Proceedings of the Institute of Acoustics
Volume 22, Part 5, 2000
pages 61- 68

THE 75 dB(A) THRESHOLD LEVEL OF THE PHYSICAL AGENTS DIRECTIVE: A FLAWED EVOLUTION

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1. INTRODUCTION

In 1993, the Council of the European Communities proposed a Directive dealing with the exposure of workers to physical agents, one of which is noise (CEC, 1993; amended by CEU, 1994). This draft Physical Agents Directive is intended to repeal the current noise-at-work regulations (CEC, 1986) and to introduce measures which are more protective. As a matter of social and employment policy, the risks arising from noise exposure must be reduced to the lowest achievable level, ultimately to below a Threshold Level, "the exposure value below which continuous and/or repetitive exposure has no adverse effect on the health and safety of workers". In respect of noise-induced hearing loss, the proposed Threshold Level is set at an $L_{EX,8h}$ value of 75 dB(A).

In the light of the definitions above, the various Articles of the proposed Directive require certain general and specific actions on the part of the employer.

1. Taking account of the availability of measures to control noise at its source, the risks arising from noise exposure must be reduced to the lowest achievable level; the aim is to get workers' daily noise exposure below 75 dB(A).
2. If noise exposure exceeds the Threshold Level, then exposed workers must be informed of the potential risk of noise-induced hearing loss.

Obviously, the Threshold Level will assume considerable importance for industry, becoming the target for any noise control programme. If that ideal cannot be achieved, then exposed workers must be informed that their hearing may be at risk from noise at work.

The draft Physical Agents Directive was accompanied by an Explanatory Memorandum which gave background on the aim of the proposal and the need for action, relying upon a draft International Standard (International Organization for Standardization, 1982 and 1985). The Memorandum stated that, during the period leading up to the 1986 Council Directive on noise at work, "scientific and technical knowledge was already sufficiently advanced to make it possible to ascertain precisely the harmful effect of noise on hearing capacity. The scientific community had already established that, from 75 dB(A) on, the risks run by workers were far from negligible." These statements may be challenged on several counts.

Over the few years before the 1986 Directive, the exposure level 75 dB(A) was being canvassed in international circles as the threshold at which *no effect whatever* would be observed in human hearing, even at the most noise-sensitive frequency 4 kHz. To imply that hearing risk, from that exposure level upward, would be "far from negligible" is an unwarranted overstatement. The effect is progressive: there is no sudden jump from no effect to "far from negligible" as the threshold is crossed. A more accurate perception may be gained by considering the Threshold Level from both directions as a transition zone or band of uncertainty *above which hearing damage is measurable and significant, and below which no effects are discernible*. This idea is supported by a number of occupational hearing loss studies involving low-level noise exposures (eg Passchier-Vermeer, 1988; Flottorp, 1995). Male workers exposed to a daily average noise level of 80 dB(A) or less showed no hearing loss except that expected for their age. Where noise exceeded an $L_{Aeq,8h}$ of 85 dB(A), a risk of noise-induced hearing loss emerged. As workplace noise increased to higher levels, the risk of hearing damage became plain.

This paper examines the background of the 75 dB(A) exposure threshold of ISO 1999, which is the foundation of the Threshold Level of the proposed Physical Agents Directive. However, it will be shown that ISO 1999 is flawed. There is considerable uncertainty in the predicted magnitude of noise-induced threshold shift, particularly for low noise exposure levels; this uncertainty persists in the Threshold Level of the draft Directive.

2. THE ISO STANDARD

The various editions (1982, 1985, 1990) of the standard ISO 1999 enable the prediction of Hearing Threshold Levels resulting from noise exposure and natural ageing. Formulae are given for the calculation of noise-induced permanent threshold shift (NIPTS) for the frequencies 500 Hz to 6 kHz. The noise is deemed to last 8 hours per day, over a period ranging from 0 to 40 years, with daily exposure $L_{EX,8h}$ ranging from 75 dB(A) to 100 dB(A).

The lower limit of applicability of the standard, an $L_{EX,8h}$ of 75 dB(A), is implicit in the calculation method. For exposure levels above 75 dB(A), and durations ranging from 10 to 40 years, the median NIPTS values, $N_{0.50}$ in dB, for both sexes are given by the equation:

$$N_{0.50} = [u + v \log q] [L_{EX,8h} - L_0]^2$$

where L_0 is a cut-off sound pressure level defined as a function of audiometric frequency,
q is the exposure time in years, and
u and v are parameters tabulated as a function of frequency.

The values of u and v (appropriate to the different frequencies) are of no interest for present purposes; the values of L_0 are reproduced below in Table 1.

Table 1: Values of L_0 for each audiometric frequency

Frequency, kHz	L_0, dB
0.5	93
1	89
2	80
3	77
4	75
6	77

Note that L_0 assumes a minimum value at 4 kHz, the audiometric frequency at which noise-induced hearing loss usually appears first. For an $L_{EX,8h}$ of 75 dB(A), the squared term in the equation above equals zero, therefore the median NIPTS is zero. For $L_{EX,8h}$ less than 75 dB(A), NIPTS is defined as zero. Other fractiles of the NIPTS distribution are also calculated using the term $[L_{EX,8h} - L_0]^2$. Therefore, NIPTS at 4 kHz is zero for all members of the population exposed to 75 dB(A) or less. In fact, a non-zero value of NIPTS at 4 kHz is not predicted until the exposure reaches 78 dB(A).

To show the influence of the quantity L_0 upon NIPTS, predicted threshold shifts are given in Table 2 for the frequencies 1–6 kHz, and for various values of $L_{EX,8h}$. Of interest here is hearing loss due to relatively low noise exposures, therefore NIPTS values are given to represent the median of the noise-exposed population and also the most noise-susceptible decile. An $L_{EX,8h}$ of 75 dB(A) yields NIPTS values of zero. Exposures of 76 and 77 dB(A) give non-zero NIPTS values for 4 kHz but rounding to the nearest integer decibel still gives entries of zero.

For an $L_{EX,8h}$ of 78 dB(A), a non-zero value of NIPTS at 4 kHz emerges for the 'tender-ear' decile after 10 years of exposure. After 20 years of exposure, the threshold shift at the median reaches 1 dB. Further exposure duration up to 40 years does not enlarge the 1 dB of NIPTS at 4 kHz, and does not produce NIPTS at any other frequency. A threshold shift of 1 dB is virtually undetectable, and is imperceptible to the person with such a loss. Even if the predicted values of NIPTS are accepted as true, the Threshold Level of the proposed Directive should not be 75 dB(A), but closer to 80 dB(A).

Table 2. Noise-induced permanent threshold shift, in dB, by ISO 1999 calculations.

Exposure duration		10 yr		20 yr		30 yr		40 yr	
	Fractile	50%	10%	50%	10%	50%	10%	50%	10%
$L_{EX,8h}$ dB(A)	Freq. kHz								
78	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
	3	0	0	0	0	0	0	0	0
	4	0	1	1	1	1	1	1	1
	6	0	0	0	0	0	0	0	0
80	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0	0
	3	0	1	1	1	1	1	1	1
	4	1	2	1	2	2	2	2	2
	6	0	1	0	1	0	1	1	1
85	1	0	0	0	0	0	0	0	0
	2	1	1	1	2	1	2	2	2
	3	3	5	4	6	4	7	5	7
	4	5	7	6	8	6	9	7	9
	6	3	4	3	5	3	6	4	6
90	1	0	0	0	0	0	0	0	0
	2	2	6	4	8	5	9	6	10
	3	8	13	10	16	11	18	12	19
	4	11	15	13	18	14	19	15	20
	6	7	12	8	14	9	15	10	15

Still referring to Table 2, it may be seen that an $L_{EX,8h}$ of 80 dB(A) is another landmark: non-zero values of NIPTS are now exhibited for the frequencies 3 and 6 kHz, as well as for 4 kHz, the most noise-sensitive frequency. The predicted NIPTS values are, however, very small. As the noise exposure assumes higher values, 85 and 90 dB(A), it may be seen that NIPTS grows quickly over the exposure duration period up to 10 years, and then less quickly over the period 10–40 years.

The behaviour of NIPTS across frequencies, exposure levels and exposure durations is determined by the workings of the equation for $N_{0.50}$ as seen above. Its derivation is based upon work undertaken for the ISO committee by Johnson (1978), forcing a synthesis of two incompatible data sets.

2.1 UK Data

Hearing surveys of noise-exposed British workers were conducted during the 1960s by the Medical Research Council working with the National Physical Laboratory. The findings of this work were condensed into a set of convenient tables (Robinson and Shipton, 1977) giving a form of NIPTS for a normal population with noise exposure every working day for a given number of years. Provision is made for various fractiles of the population, frequency (0.5–6 kHz), and sex. Adding a standard age correction gives overall Hearing Threshold Level (HTL). This NPL data formed one half of the input to Johnson's 1978 synthesis

To allow convenient use of the NPL tables, the statistical variation of both age and noise effects is loaded on to the noise component alone and *cannot* be partitioned between the two components. Johnson, nevertheless, attempted just such a separation in order to force the British data into a format compatible with other information available at the time.

2.2 Dutch Data

Johnson's other input data were contained in a report by Passchier-Vermeer (1977). The hearing loss model was given in the form which Johnson desired, as separate distributions (90%, 50% and 10%) of NIPTS and age components, with overall HTLs being obtained by summing at corresponding fractiles.

Although being in the desired format, the data were far from satisfactory. For the frequency 4 kHz, expected to show the first sign of damage by noise, the NIPTS component actually *decreased* with increasing years of exposure for the ‘tender-ear’ decile. Such a notion is, of course, false: longer noise exposure is not beneficial to the hearing. A related fault indicated that, for some durations, the ‘tender-ear’ decile had a smaller NIPTS component than the ‘tough-ear’ end of the distribution. Despite such obvious shortcomings, the Dutch data was included in the ISO 1999 model for noise-induced hearing loss.

2.3 The ISO Model

The data derived from the two sources described above were not in close agreement; in some cases, the corresponding values differ by over 20 dB. However discordant, the values were simply averaged to provide a data field which was then modelled mathematically. The curve-fitting procedure introduced two arbitrary assumptions regarding the noise exposure threshold.

1. Noise exposures of 75 dB(A), no matter for how long, produce no hearing loss. This threshold value has its origin elsewhere, as will be shown in following sections.
2. NIPTS is proportional to the excess of actual exposure over the 75 dB(A) threshold. This model for the growth of NIPTS has no foundation in experiment.

In addition to these assumptions regarding the noise exposure threshold, the mathematical model for estimating noise-induced permanent threshold shift is based upon two incompatible data sets, one of which has been mistreated, while the other is simply incorrect. The hearing loss calculation method for ISO 1999 is flawed: there is a large underlying uncertainty of the magnitude of NIPTS, particularly for low noise levels near the noise exposure Threshold Level.

3. THE WORLD HEALTH ORGANIZATION

The World Health Organization (1980) criteria on noise gave information on the estimation of hearing impairment risk, and might be thought of as an authoritative source for the ISO 75 dB(A) noise exposure threshold. A summary statement was given: “For the working environment, there is no identifiable risk of hearing damage in noise levels of less than 75 dB(A) L_{eq} (8-h). For higher levels, there is an increasing predictable risk and this must be taken into account when setting occupational noise standards.” On the specific subject of noise-induced permanent threshold shift, the important text was: “... the percentage of people who suffer an NIPTS of 5 dB (the smallest amount measurable) at the most sensitive frequency (4000 kHz) may be defined as a function of an equivalent 8-h level. [Here, the WHO document refers to a diagram attributed to US Environmental Protection Agency, 1974.] From this diagram, an 8-h equivalent level of 75 dB(A) can be identified as the limit for protection against significant NIPTS.” Whilst adding support to the ISO exposure threshold, it is clear that the WHO recommendation is a simple restatement of information from the US Environmental Protection Agency.

4. THE EPA “LEVELS DOCUMENT”

The 75 dB(A) noise exposure value featured in an important social policy document from the US Environmental Protection Agency (1974), to establish sound levels which would not adversely affect public health. Any measurable loss of hearing sensitivity, at any audiometric frequency, was deemed unacceptable. A noise-induced permanent threshold shift of 0 dB was thought ideal, but not entirely appropriate: there was no evidence to suggest that a NIPTS of 5 dB or less would be perceptible by an individual with such a hearing loss. Therefore, an imperceptibly small threshold shift at the most noise-sensitive frequency 4 kHz was thought to be of no practical significance.

The EPA recommendation was based upon a synthesis (earlier work by Johnson, 1973) of results from three occupational hearing loss surveys, one Dutch, one British, and the last American. These survey results were summarized to give the predicted maximum NIPTS for the better-hearing decile, median, and worse-hearing decile of a noise-exposed population after a 40 year working lifetime in a range of average noise levels.

Table 3. NIPTS (dB) at 4 kHz

$L_{Aeq,8h}$	Fractile		
dB(A)	90%	50%	10%
75	0	1	6
80	2	4	11
85	5	9	19
90	11	15	28

These predicted NIPTS values were the result of extrapolation below the observed exposure levels in all three surveys, down to 75 dB(A). To use the Dutch NIPTS data, a second extrapolation was made across percentiles. In the American survey, the threshold data were inflated by Temporary Threshold Shift. (It is worth noting that the US data were not included in Johnson’s 1978 work for ISO.) Despite the uncertainties of the predicted threshold shift data, these values were used to define a curve representing 5 dB NIPTS at 4 kHz; see Figure 1.

A further step involved the seemingly reasonable limiting condition that one's hearing cannot be damaged by a sound not loud enough to be audible. The worse-hearing extreme of the distribution of 4 kHz HTLs in 60 year old women was used (wrongly) to estimate what sound levels would be inaudible to younger workers. This information is superimposed on the 5 dB NIPTS line of Figure 1 by the simple expedient of equating the A-weighted exposure level of a broadband noise in free air to the magnitude of a pure tone, presented by earphone and measured in terms of dB above 'audiometric zero'. If one accepts this numerical operation, then a conclusion may be drawn from the Figure: If occupational noise exposure is limited to 75 dB(A) or less, then no US worker will suffer a NIPTS greater than 5 dB at 4 kHz.

Despite the uncertainties of this line of reasoning, the EPA recommended that an $L_{Aeq,8h}$ of 75 dB(A) would protect the hearing of the American public "with an adequate margin of safety". In fact, the recommended occupational noise threshold value was intentionally conservative to protect the *entire* American working population from an imperceptible hearing loss due to noise, even after a working lifetime of 40 years.

5. CONCLUSIONS

There are a number of issues embedded in the noise exposure Threshold Level of the European Union draft Physical Agents Directive. The Threshold Level was set at $L_{EX,8h}$ = 75 dB(A), administratively marking "the exposure value below which continuous and/or repetitive exposure has no adverse effect on the health and safety of workers". This is a statement by the Commission of the European Union of a new goal of social and employment policy, in respect of hearing damage by occupational noise.

It appears that the value 75 dB(A) originates with the International Organization for Standardization, but consideration of the contemporary literature indicates otherwise. The US Environmental Protection Agency judged that an $L_{Aeq,8h}$ of 75 dB(A) would protect the hearing of the American public "with an adequate margin of safety". In fact, this recommended occupational noise threshold value was intentionally conservative to protect the *entire* working population from even minimal hearing injury at the most noise-susceptible audiometric frequency. The WHO endorsed this goal of social policy.

Since the EPA, WHO and ISO documents were published, there have been a number of occupational hearing loss studies involving low-level noise exposures. The results suggest a region of transition between no noise effect and a clear effect. Below an $L_{EX,8h}$ value of 80 dB(A), the daily occupational noise seems to have little if any effect upon the 4 kHz threshold of even the most susceptible workers; male workers exposed to a daily average noise level of 80 dB(A) or less showed no hearing loss except that typically expected for their age. As workplace noise becomes greater, the risk of hearing damage becomes evident. Where noise exceeds an $L_{Aeq,8h}$ of 85 dB(A), there is a chance of acquiring noise-induced hearing loss. Above 90 dB(A), the risk of hearing damage becomes plain and progressively more severe for populations with higher noise exposures.

The concept of an noise exposure Threshold Level is worthwhile, indeed necessary, but the $L_{EX,8h}$ value 75 dB(A) is unnecessarily restrictive. The scientific evidence suggests that the Threshold Level could be higher without sacrificing the aim of no noise-induced hearing loss, even in the most noise-susceptible portion of the population exposed for a working lifetime.

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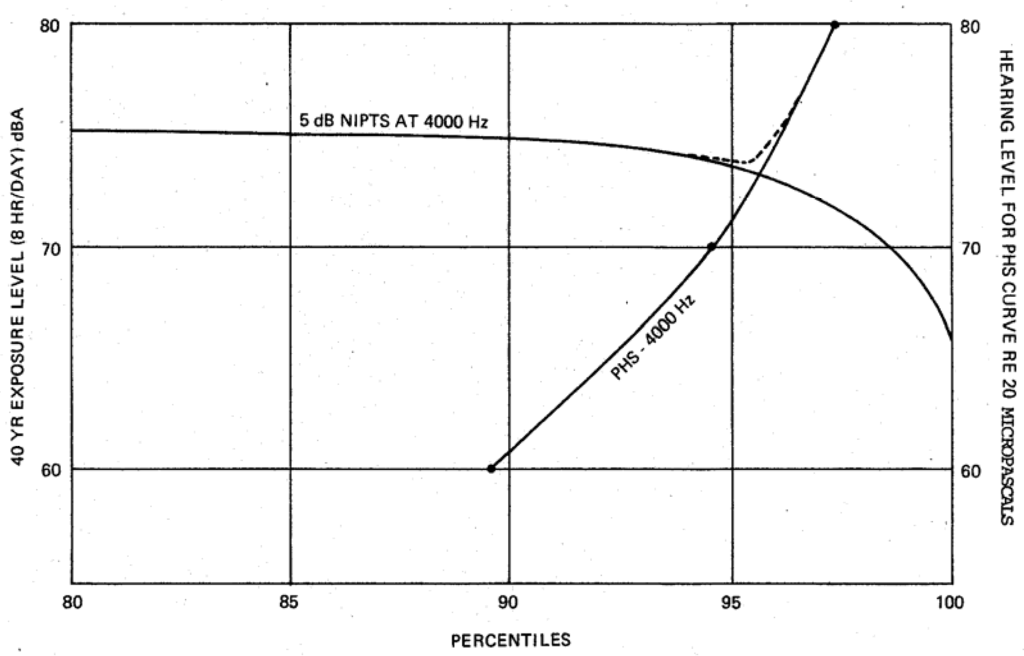

Figure 1. This diagram appeared in the Environmental Protection Agency document of 1974 bearing the caption: “Exposure Level and Hearing Level as a Function of Population Percentile, Showing the 5 dB NIPTS Curve Merging with the PHS 4000 Hz Curve”. The 5 dB NIPTS curve is set against the left-hand vertical axis of ‘40 yr exposure level (8 hr/day) dBA’. The PHS 4 kHz curve represents data from US Public Health Service for women aged 60 years; this line must be read using the right-hand vertical axis ‘ Hearing Level for PHS curve re 20 micropascals’.