noise spectrum to obtain the reduction factor

Method Three

Data Required:	A-weighted sound level of the noise
	Hearing protector mean attenuation data
Comments:	Least precise of the three methods
	Requires large correction for noise spectrum variations
	Reduction factor is constant but must be used with caution
Procedure:	Apply A-weighting to assumed "pink" noise spectrum
	Logarithmically sum octave bands
	Adjust hearing protector mean attenuation values by subtracting two standard deviations

Subtract adjusted attenuation values from A-weighted pink noise spectrum

Add empirically determined value of 8.5 dB(A) to previous value to adjust for spectrum uncertainty, to obtain estimated sound level under the protector

Subtract the value under the protector from A-weighted sound level of the pink noise to obtain reduction factor

It should apparent that the three methods presented exemplify the trade off between the complexity of the information required and the accuracy of the results obtained. Method One is the most accurate and, therefore, the most desirable to apply when possible. It requires the most complete information about the noise spectrum which necessitates the use of a Type 1 sound level meter with octave band filtering capability. Method Two involves only the magnitude of the A and C-weighted sound levels. A reduction factor is obtained which when subtracted from the C-weighted sound level of the noise yields the A-weighted sound level entering the ear. This method was developed empirically and requires a 3 dB correction for noise spectrum uncertainty. Method Three requires only the A-weighted sound level, but necessitates an 8.5 dB correction for spectrum uncertainties. It provides a factor which when subtracted from the A-weighted sound level of the noise yeilds the A-weighted sound level entering the ear.

All three methods utilize the mean attenuation data determined by the ASA STD 1-1975 procedure along with the standard deviation. In each case the mean attenuation values are adjusted by two standard deviations for statistical variation to insure that 95% of the population realize at least that amount of noise attenuation. Each method requires the ability to logarithmically sum decibel values which is more complex than basic arithmetic calculations.

SECTION V

THE HEARING PROTECTOR INDUSTRY

The Agency has experienced difficulty in obtaining quantitative information regarding the hearing protector industry. The total response to the advanced Notice of Proposed Rulemaking included ten submissions to the docket. None of the responses addressed in detail the inquiry requesting information describing the hearing protector industry. The response submitted by the Industrial Safety Equipment Association, Inc. (ISEA) states that there are presently 25-30 major manufacturers. The 17 members of ISEA are estimated to account for 80 percent of the sales volume. Their specific response to the ANPRM inquiry was, "The marketing information requested is not available in any form that we know of." The National Institute for Occupational Safety and Health (NIOSH) responded, "We have no information on this item."

A certain amount of qualitative information has been gathered, however, from ISEA, NIOSH, and others active in the field of hearing protectors. This information is presented here. In order to obtain further, more detailed information, EPA has recently distributed letter requests to nine companies selected from a list of manufacturers compiled by NIOSH. Any additional information available from readers of this document would be welcomed by the Agency.

The hearing protector industry is comprised of 25-30 major manufacturers as estimated by ISEA. However, there are numerous small manufacturers, as well as many individuals who produce custom molded ear plugs. To further complicate the picture, there are various companies who distribute hearing protectors under their own trade name which are manufactured by another company. This means the same device is marketed under different trade names and therefore, it is difficult to identify all unique devices. Also, a manufacturer of, let us say, ear muffs may market someone else's plugs so that they have a complete line of hearing protectors to offer. The list compiled by NIOSH includes 40 "manufacturers or suppliers." The list of 17 ISEA members includes five companies not appearing on the NIOSH list. That implies 45 "manufacturers or suppliers." It is not proper to consider these lists complete; only that they represent the majority of the hearing protector industry. Considering the foregoing, it seems safe to estimate that approximately 30 major manufacturers produce most of the hearing protectors marketed today.

There have been no estimates made of the number of hearing protectors manufactured. Various sources have been consulted including the Department of Commerce which periodically conducts a census of all products manufactured. Unfortunately, hearing protectors are apparently grouped under "miscellaneous" in the "personal protective equipment" category. This information is included in EPA's letter-request, in hopes of compiling some rather broad estimates of the types and quantities of each of these devices manufactured.

The current consuming market of hearing protectors is the military/industrial segment of the country. It is here where large quantities of hearing protectors are used to protect individuals from noise levels which can damage hearing permanently. Most of these purchasers are reached either by the manufacturers themselves or by distributors of personal safety equipment.

Although it is growing, the present public consumption of hearing protectors is relatively small. Very few hearing protectors are found in common retail establishments. Where they are found, the choice is very limited. Most of those found are either the malleable inserts or the ear muffs, since these devices minimize problems encountered with fit. As environmental noise levels continue to intrude and the public becomes more aware, citizen use of hearing protectors will most likely increase substantially.

SECTION VI

ECONOMIC ANALYSIS

COST IMPACT OF HEARING PROTECTOR REGULATION

A. ELEMENT OF COST

1. Number of tests required beyond present testing
2. Preparation of Labeling Verification Reports
3. Maintenance of required records
4. Compliance planning
5. Development and, or revision of product graphics, packaging and literature
6. Costs of labeling requirements over present product labeling.

B. FACTOR AFFECTING COST

1. Numbers of additional tests required
   a) Initially
      - One for each model protector
      - Three for 3-position earmuffs
   b) Annually
      - Assume product changes to 20% of models
2. Amount of Compliance Audit Testing
   - No fixed amount, may be very minimal
   - Assume average of one additional test per year
3. Cost per test
   - $1,500 - $2,000 per test per headband position.

4. Preparation of Labeling Verification Reports

o	Technical	2-weeks	$1,000
o	Clerical	2-weeks	400
o	Reproduction/Printing		100
			$1,500

(Assumed average costs, actual costs will vary with numbers of protectors labeled.)

C. NUMBER OF HEARING PROTECTOR MODELS
(FROM HEW PUBLICATION HEW (NIOSH) 76-120)

1. Ear Inserts

o	Premolded	35
o	Moldable	13
o	Non-Linear	3
		51

2. Ear Muffs

o	One-position	58
o	Three-position 18 x (3)	54
		112

3. Ear Caps

o	One-position	2
o	Two-position 1 x (2)	2
o	Three-position 1 x (3)	3
		7

TOTAL MODELS 170

D. INITIAL COSTS OF LABELING VERIFICATION TESTING (ONE-TIME)

- o *From* 170 models x $1,500 per model (testing) = $255,000
- o *To* 170 models x $2,000 per model (testing) = $340,000

$255,000 - $340,000 One-time Initial Testing Costs

E. COSTS OF COMPLIANCE AUDIT TESTING (ANNUAL)

- o Assume that each manufacturer will be required to perform one additional test each year on the average.
- o No. of Manufacturers = Approximately 41
- o Costs

  From 41 x $1,500 per test = $61,500

  To 41 x $2,000 per test = $82,000

$61,500 - $82,000 Annual Costs for Compliance Audit Testing

F. CONTINUING COSTS FO LABELING VERIFICATION TESTING (ANNUA (ANNUAL)

- o Assume that 20% of models need reverification or are new models.
- o Costs

  170 models x .20 = 34

  From 34 models x $1,500 per model (testing) = $68,000

$51,000 - $68,000 Annual Cost of Labeling Verification Testing

G. DIRECT COST OF LABELING PREPARATION (ONE-TIME)

1. This includes preparation of new or revised product graphics, packaging and literature.

2. Manufacturer Survey Summary

   8 Replies

o	Minimal Costs	4
o	Not Available	2
o	$0.10 per unit (Rounded devices)	1
o	$1,000 (Typesetting & Artwork	1

3. Costs

   o Assume 41 manufacturers

   o Assume cost for revised artwork and graphics of $3,000 per manufacturer.

   o $3,000 x 41 = $123,000

   $123,000 One-Time Direct Labeling Costs

H. ADMINISTRATIVE COSTS (ANNUAL)

1. Includes

   o Development of Compliance Plan

   o Preparation of Labeling Verification Plan

   o Maintenance of Records

   o Administrative Costs of Compliance Audit Testing

2. Assume the following personnel requirements

   o 1 week - senior-level at 50,000 per year

   o 2 weeks - mid-level at 30,000 per year

   o 2 weeks - technician/clerical at 10,000 per year

3. Costs

o	1/50 x 50,000 per year	=	$$1,000
o	2/50 x 30,000 per year	=	1,200
o	Cost of Preparation of Labeling Verification Report (3 (4))	=	1,500
			$3,700

o $3,700 x 41 manufacturers = $151,700

<u>$151,700</u> Annual Administrative Costs

I. TOTAL COSTS

1. Initial Costs (One-Time)

a)	Label Verification Testing	$255,000 - $340,000
b.	Labeling Preparation	$123,000 - $123,000

<u>Total Initial Costs</u>

<u>$378,000 to $463,000</u>

2. Annual Costs

a)	Compliance Audit Testing	$61,500 - $82,000
b)	Label Verification Testing	$51,500 - $68,000
c)	Administrative Costs	$151,700 - $151,700

<u>Total Annual Costs</u>

<u>$264,200 to $301,700</u>

SECTION VII

BIBLIOGRAPHY

1. Professor Paul L. Michael, Pennsylvania State University, Personal Protective Devices and Hearing Conservation Programs.
2. Donald C. Gasaway, Personal Ear Protection, Aeromedical Review, USAF School of Aerospace Medicine, August 1971.
3. David F. Bolka, Methods of Evaluating the Noise and Pure Tone Attenuation of Hearing Protectors, Thesis Abstract, Pennsylvania State University, December 1972.
4. P.S. Veneklasen, Methods of Noise Control:Personal Protection, Noise Control, 1, 29-33, September 1955.
5. U.S. Department of Health, Education, and Welfare, National Institute for Occupational Safety and Health, HEW (NIOSH) Pub. No. 76-120.
6. Acoustical Society of America, Standard, ASA Std 1-1975, Method for the Measurement of Real Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs.

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