

DON'T SAY IT—WRITE IT

To E. BERMAN Location NEMOURS 7451
From R. D. SNEE Location LOUVIERS 30E17 Phone No. 121-3951
Subject _____ Date _____

Attached are comments on ambient air lead standard of $10 \mu\text{g}/\text{m}^3$ which you asked me to summarize in our meeting last Thursday.

Please call me if you have any additional comments or questions.

cc: D. R. Diggs
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TEH 0470472

ARGUMENTS SUPPORTING AN AMBIENT AIR Pb STANDARD OF 10 $\mu\text{g}/\text{m}^3$

1. An Ambient Air Pb Standard of 10 $\mu\text{g}/\text{m}^3$ Represents an 80% Reduction (i.e. Safety Factor of 5) from the Occupational Air Pb Standard

An Air Pb standard of 10 $\mu\text{g}/\text{m}^3$ represents approximately an 80% reduction from the occupational Air Pb standard of 200 $\mu\text{g}/\text{m}^3$ for 8 hours, which is equivalent to a 24-hour standard of approximately 48 $\mu\text{g}/\text{m}^3$. Hence, there is a safety factor of approximately 5 associated with an air Pb standard of 10 $\mu\text{g}/\text{m}^3$ (see below).

<u>Air Pb Concentration ($\mu\text{g}/\text{m}^3$)</u>				
<u>On Duty</u> <u>(40 hrs/wk)</u>	<u>Off Duty</u> <u>(128 hrs/wk)</u>	<u>Total</u> <u>Exposure</u>	<u>%</u> <u>Reduction</u>	<u>Safety</u> <u>Factor</u>
200	2	49	79	4.8
	1	48		
	0	48		
150	2	37	72	3.6
	1	36		
	0	36		
100	2	25	60	2.5
	1	25		
	0	24		

The safety factor is defined here as the ratio of the occupational standard (24-hour equivalent) to the proposed ambient standard of 10 $\mu\text{g}/\text{m}^3$ (eq $48/10=4.8$).

2. The Current Air Pb Levels Do Not Exceed 10 $\mu\text{g}/\text{m}^3$

The first step in arriving at an air Pb standard should be to access the current situation, determine what the current air Pb levels are, and whether the current air Pb levels are producing any adverse health effects.

The maximum air Pb levels observed in the US have been those measured in California. The high California air Pb levels are due in large part to the interactions of large population centers being located in basins where the mountains prohibit the air masses from moving freely, thereby forcing air pollutant concentrations to increase. A review of studies in the literature shows that the air Pb concentrations in California are generally less than 10 $\mu\text{g}/\text{m}^3$ (see below and Table 1).

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<u>Study</u>	<u>Site</u>	<u>Date</u>	<u>Air Pb ($\mu\text{g}/\text{m}^3$)</u>			<u>Blood Pb</u>
			<u>On Duty</u>	<u>Off Duty</u>	<u>Total</u>	
Seven Cities	Pasadena				3.39	17.5
Azar et al.	LA Cab Drivers	11/70	9.42	4.22	6.10	24.6
Azar et al.	LA Office Workers	2/71	3.05	3.07	3.06	19.9
Calif Sampling Stations	Lennox	11/74			8.32	--

The data from the California Air Sampling Stations (Table 1) indicate that the air Pb levels in California are decreasing. This decrease is due in part to the introduction of unleaded gasoline required by the cars with catalytic mufflers.

The average air Pb of $6.10 \mu\text{g}/\text{m}^3$ observed for the Los Angeles Cab Drivers is the Azar et al. study and the $8.32 \mu\text{g}/\text{m}^3$ air Pb observed at Lennox in November 1974 need special comment. Both of these measurements represent air Pb levels which the general population is not exposed to. The cab drivers represent an occupationally exposed group. The average on-duty air Pb exposure of the cab drivers was $9.42 \mu\text{g}/\text{m}^3$. The average off-duty exposure was $4.22 \mu\text{g}/\text{m}^3$. The Lennox sampling station is along a freeway and is not representative of air that people would be exposed to for a 24-hour period.

3. The Blood Pb's of the General Population are Well Within Normal Limits (i.e. $\leq 40 \mu\text{g}/100 \text{ ml}$)

Now that we have established that the ambient air Pb concentrations do not exceed $10 \mu\text{g}/\text{m}^3$ for any length of time, we can conclude that $10 \mu\text{g}/\text{m}^3$ is a good air Pb standard if we can demonstrate that no adverse health effects have been observed in the general population exposed to air Pb's $\leq 10 \mu\text{g}/\text{m}^3$. The best single measure of lead poisoning is the lead concentration of the blood. The upper limit on the normal range of blood Pb concentrations in humans is generally accepted to be $40 \mu\text{g}/100 \text{ ml}$.

The group average blood Pb's of 17.5, 24.6, and 19.9 for Pasadena, Los Angeles Cab Drivers, and Los Angeles Office Workers are, respectively, 56%, 39%, and 50% less than the upper limit of $40 \mu\text{g}/100 \text{ ml}$. These differences represent group average safety margins of approximately 2.0 (i.e. 2.3, 1.6, 2.0).

The blood Pb's of the individual subjects in the general population are also less than $40 \mu\text{g}/100 \text{ ml}$. In the Azar et al. study the air Pb concentrations of the 150 subjects ranged from .22 to $9.12 \mu\text{g}/\text{m}^3$.

The Los Angeles Cab Driver with the $9.12 \mu\text{g}/\text{m}^3$ air Pb had a blood Pb of $21 \mu\text{g}/100 \text{ ml}$. The maximum blood Pb of the Los Angeles Cab Drivers, which was the group in the Azar et al. study with the highest average air Pb ($6.10 \mu\text{g}/\text{m}^3$), was $33 \mu\text{g}/100 \text{ ml}$. Only one of the 150 subjects had a blood Pb $> 40 \mu\text{g}/100 \text{ ml}$. His high blood Pb of $53 \mu\text{g}/100 \text{ ml}$ was attributed to his drinking illicit moonshine whiskey. Of the remaining 149 subjects, none had blood Pb's greater than $40 \mu\text{g}/100 \text{ ml}$, and only 3 had blood Pb's greater than $35 \mu\text{g}/100 \text{ ml}$ (the 3 blood Pb's were 36, 37, and 40).

In the Albany Study a group of subjects were exposed to an air Pb concentration of $3.2 \mu\text{g}/\text{m}^3$ for 23 hours/day. Of the seven subjects with complete blood Pb records over the 19-week exposure period, only one subject reached a peak blood Pb level of $35 \mu\text{g}/100 \text{ ml}$. The maximum values for the 7 subjects were 26, 35, 27, 30, 25, 27, 31, and $28 \mu\text{g}/100 \text{ ml}$. The peak of the group average curve was $28 \mu\text{g}/100 \text{ ml}$. A second group of subjects was exposed to an air Pb concentration of $10.9 \mu\text{g}/\text{m}^3$ for 23 hours/day over a 12-week period. The maximum blood Pb concentration reached by any of the eight subjects with complete blood Pb records was $43 \mu\text{g}/100 \text{ ml}$. The peak levels of the individual subjects were 32, 43, 39, 40, 41, 32, 39, and $38 \mu\text{g}/100 \text{ ml}$, respectively. The peak concentration of the group-average curve was $37 \mu\text{g}/100 \text{ ml}$.

The Albany Study has been criticized because it did not use Pb particles which were representative of auto exhaust. Several years earlier Kehoe had exposed two subjects to an air Pb concentration of $10.7 \mu\text{g}/\text{m}^3$ for a 28-day period. The average blood Pb's of Subjects L.D. and J.S. were well within normal limits, being 26.0 and $28.5 \mu\text{g}/100 \text{ ml}$, respectively. This suggests that the peak blood Pb's of $40 \mu\text{g}/100 \text{ ml}$ for the group in the Albany Study exposed to an air Pb of $10.9 \mu\text{g}/\text{m}^3$ could be due in part to the lead particulate used in the study. In any event, the Kehoe experiment represents another instance in which subjects, exposed to air Pb concentrations of approximately $10 \mu\text{g}/\text{m}^3$, had blood Pb's well within normal limits.

3.1 There is a Large Analytical Variation Associated with Blood Pb Determinations

It should be noted that while $40 \mu\text{g}/100 \text{ ml}$ is the upper limit of the normal range, blood Pb's in the $40\text{--}80 \mu\text{g}/100 \text{ ml}$ range are generally considered acceptable and not necessarily indicative of Pb poisoning. Blood Pb's over $80 \mu\text{g}/100 \text{ ml}$ are generally considered cause for alarm. The undetermined health significance of the $40\text{--}80 \mu\text{g}/100 \text{ ml}$ "gray area" is easy to understand when one considers the within-subject and analytical variations associated with single blood Pb determinations. Results of the AIHA Interlaboratory Studies of blood Pb analyses indicate that the standard deviation of the within-laboratory variation associated with blood Pb analyses is $\pm 12\%$. To understand the significance of this large variation, consider a blood sample with a Pb content of $40 \mu\text{g}/100 \text{ ml}$.

The AIHA Interlaboratory Studies indicated that if replicate determinations were made on this blood sample in a typical laboratory, 95% of the determinations would fall between 28 and 57 $\mu\text{g}/100\text{ ml}$.

3.2 More than 85% of the Random Variation in Single Blood Pb Determinations Is Due to Within-Subject and Analytical Variations

McLaughlin, Linch, and Snee reported a study in which blood Pb determinations were made on a large population over a five-year period. Analysis of this study showed that more than 85% of the random variation in blood Pb determinations was due to within-subject and analytical variation. The significance of the within-subject and analytical variations is apparent when one considers the fraction of blood Pb values $> 40\text{ }\mu\text{g}/100\text{ ml}$. A total of 217 subjects participated in the study for all five years. Over the five-year period approximately 4% of the blood Pb's of these subjects exceeded $40\text{ }\mu\text{g}/100\text{ ml}$ as shown below.

McLaughlin, Linch, and Snee Longitudinal Pb Study

<u>Year</u>	<u>No. of Subjects</u>	<u>Blood Pb's $> 40\text{ }\mu\text{g}/100\text{ ml}$</u>	
		<u>Number</u>	<u>Percent</u>
67	217	15	6.9
68	217	4	1.8
69	217	9	4.1
70	217	7	3.2
71	217	8	3.7
Total Determinations	1085	43	4.0 (average)

A study of the five-year average blood Pb for each of the 217 subjects showed that none of the subject average blood Pb's exceeded $40\text{ }\mu\text{g}/100\text{ ml}$, only 3, or 1.4%, exceed $35\text{ }\mu\text{g}/100\text{ ml}$ (35, 37, and $38\text{ }\mu\text{g}/100\text{ ml}$) and an additional 8, or 3.7%, exceeded $30\text{ }\mu\text{g}/100\text{ ml}$.

Hence, where single determinations indicate that 4% of these subjects had blood Pb's out of normal limits, the average blood Pb's, which are not as greatly affected by within-subject and analytical variation, indicate that all subjects were within normal limits. This should be expected, since these 217 subjects were representative of the general population and, to our knowledge, had no occupational exposure to Pb.

In the Seven Cities Study blood Pb's were obtained from approximately 2000 women who had no known occupational Pb exposure. Only three blood Pb's in this sample were $> 40\text{ }\mu\text{g}/100\text{ ml}$. The maximum blood Pb observed was $43\text{ }\mu\text{g}/100\text{ ml}$.

4. The Data in the Literature Support an Air Pb Standard of $10 \mu\text{g}/\text{m}^3$

After a review of the studies reported in the literature, one has to conclude that

- (i) The air Pb levels in California are declining.
- (ii) The current air Pb levels, even in the most highly congested areas, are less than $10 \mu\text{g}/\text{m}^3$.
- (iii) A 23-hour exposure to $10.9 \mu\text{g}/\text{m}^3$ raises a subject's blood Pb to, at most, the upper limit of the normal range.
- (iv) An air Pb standard of $10 \mu\text{g}/\text{m}^3$ would result in most areas having air Pb concentrations well below $10 \mu\text{g}/\text{m}^3$. This statement is based on the fact that only the highly congested areas have air Pb's approaching $10 \mu\text{g}/\text{m}^3$. Hence, a small fraction of the population would be exposed to, at most, $10 \mu\text{g}/\text{m}^3$ for eight hours/day, five days/week. We found that the Los Angeles Cab Drivers exposed to this air Pb level had blood Pb's which were within normal limits, the maximum blood Pb concentration being $33 \mu\text{g}/100 \text{ ml}$.
- (v) The blood Pb levels of the general population are within normal limits.

This evidence indicates that current air Pb levels are not producing any adverse health effects. Hence, an air Pb standard of $10 \mu\text{g}/\text{m}^3$, which represents a safety factor of five less than the occupational exposure TLV, is sufficient to ensure that air Pb concentrations will not present a health hazard.

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10/27/75
chm.

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TABLE 1

California Air Sampling Stations
Maximum Monthly Air Pb Concentration

<u>Site</u>	<u>1973</u>	<u>1974</u>	<u>% Change</u>
Anaheim	3.21	3.76	-17
Azusa	3.18	2.72	-14
Bakersfield	3.35	3.32	-1
Fresno	4.50	2.17	-52
La Habra	2.73	3.67	34
Lennox	14.45	8.32	-42
Los Angeles	6.45	4.85	-25
Pasadena	4.85	3.18	-34
Sacramento	1.96	1.26	-36
San Diego	4.45	2.72	-39
San Jose	2.99	2.17	-27
Santa Barbara	1.56	2.63	69
Valejo	2.54	1.96	-23

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