# Department of the Navy Technical Guidance on Occupational Ototoxicants for Industrial Hygienists

Navy and Marine Corps Force Health Protection Command

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#### **Summary of Revisions**

Version	Date	<b>Change Description</b>	Updated By

Disclaimer: The purpose of this document is to provide technical internal working guidance for the practice of industrial hygiene (IH) to Bureau of Medicine and Surgery (BUMED) IH field personnel. It is not meant to dictate official policy unless referring specifically to federal or other regulatory agency, Department of Defense (DoD), Navy, or Marine Corps policy documents. Nothing in this document is intended to contradict or circumvent official policy or legal requirements.

#### **Executive Summary**

A consistent, systematic, and structured approach for identifying and managing occupational ototoxicant risks is essential to support the health and readiness of Department of Defense (DoD) personnel [1]. This document provides technical guidance and recommendations to support the assessment of occupational ototoxicant exposures within existing Industrial Hygiene (IH) practices and medical surveillance programs. Incorporating this guidance into current procedures will help enhance the protection of Navy and Marine Corps personnel, contribute to a safer working environment, and sustain long-term mission readiness.

#### **Background**

While hazardous noise is the primary risk factor for occupational/service-connected hearing loss (see APPENDIX A for details), co-exposures to chemical and physical agents—particularly ototoxicants—can also significantly impact hearing and balance. Ototoxicants are chemicals that adversely affect the auditory and vestibular systems and may contribute to hearing loss independently or in combination with noise.

Historically, occupations such as metalworking and milling were linked to hearing loss long before the role of chemical exposure was understood [2–3]. Certain medical treatments have also been known to cause hearing damage [4–5]. Scientific recognition of ototoxic chemicals increased with the development of pharmaceuticals and growing awareness of industrial chemical risks during the 19th to mid-20th centuries [6]. These developments have since driven interest among pharmacologists, toxicologists, and industrial hygienists (IHs) in understanding ototoxicant effects [7].

According to OSHA, an estimated 22 million U.S. workers are exposed to hazardous noise and 30 million to chemicals—some of which are ototoxic. Additionally, between 5 and 10 million workers may be exposed to both noise and ototoxic solvents [8]. Despite these widespread exposures, there is currently no standardized guidance for assessing or managing ototoxicant-related risks in occupational settings. When ototoxic chemicals, such as solvents and certain metals are present in noisy environments, the potential for additive, synergistic, or independent effects on hearing must be considered during risk assessments [9]. Notably, some ototoxicants can cause hearing loss even in the absence of noise exposure and often lack occupational exposure limits (OELs) specific to auditory effects [10–11].

OPNAV M-5100.23 instructs IH to identify and assess exposure to ototoxic chemicals per the Navy and Marine Corps Force Health Protection Command (NMCFHPC), Industrial Hygiene Field Operations Manual (IHFOM) [12]. The IHFOM states that reproductive or developmental hazards, carcinogens, or ototoxic[cants] must be specifically identified and annotated in the IH survey. The IHFOM suggests using the joint OSHA and NIOSH Bulletin, *Preventing Hearing Loss Caused by Chemical (Ototoxicity) and Noise Exposure* and the ACGIH *TLVs and BEIs; Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices* as references [13-14]. It further notes that these references do not identify all known ototoxicants and further research may be necessary. Additionally, these ototoxicant references are currently recommended to be used only to aid the industrial hygienist in identifying ototoxicants for annotation in the IH survey. In the following sections, discussion of the selection methodology and comprehensive list of Navy Ototoxicants to be annotated in the IH surveys will be presented, as well as assessment and control strategies.

#### **Selection Methodology**

Hazard identification incorporates data from epidemiological, in vitro, and animal studies and physicochemical properties [15]. Initial selection criteria were used to develop a comprehensive list of occupational ototoxicants. Selections were based upon research, extensive literature review, and agreement from senior Department of the Navy (DON) Occupational Environmental Health (OEH) staff (e.g., industrial hygiene, toxicology, occupational environmental medicine, etc.). Primary sources include references developed by international and federal regulatory agencies and authoritative organizations [7, 13, 14, 16]. These sources are appropriately reviewed and scientifically sound resulting in high confidence for inclusion. Contributions to an overall exposure profile from pharmaceutical ototoxicants or other modifying factors is beyond the scope of the current guidance. For further information on pharmaceutical ototoxicants, including mechanisms/modes of action and management strategies, see reference [17]. The list of Navy-recognized occupational ototoxicants is below in TABLE 1.

Additional review of available data and ototoxicant research is planned on a continuous basis. Candidate chemicals for the ototoxicant list will be thoroughly documented with source validation, a weight of evidence review, and included upon agreement from designated OEH staff. Consideration for removal of any confirmed ototoxicant from TABLE 1 would undergo the same rigorous documentation process. DON IH staff should recognize that TABLE 1 may not be inclusive of all possible ototoxicants. Evaluation of additional chemicals for ototoxicity is critical to IH practice. Requests to review potential ototoxicants from DON staff are encouraged and can be facilitated by contacting the NMCFHPC IH Department at <a href="mailto:usn.hampton-roads.navmcpubhlthcenpors.list.nmcphc-ask-ih@health.mil">usn.hampton-roads.navmcpubhlthcenpors.list.nmcphc-ask-ih@health.mil</a>.

#### **TABLE 1: List of Ototoxicants**

TABLE 1 represents confirmed ototoxicants as described in the Selection Methodology section. Previous citations were limited and non-specific (i.e., identification by chemical class). Individual chemical warfare agents, arsenic, cadmium, Stoddard solvent, perchloroethylene, fuels, manganese, methyl ethyl ketone, and polychlorinated biphenyls are under current consideration and review. The chemicals in TABLE 1 will be annotated as ototoxicants in the Navy Standardized Industrial Hygiene Survey Report when designated as a stressor for shop processes. A Navy Defense Occupational Environmental Health Readiness System – Industrial Hygiene (DOEHRS-IH) Breakdown of Frequently Notated Ototoxicants and Corresponding Common Processes is provided in APPENDIX B.

TABLE 1: List of DON-Recognized Ototoxicants

Substance Class	Chemical
Metals	Lead and compounds (as Pb)
	Germanium dioxide
	Mercury and compounds (as Hg)
	Organic tin and compounds (as Sn)
Solvents	Benzene and isomers
	Carbon disulfide
	Ethyl benzene
	n-Hexane
	Heptane and isomers
	Methylstyrene
	Hexachlorobenzene
	n-Propylbenzene
	Styrene and isomers
	Toluene and isomers
	Trichloroethylene
	Xylene and isomers
Asphyxiants	Carbon monoxide
	Hydrogen cyanide/cyanide salts
Insecticides	Chlorpyrifos
	Diazinon
	Dichlorvos
	Ethion
	Fenthion
	Malathion
	Parathion
	Paraquat
	Pyrethroids (permethrin)

Substance Class	Chemical
Nitriles	Acrylonitrile
	3-Butenenitrile
	3,3'-Iminodiproprionitrile
	cis-Crotononitrile
	cis-2-Pentenenitrile
Platinum containing anti-neoplastic	Bleomycin
	Carboplatin
	Cisplatin

#### **Industrial Hygiene Assessment**

Federal risk assessment involves hazard identification and exposure assessment as two critical components in the overall process [15], both of which are applied in IH practice. Occupational ototoxicants, as identified in Table 1, are considered significant hazards [12, Chapter 2]. These hazards are to be specifically identified, annotated, and assessed in periodic industrial hygiene surveys to minimize exposure risks.

### Documentation OEL

Navy IH is expected to follow the OEL hierarchy as described per references [1, Chapter 1; 12, Chapter 4]. OEL development typically does not include consideration of ototoxicity as the health effect basis for derivation of the final value. Additionally, combined exposure to noise and chemicals is rarely included for the purposes of OEL establishment [18]. In traditional risk assessments, exposures are calculated as an 8-hour time weighted average (TWA) for the chemical of concern then compared to OELs. Alternatively, an aggregate calculation/hazard ratio may be performed where two or more substances are hazardous and have a similar toxicological effect on the same target organ. These methods can also be utilized when assessing ototoxicant exposure, however ototoxicants may produce adverse health effects below the OEL. In some cases, confirmed ototoxicants or potential ototoxicants may not have an established OEL. NMCFHPC advocates applying occupational exposure banding approaches [19] for provisional values as deemed necessary. Please contact NMCFHPC OEH staff at <a href="mailto:usn.hampton-roads.navmcpubhlthcenpors.list.nmcphc-ask-ih@health.mil">usn.hampton-roads.navmcpubhlthcenpors.list.nmcphc-ask-ih@health.mil</a> for assistance and additional information.

**NOTE:** When evaluating non-traditional work schedules, adjust the OEL as recommended in [12, Chapter 3].

#### **IH Surveys**

All DON IH surveys shall identify and annotate the ototoxicants listed in TABLE 1. The Navy NMCFHPC OEH staff will periodically update TABLE 1; therefore, Navy IH personnel are advised to routinely verify that they are using the most current version. TABLE 1 is not exhaustive, and additional ototoxicants may be present in the workplace. Navy IH personnel are responsible for reviewing all suspected chemical hazards by thoroughly evaluating product compositions using Safety Data Sheets (SDSs), product labels, and other relevant technical documentation.

Unlike other hazard categories such as sensitizers or reproductive toxicants, ototoxicants are not currently recognized as a distinct hazard class under the Globally Harmonized System (GHS) and typically do not include specific hazard statements or H-codes in SDSs [20]. However, many potentially ototoxic chemicals exhibit toxicity to the nervous system and/or kidneys [21], which may be reported in Section 11: Toxicological Information of the SDS.

IH personnel should ensure ototoxicants are properly identified and annotated in all IH surveys. Identified ototoxicants should be documented by shop or Similar Exposure Group (SEG), and by associated work operation or process. When feasible, commands should be advised and assisted in substituting or eliminating the use of ototoxic chemicals.

#### Hazardous Material Authorized Use List

Navy IH identifies all hazardous materials used in work operations/processes that are not on the command's HM (hazardous materials) AUL (authorized user list), which informs commands of required updates for the HM AUL [12, Chapter 2]. During periodic surveys, Navy IH should review changes in the HM AUL and document all ototoxicants in TABLE 1 not previously recognized.

#### **Quantitative Exposure Assessment**

Exposure to ototoxicants may be measured and assessed using various methods. For inhalation exposures, breathing zone measurements are recommended as the primary quantitative approach. Dermal and ingestion pathways are more challenging to evaluate. Suspected dermal exposures may be assessed using wipe tests on the worker's skin before and after processes involving ototoxicants, though this is not recommended as a common practice. Ingestion is not generally considered a significant occupational exposure route; however, some substances such as lead may pose a risk if ingested via contaminated dust. When available, biological monitoring can supplement exposure assessments in biological media, providing insight into hazardous material uptake and associated health risks [14].

#### **Workplace Control Measures**

Control measures should be used to prevent or minimize exposure to ototoxicants. A combination of interventions based on the hierarchy of controls [elimination, engineering, administrative, work practices, and personal protective equipment (PPE)] can be appropriately used.

Evidence suggests there are additive and synergistic effects of varying types of hazardous noise and ototoxicants. Being able to identify and quantify the chemicals is not solely adequate in ototoxicant exposure assessments. Additional steps are needed to properly evaluate ototoxicant exposures including monitoring the workplace for hazardous noise (continuous and impulse). This can be achieved by following the guidance and best practices outlined in [12, Chapter 6], and other DOD/Navy directives. Guidance is also provided by the ACGIH, which has established an "OTO" notation for chemicals that have been shown through evidence from animal and human study, the ability to cause hearing impairment alone or in combination with noise, even below 85 dBA TWA and below the respective chemical's OEL [14].

## Control Recommendations Engineering Controls

When substitution or elimination of ototoxicants is not feasible, engineering controls—such as isolation, enclosures, barriers, sound-absorbing surfaces, or ventilation—can help reduce exposure to both ototoxicants and noise, thereby lowering the risk of adverse health effects. Be aware that substitution and replacement for military-specific equipment is often not feasible; however, these methods of control should be a consideration in workplaces where ototoxicants may be present or where there are nonmilitary-specific tools and equipment in operation [8, 13, 22, 23].

#### Administrative Controls: Training and Communication

Administrative controls may include training workers on hazards [23], eliminating unnecessary tasks that cause noise or ototoxicant exposure, and allowing only necessary personnel to be in the vicinity of noise hazardous operations. Other administrative controls to consider when evaluating ototoxicant and noise exposures include defining hazardous noise areas and equipment (i.e., signage and labeling), relocating workers from the source, or applying shift rotation, especially in instances where workers may be exposed to noise and ototoxicants frequently and for prolonged durations [8, 13, 22, 23]. NMCFHPC IH and Occupational Toxicology staff can provide resources and effective communication strategies for training and education purposes.

#### Personal Protective Equipment (PPE)

As a last option the use of PPE may be recommended. PPE does not eliminate the hazard but relies on worker compliance and proper use. Dependent upon exposure assessments and SDS requirements, respirators may be recommended to reduce inhalation exposures. Keep in mind, many ototoxic substances can be absorbed through the skin (e.g., acrylonitrile, benzene, n-hexane, parathion, etc.). To reduce dermal exposures, the use of chemical-protective gloves, arm sleeves, aprons, and other appropriate clothing is recommended for those substances designated with a SKIN notation per NIOSH and ACGIH [14]. Proper PPE selection requires consideration of the exposure assessment and consultation of chemical SDS [8, 22, 23]. For further information or consultation please contact the NMCFHPC OEH staff at <u>usn.hampton-</u>

roads.navmcpubhlthcenpors.list.nmcphc-ask-ih@health.mil.

#### Recommendations

#### Medical Surveillance Program

The recommendation to enroll an individual into a medical surveillance program is based on DOD and OSHA regulatory requirements and/or the qualitative/quantitative exposure assessments of the various occupational chemical, biological, and physical hazards. Although enrollment in an exposure-based medical surveillance program can occur based on qualitative assessment results, it usually occurs once a quantitative exposure assessment has been performed where results indicate exposures above action level or OEL, or if OSHA has identified specific requirements in their substance specific standards [12, Chapter 2]. DON/DOD noise standards require enrollment in the Hearing Conservation Program (HCP) when personnel are exposed at least once annually to continuous or intermittent noise at a level of 85 dBA or higher as an 8-hour time-weighted average, or to impulse noise at 140 dB peak (dBP) or higher. Additionally, in accordance with DOD guidance and United States Marine Corps (USMC) policy, all Marines are considered noise-exposed and are automatically enrolled in the HCP.

In conjunction with industry best practices, exposure limits for many chemicals being set without specifically considering ototoxicity, and the potential for exposures to elicit adverse audiological effects at less than current OELs, using ½ the OEL for an action level has been carefully considered [24, 25, 26, 27, 28]. Enrollment in medical surveillance occurs after evaluation of IH survey results and collaborative determination of the likelihood of exposure to actual and potential hazards by staff representing Safety, IH, and Occupational Medicine [29]. When using qualitative and quantitative data please apply the following considerations when recommending controls, including Medical Surveillance enrollment [12]:

- If the exposure assessment, using sampling data or professional judgment following AIHA's A Strategy for Assessing and Managing Occupational Exposures, indicates that 8-hour Time-Weighted Average (TWA) or 95th percentile exposure levels are greater than or equal to 50% of the OEL for 30 days or more per year, with or without hazardous noise exposure, then:
  - o document the exposure assessment as unacceptable
  - o require the appropriate use of PPE and
  - o recommend enrollment of personnel in medical surveillance based on the potential for adverse health effects.

**NOTE:** Given that many occupational ototoxicants are not explicitly addressed within substance-specific OSHA standards, **the establishment of a comprehensive medical surveillance program covering ototoxicants should be developed utilizing the Navy's Medical Matrix** [30, 31, 32]. For ototoxicants not already covered in the Navy's medical matrix, collaboration for determining development of new programs should encompass OEH and additional professionals as appropriate. For further information or consultation please contact the NMCFHPC IH Department at <u>usn.hampton-roads.navmcpubhlthcenpors.list.nmcphc-ask-ih@health.mil.</u>

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#### **APPENDIX A: Additional Background and Historical Information**

Exposure to hazardous noise remains the Department of the Navy's (DON) top health hazard and expense with costs exceeding one billion dollars each year [30, Chapter 18]. Management of noise and prevention of injury is a significant priority within DON, both ashore and afloat. Navy Leadership is expected to support the DON Hearing Conservation Program for optimization of operational readiness and hearing preservation during military and federal service. The HCP focuses on reducing hearing loss as an integration of the DOD's policy to protect military personnel and noise-exposed civilians from hearing impairment caused by occupational and operational noise exposure through a continuous, effective, and comprehensive hearing conservation program [9]. This guidance aims to reduce hazardous occupational and operational noise exposure to enhance mission readiness, communication, and safety.

Occupational hearing loss is considered a preventable injury [33]. Hearing loss and tinnitus were the top two compensable disabilities through all periods of service dating back to World War II and continue to be among the highest compensable service-connected disability claims for new compensation recipients as well as claims for all recipients [34]. Long-standing efforts to address hearing loss began with the Army, Navy, and VA establishing auditory rehabilitation centers in the early 1940s with service HCPs being developed through the 1950s [35]. The first DoD instruction 6055.12 for HCPs was released in 1978, which provided standardized practice for collection and management of data, surveys, and audiograms. These initial efforts were refined by the services, and in 1998, hearing conservation data was consolidated into the Defense Occupational Environmental Health Readiness System for Hearing Conservation (DOEHRS-HC) [36]. In 2017, Congress mandated the establishment of the Hearing Restoration Research Program, directing scientific and medical efforts to reduce economic and health impacts of hearing loss on servicemembers [37].

Noise Induced Hearing Loss (NIHL) and tinnitus are the most prevalent occupational health risks for the Navy. Tactical training, operational combat, shipboard operations, and shore industrial environments are inherently noise hazardous occupations. Unprotected exposure to hazardous noise can cause temporary or permanent hearing loss, compromise verbal communications, degrade the ability to discern important auditory signals in the environment, and jeopardize human safety and operational efficiency [34, 38-39]. Hearing acuity is critical to individual medical readiness and mission success. Hazardous noise reduces productivity, efficiency, readiness, and hearing response. Along with substantial economic burden, there is considerable diminished quality of life for individuals with severe hearing loss [40]. Personnel enrolled in HCPs get annual hearing

tests, hearing protection device fittings, and hearing conservation education sessions to reduce noise-induced hearing loss [9].

# **APPENDIX B: Navy DOEHRS-IH Breakdown of Frequently Notated Ototoxicants and Corresponding Common Processes**

The below table presents frequently notated ototoxicants (stressors) and the commonly associated processes throughout the Navy utilizing data collected from the DOEHRS-IH in 2024 [41].

Ototoxicant	Navy Common Processes
Acrylonitrile	Adhering/Bonding/Sealing
	Plastics/Rubber Processing
	Aircraft Maintenance
	Equipment Repair/Maintenance
	Additive Manufacturing
Carbon Disulfide	HM/HW Handling & Cleanup
	Laboratory Operation
	Professional/Technical
	Fuels
Carbon Monoxide	Supplies/Materials Handling
	Aircraft/Flightline Operations
	Vehicle Maintenance Transportation
	Roads & Grounds Maintenance
Ethyl Benzene	Coating/Painting Operations
	Adhering/Bonding/Sealing
	Equipment Repair/Maintenance
	Fuels
	Cleaning-Chemical & Degreasing
Hydrogen Cyanide	Electroplating
	HM/HW Handling & Cleanup
	Fabric Work
	Laboratory Operations
	Protective Services-Fire
N-Hexane	Adhering/Bonding/Sealing
	Cleaning- Chemical & Degreasing
	Coating/Painting Operations
	Equipment Repair/Prev. Maintenance
	Aircraft Maintenance
	Professional/Technical
Lead	Weapons & Ordnance
	Brazing/Soldering/Welding/Cutting
	Coating/Paint Removal Equipment
	Repair/Prev. Maintenance
	Electrical/Electronics
	Adhering/Bonding/Sealing

Ototoxicant	Navy Common Processes
P-Xylene	Coating/Painting Operations
	Professional/Technical
N-Propylbenzene	Weapons & Ordnance
Mercury	Dental HM/HW Handling & Cleanup
	Professional/Technical
	Equipment Repair/Prev. Maintenance
	Electrical/Electronics
Toluene	Coating/Painting Operations
	Adhering/Bonding/Sealing
	Equipment Repair/Prev. Maintenance
	Aircraft Maintenance
	Cleaning- Chemical & Degreasing
Styrene	Adhering/Bonding/Sealing
	Composite Work
	Coating/Painting Operations
	Additive Manufacturing
	Plastics/Rubber Processing
Trichlorethylene	Adhering/Bonding/Sealing
	Equipment Repair/Prev. Maintenance
	Vehicle Maintenance
	Cleaning- Chemical & Degreasing
	Plastics/Rubber Processing

#### **APPENDIX C: Acknowledgements**

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