

OCCUPATIONAL LEAD POISONING PREVENTION PROPOSAL

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LEAD RULEMAKING TIMELINE

PRE-RULEMAKING &

FORMAL RULEMAKING

LEAD PRE-RULEMAKING TIMELINE

- **2010 & 2011:** California Dept. of Public Health (CDPH) request to Cal/OSHA:
 - Lower PEL, lower Action Level, lower blood lead levels for removal
 - More protective requirements for hygiene, protective clothing, training, and communication
- **2011 and 2012:** 1st and 2nd Cal/OSHA lead advisory meetings
 - Discuss medical surveillance and medical removal protections
- **2012:** National Toxicology Program Monograph On Health Effects Of Low-Level Lead
- **2013:** U.S. EPA Integrated Science Assessment for Lead

LEAD PRE-RULEMAKING TIMELINE

- **2013:** California Office of Environmental Health Hazard Assessment (OEHHA) publishes updated physiologically-based pharmacokinetic modeling for worker blood lead levels
- **2013:** CDPH recommends to Cal/OSHA Permissible Exposure Limit (PEL) of 0.5 to 2.1 $\mu\text{g}/\text{m}^3$
- **2013:** CDPH Scientific Symposium on scientific basis for proposed PEL
 - Presenters from NIOSH, CDPH, OEHHA, University of Colorado, Mount Sinai School of Medicine, Clark University, Michigan State University, UC Irvine

LEAD PRE-RULEMAKING TIMELINE


- **2014:** 3rd Cal/OSHA Advisory Meeting: Proposed PEL of 10 $\mu\text{g}/\text{m}^3$ and Action Level of 2 $\mu\text{g}/\text{m}^3$; levels higher than those recommended due to feasibility concerns
- **2015:** 4th (General Industry), 5th (Construction), and 6th Cal/OSHA Advisory Meetings
- **2016:** Revised Regulation drafts released
- **2017:** Final drafts prepared
- **2018- 2019:** SRIA prepared

LEAD PRE-RULEMAKING TIMELINE

- **2019:** Labor Code 6717.5. Requires Cal/OSHA to propose revised lead regulation and Standards Board to vote on proposal by 9/30/20
- **2020 – 2022:** Staff moved to COVID-19 work. SRIA reviewed

LEAD FORMAL RULEMAKING TIMELINE

- **March 3, 2023:** Formal rulemaking begins
- **March 3 – April 20:** 45-day Public Comment Period
- **April 20, 2023:** Public Hearing
- **July 7 - 24, 2023:** First 15-day Public Comment Period
- **October 6 - 25, 2023:** Second 15-day Public Comment Period
- **February 15, 2024:** Standards Board vote expected
- **January 1, 2025:** Effective date, if passed



Health Effects of Lead

There is no known safe level of lead in the human body

Lesley Onyon, Toxicologist
Head, Chemical Safety and Health Unit
World Health Organization

NO SAFE LEVEL OF LEAD

Agency for Toxic Substances and Disease Registry (**ATSDR**),
U.S. Department of Health and Human Services

- ATSDR develops Minimum Risk Levels (MRLs) for toxics
 - based on human and animal scientific studies
- There is no MRL for lead because the lowest lead levels measured are associated with serious adverse health effects

NO SAFE LEVEL OF LEAD

The EPA maximum contaminant level goal (MCLG) for lead in water is **ZERO**

*“EPA has set this level based on the **best available science** which shows **there is no safe level of exposure to lead.**”*


Health Effects of Lead

Lead is toxic to nearly every organ system regardless of age, gender, or exposure pathway (inhalation or ingestion). Lead can cause many health problems:

- Kidney damage
- High blood pressure
- Heart disease
- Various types of brain damage
- Cerebrovascular accident (stroke)
- Peripheral vascular disease
- Osteoporosis
- Decreased hemoglobin
- Decreased sperm count
- Infertility
- Spontaneous abortion (miscarriage)
- Reduced birth weight/premature birth
- Learning/behavior problems and kidney damage to developing infant

LEAD IS POISON

- Lead is a true poison – it has no role in the body
- Lead mimics calcium – essential in brain chemistry
 - Leads to the death of neurons and other brain cells
 - Interrupts communication between neurons, impairing learning and memory
- Lead mimics calcium in blood vessel cells and takes over some of calcium's normal activities leading to:
 - High blood pressure, coronary artery disease, heart disease, and stroke



Why Do Rulemaking for Lead?

WHY DO LEAD RULEMAKING?

- The current lead regulations (title 8 sections 1532.1 and 5198) do **not** protect workers from low-level lead poisoning
- The proposal will greatly improve lives of lead-exposed workers by reducing lead-related illness, disability, and early death

Outdated Lead Regulation

- Current Lead Permissible Exposure Limit (50 $\mu\text{g}/\text{m}^3$) and Action Level (30 $\mu\text{g}/\text{m}^3$)
 - Based on outdated toxicological, medical, and epidemiological data
 - Over **45** years old
 - Do **NOT** protect workers from all harmful effects
- Recent toxicological, medical, and epidemiological data shows very low lead exposures have serious harmful effects. No safe level found.
- It was not known that low lead levels were harmful when the 1978 PEL and Action Level were set

Outdated Lead Regulation

Keeping the existing regulation instead of the proposal would result in the following among lead-exposed workers in California in 10 years:

- 31 additional worker **deaths**
- 329 additional workers with **hypertension**
- 10 additional workers will suffer from **non-fatal heart attacks**
- 691 additional workers will suffer from **depression**

Not included are additional cases of kidney disease, heart disease, anemia, stroke, osteoporosis, damage to developing infants, etc.



Cal/OSHA and Standards Board Duty to Protect Workers

Duty to Protect Workers

Labor Code §144.6.

- In promulgating standards dealing with toxic materials or harmful physical agents, the board shall adopt that standard which most adequately assures, to the extent feasible, that **no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to a hazard regulated by such standard for the period of his working life....**

Duty to Protect Workers

Occupational Safety and Health Act of 1970

29 U.S. Code §655(b)(5)

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...**

Duty to Protect Workers

- Federal OSHA defines "**working life**" as **45 years**
- Applies even if it is rare that an employee would be exposed for 45 years
- **Upheld** by United States Court of Appeals for the District of Columbia Circuit
(*Building and Const. Trades Dept., v. Brock*, 838 F.2d 1258 (D.C. Cir. 1988))

**Modeling of
Airborne Lead to
Blood Lead Levels
to Determine
Permissible Exposure Limit
and
Action Level**

Background: Lead Exposure

- Lead is a **cumulative** poison
- Low-level chronic lead exposures result in lead accumulating in the body over years and decades
- Lead is stored in bones. It can take decades for lead stored in bones to stop releasing lead to blood after external exposure has stopped
- Existing empirical studies do not show airborne to blood lead relationship from low-level chronic lead accumulation that occurs over years and decades

MODELING IS BEST SCIENTIFIC METHOD TO DETERMINE LEAD EXPOSURE LIMITS

A physiologically-based pharmacokinetic model is the best scientific method to link blood lead levels to air lead levels at low exposures known to cause serious harm over several decades

There are **NO** chamber studies and **NO** workplace observational studies that include measurements of air lead levels and blood lead levels over the timeframe (45 years) required by the Labor Code and the OSH Act of 1970, and include the lower blood lead levels now known to cause serious harm

MODELING IS BEST SCIENTIFIC METHOD TO DETERMINE LEAD EXPOSURE LIMITS

- A physiologically-based pharmacokinetic model is not static
- Shorter term exposures can be input to compare modeling to observational studies

INTRODUCTION TO MODELING

- Physiologically-Based Pharmacokinetic (PBPK) modeling is a scientific method used to understand the health effects of chemicals
- A PBPK model is used to relate the amount of chemical exposure to the amount of chemical found in the blood and organs at different points in time.

BACKGROUND ON MODELING

- PBPK modeling is a mathematical method for predicting the absorption, distribution, metabolism, and excretion chemical substances in humans using scientific knowledge of these processes.
- PBPK models use information about the body's anatomical and physiological structure as well as biochemical processes.

BACKGROUND ON MODELING

- PBPK models use data from experiments on tissues, cells, subcellular fractions, and specific proteins and additional information from toxicological and human studies
- PBPK models undergo peer review in scientific journals and scientific advisory panels.
- Computer software contains peer-reviewed data, models, tools, and databases
 - Includes chemical properties and bioactivity information brought together for integrated analyses.

BACKGROUND ON MODELING

PBPK modeling is:

- Widely used in pharmaceutical research and drug development, and in health risk assessments
- First used in 1937
- Widespread use from the early 1970s with broader computer availability

BACKGROUND ON MODELING

- Federal OSHA used biokinetic modeling for the 1978 lead standard.
- The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) updated and refined existing PBPK model for lead in humans to determine appropriate maximum airborne lead levels in workplaces to ensure lower blood lead levels in workers
- U.S. EPA and ATSDR develop and use many PBPK models in assessment of chemicals

BACKGROUND ON OEHHA MODEL

- **1993:** Original Model developed by Richard Leggett, Oak Ridge National Laboratory, U.S. Department of Energy
- **2013:** Model updated and tested by California's Office of Environmental Health Hazard Assessment (OEHHA)
 - Addresses workplace exposures
 - Reevaluated exposures to a wide range of lead particle sizes
 - Addresses current background lead levels
- **2020:** Evaluation and updates to OEHHA Model Part I
- **2023:** Evaluation and updates to OEHHA Model Part II
 - Finding of 2022 and 2023 evaluations: 2013 model remains accurate

CDPH RECOMMENDATION BASED ON OEHHA MODELING RESULTS

- PEL of $0.5 \mu\text{g}/\text{m}^3$; 40 years*: 95% of workers would have blood lead less than $5 \mu\text{g}/\text{dl}$ **
- PEL of $2.1 \mu\text{g}/\text{m}^3$; 40 years*: 95% of workers would have blood lead less than $10 \mu\text{g}/\text{dl}$ ** and 57% would have blood lead less than $5 \mu\text{g}/\text{dl}$ *

* Labor Code & OSH Act require 45 years; not 40

**Harm occurs at blood lead levels $<5 \mu\text{g}/\text{dl}$

Cal/OSHA PROPOSED PEL

- Due to feasibility concerns, Cal/OSHA proposed PEL is 10 $\mu\text{g}/\text{m}^3$
- Cal/OSHA proposed PEL is **5 to 20 times** higher than OEHHA modeling and CDPH recommended range of 0.5 $\mu\text{g}/\text{m}^3$ to 2.1 $\mu\text{g}/\text{m}^3$
- The proposal complements the PEL with other protections, such as hygiene, housekeeping, and training
 - These protections are not completely dependent on air lead levels

Cal/OSHA Proposed Action Level

Action level ($2 \mu\text{g}/\text{m}^3$) set near high range of the maximum CDPH recommendation for PEL of $2.1 \mu\text{g}/\text{m}^3$ since PEL is not health protective.



Responses to Stakeholder Feedback

EVIDENCE OF AIR – BLOOD LEAD RELATIONSHIP IN THE WORKPLACE

CLAIM: Empirical research shows that there is no clear correlation between air lead levels and BLLs in the workplace

FALSE:

- Many long-term workplace scientific studies have found a significant relationship between air and blood lead levels.

EVIDENCE OF AIR - BLOOD LEAD RELATIONSHIP IN THE WORKPLACE

- Higher blood lead levels in similar operations correlate with higher air lead levels
- Published peer-reviewed studies listed in the Documents Relied Upon, Initial Statement of Reasons
- Studies that didn't find relationship between air and blood levels did **not** account for respirator use.
- Evaluation of scientific observational studies confirmed the OEHHA modeling as consistent with real workplace exposures

OEHHA MODEL IS UP-TO-DATE WITH CURRENT SCIENCE

CLAIM The OEHHA model is outdated and has not been revised to address deficiencies identified by industry and independent experts

FALSE:

Since publication in 2013, OEHHA has reevaluated the model to address comments from industry and independent experts and published their updated results in peer-reviewed literature (published 2020 and 2023)

OEHHA concluded that the blood lead levels and corresponding air lead levels in the 2013 model simulation results did not change

OEHHA MODEL INHALATION TRANSFER COEFFICIENT ALIGNS WITH OCCUPATIONAL STUDY RESULTS

CLAIM: The inhalation transfer coefficient in the OEHHA model is flawed. These flaws invalidate the model.

FALSE:

- The OEHHA Model inhalation transfer coefficient (ITC; fraction of inhaled lead absorbed into the body) is consistent with four recent workplace studies
- The OEHHA model uses an ITC of 30%
 - Much less than the 52% ITC maximum possible determined by OEHHA
 - Ensures blood lead level determinations are not overestimated

OEHHA MODEL ACCOUNTS FOR ABSORPTION BASED ON PARTICLE SIZE

CLAIM: The OEHHA modeling is restricted to smaller particle sizes and does not account for larger particle sizes, which are not absorbed into the blood

FALSE:

- OEHHA modeling does consider larger particle sizes
- Larger airborne particles deposit on respiratory mucosa; some are swallowed and absorbed to the blood through the gastrointestinal tract
- OEHHA model accounts for much lower absorption rate of larger particles through the gastrointestinal tract
- Even at low absorption rates, lead in blood from larger airborne particles still accounts for $\geq 10\%$ percent of all inhaled lead absorbed into blood

OEHHA MODELING CONSIDERS INDIRECT INGESTION EXPOSURE

CLAIM: Ingestion exposures were not considered in the OEHHA model developed to predict blood lead levels based on airborne exposures

FALSE:

- The OEHHA modeling includes workplace ingestion exposures
- OEHHA analyzed studies on workplace ingestion
 - Studies did not preclude the significant contribution of inhaled lead
- Studies that didn't find relationship between air and blood levels did not account for respirator use
- **Analysis of observational studies found blood lead levels were consistent with simulations from the OEHHA model**

OEHHA MODELING CONFIRMED BY RECENT WORKPLACE DATA

CLAIM: Conditions underlying the OEHHA model are not reflective of present-day conditions. The data used is from the 1960s and 1970s.

- The OEHHA model does not have reliable predictive value for current exposures

FALSE:

- Studies using data through 2008 confirmed the OEHHA model as accurate

OEHHA MODELING RESULTS CONSIDERED APPROPRIATE AND ACCURATE BY OTHER AGENCIES

- European Chemicals Agency Committee for Risk Assessment in 2020:
 - Results of the OEHHA modeling are accurate
 - OEHHA modelling approach is reasonable and appropriate
 - Better than using empirical studies
- US Dept. of Defense also used a PBPK model for airborne/ blood lead relationship
 - Results from DOD modeling were very similar to the results from OEHHA modeling

CAL/OSHA Made Industry- Recommended Changes to Proposal

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

5198 (e)(1)(B). Separate Engineering Control Airborne Limits (SECALs)

- **Initial proposal:**
 - Certain processes exempt from meeting the PEL solely with engineering & work practice controls – can rely on respiratory protection to meet the PEL
 - Processes required to meet SECALs with engineering & work practice controls
 - Initial SECAL 50 $\mu\text{g}/\text{m}^3$; after 5 years, reduced to 30 $\mu\text{g}/\text{m}^3$
- **Change:** Four additional processes in lead acid battery recycling were added to the list of processes covered by SECALs.

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

1532.1 & 5198 (f)(3)(A) Respiratory protection

- **Initial Proposal:**

- Filtering facepiece respirators prohibited

- **Change:**

- Prohibition deleted
- Certain filtering facepiece respirators (N100, R100, and P100) allowed

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

- **Subsection 5198 (i)(1)(A) General Hygiene in General Industry**
- **Initial Proposal:**
 - Prohibited consumption of food, drinks, tobacco; application of cosmetics in areas where employees are exposed to lead
 - No exceptions
- **Change:**
 - Added exception
 - Allow for access to drinking water where exposures are $\leq 50 \mu\text{g}/\text{m}^3$ to help prevent heat illness

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

Subsection 5198 (i)(2)(A) Change Rooms in General Industry

Initial Proposal:

- Employer required to provide change rooms for employees who work in areas where lead exposures > PEL
- Applied on effective date of regulation (January 1, 2025)

Change: Added one year delay (January 1, 2026) where exposures are $\leq 50 \mu\text{g}/\text{m}^3$

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

1532.1 (i)(3)(A) Showers in Construction

- **Initial Proposal:**
 - Showers required at the new proposed PEL ($10 \mu\text{g}/\text{m}^3$)
 - No feasibility exception
- **Change:** Shower requirements rolled back in construction regulation
 - Shower required at current PEL ($50 \mu\text{g}/\text{m}^3$) and as interim protection for most dangerous trigger tasks
 - Showers not required when an employer demonstrates they are not feasible

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

Subsection 5198 (i)(3)(A) Showers in General Industry.

- **Initial Proposal:**
 - Showers required at the new proposed PEL ($10 \mu\text{g}/\text{m}^3$)
 - Applied on effective date of regulation (January 1, 2025)
- **Change:** Added one year delay (January 1, 2026) where exposures are $\leq 50 \mu\text{g}/\text{m}^3$

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

Subsection 5198 (i)(4)(A) Lunchrooms in General Industry

- **Initial Proposal:**
 - Lunchrooms required at the new proposed PEL ($10 \mu\text{g}/\text{m}^3$)
 - Applied on effective date of regulation (January 1, 2025)
- **Change:** Added one year delay (January 1, 2026) where exposures are $\leq 50 \mu\text{g}/\text{m}^3$

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

1532.1 & 5198 (j)(1)(A)1. Initial Blood Lead Testing

- **Initial Proposal:** Employers required to offer initial blood lead testing to workers without exception
- **Change:** Added three exceptions to initial blood lead testing requirement covering
 - employees with intermittent exposures
 - employees who already tested in the previous two months

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

- 1532.1 & 5198 (j)(1)(B)1. Medical Surveillance
- **Initial Proposal:** Medical surveillance program required for all employees exposed \geq action level ($2 \mu\text{g}/\text{m}^3$) with one exception for employees with certain intermittent exposures
- **Change:** Added additional exception for employees with other intermittent exposures

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

1532.1 & 5198 (j)(2)(E) Elevated blood lead level response

- **Initial proposal:**
 - Employer required to have a written elevated blood lead level response plan for employee with blood lead level ≥ 10 $\mu\text{g}/\text{dl}$
 - No exceptions.
- **Change:**
 - Added exception
 - Elevated blood lead level response plan is **not** required when employee's initial blood lead level is ≥ 10 $\mu\text{g}/\text{dl}$.

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

Subsection 1532.1 & 5198 (j)(3)(A)2 Medical examinations and consultations.

- **Initial Proposal:** Employer required to offer medical exams to employees exposed \geq the action level prior to assignment
- **Change:**
 - Added an exception
 - Medical exam does not need to be offered if an employee had a lead-specific medical exam in the preceding two months

CHANGES TO PROPOSAL IN RESPONSE TO INDUSTRY FEEDBACK

Subsection 1532.1 (k)(1)(A)3. Medical removal protection.

- **Initial proposal:**
 - Required medical removal of employees from lead exposures \geq action level when average blood lead over 6 months is $\geq 20 \mu\text{g}/\text{dl}$
 - Effective 1 year after effective date of standard: no exceptions
- **Change:**
 - Added exception
 - No medical removal required if the employee's last blood test is $< 15 \mu\text{g}/\text{dl}$



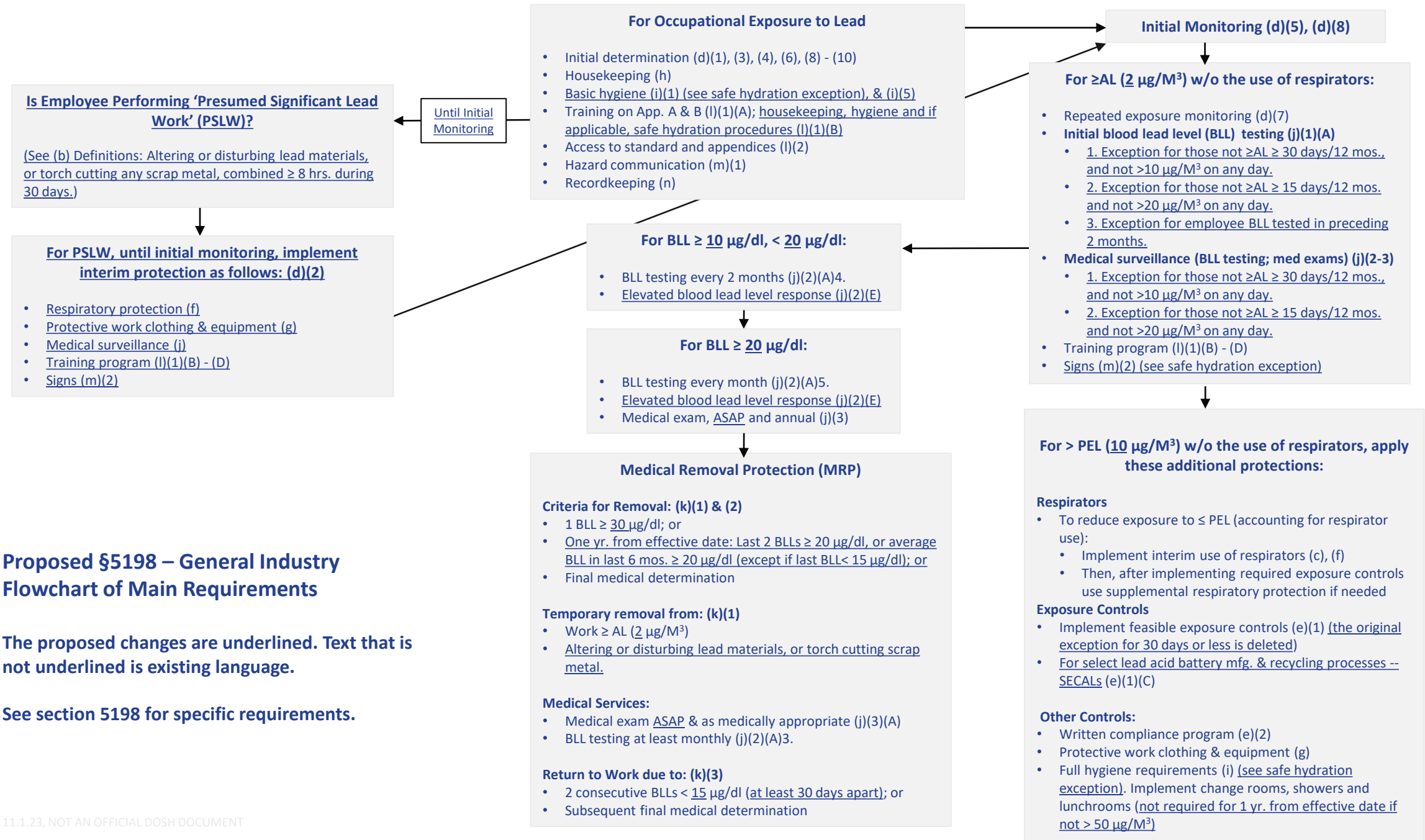
Complexity of the Regulations

Complexity of Regulations

- Existing lead regulations are complex
 - Adopted from and nearly identical to the federal OSHA regulations from 1978 (General Industry) and 1993 (Construction)
- California is required to have regulations at least as effective as federal OSHA
 - Labor Code section 142.3
 - United States Code Title 29 section 667
- Proposed lead regulations are edits to the existing lead regulations
 - Existing structure of regulations not changed
 - Stakeholders should be familiar with existing structure (30+ year-old rules)
 - Ensures the regulations are at least as effective as the federal OSHA regulations

Flowchart for Construction Regulation

Flowchart for General Industry Regulation



Proposed §5198 – General Industry Flowchart of Main Requirements

The proposed changes are underlined. Text that is not underlined is existing language.

See section 5198 for specific requirements.