Verification Considerations

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Remember to take the Continuing Education Quiz on Page 53.

NOTE: This article primarily addresses verification. A companion article will be published in 2021 addressing validation.

Introduction

We've heard it all before regarding "Verify and validate (V&V)."...

- Audiologists living in ivory towers.
- "I don't need no stinking probe mic system" (apologies to the 1948 film "The Treasure of the Sierra Madre").
- My patients love me and they trust me.
- Most hearing care professionals (HCPs) don't do V&V, why should I?

To be clear, verification is objectively proving that ABC does XYZ. With regards to hearing aid fittings, verification typically consists of electroacoustic assessment in a hearing aid test box, probe-mic measures (aka "real ear measures" or REM) and (some might argue) speech-in-noise testing. Validation is equally important, yet more subjective, as it looks at outcomes and considers whether the goals (of the consumer/patient/end-user) have been achieved. With regard to hearing aid fittings, validation can include the Client Oriented Scale of Improvement (COSI), the Abbreviated Profile of Hearing Aid Benefit (APHAB), the International Outcomes Inventory for Hearing Aids (IOI-HA), the Hearing Handicap Inventory for Adults (HHIA) or the Hearing Handicap Inventory for the Elderly (HHIE), the Speech, Spatial and Qualities of Hearing Scale (SSQ) evaluation and more.

Literature Review

Kochkin, Beck, Christensen et al (2010) reported in MarkeTrack VIII, "The Impact of the Hearing Healthcare Professional on Hearing Aid User Success" that in accordance with the American Academy of Audiology (AAA), the American Speech Language Hearing Association (ASHA), the International Hearing Society (IHS), Consumer's Reports (CRs), the Hearing Loss Association of America (HLAA) and the US Food and Drug Administration (US FDA), "quality control at the point of dispensing has not kept pace with technological improvements..." They suggested a commonsense approach to hearing aid dispensing should include the use of a hearing aid test box (i.e., analyzer) and gain and output measures verified through Real Ear Measures (REM) and more. Kochkin, Beck, Christensen



and colleagues reported data from 1141 experienced users and 884 new hearing aid users, of whom only (roughly) 40% reported REM had been conducted. Of note, there are substantial differences in success based on what occurred during the hearing aid fitting process. Indeed, comprehensive protocols have a major impact on loyalty regarding the Hearing Care Professional (HCP), hearing aid brand loyalty, the utility of hearing aids, positive-word-of mouth advertising, satisfaction, hearing handicap reduction, hearing aid usage and the reduction of hearing aids left in the drawer.

Amlani, Pumford and Gessling (2016, 2017) reported on the significant impact of REM services across various factors including audibility, consumer satisfaction, loyalty and importantly, the patient's perception of the provider. Sixty subjects (comprised of experienced, in-the-drawer and new users) compared hearing aids fitted with REM and Quick-Fit approaches. Overall findings indicated REM resulted in improved audibility, increased patient satisfaction with the device and the practitioner, and had a positive impact on patient loyalty factors for all 3 groups of hearing aid users.

Christensen and Groth (2008) reported the primary mistake made by clinicians was "failing to verify the fitting with probe-microphone measurements." The Hearing Review annual survey (2006) reported that approximately 23% of HCPs use REM "routinely." Valente reported (see Beck, 2017) that an abbreviated "greatest hits" version of Best Practices would include: a thorough audiologic evaluation; a needs assessment (including unaided

speech recognition in noise and perhaps an unaided questionnaire assessing the patient's perception of his/her unaided performance in a variety of listening situations), a Hearing Aid Evaluation (HAE) to determine which hearing aids, earmolds, and accessories to order; coupler measurements of the hearing aids to verify adherence to manufacturer specifications, which include assessing the directional microphones and noise reduction algorithms; and real-ear measures, aided speech-in-noise testing, and validation measures to assess outcomes.

Valente, Oeding, Brockmeyer et al. (2018) reported a double-blind study of 24 first time users/patients, which compared hearing aids fitted via REM, versus hearing aids fitted via first-fit methods. In essence, 4 of 5 patients preferred hearing aid fittings which were programmed via real-ear measurements based on NAL-NL2, compared to their "firstfit" programs. The REM programs provided (on average) 15% better word recognition, and a significant improvement in background noise (based on the APHAB). The authors noted numerous studies indicate first-fit hearing aid programs underamplify high frequencies, negatively affecting speech recognition and patient satisfaction with hearing aids. The authors concluded that not using REM to program hearing aids is fitting hearing aids blindly.

With specific regard to "biological" and/or "listening checks" via a hearing aid stethoscope; it is not likely that even a trained listener can detect total harmonic distortion of 2 versus 4% (4% is beyond the ANSI specification. Staab, 2017) or an equivalent input noise (EIN) difference of 2 versus 4 dB (4 dB is beyond the ANSI specification). Further a biologic listening assessment of a hearing aid through a hearing aid stethoscope is unlikely to reveal a dip of 5-10 dB at 3000 Hz, or a peak of 7 dB at 5325 Hz. Indeed, a listening check can essentially only tell us about major functional issues, such as whether the hearing aid or user controls (e.g., volume control, program button) are active and operational.

American Academy of Audiology (AAA)

In the 2005 AAA document titled "Guidelines for the Audiologic Management of Adult Hearing Impairment," Valente, Abrams, Benson et al. (page 25) under the sub-heading "3.3 Fitting and Verification of Hearing Aids," recommended "speech or speech-like" test signals should be used during verification to approximate the spectral, amplitude and temporal aspects of speech. They state (pg. 6) "Prescribed gain from a validated prescriptive method should be verified using a probe microphone approach that is referenced to ear canal SPL..." The authors note deviation from target gain is sometimes desirable. As such, REMs provide a method of establishing a repeatable, quantifiable starting point for hearing aid fitting at various loudness levels across the frequency spectrum. The authors note the HCP should verify that as sound levels increase, gain should decrease (to keep sounds comfortable) and the HCP should assure that "uncomfortable loudness levels" (UCLs) are not exceeded.

Continued on page 46

Continued from page 45

American Speech Language Hearing Association (ASHA)

In the ASHA document titled "Preferred Practice Patterns for the Profession of Audiology," in section IV (Preferred Practice Patterns), sub-section 17 (Hearing Aid Selection and Fitting), which was approved by the ASHA Legislative Council, December 21, 2006, it is stated "hearing aid verification uses real-ear measurements to establish audibility, comfort, and tolerance of speech and sounds in the environment and to verify compression, directionality, and automatic noise management performance..." Although there are many important factors in the ASHA document, one should note it is virtually impossible to listen to a hearing aid through a hearing aid stethoscope to determine if compression is working in a calibrated and succinct manner. This is a matter of critical importance to the end-user/ patient, and not an issue which can be resolved with a listening (aka biologic) check.

International Hearing Society

International Hearing Society (IHS)

In the 2019 International Hearing Society (IHS) document titled "Best Practices Recommendation for Fitting and Dispensing Hearing Aids", case history, otoscopy, listening and communication assessments, as well as audiometric tests are recommended. IHS recommends HCPs should confirm manufacturer's hearing aid specifications in a hearing aid test box, and that the HCP should verify acoustic characteristics using REMs.

Consumer's Reports

In the January 2019 Hearing Aid Buying Guide, Consumer's Reports (CR) specified that some features are more important than others. They reported that 53% of their respondents desired rechargeable batteries, smartphone compatibility and tinnitus masking were sought by 43%, and 42% desired automatic noise reduction. CR defined and addressed T-Coils, Directional Microphones, Feedback Suppression, Digital Noise Reduction and more. CR defines audiologists and hearing aid dispensers and CR suggests how to negotiate price and where one might purchase hearing aids. CR specified that when a consumer acquires new hearing aids, the HCP should do a "real-ear test, also called a real-ear measure. This involves placing a thin probe in your outer ear while you wear your hearing aid—to measure whether your hearing aid is responding appropriately to your level of hearing loss. He or she should also test your understanding of speech in both quiet and noisy areas." This statement is entirely consistent with CRs previously published recommendations, and with AAA, ASHA and IHS.

Hearing Loss Association of America (HLAA)

In the May, 2018 Hearing Loss Association of America (HLAA) publication titled "Purchasing a Hearing Aid – A Consumer Checklist" they report consumers should know whether they had a screening or a full examination, and they should know whether their insurance was charged, or was it free? Were the test results and recommendations explained thoroughly and was the impact of hearing loss discussed with regard to home, work and school, phone use and more? HLAA asks if the consumer knows the type and brand and model of hearing aid, and was their smartphone considered? HLAA asks were the controls, remote controls, apps and hearing aid features, as well as T-coils and batteries explained? And of note, HLAA asks "were real ear hearing aid measures checked or rechecked?"

Clinical Approach

As outlined above, professional and consumer groups have weighed in on REMs and, based on decades of incontrovertible evidence and outcomes, support the value of verification in the fitting of hearing aid technology. As such, there are several key clinical considerations for accurate REM acquisition, application and decision making.

Otoscopic Examination

As is true with all clinical procedures involving the placement of devices into the ear canal, a professional otoscopic examination is required prior to, and during, REM. Otoscopy identifies pre-existing conditions that might impact the measurement (e.g., cerumen, eardrum perforation), pathological issues which may require medical referral and facilitates safe and appropriate probe tube insertion relative to the ear canal and tympanic membrane.

Equipment and Patient Positioning

As REM is conducted in the sound field, acoustic reflections and background noise can cause measurement errors and therefore should be minimized during testing. Loudspeaker location (relative to the ear being tested) has been evaluated



by various researchers (e.g., Killion and Revit, 1987; Ickes et al., 1991). Two azimuths are noted as providing acceptable measurement accuracy: 0 degrees azimuth (i.e., loudspeaker directly in front of patient) and 45 degrees azimuth (i.e., loudspeaker at an angle to the ear of the patient on the side being evaluated). In contrast, 90 degrees azimuth (i.e., loudspeaker directly to the side of the patient, facing the ear to be tested) may result in significant variability/errors and should generally be avoided (Mueller, 1992; Ickes et al., 1991). Loudspeaker distance considerations must strike a compromise between measurement accuracy and patient comfort. Should the loudspeaker be too close, measurements may be impacted by distortions in the sound field (Frye and Martin, 2008) and negatively impact the patient's personal space. Should the patient distance relative to the loudspeaker be too great, the REM system may be unable to deliver the requested signal level to the measurement point. Therefore, typical recommendations regarding patient and equipment positioning include: (1) choose a quiet location and position the patient and the sound field speaker away from reflective surfaces*; and (2) position the patient directly in front of, and facing (0 degrees azimuth) the sound field speaker at a distance of 45 – 90 cm (18 – 36 in) from the center of the head.

* ANSI s3.46-2013 recommends positioning patient and loudspeaker at least twice the working distance from the nearest reflective surface. For example, if the patient is 0.5m from loudspeaker, the nearest reflective surface should be 1m away. There are special cases where these positioning guidelines are modified. For instance, REM verification of CROS/BiCROS fittings involves movement of the loudspeaker location within a range of +/- 90 degrees relative to the front of the patient depending on the verification stage (see Pumford, 2005 for more details). When in doubt, clinicians should review documentation from their specific REM system for equipment and patient positioning for the procedure in question.

Probe Tube Placement Techniques

Proper probe tube placement in the ear canal is mandatory to obtain accurate REMs. Typical probe tube placement guidelines suggest the medial end of the probe tube should be within 5 mm of the eardrum. Dirks and Kincaid (1987) illustrated the closer the probe tube is placed to the eardrum, the more accurately the measurement reflects the true SPL. an appropriate compromise between a probe tube location that is close enough to the eardrum to provide the desired high frequency measurement accuracy while avoiding patient discomfort via eardrum contact. Positioning the probe tube too far from the eardrum may incorrectly suggest the need for more high frequency gain to match prescriptive targets.

To assist with proper probe tube placement, multiple methods can be used as outlined below. Regardless of the procedure followed, otoscopy, clinical judgement, safety and common sense remain at the forefront of clinical probe tube placement techniques.

Visually-assisted Positioning Technique

Visually-assisted positioning (VAP) involves placement of the probe tube at a constant insertion depth based



Figure 1. Typical probe tube showing associated probe tube positioning marker.

Placement within 5mm has been deemed clinically appropriate as it generally results in an estimate within 2 dB of the actual SPL value at the eardrum up to 8 kHz. As one would expect, for extended high frequency bandwidth measurement, closer placement results in improved high frequency measurement accuracy. Therefore, the clinical goal is to strike on consideration of typical ear canal anatomy to result in a termination point within 5mm of the eardrum. To assist with this placement approach, HCPs can use physical markers (available on most probe tubes), inserting the probe tube into the ear canal until the marker is located at the

Continued on page 48

Continued from page 47

intertragal notch (see Figures 1 and 2). General guidelines regarding probe tube insertion depths to achieve sufficient measurement accuracy include: (1) with adult males, insert the probe tube 30-31 mm past the intertragal notch; and (2) with adult females, insert the probe tube 28 mm past the intertragal notch. These guidelines are based on average anatomical dimensions and may not apply to each patient. As such, HCPs should conduct otoscopy before, and prior to, final alignment of the probe tube marker relative to the intertragal notch.

Geometrical Positioning Technique

Geometrical positioning (GP) involves use of the outer ridge of the patient's



Figure 2. Probe module and probe tube placement using the visually assisted positioning technique.

device (earmold, hearing aid, etc.) that corresponds with the location of the intertragal notch. Once this location (i.e., the outer ridge) has been identified, lay the probe tube along the inferior portion of the device and extend the open end of the tube 5mm beyond the tip of the earpiece (see Figure 3). Note, there is significant variability in this technique and excellent clinical judgement is required as the length of the ear canal and the device are highly variable. The HCP must check all physical parameters prior to inserting the tube in the ear canal to assure a safe and accurate location. Deeply fitted devices or pediatric ear canals may have insufficient length/depth to safely accommodate a 5mm extension of the probe tube beyond the medial end of the earpiece while devices with shorter canal lengths may require a greater probe tube extension to be sufficiently close to the eardrum for accurate assessment.

Acoustical Positioning Technique

With the acoustical positioning (AP) technique, standing waves in the ear canal are used to determine proper probe tube placement. Initially, the clinician selects a narrow band 6 kHz signal to be presented at a level of 70 dB SPL. With the patient in front of the test system, the probe tube is slowly advanced into the ear canal and the location of the greatest "acoustic notch" (i.e., reduction in the response) at 6kHz is identified. Confirmation of the actual minimum location can be assessed by moving the probe tube further towards the eardrum, until the "acoustic notch" at 6 kHz resolves. Based on standing wave theory and the anatomy of the typical adult male ear canal, it can be predicted that



Figure 3. Probe tube marker setting using the geometrical positioning technique.

this notch will occur when the end of the probe tube is ~ 15 mm from the eardrum. The clinician would then simply advance the probe tube approximately 10 mm further to reach a location ~ 5mm from the ear drum. In practice, this approach can be quite challenging as acoustic reflections from objects near the patient's ear (i.e., clinician's hand) while the tube is moved will impact the response. As such, ANSI s3.46-2013 recommends that the clinician's hand be moved away from the ear and reference microphone upon approaching the minimum response so as to increase the likelihood of an accurate response.

Acoustically-Assisted Positioning Technique

With the acoustically-assisted positioning (AAP) technique, the probe tube insertion depth recommended by the VAP technique (described above) is used first. Per ANSI s3.46-2013, the HCP then measures a response in the ear canal while presenting a narrow band or broad band signal and notes the response measured in the frequency region of interest (e.g., 6 kHz). The probe tube is then advanced 2mm and the response is re-measured



using the same input level. Should no change occur, this location is used as the probe tube measurement point. Otherwise, the clinician once again moves the tube forward 2mm and remeasures, repeating these steps until such time as no change is observed in the frequency region of interest.

Although the above-mentioned probe tube placement techniques generally result in clinically appropriate REMs with good reliability, they are not always easy to execute. In an attempt to simplify the process, some REM systems provide softwaredriven probe tube placement tools that leverage the concepts of acoustical positioning, providing clinicians with the option of actively monitoring the response of a curve on the screen and/or waiting for an indication by software when the desired probe tube insertion depth is obtained. More recent approaches advance these acoustic principles by using acoustic models developed using machine learning algorithms to guide probe tube placement in realtime. For example, with Audioscan ProbeGUIDE, as a broadband noise is presented, the spectrum of sound within the ear canal is repeatedly sampled, evaluated and compared to a model developed from previous ear canal recordings. The software interface tracks the probe tube location as it is slowly inserted into the ear canal and provides a visual and audible indication when the medial end is within 5mm of the eardrum. Research (Folkeard, Pumford, Pietrobon and Scollie, 2019) has suggested this approach is effective, robust and easy-to-use and can assist clinicians with probe tube placement.

Sound Field Equalization

Ensuring that the proper input signal level and frequency spectrum is delivered during REM is important if valid results are to be achieved. REM systems provide various methods for calibrating the test environment. Each approach uses a reference microphone, often housed within a probe module that also contains the probe microphone (see Figure 4). The reference microphone monitors and adjusts the loudspeaker signal to provide the requested input signal level and spectrum to the measurement location. Commonly, modern REM systems use either the



Figure 4. Probe module containing both the probe and reference microphones with probe tube attached.

'modified pressure method with stored equalization' or 'modified method with concurrent equalization' during testing. Readers interested in learning more about these approaches and/or the substitution method of sound field equalization are referred to ANSI s3.46-2013.

Test Signal Considerations

REM systems provide several measurement signals, including but not limited to warble tones, noises, environmental sounds and

actual speech. In addition, many systems provide the ability to select a 'live' signal mode, whereby the measurement system simply acts as a spectrum analyzer and does not deliver a test signal itself. In these cases, an external sound source of interest to the clinician is generated. While non-calibrated live voice signals offer some face validity and can prove helpful in counseling, there are significant limitations in terms of their repeatability and potential for generalizability outside of the actual test environment in question. As such, calibrated speech test signals are generally recommended given their repeatability, consistency and accuracy, particularly as it relates to target matching where a specific input signal level and spectrum is required. Refer to your manufacturer's literature for test signal details and recommendations specific to your system.

Open Fittings Verification Considerations

Keeping in mind the foundational considerations for accurate REM outlined above, we can now consider how they may be applied when verifying one of the most common fitting types in the typical dispensing practice – the Open Fit Hearing Aid.

Verification of open fit products follows the same general steps and procedures with minimally vented hearing aids. For instance, clinicians should consider using a range of input levels to characterize the compression characteristics of the hearing aid and the resulting output relative to the dynamic range of the patient. In this

Continued on page 50

Continued from page 49

respect, input signals representing soft (50-55 dB SPL), average (65 – 70 dB SPL) and loud (75 – 80 dB SPL) speech in addition to maximum output verification signals (85 – 90 dB SPL) should be considered in any verification protocol. Further, REM targets do not change with the openness of the fitting. Ultimately, we are concerned with the signal level present at the eardrum - regardless of how that signal was delivered!

Nonetheless, given the additional vented amplified sound during REM with open fittings, special considerations are required for sound field calibration as amplified sound from the hearing aid can leak out of the ear canal and contaminate the reference microphone measurements. This outflow of amplified sound is problematic in cases where the 'modified pressure method with concurrent equalization' is used (i.e., the reference microphone is active during testing as previously described). The reference microphone in these cases will measure a higher sound pressure level than it would have had less venting been present as it is now measuring vented amplified sound from the open ear canal. The control loop of the REM system will subsequently lower the loudspeaker signal level, thereby reducing the input to the hearing aid microphone and the associated measured realear output of the hearing aid being tested. As a result, the unsuspecting clinician may underestimate the true amount of gain & output provided by the hearing aid for the test signal in question and inappropriately program more gain into the device than needed to match prescriptive targets. The error potential increases as high frequency gain increases, with some reports showing mistakes on the order of 10 dB or more (Mueller and Ricketts, 2006). To address this measurement artifact, the 'stored modified pressure equalization' approach be should be used to verify open fittings, such that the reference microphone will be disabled during the verification procedure and any outflow of amplified sound from the ear canal will not impact the loudspeaker signal. Provided the patient does not move from the previously calibrated test location, you can be assured you are delivering the correct input level/spectrum to the hearing aid microphone.



Figure 5. Example of a stored modified pressure method equalization prompt provided by one real-ear measurement (REM) system manufacturer upon beginning REM with an open fit device.

Fitting Protocol

A general protocol for open-fit verification is outlined below:

- 1- Conduct otoscopic examination.
- 2- Enter audiometric data and select fitting formula of choice.
- 3- Place probe tube into ear canal and insert hearing aid per chosen protocol.

- 4- Turn OFF or Mute the hearing aid.
- 5- Click on the test signal and store the equalization when prompted. *
- 6- Turn ON or Unmute the hearing aid.
- 7- Conduct verification for multiple input levels.

* Note: the activation of 'stored modified pressure equalization' can vary across systems, but typically involves first selecting a hearing aid or vent type of 'Open' from a drop-down list. This selection will typically result in the system prompting you to store equalization when a test signal is first introduced (see Figure 5). Remember that while using 'stored equalization' you will need to re-equalize the sound field should the patient move from the previous calibrated position at any point during testing. Refer to your manufacturer's literature for details specific to your system.

In addition to the above manual fitting protocol, new technologies have emerged to automate, simplify and increase the efficiency of the verification to target process. That is, a number of manufacturers have developed 'autoREMfits' that support automatic adjustment of hearing aid settings to fitting formula targets via a communication link between the hearing aid fitting software and the REM system. Versions of these approaches also automatically apply the open fit verification protocols for the fitter, muting and unmuting the hearing aid during the sound field calibration routine, to ensure the proper input signal level is provided to the hearing aid. A recent study by Folkeard, Pumford, Abbasalipour et al. (2018) of one REM system / HI manufacturer's collaborative implementation revealed target



matching performance that was equivalent to an experienced clinician using best-practice manual programming methods in significantly less time.

Summary

Hearing aid technology and verification technology continues to evolve, bringing exciting new possibilities and increasing benefits to patients. However, the need to determine what is actually being delivered to the eardrum of patients during the hearing aid fitting process remains paramount. The only way to know what is happening between the medial tip of the hearing aid and the eardrum is to measure it. Best Practice models from AAA, ASHA, and IHS all advocate REMs to verify that the hearing aid fitting is safe and appropriate. As research (e.g., Abrams et al., 2012; Leavitt & Flexer, 2012) has repeatedly shown, improved hearing and listening outcomes reflect not only the technological capabilities of the hearing aid but also the way the device is configured. In this regard, objective verification via REMs represents a critical tool that offers clinicians valuable information to determine whether the device (or feature) in question is performing appropriately. Further, in this time of increased competition and disruptive product delivery models,



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REMs represent a clinical service which serves to differentiate and highlight the value of highly trained and licensed HCPs from retail clerks who sell consumer electronics and personal sound amplification

products (PSAPs) and other over-thecounter hearing enhancement systems (Rosenblum and Beck, 2018). ■

See Verification Considerations 2020 references on page 52.

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IHS Continuing Education Test

Verification Considerations 2020 on page 44.

- 1). Real Ear Measurement (REM) is a best practice that:
 - a. is advocated by IHS, AAA, and ASHA.
 - b. verifies that a hearing aid fitting is safe.
 - c. differentiates HCPs from the OTC and direct-to-consumer competition.
 - d. all of the above

2). Speech-in-noise testing is considered Best Practice by IHS, AAA, & ASHA.

- a. true
- b. false

3). Verification is a process that demonstrates objective benefit.

- a. true
- b. false
- 4). A general protocol for open-fit verification includes turning ON or unmuting the hearing aid before you click on the test signal.
 - a. true

Name

Address.

b. false

5). Real Ear Measurement Systems provide the following measurement signals:

- a. warble tones
- b. noises
- c. environmental sounds
- d. actual speech
- e. all of the above

6). The Geometrical Positioning Technique

- a. can be quite challenging.
- b. involves use of the outer ridge of the client's device.
- c. tube placement is determined by standing waves in the ear canal.
- d. all of the above
- 7). Consumer Reports' buying guide advocate for new hearing aid users to undergo REM.
 - a. true
 - b. false

An alternative to REM is listening to a hearing aid through a hearing aid stethoscope.

- a. true
- b. false
- 9). REM is the only way to determine what is happening between the medial tip of a hearing aid and the eardrum.
 - a. true
 - b. false
- 10). When conducting REMs, an HCP should note that, in general:
 - a. as sound levels increase, gain should increase.
 - b. as sound levels increase, gain should decrease.
 - c. UCLs should be exceeded.
 - d. various loudness levels should not be tested.

For continuing education credit, complete this test and send the answer section to:

International Hearing Society • 16880 Middlebelt Rd., Ste. 4 • Livonia, MI 48154 or professionaldevelopment@ihsinfo.org

- After your test has been graded, you will receive a certificate of completion.
- All questions regarding the examination must be in writing and directed to IHS.
- Credit: IHS designates this professional development activity for one (1) continuing education credit.
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VERIFICATION CONSIDERATIONS 2020

Answer Section

(Circle the correct response from the test questions above.)

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