

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

UNITED STATES OF AMERICA *ex rel.*
MOLDEX-METRIC, INC.,

Plaintiff/Relator,

vs.

3M COMPANY,

Defendant.

CASE NO. 3:16-1533-MBS

**ORIGINAL COMPLAINT FILED IN
CAMERA**

**SEALED PURSUANT TO 31 U.S.C.
§ 3730(b)(2)**

JURY TRIAL DEMANDED

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**INTRODUCTION**

This is an action by *qui tam* Plaintiff/Relator Moldex-Metric, Inc. (“Moldex”), in the name of the United States Government, to recover penalties and damages arising from false statements made by Defendant 3M Company (“3M” or the “Company”) to the Government regarding its dangerously defective dual-ended Combat Arms™ earplugs, which 3M sold to the U.S. military for more than a decade without its knowledge of the defect. Plaintiff/Relator’s claims reveal the protracted fraud perpetrated on the military by 3M, whose dual-ended Combat Arms™ earplugs—which were standard issue in certain branches of the military during foreign conflicts between 2003 and 2015—have likely caused thousands of soldiers to suffer significant hearing loss and tinnitus in addition to exposing millions to the risk caused by 3M’s defective earplugs.¹ The indirect cost to the public of 3M’s fraud has been enormous. In addition to funding the military’s repeated purchases of the defective earplugs from 3M for more than a decade, tax payers must shoulder the massive expense of treating veterans with hearing damage and impairment, which represents the largest ongoing medical cost to the military. Plaintiff/Relator Moldex alleges as follows:

THE PARTIES

1. Moldex is a family-owned business organized and existing under the laws of California with its principal place of business in Culver City, California. It is in the business of designing, manufacturing and selling worker safety products, including hearing protection

¹ As 3M explains in a press release trumpeting its sales of its Combat Arms™ earplugs to the military, “[t]innitus, often referred to as ‘ringing in the ears,’ and noise-induced hearing loss can be caused by a one-time exposure to hazardous impulse noise, or by repeated exposure to excessive noise over an extended period of time.” Ex. 1, 3M Newsroom, *3M Hearing Protection Devices Now Added to the Federal Procurement List* (Aug. 30, 2012), available at http://solutions.3m.com/wps/portal/3M/en_US/3M-Defense-US/Defense/About-3M-Defense/News/ (last visited Apr. 25, 2016).

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products and respirators. In 2011, Moldex introduced a non-linear dual-mode earplug, called BattlePlugs®. Moldex's BattlePlugs® provided the first actual competition to 3M's Combat Arms™ earplugs in the market for non-linear earplugs approved for purchase by the military.

2. 3M Company is a corporation organized and existing under the laws of the state of Delaware with its principal place of business in St. Paul, Minnesota. Among other things, it is in the business of designing, manufacturing, and selling worker safety products, including hearing protectors and respirators. 3M has a dominant market share in virtually every safety product market, including hearing protection. 3M is one of the largest companies in the country.

JURISDICTION AND VENUE

3. This action arises under the False Claims Act, 31 U.S.C. § 3729, *et seq.*

4. Jurisdiction over this action is conferred upon the Court by 31 U.S.C. § 3732(a) and 28 U.S.C. § 3130 in that this action arises under the laws of the United States.

5. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 31 U.S.C. § 3732(a) because Defendant 3M transacts business in this District and can be found within the United States.

6. Venue is also proper because this District has general jurisdiction over 3M due to its extensive, long-standing presence. Defendant 3M operates manufacturing facilities at 1400 Perimeter Road, Greenville, South Carolina 29605-5467, which includes at least two plants. 3M has operated facilities at this location since 1974, and in 2007 began a \$100 million ongoing expansion project. Ex. 3, *History of 3M Greenville*, available at http://solutions.3m.com/wps/portal/3M/en_US/Greenville/Plant/Facility/History/ (last visited May 6, 2016). 3M touts the benefits of its active participation in the Greenville community on its website. Ex. 4, *Community Involvement*, available at

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http://solutions.3m.com/wps/portal/3M/en_US/Greenville/Plant/Community/Involvement/ (last visited May 6, 2016).

7. Venue is also proper because, in addition to the statutory bases, this District has specific jurisdiction over false statements and claims related to 3M's distribution of the Combat Arms earplugs to South Carolinian soldiers. Starting in 2004, all soldiers deployed to Iraq and Afghanistan were issued Combat Arms earplugs. Ex. 5, McIlwain, D. Scott *et al.*, *Heritage of Army Audiology and the Road Ahead: The Army Hearing Program*, AMERICAN JOURNAL OF PUBLIC HEALTH, Vol. 98 No. 12 (Dec. 2008). South Carolina is home to several Army, Air Force, Navy, and Marine military bases from which soldiers were trained and deployed to these combat zones—including Fort Jackson, Shaw Air Force Base, the Marine Corp Recruiting Depot at Parris Island, and the Naval Weapons Station Charleston. With respect to Fort Jackson, for example, 3M was the supplier of Combat Arms earplugs prior to Moldex assuming the contract in 2012.

FACTUAL ALLEGATIONS**I. 3M'S DEFECTIVE COMBAT ARMS™ EARPLUGS****3M's dual-ended Combat Arms™ earplugs**

8. 3M's dual-ended Combat Arms™ earplugs, which are non-linear, or selective attenuation, earplugs, were designed to provide soldiers with a single set of earplugs that offer them two options for hearing attenuation depending upon how the plugs are worn. If worn in the

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“closed” or “blocked” position (olive end in), the earplugs are supposed to block sound like traditional earplugs. If worn in the “open” or “unblocked” position (yellow end in), the earplugs are supposed to block, or at least significantly reduce, loud impulse sounds of battlefield explosions, while still allowing the wearer to hear quieter noises such as commands spoken by fellow soldiers and approaching enemy combatants. These earplugs were originally created by a company called Aearo Technologies (“Aearo”). 3M acquired Aearo in 2008 (and thus any liability associated with its past conduct) and hired the employees at Aearo that developed and tested the defective earplugs. These 3M employees were aware of the defects as early as 2000, several years before 3M/Aearo became the exclusive provider of the earplugs to the military.

9. As known to 3M/Aearo at the time it bid for and won the underlying Indefinite-Quantity Contracts (“IQCs”) that made it the exclusive supplier of selective attenuation earplugs to the military between 2003 and 2012, these earplugs have dangerous design defects that can cause them to loosen in the wearer’s ear, imperceptibly to the wearer and even trained audiologists visually observing a wearer, thereby permitting damaging sounds to enter the ear canal by traveling around the outside of the earplug while the user and/or audiologist incorrectly believes that the earplug is working as intended. Because the stem of the dual-ended earplug is too short, it is difficult to insert the plug deeply into some wearer’s ear canals and obtain a proper fit. Specifically, when the earplug is inserted into the ear according to standard fitting instructions, the basal edge of the third flange of the non-inserted end of the earplug is prone to press against some wearers’ ear canals and fold back to its original shape, thereby loosening the seal in their ear canals. The defect has the same effect when either end is inserted because the earplugs are symmetrical. In either scenario, the effect is that the earplug may not maintain a

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tight seal in some wearers' ear canals such that dangerous sounds can bypass the plug altogether thereby posing serious risk to the wearer's hearing unbeknownst to him or her.

10. These dangerous design defects were known to Aearo in 2000 (and later 3M) when it completed testing of the dual-ended Combat Arms™ earplugs. This is evidenced by the fact that when Aearo retested the closed end of the earplug starting in February 2000, as detailed below, its personnel rolled back the non-inserted yellow flanges in order to mitigate the loosening effect of the defect caused by the short stem. Further, the 3M/Aearo scientist who oversaw and documented this testing, and the 3M/Aearo lab technician who conducted the testing, are still employed by 3M to this day.

11. Despite this knowledge, in 2003, Aearo submitted a bid in response to the military's Request for Proposal ("RFP") to supply large quantities of these defective earplugs and entered into an IQC pursuant to which it became the exclusive supplier of earplugs to the military. When it responded to the RFP, Aearo was required to expressly certify that the earplugs complied with the Salient Characteristics of Medical Procurement Item Description ("MPID") of Solicitation No. SP0200-06-R-4202. *See* Ex. 2, Solicitation No. SP0200-06-R-4202. The earplugs did not, however, comply with those Salient Characteristics, which Aearo knew at the time it made its certification. Thus, Aearo's response to the RFP constitutes a false statement or record and each of Aearo's and later 3M's subsequent requests for payment pursuant to the IQC resulting from these false statements or records constitutes a false claim within the meaning of the False Claims Act ("FCA"). Each of Aearo's and 3M's subsequent responses to the military's RFPs and the resulting IQC payment requests constitute additional, distinct false statements and claims by 3M/Aearo for which 3M is now liable.

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II. THE SALIENT CHARACTERISTICS OF THE MILITARY’S RFPs

12. Since 2003, 3M/Aearo has been awarded multiple IQC’s in response to RFPs, including but not limited to SP0200-06-R-4202, issued by the military requesting bids to supply non-linear, selective attenuation earplugs. In response to each of these RFPs, 3M/Aearo was required to certify that its dual-ended Combat Arms™ earplugs complied with the Salient Characteristics of the associated MPIDs. The pertinent Salient Characteristics set forth in the MPID, which was uniform across all RFPs, in relevant part, are as follows:

2.1.1. Ear plugs shall be designed to provide protection from the impulse noises created by military firearms, while allowing the wearer to clearly hear normal speech and other quieter sounds, such as voice commands, on the battlefield.

2.2.2. The sound attenuation of both ends of the ear plugs shall be tested in accordance with ANSI S3.19....

2.4 Workmanship. The ear plugs shall be free from all defects that detract from their appearance or impair their serviceability.

2.5 Instructions. Illustrated instructions explaining the proper use and handling of the ear plugs shall be supplied with each unit....

Ex. 2, Solicitation No. SP0200-06-R-4202 at 41-42.

13. The Environmental Protection Agency (“EPA”) has also promulgated regulations pursuant to the Noise Control Act, 42 U.S.C. § 4901, *et seq.*, that govern the testing and attendant labeling of hearing protective devices like the dual-ended Combat Arms™ earplugs. Specifically, 40 C.F.R. § 211.206-1 provides that:

The value of sound attenuation to be used in the calculation of the Noise Reduction Rating must be determined according to the “Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs.” This standard is approved as the American National Standards Institute Standard (ANSI-STD) S3.19-1974.

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14. Additionally, 40 C.F.R. § 211.204-4(e) of the EPA regulations requires that certain “supporting information” must accompany hearing protection devices sold in the United States:

The following minimum supporting information must accompany the device in a manner that insures its availability to the prospective user. In the case of bulk packaging and dispensing, such supporting information must be affixed to the bulk container or dispenser in the same manner as the label, and in a readily visible location....
Instructions as to the proper insertion or placement of the device.

Emphasis added.

III. 3M’S DELIBERATELY FLAWED TESTING OF THE EARPLUGS, RESULTING FALSE AND MISLEADING NRRs, AND IMPROPER INSTRUCTIONS FOR USE OF THE EARPLUGS

15. Earplugs like 3M’s are sold with a listed NRR that is supposed to represent the amount of sound attenuation perceived by a test group when tested under certain conditions required by the statutorily required test methodology. The military can only purchase 3M’s dual-ended Combat Arms™ earplugs if they meet the testing standards required by the U.S. Army Public Health Command, Army Hearing Program, or equivalent standards that may be promulgated by other military services. As such, before 3M/Aearo could sell its earplugs to the military, 3M/Aearo had to test them to determine the NRR, which would be included on the product label.

16. In or around January 2000, personnel at Aearo commenced NRR testing on each end of the earplug. Rather than outsource the testing to an independent lab, Aearo chose to conduct the testing at its own E-A-RCAL laboratory (which also is now owned by 3M). Aearo’s personnel selected ten test subjects, some of whom were their own employees, to test the earplug. Aearo’s personnel tested, in no particular order: (1) the subject’s hearing without an earplug inserted; (2) the subject’s hearing with the open/unblocked (yellow) end of the dual-

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ended Combat Arms™ earplug inserted; and (3) the subject's hearing with the closed/blocked (olive) end of the earplug inserted.

17. Aearo personnel monitored the noise attenuation results of each subject as each test was performed and could stop the test if they did not get the NRR results they wanted, which violated the ANSI S3.19-1974 testing protocol. After eight of the ten test subjects had been tested on both the open and closed ends of the earplug, Aearo personnel decided not to test the last two subjects' hearing with the closed/blocked end of the earplug inserted. At that point, the average of the results for the first eight subjects suggested an NRR of 10.9, which was far below the "22" NRR that 3M/Aearo would have expected for the closed end of the plug. This result was directly attributable to the design defect in the earplugs causing some wearers to receive little or no sound attenuation, due to the imperceptible slip explained above, while others achieved the expected levels of sound attenuation.

18. Aearo personnel apparently liked the low NRRs they were getting from the same test subjects due to the design defect on the open end of the plug, however. As such, Aearo completed testing all ten of the subjects' hearing with the open end of the plug inserted and obtained a facially invalid -2 NRR, meaning the earplug would actually function as a hearing aid by amplifying sound. Aearo personnel reported the -2 NRR as a "0" NRR, which 3M/Aearo has displayed on the packaging of the dual-ended Combat Arms™ earplugs since the product was launched. Since late 2003, 3M/Aearo has touted this rating as an added benefit to the military on the theory that wearers of these earplugs would be able to hear commands from friendly soldiers and approaching enemy combatants, unimpaired, in the same way as if they had nothing in their ears.

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19. After prematurely terminating testing of the closed/blocked end of the earplug, Aearo personnel immediately investigated the cause of the closed/blocked end's implied and unacceptably low NRR and discovered that, because the stem of the earplug was so short, it was difficult to insert the plug deeply into the subject's ear canals and obtain a proper fit, as required by ANSI S3.19-1974, Section 3.2.3. Ex. 8, Acoustical Society of America Standard Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs (ASA STD 1-1975). Furthermore, Aearo personnel discovered that when the olive, closed end of the earplug was inserted into the subject's ear according to standard fitting instructions, the basal edge of the third flange of the yellow, open end of the earplug pressed against the subject's ear canal and folded backwards. When the inward pressure on the earplug was released, the yellow flanges tended to return to their original shape, thereby loosening the earplug, often imperceptibly to the test subject. The dual-ended Combat Arms™ earplugs are symmetrical and thus this problem would be experienced when the plug is reversed as well. The image below illustrates how the basal edge of the earplug interacts with the ear canal.



Image from J.G. Casali, *et al.*, *A field investigation of hearing protection and hearing enhancement in one device: For soldiers whose ears and lives depend upon it*, 11 NOISE & HEALTH JOURNAL 42, 69-90 (2009).

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20. Aearo personnel then determined that in order for a test subject to obtain proper plug insertion, the flanges on the opposite, non-inserted end of the earplugs had to be folded back prior to insertion into the test subject's ear.

21. Once it had identified the design defect of the earplugs, Aearo decided to retest the olive, closed end of the earplug starting in February 2000 using different fitting instructions. Ex. 9, 3M's Answer to First Amended Complaint in *Moldex-Metric, Inc. v. 3M Company, et al.*, No. 14-cv-1821-JNE-FLN (D. Minn.), ¶¶ 35-36. During this retest of the closed end, Aearo personnel folded back the yellow flanges on the open end of the earplug (essentially elongating the too-short defective stem) to allow the experimenter to insert the closed end of the plug deeply into the subject's ear in order to obtain a proper fit. *Id.* Furthermore, as the yellow flanges were folded back during this retest, the basal edge of the third flange of the yellow, open end of the earplug no longer pressed against the subject's ear canal, and thus did not cause the earplug to loosen during the testing. *Id.* As a result of using this manipulated fitting procedure during the retest, as 3M/Aearo was aware before it sold the earplugs to the military, Aearo's personnel achieved a "22" NRR on the closed end of the dual-ended Combat Arms™ earplug. *Id.*

22. As explained above, due to the symmetrical structure of the dual-ended Combat Arms™ earplug, the design defects that affect the fit of the earplug on the closed end of the earplug also impact the fit on the open end. It is facially obvious from the -2 NRR test data Aearo obtained on the open end of the earplug that multiple test subjects were not properly fitted with the open end, as required by ANSI S3.19-1974 Section 3.2.3. During Aearo's testing of the open end, there was not a proper seal between certain of the subjects' ear canal and the earplug, thereby allowing noise to bypass the earplug filter and go directly into the ear canal. As a result, certain test subjects had large standard deviations across trials on the open end test, which

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artificially drove down the NRR to -2 in the open position. 3M/Aearo knew before selling the earplugs to the military that, notwithstanding these facially unreliable testing results, it did not go back and retest the open end of the earplug using the “modified” fitting procedure, *i.e.*, folding back the flanges on the olive, closed end of the earplug prior to inserting the yellow, open end into the ear.

23. The reasoning for this inaction is clear: 3M/Aearo wanted a very low NRR on the open end of 3M’s Combat Arms™ earplug (like the rounded up “0” NRR it previously obtained) so that the military would be more likely to buy it. If the open end of the plug were fitted securely into the test subjects’ ears using the modified fitting procedure, the NRR would have been much higher on the open end of the earplug and hence less marketable to the military as an earplug that supposedly would allow soldiers to hear commands and approaching combatants.

24. 3M/Aearo also knowingly used the deliberately flawed retest of the closed end of the earplugs to sell dual-ended Combat Arms™ earplugs to the military with a “22” NRR in the closed position. 3M/Aearo includes standard instructions for “proper use” of the earplugs in the packaging for the earplugs as required by the EPA, Noise Control Act, and the MPID. *See* Ex. 10, Combat Arms Earplugs Instructions. 3M’s/Aearo’s standard instructions for “proper use” of its Combat Arms™ earplugs do not instruct wearers to fold back the flanges before inserting the plug into the ear. *Id.* Instead, 3M/Aearo improperly instructs wearers to simply insert the earplugs as-is into the ear canal. *Id.* By failing to instruct wearers of the dual-ended Combat Arms™ earplug to fold back the flanges on the open/unblocked end of the plug before inserting the closed/blocked end of the plug into their ears (which is necessary to achieve the “22” NRR and avoid the defect associated with the short stem), 3M/Aearo falsely overstates the amount of hearing protection provided by the closed end of the plug. 3M’s/Aearo’s packaging and

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marketing of such earplugs with a labeled NRR of “22” thereby misleads the military, and has likely caused thousands of soldiers to suffer significant hearing loss and tinnitus in addition to exposing millions more to the risk caused by 3M’s/Aearo’s defective earplugs.

25. 3M/Aearo also has continued to sell the dual-ended Combat Arms™ earplugs to the military with a “0” NRR in the open position and with standard fitting instructions, which is false and misleading for the same reasons. Given the symmetrical nature of the earplugs, the defective stem issue that causes the earplug to imperceptibly loosen when the closed end is inserted also causes the plug to loosen when the open end is inserted. As a result, soldiers who wear the plug with the yellow end inserted desiring to block out dangerous impulse noise while still being able to hear voice commands or approaching combatants are at risk of serious hearing impairment. When the seal between the earplug and the soldier’s ear canal is broken, dangerous impulse noise can bypass the filter on the open end leaving the soldier with no hearing protection at all. 3M/Aearo would not have achieved a facially invalid -2 NRR if this were not the case.

26. In sum, as 3M/Aearo was aware prior to selling the earplugs to the military, testing procedures and fitting instructions were unlawfully manipulated to obtain the NRRs it wanted on both ends of the dual-ended Combat Arms™ earplug, and 3M/Aearo has continued to use these inaccurate NRRs to market the earplugs to the military for more than ten years without disclosing the design defect in the plugs. The closed end provides a “22” NRR only if inserted using non-standard instructions for use that 3M/Aearo does not disclose to purchasers (*i.e.*, the military) nor end user wearers (*i.e.*, soldiers). This grossly overstates the noise protection offered by this end of the plug in violation of ANSI S3.19, EPA regulations, 40 C.F.R. § 211.201, *et seq.*, and the NCA, 42 U.S.C. § 4901, *et seq.* Meanwhile, the open end of the earplug’s “0” NRR

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is based on facially unreliable test data derived from tests in which the earplugs were not fitted properly in the subjects' ears.

IV. FALSE CERTIFICATIONS TO THE MILITARY

27. Although 3M/Aearo was aware when it first bid for the IQCs to supply its Combat Arms™ to the military that testing of the earplugs violated ANSI S3.19-1974, 3M/Aearo certified to the military that the testing complied with that testing standard. In response to the military's RFPs, 3M/Aearo were required to certify that testing of the earplugs was done in accordance with ANSI S3.19-1974, and thus each response by 3M/Aearo would constitute a false statement or record within the meaning of the FCA.

28. 3M/Aearo was further required to certify in response to each RFP that it provided accurate "instructions explaining the proper use and handling of the ear plugs." As discussed above, 3M/Aearo was aware at the time it bid for the IQCs that personnel folded back the flanges of the yellow, open end of the earplug when testing the closed end and did not similarly manipulate the fit of the earplugs when testing the open end. Yet, despite knowing that its flawed testing involved steps to manipulate the fit of the earplug, 3M's/Aearo's instructions for use of the earplugs do not instruct, and never have instructed, the wearer to fold back the flanges on the open end of the plug before inserting the closed end of the plug into their ears (which is necessary to achieve the "22" NRR and avoid the defect associated with the short stem). Ex. 10, Combat Arms Earplugs Instructions. Since it first began supplying the earplugs to the military, 3M's/Aearo's instructions instead have provided standard fitting instructions for inserting the earplug on both ends. *Id.* These use instructions are, therefore, facially inadequate. Certification to the contrary is a false statement for purposes of the FCA and has put soldiers at risk of suffering serious hearing impairment on the battlefield.

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29. Pursuant to Section 2.4 of the MPID, when responding to the RFPs, 3M/Aearo also was required to certify that “[t]he ear plugs shall be free from all defects that detract from their appearance or impair their serviceability.” Ex. 2, Solicitation No. SP0200-06-R-4202 at 42. As explained above, 3M/Aearo knew as early as 2000 that its dual-ended Combat Arms™ earplugs were designed with too short a stem, which causes the plugs to imperceptibly loosen in the wearer’s ear when the flanges are not rolled back. Despite this knowledge, 3M/Aearo marketed and sold the defective earplugs to the military over a period of more than a decade with fitting instructions that do not instruct the purchaser/wearer to roll back the flanges, all the while being required to certify that the earplugs were free of defects. Further, soldiers moving around on the battlefield are even more likely to experience the harmful effects of the earplug’s defects than are test subjects during an NRR test, because NRR tests typically only last a few minutes and are performed in a laboratory setting where the subject’s head remains virtually motionless during testing. Thus, such defects place thousands of soldiers at risk of suffering hearing damage or impairment.

V. THE ENORMOUS DAMAGE TO THE GOVERNMENT AND PUBLIC RESULTING FROM 3M’S FRAUD

30. The impact of 3M’s fraud cannot be overstated. In addition to the cost borne by the military for its repeated purchases of the defective earplugs, 3M’s fraud has likely contributed to the enormous medical costs associated with treating returning combat soldiers impaired by significant hearing damage and impairment. Given the imperceptibility of the defect, wearers would not have been able to detect whether the earplug had come loose. Similarly, given how imperceptible it is, military personnel, including trained audiologists, fitting the plugs and observing a wearer with the plugs inserted also likely could not perceive the

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defect. 3M was thus able to perpetrate its fraud on the military for more than ten years at enormous cost to the public.

31. The military has paid millions of dollars over the past ten plus years to purchase the defective earplugs and, unbeknownst to it, when issuing the earplugs to combat soldiers, was putting their hearing at risk. Hearing loss is a significant ongoing healthcare issue for the Department of Veteran Affairs (“VA”). Data collected by the VA indeed shows that as many as 52% of combat soldiers return from foreign conflicts with significant hearing damage, which represents the largest ongoing medical cost of the military. Ex. 12, David E. Gillespie, *Researchers Evaluate True Effects of Hearing Loss for Soldiers* (Dec. 16, 2015), available at http://www.army.mil/article/160050/Researchers_evaluate_true_effects_of_hearing_loss_for_soldiers/ (last accessed May 4, 2016). A 2015 article, for example, estimates that the VA spends more than \$1 billion per year to treat hearing loss for more than 800,000 veterans. *Id.*; see also Ex. 6, Kay Miller, *Hearing loss widespread among post-9/11 veterans*, The Center for Public Integrity (Aug. 29, 2013), available at <https://www.publicintegrity.org/2013/08/29/13283/hearing-loss-widespread-among-post-911-veterans> (last visited Apr. 25, 2016) (noting that “[t]he most-widespread injury for [post-911] veterans has been hearing loss and other auditory complications” and that “[h]earing maladies cost more than \$1.4 billion in veterans disability payments annually, according to fiscal year 2010 data from the Hearing Center of Excellence, a part of the Department of Defense.”).

32. The military likely purchased, at a minimum, one pair of 3M’s Combat Arms™ earplugs for each deployed soldier annually involved in certain foreign engagements between 2003 and 2015. See Ex. 5, McIlwain, D. Scott *et al.*, *Heritage of Army Audiology and the Road*

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Ahead: The Army Hearing Program, AMERICAN JOURNAL OF PUBLIC HEALTH, Vol. 98 No. 12 (Dec. 2008).

33. In 2006, the military entered into an IDQ with 3M/Aearo pursuant to which 3M/Aearo supplied 10,000 packages (50 pairs per package = 500,000 pairs), an estimated annual quantity of 15,000 packages (750,000 pairs), and estimated maximum of 45,000 packages (2,250,000 pairs) of 3M's/Aearo's Combat Arms™ earplugs. Ex. 11, Award Notice, 65 – Plug, Ear, Combat Arms, Dbl-Ended, 50 Pair (Dec. 19, 2006). According to the award notice for this IDQ, 3M/Aearo was guaranteed at least \$9,000,000 in sales of the earplugs in 2006. *Id.*

34. 3M's/Aearo's dual-ended Combat Arms™ earplugs were sold to the military beginning in late 2003 and continued to be sold directly and indirectly by 3M to the military until late 2015 when 3M discontinued the earplugs. Ex. 7, Discontinuation: 3M Combat Arms Earplugs Version 2 (Nov. 17, 2015). However, the defective earplugs were not recalled (and thus are likely still used by soldiers) and continue to be sold by others.

COUNT I
False Claims Act – Presentation of False Claims
31 U.S.C. § 3729(a)(1)(A)

35. Plaintiff/Relator Moldex re-alleges and incorporates by reference the allegations contained in paragraphs 1-34.

36. Defendant 3M, by and through its predecessor Aearo, and their officers, agents, supervisors, and employees, knowingly presented or caused to be presented to the United States Government false claims for payment or approval of multiple IQCs awarded under Solicitation Nos. SP0200-06-R-4202, SP0200-07-D-4103, and related solicitations for the supply of 3M's dual-ended Combat Arms™ earplugs to the military. Such false claims are in violation of 31 U.S.C. § 3729(a)(1)(A).

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37. In 2003, and several times since then and through 2015, 3M/Aearo was awarded several IQCs in response to the military's RFPs to supply large quantities of its Combat Arms™ earplugs to the military pursuant to which 3M/Aearo became the exclusive supplier of earplugs to the military. When it responded to these RFPs, 3M/Aearo was required to expressly certify that the earplugs complied with the Salient Characteristics of the MPID of the RFP. The earplugs did not, however, comply with those Salient Characteristics. Thus, every contract awarded as a result of these RFPs represents a false claim. Plaintiff/Relator is currently unaware of the specific number of such false claims, but will prove such number at trial.

38. The Salient Characteristics required earplugs designed "to provide protection from the impulse noises created by military firearms, while allowing the wearer to clearly hear normal speech and other quieter sounds, such as voice commands, on the battlefield." MPID Section 2.1.1. To meet this requirement, and in violation of ANSI S3.19-1974, as it was aware prior to supplying the earplugs to the military, 3M/Aearo took advantage of a known design defect during testing of the open/unblocked end of the earplugs by not rolling back the flanges on the opposite end prior to insertion. This resulted in an improper fit and a false NRR of -2, which 3M/Aearo have reported as an NRR of "0" and continually used to market the earplugs to the Government. Correcting for the known design defect, as it was aware before it sold the earplugs to the military, 3M/Aearo tested the closed/blocked end of the earplugs by rolling back the flanges on the opposite end prior to insertion to achieve a false NRR of "22" which 3M/Aearo knew was not accurate without instructions to roll back the flanges but nevertheless used the 22 NRR without such instructions to market the earplugs to the Government. 3M/Aearo were required to certify to the military that its earplugs had an accurate, properly tested NRR of "0"

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when worn in the open/unblocked position and an accurate, properly tested NRR of “22” when worn in the closed/blocked position.

39. The Salient Characteristics of the MPID required testing of the earplugs in compliance with ANSI S3.19-1974. MPID Section 2.2.2. 3M’s/Aearo’s testing failed to comply with ANSI S3.19-1974 because it initially tested only eight subjects on the closed end in contravention of the requirement to test no less than ten subjects on both ends. Additionally, as 3M/Aearo was aware prior to selling the earplugs to the military, 3M’s/Aearo’s testing failed to comply with ANSI S3.19-1974 because reported NRRs included test results from subjects for which 3M/Aearo knew there was not an adequate fit, thus making the result invalid. 3M/Aearo was nonetheless required to certify to the military that its testing of the earplugs complied with ANSI S3.19-1974 as required by the Solicitation.

40. The Salient Characteristics of the MPID also required that 3M/Aearo supply to the military earplugs that were “free from all defects that detract from their appearance or impair their serviceability.” MPID Section 2.4. 3M/Aearo knew as early as 2000 that its dual-ended Combat Arms™ earplugs were defectively designed with too short a stem that caused the plugs to imperceptibly loosen in the wearer’s ear when the flanges were not rolled back prior to insertion. 3M/Aearo was required to certify to the military that the earplugs were free of defects.

41. The Salient Characteristics of the MPID further required the provision of accurate “instructions explaining the proper use and handling of the ear plugs.” MPID Section 2.5. 3M’s/Aearo’s instructions for use of the earplugs do not instruct the wearer to fold back the flanges on the non-inserted end before inserting the other end of the plug into their ears (which 3M/Aearo knew was necessary to achieve the “22” NRR and avoid the defect associated with the short stem). 3M’s/Aearo’s instructions instead provide standard fitting instructions for inserting

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the earplug on both ends and are, therefore, inadequate to ensure a proper fit. 3M/Aearo was nonetheless required to certify to the military that the instructions for “proper use” of the earplugs are complete and accurate.

42. Each false statement alleged in this Count was knowingly presented, made, or used as the term “knowingly” is defined in 31 U.S.C. § 3729(b). The falsely obtained and reported NRR ratings, failure to comply with ANSI S3.19-1974, design defects requiring special fitting instructions, and the failure to provide such instructions were known to 3M/Aearo at least by 2000 when testing of the dual-ended Combat Arms™ earplugs was completed. 3M/Aearo therefore had actual knowledge of the falsity of its claims at the time it made them, but exercised deliberate indifference and reckless disregard toward such falsity in seeking payment under the IQCs awarded in connection with the RFPs.

43. 3M’s/Aearo’s false representations in being awarded the IQCs in response to the military’s RFPs were material to the Government’s decision to purchase the dual-ended Combat Arms™ earplugs. 3M’s/Aearo’s products were not eligible for such contracts unless they complied with the Salient Characteristics of the MPID. But for false certifications of compliance, the Government would not have awarded the contracts to 3M/Aearo and paid 3M’s/Aearo’s claims pursuant to the IQCs. 3M’s/Aearo’s actions therefore had a natural tendency to influence, or were capable of influencing, the payment or receipt of money.

44. As a result of required certifications, the Government did in fact award several IQCs for the purchase of dual-ended Combat Arms™ earplugs to 3M/Aearo, 3M’s/Aearo’s requests for payment under each of which constitutes a claim to the Government within the meaning of the FCA.

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45. The United States has been damaged as a result of 3M's/Aearo's violations of the FCA because it has received a product inferior to that which it specified and for which it paid. In addition to damages directly associated with the contractual cost of the earplugs, the United States has been damaged by the large and ongoing medical costs associated with treating veterans who likely suffered hearing damage and impairment as a result of the defective earplugs.

WHEREFORE, Plaintiff/Relator Moldex demands compensatory and multiple damages, costs, attorney fees, and such other legal and equitable relief as the Court may provide, including, but not limited to, exclusion or debarment.

COUNT II
False Claims Act – Use of False Statements
31 U.S.C. § 3729(a)(1)(B)

46. Plaintiff/Relator Moldex re-alleges and incorporates by reference the allegations contained in paragraphs 1-45.

47. As described above, Defendant 3M, by and through its predecessor Aearo, and their officers, agents, supervisors, and employees, knowingly made, used, or caused to be made or used false records or statements material to the United States Government's payment or approval of the false claims pursuant to multiple IQCs awarded under Solicitation Nos. SP0200-06-R-4202, SP0200-07-D-4103 and related solicitations for the supply of dual-ended Combat Arms™ earplugs to the military. Such false records or statements are in violation of 31 U.S.C. § 3729(a)(1)(B).

48. Each false record or statement alleged in this Count was knowingly presented, made, or used as the term "knowingly" is defined in 31 U.S.C. § 3729(b). The falsely obtained and reported NRR ratings, failure to comply with ANSI S3.19-1974, design defects requiring

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special instructions, and the failure to provide such instructions were known to 3M/Aearo before it was awarded the IQCs in response to each RFP. 3M/Aearo therefore had actual knowledge of the falsity of its claims at the time it made them, but exercised deliberate indifference and reckless disregard toward such falsity in seeking payment under the IQCs awarded in connection with the RFPs.

49. These required false statements in response to RFPs were material to the Government's decision to award 3M/Aearo the IQCs to purchase the dual-ended Combat Arms™ earplugs and its payments to 3M/Aearo. 3M's/Aearo's products were not eligible for such contracts unless they complied with the salient characteristics of the MPID. But for false certifications of compliance, the Government would not have awarded the contracts to 3M/Aearo and paid 3M's/Aearo's claims pursuant to the IQCs. 3M's/Aearo's actions therefore had a natural tendency to influence, or were capable of influencing, the payment or receipt of money.

50. As a result of these required fraudulent statements, the Government did in fact award several IQCs for the purchase of dual-ended Combat Arms™ earplugs, the RFP underlying each of which constitutes a false record or statement to the Government within the meaning of the FCA.

51. The United States has been damaged as a result of 3M's/Aearo's violations of the False Claims Act because it has received a product inferior to that which it specified and for which it paid. In addition to damages directly associated with the contractual cost of the earplugs, the United States has been damaged by the large and ongoing medical costs associated with treating veterans who likely suffered hearing damage and impairment as a result of the defective earplugs.

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WHEREFORE, Plaintiff-Relator Moldex demands compensatory and multiple damages, costs, attorney fees, and such other legal and equitable relief as the Court may provide, including, but not limited to, exclusion or debarment.

COUNT III
False Claims Act – Conspiracy
31 U.S.C. § 3729(a)(1)(C)

52. Plaintiff/Relator Moldex re-alleges and incorporates by reference the allegations contained in paragraphs 1-51.

53. Defendant 3M, by and through its predecessor Aearo, and their officers, agents, supervisors, and employees, conspired to defraud the United States Government in order to get false or fraudulent claims paid by the United States Government pursuant to multiple IQCs awarded under Solicitation Nos. SP0200-06-R-4202, SP0200-07-D-4103 and related solicitations for the supply of its dual-ended Combat Arms™ earplugs to the military. In furtherance of this conspiracy, 3M/Aearo and certain of its employees took substantial steps, as set forth above, to effect the objects of the conspiracy alleged herein. Such conspiracy is in violation of 31 U.S.C. § 3729(a)(1)(C).

54. At all relevant times, 3M/Aearo knew about, advanced, and conspired in directing and perpetuating the fraudulent conduct.

55. As a result of 3M/Aearo conspiring to submit required false, fraudulent claims pursuant to the IQCs to the United State Government, the United States Government paid 3M/Aearo based on these false claims.

56. The United States has been damaged as a result of 3M's/Aearo's violations of the FCA because it has received a product inferior to that which it specified and for which it paid. In addition to damages directly associated with the contractual cost of the earplugs, the United

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States has been damaged by the large and ongoing medical costs associated with treating veterans who likely suffered hearing damage and impairment as a result of the defective earplugs.

WHEREFORE, Plaintiff/Relator Moldex demands compensatory and multiple damages, costs, attorney fees, and such other legal and equitable relief as the Court may provide, including, but not limited to, exclusion or debarment.

COUNT IV
Unjust Enrichment

57. Plaintiff/Relator Moldex re-alleges and incorporates by reference the allegations contained in paragraphs 1-56.

58. By reason of the United States Government's payments pursuant to multiple IQCs awarded under to Solicitation Nos. SP0200-06-R-4202, SP0200-07-D-4103 and related solicitations for the supply of dual-ended Combat Arms™ earplugs to the military, 3M/Aearo received monies to which it was not entitled and has thereby been unjustly enriched to the detriment of the United States Government in an amount to be determined at trial.

WHEREFORE, Plaintiff/Relator demands compensatory damages, costs, attorneys fees, and such other legal and equitable relief as the Court may provide.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury on all issues triable by jury.

Date: May 11, 2016

By: *s/ James M. Griffin*
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FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

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*Attorneys for Plaintiff/Relator Moldex-Metric,
Inc.*

EXHIBIT 1
3M PRESS RELEASE
AUGUST 30, 2012



News

- [Press Releases](#)
- [Press Kits](#)
- [Multimedia](#)
- [Contact Media Relations](#)

3M Hearing Protection Devices Now Added to the Federal Procurement List;

3M and New Dynamics help military personnel combat hearing loss, while creating job opportunities for people with disabilities

Thursday, August 30, 2012 9:22 am CDT

Dateline:

St. Paul, Minn.

Five hearing protection devices from [3M](#) have been added to the U.S. AbilityOne Commission's Federal Procurement List (FPL), effective Sept. 3, 2012, to help military personnel who are often exposed to [excessive noise levels](#). 3M has a strong commitment to hearing conservation and will work with [New Dynamics Corporation](#) to protect warriors and workers from noise-induced hearing loss. As part of a co-branding agreement, New Dynamics Corporation will assemble, package and distribute the 3M devices through its government and commercial contracts, providing employment opportunities for more than 20 employees with and without disabilities.

"Military personnel are exposed to excessive noise levels during combat and training on a variety of land, air and sea missions," said Walter Pawlowski, vice president of Business Development, New Dynamics Corporation. "This noise exposure has led many personnel to experience hearing loss and tinnitus, which is currently the number-one service-related disability for veterans."

"It is our mission to help secure work for people with disabilities, and it is particularly fitting that we work with New Dynamics and 3M as their hearing protection products and services can help reduce the number of hearing-related disabilities within the military and other at-risk populations."

Tinnitus, often referred to as "ringing in the ears," and noise-induced hearing loss can be caused by a one-time exposure to hazardous impulse noise, or by repeated exposure to excessive noise over an extended period of time.

The hearing protection devices being added to the federal procurement list include a series of 3M Combat Arms Earplugs and the 3M E-A-R Yellow Skull Screws earplugs. Combat Arms Earplugs provide hear-through capabilities, which enable military personnel to hear low-level sounds, such as footsteps or spoken commands, while protecting against damaging impulse noise from explosions or firearms. Yellow Skull Screws earplugs provide high-attenuation, easy insertion and compliance with Foreign Objects and Debris (FOD) requirements in proximity with military aircraft and flight lines.

The Combat Arms Earplug is made of a washable plastic, has a triple-flange eartip to keep it in place, and features a rocker switch that is operated without removing the earplug. Military personnel can adjust the rocker with a quick "click" depending on the type of protection required for the mission. When it's in the open or "weapons fire" position, sound can travel through the sound channel filter into the ear. For noisy environments that don't require a hear-through listening capability, such as being near helicopters, troop carriers or generators, the rocker can be closed for "constant protection."

The 3M products were added to the procurement list by the U.S. AbilityOne Commission, which was established as an independent Federal agency by the Javits-Wagner-O'Day Act. The Commission administers the AbilityOne Program, which currently provides employment opportunities for more than 50,000 people who are blind or have significant disabilities. The AbilityOne Program uses the purchasing power of the federal government to buy products and services from nonprofit agencies nationwide dedicated to training and employing individuals with disabilities.

New Dynamics Corporation works closely with NISH, a national nonprofit agency whose mission is to create employment opportunities for people with significant disabilities by securing federal contracts through the AbilityOne Program.

"People with disabilities are the nation's largest untapped labor force and nearly 80 percent of these individuals do not have jobs," said NISH President and CEO Bob Chamberlin. "It is our mission to help secure work for people with disabilities, and it is particularly fitting that we work with New Dynamics and 3M as their hearing protection products and services can help reduce the number of hearing-related disabilities within the military and other at-risk populations."

Beginning Sept. 3, 2012, the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501-8506 and 41 CFR 51-2.4. National Stock Numbers (NSNs):

- NSN: 6515-01-576-8837 – Combat Arms Earplug, Single Ended, Size Small
- NSN: 6515-01-576-8861 – Combat Arms Earplug, Single Ended, Size Medium
- NSN: 6515-01-576-8869 – Combat Arms Earplug, Single Ended, Size Large
- NSN: 6515-01-466-2710 – Combat Arms Earplug, Dual Ended, Universal Size.
- NSN: 6515-01-576-8796 – Yellow Skull Screws Earplug, Single Ended, Universal Size

"3M has 40 years of experience developing innovative hearing protection products," said Doug Moses, Military Market Development, Occupational Health & Environmental Safety, 3M. "We look forward to applying our rich history with hearing protection products in support of New Dynamics and NISH to equip the U.S. Armed Forces with devices that allow them to hear mission critical communication, while helping reduce the risk of developing tinnitus and noise-induced hearing loss."

3M, Combat Arms, E-A-R, and Skull Screws are trademarks of 3M Company, used under license in Canada. AbilityOne is a registered trademark of the U.S. AbilityOne Commission.

About 3M

3M captures the spark of new ideas and transforms them into thousands of ingenious products. Our culture of creative collaboration inspires a never-ending stream of powerful technologies that make life better. 3M is the innovation company that never stops inventing. With \$30 billion in sales, 3M employs about 84,000 people worldwide and has operations in more than 65 countries. For more information, visit www.3M.com or follow @3MNews on Twitter.

About 3M Personal Protective Equipment (PPE) Safety Solutions

3M offers a comprehensive, diverse portfolio of Personal Protective Equipment (PPE) solutions providing respiratory protection, hearing protection, fall protection, reflective materials for high visibility, protective clothing, protective eyewear, head and face protection, welding helmets, and other adjacent products and solutions such as tactical safety equipment, detection, monitoring equipment, active communications equipment and compliance management. In 2012, 3M celebrates 40 years of safety leadership, recognizing the company's respiratory and hearing protection solutions introduced in 1972. Visit www.3M.com/PPESafety or m.3M.com/PPESafety.

New Dynamics Corporation, based in Middletown, N.Y., provides employment opportunities for more than 70 disabled and non-disabled employees through its government and commercial contracts for products and services. Formed in 1997, New Dynamics is a not-for-profit sister corporation of Occupations Inc. that manufactures, packages and distributes products and services commercially and to the federal government through the *U.S. General Services Administration* (GSA) and the Defense Logistics Agency.

NISH is a national nonprofit agency whose mission is to create employment opportunities for people with significant disabilities by securing federal contracts through the AbilityOne Program for its network of community-based, nonprofit agencies. Providing employment opportunities to more than 50,000 people, the AbilityOne Program is the largest single source of employment for people with disabilities in the United States. More than 600 participating nonprofit organizations employ these individuals and provide quality goods and services to the federal government at a fair price.

For more information:

- High-resolution graphics of the Combat Arms Earplugs and E-A-R Skull Screws from 3M: <http://gpimmediacollections.3m.com/index.php/3m/dmrweb?albumId=209943>
- Combat Arms Earplugs and E-A-R Skull Screws Now On the Federal Procurement List: <http://www.gpo.gov/fdsys/pkg/FR-2012-08-03/html/2012-19034.htm>
- Check out the latest industry statistics on hearing loss and the employment of people with disabilities <https://www.box.com/s/38174a762f1a09f95763>

Press Contacts:

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EXHIBIT 2
RFP SP0200-06-R-4202

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30				1. REQUISITION NUMBER	PAGE 1 OF 63
2. CONTRACT NO.	3. AWARD/EFFECTIVE DATE	4. ORDER NUMBER	5. SOLICITATION NUMBER SP0200-06-R-4202	6. SOLICITATION ISSUE DATE 8-4-06	
7. FOR SOLICITATION INFORMATION CALL: Allen Thomas, Contract Specialist			b. TELEPHONE NUMBER (No collect calls) 215-737-2320	8. OFFER DUE DATE/ LOCAL TIME 9-5-06	
9. ISSUED BY DEFENSE SUPPLY CENTER PHILADELPHIA DIRECTORATE OF MEDICAL MATERIEL 700 ROBBINS AVENUE PHILADELPHIA, PA 19111		10. THIS ACQUISITION IS <input checked="" type="checkbox"/> UNRESTRICTED OR <input type="checkbox"/> SET ASIDE: % FOR: <input type="checkbox"/> SMALL BUSINESS <input type="checkbox"/> EMERGING SMALL BUSINESS <input type="checkbox"/> HUBZONE SMALL BUSINESS NAICS: <input type="checkbox"/> SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS <input type="checkbox"/> 8(A) SIZE STANDARD:			
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED <input type="checkbox"/> SEE SCHEDULE	12. DISCOUNT TERMS		<input type="checkbox"/> 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	13b. RATING	
15. DELIVER TO See Schedule		16. ADMINISTERED BY			
17a. CONTRACTOR/OFFEROR	CODE	FACILITY CODE	18a. PAYMENT WILL BE MADE BY		
TELEPHONE NO.		18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED <input type="checkbox"/> SEE ADDENDUM			
<input type="checkbox"/> 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER					
19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES		21. QUANTITY	22. UNIT	23. UNIT PRICE
	NSN 6515-01-466-2710 Plug, Ear, Combat Arms, Double-Ended, 50 Pair Per Package (Brand Name or Equal Product) <i>(Use Reverse and/or Attach Additional Sheets as Necessary)</i>				
25. ACCOUNTING AND APPROPRIATION DATA			26. TOTAL AWARD AMOUNT (For Govt. Use Only)		
<input checked="" type="checkbox"/> 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA <input checked="" type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED			<input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED		
<input type="checkbox"/> 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA <input type="checkbox"/> ARE <input type="checkbox"/> ARE NOT ATTACHED					
<input type="checkbox"/> 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED			<input type="checkbox"/> 29. AWARD OF CONTRACT: REF. _____ OFFER DATED _____ . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:		
30a. SIGNATURE OF OFFEROR/CONTRACTOR			31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)		
30b. NAME AND TITLE OF SIGNER (Type or print)	30c. DATE SIGNED	31b. NAME OF CONTRACTING OFFICER (Type or print)	31c. DATE SIGNED		

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FOR
Plug, Ear, Combat Arms

SOLICITATION: SP0200-06-R-4202

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Solicitation No.: SP0200-06-R-4202

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FOR: Plug, Ear, Combat Arms

OFFER DUE DATE/LOCAL TIME: Sept. 5, 2006, 3:00PM Phila., PA Local Time

CANNOT COMPLY WITH SPECIFICATION

CANNOT MEET DELIVERY REQUIREMENT

NO OPEN PRODUCTION CAPACITY AT PLANT

DO NOT REGULARLY MANUFACTURE OR SELL TYPE OF ITEMS INVOLVED

OTHER (SPECIFY)

WE DO **WE DO NOT DESIRE TO BE RETAINED ON THE MAILING LIST FOR FUTURE PROCUREMENT OF THE TYPE OF ITEM(S) INVOLVED**

NAME AND ADDRESS OF FIRM (INCLUDE ZIP CODE)

TYPE OR PRINT NAME AND TITLE OF SIGNER

SIGNATURE

NOTICE TO DLA SUPPLIERS

On May 19, 2006, DoD issued an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to include additional commodities and DoD locations that require package marking with passive Radio Frequency Identification (RFID) tags (see <http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/06-4682.htm>). Contractors supplying materiel to the Department are now required to affix passive RFID tags, at the case and palletized unit load levels, to shipments of packaged petroleum, lubricants, oils, preservatives, chemicals, additives, construction and barrier materials, and medical materials to the **Defense Distribution Depots in Albany, GA; Anniston, AL; Barstow, CA; Cherry Point, NC; Columbus, OH; Corpus Christi, TX; Hill, UT; Jacksonville, FL; Oklahoma City, OK; Norfolk, VA; Puget Sound, WA; Red River, TX; Richmond, VA; San Diego, CA; Tobyhanna, PA; Warner Robins, GA; or the Air Mobility Command Terminals at Charleston Air Force Base, Charleston, SC; Naval Air Station, Norfolk, VA; and Travis Air Force Base, Fairfield, CA.** This interim rule addresses the second year of DoD's three-year roll-out plan for supplier implementation of RFID. For packaged operational rations, clothing, individual equipment, tools, personal demand items, or weapon system repair parts shipped to the Defense Distribution Depots in Susquehanna, PA, or San Joaquin, CA, contractors are already required to affix passive RFID tags at the case and palletized unit load levels. When RFID tags are required, contractors must submit advance shipment notices to DoD via the Wide Area Work Flow (WAWF) system (see http://www.acq.osd.mil/log/rfid/advance_shipment_ntc.htm). This permits RFID tag data to be associated with corresponding shipments. The DoD RFID Web site contains a Class of Supply Look-Up Tool to assist suppliers in determining if a Federal Supply Group (first two digits of the National Stock Number) or a Federal Stock Class (first four digits of the National Stock Number) is subject to the RFID requirement (see <http://www.acq.osd.mil/log/rfid/FSC.htm>). When the clause at DFARS 252.211-7006 is included in a DLA solicitation, MIL-STD-129P, Change 3, will apply. **DLA will be implementing the interim rule using a phased approach based on procurement methods, as follows:**

Requests for Proposals/Invitations for Bids issued on/after May 19, 2006 for delivery after July 1, 2006

Manual Requests for Quotation issued on/after July 19, 2006 for delivery after September 1, 2006

Automated Requests for Quotation issued on/after September 19, 2006 for delivery after November 1, 2006

Supplier options to comply with the requirements of the rule can be as simple as replacing existing military shipping label printers with RFID-enabled printers. This will allow DoD contractors to print military shipping labels with embedded RFID tags. Extensive information, including Supplier Information (Info) and Frequently Asked Questions (FAQs), is posted on the DoD RFID Web site at <http://www.dodrfid.org>. In addition, the Procurement Technical Assistance Centers (PTACS) offer no-cost RFID training, assistance, and one-on-one counseling to DoD suppliers and small businesses (see <http://www.dla.mil/db/procurem.htm>). Suppliers can also direct questions to info@dodrfid.org.

See Clause 252.211-7006 on page 18.

ADDENDUM TO STANDARD FORM 1449

1. Continuation of Block 8

Offer Due Date/Local Time: **Sept. 5, 2006, 3:00PM Phila., PA Local Time**

2. Continuation of Block 9:

<u>Mailed offers should be sent to:</u>	<u>Hand-carried offers, including delivery by commercial carrier, should be delivered to:</u>
Defense Logistics Agency	Defense Supply Center Philadelphia
Defense Supply Center	Business Opportunities Office
Philadelphia	Bldg. 36, Second Floor
P. O. Box 56667	700 Robbins Avenue
Philadelphia, PA 19111-6667	Philadelphia, PA 19111-5092

NOTE: All hand-carried offers are to be delivered between 8:00 a.m. and 5:00 p.m., Monday through Friday, except for legal federal holidays as set forth in 5 USC 6103. Offerors using a commercial carrier service must ensure that the carrier service “hand-carries” the package to the depository specified above (i.e., the Business Opportunities Office address) prior to the scheduled opening/closing time. **Package must be plainly marked ON THE OUTSIDE OF THE COMMERCIAL CARRIER’S ENVELOPE with the solicitation number, date, and time set forth for receipt of offers as indicated in Block 8 of the Standard Form 1449.**

3. Continuation of Block 17a:

Offeror’s assigned DUNS Number: _____.

4. Continuation of Block 17b:

Remittance Address is: _____

Note: The Government will mail checks to this address only in the event of an Electronic Funds Transfer (EFT) failure, pursuant to 52.232-33 (which is incorporated by reference at 52.212-5(b)(31)).

ADDENDUM TO STANDARD FORM 1449 (continued)

5. **CAGE Number:** _____

6. Are you registered with the Central Contractor Registration (CCR) database?

Yes [] No []

(If you have not registered or your registration has expired, please visit the website at www.ccr.gov)

ADDENDUM TO STANDARD FORM 1449 (continued)

6. Continuation of Blocks 19-24:

SCHEDULE OF SUPPLIES/SERVICES

**NSN 6515-01-466-2710
 PLUG, EAR, COMBAT ARMS, DOUBLE-ENDED, 50 PAIR (PER PACKAGE): SWEPT-BACK TRIPLE-
 FLANGE STYLE. OLIVE DRAB END PROTECTS USER FROM CONTINUOUS NOISE; YELLOW END
 PROTECTS USER FROM MILITARY WEAPONS NOISE.**

		Estimated Annual Quantity	<u>Unit Price</u>	<u>Total Price</u>
0001	Base Year	15,000 Packages (PG)	_____	_____
0001	Option Year	15,000 Packages (PG)	_____	_____

**Guaranteed Minimum Annual Quantity: 10,000 PG / Base Year
 5,000 PG / Option Year.**

**Estimated Maximum Annual Quantity: 45,000 PG / Base Year
 45,000 PG / Option Year.**

GENERAL NOTES - [However, see actual clause language herein for specific coverage.]

The above item is being solicited to establish an Indefinite-Delivery, Indefinite-Quantity Contract (IQC) against which delivery orders will be issued.

EVALUATION - This is a Low Price/Technically-Acceptable solicitation. The Government will award a contract resulting from this solicitation to the responsible offeror submitting the lowest price that conforms to the specification requirements.

The IQC contract will be effective for one year(i.e, Base Year), with 1 option period to extend the contract for one additional year. Total length of the contract will not exceed 2 years. See clause 52.217-9P12 contained in this solicitation.

Submission of an offer on the option year is mandatory. Failure to offer on the option year will result in the offer being eliminated from further consideration.

A determination of price reasonableness for the option year will be made prior to award.

ADDENDUM TO STANDARD FORM 1449 (continued)

6. Continuation of Blocks 19-24:

SCHEDULE OF SUPPLIES/SERVICES (Cont'd)

GENERAL NOTES (cont'd) / *However, see actual clause language herein for specific coverage.]*

The required delivery dates will be cited on each delivery order. The delivery date specified in each delivery order shall not be less than 45 days after the effective date of the delivery order.

Deliveries required for emergency situations shall be negotiated with the contractor prior to order placement.

Each delivery order will satisfy a minimum quantity of 1,400 PG and will not exceed a maximum of 5,000 PG. No more than one delivery order will be placed during any 60 day period for the duration of the contract. Pg 14

Any issued order calling for delivery beyond the contract expiration date shall be completed within the time specified in the order. However, no deliveries shall be required beyond 90 days past the contract expiration date. Pg 15

Offerors should develop their pricing based on the estimated quantities rather than the guaranteed minimum or the maximum quantities.

The Government may reject without negotiation any offer placing restrictions on the Government's ability to order quantities up to the maximum annual quantities cited on page 7.

The estimated annual quantity is the most realistic quantity that the Government expects to order in a 365 day period. The cited maximum quantity has been inflated to ensure contract coverage for unforecasted demands and applies to the Base Year and the Option Year

The Government intends to make one award. Pg 46

Alternate offers of commercial items will not be considered for award. Unless the offeror clearly indicates in its offer that the product being offered is an "equal" product, the offeror shall provide the brand name product referenced in the solicitation. Pg 46, 48

A pre-award plant survey may be required to establish the capability of unknown offerors who have not previously supplied this item. Pg 52

The Government reserves the right to request pre-award sample(s). Offerors are required to submit such samples within 15 days after the Government's request. Submission time of 15 days is vital to the Government in making a timely award. Pg 52

ADDENDUM TO STANDARD FORM 1449 (continued)

6. Continuation of Blocks 19-24:

SCHEDULE OF SUPPLIES/SERVICES (Cont'd)

Offers are to based on FOB Destination pricing. Deliveries will be to the following three destinations:

DD SUSQUEHANNA

Defense Distribution Depot Susquehanna
U Ave. Bldg 89 Door 7
New Cumberland, Pa. 17070

DD SAN JOAQUIN

Defense Distribution San Joaquin
25600 S Chrisman Road
Receiving Warehouse 10
Tracy, CA 95376-5000

DD Hill AFB

Distribution Dept Hill
7537 Wardleigh Road,
Bldg. 849W
Hill AFB, UT 84056-5734

PREVIOUS AWARD HISTORY:

A & A Glove and Safety Co.

Unit Price: \$323.00 Quantity: 3,398 PG DATE: 1/30/06

**52.212-4 CONTRACT TERMS AND CONDITIONS – COMMERCIAL ITEMS
(SEP 2005)**

This clause is now incorporated by reference. The full text may be accessed electronically at www.dla.mil/j-3/j-336/icps.htm. Once you arrive at this website, click on the Hill AFB FAR link, then click on 52.000 (located on the left-hand side of the page). Scroll down until you reach 52.212-4.

ADDENDUM TO 52.212-4

1. Addenda to 52.212-4(g)

The invoicing and payment office for orders/contracts issued by DSCP-Medical shall be as follows:

Normal Mail Delivery: **DFAS-Columbus Center
ATTN: DFAS-BVDPII/CC
P.O. BOX 182317
COLUMBUS, OHIO 43218-6248**

Overnight Delivery: **DFAS-Columbus Center
ATTN: DFAS-BVDPII/CC
3990 EAST BROAD STREET
BUILDING 21
COLUMBUS, OHIO 43213-1152**

2. Addenda to 52.212-4(i)

Substitute the following for the first sentence:

Fast Payment procedures apply to all Direct Vendor Delivery (DVD) delivery orders, regardless of dollar value, issued against this indefinite-delivery contract. The clause at 52.213-1, *Fast Payment Procedure*, and the clauses at DLAD 52.212-9001, *Application of Fast Pay to Part 12 Acquisitions* and at DLAD 52.213-9009, *Fast Payment Procedure*, are hereby incorporated by reference.

Fast Payment procedures apply to all Direct Vendor Delivery (DVD) orders \$25,000 or less. The clause at 52.213-1, *Fast Payment Procedure*, and the DLAD clauses at 52.212-9001, *Application of Fast Payment to Part 12 Acquisitions*, and at DLAD 52.213-9009, *Fast Payment Procedure*, are hereby incorporated by reference. **NOTE: Fast Pay also applies to any order, regardless of dollar value, that requires direct shipment overseas.**

ADDENDUM TO 52.212-4 (continued)

NOTE: DLAD 52.213-9009 requires the vendor to annotate the invoice or packing slip with a notice instructing the consignee to notify DSCP promptly (i.e., within 60 days) if supplies are not received, if they are damaged in transit, or if they do not conform to the specifications of the order.

3. CONTRACT CLAUSES INCORPORATED BY REFERENCE

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. The full text of any FAR, DFARS, DLAD and DSCP solicitation clause may be accessed electronically at www.dla.mil/j-3/j-336/icps.htm or obtained from the Contracting Officer. The clauses listed below are incorporated by reference only when checked.

<u>CLAUSE NUMBER</u>	<u>TITLE</u>	<u>DATE</u>	<u>SOURCE</u>
<input checked="" type="checkbox"/> 52.203-12	<i>LIMITATION ON PAYMENTS TO INFLUENCE</i>	<i>(SEP 2005)</i>	<i>FAR CERTAIN FEDERAL TRANSACTIONS</i>
<input checked="" type="checkbox"/> 52.204-4	<i>PRINTED OR COPIED, DOUBLE-SIDED ON</i>	<i>(AUG 2000)</i>	<i>FAR RECYCLED PAPER</i>
<input checked="" type="checkbox"/> 52.211-17	<i>DELIVERY OF EXCESS QUANTITIES</i>	<i>(SEP 1989)</i>	<i>FAR</i>
<input checked="" type="checkbox"/> 52.215-14	<i>INTEGRITY OF UNIT PRICES</i>	<i>(OCT 1997)</i>	<i>FAR</i>
<input checked="" type="checkbox"/> 52.219-16	<i>LIQUIDATED DAMAGES - SUBCONTRACTING PLAN</i>	<i>(JAN 1999)</i>	<i>FAR</i>
<input checked="" type="checkbox"/> 52.222-20	<i>WALSH-HEALEY PUBLIC CONTRACTS ACT</i>	<i>(DEC 1996)</i>	<i>FAR</i>
<input checked="" type="checkbox"/> 52.227-2	<i>NOTICE AND ASSISTANCE REGARDING PATENT</i>	<i>(AUG 1996)</i>	<i>FAR AND CPYRIGHT INFRINGEMENT</i>
<input checked="" type="checkbox"/> 52.232-11	<i>EXTRAS</i>	<i>(APR 1984)</i>	<i>FAR</i>
<input checked="" type="checkbox"/> 52.232-17	<i>INTEREST</i>	<i>(JUN 1996)</i>	<i>FAR</i>
<input checked="" type="checkbox"/> 52.242-13	<i>BANKRUPTCY</i>	<i>(JUL 1995)</i>	<i>FAR</i>
<input checked="" type="checkbox"/> 52.242-15	<i>STOP WORK ORDER</i>	<i>(AUG 1989)</i>	<i>FAR</i>
<input checked="" type="checkbox"/> 52.244-5	<i>COMPETITION IN SUBCONTRACTING</i>	<i>(DEC 1996)</i>	<i>FAR</i>
<input checked="" type="checkbox"/> 52.247-34	<i>F.O.B DESTINATION</i>	<i>(NOV 1991)</i>	<i>FAR</i>

ADDENDUM TO 52.212-4 (continued)

[x] 52.253-1 **COMPUTER GENERATED FORMS (JAN 1991) FAR**

[x] 252.203-7002 **DISPLAY OF DoD HOTLINE POSTER (DEC 1991) DFARS**

[x] 252.204-7003 **CONTROL OF GOVT. WORK PRODUCT (APR 1992) DFARS**

[x] 252.211-7006 **RADIO FREQUENCY IDENTIFICATION MAY 2006 DFARS**

(The requirement for use of RFID is being implemented over a three-year period. The Notice at the beginning of this document explains the phases of implementation, the affected commodities, and the destinations involved. At this point, this clause applies to Requests for Proposals and Invitations for Bid issued on/after May 19, 2006 for delivery after July 1, 2006 for purchases of Subclass of Class VIII Medical Materials that will be shipped to any of the locations listed in the notice. However, pharmaceuticals, biologicals, and reagents under Class VIII and medical-peculiar repair parts that fall under Class IX—Repair Parts and Components are currently exempt from the requirement for RFID tagging.)

[x] 252.225-7002 **QUALIFYING COUNTRY SOURCES AS (APR 2003) DFARS
SUBCONTRACTORS**

[x] 252.225-7013 **DUTY-FREE ENTRY (JUN 2005) DFARS**

[x] 252.225-7031 **SECONDARY ARAB BOYCOTT OF ISRAEL (JUN 2005) DFARS**

[x] 252.243-7001 **PRICING OF CONTRACT MODIFICATIONS (DEC 1991) DFARS**

[x] 252.246-7000 **MATERIAL INSPECTION AND RECEIVING (MAR 2003) DFARS
REPORT**

| | 52.211-9004 **PRIORITY RATING FOR VARIOUS MAR 2000 DLAD
LONG-TERM CONTRACTS**

(Applies to delivery orders for surge or sustainment requirements. May also apply to urgent requirements at contracting officer's discretion.)

[x] 52.211-9010 **SHIPPING DOCUMENTATION— DEC 2005 DLAD
MIL-STD 129P – TAKES PRECEDENCE
OVER SCHEDULE**

(Applies to all contractor shipments of packaged material to the Government.)

| | 52.217-9006 **LIMITATIONS ON USE OF SURGE AND JUL 1999 DLAD
SUSTAINMENT (S&S) INVESTMENTS**

| | 52.239-9000 **YEAR 2000 (Y2K) COMPLIANCE NOTICE JUN 2002 DLAD**

[x] 52.246-9001 **MANUFACTURING PROCESS CONTROLS & (JUN 1998) DLAD
IN-PROCESS INSPECTIONS**

ADDENDUM TO 52.212-4 (continued)

4. THE FOLLOWING ADDITIONAL CLAUSES ARE INCORPORATED IN FULL TEXT:

52.211-16 VARIATION IN QUANTITY (APR 1984) FAR

Paragraph (b): The permissible variation shall be limited to:

2% Percent increase 2% Percent decrease

This increase or decrease shall apply to:

- 1. Each contract sub-line item number (e.g., 0001AA)
- 2. The following contract sub-line item numbers:

52.215-6 PLACE OF PERFORMANCE (OCT 1997) FAR

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, intends, does not intend (check applicable block) to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of performance
(street address, city, state, county,
zip code)

Name and address of
owner and operator of
the plant or facility if
other than offeror or respondent

NOTE: If using one or more plants or facilities as indicated, offeror/respondent shall provide the following additional information for each plant location to be used in the performance of a contract resulting from this solicitation:

Operation
(cutting, shipping etc.)

Quantity by Plant

ADDENDUM TO 52.212-4 (continued)**[X] 52.216-18 ORDERING (Oct 1995)**

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from date of award through one year thereafter as well as through the option period for one additional year (i.e, 2 years total ordering time).

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

[X] 52.216-19 ORDER LIMITATIONS (Oct 1995)

(a) *Minimum order.* When the Government requires supplies or services covered by this contract in an amount of less than 1,400 PG, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order.* The Contractor is not obligated to honor --

(1) Any order for a single item in excess of 5,000 PG;

(2) Any order for a combination of items in excess of 5,000 PG; or

(3) A series of orders from the same ordering office within 60 days that together call for quantities exceeding the limitation in subparagraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (i.e., includes the *Requirements* clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 10 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

ADDENDUM TO 52.212-4 (continued)**[X] 52.216-22 INDEFINITE QUANTITY (OCT 1995) FAR**

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

(c) Except for any limitations on quantities in the *Order Limitations* clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided that the Contractor shall not be required to make any deliveries under this contract after 90 days from contract expiration.

[x] 52.227-9 REFUND OF ROYALTIES (APR 1984) FAR

(a) The contract price includes certain amounts for royalties payable by the Contractor or subcontractors or both, which amounts have been reported to the Contracting Officer.

(b) The term "royalties" as used in this clause refers to any costs or charges in the nature of royalties, license fees, patent or license amortization costs, or the like, for the use of or for rights in patents and patent applications in connection with performing this contract or any subcontract hereunder.

(c) The Contractor shall furnish to the Contracting Officer, before final payment under this contract, a statement of royalties paid or required to be paid in connection with performing this contract and subcontracts hereunder together with the reasons.

ADDENDUM TO 52.212-4 (continued)**52.227-9 (continued)**

(d) The Contractor will be compensated for royalties reported under paragraph (c) of this clause, only to the extent that such royalties were included in the contract price and are determined by the Contracting Officer to be properly chargeable to the Government and allocable to the contract. To the extent that any royalties that are included in the contract price are not in fact paid by the Contractor or are determined by the Contracting Officer not to be properly chargeable to the Government and allocable to the contract, the contract price shall be reduced. Repayment or credit to the Government shall be made as the Contracting Officer directs.

(e) If, at any time within 3 years after final payment under this contract, the Contractor for any reason is relieved in whole or in part from the payment of the royalties included in the final contract price as adjusted pursuant to paragraph (d) of this clause, the Contractor shall promptly notify the Contracting Officer of that fact and shall reimburse the Government in a corresponding amount.

(f) The substance of this clause, including this paragraph (f), shall be included in any subcontract in which the amount of royalties reported during negotiation of the subcontract exceeds \$250.

[x] 52.233-1 DISPUTES (JULY 2002) ALTERNATE I (DEC 1991) FAR

(a) This contract is subject to the Contract Disputes Act of 1978, as amended (41 U.S.C. 601-613).

(b) Except as provided in the Act, all disputes arising under or relating to this contract shall be resolved under this clause.

(c) "Claim," as used in this clause, means a written demand or written assertion by one of the contracting parties seeking, as a matter of right, the payment of money in a sum certain, the adjustment or interpretation of contract terms, or other relief arising under or relating to this contract. However, a written demand or written assertion by the Contractor seeking the payment of money exceeding \$100,000 is not a claim under the Act until certified. A voucher, invoice, or other routine request for payment that is not in dispute when submitted is not a claim under the Act. The submission may be converted to a claim under the Act, by complying with the submission and certification requirements of this clause, if it is disputed either as to liability or amount or is not acted upon in a reasonable time.

(d)

(1) A claim by the Contractor shall be made in writing and, unless otherwise stated in this contract, submitted within 6 years after accrual of the claim to the Contracting Officer for

ADDENDUM TO 52.212-4 (continued)**52.233-1 (continued)**

a written decision. A claim by the Government against the Contractor shall be subject to a written decision by the Contracting Officer.

(2)

(i) The contractor shall provide the certification specified in paragraph (d)(2)(iii) of this clause when submitting any claim exceeding \$100,000.

(ii) The certification requirement does not apply to issues in controversy that have not been submitted as all or part of a claim.

(iii) The certification shall state as follows: "I certify that the claim is made in good faith; that the supporting data are accurate and complete to the best of my knowledge and belief; that the amount requested accurately reflects the contract adjustment for which the Contractor believes the Government is liable; and that I am duly authorized to certify the claim on behalf of the Contractor."

(3) The certification may be executed by any person duly authorized to bind the Contractor with respect to the claim.

(e) For Contractor claims of \$100,000 or less, the Contracting Officer must, if requested in writing by the Contractor, render a decision within 60 days of the request. For Contractor-certified claims over \$100,000, the Contracting Officer must, within 60 days, decide the claim or notify the Contractor of the date by which the decision will be made.

(f) The Contracting Officer's decision shall be final unless the Contractor appeals or files a suit as provided in the Act.

(g) If the claim by the Contractor is submitted to the Contracting Officer or a claim by the Government is presented to the Contractor, the parties, by mutual consent, may agree to use alternative dispute resolution (ADR). If the Contractor refuses an offer for ADR, the Contractor shall inform the Contracting Officer, in writing, of the Contractor's specific reasons for rejecting the offer.

(h) The Government shall pay interest on the amount found due and unpaid from
(1) the date that the Contracting Officer receives the claim (certified, if required); or
(2) the date that payment otherwise would be due, if that date is later, until the date of payment.

With regard to claims having defective certifications, as defined in FAR 33.201, interest shall be paid from the date that the Contracting Officer initially receives the claim. Simple interest on claims shall be paid at the rate, fixed by the

ADDENDUM TO 52.212-4 (continued)**52.233-1 (continued)**

Secretary of the Treasury as provided in the Act, which is applicable to the period during which the Contracting Officer receives the claim and then at the rate applicable for each 6-month period as fixed by the Treasury Secretary during the pendency of the claim.

(i) The Contractor shall proceed diligently with performance of this contract, pending final resolution of any request for relief, claim, appeal, or action arising under or relating to the contract, and comply with any decision of the Contracting Officer.

[x] 252.211-7006 RADIO FREQUENCY IDENTIFICATION (NOV 2005) DFARS

(a) Definitions. As used in this clause—

“Advance shipment notice” means an electronic notification used to list the contents of a shipment of goods as well as additional information relating to the shipment, such as order information, product description, physical characteristics, type of packaging, marking, carrier information, and configuration of goods within the transportation equipment.

“Bulk commodities” means the following commodities, when shipped in rail tank cars, tanker trucks, trailers, other bulk wheeled conveyances, or pipelines:

- (1) Sand.
- (2) Gravel.
- (3) Bulk liquids (water, chemicals, or petroleum products).
- (4) Ready-mix concrete or similar construction materials.
- (5) Coal or combustibles such as firewood.
- (6) Agricultural products such as seeds, grains, or animal feed.

“Case” means either a MIL-STD-129 defined exterior container within a palletized unit load or a MIL-STD-129 defined individual shipping container.

“Electronic Product Code™ (EPC)” means an identification scheme for universally identifying physical objects via RFID tags and other means. The standardized EPC data consists of an EPC (or EPC identifier) that uniquely identifies an individual object, as well as an optional filter value when judged to be necessary to enable effective and efficient reading of the EPC tags. In addition to this standardized data, certain classes of EPC tags will allow user-defined data. The EPC tag data standards will define the length and position of this data, without defining its content.

“EPCglobal™” means a joint venture between EAN International and the Uniform Code Council to establish and support the EPC network as the global standard for immediate,

ADDENDUM TO 52.212-4 (continued)**252.211-7006 (continued)**

automatic, and accurate identification of any item in the supply chain of any company, in any industry, anywhere in the world.

“Exterior container” means a MIL-STD-129 defined container, bundle, or assembly that is sufficient by reason of material, design, and construction to protect unit packs and intermediate containers and their contents during shipment and storage. It can be a unit pack or a container with a combination of unit packs or intermediate containers. An exterior container may or may not be used as a shipping container.

“Palletized unit load” means a MIL-STD-129 defined quantity of items, packed or unpacked, arranged on a pallet in a specified manner and secured, strapped, or fastened on the pallet so that the whole palletized load is handled as a single unit. A palletized or skidded load is not considered to be a shipping container. A loaded 463L System pallet is not considered to be a palletized unit load. Refer to the Defense Transportation Regulation, DoD 4500.9-R, Part II, Chapter 203, for marking of 463L System pallets.

“Passive RFID tag” means a tag that reflects energy from the reader/interrogator or that receives and temporarily stores a small amount of energy from the reader/interrogator signal in order to generate the tag response. Acceptable tags are—

- (1) EPC Class 0 passive RFID tags that meet the EPCglobal Class 0 specification; and
- (2) EPC Class 1 passive RFID tags that meet the EPCglobal Class 1 specification.

“Radio Frequency Identification (RFID)” means an automatic identification and data capture technology comprising one or more reader/interrogators and one or more radio frequency transponders in which data transfer is achieved by means of suitably modulated inductive or radiating electromagnetic carriers.

“Shipping container” means a MIL-STD-129 defined exterior container that meets carrier regulations and is of sufficient strength, by reason of material, design, and construction, to be shipped safely without further packing (e.g., wooden boxes or crates, fiber and metal drums, and corrugated and solid fiberboard boxes).

(b)(1) Except as provided in paragraph (b)(2) of this clause, the Contractor shall affix passive RFID tags, at the case and palletized unit load packaging levels, for shipments of items that—

(i) Are in any of the following classes of supply, as defined in DoD 4140.1-R, DoD Supply Chain Materiel Management Regulation, API.1.11:

- (A) Subclass of Class 1 - Packaged operational rations.

ADDENDUM TO 52.212-4 (continued)**252.211-7006 (continued)**

(B) Class II - Clothing, individual equipment, tentage, organizational tool kits, hand tools, and administrative and housekeeping supplies and equipment.

(C) Class VI - Personal demand items (non-military sales items).

(D) Class IX – Repair parts and components including kits, assemblies and subassemblies, repairable and consumable items required for maintenance support of all equipment, excluding medical-peculiar repair parts; and

(ii) Are being shipped to—

(A) Defense Distribution Depot, Susquehanna, PA: DoDAAC W25G1U or SW3124; or

(B) Defense Distribution Depot, San Joaquin, CA: DoDAAC W62G2T or SW3224.

(2) Bulk commodities are excluded from the requirements of paragraph (b)(1) of this clause.

(c) The Contractor shall ensure that—

(1) The data encoded on each passive RFID tag are unique (i.e., the binary number is never repeated on any and all contracts) and conforms to the requirements in paragraph (d) of this clause;

(2) Each passive tag is readable at the time of shipment in accordance with MIL-STD-129 (Section 4.9.1.1) readability performance requirements; and

(3) The passive tag is affixed at the appropriate location on the specific level of packaging, in accordance with MIL-STD-129 (Section 4.9.2) tag placement specifications.

(d) Data syntax and standards. The Contractor shall use one or more of the following data constructs to write the RFID tag identification to the passive tag, depending upon the type of passive RFID tag being used in accordance with the tag construct details located at <http://www.dodrfid.org/tagdata.htm> (version in effect as of the date of the solicitation):

(1) Class 0, 64 Bit Tag – EPCglobal Serialized Global Trade Item Number (SGTIN), Global Returnable Asset Identifier (GRAI), Global Individual Asset Identifier (GIAI), or Serialized Shipment Container Code (SSCC).

(2) Class 0, 64 Bit Tag – DoD Tag Construct.

(3) Class 1, 64 Bit Tag – EPCglobal SGTIN, GRAI, GIAI, or SSCC.

(4) Class 1, 64 Bit Tag – DoD Tag Construct.

(5) Class 0, 96 Bit Tag – EPCglobal SGTIN, GRAI, GIAI, or SSCC.

(6) Class 0, 96 Bit Tag – DoD Tag Construct.

(7) Class 1, 96 Bit Tag – EPCglobal SGTIN, GRAI, GIAI, or SSCC.

(8) Class 1, 96 Bit Tag – DoD Tag Construct.

(e) Receiving report. The Contractor shall electronically submit advance shipment notice(s) with the RFID tag identification (specified in paragraph (d) of this clause) in

ADDENDUM TO 52.212-4 (continued)

252.211-7006 (continued)

advance of the shipment in accordance with the procedures at <http://www.dodrfid.org/asn.htm>.

[x] 252.225-7005 IDENTIFICATION OF EXPENDITURES IN THE UNITED STATES) (JUN 2005) DFARS

(a) *Definition.* "United States," as used in this clause, means the 50 States, the District of Columbia, and outlying areas.

(b) This clause applies only if the Contractor is--

(1) A concern incorporated in the United States (including a subsidiary that is incorporated in the United States, even if the parent corporation is not incorporated in the United States); or

(2) An unincorporated concern having its principal place of business in the United States.

(c) On each invoice, voucher, or other request for payment under this contract, the Contractor shall identify that part of the requested payment that represents estimated expenditures in the United States. The identification—

(1) May be expressed either as dollar amounts or as percentages of the total amount of the request for payment;

(2) Should be based on reasonable estimates; and

(3) Shall state the full amount of the payment requested, subdivided into the following categories:

(i) U.S. products--expenditures for material and equipment manufactured or produced in the United States, including end products, components, or construction material, but excluding transportation;

(ii) U.S. services--expenditures for services performed in the United States, including all charges for overhead, other indirect costs, and profit under construction or service contracts;

ADDENDUM TO 52.212-4 (continued)

252.225-7005 (continued)

(iii) Transportation on U.S. carriers--expenditures for transportation furnished by U.S. flag, ocean, surface, and air carriers; and

(iv) Expenditures not identified under paragraphs (c)(3)(i) through (iii) of this clause.

(d) Nothing in this clause requires the establishment or maintenance of detailed accounting records or gives the U.S. Government any right to audit the Contractor's books or records.

[X] 52.212-9000 CHANGES--MILITARY READINESS (MAR 2001) DLAD

The commercial changes clause at FAR 52.212-4(c) is applicable to this contract in lieu of the changes clause at FAR 52.243-1. However, in the event of a Contingency Operation or a Humanitarian or Peace Keeping Operation, as defined below, the contracting officer may, by written order, change 1) the method of shipment or packing, and 2) the place of delivery. If any such change causes an increase in the cost of, or the time required for performance, the contracting officer shall make an equitable adjustment in the contract price, the delivery schedule, or both, and shall modify the contract. The contractor must assert its right to an adjustment within 30 days from the date of receipt of the modification.

"Contingency operation" means a military operation that-

(i) Is designated by the Secretary of Defense as an operation in which members of the armed forces are or may become involved in military actions, operations, or hostilities against an enemy of the United States or against an opposing military force; or

(ii) Results in the call or order to, or retention on, active duty of members of the uniformed services under 10 U.S.C. 688, 12301(a), 12302, 12304, 12305, or 12406, Chapter 15 of U.S.C., or any other provision of law during a war or during an national emergency declared by the President or Congress (10 U.S.C. 101(a)(13)).

"Humanitarian or peacekeeping operation" means a military operation in support of the provision of humanitarian or foreign disaster assistance or in support of peacekeeping operation under Chapter VI or VII of the Charter of the United Nations. The term does not include routine training, force rotation, or stationing. (10 U.S.C. 2302 (8) and 41 U.S.C. 259 (d) (2) (B)).

ADDENDUM TO 52.212-4 (continued)**[X] 52.233-9001 DISPUTES: AGREEMENT TO USE ALTERNATIVE DISPUTE RESOLUTION (JUN 2001) DLAD**

(a) The parties agree to negotiate with each other to try to resolve any disputes that may arise. If unassisted negotiations are unsuccessful, the parties will use alternative dispute resolution (ADR) techniques to try to resolve the dispute. Litigation will only be considered as a last resort when ADR is unsuccessful or has been documented by the party rejecting ADR to be inappropriate for resolving the dispute.

(b) Before either party determines ADR inappropriate, that party must discuss the use of ADR with the other party. The documentation rejecting ADR must be signed by an official authorized to bind the contractor (see FAR 52.233-1), or, for the Agency, by the contracting officer, and approved at a level above the contracting officer after consultation with the ADR Specialist and with legal counsel (see DLA Directive 5145.1). Contractor personnel are also encouraged to include the ADR Specialist in their discussions with the contracting officer before determining ADR to be inappropriate.

(c) If you wish to opt out of this clause, check here []. Alternate wording may be negotiated with the contracting officer.

[x] 52.246-9000 CERTIFICATE OF QUALITY (DEC 1994) DLAD COMPLIANCE

The Contractor shall prepare and furnish a Certificate of Quality Compliance (COQC) for all supplies delivered under this contract. If the supplies delivered under this contract are from more than one manufacturing lot, a separate COQC shall be prepared and furnished for each manufacturing lot represented by, manufactured or produced under a product specification, original equipment manufacturer (OEM)/manufacturer's part number, commercial, industry or military standard, or drawings, or other technical data.

(a) This Certificate shall contain the following:

(1) The Contractor's name, address, and commercial and Government entity (CAGE) code number (if assigned), the contract/order number, the applicable specification, drawing, or standard (including revision/amendment and date), identification of the specific supplies manufactured or produced (including National Stock Number, nomenclature, type, grade, and class, if applicable); for metal products, the COQC shall include the alloy designation and condition (finish and temper), if applicable. If the contractor is not a manufacturer, the Certificate shall include the name, address and CAGE Code (if assigned) for each of the entities through which the supplies or materials, components, subassemblies, assemblies or parts passed, so that traceability to the manufacturer will be readily discernible therefrom.

(2) The identification of each parameter for which the contract, specification, drawing, or standard required inspection or testing;

ADDENDUM TO 52.212-4 (continued)**52.246-9000 (continued)**

(3) The identification of the specific requirement for each of the parameters in (2), above, for the particular material being produced and covered by the certificate;

(4) The actual results of inspections or tests conducted by the contractor to demonstrate conformance with each of the specific requirements of (3), above;

(5) The marking requirement for the material and the source of this requirement (contract and specification or standard); and

(6) A statement, signed by an authorized contractor representative responsible for quality assurance, that (i) the lot has been produced, sampled, tested, and inspected, and marked in accordance with all contract and specification requirements; and (ii) the material complies with all of the contract and specification requirements.

(b) For contracts assigned for Government inspection at source, the Contractor shall have the completed certificate available for review by the Government representative when the material is presented for acceptance by the Government. In the case of destination –inspected material, the Contractor shall attach a copy of the completed certificate to the packing list sent with each shipment to each shipping point designated in the contract. For source inspected material, a copy may (but need not) accompany the shipment. If the Contractor offering the material to the Government is not the manufacturer of the material, the Contractor is responsible for obtaining a certified test report from the manufacturer, including it as part of this COQC, and for demonstrating that the specific material being offered under this certificate is covered by the certified test report.

(c) Unless otherwise specified by the contract, the Contractor shall be responsible for retaining the certificate for a period of 4 years. When requested by the Contracting Officer, the Contractor shall make the certificate available for review by the Government at any time during the period the certificate is required to be retained.

[X] 52.217-9P12 OPTION FOR INDEFINITE-DELIVERY, INDEFINITE-QUANTITY CONTRACT TERM EXTENSION (MAR 2004) DSCP

(a) Acceptance of the option provision(s)/clauses contained herein is mandatory. Failure to indicate acceptance of the option by annotating the offeror's option price in the Schedule or elsewhere in the solicitation will be deemed non-acceptance of the option and may result in rejection of the offeror's entire bid/proposal.

(b) Offerors may offer options at unit prices which differ from the unit prices for the base ordering period. These prices may vary with the quantities actually ordered and the dates when ordered.

(c) The contracting officer may extend the term of this contract for one additional 1-year period(s) by written notice to the contractor within the

ADDENDUM TO 52.212-4 (continued)**52.217-9P12 (continued)**

timespecified in the Schedule; provided that the contracting officer shall give the contractor a preliminary written notice of intent to extend at least 60 days before expiration of the contract. The preliminary notice does not commit the Government to an extension.

(d) Performance under the option period shall continue at the same performance level specified for the basic contract.

(e) The option to extend the term of the contract shall be exercised not later than three (3) days before the expiration date of the contract.

(f) The option is deemed exercised when mailed or otherwise furnished to the contractor.

(g) If the contracting officer exercises this option, the extended contract shall be considered to include this option clause and the minimum and maximum quantities specified in the award for that option period will apply.

(h) The total duration of any options exercised under this clause, shall not exceed one year.

(i) The following provisions apply only to negotiated acquisitions:

(1) If an option has been priced under this solicitation and is to be exercised at time of award of the basic contract, the submission of certified cost or pricing data shall be required prior to award where the combined dollar value of the basic contract and option exceeds \$550,000, unless an exemption thereto is appropriate in accordance with FAR 15.403-1.

(2) Prior to the award of any contract which will contain one or more priced options totaling \$550,000 or more, the submission of certified cost or pricing data covering the basic contract and the option(s) shall be required regardless of when the option(s) may be exercised, unless an exemption thereto is appropriate in accordance with FAR 15.403-1.

[x] 52.246-9P02 SUPPLIER RESPONSIBILITY FOR TESTING OF (JAN 1992) DSCP MATERIALS AND COMPONENTS

If the value of the entire quantity of a material/component used in the assembly/production of all end items under this contract does not exceed \$3,000, the contractor need only furnish a Certificate of Compliance for that material/component. This authority supersedes any other contract requirement to the contrary. The Government, however, reserves the right to select sample units to verify that such materials/components are in strict compliance with the specification requirements. The Certificate of Compliance shall contain the following information:

ADDENDUM TO 52.212-4 (continued)

52.246-9P02 (continued)

- (a) Item identification of the material/component.
- (b) Reference to the specification for the material/component.
- (c) Lot, batch, control or serial number of the material/component.
- (d) Quantity and dollar value of the material/component.
- (e) Name of supplier of the material/component.
- (f) Date of purchase.
- (g) National Stock Number (NSN), item identification and lot number of the end item.
- (h) The approximate number of end items to be manufactured from the material/component.

I certify that the above material(s) or component(s) presented for acceptance under the terms of contract no. DLA _____ comply with the applicable specification(s) and/or contract requirements and that the information furnished above is accurate.

SIGNED _____
 TITLE _____
 COMPANY _____
 DATE _____

ADDENDUM TO 52.212-4 (continued)

[X] 52.246-9P12 INSPECTION AND ACCEPTANCE BY THE GOVERNMENT (JAN 1992) DSCP

(a) Saving and reserving to the Government all rights under the inspection provision, the following is applicable to this acquisition:

Inspection at Acceptance at
[] Contractor's Plant and [] Contractor's Plant

[X] Destination [X] Destination

upon execution of DD Form 250 by the authorized Government representative.

(b) Resultant award or contract will contain the name and address of the office responsible for performance of inspection.

(c) Offeror shall indicate below the location where supplies will be inspected:

Plant: _____
Street: _____
City/St/Zip: _____

[X] (d) Notwithstanding the foregoing designation of destination as the place for inspection and acceptance of supplies furnished hereunder, the Government reserves the right to require inspection and acceptance at contractor's plant. Said right may be exercised either before award or during the course of performance of any resultant contract. Should said right be exercised during the course of performance, only the undelivered portion of the contract quantities will be subject to inspection and acceptance at contractor's plant. In view of the foregoing, offerors are required to supply the information requested in paragraph (c), above.

**52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO
IMPLEMENT STATUTES OR EXECUTIVE ORDERS --
COMMERCIAL ITEMS (APR 2006)**

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive Orders applicable to acquisitions of commercial items:

- (1) 52.233-3, *Protest after Award* (AUG 1996)(31 U.S.C 3553).
- (2) 52.233-4, *Applicable Law for Breach of Contract Claim* (OCT 2004) (Pub. L 108-77, 108-78)

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

- (1) 52.203-6, *Restrictions on Subcontractor Sales to the Government* (JUL 1995), with *Alternate I* (OCT 1995)(41 U.S.C.253g and 10 U.S.C.2402).
- (2) 52.219-3, *Notice of Total HUBZone Set-Aside* (Jan 1999) (15 U.S.C. 657a).
- (3) 52.219-4, *Notice of Price Evaluation Preference for HUBZone Small Business Concerns* (JUL 2005) (if the offeror elects to waive the preference, it shall so indicate in its offer)(15 U.S.C. 657a).
- (4) [Reserved]
 - (5) (i) 52.219-6, *Notice of Total Small Business Set-Aside* (JUNE 2003)(15 U.S.C. 644).
 - (ii) Alternate I (OCT 1995) of 52.219-6.
 - (iii) Alternate II (MAR 2004) of 52.219-6.
 - (6) (i) 52.219-7, *Notice of Partial Small Business Set-Aside* (JUNE 2003)(15 U.S.C. 644).
 - (ii) Alternate I (OCT 1995) of 52.219-7.
 - (iii) Alternate II (MAR 2004) of 52.219-7.
- (7) 52.219-8, *Utilization of Small Business Concerns* (MAY 2004)(15 U.S.C. 637 (d)(2) and (3)).
- (8) (i) 52.219-9, *Small Business Subcontracting Plan* (JUL 2005)(15 U.S.C. 637 (d)(4)).
 - (ii) Alternate I (OCT 2001) of 52.219-9.
 - (iii) Alternate II (OCT 2001) of 52.219-9.
- (9) 52.219-14, *Limitations on Subcontracting* (DEC 1996)(15 U.S.C. 637(a)(14)).

52.212-5 (continued)

___ (10) (i) 52.219-23, *Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns* (SEP 2005)(10 U.S.C. 2323) (if the offeror elects to waive the adjustment, it shall so indicate in its offer).

___ (ii) Alternate I (JUNE 2003) of 52.219-23.

___ (11) 52.219-25, *Small Disadvantaged Business Participation Program-Disadvantaged Status and Reporting* (OCT 1999)(Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).

___ (12) 52.219-26, *Small Disadvantaged Business Participation Program-Incentive Subcontracting* (OCT 2000)(Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).

___ (13) 52.219-27, *Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside* (May 2004)

x (14) 52.222-3, *Convict Labor* (JUNE 2003)(E.O. 11755)

x (15) 52.222-19, *Child Labor—Cooperation with Authorities and Remedies* (JAN 2006)(E.O. 13126)

x (16) 52.222-21, *Prohibition of Segregated Facilities* (FEB 1999).

x (17) 52.222-26, *Equal Opportunity* (APR 2002)(E.O.11246).

x (18) 52.222-35, *Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans* (DEC 2001)(38 U.S.C. 4212).

x (19) 52.222-36, *Affirmative Action for Workers with Disabilities* (JUN 1998)(29 U.S.C.793).

x (20) 52.222-37, *Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans* (DEC 2001)(38 U.S.C. 4212).

x (21) 52.222-39, *Notification of Employee Rights Concerning Payment of Union Dues or Fees* (DEC 2004) (E.O. 13201)

___ (22)(i) 52.223-9, *Estimate of Percentage of Recovered Material Content for EPA-Designated Products* (AUG 2000)(42 U.S.C. 6962(c)(3)(A)(ii))

___ (ii) Alternate I (AUG 2000) of 52.223-9 (42 U.S.C. 6962(i)(2)(C))

Paragraphs (23) through (25) are not applicable and have been deleted.

x (26) 52.225-13, *Restrictions on Certain Foreign Purchases* (FEB 2006)(E.O.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

___ (27) [Reserved]

___ (28) [Reserved]

52.212-5 (continued)

___ (29) 52.232-29, *Terms for Financing of Purchases of Commercial Items* (FEB 2002)(41 U.S.C. 255(f), 10 U.S.C. 2307(f)).

___ (30) 52.232-30, *Installment Payments for Commercial Items* (OCT 1995)(41 U.S.C. 255(f), 10 U.S.C. 2307(f)).

x (31) 52.232-33, *Payment by Electronic Funds Transfer-Central Contractor Registration* (OCT 2003)(31 U.S.C. 3332).

Paragraph (32) is not applicable and has been deleted.

___ (33) 52.232-36, *Payment by Third Party* (MAY 1999)(31 U.S.C. 3332).

___ (34) 52.239-1, *Privacy or Security Safeguards* (AUG 1996)(5 U.S.C.552a).

Paragraph (35) is not applicable and has been deleted.

Paragraph (c) is not applicable and has been deleted.

52.212-5 (continued)

(d) *Comptroller General Examination of Record.* The Contractor agrees to comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, *Audit and Records -- Negotiation.*

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c) and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in paragraphs (i) through (vii) of this paragraph in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—

(i) 52.219-8, *Utilization of Small Business Concerns* (May 2004) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$500,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(ii) 52.222-26, *Equal Opportunity* (April 2002)(E.O.11246).

(iii) 52.222-35, *Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans* (December 2001)(38 U.S.C. 4212).

(iv) 52.222-36, *Affirmative Action for Workers with Disabilities* (June 1998)(29 U.S.C.793).

(v) 52.222-39, *Notification of Employee Rights Concerning Payment of Union Dues or Fees* (DEC 2004) (E.O. 13201)

(vi) 52.222-41, *Service Contract Act of 1965, As Amended* (JUL 2005), flow down required for all subcontracts subject to the Service Contract Act of 1965 (41 U.S.C. 351, et seq.).

(vii) 52.247-64, *Preference for Privately-Owned U.S.- Flag Commercial Vessels*

52.212-5 (continued)

(FEB 2006)(46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64,

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

ADDENDUM TO 52.212-5

[X] 252.212-7001 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS APPLICABLE TO DEFENSE ACQUISITIONS OF COMMERCIAL ITEMS (MAY 2006) DFARS [DSCP MODIFIED]

- (a) The Contractor agrees to comply with the following Federal Acquisition Regulation (FAR) clause, which, if checked, is included in this contract by reference to implement a provision of law applicable to acquisitions of commercial items or components.
- 52.203-3 *Gratuities* (APR 1984) (10 U.S.C. 2207).
- (b) The Contractor agrees to comply with any clause that is checked on the following list of Defense FAR Supplement clauses, which, if checked, is included in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items or components.
- 252.205-7000 *Provision of Information to Cooperative Agreement Holders* (DEC 1991) (10 U.S.C. 2416).
- 252.219-7003 *Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan* (DoD Contracts)(APR 1996) (15 U.S.C. 637).
- 252.219-7004 *Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan (Test Program)* (JUN 1997) (10 U.S.C. 637 Note).
- 252.225-7001 *Buy American Act and Balance of Payments Program* (JUN 2005) (41 U.S.C. 10a-10d, E.O. 10582).
- 252.225-7012 *Preference for Certain Domestic Commodities.* (JUN 2004) (10 U.S.C. 2533a).
- See full text version of this clause at the end of this Addendum.*
- 252.225-7014 *Preference for Domestic Specialty Metals* (JUN 2005) (10 U.S.C. 2533a).
- See full text version of this clause at the end of this Addendum.*
- 252.225-7015 *Restriction on Acquisition of Hand or Measuring Tools* (JUN 2005)(10 U.S.C. 2533a).
- See full text version of this clause at the end of this Addendum.*

ADDENDUM TO 52.212-5**DFARS 252.212-7001 (continued)**

- 252.225-7016 *Restriction on Acquisition of Ball and Roller Bearings* (MAR 2006) (Section 8065 of Public Law 107-117 and the same restriction in subsequent DoD appropriations acts).
- 252.225-7021 *Trade Agreements* (FEB 2006) (19 U.S.C. 2501-2518 and 19 U.S.C. 3301 note).
- 252.225-7027 *Restriction on Contingent Fees for Foreign Military Sales* (APR 2003) (22 U.S.C. 2779).
- Para (b): Government(s) of _____*
- 252.225-7028 *Exclusionary Policies and Practices of Foreign Governments* (APR 2003) (22 U.S.C. 2755).
- 252.225-7036 *Buy American Act--Free Trade Agreements--Balance of Payments Program* (JUN 2005) (___ Alternate I) (JAN 2005) (41 U.S.C. 10a-10d and 19 U.S.C. 3301 note).
- 252.225-7038 *Restriction on Acquisition of Air Circuit Breakers* (JUN 2005) (10 U.S.C. 2534(a)(3)).
- 252.226-7001 *Utilization of Indian Organizations, Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns* (SEP 2004)(Section 8021 of Pub. L. 107-248 and similar sections in subsequent DoD appropriations acts).
- 252.227-7015 *Technical Data--Commercial Items* (NOV 1995) (10 U.S.C. 2320).
- 252.227-7037 *Validation of Restrictive Markings on Technical Data* (SEP 1999) (10 U.S.C. 2321).
- 252.232-7003 *Electronic Submission of Payment Requests* (MAY 2006) (10 U.S.C. 2227)
- 252.237-7019 *Training for Contractor Personnel Interacting with Detainees* (SEP 2005)(Section 1092 of Pub. L. 108-375)
- 252.243-7002 *Requests for Equitable Adjustment* (MAR 1998) (10 U.S.C. 2410).
- 252.247-7023 *Transportation of Supplies by Sea* (MAY 2002) (___ Alternate I) (MAR 2000) (___ Alternate II) (MAR 2000) (Alternate III) (MAY 2002) (10 U.S.C. 2631).
- 252.247-7024 *Notification of Transportation of Supplies by Sea* (MAR 2000) (10 U.S.C. 2631).

NOTE: Contractor agrees to comply with clause 252.247-7024, which is included in this contract by reference, when it represents in its offer that it does not anticipate that supplies will be transported by sea.

ADDENDUM TO 52.212-5

DFARS 252.212-7001 (continued)

(c) In addition to the clauses listed in paragraph (e) of the *Contract Terms and Conditions Required to Implement Statutes or Executive Orders--Commercial Items* clause of this contract (Federal Acquisition Regulation 52.212-5), the Contractor shall include the terms of the following clauses, if applicable, in subcontracts for commercial items or commercial components, awarded at any tier under this contract:

- 252.225-7014 This clause is not applicable and has been deleted.
- 252.237-7019 *Training for Contractor Personnel Interacting with Detainees* (SEP 2005) (Section 1092 of Pub. L. 108-375)
- 252.247-7023 *Transportation of Supplies by Sea* (MAY 2002) (10 U.S.C. 2631).
- 252.247-7024 *Notification of Transportation of Supplies by Sea* (MAR 2000) (10 U.S.C. 2631).

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SECTION C - DESCRIPTION/SPECIFICATION

ITEM IDENTIFICATION

PLUG, EAR, COMBAT ARMS, DOUBLE-ENDED, 50 PAIR: SWEPT-BACK TRIPLE-FLANGE STYLE. OLIVE DRAB END PROTECTS USER FROM CONTINUOUS NOISE; YELLOW END PROTECTS USER FROM MILITARY WEAPONS NOISE.

SHALL BE IN ACCORANCE WITH MEDICAL PROCUREMENT ITEM DESCRIPTION NO. 2 DATED 16 JULY 2006.

PRESERVATION, PACKAGING, PACKING, LABELING AND MARKING FOR 6515-01-466-2710 SHALL BE AS SPECIFIED IN MEDICAL PROCUREMENT ITEM DESCRIPTION NO. 2.

6515-01-466-2710 27 JULY 2006

SECTION D - PACKAGING AND MARKING

PREPARATION FOR DELIVERY

```

=====
| CERTIFICATION REQUIREMENT FOR NON-      |
| MANUFACTURED WOOD PACKING MATERIAL (NMWPM) |
|  --  --  --  --  --  --  --  --  --  |
|   APPLICABLE TO ALL COMMERCIAL/GOVERNMENT |
|   EXPORT SHIPMENTS OF SUPPLIES PACKED    |
|   IN/ON NMWPM AND DESTINED FOR DELIVERY TO |
|   EUROPE ON/AFTER OCTOBER 1, 2001, EITHER |
|   DIRECTLY TO THE CUSTOMER OR THROUGH A   |
|   DEFENSE DEPOT OR OTHER CONSOLIDATION    |
|   POINT.                                  |
|  --  --  --  --  --  --  --  --  --  |
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| ALL WOODEN PALLETS AND WOODEN CONTAINERS |

| PRODUCED ENTIRELY OR IN PART OF |

| NON-MANUFACTURED SOFTWOOD SPECIES SHALL |

| BE CONSTRUCTED FROM HEAT-TREATED (HT TO |

| 56 DEGREES CENTIGRADE FOR 30 MINUTES) |

| CONIFEROUS MATERIAL AND CERTIFIED |

| ACCORDINGLY BY AN ACCREDITED AGENCY |

| RECOGNIZED BY THE AMERICAN LUMBER STANDARD |

| COMMITTEE, INCORPORATED (ALSC), IN |

| ACCORDANCE WITH THE LATEST REVISION OF THE |

| ALSC NON-MANUFACTURED WOOD PACKING POLICY |

| AND NON-MANUFACTURED WOOD PACKING |

| ENFORCEMENT REGULATIONS (SEE URL: |

| HTTP://WWW.ALSC.ORG/) . |

|

| ALL WOODEN PALLETS AND WOODEN CONTAINERS |

| PRODUCED ENTIRELY OF NON-MANUFACTURED |

| HARDWOOD SPECIES SHALL BE IDENTIFIED BY A |

| PERMANENT MARKING OF "NC-US", 1.25 INCHES |

| OR GREATER IN HEIGHT, ACCOMPANIED BY THE |

| CAGE CODE OF THE PALLET/CONTAINER |

| MANUFACTURER AND THE MONTH AND YEAR OF THE |

| CONTRACT. ON PALLETS, THE MARKING SHALL BE |

| APPLIED TO THE STRINGER OR BLOCK ON |

| DIAGONALLY OPPOSITE SIDES AND ENDS OF THE |

| PALLET AND SHALL BE CONTRASTING AND CLEARLY |

| VISIBLE. ON CONTAINERS, THE MARKING SHALL |

| BE APPLIED ON A SIDE OTHER THAN THE TOP OR |

| BOTTOM, AND SHALL BE CONTRASTING AND CLEARLY |

| VISIBLE. |

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|  --  --  --  --  --  --  --  --  --  |
| FAILURE TO COMPLY WITH ALL THE REQUIREMENTS |
| OF THIS RESTRICTION MAY RESULT IN REFUSAL, |
| DESTRUCTION, OR TREATMENT OF MATERIALS AT |
| THE POINT OF ENTRY. |
|  --  --  --  --  --  --  --  --  --  |
|
| DEFENSE CONSOLIDATION POINTS INCLUDE THE |
| FOLLOWING: |
|   A.  DEFENSE DISTRIBUTION DEPOTS, |
|   SUSQUEHANNA, PA, AND SAN JOAQUIN, CA |
|   B.  CONTAINER FREIGHT STATION, NORFOLK, VA |
|   C.  ARMY PREPOSITIONED SHIP (APS 3) |
|   UPLOAD SITE, CHARLESTON, SC (DODAAC W81X89 |
|   AND W81YUK) |
|   D.  MARINE CORPS BLOUNT ISLAND COMMAND, |
|   JACKSONVILLE, FL 32226-3404 |
|   E.  AERIAL PORTS OF EMBARKATION, |
|   DOVER, DE; TRAVIS AIR FORCE BASE, CA; |
|   NAVAL AIR STATION, NORFOLK, VA; AND |
|   CHARLESTON AIR FORCE BASE, SC. |
=====

```

PACKAGING AND PACKING SHALL BE

- . PACKAGING - MILITARY
- . PACKING - LEVEL B

IN ACCORDANCE WITH APPLICABLE SPECIFICATION CITED IN SECTION 'C'.

UNITIZED LOADS COMMENSURATE WITH THE LEVEL OF PACKING SPECIFIED IN THE CONTRACT OR ORDER SHALL BE USED WHENEVER TOTAL QUANTITY FOR SHIPMENT TO

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ONE DESTINATION EXCEEDS 250 LBS (EXCLUDING THE PALLET) OR 20 CU FT. LOADS SHALL BE UNITIZED ON TYPE IV OR TYPE V 4-WAY ENTRY PALLETS. PALLET SHALL HAVE A LENGTH OF 40 INCHES AND A WIDTH OF 48 INCHES. PALLET LOADS, INCLUDING THE PALLET, SHALL NOT EXCEED 54 INCHES IN HEIGHT, 43 INCHES IN LENGTH AND 52 INCHES IN WIDTH. QUANTITY FOR SHIPMENT TO ONE DESTINATION OF LESS THAN 250 LBS OR 20 CUBIC FEET NEED NOT BE PALLETIZED.

APPLICABLE TO EQUIPMENT ITEMS HAVING A HEIGHT OF 48 INCHES OR GREATER:

IF A PROPERLY PALLETIZED LOAD (EQUIPMENT ITEM AND PALLET) EXCEEDS 54 INCHES IN HEIGHT, HEIGHT LIMITATION NEED NOT BE ADHERED TO.

NOTE: THE PALLETIZATION STANDARD, MIL-STD-147D, HAS BEEN REDESIGNATED AS A PALLETIZATION HANDBOOK, MIL-HDBK-774 DATED 25 MARCH 1996. THEREFORE, THIS DOCUMENT MAY NO LONGER BE CITED AS A REQUIREMENT; IT IS NOW USED FOR GUIDANCE PURPOSES ONLY. THE ONLY PHYSICAL CHANGE TO THE DOCUMENT IS THE COVER SHEET DESIGNATING IT AS A HANDBOOK. THEREFORE, IF YOU HAVE A COPY OF MIL-STD-147D ON HAND, YOU MAY USE IT FOR GUIDANCE WHEN PALLETIZING YOUR SHIPMENTS. COPIES OF MIL-HDBK-774 MAY BE OBTAINED FROM THE DEFENSE PRINTING SERVICE DETACHMENT OFFICE, BLDG 4D (NPM-DODSP), 700 ROBBINS AVENUE, PHILADELPHIA, PA 19111-5094.

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.
MARKING SHALL BE AS SPECIFIED IN MEDICAL MARKING STANDARD NO. 1 DATED 19 JULY 1999, EXCEPT, IN PARA. V.C.2., DELETE LAST SENTENCE (WHEN LABELS ARE USED . . . SHIPMENT AND STORAGE.) ENTIRELY AND SUBSTITUTE: "APPLICABLE TO EXTERIOR (SHIPPING) CONTAINER AND UNITIZED LOAD: WHEN LABELS ARE USED, THEY SHALL BE WEATHER-RESISTANT, REMAIN SECURELY AFFIXED AND HAVE A FINISH CAPABLE OF WITHSTANDING NORMAL HANDLING DURING SHIPMENT AND STORAGE."

.
MARKINGS SHALL INCLUDE BAR CODES, AS FOLLOWS:

.
UNIT - BAR CODES ARE NOT REQUIRED UNLESS THE UNIT IS ALSO THE EXTERIOR (SHIPPING) CONTAINER.

.
INTERMEDIATE PACKAGE - BAR CODES ARE NOT REQUIRED.

.
EXTERIOR (SHIPPING) CONTAINER - BAR CODES (NSN AND PIIN) SHALL BE SUPPLIED ON THE IDENTIFICATION-MARKED SIDE OF THE CONTAINER.

.
UNITIZED LOAD - BAR CODES (NSN AND PIIN) SHALL BE SUPPLIED ON THE IDENTIFICATION MARKED SIDES OF THE LOAD.

.
NOTES:

.
SEE MEDICAL MARKING STANDARD NO. 1 FOR PLACEMENT OF ALL REQUIRED MARKINGS.

.
BAR CODES SHALL INCLUDE THE HUMAN READABLE INTERPRETATION (HRI).

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.
. PIIN REFERS TO THE CONTRACT OR ORDER NUMBER,
TOGETHER WITH DELIVERY ORDER NUMBER, WHEN
APPLICABLE.
.

.
MIL-STD-1189B (STANDARD DEPARTMENT OF DEFENSE
BAR CODE SYMBOLOGY) HAS BEEN CANCELLED AND
REPLACED BY COMMERCIAL BAR CODE STANDARD
ISO/IEC 16388 (INFORMATION TECHNOLOGY -
AUTOMATIC IDENTIFICATION AND DATA CAPTURE
TECHNIQUES - CODE SYMBOLOGY SPECIFICATION - CODE
39). COPIES OF ISO/IEC 16388 ARE AVAILABLE FROM
ANSI, 25 WEST 43RD STREET, NEW YORK, NY 10036,
WWW.ANSI.ORG.

.
COPIES OF MEDICAL MARKING STANDARD NO. 1 MAY BE
OBTAINED BY CONTACTING DEFENSE SUPPLY CENTER
PHILADELPHIA, ATTN: DSCP-MSBA (L. CONNORS),
BLDG 6A SOUTH, 700 ROBBINS AVENUE,
PHILADELPHIA, PA 19111-5092.
PHONE: (215)737-4189 / FAX: (215)737-8150
EMAIL: LCONNORS@DSCP.DLA.MIL

PGC 46852

MEDICAL PROCUREMENT ITEM DESCRIPTION	NUMBER	DATE
	2	16 July 2006
NATIONAL STOCK NO.	ITEM IDENTIFICATION	
6515-01-466-2710	PLUG, EAR, Combat Arms, Double-Ended, 50 pair	

1. SCOPE.

1.1 This Medical Procurement Item Description covers military-unique, double-ended ear plugs suitable for use as hearing protectors for military personnel in chronically noisy environments.

1.2 Shall be Aearo Corporation's P/N 370-1000, or equal. "Equal" items shall possess the salient characteristics as specified herein.

2. SALIENT CHARACTERISTICS.

2.1 General. Shall be double-ended, swept-back triple-flange style ear plugs.

2.1.1 Ear plugs shall be designed to provide protection from the impulse noises created by military firearms, while allowing the wearer to clearly hear normal speech and other quieter sounds, such as voice commands, on the battlefield.

2.1.2 The end designed for protection from chronic noises shall be camouflage green or another suitable dark color; the end designed for protection from impulse noises shall be yellow or another suitable bright color. The ear plugs shall meet all requirements as set forth herein.

2.2 Sound attenuation. At each frequency listed below, each end of the ear plug shall provide the level of sound attenuation as specified. Sound attenuation shall be measured in decibels (dB).

SOUND ATTENUATION OF THE CAMOUFLAGE GREEN END OF THE EAR PLUG		SOUND ATTENUATION OF THE YELLOW END OF THE EAR PLUG	
Sound Frequency, Hz	Minimum Mean Attenuation, dB	Sound Frequency, Hz	Minimum and Maximum Mean Attenuation, dB
125	25 dB	125	0 dB to 10 dB
250	25 dB	250	0 dB to 10 dB
500	25 dB	500	0 dB to 10 dB
1000	25 dB	1000	5 dB to 15 dB
2000	30 dB	2000	10 dB to 20 dB
4000	35 dB	4000	10 dB to 20 dB
8000	40 dB	8000	10 dB to 25 dB

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2.2.1 The yellow end of the earplug shall incorporate a passive non-linear technology that has been empirically shown to provide a level-dependant increase in sound attenuation above a sound pressure level of 115 dBp(peak). It shall also provide this protection at sound-pressure levels up to 190 dBp(peak), even after the user has been exposed to 100 free-field noise impulses of 190 dBp(peak), minimum.

2.2.2 The sound attenuation of both ends of the ear plugs shall be tested in accordance with ANSI S3.19. A laboratory accredited in accordance with the requirements of the U.S. Department of Commerce's National Voluntary Laboratory Accreditation Program (NVLAP) shall perform the sound attenuation testing.

2.3 Material. The ear plugs shall be made of thermoplastic elastomeric polymer. This material shall be non-allergenic and non-toxic.

2.4 Workmanship. The ear plugs shall be free from all defects that detract from their appearance or impair their serviceability.

2.5 Instructions. Illustrated instructions explaining the proper use and handling of the ear plugs shall be supplied with each unit. Instructions shall be legible and easy to read. Instructions shall be printed in permanent black or navy blue ink on a suitable sheet of paper which shall be placed inside the unit package prior to sealing. As an alternate, instructions may be printed on a suitable, clearly visible location on the unit container in permanent black or navy blue ink.

3. REGULATORY REQUIREMENTS.

3.1 Federal Food, Drug and Cosmetic Act. If the product covered by this document has been determined by the U. S. Food and Drug Administration to be under its jurisdiction, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder. In addition, the offeror/contractor shall comply, and be responsible for compliance by its subcontractors/suppliers, with the requirements of all other applicable Federal, State and local statutes, ordinances, and regulations.

3.2 Recovered materials. The offeror/contractor is encouraged to use recovered material in accordance with Federal Acquisition Regulation Subpart 23.4 to the maximum extent practical.

4. QUALITY ASSURANCE PROVISIONS.

4.1 Responsibility for inspection. Unless otherwise specified in the contract or purchase order, the contractor is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified in the contract or purchase order, the contractor may use his own or any facilities suitable for the performance of the inspection requirements specified herein, unless disapproved by the Government. The Government reserves the right to perform any of the inspections set forth in the specification where such inspections are deemed necessary to assure supplies

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and services conform to prescribed requirements.

4.2 Inspection. Inspection, as used herein, shall be defined as the examination and testing of an item. Examination shall be defined as unaided visual, auditory, tactile, or olfactory investigation. Testing shall be defined as the use of laboratory equipment and procedures to determine various properties of an item. Inspections shall be conducted to determine compliance with specification requirements. Where feasible, the same sample shall be used for the determination of two or more inspection characteristics. For inspection purposes, the unit of product shall be one pair of ear plugs.

4.3 Sampling for inspection.

4.3.1 For each specified salient characteristic, except "Sound Attenuation", sampling for inspection shall be conducted in accordance with ANSI/ASQ Z1.4. A sampling shall be performed for each salient characteristic. Inspection level S-2 shall be used; acceptable quality level (AQL) shall be 1.0 percent.

4.3.2 Sound attenuation. Sampling for inspection of sound attenuation of the level-dependent yellow end shall be 100 percent, and shall be verified using an acoustical impedance test. Sampling for inspection of the sound attenuation of the camouflage green end shall be conducted in accordance with ANSI/ASQ Z1.4. Inspection level S-2 shall be used; the AQL shall be 1.0 percent.

4.4 Records. Records of inspections performed by or for the contractor shall be maintained by the contractor and made available to the Government upon the Government's request, at any time, or from time to time, during the performance of the contract and for a period of three years after delivery of the supplies to which such records relate.

4.5 Contractor certification. The contractor shall certify that the product offered meets the salient characteristics of this document and conforms to the producer's own drawings, specifications, standards, and quality assurance practices. The Government reserves the right to require proof of such conformance prior to first delivery and thereafter as may be otherwise provided for under the provisions of the contract.

5. PACKAGING.

5.1 Preservation. Preservation shall be military.

5.1 Unit. Package (PG). One package containing 50 pairs of ear plugs, as specified, constitutes one unit. Unit package shall be any suitable sealed commercial container capable of protecting the contents from damage, and shall be designed to permit easy dispensing of the ear plugs. Illustrated instructions for use, as specified in para. 2.5, shall be supplied with each unit.

5.1.2 Intermediate package. Intermediate package may be supplied at the option of the contractor.

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5.2 Packing. Packing shall be level B.

5.2.1 Exterior (shipping) container. Twenty-four units shall be packed in an exterior (shipping) container designed for a type 2 load and conforming to ASTM D 5118, class domestic. Closure shall be as specified in ASTM D 1974, closure method 1E.

5.2.3 Unitization. Material shall be unitized as specified in the contract or order.

5.3 Marking.

5.3.1 Unit. Each unit shall be marked as specified in Medical Marking Standard No. 1 for military material. In addition, markings shall include the item identification, and the manufacturer's name, address and telephone number.

5.3.3 Intermediate package (if supplied), exterior (shipping) container and unitized load. Each intermediate package (if supplied), exterior (shipping) container and unitized load shall be marked as specified in Medical Marking Standard No. 1.

6. NOTES.

6.1 Sources of documents.

6.1.1 The Federal Food, Drug and Cosmetic Act is available from the Food and Drug Administration, Washington, DC 20204.

6.1.2 ASTM Standards are available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

6.1.3 ANSI Standards are available from the American National Standards Institute, 11 West 42nd Street, New York, NY 10036-8002.)

6.1.4 Medical Marking Standard No. 1 is available from Defense Supply Center Philadelphia, ATTN: DSCP-MSBA (L. Connors), Bldg 6A South, 700 Robbins Avenue, Philadelphia, PA 19111-5092, email Loretta.Connors@dla.mil.

**52.212-1 INSTRUCTIONS TO OFFERORS -- COMMERCIAL ITEMS
(JAN 2006)**

This provision is now incorporated by reference. The full text can be accessed electronically at www.dla.mil/j-3/j-336/icps.htm. Once you arrive at this website, click on the Hill AFB FAR link, then click on 52.000 (located on the left-hand side of the page). Scroll down until you reach 52.212-1.

ADDENDUM TO 52.212-1

1. Addenda to 52.212-1 (b) Submission of offers.

Mailed offers should be sent to:

Defense Logistics Agency
Defense Supply Center Philadelphia
P. O. Box 56667
Philadelphia, PA 19111-6667

Hand carried offers, including delivery by commercial carrier, should be delivered to:

Defense Supply Center Philadelphia
Business Opportunities Office
Bldg. 36, Second Floor
700 Robbins Avenue
Philadelphia, PA 19111-5092

NOTE: All hand-carried offers are to be delivered between 8:00 a.m. and 5:00 p.m., Monday through Friday, except for legal federal holidays as set forth in 5 USC 6103. Offerors using a commercial carrier service must ensure that the carrier service “hand-carries” the package to the depository specified above (i.e., the Business Opportunities Office address) prior to the scheduled opening/closing time. **Package must be plainly marked ON THE OUTSIDE OF THE COMMERCIAL CARRIER’S ENVELOPE with the solicitation number, date, and time set forth for receipt of offers as indicated in Block 8 of the Standard Form 1449.**

Facsimile offers (if authorized) or facsimile offer modifications/withdrawals should be transmitted to: (215) 737-9300, 9301, 9302 or 9303

Faxed offers ARE ARE NOT authorized for this solicitation.

ADDENDUM TO 52.212-1 (continued)

Facsimile offers that fail to furnish required representations, or information, or that reject any of the terms, conditions and provisions of the solicitations, may be excluded from consideration. Facsimile offers must contain the required signatures. The Government reserves the right to make award solely on the facsimile offer. However, if requested to do so by the Contracting Officer, the apparently successful offeror agrees to promptly submit the complete original signed proposal. The Government will not be responsible for any failure attributable to the transmission or receipt of the facsimile offer.

Special Instructions for the Submission of Source Selection Information:

The Government will consider other factors in addition to price when evaluating proposals to determine the best overall expected value. To facilitate evaluation of your proposal in accordance with the factors listed in FAR 52.212-2, please prepare your proposal in accordance with the special instructions attached in paragraph 7 of this addendum and submit such information as an attachment to your offer.

2. Addenda to 52.212-1(c) *Period for acceptance of offers.*

Period of acceptance is 120 days.

3. Addenda to 52.212-1(e) *Multiple offers.*

Alternate offers of commercial items will not be considered for award. Although such offers will not be considered for award, alternate offers of commercial items may, however, be submitted by offerors for consideration by the Government for market research purposes on future acquisitions.

4. Addenda to 52.212-1(g), *Contract Award*

Evaluation - lowest price/technically acceptable solicitation. The Government intends to evaluate and award a contract to the low responsible offeror whose offer conforms to the specification requirements. Price will be the determining factor in evaluating offers for award. The Government, however, reserves the right to conduct discussions if determined by the Contracting Officer to be necessary.

4. Addenda to 52.212-1 (h) *Multiple awards.*

The Government intends to make one award.

Offers may be submitted for quantities less than those specified.

ADDENDUM TO 52.212-1 (continued)**5. Solicitation Provisions Incorporated by Reference :**

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. The full text of any FAR, DFARS, DLAD and DSCP solicitation provision may be accessed electronically at www.dla.mil/j-3/j-336/icps.htm or obtained from the Contracting Officer.

The following provisions are incorporated by reference:

<u>PROVISION #</u>	<u>TITLE</u>	<u>DATE</u>	<u>SOURCE</u>
52.216-27	<i>SINGLE OR MULTIPLE AWARDS</i>	<i>(OCT 1995)</i>	<i>FAR</i>
52.217-5	<i>EVALUATION OF OPTIONS</i>	<i>(JUL 1990)</i>	<i>FAR</i>
x 52.222-24	<i>PREAWARD ON-SITE EQUAL OPPORTUNITY COMPLIANCE EVALUATION</i>	<i>(FEB 1999)</i>	<i>FAR</i>
x 52.233-2	<i>SERVICE OF PROTEST</i>	<i>(AUG 1996)</i>	<i>FAR</i>
x 252.209-7001	<i>DISCLOSURE OF OWNERSHIP OR CONTROL BY THE GOVERNMENT OF A TERRORIST COUNTRY</i>	<i>(SEP 2004)</i>	<i>DFARS</i>
x 52.233-9000	<i>AGENCY PROTESTS</i>	<i>(SEP 1999)</i>	<i>DLAD</i>

6. The following provision is incorporated in full text:

|x| 52.207-4 **ECONOMIC PURCHASE QUANTITY - SUPPLIES (AUG 1987) FAR**

(a) Offerors are invited to state an opinion on whether the quantity(ies) of supplies on which bids, proposals or quotes are requested in this solicitation is (are) economically advantageous to the Government.

ADDENDUM TO 52.212-1 (continued)

52.207-4 (continued)

(b) Each offeror who believes that acquisitions in different quantities would be more advantageous is invited to recommend an economic purchase quantity. If different quantities are recommended, a total and a unit price must be quoted for applicable items. An economic purchase quantity is that quantity at which a significant price break occurs. If there are significant price breaks at different quantity points, this information is desired as well.

ITEM	OFFEROR RECOMMENDATIONS		
	QUANTITY	PRICE_ QUOTATION	TOTAL

(c) The information requested in this provision is being solicited to avoid acquisitions in disadvantageous quantities and to assist the Government in developing a data base for future acquisitions of these items. However, the Government reserves the right to amend or cancel the solicitation and resolicit with respect to any individual item in the event quotations received and the Government’s requirements indicate that different quantities should be acquired.

[x] 52.211-6 Brand Name or Equal (Aug 1999) FAR

(a) If an item in this solicitation is identified as “brand name or equal,” the purchase description reflects the characteristics and level of quality that will satisfy the Government’s needs. The salient physical, functional, or performance characteristics that “equal” products must meet are specified in the solicitation.

(b) To be considered for award, offers of “equal” products, including “equal” products of the brand name manufacturer, must—

Meet the salient physical, functional, or performance characteristic specified in this solicitation;

Clearly identify the item by—

- (i) Brand name, if any; and
- (ii) Make or model number;

Include descriptive literature such as illustrations, drawings, or a clear reference to previously furnished descriptive data or information available to the Contracting Officer; and

Clearly describe any modification the offeror plans to make in a product to make it conform to the solicitation requirements. Mark any descriptive material to clearly show the modification.

ADDENDUM TO 52.212-1 (continued)

52.211-6(continued)

(c) The Contracting Officer will evaluate “equal” products on the basis of information furnished by the offeror or identified in the offer and reasonably available to the Contracting Officer. The Contracting Officer is not responsible for locating or obtaining any information not identified in the offer.

(d) Unless the offeror clearly indicates in its offer that the product being offered is an “equal” product, the offeror shall provide the brand name product referenced in the solicitation.

[x] 52.215-20 REQUIREMENTS FOR INFORMATION OTHER THAN COST OR PRICING DATA (OCT 1997), ALTERNATE IV (OCT 1997) FAR

(a) Submission of cost or pricing data is not required.

(b) Provide information described below:

(1) For commercial item(s), the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information shall include—

(i) Sales information, **optional** for each individual item, as follows:

Total Sales to the General Public	_____	(Quantity)
(Other than to the U.S. Government	_____	(Most recent sales period
or its instrumentalities) at Catalog Price		available — 3 mos. min.)

PLUS

Total Sales to the General Public at	_____	(Quantity)
Other than Catalog Price.	_____	(Most recent sales period
		available — 3 mos. Min.)

EQUALS

Total Sales to the General Public	_____	(Quantity)
	_____	(Most recent sales period
		available — 3 mos. Min.)

The lowest price sale to the General	_____	(Date)
Public.	_____	(Unit Price)
(Identify date, price, and quantity).	_____	(Quantity)

The lowest price sale to the General	_____	(Date)
Public under terms and conditions that	_____	(Unit Price)
are the most comparable to those	_____	(Quantity)
solicited by the Government.		

ADDENDUM TO 52.212-1 (continued)**52.215-20 (continued)**

(Identify date, price, and quantity).

(ii) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages which include the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished); e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities. **If offer prices are, or are based on, discounted catalog prices**, furnish, in lieu of or in addition to the price information required by the previous sentence, the following information **for each different discount offered**:

(A) Identify the largest discount offered currently or within the preceding 12 months to any customer for that item or items.

(B) If the offered discount is lower than the largest discount offered to any customer —

(I) justify why you are unable and/or unwilling to offer that largest discount; and

(II) identify the largest discount offered currently or within the preceding 12 months to any customer for that item or items under terms and conditions that are the most comparable to those sought by the Government.

(C) If the offered discount is lower than the largest discount offered to any customer under the most comparable terms and conditions, justify why you are unable and/or unwilling to offer that largest discount.

(iii) For market-priced items, the source and date or period of the market quotation or other basis for the market price, the base amount, and applicable discounts. In addition, describe the nature of the market.

(2) For items on a FSS and/or Veterans Affairs (VA) contract, regardless of whether they are or are not commercial items, furnish a copy of, or the appropriate pages from, the FSS and/or VA contract. Unless offerors can justify that the proposed contract terms and conditions under this acquisition are less favorable than those under their FSS and/or VA contracts, award prices under this acquisition may not exceed the FSS and/or VA contract prices. For items included on an active Federal Supply Service (FSS) Multiple Award Schedule contract, proof that an exception from the submission of certified cost and pricing data has been granted for the schedule item is required if the offeror has not furnished the information required by (1) above that is adequate for the Contracting Officer to determine that the offered item(s) are commercial items.

(c) Delay in furnishing the appropriate information other than cost or pricing data that is required by paragraph (b) above and that is adequate for evaluating the reasonableness of

ADDENDUM TO 52.212-1 (continued)**52.215-20 (continued)**

the offered prices, may delay any potential award to that offeror. As a consequence, if the Government has indicated elsewhere in this solicitation that multiple awards are intended, delivery orders that might otherwise have been placed with that offeror may be placed with awardees that furnished the required information on a timely basis. Failure to furnish the appropriate information other than cost or pricing data that is required by paragraph (b) above and that is adequate for evaluating the reasonableness of the offered prices may result in a determination that there is insufficient information to determine the offer prices to be fair and reasonable. The Contracting Officer may determine that cost or pricing data (and an audit) is required. If ultimately there is insufficient information to determine the offer prices to be fair and reasonable, the Contracting Officer has no choice but to determine the offer prices to be unreasonable. Unreasonable offer prices may be rejected for award.

[x] 52.216-1 TYPE OF CONTRACT (APR 1984) FAR

The Government contemplates award of a Firm Fixed Price, Indefinite-Delivery, Indefinite-Quantity (IQ) Contract resulting from this solicitation.

[x] 52.252-1 SOLICITATION PROVISIONS INCORPORATED (FEB 1998 FAR BY REFERENCE

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this/these address(es):

<http://www.dla.mil/j-3/j-336/icps.htm>

[x] 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998) FAR

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<http://www.dla.mil/j-3/j-336/icps.htm>

ADDENDUM TO 52.212-1 (continued)**[x] 52.209-9P07 PRE-AWARD PLANT SURVEY (JAN 1992) DSCP**

To determine the responsibility of prospective contractors, the Government reserves the right to conduct physical surveys of the plants which are to be used in the performance of a contract. In the event the Government is prevented from making such survey by the offeror or its proposed subcontractor, the offer may be rejected. As a part of the pre-award survey, the offeror may be required to obtain from its intended sources of supply, letters confirming availability of components, materials, machinery and tooling.

[x] 52.209-9P08 PRE-AWARD SAMPLE(S) (MAY 2004) DPSC

(a) The submission of samples of supplies proposed to be furnished by the successful offeror may be required prior to making any award under this solicitation. The following item(s), in the quantity(ies) specified, is (are) subject to this pre-award sample provision:

ITEM NUMBER

NUMBER OF UNITS REQUIRED

10 Pairs

(b) Any offeror who has not previously furnished to the Government the items called for under this solicitation, or substantially similar items, will be requested to submit samples to the Government prior to award. Samples must be submitted within the time specified by the Government and must be produced by the offeror or its designated subcontractor at the place of performance identified by the offeror in this solicitation. Together with the pre-award samples, the offeror shall submit its protocol consisting of an analysis of materials and test data which establishes that the offered item conforms to all design and performance characteristics specified in this solicitation. Additional pre-award samples and contractor-supplied protocol will not be accepted or requested if the original samples and protocol are not approved.

(c) Samples will be shipped to Defense Supply Center Philadelphia, Directorate of Medical Materiel Laboratory, ATTN: Code MQA, 700 Robbins Avenue, Philadelphia, Pa. 19111-5092, unless otherwise directed by the contracting officer. In the submission of samples:

(1) Samples and protocol, consisting of test data and analysis of materials, shall be submitted at no cost to the Government within 15 calendar days after receipt by the offeror of the Government's request for such samples. NOTE: Offerors are cautioned that the submission time is vital to the Government in making a timely award. Offerors must be prepared to submit samples and protocol timely, as late receipt may render the offer ineligible for award.

(2) The contracting officer shall advise the offeror of the results of the evaluation by written notice within 30 calendar days after receipt of the sample.

(d) The samples referred to in the preceding paragraphs are not bid samples; rather, these samples are for the purpose of establishing the offeror's capability, if awarded a contract, to produce items conforming to the specifications. Failure to furnish the requested number of samples within the time specified above, failure to furnish samples conforming to the specifications, or failure to furnish the protocol, consisting of test data and analysis of materials required by the preceding paragraph, may result in rejection of the offer. Offerors are cautioned that upon receipt of any award hereunder, they are obliged to deliver supplies which comply with

ADDENDUM TO 52.212-1 (continued)

52.209-9P08 (continued)

the specifications regardless of whether any sample submitted hereunder deviates in any way from the specification requirements.

[x] 52.217-9P14 EVALUATION OF OPTIONS (JAN 1992) DPSC

(a) If award by line item is permitted by the solicitation, the Government will evaluate offers for award purposes by adding the proposed price per line item for the basic quantity with the proposed price for the corresponding option quantity line item. If a single award for all items is specified in the solicitation, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. If award by lot is specified in the solicitation the Government will evaluate offers for award purposes by adding the total price for each lot with the proposed total price for the corresponding option quantity lot. Evaluation of options will not obligate the Government to exercise the option(s).

(b) Should offerors propose option prices which vary (for example, with quantities actually ordered and the dates when ordered), these offers will be evaluated using the highest option price offered for each item.

(c) The Government reserves the right to make awards for quantities less than those solicited. However, in no event will an award be made for a portion of the basic quantity without a corresponding portion of the option quantity.

**52.212-3 OFFEROR REPRESENTATIONS AND CERTIFICATIONS
COMMERCIAL ITEMS (MAR 2005) ALTERNATE I (APRIL 2002) [DSCP
MODIFIED]**

The offeror shall only complete paragraph (j) of this provision if he has completed the annual representations and certificates electronically at <http://orca.bpn.gov> . If the offeror has not completed the annual representations and certifications electronically at the ORCA website, he shall complete paragraphs (b) through (i) of this provision.

[Please note that the representations and certifications submitted via the On-Line Representations and Certifications Application (ORCA) website only address representations and certifications required by the FAR; however, there may be additional representations and certifications required by the DFARS, DLAD, and local regulations. Therefore, notwithstanding the instruction in the paragraph above to “complete only paragraph (j)” if representations and certifications have been provided electronically via the ORCA website, the certification requirements contained in paragraphs (f) and (g) of this provision may still apply (i.e., completion of the DFARS Buy American Act/Balance of Payments Program Certificate, the DFARS Trade Agreements Certificate, or the DFARS Buy American Act/Free Trade Agreements/Balance of Payments Program Certificate). If applicable, these certificates will be included in the solicitation and must be completed by the offeror even if the offeror has completed the representations and certifications at the ORCA website.]

(a) **Definitions.** As used in this provision:

“Emerging small business” means a small business concern whose size is no greater than 50 percent of the numerical size standard for the NAICS code designated.

“Forced or indentured child labor” means all work or service –

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

“Service-disabled veteran-owned small business concern”-

(1) Means a small business concern-

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

52.212-3 (continued)

"Small business concern" means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and size standards in this solicitation.

"Veteran-owned small business concern" means a small business concern-

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

"Women-owned business concern" means a concern which is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

"Women-owned small business concern" means a small business concern --

(1) That is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

(b) Taxpayer identification number (TIN) (26 U.S.C. 6109, 31 U.S.C. 7701). (Not applicable if the offeror is required to provide this information to a central contractor registration database to be eligible for award.)

(1) All offerors must submit the information required in paragraphs (b)(3) through (b)(5) of this provision to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the Internal Revenue Service (IRS).

(2) The TIN may be used by the government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

(3) *Taxpayer Identification Number (TIN).*

TIN: _____.

TIN has been applied for.

TIN is not required because:

Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in

52.212-3 (continued)

the United States and does not have an office or place of business or a fiscal paying agent in the United States;

- Offeror is an agency or instrumentality of a foreign government;
 Offeror is an agency or instrumentality of the Federal Government;

(4) *Type of organization.*

- Sole proprietorship;
 Partnership;
 Corporate entity (not tax-exempt);
 Corporate entity (tax-exempt);
 Government entity (Federal, State, or local);
 Foreign government;
 International organization per 26 CFR 1.6049-4;
 Other _____.

(5) *Common parent.*

- Offeror is not owned or controlled by a common parent:
 Name and TIN of common parent:
Name _____
TIN _____

(c) Offerors must complete the following representations when the resulting contract will be performed in the United States or its outlying areas. Check all that apply.

(1) *Small business concern.* The offeror represents as part of its offer that it is, is not a small business concern.

(2) *Veteran-owned small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents as part of its offer that it is, is not a veteran-owned small business concern.

(3) *Service-disabled veteran-owned small business concern. [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(2) of this provision.]* The offeror represents as part of its offer that it is, is not a service-disabled veteran-owned small business concern.

(4) *Small disadvantaged business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents, for general statistical purposes, that it is, is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(5) *Women-owned small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents that it is, is not a women-owned small business concern.

NOTE: Complete paragraphs (c)(6) and (c)(7) only if this solicitation is expected to exceed the simplified acquisition threshold.

52.212-3 (continued)

(6) *Women-owned business concern (other than small business concern).*
[Complete only if the offeror is a women-owned business concern and did not represent itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it [] is, a women-owned business concern.

(7) *Tie bid priority for labor surplus area concerns.* If this is an invitation for bid, small business offerors may identify the labor surplus areas in which costs to be incurred on account of manufacturing or production (by offeror or first-tier subcontractors) amount to more than 50 percent of the contract price:

(8) *Small Business Size for the Small Business Competitiveness Demonstration Program and for the Targeted Industry Categories under the Small Business Competitiveness Demonstration Program.* **[Complete only if the offeror has represented itself to be a small business concern under the size standards for this solicitation.]**

(i) *(Complete only for solicitations indicated in an addendum as being set-aside for emerging small businesses in one of the designated industry groups (DIGs).)*
 The offeror represents as part of its offer that it [] is, [] is not an emerging small business.

(ii) *(Complete only for solicitations indicated in an addendum as being for one of the targeted industry categories (TICs) or designated industry groups (DIGs).)*
 Offeror represents as follows:

(A) Offeror's number of employees for the past 12 months (check the Employees column if size standard stated in the solicitation is expressed in terms of number of employees); or

(B) Offeror's average annual gross revenue for the last 3 fiscal years (check the Average Annual Gross Number of Revenues column if size standard stated in the solicitation is expressed in terms of annual receipts).

(Check one of the following):

Number of Employees	Average Annual Gross Revenues
50 or fewer	\$1 million or less
51-100	\$1,000,001-\$2 million
101-250	\$2,000,001-\$3.5 million
251-500	\$3,500,001-\$5 million
501-750	\$5,000,001-\$10 million
751-1,000	\$10,000,001-\$17 million
Over 1,000	Over \$17 million

(9) **(Complete only if the solicitation contains the clause at FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, or**

52.212-3 (continued)

FAR 52.219-25, *Small Disadvantaged Business Participation Program-Disadvantaged Status and Reporting*, and the offeror desires a benefit based on its disadvantaged status.)

(i) General. The offeror represents that either-

(A) It is, is not certified by the Small Business Administration as a small disadvantaged business concern and is identified on the date of this representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration PRO-Net, and that no material change in disadvantaged ownership and control has occurred since its certification, and, where the concern is owned by one or more individuals claiming disadvantaged status, the net worth of each individual upon whom the certification is based does not exceed \$750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); or

(B) It has, has not submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantaged business concern in accordance with 13 CFR 124, Subpart B, and a decision on that application is pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

(ii) Joint Ventures under the Price Evaluation Adjustment for Small Disadvantaged Business Concerns. The offeror represents, as part of its offer, that it is a joint venture that complies with the requirements in 13 CFR 124.1002(f) and that the representation in paragraph (c)(9)(i) of this provision is accurate for the small disadvantaged business concern that is participating in the joint venture. ***[The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint venture: _____.]***

(10) ***HUBZone small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]*** The offeror represents as part of its offer that -

(i) It is, is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns Maintained by the Small Business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR part 126; and

(ii) It is, is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (c)(10)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. ***[The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture: _____.]*** Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

(11) ***(Complete if the offeror has represented itself as disadvantaged in paragraph (c)(4) or (c)(9) of this provision.) [The offeror shall check the category in which its ownership falls]:***

52.212-3 (continued)

- Black American
 Hispanic American
 Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians)
 Asian-Pacific American (persons with origins from Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Japan, China, Taiwan, Laos, Cambodia (Kampuchea), Vietnam, Korea, the Philippines, U.S. Trust Territory or the Pacific Islands (Republic of Palau), Republic of the Marshall Islands, Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, Guam, Samoa, Macao, Hong Kong, Fiji, Tonga, Kiribati, Tuvalu, or Nauru).
 Subcontinent Asian (Asian-Indian) American (persons with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, the Maldives Islands, or Nepal)
 Individual/concern, other than one of the preceding.

- (d) Representations required to implement provisions of Executive Order 11246 --
- (1) *Previous contracts and compliance.* The offeror represents that --
- (i) It has, has not, participated in a previous contract or subcontract subject either to the *Equal Opportunity* clause of this solicitation; and
- (ii) It has, has not, filed all required compliance reports.
- (2) *Affirmative Action Compliance.* The offeror represents that --
- (i) It has developed and has on file, has not developed and does not have on file, at each establishment, affirmative action programs required by rules and regulations of the Secretary of Labor (41 CFR parts 60-1 and 60-2), or
- (ii) It has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

(e) *Certification Regarding Payments to Influence Federal Transactions (31 U.S.C.1352).* **(Applies only if the contract is expected to exceed \$100,000.)** By submission of its offer, the offeror certifies to the best of its knowledge and belief that no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress or an employee of a Member of Congress on his or her behalf in connection with the award of any resultant contract.

(f) *Buy American Act Certificate.* **[The certificate in DFARS 252.225-7000 or 7020 shall be completed if it is provided in the Addendum to FAR provision 52.212-3.]**

(g) *Buy American Act--Free Trade Agreements--Israeli Trade Act Certificate.* **[The certificate in DFARS 252.225-7035 shall be completed if it is provided in the Addendum to FAR provision 52.212-3.]**

52.212-3 (continued)

(h) *Certification Regarding Debarment, Suspension or Ineligibility for Award (Executive Order 12549). (Applies only if the contract value is expected to exceed the simplified acquisition threshold.)* The offeror certifies, to the best of its knowledge and belief, that the offeror and/or any of its principals--

(1) Are, are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(2) Have, have not, within the three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: Commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a Federal, state, or local government contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(3) Are, are not presently indicted for, or otherwise criminally or civilly charged by a Government entity with, commission of any of these offenses.

(i) *Certification Regarding Knowledge of Child Labor for Listed End Products (Executive Order 13126). [The Contracting Officer must list in paragraph (i)(1) any end products being acquired under this solicitation that are included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, unless excluded at 22.1503(b)]. [List available at www.dol.gov/ilab/]*

(1) Listed end products.

Listed End Product

Listed Countries of Origin

(2) *Certification. [If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.]*

52.212-3 (continued)

(i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.

(ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

(j)(1) *Annual Representations and Certifications.* Any changes provided by the offeror in paragraph (j) of this provision do not automatically change the representations and certifications posted on the Online Representations and Certifications Application (ORCA) website.

(2) The offeror has completed the annual representations and certification electronically via the ORCA website at <http://orca.bpn.gov>. After reviewing the ORCA database information, the offeror verifies by submission of this offer that the representation and certifications currently posted electronically at FAR 52.212-3, *Offeror Representations and Certifications—Commercial Items*, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs _____.

(Offeror to identify the applicable paragraphs at (b) through (i) of this provision that the offeror has completed for the purposes of this solicitation only, if any. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer. Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.)

ADDENDUM TO 52.212-3(f)

252.225-7020 Trade Agreements Certificate (JAN 2005) DFARS

(a) *Definitions* “Designated country end product”, “nondesignated country end product”, “qualifying country end product”, and “U.S.-made end product” have the meanings given in the Trade Agreements clause of this solicitation.

(b) *Evaluation.* The Government--

(1) Will evaluate offers in accordance with the policies and procedures of Part 225 of the Defense Federal Acquisition Regulation Supplement; and

(2) Will consider only offers of end products that are U.S.- made, qualifying country, or designated country end products, unless

(i) There are no offers of such end products;

(ii) The offers of such end products are insufficient to fulfill the Government’s requirements; or

(iii) A national interest waiver has been granted.

(c) *Certification and identification of country of origin.*

(1) For all line items subject to the *Trade Agreements* clause of this solicitation, the offeror certifies that each end product to be delivered under this contract, except those listed in paragraph (c)(2) of this provision, is a U.S.-made, qualifying country, or designated country end product.

(2) The following supplies are other nondesignated country end products:

Line Item Number

Country of Origin

**ADDENDUM TO 52.212-3
252.212-7000 OFFEROR REPRESENTATIONS AND CERTIFICATIONS--
COMMERCIAL ITEMS (JUN 2005) DEARS**

(a) Definitions.

As used in this clause--

(1) Foreign person means any person other than a United States person as defined in Section 16(2) of the Export Administration Act of 1979 (50 U.S.C. App. Sec. 2415).

(2) United States means the 50 States, the District of Columbia, outlying areas, and the outer Continental Shelf as defined in 43 U.S.C. 1331.

(3) United States person is defined in Section 16(2) of the Export Administration Act of 1979 and means any United States resident or national (other than an individual resident outside the United States and employed by other than a United States person), any domestic concern (including any permanent domestic establishment of any foreign concern), and any foreign subsidiary or affiliate (including any permanent foreign establishment) of any domestic concern which is controlled in fact by such domestic concern, as determined under regulations of the President.

(b) Certification.

By submitting this offer, the Offeror, if a foreign person, company or entity certifies that it--

(1) Does not comply with the Secondary Arab Boycott of Israel; and

(2) Is not taking or knowingly agreeing to take any action, with respect to the Secondary Boycott of Israel by Arab countries, which 50 U.S.C. App. Sec. 2407(a) prohibits a United States person from taking.

(c) Representation of Extent of Transportation by Sea. (This representation does not apply to solicitations for the direct purchase of ocean transportation services).

(1) The Offeror shall indicate by checking the appropriate blank in paragraph (c)(2) of this provision whether transportation of supplies by sea is anticipated under the resultant contract. The term "supplies" is defined in the *Transportation of Supplies by Sea* clause of this solicitation.

(2) Representation.

The Offeror represents that it--

___ **Does** anticipate that supplies will be transported by sea in the performance of any contract or subcontract resulting from this solicitation.

___ **Does not** anticipate that supplies will be transported by sea in the performance of any contract or subcontract resulting from this solicitation.

(3) Any contract resulting from this solicitation will include clause 252.247-7023, *Transportation of Supplies by Sea* clause. If the Offeror represents that it will not use ocean transportation, the resulting contract will also include the Defense Federal Acquisition Regulation Supplement clause at 252.247-7024, *Notification of Transportation of Supplies by Sea*.

EXHIBIT 3

HISTORY OF GM GREENVILLE



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History of 3M Greenville

3M Greenville is located at Donaldson Center Industrial Air Park in Greenville, S.C. Formerly known as Donaldson Air Force Base, this area was originally a military air base which has been transformed into what it is today: a large industrial park with over 80 employers and 4,000 employees.

The Greenville Film Plant was acquired from Olin Corporation in 1974. The plant was built by Olin in 1971 and opened in 1972. A major expansion took place in the Film Plant in 1982 and 1983. In 2007, a \$100 Million expansion project began that will result in the construction of a new Film Line building, creating additional manufacturing capability at the Film Plant.

In 1975, construction was started at the Greenville Tape Plant and it started operation in 1976. Additional converting facilities were added to the Tape Plant in 1983 and manufacturing capacity was added in 2003.

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EXHIBIT 4

COMMUNITY INVOLVEMENT



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Community Involvement

We understand the importance of giving back to our community through volunteerism and financial support. 3M Greenville actively supports many community enrichment activities in the Greenville area in the areas of health and human services and education. We have supported a variety of activities and programs, including the following:

- [United Way](#)
- [Junior Achievement](#)
- [3M Community Impact Grants](#)
- [3M Ingenuity Grants](#)
- [Keystone Key Issues Sponsorships](#)
- [Educational Scholarships](#)
- [Various grants to non profit agencies](#)

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EXHIBIT 5
HERITAGE OF ARMY AUDIOLOGY
DECEMBER 2008

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Heritage of Army Audiology and the Road Ahead: The Army Hearing Program

Noise-induced hearing loss has been documented as early as the 16th century, when a French surgeon, Ambroise Paré, wrote of the treatment of injuries sustained by firearms and described acoustic trauma in great detail. Even so, the protection of hearing would not be addressed for three more centuries, when the jet engine was invented and resulted in a long overdue whirlwind of policy development addressing the prevention of hearing loss.

We present a synopsis of hearing loss prevention in the US Army and describe the current Army Hearing Program, which aims to prevent noise-induced hearing loss in soldiers and to ensure their maximum combat effectiveness. (*Am J Public Health*. 2008;98:2167–2172. doi:10.2105/AJPH.2007.128504)

| D. Scott McIlwain, AuD, Kathy Gates, AuD, Donald Ciliax, PhD

MILITARY CONFLICTS HAVE

long been identified as a source of physical disability. Veterans' benefits were first documented in this country in 1636, when money was provided to individuals disabled in the Plymouth colony's defense.¹ Even before World War I, military veterans were receiving compensation for hearing loss. The medical records of Union Army soldiers document that 33% had diagnosed hearing loss.² Soldiers with disabilities from their military service were guaranteed a larger pension as compensation. Even though the method of measuring an individual's hearing acuity in the late 1800s is questionable by today's standards, hearing loss was recognized by the government as a disability. The General Law of 1862 and the Disability Act of 1890 were two major legislative movements that made this possible.³

Figure 1 delineates four distinct periods in the development of

hearing loss prevention. There are specific developmental milestones in each period. These policies were the first of many seminal events that would influence the evolution of a program known as the Army Hearing Program; however, the road ahead would be full of challenges.

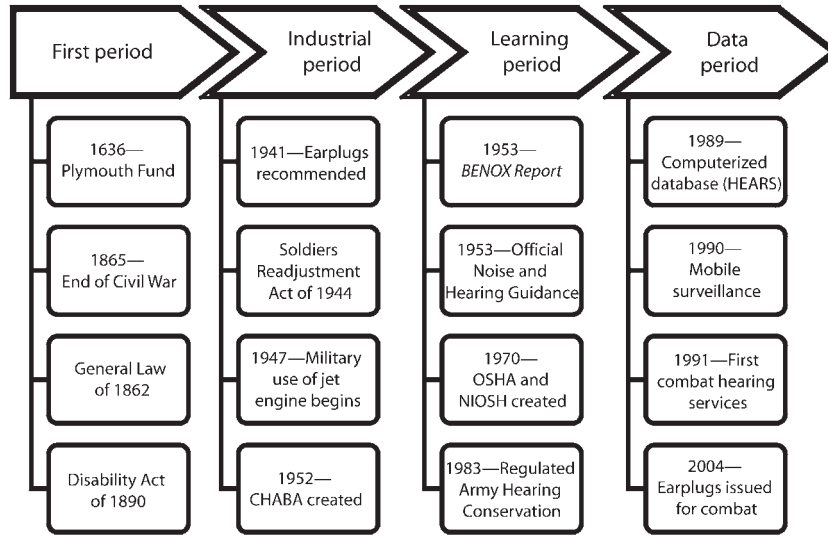
CHANGING ATTITUDES

In the period from the American Civil War to World War I, new occupational hazards evolved. One of the most prevalent of these was hazardous noise. The pervasive attitude of the early 1900s was that hearing loss could be prevented by developing a tolerance to noise. Consequently, any attempts to avoid loud sounds or to protect oneself from them were interpreted as weakness.⁴ This “tolerance” theory was scientifically examined in 1941 when the US Army opened the Armored

Medical Research Laboratory at Fort Knox, Kentucky. This laboratory completed a landmark study in 1944 resulting in the recommendation that gun crews, gunnery instructors, and others regularly exposed to gunfire blasts be provided hearing-protective devices. The hearing protector of choice was the V-51R, single-flange earplug.⁵ Although hearing protection was now being considered, it still was not deemed a requirement.

Even though hearing conservation programs did not exist at the end of World War II, the army and navy surgeons general placed great emphasis on aural rehabilitation for veterans returning to their civilian lives. With the medical and administrative infrastructure not prepared to deal with the large numbers of veterans returning from war, Congress passed the Soldiers Readjustment Act of 1944 that made services more

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Note. OSHA = Occupational Safety and Health Administration; NIOSH = National Institute for Occupational Safety and Health; CHABA = Armed Services Committee on Hearing and Bioacoustics; BENOX = Biological Effects of Noise Exploratory Study; HEARS = Hearing Evaluation and Reporting System.

FIGURE 1—Four distinct periods in the development of the Army Hearing Program.

the sound of enemy weapons as such an important means of identification that they rarely made use of captured equipment because it resulted in their being fired upon by friendly troops.”^{8(p20)}

QUEST FOR ANSWERS

During this same year, the navy requested a special investigation of noise hazards because of how near sailors were to jet engine noise on aircraft carriers. The report concluded that the effects of the loud sounds produced by jet engines were much greater and more serious than commonly assumed. These findings spurred the creation of the Armed Services Committee on Hearing and Bioacoustics (CHABA), which addressed the effects and control of noise, auditory discrimination, speech communications, and fundamental mechanisms of hearing and auditory standards.⁶ This was the first major step to support the policy development for hearing-loss prevention. Immediately, CHABA commissioned a working group to study the effects of high-intensity noise on the human body. In December 1953, the results of this landmark study were released. The study was called the Biological Effects of Noise Exploratory Study but is referred to as the *BENOX Report*.⁷ The report covered aural pain, hearing loss and protection, limiting factors for protecting the ear from noise, communication, orientation in space, and the psychological, neuropsychological, and central nervous system effects of noise.⁷ It recommended, for the first time ever, monitoring for the prevention of noise-induced hearing loss as well as the establishment of a database to track hearing loss. As a result of the *BENOX Report* and the wide dissemination of its results, prevention was

available and efficient. This act reorganized the Veterans Administration (VA), which had been established in 1930 by combining the Veterans Bureau, the Bureau of Pensions, and the National Home for the Disabled Volunteer Soldier.¹ To further meet the great demand for aural rehabilitation services, many universities with audiology clinics also provided government-sponsored aural rehabilitation services for the veterans.

THE JET ENGINE

Even though World War II was a major contributing factor in the evolution of hearing conservation, it was not until after the war that the most significant event occurred. The Army Air Corps became a separate branch of service from the US Army and was renamed the US Air Force. Concurrently, this new branch of service introduced the jet engine

aircraft to the military. No sound of that volume and duration had ever before been experienced. It was immediately noted that exposure to jet engine noise caused permanent hearing loss in a brief time. It also made verbal communication impossible and caused a series of physical manifestations described as “ultrasonic sickness.” Symptoms included earache, headache, excessive fatigue, irritability, and feelings of fear.⁶ Initially, it was believed that these symptoms were caused by inaudible, ultra-high-frequency sounds being generated by the jet engines. These symptoms, widely reported by air force maintenance crews, triggered a medical study that revealed that the illness was real; however, research attributed it to high levels of audible frequencies.⁷

As a result, the US Air Force published the first military regulation on hearing conservation in 1948. AFR 160-3, “Precautionary

Measures Against Noise Hazards,” is significant not only because it was the first enforceable regulation in the history of hearing conservation, but it also placed responsibility for the new program on the medical leadership at air force installations. Some of the preventive measures described in AFR 160-3 include limiting noise exposures in terms of overall sound levels and using cotton wads moistened with paraffin as hearing protection for exposures to hazardous noise.

In 1952, the Office of Naval Research reported the results of extensive interviews with hundreds of returning frontline soldiers who indicated that in combat, “sound was more important than all other means of equipment identification.”^{8(p20)} Combat-relevant sound sources included aircraft, mortar and artillery rounds, rifle and machine gunfire, and various other weapons. According to the report, “The men regarded

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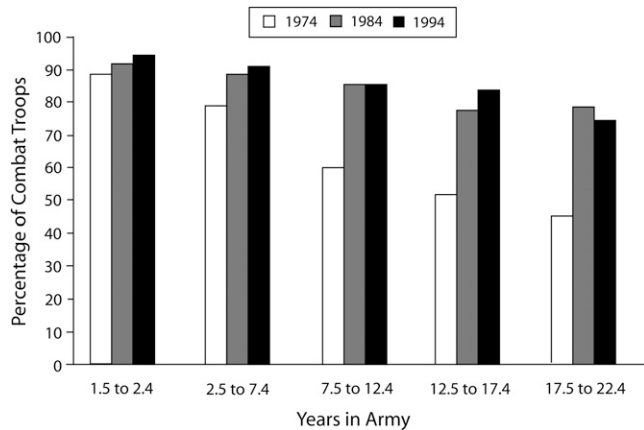


FIGURE 2—Percentage of combat troops with acceptable hearing, by length of time in the army.

considered the best solution to noise-induced hearing loss. The American Academy of Otolaryngology and Otolaryngology published the first written guide on hearing conservation outside of the military in 1953. Three years later, the army published Technical Medical Bulletin 251, “Noise and Conservation of Hearing.” Even though this was the first step taken by the army to initiate a hearing conservation program, technical medical bulletins are not enforceable regulations and only are considered a guide based on standard practices. Later in the year, the air force renamed regulation AFR 160-3 “Hazardous Noise Exposure,” and it became the basis of the first comprehensive hearing conservation program inside or outside the military. All of the essential components of a hearing conservation program by today’s standards were included in this document.

ARMY AUDIOLOGISTS

Between 1965 and 1967, the army acquired its first six military

audiologists. They were not used to implement and enforce hearing conservation standards, however, but instead worked in army medical centers performing clinical duties. It was not until 1970 that 25 additional army audiology positions were added to the inventory. These new audiologists spent only half of their time working in hearing conservation and the other half in the clinical setting; nevertheless, their impact was astounding. Figure 2 shows a significant decrease in hearing loss in the US Army over time that is directly attributable to the hearing conservation efforts of the new audiologists.^{9–11} The data are broken down by length of time in service because of the often gradual nature and delayed onset of noise exposure.

These new army audiologists recognized that they were facing serious obstacles in implementing hearing conservation, including bureaucratic red tape, the lack of formal hearing conservation education in their audiology programs, a slowly changing military culture, and a lack of

standardization of hearing conservation programs at individual installations. In 1968, to facilitate collegiality and professional development among military audiologists, an organization called the Military Audiology and Speech Pathology Society (now known as the Military Audiology Association) was formed. It was instrumental in the future of hearing conservation because it provided a foundation for the standardization of military hearing conservation programs and a way to mentor and educate audiologists with little or no hearing conservation experience.

MAJOR LEGISLATION

In 1970, the Federal Government enacted Public Law 91-596, the Occupational Safety and Health Act, which allowed for the creation of the Occupational Safety and Health Administration as the enforcement agency within the US Department of Labor.¹² The same year, the National Institute for Occupational Safety and Health (NIOSH) was created to develop criteria for safe occupational exposures to workplace hazards. In addition, the VA announced that it had paid over \$52 million that year for hearing loss as a primary disability. That number did not include compensation for hearing loss with a concurrent disability or cost of hearing aids, batteries, or repairs. Further, the VA estimated that 20% of all veterans being discharged from the army were entering claims for hearing loss.⁹

In 1972, NIOSH published *Criteria for a Recommended Standard: Occupational Exposure to Noise*.¹³ To reduce the risk of noise-induced hearing loss, NIOSH suggested a recommended equivalent level of 85 dB as an 8-hour time-weighted average,

with a 5-dB exchange rate as well as methods for determining noise exposure.⁶ The exchange rate is the rate at which sound energy is averaged over time and is often referred to as dose. If the intensity of an exposure increases by 5 dB, then the dose doubles. The dose of noise exposure determines how much time an individual can safely be exposed to hazardous noise. These standards would be an initial benchmark to hazardous exposure levels in the military.

Even with the quantifying of hazardous noise exposure and laws to enforce the standards, there was still no system in place to capture hearing conservation audiometric data and to measure compliance. In 1974, a new system for tracking hearing conservation compliance was being developed, the Hearing Evaluation and Reporting System (HEARS). (The name would later be changed to Hearing Evaluation Automated Registry System.)

A SCATHING INVESTIGATIVE REPORT

In 1976, the General Accounting Office (now the Government Accountability Office) released an investigative report on government working conditions.¹³ It showed that more than half of US government employees—including those of the Department of Defense—were working in environments that did not have adequate procedures for identifying and rectifying occupational health hazards. Further, the report requested that Congress amend the Occupational Safety and Health Act to bring federal agencies under the inspection control of the Department of Labor.¹³ As a result, military audiologists and other government employees achieved standardization in

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TABLE 1—Incidence of Diagnosed Noise-Induced Hearing Loss in the US Army: April 1, 2003, to March 31, 2004

Condition Diagnosed	No. of Postdeployment Troops (n = 806), %	No. of Nondeployed Troops (n = 141 050), %
Acoustic trauma	45 (5.6)	78 (0.1)
Permanent threshold shift	236 (29.3)	639 (0.5)
Tinnitus	248 (30.8)	2101 (1.5)
Eardrum perforation	13 (1.6)	88 (0.1)
Moderately severe hearing loss or worse	127 (15.8)	3140 (2.2)
Any of the above	553 (58.6)	5668 (4.0)

Note. Postdeployment troops are soldiers who had recently returned from active duty in Iraq or Afghanistan; nondeployed troops are soldiers who had not served in combat.

terms of a ceasefire and the allied troops began to be sent home. To facilitate the redeployment of US soldiers back to the United States, 11 army audiologists were sent to Saudi Arabia with 11 MOHVs. During the 2-month redeployment process, 29 192 hearing screenings and 5254 comprehensive audiometric follow-up evaluations were conducted. A manpower resource model estimated that 82 weeks (3280 work hours) of postdeployment audiometric evaluations were saved by providing the service in Kuwait while the soldiers waited to fly home.¹⁶ This program was a success because many of the units deployed were reserve and national guard forces and would not have ready access to audiological services once they returned to civilian life. Unfortunately, funding for the MOHV concept was not sustained after the military drawdown of the early 1990s.

In 1998, HEARS was upgraded to include an online portal for submitting hearing conservation data. The new system, called the Defense Occupational Environmental Health Readiness System for Hearing Conservation (DOEHRS-HC), made accessing data faster and significantly less laborious. In an attempt to increase compliance, Department of the Army Pamphlet 40-501 was updated to state that monitoring of hearing conservation was to be conducted with DOEHRS-HC.

All of the hearing conservation efforts of the past have led to significant improvements in levels of hearing loss in the army and are a direct result of army audiologists' influence on program compliance. Acceptable hearing is defined as when the pure tone average (500 Hz, 1000 Hz, and 2000 Hz) is no worse than 30 dB in each ear, with no individual

military hearing conservation in 1978 with the publication of Department of Defense Instruction (DODI) 6055.12. This document provided guidance and requirements for implementing hearing conservation.¹⁴

To implement DODI 6055.12, the army published TB MED 501, *Hearing Conservation*, in 1980. DODI 6055.12 was updated in 1987 to implement new requirements by the 1983 Federal Noise Amendment.¹⁵ The new policy identified specific roles and responsibilities within a hearing conservation program and thereby paved the way for the first enforceable regulation to be published on the subject in the US Army. This new implementing document was called Department of the Army Pamphlet

40-501, *Hearing Conservation Program*.

AUTOMATION AND MOBILITY

In the same decade that the Internet was introduced to the public, the military's goal of computer-automated data capture became a reality. In 1989, the Occupational Health Management Information System provided funding for the development and distribution of HEARS by the US Army Environmental Hygiene Agency.

In 1990, an effort was made to increase compliance of occupational health screening by combining the services into a mobile vehicle called the military occupational health vehicle (MOHV).

Subsequently, the army purchased 16 of them for use worldwide. This development facilitated the promotion of the newly developed HEARS by taking the monitoring equipment and services to the soldiers, a convenience that commanders favored. Although comprehensive occupational health screenings were the goal, the MOHV was primarily used for hearing monitoring, the other health services preferring that screenings be conducted in a fixed facility.

By January 1991, over half a million allied troops were deployed in Saudi Arabia and throughout the Gulf region to liberate Kuwait from the Iraqi invasion. The allied armies launched the ground war on February 23; by March 31, Iraq accepted the

TABLE 2—Effect of Tank Crewmen's Ability to Understand Spoken Orders on Their Performance in Combat Situations in the US Army

Task	Good Word Intelligibility	Poor Word Intelligibility
Time required to identify target, seconds	40	90
Incorrect command heard, %	1	37
Correct target identification, %	98	68
Correct targets engaged, %	94	41
Incorrect target engaged, %	0	8

Source. References 9 and 21.

Note. "Good word intelligibility" means understanding 50% or more of what was said to them; "poor word intelligibility" means understanding less than 50%.

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threshold greater than 35 dB and thresholds not exceeding 55 dB at 4000 Hz.

ARMED CONFLICT AND HEARING LOSS

Whether in peacetime or wartime, hazardous noise is one of the primary occupational hazards in the army, and the risk of soldiers incurring noise-induced hearing loss is greater than it has been in over 30 years. This is a result of current combat operations, increased numbers of combat soldiers, extended periods of weapons training, and the deployment of new and more powerful noise sources from weapons systems, vehicles, and aircraft. US forces in Iraq and Afghanistan have experienced a substantial number of blast injuries from improvised explosive devices, rocket-propelled grenades, and mortar rounds. These types of explosions remain the single largest cause of injury in the war in Iraq (Operation Iraqi Freedom) and compose 47% of all medical evacuations.¹⁷ As a result, developments in protecting soldiers from these types of hazards are paramount.

The combat arms earplug was introduced into the military at the start of the war in Afghanistan (Operation Enduring Freedom). However, as with most hearing protection, it was shunned for operational use and, at approximately \$6.00 per pair, was considered prohibitively expensive by individual army units. The device allows soft sounds to flow unimpeded through a filter but blocks loud impulse sounds, such as an explosion or a rifle discharging. This allows effective communication, enables situational awareness, and provides protection from hazardous weapons firing and explosions. With units' strength decreasing because of hearing

loss, commanders began to recognize that hearing readiness is an extremely important factor of a unit's performance in combat. All deploying soldiers were therefore issued the earplugs in 2004. In fact, the US Marine Corps was so convinced of the effectiveness of the combat arms earplug that it ordered over 20 000 pairs, thereby temporarily depleting the entire national stock in 2003.¹⁷

AUDIOLOGY IN IRAQ

During the first year of the war in Iraq, an average of one soldier a day was medically evacuated for complaints related to hearing loss. Consequently, recommendations were made in October 2003 for an audiology support program that would use a minimum of 9 hearing conservation technicians assigned to locations of dense troop population. To curb the need for medically redeploying soldiers, it was recommended that one army audiologist serve as a consultant, examine follow-up patients, assign duty limitations, dispense hearing aids, verify threshold shifts, and evaluate any possible pathology identified by the hearing monitoring. Initially, only one audiologist with no support staff was authorized, who used old equipment that had been donated by a clinic in Landstuhl, Germany.¹⁸ By 2006, new audiology equipment had been acquired; by 2007, five outlying screening sites had been established.

Also during the first year of the Iraq war, a study was conducted in army medical facilities comparing hearing loss among soldiers who had been exposed to combat in Afghanistan or Iraq and among those who had not.¹⁹ As shown in Table 1, soldiers who had served in combat had significantly higher

rates of hearing loss than did those who had not served in combat.

THE ARMY HEARING PROGRAM

Providing these reactive audiology services in a combat zone was logical, but the concept was not wholly sound, because it negated the need for maintenance of soldiers' hearing readiness while in a combat environment. The hearing conservation paradigm had shifted, and it now had to consider the soldiers on the battlefield. As a result, a restructuring occurred, and a contemporary model called the Army Hearing Program was born.

The Army Hearing Program is charged with preventing noise-induced hearing loss in soldiers and ensuring their maximum combat effectiveness in training as well as during deployments. To accomplish this mission, four pillars of service were established: operational hearing services, hearing conservation, clinical services, and hearing readiness. The program aims to maintain a high state of readiness and to protect hearing without compromising the effectiveness of the soldier.

HEARING AND PERFORMANCE

A study evaluating the importance of hearing for soldiers in combat was conducted at the US Army Human Engineering Laboratory, which investigated the impact of noise and other variables on the mission effectiveness of tank crews.²⁰ The study found that a crewman's ability to understand verbal orders influenced their response times as well as their performance of specific tasks. As shown in Table 2, poor understanding led to slower response

times, which can mean the difference between life and death on the battlefield. Communication in a tactical environment is of utmost importance.

The problem of protecting hearing while enhancing soldiers' communication ability and situational awareness was solved with a new generation of hearing protection. This new category of equipment was called tactical communications and protective systems (TCAPS). In 2007, TCAPS were introduced into the army as a possible solution to an age-old problem. TCAPS compose a new category of electronic hearing protection that uses active noise reduction to soften noise and enhance speech discrimination while at the same time reducing noise by up to 40 dB. In addition to being light and rugged, TCAPS provide protection and let soldiers monitor environmental sounds, communicate, accurately gauge auditory distance, and localize sound sources without hindrance. Further, the devices allow radio connections specifically used by the military to be processed without interrupting the signal when the TCAPS are actively blocking environmental sounds. Although this category of device is still being studied and protocols for use are being created, it represents a new era in the history of hearing protection.

STRONG ARGUMENTS

With hearing conservation programs documenting marked initial improvements, the anticipated cost of veterans' disability claims and payments were expected to decrease over time.^{10,11} However, with the start of the war in Afghanistan in 2001 and the war in Iraq in 2003, this proved not to be the case. Current data show

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that 51.8% of combat soldiers have moderately severe hearing loss or worse,²¹ mainly because of the loud sounds associated with combat. The implications for the army are great. When soldiers reach these levels of hearing loss, they must be evaluated for the ability to perform their duties safely and effectively. Depending on the findings, they may be given the option of changing to a job that does not put their hearing at further risk or leaving the service with a medical discharge. In light of this, 10 much-needed army audiology positions were added in 2007. These positions will have a positive impact on the Army Hearing Program, but there will still be only two thirds as many army audiologists as there were before the military drawdown of the early 1990s. Still, with war, there are some injuries related to noise-induced hearing loss that cannot easily be prevented, such as traumatic brain injury, dizziness, auditory neuropathy, and central auditory processing disorders. Evaluation and management of these injuries are also within the scope of the practice of audiologists and further strengthen the need for adding more military audiology accessions to support the war effort.

In 2006, the number of new applicants granted primary disabilities for hearing loss and tinnitus was 49 606 and 61 269, respectively. Combined, the total disability payments for hearing loss and tinnitus were over \$1 billion, marking a 319% increase since the beginning of the war in Afghanistan in 2001. Tinnitus was responsible for the largest number of primary disabilities in 2007, followed closely by hearing loss.²² To complicate matters, the average process time for applying for hearing-loss disability by veterans

in 2007 was 789 days,²³ showing the need to improve the entitlement process. Prevention, however, is still the best answer not only from a cost-benefit standpoint but for the quality of the lives of veterans and their families. The Army Hearing Program represents a means to eliminate hearing loss as a result of battlefield conditions in the 21st century. ■

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Contributors

D.S. McIlwain originated the topic, wrote most of the essay, and led and supervised the literature review and analyses of information in this essay. K. Gates and D. Ciliax wrote significant portions of the essay, assisted in analyses, and provided editorial support.

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EXHIBIT 6
HEARING LOSS WIDESPREAD
AMONG POST 9-11 VETERANS
MAY 4, 2016

National Security

Hearing loss widespread among post-9/11 veterans

Veterans Affairs Dept. buys one out of every five hearing aids sold annually in the U.S.

By Kay Miller  6:00 am, August 29, 2013 Updated: 12:19 pm, May 19, 2014

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Marine Corps reservist Mauricio Mota served in five combat zones between 1987 and 2008, the last one in Iraq, where he slept next to what he described as “deafening” field generators and rode in loud helicopters. In training he fired an even louder weapon, a “bunker buster.”

Toward the end of his Iraq tour, the now-retired staff sergeant said he realized his hearing had gone bad. “I found myself telling others, ‘Wear some ear protection so you don’t go deaf like me,’” he said.

Among post-9/11 veterans, 414,000 have come home with hearing loss and tinnitus, or ringing in the ears. The most-widespread injury for veterans has been hearing loss and other auditory complications, according to interviews and benefits data. Hearing maladies cost more than \$1.4 billion in veterans disability payments annually, according to fiscal year 2010 data from the Hearing Center of Excellence, a part of the Department of Defense. At least \$216 million was spent that same year for hearing aids and related devices, according to an advisory committee report to the VA.

Paying an average of \$348.15 each, the VA buys one in five hearing aids sold annually in the U.S., according to that 2010 spending report, the last year that data was available.

While much of the public concern about injuries suffered by post-9/11 troops has focused on missing limbs, traumatic brain injuries and post-traumatic stress disorder, Scott C. Forbes, immediate past-president of the Association of Veterans Administration Audiologists, said “Actually, I think the signature injury is an auditory injury.”

Hearing injuries are the most commonly documented trauma, said Forbes, a Marine veteran who has a doctorate in audiology and served during the Gulf War/Somalia conflicts. He has been a VA audiologist for 13 years. The most common disability among all veterans is hearing related, according to a



Veteran Mauricio Mota now uses a hearing aid for his left ear after returning from war. Kay Miller/News21

January 2011
Government
Accountability
Office report.

Despite being such a prevalent condition, hearing problems don't get much attention, because "in general, very few people die because of hearing loss," said Theresa Schulz, a retired Air Force audiologist who now works in a similar capacity for Honeywell Safety Products.

Rep. Dan Benishek, R-Mich., chairman of the Subcommittee on Health of the House Veterans Affairs Committee, said in a telephone interview that 25 to 30 percent of VA disability claims involved hearing. Among them, "almost 99 percent" eventually are approved, he said. Benishek, who is a physician, has proposed that every service member gets a full audiology examination at discharge. His bills have been sent to the Congressional Budget Office to determine their impact on federal spending.

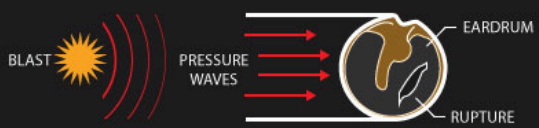
Mota took occasional hearing tests, but always managed to pass, he said. He didn't recall hearing protection being issued, but said, "I think it was always around somewhere."

Shortly after his discharge, Mota was with his family at a mall when he stopped at a hearing professional's office to get tested.

Post 9/11 Veterans prone to ear injuries

Blast injuries from improvised explosive devices have been a major cause of trauma in the Post 9/11 wars. The ear is especially prone to flying debris and blast pressures.

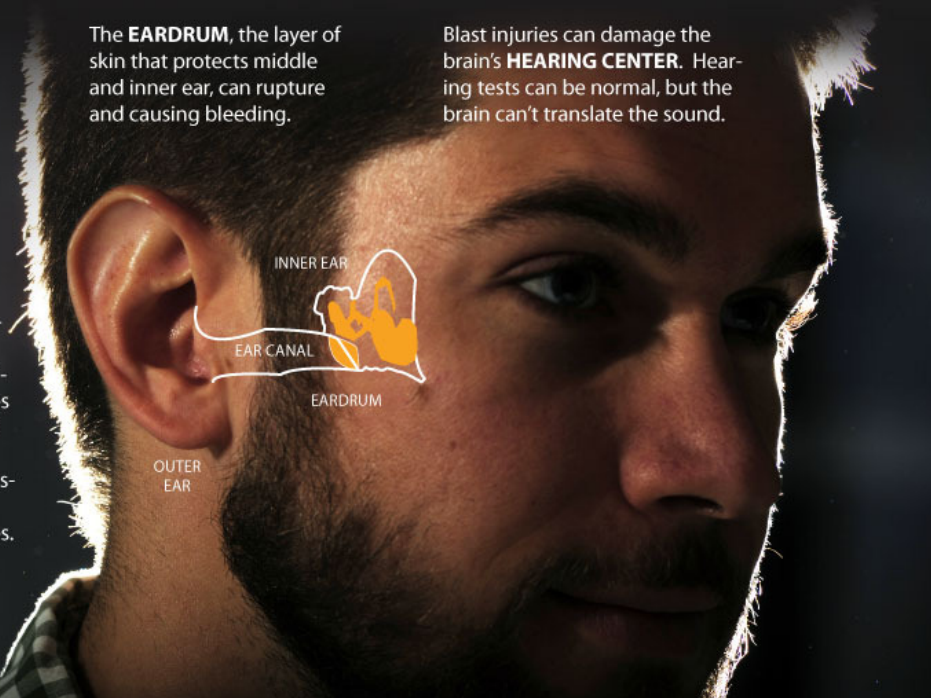
BLAST OVERPRESSURE: An explosion can cause a blast wave, described as a sensation of being shoved by something massive, and then being sucked back. It can rupture the eardrum.



The **OUTER EAR** can be damaged by flying debris, leading to severe, deforming cuts and tears.

The **EARDRUM**, the layer of skin that protects middle and inner ear, can rupture and causing bleeding.

Blast injuries can damage the brain's **HEARING CENTER**. Hearing tests can be normal, but the brain can't translate the sound.



Hearing and balance problems occur when the delicate structures of the **INNER EAR** are disrupted by pressure and vacuum waves.

CREDIT: Kay Miller

SOURCES: American Speech-Language-Hearing Association, Department of Veterans Affairs, original reporting

Back Home

NEWS 21 The challenges facing post-9/11 veterans returning from the wars in Iraq and Afghanistan

Stories in this series

Immediately, he was fitted with his first two hearing aids.

“I walked out of that office and the world just opened up,” he said, “and the first sound I remember hearing was actually the ‘click click’ of a woman’s high heels.”

Last year at a Marine Corps ball, he noticed that many of his buddies seemed to have trouble hearing, too.

“I would say provocative things to someone to see how they’d respond,” said Mota, who works now as a charge nurse in a Gallup, N.M., hospital operating room, “and I could tell by the answer if they’d actually heard what I said.”



Post 9/11 veterans come home to a nation that cannot address their

needs

By News21 Staff August 25, 2013



Some charities claiming to support veterans spend heavily on overhead instead

By Chad Garland and Andrew Knochel
September 6, 2013



One fifth of female

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Master Sgt. Charles Peworski's last hearing test was in 2004 despite the fact that he knows his hearing is a problem. When he and his fellow reservists gather to celebrate the Marine Corps anniversary, they joke about their hearing, or rather, the lack of it.

“We laugh about it. Out of the 10 guys in my unit, when we get together we say, ‘You know I can’t hear ... talk to my good ear,’” he said.

If there is a good ear.

One of his Marine buddies wears hearing aids in both ears; necessary, he said, because of noise exposure over his career.

Peworski was exposed to several factors that cause hearing impairment for military personnel: loud noises from trucks and helicopters, as well as machine-gun bursts and artillery fire.

In October 2008, Congress mandated a Pentagon-based office that would



Charles Peworski has received more than 20 military and civilian awards, including the Marine Corps "Combat V" award for heroism and bravery. He served with the U.S. Marine Corps, suffering injuries while deployed and now deals with hearing loss. Kay Miller/News21

determine ways to prevent, diagnose, mitigate, treat, rehabilitate and research hearing loss and auditory issues for active-duty service members and veterans.

Experts say too few returning veterans, like most people, don't seek medical attention for their hearing loss when they first notice it. They just live with it.

"We know that it is usually seven years between the time someone notes a problem with their hearing and the time they actually seek medical attention for it," said Nancy Macklin, director of events and marketing for the Hearing Loss Association of America.

Prolonged excessive noise damages hearing, according to the National Institute of Deafness and Other Communication Disorders (NIDCD), a division of the National Institutes of Health. Loud noises destroy the ear's special cells, called "hair cells." The ear cannot grow new hair cells.

Hair cells are one aspect of how hearing works; they help translate sound into a signal the brain interprets, or "hears."

Loud noises also damage the auditory nerve, another hearing component that helps translate sound waves into signals the brain understands.

Hearing also can be damaged significantly by a single impulse sound — gunfire, for example.

Normal conversation is considered to be "safe" at a sound level of 60 decibels, according to the NIDCD.

On flight decks, noise levels are around 130 decibels and helicopter noise is around 100 decibels, according to military noise assessment. A soldier near an M60 machine gun is exposed to 150 decibels and within 50 feet of an exploding grenade, 160 decibels.

Blast pressure also damages hearing. Eardrums can rupture at pressure as low as 5 pounds per square inch, a fraction of what it takes to damage internal organs. Explosives used in Iraq and Afghanistan create pressure that exceeds 60 psi, according to VA audiology research. The pressure that damages lungs and intestines is 56-76 psi.

Another feature of blast injury/hearing impairment is that it likely will show up later, often as part of blast-induced traumatic brain injury.

Brett Buchanan, an Army veteran, is a claims agent for Allsup, a Belleville, Ill.-based national disability representation company that helps veterans through

their medical appeals.

“Hearing loss and tinnitus are classic examples of medical issues that veterans may or may not be aware they have,” he said. “Earlier is better, and that applies to medical treatment and filing the claim for compensation.”

If veterans wait seven years, Buchanan said, their time discharged might be longer than the time they served on active duty. Upon discharge, veterans should get a baseline audiology examination, he said.

“Ultimately when the VA adjudicator looks at your claim and sees that you entered at this hearing threshold and left at this hearing threshold, and that every year after discharge your hearing has gotten progressively worse even though you were working in an office environment, it just lends credibility to your case that the hearing loss you experience today is due to that noise exposure in service,” Buchanan said.

Retired Army Capt. Mark A. Brogan was severely wounded in Iraq when a suicide bomb attack blew away part of his skull. Beyond his surviving that 2006 blast, Brogan said he is amazed by how much his hearing-assistive devices improved his life.

Brogan uses a device called CapTel lets him hear and read a transcription of telephone conversations as he listens to them.

“I had to find ways to re-engage and I just happened to discover a local HLAA (Hearing Loss Association of America) chapter,” Brogan said by phone from his Knoxville, Tenn., home. After speaking at an association convention, he now is invited to speak on many speaking panels, for organizations such as the HLAA and the Veterans of Foreign Wars.

Army Col. Vickie Tuten, associate director for the Hearing Center of Excellence, and Kyle Dennis, the VA representative to the center, work together to assure veterans’ well-being.

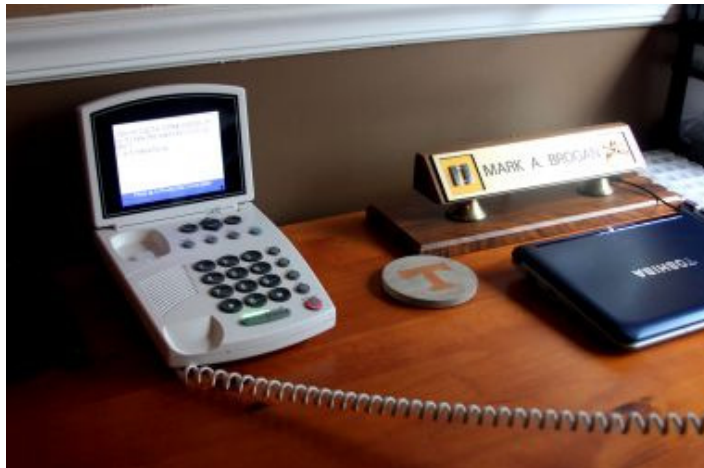
The VA and the Defense Department had worked together for about a decade, but the formal establishment of the HCE and its “one voice,” Dennis said, “is a welcome development.” That focused effort also could lead to much-needed advances in technology. For example, service members in 2011 told the GAO



Post-9/11 veteran Mark Brogan uses a CapTel phone, which allows him to read a transcription of a conversation while someone is talking to him, because of his hearing loss. Brogan lost most of his hearing when a suicide bomber detonated behind him during a mission in Iraq in 2006. Anthony Cave/News21

that they do not always wear hearing protection because of concerns with “comfort and communication.”

“There is emerging technology for the future to protect the hearing of our service members,” Tuten said. “We will see a time in the future that we won’t have to accept hearing loss as part of military service.”



The CapTel phone transcribes what the person on the phone is saying, allowing a hearing-impaired user to see and read the phone conversation. Mark Brogan had his right temporal lobe removed because of the damage he suffered as a result of the suicide bomb. Anthony Cave/News21

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EXHIBIT 7
DISCONTINUATION OF EARPLUGS
LETTER
NOVEMBER 17, 2015



November 17, 2015

**Discontinuation:
3M™ Combat Arms Earplugs Version 2
3M™ E-A-R™ ARC Plug™ Earplugs**

Dear Distributor:

3M has made the decision to discontinue 3M™ Combat Arms™ Earplugs – Version 2 and 3M™ E-A-R™ ARC Plug™, effective immediately.

3M recommends that purchasers interested in Combat Arms™ Earplugs – Version 2 consider 3M™ Combat Arms™ Earplugs – Generation 4 as an alternative. There is no alternative currently available for the ARC Plug.

3M strives to provide the highest quality of hearing protection products in the marketplace, and we regret any inconvenience this product discontinuation notice may cause. Please let us know if you have any questions surrounding this change.

Please feel free to reach out to me with any questions.

Jason R. Jones

Jason Jones / US Marketing Manager – Hearing Solutions
3M Personal Safety Division
651-737-1955
jjones4@mmm.com


3M Personal Safety Division

3M Center, Building 235-02-W-70 St. Paul, MN 55144-1000

www.3M.com/Hearing

800 328 1667 Sales Assistance

800 243 4630 Technical Assistance

DISCONTINUATION NOTICE

3M™ Combat Arms Earplugs Version 2
3M™ E-A-R™ ARC Plug™ Earplugs

November 17, 2015

Dear 3M Customer,

3M has decided to discontinue the 3M™ Combat Arms™ Earplugs – Version 2 (370-1000, 370-1011) and 3M™ E-A-R™ ARC Plug™ (370-2000), effective immediately.

Below are the impacted SKUs and replacement options.

The SKUs below are discontinued as of November 17, 2015. Please inform channel partners and customers that this product is discontinued.

The Combat Arms and ARC SKUs below are discontinued immediately:

Product Number (US)	SKUs	Description
370-1000	70071613031, 70071521218, JH200153569	3M™ Combat Arms™ Gen 2 Dual-Ended
370-1011	70071521226, XH000712139	3M™ Combat Arms™ Gen 2 Dual-Ended Blister Pack
370-2000	70071521275, 7000052749	E-A-R™ ARC Plug™ Uncorded, Carrying Case

The SKUs below are Combat Arms replacement alternatives to consider:

Product Number (US)	SKUs	Description
370-1030	70071613049, 70071561511, 70071613072	3M™ Combat Arms™ Gen 4 Single-Ended Small
370-1031	70071561529, 70071613056, 70071613080	3M™ Combat Arms™ Gen 4 Single-Ended Medium
370-1032	70071561537, 70071613064	3M™ Combat Arms™ Gen 4 Single-Ended Large

*Note that the 370-2000 is a medium sized earplug.

The Combat Arms Single-Ended earplugs will provide the Impulse Noise protection that the 370-2000 provides, but the Combat arms are not arc flash fire rated, as the 370-2000.

Thank you,

Marisa Kowalsky | Global Marketing Supervisor- Hearing Protection

3M Personal Safety Division

3M Center, Building 235-02-D-90 | St. Paul, MN 55144-1000

Office: +1-651-736-4299 | Mobile: +1-651-592-5646

3M00169174

EXHIBIT 8
ASA STD-1-1975
(ANSI S3.19-1974)

ASA STD 1-1975

ACOUSTICAL SOCIETY OF AMERICA STANDARD
Method for the Measurement of Real-Ear Protection of
Hearing Protectors and Physical Attenuation of Earmuffs

Standards Secretariat
Acoustical Society of America
335 East 45th Street
New York, New York 10017

Published by the American Institute of Physics for the Acoustical Society of America

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Acoustical Society of America Standard Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs

1 GENERAL

1.1 Scope

This standard specifies the psychophysical procedures, physical requirements, and means of reporting results for measuring the protective and attenuation characteristics of wearable devices that are used to protect the auditory system against excessive sound.¹

1.2 Real-Ear Protection Method

Procedures described in the real-ear (primary) method are performed by psychoacoustic test on human subjects and are designed to measure real-ear protection at hearing threshold for completely developed hearing protectors. This primary method is described in Section 3.

1.3 Physical Attenuation Method

Procedures described in the physical attenuation (supplemental) method are performed by physical test on a dummy head and are designed to measure sound attenuation at relatively high sound pressure levels.² The physical attenuation test is intended to supplement the real-ear protection test and it is described in Section 4.

1.4 Applications

The primary method of this standard applies to communication units, special helmets including safety helmets, pressure suits and other systems with sound-protective features, and to hearing-protective devices used in combination with one another, that is, earplugs plus earmuffs. The supplemental method applies to earmuff-type devices and provides data for use in earmuff design and production quality control, as well as

for various other attenuation performance specification purposes. Earplugs may not be evaluated by this method. Neither the primary nor supplemental method is applicable for testing the nonlinear devices, amplitude-sensitive devices, and other hearing-protective devices with features designed to operate exclusively against impulsive noises. These devices are included only insofar as their performance complies with the requirements of the standard. Standard methods for the real-ear evaluation of these devices are not established; consequently, the effectiveness of their special features cannot be adequately described in a uniform manner.

2 DEFINITIONS

2.1 Hearing Protector

A device that is worn to prevent the harmful effects of sound on the auditory system.

2.1.1 Earplug. A hearing protector worn within the external ear canal (aural) or in the concha against the entrance to the external ear canal (semi-aural).

2.1.2 Earmuff. A hearing protector usually comprised of headband and earcups with a soft outer ring intended to fit snugly against the pinna (supra-aural) or the sides of the head around the pinna (circumaural).

2.1.3 Communication Headset. A device (earplug or earmuff) designed primarily for communication which may also provide or be used for hearing protection.

2.1.4 Helmet. A device, sometimes functioning as a hearing protector, that usually covers a substantial part of the head.

2.2 Open Threshold of Audibility

The minimum effective sound pressure level for a specified signal that is capable of evoking an auditory sensation when a hearing protector is not worn.

2.3 Occluded Threshold of Audibility

The minimum effective sound pressure level, for a specified signal, that is capable of evoking an auditory sensation when the hearing protector under test is worn.

¹The psychophysical procedures and physical requirements specified in this standard are documented in the following technical report: P.L. Michael and D.F. Bolka, "An Objective Method for Evaluating Ear Protectors," Technical Report, Public Health Service, U.S. Department of Health, Education, and Welfare (15 June 1972).

²A real-head physical attenuation method (that is, microphone under an earcup worn by subject), as has sometimes been applied in research and development work, is not standardized in this document. Data and experience with this method have been examined and found to be insufficient for development of a uniform procedure suitable for standardization at this time.

TABLE 1. Maximum permissible ambient noise.*

Frequency in hertz			Center	Octave band level in decibels re 20 $\mu\text{N}/\text{m}^2$ (20 μPa)
Lower	Limits	Upper		
90		180	125	24
180		355	250	18
355		710	500	16
710		1 400	1000	16
1400		2 800	2000	14
2800		5 600	4000	9
5600		11 200	8000	30

*The levels in Table 1 were obtained from the calculations in Appendix A. The octave band levels specified above are based on preferred center frequencies in accordance with American National Standard Preferred Frequencies and Band Numbers for Acoustical Measurements, S1.6-1967(1971), in order to correspond with third-octave-band test signals employed in this standard.

Any audible noise in the room is likely to cause masking over a portion of the range of test signals. This will elevate the open threshold and result in erroneously small values of real-ear protection for the device under test. Many rooms that cannot meet the limiting ambient noise continuously will be suitable if test periods are selected during times of minimum noise. In case extraneous noise becomes audible in such rooms, means should be employed whereby the listener may signal the tester to stop the test.

Physiological noises may occur under earmuff devices at sufficient levels to cause masking over the low-frequency portion of the range of test signals. This will elevate the occluded threshold and result in erroneously high values of real-ear protection for the device under test.

2.4 Real-Ear Protection at Threshold

The mean value (in decibels) of the occluded threshold (hearing protector in place) of audibility minus the open threshold of audibility (ears open and uncovered) for all listeners on all trials under otherwise identical test conditions.

2.5 Dummy Head

A device that approximates certain physical characteristics and dimensions of an average adult male human head and is used for measuring the attenuation of circumaural hearing protectors.

2.6 Earmuff Attenuation

The algebraic difference (in decibels) between the band pressure levels of the test signals measured at the microphone of the dummy head with and without the earmuff in position.

2.7 Random Incidence Field

A sound field in which the angle of arrival of sound at a given point is random in time.

2.8 Reverberation Time

The time that would be required for the mean-square sound pressure level, originally in a steady state, to fall 60 dB after the source is stopped.

3 REAL-EAR METHOD (Primary)

3.1 Physical Requirements

3.1.1 Acoustic Environment of Test Room

3.1.1.1 Ambient Noise. The ambient noise (with instrumentation on and no test signal present) at the position of the listener in the test room shall not exceed the values given in Table 1, measured with the listener absent from the room.

3.1.1.2 Test Sounds. Third-octave bands of noise shall be used as test sounds for measuring real-ear protection at threshold for at least the bands with the following center frequencies: 125, 250, 500, 1000, 2000, 3150, 4000, 6300, and 8000 Hz. Test signals interrupted or pulsed a maximum of one time per second with a 50% duty cycle and without audible transients are required for the psychophysical procedures. When hearing protectors provide small or negative protection at some test bands, measurements should also be taken at the third-octave bands immediately adjacent to these bands and results reported in the data.

3.1.1.3 Sound Field Characteristics. An acceptable sound field as approximated by the following conditions is desired.

(1) The sound shall be generated in a room whose reverberation time in the test space (without subject) shall be between 0.5 and 1.6 seconds for each of the test bands.

(2) The sound pressure level measured at six positions relative to the center of the subject's head (without subjects), ± 10 cm (± 3.9 in.) in front-back dimension and ± 15 cm (± 5.9 in.) in the up-down and right-left dimensions, shall remain within a range of 6 dB for all test bands (see 3.1.1.2). The difference in sound pressure level between the right-left positions shall not exceed 2 dB.

3.1.1.4 Sound Field Measurement. A directional (cosine or cardioid) microphone that exhibits in its free-field polar response at least 10-dB front-to-side and front-to-back rejection for each test band shall be used to measure the sound field at the test space. The sound field shall be considered to approximate a random incidence field if, when the microphone is rotated about the center of the test space through 360° in each of the three perpendicular planes of the room, the observed sound pressure level in each test band remains within the variation allowed in Table 2.

3.1.2 Test Apparatus. Test equipment shall include the following: white noise generator, third-octave band filter set, control circuits (on-off switch and calibrated attenuators), loudspeakers with power amplifier, and a head-positioning device.

3.1.2.1 White Noise Generator. The signal source shall generate a signal voltage whose spectrum level measured in a band 1 Hz wide is uniform within ± 2 dB over the frequency range of 50 to 10 000 Hz.

3.1.2.2 Third-Octave Filter Set. A third-octave filter set whose particular bandwidths, band-edge frequencies, and other characteristics conform to those specified as Class III filters in American National Standard Specifications for Octave, Half-Octave, and Third-Octave Band Filter Sets, S1.11-1966 (R1971), shall be used. The mode of operation of the filters in changing from one contiguous band to another shall be a discrete step function; a gradual, continuously adjustable mode of change is not acceptable. Only filter sets allowing direct access to band outputs prior to summing shall be used.

3.1.2.3 Control Circuits

(1) Attenuators that provide a test signal range of at least 90 dB in each test frequency band shall be used. Attenuation steps shall be 2.5 dB or smaller. The attenuators shall be calibrated at levels at which the system is used, in the minimum steps, when connected in the system. Corrections for measured departures from linearity shall be applied to the data.

(2) Procedures which employ an attenuation network that is operated manually by the subject shall have some calibrated means to vary the signal presented to the subject attenuator. Performance characteristics of

TABLE 2. Allowable random incidence field response variation for corresponding microphone free-field rejection.*

Microphone free-field rejection (dB)	Allowable random incidence field response variation
> 25	6
20	5
15	4
10	3
< 10, microphone not suitable	

*The variation in microphone response as the microphone is rotated in a random incidence field is related to the directional characteristics of the microphone and the degree of randomness of the field. Allowable sound field response variations must be presented in terms of the free-field directional response characteristic of the microphone. Table 2 presents the free-field rejection values of directional microphones and corresponding allowable sound field variations for purposes of this standard. The microphone free-field rejection may be obtained by measurement or from the microphone manufacturer.

attenuation networks shall be at least equal to the requirements of (1).

(3) The signal on-off switch shall operate in such a manner that no transient or extraneous noises are audible to the normal ear. After operation of the switch, the time required for the sound pressure level of the test signal to rise from -20 to -1 dB, with reference to its final steady value, shall be not less than 0.02 second and not more than 0.10 second, and the time required for the sound pressure of the signal to fall by 20 dB shall be not less than 0.005 second and not more than 0.10 second. This requirement is consistent with American National Standard Specifications for Audiometers, S3.6-1969 (R1973), and shall be met by the electronic system feeding the loudspeakers.

3.1.2.4 Loudspeakers

(1) The loudspeakers used in conjunction with the apparatus described in 3.1.2 shall provide a sound field such that at any test band the sound pressure level at the listener's position can be varied from at least 20 dB above the occluded threshold of hearing to 10 dB below the open threshold of hearing. For most protective devices this is equivalent to a level of 70 dB above to a level of 10 dB below³ the threshold of audibility.

(2) At least one loudspeaker shall be placed on the surface of each of the three major planes (ceiling-floor plane and two opposing wall planes) of the room.⁴ Each loudspeaker shall be housed in a configuration that

³This may be calculated on the basis of electrical calibration.

⁴In order to achieve the desired sound field, it may be necessary to employ as many as nine loudspeakers, three in each room plane. A simple installation is to mount three individual

approaches an "infinite" baffle. No loudspeaker shall have its axis oriented directly toward the subject (minimum orientation of 5° off).

3.1.2.5 Head-Positioning Device. Some means shall be used to provide a reference for maintaining the listener's head in a constant position (not a head rest; a plumb bob to the nose of the listener has proved acceptable). This device shall not transmit to the listener's head any vibrations that might affect the measurements or present a reflective or absorptive surface that might alter the level of the sound at the ears of the subject.

3.1.3 Distortion. The entire system shall produce less than 5% total harmonic distortion, measured at the position of the subject's head, while the stimulus system is operated at maximum sound pressure level, with discrete tone inputs corresponding to the center frequencies of the test bands ranging from 250 to 6300 Hz. When the test room is excited with a test band at maximum sound pressure level, the levels measured in adjacent bands shall be consistent with the filter characteristics specified for the third-octave band filter, Class III, on page 16 of American National Standard S1.11-1966 (R1971).

3.1.4 Earmuff Device Force Measurement. Some means shall be provided for the measurement of force exerted against the sides of the head by earmuff devices mounted on suspension systems. The measurements shall represent the force found in new, unused hearing protectors separated to a distance of 14.35 cm (5.65 in.) between earcups (medium head width) and 13.08 cm (5.15 in.) between the inside of the headband and an imaginary line through the pivot points of the attachments of the headband to the earcups (median head height). These data shall be reported along with the real-ear protection data.

3.2 Listeners

3.2.1 Listeners to be used in the tests described in the following section shall have hearing threshold levels in either ear no higher than 10 dB at the 250-1000-Hz test frequencies and no higher than 20 dB at any other test frequency as measured by a standard audiometer (American National Standard S3.6-1969).

3.2.2 No listener shall be selected as a subject for these tests whose variability for the open threshold of audibility described under 3.3.2 is such that the range on three successive open threshold measurements at any test

loudspeakers on each of three single sheets of plywood (at least 1.9 cm or 0.75 in. thick), one for each of the three room planes (axes). At least one 30.5 cm or 12 in.—or larger—diameter loudspeaker should be employed in each room plane. Base reflex, ducted port, acoustic suspension, etc., loudspeaker systems should not be used.

band between the 250- and 4000-Hz bands is greater than 6 dB.

3.2.3 Listeners who satisfy the other requirements of this standard and who do obtain an adequate fit with the test item (3.3.3.1) may not be dismissed for reporting small amounts of protection. In reporting the results, listeners for whom an adequate fit cannot be obtained should be noted, but should not be included in the evaluation.

3.3 Test Procedures

3.3.1 Instructions to Listeners

3.3.1.1 Listeners shall be completely informed regarding the test situation and procedure.

3.3.1.2 The listener shall be seated in such a way that, using the head-positioning reference device, the listener's head will be placed in the same "fixed" position in the sound field for all repeated measurements.

3.3.2 Open Threshold of Audibility

3.3.2.1 Procedure

(1) In order to allow for accommodation to the test situation, listeners shall be seated in the test room, with no signals present, for a minimum period of 5 minutes prior to the initial trial of a test session, after which time the threshold determinations may begin. The listener should not have been exposed to excessive noise for at least 1 hour prior to the test.

(2) The listener's ears shall be uncovered and unprotected. The control attenuation for each of the test bands listed in 3.1.1.2 shall be varied until a level is reached at which the signal is just audible.⁵ This level shall be the open threshold of audibility. An open threshold for all test bands shall be measured immediately before or after each set of occluded thresholds, the order to be alternated.

(3) Any psychophysical or audiometric technique⁶ suitable for threshold determinations of individual signals within the limits of 3.1.1.2 shall be used, and the same technique shall be used for measuring the open and the occluded thresholds.

(4) Some means shall be provided to vary each presentation so that the level of the test signal presented

⁵ A recommended procedure is to present the signal at an audible level, to decrease the level until the signal is not heard, and then to increase the level until the tone is just heard. Threshold level is considered to be the lowest level of the signal which is heard on at least 50% of the trials during three or four ascents and descents across this lowest-level value.

⁶ I. J. Hirsh, *Measurement of Hearing* (McGraw-Hill, New York, 1952), Chap. 4, pp. 95-101; or D. E. Robinson and C. S. Watson, "Psychophysical methods in modern psychoacoustics," in *Foundation of Modern Auditory Theory*, J. V. Tobias, Ed. (Academic, New York, 1972), Vol. 2, Chap. 3.

to the subject attenuator shall differ from trial to trial. The total value recorded for each trial shall be the variation introduced by the experimenter combined with the subject's response and shall be reflected in the subject's attenuator setting.

3.3.2.2 Recording Data. The final results of the hearing protection test will be expressed in terms of the difference between attenuator settings, that is, the mean-occluded minus the mean-open threshold levels in decibels. Therefore, only attenuator settings (which represent threshold levels) need to be recorded.

3.3.3 Determining Occluded Threshold of Audibility

3.3.3.1 Fitting Hearing Protectors. The fitting of hearing-protective devices is critical to acoustic fit and the amount of hearing protection obtained; therefore, the method of installation for occluded threshold determinations shall be reported as "subject (average) fit" or "experimenter (best) fit." Eyeglasses should not be worn during earmuff evaluations. Special studies of earmuff effectiveness with eyeglasses should be clearly identified.

(1) *Subject Fit.* The experimenter is to give each listener precise instructions on fitting the hearing protectors, in accordance with instructions from the manufacturer, and to select the proper size hearing protector for the listener. Earplugs shall be inserted and earmuffs shall be put on by the listener. Additionally: (a) After the hearing protector has been installed, a white noise shall be introduced whose overall sound pressure level at the listener's position is 60 to 70 dB with reference to $20 \mu\text{N}/\text{m}^2$ ($20 \mu\text{Pa}$). The listener shall be instructed to manipulate the hearing protector until satisfied that the noise is minimal. (b) After the test is begun, further manipulation of the hearing protector in order to gain attenuation improvement at a specific test signal is prohibited.

(2) *Experimenter Fit.* When optimum protector performance is desired, the experimenter shall personally check each hearing protector installation to assure a good fit and acoustic seal after 3.3.3.1(1)(a) is completed. When he deems necessary, the experimenter shall reinsert earplugs and readjust other protectors to a "best" fit prior to testing but not after the test has begun. The results obtained using this fitting procedure shall be reported as "experimenter fit" protection.

3.3.3.2 Occluded Threshold Levels. After the hearing protector has been installed in accordance with 3.3.3.1, a threshold of audibility for the test signals shall be measured in exactly the same way as prescribed for the open thresholds (3.3.2). These levels shall be the occluded thresholds.

3.3.3.3 Number of Hearing Protector Units. A minimum of two individual units of a hearing protector

model that is manufactured in standard sizes shall be used alternately in the execution of this test.

3.4 Processing and Reporting the Data

3.4.1 Minimum Samples. The real-ear protection at threshold for each listener shall be based, for each test signal, on measures of open thresholds made on no less than three separate trials and on measures of occluded thresholds made on no less than three separate trials. Each separate trial shall include a refit of the hearing protector. Frequent rest periods shall be provided the subject during the threshold determinations. Measurements shall be made on not less than ten subjects.

3.4.2 Measurements to Be Reported. The measurements shall be summarized for at least each of the nine specified test signals (one-third octave band) in terms of a grand mean and a standard deviation of the protection values. Standard deviations (σ) shall be computed using the formula

$$\sigma = \sqrt{\frac{\sum d^2}{N-1}}$$

where d is the difference between the grand mean and an individual observation and N is the number of observations (30, ten subjects with three measures each). There will be as many real-ear protections and standard deviations as there are test signals, and the data shall, therefore, be summarized in a table or graph that displays real-ear protection at threshold and standard deviation as a function of the frequency of the one-third-octave test bands of noise.

3.4.2.1 When hearing protection data are presented in graphic form, a paper shall be used whose frequency scale along the abscissa is in equal intervals of one-third-octave-band center frequencies and whose hearing protection scale along the ordinate is linear in decibels. The length for a decade of third octaves shall be equal to the length for 25 dB.

3.4.2.2 The method used to establish that the ambient noise level in the test room did not mask thresholds of audibility (3.1.1.1) shall be described.

3.4.2.3 Listeners shall be described in terms of age, sex, and manner of selection.

3.4.2.4 The psychophysical procedure used for obtaining thresholds (3.3.2 and 3.3.3) shall be described.

3.4.2.5 The manner of hearing protector installation shall be described as subject fit or experimenter fit and also noted on the graphic or tabular displays of the protection data.

3.4.2.6 The earmuff force measurements shall be described and noted on the graphic or tabular displays, or both, of the hearing-protection data.

4 PHYSICAL METHOD (Supplemental)

4.1 Physical Requirements

4.1.1 Test Room

4.1.1.1 *Acoustic Test Field.* A random incidence sound field, as approximated by the following conditions, is desired for each third-octave-band test frequency from 80 to 10 000 Hz.

(1) A broad-band electrical noise source, whose spectrum level in 1-Hz bands is uniform within ± 2 dB over the frequency range of 50 to 12 500 Hz, shall be presented to a third-octave contiguous filter set ranging from 80 to 10 000 Hz center frequency to provide the test signals. Each of the test bands beginning at 125 Hz and extending to 8000 Hz center frequency shall be measured.

(2) The band pressure level at the microphone for each test band frequency shall be not less than 85 dB

with reference to $20 \mu\text{N}/\text{m}^2$ ($20 \mu\text{Pa}$) and shall be at least 60 dB higher than the level of the test room ambient noise in each test frequency band.

(3) The random incidence characteristics of the sound field shall be determined in accordance with 3.1.1.4. The sound field used in the primary method is adequate for the physical measures when the band pressure level requirement of (2) is satisfied.

4.1.2 Apparatus

4.1.2.1 *Dummy Head.* The dummy head shall be constructed in accordance with the critical surface dimensions as shown in Fig. 1. The two nonparallel surfaces, representing the sides of the human head, and the curved surface representing the top of the human head shall be covered with artificial flesh.⁷ There shall also be provided in one or both surfaces, as shown in Fig. 1, a centrally located mounting means that shall accept a laboratory standard type microphone (American National Standard type L or M pressure microphone) or

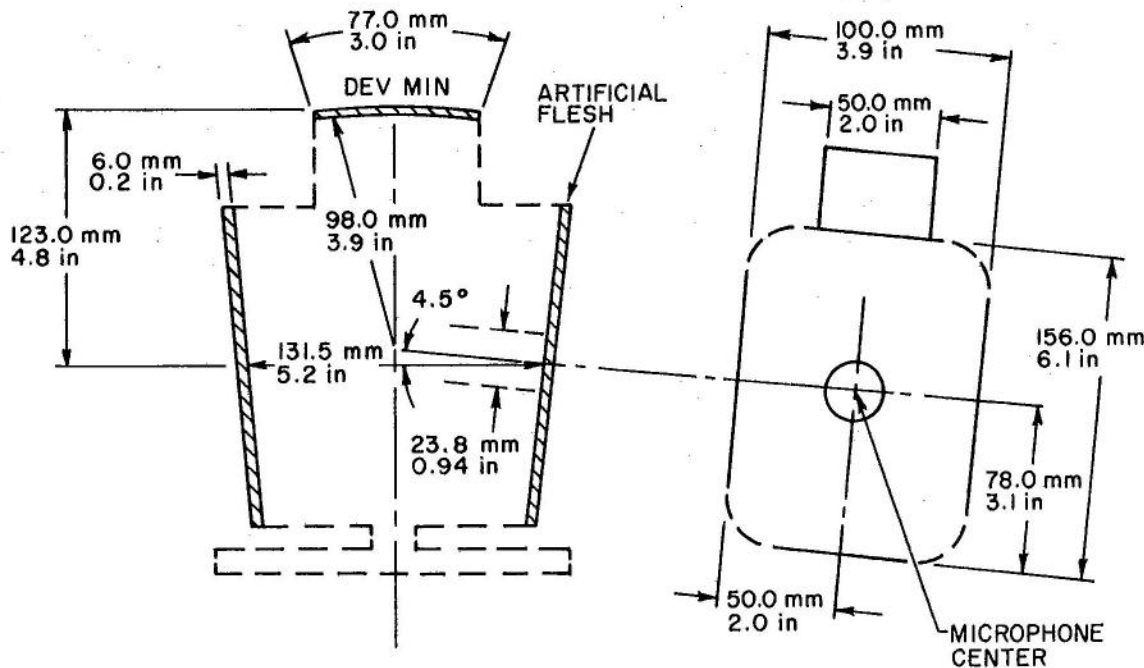
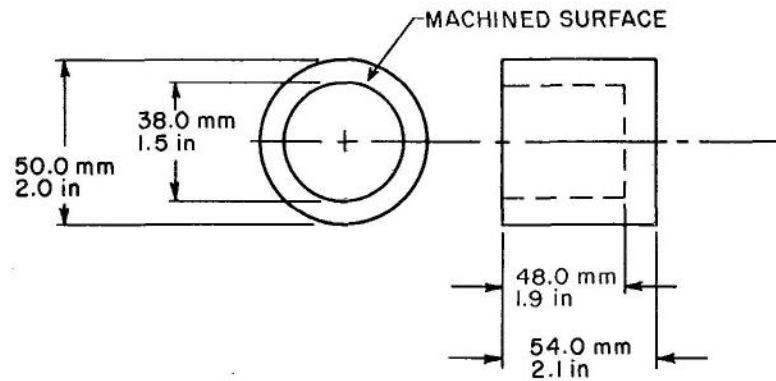


FIG. 1. Dummy head.

NOTES:

- (1) All dimensions are references to the hard surface beneath the artificial flesh.
- (2) Dashed lines indicate unspecified contour or structure.
- (3) Tolerance is ± 2.0 mm unless otherwise noted.
- (4) The configuration of the dummy head was formulated by Subcommittee 30.10 of the Standards Committee of the IEEE Group on Audio and Electroacoustics.

FIG. 2. Acoustic isolation test cup.



NOTES: One metal cup fabricated to the dimensions shown has provided adequate isolation in practice.

a microphone normally used on an American National Standard type II sound level meter. Adapters shall be used with microphones having outside diameters less than 0.936 in. \pm 0.0002 in. The diaphragm of the microphone shall be coplanar with the outer surface of the artificial flesh.

(1) The acoustic isolation of the dummy head shall be no less than 60 dB in any test frequency band in the range of interest. Isolation shall be determined as the difference at each test band between the output of the microphone uncovered and of the microphone covered with a thick-walled metal cup, grease sealed to the hard surface of the dummy head (before artificial flesh is attached). A sample test cup is shown in Fig. 2.

(2) The artificial flesh shall be fabricated to a thickness of 6.0 mm \pm 1.0 mm (0.2 in. \pm 0.04 in.) and applied to the critical surface as shown in Fig. 1. The material as applied shall exhibit a reading of 20 ± 5 , when measured with a Shore "00" durometer, or the equivalent.

4.1.2.2 Observed Sound Pressure Level Apparatus. An automatic graphic level recorder (pen speed of 10 mm/sec and paper speed of 25 mm/sec have proved satisfactory) synchronized with either a stepping-type or a continuously swept third-octave filter set is the recommended instrument for measuring the sound pressure level. A manually scanned filter may be used with a voltmeter readout (slow meter response is mandatory). A simultaneous visual/graphic analyzer or a standard sound pressure level meter with third-octave-band analyzer may also be employed. The measuring system used shall be calibrated to measure band pressure level with reference to $20 \mu\text{N/m}^2$ (20 μPa).

⁷One suitable artificial flesh material has the trade name "Satin Flex Plastiflex 664" and is obtainable from General Fabricators, Inc., 11826 Sheldon Street, Sun Valley, California 91352. When the material is supplied in bulk form, it needs to be made into the thin sheets required by this standard in accordance with the vendor's instructions for working with the material.

4.1.2.3 Headband Force Apparatus. The apparatus for the measurement of headband force is described in Fig. 3.

4.2 Test Procedures

4.2.1 Attenuation Measurement

4.2.1.1 Earmuff Placement. The earmuff shall be positioned in the following manner: The adjustable headband shall be extended to its largest size. The hearing protector shall be spread and placed on the dummy head with the circumaural seals centrally located on the appropriate surfaces. The headband shall be contracted so as to rest firmly upon the curved surface of the dummy head.

NOTE: Nape spring hearing protectors or those that do not have rigid headband springs shall be positioned on the dummy head in accordance with manufacturer's instructions. The applicable conditions of 4.2.1.1 shall be met.

4.2.1.2 Measurement. The band pressure levels at the microphone shall be measured for the acoustic test field without earmuffs. The hearing protector shall be placed over the microphone in accordance with 4.2.1.1 and the band pressure levels measured again. Readings are taken at the preferred center frequency when continuously swept filter sets are used.

(1) The measurements shall be taken for each earcup of the hearing protector in position covering the test microphone.

(2) When the measured difference in band pressure levels between the right and left earcups is less than 5 dB, the arithmetic average of the two values shall be reported. When the measured difference between earcups is 5 dB or greater, the attenuation of each earcup shall be reported.

4.2.1.3 Hearing Protector Attenuation. The algebraic difference in band pressure level, in decibels, for each

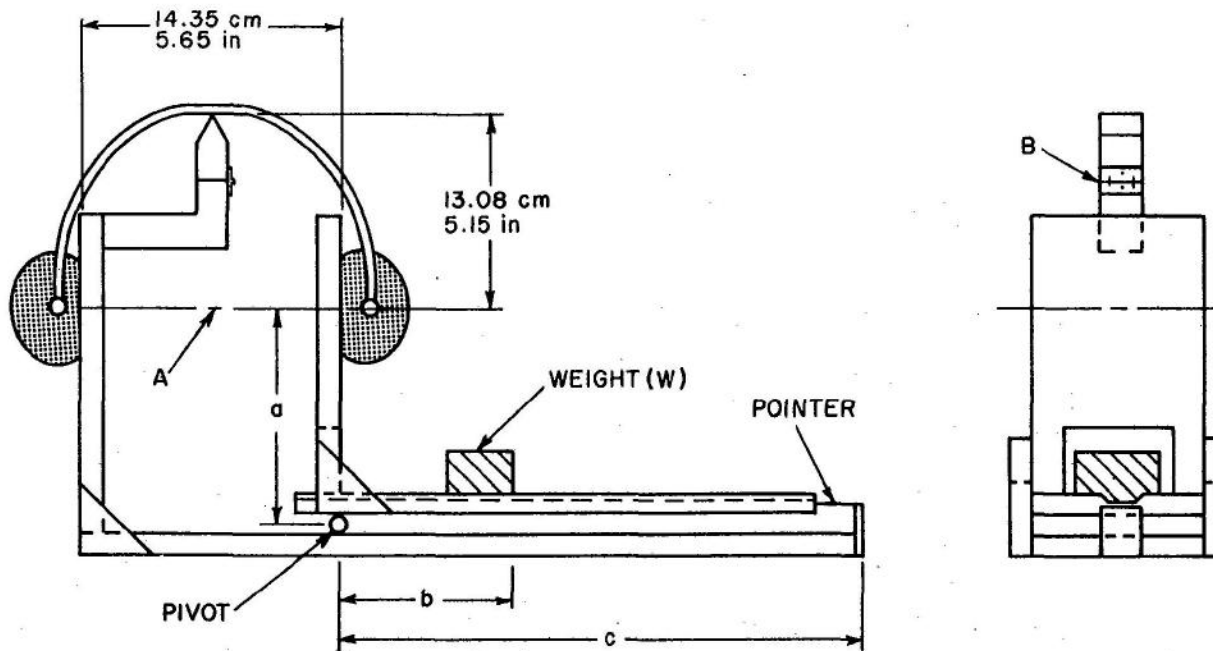


FIG. 3. Force measurement system.

NOTES:

- (1) A: Centerline passes through pivot point of earcup attachment to headband.
- (2) B: After correct headband distance is obtained, move out of way for force measurement.
- (3) *Construction:* Almost any material can be used providing that the units are made sufficiently rigid. The only critical dimensions are the earcup separation distance (14.35 cm or 5.65 in.) and the headband extension distance (13.08 cm or 5.85 in.). For best results, dimension "a" should be 12.0 cm (4.72 in.) to 15.0 cm (5.90 in.) and dimension "c" should be 30.5 cm (12 in.). A good free-working hinge with a small center pin is satisfactory as the pivot point. Weight is recommended to be about 900 g (about 2 lb).
- (4) *Calibration:* With the pointer aligned, the distance between the two faces must be read 14.35 ± 0.2 cm. If the construction is such that the weight can be moved over the pivot point, then the zero force location is found by positioning the weight where it just balances. The force (F) at any location at a distance b that the weight has moved from the zero point is found by $F=bW/a$. A scale of grams (pounds) can be marked.
- (5) *Operation:* The earmuff to be measured is positioned so that the points of attachment of the headband to the earcups are located at the centerline marks (13.08 cm) and the headband contacts the vertical post. The post is moved away, and the weight is positioned to where the pointers are aligned. The force is read from the scale which converts weight location into grams. When the pointers are aligned, the distance of 14.35 cm is automatically satisfied.
- (6) *Accuracy:* The positioning of the earcup must be done with care in order to ensure that the point of attachment of the cup to the headband is the distance a from the pivot point. Practically, this is the largest source of error. With care, the position will be in error less than 0.3 cm for a maximum measurement error of $0.3 \text{ cm} \div 12 \text{ cm} = 2.6\%$ (2.1% for $a = 15 \text{ cm}$). Actual measurements of ten different hearing protectors by three different persons have shown that 95% of the measurements will be within $\pm 5 \text{ g}$ (about 2 ounces).

test frequency band with and without the hearing protector in place on the dummy head is considered to be the attenuation of the device.

4.3 Reporting the Data

4.3.1 The hearing protector attenuation data shall be presented in graphic form, with the data points connected by straight lines, on a paper whose frequency scale along the abscissa is in equal intervals of one-third-

octave-band center frequencies and whose attenuation scale along the ordinate is linear in decibels. The length for a decade of third octaves shall be equal to the length for 25 dB. The ordinate shall be labeled in 14 equal intervals of 5 dB ranging from 60 dB at the abscissa to -10 dB. Subdivision of the ordinate is acceptable.

4.3.2 The graph shall be clearly labeled to indicate a physical measurement method. The date, model number, headband force, individual conducting the test, and any other appropriate data shall be included on the graph.

Appendix A: Calculation of Maximum Permissible Noise Levels

This Appendix is not a part of Acoustical Society of America Standard Method for the Measurement of Real-Ear Protection of Hearing Protectors and Physical Attenuation of Earmuffs, ASA STD 1-1975, but is included for information purposes only.

The maximum permissible noise levels in the octave bands contained in Table 1 of the standards were calculated applying the data in Table A1 to the following formula:

$$L_N = T + C_N - C_B,$$

where the masking level is assumed to be zero,

$$T = \text{hearing threshold levels from ISO R226}^{A1} \text{ at } (re\ 20\ \mu\text{N/m}^2) (20\ \mu\text{Pa}),$$

$$C_N = 10 \log_{10} (NB/1\ \text{Hz}),$$

and

$$C_B = \text{critical band for two-ear listening.}^{A2}$$

TABLE A1. Data for calculating maximum permissible noise levels.

Frequency (Hz)	Noise band (Hz)	T (dB)	C_N (dB)	C_B (dB)	L_N (dB)
125	90- 180	20.8	19.5	16.0	24
250	180- 355	11.2	22.4	15.5	18
500	355- 710	6.0	25.5	15.5	16
1000	710- 1400	4.2	28.4	16.5	16
2000	1400- 2800	1.0	31.5	18.5	14
4000	2800- 5600	- 3.9	34.5	21.0	9
8000	5600-11200	15.3	37.5	23.0	30

*Reduced from 10 to 9 dB to be equal to level in band centered at 3000 Hz.

^{A1}ISO (International Organization for Standardization) Recommendation R226-1961, Normal Equal-Loudness Contours for Pure Tones and Normal Threshold of Hearing under Free Field Listening Conditions.

^{A2}N. R. French and J. C. Steinberg, "Factors Governing the Intelligibility of Speech Sounds," J. Acoust. Soc. Am. 19, 90-119 (1947), Fig. 7.

EXHIBIT 9
3M'S ANSWER TO FIRST
AMENDED COMPLAINT

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

<p>MOLDEX-METRIC, INC., Plaintiff, vs. 3M COMPANY and 3M INNOVATIVE PROPERTIES COMPANY, Defendants.</p>	<p>Civil No. 14-1821 (JNE/FLN)</p>
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ANSWER TO FIRST AMENDED COMPLAINT

Defendants 3M Company and 3M Innovative Properties Company (together, “3M”) hereby answer and respond to the First Amended Complaint for Monopolization and Attempted Monopolization, Unfair Competition, and Malicious Prosecution (the “First Amended Complaint”) filed by Moldex Metric, Inc. (“Moldex”).

NATURE OF THE ACTION

The allegations in this section of the First Amended Complaint contain Moldex’s characterizations of its claims and legal conclusions, to which no response is required. To the extent that a response is required, 3M denies the allegations in this section, except it admits that: it filed a patent infringement lawsuit against Moldex in this Court on March 8, 2012, in which 3M alleged that Moldex’s BattlePlugs® earplugs and several of its M-Series earmuffs infringe two U.S. patents (U.S. Patent No. 6,070,693 (the “693 Patent”) and U.S. Patent No. 7,036,157 (the “157 Patent”)), respectively (the “Underlying Lawsuit”); and that the parties engaged in discovery and briefed dispositive

motions in the Underlying Lawsuit. 3M states that its conduct in pursuing its infringement claims against Moldex was proper and was not objectively baseless, or subjectively motivated to interfere with Moldex's business, and that 3M voluntarily dismissed its allegations in the Underlying Lawsuit after discovery, including because discovery revealed that its potential recoverable damages did not justify the expense and burden of continued litigation. 3M specifically denies that it engaged in monopolistic, anticompetitive, or wrongful conduct.

3M further admits that it markets a non-linear, dual mode earplug under the "Combat Arms" trademark, with a "0" Noise Reduction Rating ("NRR"), which was calculated in accordance with U.S. Environmental Protection Agency ("EPA") regulations. The EPA regulations expressly require that the NRR be calculated following a specific formula and that it be included on the label of those products.

1. 3M admits upon information and belief the allegations in paragraph 1.
2. 3M admits the allegations in the first and second sentences of paragraph 2.

The third sentence of paragraph 2 purports to state a legal conclusion that does not require a response. To the extent a response to the third sentence of paragraph 2 is required, 3M denies the allegations.

3. 3M admits the allegations in paragraph 3, except states that 3M Innovative Properties Company owns the 3M group's intellectual property.

4. 3M admits that the First Amended Complaint purports to assert claims under certain antitrust laws of the United States, including Title 15 of the United States Code.

5. 3M admits the allegations in paragraph 5.

6. 3M admits the allegations in paragraph 6.

7. 3M admits the allegations in paragraph 7.

8. 3M denies the allegations in paragraph 8, except admits Moldex alleges that this action involves “non-linear” or “selective attenuation” earplugs, some of which are purchased and used by the U.S. military and that such earplugs can be worn by soldiers in the field so that they are protected from the intense impulse sounds of battlefield explosions while still being able to communicate with their colleagues. 3M further admits that non-linear earplugs are designed to block or attenuate sounds of different amplitude and frequency to differing degrees, such that the wearer is protected from intense impulse sounds while still being able to hear sounds of different amplitude or frequency.

9. 3M denies the allegations in paragraph 9, except admits that the United States military is the largest purchaser of Combat Arms earplugs.

10. 3M denies the allegations in paragraph 10, except admits that this action involves a type of hearing protector known as an earmuff.

11. 3M denies the allegations in paragraph 11, except admits that hearing protectors, including earplugs and earmuffs, are sold with a listed NRR, which is calculated according to a formula provided for by certain federal regulations. 3M further admits that it has conducted NRR testing at a laboratory operated by 3M personnel that has been approved for such testing.

12. 3M denies the allegations in paragraph 12.

13. 3M denies the allegations in paragraph 13.

14. The allegations in paragraph 14 purport to state legal conclusions that do not require a response. To the extent that a response is required, 3M denies the allegations in paragraph 14, except admits that it has manufactured and sold five versions of its Combat Arms non-linear earplug, each of which uses a sound channel with constrictions and openings to produce its non-linear sound attenuation effect. 3M further admits that its Combat Arms earplugs allow the user to set the earplug for a second mode of operation.

15. 3M denies that Moldex's BattlePlugs® provided the first actual competition to 3M's Combat Arms earplug. 3M lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in paragraph 15.

16. 3M denies the allegations in paragraph 16, except admits that it filed a claim against Moldex for infringement of the '693 Patent in the Underlying Lawsuit.

17. The allegations in paragraph 17 purport to state legal conclusions that do not require a response. To the extent a response is required, 3M denies the allegations in paragraph 17.

18. The allegations in paragraph 18 purport to state legal conclusions that do not require a response. To the extent a response is required, 3M denies the allegations in paragraph 18, except admits that the quotation in paragraph 18 is contained in the summary of the invention in the '693 Patent.

19. 3M denies the allegations in paragraph 19, except admits that it currently offers two versions of its Combat Arms earplug, and that one version operates by blocking the non-linear sound channel with a plug or block operated by a toggle device.

20. The allegations in paragraph 20 purport to state legal conclusions that do not require a response. To the extent a response is required, 3M denies the allegations in paragraph 20.

21. 3M denies the allegations in paragraph 21, except states that it was contacted by Moldex following 3M's filing of the Underlying Lawsuit regarding 3M's allegations based on the '693 Patent, and that 3M continued to pursue the Underlying Lawsuit.

22. 3M lacks sufficient knowledge or information to form a belief as to the truth of the allegations in paragraph 22 regarding the introduction of the M-series earmuffs. The remaining allegations in paragraph 22 purport to state legal conclusions that do not require a response. To the extent a response is required, 3M denies the remaining allegations in paragraph 22, except admits that, in the Underlying Lawsuit, 3M also brought a claim against Moldex alleging that several of Moldex's M-series earmuffs infringe the '157 Patent.

23. 3M denies the allegations in paragraph 23, except states that it was contacted by Moldex following the filing of the Underlying Lawsuit regarding 3M's allegations based on the '157 Patent and that 3M continued to pursue the Underlying Lawsuit.

24. The allegations in paragraph 24 purport to state legal conclusions that do not require a response. To the extent that a response is required, 3M denies the allegations in paragraph 24, except admits that Moldex filed a motion for summary judgment of non-infringement of the '693 Patent on January 18, 2013 and that a hearing was set for March 21, 2013. 3M further admits that it offered Moldex a covenant not to sue, and subsequently filed a motion to dismiss its claims regarding the '693 Patent with prejudice and to dismiss Moldex's counterclaims of non-infringement and invalidity of the '693 Patent without prejudice. 3M also admits that, on June 19, 2013, the Court dismissed 3M's claims with prejudice and dismissed Moldex's counterclaims without prejudice.

25. The allegations in paragraph 25 purport to state legal conclusions that do not require a response. To the extent that a response is required, 3M denies the allegations in paragraph 25, except admits that 3M pursued its allegations based on the '157 Patent after 3M offered Moldex a covenant not to sue regarding the '693 Patent. 3M further admits that it sought discovery from Moldex regarding the '157 Patent, including depositions from the eight named Moldex employees.

26. The allegations in paragraph 26 purport to state legal conclusions that do not require a response. To the extent that a response is required, 3M denies the allegations in paragraph 26, except admits that it offered Moldex a covenant not to sue regarding the '157 Patent in May 2013. 3M further admits that, on June 19, 2013, the Court dismissed 3M's claims regarding the '157 Patent with prejudice and dismissed Moldex's counterclaims without prejudice.

27. The allegations in paragraph 27 purport to state legal conclusions that do not require a response. To the extent that a response is required, 3M denies the allegations in paragraph 27, except states that it corresponded with Moldex regarding dismissal of its patent claims, and refers to the parties' communications for their contents.

28. 3M denies the allegations in paragraph 28.

29. The allegations in paragraph 29 purport to state legal conclusions that do not require a response. To the extent that a response is required, 3M denies the allegations in paragraph 29, except admits that it participates in the Javits-Wagner-O'Day ("JWOD") federal Ability One Program. 3M further admits that it sells Combat Arms products with an NRR rating of "0." 3M lacks sufficient knowledge or information to form a belief as to the truth of the allegation in the last sentence of paragraph 29.

30. 3M denies the allegations in paragraph 30, except admits that it acquired Aearo Technologies, Inc. ("Aearo") and the Combat Arms brand in 2008.

31. 3M admits that it reports a 0 NRR for the open end and 22 NRR for the closed end for the Combat Arms earplug, version two ("CAEv.2"). 3M otherwise denies the allegations in paragraph 31.

32. The allegations in paragraph 32 purport to state legal conclusions that do not require a response.

33. 3M denies the allegations in paragraph 33, except as follows. 3M admits that, in January 2000, the EARCAL laboratory (then operated by Aearo) tested both ends of the CAEv.2, which has two insertable ends. 3M admits that some of the test subjects were Aearo employees. 3M admits that Aearo performed tests without an earplug

inserted and with the CAEv.2 inserted. 3M admits that Aearo monitored the results of these tests. Based on these test results, 3M reported an NRR value of a “0” on its packaging for CAEv.2.

34. 3M denies the allegations in paragraph 34, except as follows. 3M admits that, Aearo conducted tests on the closed end of CAEv.2 in January 2000, and prepared a report relating to the testing. The contents of the report speak for themselves.

35. 3M denies the allegations in paragraph 35 except as follows. 3M admits that, in 2000, two Aearo employees conducted a new test on the closed end of CAEv.2. During this test, the yellow flanges on the open end of the earplug were folded back. Based on these test results, it reported an NRR value of “22” on its packaging.

36. 3M denies the allegations in paragraph 36 except as follows. 3M admits that Aearo did not conduct tests of the open end of CAEv.2 in which it folded back the green flanges.

37. 3M denies the allegations in paragraph 37.

38. 3M denies the allegations in paragraph 38.

39. Responding to paragraph 39, 3M repeats its responses to paragraphs 1 through 38 and paragraphs 43 through 51 of the First Amended Complaint, incorporating them by reference as if set forth in full.

40. 3M denies the allegations in paragraph 40.

41. 3M denies the allegations in paragraph 41.

42. 3M denies the allegations in paragraph 42.

43. Responding to paragraph 43, 3M repeats its responses to paragraphs 1 through 42 of the First Amended Complaint, incorporating them by reference as if set forth in full.

44. 3M denies the allegations in paragraph 44.

45. 3M denies the allegations in paragraph 45.

46. 3M denies the allegations in paragraph 46, except as follows. 3M admits that it voluntarily dismissed its claims in the Underlying Lawsuit.

47. Responding to paragraph 47, 3M repeats its responses to paragraphs 1 through 46 of the First Amended Complaint, incorporating them by reference as if set forth in full.

48. 3M denies the allegations in paragraph 48.

49. 3M denies the allegations in paragraph 49.

50. 3M denies the allegations in paragraph 50.

51. 3M denies the allegations in paragraph 51.

52. 3M denies all allegations of the First Amended Complaint to the extent not expressly admitted.

53. 3M denies that Moldex is entitled to the relief sought in its prayer for relief paragraphs.

AFFIRMATIVE DEFENSES

First Affirmative Defense

54. The First Amended Complaint fails to state a claim upon which relief against 3M may be granted.

Second Affirmative Defense

55. Moldex's claims are barred insofar as they challenge the exercise of rights protected by the First Amendment of the United States Constitution and the *Noerr-Pennington* doctrine.

Third Affirmative Defense

56. There has been no antitrust injury and no harm to competition caused by 3M's conduct as alleged in the First Amended Complaint.

Fourth Affirmative Defense

57. Moldex has failed to mitigate its damages, if any.

Fifth Affirmative Defense

58. Moldex's claim for false advertising is time-barred.

Sixth Affirmative Defense

59. Moldex's amended claim for unfair competition is barred in whole or in part by the doctrine of unclean hands.

60. Aearo (which was acquired by 3M in 2008) developed one of the first selective nonlinear attenuating earplugs, known as the "Combat Arms Earplug Version 1" in the late 1990s. In the late 1990s, various United States military personnel, including military audiologist Douglas Ohlin, began discussions with Aearo to develop a new

Combat Arms earplug that would have two insertable ends, with each offering a differing level of attenuation. The military was interested in this type of earplug because, among other reasons, it would eliminate the need for soldiers to carry two sets of earplugs to get two different levels of protection from noise. Aearo and the military worked together to develop a prototype product, which later became known as “version two” or “generation two” (“CAEv.2”)—and which Moldex’s Amended Complaint refers to as the “dual-ended Combat Arms.”

61. The military, represented by Doug Ohlin, rejected the first prototype CAEv.2 because a pair of them could not fit vertically into the specific carrying case that was designed by Mr. Ohlin and issued to all noise-exposed Army personnel. Mr. Ohlin, speaking on behalf of the Army, asked Aearo to redesign the product to shorten the stem so that a pair would fit more conveniently into the carrying case, which Aearo did.

62. In early 2000, Aearo performed tests on the “open” and “closed” ends of CAEv.2. The military was aware of these tests, the conditions under which they were performed, and the results obtained. Aearo and Mr. Ohlin, speaking on behalf of the military, agreed that testing on the “closed” end should be performed by folding back the yellow flanges on the opposing end.

63. Mr. Ohlin was fully aware of the methods used to test both the open and closed ends of CAEv.2, and the military proceeded to order the product for use by the military for over ten years.

64. The military has instructed military personnel regarding how to fit CAEv.2.

65. Despite these facts, Moldex amended its Complaint to add new allegations that 3M's NRR testing of CAEv.2 violated the Noise Control Act of 1972, 42 U.S.C. § 4901 et seq. ("Act"). Moldex added this claim even though Moldex was aware that Moldex had presented inaccurate information to the government regarding earplugs. Moreover, Moldex added this claim even though Moldex was aware that NRR data reported on Moldex's Internet brochures and packaging for its M-Series and Special Ops earmuffs had not complied with the Act. Moldex's conduct regarding earplugs and earmuffs constitutes unclean hands.

66. The Act directs the Environmental Protection Agency ("EPA") to publish regulations governing noise-producing and noise-reducing products. *See* 40 C.F.R. § 211 et seq. ("Regulations"). The Regulations require certain noise-reducing products, including earmuffs, to display a label that includes the product's NRR along with "supporting information" used to arrive at that NRR. *See id.* § 211.204-4. Every NRR label must include "[t]he mean attenuation and standard deviation values obtained for each test frequency according to § 211.206, and the NRR calculated from those values." *Id.* § 211.204-4(a). In addition, "[t]he Noise Reduction Rating for the label must be calculated using the Labeled Values of mean attenuation that will be included in the supporting information required by § 211.204-4." *Id.* § 211.211(b).

67. The mean attenuation and standard deviation values listed on certain Internet brochures for Moldex's M1 and M1 Special Ops earmuffs did not support the claimed NRR of 29. When the values listed on those labels are used to calculate an NRR pursuant to the formula specified in § 211.207, the result is an NRR of 26 at most. By

overstating the NRR of these earmuffs, Moldex violated § 211.204–1, which provides that “[t]he value stated on the label must be no greater than the NRR value determined by using the computation method of 211.207 of this subpart.” Moldex further violated § 211.211(b) which requires the labeled NRR to be “calculated using the Labeled Values of mean attenuation.” The front pages of certain brochures for Moldex’s M1 and M1 Special Ops earmuffs also featured a graphic touting an NRR of 33—an even more egregious overstatement of the protection actually provided.

68. Certain Moldex Internet brochures further violated the Regulations by reporting identical mean attenuation and standard deviation data for the M1 and Special Ops M1, and the M2 and Special Ops M2, respectively. On information and belief, these products are made from different materials, presumably resulting in different sound attenuation characteristics. Moldex violated § 211.211(b) by failing to separately test and report data for these earmuffs, which requires a manufacturer’s labels “take into account . . . product variability.”

69. It appears that at some point after the deposition of a Moldex employee on November 30, 2015, Moldex replaced the incorrect and misleading brochures with ones reporting entirely new sets of NRR data for its M1 and M1 Special Ops earmuff. These new replacement brochures indicated a revision date of “01/15,” which was inaccurate on its face.

70. Moldex listed the erroneous NRR data featured in the incorrect and misleading brochures elsewhere on its website. Indeed, Moldex affirmatively directed

consumers who seek “Attenuation Data” for the M-Series and Special Ops earmuffs to this misleading and inaccurate NRR data.

71. The mean attenuation and standard deviation values listed on the packaging of certain Moldex M1 earmuffs did not support the claimed NRR of 29. The overstatement of the NRR for these earmuffs violated § 211.204–1, which provides that “[t]he value stated on the label must be no greater than the NRR value determined by using the computation method of 211.207 of this subpart.” It also violated § 211.211(b) which requires the labeled NRR to be “calculated using the Labeled Values of mean attenuation.”

72. The mean attenuation and standard deviation values listed on the packaging of certain Moldex M2 earmuffs did not support the claimed NRRs of 26 (over-the-head) or 24 (behind-the-head and under-the-chin). The overstatement of the NRR for these earmuffs violated § 211.204–1, which provides that “[t]he value stated on the label must be no greater than the NRR value determined by using the computation method of 211.207 of this subpart.” It also violated § 211.211(b) which requires the labeled NRR to be “calculated using the Labeled Values of mean attenuation.”

73. Despite the requirements for proper labeling detailed by the Regulations and mandated by the Act, Moldex gave potential consumers information that did not reflect the actual NRR and its underlying associated data.

74. Moldex was on notice of its violations of the Act and the inaccurate information it provided to the government regarding earplugs before it filed its Amended

Complaint, and its conduct warrants the application of the doctrine of unclean hands to Moldex's amended unfair competition claim.

By asserting an affirmative defense herein, 3M does not assume the burden of proof or persuasion not otherwise required by applicable law.

WHEREFORE, 3M respectfully requests that the Court enter judgment dismissing the First Amended Complaint in its entirety with prejudice and awarding 3M the costs, disbursements and attorneys' fees it incurs in defending against the First Amended Complaint, together with such other and further relief to 3M as the Court determines to be just and proper under the circumstances.

Dated: February 5, 2016

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**Attorneys for Defendants 3M Company
and 3M Innovative Properties Company**

EXHIBIT 10
AEARO COMPANY 2006
COMBAT ARMS INSTRUCTIONS



NSN NUMBER:
6515-01-466-2710



MORE THAN A HEARING PROTECTOR

The Combat Arms™ Earplugs not only provide hearing protection, they help provide situational awareness by protecting against concussive disorientation effects associated with impulse noise (i.e., weapons fire, improvised explosive devices, etc.).

The patented Hear-Through™ design allows wearers to hear low-level sounds critical to mission safety – conversation, footsteps, rifle bolts, approaching enemies. When needed, the plug's "filter" reacts to provide instant protection from high-level noises. It's that easy. It's that quick.

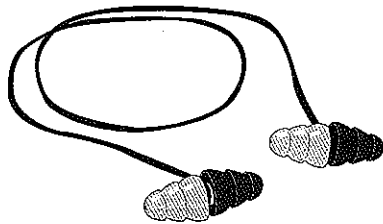
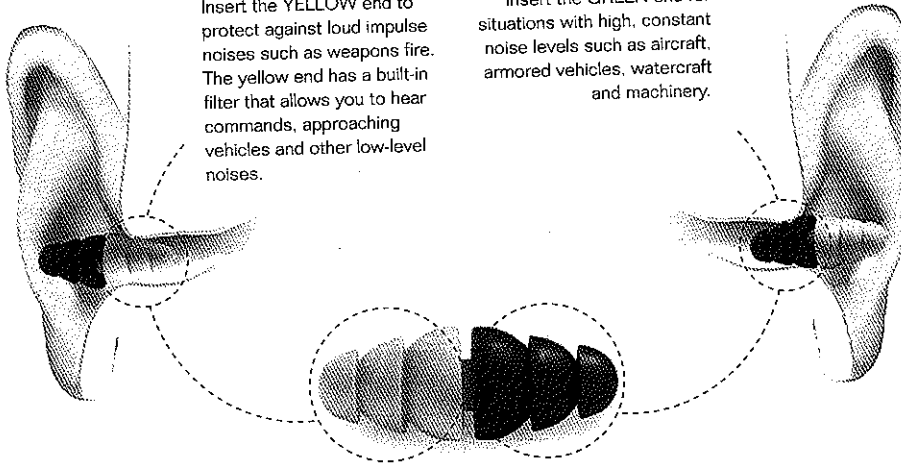
DUAL-ENDED DESIGN MEETS CRITICAL PROTECTION NEEDS

Yellow End Weapons Fire

Insert the YELLOW end to protect against loud impulse noises such as weapons fire. The yellow end has a built-in filter that allows you to hear commands, approaching vehicles and other low-level noises.

Green End Steady Noises

Insert the GREEN end for situations with high, constant noise levels such as aircraft, armored vehicles, watercraft and machinery.

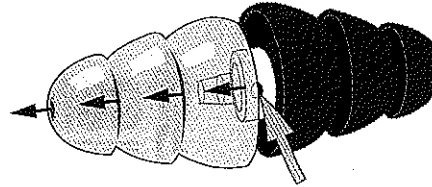


Now Available with Lanyard Attachment:

A black flame retardant lanyard has been provided for your convenience. To attach the lanyard to the earplugs, fit the loop at one end of the lanyard over either end of the earplug and push forward until the loop rests in between each of the earplug tips (over the white stem). Repeat with the other loop and earplug. To remove the lanyard, simply reverse the steps above. Note: The lanyard has been designed to fit loosely over the white stem so as to not impede the functionality of the filter.

EXPLANATION OF THE HEAR-THROUGH PROTECTION

Sound travels into the opening at the middle of the plug and then down the sound channel to the special filter. The filter allows lower-level sounds to pass without interruption, but high-level impulsive noises are restricted. The more intense the impulse, the more it is limited.



INSTRUCTIONS FOR USE:

Determine the proper end (green or yellow) for insertion depending upon your application needs. Grasp the earplug by the stem and insert into ear canal. Adjust plug for best sealing performance.



⚠ CAUTION:

Remove slowly with twisting motion to gradually break the seal. Rapid removal may damage eardrum.

Fitting tips:

Fitting is easier if ear is pulled upward and outward during insertion and is also improved if the sealing rings of the outward directed plug are rolled back upon themselves. Some individuals with smaller ear canals may experience discomfort with the dual-ended Combat Arms Earplug due to their restricted canal opening. A single-sided version of the Combat Arms Earplug is also available and will often times provide greater comfort for smaller ear canals. Single-Sided Combat Arms Earplug - NSN # 6515-01-512-6072.

Cleaning:

Plug tips may be cleaned with water and soap. Avoid any blockage of the channel through the yellow tip. This tip may be removed for cleaning by pulling it away from the remaining earplug assembly. Carefully replace after cleaning. Regularly examine the plugs for tears and cracks under any of the flanges. Replace as necessary.

⚠ CAUTION:

Inserting the yellow tip end under conditions of continuous hazardous noise can result in under protection and hearing loss. Improper fit of this device will reduce its effectiveness in attenuating noise. Follow Instructions For Use for proper fit.

The EPA has selected the NRR as the measure of a hearing protector's noise reducing capabilities. Aearo Technologies makes no warranties as to the suitability of the NRR as a measure of actual workplace protection since such protection is highly dependent on user training, motivation, and utilization. A better estimate of workplace protection can be obtained by derating the labeled NRR of this, or any other hearing protector, by 50%.

ATTENUATION DATA (ANSI S3.19-1974)

Combat Arms - Yellow Level-Dependent End

Frequency (Hz)	125	250	500	1000	2000	3150	4000	6300	8000	NRR	CSA CLASS
Mean (dB)	4.7	4.2	6.0	9.5	16.7	18.6	16.3	16.7	17.2	0	-
SD (dB)	4.0	4.3	5.0	6.7	4.9	5.7	5.8	6.1	6.8		

Combat Arms - Green Steady State End

Frequency (Hz)	125	250	500	1000	2000	3150	4000	6300	8000	NRR	CSA CLASS
Mean (dB)	32.7	31.8	33.0	32.0	34.5	37.3	38.9	43.8	43.3	22	AL
SD (dB)	5.9	6.1	6.5	5.5	4.1	5.3	6.1	6.7	6.9		

The level of noise entering a person's ear when a hearing protector is worn as directed is closely approximated by the difference between the A-weighted environmental noise level and the NRR.

Example:

1. The environment noise level as measured at the ear is 92 dBA.
2. The NRR is 22 decibels (dB).
3. The level of noise entering the ear is approximately equal to 70 dBA.

⚠ Caution:

For noise environments dominated by frequencies below 500 Hz, the C-weighted environmental noise level should be used. The NRR used in the above example was achieved under laboratory conditions.

Although hearing protectors can be recommended for protection against the harmful effects of impulse noise, the Noise Reduction Rating (NRR) is based on the attenuation of continuous noise and may not be an accurate indicator of the protection attainable against impulse noise such as gunfire. (Wording required by EPA.)

⚠ Caution:

Earplugs must be worn at all times in noisy surroundings for proper protection.

EXHIBIT 11
AWARD NOTICE
DECEMBER 15, 2006

65 -- Plug, Ear, Combat Arms, Dbl-Ended, 50 Pair

General Information

Document Type: Award Notice
Solicitation Number:
Posted Date: Dec 19, 2006
Archive Date: Dec 30, 2006
Classification Code: 65 -- Medical, dental & veterinary equipment & supplies
SetAsides: N/A
Naics Code: 339112 -- Surgical and Medical Instrument Manufacturing

Contracting Office Address

Defense Logistics Agency, Logistics Operations, Defense Supply Center
Philadelphia - Medical, 700 Robbins Avenue, Philadelphia, PA, 19111-5096,
UNITED STATES

Description

Contract Award Date: Dec 15, 2006
Contract Award Number: SP0200-07-D-4103
Contract Award Amount: \$9,000,000./Base Year; \$9,000,000./Option Year
Contract Line Item Number:
Contractor: Aearo Company 5457 W. 79th Street Indianapolis,
IN 46268-1675

Point of Contact

Allen Thomas, Contract Specialist, Phone 215-737-2320, Fax 215-737-3120,
Email Allen.C.Thomas@dla.mil - Allen Thomas, Contract Specialist, Phone 215-
737-2320, Fax 215-737-3120, Email Allen.C.Thomas@dla.mil

EXHIBIT 12
RESEARCHERS EVALUATE
TRUE EFFECTS OF HEARING
LOSS FOR SOLDIERS
DECEMBER 16, 2015

Homepage > News Archives > Article

Researchers evaluate true effects of hearing loss for Soldiers

December 16, 2015

By **David E. Gillespie, BACH Public Affairs**



Story Highlights

- For more than 30 years, auditory fitness levels have been measured annually using an audiometry test.
- Research aims to establish a standard for hearing loss profile that is more real world and realistic.
- Audiologists want to know if the audiometry test's long-established hearing profiles are an accurate measure of a Soldier's ability to move, shoot and communicate.



FORT CAMPBELL, Ky. (Dec. 16, 2015) -- Army Medicine audiology researchers are studying how hearing loss affects Soldier performance on the battlefield, giving commanders a better understanding of real-world limitations, and helping create a new, more realistic, standard for hearing profiles.

For more than 30 years, auditory fitness levels have been measured annually using an audiometry test, also known as the Defense Occupational and Environmental Health Readiness System Hearing Conservation, with a certain hearing-loss threshold prompting a mandatory medical review board.

So while many Soldiers have been labeled non-deployable because of hearing loss, the U.S. Department of Veterans Affairs, or VA, spends more than \$1 billion in compensation per year to treat hearing loss for more than 800,000 veterans. Data collected by the VA shows as many as 52 percent of combat Soldiers have moderately severe hearing loss or worse, mostly because of the loud sounds associated with combat.

However, researchers want to know if the audiometry test's long-established hearing

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5/4/2016

Researchers evaluate true effects of hearing loss for Soldiers | Article | The United States Army

profiles are an accurate measure of a Soldier's ability to move, shoot and communicate.

"We are working on a research protocol that is looking at the effects of hearing loss on Soldier performance in realistic battlefield scenarios," said Lt. Col. Amy Blank, an audiologist from Walter Reed National Military Medical Center.

Those realistic battlefield scenarios were in the form of team-level maneuvers across a wooded training area on Fort Campbell, which provided an ideal location for Blank and Benjamin Sheffield, a research audiologist from Army Public Health Center (Provisional).

"My partners in this research developed a hearing loss simulator, which Soldiers mount on top of their helmets," Blank said. "The device superimposes hearing loss through earphones inserted into the ears, allowing us to evaluate how well they are performing in a scenario where they have a start point, waypoints to obtain, and an endpoint."

Soldiers, from the 101st Airborne Division (Air Assault), donned the equipment and formed four competing teams, each of which simulated varying levels of hearing loss. The Army's current auditory fitness-for-duty system characterizes those levels as hearing profiles H1, H2, or H3, with the latter being the worst of the three profiles. Each team's mission was to navigate to each of three waypoints and reach their endpoints as quickly as possible.

"There are other teams on the battlefield and they have to engage teams if they come across them. The objective is to get from start to finish and be the first to arrive. That is difficult when we superimpose simulated hearing loss on the Soldiers," Blank said.

"We have a pretty sophisticated way of collecting data," added Sheffield, as he fitted helmets with video cameras, binaural microphones and hearing-loss simulation devices. "Through word of mouth and a bit of research, we found this HITS [Homestation Instrumentation Training] System here at Fort Campbell. We recognized this would be the perfect platform to move to the next step in our research. Also, we have the 101st Airborne here at Fort Campbell, a good unit well experienced in this type of combat."

In the proof-of-concept phase, Blank and Sheffield had performed similar tests on West Point cadets using paintball-based scenarios with the same hearing-loss simulators, but with a woodsball or "every man for himself" format.

The HITS system at Campbell opened up a new wealth of data possibilities, Sheffield said. HITS is an automated information system designed to support collective maneuver training and captures position and weapons effects data for real-time monitoring or playback. Inside a portable control room, Blank and HITS technicians monitored a wall of computer screens, where color-coded icons gave a birds-eye view of the action unfolding nearby on Fort Campbell's Camp Hinsch training area.

"It provides an opportunity for us to automatically monitor what is happening. They have the MILES [Multiple Integrated Laser Engagement System] gear and use their real weapons," Sheffield explained, noting that previous testing using paintball was limited because it was inherently quieter and just did not sound the same. "All of that affects our results. So, in terms of accuracy here, we know who is shooting who and when it is happening very precisely, and we also have a way of very easily tracking their movement."

In early studies, researchers saw a change in strategy as a function of hearing loss. "In the woodsball scenario," Sheffield said, "Soldiers in the more difficult hearing loss profiles tended to camp out or hide in order to maintain their survivability, but we saw a very significant drop off in their ability to engage the enemy. So, their lethality dropped off to half what it was in a normal hearing setting."

While the collected data will be studied for months to come, Sheffield said the research has already produced clear results.

"I can already safely say we are seeing trends that will hold up. We are definitely seeing that the normal hearing team is winning close to 40-percent of the rounds. There are four teams per round; chance would be 25 percent; and the severe hearing loss profile we are testing is winning less than 15 percent of the time. So we are definitely seeing a significant difference there. The mild to moderate losses we are testing fall between there, close to 25-30 percent," Sheffield said.

One Soldier participating in the study said the simulated hearing loss was an eye opener, prompting the use of other tactics.

"When I couldn't hear very well, it made me a lot more cautious. I felt like I needed to be more vocal to my Soldiers to my left and right. I couldn't tell if they could hear me or not, so it really affected our movement," said Sgt. Nimrud Velasco, 101st Airborne Division (Air Assault).

"There are a lot of things that surprised me on this testing. On setting number four, which is pretty much complete hearing loss, I had a hard time being able to direct where we were going or what I wanted the team to do to be able to continue the mission," Velasco said. "Being able to move to the objective is hard if you can't communicate effectively. You have to constantly look to your left and your right just to be able to communicate with the team leader and your Soldiers. It's tough."

5/4/2016

Researchers evaluate true effects of hearing loss for Soldiers | Article | The United States Army

In the end, Velasco said his team compensated by relying on hand-and-arm signals.

"Somehow, we got it done. You have to work with what you have and continue the mission," he said.

All of that could only be observed with this type of research, Blank explained.

"Lab derived testing is not real world. The sound they hear - the background noise - is not combat noise. This is a step in the process to make it more real world for the commanders on the ground so when their Soldiers are given a profile, they completely understand what that profile means and what the limitations are for that Soldier," Blank said.

Whether at war or at peace, hazardous noise is a prevalent occupational hazard in the Army and remains the most common military service-related injury reported by the VA. The intent of this research is to establish a standard for hearing loss profile that is more real world and realistic.

"Right now, when we profile Soldiers and they get to an H3 profile, it requires a medical board. Some of those Soldiers are released from service because of the amount of hearing loss they have," Blank said. "But none of that really is looking at how well a Soldier is localizing and functioning in an infantry type environment, detecting sound in a woods type environment. This is looking at more real-world experiences for the Soldiers."

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