October 28, 2022

Mr. Andrew Levinson
Director
Directorate of Standards and Guidance
U.S. Department of Labor
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**VIA *Regulations.gov***

RE: Advanced Notice of Proposed Rule Making (ANPRM) – Blood Lead Level for Medical Removal
87 Fed. Reg. 38,343; Regulations.gov Docket No. OSHA-2018-0004

Dear Mr. Levinson:

Battery Council International (BCI) appreciates the opportunity to participate in the Occupational Safety and Health Administration Division of Occupational Safety and Health's (OSHA's) review of occupational lead standards. Because this inquiry could have dramatic effects on workers and industries across the nation, it must be thorough, deliberate, and based on the best available scientific, economic, and real-world information applicable to today's workplaces.

BCI greatly appreciates the numerous in-depth questions posed by OSHA in the ANPRM. These appear to demonstrate OSHA's commitment to conducting the necessary level of review. As described below, many of the topics and questions raised will require serious consideration by the agency and impacted industry and workers, and will require the collection of new data and new analyses. BCI and its members are committed to active and constructive engagement with OSHA throughout this process. We thus have provided responses to many of the issues the ANPRM raises and OSHA's questions that are relevant to our member's concerns for which we have been able to complete our member-consultation.

## I. <u>BCI AND THE LEAD BATTERY INDUSTRY'S OCCUPATIONAL SAFETY AND HEALTH LEADERSHIP</u>

BCI is a non-profit trade association whose members are engaged in the manufacture, distribution, and recycling of rechargeable batteries around the world.

BCI's manufacturing members manufacture lead batteries and battery components for automotive low voltage applications (*e.g.,* combustion-engine SLI and EV auxiliary batteries); marine, recreational, and powersports vehicle power; stationary back-up power applications; grid-connected energy storage; industrial vehicle motive power (*e.g.*, forklifts, mining vehicles); military applications; and innumerable other critical applications. BCI members account for over 98% of U.S. lead battery production. The lead battery manufacturing industry is the single largest user of lead in the nation, with lead battery production accounting for approximately 92% of the lead consumed in the United States each year.[1]

BCI's battery recycler members also represent 100% of the U.S. lead battery recycling (*i.e.*, secondary lead smelting) capacity, which itself accounts for 100% of U.S. lead metal production. Battery recyclers are responsible for the facilities and processes that ensure that approximately 99% of used lead batteries are recycled to reclaim their various lead components as raw materials to manufacture new lead batteries.

Our industry promotes lead battery recycling by collecting and recycling lead batteries, encouraging the enactment of mandatory lead battery recycling laws, and supporting ongoing consumer and industry education efforts. BCI's members have approximately 25,000 employees in the U.S. They are located in every state and employed in battery manufacturing, sales, distribution, maintenance, and recycling.

The lead battery industry also possesses the nation's largest pool of industrial lead EHS and industrial hygiene professionals and experts. We stand ready to partner with OSHA to offer the agency assistance in evaluating and understanding real-world lead control and worker protection measures that no other industry can match.

Through BCI members' considerable efforts, and unwavering commitment to understanding and controlling lead exposures and to the safe operations of its members' facilities, members of the lead battery industry are probably the nation's companies most attuned to the safe use of lead. Since 1997, BCI-member battery manufacturing and recycling companies voluntarily have implemented a highly-effective program to achieve employee occupational health goals significantly more protective than those required by OSHA.

As you know, at the program's beginning, the industry signed a five-year program agreement with OSHA.[2] Based on the success of the first five-year effort, the industry voluntarily continued the program and has regularly strengthened it. BCI and its members also worked collaboratively with OSHA to develop the OSHA eTools for battery manufacturing[3] and lead battery recycling facilities.[4]

The program continues to spur reductions in worker blood lead levels and drive continuous improvement across the industry. The most recent program updates were adopted in April 2022 and provide the framework for meeting lower blood lead levels, with a goal of maintaining blood lead levels at or below 20 µg/dL by 2025 for all workers.[5] These voluntary efforts demonstrate the industry's commitment to protecting workers from inappropriate lead exposures, and have helped industry

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[1] U.S. Geological Survey, 2022 Minerals Yearbook, Lead, *available at* https://pubs.usgs.gov/periodicals/mcs2022/mcs2022-lead.pdf.

[2] U.S. Occupational Safety and Health Administration, Press Release 96-457, OSHA, Lead Industries Announce Voluntary Industry Initiative to Reduce Worker Exposure to Lead (Oct. 30, 1996).

[3] U.S. Occupational Safety and Health Administration, Lead: Battery Manufacturing eTool https://www.osha.gov/etools/battery-manufacturing.

[4] U.S. Occupational Safety and Health Administration, Lead: Secondary Lead Smelter eTool https://www.osha.gov/etools/lead-smelter.

[5] Additional information available at: https://batterycouncil.org/page/BCI-Blood-Lead-Program

participants achieve year-over-year reductions in workforce blood lead levels for the last two and a half decades.

The result of these efforts has been profound. Today, a significant majority of BCI member company employees in lead-exposed positions have blood lead levels below 10 µg/dL, and the average blood lead level across the industry is below 9 µg/dL. BCI believes these advances likely are informative to OSHA's analysis of potential changes to the regulatory framework.

## II. INDUSTRY ENGAGEMENT IN ONGOING STATE RULEMAKINGS

BCI and our members have been actively engaged in the deliberative and rulemaking processes in the various states that have evaluated and/or adopted revisions to their state implementations of lead occupational exposure rules. BCI provides responses and comment on certain provisions of those state efforts about which OSHA has requested comment below. In this section, however, we provide our overarching perspectives on those efforts.

As an initial matter, BCI commends Michigan, California, and Washington for their dedication to carefully evaluating the appropriate and feasible worker health protections, and each state's concerted efforts to engage with industry, impacted employees, and other stakeholders to seek input as to the practical realities of controlling lead exposures in workplaces. While BCI is still very concerned that some of the approaches being considered by those states will create more issues than they resolve, the collaborative approach of those states' various stakeholder engagement sessions has been productive and pointed the way to significant improvements. BCI encourages OSHA to engage in a similar process of open and continuing dialogue.

In particular, BCI applauds the state of Michigan for clearly focusing its regulatory update efforts on worker blood lead levels as the primary indicator of worker health. BCI believes the approach taken by MI-OSHA – viewing blood lead level medical removal and return to work thresholds as *the* critical factors in protecting employees' health – is the right approach. This approach protects worker health without undue disruption and interference with company operations. MI-OSHA correctly recognized that, given companies' various and unique operational conditions, the EHS professionals at each facility are best positioned determine how to protect workers.

## III. OSHA MUST MEET ITS STATUTORILY MANDATED SUBSTANTIVE AND PROCEDURAL REQUIREMENTS

The Occupational Safety Act of 1970 (OSH Act) requires that the agency perform an independent and accurate evaluation of adverse health impacts associated with lead exposure in US workplaces in the forthcoming rulemaking and propose only those standards that are supported by the best available science, feasible, and sufficient and necessary to protect US workers. Notably, these need not be identical to those applied to workers in other nations, who may face very different legal prerequisites, historical practices, and current circumstances.

The OSH Act authorizes the promulgation of occupational safety and health standards which shall identify the conditions or practices deemed reasonably necessary to provide a safe workplace. 29 U.S.C. § 652. OSHA is required to meet specific statutory elements for the development and adoption of occupational safety and health standards. 29 U.S.C. § 655. The Act provides the following guidance to the agency in setting these standards:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. . . . In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. [29 U.S.C. § 655(b)(5).]

OSHA must make formal findings with regard to each of the elements set forth above. OSHA may not defer these tasks to other government entities, such as agencies of California or Washington.

## A. OSHA Must Establish a Need for the Standard.

As explained in our comments, BCI supports OSHA efforts to thoughtfully evaluate potential changes to the lead standard and the applicable blood lead criteria. As stated above and explained further herein, the industry established voluntary programs decades ago that today seek blood lead levels well below the current regulatory limits. BCI encourages OSHA to ensure that workers in all industries are adequately protected from occupational lead exposure.

Lowering the Permissible Exposure Limit (PEL) (and/or the Action Level) included in the lead standard is another matter entirely. The vast experience that BCI and our members have developed in this area suggests that there is real question about whether a lower PEL will materially improve workplace protections. As discussed in these comments, both industry experience and new and ongoing studies demonstrate that very low blood lead levels in workers are readily achievable in work areas with air lead levels approaching today's PEL – even without respiratory PPE. Further, and important to the regulatory decision-makers, expansion of this rulemaking to lower the current PEL and/or Action Level may not be legally supportable under Section 6 of the OSH Act, and almost certainly will turn a rulemaking process generally supported by both industry and employees into one that results in a revised rule that will face a multitude of legal challenges.

As an initial matter, before adopting a new or revised occupational health standard under Section 6 of the Act, OSHA must identify an existing "significant risk" that the standard will protect against (establish evidence that current workplaces are "unsafe" in the language of the courts), and then develop a record showing that its proposed standard (*e.g.*, a lower PEL) is "'reasonably necessary' or appropriate to provide safe or healthful employment." *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 614-15 (1980).

In particular with regard to the PEL for lead, establishing these two fundamental legal prerequisites is not as obvious as some may believe. Battery industry data shows that when companies operate in compliance with the current federal air lead requirements, the large majority of battery plant workers nationwide already have blood lead levels below the lower medical removal levels suggested by Michigan, California, and Washington. Furthermore, under our voluntary industry program, BCI members have committed to having 100% of industry employees maintain blood lead levels below 20 µg/dL by the end of 2025. This data indicates that a lower PEL is not necessary to achieve the identified risk reduction objective.

Before imposing more restrictive standards, therefore, OSHA's findings will need to recognize and be squared with this data and also must avoid undermining the approaches that have been successful to reach the blood lead levels at battery manufacturing and recycling facilities across the nation.

## B. <u>OSHA Must Establish a "Material" Impairment is Present.</u>

In addition to establishing the need for a revised standard, OSHA also must look to whether the standard would address a "material" impairment. 29 U.S.C. § 655(b)(5). This statutory language has been judicially interpreted as requiring that OSHA connect the presence of the toxic substance to a "material" impairment. *Indus. Union Dep't, AFL-CIO v. API*, 448 U.S. 607, 647-48 (1980). Thus, in adopting its standards OSHA must demonstrate, with substantial evidence, that use of a toxic substance creates a significant risk of material health impairment. *Id*. at 653.

As noted above and elsewhere, the relationship between workplace air lead levels and blood lead levels is not as definitive or straightforward as some would suggest, and many workers are already achieving well-controlled blood lead levels in a wide variety of work areas. Therefore, in particular with regard to the PEL and Action Level, OSHA must be very thoughtful in properly addressing this issue.

## C. <u>OSHA Must Establish that the Standard is Feasible</u>

The OSH Act also requires that standards be feasible for the regulated community. Specifically, Section 6(b)(5) of the Act states that OSHA shall "set the standard which most adequately assures, *to the extent feasible*, on the basis of the best available evidence, that no employee will suffer material impairment . . . ." (Emphasis added).

The meaning and interpretation of the term "feasibility" has been addressed by the Supreme Court. In *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 508-9 (1981), the Supreme Court held that the plain meaning of the word "feasible" is "capable of being done," and that the legislative history of the Act highlighted Congress' concern that the Act not force an "impossible standard," but instead required that any standard promulgated be "capable of economic and technological accomplishment."[6]

OSHA's finding on feasibility must meet the two-part test set forth in *United Steelworkers v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980) , which holds that standards must be both technologically and economically feasible. *Id.* at 1264.

### 1. <u>Technological Feasibility</u>

A "technologically feasible" standard is one where there is a "reasonable possibility that the typical firm" will be able to implement it. *United Steelworkers v. Marshall*, 647 F.2d 1189, 1272 (D.C. Cir. 1980).

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[6] *See OSHA's Feasibility Policy: The Implications of the Infeasibility of Respirators*, 129 Harv. L. Rev. 2235 (2016) (Senators expressed fear that the original language of the OSH Act would "close every business in [the] nation.").

OSHA may set standards that force the industry to develop new technology, but must make a finding that the standards can actually be attained by industry. *Id.* at 1264-65.

Currently, at least with regard to battery manufacturing and recycling, BCI believes OSHA is likely to find that its burden on technological feasibility cannot be met to justify any substantial revisions to the PEL or many of the other provisions of the current lead standard. As noted above, under a voluntary industry program, BCI members have committed to having 100% of their employees maintain blood lead levels below 20 µg/dL by the end of 2025. As BCI members move towards accomplishing this goal they are already investing in the most technologically feasible engineering controls available. If OSHA were to assert that they should be implementing more restrictive controls (or inconsistent controls to those currently being developed and implemented), it must be able to demonstrate that the industry is somehow capable of doing more. Based on BCI's knowledge of the current state of technology and the operation of member facilities, it seems there would be a very serious question about the technological feasibility of meeting a significantly lower PEL or other ancillary provisions of the standard.

### 2. Economic Feasibility

Economic feasibility relates to the potential for a significantly adverse economic impact on the regulated community. OSHA must assess whether there is a "reasonable likelihood that these costs [association with new or revised provisions in a rule] will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms." *United Steelworkers, supra,* 647 F.2d at 1272. OSHA must show "reasonable assessment of the likely range of costs of its standard, and the likely effects of those costs on the industry." *Id.* at 1266.

OSHA likely will face a substantial challenge in addressing economic feasibility in the forthcoming rulemaking, especially if it expands the rulemaking to reduce the PEL or Action Level. In 1978, when OSHA promulgated the standard., the Court agreed with OSHA's economic feasibility analysis finding that even though compliance costs would force the industry to raise retail automotive battery prices $1.75 (equivalent to more than $8.25 in October 2022)[7], the automotive demand for batteries and the lack of substitutes and foreign competition meant that demand would be "too inelastic for such a retail increase to harm the industry." *United Steelworkers*, 647 F.2d at 1292. OSHA cannot assume that this remains true. In today's global economy, the market, competitiveness and need for batteries has shifted significantly. What qualified as economically feasible in 1978 must be reconsidered in the context of the modern marketplace.

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[7] https://www.bls.gov/data/inflation_calculator.htm.

## IV. RESPONSES TO INDIVIDUAL QUESTIONS POSED BY OSHA'S ANPRM

BCI has made an earnest, genuine, and robust effort to identify, gather, and compile as much relevant and responsive information as it could in the time period it had to provide comment on the ANPRM. This information has been correlated with the questions OSHA identified in the ANPRM, and has been able to develop responses to many of the sixty-one (61) questions posed by OSHA in the ANPRM. For ease of reference, these sections use headers consistent with those in the ANPRM. BCI may have additional information or data to share about both the questions answered below and the additional questions as the rulemaking process proceeds, and BCI looks forward to working with OSHA to further evaluate these issues.

### A. Blood Lead Triggers for Medical Removal Protection

#### 1. Requirements for Medical Removal (Question 1)

*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 in the ANPRM?*

*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.*

BCI believes it is appropriate for OSHA to evaluate an update to the mandatory medical removal levels.

As an initial matter, BCI believes that the blood lead levels chosen by California, Washington, and Michigan as part of their state lead standards efforts represent the lowest feasible levels, and correlate with conservative health objectives based on the state of today's science.

The levels selected in the three states also accord with those recommended by academic as well as other scientific bodies such as NIOSH and ACOEM, other regulatory jurisdictions that set mandatory removal levels (*e.g.*, New Zealand and Australia) and industry's own voluntary programs.[8]

In terms of the structure of the rule, the current general industry standard for lead provides the employer "shall remove an employee from work having an exposure to lead at or above the action level on each occasion that" either:

- "a periodic and a follow-up blood sampling test conducted pursuant to this section indicate that the employee's blood lead level is at or above 60 µg/100 g of whole blood" (29 C.F.R. § 1910.1025(k)(1)(i)(A)); or

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[8] *See, e.g.*, American College of Occupational and Environmental Medicine, Position Statement, Workplace Lead Exposure, JOEM Volume 58, Number 12, December 2016; Cal/OSHA, Draft Changes Submitted for Standardized Regulatory Impact Analysis [to 8 C.C.R. § 5198] (Nov. 11, 2016); Washington/DOSH; WISHA Lead Rule—Stakeholder Review Draft (June 2019); Industry Voluntary Program ; https://batterycouncil.org/page/BCI-Blood-Lead-Program.

- "the average of the last three blood sampling tests conducted pursuant to this section (or the average of all blood sampling tests conducted over the previous six (6) months, whichever is longer) indicates that the employee's blood lead level is at or above 50 µg/100 g of whole blood; provided, however, that an employee need not be removed if the last blood sampling test indicates a blood lead level below 40 µg/100 g of whole blood." 29 C.F.R. § 1910.1025(k)(1)(i)(B).

BCI recommends the retention of the framework of establishing two thresholds for medical removal: a higher level requiring medical removal upon a single confirmed blood lead test, and a lesser level triggering medical removal after a series of tests averaged over six months. Further, BCI recommends retaining the current model that allows an employee to remain in their position if their most recent blood lead result demonstrates a reduction below the medical removal level; given the blood lead under consideration today, that allowance should be triggered if the most recent BLL test is below the 6-month average medical removal level.

BCI also recommends OSHA transition to the modern practice of referring to blood lead levels using the units of micrograms per deciliter (µg/dL). The current regulations are written using the units of micrograms lead per 100 grams of whole blood. OSHA's current Appendices note the equivalency among the various common units, but the inconsistency can create confusion.[9] For consistency, BCI uses µg/dL herein, unless specifically referring to today's OSHA standard or other reference which uses a different unit.

## Long-Term Averaging Medical Removal Threshold

As noted above, BCI believes the long-term average medical removal threshold should be set no lower than 20 µg/dL, which is the lowest feasible level for a medical removal criteria and, as discussed below, represents a conservative threshold based on modern scientific data relevant to workplace exposures. With regard to the removal exemption for demonstrated reductions, BCI believes that it would be appropriate to allow a worker to remain in their position if their most recent blood lead level test shows a blood lead level (BLL) at or below the 6-month average blood lead criteria.

BCI urges that medical removal levels be set based on findings of studies relevant to setting occupational blood lead removal levels as was done by Safe Work Australia (SWA) and the American Council of Governmental Industrial Hygienists (ACGIH.). For example, ACGIH set a BEI (Biological Exposure Index) of 20 µg/dL "[t]o reduce the risk of neurological and neurobehavioral effects and reproductive effects associated with lead exposure."[10]

However, OSHA should avoid inadvertently disincentivizing proactive, regular health monitoring. Accordingly, the standard should not base medical removal to a fixed number of blood lead tests (*e.g.*, "last three tests") unless the requirement is linked with a time-based averaging period (*e.g.*, six months). Without that linkage, such a requirement will discourage proactive monitoring. Employers and employees might choose to voluntarily test blood lead levels more frequently than required by the

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[9] "Blood lead levels (PbB) are most often reported in units of milligrams (mg) or micrograms (µg) of lead (1 mg=1000 µg) per 100 grams (100g), 100 milliliters (100 ml) or deciliter (dl) of blood. These three units are essentially the same." 29 CFR 1910.1200 App. A. (II)(B)(3).

[10] ACGIH, 2020. TLVs and BEIs based on the Documentation of the Threshold Limit Values for Chemical Substances and Physical Agents.

regulations if an employee needs additional feedback on the progress implementing changes to work practices to reduce exposures. OSHA's rules should encourage such voluntary, proactive health monitoring, not inadvertently discourage it.

In evaluating appropriate levels, OSHA should evaluate a principal source of new information: the Study for Promotion of Health in Recycling Lead (SPHERL).[11] SPHERL is a prospective 2-year follow-up study of lead workers with exposure levels varying between and within individuals and addresses the extent to which between-subject differences or within-subject changes in lead exposure may have a measurable effect on blood pressure, the cardiovascular system, renal function, the autonomic nervous system, peripheral nerve conduction velocity, neurocognitive function, and quality of life.

To date, SPHERL has produced more than a dozen peer-reviewed publications and has provided results that have demonstrated no adverse effects on key cardiovascular, neurological, or renal health outcomes as mean BLLs have increased from background (non-occupationally exposed) concentrations of approximately 4 µg/dL to over four times the background level, or around 16 µg/dL. [12] Although mean BLLs were around 16 µg/dL, in SPHERL after one or two years of occupational exposure, more than one-half of the study cohort had BLLs in excess of 20 µg/dL, with some in the cohort having BLLs over 30 µg/dL. The absence of effects in SPHERL participants at these elevated BLLs further supports identification of BLLs in the range of 20 to 30 µg/dL as the trigger for removing a worker from lead-exposed work. The SPHERL study is discussed in detail in the comments of the International Lead Association, whose comments BCI hereby incorporates by reference.

## Single Test Removal Level

One issue OSHA will need to evaluate is whether the levels under consideration for triggering medical removal are best represented by single point-in-time testing as compared with longer term averaging. In 1978, OSHA established the upper "single test" medical removal level threshold at a blood lead level above which OSHA determined appropriate that "at no time should any worker have a [BLL] greater than…"[13]

OSHA further explained that the single medical removal level of 60 µg/100 g was selected due to concerns that a single test results (with confirmation within two weeks) of 60 µg/100 g was indicative of a previously unidentified period of time during which the employee likely had experienced BLLs greater

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[11] Hara A, Gu YM, Petit T, Liu YP, Jacobs L, Zhang ZY, Yang WY, Jin Y, Thijs L, Wei FF, Nawrot TS, Staessen JA. Study for Promotion of Health in Recycling Lead - Rationale and Design. Blood Press. 2015 Jun; 24(3):147-57.

[12] *See* Yang WY, Efremov L, Mujaj B, Zhang ZY, Wei FF, Huang QF, Thijs L, Vanassche T, Nawrot TS, Staessen JA. Association of office and ambulatory blood pressure with blood lead in workers before occupational exposure. J Am Soc Hypertens. 2018 Jan;12(1):14-24; Yu CG, Wei FF, Yang WY, Zhang ZY, Mujaj B, Thijs L, Feng YM, Boggia J, Nawrot TS, Struijker-Boudier HAJ, Staessen JA. Central hemodynamics in relation to blood lead in young men prior to chronic occupational exposure. Blood Press. 2019 Oct;28(5):279-290; Yu YL, Yang WY, Thijs L, Melgarejo JD, Yu CG, Wei DM, Wei FF, Nawrot TS, Zhang ZY, Staessen JA. Two-Year Responses of Office and Ambulatory Blood Pressure to First Occupational Lead Exposure. Hypertension. 2020 Oct; 76(4):1299-1307.

[13] Occupational Exposure to Lead, Attachment to the Preamble for the Final Standard, 43 Fed. Reg. 54,354 at 54,433 (Nov. 21, 1978).

than the long-term averaging medical removal threshold, and that the risks presented at BLLs above 50 µg/100 g warranted prompt medical removal.[14]

The same considerations may not be applicable at the blood lead levels in the range under review today. In 1978, and until very recently, longitudinal studies tracking occupationally exposed individuals over extended periods of time were scarce. That is no longer the case with the publication of the results from the SPHERL study, discussed elsewhere in these comments and in extensive detail in the comments filed by the International Lead Association. And bodies such as the National Academies of Sciences, Engineering, and Medicine have confirmed that the health effects from lead are primarily from accumulation in the body over prolonged exposures.[15]

A new examination of this framework could suggest OSHA consider reducing the emphasis on a single-test mandatory removal level in favor of more refined approaches with primary reliance on longer-term averaging medical removal thresholds. For example, if the 6-month average medical removal level is established at 20 µg/dL, in a circumstance where an employee demonstrated a confirmed BLL test above 30 µg/dL - but with a six-month average BLL below 20 µg/dL - it would be more appropriate for OSHA to require actions such as mandatory remedial training or exposure assessment instead of medical removal. The anticipation is that with prompt attention the worker would be able to reduce their exposure sufficiently to maintain their blood lead level below the 6-month average medical removal threshold.

BCI agrees that mandatory and immediate medical removal based on a single confirmed blood lead test is necessary and appropriate for workers whose blood lead level exceeds 60 µg/dL (a level rarely, if ever, seen in today's well-managed work environments).

## Non-Occupational Exposure Will Create Confounding Influences on Worker Blood Lead Levels

As OSHA considers lowering the BLLs which require medical removal, the agency must recognize that BLLs higher than those under consideration have been observed in the general population due to non-occupational exposures. For example, studies have identified recreational firearms users with median blood lead levels well in excess of the removal levels under consideration.[16]

BCI is concerned that employers will be unnecessarily and unduly required to provide medical removal benefits for workers with non-occupational exposures. Under current federal and state rules, employers are required to provide up to 18 months of medical removal benefits to any employee whose blood lead levels exceed the specified criterion. This rule is strictly based on an employee's blood lead level and does not provide for reducing or waiving the removal period for exposures that are not work-related. This means that an employer could be required to provide full-time pay, and maintain seniority, even for employees whose blood lead levels are caused by sources of lead outside of the workplace. This is

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[14] *See* 43 Fed. Reg. at 54,461.

[15] National Academies of Sciences, Engineering, and Medicine 2022. *Advancing the Framework for Assessing Causality of Health and Welfare Effects to Inform National Ambient Air Quality Standard Reviews*, p. 104. Washington, DC: The National Academies Press. https://doi.org/10.17226/26612.

[16] Laidlaw MAS, Filippelli G, Mielke H, Gulson B, Ball AS. 2017. Lead exposure at firing ranges—a review Environmental Health 16(34) doi: https://doi.org/10.1186/s12940-017-0246-0. (A review of numerous studies of non-occupational exposures and resulting observed blood lead levels).

unfair to not only the employer but all of the removed employee's coworkers. This would be extremely costly, and has the potential to place a severe and undue economic and technical burdens on employers.

Today's medical removal criteria are generally higher than the levels that would normally be anticipated from non-occupational or infrequent recreational exposures (although exceedances have been observed even from recreational exposures). This means that it is relatively rare for employers to be required to provide medical removal benefits due to non-occupational sources of lead exposure. However, such removals are likely to become much more common – perhaps, indeed, regular – under a revised rule. Numerous peer reviewed literature studies have identified individuals with blood leads in excess of the levels under consideration due to recreational and/or non-occupational activities—even including individuals with no known lead exposures at work.[17]

This suggests that under reduced medical removal numerical criterion it would no longer be appropriate for the medical removal provisions to assume that every blood lead level above the numerical criterion is attributable to workplace exposures. Employers must be provided a mechanism to be relieved from providing medical removal benefits for workers whose elevated blood lead levels have been caused by or are maintained at an elevated level due to non-occupational exposures.

To address this concern, BCI supports the concept embodied in the text in the Washington draft rule at WAC 296-857-30010, *i.e.*, medical removal benefits are not required when: (1) The employer has reassessed exposures in the work area and convincingly confirmed that ongoing exposures remain below all action levels, or (2) A physician performs a medical examination and concludes that there is a source of the blood lead not associated with the workplace.

## **OSHA Must Provide an Implementation Schedule to Allow Sufficient Time for Workers and Employers to Meet new Blood Lead Requirements**

Finally, to the extent OSHA proposes substantial revisions to the current lead standard, with regard to BLLs,[18] BCI urges OSHA to ensure appropriate time to meet the new standards by including phase-in periods for new requirements over reasonable periods of time, as was done when the first lead standard was promulgated in 1978 and similar to the phase-in periods OSHA most recently included in the beryllium standard. Final Standard for Occupational Exposure to Lead, 43 Fed. Reg. 52952 (Nov. 14, 1978).[19]

This phased-in approach allowed employers to build an effective program to comply with the standard without imposing immediate exorbitant costs on the regulated community. *Id*. at 52975. A similar approach should be adopted now if OSHA makes any significant revisions to the mandated medical removal threshold.

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[17] See, *e.g.*, *Lead exposure at firing ranges—a review,* Laidlaw *et. al.*, Environmental Health (2017) 16:34 at Page 6.

[18] Implementation schedule concerns for other potential rule elements are addressed *infra*.

[19] *See* section XX *infra* for phase-in considerations for other elements of the changes under consideration.

### 2. Requirements for Return to Lead- Exposed Work (Question 2)

*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.*

If the numerical medical removal criterion is 20 µg/dL, measured as explained in our response to Question 1, BCI believes 15 µg/dL is an the lowest feasible level at which to allow a worker to return to their previous work position.[20]

However, the current general industry standard's requirement that the return-to-work testing must be based on "two consecutive tests" below the numerical criterion would not be appropriate at the levels under consideration. At the levels now under review, a single test below the return-to-work level would be sufficient to demonstrate that the removal has adequately reduced the worker's blood lead level. Because the worker was removed from exposure, there will have been no potential for the worker's blood lead level to re-increase unless the worker has been exposed to non-occupational sources. Extending the removal period by imposing a "waiting period" for return after a blood lead test is unnecessary and would be highly costly to employers and often unfair to other workers.

## B. Medical Surveillance Provisions

### 1. Medical Examination and Consultation Requirements (Question 3)

*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).*

BCI supports following the consensus among medical and occupational health professionals that the best practice is to eliminate the requirements for ZPP testing.

BCI also believes that a full medical examination should include a consultation between the physician and the employee regarding non-occupational exposures. While occupational exposure may (or may not) underlie a particular individual's BLL test result, non-occupational exposures can meaningfully contribute to those levels, or even exceed the contribution to BLLs stemming from occupational exposures – particularly at the lower blood lead levels now under consideration. In addition to lead paint or lead in drinking water, recreational or second-job exposures can have a significant influence.[21] Reducing an individual's blood lead will require addressing all potential sources of lead exposure, and employers cannot control and may be unaware of exposures outside the workplace.

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[20] Footnote 11 in the ANPRM misstates the return to work level in the California draft rules. The most recent publicly-available draft would propose a return to work level of 15 µg/dL.

[21] *Lead exposure at firing ranges—a review,* Laidlaw *et. al.*, Environmental Health (2017) 16:34.

### 2. Triggers for Routine Blood Lead Monitoring (Questions 4 and 5)

*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.*

BCI does not believe that any change in the Action Level is necessary. The current Action Level appropriately defines the criteria for identifying areas of a facility in which airborne lead exposures would be reasonably anticipated to lead to blood lead levels of concern. Reducing the air-lead Action Level would dramatically increase the scope of workers covered nationwide, without necessarily providing meaningful increases in protection. However, employers should and can be encouraged to determine whether there are particular employees in work areas below the Action Level for which medical monitoring should be conducted or other practices implemented.

To the extent OSHA is seriously evaluating a lower Action Level, BCI urges OSHA to recognize that the Action Level of 2 µg/m$^3$ being proposed by California is far too low to be practical or feasible in most work environments, and will have the inappropriate effect of sweeping in testing requirements for many employees who do not need such measures. The types of activities that will create an air lead of 2 µg/m$^3$ are far too numerous and difficult to define.[22]

It is BCI's experience that when dealing with low level exposures, air lead levels are not the primary route of concern in workplace settings and do not have sufficient correlation with BLLs to justify primary reliance on very low Action Levels.

Also, BCI encourages OSHA to distinguish between air lead levels triggering medical surveillance, whether or not designated as an "action level," from air lead level thresholds related to engineering controls and/or PPE requirements. The air lead level that triggers testing or medical surveillance may not be the same as the levels appropriate to trigger other obligations.

*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*

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[22] In this regard, BCI believes that the scope of covered industries identified in California's Economic Impact Assessment (identifying 228,000 California workers that will be subject to the rule) significantly underestimates the scope of facilities and workers that will actually be covered because California appears to have underestimated lead exposure levels in many facilities that will be subjected to Cal/OSHA's new rules, if they are adopted as currently described.

*lead-content metals, as Washington DOSH's stakeholder review draft and Cal/OSHA's discussion draft contemplate? Please explain your answer.*

In facilities with comprehensive air monitoring, such as battery manufacturing plants and secondary lead smelters, additional triggers for medical monitoring programs are unnecessary and will prove to be unduly complicated and expensive (particularly if OSHA lowers the relevant action level).

## Multiple Criteria Would Create Unnecessary Complexity

As noted elsewhere, BCI opposes the inclusion of additional non lead-in-air Action Levels. However, if non-air-lead-level triggers are included in a final revised standard, OSHA should allow employers to determine applicability or non-applicability of the pertinent requirement using any one of the triggers established, with primary reliance on air-lead sampling. Once an employee is determined to be covered by the medical monitoring provisions under an applicable trigger, no purpose would be served by requiring the employer to determine or document the applicability of any other potentially applicable trigger, but considerable expense and disruption could be imposed if data associated with those other triggers were required to be collected and/or documented.

## The Washington DOSH Approach is Overly Complex, Unworkable, and Unsupported

BCI urges OSHA to avoid adding undue complexity and attendant monitoring, documentation and general paperwork burdens to a revised standard. Adding multiple new and substantively different triggers for medical monitoring—as is the case in the current Washington draft—would require employers to track numerous unrelated measurements and criteria, dramatically increasing administrative burdens and expense. In this regard, Washington DOSH's draft panoply of triggers is confusing, unworkable, uses unreasonably low levels of lead content, and will lead to higher compliance burdens without a measurable benefit.

In the ANPRM, OSHA posits that the Washington draft includes four additional triggers for placing a worker in medical monitoring. However, this understates the reality of the draft's myriad triggers. In fact, the current Washington draft contains several types of triggers; the four noted in the ANRPM constitute just some of those that Washington DOSH would impose.

In total, the proposed Washington rule contains at least 18 different triggers that could subject employers and workers to some form of medical monitoring requirements. These can be summarized as follows:

- Seven defined "Action Levels" (Draft WAC 296-857-10030, Tables 3, 4, and 5)
- Eight negative "indications" which void an employer's otherwise valid determination of non-applicability, and which use different thresholds than the "Action Levels" (Draft WAC 296-857-10050(2)(f)).
- Any work within a structure built prior to 1978 without testing all paint and other coatings (Draft WAC 296-857-10050(1)(a)(ii))
- Any spill or exposure incident (Draft WAC 296-857-30010(1)(c))
- Workers without a BLL test within 3 years (Draft WAC 296-857-30010(1)(d))

The result of this litany of triggers, criteria, and negative "indications" is that it will be difficult, if not impossible, for most employers to determine and track if and which of their employees are or are not covered by various aspects of the rules. Many employers may either unknowingly violate the rule or unnecessarily implement costly compliance measures. This will dramatically increase the burden on employers and will generate significant confusion. OSHA is well aware that the establishment of an overly burdensome or confusing standard is not an effective way to regulate, and often results in a successful legal challenge or ineffective implementation by employers, neither of which work to achieve the intended purpose of the standard.

Moreover, Washington DOSH has not substantiated the nexus between the new criteria and a material impairment sought to be ameliorated. Specifically, the agency has not presented reliable data or evidence that the triggers— other than lead in air –have any correlation to worker blood lead levels that would suggest – much less be sufficient to justify – regulation.

## <u>The Proposed "Lead Content" Threshold Proposed by Washington DOSH Are Infeasible</u>

In addition to the unnecessary complexity and burdens that would be created under the Washington DOSH draft rules, DOSH also failed to adequately address or assess the practical realities of the lead content of common materials. For example, as described in this section, an initial analysis suggests that the Washington DOSH draft would require all steel workers and plumbers to assume that their work is covered by the rule, despite the fact there is no evidence such a broad inclusion is necessary.

Lead is a naturally occurring element that co-exists with metal ores and is present in trace quantities in many metals produced by recycling. Thus, many metal products and materials, even those with the same nominal specifications, may vary in terms of their lead content. It thus is highly questionable that the 50 ppm (0.005%) lead content criteria for "hot work, burning or other processes which aerosolize materials" in the Washington DOSH draft (Draft WAC 296-857-10050(f)) is economically or even technologically feasible.

For example, steel is generally ordered using the chemical content disclosures required by ASTM industry standards for each grade of steel. Many of these standards do not require disclosure of lead content because lead is a common scrap steel trace contaminant and does not affect the commercial properties of steel below *de minimis* levels — including levels greater than 50 ppm. BCI understands that many steel manufacturers aim to keep the lead content of "standard" grades of steel below either 200 ppm (0.02%) or 400 ppm (0.04%), but some "non-leaded" grades of stainless steel may contain as much as 4,000 ppm lead (0.4%).[23]

This suggests that a 50 ppm applicability trigger level would impose regulatory obligations whenever standard commercial grades of steel are used. But, because 50 ppm is below the typical disclosure threshold for new steel, employers may have no way of definitively knowing whether their steel work is covered by the rule without conducting lead-content testing. Such burdens are unnecessary,

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[23] *See also* USEPA, Assessing the Management of Lead in Scrap Metal and Electric Arc Furnace ["EAF"] Dust, Final Report, EPA530-R-09-004 (April 2009) (reporting that "[c]onventional non-leaded steel contains <0.01% [100 ppm] lead"; non-leaded stainless steels may contain 100 to 4000 ppm lead; and that some EAFs control lead in the reclaimed steel to less than 300 ppm). Some types of machine steel, *e.g.*, Grade 12L14, contain by specification 1500 to 3500 ppm lead.

particularly in light of the fact that no basis has been presented to support the proposition that welding, cutting, grinding, or even drilling steel and other metals is unsafe.

The 50 ppm trigger is also defined in the Washington DOSH draft to apply to welding tasks in any location or surface "where lead *containing* coatings were used." (emphasis added) From 1977 until 2009 "non-lead" paints were permitted under federal law to contain up to 600 ppm lead (dry weight), and since 2009 "non-lead" paints are permitted to contain 0.009% (90 ppm) lead. Therefore, any person working with <u>any</u> painted surface would be required to assume his or her work is subject to the provisions of the Washington DOSH draft.

Finally, although Federal law requires plumbing solder and fixtures used for drinking water to be certified as "lead free," Congress and EPA have defined that to mean having a lead content of not more than 0.2% (2,000 ppm) for solder, and 0.25% (2,500 ppm) for fixtures. 49 § U.S.C. 1417(c)(1), 40 C.F.R. §§ 143.12(a) and 143.19. EPA's regulations also allow such products to be marketed as "lead free," and require non-lead free products to be clearly labeled as such. 40 C.F.R. § 143.18(a). The current Washington DOSH draft thus would be completely misaligned with federal law and regulation by subjecting plumbers to extensive regulation for exposure to lead due to their use of a product certified under federal law as "lead free."

In summary, the lead content threshold in the Washington draft is over-broad and impossible to comply with technologically, economically, and practically. It ventures far outside the established regulatory framework and would have farther reaching effects than Washington DOSH appears to realize.

BCI urges OSHA to exercise extreme caution in considering the current Washington DOSH draft applicability triggers. BCI encourages OSHA to avoid following that draft's model of adopting numerous applicability triggers, and in no event should OSHA adopt the specific triggers under consideration by Washington.

## <u>The Mere Contact with Lead-Content Metals is Not an Appropriate Criteria for Medical Monitoring</u>

The mere contact with lead containing objects or substances is not a reasonable basis to require the use of impermeable PPE, or to require medical monitoring.

Dermal absorption of inorganic /elemental lead is not considered a significant exposure pathway. Several comprehensive reviews of lead toxicity and exposure have not demonstrated any significant uptake of inorganic / elemental lead through the skin. ATSDR (2020)[24] noted that while dermal exposure is theoretically possible, that it "is much less efficient than" the inhalation and ingestion (oral) route and that the significance of the dermal absorption pathway as a contribution to total body burden "remains an uncertainty", but that "dermal absorption of inorganic Pb is substantially lower than absorption from the inhalation or oral route." EPA human health risk assessment guidance states that dermal absorption "is not considered a significant pathway for inorganic lead" (EPA 1994),[25] as a result, dermal absorption

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[24] Agency for Toxic Substances and Disease Registry (ATSDR) (2020). Toxicological Profile for Lead.

[25] United States Environmental Protection Agency (EPA). 1994. Technical Support Document: Parameters and Equations Used in the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children (v 0.99d). Prepared by the Technical Review Workgroup for Lead for the Office of Emergency and Remedial Response, U.S. Environmental Protection Agency. Washington, DC.

is not included in EPA's Integrated Exposure Uptake Biokinetic Model or Adult Lead Model, which are the EPA-recommended lead models used to predict blood lead levels from exposure to lead at contaminated sites. According to ECHA (2020)[26], dermal absorption of inorganic lead through unabraded human skin is considered to be "minimal" and "makes a negligible contribution to systemic lead levels", estimated to have uptake rates at less than 0.01%. Safe Work Australia (2014)[27] also noted that dermal absorption of inorganic lead compounds is negligible, and German AGS (2022)[28] recognized that while oral intake can occur through hand-to-mouth contact due to lack of hygiene, that dermal intake can be disregarded.

This data suggests that the Washington DOSH draft's requirements triggering requirements based on a Metals Action Level for workers "touching" metals containing lead is not justified, and OSHA should exercise caution in considering such a trigger.

### 3. Frequency of Blood Lead Monitoring (Question 6)

> *Question 6*: *Should OSHA consider revising the required frequency and the BLLs related to the schedule of blood lead testing in the current standard?*

BCI believes that the testing frequency and schedule embodied in the current federal lead rule are, and will remain, appropriate. The current testing regime is well understood by both EHS professionals and workers.

However, BCI supports the concept embodied in the Cal/OSHA and Washington DOSH drafts to make available blood lead testing prior to a worker's assignment to a covered position, or as soon as possible if work is subsequently determined to be covered by medical surveillance requirements. This step can provide a critical baseline so that workers and employers can gauge the impact a particular work position may have on pre-existing or non-occupational lead exposures.

### 4. Analytical Methods for BLL Testing (Questions 7 through 10)

> *Question 7*: *Should OSHA consider revising its standard to require the use of a blood lead analysis laboratory that has been approved under the CMS blood lead laboratory monitoring system pursuant to the CLIA regulations, consistent with OSHA's 2018 memorandum? Please explain your answer.*

BCI supports using appropriate requirements for blood lead testing laboratories, including CLIA or an equivalent third-party approval. If OSHA pursues substantial changes to the Action Level or other medical surveillance triggers, the nation will need a substantial increase in blood lead testing capacity. For example, Cal/OSHA's state mandated Standardized Regulatory Impact Assessment (SRIA) estimates that the agency's draft updated standard would apply to a much larger universe of facilities and operations than are regulated under the current standard: a minimum of more than 228,000 California

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[26] ECHA European Chemical Agency (2020). In Support of the Committee for Risk Assessment (RAC) for Evaluation of Limit Values for Lead and Its Compounds at the Workplace. ECHA/RAC/A77-O-0000006827-62-01/F.

[27] Safe Work Australia (2014). Review of hazards and health effects of inorganic lead – implications for WHS regulatory policy. Canberra: Safe Work Australia.

[28] Germany AGS (2021). Technical Rules for Hazardous Substances – Lead. TRGS 505.

workers, or 1.2% of the California workforce.[29] It appears that Cal/OSHA estimates that at least 200,000 of those workers, or 1% of the workforce, would be subject to medical surveillance.[30]

BCI believes the Cal/OSHA SRIA analysis under-estimates the number of workers impacted. Nonetheless, extrapolating from the California SRIA suggests that, were OSHA to adopt that rule's medical surveillance triggers, more than 2 million workers nationwide would be subject to blood lead testing at least once per year. Were OSHA to consider such an expansion in the scope of workers covered, OSHA will need to ensure that blood lead testing laboratory capacity actually will be available to handle any increased volume of testing.[31]

### 5. Employee Notification of BLL Results (Question 11)

> *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? If not, what criteria should be used to determine which employees should be notified of their results? Please explain your answer.*

BCI supports providing all workers access to their own blood lead testing results. Worker knowledge and self-assessment are fundamental to empowering workers to control their own health. Not only is such access appropriate, it is also among the most effective methods for providing workers the information they need to self-monitor their work practices. Informing a worker of the impacts of his or her good hygiene practices through awareness of blood lead levels is a highly effective practice.

The current regulations' requirement for providing employees with test results "within 5 working days"[32] is an appropriate length of time given the practicalities of modern workplace environments. However, practice has shown that additional clarity is required for situations where an employee is not present at the job site during those five days. For workers that are not present during those days, but later return to work (*e.g.*, because they were on vacation), the rules should be clarified to measure "working days" in terms of the employee's work schedule, rather than a calendar. BCI suggests that access to results be provided to the employee "within 5 working days of the employer's receipt of the biological monitoring results, or no later than the employee's fifth working day after the employer's receipt of the biological monitoring results, whichever is later."

OSHA should also update the regulations to recognize that most modern workplaces provide electronic access to employee records (*e.g.*, a secure employee website), and that printed employee

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[29] California Department of Industrial Relations, Standardized Regulatory Impact Assessment: Revisions to Occupational Lead Standards (February 2019, revised August 2020), page 9. https://dof.ca.gov/wp-content/uploads/Forecasting/Economics/Documents/SRIA_DIR_Lead_Safety_Standards_Revised200830.pdf

[30] *Id.,* Figure 1.

[31] It is also worth noting that the U.S. is currently facing a severe shortage of blood specimen collection tubes. https://www.fda.gov/medical-devices/letters-health-care-providers/update-blood-specimen-collection-tube-conservation-strategies-letter-health-care-and-laboratory

[32] 29 C.F.R. 1910.1025(j)(2)(iv).

communications may no longer be the norm. The regulations should be updated to explicitly allow employers to provide biological monitoring results to employees through electronic means.[33]

### 6. ZPP (Question 12)

*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.*

*See* BCI's response to Question 3.

### 7. Provisions for Worker Privacy (Question 13)

*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.*

No. Providing effective training and health services requires EHS professionals and supervisors to know each worker's individual blood lead level. In today's battery manufacturing and recycling facilities, EHS staff and supervisors use each worker's blood lead data to provide that worker with individualized training and instruction. Individualized blood lead data are necessary to help EHS staff and supervisors identify those workers at risk or that need additional assistance.

Within a given facility, routes of exposure can vary significantly by work area, and even within a job category or department. Further, individual work practices and behavior (some outside the workplace) are often the primary drivers of blood lead levels at lower exposure levels (*e.g.*, hand-washing practices, PPE protocol adherence, hand-mouth hygiene, cigarette smoking, work posture/proximity to work-surface, compliance with workstation cleanliness measures/techniques, etc.).

Our members' observations in workplaces show that two employees in the same department, or even the same workstation on separate shifts, can have significantly different blood lead levels if one has superior hygiene or work practices.

If employers are restricted from knowing individuals' BLLs, EHS staff and supervisors would not have the information needed to address individual worker exposures. *This could severely impede the ability for employers to provide proper training, remedial attention, PPE, etc.* Obfuscating which employees have elevated BLLs would hamper efforts to identify workers most at risk. Reliance on workers to convey this critical information to their employers is imperfect at best, it is imperative that employers have the information necessary to ensure their workers are sufficiently protected from lead exposure. Having accurate blood lead level data is essential to that objective.

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[33] For employees that have resigned or are terminated before the test results are returned, OSHA should clarify that the employer is not required to provide test results to the former employee, except through a properly submitted medical records request in accordance with 29 C.F.R. § 1910.1020.

BCI members have observed this in practice in certain other countries where employers are restricted to knowing only that "somewhere in the facility" or "somewhere in a work area" one or more employees have an elevated blood lead level. The experience of those facilities indicates that lack of information leads to higher overall blood lead levels among employees because trouble spots or workers with poor hygiene and work habits cannot be readily identified and therefore individual (re)training is not possible.

## C. Permissible Exposure Limit (PEL) (Questions 14 through 16)

*Question 14: Should OSHA consider reducing its PEL of 50 µg/m$^3$ for occupational lead exposure or its action level of 30 µg/m$^3$? 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 USC § 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. (Please note that OSHA requests detailed information on costs of already-existing requirements and voluntary practices in a series of provision-specific questions in Section H, Questions for Employers on Current Practices).*

OSHA should not reduce its PEL of 50 µg/m$^3$ for occupational lead exposure or its Action Level of 30 µg/m$^3$. With proper adjustment to medical removal levels and worker hygiene requirements, there is no need for OSHA to adjust the PEL which is the trigger for implementation of engineering controls. Modern experience has shown that at air-lead levels below the current PEL of 50 µg/m$^3$, work practices, modern hygiene practices, PPE, and other EHS solutions can more efficiently and effectively control blood lead levels among employees than would reductions in air-lead levels.

Moreover, because of flaws in some of the models, and associated uncertainty with respect to the relationship between airborne lead concentrations and BLLs, OSHA should describe in greater detail how it intends to derive any updated PELs or Action Levels as soon as possible, and before it proposes updates. Having as thorough an understanding of OSHA's views on this topic as early as possible, even before a proposed rule, will help BCI (and presumably other industries) provide critical understanding and information to OSHA on the implications and feasibility of lowering the PEL

### Bulk Air Controls Are the Least Cost-Effective Means to Control Exposures

Bulk air-lead controls are the most expensive, and least effective, controls among the options OSHA is considering. The control of lead in air within a facility requires the collection and removal from the facility of the air potentially containing particulate. Pursuant to regulations and conditions established by EPA and state permitting authorities, that air is filtered through various mechanisms to remove lead particulate prior to release. Thus, any increase in the amount of lead to be removed from the air inside the facility necessarily requires the addition of more filtration equipment. This is a highly capital and equipment intensive proposition that requires not just adding ventilation, but also potentially requiring redesign of a facility's production environment, equipment modifications, facility structural improvements, and state and/or federal approval of modified air emission permits. It also will lead to additional lead being exhausted into the ambient air.

For facilities without existing infrastructure, reducing interior air lead levels to a reduced PEL likely will be unachievable without significant updates to a facility's physical plant. In recent years, BCI members have reported that new lead control baghouses, at facilities that already have air-handling ductwork and an air permit, designed to operate in compliance with <u>today's</u> OSHA and EPA rules, can cost between $800,000 and $8 million, depending on the situation and facility size. Achieving significantly reduced PELs likely also will be technologically unachievable in many circumstances, potentially leading to plant closures and resulting layoffs.

BCI urges OSHA to reevaluate the appropriateness of attempting to primarily rely on air lead levels below 50 µg/m$^3$ to achieve desired blood lead levels. Focusing on more practical and feasible worker protection measures has proven protective, acceptable to workers, and cost-effective. Simply reducing the PEL would fail to properly protect workers by imposing very high costs on their employers—putting jobs, wages, and benefits at risk—without providing employees with the modern protective measures shown to be most effective. OSHA should consider holistically how best to protect today's workers, building upon the dramatic improvements in worker protection achieved by the lead battery industry, among others.

Furthermore, the PEL-first approach does not make sense in today's work environments. A considerable amount of scientific research and improvements in worker safety systems, policies, and practices have accumulated since the 1970s. These systems, policies, and practices, when used in combination with air lead levels controlled to current levels, provide a much more sound focus for regulatory revision than does a primary reliance on a PEL. OSHA should build upon the lead battery industry's experience and focus its attention on the methods that have been proven to be most successful in reducing worker blood lead levels, not PELs.

## <u>Air-Lead / Blood Lead Modeling is Not Reliable</u>

### <u>*Newer Data Shows Existing Air-Lead to Blood-Lead Models Likely Overstate the Relationship*</u>

In addition to the considerations stated above, the relationship between air lead concentrations and blood lead levels is highly uncertain and variable and cannot be considered constant over various occupational settings, thus making a focus on reducing plant air levels inappropriate.

As discussed in extensive detail in the comments from the International Lead Association, an ongoing study – anticipated to be published in 2023 – has evaluated the air-lead, blood-lead relationship among a cohort of workers in a modern battery manufacturing facility. The initial findings demonstrate that the existing modeling efforts dramatically over-estimate blood lead levels among workers. Initial analysis have compared the Leggett+ model to the new dataset to derive Mean Square Error (MSE)[34] values comparing the 50th percentile predicted BLLs to measured BLLs, and 95th percentile predicted BLLs to measured BLLs (30.2 and 619.1 respectively). Furthermore, the initial analyses derived a coefficient of determination ($R^2$)[35] value, which compares the fit of the chosen model with that of a horizontal straight line (the null hypothesis). The R2 for the 50th percentile and 95th percentile Leggett+ predicted BLLs

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[34] MSE is an absolute measure of the goodness of fit, where a lower value indicates a better model fit and an MSE of 0 indicate a perfect model fit for the data.

[35] R2 compares the fit of the chosen model with that of a horizontal straight line (the null hypothesis), and a larger value indicates a better fit between prediction and actual value.

and measured BLLS are -2.65 and -73.8 respectively. Both the MSE and R2 results suggest a very poor model fit to real data.

Further, the initial analysis of the new dataset suggests that and that the variability in blood lead results within the observed dataset suggests that current approaches to PBPK modeling may not be able to accurately predict workplace blood lead levels at all. Statistical analyses of the new dataset suggest this conclusion. Specifically, the $R^2$ and MSE values calculated for the 91-worker data set of 0.022767 (P = 0.081885) and 7.997359, respectively, suggest a poor model fit, and do not support a statistically significant relationship between occupational air lead concentrations and corresponding blood lead concentrations.

BCI refers to the comments of the International Lead Association for a full discussion of these initial results.

## ***Specific Issues with the Leggett Model***

The modeling effort underlying the Cal/OSHA proposal, Cal-OEHHA's "Leggett Plus" pharmacokinetic model, contains numerous underlying flaws which cause it to be a poor basis for regulatory rulemaking. During various rulemaking hearings in California, industry commenters and independent experts brought specific questions and issues to the attention of the authors, but these concerns have not been addressed to date.

For example, the model relied on outdated and inapposite particle size data and unnecessarily limited the modeled particle sizes to those under 15 µm. Data that BCI provided to the California authors shows that the particles in domestic lead battery manufacturing facilities have an average mass median aerodynamic diameters (MMAD) ranging from approximately 21 to 32 µm, and in recycling facilities ranging from 15 to 25 µm.[36] This particle size issue is meaningful because larger particle sizes present less risk of blood lead uptake than smaller particle sizes, even at the same air-lead levels. Smaller particles (*i.e.*, <8 µm) are more likely to be deposited in the pulmonary region and fully absorbed, and larger particles (*i.e.*, >8 µm) are more likely to be swallowed and only partially absorbed in the gastrointestinal tract. Larger particles may also be expelled from the body. Thus, workers in industries or specific roles that involve constant exposure to fine particles are expected to exhibit stronger relationships between air lead and blood lead than workers in industries or roles where airborne lead predominantly consists of larger particles. The model thus does not reflect real-world worker exposure in the lead-acid battery manufacturing or recycling industries.[37]

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[36] Data provided to Cal/OSHA in 2014; subsequently published at: Petito Boyce C, Sax SN, Cohen JM. Particle size distributions of lead measured in battery manufacturing and recycling facilities and implications in setting workplace lead exposure limits. J Occup Environ Hyg. 2017 Aug;14(8):594-608.

[37] Other chemical properties (*e.g.*, chemical speciation, density) can also impact the absorption of lead compounds. Less soluble forms of lead, such as lead sulfide and some lead-containing ceramic compounds, are generally regarded as less hazardous than more soluble forms. For example, despite lead zirconate (a ceramic compound) being of respirable size (i.e., <5 µm) and containing 60% lead, Roy et al. (1989) concluded it was three times less soluble than lead oxide in human serum. In the facility where it was manufactured, mean air lead levels of 1,400 to 2,700 µg/m$^3$ (personal samples) were reported, however, mean BLLs of employees ranged from 20 to 26 µg/dL blood. For context, the Leggett+ model predicts BLLs (at 50th percentile of population) in this range are associated

Other issues also impact the model's accuracy.  For example, the model used by Cal/OSHA failed to apply the appropriate Multiple-Path Particle Dosimetry (MPPD) Model inhalability adjustment factor to accommodate particle sizes larger than 8 µm.  This appears to have been simply an oversight, because elsewhere the modeling used particles sizes up to 15 µm.  Nonetheless, the error changes the results. The model also relied on inadequate inhaled particle clearance models and used an outdated version of the model despite recognizing that an improved ICRP model is now available.  In addition, the modeling contained a mass-balancing error.

BCI's analysis indicates that correcting these errors will have a significant impact on the model's predicted relationship between air-lead levels and blood lead levels.  Necessary corrections related to the Leggett + model's derivation of the Inhalation Transfer Coefficient (ITC) (an estimate of the fraction of inhaled lead that is absorbed in the body) based on the issues with MPPD and particle size assumptions discussed above could alter that parameter by as much as three-fold, which would have significant implications for the BLLs predicted by the model.  These and other issues with the model are discussed in more detail in **Appendix A**, which provides a copy of an analysis titled, *Review of CalEPA/OEHHA Worker Air/Blood Lead Modeling Approach*, which was prepared by Gradient in October of 2018.

### *Conclusions of International Agencies*

Several international agencies have also attempted to quantify the air lead-BLL relationship to support development of occupational exposure limits (OELs) for lead.

An OEL assumes there is a direct correlation between concentrations of lead in air in the workplace and BLLs in workers.  Although inhalation is a complete exposure pathway when workers are not wearing respirators, there is no consistent relationship between air lead and blood lead.  The magnitude of exposure varies markedly across workplaces and is heavily influenced by multiple factors including but not limited to particle size, solubility, personal versus area air lead measurements, the temporal relationship of air measurements with BLL measurements, respirator use and other practices impacting the accuracy of air lead measurements for exposure, if air concentrations represent total lead or respirable lead, smoking status, hygiene practice (*i.e.*, likelihood of hand mouth interaction), length of employment, and inter-individual variability in lead absorption (Safe Work Australia 2014, LDAI 2008).

Safe Work Australia (2014) recognized that although a relationship exists between workplace airborne lead concentrations and BLLs, quantifying that relationship introduces multiple other influential factors including how air lead is measured and when, particle size, when a BLL is measured relative to the air lead measurements, an individual's smoking and personal hygiene habits, and the variability in individual lead absorption rates, among others.

OSHA should consider relevant scientific criteria on the relationship between air lead concentrations and blood lead levels in determining the appropriateness of a PEL and whether a reduction in the PEL is warranted.  This information, along with the entire body of science, must be reviewed in a balanced manner.  Overall, it is BCI's view that any significant reduction in the PEL that triggers a need to modify engineering controls in U.S. facilities is ultimately unwarranted in that there are better, more effective

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with air lead 8-hour TWAs of 18 to 25 µg/m$^3$.  Thus, in this workplace, the Leggett+ model would overpredict BLLs at least 50-fold.

(and much more cost efficient) ways to achieve the goal of controlling workers' exposure to lead, and, further, that a PEL-based regulatory solution is likely to mire OSHA in litigation over the revised standard that could undo the agency's considerable efforts in updating the lead standard.

> *Question 15: Cal/OSHA's discussion draft includes a 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?*

While BCI does not believe changes the PEL are necessary, should OSHA decide to pursue reductions to the PEL, BCI strongly supports the inclusion of Separate Engineering Control Air Limits (SECALs) as contained in the Cal/OSHA draft, or the analogous Secondary Permissible Exposure Limit (SPEL) as suggested in the Washington draft.

OSHA should implement SECALs consistent with other OSHA standards using the hierarchy of controls approach widely regarded in the industrial hygiene community.[38] SECALs, when adopted, require employers to rely on respiratory protection in accordance with 1910.134 when engineering and/or work practices controls are instituted and demonstrated to be insufficient to reduce exposures below the PEL. Importantly, unlike virtually all other OSHA chemical standards, the lead standard has a mechanism whereby controls, including respiratory protection, can be confirmed to be effective by required blood lead testing, which is typically considered to be a marker of recent exposure. Thus, SECALs should be strongly considered by OSHA, based on precedent, and demonstrative evidence from industries that currently rely on a combination of industrial hygiene controls, including respiratory protection, and that show results of blood lead testing to be below required and recommended established worker removal levels.

The need for OSHA to consider a SECAL or SPEL stems from the requirement in the OSH Act that OSHA adopt only standards which are "feasible." 29 U.S.C. § 655(b)(5); *United Steelworkers of Am., AFL-CIO-CLC v. Marshall*, 647 F.2d 1189, 1264 (D.C. Cir. 1980). This requires the agency to perform an independent feasibility analysis for each industry impacted and make an affirmative finding that any proposed standard is technologically and economically feasible for impacted industries.[39] We expand on what that means in the remainder of this section.

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[38] "SECAL" was first used as a term of art by OSHA in the cadmium standard. Several other OSHA industrial hygiene standards also provide allowances for certain industries or processes where feasibility of achieving a PEL with engineering controls and/or work practice controls alone has not been established; in other words, SECALs have been used by OSHA for many standards over different time periods. These standards include the current lead standard (1910.1025), the hexavalent chromium standard (1910.1026), and the asbestos standard (1910.1001). Additionally, the California-proposed updated lead standard also uses of a SECAL for processes in the manufacturing of lead-acid batteries. While not defined as a SECAL, Washington State's secondary PEL (SPEL) is a SECAL, where exposures below 50 µg/m$^3$ (but above the proposed PEL) can be controlled with any combination of controls, and exposures over 50 µg/m$^3$ must be controlled by feasible engineering and administrative systems.

[39] *American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490 (1981), *see also United Steelworkers v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980).

If OSHA chooses not to use SECALs, its regulatory approach should continue to include the provision currently in the standard and included in virtually all OSHA chemical standards[40] that allows employers to rely on respiratory protection if engineering and work practices controls have been demonstrated not to be feasible.

**The Standard Must be "Technologically Feasible" for Regulated Industry to Achieve**

As described above, with regard to technological feasibility, OSHA must assess the available technological methods to achieve new standards and must make a finding that these methods are available to industry. *See United Steelworkers*, 647 F.2d. at 1272. OSHA must assess the available technological methods to achieve any new standard—including methods for measuring compliance—and must make a finding that these methods are available for use at both existing and new facilities. Theoretical technologies or methods are not a sufficient basis on which to make a feasibility finding.

Even if air control technology is available for new construction, many existing manufacturing facilities may not be physically able to be retrofitted with the available technology to achieve a reduced PEL. This is because significant reductions in air-lead levels may require the installation of very large amounts of air handling equipment, modification of workstations, or new manufacturing equipment with integrated dust removal systems. The physical structures of older buildings simply may not be able to accommodate the additional equipment required. For example, rooftops and walls may not have been engineered or constructed to bear the additional loads imposed by these new systems, and existing openings may not be appropriate for the provision of negative pressure makeup air. Other facilities simply may not have the space to install new ductwork, dust collecting bag-houses, and the relevant mechanical systems.

Additionally, significant reductions in the PEL and Action Level, such as those proposed in California, would substantially increase the potential for sample contamination to impact measurement reliability, given the presence of lead in the environment in some regions. Background concentrations of lead in the environment are far greater than many of those other substances for which OSHA has chemical standards.[41] For an action level of 2.5 $\mu g/m^3$ as proposed by California, even very small amounts of lead introduced into a sample may exceed this threshold, thus triggering additional requirements.

OSHA must analyze the technological hurdles and determine that industry can in fact achieve any proposed Action Level and/or PEL. BCI is skeptical that this standard can be met for a PEL and/or Action Level reduction as low as being considered by California and Washington.

**The Standard Must be "Economically Feasible" for Regulated Industry to Achieve**

Even if additional control methods are technologically feasible, as noted above OSHA also must assess the economic impact of a new PEL and/or Action Level, and make a finding that the standard will not have an unacceptable adverse economic impact. BCI's experience reveals, however, that the standards

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[40] Asbestos (1910.1001), Benzene (1910.1028), Beryllium (1910.1024), Arsenic (1910.1018), Formaldehyde (1910.1048), Methylene chloride (1910.1052), respirable crystalline silica (1910.1053), Methylenedianiline (1910.1050), 1,3 butadiene (1910.1051), Ethylene oxide (1910.1047), Acrylonitrile (1910.1045).

[41] Agency for Toxic Substances and Disease Registry (ATSDR), 2020. Toxicological Profile for Lead.

urged by some agencies and stakeholders may promptly put employers out of business or force them to replace many workers with robotics.

The complexity of the economic challenge is exacerbated by the characteristics of lead particle sizes. In battery manufacturing facilities, particles tend to be relatively large, which makes stringent engineering control technologies especially expensive. In 2014, BCI commissioned an independent analysis of the particle size distributions in a cross-section of nine lead battery manufacturing and five recycling facilities. This study provides reliable and well-supported insight into the actual sizes of the lead particles in the air of modern-day U.S. facilities.[42] It found that the particle sizes in the study facilities were predominantly relatively large particle sizes, with average MMADs ranging from approximately 21 to 32 µm at battery manufacturing facilities, and from 15 to 25 µm at recycling facilities. This means that the equipment needed to achieve very low PELs is more complex and more costly than would be required if ambient air contained smaller lead particles.

It is not simply a question of whether compliance with a PEL is infeasible for specific processes, as posed in Question 15. With each lower increment of a potential PEL concentration target, the ability of engineering controls to achieve the desired target is greatly diminished. Effectiveness follows the law of diminishing returns. Engineering controls in the lead battery and production industries are often in the form of process hooding and ventilation. The degree to which hooding can be enhanced to pursue lower target concentrations is a matter of limiting the size of access enclosures. This can only go so far as some minimal operator access to processes defines how “tight” any hooding can be. Beyond that point, the only improvement to engineering controls comes from increasing the hoods’ capture velocities, *i.e.*, extract more air. As an initial matter, excessive negative pressure or air movement in a machine can interfere with the proper operation of the equipment. Further, the movement of more air consumes more energy (a secondary environmental effect) and increases the emissions of lead to the atmosphere, even with robust emission controls.[43] And, at some point, engineering controls (ventilation) simply cannot achieve a given PEL level.

## If OSHA Reduces the PEL, SECALs Could Address Some Feasibility Concerns

As noted above, BCI believes heavy reliance on a PEL for lead is an outdated method of regulation and not the best means of protecting workers in modern, well-controlled work environments. However, if OSHA decides to reduce its PEL, one regulatory approach for addressing economic feasibility concerns is to establish SECALs for certain plant areas.

This approach was utilized by OSHA in the cadmium standard and is incorporated in California’s most recent draft of revisions to its lead standard. When employed, the SECAL framework establishes a single PEL, but also includes a number of SECALs for specific work areas in specific industry facilities. In these

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[42] Petito Boyce C, Sax SN, Cohen JM. Particle size distributions of lead measured in battery manufacturing and secondary smelter facilities and implications in setting workplace lead exposure limits. J Occup Environ Hyg. 2017 Aug; 14(8):594-608.

[43] The National Emission Standards for Hazardous Air Pollutants (NESHAP) for the lead-acid battery production industry (40 C.F.R. Part 63 Subpart PPPPPP) and lead-acid battery recycling industry (40 C.F.R. Part 63 Subpart X) both express lead emission limitations in the form of maximum allowed concentrations of lead in the exhaust gases (µg/m$^3$). More detail is provided in response to Question 29.

areas a higher particulate level is allowed, so long as specified additional worker protection measures are implemented.

OSHA explained the SECAL framework when the cadmium standard was promulgated: "Employers in a particular industry covered by the SECAL will be obligated to achieve the SECAL by engineering and work practice controls to the extent feasible and to protect employees from exposures above the PEL by any mix of compliance methods, including . . . work practice controls and respirators."[44] That is, OSHA recognized the economic and technical infeasibility of facility-wide reliance upon engineering controls to meet the PEL, and provided for alternate frameworks.

The industry sectors granted SECALs in the cadmium standard were approved by OSHA based on "evidence on current exposures and [because] the effectiveness of additional controls indicated that the [cadmium] PEL of 5 µg/m$^3$ is not feasible with engineering controls . . . ."[45] The SECALs were set at the levels OSHA determined were "the lowest feasible level that could be achieved by engineering and work practice controls" in those areas.[46] OSHA determined that a "two-tier [SECAL] structure . . . is simultaneously more protective of workers' health and feasible."[47]

With respect to battery manufacturing facilities, as part of the ongoing Cal/OSHA process, BCI members in California identified the following areas as those for which a SECAL was most immediately required for feasibility reasons:

- oxide production;
- paste mixing;
- grid pasting and parting;
- battery assembly;
- grid production and small parts casting; and
- plate formation.

Further analysis as to other manufacturing processes, and other types of facilities will be required for nation-wide consideration.

During the California rulemaking, a subset of industry manufacturers in that state conducted an initial assessment of potential compliance costs. Using a generic engineering analysis, at that time those companies estimated that the engineering controls required to meet a PEL of 10 µg/m$^3$ in just the listed six areas of a typical California battery manufacturing plant would exceed their economic ability to implement those controls – even if the technical engineering challenges could be overcome. Using the methodology described by OSHA for assessing economic feasibility,[48] these companies determined that the necessary controls would be economically infeasible, with an estimated annualized cost exceeding

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[44] Preamble to Final Cadmium Standard, 57 Fed. Reg. 42,102, 42,336 (Sept. 14, 1992).
[45] *Id*. at 42,212.
[46] *Id*. at 42,336.
[47] *Id*. at 42,343.
[48] *See* OSHA Silica PEL, Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (Silica PEL PEA) at page VI-5 (2013), Docket No. OSHA-2010-0034-1720 ("[I]n the absence of evidence to the contrary, OSHA generally considers a standard to be economically feasible for an industry . . . when the annualized costs of compliance are less than a threshold level of ten percent annual profits.").

45% of annual state industry profits. (This exceeds the level OSHA has previously accepted to be the maximum that can be accepted as "feasible.") Costs to ensure compliance of an entire facility would be even greater.

At this time, BCI does not know whether the analysis from the California facilities can be extrapolated nationally. Nearly a decade has passed since that analysis was conducted, and the California facilities tend to be smaller in size than other facilities nationwide and may be at different stages of modernization, so the costs necessary to achieve lower air lead levels in those facilities may not be representative of other facilities. However, more recent information from real-world baghouse improvement projects around the country suggests that the estimates generated for California actually may underestimate the actual cost for national compliance. Further, Cal/OSHA also did not consider the feasibility of achieving their proposed PEL for facilities other than lead battery manufacturing, such as recyclers.

Building on the work of the California regulators and stakeholders, the SECAL concept was further refined through collaborative discussion between industry and Washington DOSH. BCI believes that the resulting SPEL concept embodied in the Washington proposal is a more refined and more broadly applicable methodology of providing feasibility protection to all industries, without OSHA needing to evaluate every type of production area in all facilities, and thus may be a preferable approach for OSHA to consider if PEL reductions are proposed.

Under a SPEL, employers must institute mandatory PPE and hygiene in any and all areas above the PEL but below the SPEL. (Under the Washington DOSH draft, this would be 50 $\mu g/m^3$ $TWA_{8e.}$) The employer has the obligation to identify those areas and implement the proper measures – rather than the regulatory agency addressing each such area in the rules. The Washington proposal then requires all feasible engineering and administrative controls to achieve the SPEL. PPE and respirators must protect workers at all times air leads are above the PEL (as an 8-hour TWA).

BCI member experience has demonstrated that BLLs can be readily controlled through PPE and work practices in areas that have air leads under today's PEL, so this approach appears sensible.

Our manufacturer and recycler members have a long and proven record of using a combination of comprehensive worker health protection practices in these areas (engineering control and work practices plus PPE, hygiene, and education) to achieve worker blood lead levels far below those currently required by OSHA. That track record of success provides a substantial basis to give OSHA confidence that workers in the lead battery and recycling sectors would continue to be more than adequately protected by either a SECAL or SPEL approach.[49]

BCI looks forward to working with OSHA to evaluate the technical and economic feasibility of potential changes to the PEL and the SECAL and SPEL concepts.

> *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*

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[49] As explained in BCI's prior comments, engineering control potentially feasible for smaller facilities may be technologically and economically infeasible for the existing large-scale facilities typical of lead battery manufacturers and secondary lead smelters.

*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.*

BCI supports OSHA retaining the 30-day exemption included in Section 1910.1025(e)(1)(ii) of the standard. Because most production work areas have workers present more than 30 days per year, this is not an exemption from engineering controls in standard work areas, but rather should be read as an allowance that infrequently accessed areas need not be as extensively controlled through engineering controls. In such infrequently accessed areas and situations, proper respiratory protection is an appropriate and necessary protective measure. This provision thus creates a necessary and appropriate compliance path for those areas.

## D. Personal Protective Equipment (PPE), Hygiene, and Training (Questions 17 through 22)

*Question 17*: *The Washington DOSH stakeholder review draft would require employers to provide and ensure the use of impermeable PPE when employees are working with lead compounds that may be absorbed through the skin for any work covered by the scope of the rule. Should OSHA consider a similar requirement for its lead standards? Please explain your answer and any evidence available on the feasibility and cost of this requirement if adopted by OSHA.*

BCI does not believe impermeable PPE is necessary for handling inorganic lead compounds and urges OSHA to not include such a requirement in the standard. The oral and the inhalation routes are the most significant routes of exposure to inorganic lead, while absorption directly through the skin is considered negligible, on the order of <0.01%.[50] Based on this data, and the information presented in response to Question 5, it is unlikely this requirement would meet the provisions of the OSH Act to establish obligations that are necessary to control material impairment of health.

This contrasts sharply with concerns regarding exposure to *organic* lead compounds, such as tetraethyl lead. Those organic compounds are lipophilic substances that can penetrate intact skin in larger quantities compared to inorganic lead compounds, with the amount of organic lead absorbed being proportional to the surface area exposed, the concentration, and the specific lipophilicity of the organic lead compound. (For example, tetraethyl lead is more readily absorbed than tetramethyl lead). The result is that dermal uptake estimates for lead alkyls approaching 6%.[51] Organic lead compounds have a different toxicity and metabolic profile compared to inorganic lead compounds – *i.e.*, higher neurotoxic potency compared to inorganic lead compounds – and are metabolized more rapidly and display much faster excretion.[52]

However, most industrial users of lead are not engaged in the manufacture or use of alkyl lead compounds. (Battery manufacturers and second smelters certainly are not.) BCI thus does not believe it

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[50] https://echa.europa.eu/documents/10162/44ac1a9b-5a73-f8fc-5bbb-961054c1548b.

[51] https://echa.europa.eu/documents/10162/44ac1a9b-5a73-f8fc-5bbb-961054c1548b

[52] https://echa.europa.eu/documents/10162/ed7a37e4-1641-b147-aaac-fce4c3014037

necessary or appropriate for OSHA to add to the lead standard the requirement for employers to provide and ensure the use of impermeable PPE in the U.S. battery manufacture or recycling industries.

See also BCI's response to Question 5.

> *Question 18*: *The Washington DOSH stakeholder review draft would require employers to prohibit workers covered by the scope of the rule from cleaning or laundering protective clothing or equipment at home. Should OSHA consider a similar requirement for its lead standards? Please explain your answer and any evidence available on the feasibility and cost of this requirement if adopted by OSHA.*

BCI supports employers being required to provide laundry services at facilities with work areas that have air-lead levels above today's PEL.

On-site laundry and third-party laundry services can be highly costly programs to implement. OSHA should not require such services for areas with low levels of lead exposure. At lower levels of lead in air, or other circumstances, it may be unnecessary to impose a similar requirement. OSHA will need to evaluate the levels at which the presence on lead on clothing necessitates such services.

Further, OSHA will need to consider the feasibility of providing laundry services for field technicians or service workers who may not return to a corporate facility on a daily basis, if ever. Particularly in rural areas, the employer may have no ability to provide such services on a regular basis, and third-party laundry services capable of this task may be unavailable.

> *Question 19: The Washington DOSH stakeholder review draft includes requirements that employees be provided with hygiene facilities and PPE when any of the following criteria are met:*
>
> *Employees work in areas with surfaces at a "Surface Action Level" of 1000 µg/dm² (equivalent to 9290 µg/ft²);*
>
> *Employees disturb or touch metals with a "Metals Action Level" of 20 percent or more lead content by weight;*
>
> *Employees disturb any materials with a "Non-metal Action Level" of 0.5 percent or more lead content by weight (5000 ppm); or*
>
> *Employees welding, burning, or grinding, or otherwise creating aerosols or fumes from materials with a "Burning/Grinding/Blasting Action Level" of 0.1 percent or more lead content by weight (1000 ppm).*
>
> *Material content criteria (items #2 through 4) are applied during any activity that could release lead or lead compounds from the material in a form that could be inhaled, ingested, or absorbed through the skin. The metals action level (item #2) also applies when workers directly contact the metal with skin, personal protective equipment, or clothing.*
>
> *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 requirements if adopted by OSHA.*

As stated above, adopting multiple triggers will make the standard applicable to many more employers than anticipated. Additionally, it will make it difficult for the employer to know when to take certain actions.

Hygiene facilities are appropriate and necessary to provide workers with the means to hand-wash, change clothes, and (if appropriate) shower. However, the triggers Washington is considering are too varied, numerous, and set at too low a level to be workable. They thus are impracticable and difficult to implement. In BCI's view, OSHA should not adopt multiple and variable additional triggers.

OSHA has previously taken a position that lead content of lead-based paint (LBP) or lead-containing paint should not be relevant under the lead standard[53] based on the well-founded principles of industrial hygiene that exposure assessments (*e.g.*, quantitative air sampling) are the best metric to understand exposure risk. Material content is not an appropriate surrogate for exposures without a comprehensive evaluation of corresponding exposure.[54] The Washington-proposed standard has set out tasks, such as use of power tools to cut, grind, sand, or scrape lead-containing coating, and welding, which would automatically trigger respiratory protection, but this proposed rule would be rendered irrelevant by requirements for air sampling or other objective data demonstrating whether an overexposure could occur. Ultimately, an airborne action level is a better approach to evaluate exposure-risk than relying on the lead content of materials, along with practical work practice and PPE requirements for those exposed (e.g., handwashing, use of gloves).

The scientific justification relied on by the State of Washington for surface benchmarks (lead action level of 1000 µg/dm2 [9290 µg/ft2], housekeeping clean area requirements of 4.3 µg/dm$^2$ [40 µg/ft$^2$] and 43 µg/dm$^2$ [400 µg/ft$^2$], and lead control area benchmark of 27 µg/dm$^2$ [250 µg/ft$^2$]) is not apparent. The trigger for applicability to the proposed Washington rule of 4.3 ug/dm$^2$ [40 ug/ft] is less than the definition of a lead dust hazard on window sills in residences with small children, the most sensitive subpopulation as it pertains to lead exposure.[55] Studies evaluating lead dust loading levels on surfaces in residences throughout the U.S. have shown concentrations that not infrequently exceed 40 µg/ft$^2$.[56] Moreover, the complexity and the scope of the Washington standard, including its expanded use of action levels and its confusing safe harbor protocols, would make it more difficult to implement with uncertain added benefit. Surface sampling is also subject to significant variability depending on the surface being sampled and the person conducting the sampling.[57]

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[53] OSHA interpretation letter dated September 10, 2008.

[54] OSHA studied the relationship of silica-containing building materials and controls in the OSHA respirable crystalline silica construction standard in order to determine when respiratory protection should be instituted in the absence of exposure data.

[55] Agency for Toxic Substances and Disease Registry (ATSDR), 2020. Toxicological Profile for Lead.

[56] EPA, 2013. Integrated Science Assessment for Lead. EPA/600/R-10/075F.

[57] Beaucham C, Ceballos D, King B. 2017. Lessons learned from surface wipe sampling for lead in three workplaces. J Occup Environ Hyg. 14(8):609–617. doi:10.1080/15459624.2017.1309047.

The above surface benchmarks represent an imperceptibly low concentration of lead on surfaces in workplaces. A microgram of lead is equivalent to one-millionth of a gram (and about 0.000000002 pounds). A sugar packet, for example, typically contains between 2 to 4 grams of sugar; 40 µg spread over a standard vinyl floor tile (amounting to a foot squared), for example, would mean between 0.00001% and 0.00002% of a sugar packet distributed over that floor tile to obtain a concentration of 40 µg/ft$^2$ (the housekeeping clean area benchmarks in the Washington state proposed standard). Put another way, a sugar packet spread evenly over two or more football fields would result in concentrations of approximately 40 µg /ft$^2$.

If OSHA intends to evaluate surface lead levels criteria to trigger medical surveillance, it must first assess whether a meaningful correlation exists between surface lead-dust levels and blood-lead levels in occupational environments. This evaluation must look at the differences in different types of work environments and areas within a worker's daily activities, and not apply a single standard to all areas of a facility. This is because differences in types of surfaces (*e.g.*, floors, worktables, dining tables), the location of surfaces (*e.g.*, eating areas, production areas, changing areas), and the exposure pathways (*e.g.*, re-entrainment of dust, ingestion) will make meaningful changes to the risk potential. For example, the presence of lead-bearing dusts in a production work area is both anticipated and does not materially increase worker risks so long as appropriate hygiene protocols are followed and/or PPE is worn. On the other hand, lead dusts in eating areas would be more relevant.

Any potential additional benchmark and sampling program should be evaluated in view of the existing housekeeping and hygiene requirements found not only in the lead standards but also the prohibition of allowing eating or drinking in the area where employees are exposed to a toxic substance (which BCI strongly supports).[58]

While it may be worth OSHA's considering acceptable cleaning protocols, there is no apparent benefit to specifying prescriptive lead surface benchmarks for inclusion in a medical surveillance program, particularly in production areas where lead dust is anticipated.

## E. Safe Harbor Compliance Protocols

### 1. Well Managed Blood Lead Levels Safe Harbor Protocol (Question 23)

*Question 23: Should OSHA consider a safe harbor protocol approach similar to the Well Managed Blood Lead Levels protocol described in the ANPRM, 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?*

Yes. BCI believes that OSHA should assess safe harbor protocols that would incentivize employers to focus on successful measures by demonstrating employers have met the health goals of the agency, as measured by actual employee blood lead level test results. The concept behind the draft Well Managed

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[58] 29 CFR 1910.141(g)

Blood Lead Levels protocol is sound and provides an incentive for employers to establish a robust and health-outcomes focused EHS program to protect workers.

By incentivizing employers to focus on the health measure of greatest importance – blood lead levels – OSHA will likely find new and more productive ways of working cooperatively with regulated facilities to improve worker health outcomes.

### 2. Safe Harbor Protocol for Handling Lead-Containing Articles in Retail Settings (Question 25)

*Question 25: Should OSHA consider a safe harbor protocol approach similar to the Retail Settings protocol described in the ANPRM, which is being considered for adoption in Washington? What aspects of the protocol would be beneficial? Are there issues, concerns, or different approaches to a "safe harbor" for retail settings that OSHA should consider?*

No. BCI opposes the retail safe harbor embodied in the current Washington DOSH draft rule. It is unnecessary and imposes burdens and costs on retail employers and employees that are not justified. The retail settings covered by the "safe harbor" simply should not be subject to the general rule from which it ostensibly provides relief because there is no meaningful risk of exposure.

There is no evidence to support a need to regulate retail establishments that sell articles containing lead, such as electronics, batteries, and packaged ammunition or fishing weights. There also is no support for the proposition that the usual retail handling of these products (by workers or customers) poses any risk of "material impairment" to the health of retail employees. These products generally are manufactured or packaged in a way as to virtually eliminate exposure to any lead in such products in retail settings; *e.g.*, battery encasements, ammunition and fishing weights in solid state form.

Retail products such as ammunition and fishing weights are generally distributed in retail packaging that prevents workers from touching them, pose little to no risk of lead dust emission, and have been safely handled for decades without undue concerns of worker exposure. And, even if the products are removed from the packaging, retail employees simply do not perform the types of actions on these products that might be expected to release lead dust (*e.g.*, grinding, welding, etc.). In a typical retail setting, there is no realistic risk of exposure from retail products sufficient to justify such onerous regulation.

It merits note that an "article" is defined under OSHA's Hazard Communication Standard as "a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, *e.g.*, minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees." 29 C.F.R. § 1910.1200(c).

The basis for the articles exemption, as stated in the definition of "article," is that an article "does not pose a physical hazard or health risk to employees." OSHA thus previously generally has concluded that the presence of chemicals in articles poses no risk of exposure such that there would be a need to disclose that chemical's presence.[59]

Logically, therefore, it follows that there is no reasonable basis for the proposition that lead-bearing articles in a retail setting warrant subjecting retailers and their employees to stringent lead control requirements if the products themselves pose such little risk as to not require a chemical disclosure label or SDS. In reality, the Washington draft rule does not provide an exemption as would be appropriate for articles, but instead imposes a set of unnecessary mandatory inventory control, housekeeping and other measures simply to avoid even more extreme and unnecessary regulation.

## F. Environmental Effects (Questions 28 and 29)

> *Question 29: Are there any situations in which reducing lead exposures to employees would be inconsistent with meeting environmental regulations?*

BCI understands this question, in view of the preamble at 87 Fed. Reg. 38,356, to be asking if any of the actions proposed by OSHA in the ANPRM for workplace lead requirements and protocols would (1) have unintended or negative environmental impacts "outside of the workplace (*e.g.*, exposure to the community through contaminated air/water, contaminated waste sites, etc.);" or (2) affect compliance with existing environmental regulations or permitting schemes.

The answer to both these questions is yes.

With regard to the first portion of the question, it is best to consider the principal current environmental regulations governing battery manufacturing and recycling:

NSPS/NEHSAP. With respect to unintended negative impacts to the environment, the New Source Performance Standards (NSPS) for lead-acid battery manufacturing plants (40 C.F.R. Part 60, Subpart KK) and secondary lead smelters (*i.e.,* battery recyclers) (40 C.F.R. Part 60, Subpart L), as well as the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the lead-acid battery production industry (40 C.F.R Part 63 Subpart PPPPPP) and lead-acid battery recycling industry (40 C.F.R. Part 63 Subpart X), all have set lead emission limitations as maximum allowed concentrations of lead in exhaust gases, in grains per dry standard cubic feet [of exhaust air] (gr/dscf).[60] This is true under both the existing EPA regulations and the presently proposed updates to those regulations, on which BCI has provided extensive comments.[61]

Achieving lower PELs within lead battery production facilities will unavoidably require moving more air, perhaps vastly larger quantities of air, and associated entrained lead particles, from production areas

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[59] 29 C.F.R. § 1910.1200(b)(6)(v).

[60] *See* 40 C.F.R. § 60.372 (lead battery manufacturing NSPS); 40 C.F.R. § 60.122 (secondary smelting NSPS); 40 C.F.R. § 63.11423 (lead battery manufacturing NESHAP, referencing battery NSPS); 40 C.F.R. § 63.543 (secondary smelting NESHAP).

[61] EPA, Review of Standards of Performance for Lead Acid Battery Manufacturing Plants and National Emission Standards for Hazardous Air Pollutants for Lead Acid Battery Manufacturing Area Sources Technology Review, 87 Fed. Reg. 10,134 (Feb. 23, 2022) (NSPS/NESHAP proposed updates); regulations.gov Comment ID No. EPA-HQ-OAR-2021-0619-0048 (BCI comments)

within the facility and through emissions control technologies. This will have several implications pertinent to OSHA's rulemaking effort.

First, exhausting more air, when the regulatory compliance criteria is expressed in gr/dscf, means that a facility would be able to emit a correspondingly higher amount of lead into the air while still complying with the NSPS/NESHAP standards.

Second, and relatedly, filter-media based emissions control devices are not constant efficiency devices, but rather variable efficiency devices which achieve higher efficiencies *when inlet loadings are higher*.[62] BCI thus expects that not only would more lead be leaving the indoor portions of the facility, but that lead (once mixed with the vastly larger amounts of air needed to achieve the reduced PEL) would present a lower inlet concentration in terms of gr/dscf, thereby reducing the efficiency of any filter media based control devices in place. For example, a 50,000 cubic feet per minute (cfm) baghouse removing air laden at 100 $\mu g/m^3$ will emit the same amount of lead to the atmosphere as the same 50,000 cfm baghouse removing air from a workspace at 25 $\mu g/m^3$. Emissions are primarily dependent on the amount of air moved, rather than the amount of lead removed from the workspace.

Third, reducing the PEL could alter cost estimates for compliance with EPA's proposed updated NSPS and NESHAP standards that BCI has already commented on, as discussed above. If anything, retrofit costs needed to comply with elements of the proposed updated NSPS/NESHAP would be expected to increase if the equipment being upgraded also had to support compliance with reduced PELs. Allocating costs between upgrades necessitated by NSPS/NESHAP updates and PEL updates would be challenging, however, BCI is available to assist OSHA (and EPA) with any analysis that may be required. It also bears noting that a component of the increased costs would be from the additional power needed to move the higher volumes of air – additional power which would have to be generated by the existing grid, thereby increasing any associated environmental effects from power generation.

<u>NAAQS</u>. The National Ambient Air Quality Standards (NAAQS) include several air pollution controls, including a limit on the concentrations of lead in ambient air. That concentration is measured against a rolling average of .15 $\mu g/m^3$. (Unlike NSPS and NESHAPs, this is a value that is not sensitive to the total volume of exhausted air.) Today, battery manufacturing facilities do not contribute to exceedances of the NAAQS lead limit in anywhere in the nation. But increased emissions resulting from compliance with lower PELs would be expected to contribute to higher 3-month rolling average ambient air lead readings.

With regard to the second portion of the question– whether reducing exposure within the workplace, through lowered PELs or otherwise, would complicate compliance with existing environmental regulations or permitting schemes – the answer is also yes. It is likely that modifications necessary to comply with lowered PELs would also trigger reevaluation of state air permits and the associated need to perform additional air modeling on re-designed emissions equipment.

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[62] The science behind this, and the effects of this, are discussed at length in Attachment A to BCI's comments on EPA's proposed updates to the NSPS and NESHAP, *supra*.

Additional facility and sanitation requirements necessitated by this rule could also require revision of facilities' National Pollution Discharge Elimination System (NPDES) permits or affect waste management activities subject to regulation under the Resource Conservation and Recovery Act (RCRA).

OSHA should not mandate specific control technologies or compliance dates without reference to, and accommodation of, permit requirements (and associated submittal/review timeframes) arising from other state and federal air, water, and waste permitting regimes.

## G. Duplicative, Overlapping, or Conflicting Rules (Questions 30 and 31)

*Question 30*: *Are there any federal regulations that might duplicate, overlap, or conflict with modifications to the current lead standards? If yes, please identify and explain how they would duplicate, overlap, or conflict.*

Please refer to answer to Question 29.

*Question 31: Are there any federal programs in areas such as defense or energy that might be impacted by modifications to the current lead standards? If yes, please identify and explain how they would be impacted.*

Lead battery manufacturing provides 50% of the nation's energy storage capacity.

The United States is home to a significant amount of lead battery manufacturing, recycling, and mining activity. The lead battery industry generates a $26.3 billion economic contribution to the national economy and employs nearly 25,000 people.

Global events have created foreign supply chain disruptions and increased threats to our country's security, safety, economy, and clean energy goals. The lead battery industry has an established North American network to manufacture, collect, recycle and remanufacture lead batteries. This, coupled with a 99% U.S. recycling rate, makes lead batteries a model of resiliency and reliability.

Moreover, that model is essential to companies who manufacture new lead batteries in the U.S. They rely on the lead battery industry's successful, closed-loop economy for a consistent supply of high-quality, cost-stable inputs – especially recycled lead, which is infinitely recyclable. This proven manufacturing model helps to inoculate the industry to supply chain disruption from trade policies and trade interruptions.

86% of North American lead metal demand is met by North American recyclers.

Recently, the Department of Defense began stepping up efforts to reduce our country's dependence on imported critical materials in order to strengthen battery critical materials supply chains. For the battery industry overall, that means reducing the amount of materials needed for battery production and recycling spent-battery materials. The domestic lead battery manufacturing supply chain offers a bulwark against the pressures facing battery chemistries dependent on foreign supply chains for critical minerals and other input materials.

Lead batteries are and their domestic supply chain is ensuring essential battery power remains available for:

- National security and defense
- Utilities and renewable energy
- Medical and public safety
- Transportation and logistics
- Grid resiliency
- Communication networks and data centers

## H. <u>Questions for Employers on Current Practices</u>

*Question 33: If you use criteria more stringent than OSHA's requirements for notifying employees of their BLL and ZPP results, how do your criteria differ from OSHA's requirements?*

As noted above, BCI believes it is appropriate and proper to provide workers with a copy of their BLL and (if the revised standard retains ZPP testing) ZPP test results in a timely manner, and to provide them the opportunity to request additional information from employer's EHS staff. *See* Questions 3 and 12 for more details.

*Question 3*5: *What are your current costs of medical removal per employee (where possible, please monetize in terms of dollars per time unit (e.g., per month, per year))? Would your company be able to reassign the medically removed worker to a job at least at the clerical level that the employee would find acceptable? Please include specific examples of hourly wages (per job category) for the employee's regular occupation and the hourly wages for the medically assigned clerical job, if available.*

BCI does not currently have reliable data on the current costs of medical removal per employee because medical removal under the OSHA standard's mandatory medical removal thresholds is incredibly rare across the industry, and has been for at least the last 20 years.

In calculating the cost of medical removal under any revised standard, OSHA will need to consider the entire economic impact of a medical removal event beyond just the hourly wages of the directly removed employee. In addition to the removed employee's wages during the period of removal, employers will have increased costs for items including, but not limited to: temporary / replacement worker wages, replacement worker training costs, lost production quality / capacity, medical staff costs to monitor the removed employee, medical monitoring costs for the replacement worker, and many other impacts.

*Question 46: If your firm purchases clothing and equipment to protect employees from lead exposure, please estimate the PPE costs necessary to comply with the current OSHA lead standard. Please give costs on a per employee basis and at an aggregated level, if available.*

BCI member companies provide clothing and equipment to their employees to protect from lead exposure. The chart below lists the types of PPE provided and, based on an informal survey of BCI members, provides the costs per year per employee. The amounts below represent the upper level of the range of PPE costs received to date. These costs are impacted by a number of factors, including the overall size of the facility (some facilities experience economies of scale), the number of employees in the BLL monitoring program, and that not all facilities provide the same types of PPE.

| **Type of PPE** | **Costs per Employee Per Year** |
|---|---|
| Gloves | $596 or more |
| Respirators | $1,500 or more |
| Protective Suits | $1,500 or more |
| General Safety Equipment/Misc. | $333 or more |
| Disposable Gowns | $86 or more |
| Shoe Booties | $90 or more |
| Goggles | $65 or more |
| Face Shields | $35 or more |

## I. BLLs and Lead Dust Contamination (Questions 54 through 58)

*Question 53: Have you taken lead dust surface measurements in your work environment? If so, what are your procedures and current costs for this testing? Please specify the labor and equipment costs for the testing. Have you experienced any impediments or limitations when using wipe sampling to identify surface contamination with lead? What can be done to overcome these barriers?*

Please refer to question 19.

## V. IMPACT ON SMALL BUSINESS ENTITIES (QUESTIONS 58 THROUGH 61)

*Question 58: How many and what kinds of small businesses or other small entities in your industry could be affected by lower protective BLL triggers in the OSHA lead standard for general industry? Describe any such effects.*

Utilizing the small business definitions and size standards adopted by the U.S. Small Business Administration (SBA) (13 C.F.R. § 121.201), BCI members include at least 10 small businesses:

- 335910 Battery Manufacturing
- At least 10 entities

- 331492 Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)
- One or more entities

- 325998 All Other Miscellaneous Chemical Product and Preparation Manufacturing
- One or more entities

Battery Council INTERNATIONAL

# APPENDIX A

## Review of CalEPA/OEHHA Worker Air/Blood Lead Modeling Approach

Gradient – October 19, 2018

# Review of CalEPA/OEHHA Worker Air/Blood Lead Modeling Approach

Prepared for
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October 19, 2018

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# Abbreviations

| | |
|---|---|
| ALM | Adult Lead Model |
| ALV | Alveolar |
| BCI | Battery Council International |
| BMF | Battery Manufacturing Facility |
| CalEPA | California Environmental Protection Agency |
| ET | Extrathoracic |
| GI | Gastrointestinal |
| GSD | Geometric Standard Deviation |
| HRTM | Human Respiratory Tract Model |
| IAF | Inhalability Adjustment Factor |
| ICRP | International Commission on Radiological Protection |
| ILA | International Lead Association |
| IEUBK | Integrated Exposure Uptake Biokinetic |
| ITC | Inhalation Transfer Coefficient |
| MMAD | Mass Median Aerodynamic Diameter |
| MPPD | Multiple-Path Particle Dosimetry |
| OEHHA | Office of Environmental Health Hazard Assessment |
| PbA | Air Lead |
| PbB | Blood Lead |
| PBPK | Physiologically-Based Pharmacokinetic |
| PSD | Particle Size Distribution |
| RIVM | National Institute of Public Health and Environment (Netherlands) |
| SAB | Science Advisory Board |
| SSF | Secondary Smelter Facility |
| TB | Tracheobronchial |
| US EPA | United States Environmental Protection Agency |

# Executive Summary

As requested by the International Lead Association (ILA) and the Battery Council International (BCI), Gradient has reviewed the technical approach used by the California Environmental Protection Agency/Office of Environmental Health Hazard Assessment (CalEPA/OEHHA) to evaluate worker lead exposures, as presented in the October 2013 report *Estimating Workplace Air and Worker Blood Lead Concentration using an Updated Physiologically-based Pharmacokinetic (PBPK) Model* (CalEPA, 2013). The OEHHA report presents the modeling methodology the Agency used to estimate blood lead (PbB) concentrations corresponding to specified air lead (PbA) concentrations and provides results that are intended to support efforts to develop workplace standards for lead exposures. This review focuses on several aspects of the OEHHA modeling approach that raise questions regarding the validity of the modeling results and the conclusions drawn based on those results. Additional comments may be prepared regarding the OEHHA approach as the process of evaluating California workplace exposure standards for lead proceeds.

The multi-step modeling approach described in the OEHHA report addresses a number of factors that influence workplace exposures to airborne lead, including the role of particle size in deposition and absorption in the body. The approach includes a model that predicts how particles of varying size distributions will be deposited in different regions of the respiratory tract (*i.e.*, the Multiple-Path Particle Dosimetry [MPPD] Model) and another model that predicts PbB concentrations resulting from assumed lead exposure levels (*i.e.*, the Leggett+ model). The approach also incorporates assumptions regarding factors such as rates of particle clearance from the body, breathing rates, lead absorption rates from various body compartments, and the variability of PbB concentrations in exposed populations.

The analysis presented in this review identified a number of corrections and modifications that are needed to address errors in the modeling approach and strengthen the scientific foundation of the results, including:

- Correcting the application of the MPPD model to include an MPPD model-recommended inhalability adjustment factor (IAF) when evaluating larger particles (*i.e.*, particles with a mass median aerodynamic diameter [MMAD] greater than 5-8 μm);
- Modifying the derivation of the Inhalation Transfer Coefficient (ITC), which estimates the fraction of inhaled airborne lead on particulates that is absorbed in the body, to reflect:
  - Current scientific knowledge regarding the clearance of inhaled/deposited particles from the body, and the timing of particle clearance from the respiratory tract to the gastrointestinal (GI) tract; and
  - Corresponding changes in the duration of various GI conditions that would be encountered by particles transported to the GI tract and the resulting time-weighted average values for lead absorption from the GI tract; and
- Expanding the particle size range considered in the modeling efforts to reflect additional available data, including data recently collected by BCI members at battery manufacturing and secondary smelter facilities.

As illustrated in this review, the current OEHHA model results overestimate the mass of inhaled particulates that will be deposited in the respiratory tract, the fraction of inhaled lead that will be deposited and absorbed into the body, and the resulting PbB concentration for a given PbA exposure. The current approach also led OEHHA to incorrectly conclude that particle size (in the 1-15 μm MMAD size range) does not affect the fraction of lead from airborne particulates that will be transferred to the blood (*i.e.*, following inhalation, deposition, and absorption). Consequently, the model yields inaccurate predictions of the PbB concentrations that would be associated with specific PbA concentrations, and does not provide a sound basis for evaluating potential workplace exposures or standards. As a result, OEHHA should conduct additional modeling, applying the recommended corrections and modifications reflecting the best currently available science. Only by implementing the recommended changes will the revised modeling yield results that more accurately reflect the current state of the science.

# 1 Introduction

As requested by the International Lead Association (ILA) and the Battery Council International (BCI), Gradient has reviewed the technical approach used by the California Environmental Protection Agency/Office of Environmental Health Hazard Assessment (CalEPA/OEHHA) to evaluate worker lead exposures, as presented in the October 2013 report *Estimating Workplace Air and Worker Blood Lead Concentration using an Updated Physiologically-based Pharmacokinetic (PBPK) Model* (CalEPA, 2013). The OEHHA report presents the modeling methodology the Agency used to estimate blood lead (PbB) concentrations corresponding to specified air lead (PbA) concentrations and provides results that are intended to support efforts to develop workplace standards for lead exposures. This review focuses on several aspects of the OEHHA modeling approach that raise questions regarding the validity of the modeling results and the conclusions drawn based on those results. Additional comments may be prepared regarding the OEHHA approach as the process of evaluating California workplace exposure standards for lead proceeds.

The multi-step modeling approach described in the OEHHA report addresses a number of factors that influence workplace exposures to airborne lead, including the role of particle size in deposition and absorption in the body. The approach includes a model that predicts how particles of varying size distributions will be deposited in different regions of the respiratory tract (*i.e.*, the Multiple-Path Particle Dosimetry [MPPD] model) and another model that predicts PbB concentrations resulting from assumed lead exposure levels (*i.e.*, the Leggett+ model). The approach also incorporates assumptions regarding factors such as rates of particle clearance from the body, breathing rates, lead absorption rates from various body compartments, and the variability of PbB concentrations in exposed populations.

This review focuses on aspects of the modeling approach that significantly influence the model results. The review also identifies the following specific quantitative corrections and modifications to OEHHA's modeling approach:

- Correcting the application of the MPPD model to include an MPPD model-recommended inhalability adjustment factor (IAF) when evaluating larger particles (*i.e.*, particles with a mass median aerodynamic diameter [MMAD] greater than 5-8 µm);
- Modifying the derivation of the Inhalation Transfer Coefficient (ITC), which estimates the fraction of airborne lead from particulates that is absorbed in the body, to reflect:
    - Current scientific knowledge regarding the clearance of inhaled/deposited particles from the body and the timing of particle clearance from the respiratory tract to the gastrointestinal (GI) tract; and
    - Corresponding changes in the duration of various GI conditions that would be encountered by particles transported to the GI tract and the resulting time-weighted average values for lead absorption from the GI tract; and
- Expanding the particle size range considered in the modeling efforts to reflect additional available data, including data recently collected by BCI at battery manufacturing and secondary smelter facilities.

As illustrated in this review, implementing these recommended modifications demonstrates that the current OEHHA approach overestimates the fraction of lead from airborne particles that will be absorbed into the body, particularly for larger particles. As a result, the current OEHHA approach overestimates the PbB concentration predicted to be associated with a specific PbA concentration and underestimates the PbA concentration associated with a specific target PbB concentration. In addition, calculations using the modified approach indicate that a central conclusion of the OEHHA report is not correct, *i.e.*, the modified calculations show that the ITC values differ depending on the assumed particle size distribution of lead exposures (including consideration of particles in the 1-15 μm and greater MMAD size range). To correct these errors and strengthen the scientific foundation for the OEHHA analysis, the recommended changes will increase the reliability of the modeling efforts by correctly applying the selected models, best reflecting current scientific knowledge and available data, and providing a more accurate and technically sound foundation for decision-making regarding occupational exposure limits.

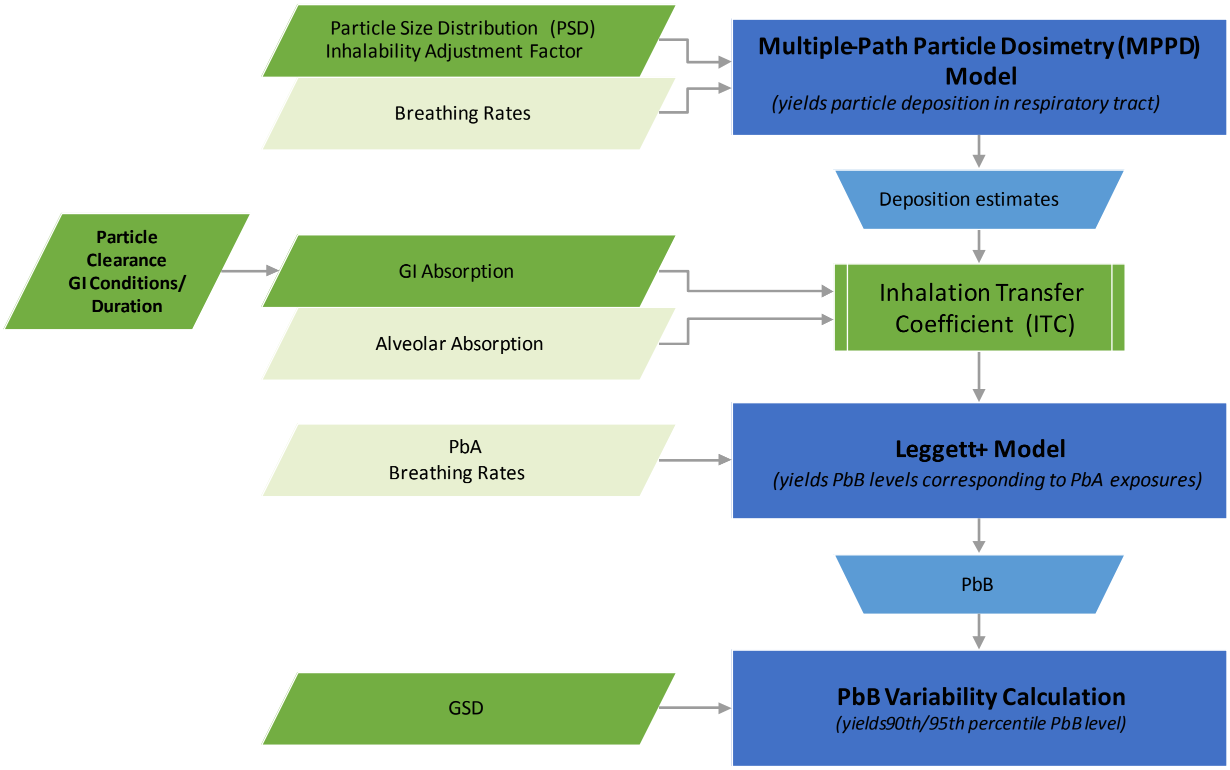
Section 2 of this review briefly summarizes the OEHHA modeling approach, while Section 3 reviews the recommended corrections and modifications, and the basis for these recommendations. Section 4 illustrates the implications of the recommended changes for the modeling results and for evaluating potential occupational exposure limits.

# 2 Overview of OEHHA Modeling Approach

The OEHHA PBPK report (CalEPA, 2013) describes the modeling approach that the Agency used to estimate PbB concentrations corresponding with workplace PbA concentrations. This modeling approach includes four main steps:

1. Particle deposition in the respiratory tract: Data regarding the particle size distribution of airborne particles, PbA concentrations, and other assumptions (such as breathing patterns and rates) were applied in the MPPD model to estimate the deposition of inhaled particles in three compartments of the respiratory tract.
2. Particle clearance processes and lead absorption: Information regarding clearance of inhaled particles (particularly to the GI tract) was combined with information regarding the timing and extent of lead absorption from the respiratory and GI tracts to estimate the overall percentage of lead from inhaled particles that is transferred to the blood (the ITC).
3. Mean modeled PbB concentrations: Information regarding lead absorption was combined with other exposure assumptions within a PBPK model (the OEHHA-developed Leggett+ model) to develop central tendency estimates of PbB concentrations associated with various PbA concentrations.
4. High-end modeled PbB concentrations: An estimate of worker population variability in PbB concentrations was used to develop high-end estimates of PbB concentrations associated with various PbA concentrations.

The key elements of the OEHHA modeling approach are summarized in Figure 2.1.



Note: GI = gastrointestinal; GSD = geometric standard deviation; PbA = air lead; PbB = blood lead.

**Figure 2.1 Overview of CalEPA/OEHHA Lead Modeling Approach**

## 2.1 Particle Deposition

Entry, deposition, and retention of airborne particles in the respiratory tract are dependent on several factors, including exposure concentration and duration, breathing patterns and rates, and particle properties (*i.e.*, size, shape, and chemical composition) (US EPA, 2009a). It is well established that particle size is the major determinant of the fraction of particles that are deposited in and cleared from the various regions of the respiratory tract (Hinds, 1999; US EPA, 2009a). To evaluate particulate deposition, the human respiratory system has generally been divided into three major regions: 1) the extrathoracic (ET) region, which includes the nose, mouth, pharynx, and larynx; 2) the tracheobronchial (TB) region, which includes the region from the trachea to the terminal bronchioles; and 3) the pulmonary or alveolar (ALV) region, which includes the alveoli where gas exchange takes place (Figure 2.2). These three regions of the respiratory tract differ in structure, airflow patterns, function, and the corresponding sizes of particles that penetrate and deposit in each region. A variety of factors influence the mechanisms of particle deposition; together with particle characteristics, these factors determine overall deposition in each region. As discussed further below, the ultimate fate of the particles differs depending on where particles deposit. For example, particles that deposit in the ALV region will be absorbed, while most particles that deposit in the ET and TB regions will be moved toward the trachea, swallowed, and ultimately ingested and subjected to absorption in the GI tract; however, a portion of the particles that deposit in the ET region will be cleared from the body prior to absorption.

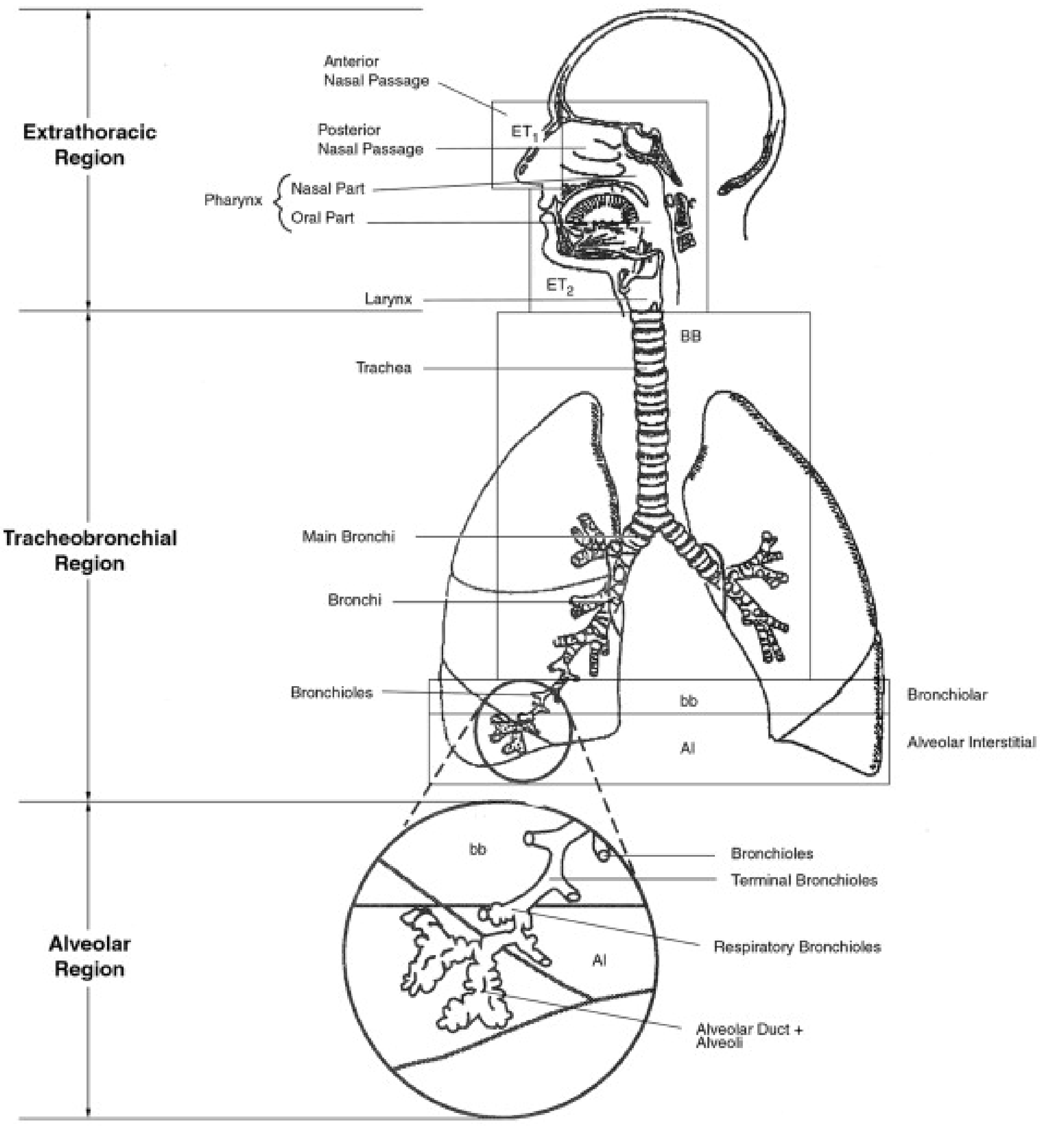


**Figure 2.2 Major Regions of the Human Respiratory System.** Source: Hofmann, 2011.

Several mathematical models have been developed to predict total and regional deposition of particles in the respiratory system (Rostami, 2009; Hofmann, 2011; Heyder, 2004; Anjilvel and Asgharian, 1995; Asgharian *et al*., 2001). To model particle deposition, OEHHA used the MPPD model, a whole-lung deposition model that incorporates respiratory tract geometry, particle size distribution data, and data on breathing patterns to calculate the fraction of deposited particles in each of the three major regions of the respiratory tract. The model documentation indicates that the model was designed to predict deposition and clearance of particles ranging in size from ultrafine (< 0.01 µm) to coarse (~20 µm); however, larger particle sizes can also be entered in the model (Price, 2014). As the MMAD values increase beyond the identified target model range, a greater degree of uncertainty might be expected; however, model deposition estimates are consistent with researcher observations and predictions of reduced inhalability/deposition efficiency for larger particle sizes.

The MPPD model was first developed by the CIIT Center for Health Research, with support from the National Institute of Public Health and Environment (RIVM) in the Netherlands (Netherlands RIVM, 2002), and was updated in 2006 (v. 2.11).[1] The MPPD model has been used in a variety of contexts, *e.g.*, by the United States Environmental Protection Agency (US EPA, 2009a) to evaluate air quality standards for particulate matter, by other researchers (*e.g.*, Oller and Oberdorster, 2010) to assess human and animal exposures to nickel, and in a comprehensive evaluation of the potential health impacts of occupational exposures to lead, conducted by the lead industry in response to a request from the European Commission (LDAI, 2008). The theoretical basis for the model is described by Anjilvel and Asgharian (1995), with additional details available in Rostami (2009), Hofmann (2011), and Asgharian *et al*. (2001).

In the evaluations presented in its report (CalEPA, 2013), OEHHA relied primarily on particle size distributions and PbA concentration data measured in secondary smelter, radiator, battery manufacturing, and lead powder facilities in Korea (Park and Paik, 2002). Apparently based on the data from this study, OEHHA focused the analyses it presented in its report primarily on particles with an MMAD of up to approximately 15 μm. OEHHA's report also presents analyses reflecting simulations of different activity levels, such as resting, sitting, light work, moderate work, and heavy work, which were obtained by varying inputs to the MPPD model (*i.e.*, breaths/min and tidal volume).

## 2.2 Particle Clearance/Lead Absorption

As noted above, the fate of lead from particles deposited in the respiratory tract depends on particle clearance and lead absorption processes that vary with regard to their timing and the extent to which they occur (Hofmann, 2011; Rostami, 2009; Smith *et al*., 2011, 2013; US EPA, 2009a). Particles that are deposited in the ALV region are cleared more slowly, and 100% of the lead from particles deposited in this region is assumed to be absorbed into the body. By contrast, particles deposited in the ET and TB region are cleared more rapidly, with most particles being transferred to the GI tract (where the lead is absorbed to a substantially lesser degree than from the ALV region of the respiratory tract). Some portion of the deposited particles is also completely cleared from the body with none of the lead from such particles being absorbed (*e.g.*, particles that are removed from the ET region by nose blowing or wiping). In the OEHHA approach, information regarding particle deposition and lead absorption was combined to yield the ITC, which represents the percentage of the lead on the inhaled particles that was ultimately deposited and absorbed in the body.

In the OEHHA approach, lead from particles that are deposited in the ALV region of the respiratory tract is assumed to be 100% absorbed. By contrast, lead-bearing particles deposited elsewhere in the respiratory tract are assumed to be transported to the GI tract, with lead absorption varying based on the conditions the particle encounters when it reaches the GI tract (*i.e.*, a fed, fasting, or between-meals state). The following equation illustrates the overall ITC calculation used in the OEHHA modeling:

---

[1] The MPPD model is available for download at http://www.ara.com/products/mppd.htm.

$$ITC = [\%Dep_{ALV} \times Ab_{ALV}] + [\%Dep_{non-ALV} \times Ab_{GI-non-ALV}]$$

where:

| | | |
|---|---|---|
| $\%Dep_{ALV}$ and $\%Dep_{non\text{-}ALV}$ | = | the percent of inhaled particles deposited in the alveolar and other (non-alveolar) regions of the respiratory tract, respectively (as calculated using the MPPD model) |
| $Ab_{ALV}$ | = | Lead absorption from the alveolar region to the bloodstream (assumed to be 100%) |
| $Ab_{GI\text{-}non\text{-}ALV}$ | = | Lead absorption from the GI tract following particle transport from the non-alveolar regions of the respiratory tract to the GI tract |

The calculation applied in the OEHHA modeling approach essentially assumed that particles deposited in the non-alveolar regions of the respiratory tract are transported to the GI tract at a steady rate throughout the day. As a result, the value of $Ab_{GI\text{-}non\text{-}ALV}$ used in the OEHHA calculations is a 24-hour time-weighted average calculated using the following formula:

$$Ab_{GI-24hr} = \frac{\left[\left(Ab_{fast} \times D_{fast}\right) + \left(Ab_{bet} \times D_{bet}\right) + \left(Ab_{fed} \times D_{fed}\right) + \left(Ab_{no} \times D_{no}\right)\right]}{24}$$

where the Ab and D values are the GI absorption, and durations of various GI conditions, as shown in the following table:

| GI Condition | GI Absorption (Ab) | Duration (hr/day) (D) |
|---|---|---|
| Fasting | 50% | 10 |
| Between meals | 19% | 10 |
| Fed | 12% | 2 |
| No absorption | 0% | 2 |

OEHHA identified the GI absorption values based on limited available scientific literature (*i.e.*, nine studies conducted between the late 1960s and the mid-1980s that typically reflect small numbers of subjects exposed to ingested lead under a variety of conditions). OEHHA's duration assumptions are based on professional judgment (with negligible information provided regarding the basis for OEHHA's choices) and yield a time-weighted GI absorption value of 30%. When OEHHA applied this value in the ITC formula for the GI absorption from particles deposited in the non-alveolar regions ($Ab_{GI\text{-}non\text{-}ALV}$), it calculated that the value of the ITC was also 30%. This ITC value plays a critical role in linking the information regarding particle size/deposition/absorption with the PBPK modeling conducted in the next step.

## 2.3 Blood Lead Modeling

In the next step of its modeling process, OEHHA applied the ITC estimate, together with other exposure assumptions (*e.g.*, breathing rates), within a PBPK model to predict the PbB concentrations that would result from workplace exposure to specific PbA concentrations. Such models integrate information regarding how lead is absorbed, distributed, and eliminated from the body to predict PbB concentrations associated with various exposure conditions. OEHHA evaluated several lead models – focusing primarily on models developed by Bert *et al*. (1989), Leggett (1993), and O'Flaherty (1993, 1995) – and selected the Leggett model for use in its evaluations. OEHHA modified the original Leggett Model to include various aspects of workplace exposure not reflected in the original structure (*e.g.*, use of the ITC) and renamed the resulting modified model as the Leggett+ model. Although OEHHA consulted with a limited number of external scientists while developing the Leggett+ model, the modified model has not been subject to broader scientific peer review.

A primary driver in OEHHA's choice of the Leggett model appears to have been the model's availability in a form that could readily be worked with and modified (*e.g.*, as discussed on pp. 40-42 of the OEHHA report). The relative technical merits of the reviewed models (*e.g.*, with regard to the validity of the PbB predictions generated by each model) were only briefly discussed.

## 2.4 Population Blood Lead Variability

In the final step of its modeling effort, OEHHA derived high-end estimates (*i.e.*, 90th and 95th percentile values) of PbB concentrations associated with specific PbA concentrations using an estimate of the population variability in PbB concentrations (*i.e.*, the geometric standard deviation [GSD] of the PbB concentrations). The GSD estimate was applied in the standard formula for calculating percentiles in a lognormal distribution; *e.g.*, for the 95th percentile, the following formula was used:

$$\text{PbB (95}^{\text{th}}\text{ percentile)} = \text{PbB (50}^{\text{th}}\text{ percentile)} \times \text{GSD}^{1.64}$$

Such an approach has been used in other PbB modeling efforts, particularly for analyses supporting development of soil cleanup levels in residential settings, focusing primarily on young children (*e.g.*, Griffin *et al*., 1999; Bowers and Mattuck, 2001). Appropriate estimates of population variability for such calculations are not intended to reflect differences in the exposure conditions or sources under consideration (*e.g.*, when setting soil cleanup levels, differences in the soil lead concentrations to which individuals are exposed). Instead, such variability estimates are intended to reflect various aspects of interindividual- or community-level variability, which can be related to differences in behavior patterns (*e.g.*, soil ingestion rates), biological responses to lead exposure (*e.g.*, absorption), or other exposure sources and pathways (*e.g.*, dietary sources) (*e.g.*, US EPA, 2009b; 2011). As a result, when deriving GSDs for use in PbB modeling, GSDs should be based on data from population groups/subgroups with comparable exposure levels.

OEHHA chose a GSD of 1.6 to estimate the variability in PbB concentrations in lead-exposed worker populations. As described by OEHHA, this value reflects data from the general population, particularly from studies in children in residential settings (Griffin *et al*., 1999; White *et al*., 1998). OEHHA selected this value recognizing the limited appropriate data for determining a GSD for PbB modeling in worker populations. For additional context for its choice, OEHHA also examined GSD values calculated from several older worker PbB studies (Gross, 1979, as cited in CalEPA, 2013, 1981; Griffin *et al*., 1975; Williams *et al*., 1969; and Azar *et al*., 1975). Based on estimated lead intake levels, OEHHA calculated GSDs that were less than (for worker groups estimated to have low or medium lead intake) and greater than (for worker groups estimated to have high lead intake) the GSD of 1.6 used in the calculations. OEHHA used the selected GSD to estimate 90th and 95th percentile PbB concentrations based on the 50th percentile values predicted by the PBPK model.

# 3 Key Issues with OEHHA's Modeling Approach

This review of the OEHHA modeling report identified a number of issues that raise questions regarding the validity of the quantitative model results and several of OEHHA's conclusions. In particular, OEHHA's conclusion that the ITC does not vary greatly for particle size distributions in the range of 1-15 µm MMAD does not reflect accurate, up-to-date, and complete consideration of the available models and scientific data, and is not supported by the modified analyses presented below. Key corrections and modifications that are needed to strengthen the scientific foundation of the modeling approach are as follows:

- Correcting the MPPD modeling conducted for larger particles (> 5-8 µm) to reflect an adjustment factor built into the model for larger particles;
- Modifying the ITC calculation to reflect updates in the underlying science and models, and corresponding changes in GI absorption assumptions; and
  - Including a more comprehensive range of workplace particle sizes (particularly particles with MMAD values > 15 µm) in the modeling scenarios.

The following sections focus on these key issues with OEHHA's modeling approach and assumptions and present recommendations for quantitative corrections and modifications to the modeling approach. These sections also briefly discuss other efforts that should be undertaken to better document and justify certain modeling choices (*e.g.*, regarding particle size data, GI absorption, GSD values, and model validation) and to better assess the consistency of the model results with workplace observations, before regulatory conclusions are based upon these results.

## 3.1 Correction to MPPD Modeling for Larger Particles (Use of an Inhalability Adjustment Factor)

OEHHA used the MPPD model to estimate deposition of lead-containing particles of various sizes within three major regions of the respiratory tract. The MPPD model includes an IAF, which the model documentation indicates is to be applied when modeling deposition of particles with an MMAD >8 µm (and model developers indicate may be appropriate for particles >5 µm; Price, 2014). This factor accounts for the fact that the data underlying the MPPD model development primarily reflect studies of smaller particles (generally < 10 µm) and also reflect different air flow conditions (*i.e.*, higher wind speeds) than would typically be encountered in indoor workplaces. The IAF is intended to account for available data indicating that larger particles encountered in indoor environments will not be inhaled and deposited in the respiratory tract to the same extent as predicted by the unadjusted MPPD model (Brown, 2005; Asgharian *et al*., 2001; Menache *et al*. (2005).

However, the results presented in the OEHHA report do not indicate that OEHHA used the IAF in its modeling, even when modeling larger particle size categories (*e.g.*, data from the Park and Paik [2002] study for battery manufacturers [MMAD = 14.1 µm] or lead powder [MMAD = 15.1 µm]). This omission has important impacts on the model predictions. As illustrated by the analyses summarized in Table 3.1 and Figure 3.1, if the IAF is omitted from the modeling calculations for larger particle size categories, the overall percentage of inhaled particles calculated to be deposited in the respiratory tract is greater than the percentage that is calculated when correctly applying the IAF. As a result, the amount of absorbed lead will also be overestimated, and the PbB concentration estimated to correspond to a specific PbA concentration will also be greater. As shown in Table 3.1 and Figure 3.1, the difference between the deposition calculated to occur with *vs*. without the IAF is greater for larger particle sizes (*i.e.*, the degree to which lead absorption will likely be overestimated increases as particle size increases).

**Table 3.1 Impact of Use of the Inhalability Adjustment Factor on Particle Deposition Estimates from the Multiple-Path Particle Dosimetry Model**[2]

| MMAD (µm) | Particle Deposition (%) | | | |
|---|---|---|---|---|
| | Total Respiratory Tract | | ET Region | |
| | w/IAF | w/o IAF | w/IAF | w/o IAF |
| 8 | 72 | 92 | 65 | 85 |
| 10 | 66 | 94 | 60 | 88 |
| 15 | 55 | 96 | 52 | 92 |
| 20 | 51 | 97 | 48 | 95 |

Note:
MMAD =mass median aerodynamic diameter; ET = extrathoracic; IAF = Inhalability Adjustment Factor.

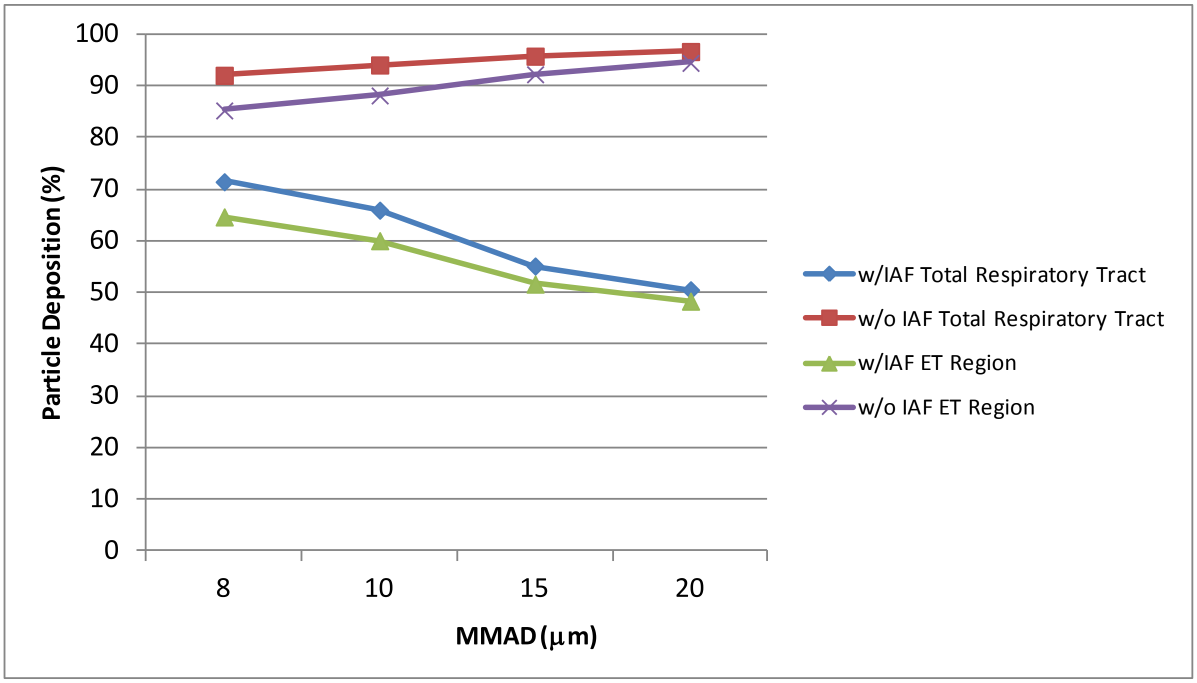


**Figure 3.1 Summary of Inhalability Adjustment Factor Impacts on Particle Deposition Estimates From the Multiple-Path Particle Dosimetry Model** (model assumptions are same as indicated for results in Table 3.1.)

The MPPD model documentation specifies that this necessary correction should be made to the OEHHA modeling approach (Netherlands RIVM, 2002, 2006). Specifically, the MPPD model documentation

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[2] Table shows MPPD model results using a GSD of 4 µm, the Yeh-Schum 5-lobe model, and assuming a unit density particle (0.01 µg/m$^3$), 20 breaths/min, tidal volume of 1042 mL, and oronasal augmenter breathing pattern.

states that "This adjustment is relevant for particle sizes…larger than about 8 microns for humans; the probability that particles larger than these are inhaled is less than 1.0 and decreases with increasing particle size. This attenuation occurs because of inertial effects." The model developers have indicated that it may also be appropriate to use this adjustment factor for smaller particles (*i.e.*, particles >5 µm) (Price, 2014).

It is also noted that inconsistencies are evident between some of the MPPD modeling results reported by OEHHA for larger particle sizes and observations of likely particle deposition patterns by other researchers. For example, in his paper describing the basis for the Leggett model, Leggett (1993) observed that "A value [for retention of inhaled particles in the lungs] of about 0.35-0.40 may be a reasonable central estimate, but deposition fractions as low as 0.15 or as high as 0.75 may not be uncommon." By contrast, some of the MPPD modeling results provided by OEHHA suggested that approximately 100% of the inhaled particles (*i.e.*, a deposition fraction of 1.0) would be deposited in the respiratory tract, exceeding the central (0.35-0.4) and high end (0.75) deposition fraction estimates suggested by Leggett. As one example, OEHHA's MPPD modeling efforts for battery manufacturing workers at rest (reflecting a larger particle size but excluding the IAF) suggested that 97% of the particles would be deposited in the ET region, 2% would be deposited in the TB region, and 0.6% would be deposited in the ALV region (yielding a total deposition fraction of 0.996).

## 3.2 Modifications to Inhalation Transfer Coefficient Calculation

The ITC is used to estimate lead absorption from inhaled airborne particles, taking into account particle deposition and clearance from various regions of the respiratory tract and differences in lead absorption in different parts of the body. Based on the review reflected in this report, two aspects of the ITC calculation need to be modified to better reflect current scientific knowledge and modeling approaches:

- The patterns of particle clearance (to reflect the existence of rapid and slow phases of clearance to the GI tract, as well as clearance to the external environment) and differences in such patterns for different respiratory tract regions), and
- Differences in GI absorption corresponding to these different clearance patterns.

As described in Section 2.2, OEHHA's assumptions yielded a time-weighted GI absorption value of 30%. When OEHHA applied this value in the ITC formula for the GI absorption from particles deposited in the non-alveolar regions ($Ab_{GI\text{-}non\text{-}ALV}$), it calculated that the value of the ITC was also 30%.

### 3.2.1 Modifications to Particle Clearance Assumptions

A number of studies and other information sources (discussed below) indicate that particle clearance from the non-alveolar regions of the respiratory tract (*i.e.*, the ET and TB regions) does not occur at a single steady rate (as assumed by OEHHA and discussed in Section 2.2), but instead is a complex process with a number of phases and with differing rates estimated for various respiratory tract compartments. Moreover, available scientific data indicate that some of the particles deposited in the ET compartment of the respiratory tract are cleared from the body to the external environment as a result of nose blowing and other similar processes. Thus, such particles are not transferred to the GI tract, and the lead from such particles is not absorbed into the body.

To more accurately reflect these processes, the estimate of the percentage of inhaled particles deposited in the non-alveolar regions of the respiratory tract applied in the ITC formula presented in Section 2.2 ($\%Dep_{non\text{-}ALV}$) should be revised as follows:[3]

- The two components of the total percentage of particles deposited in the non-alveolar regions (*i.e.*, the percentage of particles deposited in the ET region [$\%Dep_{ET}$] and in the TB region [$\%Dep_{TB}$]) should be addressed separately rather than as a combined value (*i.e.*, the parameter $\%Dep_{non\text{-}ALV}$ used in OEHHA's formula).
- The percentage of the particles deposited in the ET region (as derived using the MPPD model) should be apportioned into three categories, *i.e.*, a fraction of particles that is cleared from the body to the external environment ($Clr_{ET\text{-}ext}$), a fraction that is rapidly cleared to the GI tract ($Clr_{ET\text{-}rapid}$), and one that is slowly cleared to the GI tract ($Clr_{ET\text{-}slow}$).
- The percentage of the particles deposited in the TB region (as derived using the MPPD model) should also be apportioned between a fraction that is rapidly cleared and one that is more slowly cleared to the GI tract (using $Clr_{TB\text{-}rapid}$ and $Clr_{TB\text{-}slow}$).

A conceptual illustration of OEHHA's ITC calculation is shown in Figure 3.2, while the proposed modifications to the ITC calculation are illustrated conceptually in Figure 3.3.

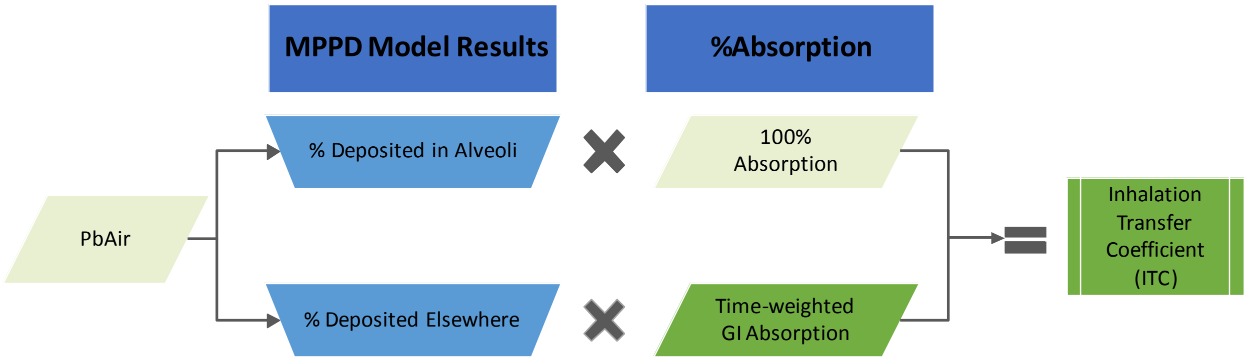

**Figure 3.2 Overview of OEHHA Gastrointestinal Absorption/Inhalation Transfer Coefficient Calculations**

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[3] The parameter abbreviations defined in these bullets (*e.g.*, $\%Dep_{ET}$) are applied in the equation presented in the discussion following Figure 3.3.

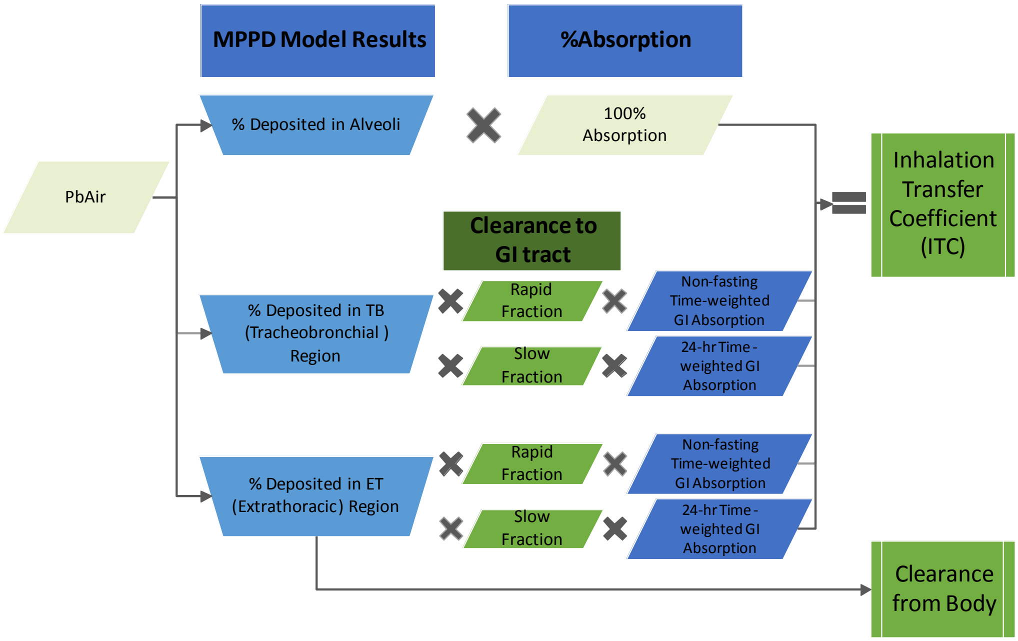

**Figure 3.3 Overview of Modified Gastrointestinal Absorption/Inhalation Transfer Coefficient Calculations**

Applying these changes alters the non-alveolar portion of the OEHHA formula presented above for calculating the ITC. Specifically, the following formula was used by OEHHA:

$$ITC = [\%Dep_{ALV} \times Ab_{ALV}] + [\%Dep_{non-ALV} \times Ab_{GI-non-ALV}]$$

while the following equation reflects the recommended modifications:

$$ITC = [\%Dep_{ALV} \times Ab_{ALV}]$$

$$+ \left[\%Dep_{ET} \times Clr_{ET-rapid} \times Ab_{ET-rapid}\right] + [\%Dep_{ET} \times Clr_{ET-slow} \times Ab_{ET-slow}]$$

$$+ \left[\%Dep_{TB} \times Clr_{TB-rapid} \times Ab_{TB-rapid}\right] + [\%Dep_{TB} \times Clr_{TB-slow} \times Ab_{TB-slow}]$$

No modifications are proposed for the assumptions for the alveolar portion of the modified equation (*i.e.*, the first line of the modified equation); as in the original equation, it is assumed that 100% of the lead deposited in the alveolar region will be absorbed. Recommended values for the other elements of this equation, and the basis for the proposed values, are described below. Because none of the lead associated with particles that are cleared from the body (*i.e.*, %Clr$_{\text{ext}}$) is absorbed, such particles do not contribute to the ITC calculation and are not included in this equation.

Recommended values for the clearance parameters that should be included in the modified calculations (*i.e.*, Clr$_{\text{ET-rapid}}$, Clr$_{\text{ET-slow}}$, Clr$_{\text{TB-rapid}}$, and Clr$_{\text{TB-slow}}$, as well as Clr$_{\text{ext}}$) are based on several lines of evidence, including information in the scientific literature as described below. The underlying scientific literature provides information and rates for different modes of particle clearance to the GI tract (including some processes that occur within a time frame of minutes after inhalation and others that occur over longer time frames). However, the primary focus in identifying recommended clearance parameters for the above modified calculation was to determine a conservative (*i.e.*, health-protective) estimate of the degree of clearance that would occur prior to the existence of fasting conditions in the GI tract (assumed to begin a number of hours after the completion of the work day exposures and the final food intake of the day, and to persist during the sleeping period). This focus was selected because, in the OEHHA approach, fasting conditions are assumed to yield lead absorption that is substantially greater than absorption under other GI conditions (*i.e.*, the 50% GI absorption OEHHA assumed for fasting conditions is 2.5 times that for between-meal conditions [19%] and more than 4 times that for fed conditions [12%]). Thus, in deriving these recommended modifications, values were extracted from the scientific literature reflecting the approximate percentages of inhaled particles that would be cleared to the GI tract on the order of hours ("rapid" clearance) *vs*. the percentage that would be cleared over a substantially greater time frame ("slow" clearance).

Values for the percentages of deposited particles assigned to the clearance parameter categories are summarized in the following table. The basis for these recommended modifications to the OEHHA ITC calculation approach is summarized below. Additional discussion of corresponding modifications to assumptions regarding GI absorption conditions is provided in Section 3.2.2 of this review.

**Table 3.2 Summary of Recommended Particle Clearance Assumptions for Extrathoracic and Tracheobronchial Regions (for use in modified Inhalation Transfer Coefficient equation)**

| Lung Region of Particle Deposition | % of Deposited Particles Cleared from Body (%Clr$_{ext}$) | % of Deposited Particles Cleared to GI Tract (%Clr$_{ET}$ and %Clr$_{TB}$) | |
|---|---|---|---|
| | | Rapid | Slow |
| *Data for all particle sizes* | | | |
| ET | 19 | 36 | 45 |
| TB | NA | 40 | 60 |
| *Data for larger particles only* | | | |
| ET | 13 | 62 | 25 |
| TB | NA | 75 | 25 |

Notes:
GI = gastrointestinal; ET = extrathoracic; TB = tracheobronchial; NA = not applicable.
Basis for recommended values provided in the following text.

The values presented in Table 3.2 are based on a number of lines of evidence including:

- Scientific research and consequent changes in progress to the ICRP model: The Human Respiratory Tract Model (HRTM) for Radiological Protection developed by a Task Group of the International Commission on Radiological Protection (ICRP) forms an important foundation for inhalation exposure modeling efforts, including elements of the Leggett+ model used by OEHHA to model lead exposures (Leggett, 1993; CalEPA, 2013). As recognized in the OEHHA report, the ICRP model documentation (ICRP, 1994) has served as a "key reference work in this area for nearly 20 years" (CalEPA, 2013). The ICRP model was specifically developed to predict deposition and dose to organs and tissues for male and female adults and children from inhalation of radioactive particles and has been developed and validated based on an extensive body of literature. Although initially published in 1994 (ICRP, 1994), recent modifications have been developed and adopted by ICRP for inclusion in the model (Smith *et al*., 2013). These changes are based in part on data collected in a human volunteer study (Smith *et al*., 2011), in which researchers evaluated the retention of particles in the ET region in a group of nine volunteers exposed to particles of various sizes (*i.e.*, 1.5, 3, and 6 µm), both at rest and while performing light exercise. The authors determined that, on average, approximately 20% of particles were cleared *via* nose blowing. Data summarized in Smith *et al*. (2013; *e.g.*, Table 3) showed that the fraction of deposited particles cleared by mucociliary action was greater, and the time for 50% of such clearance to occur was shorter, for experiments using larger particles (up to 6 µm) and with exercise (relative to results for smaller particles or for resting conditions). These new data have resulted in changes to the ET component of the ICRP model that better address the timing of particle clearance from this respiratory tract region as well as deposited particle clearance from the body *via* nose blowing and similar processes. The recommended values for particle clearance from the ET region listed in Table 3.2 are drawn from this research and the resulting changes to the ICRP model (*e.g.*, Tables 3 and 4 of Smith *et al*., 2011, and Table 1 of Smith *et al*., 2013).

In his comments on OEHHA's modeling efforts (Ginsberg, 2012), Dr. Gary Ginsberg (one of OEHHA's external scientific reviewers) noted that the model included "no accounting for loss of deposited material by coughing, sneezing, and nasal discharge." Although the OEHHA report specifically acknowledges the study conducted by Smith *et al*. (2011) and the role of nose blowing in particle clearance, the Agency states that it "made no attempt to address nose blowing as a pathway for clearing particles from the head region".

- Information regarding clearance processes and timing for the TB region is more sparse; however, ICRP (1994) documentation cites studies indicating that the slow clearance fraction for larger particles (*i.e.*, 6 μm) is approximately 25%, while the fraction for smaller particles is approximately 60% (Stahlhofen and Scheuch, 1990, as cited in ICRP, 1994). The recommended values for particle clearance from the TB region listed in Table 3.2 reflect these findings. In the calculations conducted to support the analyses presented in this review, the fraction of particles deposited in the TB region estimated by the MPPD model was generally relatively small, particularly relative to deposition in the ET region (*i.e.*, generally on the order of single digit percentages). A similar relationship among the estimated deposition fractions is reflected in the modeling analysis results included in the OEHHA report (*e.g.*, Tables B-2 and B-3 of CalEPA, 2013). As a result, assumptions regarding the percentages of these particles that undergo rapid *vs*. slow clearance have a correspondingly smaller influence on the overall ITC calculation.

- <u>Comments from an OEHHA external scientific reviewer regarding modeling approach</u>: Dr. Richard Leggett is one of OEHHA's external scientific reviewers for its modeling approach and is the original developer of the Leggett model that provides one of the crucial foundations for OEHHA's lead modeling efforts. In his peer review (Leggett, 2012), Dr. Leggett noted that the OEHHA modeling was likely to be overestimating the degree to which inhaled particles would be transferred to the GI tract during fasting conditions, stating that "the preponderance of the respiratory deposition of Pb during an 8-hour work day that will eventually be swallowed is likely to be swallowed before the next fasting period begins." Based on modeling efforts reflecting the adopted changes to the ICRP model, he estimated that approximately 80-85% of the inhaled particulate lead would reach the GI tract outside of the time of fasting conditions. His calculation suggests that a greater percentage of particles could be assigned to the rapidly cleared fraction than what is presented in Table 3.2. Such a modification would further reduce the proportion of inhaled/deposited particles that are assumed to be subjected to GI absorption under fasting conditions, and thus would further reduce the predicted degree of lead absorption.

  Dr. Leggett also noted the role of nose blowing and similar processes for particle removal and stated that the modeling he conducted based on the revised ICRP model "predicts that more than 20% of the Pb deposited in the respiratory tract is removed to the environment" *via* such processes. Again, this statement suggests that the values presented above for $\%Clr_{ext}$ represent a conservative (*i.e.*, health-protective) estimate of the proportion of deposited particles that would be subjected to such clearance processes, particularly for larger particles. That is, Dr. Leggett's statements suggest that the recommended values presented in Table 3.2 are likely to overestimate lead absorption, and thus would overestimate the PbB concentration predicted to be associated with a specific PbA concentration.

- Other studies in the scientific literature: Other scientific studies provide additional support for the recommended modifications. General support for the existence of rapid and slow clearance fractions is discussed in a review by Hofmann (2011). Smith *et al*. (2013) reported observations from studies indicating that a fraction of approximately 50% of the particles deposited in the ET region would be cleared within 4-5 hours after exposure (Lippmann, 1970, and Fry and Black, 1973, both as cited in Smith *et al*., 2013). Similarly, Smith *et al*. (2011) reported results from several studies that observed removal by nose blowing and similar removal processes of approximately 15-20% of particles deposited in the ET region (Hounam, 1975, and Hounam *et al*., 1983, both as cited in Smith *et al*., 2011).
- Results from MPPD model using clearance module: Gradient undertook exploratory calculations using the clearance module of the MPPD model and assumptions used by OEHHA to model exposures for battery workers at rest (*e.g.*, exposures during 6 hours of an 8-hour work day). (As discussed above, the OEHHA calculations did not include consideration of clearance of deposited particles to the external environment *via* processes such as nose blowing.) The clearance module is based on data regarding average mucous velocities reflected in the ICRP model (ICRP, 1994). These analyses indicated that a substantial proportion of the deposited particles would be rapidly cleared to the GI tract (*e.g.*, approximately 40% within 7 hours), and also suggested that some of the slowly cleared particles might not be cleared to the GI tract until after the beginning of the following food consumption/work day cycle. (It is noted that the current version of the MPPD model does not reflect the recent changes to the ICRP modeling approach to account for rapid clearance processes; thus, these analyses based on the current MPPD model are likely to underestimate the fraction of deposited particles that would be rapidly cleared to the GI tract.) These two factors would tend to reduce the proportion of the deposited particles that would encounter fasting GI conditions.

Because these updates regarding particle clearance patterns are not included in the current OEHHA modeling approach, the OEHHA approach overestimates the proportion of the deposited particles that will be subjected to the most aggressive, fasting GI absorption conditions. Consequently, the model also overestimates lead absorption – and the corresponding PbB concentration – for specific PbA concentrations.

### 3.2.2 Modifications to GI Absorption Approach

As described in the preceding section, the modified clearance approach and other supporting information indicate that a substantial portion of the particles that are deposited in the respiratory tract will be cleared to the GI tract within the rapid clearance phase. As a result of this shorter clearance time, these particles are likely to reach the GI tract during or shortly after the work day and are unlikely to reach the GI tract during fasting conditions. By contrast, the transport of particles subjected to slow clearance processes is likely to be more similar to the process assumed in the OEHHA approach (*i.e.*, a process that is occurring throughout the day). To account for the differences in particle timing in reaching the GI tract for these two distinct phases, two separate GI absorption estimates are needed.

For the rapidly cleared particles, the time-weighted adjustment factor should be calculated using the following modified version of the OEHHA formula that was shown in Section 2.2:

$$Ab_{GI-rapid} = \frac{\left[(Ab_{bet} \times D_{bet}) + \left(Ab_{fed} \times D_{fed}\right)\right]}{14}$$

and using the Ab (GI absorption) and D (duration of various GI conditions) values shown in the following table:

| GI Condition | GI Absorption (Ab) | Duration (hr/day) (D) |
|---|---|---|
| Between meals | 19% | 10 |
| Fed | 12% | 4 |

This formula, and the associated parameter values, reflect the following modifications from the original formula:

- The component of the original formula addressing the fasting state ($Ab_{fast} \times D_{fast}$) is omitted because the available information regarding the rapid clearance phase indicates that it is unlikely that the rapidly cleared particles would encounter fasting conditions in the GI tract to any significant extent.
- The component of the original formula addressing the "no absorption" state ($Ab_{no} \times D_{no}$) is omitted because OEHHA did not provide any basis for this element of the formula in its report, and no support for such an assumption was identified in the scientific literature or based on exploratory results from the clearance phase of the MPPD model. Thus, the value of $D_{no}$ effectively should be set at 0 hours.
- The duration of the fed state ($D_{fed}$) is increased from 2 hours per day (in the original formula) to 4 hours per day based on information in the scientific literature indicating that the impact of food intake on reducing lead absorption persists for up to several hours after food intake. For example, James *et al*. (1985), one of the studies reviewed by OEHHA, reported that the influence of meals on lead uptake persisted for up to 3 hours after food consumption. Assuming a food impact of approximately 1.5-2 hours/meal or snack, and the potential for multiple meals or snacks during the day, the assumed 4 hours of "fed" state absorption conditions reflects a reasonably conservative estimate for this parameter. By contrast, the OEHHA assumption of 2 hours/day of fed conditions per 24-hour day is likely to underestimate the duration of such conditions for most individuals.

The assumption that rapidly cleared inhaled particles have a low likelihood of encountering fasting GI conditions also includes consideration of the likely timing of food intake relative to a typical work day. In particular, GI conditions during the work day and for a number of hours after the work day are most likely to reflect "fed" and "between-meal" conditions as a result of typical meal and/or snack intake patterns. By contrast, "fasting" conditions are most likely to occur well after the completion of the work day (and inhalation exposures) – particularly during sleep.

Assuming 10 hours of between-meal GI absorption conditions, 4 hours of "fed" state conditions (for a total of 14 hours), and the corresponding GI absorption values listed in the table above, the time-weighted GI absorption value for rapidly cleared particles is calculated to be 17%.

These modifications are based on the scientific literature and other support described above for quantifying the impacts of the rapid and slow clearance processes. In addition, as noted above, these modifications considered professional judgment regarding the likely distribution of fed, fasting, and between-meal states relative to the timing of workplace exposures.

For the slowly cleared particles, the time-weighted GI absorption value ($Ab_{GI\text{-}slow}$) is calculated using essentially the same formula as used in the OEHHA calculation, with the following exceptions: the values of $D_{no}$ and $D_{fed}$ were changed to 0 hours/day and 4 hours/day, respectively, as described above.

Using these assumptions, the time-weighted GI absorption value for slowly cleared particles is calculated to be 31%.

As discussed in Section 4 of this review, when combined with other recommended modifications to the OEHHA modeling approach, these modified GI absorption values yield ITC values that are less than the value derived by OEHHA (30%) and that vary depending on particle size. Key elements of the OEHHA and modified clearance/absorption approaches are compared in Table 3.3.

**Table 3.3 Comparison of Key Elements of Clearance/Absorption Approach**

| | **OEHHA Approach** | **Modified Approach** |
|---|---|---|
| Clearance to External Environment (*e.g.*, *via* nose blowing) | Not included | ≈15-20% of particles deposited in ET region[a] |
| Clearance to GI Tract | Essentially steady-state process throughout 24-hour day | Rapidly and slowly cleared fractions[a] |
| GI Absorption | 30%<br>(24-hour time-weighted value) | 17% (rapidly cleared fraction)<br>31% (slowly cleared fraction)<br>(*reflecting differing role of fasting period in absorption*)[b] |
| Fed State Duration | 2 hours/day | 4 hours/day (*to reflect greater influence of meals on absorption*)[c] |

Notes:

ET = Extrathoracic; GI = gastrointestinal; ICRP = International Commission on Radiological Protection; OEHHA = Office of Environmental Health Hazard Assessment.

(a) Derived primarily from documentation of changes to the ICRP respiratory tract model (as documented in Smith *et al*., 2011, 2013, as well as Hoffman, 2011, Leggett, 2012 , and Ginsberg, 2012).

(b) Re-calculated to correspond with changes in the assumed patterns of particle clearance.

(c) Reflecting information in James *et al*. (1985).

It is noted that the original OEHHA GI absorption assumptions (*i.e.*, 30% as a 24-hour average and 12-50% for various GI conditions), as well as the two modified GI absorption assumptions described above for rapidly-cleared (17%) and slowly-cleared (31%) deposited particles, are generally significantly greater than the value (8%) used in the development of the prior lead workplace standard as well as in other lead assessments and models (*e.g.*, the O'Flaherty lead model, which has been used in a variety of lead exposure evaluation contexts). Most of the GI absorption values are also greater than the default value of 15% for the Leggett model. The assumption of 8% GI absorption of ingested lead applied for adults in the O'Flaherty model reflects consideration of the substantial reductions in GI absorption that occur between birth (when GI absorption of lead is estimated to be approximately 58%) and the age of approximately 8 years old and above (where absorption is estimated to be approximately 8%) (O'Flaherty, 1997). Studies reflecting both fed and fasted conditions were cited in the documentation for the O'Flaherty model assumption (O'Flaherty, 1993), *i.e.*, Rabinowitz *et al*. (1980), Chamberlain *et al*. (1978), and Watson *et al*. (1986). The studies by Rabinowitz *et al*. (1980) and Chamberlain *et al*. (1978) were also considered by OEHHA in its calculations, together with an additional seven studies. The original OEHHA GI absorption values played an important role in OEHHA's assumed ITC of 30% and its conclusion that particle size distributions between 1 and 15 μm do not significantly impact the ITC value. The substantial variation of the OEHHA assumptions from previous assumptions regarding GI absorption and the limitations in the scientific foundation for the OEHHA assumptions argue for care in applying these assumptions and interpreting the results of analyses using these assumptions. Specifically, assuming a GI absorption rate of 30% increases the potential contributions of particles deposited in the ET and TB regions of the respiratory tract to overall lead exposures and subsequent impacts on blood lead levels. Therefore, application of such an approach must take special care to 1) accurately characterize particle size and mass distributions for representative exposure conditions, 2) account for the transport timing and ultimate fate of such particles, and 3) consider the impact of particle size and density on model estimates for particle deposition within the various regions of the respiratory tract.

## 3.3 Consideration of Expanded Particle Size Range

To model particle deposition using the MPPD model, OEHHA relied primarily on data reported by Park and Paik (2002) of particle size distributions (PSDs) and PbA concentrations from measurements of 117 workers in the secondary smelter (2 facilities), radiator (3 facilities), battery manufacturing (4 facilities), and lead powder production (3 facilities) industries in Korea. The PSDs ranged from 1.3-15.1 µm MMAD. The authors noted a significant difference across industries in average particle sizes and in the fraction of particles in the respirable range (as defined by both the Occupational Safety and Health Administration and the American Conference of Industrial Hygienists).

OEHHA did not explain its rationale for using the study by Park and Paik (2002) as the primary basis for the particle size distributions (MMAD and GSD) that were used to generate absorption estimates. OEHHA also conducted only limited analyses of data from two other studies (Liu *et al*., 1996, Spear *et al*., 1998). It is unclear how these data were considered in the overall analysis, and OEHHA did not show data for the deposition analyses from Spear *et al*. (1998). The OEHHA report also did not appear to reflect incorporation of data from other studies of specific industries within its modeling effort, even when such studies were mentioned in the report (*e.g.*, Hodgkins *et al*., 1991 for battery manufacturing facilities [BMFs]).

Data have also been collected recently by BCI members at nine BMFs and five secondary smelter facilities (SSFs) (Petito Boyce *et al*., 2017). One important finding from this study highlights the significance of sampling method on determining representative particle size distributions and mass concentrations. Specifically, PbA concentrations reported by Petito-Boyce *et al*. (2017) illustrate in particle collection effectiveness and the availability of correction factors for the cascade impactor, but not the cassette sampler. Cassette samplers are demonstrably less effective in collecting larger particle sizes, as previously discussed in a number of studies (Spear *et al*., 1998; Rubow *et al*., 1987; Buchan *et al*., 1986; Davies *et al*., 1999; Spear *et al*., 1997; Stefaniak *et al*., 2009; Teikari *et al*., 2003 Petito Boyce *et al*., 2017). This reduced effectiveness is of particular importance when evaluating data for airborne particulates consisting predominantly of larger-sized particles. It is important to note that additional factors including sampling position for the sampler inlet and the jet flow velocity may also yield different PbA concentration results between cassette and cascade impactor sample data (Huang and Tsai 2001).

Furthermore, particle size distribution data reported in the BCI study indicate that the Park and Paik (2002) data used by OEHHA in its modeling do not adequately represent airborne particle exposures for lead workers in these industries in the US. For example, Park and Paik (2002) reported an average MMAD of 14.1 µm for four BMFs, whereas the analysis of the BCI BMF data yielded average MMADs ranging from 21 to 32 µm for the three job categories evaluated in the study. In addition, Hodgkins *et al*. (1991) reported a range of particle sizes by job in two facilities in the US of 11 to 23 µm. A greater contrast was seen in the data for the SSFs, where Park and Paik (2002) reported an average MMAD of 4.9 µm, based on a limited number of samples (*i.e.*, six samples collected at two SSFs), whereas the analysis of the BCI SSF data (representing 68 samples collected at five facilities) yielded average MMADs for the five job categories evaluated in the study ranging from 15 to 25 µm (Petito Boyce *et al*., 2017). A comparison of sampling approaches and results from published studies and the BCI study are summarized in Table 3.4 below.

**Table 3.4 Comparison of Published Data with BCI Study Results (2002, adapted from Petito Boyce *et al.*, 2017)**

| Job Site | Study | Approaches | Data Analysis | Results | Comparison with Petito-Boyce (2017) |
|---|---|---|---|---|---|
| Battery Manufacturing Facilities | Hodgkins *et al.* (1991) | 8-stage Marple cascade impactor samplers<br>2 US facilities (40 samples) | No effectiveness corrections | MMAD (pasting): 23 and 13 µm<br>MMAD (stacking and cast-on-strap): 12-18 µm | BCI avg. MMAD (pasting): 24 µm<br>BCI avg. (assembly): 21 µm |
| | Liu *et al.* (1996) | 4- to 8-stage Marple cascade impactor samplers<br>1 US facility (44 samples) | MMADs not reported<br>Collected "loose" particles when disassembling samplers | Avg. lead mass for particles >10 µm: ~71-79%<br>Avg. lead mass for particles <1 µm: 0.6-3.4% | BCI avg. lead mass for particles > 10 µm for predominant pattern of BCI samples: ~60-70% (including non-detect results)<br>BCI ag. lead mass for particles <1 µm: 1.4-3.3% |
| | Park and Paik (2002) | 8-stage Marple cascade impactor samplers<br>4 Korean facilities (44 samples) | Results blank- and efficient-corrected | Avg. MMAD (GSD): 14.5 µm (1.5)<br>Avg. lead mass for particles <1 µm: ~5.0% | Avg. MMAD (GSD): 21-32 µm (~2.5-7)<br>Avg. lead mass for particles <1 µm: ~1.4-3.3% |
| Secondary Smelter Facilities | Park and Paik (2002) | 8-stage Marple cascade impactor sampler<br>2 Korean facilities (6 samples) | Results blank- and efficiency-corrected | Avg. MMAD (GSD): 4.9 µm (5.0)<br>Avg. lead mass for particles <1 µm: ~25.0% | Avg MMAD (GSD): 15-25 µm (~2.5-8)<br>Avg. lead mass for particles <1 µm: ~1.4-3.3% |

Notes: BCI = Battery Council International; GSD = Geometric Standard Deviation; MMAD = Mass Median Aerodynamic Diameter.

Notably, the BCI study results highlight a large amount of variability within and across facility and job categories. Table 3.5 and 3.6 summarize the MMADs reported for various job categories at battery manufacturing facilities and secondary smelter facilities respectively. Across all BMF job categories, the range of MMADs was approximately an order of magnitude. For the SSF facilities, greater variability was observed in the MMADs for the furnace categories compared to other categories. Differences in facility processes or worker activities during sampling events may account for the variability observed across facilities and job categories.

**Table 3.5 Summary of Mass Median Aerodynamic Diameters Across Battery Manufacturing Facilities and Job Categories (average of 3 samples collected in each facility/job location) and for All Facilities Combined for Each Job Category (adapted from Petito Boyce *et al*. 2017)**

| Facility Number | Job Category | N | MMAD Average +/- SD (µm) | MMAD Values[A] (µm) | GSD Values[B] | Average Percent of Lead Mass for Particles <1 µm |
|---|---|---|---|---|---|---|
| 1 | Assembly | 3 | 20 +/- 14 | 5.0; 20; 33 | 11; 2.9; 3.6 | 8.6 |
| 2 | | 4 | 25 +/- 4.2 | 19; 24; 27; 28 | 2.9; 2.9; 3.0; 2.7 | 0.16 |
| 3 | | 2 | 10 +/- 7.9 | 4.6; 16 | 6.1; 3.2 | 11 |
| 4 | | 3 | 26 +/- 7.3 | 19; 25; 34 | 3.1; 3.2; 3.1 | 0.27 |
| 5 | | 3 | 16 +/- 5.6 | 9.9; 18; 21 | 3.3; 3.6; 3.3 | 1.5 |
| 6 | | 2 | 15 +/- 7.0 | 9.8; 20 | 4.0; 4.2 | 3.4 |
| 7 | | 3 | 15 +/- 7.9 | 9.0; 12; 24 | 6.1; 4.1; 3.1 | 5.1 |
| 8 | | 2 | 34 +/- 7.6 | 29; 40 | 3.1; 3.7 | 0.19 |
| 9 | | 2 | 30+/- 5.8 | 26; 34 | 3.3; 7.1 | 2.0 |
| **All Facilities** | | **24** | **21 +/- 9.5** | **4.6-40 (range)** | **2.7-11 (range)** | **3.3** |
| 1 | Casting | 3 | 46 +/- 39 | 21; 26; 90 | 4.8; 2.6; 6.7 | 1.2 |
| 2 | | 3 | 47 +/- 16 | 35; 40; 66 | 3.7; 5.1; 6.0 | 0.81 |
| 3 | | 3 | 15 +/- 6.4 | 7.9; 18; 20 | 12; 4.6; 17 | 13 |
| 4 | | 3 | 30 +/- 1.9 | 28; 31; 32 | 3.2; 4.2; 3.7 | 0.48 |
| 5 | | 3 | 20 +/- 17 | 8.4; 13; 39 | 3.3; 3.7; 5.5 | 2.7 |
| 6 | | 3 | 12 +/- 1.3 | 11; 11; 13 | 4.1; 4.3; 4.2 | 4.4 |
| 7 | | 2 | 60 +/- 6.8 | 55; 65 | 6.2; 7.4 | 1.6 |
| 8 | | 3 | 29 +/- 15 | 12; 36; 38 | 2.8; 4.4; 3.6 | 0.64 |
| 9 | | 3 | 42 +/- 28 | 22; 30; 73 | 3.8; 3.7; 4.6 | 0.60 |
| **All Facilities** | | **26** | **32 +/- 22** | **7.9-90 (range)** | **2.6-17 (range)** | **2.8** |
| 1 | Pasting | 3 | 27 +/- 3.9 | 22; 28; 30 | 2.9; 3.3; 3.6 | 0.28 |
| 2 | | 3 | 35 +/- 4.7 | 32; 32; 40 | 3.0; 3.0; 3.4 | 0.08 |
| 3 | | 3 | 30 +/- 11 | 18; 30; 41 | 3.4; 4.1; 4.1 | 0.68 |
| 4 | | 3 | 21 +/- 4.5 | 17; 22; 26 | 2.8; 2.9; 3.1 | 0.23 |
| 5 | | 3 | 15 +/- 7.4 | 10; 11; 23 | 2.5; 2.4; 3.2 | 0.38 |
| 6 | | 3 | 13 +/- 1.5 | 11; 12; 14 | 3.9; 5.3; 3.3 | 3.8 |
| 7 | | 3 | 20 +/- 8.4 | 12; 19; 29 | 2.6; 3.9; 3.3 | 0.71 |
| 8 | | 3 | 34 +/- 17 | 17; 36; 51 | 2.6; 3.3; 4.2 | 0.20 |
| 9 | | 3 | 23 +/- 8.9 | 13; 25; 31 | 2.5; 3.9; 3.3 | 0.43 |
| **All Facilities** | | **27** | **24 +/- 11** | **10-51 (range)** | **2.4-5.3 (range)** | **0.8** |

Notes:

GSD = Geometric Standard Deviation; MMAD = Mass Median Aerodynamic Diameter; SD = Standard Deviation.

(A) MMAD values listed in order from smallest to largest. As described in the METHODS/Data Analysis/Statistical Analyses and Data Adjustments section, five outliers were identified in the BMF study data (four in the Assembly job category samples – one each from Facilities 3, 6, 8, and 9; and one in the Casting job category samples – from Facility 7). Outlier data points were not included in the statistical summaries presented in the table above, nor in the subsequent data analyses (*i.e.*, the MPPD modeling or exploratory absorption evaluations).

(B) GSD values listed in order corresponding to MMAD values in MMAD column.

**Table 3.6 Summary of Mass Median Aerodynamic Diameters Across Secondary Smelter Facilities and Job Categories (average of 3 samples collected in each facility/job location) and for All Facilities Combined for Each Job Category (adapted from Petito Boyce *et al.*, 2017)**

| Facility Number | Job Category | N | MMAD Average +/- SD (µm) | MMAD Values[A](µm) | GSD Values[B] | Average Percent of Lead Mass for Particles <1 µm |
|---|---|---|---|---|---|---|
| 1 | Blast Furnace | 2 | 13 +/- 16 | 1.6; 24 | 41; 2800 | 40 |
| 2 | | 3 | 16 +/- 7.5 | 8.5; 15; 23 | 1.6; 3.3; 2.7 | 0.42 |
| 3 | | 3 | 18 +/- 2.2 | 16; 18; 20 | 2.9; 2.1; 3.9 | 0.59 |
| 4 | | 3 | 16 +/- 5.0 | 12; 14; 21 | 2.1; 2.2; 2.5 | 0.03 |
| 5 | | 3 | 25 +/- 4.2 | 21; 25 29 | 3.5; 4.8; 3.3 | 0.98 |
| **All Facilities** | | **14** | **18 +/- 7.3** | **1.6-29 (range)** | **1.6-2800 (range)** | **6.1** |
| 1 | Casting | 3 | 27 +/- 5.4 | 21; 29; 31 | -11; 5.8; 4.3 | 4.7 |
| 2 | | 3 | 21 +/- 5.8 | 15; 20; 27 | 2.4; 3.1; 2.9 | 0.19 |
| 3 | | 3 | 14 +/- 2.5 | 11; 13; 16 | 2.4; 2.2; 7.1 | 2.7 |
| 4 | | 2 | 13 +/- 0.97 | 12; 13 | 6.3; 5.8 | 8.0 |
| 5 | | 3 | 33 +/- 4.3 | 30; 31; 38 | 3.0; 3.0; 4.0 | 0.20 |
| **All Facilities** | | **14** | **22 +/- 8.8** | **11-38 (range)** | **2.2-11 (range)** | **2.8** |
| 1 | Material Handling | 3 | 17 +/- 2.0 | 15; 16; 19 | 3.0; 2.8; 2.8 | 0.45 |
| 2 | | 3 | 16 +/- 3.8 | 13; 14; 20 | 2.3; 2.0;- 2.3 | 0.05 |
| 3 | | 2 | 14 +/- 2.3 | 12; 15 | 2.7; 2.7 | 0.48 |
| 4 | | 3 | 15 +/- 1.7 | 13; 15; 16 | 2.0; 2.7; 4.2 | 0.97 |
| 5 | | 2 | 16 +/- 0.7 | 16; 17 | 2.6; 2.6 | 0.17 |
| **All Facilities** | | **13** | **15 +/- 2.3** | **12-20 (range)** | **2.0-4.2 (range)** | **0.44** |
| 1 | Refining | 3 | 25 +/- 7.2 | 17; 25; 31 | 3.0; 6.3; 5.0 | 2.0 |
| 2 | | 3 | 29 +/- 14 | 17; 27; 44 | 2.2; 3.1; 2.6 | 0.07 |
| 3 | | 3 | 23 +/- 6.5 | 18; 20; 30 | 4.4; 2.9; 3.7 | 1.1 |
| 4 | | 3 | 19 +/- 10 | 12; 14; 30 | 2.4; 3.2; 3.7 | 0.64 |
| 5 | | 3 | 22 +/- 5.8 | 17; 21; 28 | 3.6; 3.1; 4.8 | 1.2 |
| **All Facilities** | | **15** | **23 +/- 8.5** | **12-44 (range)** | **2.2-6.3 (range)** | **1.0** |
| 1 | Reverb Furnace | 3 | 14 +/- 11 | 3.5; 15; 24 | 8.3; 6.1; 2.4 | 12 |
| 2 | | 3 | 18 +/- 6.1 | 13; 15; 25 | 3.1; 2.8; 4.4 | 0.48 |
| 3 | | 3 | 19 +/- 12 | 11; 14; 33 | 2.8; 3.0; 4.4 | 0.88 |
| 5 | | 3 | 51 +/- 39 | 20; 39; 95 | 3.0; 3.3; 5.4 | 0.26 |
| **All Facilities** | | **12** | **25 +/- 24** | **3.5-95 (range)** | **2.4-8.3 (range)** | **3.3** |

Notes:

GSD = Geometric Standard Deviation; MMAD = Mass Median Aerodynamic Diameter; SD = Standard Deviation.

(A) MMAD values listed in order from smallest to largest. As described in the METHODS/Data Analysis/Statistical Analyses and Data Adjustments section, two outliers were identified in the SSF study data (one in the Blast Furnace job category samples from Facility 1 and one in the Casting job category samples from Facility 4). Outlier data points were not included in the statistical summaries presented in the table above, nor in the subsequent data analyses (*i.e.*, the MPPD modeling or exploratory absorption evaluations).

(B) GSD values listed in order corresponding to MMAD values in MMAD column.

Such variability within and across facility and job categories may account for some of the differences observed between previously published data and the BCI study results. Alternatively, differences may be attributable to the broader range of job categories included in the BCI study, or possible differences between processes and controls in Korean and US industries. For example, hygiene or other exposure control mechanisms employed in newer facilities may reduce exposure routes including ingestion of particles that may accumulate on worker hands during smoke breaks or lunch breaks. Furthermore, exposure control mechanisms may impact particle size distributions, with subsequent impacts on particle deposition in the lung and impacts on blood lead. Issues related to variability within and across facility and job categories, as well the implications of exposure controls in newer facilities, suggest that the more limited Park and Paik (2002) data may not be representative of industry wide exposure conditions and particle size distributions, particularly for US secondary smelters.

These findings from the BCI studies and other studies in the scientific literature indicate that the PSD data used by OEHHA in its MPPD modeling is not fully representative of likely exposure conditions in US industries and forms an insufficient basis for modeling to support evaluations of occupational exposure limits. In particular, such modeling should not be limited to the 1-15 μm MMAD size range, because available data indicate that workplace settings exist with average MMAD values that are greater than this range. By incorporating data such as the findings from the BCI studies in its modeling efforts, OEHHA would expand the particle size range, geographic coverage, sampling time frame, and sample size reflected in its analyses.

## 3.4 Other Recommendations

Several other components of the OEHHA analyses merit additional documentation and discussion. In particular, OEHHA should better document and justify certain key choices made in the modeling process, including demonstrating that its choices reflect a systematic and critical review of the scientific literature and other relevant information. As noted above, these components include the Agency's justification for relying primarily on the PSD data collected by Park and Paik (2002) as inputs for its MPPD modeling and additional evaluation of the limitations in the scientific foundation for the GI absorption estimates used in its modeling. The OEHHA report should also include a more rigorous evaluation of its GSD selection process and the degree to which the selected value is likely to represent inherent interindividual- or worker population-level variability. In particular, the report should acknowledge that the comparison GSDs that OEHHA calculated based on worker data reflect older studies (the most recent study reviewed was published in 1981) and thus may not be representative of current worker exposure patterns.

In a related issue, the OEHHA report should further discuss the implications of using data from older workplace studies to conduct initial modifications to the PBPK model and validate the final model predictions. Again, a primary topic that should be discussed is the issue of whether the model developed based on data reflecting studies of older workplace conditions provides a suitable basis for estimating potential exposures in current worker populations. For example, one of the two studies that OEHHA relied on to assess the performance of the Leggett+ model was a study of battery factory workers (Williams *et al*., 1969). In other evaluations of this study, it has been specifically noted as an exposure setting where "hand to mouth lead transfer" and "personal working habits" may have played an important role in the observed PbB levels (Hammond *et al*., 1981). Similarly, the OEHHA report should also further consider the degree to which the model predictions are consistent with and representative of observations in current workplaces.

In considering the validity of the Leggett model predictions, OEHHA should also consider concerns regarding the technical validity and accuracy of the Leggett model that have arisen in previous model applications. In its modeling efforts, OEHHA noted that its initial case study applications of the Leggett model resulted in "significant under predictions" of worker PbB levels, and that they needed to adjust the model to yield predicted PbB concentrations that more closely matched observed levels. In previous applications of the Leggett model to assess community lead exposures in children (*e.g.*, in components of US EPA's evaluation of the National Ambient Air Quality Standard for lead [as documented in US EPA, 2013]), the Leggett model has yielded higher predicted PbB levels than other models (*e.g.*, US EPA's Integrated Exposure Uptake Biokinetic [IEUBK] model or the O'Flaherty model; US EPA, 2006). In another application, US EPA's Science Advisory Board (SAB) supported the Agency's decision to conduct evaluations of adult lead exposures using its Adult Lead Model[4] (ALM) rather than the Leggett model when developing lead dust standards for residences. Specifically, the SAB stated that in that application the ALM "yields more plausible estimates of average population PbB concentrations" than the Leggett model (US EPA SAB, 2011). Similarly, for the corresponding evaluations of children's lead exposures, the SAB identified US EPA's IEUBK model as "the clearly preferred model" rather than the Leggett model. These concerns indicate the need for careful validation and interpretation of the Leggett/Leggett+ model results before relying on the Leggett+ model to support regulatory decisions.

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[4] US EPA's ALM is a simplified steady-state model that uses a set biokinetic slope factor to estimate a PbB concentration corresponding to an estimated daily intake of lead.

# 4 Implications of Recommended Corrections and Modifications for Modeling Results

This section summarizes the differences between the OEHHA modeling approach and the recommended corrected/modified approach. Example calculations are provided, illustrating the quantitative implications of the recommended changes for the modeling results. In particular, these analyses focus on the implications of the changes for the calculated ITC values and the PbB concentrations predicted to be associated with specific PbA concentrations. It is noted, however, that this discussion does not imply endorsement of the use of the OEHHA modeling approach to support regulatory decision-making, even if the recommended corrections and modifications are undertaken. As discussed in this review, even if the proposed changes are made, other fundamental concerns regarding the OEHHA approach will remain and require further evaluation (*e.g.*, questions regarding the validity of the Leggett+ model predictions for current workplace conditions , particularly in light of OEHHA's use of older studies that are unlikely to be reflective of current conditions in its model validation efforts).

The recommended corrections and modifications to the OEHHA modeling approach described above result in the following changes to the model predictions:

- For all particle sizes, a fraction of deposited particles are completely cleared from the body (*e.g.*, through nose blowing), and thus are never cleared to the GI tract or absorbed;
- For all particle sizes, a smaller fraction of particles are cleared to the GI tract during fasting conditions (*i.e.*, under the highest assumed GI absorption conditions); and
- For larger particles, a smaller fraction of particles are deposited in the respiratory tract.

All of these modifications result in a smaller fraction of the lead from inhaled airborne particles being absorbed into the body. As a result, using the corrected/modified approach, the PbB concentration predicted to be associated with a specific PbA concentration is reduced and the PbA concentration associated with a specific target PbB concentration is increased.

In addition, calculations using the modified approach demonstrate that a central conclusion of the OEHHA report is not correct. In contrast to statements made in the OEHHA report, the ITC calculation does in fact differ depending on the particle size distribution to which exposure occurs (including consideration of particles in the 1-15 µm and greater MMAD size range), particularly when considering the appropriate adjustment for larger sized particles in the MPPD model. As a result, this important feature of workplace exposure characterization must be appropriately addressed in determining health-protective, scientifically sound workplace exposure levels, *i.e.*, by applying the corrections and modifications described in this review.

## 4.1 Implications for ITC Values

A number of calculations were undertaken to explore the implications of these recommended modifications for the OEHHA modeling results. As a first step, the impacts of the modifications on the calculated ITC values were explored. These calculations were conducted using various combinations of the following model assumptions:

- Applying the modified clearance approach to estimate the lead absorption (as reflected in the ITC) associated with various particle deposition distributions generated by the MPPD model;
- Correcting the MPPD model analyses for larger particle sizes (MMAD > 8 μm) by applying the IAF; and
- Applying an assumed particle size (MMAD = 20 μm or greater) in the MPPD model that is greater than that evaluated in the OEHHA report (MMAD up to 15 μm) to estimate the impact of larger particle sizes on deposition in the three regions of the respiratory tract.

Various particle sizes and activity levels were considered in these calculations.

As illustrated by the evaluations summarized in Table 4.1, these corrections and modifications confirm that the ITC value is in fact highly influenced by particle size and related assumptions (including consideration of particles in the 1-15 μm and greater MMAD size range). In addition, consideration of updated knowledge regarding particle clearance also substantially affects the ITC calculation. Specifically, the first row of this table lists the ITC value (0.3, or 30%) that OEHHA reported from its calculations for a variety of particle sizes (up to an MMAD of approximately 15 μm) and exposure conditions. As noted above, its calculations did not include use of the IAF for particle sizes > 8 μm. The next section of Table 4.1 (OEHHA Baseline) illustrates the changes in the ITC that result when the IAF is applied for an assumed particle size of 14 μm in the MPPD model (the particle size used in the OEHHA modeling based on BMF data) and/or when the modified clearance approach is included in the ITC calculations. As can be seen, when both of these corrections/modifications are made, the resulting ITC (0.16-0.17) is approximately one-half of the value originally derived by OEHHA.

**Table 4.1 Impacts of Modifications on Inhalation Transfer Coefficient Values**

| Analysis | Modifications | Resulting ITC[a] |
|---|---|---|
| OEHHA Baseline (larger or smaller particles) | – | 0.3 |
| OEHHA Baseline (larger particles)[b] | Add IAF only | 0.25-0.28 |
| | Add modified clearance approach only | ≈0.2 |
| | Add modified clearance approach and IAF | 0.16-0.17 |
| BCI BMF Baseline[c] | Includes larger particle size and IAF | 0.16 |
| | Add modified clearance approach | ≈0.1 |
| OEHHA (smaller particles)[d] | Add modified clearance approach | 0.22-0.23 |

Notes:

BCI = Battery Council International; BMF = battery manufacturing facility; IAF = Inhalability Adjustment Factor; ITC = Inhalation Transfer Coefficient; OEHHA = Office of Environmental Health Hazard Assessment.

(a) Range in ITC values reflects differences observed for different assumed activity levels.

(b) Calculations conducted using MMAD = 14.1 μm, the value for BMFs used in the OEHHA analyses.

(c) Calculations conducted using MMAD = 20 μm, reflecting the high end of the particle size distribution range identified in the MPPD model documentation, as well as observations reflected in the results from the BCI BMF and SSF Studies.

(d) Calculations conducted using MMAD = 4.9 μm, the value for SSFs used in the OEHHA analyses.

Similarly, as shown in the next section of Table 4.1 (BCI BMF Baseline), when a larger particle size is employed (*e.g.*, a particle size of 20 µm to reflect the high end of the particle size distribution range identified in the MPPD model documentation, as well as observations reflected in the results from the BCI BMF and SSF Studies), substantial reductions in the ITC are observed. When the larger particle size is used and the IAF is correctly applied, the calculated ITC of 0.16 is again determined to be approximately one-half of the value originally derived by OEHHA. When the modified clearance approach is also included, the calculated ITC drops to approximately one-third of the value originally derived by OEHHA (*i.e.*, ≈0.1). As discussed below, consideration of additional modifications to these calculations indicates that ITC values less than 0.1 could be derived for some sets of exposure assumptions.

Figure 4.1 graphically illustrates some of the impacts of the recommended changes on the modeling results. This figure compares results from the MPPD model for the OEHHA Baseline modeling for larger particles (*i.e.*, excluding the IAF and reflecting a particle size of 14 µm and a GSD of 1.5) and MPPD results obtained using a larger particle size (*i.e.*, 20 µm and a GSD of 4) and the IAF. As can be seen, applying just these changes in the MPPD modeling yields dramatically different results. In particular, the percentage of particles predicted to be deposited in the ET region decreases by approximately one-third to more than one-half of the amount predicted by the original OEHHA analyses (*i.e.*, a decrease in the deposition fraction from 0.89 to 0.58 for the calculations reflecting moderate activity and a decrease from 0.97 to 0.44 for the calculations reflecting resting conditions).

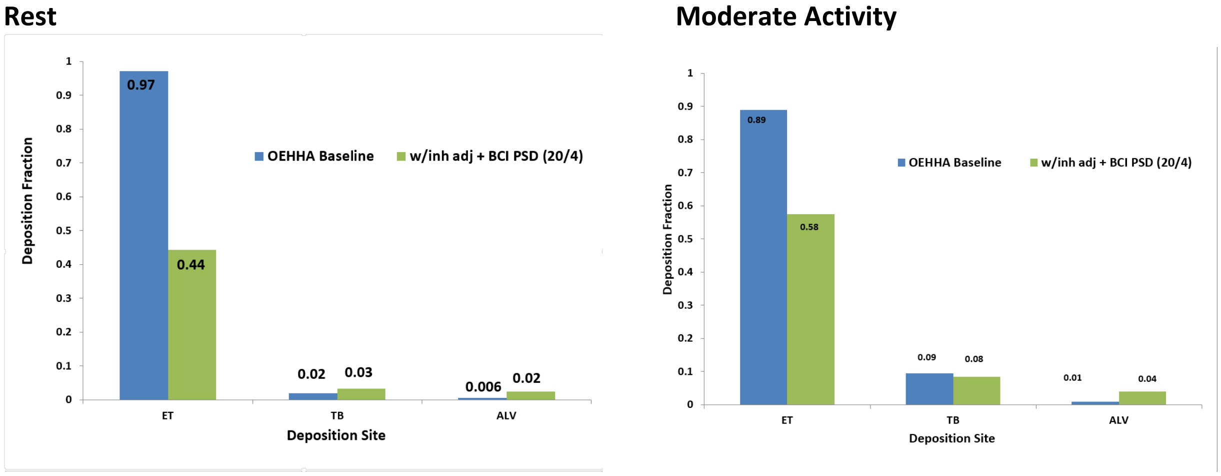

**Figure 4.1 Implications of Including the Inhalability Adjustment Factor and Larger Particle Size for Multiple-Path Particle Dosimetry Modeling Results**

The last section of Table 4.1 (OEHHA [small particles]) demonstrates that, even for small particles, OEHHA's original ITC of 0.3 does not reflect likely lead absorption from these particles. Specifically, when OEHHA baseline analyses for smaller particles (*e.g.*, ~5 µm, the size range that OEHHA assessed for SSFs) are adjusted to reflect the modified clearance approach based on updates to the ICRP model, the resulting ITC is reduced from 0.3 to 0.22-0.23 (22-23%).

As noted in the supporting documentation described in this review, a number of the corrections and modifications reflected in Table 4.1 represent conservative (*i.e.*, health-protective) assumptions, that is, they may overestimate particle deposition and lead absorption. For example, studies in the scientific literature and the calculations provided by Dr. Leggett during his review of the OEHHA report indicate that the percentage of deposited particles subject to rapid clearance processes could be greater than assumed in the calculations underlying Table 4.1. Similarly, exploratory calculations using the MPPD model indicate decreases in model predictions of particle deposition with increases in particle size to values > 20 µm.[5] Clearance from the body by processes such as nose blowing, and the duration of food intake impacts on GI absorption of lead, could also be greater than assumed in the Table 4.1 calculations.

Exploratory calculations indicate that some combinations of alternative modifications to these assumptions could yield an ITC that is even less than the values reported in Table 4.1. For example, the combination of the following modified assumptions yields an ITC value of 0.07 (7%):

- Using the largest particle size observed in the BCI studies (32 µm), with a GSD of 5 and assuming resting conditions;
- Assuming a greater percentage of deposited particles undergo rapid clearance processes (*i.e.*, 70% for the ET region and 100% for the TB region), and thus are not subject to GI absorption under fasting conditions;
- Assuming that 20% of deposited particles are removed *via* nose blowing; and
- Assuming that the duration of "fed" conditions in the GI tract is 6 hours per day (rather than 4 hours) and that the duration of "between-meal" conditions is correspondingly reduced.

These analyses demonstrate that OEHHA's conclusion that particle size (including consideration of particles in the 1-15 µm MMAD size range) does not affect overall lead absorption (as reflected in the ITC) is incorrect and not supported by current scientific knowledge regarding particle deposition and clearance. As illustrated in Table 4.1, particle size clearly influences the ITC calculation using the corrected and updated model. Moreover, for workplaces with predominantly larger particle sizes (such as those included in the BCI studies), a more appropriate value for the ITC is closer to 0.1, or possibly lower, rather than the 0.3 value calculated in the OEHHA report. In addition, even for smaller particle sizes, including the updated science regarding particle clearance yields ITC estimates that are less than the value calculated by OEHHA (*e.g.*, 0.22 or 0.23 *vs*. 0.3).

As a result, these analyses call into question both the OEHHA modeling results and their soundness as a basis for determining occupational exposure levels. Moreover, the modified estimates represent conservative changes to the ITC calculation. Alternative assumptions can yield ITC estimates that are even lower, which would result in lower predicted PbB concentrations for specific PbA concentrations. Because the ITC value has such important implications for the PbB concentrations predicted to be associated with specific PbA exposures, these types of analyses warrant careful consideration in conducting the modeling to support determination of occupational exposure limits. Without these corrections and modifications, the current OEHHA analyses are incorrect and inadequate for supporting policy decision-making.

## 4.2 Implications for PbB Predictions

Additional analyses were undertaken to explore the implications of the recommended changes for the PbB levels predicted to be associated with specific PbA concentrations using the OEHHA modeling approach. The modeling results derived by OEHHA (CalEPA, 2013) are summarized in Table 4.2. Table 4.3 provides example results obtained using benchmark alternative values for the ITC, reflecting the range of

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[5] Although the MPPD model documentation indicates that the target size range for model analyses is from < 0.01 to ~20 µm, the model accommodates input values that are greater than 20 µm (Price, 2014). Using MMAD values ranging from 20 to 32 µm (the maximum average MMAD value observed in the BCI studies), a GSD of 4, and assuming resting conditions, the predicted total deposition fraction decreased from 0.51 to 0.45. The observations for the three regions of the respiratory tract are as follows: from 0.48 to 0.42 for the ET region, from 0.009 to 0.02 for the TB region, and no change for the ALV region.

values derived based on the recommended model changes (as summarized in Table 4.1; *i.e.*, correctly using the IAF for larger particle sizes, updating the clearance and absorption assumptions, and expanding the particle size range considered) and including consideration of the potential for even lower ITC values to be obtained using alternative assumptions (*i.e.*, using an example benchmark ITC value of 0.05 to explore the implications of such calculations). As can be seen in Table 4.3, when the ITC is decreased by a factor of 3, the PbA concentration estimated to be associated with a specific 95th percentile PbB concentration increases by a factor of approximately 3; for example, for a target 95th percentile PbB concentration of 20 µg/dL, the corresponding PbA concentration increases from 5.9 µg/m$^3$ (using the OEHHA baseline assumptions, including an ITC value of 0.3) to 17.6 µg/m$^3$ (using the recommended changes, including an ITC value of 0.1). If the ITC is decreased by a greater amount (*e.g.*, the factor of 6 decrease that would be represented by an ITC value of 0.05), the PbA concentration would be increased by a corresponding greater amount.

**Table 4.2 Overview of OEHHA Modeling Results**

| 8-hr TWA PbA (µg/m$^3$) | Predicted PbB (µg/dL) 95th percentile |
|---|---|
| 0.5 | 5 |
| 2.1 | 10 |
| 6.0 | 20 |
| 10.4 | 30 |

Notes:
TWA = time-weighted average; PbA = air lead; PbB = blood lead; OEHHA = Office of Environmental Health Hazard Assessment.
Excerpt from Table S-1 of CalEPA (2013).

**Table 4.3 Summary of Impacts of Alternative Inhalation Transfer Coefficient Values on Air Lead Results**

| 95th Percentile PbB (µg/dL) | 50th Percentile PbB (µg/dL) | PbA (µg/m$^3$) @ ITC = 0.3 | @ ITC = 0.2 | @ ITC = 0.1 | @ ITC = 0.05 |
|---|---|---|---|---|---|
| 5 | 2.3 | 0.5 | 0.7 | 1.5 | 2.9 |
| 10 | 4.6 | 2.1 | 3.2 | 6.4 | 12.8 |
| 20 | 9.3 | 5.9 | 8.8 | 17.6 | 35.2 |
| 30 | 13.9 | 10.3 | 15.5 | 30.9 | 61.9 |

Notes:
ITC = Inhalation Transfer Coefficient; PbA = air lead; PbB = blood lead.

As discussed above, by implementing the recommended changes, the modeling will eliminate the specific errors in the modeling approach described above and yield results that better reflect the current state of the science. These changes are needed to provide a meaningful basis for determining health-protective occupational exposure limits, particularly for certain types of workplaces. In particular, the current OEHHA model results overestimate the mass of inhaled particles that will be deposited in the respiratory tract and the fraction of inhaled lead that will be deposited and absorbed into the body. The current approach also led OEHHA to incorrectly conclude that particle size (including consideration of particles in the 1-15 µm MMAD size range) does not affect the fraction of lead from airborne particulates that will be transferred to the blood (*i.e.*, following inhalation, deposition, and absorption). Consequently, the model yields inaccurate predictions of the PbB concentrations that would be associated with specific PbA concentrations, and does not provide a sound basis for evaluating potential workplace exposures or standards. As a result, OEHHA should conduct additional modeling applying the recommended changes to provide a scientifically sound foundation for setting occupational exposure limits.

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