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# Provisional Blood Lead Guidelines for Occupational Monitoring of Lead Exposure in the DoD



Pre-Decisional

Prepared for

Office of the Deputy Under Secretary of Defense, Installations and Environment  
Environment, Safety, and Occupational Health (ODUSD-I&E-ESOH)

Prepared by U.S. Army Public Health Command

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**Provisional Blood Lead Guidelines for Occupational Monitoring of Lead Exposure in the DoD**

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# Provisional Blood Lead Guidelines for Occupational Monitoring of Lead Exposure in the DoD

## 1 References

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See Appendix A for a list of references.

## 2 Purpose

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The objective of this technical report is to propose new Department of Defense (DoD) occupational blood-lead level (BLL) guidelines that are protective for both DoD Civilian employees and Service members.

## 3 Authority

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This report was prepared at the request of Mr. John Seibert, Assistant for Safety, Health and Fire, Office of the Deputy Under Secretary of Defense (Installations and Environment) in response to a National Academy of Sciences (NAS) report entitled “Potential Health Risks to DoD Firing-Range Personnel from Recurrent Lead Exposure” (NRC, 2013).

## 4 Scope

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This report addresses the development of new DoD BLL guidelines that will protect DoD Civilian employees and Service members, whether exposures occur during weapons firing or during the performance of other work tasks that may involve lead exposure. Once accepted, the new guidelines will need to be incorporated into a comprehensive DoD lead surveillance program which will address selection criteria for the population undergoing surveillance, and other specific screening and testing elements. The DoD Working Groups for Industrial Hygiene and Occupational Medicine will each have a role, to be established, in setting these monitoring and medical surveillance specifics.

## 5 Background

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Research findings over the past decade have demonstrated adverse health effects of lead in adults at BLLs previously considered acceptable in the workplace. The National Toxicology Program (NTP) released a monograph on the Health Effects of Low-Level Lead in June 2012 (NTP, 2012), while the U.S. Environmental Protection Agency (EPA) recently completed an Integrated Science Assessment of Lead in support of its review of the National Ambient Air Quality Levels for Lead (USEPA, 2013). In 2010, the Centers for Disease Control and Prevention (CDC) revised the case definition of an elevated adult blood lead to  $\geq 10$  micrograms per deciliter ( $\mu\text{g}/\text{dL}$ ) (CDC, 2010b) advising that clinical laboratories should report results exceeding that level to public health authorities. These efforts signal the prospect of lower future regulatory exposure levels for soil, water, and air. This

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evolving climate in the regulation of lead, with its potential impact on the DoD mission, prompted the Department of Defense to request the National Research Council (NRC) of the National Academy of Sciences (NAS) to evaluate potential health risks of lead exposure to military personnel (DoD, 2012), with an emphasis on small arms ranges. Given that worker exposure to lead in general industry is regulated by the Occupational Safety and Health Administration (OSHA) Code of Federal Regulations (CFR) 1910.1025 (OSHA, 1978), the charge to the NAS committee was to determine whether the current DoD exposure standards (OSHA general industry standard) were adequate for protection of military and Civilian workers. The task description was as follows:

“The committee will assess the potential health risks to Department of Defense firing range instructors and other personnel who experience recurring environmental exposures to lead at small-arms firing ranges. Information will be evaluated on recurrent lead exposures at such firing ranges, and relevant toxicological and epidemiological information on any carcinogenic and non-carcinogenic effects of exposure to lead will be evaluated. The evaluated information will include assessments by the Environmental Protection Agency and the National Toxicology Program. The committee will assess whether current exposure standards used at ranges are protective and will evaluate potential risk management options. The committee will publish a final report on their findings.” (DoD, 2012).

To address this objective, the committee reformulated their charge into the following specific questions (NRC, 2013) (pp.10-11).

1. Are OSHA's guidelines for using BLLs adequate to protect DoD firing range personnel?
2. Is the current OSHA Permissible Exposure Limit (PEL) sufficiently protective of DoD firing-range personnel?
3. Is the current OSHA action level for medical surveillance appropriate?
4. Were data gaps identified in answering the above questions? Is research needed to fill those gaps?

Because the OSHA standard as originally written implied that blood values of 40 µg/dL and below may not be associated with significant health risks, the NAS committee evaluated the health effects of lead below this level. The committee used recent reports published by the NTP (NTP, 2012) and USEPA (USEPA, 2013) as references as well as more recent studies not considered in these reviews. Epidemiological studies were primarily used, although few such studies of firing range personnel were available. The committee's emphasis was on clinical outcomes (disease) rather than measures of early biological effect. BLLs were used as a measure of recent exposure. Bone lead concentration (which was not available when the OSHA standards were originally developed) or cumulative blood lead index (CBLI) (average blood lead x years of exposure) was used as a measure of chronic exposure. The adverse health effects reported at BLLs <40

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µg/dL are summarized in the NRC report (page 166-167), followed by the health effects related to chronic exposure measured by bone lead or CBLI. These results showed how lower BLLs, as well as chronic exposure estimated by bone lead measurements or CBLI, are now associated with adverse health effects in adults.

The NRC report concluded that “BLL (40 µg/dL) was judged by the committee to be inadequate for protecting personnel who had repeated exposure on firing ranges; thus the OSHA PEL for lead would also be insufficiently protective.” (p.168). The NAS committee also concluded that the “Action Level for lead would have to be lowered in conjunction with the PEL.”

The NAS committee recommended in their report (p.6) that DoD should “review its guidelines and practices for protecting workers from lead exposure on firing ranges. One consideration should be a lowering of the acceptable BLLs to more stringent levels that reduce the risk of adverse health effects.” Although the conclusions specifically mention small arms ranges, any guidelines developed by the DoD would apply to all DoD workers, just as the OSHA standard is for the U.S. general industry workforce. It was also recommended (p. 6) that the DoD should – “consider analyzing BLLs of a representative sample of range workers in all the services and comparing them with BLLs linked to adverse health outcomes.... Protecting workers from exposure to lead involves an integrated approach that combines protective air and BLL guidelines, environmental monitoring to ensure that the guidelines are met, environmental controls to minimize exposure to lead, and appropriately designed medical surveillance.”

In assessing potential health risk options, the NAS committee suggested alternative management guidelines for BLLs (pp.169-170). These were used as the point of departure for development of this report. Several publications have recommended the use of a BLL of 20 µg/dL as a decision point for medical removal of workers, to minimize health risks from lead exposure (Kosnett et al, 2007; Schwartz and Hu, 2007). It has also been recommended that “for the prevention of the chronic health effects of cumulative doses tibia lead levels should not be allowed to exceed 15 µg/g” and this could be achieved by keeping the average blood lead of 20 µg/dL for 10-20 years (Schwartz and Hu, 2007). Multiple professional and governmental agencies recommend lowering adult occupational medical management guidelines from the current values identified in OSHA regulations to lower BLLs (ACOEM, 2010; CDPH, 2009; Kosnett et al, 2007).

While a review of cancer effects was provided in Chapter 5 (NRC, 2013), the committee’s conclusions are based solely on non-cancer endpoints. Although lead has been identified as probably carcinogenic in human, these findings are based on animal studies and report concluded that “the available human studies on cancer were insufficient for the committee to draw a conclusion about BLLs that might be associated with cancer” (p.165).

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Finally, the NRC report (pp.166-167) summarized pertinent health effects that the NAS committee found to be relevant for DoD firing-range personnel, including studies using BLL and bone lead measurements. Although some studies show health effects associated with BLLs < 10 µg/dL, the NRC report pointed out that health effects associated with BLLs in adults today may be influenced by lead exposures that many individuals experienced earlier in life ((NRC, 2013)(p.5) that may or may not be from occupational exposures. For populations currently employed by the DoD, the effect of early-life, pre-employment, or lead exposure outside of employment (i.e. recreational shooting) cannot be distinguished from the effect of concurrent occupational lead exposure without additional long-term studies. Since the publication of the NRC report, several new reports relevant to Pb exposure at small arms ranges have been published (CDC, 2013; CDC, 2014) confirming that blood leads can be increased in this cohort, although it was not always clear if the exposure is from ranges or other activities.

The proposed guidelines in this document are the beginning of a DoD effort to develop a standard for occupational exposure to lead that will protect against health risks associated with lower BLLs at all DoD sites, including ranges. While this report is in part a response to the recommendations made in the NRC report, it was not intended to be a comprehensive review of the toxicology literature, as this has already been carried out by other agencies (NTP, 2012; USEPA, 2013), but was intended to propose the best option in BLL-based guidelines for the DoD. The entire NRC report is available online at the National Academies Press ([http://www.nap.edu/catalog.php?record\\_id=18249](http://www.nap.edu/catalog.php?record_id=18249)).

## 6 Current Practices

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Several BLL associated policies and practices are in effect across the DoD. The Navy and Marine Corps Public Health Center (NMCPHC) has a series of technical manuals (<http://www.med.navy.mil/sites/nmcphc/Pages/Home.aspx>) that provide guidance for medical surveillance (NMCPHC, 2011), while the Air Force Institute of Aerospace Medicine currently uses the OSHA standard as the basis of its occupational programs (Whitney, 2014)(personal communication). Listed below (Table 1) are those that the Army currently follows. While different policies and procedures may exist across the DoD, the basis for all policies and practices with respect to lead exposure has been the OSHA standard.

The OSHA lead standard for general industry was promulgated in 1978 (29 CFR 1910.1025) (OSHA, 1978). Outside of military-unique activities, Service members who perform the same duties as their Civilian counterparts are also covered by this standard. The OSHA standard establishes air exposure limits for lead: a PEL of 50 µg/m<sup>3</sup> and an action level (AL) of 30 µg/m<sup>3</sup>. Medical surveillance (including BLL measurement) is required for employees who are or may be exposed to the AL for more than 30 days per year. Employees with a single confirmed BLL of 60 µg/dL or an average BLL of 50 µg/dL must be removed from the workplace where lead exposure occurred. Employees may return to work after having two BLL readings

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<40 µg/dL. The standard also has extensive requirements related to hazard awareness training, implementation of engineering controls, use of respirators, change of clothing and other mechanisms to prevent exposure to lead.

The American Conference of Governmental Industrial Hygienists' (ACGIH<sup>®</sup>) Biological Exposure Indices (BEI<sup>®</sup>) for BLLs is 30 µg/dL (ACGIH, 2013) and dates to 2001. It includes a note that women of childbearing potential who have BLLs over 10 µg/dL may be at risk for having a child who has levels greater than the current guideline from the Centers for Disease Control and Prevention. The ACGIH<sup>®</sup> guideline does not establish parameters for an extensive lead exposure control program as OSHA does but does set an air exposure Threshold Limit Value (TLV) recommendation of 50 µg/m<sup>3</sup> in order to be protective of the BLLs.

The DoD Occupational Medical Examinations and Surveillance Manual 6055.05-M (DoD, 2008) is the key reference for DoD occupational healthcare providers and occupational healthcare professionals responsible for identifying workplace exposures and work related health risks by job title, work place, or individual exposures. In addition to mandatory medical examinations under OSHA, occupational medical surveillance in the Army is usually initiated for workplace exposures greater than one half the PEL (OSHA Z table substances) or the ACGIH<sup>®</sup> TLV.

The U.S. Army Special Operations Command (USASOC) operates shoot houses that have potentially high short-duration exposures. With increasing concerns about the effects of lower lead levels on human health, the U.S. Army has initiated proactive approaches involving special operations. Recently, USASOC Regulation 40-8, Occupational and Environmental Risk Management for Shoot House and Indoor Firing Ranges was updated (USASOC, 2013) to include increased surveillance and protection at shoot houses.

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Table 1. Summary of Current Blood Lead Level (BLL) Policies and Practices in the U.S. Army.

<b>American Conference of Governmental Industrial Hygienists Biological Exposure Indices (BEI®) (2001)</b>		<b>OSHA 1910.1025 Lead in Industry (1978)</b>		<b>DoD Occupational Medicine Evaluation and Surveillance Manual 6055.05-M (Incorporating change 1, September 16, 2008)</b>		<b>USASOC Regulation 40-8 Occupational and Environmental Risk Management for Shoot Houses and Indoor Firing, Nov 2013.</b>		
The BEIs are guidance values for assessing biological monitoring results. The BEI generally indicates a concentration below which nearly all workers should not experience adverse health effects.		BLL testing is initiated for workers exposed to lead in air at concentrations greater than the Action Level (AL) (30 µg/m <sup>3</sup> ) for more than 30 days per year.		BLL testing is initiated for workers exposed to lead in air at concentrations greater than the Action Level (AL) (30 µg/m <sup>3</sup> ) for more than 30 days per year at a minimum. Installation occupational health and safety personnel are responsible for identifying at risk workers.		Standards apply to military, civilian and contractor personnel assigned or attached to organizations and units of USASOC.		
BEI = 30 µg/dL BEI = < 10 µg/dL for women of childbearing potential	BEI is not intended to be a sharp distinction between a hazardous and a nonhazardous exposure nor is it intended to be used as an action level for removal from lead exposure. Those entering the workforce with levels exceeding the BEI should be monitored, and their exposure to lead controlled such that their blood lead rises no further.	0-39 µg/dL	-No Action -Repeat Every 6 months	<5 µg/dL	-None indicated -Keep pregnant women or women who may become pregnant at this level	Personnel repetitively exposed during the course of duties (Trainers, maintenance workers)	≤ 20 µg/dL	Results are briefed. Personnel retested IAW unit standard, but within 6 months.
		40 to 59 µg/dL	-Increase BLL monitoring to every 2 months until BLL is < 40 µg/dL on two consecutive blood draws.	5-9 µg/dL	Reduce exposure for pregnant women or women who may become pregnant	Personnel repetitively exposed during the course of duties (Trainers, maintenance workers)	> 20 µg/dL	Results briefed. If 4 week retest if results are not below 20µg/dL, individual is removed from training. Licensed healthcare provider (PLHCP) may adjust retest period.
		≥ 60 µg/dL OR average of last three BLL ≥ 50 (unless last BLL is < 40)	-Removal from exposure to lead. -Repeat BLL testing within two weeks and initiate monthly BLL testing -Return to work when two consecutive BLL samples < 40 µg/dL	10-19 µg/dL	-Reduce exposure for pregnant women or women who may become pregnant -Increase biological monitoring	Personnel repetitively exposed during the course of duties (Trainers, maintenance workers)	≥ 30 µg/dL	Results briefed. Individual removed from training. Retest in 4 weeks or as per PLHCP.
		20-39 µg/dL	As above for BLL 10-19 µg/dL -Approach 1: Consider removal from lead exposure if BLL does not fall <20 µg/dL with exposure control, or if medical conditions are present that increase the risk of continued exposure -Approach 2: Remove from exposure until BLL = 10 µg/dL	Personnel exposed during course of duties other than trainers or maintenance.	≥30 µg/dL	Results are briefed. Retest in 4 weeks. Remove from operations if not below 30 ug/dL. PLHCP to set retest period.		
		40-79 µg/dL	-Remove from exposure -Refer for prompt medical evaluation Consider chelation therapy	Personnel exposed other than trainers or maintenance.	≥ 40 µg/dL	Results are briefed. Individual removed from operations. Retest in 4 weeks or per PLHCP.		

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As listed above (Table 1), the current practice for determining inclusion in a medical surveillance program primarily relies on exposure monitoring. Since the goal of new BLL guidelines (and any new standard) will be to achieve a higher level of worker protection, new or updated medical management enrollment criteria may need to be multifocal, shifting emphasis from solely airborne exposure criteria to include other descriptors of increased risk such as job title or military occupational series (MOS), knowledge of potential for exposure based on industrial hygiene expertise, supervisor request, or medical recommendation. The DoD Working Groups for Industrial Hygiene and Occupational Medicine will each have a future role in establishing these criteria.

## 7 Proposed Blood Lead Guidelines

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The proposed BLL guidelines presented in this report are based on the scientific literature referenced in the concluding chapter of the NRC report, in which alternative management guidelines for BLLs were outlined (pp. 169-171), and specifically on prescriptive recommendations made by Kosnett et al. (2007) in “Recommendations for Medical Management of Adult Lead Exposure” (Kosnett et al, 2007) and the American College of Occupational and Environmental Medicine (ACOEM, 2010). The new BLL guidelines are stratified, where increasing BLLs require an escalating series of actions that are proportionate to the level of concern or risk. These actions will be tied to new exposure criteria that will be established at a later date by the DoD Industrial Hygiene Working Group. The tiered approach is summarized below in Table 2.

The new BLL guidelines should be utilized to ensure the highest possible percentage of DoD Civilian employees and Service members have BLLs <10 µg/dL. Maintaining BLLs <10 µg/dL will prevent or lower future risks of cardiovascular or neurological effects. While the OSHA standard was concerned primarily with short term risks, these new guidelines aim to prevent long term health effects from lead exposure.

The new BLL guidelines reflect emphasis on levels low enough to avoid chronic adverse health effects while ensuring effective medical management for acute cases. Prevention of acute health effects from high BLLs involves individual case management, whereas prevention of chronic effects with lower BLLs would involve more comprehensive population-wide efforts to avoid long term elevated BLLs. Linking bone lead to BLLs in the calculation of BLLs ((NRC, 2013)(p.167) associated with health effects represents an important shift in thinking from merely considering the acute effects of lead exposure (vis-à-vis BLLs) and their amelioration, to the prevention of lead poisoning as a chronic disease.

- BLLs < 10 µg/dL. Requires no initial action but does not necessarily indicate unexposed individuals, especially where levels approach 10 µg/dL. For women who are pregnant or lactating BLLs should be kept < 5 µg/dL. For the general working population, keeping the BLL < 10 µg/dL over a working lifetime ensures that tibia lead, an acceptable measure of cumulative or chronic exposure, should not exceed 15 µg/g, which has been recommended in the research literature (Schwartz and Hu, 2007) to minimize adverse chronic health effects. When a change in job/task involves a higher risk of lead exposure, there should be a repeat screening. The implementation of additional guidelines for women Service members and Civilian employees of child

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bearing age is based on the recommendations from the Centers for Disease Control and Prevention (CDC, 2010a) and the American College of Obstetricians and Gynecologists (ACOG, 2012).

- BLLs 10-19 µg/dL. Requires follow up. This intermediate range represents higher lead exposure with increased population risk for cardiovascular, renal, reproductive, and neurological health effects, especially when BLLs remain at this level for a sustained period. This range will require continued monitoring and follow-up to ascertain if it indicates a transient BLL peak or a consistently high BLL. Medical evaluation and industrial hygiene assessment can be carried out with the goal of reducing the BLL to less than 10 µg/dL (requiring no initial action) or prevention of increases above 20 µg/dL (requiring medical management). Bone lead determination may be conducted to determine if there is a high cumulative exposure. Personal behavior may be evaluated, as changes effected through education may be important in the reduction of exposure in this category. Further input will be required from the Occupational Medicine Working Group (OMWG) and the Industrial Hygiene Working Group (IHWG) on the management of this BLL range.
- BLLs ≥ 20 µg/dL. Requires medical management. Requires removal from exposure if a second BLL measured within 4 weeks is ≥ 20 µg/dL, or if a single value measures ≥ 30 µg/dL. These elevated BLLs require monthly biomonitoring until BLLs have fallen satisfactorily. Medical evaluation and industrial hygiene assessment should be carried out. Return to work may be authorized when BLLs fall below the midpoint of the 10-19 µg/dL range (<15 µg/dL). Return to work at <15 µg/dL, rather than < 20 µg/dL, ensures that the BLL is below the middle of the next lowest range. With a measurement uncertainty of ±2 µg/dL (CDC, 2012) on BLLs, a value of 19 could range between 17-21 µg/dL. Using the same assumption, a value of 15 µg/dL could range from 13-17 µg/dL. It would therefore be better public health practice to safe side the return to work BLL at <15 µg/dL. However, it should also be recognized that some elevated BLL cases will be refractory even when exposure is eliminated (where contributing bone-Pb reserves are high for example) and that this return to <15 µg/dL may not always be achievable in the short term. The medical provider will assess each case.

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Table 2. Health Effects and Risk Management for Lead-Exposed DoD Personnel Based on Blood Lead Levels

Blood Lead level (µg/dL)	Short-term Risks At this BLL <1 year	Long-term Risks At this BLL ≥1 year	Actions
< 5	None documented	None documented	<p><u>Management:</u> None indicated but keep women who are pregnant, lactating, or trying to become pregnant at this level. Active duty females follow specific military branch regulations. Educate on health risks.</p> <p><u>Surveillance:</u> DoD Industrial Hygiene and Occupational Medicine Working Groups will determine selection and medical surveillance criteria. Individuals selected for BLL surveillance should be repeated at least annually; more frequently at the discretion of a medical provider.</p>
5–9	<p>Possible spontaneous abortion</p> <p>Possible postnatal developmental delay</p>	<p>Possible spontaneous abortion</p> <p>Possible postnatal developmental delay</p> <p>Possible hypertension and kidney dysfunction</p>	<p><u>Management:</u> Recommend reduction/avoidance of lead exposure for women who are pregnant, lactating, or trying to become pregnant. Active duty females follow specific military branch regulations. Educate on health risks.</p> <p><u>Surveillance:</u> DoD Industrial Hygiene and Occupational Medicine Working Groups will determine selection and medical surveillance criteria. Individuals selected for BLL surveillance should be repeated at least annually; more frequently at the discretion of a medical provider.</p>
10–19	<p>Possible spontaneous abortion</p> <p>Possible postnatal developmental delay</p> <p>Reduced birth weight</p>	<p>Possible spontaneous abortion</p> <p>Possible postnatal developmental delay</p> <p>Reduced birth weight</p> <p>Hypertension and cardiovascular disease</p> <p>Possible kidney dysfunction</p> <p>Possible subclinical neurocognitive deficits</p>	<p><u>Management:</u> As above for BLL 5-9 µg/dL, plus: Evaluate and decrease lead exposure. Educate on health risks.</p> <p>Consider removal from lead exposure to avoid long-term risks if exposure control over an extended period does not decrease BLL &lt; 10 µg/dL, or if medical condition<sup>a</sup> presents that elevates risk of adverse effects with continued exposure.</p> <p><u>Surveillance:</u> BLL repeated at least every 3 months; more frequently at the discretion of a medical provider.</p>

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<p align="center">20–29</p>	<p>Possible spontaneous abortion</p> <p>Possible postnatal developmental delay</p> <p>Reduced birth weight</p>	<p>Possible spontaneous abortion</p> <p>Possible postnatal developmental delay</p> <p>Reduced birth weight</p> <p>Hypertension and cardiovascular disease</p> <p>Possible kidney dysfunction</p> <p>Possible subclinical neurocognitive deficits</p>	<p><u>Management:</u> Remove from lead exposure if repeat BLL remains <math>\geq 20</math> <math>\mu\text{g}/\text{dL}</math> within 4 weeks. Educate on health risks.</p> <p><u>Surveillance:</u> Monthly BLL testing. Consider return to lead work after 2 BLLs <math>&lt; 15</math> <math>\mu\text{g}/\text{dL}</math> a month apart, then monitor as above.</p>
<p align="center">30–39</p>	<p>Spontaneous abortion</p> <p>Possible postnatal developmental delay</p> <p>Reduced birth weight</p>	<p>Spontaneous abortion</p> <p>Reduced birth weight</p> <p>Possible postnatal developmental delay</p> <p>Hypertension and cardiovascular disease</p> <p>Possible kidney dysfunction</p> <p>Possible neurocognitive deficits</p> <p>Possible nonspecific symptoms<sup>b</sup></p>	<p><u>Management:</u> Remove from lead exposure. Educate on health risks.</p> <p><u>Surveillance:</u> Monthly BLL testing. Consider return to lead work after 2 BLLs <math>&lt; 15</math> <math>\mu\text{g}/\text{dL}</math> a month apart, then monitor as above.</p>
<p align="center">40–79</p>	<p>Spontaneous abortion</p> <p>Possible postnatal</p>	<p>Spontaneous abortion</p> <p>Reduced birth weight</p>	<p><u>Management:</u> Remove from lead exposure. Refer for prompt medical evaluation. Educate on health risks.</p>

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	<p>developmental delay</p> <p>Reduced birth weight</p> <p>Nonspecific symptoms</p> <p>Neurocognitive deficits</p> <p>Sperm abnormalities</p>	<p>Postnatal developmental delay</p> <p>Hypertension and cardiovascular disease</p> <p>Kidney dysfunction/nephropathy</p> <p>Neurocognitive deficits</p> <p>Subclinical peripheral neuropathy</p> <p>Sperm abnormalities</p> <p>Anemia, Colic</p> <p>Possible gout</p> <p>Nonspecific symptoms<sup>b</sup></p>	<p>Consider chelation therapy for BLL &gt; 50 µg/dL with significant symptoms or signs of lead toxicity.</p> <p><u>Surveillance</u>: Monthly BLL testing. Consider return to lead work after 2 BLLs &lt; 15 µg/dL a month apart, then monitor as above.</p>
<p>≥ 80</p>	<p>All of the above</p> <p>Encephalopathy</p> <p>Anemia</p> <p>Colic</p>	<p>All of the above</p>	<p><u>Management</u>: Remove from lead exposure. Refer for immediate/urgent medical evaluation. Educate on health risks.</p> <p>Probable chelation therapy</p> <p><u>Surveillance</u>: Monthly or more frequent BLL monitoring. Consider return to lead work after 2 BLLs &lt; 15 µg/dL one month apart, then monitor as above.</p>

<sup>a</sup>Medical conditions that may increase the risk of continued exposure include chronic renal dysfunction (serum creatinine > 1.5 mg/dL for men and > 1.3 mg/dL for women, or proteinuria), hypertension, neurologic disorders, and cognitive dysfunction. <sup>b</sup>Nonspecific symptoms may include headache, fatigue, sleep disturbance, anorexia, constipation, arthralgia, myalgia, and decreased libido.

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Although the proposed recommendations above do not require universal action when BLLs are at or below 10 µg/dL, medical providers who believe an individual may be at increased risk of harm at these lower BLLs can and should take action. Reproductive and developmental concerns should be addressed and women of childbearing potential who are pregnant, planning a pregnancy or not actively prohibiting pregnancy should maintain a BLL of less ≤ 5 µg/dL. For women with BLL ≥ 5 µg/dL who are pregnant or lactating, refer to the CDC and ACOG guidelines (ACOG, 2012; CDC, 2010a). Women cannot be discriminated against (UAW vs Johnson, 1991), but should be provided education and offered administrative, engineering and dermal/respiratory protection in order to protect the fetus from developmental lead effects.

Defining health effects and the appropriate response at the 10-19 µg/dL BLL range is a challenge, and may require further discussion with respect to the implementation of these values. For example, some Service members will have varied and/or transient high exposures (i.e. shoot houses), which may not be easily tracked or reported. A more extensive medical evaluation for personnel with BLLs in this range should delve into individual health risks or susceptibilities including cardiovascular, renal or neurological effects. Individual behavior with respect to personal hygiene, work practices and diet may be an important determinant of these elevated BLLs and should be addressed in education. In all cases clinical judgment may supersede the recommended responses. Discussion and education of health risks should be conducted privately between a knowledgeable healthcare provider, preferably occupational medicine trained, and the employee or Service member. A strong communication plan throughout the DoD will be necessary to impact and modify behaviors that increase the risk of exposure to lead.

In addition to suggesting options for risk assessment, the NRC report listed studies showing relevant health effects, including hearing loss, neurological effects, and reproductive effects at BLLs significantly less than 40 µg/dL (pp. 166-167 or in Tables 4.1-4.6). Most of these studies have already been included in reviews by the NTP (NTP, 2012) and EPA (USEPA, 2013) and have been captured in the proposed guidelines. Consideration was also given to amending the health effects in Table 2 based on more recent evidence. For example, a major concern for the DoD is hearing loss (GAO, 2011), and although several studies were listed as evidence for hearing loss (Chuang et al, 2000; Hwang et al, 2009; Park et al, 2010) they were found to be insufficient evidence to conclude that lead alone is the present cause of reported hearing loss; furthermore, the NAS committee noted (NRC, 2013)(p169) that “the interactions between lead and noise have been incompletely evaluated”. Several studies found associations between low BLL and essential tremor (Dogu et al, 2007; Louis et al, 2005; Louis et al, 2011; Louis et al, 2003), but given that a large portion of the population has had low BLLs, a higher background prevalence than 1-6% would have been expected in such studies, and the NAS committee’s conclusion was that “prospective studies of incident cases of essential tremor with measures of cumulative lead exposure are needed” (NRC, 2013) (p76). Effects of lead on sperm parameters were provided in three key

studies (Hsu et al, 2009; Kasperczyk et al, 2008; Telisman et al, 2000) in addition to those provided by the NTP and EPA (De Rosa et al, 2003; Mahmoud et al, 2005; Naha et al, 2005; Telisman et al, 2000). While there is sufficient evidence of effects on sperm parameters at high BLLs (>40 µg/dL), studies citing effects at lower BLLs include co-exposures and confounding factors that could not be ruled out. Moreover, sperm parameters are difficult to standardize and are subject to wide regional, national, and local variations (Carlsen et al, 1992; Handelsman and Cooper, 2013) making true effects difficult to identify.

The recommended guidelines in the report evolved from recommendations made in the NRC report. However, it is recognized that the literature is changing with respect to adverse health effects at lower BLLs. Since health effects based on BLLs are based on a weight-of-evidence approach, critical review of the literature should continue so that the guidelines can be updated, where necessary, and relevant health effects can be added. It is therefore recommended that Table 2 be updated in a systematic panel-of-expert review process at some future date.

Finally, it should be noted that the Tri-Services Toxicology Consortium has peer reviewed and endorsed these guidelines. The DoD Working Groups for Industrial Hygiene and Occupational Medicine have also reviewed and approved the proposed guidelines and will further develop surveillance and management actions consistent with these BLLs.

## 8 Discussion

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The BLL guidelines proposed in this document can be used as decision points in the reduction of occupational exposures in all DoD personnel so that measured BLLs are maintained as low as reasonably achievable. While the proposed values are also in alignment with more protective policies already in place in some Services, a more uniform approach is necessary across the DoD. The overall objective of the proposed guidelines is to reduce BLLs so that the highest possible percentage of DoD personnel falls into the < 10 µg/dL category. It is likely that a combination of product replacement, range design, engineering controls, education and modification of behavior will all contribute to reaching this ultimate goal. Though other DoD working groups will develop air exposure limits and management strategies in follow-up efforts, some considerations for their development are discussed below.

The development of a model that correlates environmental exposure with the recommended lower BLLs in this report will be necessary if new occupational exposure limits for DoD are to be established. Whereas the OSHA standards were designed to keep BLLs below a threshold based on a dose-response model, the new BLL values recommended here are based on association with adverse health effects, but do not yet have a calibrated occupational and/or environmental model

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of exposure. Recently, CalEPA Office of Environmental Health Hazard Assessment (OEHHA) developed a model that estimates BLLs based on airborne lead concentrations (CalEPA, 2013). The model shows that over a working lifetime at a PEL of  $2.1 \mu\text{g}/\text{m}^3$ , 95% of workers would have a BLL less than  $10 \mu\text{g}/\text{dL}$  or 95% would have a BLL less than  $5 \mu\text{g}/\text{dL}$  at a PEL of  $0.5 \mu\text{g}/\text{m}^3$ . The results of this report are the basis of a California Department of Health – Occupational Lead Poisoning Prevention Program (CDPH-OLPPP) recommendation to Cal/OSHA for a health based permissible exposure limit for Pb based on a BLL 5-10  $\mu\text{g}/\text{dL}$  (CDPH, 2013), which is currently under review. The applicability of this model to DoD occupational exposures has yet to be assessed. At the Public Health Command, an epidemiologic evaluation has been proposed, coordinated by the PHC Environmental Medicine Program (Abraham, 2014) which would estimate and evaluate associations between blood lead levels and demographic characteristics using historical BLLs and environmental lead exposure measurements from various DoD databases. This study may provide supporting information to assess appropriate models of exposure for the DoD.

As acceptable BLLs are lowered, controlling environmental exposures and measuring the effectiveness of such controls will become even more important. Estimating lead exposure is complex and requires consideration of both the inhalation and ingestion routes and their relative importance. For proper characterization of exposure, additional information will therefore be needed regarding the relative importance of the main routes (inhalation vs. ingestion) and sources of exposure. Furthermore, particle size fractions associated with airborne lead, particularly at small arms ranges need to be characterized so that an appropriate air measurement standard and sampling methodology can be redefined.

It should be noted that while occupational exposure to lead is more likely to generate cohorts of elevated BLLs, an unexpectedly elevated BLL in a single individual could also indicate exposure due to a hobby, recreational activity, or other exposure source outside of work. Personal practices may thus contribute to individuals with higher than expected BLLs, especially where adequate engineering and administrative controls are in place. The role of individual behavior will thus become more critical when lower blood lead guidelines are in place. Therefore, in addition to occupational monitoring, a strong communication plan detailing the risks associated with lead exposure should be clearly available, so that personnel fully understand how modification of individual behavior can prevent unnecessary exposure to lead.

Biological exposure to lead is assessed using blood lead or bone lead measurements. It is estimated that of the total body burden of lead, about 90% is found in bone, 2-8% in soft tissues, and 1% in blood (Barltrop and Smith, 1972; Rabinowitz, 1991; Rabinowitz et al, 1976). Of the total blood fraction, over 90% is found in erythrocytes (Barltrop and Smith, 1972). This overall distribution of body burden depends on exposure and age as well as other factors. At older ages and

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with other physiological stressors, the blood lead can be a composite of current exposure and lead remobilized from bone (past exposure). The most reliable indicator of cumulative exposure to lead is X-ray fluorescence (XRF) measurement of lead deposited in the tibia (Todd and Chettle, 1994); this lead has a 30-year half-life. However, the most commonly used measure of exposure is blood lead from venipuncture. Since erythrocytes have a life span of about 120 days, blood lead gives an estimate of recent systemic exposure with an average elimination half-life of 30 days (Rabinowitz et al, 1976). In occupational settings, blood lead will therefore be a composite of recent exposure combined with redistribution of lead stored in bone from past exposure. Even after cessation of external exposure, bone lead reservoirs can contribute substantially to BLLs for years. A low BLL will not necessarily indicate low cumulative exposure, and health effects due to high past exposure may confound studies when current BLLs are found to be low. Studies that use bone lead to capture cumulative exposures may better predict chronic adverse health outcomes, whereas BLLs may be associated with shorter duration effects. Although BLLs are the most common approach to monitoring individual exposure to lead, bone lead studies could be used to estimate long term occupational exposures, particularly in cases that are difficult to assess. Future discussion and assessment of the utility of bone lead as a measure of chronic exposure is needed.

With respect to women Service members, the implementation of separate guidelines to keep BLLs lower than those in men is an issue that may need further discussion. Exposure of women Service members to lead is likely lower than that of men, at least in terms of population number. However, this is likely to change as the Army moves to involve women in all aspects of training and warfare, including shoot house training. This issue is likely to become increasingly important in the future.

While industrial hygiene efforts are important in reducing lead exposure, the DoD is also working on replacing lead in small arms projectiles and primers. The Army is currently fielding the 5.56mm M855A1 Enhanced Performance Round which has a lead-free projectile (Woods, 2010), although there is currently a prohibition against using this round in many shoot house facilities due to concerns about round penetration and travel distance. Another DoD effort is examining the replacement of lead-based primers (Eck, 2014) while the Air Force has been using lead-free frangible bullets since 2004 (AFIOH, 2008). Substitution dramatically reduces the risk of exposure, and in the long term is the best way to eliminate the health risks associated with lead. While the BLL guidelines proposed here offer improved protection for DoD personnel exposed to lead, eliminating or reducing lead in ammunition, including the projectile and the primer, would likely have a significant impact on BLLs across the DoD.

## 9 Recommendations and Measurement of Progress

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### Recommendations

1. The DoD should adopt the BLL management guidelines outlined in Table 2.
2. Consider a future peer-reviewed revision of the guidelines to review health effects based on emerging studies.
3. Redefine the medical surveillance enrollment criteria from the current OSHA standards based on air exposures to selection based on job categories, tasks, and/or exposure levels. The selection criteria will need to be part of a comprehensive lead medical surveillance program which will be driven by IHWG and OMWG
4. Review and improve the tracking of BLLs, especially in transient military populations that have probability for high exposures. Improve databases so that job classification can be linked to BLLs.
5. Conduct studies on the relative importance of routes of exposure and the particle size distribution of airborne lead so that appropriate exposure standards and controls can be designed and implemented.
6. Develop or adapt an exposure/dose model that can be used to establish appropriate environmental/occupational standards that correlate with the revised lower BLL guidelines.
7. Expedite product substitution for lead in ammunition and explosives.
8. Explore the utility and applicability of bone lead for studies of DoD populations.
9. Consider a National Health and Nutrition Examination Survey (NHANES)-like or prospective study on DoD personnel examining measurable adverse health effects and BLL (or bone Pb).

### Measurement of Progress

1. Form a multidisciplinary DoD standing committee to review and monitor lead exposure, improvements, blood lead distributions, and track the evolution of new lead exposure standards.
2. Continue to monitor and evaluate emerging evidence of health effects of blood lead at levels listed in Table 2.
3. Periodically review BLL data in applicable DoD databases to assess the effectiveness of DoD-wide efforts to reduce lead exposure as well as monitor trends.
4. Review the Defense Occupational and Environmental Health Readiness System (DOEHRS) Industrial Hygiene database to assess trends in exposure.

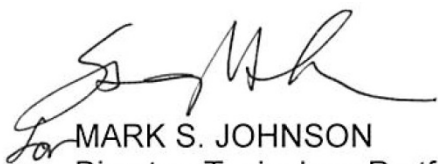
## 10 Point of Contact

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### APPENDIX A

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