

American College of Occupational and Environmental Medicine
Docket No. OSHA–2018–0004

Following are ACOEM's responses to many of the questions posed by the agency in the ANPRM:

OSHA Question 1: *Should OSHA consider changing the BLL at which an employee in general industry or construction is to be removed from lead exposure to match any of the approaches described above? Is there a different BLL trigger for removing a worker from lead-exposed work that you would suggest? Please explain your answer and provide supporting information or data, if available.*

ACOEM affirms the recommendation set forth in its 2016 position statement on Workplace Lead Exposure (Holland & Cawthorn 2016) that the goal of workplace protections and policies should be to maintain all workers' BLLs less than 10 µg/dL. To the extent that OSHA's question #1 refers specifically to medical removal protection (MRP) benefits under the OSHA lead standards, ACOEM affirms its position that mandatory MRP should be promptly instituted for a single BLL ≥ 30 µg/dL, or for two successive BLL ≥ 20 µg/dL measured at a 4-week interval. This same recommendation was issued by a panel of experts in 2007 (Kosnett et al 2007), and the California Department of Public Health (CDPH 2019). ACOEM emphasizes that the existence of MRP triggers at these BLLs does not indicate that health concerns and the need for lead exposure mitigation should begin at the mandatory MRP BLL. Rather, as discussed further below, a series of graded educational, industrial hygiene, and medical surveillance interventions preceding mandatory MRP should be instituted at lower BLL thresholds, including discretionary MRP based on a physician's evaluation of an individual worker's health and reproductive status.

As shown in Table 2 of the OSHA ANPRM notice of June 28, 2022 (OSHA 2022) elevated lead exposure is associated with a myriad of multisystemic adverse health effects. Although it was inexplicably not cited in that table, ACOEM finds particularly compelling the epidemiological studies that establish that long term (years to decades) exposure to blood lead concentrations in the range of 10 to 25 µg/dL substantially increase the risk of **death** from cardiovascular and cerebrovascular disease. The general U.S. population experienced years to decades of BLLs that averaged in this range from the 1940s through the early 1980s (Sawyer et al 1940; Robinson et al 1958; Hofreuter et al 1961; Working Group on Lead Contamination 1965; Goldwater & Hoover 1967; Thomas et al 1967; EPA 1973; Mahaffey et al 1982; NCHS 1984). During this time, the widespread use of leaded gasoline and the common presence of lead in residential paint, soldered food and beverage containers, and plumbing for potable water resulted in ubiquitous lead exposure. Consequently, the health effects experienced by the general population during this time period has particular relevance to the risk posed by contemporary occupational exposure at similar BLLs.

Five large prospective cohort studies of individuals from the general population who lived a considerable proportion of their lives when BLLs averaged 10 to 25 µg/dL have revealed a significant association between markers of lead exposure or lead burden and cardiovascular mortality. The National Health and Nutrition Evaluation Surveys (NHANES) conducted by the National Center for Health Statistics of the U.S. Centers for Disease Control and Prevention are large stratified, multistage probability surveys designed to select a representative sample of the civilian, noninstitutionalized U.S. population. Lustberg and Silbergeld (2002) examined the mortality experience through 1992 of adult participants in NHANES II who were age 30 to 74 years between 1976 to 1980 and who had a baseline blood lead concentration of less than 30 µg/dL (N = 4190). After adjustment for multiple potential confounders (age, sex, location,

education, race, income, smoking, BMI, and exercise), BLLs of 20 to 29 µg/dL at baseline were associated with 39% increased mortality from circulatory disease (RR 1.39; 95% CI 1.01-1.91), and BLLs of 10 to 19 µg/dL were associated with 10% increased mortality from circulatory disease (RR 1.10; 95% CI 0.85 – 1.43), compared with baseline BLLs less than 10 µg/dL.

A similar prospective cohort study was conducted by Schober et al (2006) on a subset of participants in NHANES III who were recruited in two successive 3-year phases between 1988 to 1994. Baseline blood lead concentration was available from 9,762 subjects ≥40 years of age. Mortality status and cause were assessed through 2000 (median length of follow-up 8.55 years). After adjustment for multiple potential confounders including sex, race/ethnicity, education, and smoking status, Cox proportional hazards regression using age as the time scale to examine the relative hazard (relative risk) found that BLLs >10 µg/dL at baseline were associated with a 55% increase in mortality from cardiovascular disease (RR 1.55, 95% CI 1.16-2.07), and BLLs of 5 to 9 µg/dL were associated with a 20% increase in mortality (RR 1.20; 95% CI 0.93 – 1.55), compared with BLLs less than 5 µg/dL. The test for trend by BLL group was also statistically significant (P <0.01). The group containing a baseline BLL >10 µg/dL had a median BLL of 11.8 µg/dL, with few subjects having BLL >20 µg/dL. Because of the phase out of lead in gasoline beginning in the late 1970s, and the decline in BLL with reduction in all exogenous exposure, the blood lead concentrations of individuals >40 years of age at the time of their recruitment into NHANES III were likely lower than the BLLs they experienced earlier in their lives. However, since the subjects were a representative sample of the general U.S. population, their *cumulative* lead exposure was strongly influenced by BLLs in the 10 to 25 µg/dL range that were typical from the 1940s to 1970s.

Menke et al (2006) conducted a different Cox regression analysis of the mortality experience through 2000 of NHANES III participants >17 years of age at baseline whose blood lead concentration was less than 10 µg/dL (N = 13,946). After adjusting for multiple potential confounders, successive terciles of baseline BLLs were associated with increased risk of death from myocardial infarction and stroke. Compared to subjects in the lowest tercile of BLL (≤1.93 µg/dL) those in the highest tercile BLL (≥3.63 µg/dL) experienced an 89% increased risk of death from myocardial infarction (RR 1.89; 95% CI 1.04-3.43) and a 151% increased risk of death from stroke (RR 2.51; 95% CI 1.20 – 5.26). As with the analysis by Schober et al (2006), the cumulative lead exposure of the participants, and likely their baseline blood lead concentration at the time of recruitment between 1988 to 1994, were strongly influenced by BLLs in the 10 to 25 µg/dL range experienced earlier in life.

Lanphear et al (2018) extended the analysis of Menke et al (2006) by reporting the cause-specific mortality experience of NHANES III participants through 2011 (N = 14,289; median 19.3 years of follow-up). In examining the risks associated with an increase in baseline log-transformed BLL from 1.0 to 6.7 µg/dL (10th to 90th percentile), after adjustment for multiple confounders the hazard ratio (relative risk) for cardiovascular disease mortality increased 70% (HR 1.70; 95% CI 1.30 – 2.20), and that for ischemic heart disease mortality increased by 108% (HR 2.08; 95% CI 1.52 – 2.85). When the relationship between baseline blood lead and mortality was fitted by five-knot restricted cubic splines to visualize the shape of the dose-response curve, the steepness of the relationship between blood lead and both cardiovascular mortality and ischemic heart disease mortality were steeper in subjects with a baseline blood lead <5 µg/dL than for those baseline blood lead 5 to 10 µg/dL. In addition, the relationship between baseline blood lead and both cardiovascular mortality and ischemic heart disease mortality were greater in subjects who were younger than 50 years of age at baseline compared to those who were older.

Because lead accumulates in bone with a half-life of years to decades, measurement of lead in bone by noninvasive K x-ray fluorescence (KXRF) offers advantages over blood lead as a biomarker of long-term cumulative lead exposure (Hu et al 2007). The Normative Aging Study (NAS) is a multidisciplinary longitudinal study of aging in men begun in 1963 when 2,280 healthy men from the Greater Boston area between the ages of 21 and 80 years were enrolled. In the 1990s (mean 1994 ± 3 years) KXRF measurement of lead in bone and blood lead were collected on a subset of active participants (Weisskopf et al 2009; Weisskopf et al 2015). In the fully adjusted model confined to subjects who were <45 years of age at the time of NAS study entry (N = 637), hazard ratios for cause specific mortality through 2007 were assessed by tercile of patella lead concentration. Analyses were adjusted for age at KXRF measurement, smoking, and education, as well as occupation and salary and parental age and occupation at NAS study entry. Inverse probability weighting based on selected health characteristics (such as diastolic blood pressure and BMI) were applied as an additional adjustment so that the subpopulation who participated in the KXRF measurements were representative of all NAS subjects alive at the time of the KXRF sub-study enrollment. Using individuals in the lowest tercile of patella bone lead (<20 µg Pb per gram of bone mineral) as the reference group, subjects in the highest tercile of bone lead (>31 µg/g) exhibited a relative risk of 2.47 (95% CI 1.23 – 4.96) for all cardiovascular mortality, and a relative risk of 5.20 (95% CI 1.61 – 16.8) for ischemic heart disease mortality. Blood lead, which averaged ≈5 µg/dL at the time of the KXRF substudy enrollment, was not a predictor of mortality (Weisskopf et al 2015). This prospective cohort study demonstrated that bone lead, a biomarker of cumulative lead exposure, was predictive of cardiovascular mortality in individuals who lived a significant proportion of their lives at a time when BLLs of 10 to 25 µg/dL were common.

Other epidemiological, clinical, and experimental studies are coherent in establishing lead exposure as a cause of death from cardiovascular disease. At low to moderate dose, lead has been demonstrated to increase blood pressure, alter cardiac conduction, increase vascular reactivity, induce oxidative stress, increase expression of pro-inflammatory cytokines, and alter endothelial cell function (ATSDR 2020). Occupational cohort mortality studies have observed an increased standardized mortality rate for cardiovascular disease in lead smelter workers (Gerhardsson et al 1995), and a significant relationship between blood lead and cardiovascular mortality within occupational cohorts assembled from large medical surveillance datasets (Steenland et al 2017; Barry & Steenland 2019).

ACOEM considers the weight of the evidence supporting the need for revised standards to reduce occupational lead exposure and the blood lead levels of workers to be among the most conclusive and compelling that has ever existed for a workplace chemical regulated by OSHA. First, a key health endpoint of demonstrable concern is death, as compared to subtle or subclinical changes in organ function. Second, the abundant epidemiological data that support the causal relationship arise from multiple large, well-controlled, prospective cohort studies – the most rigorous and persuasive epidemiological study design. Third, causal inference is supported not only through multiple high quality epidemiological studies that have extensively adjusted for confounders and bias, but also by numerous experimental and clinical observations that have identified plausible modes of action at consistent doses. Fourth, because cardiovascular mortality is the most prevalent cause of death in the U.S. population, the more than 50% increase in mortality risk associated with BLLs in the range of 10 to 25 µg/dL results in a marked increase in the absolute number of deaths. Fifth, the magnitude of the cardiovascular mortality risk arising from lead exposure exceeds that of other prominent risk factors, such as smoking, elevated cholesterol, and hypertension, that have been the subject of extensive public health concern. Finally, blood lead levels of a magnitude linked to cardiovascular mortality remain prevalent in numerous workplaces.

ACOEM recommends that OSHA lead standards require a qualified supervising physician to review, interpret and respond to all BLLs and other data obtained as part of workplace lead biomonitoring and medical surveillance program. As stated earlier, the goal of such a program should be to maintain all BLLs less than 10 µg/dL. Although MRP should be mandated for a single BLL ≥30 µg/dL or two BLLs at 4-week intervals ≥20 µg/dL, the supervising physician should have the independent discretion and authority to order MRP at a lower BLL based upon an individual worker's medical history or health status. In revising its lead standards, OSHA should explicitly acknowledge that medical conditions, including 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 may pose a risk of material impairment of an employee's health at BLLs that chronically are ≥10 µg/dL. Accordingly, such conditions may indicate the need for physician-ordered MRP at BLLs ≥10 µg/dL, or at lower BLLs based on physician discretion (Kosnett et al 2007). In view of some evidence of the adverse impact of low-level prenatal lead exposure on neurodevelopment and reproductive outcome, and the absence of any identifiable BLL threshold for the deleterious effects of postnatal lead exposure on neurocognitive development (CDC 2010; ATSDR 2020) it is advisable for women who are or who may become pregnant to avoid occupational lead exposure that would elevate BLL concentrations above the CDC reference value for lead (currently 3.5 µg/dL) (CDC 2022).

Consistent with our recommendation that a qualified physician be given the discretion to order MRP or other lead exposure reduction for a worker at any BLL based upon the worker's health status or condition, ACOEM further recommends that all workers eligible for biological monitoring (including BLL testing) under a revised OSHA lead standard annually complete a confidential health history form that should be forwarded to a qualified supervising physician for review. This health history form should report on health conditions, including but not limited to all of those cited in the paragraph above, that may increase the worker's risk of material health impairment from lead exposure. In addition to reporting whether the worker is known to have hypertension, the form should also document an annual measurement of the employee's blood pressure. This health information, together with review of all biological monitoring test results, will assist the physician's determination of the need for ordering discretionary MRP or other reductions in an employee's occupational lead exposure. Physicians should be empowered to request confidential consultation, including physical examination, of any employee who completes a health history form. Employees should have the option of supplementing or revising the information provided on the annual health history form at any time for further physician review based on changes in their health status (including reproductive status).

ACOEM believes that the workplace lead exposure conditions acceptable for a worker undergoing MRP should be more protective than mere removal from work involving airborne exposure to lead at or above the action level (AL), which is 30 µg/m³ under the current OSHA lead standards. As further explained in ACOEM's responses to OSHA ANPRM Questions 5 and 14 regarding requirements for blood lead testing and revised PEL/AL respectively, ACOEM believes that substantial lead exposure may occur in certain job conditions or activities not subject to exceedance of an airborne AL, and that the PEL and AL should be reduced. Consistent with the recommendations of Kosnett et al (2007), ACOEM believes that "removal from occupational lead exposure will usually require transfer of the individual out of any environment or task that might be expected to raise the blood lead concentration of a person not using personal protective equipment above background levels," currently approximately 3.5 µg/dL at the 97.5th percentile. The suitability of alternative job tasks or locations at a workplace for an employee undergoing MRP could be discerned in part by the pattern of blood lead concentrations documented in

other workers who engage in candidate alternative tasks or work in other locations without the use of PPE. In addition, consistent with the Cal/OSHA 2016 discussion draft lead standards pertaining to “temporary removal due to elevated blood lead levels” MRP should result in a removal of an employee “from work having an exposure to lead at or above the action level, and from work altering or disturbing any material containing lead at a concentration equal to or greater than 0.5% by weight” (Cal/OSHA discussion draft for General Industry [Cal/OSHA 2016a]), and additionally from work that constitutes any trigger task defined in the Cal/OSHA discussion draft for Construction (Cal/OSHA 2016b). The rationale for these stringent criteria pertaining to suitable alternative work during MRP is to facilitate relatively rapid reduction in BLL, and to reduce to the greatest extent feasible further hazardous exposure to lead.

While the stated goal to maintain workers’ BLL below 10 µg/dL (or <3.5 µg/dL in the case of women who are or may become pregnant) is supported by extensive scientific evidence, the evidence does not establish that these same BLLs constitute thresholds below which adverse effects are unlikely to occur. Based on contemporary medical knowledge, these BLL values provide at best a slim margin of safety. It is possible that future epidemiological studies of adult populations who have seldom or never sustained BLLs above 10 µg/dL will detect a lead-related risk of cardiovascular morbidity and mortality, as well as other significant health effects associated with long-term exposure. The emergence of such findings will require further protective policies and regulations. A principle of regulatory toxicology and public health holds that standards governing hazardous exposures should offer a margin of safety below levels that pose a significant adverse risk to health. In issuing its 2016 final rule on occupational exposure to respirable crystalline silica, OSHA explicitly noted that “OSHA may incorporate a margin of safety even if it theoretically regulates below the lower limit of significant risk” (OSHA, *Federal Register* 2016). In view of this, it would be reasonable for OSHA to enact occupational lead standards whose goal is to maintain all worker blood lead concentrations less than 5 µg/dL, or less than the CDC reference value in the case of workers who are or may become pregnant.

OSHA Question 2: *Should OSHA consider changing the BLL below which an employee shall be returned to lead exposure to 15 µg/dL? Is there a different BLL trigger for returning a worker to lead-exposed work following medical removal that you would suggest? Please explain your answer and provide supporting information or data, if available.*

ACOEM believes that following MRP for an elevated blood lead concentration, return to work should be considered, based on a physician’s review of the worker’s health and work status, when BLL has declined to less than 15 µg/dL. BLLs assessed for the purpose of return to work decisions after MRP should be measured at monthly intervals. ACOEM believes that considering intraindividual and laboratory variability, a return to work BLL of 15 µg/dL will usually reflect a true reduction the worker’s BLL. As noted in ACOEM’s response to OSHA ANPRM Question 1, the physician who supervises workplace biological monitoring and medical surveillance for the worker should have the discretion, on a case-by-case basis, to continue MRP until a worker’s BLL has declined to a value <15 as necessary to avoid material impairment to a worker’s health from lead exposure. This will include consideration of a worker’s reproductive status, and their ability to procreate a healthy child.

ACOEM believes that return of a worker after MRP should be predicated on the supervising physician’s assessment that the conditions that resulted in MRP, including but not limited to lead exposure resulting in a BLL that may have triggered MRP, are unlikely to resume. Consistent with provisions proposed in the

draft lead standards of Cal/OSHA (and a similar requirement proposed by the Washington state Division of Occupational Health and Safety (DOSH 2019)), employers should be required to issue a “written elevated blood lead level response plan with a description of specific means that will be employed to reduce and maintain employee blood lead levels below 10 µg/dL” (Cal/OSHA discussion draft 2016 §5198(j)(2)(D)). The physician’s decision to authorize return to work after MRP may be based, in part, on a review of this written plan and communication with the employer, the employer’s industrial hygiene, safety, or engineering consultants, and/or the employee to assess the suitability of the response plan and its implementation.

OSHA Question 3: *Are these still appropriate tests or should a full medical examination include any other tests? OSHA is also requesting comment on the appropriateness of including the ZPP given its limitations (see also Section #6, “ZPP” below).*

ACOEM concurs with the recommendation of Kosnett et al (2007) that, with the exception of ZPP, the content of the baseline or preplacement history and physical examination for lead-exposed workers should continue to follow the comprehensive scope set forth in the OSHA lead standard for general industry. Measurement of serum creatinine will identify individuals with chronic renal dysfunction who may be subject to increased health risks from lead exposure. With the exception of an annual blood pressure measurement and a brief questionnaire (health history form) regarding the presence of medical conditions (such as renal insufficiency) or reproductive status that might increase the risk of adverse health effects of lead exposure, medical evaluations for lead-exposed workers should be unnecessary as long as blood lead concentrations are maintained <20 µg/dL.

Note: *ACOEM is providing a combined narrative response to OSHA’s questions 4 and 5:*

OSHA Question 4: *Should OSHA consider expanding its criteria for blood lead monitoring to resemble the ongoing blood lead monitoring criteria that Washington DOSH and/or Cal/OSHA is considering? Are there different criteria you would suggest? Please explain your answers.*

OSHA Question 5: *Should OSHA consider adding criteria other than airborne lead exposure to its requirements for blood lead testing, such as contact with lead-contaminated surfaces, disturbance of lead-containing materials or direct contact with high-percentage lead materials? In particular, should OSHA consider adopting criteria based on contact with lead-contaminated surfaces, disturbance of lead-containing materials, or contact high lead-content metals, as Washington DOSH’s stakeholder review draft and Cal/OSHA’s discussion draft contemplate? Please explain your answer.*

ACOEM believes that OSHA should expand the criteria that mandate biological monitoring (including blood lead testing) and medical surveillance in both its general industry and construction lead standards. ACOEM endorses the expanded criteria for these programs set forth in the Cal/OSHA discussion draft standards of 2016.

The current OSHA standard for general industry, which relies entirely on employee exposure to airborne lead at or above the current action level of 30 µg/m³ for more than 30 days per year to trigger biological monitoring, is inadequately protective of worker health for several reasons:

1. As discussed further in ACOEM's response to ANPRM Question 14, validated biokinetic modeling and epidemiological data have established that workplace exposure to airborne lead should be considerably less than $30 \mu\text{g}/\text{m}^3$ in order to maintain the 95th percentile worker's blood lead concentration less than $10 \mu\text{g}/\text{dL}$ after months of steady state exposure. In the case of the females of reproductive age, on the order of 1 month of exposure at $10 \mu\text{g}/\text{m}^3$ would likely result in the 95th percentile worker's blood lead level exceeding the CDC blood reference value of $3.5 \mu\text{g}/\text{dL}$.
2. Occupational health professionals have found that many lead-exposed workers have elevated BLLs even when air lead levels are below the current Action Level of $30 \mu\text{g}/\text{m}^3$. In such situations, lead ingestion via hand-to-mouth activity probably accounts for the exposures, rather than inhalation of airborne lead. These risks can be quite significant in industries that grind, polish, or otherwise disturb lead-containing materials such as brass alloys, tin-lead solder, pottery glaze, lead weights, and bullet fragments, among others. BLLs in such workers can often exceed 10 to $20 \mu\text{g}/\text{dL}$ and may occasionally range as high as 50 to $60 \mu\text{g}/\text{dL}$ even when air lead levels are below $30 \mu\text{g}/\text{m}^3$.

ACOEM believes that exclusive reliance on the airborne lead monitoring fails to identify the severity of lead hazards in many workplaces. California's pending rulemaking on state lead standards included a cost-benefit analysis published in 2020 (Rohland-Holst et al). This study, a "Standardized Regulatory Impact Analysis (SRIA)," estimated the number of employees in various industries who were likely to have significant workplace exposure to lead. Extrapolated from California to the nation as a whole, the data suggest that as many as 2 million American workers have occupational lead exposure high enough to elevate BLL's above 5 to $10 \mu\text{g}/\text{dL}$. The great majority of these workers will not currently fall under the scope of the OSHA lead standards, because in most of their workplaces, air lead levels are below $30 \mu\text{g}/\text{m}^3$.

3. The current OSHA standard's exclusive reliance on exceedances of airborne lead action levels to trigger the need for blood lead testing has long been suspected to contribute to widespread undercompliance with this aspect of biological monitoring. Employers in many lead-using workplaces, especially those with relatively few employees or low to moderate exposure levels, fail to conduct air monitoring, and thus never obtain evidence of action level exceedance. This was documented by Rudolph et al (1990) soon after the establishment of the California Occupational Blood Lead Registry as a component of laboratory-based surveillance for occupational lead poisoning. In that study, only 2.6% of workplaces engaged in lead-using processes (employing an estimated 205,000 workers) were estimated to have ever done environmental monitoring for lead. Moreover, only 1.4% of these workplaces had routine biological monitoring programs. A study conducted by the Los Angeles County Department of Health Services in 1992 (Papanek et al), and another in Ohio in 2000 (Okun 2000) likewise found low compliance with all lead monitoring requirements. For more than 30 years, the Occupational Lead Poisoning Prevention Program (OLPPP) of the California Department of Health has conducted extensive education, surveillance, and outreach for primary and secondary prevention of the problem. Nevertheless, OLPPP continues to conclude that "many employers fail to provide BLL testing to their lead-exposed workers" and that the blood lead data reported to the state blood lead registry "likely represent a significant underestimate of the number of California workers exposed to lead" (Payne et al 2016).
4. Even when it is conducted, air monitoring for lead may fail to document substantial lead exposure (and hence exceedance of the airborne action level) if such monitoring were scheduled or performed in a manner that avoided places and times when peak workplace exposure occurred. In many such cases it would be challenging for OSHA to ascertain that this may have occurred.

ACOEM endorses the approach set forth in the Cal/OSHA general industry standard discussion draft of 2016 [§5198 (j) Medical Surveillance] that would require implementation of a medical surveillance program, to include periodic blood lead monitoring, for workers exposed at or above an Action Level of 2 [two] $\mu\text{g}/\text{m}^3$ for 10 or more days per year, and for employees who perform “a trigger amount of lead work.” A trigger amount of lead work, which is specified in detail in §5198 (b) Definitions, is based on altering or disturbing material that contains lead at a concentration $\geq 0.5\%$ by weight, or torch cutting any scrap metal. (Note: provisions are made in the discussion draft concerning the duration per month of these activities and the magnitude of BLLs that are observed in involved employees over time). ACOEM believes that the approach to require medical surveillance and blood lead monitoring on workers who alter or disturb lead containing material irrespective of airborne exposure is essential to assure adequate worker protection. In like manner, ACOEM endorses the approach set forth in the Cal/OSHA construction standard discussion draft of 2016 that requires medical surveillance based on exceedance of an airborne action level and based on performance of various trigger tasks associated with lead exposure for a specified duration.

OSHA Question 6: *Should OSHA consider revising the required frequency and the BLLs related to the schedule of blood lead testing? Would requirements similar to those included in Washington DOSH and Cal/OSHA’s drafts be appropriate? If not, what would be an appropriate frequency for blood lead testing? Please explain your answer.*

ACOEM agrees with the proposed schedule for BLL testing set forth in the Cal/OSHA discussion draft lead standards, which are similar to those recommended in ACOEM’s 2016 position statement (Holland and Crawford 2016).

The Cal/OSHA general industry draft (Cal/OSHA, 2016a) would require BLL testing:

1. Prior to assignment for work covered by subsection (j)(1)(A); or as soon as possible when work is first determined to be covered by subsection (j)(1)(A);
2. For each employee covered under subsection (j)(1)(A), at least every 2 months for the first 6 months and every 6 months thereafter
3. After a change in task resulting in or likely to result in higher lead exposure, at least every 2 months for the first 6 months and every 6 months thereafter;
4. At least every 2 months for each employee whose last blood sampling and analysis indicated a blood lead level was at or above 10 $\mu\text{g}/\text{dL}$ but below 20 $\mu\text{g}/\text{dL}$ of whole blood. This frequency shall continue until two consecutive blood lead levels taken at least 30 days apart, are below 10 $\mu\text{g}/\text{dL}$ of whole blood, and
5. At least monthly for each employee whose last blood lead level was at or above 20 $\mu\text{g}/\text{dL}$ of whole blood, and during the removal period of each employee removed from exposure to lead due to an elevated blood lead level.

The Cal/OSHA construction industry draft (Cal/OSHA, 2016b) would require BLL testing:

1. For each employee covered under subsection (j)(1)(B), initially in accordance with (j)(1)(A), and then at least every 2 months for the first 6 months after initial placement, and also for the 6 months after any change in task resulting in higher exposure; and then every 6 months thereafter; and
2. For each employee covered under subsections (j)(1)(A) or (B) whose last blood test indicated a blood lead level at or above 10 $\mu\text{g}/\text{dL}$ but below 20 $\mu\text{g}/\text{dL}$ of whole blood, at least every two months. This

frequency shall continue until two consecutive blood lead levels taken at least 30 days apart, are below 10 µg/dL, and

3. At least monthly for each employee whose last blood test indicated a blood lead level at or above 20 µg/dL of whole blood, and during the removal period of each employee who is removed from exposure to lead due to an elevated blood lead level
4. At least monthly, as interim protection in accordance with (d)(2)(E), for each employee conducting a level 3 trigger task as listed in (d)(2)(D), including a blood test taken within 3 days after discontinuing all level 3 trigger task work; and
5. At least monthly for each employee whose airborne exposure is above 500 µg/m³ without regard to the use of respirators. Including a blood test taken within 3 days after discontinuing all work associated with airborne exposure above 500 µg/m³.

ACOEM believes this frequency of blood lead testing will facilitate recognition of potentially hazardous lead exposure and will provide for secondary prevention of lead-related adverse health effects.

OSHA Question 11: *“Should OSHA revise its general industry standard to require employers to notify all employees who receive blood lead testing of their results, similar to the requirements of its construction standard and requirements under consideration by Washington DOSH and Cal/OSHA?”*

Yes, ACOEM concurs with the need to revise the general industry lead standard to require that employees be notified of every BLL test result, as well as all other biological monitoring test results, within 5 days of the date that results are available from the clinical laboratory. In addition, ACOEM believes that further revisions are necessary regarding the manner in which the employee notification occurs:

- A. Employee notification of the BLL results should occur in the form of a letter addressed to and sent directly to the employee from a licensed physician charged with supervising the biological monitoring and medical surveillance program conducted for lead-exposed employees. It would be acceptable for the letter to be transmitted by confidential mail or email or hand delivery at the workplace, depending on the preference identified in advance by each employee.
- B. The physician should also include in the letter to the employee the following:
 - a. Interpretative guidance concerning the BLL test results respect to adverse health outcomes that have been associated with a range of BLL exposures;
 - b. A cumulative log of all the employee’s past BLL test results;
 - c. The minimum time interval at which another BLL test should be conducted.
 - d. The physician's opinion as to whether the employee has any detected medical condition which would place the employee at increased risk of material impairment of the employee's health from exposure to lead;
 - e. Any recommended special protective measures to be provided to the employee, or limitations to be placed upon the employee's exposure to lead;
 - f. Any recommended limitation upon the employee's use of respirators, including a determination of whether the employee can wear a powered air purifying respirator if a physician determines that the employee cannot wear a negative pressure respirator;
 - g. The results, along with interpretative guidance, any other biological monitoring tests, including pregnancy or fertility tests, and medical examinations, that have been conducted as part of the medical surveillance program and biological monitoring program;

- h. Notification of any medical condition, occupational or nonoccupational, that has become apparent to the physician as a result of review of all the employee's medical surveillance data, that dictates further medical examination or treatment;
 - i. As proposed by Cal/OSHA discussion draft general industry lead standard 2016 §5198(j)(C) [Employee notification], a statement that the revised lead standard requires the employer to make medical examinations and consultations available, as soon as possible, upon notification by an employee either that the employee has developed signs or symptoms commonly associated with lead intoxication, that the employee desires medical advice concerning the effects of current or past exposure to lead on the employee's ability to procreate a healthy child, or that the employee has demonstrated difficulty in breathing during a respirator fit test or during use;
 - j. Updated provisions regarding Medical Removal Benefits (see further ACOEM response to Question 1);
 - k. A means by which the employee can confidentially contact the physician to discuss further questions or health concerns regarding occupational lead exposure.
- C. Upon their request, employees who participate in biological monitoring and medical surveillance conducted for lead-exposed employees should have the option of requesting that the physician letter be confidentially translated to Spanish, or such other language as may be appropriate for the employee.

ACOEM believes that the interpretation of blood lead levels (BLLs) and trends of them over time requires an understanding of the toxicology and toxicokinetics of lead in the body. Because of this complexity, the review and communication of the BLL test results and the results of other evaluations should be conducted by a physician with requisite training and knowledge regarding lead, including the adverse effects of lead and conditions predisposing to them. ACOEM believes that direct communication between the physicians who supervise the biological monitoring and medical surveillance program and each participating employee emphasizes the medical significance and importance of these programs. Each physician engaged in the review, interpretation, and communication of biological monitoring and medical surveillance data collected in accordance with provisions of a revised OSHA lead standard should be provided access to all prior health data, lead exposure data, industrial hygiene information, restrictions and medical removal experience pertaining to the employee's lead exposure.

ACOEM believes that to assist physicians in the formulation of written communication to the employee, OSHA should issue, as an appendix to the revised lead standard or other means, recommended interpretative guidance on the relationship between blood lead, other medical tests, risks to current and future health status, and lead exposure. OSHA's suggested interpretative guidance should be updated periodically to reflect the evolving state of scientific and medical knowledge pertaining to the assessment, prevention, and management of the health effects of lead. Such interpretative guidance should be subject to expert peer review.

OSHA Question 12: *Should OSHA remove the requirement for ZPP testing currently included in its lead standards? Please explain your recommendation to continue or discontinue ZPP testing as part of medical surveillance for lead-exposed workers.*

ACOEM believes that since ZPP is insufficiently sensitive when BLLs are below 25 µg/dL, ZPP testing should no longer be required as part of routine baseline and periodic medical surveillance (Holland and Crawford 2016). Instead, ZPP testing should be considered as an optional test which may be ordered in

specific circumstances, according to the judgment of the examining physician. Because there is may be lag of several weeks between acute elevations in BLL >30 to 40 µg/dL and the appearance of an elevated ZPP, measurement of BLL and ZPP in certain circumstances may have some utility in assessing the temporal pattern of a highly elevated BLL.

OSHA Question 13: *Should OSHA update the lead standards' employee privacy protections, including restriction of employer access to an individual employee's BLL measurements? Please explain your recommendation.*

ACOEM believes that the approach to privacy protection that exists in the current OSHA lead standards is satisfactory. This approach permits the employer to receive the results of all employee BLL test results, and the contents of "written medical opinions" under the provisions of section 1910.1025(j)(3)(v). As proposed in the Cal/OSHA discussion drafts on Written Medical Opinions, this written opinion should include, "The physician's opinion as to whether the employee has any detected health-related condition which would place the employee's health, including the ability to procreate a healthy child, at increased risk of material impairment of the employee's health from exposure to lead." Findings, including laboratory results or diagnoses unrelated to an employee's occupational exposure to lead, should not be disclosed.

ACOEM believes that effective reduction of occupational lead exposure and the prevention of related adverse health effects often requires cooperative interaction between employees, employers, industrial hygienists, industrial engineers, physicians and other health and safety professionals. This process may be enhanced by integrating information on work practices, engineering controls, exposure data, use of personal protective and individual employee blood lead levels. Accordingly, ACOEM does not recommend action to restrict employer access to individual employee's BLL measurements. Notwithstanding the foregoing, employer retaliation or discrimination against an employee based on medical findings, including BLLs, should be strictly prohibited.

OSHA Question 14: *Should OSHA consider reducing its PEL of 50 µg/m³ for occupational lead exposure or its action level of 30 µg/m³? At what level do you believe the PEL should be set to reduce the harmful effects of lead exposure in exposed workers? Do you think this level would be technologically and economically feasible for affected industries (see OSH Act Sec. 6(b)(5), 29 U.S.C. 655(b)(5))? Please explain your answer and, if available, provide data pertinent to the benefits, feasibility, and expected increase in costs of revising the federal PEL or action level for airborne lead.*

ACOEM believes that effective worker health protection requires a reduction of the current lead standards' PEL and action level for lead. Numerous epidemiological studies have demonstrated a significant positive relationship between airborne lead concentration and workers' blood lead concentrations. Biokinetic models based on the toxicokinetics of lead have used epidemiological data as a means of calibrating and confirming the models (NASEM 2020). Recently, two independently developed biokinetic models, the Leggett+ model and the DoD-O'Flaherty model, have been published to assist regulators in the identification of airborne occupational exposure limits (i.e., permissible exposure limits) for lead that would maintain workers' blood lead concentration below various thresholds. The Leggett+ model (Vork et al 2013; Vork & Carlisle 2020), published by the California Office of Environmental Health Hazard Evaluation at the request of the California Department of Health,

estimated various concentrations of lead in workplace air inhaled by workers without respiratory protection that could result in specified lead concentrations in workers' blood. Assuming 40 years of working life exposure beginning at age 25 and a background blood lead concentration of 1.5 µg/dL, the model predicted that an 8-hour time weighted average PEL of 2.1 µg/m³ would result in a 95th percentile BLL of 10 µg/dL. A PEL of 10.4 µg/m³ would yield a 95th percentile BLL of 30 µg/dL.

The DoD-O'Flaherty biokinetic model (Sweeney 2019; Sweeney 2021), based on a model first developed by O'Flaherty, differed from the Leggett+ model by relying on somewhat different physiological assumptions, and by considering the impact of a worker's birth year and accumulated lifetime lead exposure to assess the impact of adult workplace lead exposure. It predicted the blood lead distribution that would have existed in the DoD workforce on January 1, 2018, had the current DoD workforce, composed of men and women of various ages, been historically exposed full-time to specified levels of airborne lead since they were 18 years of age. The DoD-O'Flaherty model related various candidate occupational exposure levels to corresponding predictions of the 95th percentile BLL. It predicted that a PEL of 3.6 µg/m³ would yield a 95th percentile blood lead concentration of 10 µg/dL (Sweeney 2019). In a formal review of the DoD-O'Flaherty model, the National Academies of Science, Engineering, and Medicine found that the Leggett+ model and DoD-O'Flaherty model "described available BLLs with similar accuracy... The consistency of simulated BLLs between the DoD-O'Flaherty model and Leggett+ model provided additional evidence of the reasonableness of the model inputs and assumptions" (NASEM 2020).

The California Department of Public Health has recommended that Cal/OSHA adopt a PEL of either 0.5 or 2.1 µg/m³ in order to maintain workers' BLL less than 10 µg/dL. (CDPH 2013). The Cal/OSHA discussion draft of 2016 proposed a PEL of 10 µg/m³ and an Action Level of 2 µg/m³.

In establishing requirements for: 1) basic hygiene requirements for all workers with occupational lead exposure; 2) medical surveillance requirements (including blood lead measurements) that would be required if an Action Level of 2 µg/m³ were exceeded for ≥10 days per year, or irrespective of air measurements if a "trigger amount of lead work" were performed; 3) exposure monitoring at least every 12 months if the Action Level were exceeded, with more frequent monitoring dependent on the magnitude exposure; and 4) a written plan for investigation and deficiency correction in the case of a blood lead ≥10 µg/dL, Cal/OSHA's discussion draft standard evinced a commitment to the goal of keeping blood lead concentrations less than 10 µg/dL for all lead workers. However, by establishing a PEL of 10 µg/m³, Cal/OSHA sought to provide employers with flexibility in the approach to maintaining all workers' blood lead levels below this value.

As noted in discussions held before the Cal/OSHA Advisory Meetings for Revision of the General Industry and Construction Lead Standards, it was recognized that the selection of PEL carries with it an implication for work that can be performed with various types of respirators based on their respective protection factors. For example, abrasive blasting of lead-coated surfaces (such as steel bridges covered with lead paint) is customarily performed by workers inside enclosures equipped with supplied air respirators with protection factors of 1000. If the PEL were 2 µg/m³, this work could be performed with a supplied air respirator only if the exposure within the enclosure were less than 2,000 µg/m³. According to some stakeholder comments at meetings of the Cal/OSHA Advisory Meetings, air levels inside enclosures during abrasive blasting may sometimes be in the range of 5,000 µg/m³. The selection of a PEL of 10 would allow supplied air respirators to be used inside an enclosure provided the exposure were less than 10,000 µg/m³. In like manner, full-face respirators have a protection factor of 50. A PEL of

10 ug/m³ would allow employers to use full face respirators in environments where air levels extended up to 500 ug/m³, instead of up to 100 ug/m³ as would be the case with a PEL of 2 ug/m³.

A Standardized Regulatory Impact Assessment (SRIA) issued by the California Department of Industrial Relations in 2020 found that Cal/OSHA's proposed revisions to the occupational lead standards were feasible and were associated with a large benefit-cost ratio (Roland-Horst et al 2020). CDIR concluded, "As the full, long-term benefits of the proposed regulatory revisions are realized, the annual benefit-cost ratios for this regulation are quite high and sustained, with benefits expected to be substantially larger than compliance costs. However, compliance costs begin to accrue immediately while the health benefits manifest themselves over time (Figure 3). The estimated aggregate breakeven point under the assumptions of this assessment would occur approximately within the first 7 years after the proposed revisions come into effect. It should also be recalled that the benefit estimates used in this study are not comprehensive and total benefits are expected to be substantially higher" (Roland-Horst et al 2020). According to Figure 3 in the SRIA, if the revised lead standards were introduced in 2020, the net financial benefit by 2040 would be approximately \$3,800,000,000.00 (3.8 billion dollars) unadjusted for inflation.

ACOEM considers the Cal/OSHA proposal for a PEL of 10 µg/m³ and an action level of 2 µg/m³ to be feasible and health protective when combined with the additional provisions set forth in proposed Cal/OSHA discussion draft standards. ACOEM urges OSHA to revise its federal OSHA lead standards to include a PEL and Action Level at least as stringent (i.e., health protective) as the Cal/OSHA proposal.

Note: ACOEM is providing a combined narrative response to OSHA's questions 15 and 16:

OSHA Question 15: *Cal/OSHA's discussion draft includes a Separate Engineering Control Airborne Limit (SECAL) for selected processes in lead acid battery manufacturing. Should OSHA consider implementing a SECAL for occupational lead exposure for specific processes if industry-wide compliance with a proposed revision to the PEL is demonstrably infeasible for specific processes?*

OSHA Question 16: *Should OSHA consider removing the provision of OSHA's general industry lead standard that allows employers to use respiratory protection to comply with the PEL for workers exposed to lead above the PEL for 30 days or less per year? Please explain your answer and, if applicable, your recommendation on how employers should be required to limit exposures of workers exposed above the PEL for 30 days or less per year.*

ACOEM believes it may be acceptable for OSHA to consider implementation of a SECAL for selected processes provided that a comprehensive, multi-faceted, impartial, and transparent assessment by OSHA demonstrate that adherence to a proposed PEL of 10 µg/m³ (or lower) is demonstrably infeasible for specific processes in specific industries.

ACOEM believes that OSHA should remove the provision of OSHA's general industry lead standard (1910.1025(e)1) that require the implementation of engineering and work practice controls only when "any employee is exposed to lead above the permissible exposure limit *for more than 30 days per year*" (emphasis added). ACOEM instead endorses the approach proposed in the Cal/OSHA general industry draft of 2016 [§5198 (e)(1)(A)] that states, except for the case of a SECAL, "where any employee is exposed to lead above the permissible exposure limit, the employer shall implement engineering, and work practice controls, including administrative controls, to reduce and maintain employee exposure to

lead at or below the permissible exposure limit except to the extent that the employer can demonstrate that such controls are not feasible.”

ACOEM believes that clinical experience and biokinetic modeling demonstrate that employees who sustain high dose airborne exposure while performing tasks for less than 30 days per year may experience cumulative lead exposure, and a cumulative blood lead index (expressed as $\mu\text{g}/\text{dL}\cdot\text{days}$) that exceed that of employees exposed at the PEL for a full working year. It depends on the magnitude of the exposure and absorbed lead dose associated with the task(s) conducted. This can be illustrated by simulations run with biokinetic models such as Leggett+ (Vork and Carlisle 2020) or the EPA All Ages Lead Model (EPA 2019). The chronic health effects of lead are associated with cumulative lead exposure. For employees who are or may become pregnant, short term high dose exposure for less than 30 days can exert adverse reproductive effects. Although respiratory protection may remain part of a program to protect workers engaged in lead work less than 30 days per year, the employees should still benefit from feasible engineering and work practice controls.

Note: ACOEM is providing a combined narrative response to OSHA’s questions 19 and 20:

OSHA Question 19: *Should OSHA add hygiene and PPE provisions similar to any or all of those described above, which are being considered for adoption by Washington DOSH? Please explain your answer and, if available, provide information on the feasibility and cost of these.*

OSHA Question 20: *Are there issues or concerns related to surface contamination or material content criteria for hygiene and PPE requirements that OSHA should consider?*

ACOEM does not agree with the criteria proposed by Washington DOSH to trigger hygiene requirements and PPE cited in the OSHA ANPRM section D(19). ACOEM believes these trigger criteria proposed by Washington DOSH are insufficiently protective of worker health. No scientific foundation has been presented to justify the criteria as a threshold for the demonstration of potentially hazardous occupational lead exposure. ACOEM believes that substantial worker lead exposure may in fact occur when employees work in areas containing surface lead contamination far below a “surface action level” of $1,000 \mu\text{g}/\text{dm}^2$ (equivalent to $9290 \mu\text{g}/\text{ft}^2$). In like manner, ACOEM believes that clinical experience and the scientific literature have demonstrated that metals, such as brass or other lead alloys, that contain considerably less than 20% lead by weight may be the source of potentially hazardous levels of lead exposure when altered or disturbed in the workplace.

ACOEM concurs with more health protective provisions proposed in the Cal/OSHA discussion draft lead standards including but not limited to the requirements for general hygiene education, and hazard communication whenever there may be “occupational exposure to lead.”

OSHA Question 23: *Should OSHA consider a safe harbor protocol approach similar to the Well Managed Blood Lead Levels protocol described above, which is being considered for adoption in Washington State? What aspects of the protocol would be beneficial? Are there issues, concerns, or different approaches to a “safe harbor” based on well-managed BLLs that OSHA should consider?*

ACOEM recommends that OSHA **NOT** consider a safe harbor protocol approach similar to the Well Managed Blood Lead Levels protocol described by the Washington 2019 draft rule WAC 296-857-50060.

For the reasons cited below, there is considerable doubt that a safe harbor of this nature would efficiently or satisfactorily detect and prevent hazardous lead exposures.

Under the protocol entitled “Well Managed Blood Lead Levels” set forth in the 2019 draft version of WAC 296-857-50060 “the employer is given greater flexibility for implementing personal protective equipment, work practices, and lead controls where the employer demonstrates that their program effectively controls employee blood lead levels.” For workplaces determined to fulfill the provisions of this safe harbor, the main rule’s permissible exposure level (PEL) of 20 $\mu\text{g}/\text{m}^3$ would not be enforced, and only the secondary permissible exposure level of 50 $\mu\text{g}/\text{m}^3$ would apply. Certain provisions mandated under the main rule for workers exposed above the PEL of 20 $\mu\text{g}/\text{m}^3$ would not apply until exposure was $\geq 50 \mu\text{g}/\text{m}^3$. These provisions would include requirements for changing facilities, showers, separate eating facilities, weekly change out of PPE, and written periodic control plans for tools and work practices. Moreover, for workplaces meeting this safe harbor “the department will not conduct scheduled inspections at the establishment.” To comply with this safe harbor, baseline and at least annual BLLs must be collected for all exposed and potentially exposed workers. The annual average BLL for workers exposed above the PEL of 20 $\mu\text{g}/\text{m}^3$ must be below 10 $\mu\text{g}/\text{dL}$, and no worker should have a BLL of $\geq 20 \mu\text{g}/\text{dL}$. All other workers onsite must have BLLs less than 10 $\mu\text{g}/\text{dL}$. An employer can remain in compliance with this safe harbor even if “infrequent” BLLs above 20 $\mu\text{g}/\text{dL}$ are detected provided that the employer “documents the exposure incident responsible for the elevated blood lead level and takes corrective action effectively preventing further exposures.” Also, an “infrequent” BLL $>20 \mu\text{g}/\text{dL}$ would not interfere with safe harbor designation if the involved worker’s baseline BLL was $>20 \mu\text{g}/\text{dL}$. In accordance with the main rule, workers with BLL $>10 \mu\text{g}/\text{dL}$ must be reported to the Department of Occupational Safety and Health (DOSH), and those who have a BLL $>10 \mu\text{g}/\text{dL}$ for more than 4 months “must have their case reviewed by a physician.”

To qualify for this safe harbor, employers must submit documents annually for each worksite describing a lead control program, assessment of lead exposure risks, names, and exposure levels of all workers onsite in the previous two years, all blood lead testing results, and actions taken in response to lead exposure risks and elevated BLLs.

Rationale to support this safe harbor: Although cumulative lead exposure and take-home lead are important health and safety factors, cross-sectional worker blood lead levels are a primary target of efforts to address the health risks associated with occupational lead exposure. This protocol gives employers wide latitude in devising their own methods to protect workers, including increased reliance on personal protective equipment such as respirators.

Rationale to oppose to this safe harbor: Multiple aspects of this safe harbor provision are problematic:

1. Under this safe harbor, workplaces in which half of employees have BLLs between 10 and 19.9 $\mu\text{g}/\text{dL}$ would still be considered to have “well-managed blood lead levels.” Tolerance for this extent of lead absorption in a workforce would ignore conclusive evidence that BLLs chronically in this range pose a risk of serious morbidity and mortality (see further ACOEM comments on OSHA ANPRM Question 1).
2. Under this safe harbor, several worker protection provisions of the standard would be enforced only after the annual average BLL in the workplace exceeded 10 $\mu\text{g}/\text{dL}$, or a single worker had a BLL $\geq 20 \mu\text{g}/\text{dL}$. Furthermore, no methodology is presented for determination of the annual “average” BLL in a workforce. Calculation of an annual average BLL may be challenging in workplaces experiencing changes in the number of employees and their duration of service over the course of the year. This

may include changes in employment prompted by departure from the workforce of workers with elevated BLLs. This safe harbor provision does not specify what type of work duties would classify an individual as a lead worker whose blood lead level should be included in calculation of the workplace annual average. It is concerning that some establishments might calculate “average” BLL values for the workforce by including blood lead measurements obtained on clerical or other workers unexposed to lead in an effort to diminish the average value. At the same time, there may be an incentive to omit blood lead monitoring on workers who in fact had high BLLs in order to depress the overall workplace average BLL. Annual blood level measurements in an establishment could be timed to avoid intermittent or seasonal periods of high lead exposure that might otherwise be detected by exposure monitoring. Blood lead measurements conducted prior to a change in work practices or production methods that may increase lead exposure would fail to detect this increase.

3. It appears that this safe harbor may allow increased reliance on use of personal protective equipment, including respirators, as a means to reduce blood lead concentrations. This would be contrary to the traditional hierarchy of exposure controls in which feasible engineering controls and work practices are preferred methods of mitigating hazardous exposures.
4. Although this safe harbor provision stipulates it may apply to an establishment if employee exceedances of the 20 µg/dL threshold were “infrequent,” no definition of what constitutes “infrequent” is offered.
5. This safe harbor provision refers to a mandatory “physician review” of workers who maintain BLLs >10 µg/dL but offers no explanation of what such a review would entail, or what corrective actions would be required.
6. There are apparently no case studies that have documented the health, safety, or cost experience of a representative workplace that adhered to this specific safe harbor.

OSHA Question 24: *Should OSHA consider a safe harbor protocol approach similar to the Clean Areas protocol described above, which is being considered for adoption in Washington State? What aspects of the protocol would be beneficial? Are there issues, concerns, or different approaches to a “safe harbor” based on identification of clean areas using surface sampling that OSHA should consider?*

ACOEM recommends that OSHA **NOT** consider a safe harbor protocol approach similar to the Clean Areas protocol described by the Washington draft rule WAC 296-857-50050. For the reasons set forth below, there is no assurance that a safe harbor of this nature would effectively detect and prevent hazardous lead exposures. Sufficient scientific foundation is lacking to exempt workers from the protection of OSHA lead standards based on an assessment that their work area contains less than certain thresholds of surface lead loading. Although lead surface loading assessments conducted by an industrial hygienist or other certified specialist might rule-in the potential for substantive lead exposure, criteria for the application of a lead standard should always include an examination of air lead concentrations and an assessment of whether workers are engaged in defined lead-related work or tasks, such as the “trigger amount of lead work” defined in the Cal/OSHA discussion draft lead standards of 2016 [cf. §5198 (b), and § 1532.1 (a) and (b)].

The draft Washington “Clean Areas” protocol (WAC 296-857-50050) allows an employer to designate part of a facility as “clean” and to exempt workers in those areas who do not engage in “lead-related tasks” from the lead rule. This protocol applies to “establishments which have lead but are successfully controlling lead hazards.” The rule cites as an example the offices in a worksite where weights or

batteries are manufactured. This safe harbor also applies to facilities where lead is present in building materials but is undisturbed.

Under this safe harbor, the key criteria for designation of a “lead-free area” are the employer’s assumption that “no lead exposure” occurs in the area, and the demonstration by surface lead sampling that all worker accessible surfaces contain lead at a value of less than 4.3 $\mu\text{g}/\text{dm}^2$. The rule requires an initial single sample test in “worst case conditions, prior to cleaning and representative of surfaces regularly touch [sic] by workers.” It also specifies the size and number of surface areas that should be sampled. If initial sampling revealed elevated surface lead levels, then the area may still be designated “clean” if on subsequent four sample testing “no samples are above 43 $\mu\text{g}/\text{dm}^2$, the third samples are below 27 $\mu\text{g}/\text{dm}^2$, and the fourth samples are not significantly below the third samples.” The safe harbor calls for “repeat representative testing every six months unless third samples are below 4.3 $\mu\text{g}/\text{dm}^2$. If third samples are below 4.3 $\mu\text{g}/\text{dm}^2$, sampling is repeated every 2 years.”

Rationale in favor of this safe harbor: This safe harbor allows employers to designate areas of a facility and workers in that area that will not fall under any of the lead rules, likely resulting in employer cost-savings.

Rationale in opposition to this safe harbor. Multiple aspects of this proposed safe harbor are problematic:

1. No scientific foundation, including a validated biokinetic model, has been established or presented that adequately relates workplace surface lead loading with employee blood lead concentrations. Accordingly, a scientific justification is lacking for the quantitative lead surface loading thresholds proposed under this safe harbor, i.e., 43 $\mu\text{g}/\text{dm}^2$, 27 $\mu\text{g}/\text{dm}^2$, and 4.3 $\mu\text{g}/\text{dm}^2$. This lack of foundation applies not only to surfaces involved with work activities, but also to worksite surfaces used for other activities such as eating, drinking, or preparing food. It may be noted that the U.S. EPA and U.S. Department of Housing and Urban Development (HUD) in 2021 implemented revised clearance standards for lead dust in residential floors and windowsills of 10 $\mu\text{g}/\text{ft}^2$ ($\approx 1.0 \mu\text{g}/\text{dm}^2$) and 100 $\mu\text{g}/\text{ft}^2$ ($\approx 10.8 \mu\text{g}/\text{dm}^2$). However, these clearance values were based on mechanistic models (including the IEUBK model) and epidemiological studies pertaining to residential exposure to young children. They were not intended nor were they demonstrated to apply to occupational lead exposure. In the workplace, adults may be continuously exposed to numerous lead contaminated surfaces including tabletops, tools, instruments, packages, and furniture, as well as surfaces used for eating or food preparation. The chemical form and solubility of inorganic lead on workplace surfaces may differ from that encountered by children in residences, and surface lead in the workplace may become mixed with various chemicals, such as solvents, cleaning agents, polishes, and oils, that may alter how it may be absorbed into the body.
2. Reliance on surface wipe sampling of worker accessible surfaces to establish that an area is “clean” or “lead free” is based on unvalidated assumptions. Wipe sampling is customarily applied to flat surfaces such as countertops or floors, but well-validated methods or protocols do not exist to quantitate lead loading on other worker accessible surfaces, such as irregular surfaces on and inside of parts or machinery, certain tools, utensils, and instruments. Although the draft Washington state lead standard provides some basic instructions on the performance of surface wipe sampling (WAC 296-857-60010, Surface Sampling—General), it does not specify that the sampling be performed by industrial hygienists or other properly trained and certified specialists, or that the proficiency of the sampling be subject to review or verification.

3. This safe harbor assumes, in the absence of scientific foundation provided by research or well documented case studies, that if certain thresholds of surface lead loading are not exceeded exclusively at the time of a wipe sampling event conducted once every 2 years area, then no substantive potential for occupational lead exposure by ingestion or inhalation will occur or has occurred in the work area. No validated justification is available to support the proposed two-year interval between surface wipe sampling requirements. Although the proposed safe harbor provides that biannual surface sampling be conducted “in worst case conditions, prior to cleaning and representative of surfaces regularly touch [sic] by workers,” the terms that characterize these particular provisions are ill-defined. For example, the minimum time interval that should elapse between any prior surface cleaning and the surface sampling event is not specified. There is no assurance nor documentation that the lead loading on a surface that is cleaned in the course of business operations will accurately reflect the amount of airborne lead dust or fume that a worker may inhale, or that a worker may absorb through the skin or ingest by direct or indirect hand to mouth transfer of a lead-containing substance that is handled, manipulated, or disturbed but not disseminated to workplace surfaces.
4. The proposed safe harbor indicates that employers need not “implement the requirements of the rule for workers in clean areas who do not have any *lead-related tasks*” [emphasis added]. However, no definition is offered for what constitutes a “lead-related task.” Moreover, workers exempted from protection under the rule because their job duties may not be considered to involve “lead-related tasks” could nonetheless be subject to by-stander exposure or other unanticipated lead exposure pathways (e.g., lead translocated within the workplace on shoes or clothing, or by intermittent movement of lead contaminated materials through a work area).

Information provided to OSHA by ACOEM in response to OSHA Questions 32, 33, 34, 42, 44, and 51.

Section H of OSHA’s Advance Notice of Proposed Rule Making, entitled, “Questions for Employers on Current Practices” requests comments that report on current employer practices regarding management of workplace lead exposure. In this regard, ACOEM is making available to OSHA via this link <https://vimeo.com/764669383> a presentation recorded at ACOEM’s American Occupational Health Conference in Denver, Colo., on May 10, 2017. The audio-visual presentation is an mp4 video file entitled “Gerry Manley, RSR AOHC May 10, 2017 ACOEM.” Mr. Manley was Vice President for EHS Compliance of the RSR Corporation, a secondary lead smelting company that operates lead acid battery recycling facilities in California, Indiana, and New York. In 2017, RSR Corporation was reprocessing 30 million scrap lead acid batteries annually and supplying 300,000 tons of recycled lead to battery manufacturers. Mr. Manley’s presentation, entitled “Effectively Managing Lead Exposure in Industry: A Case Study of RSR’s Success in the Secondary Lead Recycling Industry” reported on his company’s progress in reducing employee blood lead levels, and its support for revisions in medical removal protection proposed under the Cal/OSHA 2016 discussion draft lead standard for general industry. As reported in Mr. Manley’s presentation, the average BLL of RSR employees in 2017 was 8.7 µg/dL. Mr. Manley also presented data indicating RSR’s progress obtaining BLL reductions in employees with long job tenure.

ACOEM is also submitting as an informational attachment for OSHA a document by the Association of European Automotive and Industrial Batteries Manufacturers (EUROBAT) downloaded from EUROBAT and the European Commission website. The document was entitled “EUROBAT Feedback on Call for evidence for an impact assessment – Directive protecting workers from risks related to exposure to chemical agents (98/24/EC) 21 March 2022.” The document stated in part, “EUROBAT agrees with the Government Interest Group (GIG)’s view presented in the ACSH [EC Advisory Committee on Health and

Safety at Work] opinion with regards to the BLV [biological limit value], i.e. that the existing BLV should be revised down from 700 µg Pb/L blood to 150 µg Pb/L blood....EUROBAT concurs with the three interest groups of the ACSH that medical surveillance should be triggered at a level corresponding to workplace exposure and be lower than the 150 µg Pb/L BLV.” The file containing the EUROBAT document is attached as a pdf file entitled, “EUROBAT and BLV BLL of 15 µg-dl 2022.pdf.”

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