Report of the ARA Committee on Amplification*

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My purpose here this afternoon is to discuss hearing aid characteristics and specifications as they have been considered by the Amplification Subcommittee of the Academy.

Before doing that, however, I feel it is important to briefly describe the gestation period and the birth of the new hearing aid standard. The American National Standards Institute Writing Group For Hearing Aid Characteristics has been in existence for quite a number of years. This group is made up of some very knowledgeable and dedicated individuals from the hearing aid industry and four audiologists who were selected for the writing group because of their past experiences with amplification systems. Since 1967, when I became a member of the Writing Group, the group has met at regular intervals to work out a new standard. It acted as a masterpiece of bureaucracy. New ideas were presented, and new ideas were destroyed. New concepts were devised, and new concepts were demolished. New philosophies were discussed, and new philosophies were detonated. I do not point a finger of guilt at any individual or at any group of individuals. I simply state that all of the members of the writing group were knowledgeable and emphatic in their belief that their ideas were best.

During the spring of 1974, the writing group met at Columbia, Maryland. During the course of this meeting, Mr. Michael Gluck of the Food and Drug Administration was introduced to the group. Mr. Gluck indicated that he really did not have any experience with hearing aids but had been hired to prepare a potential Food and Drug Administration Hearing Aid Standard. He further went on to point out that he was attending the meeting in order to gain some information from this group of experts. As a group, we tended to preen and prance in order to demonstrate to this young man just how great was our expertise. Our next meeting was four months later, and at that time Mr. Gluck passed out to us the third draft of the proposed Food and Drug Administration Standard. To say the least, we were both horrified and dumbfounded. The

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proposed FDA standard contained rigorous test procedures and also contained tolerances for every tested characteristic. I am of the opinion that if that third draft had actually become a standard, there would not be a single hearing aid that could have been sold in the United States. Mr. Gluck implied that the writing group did not seem to be making much progress, and therefore, it would be necessary for him to move ahead on his own. The writing group responded by stating that we could have a finalized version of the new standard within seven to eight months.

Will wonders never cease? Vested interests were dropped. Pet arguments were modified. Dogmatic stances were shifted. Concession and conciliation became the words of the day. Across writing group members, traditional barriers were dropped and concessions were made according to the expertise of the individual members. By late Spring of 1975 a final proposed standard was submitted to the Bioacoustics Group (S-3) of the American National Standards Institute. At the time of this presentation the proposed standard is still being voted on with a high likelihood for success. It is also our understanding that this proposed standard will also form the nucleus of the impending FDA standard.

With this information as background, the Amplification Subcommittee met during July of 1975 at Soquel, California. I summarized for the Committee the contents of the proposed standard and the Committee then itemized some areas of concern. Since that time the Committee has been polled regarding these areas of concern and responses have been obtained for ten specific items. Without going into a review of the content of the new standard, it would seem appropriate to summarize the reactions of the committee to the ten items of concern.

- 1. H.F. Gain—The proposed new standard calls for a high frequency gain measurement that will be the average of 1000, 1600 and 2500 Hz. Eighty-six percent of the committee recommended the inclusion of at least one lower frequency, preferrably 500 Hz. Fourteen percent felt that, since the trend is towards more high frequency amplification, the proposed three frequencies would be very appropriate. It should be noted, however, that a gain curve will be shown on the manufacturer's specifications, and gain could be computed at any frequencies that the reader desires.
- 2. Test Box—The proposed new standard continues to call for control in the test box between the frequencies of 200 and 5000 Hz. Since many hearing aids are now being built with an extended high (and sometimes low) frequency emphasis, the point was raised that it might be appropriate to extend both the high and low frequency ends of the control region within the test box. Significantly, 50% of the committee recommended that the control range be expanded, generally to the region from 100 to 6500 Hz. They also recommended that a grace period be estab-

lished to allow owners of existing test boxes to have their equipment converted or to obtain new equipment. On the other hand, 50% of the committee felt that the present 200 to 5000 Hz control region was very adequate. Fortunately we have not reached that point in the state of the art where we all agree with each other, and the recommendations concerning the test box will surely require further examination by the Committee.

- 3. Individual Frequency Responses—The item of requiring manufacturers to provide individual frequency responses with each hearing aid was raised. In this particular instance the total responses will exceed 100% since some of the members responded in such a way that they could be categorized in two different groups. Interestingly, 75% of the committee were emphatically in favor of having individual frequency responses supplied with every instrument. Twenty-five percent were in favor of the individual responses but indicated they would need to know what this would do to the cost of the instrument before they would actually make a recommendation. Another 25% felt that individual responses measured by the manufacturer were of no value whatsoever. Their recommendation was that responses should be measured after the instrument has suffered its way through the U.S. postal service and has arrived at its final destination.
- 4. Specification Sheets—This item dealt with the amount of information that committee members felt they wanted or needed to appear on hearing aid specification sheets. It was initially suggested that all specification sheets should provide a basic frequency response curve, flow-on gain curve, saturation sound pressure level curve, volume control taper curve, harmonic distortion curve and a family of frequency response curves. As this item was considered and a final ballot taken, it immediately became apparent that there was very little uniformity of thinking among the committee members. Thirty-three percent felt that the previously mentioned list of characteristics would be appropriate. On the other hand, 66% of the Committee recommended changes in the required listing of characteristics and no two individuals in this group appeared to agree with each other. This item certainly needs more consideration from committee members and from audiologists in general.
- 5. SSPL—At one point in time, the proposed new standard had in it a cautionary statement regarding saturation sound pressure level. If SSPL exceed 132 dB at any frequency, then the data sheet and instruction manual for that aid would contain the following message: "Special care must be exercised in the fitting of hearing aids with a maximum sound pressure level capability greater than 132 dB as there may be risks to the residual hearing of the hearing aid user." The committee was 100% in favor of the 132 dB cautionary statement. In fact, 75% of the committee

members favored some level even lower than 132 dB. At any rate, the concept of a high intensity saturation cautionary statement received the unanimous support of the committee.

- 6. I.M.—T.D.—Some concern was expressed that there were no specifications for the measurement or interpretation of inter-modulation distortion and transient distortion. This matter was considered in detail, and once again there was a wide divergence of opinions. Twenty-five percent of the Committee indicated there should be standards for both measurement and interpretation but did not make any recommendations as to what these standards should be. Fifty percent of the group decided to play it conservatively and recommended that we encourage further research in this area. Finally, the last 25% said it would not be realistic or meaningful to draw up any kind of specifications regarding either intermodulation distortion or transient distortion at this time. Once again, additional consideration will be needed to reach consensus.
- 7. Broad Band or Pure Tone—The committee discussed the possibility of using a broad band stimulus (such as white noise or filtered white noise) instead of pure tone stimuli for measuring hearing aid characteristics. Three quarters of the committee members favored a retension of the pure tone stimuli. It should also be pointed out that while our deliberations were taking place, an excellently controlled round-robin study was being conducted under the leadership of Dr. John Sinclair and Mr. William Ely, both of whom are nationally recognized hearing aid engineers. They found that, while broad band noise is faster to use, the variability of results from laboratory to laboratory was so great as to negate any potential good from the broad band stimuli.
- 8. Coupler Systems—The matter of Zwislocki coupler measurements versus standard 2cc coupler measurements was discussed at length. Eighty-six percent of the committee voted to continue with the standard 2cc coupler. Comments from this group centered on the standardization of the 2cc coupler measurements, the low cost of the 2cc coupler as compared to the Zwislocki coupler and reflected the fact that a transfer function could be provided that would allow people making measurements to convert 2cc measurements to their Zwislocki measurement counterpart. The final 14% of the group offered no comment on this subject.
- 9. Auditory Trainers—The question was raised as to whether the proposed standards should apply to auditory training units as well as hearing aids. Since we have not had standards for auditory training units prior to this time, would the imposition of rigid standards propose a hardship on the manufacturers of ATU's? Once again, 100% of the committee were decidedly in favor of applying standards to auditory training units. It was recognized that the proposed standards for hearing aids would not be directly applicable to auditory training units, but it was felt by many of

the committee members that the Committee should continue to consider the types of standards that would be appropriate for auditory training units.

10. Directional Microphones—The committee discussed positioning of directional microphone hearing aids in the test chamber so as to yield optimal front-to-back ratios. The questions were asked, would this information be enough to tell you what you need to know about such hearing aids? Also, is there any other information about directional microphone hearing aids that should be included? Sixty-six percent of the group felt that front-to-back ratios would be appropriate and adequate. The remaining one-third of the group opted for curves from the ninety and 270 degree azimuths, or complete 360 degree polargrams.

As you can readily see, the committee has covered a broad range of subject areas. As with most committees, there were areas of spectacular agreement and areas of dismal disagreement. The group feels strongly that work should continue and we will plan to consider and deal with those areas where consensus could not be reached. Thank you for the opportunity of making this presentation.