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FOOD AND DRUG ADMINISTRATION
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SUMMARY

On May 8, 1992, the National Institute for Occupational Safety and Health (NIOSH) received a management request for a health hazard evaluation at the Food and Drug Administration (FDA) in Cincinnati, Ohio. The request concerned potential exposures of office workers to lead from lead-based paint.

The NIOSH investigator conducted an initial site visit on June 23, 1992, and an industrial hygiene survey on July 14, 1992. During the industrial hygiene survey, air and surface sampling were performed. Area air samples for lead revealed levels which ranged from less than the minimum detectable concentration (MDC) of 0.03 micrograms per cubic meter ($\mu g/m^3$) to less than the minimum quantifiable concentration (MQC) of 0.09 $\mu g/m^3$ for an average sample volume of 968 liters. These data are well below the Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PEL) of 50 $\mu g/m^3$. The surface wipe concentrations were well below the Housing and Urban Development (HUD) criteria for interior surfaces, with concentrations ranging from less than 1.86 to 39.0 micrograms per square foot ($\mu g/ ft^2$). Bulk samples of paint were also collected and the analysis revealed levels from 110 to 52,000 micrograms per gram ($\mu g/g$) or from 0.01 to 5.2 percent by weight, respectively.

Air monitoring and surface sampling indicated that a health hazard did not exist from exposures to lead. However, the results of the bulk samples indicate a potential for future exposures to lead from the deteriorating paint throughout the facility. Recommendations for the development and implementation of a management program to prevent further release of lead, along with suggestions on the removal of deteriorated paint are presented in this report.

Keywords: SIC 9641 (Regulation of Agricultural Marketing and Commodities); lead; indoor environmental quality (IEQ); heating, ventilation, and air conditioning (HVAC) units.

INTRODUCTION

On May 8, 1992, the National Institute for Occupational Safety and Health (NIOSH) received a request for a health hazard evaluation from an employer representative at the Food and Drug Administration (FDA) in Cincinnati, Ohio. NIOSH was requested to evaluate possible contamination of the first floor from lead-based paint.

BACKGROUND

In the FDA building, both the interior and exterior of the two heating, ventilating, and air conditioning (HVAC) units, as well as the exteriors of the air handling units (AHU) are painted. In April 1992, there was a steam leak within the HVAC # 6 located in the basement. The leak caused the paint on the wall of the unit to peel and to be distributed throughout the first floor. The safety director collected bulk samples of the paint and submitted the samples for lead analysis. The results revealed that the samples contained lead varying from 500 to 1,000 parts per million (ppm). Based on the results of the samples, NIOSH was requested to conduct a health hazard evaluation.

On June 23, 1992, an initial site visit was performed; a follow-up industrial hygiene survey was conducted on July 14, 1992. Area air, surface wipe, and bulk samples were collected to assess worker exposures to airborne lead, and lead-contaminated surface dust.

ENVIRONMENTAL METHODS

A. *Air monitoring*

Area air samples were collected on 37-millimeter (mm), 0.8 micron (μm) pore size, cellulose ester membrane filters in closed-face cassettes according to the NIOSH Method 7300.[1] The cassettes were connected via Tygon® tubing to Gillian Hi Flow Sampler® battery-operated personal sampling pumps. Sample air was drawn through the filters at a flow rate of 2 liters per minute (ℓ/min). After sampling, the filters were removed from the cassette, digested, and analyzed for lead using atomic absorption, graphite furnace. The analytical limit of detection is 0.03 micrograms (μg) of lead per sample, which equates to a minimum detectable concentration of 0.031 microgram per cubic meter ($\mu g/m^3$), assuming a sample volume of 968 liters.

The sampling pumps were calibrated on-site prior to and after sampling using the Kutz Pocket Flow Calibrator™ mass flowmeter, which was calibrated against a primary standard. For subsequent calculation of sample volumes, the mean pre- and post sampling flow rates were used. A minimum of two field blanks were prepared and submitted with the sample set.

B. *Surface Wipe Samples*

Samples were collected using commercial pre-moistened Wash 'n Dri™ wipes according to the draft NIOSH Method 0700. A template 10 square centimeters (cm^2) in size, was placed over the sample area. Disposable gloves were donned, and the entire area was wiped with a series of vertical strokes in an "S"-pattern. The exposed side of the pad was folded inward and the area was wiped with a series of "S"-strokes at a 90° angle to the previous pattern. This procedure was repeated one more time and the wipe was then placed in a new sealable plastic bag.

The wipes were digested in nitric acid and 30% hydrogen peroxide, heated, and quantitatively transferred to 25 milliliter (ml) volumetric flasks. The solutions were analyzed for lead by atomic absorption, graphite furnace, according to NIOSH Method 7105.[1] The analytical limit of detection is 0.2 µg of lead per sample.

C. *Bulk Samples*

Bulk samples of paint were collected by transferring 1-10 grams of material into a new plastic bag with a zip-lock mechanism. Samples were ground with a mortar and pestle, weighed, wet-ashed with concentrated nitric and perchloric acids, and dissolved in dilute solutions of the same acids. The resulting samples were analyzed for trace metals by inductively coupled argon plasma, atomic emission spectroscopy (ICP-AES), according to NIOSH Method 7300.[1] The limit of detection is 3 µg of lead per sample.

EVALUATION CRITERIA

A. *General Guidelines*

As a guide to the evaluation of the hazard posed by workplace exposures, NIOSH field staff employ environmental evaluation criteria for assessment of a number of chemical and physical agents. These criteria are intended to suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. It is, however, important to note that not all workers will be protected from adverse health effects if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy).

In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the evaluation criterion. These combined effects are often not considered in the evaluation criteria. Also, some substances are absorbed by direct contact with the skin and mucous membranes, and thus potentially increase the overall exposure. Finally,

evaluation criteria may change over the years as new information on the toxic effects of an agent become available.

The primary source of environmental evaluation criteria for the workplace are: 1) NIOSH Criteria Documents and RELs,[2] 2) ACGIH TLVs,[3] and 3) OSHA PELs.[4] The OSHA standards may be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH RELs, by contrast, are based primarily on concerns relating to the prevention of occupational disease. It should be noted that industry is legally required to meet those levels specified by an OSHA standard.

A time-weighted average (TWA) exposure refers to the average airborne concentration of a substance during a normal 8- to 10-hour workday. Some substances have recommended short-term exposure limits or ceiling values which are intended to supplement the TWA where there are recognized toxic effects from high short-term exposures.

B. *Lead*

Inhalation of lead dust and fume and ingestion resulting from hand-to-mouth contact with lead-contaminated food, cigarettes, clothing, or other objects are the major routes of worker exposure to lead. Once absorbed, lead accumulates in the soft tissues with the highest accumulation initially in the liver and kidneys. Lead absorption is cumulative, and is eliminated from the body very slowly. Over a period of time, the lead is redistributed, being deposited mostly in bones, and also, in teeth, and hair.[5-6]

The frequency and severity of symptoms associated with lead exposure increase with increasing blood lead levels (BLLs). Signs and symptoms of acute lead intoxication include weakness, excessive tiredness, irritability or anxiety, constipation, anorexia, abdominal discomfort, colic, anemia, high blood pressure, and possibly neuromuscular dysfunction, accompanied by motor weakness that may progress to paralysis of the extensor muscles in the wrist ("wrist drop").[5,7,8]

An increase in an individual worker's BLL can mean that the worker is being overexposed to lead. While the BLL is a good indication of recent exposure to lead and current absorption of lead, it is not a reliable indication of the total body burden of lead.[9] Lead can accumulate in the body over time and produce health effects long after the exposure has stopped. Long-term overexposure to lead may cause infertility in both sexes, fetal damage, nephropathy (chronic kidney disease), and anemia.

Under the OSHA standard regulating occupational exposure to inorganic lead in general industry, the PEL is 50 $\mu g/m^3$ as an 8-hour TWA. The standard requires semi-annual monitoring of BLL for employees exposed to airborne lead at or above the Action Level of 30 $\mu g/m^3$ (8-hour TWA). The standard also specifies that employees whose average BLL is greater than or equal to 50 micrograms of lead per deciliter of blood ($\mu g/dl$) be medical removed, and provided with economic protection.[4] The NIOSH REL for lead is less than 100 $\mu g/m^3$ as a TWA

for up to 10 hours. This REL is an air concentration to be maintained so that the blood lead in the worker will remain below 60 µg/100 grams of whole blood.[2] NIOSH is presently reviewing the literature on the health effects of lead and may re-evaluate its REL.

Recent studies suggest that there are adverse health effects at BLLs below the current evaluation criteria for occupational exposure. A number of studies have found neurological effects in workers with BLLs of 40 to 60 µg/dl. In males, BLLs are associated with increases in blood pressure. This effect has been observed at BLLs of less than 10 µg/dl. Studies have suggested decreased fertility in men at BLLs as low as 40 µg/dl. Prenatal exposure to lead is associated with reduced gestation age, birth weight, and early mental development at prenatal maternal BLLs as low as 10 to 15 µg/dl.[10] The World Health Organization (WHO) has recommended an upper limit of 40 µg/dl for occupationally exposed adults.[11]

In recognition of the health risks associated with exposure to lead, a goal for reducing occupational exposure was specified in *Healthy People 2000*, a recent statement of national consensus and U.S. Public Health Service policy for the health promotion and disease prevention. The goal for workers exposed to lead is to eliminate all exposures that result in BLLs greater than 25 µg/dl, by the year 2000.[12]

C. *Lead in Surface Dust*

There are no Federal standards governing the level of lead in surface dust in either occupational or non-occupational settings. However, lead- contaminated surface dust in either setting represents a potential exposure to lead through ingestion. This may occur either by direct hand-to-mouth contact with the dust, or indirectly from hand-to-mouth contact with food, cigarettes, or other objects contaminated with lead. Housing and Urban Development (HUD) has recommended the following final clearance standards for lead in house dust on specific interior surfaces following abatement: floors - 200 $\mu g/ft^2$; window sills - 500 $\mu g/ft^2$; and window wells - 800 $\mu g/ft^2$.[13]

RESULTS AND DISCUSSION

The results from the area air samples performed are presented in Table 1. Ten area air samples were collected throughout the first floor. The first floor lay-out is shown in Diagram 1 to illustrate the sample locations. Area airborne lead concentrations ranged from less than the minimum detectable concentration (MDC) of 0.03 $\mu g/m^3$ to less than the minimum quantifiable concentration (MQC) of 0.09 $\mu g/m^3$ for an average sample volume of 968 liters. These values are well below the OSHA PEL of 50 $\mu g/m^3$, the most stringent current standard.

Results from the surface wipe samples are shown in Table 2. Seventeen wipe samples of various surfaces throughout the building; including desktops, computer stations, and cafeteria tables, were collected during the survey. The lead concentrations ranged from

below the limit of detection (0.2 µg/sample) to 4.23 µg/sample. The lead concentrations were then converted to $\mu g/ft^2$ and compared to the HUD criteria for surface dust after lead abatement, as an indication of the degree of contamination. The results were from less than 1.86 to 39.0 $\mu g/ft^2$. All samples were well below the HUD criteria for interior surfaces, which range from 200 to 800 µg/ft depending on the specific surface. Even though the steam leak only affected HVAC # 6, which serves the first floor, there were low levels of lead throughout the building. It is possible that these concentrations may actually be the normal background lead levels at the facility, rather than related to the incident which occurred in April.

The results of the bulk samples are included in Table 3. The paint chip samples ranged from 110 to 52,000 micrograms per gram (µg/g) or from 0.01 to 5.2 percent by weight, respectively. Under HUD regulations, painted surfaces with lead concentrations at or above 1.0 microgram per square centimeter ($\mu g/cm^3$) or 0.5% by weight must be abated by Public Housing Authorities. However, this regulation has been developed to eliminate the hazard of lead-based paint in housing and thereby, protect children, who are much more susceptible than adults to lead poisoning.[13]

CONCLUSIONS AND RECOMMENDATIONS

The air monitoring and surface sampling indicate that the workers were not overexposed to airborne lead or to surface lead contamination which would pose a potential health hazard by ingestion. However, the bulk results indicated that there are potential sources of lead in the building. All of the painted surfaces in the HVAC systems and their ductwork contain lead-based paint. Lead exposure can cause serious health effects. However, the mere presence of lead does not necessarily pose a health threat. When lead-based paint is properly managed, release of lead into the air can be minimized, and the risk of health effects associated with lead exposures can be reduced to a negligible level. The following recommendations are offered with respect to the situation of the lead-based paint in the FDA building.

1. A lead management program should be developed and implemented. The objectives of this program should be to maintain the lead-based paint which is in good condition, and to prevent further release of lead.

2. A physical and visual inspection of the building should be performed and bulk samples of suspected materials should be collected to determine if lead is present. If lead-based paint is found, the material's characteristics, condition, quantity, and location should be noted and warning signs should be posted. The program may be sufficient if the paint is intact. However, if there is significant damage, such as the situation in the basement HVAC unit #6, response alternatives will be necessary. A possible alternative is to clean and remove the deteriorated paint. The HVAC unit should be shut down and double (six) mil polyethylene plastic sheeting should be securely taped to the door ways, floor, heating and cooling coils, fan, and filters within the HVAC to prevent lead contamination. The loose material should be removed utilizing a "wet" scrapping method. The painted surface should be treated prior to and during the scrapping process with a high phosphate solution. During this

procedure, air monitoring should be performed and the appropriate protective clothing should be worn. After the loose painted is removed, the surface should be sealed with a durable lead-free enamel paint. This will encapsulate any remaining lead dust. When this procedure is complete, any remaining debris should be removed with a damp sponge or high efficiency particulate air (HEPA) filtered vacuum. Prior to disposal of the paint, a small representative bulk sample should be submitted for Toxicity Characteristic Leaching Procedure (TCLP) to determine if the material is hazardous and Extraction Procedure Leach Test (EP TOX) to determine if it is subject to a land-ban. The results of these tests will determine the means of the paint disposal.[14,15,16] Any questions concerning the waste disposal should be directed to the Ohio Environmental Protection Agency (EPA) at (614) 644-2956. Other possible response alternatives include replacement, encapsulation, enclosure, or total removal. Qualified, trained, and experienced contractors and/or industrial hygienists should be consulted to perform and monitor this work.

3. As part of the program, surveillance and re-inspection of the material should be performed regularly to assess and document any changes in the material's condition.

4. The maintenance and service personnel should be properly trained and protected. The workers should know the location of the lead-based paint, the potential health effects associated with lead exposures, and precautions which should be taken (i.e., welding, cutting, and abrasive treatment on lead-based painted material should not be conducted without the proper protection).

AUTHORSHIP AND ACKNOWLEDGEMENTS

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1. Safety Director, FDA
2. Union Representative, American Federation of Governmental Employees, Local 3831.
3. OSHA Region V.

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

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Table 1

Area Air Sampling for Lead
Food and Drug Administration
Cincinnati, Ohio-
HETA 92-261

Sample Number	Location	Start Time	Stop Time	Avg. Flow (ℓ/min)	Volume (ℓ)	Concentration ($\mu g/m^3$)
7545-1	Administration Area	7:14	15:24	2	980	ND*
7545-2	Investigation Branch	7:16	15:26	2	980	ND*
7545-4	Office # 65	7:19	15:29	2	980	ND*
7545-5	Lab Extension Branch	7:24	15:44	2	1000	(0.7)
7545-6	1st Floor Lab	7:26	15:26	2	960	ND*
7545-8	Office # 118	7:30	15:30	2	960	ND*
7545-9	Compliance Secretaries' Area	7:36	15:36	2	960	ND*
7545-10	Investigation Supervisor Secretaries' Area	7:39	15:39	2	960	(0.05)
7545-11	Office # 131	7:49	15:45	2	952	ND*
7545-12	Outside	8:06	15:41	2	910	(0.04)

* = value below the minimum detectable concentration (MDC); < 0.03 $\mu g/m^3$
( ) = value between MDC and the minimum quantifiable concentration (MQC); 0.087 $\mu g/m^3$

Table 2
Surface Wipe Samples for Lead
Food and Drug Administration
Cincinnati, Ohio
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Sample Number	Location	Lead µg/sample	Concentration (µg/ft^2)
7545-101	1st floor Office # 56; desk	ND*	ND*
7545-102	1st floor Office # 117; computer desk	1.7	15.8
7545-103	1st floor Office # 116; desk	0.6	5.6
7545-104	1st floor Compliance Secretaries' area; file cabinet	1.7	15.8
7545-105	1st floor Dir. of Investigation Secretary's area; desk	3.6	33.4
7545-106	1st floor Dictation area; desk	4.2	39
7545-108	1st floor Fiscal area; desk	0.6	5.6
7545-109	1st floor Investigation branch; Rabe's desk	0.8	7.4
7545-112	1st floor Office # 131; desk	3.4	31.6
7545-113	1st floor Supervisory CSO; Cartwright's desk	0.7	6.5
7545-114	2nd floor DPU office; Dave's desk	(0.2)	(1.9)
7545-115	2nd floor DPU office; Siemer's desk	(0.2)	(1.9)
7545-116	2nd floor Lab Director's office; book shelf	ND*	ND*
7545-117	Basement; housekeeping desk	0.9	8.4
7545-118	Basement; contractor's desk	1.3	12.1
7545-119	Basement; cafeteria table	ND*	ND*
7545-120	Basement; cafeteria table	(0.1)	(0.9)

* = value below the limit of detection (<0.2 µg/sample)
( ) = value between the limit of detection (0.2 µg/sample) and the limit of quantitation (0.37 µg/sample)

Table 3

Bulk Samples for Lead
Food and Drug Administration
Cincinnati, Ohio
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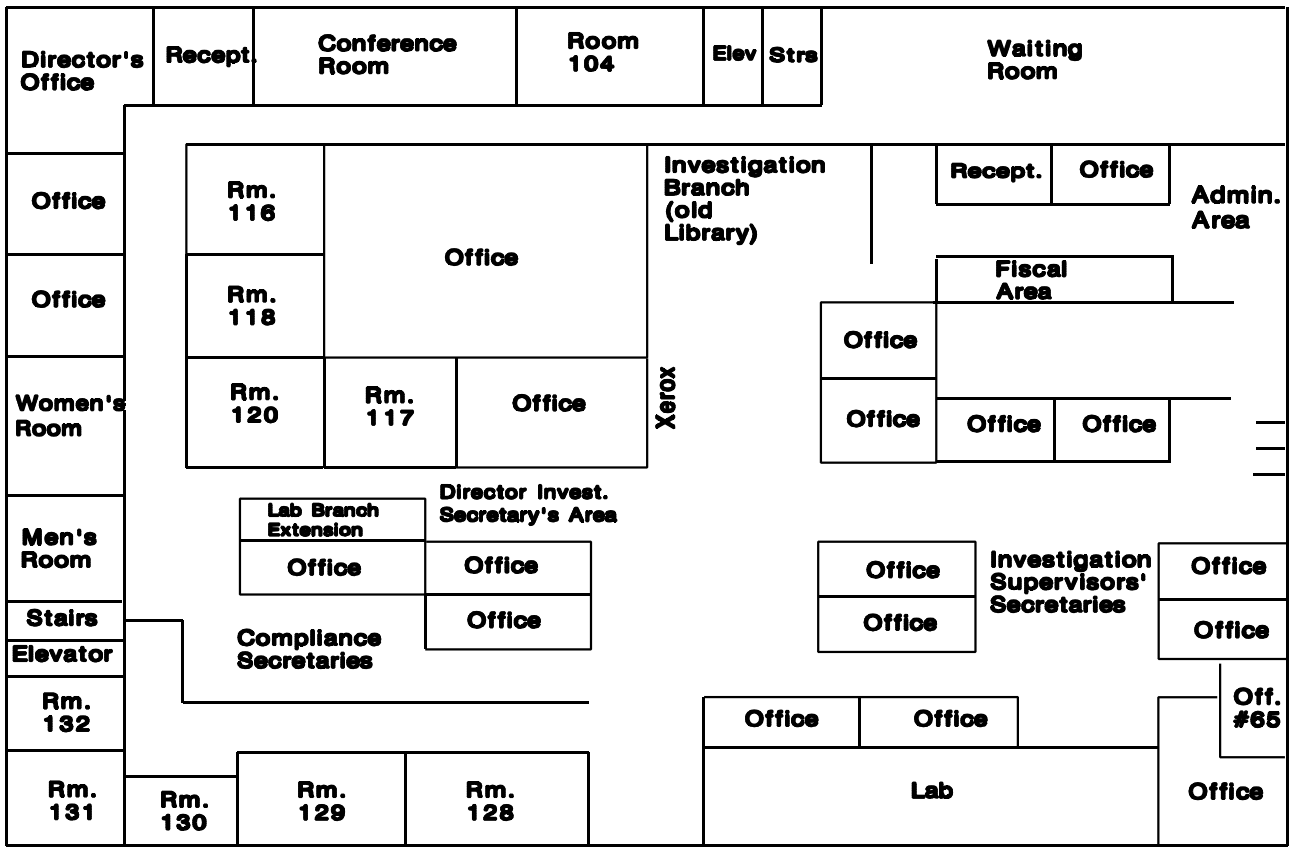
Sample Number	Location	Concentration (µg/g)	Percent (%) by weight
7545-200	HVAC # 2; wall (green paint)	52,000	5.2
7545-201	HVAC # 2; pipe insulation (green paint)	110	0.01
7545-202	HVAC # 2; pipe insulation (orange paint)	43,000	4.3
7545-203	Lab F air handler unit; ductwork (yellow paint)	150	0.02
7545-204	Lab F air handler unit; wall (green paint)	390	0.04
7545-205	Air handler # 4; ductwork (yellow paint)	670	0.07
7545-206	HVAC # 6; wall (green paint)	3,100	0.31

Diagram 1
First Floor Lay-out
Food and Drug Administration
Cincinnati, Ohio
HETA 92-261



Note: Drawing not to scale.