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# **Significance of Permanent Threshold Shift**

## **Risk Significant Injury (RSI) Implementation Guidance**

### **RSI Technical Working Group**

#### **April 2022**

#### **PURPOSE**

The purpose of this RSI implementation guidance is to present parameters of permanent noise induced hearing loss and when permanent hearing loss may be considered significant or not significant in line with DoD Instruction 3200.19<sup>1</sup>. The properties, parameters, and ultimately the significance of noise induced hearing loss described in this document are relevant to all non-lethal weapon (NLW) systems capable of causing this type of injury.

The intent of this work is to establish an RSI estimation framework that is as accurate as possible given the available data. An overly conservative estimation of RSI can add cost, schedule, and performance risks to a system development program. However, when definitive data sets are lacking, choosing an estimate for RSI that would be viewed as conservative by the majority of subject matter experts allows for the establishment of methodologies and models that can make a verifiable, valid, and quantitative statement such as “the RSI of this system does not exceed X%.”

#### **BACKGROUND**

DoD policy (DoDD 3000.03E<sup>2</sup>) states that NLWs are “developed and used with the intent to minimize the probability of producing fatalities, significant or permanent injuries, or undesired damage to materiel, but do not, and are not intended to, eliminate risk of those actions entirely.” While NLWs are intended to produce reversible effects, reversibility is not guaranteed. The RSI for any given weapon shall be identified by the combat developer to assist in materiel development and enable force commanders to understand the potential risks associated with the use of specific NLWs. Characterization of the human effects resulting from NLW use shall be conducted during the materiel development process to assess the likelihood of achieving the desired effect(s) and to identify the RSI for counter-personnel systems, as well as the RSI for collateral damage to humans from counter-materiel systems. Understanding RSI enables the ability to maximize efforts in producing an effective, suitable NLW with minimized injury risk. By calculating and characterizing the probability of significant injury, appropriate parameters for NLW’s can be established.

RSI is a metric intended to evaluate the risk of a NLW (when functioning properly and employed as intended) causing permanent injury. Risk should be included as a performance attribute although there is not a fixed value for all NLWs. The value is established based on the likelihood of a permanent injury given only limited first responder care (LFRC) treatment. RSI is associated with the acceptable (yet still unintended) level of non-reversibility. For example, if the RSI of a particular NLW, device, or munition is assigned an RSI requirement of 10%, there is a 10% probability that the target may sustain a permanent injury preventing the target from returning to his or her pre-engagement functionality.

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<sup>1</sup> DOD. 2012. Non-Lethal Weapons (NLW) Human Effects Characterization. Department of Defense Instruction (DODI) 3200.19. Washington, DC: USD(AT&L), May 17.

<sup>2</sup> DOD. 2013. DoD Executive Agent for Non-Lethal Weapons (NLW), and NLW Policy. Department of Defense Directive (DODD) 3000.03E. Washington, DC: USD(AT&L), April 25.

Non-reversibility, applied to humans, is fundamentally a measure of permanent injury<sup>3</sup> which is defined in terms of the physical damage that restricts the employment or other activities of the person for the rest of his or her life. Many injuries can be successfully treated with advanced medical care either by preventing permanently disabling outcomes from occurring or by mitigating the impact of permanently damaged tissue or structures.<sup>4</sup> Therefore, the probability that an injury caused by a NLW will result in a permanently (i.e. non-reversible) disabling outcome depends on the level of medical treatment assumed. DoDI 3200.19 states that injuries that cannot be treated with LFRC, presumably to prevent a permanently disabling outcome, are considered “significant.” In other words, RSI is the likelihood (i.e. probability) that a NLW system will cause a permanent injury (physical damage to a person that permanently impairs physiological function and restricts the employment or other activities of that person for the rest of his or her life) assuming only LFRC level of treatment (self-aid, buddy-aid, combat lifesaver skills).

Rather than being strictly prescriptive, RSI Implementation Guidance documents like this one are intended to provide the DoD NLW community with relevant, peer-reviewed, RSI-focused human effects analysis to incorporate into developmental NLW efforts. These documents are consistent with the policy guidance in DoDI 3200.19 and can be assumed to represent a best practice for the particular topic covered.

### **Probability of Significant Injury Given it Occurred, $P(SI|IO)$**

Expressed as a percentage, RSI can be written as the product of two separate conditional probabilities, where  $P(IO)$  is the probability that an injury will occur and  $P(SI|IO)$  is the probability that the injury is significant, given it did occur, as stated in Equation (1).

$$\text{Eq. (1)} \quad RSI = P(IO) * P(SI|IO)$$

The focus of this Implementation Guidance is not to define the probability of an injury occurring, but instead on estimating the  $P(SI|IO)$  term of the RSI equation. However, the available data is limited and relevant data sets are not easily developed via experimentation; therefore, assumptions must be made. In cases where assumptions are made for this Implementation Guidance, the more conservative estimate is usually used, meaning the estimates errs in the direction of estimating more injuries than will actually occur as stated in Equation (2).

$$\text{Eq. (2)} \quad P(SI|IO)_{estimated} > P(SI|IO)_{actual}$$

### **THE SIGNIFICANCE OF PERMANENT THRESHOLD SHIFT**

The focus of this document is on the type of injury which can be collectively referred to as noise induced hearing loss. A permanent threshold shift (PTS) is “the irreversible hearing loss that results from exposure to intense impulse or continuous sound, as opposed to the reversible temporary threshold shift (TTS) that also results from some exposure”.<sup>5</sup> As its name indicates, the primary mechanism of injury for this type of injury is caused by loud noises in relative proximity to the human ear permanently damaging or

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<sup>3</sup> Injuries that result in death represent the extreme end of “permanent injury” but nonetheless, death as an outcome fits entirely within the definition of permanent injury. That is, injuries that result in death are considered permanent injuries.

<sup>4</sup> Examples of treatment that mitigates the impact of rather than preventing a permanent injury include hearing aids, prosthetics, and/or corrective surgical interventions.

<sup>5</sup> Farlex Partner Medical Dictionary 2012, as cited by King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

destroying sensitive hair cells in the inner ear. As such, this injury type can occur through the use of non-lethal weapons that employ intense impulse or continuous sound. A review and analysis of the literature<sup>6</sup> identifies attributes of a PTS injury and associated indicators of injury significance.

According to the Centers for Disease Control (CDC), hearing loss is “a decrease in your ability to hear or understand speech and sounds around you.”<sup>7</sup> The CDC states that in some cases the loss can be temporary, but permanent loss results when “vital” parts of the organ have been damaged “beyond repair.” The CDC indicates that although damage of any part of the ear can lead to hearing loss, specifically damage to hair cells in the [inner] ear can lead to hearing loss. The CDC notes that once hearing loss is measurable or noticeable, “many hair cells have been destroyed and cannot be repaired,” indicating the permanency of the condition.<sup>8</sup> Permanent hearing loss can, when the magnitude of loss is great enough, restrict employment and other activities for the rest of the affected individual’s life, and can therefore be described as significant. No other complications related to this type of inner ear injury are addressed in this document.

### **Units of Measure for Sound**

Sound is a mechanical vibration that is transmitted through a medium such as air. The frequency of the sound defines the tone or pitch, and the amplitude of the vibrations corresponds to the intensity or loudness. The average human can detect sound frequencies in the range of 20 Hz to 20000 Hz.<sup>9</sup> Human speech generally falls in the middle frequencies between 500 and 8000 Hz.<sup>10</sup> The intensity of a sound is highly correlated to risk of causing PTS. The human ear can detect and is routinely exposed to sound pressure amplitudes that span several orders of magnitude. Due to this fact, sound amplitudes are often converted into sound pressure levels (SPL) which utilizes a base-10 logarithmic scale and are measured in the dimensionless units of decibels (dB). The average human identifies sounds, without discomfort, in a range from 0 dB to approximately 140 dB.

### **Physiological Effects of Sound on the Ear**

In the human ear, sound vibrations proceed through a series of specialized physiological structures until they are converted into a neurological signal that travel to the brain to be perceived as hearing. The hair cells in the inner ear act as transducer, changing the mechanical energy in the sound vibration to electrochemical signals used by neurons.

When sounds have high SPLs they can permanently damage the hair cells of the inner ear, leaving them unable to recover and properly activate neurons in the future.<sup>11</sup> Known as sensorineural<sup>12</sup> hearing loss

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<sup>6</sup> King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>7</sup> CDC.gov. 2018. Accessed on January 18, 2018 at:

[https://www.cdc.gov/nceh/hearing\\_loss/how\\_does\\_loud\\_noise\\_cause\\_hearing\\_loss.html](https://www.cdc.gov/nceh/hearing_loss/how_does_loud_noise_cause_hearing_loss.html). Page last reviewed and updated February 6, 2017. Content source (listed on page): National Center for Environmental Health.

<sup>8</sup> Ibid.

<sup>9</sup> ANSI 2013, as cited by King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>10</sup> (Rutka 2013; van der Willigen 2008, as cited by King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>11</sup> Price 2005; SCENIGR 2008, as cited by King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>12</sup> Differentiated from conductive hearing loss.

(SNHL),<sup>13</sup> this damage is what leads to PTS. According to the CDC, up to 30% to 50% of the hair cells can be damaged or destroyed before changes in hearing can be measured by a hearing test.<sup>14</sup> According to the same source, repeated exposures to loud noises will eventually destroy many hair cells and the hearing loss progresses as long as the exposure continues.

### **Severity**

Both temporary and permanent threshold shifts can occur as a result of noise induced inner ear injury. According to the CDC, temporary noise induced hearing loss occurs when loud noises “bend” hair cells, without permanently damaging them. After some recovery time (a few hours to a few days), the hair cells straighten up and resume functioning as normal.<sup>15</sup> RSI explicitly refers to injuries that result in a permanently disabling outcome. Therefore, RSI assessments should only consider sensorineural hearing loss that is permanent with permanent threshold shift as the surrogate measure for level of impairment leading to restrictions in employment and other activities for the remainder of the affected individual’s lifetime.

Permanent threshold shift is usually quantified by measuring a person’s hearing threshold over a series of particular pure-tone frequencies. Standards based on pure-tone hearing thresholds are widely used. Although the exact combination of pure tone frequencies used to assess hearing loss varies between interest groups and organizations, selected frequency attempt to cover (1) those frequencies needed for comprehension of speech, including speech consonants and (2) those frequencies often lost first with noise induced hearing loss.<sup>16</sup> The United States Veterans Affairs Schedule for Rating Disabilities (VASRD) uses a pure tone audiometry test to quantify hearing loss. PTS is determined by averaging the hearing thresholds of each ear at pure-tone frequencies 1000, 2000, 3000, and 4000 Hz and then combining the averaged results to determine disability<sup>17</sup> for each ear. This process ultimately produces a score, where any pure-tone threshold average between 0 and 41 dB hearing loss in either one or in both ears is given a rating of 0% disability, in other words, it is not considered a disability.

According to the World Health Organization, disabling hearing loss “refers to hearing loss greater than 40dB in the better hearing ear in adults and greater than 30 dB in the better hearing ear in children”.<sup>18</sup> However, King and Cazares<sup>19</sup> point out that the WHO grades a hearing loss of 26-40dB (ISO<sup>20</sup> value) in the better ear as “Slight Impairment,” with the accompanying definition of “able to hear and repeat words

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<sup>13</sup> Rutka 2013; SCENIHR 2008, as cited by King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>14</sup> CDC.gov. 2018. Accessed on January 18, 2018 at: [https://www.cdc.gov/nceh/hearing\\_loss/how\\_does\\_loud\\_noise\\_cause\\_hearing\\_loss.html](https://www.cdc.gov/nceh/hearing_loss/how_does_loud_noise_cause_hearing_loss.html). Page last reviewed and updated February 6, 2017. Content source (listed on page): *National Center for Environmental Health*.

<sup>15</sup> Ibid.

<sup>16</sup> King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>17</sup> DVA (1999) as cited by King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>18</sup> WHO. 2018. Accessed on January 18, 2018 at: [http://www.who.int/pbd/deafness/hearing\\_impairment\\_grades/en/](http://www.who.int/pbd/deafness/hearing_impairment_grades/en/)

<sup>19</sup> King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>20</sup> ISO = International Organization for Standardization

spoken in normal voice at 1 metre [sic].” The same source indicates that  $\leq 25$  dB hearing loss corresponds to no impairment.<sup>21</sup>

Between these sources, it seems that there is at least a general agreement that  $>40$ dB hearing loss is associated with some level of disability. On the other end of the spectrum, a  $\leq 25$  dB hearing loss corresponds to no impairment. The in-between range, i.e. hearing loss of 26-40dB in the best ear, accordingly represents the continuum between no disability and a definitive level of disability. King and Cazares<sup>22</sup> conclude that “depending on the assumptions that one chooses to make, this range [26-40 dB (HL)] of average hearing thresholds could be considered either significant or not significant.<sup>23</sup> Given the previously stated USDVA determination of 0% disability for a pure-tone average<sup>24</sup> 0-41 dB (HL), and the WHO grade of 26-40 dB (HL) as ‘slight impairment’ with the accompanying definition of “able to hear and repeat words spoken in normal voice at 1 metre [sic]”<sup>25</sup> a pure-tone threshold average of  $\leq 40$  dB (HL) is unlikely, for most people, to restrict employment or other activities for the rest of the individual’s life. **Therefore, for this RSI Implementation Guidance, the end state of interest is permanent sensorineural hearing loss (PTS) disability where pure-tone threshold hearing average <sup>26</sup>  $>40$  dB (HL) in at least one ear. Conversely a noise induced inner ear injury with a PTS of  $\leq 40$  dB (HL) indicates a non-significant injury.**

### **Assumptions and Errors**

In many ways the establishment of this PTS threshold as a single metric for a disabling outcome is similar to the establishment of a medical screening criterion. The criterion, assuming it is a good one, is certainly highly correlated with outcome of interest and is easily or relatively easy to measure. However, like many screening criteria, our PTS criterion will not be without error on case-by-case basis. There are two major assumptions made in this implementation guidance:

1. Everyone in the target population has normal hearing (an average hearing threshold of 25db or less), without a preexisting condition of hearing loss.
2. A pure-tone threshold average of  $\leq 40$  dB (HL) is unlikely, for most people, to restrict employment or other activities for the rest of the individual’s life.

The first assumption is made because in this guidance, a hypothetical application is considered across multiple engagements and targets and not for a specific individual. If there was reason to believe that the target population has a different set of characteristics than the broader normalized population, those additional considerations could be made.

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<sup>21</sup> King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>22</sup> Ibid.

<sup>23</sup> In their findings King and Cazares (2015) recommend a lower, more conservative value of  $>26$ dB (HL) as the indicator of significance. In support of this recommendation they present United States Military standards for recruitment (DoDI 6130.03) as analogous to the restriction of employment and other activities. In other words, if there is a chance that a threshold average of 26-40 dB hearing loss could prevent an individual from joining the United States Military, then it should be considered significant. Given that U.S. Military recruits are a highly specialized subset of the population held to a high physical standard; this may be an overly conservative assumption.

<sup>24</sup> For the pure-tone audiometry test, hearing loss is quantified by averaging the hearing thresholds of each ear at pure-tone frequencies 1000, 2000, 3000 and 4000 Hz and then combining the results for both ears together (DVA 1999, as cited by King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>25</sup> King, A., and Cazares, S. 2015. Significance of Permanent Threshold Shift Potentially Caused by Sound-Based Non-Lethal Weapons. IDA Document D-5692. Alexandria, VA: Institute for Defense Analyses, December.

<sup>26</sup> Ibid.

The second assumption is made based on above VA and WHO characterizations of disability due to hearing loss. Sources of potential Type II Errors or false-negative results might include individuals who have occupations where hearing standards or demands are especially restrictive like military enlistment or simply being a professional musician. In those cases, levels of PTS below 40dB may restrict employment and would, in that sense, be a disabling outcome. Outside of specific occupational requirements for hearing, there are variations across individuals regarding the level of dependence on a particular sense for day-to-day functionality. One could imagine an individual with severe visual impairment who relies heavily on their sense of hearing for compensating functionality. Any loss of hearing for this individual, perhaps well below our 40dB threshold, would be functionally disabling.

In summary, when a target population deviates from the assumptions, we should expect that there will be cases where an actual PTS measurement on an individual<sup>27</sup> that was exposed to an acoustic-based non-lethal weapon fails to accurately predict whether that person has permanently impaired physiological function restricting the employment or other activities of that person for the rest of his or her life. On an individual basis, as with medical screening criteria, we should expect both false-positives, i.e. Type I Errors, and false-negatives, i.e. Type II Errors, from our RSI criterion.

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<sup>27</sup> This is hypothetically speaking only. There is no requirement inherent in DoDI 3200.19 to assess the actual collateral damage of NLW after employment. The requirement is that development efforts consider and characterize potential target human effects and establish an acceptable level of RSI given future employment of the system.