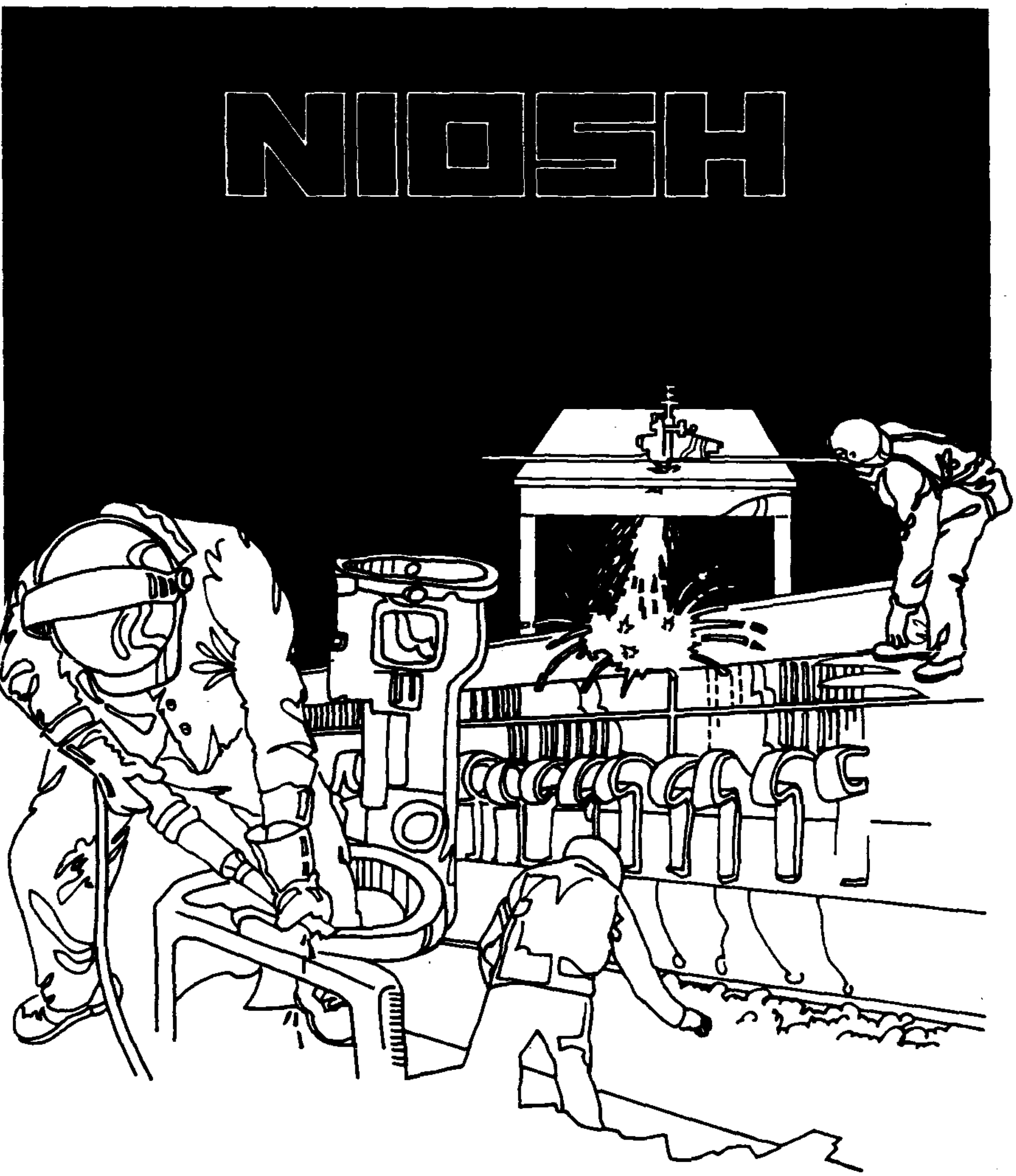
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ Public Health Service
Centers for Disease Control ■ National Institute for Occupational Safety and Health



Health Hazard Evaluation Report

HETA 88-054-1936
U.S. CUSTOMS SERVICE
WASHINGTON, D.C.

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to Federal, state, and local agencies; labor; industry and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

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NIOSH INVESTIGATORS:
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I. SUMMARY

On October 30, 1987, the National Institute for Occupational Safety and Health (NIOSH) received a request from the National Treasury Employees Union to assess the extent of polychlorinated biphenyl (PCB) contamination in a transformer vault within the U.S. Customs Headquarters, Washington, D.C.

NIOSH investigators conducted an initial site visit on February 3, 1988, and an industrial hygiene survey on March 29, 1988. During the industrial hygiene survey, air and surface sampling was performed in and around Room B100, the room which contains the transformer vault. Area air sampling found no detectable levels of PCBs in the transformer vault, in other areas in Room B100, in an adjacent office and projection room (B102) or in the hallway. Surfaces within Room B100, including the transformer vault, were heavily contaminated with PCBs, with surface concentrations ranging from 3720 to 148,000 micrograms per square meter (ug/m^2). The basement hallway, which runs perpendicular to Room B100, was slightly contaminated with PCBs, with surface concentrations of 224, 234, and 321 ug/m^2. Surface sampling in Room B102 office found PCB levels well below the recognized background concentration of 100 ug/m^2.

On the basis of these results, the NIOSH investigators found strong evidence that a potential health hazard from PCB surface contamination exists in Room B100 of the U.S. Customs Headquarters. Also, PCB surface concentrations in the adjacent hallway are slightly above the recognized background concentration. Recommendations are made in Section VIII for cleanup of these areas.

KEYWORDS: SIC 9311 (Public Finance, Taxation, and Monetary Policy), polychlorinated biphenyls (PCBs), Aroclor 1260, Aroclor 1254, transformer vault.

II. INTRODUCTION

On November 9, 1987, the National Institute for Occupational Safety and Health received a request for a health hazard evaluation from the National Treasury Employees Union. NIOSH was requested to evaluate possible contamination of a transformer vault and surrounding areas from a leak involving oils known to contain PCBs. The vault and other areas are located in the basement of the U.S. Customs Headquarters in Washington, D.C.

III. BACKGROUND

In the Fall of 1987, an electrical transformer located in Room B100 of the U.S. Customs Headquarters in Washington, D.C. leaked approximately 30 gallons of a cooling oil which was known to contain PCBs. The transformer is located in vault C-7-B which contains a six inch concrete dike designed to contain such spills. Adjacent to the vault is a mechanical room which contains an air handling unit (AHU), a projection room, and a large office. The vault is reached by passing from the main hallway through a mechanical room. A series of doorways provide a means of egress from the main hallway, through the office and projection room, with the latter having direct access to the vault. A map of these areas is shown in Figure I of this report.

Upon discovering the leak, officials within the Customs Service contacted the General Services Administration (GSA) to initiate a spill cleanup. GSA retained the services of an outside contractor to cleanup the spill and to perform clearance sampling as required in the Toxic Substances Control Act (TSCA, 40 CFR Part 761, effective May 4, 1987). In reviewing the report submitted by the outside contractor, the NIOSH investigators found that they did not follow the surface sampling protocol described in the TSCA PCB spill cleanup policy. Because of this, the NIOSH investigators performed surface and air sampling for PCBs, using the TSCA protocol to assess the extent of any remaining contamination of the vault and surrounding areas.

IV. SAMPLING AND ANALYTICAL METHODOLOGY

A. Air

Airborne PCBs are collected by drawing air through a glass tube containing 150 milligrams (mg) of florisil adsorbent (100 mg front section and 50 mg backup section) at a flow rate of 1.0 liters per minute (lpm) using calibrated, battery-operated sampling pumps. This method generally conforms to the NIOSH sampling and analytical method 5503,[1] with modifications. The modifications involve sampling at higher than specified flow rates, resulting in greater sampled air volumes. NIOSH's experience indicates that breakthrough is not a problem when sampling atmospheres contaminated with less than a few micrograms PCB/cubic meter of air (ug/m^3). The obvious advantage of this modification is a reduction in the limit of detection (on a ug/m^3 basis).

At the laboratory, each florisil tube is separated into front and backup sections. Each section is desorbed in 1 milliliter (ml) of hexane with sonication for one-half hour to release the PCBs from the florisil for analysis.

B. Surfaces

A wet-wipe protocol is used to assess surface contamination of PCBs. The surface wipe samples are collected using 3" x 3" Soxhlet-extracted cotton gauze pads. The sampling procedure consists of marking off a surface into 0.25 m^2 areas using a metal tape measure or other appropriate device. Each 0.25 m^2 area is wiped with the gauze pad, previously wetted with 8 ml of pesticide-grade hexane. The wet-wipe sample pad is held with a gloved hand; a fresh, non-linear polyethylene, unplasticized glove is used for each sample. The surface is wiped in two directions, the second direction at a 90^0 angle to the first. Each gauze pad is used to wipe only one 0.25 m^2 area. The gauze pad sample is then placed in a glass sample container equipped with a Teflon-lined lid and submitted to the laboratory for analysis.

The gauze samples are prepared for analysis by extraction; they are shaken for 30 minutes in 40 ml of hexane. The hexane is transferred to a concentrator tube, and the gauze is rinsed twice with 10 ml of hexane. The concentrated hexane eluent is cleaned on a florisil column, and the sample is brought to a final volume of 3 ml.

For both the air and surface samples, the gas chromatographic analysis is typically performed on a Hewlett-Packard Model 5730A gas chromatograph equipped with an electron capture detector and accessories for capillary column capabilities. A 30 m x 0.31 mm fused silica WCOT capillary column, coated internally with DB-5, is used with temperature programming from 210°C (held for two minutes) to 310°C at a rate of 8°C/minute. Five percent methane in argon is used as the carrier gas. The capillary injector is operated in the splitless mode.

The presence of an Aroclor is determined by comparison with standard samples of Aroclors 1016, 1221, 1232, 1242, 1248, 1254, and 1260 obtained from the U. S. Environmental Protection Agency (EPA). Quantitation is performed by summing the peak heights of the five major peaks of the standards and comparing those sums to the sums of the same peaks in the sample.

Air and surface PCB concentrations are calculated by dividing the quantity of individual Aroclor measured in the sample by the sampled volume of air (m^3) or surface area (m^2), respectively. For air samples, the instrumental limit of detection (lowest amount that could be detected in a sample) is typically around 0.02 ug/sample, and the calculated limit of quantitation (the lowest amount that can be accurately measured in a sample) is 0.16 ug/sample. For surface samples, the limits of detection and quantitation may vary by Aroclor type.

V. EVALUATION CRITERIA - PCBs

A. Health Effects

PCBs are chlorinated aromatic hydrocarbons that were manufactured in the United States from 1929 to 1977 and primarily marketed under the trade name Aroclor.[2] They found wide use because they are heat stable; resistant to chemical oxidation, acids, bases and other chemical agents; stable to oxidation and hydrolysis in industrial use; and have low solubility in water, low flammability, and favorable dielectric properties. Additionally, they have low vapor pressure at ambient temperatures and viscosity-temperature relationships that were suitable for a wide variety of industrial applications. PCBs have been used commercially in insulating fluids for electrical equipment, hydraulic fluids, heat transfer fluids, lubricants, plasticizers, and components of surface coatings and inks.[3]

The different PCB mixtures marketed under different trade names are often characterized by a four-digit number. The first two digits denote the type of compound ("12" indicating biphenyl), and the latter two digits giving the weight percentage of chlorine, with the exception of Aroclor 1016. In other commercial preparations the number code may indicate the approximate mean number of chlorine atoms per PCB molecule (Phenoclor, Clophen, Kanechlor) or the weight percentage of chlorine (Fenclor).

Dietary PCB ingestion, the major source of population exposure, occurs especially through eating fish, but PCB residues are also found in milk, eggs, cheese, and meat. PCB residues are detectable in various tissues of persons without known occupational exposure to PCB. In past years, reported mean whole blood PCB levels ranged from 1.1 to 8.3 parts per billion (ppb), and mean serum PCB levels from 2.1 to 24.2 ppb, for persons without known occupational exposure.[4] Mean serum PCB levels among workers in one capacitor manufacturing plant studied by NIOSH ranged from 111 to 546 ppb, or approximately 5 to 22 times the background level in the community. Mean serum PCB levels among workers in transformer maintenance and repair typically range from 12 to 51 ppb, considerably lower than among workers at capacitor manufacturing plants.[5]

PCB toxicity is complicated by the presence of highly toxic impurities, especially the polychlorinated dibenzofurans,[6] which vary in amount depending on the manufacturer[7] and percent chlorination,[8] and which are found in increased concentration after incomplete pyrolysis of the PCB.[9,10] Furthermore, different animal species, including humans, vary in their pattern of biologic response to PCB exposure.[11]

Two human epidemics of chloracne, "Yusho" and "Yu-cheng," from ingestion of cooking oil accidentally contaminated by a PCB heat-exchange fluid used in the oil's pasteurization, have been described in detail.[12,13] Although PCB was initially regarded as the etiologic agent in the Yusho study, analyses of the offending cooking oil demonstrated high levels of PCDF and polychlorinated quarterphenyls, as well as other unidentified chlorinated hydrocarbons, in addition to PCB.[14]

The results of individual studies of PCB-exposed workers are remarkably consistent. Among the cross-sectional studies of the occupationally exposed, a lack of clinically apparent illness in situations with high PCB exposure seems to be the rule. Chloracne was observed in recent studies of workers in Italy,[15] but not among workers in Australia,[16] Finland,[16] or the United States.[5,18-20] Weak positive correlations between PCB exposure or serum PCB level, and serum aspartate aminotransferase (SGOT) level,[15,17-19] serum gamma-glutamyltranspeptidase (GGTP) level,[5,15,19,20], and plasma triglycerides[5,21,22] have been reported. Correlations between plasma triglycerides[23] and GGTP[24] have also been found among community residents with low-level PCB exposures. Causality has not been imputed to PCBs in these cross-sectional studies.

The International Agency for Research on Cancer (IARC) has concluded that the evidence for PCB carcinogenicity in animals and humans is limited. "Certain polychlorinated biphenyls are carcinogenic to mice and rats after their oral administration, producing benign and malignant liver neoplasms. Oral administration of polychlorinated biphenyls increased the incidence of liver neoplasms in rats previously exposed to N-nitrosodiethylamine."[25]

In a mortality study among workers at two capacitor manufacturing plants in the United States,[26] a greater than expected number of observed deaths from cancer of the liver and cancer of the rectum were noted. Neither increase was statistically significant for both study sites combined. In a recent update of this study,[27] however, with follow-up through 1982, the excess in liver/biliary tract cancer was statistically significant (5 observed vs. 1.9 expected). The excess in cancer of the rectum was still elevated but not statistically significantly so. In this mortality study, the personal time-weighted average exposures in 1976 ranged from 24 to 393 ug/m^3 at one plant, and from 170 to 1260 ug/m^3 at the other. During the time period (1940-1976) when most of the workers were exposed, the levels were probably substantially higher. At one of the plants, the geometric mean serum PCB levels in 1976 were 1470 ppb for 42% chlorinated biphenyls and 84 ppb for 54% chlorinated biphenyls.

In a mortality study among workers at a capacitor manufacturing plant in Italy,[28] males had a statistically significant increase in the number of deaths from all neoplasms. When these were analyzed separately by organ system, deaths from neoplasms of the digestive organs and peritoneum (3 observed vs. 0.88 expected) and from lymphatic and hematopoietic tissues (2 observed vs. 0.46 expected) were elevated. This study was recently expanded to include vital status follow-up through 1982 for all workers with one week or more of employment.[29] In the updated results, there was a statistically significant excess in cancer among both females (12 observed vs. 5.3 expected) and males (14 observed vs. 7.6 expected). In both groups there were statistically non-significant excesses of lymphatic/hematopoietic cancer and a significant excess of digestive cancer among males (6 observed vs. 2.2 expected).

B Environmental Evaluation Criteria

1. General

As a guide to the evaluation of the hazards posed by work place 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 work place 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 sources of environmental evaluation criteria for the work place are: 1) NIOSH criteria documents and recommended exposure limits (RELs), 2) the American Conference of Governmental Industrial Hygienists' (ACGIH) threshold limit values (TLVs), and 3) the federal Occupational Safety and Health Administration's (OSHA) permissible exposure limits (PELs). Often, the NIOSH recommendations and ACGIH TLVs are lower than the corresponding OSHA PELs. The NIOSH RELs and ACGIH TLVs are usually based on more recent information than are the OSHA standards. The OSHA PELs may also be required to take into account the feasibility of controlling exposures in various industries where the agents are used; the NIOSH-recommended exposure limits, 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 PEL.

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.

2. PCB

a. Air

In February 1986, NIOSH reiterated its previous recommendation that exposure to PCB in the workplace not exceed 1 ug/m^3 (based upon the recommended sampling and analytical method in use at the time), determined as a TWA for up to a 10-hour workday, 40-hour workweek.[30] This recommended exposure limit was based on the findings of adverse reproductive effects in experimental animals, on the conclusion that PCBs are carcinogens in rats and mice and, therefore, potential human carcinogens in the workplace, and on the conclusion that human and animal studies have not demonstrated a level of exposure to PCBs that will not subject the worker to possible liver injury.(31)

In 1971, based on the 1968 ACGIH TLVs, OSHA promulgated its permissible exposure limits of 1 mg/m^3 for airborne chlorodiphenyl products (PCB) containing 42% chlorine and 0.5 mg/m^3 for chlorodiphenyl products containing 54% chlorine, determined as 8-hr TWA concentrations (29 CFR 1910.1000). The TLVs, which have remained unchanged at 1.0 and 0.5 mg/m^3 through 1987, are based on the prevention of (non-carcinogenic) systemic toxicity.[32] The OSHA PEL and the ACGIH TLV values include a "skin" notation, which refers to the potential contribution to overall exposure by the cutaneous route, including the mucous membranes and eyes, by either airborne or direct skin contact with PCB.

b. Surfaces

NIOSH recommends that occupational exposures to carcinogens be reduced to the lowest feasible level. Results of several investigations of PCB surface contamination in office buildings indicate that there is a "background" level of surface contamination in the range of 50 to 100 micrograms per square meter (ug/m^2).[33-36] Therefore, for surfaces in the occupational environment that may be routinely contacted by the unprotected skin, NIOSH investigators have recommended that PCB contamination not exceed 100 ug/m^2 (the lowest feasible level considering background contamination).

The risk posed by this level of contamination was assessed by the Environmental Protection Agency (EPA) in its PCB spill cleanup policy.[37] In the "Development" section of the policy (Risks Posed by Leaks and Spills of PCBs), the EPA states that the estimated level of oncogenic risk associated with dermal exposures to 50 ug/m^2 of PCBs on hard, indoor, high-contact surfaces is between 1×10^{-5} and 1×10^{-6} (between 1 in 100,000 and 1 in 1,000,000 excess deaths, usually stated in terms of workers with a 30-year work history). Although the EPA document did not provide a risk estimate for the cleanup criterion it established for high-contact indoor surfaces (1,000 ug/m^2), it did state, "EPA also believes that the surface standards of ... 1,000 ug/m^2 for indoor low-contact surfaces (and vaults) and high-contact surfaces in a restricted access industrial facility would not present significant risks to workers or the the general population." However, since there is a considerable degree of uncertainty associated with such a risk assessment calculation, EPA also stated that, "...the results of these [EPA] studies indicate that high-contact surfaces such as manually operated machinery may require surface standards more stringent than the 1,000 ug/m^2 standard." The EPA surface contamination standards of 1,000 ug/m^2 for high- and low-contact indoor surfaces and 10,000 ug/m^2 for low-contact indoor surfaces, with encapsulation, are legally enforceable under the TSCA Polychlorinated Biphenyl Spill Cleanup Policy (40 CFR 761).

VI. RESULTS

Air Sampling

Area air sampling was performed in the vault and adjacent areas in the basement of the U.S. Customs Headquarters. The following locations were targeted for this sampling regimen: B100 Vault Room, B100 Mechanical Room, B100-outside Vault Room on window ledge, B102 Projection Room, B102 Office, and the main hallway outside of B102. Data from this area air sampling are presented in Table I. All six of these samples reported non-detectable levels of PCBs, with each sample being analyzed for the following Aroclors: 1016, 1221, 1232, 1242, 1248, 1254, 1260.

Surface Sampling

Results from the surface sampling for PCBs are presented in Table 2. Each of these samples were analyzed for the following Aroclors: 1016, 1221, 1232, 1242, 1248, 1254, 1260. Concentrations of PCBs (Aroclor 1260), on the floor and within the diked area of the B100 Vault Room, ranged from 10,000 to 148,000 ug/m^2. The B100 Mechanical Room, which is passed through before entering the Vault Room, had PCB concentrations on the floor of 3720 and 8000 ug/m^2; a sample taken on the window ledge produced a concentration of 5705 ug/m^2. A sample taken from the inlet for the AHU found a concentration of 560 ug/m^2. The handles and knobs of doors leading to and from B100 were also sampled, with these producing surface concentrations from 5 to 176 ug/m^2.

The possible spread of contamination from the vault was evaluated by performing surface sampling in the adjacent hallway and office area. Concentrations of Aroclor 1254 in the two nearby hallway intersections were 234 and 321 ug/m^2. Accordingly, the black rubber mat in the hallway and outside of the B100 doorway had an Aroclor 1260 level of 224 ug/m^2. Finally, the surface of a table in the B102 office area had a surface concentration of 6 ug/m^2.

VII. DISCUSSION

The area air sampling results show that no measureable levels of PCBs were found in Rooms B100, B102, the Projection Room, or the hallway. These findings are consistent with the fact that PCBs have a low vapor pressure and do not readily volatilize.

Despite past cleanup efforts, PCB surface contamination still exists in the B100 Vault and Mechanical Rooms. Levels within these areas range from 3 to 148 times higher than the existing EPA cleanup standard (1000 ug/m^2) for a restricted access area.

Since the hallway and offices adjacent to Room B100 are public access areas, i.e. areas routinely used by the occupants of a building, surface contamination with PCBs should not exceed the background level of 100 ug/m^2. Surface sampling of these areas indicates that the hallway is slightly contaminated with PCBs, with levels between 2 and 3 times the recognized background level. Surface sampling in the B102 Office found PCB levels well below the recognized background concentration, indicating that PCB contamination from the spill has not migrated into this area.

VIII. RECOMMENDATIONS

The following recommendations are made per the conditions observed and the data collected during the NIOSH survey:

1. The contaminated surfaces in B100, as indicated by NIOSH's surface sampling, should be cleaned to below the EPA standard of 1000 ug/m^2 for both high- and low-contact surfaces in a restricted access area. The door to B100 should be locked and no entry allowed until this cleanup is completed. This cleanup should be performed using methods described by the EPA in their PCB spill cleanup policy.[37]

2. Since the hallway is considered a public access area, it should be cleaned to below the NIOSH recognized background concentration of 100 ug/m^2. Again, this cleanup should be performed using methods described by the EPA in their PCB spill cleanup policy.[37]

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XI. DISTRIBUTION AND AVAILABILITY OF REPORT

Copies of this report are currently available upon request from NIOSH, Hazard Evaluations and Technical Assistance Branch, 4676 Columbia Parkway, Cincinnati, Ohio 45226. After 90 days, the report will be available through the National Technical Information Service (NTIS), 5285 Port Royal, Springfield, Virginia 22161. Information regarding its availability through NTIS can be obtained from NIOSH Publications Office at the Cincinnati address. Copies of this report have been sent to:

1. National Field Representative, National Treasury Employees Union.
2. President, NTEU Local 128.
3. Director of Headquarter Services Division, U.S. Customs Service.
4. Safety and Health Officer, U.S. Customs Service.
5. NIOSH, Boston Region
4. OSHA, Region III

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.

FIGURE I

Map of Survey Areas
U.S. Customs Service
HETA 88-054
March 29, 1988

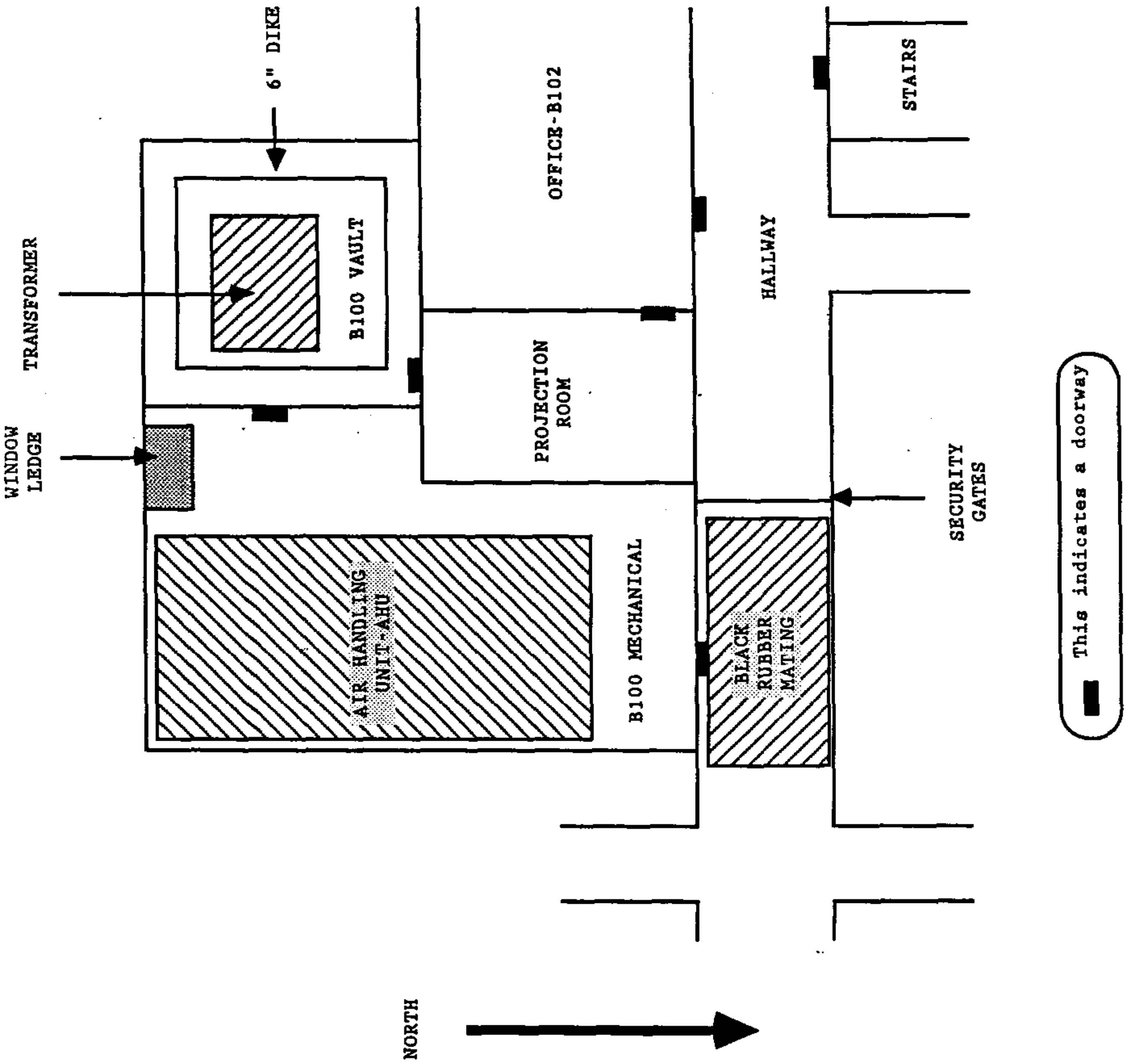

Table I

Results from Area Air Sampling for PCBs
U.S. Customs Service
HETA 88-054
March 29, 1988

Sample Location	Sample Time	Sample[1] Volume	Concentration[2]
B100 Vault Room	10:08-16:53	405	ND[3]
B100 Window Ledge	10:07-16:53	406	ND[3]
B100 Mechanical Room	10:05-16:53	408	ND[3]
Projection Room	10:03-16:53	410	ND[3]
B102 Office Area	10:03-16:53	410	ND[3]
Hallway Intersection Near Stairs	10:09-16:53	404	ND[3]
NIOSH REL			1

[1] Units expressed in liters of air.

[2] Units expressed in micrograms of a specific Aroclor per cubic meter of air. Samples were tested for the following Aroclors: 1016, 1221, 1232, 1242, 1248, 1254, 1260.

[3] ND - levels were below the detection limit for this method. LODs ranged from 0.05 to 0.27 ug/sample for the seven Aroclors.

Table II

Results from Surface for PCBs
U.S. Customs Service
HETA 88-054
March 29, 1988

Sample Location	Area[1] Sample	Concentration[2]
Floor in front of transformer, B100	0.25	10,000
Floor in Northwest corner of dike, B100	0.25	38,000
Floor in Southwest corner of dike, B100	0.25	40,000
Floor under transformer's drain valve, B100	0.25	48,000
Stenciled square marked "#2" on floor, B100	0.01	126,213
Floor in southwest corner of dike, B100	0.25	148,000
North wall of vault, B100	0.25	112
West wall of dike	0.25	25,200
Floor 5 ft. from vault door, B100	0.25	8,000
Floor 10 ft. from vault door, B100	0.25	3,720
Window ledge, B100	0.09	5,705
Floor near pump G-83, B100	0.25	1,920
Inlet area of AHU, B100	0.25	560
Handle of vault door, B100	0.25	176
Knob of projection room door, B100	0.25	40
Door leading to B100, hallway	0.25	5
Black rubber mat in hallway, outside of B100	0.25	224
Hallway intersection west of security gates	0.25	234*
Hallway intersection east of security gates	0.25	321*
Surface of table in B103	0.25	6
NIOSH REL		100
EPA Surface Standard, Low Contact Surface		1,000
EPA Surface Standard, High Contact Surface		1,000
LOD - Aroclor 1260		0.15 ug/sample
LOQ - Aroclor 1260		0.49 ug/sample
LOD - Aroclor 1254		0.43 ug/sample
LOQ - Aroclor 1254		1.4 ug/sample

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[1] Units expressed in meters squared (m^2).

[2] Units expressed in micrograms of a specific Aroclor per square meter. All values are for Aroclor 1260 except for those indicated (*) as being Aroclor 1254. Levels of all other Aroclors were below the LOD for this method.