

**Department of Labor Responses to Recommendations from the June 2017 Public Meeting  
of the Advisory Board on Toxic Substances and Worker Health**

**Recommendation #1**

Presumption for Solvent-Related Hearing Loss

A claim would meet the presumption for solvent-related hearing loss if there is:

- (1) A diagnosis of sensorineural hearing loss, and
- (2) Significant solvent exposure

Significant solvent exposure is defined as having any one of the following exposures:

- (1) Work for at least a total of 7 years (or equivalent) in any of the job titles on the job title list in current presumption, or in any construction or maintenance job,
- OR
- (2) Reported exposure to one or more of the following: styrene toluene, MEK, MIBK, N-hexane, xylene, ethylbenzene TCE, or carbon disulfide on the Occupational Health Questionnaire (OHQ), or evidence for exposure to organic solvents in the Site Exposure Matrices (SEM), for at least a total of 7 years (or equivalent),
- OR
- (3) Reported exposures to organic solvent mixtures on the OHQ, or evidence for exposure to organic solvent mixtures in the SEM, for at least a total of 7 years (or equivalent),
- OR
- (4) Solvent exposure for at least a total of 7 years (or equivalent) established through work history and Direct Disease Linked Work Processes (DDLWP).

Additionally, claims examiners should not routinely deny claims for solvent induced hearing loss if the worker has had fewer than 7 years of exposure, does not have a DDLWP for task, or is not in a labor category on list. Claims that do not meet the requirements set forth here but do have reported exposure to organic solvents for at least 5 years cumulative should be sent for IH review.

**Response:**

**In order to properly respond to this set of recommendations, it is important to clarify the current hearing loss presumption OWCP utilizes, in its entirety. The Federal (EEOICPA) Procedure Manual (PM), Exhibit 15-4 provides guidance on the existing hearing loss presumption applied by OWCP. Unlike the presumption offered in the Board's recommendations, in OWCP's current presumption, ALL of the following must be met:**

- **The file contains a diagnosis of *bilateral* (emphasis added) sensorineural hearing loss;**
- **Verified covered employment within at least one specified job category listed in the PM for a period of 10 consecutive years prior to 1990; and**
- **The employee was concurrently exposed to at least one of the organic solvents listed in the PM.**

When it developed this presumption, OWCP determined that human epidemiological evidence shows that exposure to specific solvents has an *additive* effect to hearing loss for employees with concurrent exposure to excessive levels of occupational noise. Scientific literature published in peer-reviewed journals confirms a relationship between bilateral sensorineural hearing loss and simultaneous exposure to noise (above 85 dBA) and solvents. From this literature, the program identified the following list of ototoxic solvents: Ethyl Benzene, Methyl Ethyl Ketone, Methyl Isobutyl Ketone, Styrene, Toluene, Trichloroethylene and Xylene. The literature OWCP relied on in developing its hearing loss presumption is attached (Exhibit 1) for reference.

After it identified those toxins, OWCP proceeded to ascertain the labor categories maintained in SEM in which employees would have possibly been exposed to those specific substances. OWCP industrial hygienists further refined these results by classifying those labor categories most likely to have had the potential for exposure to a constant level of excessive noise above 85 dBA. The final work product was a list of labor categories that the program considered to have had likely exposure to both solvents known to be associated with hearing loss and noise. While OWCP determined that employees in these job categories likely had exposure to the named solvents, the job categories are very broad, and the duties of the employees within those categories will vary depending on the facility. Therefore, when applying OWCP's presumption, the claims examiner must also establish that the employee was specifically exposed to one of the seven (7) solvents listed above (through review of SEM, the OHQ, or other documents in the case file).

With regard to duration, OWCP applied a 10-year unbroken duration of exposure to solvents and noise in establishing a presumption. OWCP considered the consecutive 10-year duration standard as a claimant-favorable interpretation of the available human epidemiologic literature, as the literature overall supported a minimum of 12.3 years' duration. The literature (human studies) specifically indicated that there was no effect at five (5) years, seven (7) years and eight (8) years (*Envir Health Presp* 114(8): 1283-1286, 2006; *Ann Occp Hyg* 47:493-502, 2003; *Inter J Occ Med Envir Health* 21(3):191-200, 2008).

With a clear understanding of OWCP's current presumption and rationale for that presumption, it is important to clarify the differences and similarities between the Board's recommendation and the current presumption:

- While the Board's recommendations align with OWCP's requirement that there be a diagnosis of sensorineural hearing loss and significant solvent exposure, the Board does not specifically state that the diagnosis must be bilateral.
- Although in its *rationale* for these recommendations, the Board mentions the fact that there is a synergistic effect between solvent exposure and noise, in its actual recommendation, the Board only requires a diagnosis and evidence of "significant solvent exposure," then provides a definition of that phrase without making reference to noise. This is an important difference between OWCP's presumptions that include exposure to a certain level of noise and solvent exposure combined, because the literature does not support hearing loss with solvent exposure alone.

- In its definition of “significant solvent exposure,” the Board lists four individual ways this standard can be met. In contrast, OWCP requires a combination of various factors in order to meet its presumption (which includes a noise component):
  - The Board limits the duration of exposure to seven (7) years of employment, without indicating that this time period must be consecutive or occur prior to 1990, as in OWCP’s presumption;
  - The Board’s recommendation is similar to OWCP’s in requiring that the employee be employed in one of OWCP’s listed labor categories; however, it is unclear whether the Board chose this list based on exposure to solvents and noise. In addition, the Board added the broad category of “any construction or maintenance job;”
  - The Board indicates that even if an employee does not work in one of the listed labor categories, if he/she reports exposure to one of nine (9) solvents, or there is evidence of such exposures in SEM for at least seven (7) years, he/she meets the presumption. OWCP lists seven (7) of the nine (9) organic solvents in its presumptive list, while the Board adds N-hexane and carbon disulfide;
  - The Board further indicates that even if the employee is not employed in one of the labor categories, and did not report any exposure to the listed solvents, he/she still meets the presumption if there are reported exposures to organic solvent *mixtures* for at least seven (7) years (without listing any specific toxic substances within those mixtures); and
  - Finally, the Board indicates that even if none of the above are met, if OWCP can establish solvent exposures through work history or the Direct Disease Work Link Process (DDWLP) in SEM, the presumption of significant exposure should be met.

In response to the Board’s specific recommendations on this issue, OWCP requests additional information from the Board before it agrees to change its current presumption.

1. OWCP requests that the Board clarify whether the diagnosis of sensorineural hearing loss should be bilateral.
2. With regard to the Board’s recommendation to reduce the duration to seven (7) years, OWCP requests clarification regarding the application of available scientific evidence. The Board states that significant exposure can mean that an employee worked for seven (7) years, or equivalent, in any of the job titles from the current presumption, or in any construction or maintenance job. The rationale supplied to support this recommendation comes from studies of toluene exposure effects at seven (7) years (Scand J Work Envir Health 23:289-298, 1997) of exposure. Upon review of the specific article referenced, *Toluene-induced hearing loss among rotogravure printing workers*, it is noted that the mean tenure of the group at the studied company was seven (7) years, with exposure to both noise and solvents. However, the authors specifically stated, “Since the workers who participated in the study had a relatively short noise exposure time, it is likely that they have not been exposed long enough to allow for the noise effects to be detectable.” In their

conclusions, the authors indicated that the findings of the study underscored the need for further research on the ototoxicity of industrial chemicals. This study does not support the Board's recommendation that seven (7) years duration of exposure to solvents and noise is sufficient to trigger a cause and effect between hearing loss and this level of exposure. OWCP also requests that the Board clarify whether the seven (7)-year duration should be a consecutive or aggregate period based on the relevant epidemiological literature. As noted above, OWCP interprets the characterization of tenure of exposure to mean a consecutive period of exposure to solvents and noise. If the Board provides additional insight as to its view of this issue with supporting rationale, OWCP would be in a more informed position to consider a revision to its current presumption.

3. With regard to the Board recommendation regarding applicable labor categories that have significant solvent exposure, as explained earlier, the labor categories referenced in PM Exhibit 15-4 come from an analysis of specific ototoxic solvents associated with job titles that also have a concurrent exposure to excessive noise (in excess of 85 dBA). The Board, in Recommendations #1 and #2, separates labor categories and solvent exposures into distinct and separate criteria. Moreover, while the Board references the synergistic effects of noise and solvents in its rationale, it does not reference noise as being a factor in shaping its hearing loss presumption recommendations. OWCP requests that the Board clarify whether its recommendation considers the combination of noise and the specified solvents, and if so, the level of exposure to noise that would be required to meet the threshold.
  - a. With regard to the recommendation to include the broad categories of "construction and maintenance" in the list of labor categories, OWCP requests that the Board provide the information regarding this category OWCP outlined in its November 9, 2017 response to Recommendation #1.
4. With regard to the Board's recommendation to add the two toxic substances to the hearing loss presumption (as mentioned above), based on human studies, OWCP agrees that it is appropriate to add N-hexane and carbon disulfide to the existing list of presumptive toxic substances (*Envir Health Persp* 111(13): 1620-1624, 2006; *Int J Audiol* 53(6): 370-370, 2014).
5. As stated above, as part of OWCP's presumption for hearing loss, in order to presume significant exposure, the employee's employment must have occurred prior to 1990. The Board's recommended presumption does not include any such limit. As with OWCP's other presumptions, OWCP undertook significant research to determine that there would have been a higher level of exposure to noise and solvents prior to 1990, when there were less safety regulations in place. The Occupational Safety and Health Administration (OSHA) promulgated its Hearing Conservation Amendment in 1981 with a modification in 1983, and therefore, the program determined that by 1990, agencies would have had time to comply with the standards set forth by OSHA with regard to hearing loss. OWCP requests that the Board provide medical health science justification or specific DOE operational data that supports the basis for placing no exposure demarcation date for use in the recommended presumption.

6. With regard to solely utilizing reported exposures to organic solvent mixtures, OWCP does not agree with this recommendation for the following reasons. Organic solvent mixtures could potentially represent the intermingling of several ingredients for which a specific solvent could represent a relatively small or high percentage of the total mixture. The Board has not provided guidance on what it considers a sufficient proportion of a qualifying solvent ingredient that would qualify an employee who is exposed to the mixture as being "significantly exposed." Even if agreement on such a threshold were possible, OWCP would then need to categorize such mixtures for the purposes of generalization in case adjudication. OWCP does not collect or maintain this type of information on mixtures presently. Moreover, in 2013, the Institute of Medicine (IOM) specifically recommended to OWCP that the program remove information regarding the constituents of mixtures from the SEM. IOM recommended that SEM only base health effect links on the mixture itself, not constituent components. Based on this recommendation, OWCP removed from SEM all information regarding health effects associated with constituents of mixtures. The recommendation of the Board directly contradicts the considered recommendation of IOM. In addition to the challenges of defining organic solvent mixtures, the program has already expressed concern with regard to claimants' self-selecting toxic substance exposures. OWCP does not agree that the program should allow self-reported exposures to organic solvent mixtures on the OHQ to serve as a sole basis for making factual findings.
7. With regard to the recommendation that solvent exposure be established through work history and DDWLP, OWCP does not agree with this recommendation because there is no DDWLP currently maintained in the SEM that relates to hearing loss. OWCP added DDWLP to SEM based on specific data linking performance of specific work processes to a particular health effect. Presently, OWCP does not maintain any DDWLP related to hearing loss health effects. Moreover, as noted previously, the existing hearing loss presumption establishes a standard predicated on solvent exposure as having an additive effect to employees exposed to excessive levels of occupational noise and solvents.

## **Recommendation #2**

### Definition of "chronic respiratory disorder "

The Advisory Board recommends that the following criteria be used to define a clinical course consistent with a "*chronic respiratory disorder*" for use in evaluating pre-1993 CBD claims:

- i) Respiratory symptoms (e.g. shortness of breath, cough) that are chronic\*, and
- ii) One of the following:
  - a) Abnormal pulmonary function tests (PFTs), or
  - b) Abnormal chest imaging (chest x-ray or CT scan), or
  - c) Hypoxemia, or

d) Use of respiratory medications such as asthma or COPD inhalers.

\*"Chronic" indicates symptoms (or medication usage) that are present for more than three months, to differentiate from symptoms (or medication usage) related to an acute infection or other problem that resolves. If the Claims Examiner cannot determine, based on the record, whether the condition was present for more than three months, then the case should be referred to a CMC to determine if the condition was a chronic respiratory disorder.

**Response:**

**OWCP agrees with the recommendation of the Board with regard to how it suggests the program define a chronic respiratory disorder. OWCP procedural guidance now requires evidence communicating "the existence of a long term, prolonged pulmonary disease process" (Reference PM Version 1.1, Chapter 18-Eligibility Criteria for Non-Cancerous Conditions pg. 200-201). OWCP agrees that the recommendation of the Board is useful in establishing uniform guidance for physicians to consider when assessing a claim for CBD. However, OWCP considers it important to allow wide latitude to the reviewing physician to allow them to determine whether the available medical evidence constitutes the establishment of a chronic respiratory disorder. As such, OWCP agrees to add the Board's recommendation to procedural guidance relating to the assessment of chronic respiratory disorder in a CBD claim, but it will not apply it as a dispositive standard.**

**Recommendation #3**

Revision of sections of the Procedure Manual and related materials relevant to Part B conditions.

The Advisory Board recommends a substantial revision of sections of the Procedure Manual and related materials relevant to Part B conditions, taking into consideration the comments in this document and other feedback from the Advisory Board.

**Response:**

**OWCP welcomes the recommendations of the Board with regard to suggested edits to the PM regarding Part B conditions. OWCP agrees to consider these comments as part of the next edition of the PM. In response to the series of additional comment and suggestions in the section of the report named, "RESPONSES TO DOL'S SPECIFIC COMMENTS AND QUESTIONS," OWCP must evaluate those specific recommendations carefully. In the past, OWCP has worked closely with medical experts to inform how OWCP communicates medical information in the PM. In addition, OWCP has contractually sought input from experts in medical health science to develop specific recommendations for assessing medical evidence relating to occupational illnesses. OWCP will undertake an analysis of the Board's input in concert with prior expert advice provided to the program to decide how to best edit the Procedure Manual. OWCP will also be mindful of Board recommendations that are within the confines of their statutory mandate versus those that relate solely to internal procedures.**

## Hearing Loss References

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