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The Greater New Bedford PCB Health Effects Study 1984-1987

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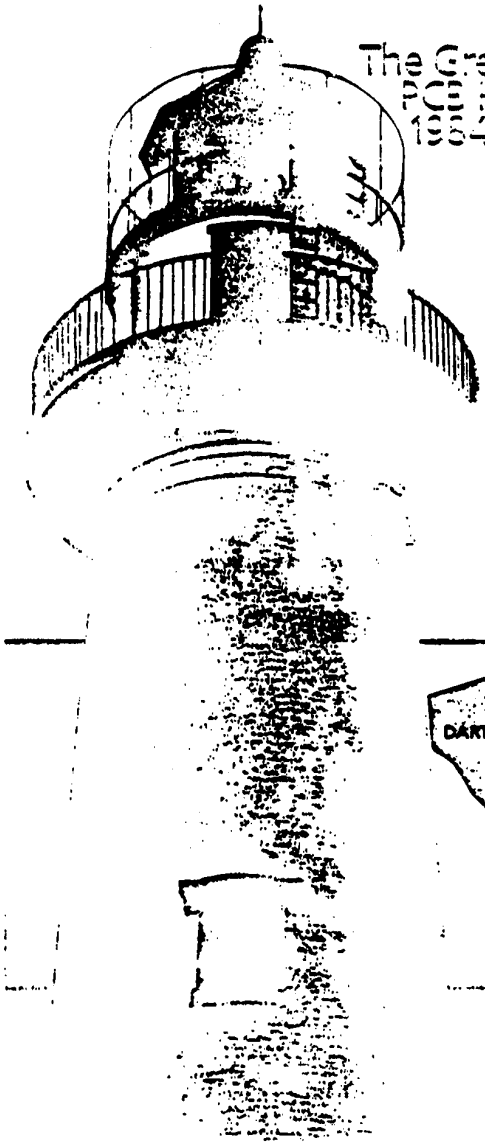

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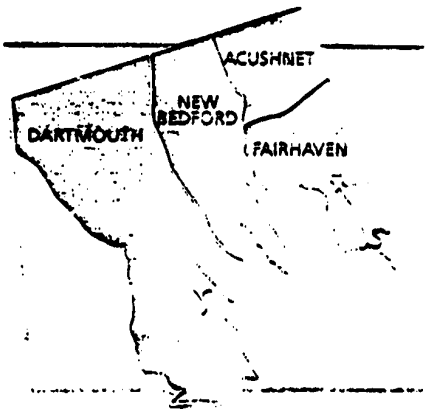

MONS 027596

FINAL REPORT

OF

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

1984 - 1987

JUNE, 1987

BOSTON, MASSACHUSETTS

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
150 TREMONT STREET
BOSTON, MASSACHUSETTS

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This work was conducted by the Massachusetts Department of Public Health (MDPH) and the Massachusetts Health Research Institute (MHRI), with the assistance of the Center for Environmental Health, Centers for Disease Control, U.S. Public Health Service. Partial funding was provided by the Agency for Toxic Substances and Disease Registry (ATSDR), U.S. Public Health Service, from the Comprehensive Environmental Response, Compensation, and Liability Act trust fund (Superfund), through an interagency agreement with the Environmental Protection Agency (EPA).

Additional information on this project may be obtained by writing:

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ABSTRACT

The Greater New Bedford PCB Health Effects Study (GNBHES) design consisted of two phases: Phase I was designed to determine the prevalence of elevated serum polychlorinated biphenyls (PCBs) levels ($\geq$30 parts per billion (ppb)) among residents of the Greater New Bedford population and to test the hypothesis that serum PCB level is associated with elevated blood pressure measurements. Phase I also sought to identify 150 exposed ($\geq$30 ppb) persons who would participate in a Phase II study to determine the relationship between serum PCB level and a variety of health outcomes.

In 1976, PCBs were found in high concentrations in the Acushnet River estuary adjacent to New Bedford and Fairhaven. Numerous environmental investigations identified PCB contamination of harbor sediment and overlying waters, seafoods harvested from the New Bedford Harbor, and municipal sludge and wastewater. This evidence of widespread environmental contamination extended the concern of human exposure to PCBs from persons occupationally exposed in local electrical manufacturing plants to include persons in the general population who consumed fish from contaminated areas.

Phase I of the GNBHES called for random selection of 1784 residents of New Bedford, Acushnet, Dartmouth, and Fairhaven between the ages of 18 and 64 years. Of the 1482 residents considered eligible for inclusion in the study, 840 individuals chose to participate, a response rate of 57% (Prevalence Study) and were analyzed for individual serum PCB levels. Eleven of the 840 or 1.3% were identified with elevated PCB levels ($\geq$ 30 ppb). Blood pressure levels did not appear to be correlated with serum PCB

levels in the prevalence study group. To identify 150 persons with elevated serum PCB levels (justification for proceeding to Phase II), a contingency plan was implemented to recruit non-randomly selected participants (Enrichment Study) who were at high risk for exposures to PCBs. Seven of these 110 participants or 6.4% in the Enrichment Study had levels $\geq$ 30 ppb.

Specimens of urine and blood were collected from participants in both the prevalence and enrichment studies for analysis of blood lead, urinary arsenic, and urinary mercury. A 10% subset of these specimens was tested for these heavy metals. No evidence was found of excessive exposure to toxic forms of any of the elements tested.

Eligible individuals who refused to participate in the prevalence study appeared to be similar to participants with regard to sex, town of residence, employment history or seafood consumption.

The low prevalence of elevated serum PCB levels that was found in the randomly selected group indicates that significant exposure to PCBs is not occurring in the Greater New Bedford population. However, individuals who eat locally caught seafood from inner New Bedford Harbor tend to have higher concentrations of serum PCBs. Continuation of the study to Phase II with a major health effects phase is not recommended because of the small number of persons found with elevated serum PCB levels.

ACKNOWLEDGMENTS

The Massachusetts Department of Public Health (MDPH), the Massachusetts Health Research Institute (MHRI) and the United States Centers for Disease Control (CDC) gratefully acknowledge the contributions of the staff of the Greater New Bedford PCB Health Effects Study. It was through their hard work and sincere dedication to the community and to the field of environmental health that this difficult epidemiological investigation was completed. The staff included over 20 individuals during a 3 year investigation period; the names and disciplines represented by these individuals as well as the contributions of those acknowledged below are included in Appendix A.

We would like to acknowledge several other agencies and individuals for their assistance with this investigation. They include: the offices of U.S. Senator Edward M. Kennedy (D - Mass.); U.S. Congressman Gerry Studds (D - Mass.); Massachusetts State Senator William Q. MacLean (D - New Bedford); former Massachusetts State Representative Roger Goyette: the MDPH Division of Data Processing; the MDPH Registry of Vital Records. statistics unit; the local media; the New Bedford Immigrant's Assistance Center; the city/town governments of New Bedford, Dartmouth, Fairhaven and Acushnet; the Massachusetts Division of Marine Fisheries (DMF); the office of MDPH Assistant Commissioner Gerald Parker; the MDPH Central Library; the staff of the MDPH Center for Environmental Education and Information; Mrs. Pearl Russo of the MDPH Office of Public Information; Mr. John Figler, CEH/CDC former liaison to the U.S. EPA Region I. Most important, the support and cooperation of the residents of Acushnet, Dartmouth, Fairhaven and New Bedford in this important public health investigation are greatly appreciated.

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CHAPTER I

INTRODUCTION

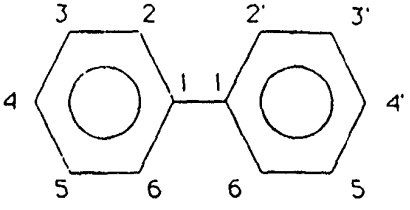
HISTORICAL OVERVIEW

Polychlorinated biphenyls (PCBs) refer to a class of chemical compounds with 209 possible congeners in which chlorine atoms have replaced some or all of the hydrogen atoms in the biphenyl molecule (Figure 1). The number and location of the chlorine atoms are responsible for the PCBs' chemical properties and toxicity. In general, the higher the chlorine content of the compound, the more persistent it is. PCBs are generally odorless and colorless, have excellent thermal and chemical stability, are fire resistant, non-conductive and virtually insoluble in water. (1) These properties made PCBs ideal for a variety of industrial applications.

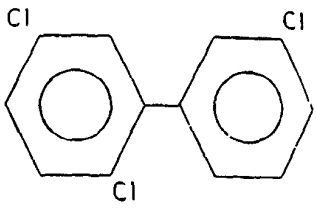
During the years of PCB use in Greater New Bedford, the Acushnet River estuary and New Bedford Harbor became contaminated with PCBs through the discharge of contaminated waste water and improper disposal of defective capacitors. In New Bedford, PCB use began in the early 1940s. PCBs were used primarily as a liquid coolant in the manufacture of electrical transformers and capacitors. Other possible industrial uses for PCBs were lubricants, machine tool cutting oils, and immersion oil for microscopes. In addition, they were added to a variety of other products including paints, adhesives, sealants, varnishes, dedusting agents, pesticides, herbicides, and carbonless copy paper (2,3,4). The U.S. Environmental Protection Agency (EPA) officially banned the manufacture of PCBs and their use in open systems in 1979 (44 FR 31515).

PCBs entered the aquatic food chain by binding with sediments and

FIGURE 1



STRUCTURAL FORMULA OF
THE BIPHENYL MOLECULE



STRUCTURAL FORMULA OF
3,3',6-TRICHLOROBIPHENYL

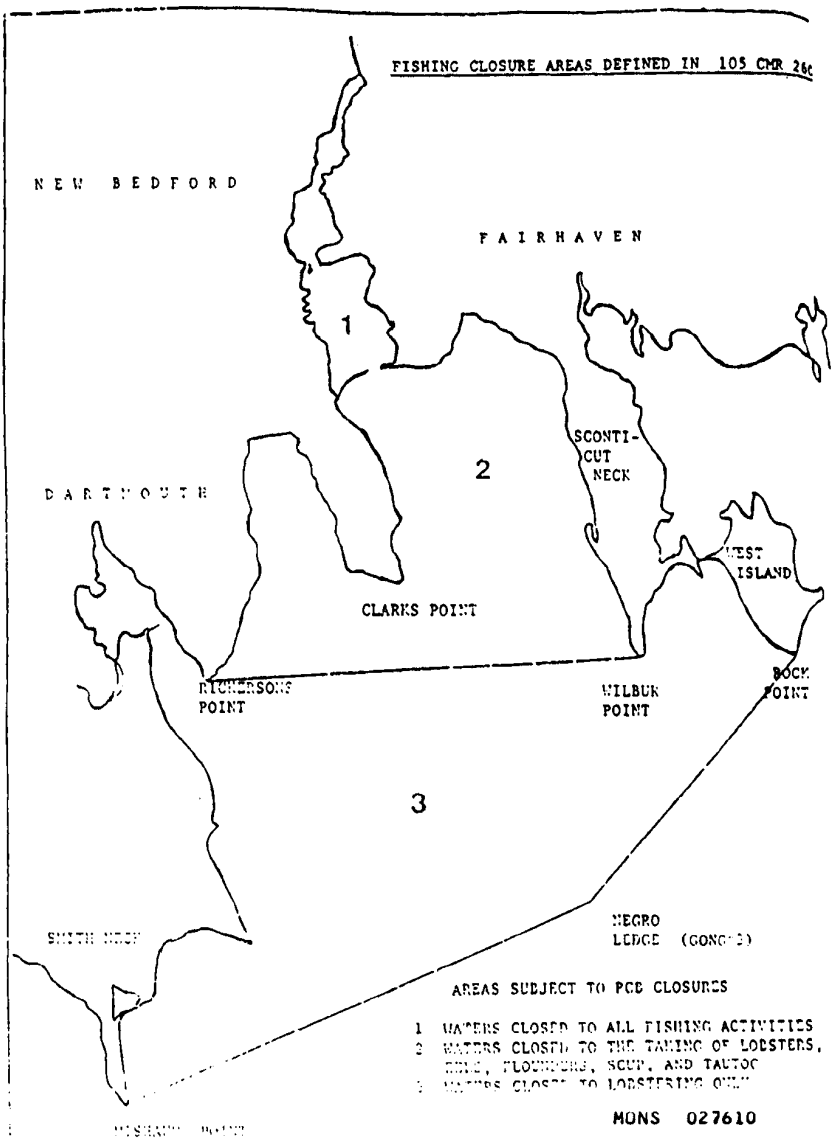
The biphenyl molecule has ten positions that are available for chlorine atoms (the positions labeled 2-6 and 2'-6'). There are 209 possible compounds (PCB congeners) that can be formed by different levels of chlorination. For example, there are 24 possible trichlorobiphenyls (PCBs with 3 chlorine atoms), but only one decachlorobiphenyl (10 chlorine atoms).

particles eaten by lower forms of aquatic life. The PCBs were then passed up through the food chain via predator/prey relationships (2) resulting in the contamination of higher forms of marine life such as fish and lobster. The levels of PCBs in fish in New Bedford were greater than the 5 parts per million (ppm) tolerance set by the U.S. Food and Drug Administration (FDA) in 1973. (5) More recently, the FDA tolerance was lowered to 2 ppm. (6) Since PCBs bioaccumulate, the most logical route of exposure to PCBs for the 140,000 Greater New Bedford residents was ingestion of contaminated seafood. In response to these findings, the MDPH promulgated regulations to close the contaminated area to commercial fishing in September of 1979. (7)

The closure area (Figure 2) was divided into three sections. The most contaminated area, identified as Area 1, included waters north of the hurricane dike in New Bedford Harbor and was closed to all fishing. Area 2, south of Area 1, extended out to Ricketson's Point in South Dartmouth and westerly across to Wilbur Point on Sconticut Neck in Fairhaven. Area 2 was closed to lobstering and to the taking of bottom-feeding fish including flounder, eels, scup and tautog. Area 3, south of Area 2, was closed only to lobstering and extended out to Mishaum Point in South Dartmouth, westerly across to gong #3 on Hursett Rock and continued northwest to Rock Point on West Island in Fairhaven. The entire closure area encompasses approximately 28 square miles.

Although regulatory intervention has prevented commercial fishermen from obtaining seafood in the contaminated area, recreational fishing still occurs because of difficulties in enforcing these types of activities. As a result, the EPA and the Massachusetts Department of Environmental Quality Engineering (DEQE) installed numerous bilingual warning signs around the closure area.

FIGURE 2


FISHING CLOSURE AREAS DEFINED IN 105 CMR 26(
NEW BEDFORD
FAIRHAVEN
1
2
SCONTI-
CUT
NECK
DARTMOUTH
WEST
ISLAND
CLARKS POINT
RICHARDSONS
POINT
WILBUR
POINT
ROCK
POINT
3
NEGRO
LEDGE (GONG'D)
AREAS SUBJECT TO PCB CLOSURES
1 WATERS CLOSED TO ALL FISHING ACTIVITIES
2 WATERS CLOSED TO THE TAKING OF LOBSTERS,
FINFISH, FLOUNDERS, SCUP, AND TAUTOG
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Another source of non-occupational PCB exposure among residents of the Greater New Bedford area was via skin contact with contaminated soil present in the environment. There are several sites (e.g., landfills, river banks) throughout the area in which high levels of PCBs have been discovered in the soil. (8) Analyses of soil samples revealed high levels in Greater New Bedford. This route of exposure to PCBs was examined in a study conducted by the MDPH in 1984 in Norwood, Massachusetts (Figure 3), and also in other sites in the U.S. investigated by the Centers for Disease Control (CDC). Some of the highest levels of PCBs discovered in soil in the U.S. were observed in Norwood (220,000 parts per million (ppm)). This investigation involved collection of human serum to be analyzed for PCB. MDPH selected a group of 90 people thought to be at the greatest risk of exposure. The mean serum PCB level was 4.9 ppb. From this study it would appear that contact with ambient soils may not be a significant exposure route to PCBs.

In 1981 and 1982, two pilot studies of serum PCB levels of volunteers who reported eating local seafood were conducted by CDC and MDPH in New Bedford. (9) In the first study, nine of the 21 (43%) subjects had serum PCB levels greater than or equal to 30 ppb. In the second study, 31% of the 51 subjects tested at levels greater than or equal to 30 ppb. At that time, the CDC estimated that only one percent of the U.S. population would be likely to have levels greater than 30 ppb. (10)

A recent review of the laboratory and human studies on PCBs (11) indicated that PCBs are carcinogenic, affect reproduction, supress the immune response, and produce hepatic porphyria when ingested in a variety of species. Once ingested, PCBs are stored in fatty tissues including human milk fat. Evidence suggests that the more chlorinated or more toxic

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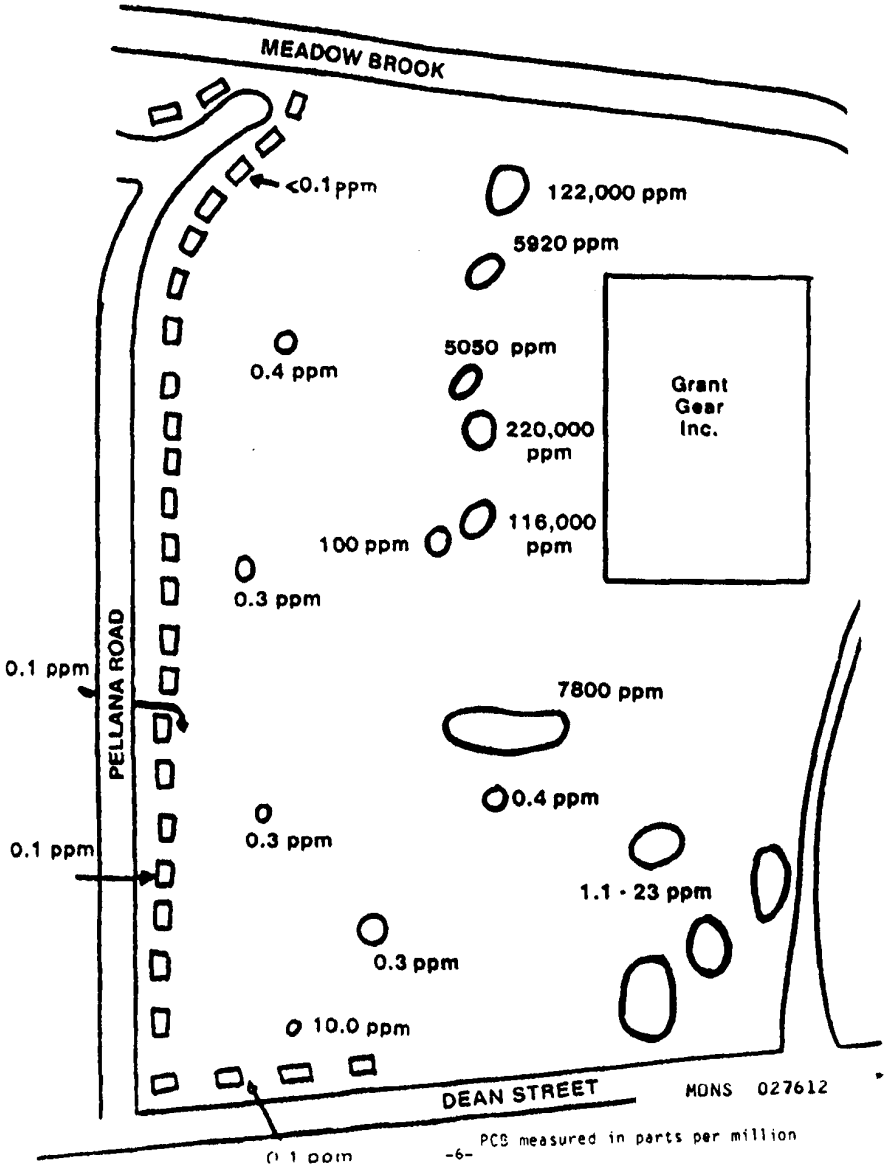
FIGURE 3 PCBs IN SOIL - NORWOOD



PCB measured in parts per million

compounds are excreted from the body quite slowly. (12)

There have been few cross-sectional studies of humans exposed to PCBs. However, no studies demonstrated sufficient statistical power or were followed long enough to support or refute whether PCBs were carcinogenic in humans. One study reported a strong association between serum PCB level and diastolic blood pressure readings; however, this association was weakened when age was controlled (13). Other studies reported that high PCB levels were associated with high serum cholesterol levels, elevated triglyceride levels and induction of liver enzymes.

The studies which contribute the most information about general population serum PCB levels are the ones conducted in Michigan to evaluate a widespread PCB contamination episode. One Michigan study reported a geometric mean serum PCB level of 6.4 ppb (14). In other surveys almost exclusively of volunteer populations, one can expect to see 95% of serum levels falling below 20 ppb and 99% falling below 30 ppb. (15, 19)

Because seafood consumption is now regarded as the most plausible nonoccupational route of exposure, concerted inquiry has been mounted in populations known to consume contaminated fish. The largest study to date was in the town of Triana, Alabama in 1979. This was a cross-sectional study of 600 rural black residents to determine the possible consequences of consuming fish contaminated by DDT, the result of the presence of a DDT manufacturing facility. Mean fish consumption was documented at 4.3 fish meals per month before the publicizing of the study. During the analysis of blood serums, PCB levels ranging from 3.2 to 158 ppb were noted, with the geometric mean being 17.2 ppb. (13)

Fish consuming populations have also been evaluated in Michigan. These populations are generally composed of sports fishermen or volunteers.

In 1973, Humphrey (16) looked at a small population of heavy fish eaters from the Lake Michigan area and documented a 4-fold increase in PCB levels as compared to non-fish eaters. A larger study of 572 Michigan sports fishermen (17) showed a lower mean PCB level of 21.7 ppb, but again higher concentrations for heavy (i.e. more frequent) versus light fish eaters.

In the Triana study, serum cholesterol was positively associated with serum PCB levels. Independent of other major predictors of PCB level such as age, sex, fish consumption, body mass index and alcohol consumption. Triana results introduced the hypothesis that PCBs may be related to elevated blood pressure. Kreiss et al found diastolic blood pressure measurements and serum PCB levels were significantly related. A major weakness of the study was the collinearity between DDT and PCB levels in the Triana population. An analysis performed with patients from the Yusho (PCB poisoning) incident did not show a relationship between blood pressure and PCB levels (18). Therefore, this relationship is open to question.

The literature demonstrates further work is necessary in two areas: 1) greater attention must be paid to the PCB-elevated blood pressure hypothesis, and 2) larger non-volunteer populations must be examined for the prevalence of PCB exposure while both occupational and non-occupational exposures are examined simultaneously.

Introduction to the Greater New Bedford Health Effects Study

As a result of the widespread environmental contamination (i.e., heavy metals, PCBs, etc.) and of the preliminary findings of the 1981 and 1982 pilot studies (9), a proposal for a two-phase epidemiological investigation was developed by the MDPH in cooperation with the CDC. The first phase was designed to determine the prevalence of elevated serum PCB levels in the

Greater New Bedford population (i.e., residents of Acushnet, Dartmouth, Fairhaven and New Bedford), and to determine whether there was a relationship between serum PCB levels and systolic/diastolic blood pressure levels. The second phase was designed to compare two groups of 150 individuals each and examine possible health effects associated with PCB exposure. On the basis of studies conducted in other communities that included presumably unexposed cohorts, CDC estimates that 99% of unexposed persons in the United States have PCB levels less than 30 ppb and 95% have levels below 20 ppb (19). An exposed group, that is, individuals with serum PCB levels greater than 30 ppb, would be compared in the second phase of the study to an unexposed group of individuals with serum PCB levels less than 10 ppb for a variety of clinical and laboratory measurements.

After a review of the first 322 serum specimens (Table 1), it was determined that the first phase data would not identify a sufficient number of exposed individuals to study in the second phase. Only 4 (1.2%) of the entire group of 322 individuals had serum PCB levels $\geq$ 30 ppb. Preliminary data analyses suggested that those residents with serum PCB levels greater than or equal to 15 ppb had consumed a great deal of contaminated seafood caught in and around the closure area. This observed difference remained constant even after confounding variables were removed.

On the basis of these findings, the MDPH and the CDC decided to conduct an Enrichment Study. The Enrichment Study consisted of Greater New Bedford residents suspected to be at high risk for PCB exposure because of ingestion of moderate to high amounts of seafood from the contaminated areas and an occupationally exposed group obtained from the list of 1981 pilot participants. The goal of recruiting these individuals was to provide 150 exposed residents necessary for conducting Phase II.

Table 1.

Serum PCB Results for 322

Greater New Bedford Residents

PCB level	Aroclor 1254	
	n	%
30 + ppb	4	1.2
20 - 29.99 ppb	4	1.2
10 - 19.99 ppb	28	8.7
0 - 9.99 ppb	286	88.8

n = number of respondents

% = percent of results on 322 respondents

ppb = parts per billion

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CHAPTER II

METHODS

The objectives of the Greater New Bedford PCB Health Effects Study were to:

1) determine the prevalence of PCB exposure among residents of Greater New Bedford, and

2) to determine whether or not a relationship exists between serum PCB levels and levels of systolic and diastolic blood pressure.

Phase I also sought to identify 150 exposed ($\geq$30 ppb) persons who would participate in a Phase II study. These objectives were met by obtaining a cross-sectional, random sample (stratified by age and sex) of 840 residents of Acushnet, Dartmouth, Fairhaven and New Bedford. This chapter focuses on the methodological design of the Greater New Bedford PCB Health Effects Study.

SETTING

The Greater New Bedford area encompasses four cities and towns (Acushnet, Dartmouth, Fairhaven and New Bedford) within the Southeastern section of the State of Massachusetts. The total population is 140,000; the greatest number of individuals residing in the City of New Bedford. It is culturally diverse with 36% of the residents speaking Portuguese, 6% Spanish and 58% English. New Bedford is approximately 66 miles from Boston, the major metropolitan center in Massachusetts. New Bedford has long been identified as the whaling capital of the world. Herman Melville

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may have described New Bedford best when he said, "The town itself is perhaps the dearest place to live in, in all New England. It is a land of oil, true enough: but not like Canaan; a land, also, of corn and wine. The streets do not run with milk; nor in the springtime do they pave them with fresh eggs. Yet, in spite of this, nowhere in all America will you find more patrician-like houses; parks and gardens more opulent, than in New Bedford." (20)

The remaining three towns within the study area are much smaller in terms of both geographic boundaries and total population. Further, the ethnic variation of each of these three towns is somewhat different from that of the City of New Bedford.

SAMPLE

Statisticians at the CDC and statistical consultants using a variety of power calculations concurred that a sample of 840 individuals was adequate to detect a doubling of the prevalence of elevated serum PCB levels to 2% or more at a .05 significance level and a power of .80 (Appendix W). Although the original sampling plan (Appendix Z) placed this estimate much higher, the recalculated sample size was determined to be adequate. The age range of the sample was 18 to 64 years. Children were excluded because it was unlikely that they had elevated serum PCB levels due to limited time exposure. Persons 65 years and older were also excluded from the study because they were more likely to have other pathologies that would confound interpretation of the findings.

After a review of available source lists (e.g., documents listing households, addresses, residents) from which the sample could be drawn, it was determined that the most appropriate and complete sampling vehicles

were the annual census that each city and town in Massachusetts was required to conduct. The census lists are ordered by wards (New Bedford only), and then, by precinct (all other towns). Streets within each precinct are listed alphabetically and individual residents 17 years of age and older are ordered by street number. Census lists for each city/town were updated by study staff to make address changes and additions by using various other city/town records (e.g., voter registration change of address forms).

In order to obtain a representative sample of the four town area, a two level proportional stratification by city/town, and then by sex within each community was performed. Accordingly, each town was sampled in proportion to its contribution to the total male and female 18 to 64 years old population. Based on 1980 Federal Census figures, these proportions were 65.5% from New Bedford, 17.4% from Dartmouth, 10.9% from Fairhaven, and 6.3% from Acushnet.

The MDPH Division of Data Processing generated a list of random numbers for each town, using a modified Statistical Analysis System (SAS) Program for Random Number Generation. Each number represented a page number and a line number in a particular town's census. Accordingly, every person listed on any randomly selected page had an equal probability of selection for the study. An eligible individual was defined as any person 18 to 64 years of age who had lived in the Greater New Bedford area for five years or more since 1940.

In order to compensate for ineligible individuals and an assumed 75% participation rate, 3900 random numbers were generated. These numbers were batched in groups of 133 with each city/town represented proportionally. At the beginning of the study, the census for several wards in New Bedford

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had not been updated. Consequently, a number of empty lines for selected random number pages resulted. In order to select the appropriate proportions in the sample, it was necessary to assign more random numbers per batch for New Bedford. Later, during the course of the study, when the update of the census was completed, individuals who would have been sampled earlier were identified and invited to participate in the study.

Community outreach efforts such as press conferences, newspaper, radio and television coverage and distribution of posters, as well as solicitation letters to the local medical and business communities, (Appendices C and D), preceded initial contact with selected respondents and continued throughout the study period.

Selected residents were sent a letter in English and Portuguese signed by the Commissioner of the Massachusetts Department of Public Health as well as by representatives of the four local Boards of Health. The letter served to inform a resident of his/her random selection in the Greater New Bedford Health Effects Study and explained the purpose of the study (Appendix B). Telephone follow-up by study staff determined age and residence eligibility of each candidate. An appointment was scheduled for all eligible individuals who agreed to participate. Postcards confirming each appointment and reminding the subject to fast for 12 hours before the appointment were mailed 1 week before the appointment.

If, at the time of initial telephone contact, an individual was identified who did not speak English, the candidate's cover sheet was distributed to a bilingual interviewer. The same protocol was followed for English, Spanish and Portuguese speaking candidates. Attempts were made from the beginning to offset any logistical reasons for refusal. For instance, when transportation was identified as an obstacle for

participation in the study, cabfare was supplied by the project.

A cover sheet with a call record (Appendix J) was used to record efforts to reach randomly selected individuals. Calls and home visits were recorded with the date and time of the phone call or home visit and the interviewer identification number (a home visit was determined as an actual trip to the address listed for a resident in the city/town census listing). Candidates who initially refused to participate were recorded as "IR", and space was provided to record the reason for refusal and any other pertinent comments. Follow up calls to these individuals continued until there was a final disposition of each case. The disposition of all home visits/phone to possible participants was recorded on individual cover sheets.

Staffing and scheduling were designed to maximize subject participation. There were five staff interviewers. One interviewer was bilingual in English and Portuguese and another interviewer was trilingual in English, Spanish, and Portuguese. The study office was open two evenings a week and every other Saturday. Saturday was the most popular choice of participants, and 23.3% of the interviews took place on that day.

A campaign to follow-up individuals who had initially refused to participate was established in October, 1985. These individuals received a second telephone call and were again asked to participate. If the candidate refused a second time during this call, they were asked to complete the refusal questionnaire (Appendix H and I) and he/she was coded as final refusal. This procedure was also used for home visits to individuals who did not have a telephone or did not have a phone number listed in the local telephone directory.

In order to attain a final disposition for all randomly selected candidates, study staff made a maximum of thirty telephone calls and

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four home visits for each individual. If in the course of a home visit no one was home, a letter was left for the person, which explained the purpose of the study and asked him/her to call the study office (Appendix E). Study staff visited homes in a sequence of day, evening, and Saturday visits over a period of time to ensure contact with individuals who were working or were otherwise occupied outside the home. Individuals who proved especially difficult to locate or contact were sent certified letters. Because the home visit and certified letter approaches were costly in terms of staff time and monies, a decision was made in February of 1986 to code an initial refusal resulting from a home visit or a certified letter as a final refusal. There was no further effort made to recontact such individuals. All other initial refusals, with few exceptions, were contacted a second time before their status was finalized. Possible participants whose letters were marked as non-deliverable by the postal service and returned to the study office were classified as non-traceable, after the address had been double checked in the census. Ninety persons fell into this category. Tracking efforts led to no information on the current whereabouts of these individuals. Clear distinctions were drawn between non-traceable individuals and final refusals. These distinctions included evidence that the randomly selected individual did exist other than as a census listing. Family, friends or neighbors were interviewed to verify if an individual was, in fact, refusing to answer our telephone calls or letters. Lack of a response by mail or telephone was not considered a refusal without appropriate staff follow-up. The final disposition for all randomly selected individuals is shown in Figure 4.

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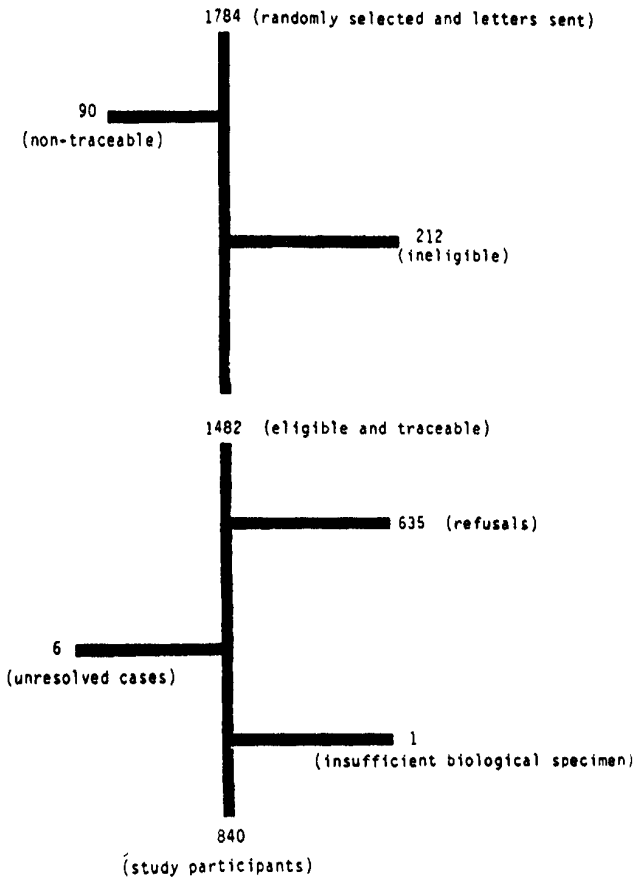
FIGURE 4

FINAL DISPOSITION OF THE RANDOM SELECTION PROCESS
FOR
THE GREATER NEW BEDFORD HEALTH EFFECTS STUDY



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MEASUREMENT

A variety of tests were conducted on participants of the Greater New Bedford PCB Health Effects Study. They included measurements of blood pressure, skinfold thickness, height and weight. Biological specimens were collected for analyses of serum PCB, blood lead, and urinary arsenic and mercury.

In addition to physical and biological testing, subjects were also requested to respond to a questionnaire (Appendix L). Individuals recruited for participation in the Enrichment study were also required to respond to a series of questions in the enrichment screening questionnaire (Appendix G) before being asked to participate in the study.

Questionnaire Development

A draft survey was included in the 1984 project protocol, but it needed improvements in coding instructions, question format and preparation for computerization. Copies of previous questionnaires from local surveys, the CDC, and the National Center for Health Statistics (NCHS) were collected as source documents. Many of the questions were extracted from previous national surveys to provide reliability and content validity as well as comparison data. The major health questions were from the NCHS 1985 Health Interview Survey (medical and occupational sections only) which were adapted from PCB questionnaires developed by the CDC. Other questions on occupation were from the Census Bureau. Seafood questions were developed with project staff and consultants.

A draft survey instrument was developed before pretesting. An Interviewer's Manual (Appendix U) was developed to accompany the questionnaire. Additional materials needed for use during interviewing

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were supplied by the Division of Marine Fisheries (DMF), and "prompt" cards were prepared by interviewing staff.

Interviewer training began in the spring of 1985 and continued through the fall of 1985. In addition, regular informational sessions were held to discuss any problems. A final draft was then pretested on 25 randomly selected respondents. This pretest began on April 22, 1985. Final reformatting changes were completed following the pretest, and the actual prevalence data collection began on May 10, 1985. All other methods and procedures including laboratory testing had been rehearsed during the pretest. A Portuguese translation was completed in June, and the trilingual interviewer did her own translations as needed for Spanish participants. A systematic procedure for editing and computer-coding was also developed.

Enrichment Screening Questionnaire Development

Based on preliminary data analyses of the Phase I serum samples, a screening questionnaire gauging potential occupational and environmental exposures was developed to ensure identification of persons more likely to be at risk of exposure to PCBs and, subsequently, have elevated serum PCB levels. Individuals were identified by existing fishing/lobstering license records obtained from local city/town halls and the DMF.

The questionnaire was administered over the telephone to all potential respondents before they were asked to participate in the study. The questionnaire consisted of age, residence years, past or present employment at either of the two electrical manufacturing firms in the Greater New Bedford area and an abbreviated history of fish/shellfish consumption taken from the Phase I interview. This included: 1) types of

fish and shellfish consumed, 2) frequency of consumption, 3) total number of years of consumption, and 4) whether the seafood consumed had been caught locally (i.e., in the closure area).

All the answers to questions on the screening questionnaire were weighted numerically according to their PCB exposure potential. Since local lobsters have been shown to have consistently higher PCB concentrations than, for example, local tautog (21), a person reporting frequent consumption of local lobster received more points than a person reporting frequent consumption of local tautog. Likewise, a person living in the Greater New Bedford area for 50 years received more points than a person in residence only 10 years.

Initially, all candidates who accumulated at least 100 points were considered eligible for the Enrichment Study. This requirement was later amended to include only persons with greater than 125 points who also consumed local seafood.

Refusal Questionnaire Development

To assess the comparability between the refusal population and the study participants, another questionnaire was developed to administer to refusers after all attempts at follow-up were exhausted (Appendices H and I). The questionnaire was designed to solicit a maximum amount of information with a minimum time commitment on the part of the refuser. Information regarding age, sex, residence and occupation were obtained from the individual's cover sheet. Native language was determined by the staff person administering the refusal questionnaire. Information for other important areas of comparison was obtained from the individual refusal either on the telephone, during a home visit or through the mail.

Questions included: 1) previous or present employment at one of the local capacitor manufacturing firms, 2) quantity and source of any seafood consumed, and 3) recurring medical conditions. Reason for refusal was included to provide information on why individuals were refusing to participate.

Quality Control

All interviews except those conducted in a foreign language were tape recorded for quality control. Other exceptions included respondents who agreed to complete the interviews, but refused to have the proceedings tape recorded, and some tapes were not of sufficient mechanical quality. Of the 840 prevalence interviews, 582 (69%) were taped, and for the Enrichment Study, 97% of 110 (88%) interviews were taped.

The standardized quality control plan involved listening to every fifth tape completely. For the Prevalence Study, 252 tapes were listened to completely (30%); for the Enrichment Study, 42 tapes (38.2%) were listened to completely. The primary goal was to insure accuracy, i.e., to eliminate coding errors, to monitor interviewing techniques, etc. Comments were recorded on quality control sheets and used for final editing. The section of the questionnaire that focused on seafood consumption (Questions 23-35) was listened to on every available tape because of its detailed nature.

Editing was designed to ensure accuracy and standardization of coding. In the case of missing information, a decision based on the importance of the question, was made whether or not to call back the respondent. Coding of census tracts was done by using Regional Census Codes; occupational coding was done by using NIOSH occupation codes.

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Quality control of the occupational coding was performed by the staff in the statistics unit of Vital Records at MDPH. Coding of medical conditions was done according to the International Classification of Diseases (1975 revision).

A complete set of computer codes was established by October 4, 1985, and edited interviews were sent to the MDPH Division of Data Processing at a rate of 30 to 40 per week. All interviews were verified by staff for any discrepancies between the survey instrument and the computer printout to check for key punching errors. After this verification and editing process, the corrections were resubmitted to Data Processing for entry.

Blood Pressure Measurement Protocol

The Hawksley Random Zero Sphygmomanometer, a mercury manometer manufactured in Britain and designed to eliminate observer bias, was used for this study to minimize observer bias and digit preference. The zero point is varied randomly between 0 and 20mm Hg. The true zero point cannot be determined until after the blood pressure is taken. Then the value is subtracted from the measurement (Appendix AA).

Three blood pressure measurements were recorded for each of the study participants, once each at the beginning, middle and the end of the interview. Each subject was classified with a normal, borderline, or definite high blood pressure. Normal blood pressure was defined as a systolic measurement of less than 140mm Hg and a diastolic measurement of less than 90mm Hg. Borderline high blood pressure was defined as a systolic measurement of 140 to 159mm Hg and a diastolic measurement of 90 to 104mm Hg. Definite high blood pressure was defined as a systolic measurement greater than 160mm Hg and a diastolic measurement greater than

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104mm Hg. Individuals with borderline or high blood pressure were referred to a nurse or physician within a month for a repeat measurement and/or treatment. If subjects stated that they did not have a regular source of health care, they were referred to the Greater New Bedford Community Health Center Blood Pressure Clinic. Respondents with a systolic blood pressure of greater than 200mm Hg or a diastolic blood pressure of greater than 115mm Hg were referred to the emergency room at one of the local hospitals.

Physical Measurements

Since PCBs concentrate in fat tissue, it was important to obtain an accurate estimate of skinfold thickness and measurements of height and weight (Appendix AA). These latter measurements were also used to establish body mass index (wt/ht^2) for individual study participants.

Laboratory Measurements

Laboratory analyses were done for serum PCBs, serum chlorinated hydrocarbons, PCB congeners, blood lead, and urinary arsenic and mercury levels (Figures 5, 6, 7). Determinations of serum PCB levels were done in the Environmental Laboratory at the Massachusetts Department of Public Health's Center for Laboratories (MDPH/CL). Serum chlorinated hydrocarbons, PCB congeners, blood lead and urinary arsenic and mercury determinations were done at the Division of Environmental Health Laboratory Sciences, Center for Environmental Health, U.S. Centers for Disease Control (CEH/CDC). As a quality control check, CEH/CDC performed PCB analyses on a subset of serum specimens also analyzed by MDPH/CL for serum PCBs. A 5% subset of specimens was assayed for chlorinated hydrocarbons by CEH/CDC using packed column gas chromatography with electron capture detection.

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FIGURE 5
SERUM HANDLING, PROCESSING AND ANALYSIS AT CL/MDPH

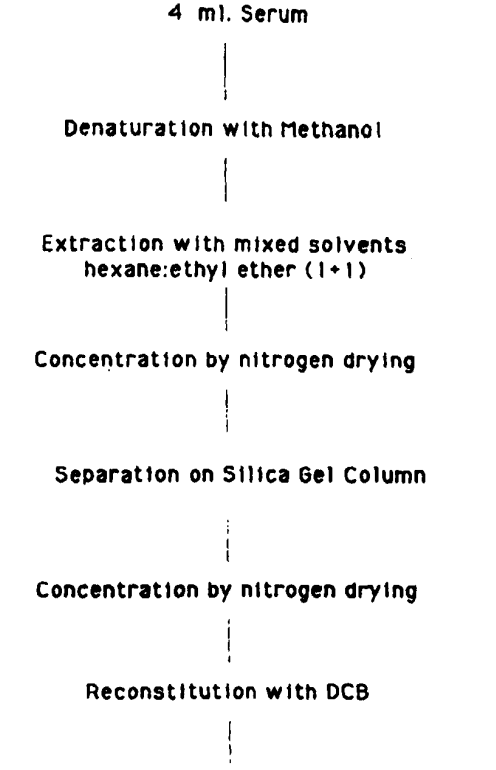

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FIGURE 6

URINE COLLECTION

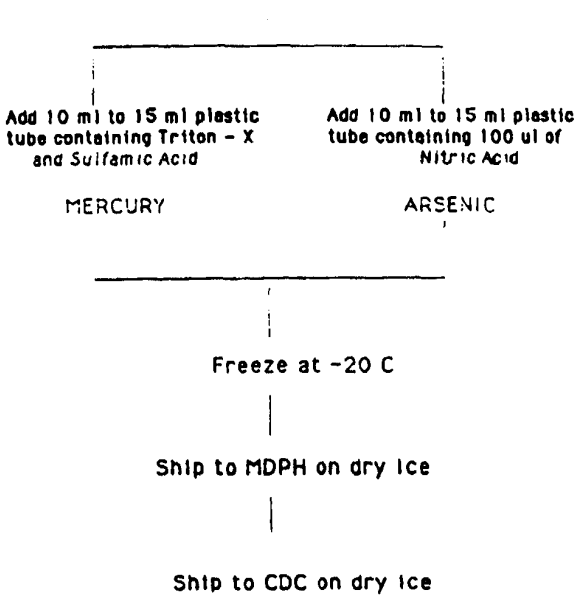

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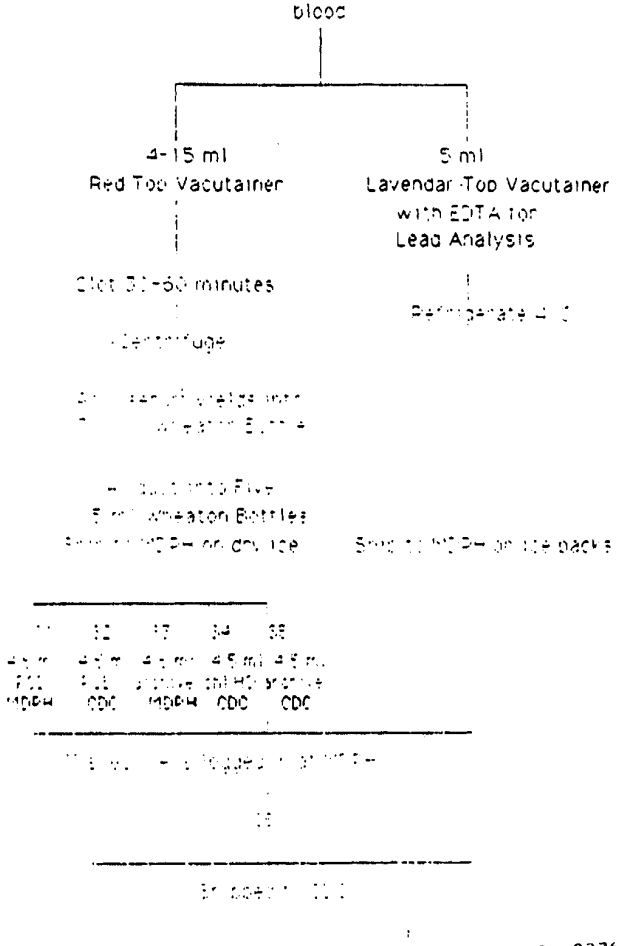
FIGURE 7

BLOOD AND SERUM COLLECTION



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Capillary column gas chromatography was used to measure specific PCB congeners in a group of 25 sera found by MDPH/CL to have the highest levels of PCBs in the New Bedford cohort. Data on chlorinated hydrocarbons are reported in Appendix GG. Data on PCB congeners will be reported when analyses are completed at a later date.

The accurate quantitation of PCBs is a challenging task because of the heterogeneity of PCBs, the changes that occur in these compounds during their transport through the ecosystem, and the differences in the response of instrument detectors to the invididual PCB isomers. Recently, attention has been focused on the accuracy of PCB quantitation in regard to the advantages of capillary gas chromatography (CGC) for component identification and regression analyses for quantitation (22, 23). Although CGC has been reported recently to provide improved accuracy, packed column gas chromatography (PCGC) was selected for quantitation in this study for the following reasons: 1) There was more experience with the PCGC method, and systematic biases could be controlled better compared with CGC. 2) The large number of serum PCB analyses (more than 1000) that were expected to be done in the study would require an enormous laboratory effort, and the time and cost required for CGC would be prohibitive. 3) The lesser accuracy that might be expected for an individual result by PCGC as compared with CGC would be offset by the added reliability and reproducibility of PCGC given the availability of well characterized control serums analyzed by PCGC. 4) PCGC accuracy can be further assessed efficiently by analyzing a subset of serum specimens by CGC.

Analysis of PCBs in human serum

The method used for quantitation of PCBs in serum is described in CDC

Laboratory Update 81-108, "Polychlorinated Biphenyl Determination at Parts-Per-Billion Level in Serum" (24), and in the detailed "Analysis Protocol for PCBs and Other Chlorinated Compounds of Environmental Concern: CDC - New Bedford Study," that is included in a condensed form as Appendix DD. This method is based on the work by Burse et al. (25) to quantitate PCBs in serum. Briefly, the method (Figure 5) consists of serum denaturation with methanol, solvent extraction, separation and concentration of compounds on activated silica gel, separation by gas chromatography, detection by electron capture, and quantitation by peak area integration. Quantitation of PCBs by peak areas was done by comparison of sample chromatograms with standard chromatograms for Aroclor 1254 (AR 1254) as described by Webb and McCall (26). PCB values are reported as parts per billion (ppb) PCB calculated as AR 1254 (ppb PCB as AR 1254).

In addition to the AR 1254 standards included in each chromatography run, an AR 1242 in vivo goat serum pool was included in all but five analytical runs. Quantitation of peaks eluting before DDE using the AR 1242 standard was also done as an alternative method of quantitation.

Experience of the MDPH Lab in the Analysis of PCBs

The MDPH/CL has considerable experience in the analysis of PCBs in human serum at the parts per billion level. During 1981-82, MDPH/CL participated in an interlaboratory study that was directed by CEH/CDC. Twenty-five laboratories (20 state and 5 private) of the 54 state/territorial and 117 private laboratories invited, participated in an assessment of the CDC proposed method to quantitate serum PCB levels in blood. Results of this study were published by Burse et al (27) in 1983.

Following participation in the CEH/CDC Collaborative Study, MDPH/CL

staff also gained experience through on-site training at CEH/CDC. During 1983, two analysts spent one week at the CDC laboratories receiving hands-on training in the analysis of serum PCBs. This experience enabled MDPH/CL to minimize interlaboratory differences for serum PCB analyses between their lab and CEH/CDC.

In addition to the Greater New Bedford Health Effects Study, the MDPH/CL has performed analyses for serum PCBs routinely including two other large surveys. During 1984, 90 residents of Norwood, Massachusetts, who lived near an industrial site with soil highly contaminanted with PCBs were tested for PCB levels in their serum. (28) In 1985, 57 serums from electrical workers for a Rhode Island company were analyzed for serum PCB levels. (29)

MDPH/CL also has experience in the analysis of PCBs in finfish, shellfish and environmental samples. PCB analyses for surveillance and regulatory programs have been done since 1981, and the types of samples tested include lobsters, bluefish, clams, surface wipes, water and retail food samples. Comparison of the results of the analysis of the same samples has shown good agreement among MDPH/CL, the federal Food and Drug Administration Laboratory (Region I, Boston), and the National Marine Fisheries Laboratory (Gloucester, MA).

Sample Handling Procedures

The procedures for collection, shipment, processing, and storage of serum and urine samples from study participants are described in detail in the "Specimen Collection and Shipping Protocol" (Appendix V). Handling of urine samples that were collected for shipment to CEH/CDC for analysis for metals are also described in Appendix V and Appendix BB. The procedures

related to serum specimens are briefly presented here.

Venous blood was collected from each participant into four, 15 ml red-top vacutainers and processed on site to remove the serum. For each individual a serum composite was made in a 30 ml hexane-rinsed Wheaton vial. Then 4.5 ml of the pooled serum was aliquoted into each of five-5ml labeled Wheaton vials that were stored at -20 C. The vials were labeled with the standard study identification number and a suffix of 1 to 5, and assigned for testing at the following laboratories:

Serum 1 (S1), PCB analysis at MDPH

S2, PCB analysis at CDC

S3, Archive sample at MDPH

S4, Chlorinated hydrocarbons analysis at CDC

S5, Archive sample at CDC.

Transport of serums between the New Bedford Study Clinic and the MDPH/CL and between MDPH/CL and CEH/CDC was done on dry ice in insulated shipping containers. The New Bedford/MDPH serum shipments went by messenger as needed. The MDPH/CDC shipments were sent by overnight mail (commercial or U.S. Post Office) on Mondays, Tuesdays or Wednesdays only as needed.

Serum samples were stored at -20 C until scheduled for analysis. Study samples were usually run in batches of 19 serums with appropriate controls.

Equipment and Reagents

Apparatuses: A Perkin-Elmer Sigma 2000 gas-liquid chromatograph equipped with a P-E model AS-300 automatic sampler and an Ni^{63} electron capture detector were used. The chromatograph was controlled and data

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calculated and recorded by a Perkin-Elmer Model LCI-100 Integrator. A glass 6 foot X 1/8 inch (i.d.) column with 3% SE-30 on 80/100 mesh Gas Chrom Q was used for chromatography.

Reagents: The solvents used were N-hexane, methanol and ethyl ether and were pesticide grade quality (Burdick and Jackson). Sodium sulfate, used as a drying agent, was anhydrous, reagent grade (Fisher Scientific). Silica Gel, Woelm 70-150 mesh, was used as a preliminary separation and concentration medium to extract PCBs from serum.

PCB standards were supplied by CEH/CDC and were Monsanto Corporation Aroclor 1242, Lot KE-06-411 and Aroclor 1254, Lot AK38. These standards were used for calibration and supplied as stock solutions in iso-octane at concentrations of 0.1095 mg/ml for Aroclor 1242 and 0.2030 mg/ml for Aroclor 1254. Stock solutions were diluted with hexane to make working solutions of 134 ppb for AR 1242 and 141 ppb for AR 1254. Decachlorobiphenyl (DCB) Analabs Lot RCS-051, was used as an internal standard for quantitation. DCB was provided by CEH/CDC at a concentration of 0.0103 mg/ml and diluted with hexane to make a working solution of 51 ppb.

Extraction and Clean-up of PCBs from Human Serum

To accurately measure PCBs present in serum, it is necessary first to separate the PCBs from normal blood components and contaminants present in blood. Natural and man-made materials that may be found in blood can interfere with the detection, identification, and quantitation of PCBs. The procedure for extraction and clean-up, detailed in Appendix DD, is described here. Usually 19 study serum samples were processed at one time. Each serum specimen was mixed with methanol and after centrifugation, the

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PCB-containing supernatant was withdrawn. The serum was extracted two more times and the extracts combined. Each pooled extract was concentrated by a nitrogen stream and then passed through a small (18 cm x 9 mm) glass column that contained silica gel sandwiched between two anhydrous sulfate layers. The portion of the effluent from the silica gel column that was retained (15 ml following the first 7 ml washed through the column with hexane) was stabilized with paraffin and evaporated to near dryness with a gentle flow of nitrogen. The concentrate was reconstituted with a one ml volume of the internal standard (DCB), and was then ready for analysis by gas chromatography electron capture.

Gas Chromatography Electron Capture Analysis of Serum Extracts

Nineteen samples were analyzed in a set defined as an analytical run. An analytical run was comprised of 19 serum extracts, five quality control serum extracts and nine calibration standards. Samples were automatically injected and data recorded by laboratory microprocessor instrumentation that produced a hard copy chromatogram. or picture of the gas chomatography. Examples of the analytical output are shown in the graphs in Appendix EE that depict an AR 1254 calibration standard, a low PCB level quality control sample, a high PCB level quality control standard, a low PCB level study sample and a high PCB level study sample. Gas chromatography of one analytical run containing 19 study samples, standards and controls took approximately 22 hours.

Quantitation of PCBs present in human serum samples was determined by the CDC method procedure based on the Webb and McCall method. As discussed earlier, all samples were quantitated in reference to AR 1254 and reported as parts per billion AR 1254. Samples were also quantitated as parts per

billion AR 1242 as an alternate measure of exposure.

Quality Assurance of the Laboratory Analyses

Quality assurance of laboratory analyses for PCBs was achieved by three means, which are described in detail in the "Analysis Protocol for PCBs and Other Chlorinated Compounds of Environmental Concern: CDC - New Bedford Study" (Appendix DD) and "Quality Control Report from CEH/CDC" (Appendix KK).

1. The comparability of MDPH/CL and CEH/CDC was established through replicate analyses of the same series of known samples, in vitro and in vivo spiked pools. Criteria were established based on the target (average) values obtained.

   a. For control samples over 20 ppb, MDPH/CL results must be within 15% of the target value and the CDC mean.

   b. For control samples less than 20 ppb, MDPH/CL results must be within 25% of the target value and the CDC mean.

   c. For control samples over 20 ppb, MDPH/CL coefficient of variation must be less than 15%.

   d. For control samples less than 20 ppb, MDPH/CL coefficient of variation must be less than 25%.

2. Quality control limits were established for each laboratory, and quality control rules (decision criteria) were defined to reject analyses when limits were exceeded. The analytical system would be declared "out-of-control" if any one of three events occurred either singly or in combination, and analyses would continue only after review and discussion of the analytical situation with CEH/CDC.

   a. If the values for quality control samples obtained during a

single analytical run fall outside the 99% confidence limits established for the control samples.

b. If two consecutive values of the same control sample fall either above or below the 95% confidence limits for that control sample.

c. If 10 consecutive values for the same control sample fall either above or below the mean value of the control sample.

3. CEH/CDC analyzed a subset of the specimens analyzed by CL/MDPH and comparability of results was monitored throughout the study.

Quality control was maintained by including five quality control samples in every analytical run. These quality control samples included: a low or high bench control serum (prepared in vivo), a low or high external control serum (prepared in vivo), a base bovine serum, a chlorinated hydrocarbon serum (prepared in vitro), and an AR 1242 control serum (prepared in vivo). A calibration standard was analyzed prior to the initiation of sample analysis. If the chromatography pattern or the response factors for known peaks were inadequate, the analytical run would not be started. When the calibration standard showed characteristic peaks and response levels, an analytical run was initiated in which a calibration standard was inserted between every four serum extracts to check chromatography patterns and update the calibration standard in the integrator.

Each analytical run included a low or high "external" control serum that was inserted by the Laboratory Data and Sample Coordinator to a randomly selected position in a rack of samples that were scheduled for an analytical run. The Coordinator, in consultation with the Study Project Director and Laboratory Director, would select the study serum samples for analysis in analytical runs. These samples would be placed in a test tube

rack along with the external control sample and delivered to the laboratory analyst.

Samples were queued into the automatic sampler in even-numbered positions and vials containing hexane were inserted at the odd-numbered positions to avoid a carry-over effect from samples with a high concentration of PCBs. These hexane-containing vials provided a wash cycle for the automatic sample injector.

Serum PCB Levels Calculated as Parts Per Billion Aroclor 1242

Serum PCB concentrations were calculated as ppb Aroclor 1242 as well as in ppb AR 1254 to ensure that any significant recent exposures would not be underestimated. An Aroclor 1242 calibration standard and quality control serum were used as the basis for identifying Aroclor 1242 chromatographic patterns and for quantitation (See Laboratory Methods). The prevalence estimate of elevated serum PCB levels using AR 1242 values did not identify appreciably more persons other than those already identified using the AR 1254 quantitation values (Appendix HH). Therefore, reported values for serum PCB levels were expressed as AR 1254 to maintain clarity without sacrifice of accuracy.

Sample Collection Methods

The following sections describe the laboratory procedures that were followed in the Greater New Bedford PCB Health Effects Study Clinic for the proper collection, processing, storage and shipment of physiologic specimens from the study subjects. Procedures were strictly followed to avoid contamination, loss, or degradation of the specimens. A schedule was established for collecting a specimen in which a 12 hour fast requirement

preceeded the phlebotomy appointment. Blood-drawing occurred in the study clinic or in participants' homes when necessary. An aseptic phlebotomy technique was maintained at all sites.

Blood and urine collection and processing were performed under carefully controlled conditions. Serum separation took place on site in the clinic laboratory. Glassware used (e.g. pipets, storage vials) had been cleaned with acetone and hexane.

The subjects were given specific instructions in either English or Portuguese to ensure proper collection of urine specimens and to avoid potential contamination from ambient air, contact with any parts of the body, clothing, or external surfaces. Urines were processed on site at the clinic laboratory under a fume hood. The urines were processed within 1/2 hour of collection. On rare occasions, urine specimens that were not processed immediately were refrigerated promptly at 4° to 8° C and the delay in processing of these specimens was noted.

During pilot testing of the blood collecting procedures, a multiple sample needle was compared to a butterfly needle. After pilot testing of the butterfuly needle with Lue-adapter, these phlebotomy instruments were found to be awkward for the phlebotomist and more painful to the subject. Therefore, standard vacutainer needles and tubes were used throughout the study.

At the beginning of each day when a respondent was scheduled for an appointment, a "Urine Laboratory Blank" was prepared according to study protocol, that substituted deionized water instead of urine. A preprinted "Lab Blank" label was placed on each Arsenic and Mercury analysis tube. The blanks were frozen upright at -20° C.

In March, 1986, two sets of "Serum Lab Blanks" were prepared. Two

sets of four vials each (e.g., two screw top, two crimp top Wheaton vials) were sent to MDPH/CL. One set of vials was subsequently sent to CEH/CDC. All specimens as well as "Serum Lab Blanks" and "Urine Laboratory Blanks" were transported by an MDPH employee to MDPH/CL in Boston. Messenger delivery of the specimens never took more than 85 minutes. Serum samples destined for the CEH/CDC were checked against the shipping manifest that was prepared in New Bedford. All shipments to CEH/CDC were sent via overnight courier.

All records associated with each subject's specimens were maintained to ensure that all information was properly collected and accurate. All specimens were labeled promptly to avoid label record errors on the subject's specimen. A list of computer codes for comment section of the shipping manifest was designed. This allowed for consistency in coding all deviations from the protocol for specimen collecting, processing and storage.

The specimens from each subject were packed upright and secure in a styrofoam shipper with bubble pack material, serum specimen freezer boxes with dividers, and urine tube freezer boxes with dividers. Frozen ice packs were placed at the bottom and top of the shipper and stored with the cover off in the freezer overnight preceding a shipment to the MDPH/CL Whole blood specimens were kept separate and shipped in a smaller styrofoam shipper equipped with a cold pack. Each shipment was accompanied by a complete, numbered manifest. A copy of the manifest was kept at the clinic laboratory to ensure against loss and to serve as a record of all specimens collected.

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DATA ANALYSIS

The purposes of Phase I of the Greater New Bedford PCB Health Effects Study were:

* To determine the prevalence of elevated serum PCB levels in the local population, and to identify 150 individuals with serum PCB levels $\geq$ 30 ppb to participate in the Phase II clinical investigation.
* To investigate the possible association of serum PCB levels with blood pressure readings in study subjects. (Note: On the basis of a review of the literature, extraneous variables (e.g. residential and occupational histories, dietary habits, health status and demographic characteristics were collected).

Therefore, the data analysis strategies were directed towards a description of the pertinent variables (e.g., serum PCB levels, seafood consumption, occupational histories, health status, blood pressure readings and selected demographic characteristics). In addition, if patterns were found among correlational data, appropriate models would be designed to highlight predictive relationships among independent variables (e.g., diastolic blood pressure readings, age, body weight) and the dependent variable (e.g., serum PCB level).

A generic statistical strategy was applied to the study's data. The strategy included four steps that thoroughly investigated relationships among and between all variables. First, descriptive statistics (e.g., means, standard deviations, ranges, medians, quartile analyses) were applied to provide an overall picture of the sample from the Greater New Bedford area and subsequently, a comparison with the total population. Also, the descriptive statistics provided an overview of interval level

variables such as blood pressure readings and other selected demographic variables such as age. Chi-square tests for differences were utilized for selected data.

Second, bivariate relationships between groups were explored. These included differences in serum PCB levels and participation rates in the Portuguese versus non-Portuguese groups, females versus males, as well as differences between means of blood pressure readings (both systolic and diastolic readings) taken at three time points during data collection. These data also provided indications of strata that may or may not be utilized in univariate and multivariate modeling.

Third, correlation matrices were run on variables of interest, based on a review of the literature as well as the descriptive variables (i.e., systolic/diastolic blood pressure readings, age, body mass, PCB serum levels). These correlations demonstrated patterns and trends for the prevalence sample and the enrichment sample. In addition, the correlations provided a basis for choosing modeling designs.

Fourth, several univariate and multivariant models were attempted. Multiple regression models were used to confirm relationships demonstrated in the correlation matrices. In addition, several multiple regression and covariance models were attempted by using variables found to be significant predictors from previous studies. However, none of the models demonstrated significant predictive relationships between the independent variables (e.g., systolic/diastolic blood pressure readings, age, body mass) and the dependent variable (e.g., serum PCB levels). The variables were also placed in a logistic regression to stabilize weights of the predictors; however, these models were not significant as well.

All data were coded and key punched on an IBM mainframe at the

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Massachusetts Department of Public Health. All data entries were extensively edited and cross verified to insure accuracy. The statistical package applied to these data was the Statistical Analysis System (SAS) (1982). This all-purpose data analysis system provides information storage and retrieval, data modification and programming, statistical analysis, file handling, and report writing (SAS, 1982, p. III).

LIMITATIONS

The design of the Greater New Bedford PCB Health Effects Study was a cross sectional random sample, stratified by age and sex in order to determine prevalence. Because of the response rate (57%), it may be possible that non-participants differed greatly from participants and that the results do not reflect an accurate assessment of PCB exposure in Greater New Bedford. The development and usage of the refusal questionnaire was helpful in assessing characteristics of non-participants. However, questions in the refusal questionnaire were necessarily broad and can be used only to make general assumptions about the refusal population. In addition, the refusal questionnaire was administered in a less regulated manner and via different means (i.e., mostly by telephone or through the mail) and to a population, by definition, less willing to cooperate.

It should also be noted that this investigation was conducted several years after the various fishing bans went into effect. Seafood consumption patterns may have changed over the 7-year period that the ban has been in effect and may thus complicate conclusions being drawn regarding the effects of contaminated seafood consumption on serum PCB level.

Although strong emphasis was placed on quality control of survey data obtained from the interviews, it is possible that the quality of

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information collected varied from interviewer to interviewer. In all, five individuals served as interviewers for this investigation. The interviews were conducted in Spanish, English and Portuguese. It is important to note that these interviews were administered tri-lingually, and therefore variation in the execution of survey questions was a strong possibility. However, all interviewers received identical training and were assessed before they entered the field settings.

One of the major limitations of a cross-sectional epidemiological investigation regards polarization (i.e., groups of people moving into a specific area for unknown periods of times) within the study area. However, in this study, every resident was randomly selected and a minimum age and residency requirement was set. As a result, no residents were allowed admission into the study if they had recently moved into the study area.

HUMAN SUBJECTS PROTECTION

Before the initiation of field operations in the Greater New Bedford area, the study protocol was presented to the Human Subject Review Committee at the Lemuel Shattuck Hospital in Boston, Massachusetts. All Massachusetts Department of Public Health proposals are submitted to this committee for ethical and other considerations. The committee voted to approve the study protocol on May 24, 1984 (Appendix CC). Confidentiality of information supplied by study participants was maintained by assigning coded identification numbers. Identifying information was stored in locked file cabinets located at the field office in New Bedford. The field office was protected by a sensory alarm system. Upon entering the study office, each participant was asked to review and sign a statement of informed

consent (Appendix K). Each participant was informed that they could refuse to answer specific questions or withdraw from the study at any time during the course of the interview.

CHAPTER III

RESULTS

The purpose of the Greater New Bedford Health Effects Study (GNBHES) was to determine the prevalence of elevated serum PCB levels among a group of randomly selected residents, and to test the hypothesis that serum PCB level is associated with measurement of diastolic blood pressure. Phase I also sought to identify 150 individuals with serum PCB levels $\geq$ 30 ppb in order to proceed to Phase II.

This chapter presents the results of a number of descriptive analyses within the two samples studied (prevalence and enrichment), and subgroups within the respective samples. A series of bivariate relationships are examined, as well as a review of correlational patterns and trends. Statistical models (e.g., multiple regression, stepwise regression, etc.) are used where both appropriate and applicable. In addition, the results of the random selection and the results of analyses of refusal questionnaire data are both presented.

PREVALENCE

Participation Rates

The participation rate was calculated by using only eligible individuals who had been contacted by a staff person (i.e., participants and refusers). Overall, 57% of eligible randomly selected candidates agreed to participate and completed the interview and laboratory testing. The participation rate varied little with age, sex, and residence. Chi square tests for differences in participation were performed for each variable (i.e., age, sex and residence). Age was significantly associated

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with participation for females (x^2 = 11.865 with 4 d.f. p = .018). However, other observed variations were not statistically significant (Table 2).

Characteristics of the Participant Sample

Although the City of New Bedford was significantly oversampled and Fairhaven, Acushnet, and Dartmouth were only slightly undersampled (Table 3), when the sample was stratified by age and sex, it is evident that, with few exceptions, is representative of the four town area (Table 4). The participant sample was also compared to federal census data for a number of other demographic characteristics such as industry of employment, education and ethnicity (Portuguese or non-Portuguese). The census figures were five years old when study data collection began. In some instances, these census data are not comparable, so these findings are presented only for general comparison and should be interpreted with caution.

In general, the participant population was similar to what was reported in the federal census with regard to industry of employment. The participant sample contained an average of 8.5% more Portuguese persons on a town to town basis and contained an average of 15.5% more high school graduates and 7.5% more college graduates. The federal census bases its estimates on total population figures for ethnicity and on persons 25 and older for education. The inclusion of persons younger than 18 (in the case of ancestry) and persons older than 64 (in both cases) may have had a dilutional effect on the numbers. In addition, the observed figures are indicative of a population in change and concur with past trends.

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Table 2.

Participation Rates

	MALES			FEMALES		
	SELECTED	PARTICIPATED	%*	SELECTED	PARTICIPATED	%
New Bedford						
AGES: 18 - 24	89	47	52.8	92	50	54.3
25 - 34	126	73	57.9	151	92	60.9
35 - 44	99	52	52.5	104	61	58.6
45 - 54	88	58	65.9	86	54	62.8
55 - 64	90	46	51.1	148	73	49.3
Don't Know	1	-	-	1	-	-
ALL	493	276	56.0	582	330	56.7
Dartmouth						
AGES: 18 - 24	20	11	55.0	17	10	58.8
25 - 34	15	9	60.0	17	10	58.8
35 - 44	29	16	55.2	29	20	69.0
45 - 54	29	15	51.7	18	10	55.5
55 - 64	26	13	50.0	23	12	52.2
ALL	119	64	53.8	104	62	59.6
Fairhaven						
AGES: 18 - 24	9	3	33.3	6	5	83.3
25 - 34	15	9	60.0	20	18	90.0
35 - 44	12	9	75.0	6	5	83.3
45 - 54	13	3	23.1	13	4	30.8
55 - 64	14	10	71.4	10	4	10.0
ALL	63	34	54.0	55	36	65.5
Acushnet						
AGES: 18 - 24	7	3	42.9	5	4	80.0
25 - 34	12	7	58.3	5	4	80.0
35 - 44	2	2	100.0	10	9	90.0
45 - 54	7	2	28.6	3	2	66.6
55 - 64	3	3	100.0	5	2	49.0
Don't Know	1	-	-	-	-	-
ALL	32	17	53.1	28	21	75.0
TOTAL	707	391	55.3	769	449	58.4

* % IS PERCENT OF PEOPLE SELECTED WHO PARTICIPATED

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Table 3.

Total Expected and Observed Participation by City/Town

	Expected	Actual		
	n	n	X^2	p
New Bedford	550	606	5.711	.0169*
Dartmouth	146	126	2.7397	.0979
Fairhaven	92	70	7.348	.0067*
Acushnet	52	38		
TOTAL	840	840		

(expected values were calculated from 1980 federal census data.)

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Table 4.

Expected vs. Observed
Participant Sample by Age, Sex and Residence

	Males		Females	
	Pe*	Po+	Pe*	Po+
	n	n	n	n
New Bedford				
Total	256	276	294	330
18-24	55	47	61	50
25-34	64	73	68	92**
35-44	40	52	46	61***
45-54	45	58	52	54
55-64	52	46	66	73
Dartmouth				
Total	71	64	75	62
18-24	16	11	16	10
25-34	16	9	17	10
35-44	13	16	14	20
45-54	13	15	13	10
55-64	13	13	15	12
Fairhaven				
Total	45	34	47	36
18-24	9	3	8	5
25-34	11	9	12	18
35-44	8	9	8	5
45-54	8	3	9	4
55-64	9	10	10	4
Acushnet				
Total	26	17	26	21
18-24	5	3	4	4
25-34	6	7	6	4
35-44	5	2	6	9
45-54	5	2	5	2
55-64	5	3	6	2

*Expected number of participants from age group [1].
+Observed number of participants from age group.

**Indicates statistical significance at $p \leq .01$
***Indicates statistical significance at $p \leq .05$

[1] Expected rates are based on % contribution of each age, sex and town group according to the 1980 federal census data.

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PCB Level

The alternate quantitation of PCBs as pre DDE Aroclor 1242 resulted in low levels of serum PCBs with only two individuals exceeding 30 ppb (Appendix HH). Further discussion of PCB serum levels will be restricted to Aroclor 1254 Quantitation only. Table 5 and Figure 8 present the distribution of serum PCB levels as Aroclor 1254 among participants of the Prevalence Study for males, females, and the total prevalence population. Only 1.3% of the total study group (n = 840) had serum PCB levels greater than or equal to 30 ppb (the CDC estimate of an elevated serum PCB level). This same percentage was observed among the male (n = 391) and female (n = 449) prevalence study groups (mean levels were 5.9 ppb and 5.8 ppb respectively) when stratified by sex.

The range in serum PCB levels for the total prevalence group was 0.38 to 154.2 ppb. The range among females was 0.38 to 154.2 ppb and among males the the observed range was 0.50 to 60.92 ppb.

Serum PCB Level by Reported Ethnicity

Table 6 presents variations in serum PCB levels among Portuguese/Cape Verdean and Non-Portuguese/Cape Verdean males. Slightly higher mean and median levels were observed among males of Portuguese or Cape Verdean descent (6.76 ppb vs. 4.76 ppb and 4.63 ppb vs. 3.58 ppb).

Similar differences were observed among female prevalence participants. Table 7 shows the serum ppb range as well as the mean, median and standard deviation among Portuguese/Cape Verdean (n = 208) and Non-Portuguese/Cape Verdean females (n = 241). The range in serum PCB level among Portuguese/Cape Verdean was 0.85 to 154.2 ppb with a median of 4.41 ppb, the range for non-Portuguese/Cape Verdean was 0.38 to 45.88 ppb

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TABLE 5.

Distribution of Serum PCB Levels
Prevalence

Serum PCB Level*	Males n=391		Females n=449		Total n=840	
	n	%	n	%	n	%
0.0 - 1.49	30	7.8	26	5.8	56	6.7
1.5 - 2.99	93	23.8	120	26.7	213	25.4
3.0 - 4.49	91	23.3	111	24.7	202	24.1
4.5 - 5.99	62	15.9	63	14.0	125	14.9
6.0 - 7.49	24	6.1	40	8.9	64	7.6
7.5 - 8.99	27	6.9	30	6.7	57	6.8
9.0 - 10.49	18	4.6	20	4.5	38	4.5
10.5 - 11.99	4	1.0	10	2.2	14	1.7
12.0 - 13.49	10	2.6	3	.7	13	1.5
13.5 - 14.99	7	1.8	3	.7	10	1.2
15.0 - 16.49	4	1.0	3	.7	7	.8
16.5 - 17.99	6	1.5	6	1.3	12	1.4
18.0 - 19.49	1	.3	3	.7	4	.5
19.5 - 20.99	4	1.0	1	.2	5	.6
21.0 - 22.49	2	.5	1	.2	3	.4
22.5 - 23.99	2	.5	2	.5	4	.5
24.0 - 25.49	-	-	1	.2	1	.1
25.5 - 26.99	-	-	-	-	-	-
27.0 - 28.49	-	-	-	-	-	-
28.5 - 29.99	1	.3	-	-	1	.1
30+	5	1.3	6	1.3	11	1.3
NEXT TO HIGHEST		45.68		61.72		61.72
HIGHEST		60.92		154.20		154.20
MEAN		5.92		5.77		5.84
MEDIAN		3.88		3.88		3.88
STANDARD DEVIATION		6.24		8.92		7.78
25TH		2.68		2.63		2.67
75TH		6.83		6.44		6.65

*PCB measured in parts per billion.

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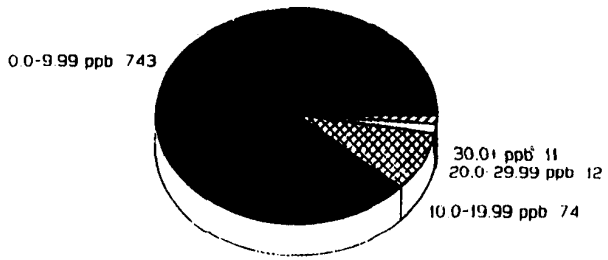
DISTRIBUTION OF AROCLOR 1254 SERUM LEVEL PREVALENCE DATA n=840

FIGURE 8



pcb measured in parts per billion

Table 6.

Distribution of Serum PCB
Portuguese/Cape Verdean vs. Non-Portuguese/Cape Verdean
Prevalence

Males

Serum PCB Level*	Portuguese n=207 n	Portuguese n=207 %	Non-Portuguese n=184 n	Non-Portuguese n=184 %
0.0 - 1.49	14	6.8	16	8.7
1.5 - 2.99	46	22.2	47	25.5
3.0 - 4.49	41	19.8	50	27.2
4.5 - 5.99	32	15.5	30	15.9
6.0 - 7.49	8	3.9	16	8.7
7.5 - 8.99	20	9.7	7	3.8
9.0 - 10.49	13	6.3	5	2.7
10.5 - 11.99	3	1.5	1	.5
12.0 - 13.49	6	2.9	4	2.2
13.5 - 14.99	5	2.4	2	1.1
15.0 - 16.49	3	1.5	1	.5
16.5 - 17.99	5	2.4	1	.5
18.0 - 19.49	-	-	1	.5
19.5 - 20.99	3	1.5	1	.5
21.0 - 22.49	2	1.0	-	-
22.5 - 23.99	2	1.0	-	-
24.0 - 25.49	-	-	-	-
25.5 - 26.99	-	-	-	-
27.0 - 28.49	-	-	-	-
28.5 - 29.99	-	-	1	.5
30 +	4	1.9	1	.5
HIGHEST		45.68		60.92
NEXT TO HIGHEST		38.85		29.52
MEAN		6.76		4.96
MEDIAN		4.63		3.58
STANDARD DEVIATION		6.66		5.63
25TH PERCENTILE		2.84		2.50
75TH PERCENTILE		8.76		5.66

*PCB measured in parts per billion.

Table 7.

Distribution of Serum PCB
Portuguese/Cape Verdean vs. Non-Portuguese/Cape Verdean
Prevalence

Females

Serum PCB Level*	Portuguese n=208		Non-Portuguese n=241	
	n	%	n	%
0.0 - 1.49	10	4.8	16	6.6
1.5 - 2.99	53	26.4	67	27.8
3.0 - 4.49	42	20.2	69	28.6
4.5 - 5.99	31	14.9	32	13.3
6.0 - 7.49	18	8.7	22	9.1
7.5 - 8.99	19	9.1	11	4.6
9.0 - 10.49	10	4.8	10	4.2
10.5 - 11.99	7	3.4	3	1.2
12.0 - 13.49	2	1.0	1	.4
13.5 - 14.99	2	1.0	1	.4
15.0 - 16.49	2	1.0	1	.4
16.5 - 17.99	3	1.4	3	1.2
18.0 - 19.49	2	1.0	1	.4
19.5 - 20.99	-	-	1	.4
21.0 - 22.49	1	.5	-	-
22.5 - 23.99	1	.5	1	.4
24.0 - 25.49	-	-	1	.4
25.5 - 26.99	-	-	-	-
27.0 - 28.49	-	-	-	-
28.5 - 29.99	-	-	-	-
30 +	5	2.4	1	.4
HIGHEST	154.20		45.88	
NEXT TO HIGHEST	61.72		24.46	
MEAN	6.85		4.87	
MEDIAN	4.41		3.71	
STANDARD DEVIATION	12.10		4.49	
25TH PERCENTILE	2.76		2.52	
75TH PERCENTILE	7.55		5.86	

*PCB measured in parts per billion.

with a median of 3.71 ppb.

Serum PCB Level and Age

Figure 9 shows the relationship of serum PCB level to age among prevalence participants (n = 840). In the five age groups into which participants were categorized (i.e., 18-24, 25-34, 35-44, 45-54, 55-64) the mean serum PCB levels were: 2.59, 3.84, 5.30 8.18 and 8.96 ppb respectively.

Serum PCB Level by Age, Sex and Residence

Serum PCB level was examined in relation to age, sex and residence for prevalence participants (n = 840). The range in serum PCB levels are presented as well as the mean, median and standard deviation for each subgroup. These data are presented in Table 8. It should be noted that the data broken down by city and town do not yield sufficient statistical power to determine differences in serum PCB levels within each of these sub-categories.

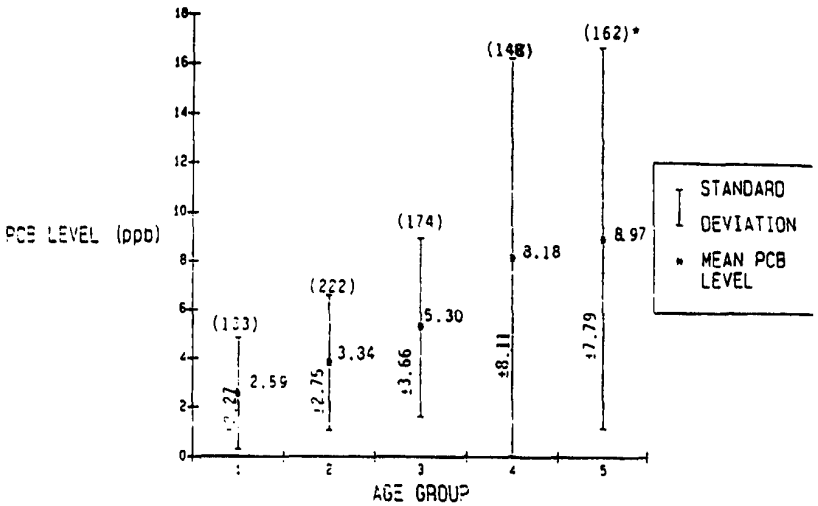
Seafood Consumption

The relationship of serum PCB level to fish consumption is an area of great concern both in the Greater New Bedford area and elsewhere. It has been noted that seafood consumption is the primary source of PCB exposure in the United States today. (13) This finding has been a particular concern in the Greater New Bedford area due to the massive PCB contamination of local seafood species over and above that of the fish in the general commercial marketplace. For this reason an extensive amount of information on fish consumption was collected for both general and locally

FIGURE 9

MEAN and STANDARD DEVIATION
SERUM PCB LEVEL[1] by AGE GROUP

PREVALENCE



( ) = number of persons in age group

1 = 18-24 years old
2 = 25-34 years old
3 = 35-44 years old
4 = 45-54 years old
5 = 55-64 years old

* One outlier was eliminated as the level was more than twice the second highest.

1 PCB measured in parts per billion

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Table 8.

Serum PCB Levels* by Residence, Age and Sex
Mean and Standard Deviation, Range and Median
Prevalence

	New Bedford n = 606		Dartmouth n = 126		Fairhaven n = 70		Acushnet n = 38	
Age	M	F	M	F	M	F	M	F
18 - 24								
Mean	2.44	2.63	2.90	3.30	2.24	2.66	2.21	1.89
S.D.	2.90	2.17	1.15	1.48	1.33	0.71	0.83	0.52
Minimum	0.50	0.85	1.53	1.23	0.92	1.62	1.28	1.31
Maximum	21.05	14.32	5.62	5.50	3.58	3.61	2.88	2.53
Median	1.71	2.12	2.58	3.55	2.22	2.71	2.48	1.85
25 - 34								
Mean	4.12	3.74	3.52	3.94	3.60	4.00	3.09	2.82
S.D.	3.91	2.03	2.09	2.75	1.78	1.60	0.66	0.53
Minimum	0.75	0.38	1.47	0.94	0.74	1.63	2.07	2.35
Maximum	29.53	10.49	7.78	9.21	6.45	7.31	3.74	3.50
Median	3.00	3.34	2.99	2.85	3.57	3.89	3.52	2.71
35 - 44								
Mean	5.76	4.91	5.30	4.21	6.28	6.34	13.11	4.49
S.D.	4.69	3.04	2.60	2.31	2.77	1.59	10.92	2.66
Minimum	0.99	1.16	1.39	0.99	3.59	5.03	5.39	1.39
Maximum	21.44	17.23	9.86	9.96	12.11	8.66	20.84	10.32
Median	3.74	3.89	5.18	3.77	6.41	5.35	13.11	4.51
45 - 54								
Mean	8.98	7.06	9.22	9.74	8.79	7.14	5.09	3.82
S.D.	9.64	5.34	8.18	12.96	5.08	6.71	4.49	0.08
Minimum	1.09	1.55	4.16	2.54	3.42	2.72	1.92	3.76
Maximum	60.92	30.55	36.61	45.88	13.51	17.13	8.27	3.88
Median	5.57	5.31	6.83	6.12	9.43	4.35	5.09	3.82
55 - 64								
Mean	8.74	11.61	11.33	7.31	5.35	9.47	5.56	7.12
S.D.	7.07	19.26	8.75	2.28	1.01	6.05	0.61	3.41
Minimum	1.71	1.95	2.68	3.30	3.99	3.28	5.12	4.71
Maximum	45.68	154.20	36.06	12.58	6.84	15.63	6.25	9.53
Median	6.88	6.96	9.56	7.54	5.32	9.49	5.30	7.12

*PCB measured in parts per billion

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caught seafood. A map of the local areas of harbor/estuary contamination was shown to the respondents to make sure that each was using the same local boundaries to identify fishing areas. Consumption of locally caught species was of special interest in determining how serum PCB level might be affected.

Seafood Source

The most frequently mentioned source from which people obtain seafood is fish retailers (Table 9). Over half of Greater New Bedford obtains fish from this source alone. When combined with supermarkets and restaurants, it accounts for 78.2% of all seafood. This number is in sharp contrast to the 12.9% of the population who obtain fish by catching it themselves or from a family or friend who has caught it. This pattern has not changed appreciably from past years (Table 10). Ten years ago, slightly over half (52.1%) of Greater New Bedford residents obtained their fish primarily from local retailers, and when combined with supermarkets and restaurants, they accounted for 73.6% of all primary seafood sources. Similarly, only a small percentage of people (14.8%) obtained their seafood by catching their own or from a family member or friend who had caught it.

Looking specifically at sources of seafood caught and consumed from locally contaminated areas, most people (61.5%) report that they do not currently consume this seafood (Tables 11 and 12). This response is somewhat similar (56.6%) to that of past sources of local seafood before the fishing closure took effect. This number would indicate that even before the general discovery of the massive contamination problems, the majority of the general public in the Greater New Bedford area was not directly or knowingly catching and eating fish from these areas. Among

Table 9.

Present Source of General Seafood

Primary Source of Fresh Seafood Today:	Prevalence n = 840	Enrichment n = 110
	Percent of participants	
CATCH OWN	4.2%	34.5%
FAMILY/FRIENDS CATCH	8.7	6.4
LOCAL FISHERMEN	6.9	8.2
FISH RETAILERS	54.3	40.9
SUPERMARKETS/GROCERY	14.1	6.4
RESTAURANTS	9.8	3.6
GOT NONE	2.0	-
DON'T KNOW	-	-

Table 10.

Past Source of General Seafood

Primary Source of Fresh Seafood Ten Years Ago:	Prevalence n = 840	Enrichment n = 110
	Percent of participants	
CATCH OWN	5.2%	44.5%
FAMILY/FRIENDS CATCH	9.6	5.5
LOCAL FISHERMEN	5.2	7.3
FISH RETAILERS	52.1	35.5
SUPERMARKETS	12.1	5.5
RESTAURANTS	9.2	.9
GOT NONE	4.6	-
DON'T KNOW	1.7	.9

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Table 11.

Present Source of Local Seafood

	Prevalence n = 840	Enrichment n = 110
Primary Source of Local Seafood Today:	Percent of participants	
CATCH OWN	6.4%	52.7%
FAMILY/FRIENDS CATCH	9.0	13.6
LOCAL FISHERMEN	.8	-
FISH RETAILERS	10.9	10.0
SUPERMARKETS/GROCERY	2.5	-
RESTAURANTS	2.4	.9
GOT NONE	61.5	20.9
DON'T KNOW/MISSING	6.4	1.8

Table 12.

Past Source of Local Seafood

	Prevalence n = 840	Enrichment n = 110
Primary Source of Local Seafood Ten Years Ago:	Percent of participants	
CATCH OWN	9.0%	62.7%
FAMILY/FRIENDS CATCH	11.5	10.9
LOCAL FISHERMEN	.4	-
FISH RETAILERS	11.3	10.9
SUPERMARKETS/GROCERY	2.5	-
RESTAURANTS	1.8	-
GOT NONE	56.6	12.7
DON'T KNOW	6.9	2.7

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persons who do currently eat or who have ever eaten locally caught seafood, catching one's own or having a family/friend catch the fish is mentioned as the most frequent source, i.e., 15.4% presently compared to 20.5% 10 years ago. There would appear to be a slight drop in local seafood consumption in the past 10 years.

Trends in seafood consumption

Among the general population (i.e., prevalence participants) of Greater New Bedford overall fish consumption has only decreased among 12.9% of the people. In contrast, 87.1% report either similar or higher consumption levels over the past 10 years (Table 13). This finding is in sharp contrast to that for trends in local fish consumption which show that people who are or have been local fish consumers, most (61.1%) have decreased their consumption, while 36.3% report equivalent or increased trends.

Preferred species

A number of species have been identified as being likely to have PCB residues if they are taken from contaminated areas. These have been identified by the U.S. Food and Drug Administration (FDA) and others. Table 14 presents a summary of these particular species and the percent of people who consume these. Although these results indicate a range in popularity, some percentage of the prevalence participants does consume each of these species. Comparing frequency of consumption of thse species when obtained from locally closed areas as opposed to all possible sources, one sees that far lower consumption frequencies occur with locally caught fish. Since there can be overlap in responses, one person can report

Table 13.

Trends in Consumption Among Consumers of Seafood*

	Prevalence		Enrichment	
	All Fish N = 840	Local Fish N = 145	All Fish N = 110	Local Fish N = 83
	%	%	%	%
Increase	36.4	9.7	42.7	18.1
Same	50.7	27.6	45.5	43.3
Decrease	12.9	62.8	11.8	38.6

* Local fish analyses restricted to participants reporting consumption of two or more local species.

Table 14.

Percent Consuming* Various Species

Fish/Shellfish	Prevalence N = 840		Enrichment N = 110	
	All Fish	Local Fish	All Fish	Local Fish
Clams, quahogs	82.4%	23.3%	99.1%	70.9%
Mussels	20.2	2.0	52.7	19.1
Eel	9.2	1.9	53.6	24.5
Bluefish/Striped Bass/Mackerel	54.3	13.4	90.0	70.0
Scup, tautog, fluke flounder, cod or sea trout	87.3	17.1	100.0	59.1
Lobster	74.4	13.0	96.4	62.7
Catfish, carp, buffalo fish, trout, chub, and drum	14.4	-	40.9	-

* Self reported consumption

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consumption of a number of different species. It is notable that only 2% of the population of Greater New Bedford reports eating eels from the closed areas. This species is known to accumulate extremely high body burdens of PCB.

SERUM LEVELS OF PCB AND SEAFOOD CONSUMPTION

A. Quartile Analysis by Type of Consumption.

Information on local seafood consumption, i.e. source, consumption of specific species and frequency of consumption, was displayed by quartile level of PCB to see if any of these responses were more frequent among those persons with higher serum PCB levels. This information is fully described for both males and females in Tables 15 and 16.

No discernible trends in serum PCB level were seen among men or women by source either currently or 10 years ago. Some data cells were quite small, and because overall serum PCB levels were low differences between quartiles were minor, therefore it may not be possible to observe trends. It is noteworthy, however, that among both males and females who report getting no local fish either currently or ten years ago, there does not appear to be a preponderance of lower serum PCB levels.

A number of questions were asked about local lobster, a popular species. The 1979 closure primarily affected this species since it was the only commercial species taken from the inner harbor. It was also a popular sport species. Monitoring programs conducted to measure PCB residue levels in lobster have consistently shown levels which exceed the tolerance of 2.0 ppm first set by the FDA and later adapted by the MDPH.

Table 15.

Questions on Local Seafood by Quartile
Prevalence - Males

PCB* Level Range:	Number of Persons Reporting 1st 0.5-2.68 n=99	2nd 2.69-3.93 n=97	3rd 3.94-6.84 n=98	4th 6.85-60.92 n=97
OBTAINING LOCAL SEAFOOD - CURRENT				
Catch own	9	8	8	9
Family/friends catch	6	5	4	5
Other local fishermen	1	-	-	-
Local fish retailers	9	12	9	10
Supermarkets	3	5	1	1
Restaurants	4	3	3	1
Get none	62	55	66	66
Don't know	4	10	7	5
OBTAINING LOCAL SEAFOOD - 10 YEARS AGO				
Catch own	13	9	18	13
Family/friends catch	8	10	8	7
Other local fishermen	1	-	-	-
Local fish retailers	12	15	11	11
Supermarkets	1	3	2	-
Restaurants	2	3	1	2
Get none	52	51	53	61
Don't know	9	7	5	3
HAS EATEN LOCALLY TRAPPED LOBSTER				
Five or more times -- yes	13	16	13	9
TIME OF LIFE ATE LOCALLY TRAPPED LOBSTER MOST FREQUENTLY				
Child	2	4	2	2
Teenager	7	6	2	-
Adult	4	6	9	7
FREQUENCY OF EATING LOCAL LOBSTER				
Two or more times/week	1	2	2	1
At least once/week	1	3	2	1
Less than once/week, at least once/month	4	4	4	4
Less than once/month, at least once/year	7	7	5	3
Less than once/year	-	-	-	-

*PCB measured in parts per billion

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Local Seafood Table
Males (Prevalence) - cont'd.

PCB* Level Range:	1st 0.5-2.68 n=99	2nd 2.69-3.93 n=97	3rd 3.94-6.84 n=98	4th 6.85-60.92 n=97
CONSUMPTION OF LOCALLY TRAPPED LOBSTER				
Increased	1	2	1	1
Same	4	3	3	2
Decreased	8	11	9	6
PARTS OF LOBSTER EATEN				
Claws and tail only	8	9	6	2
Also tomalley	5	7	7	7
SEAFOOD HARVESTED LOCALLY EVER EATEN				
Clams and Quahogs	21	25	33	22
Mussels	4	2	2	1
Eel	2	4	1	4
Blue Fish, Striped Bass or Mackerel	13	14	17	13
Scup, Tautog, Fluke, Cod, or Sea Trout	17	22	17	20

*PCB measured in parts per billion

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Table 16.

Questions on Local Seafood by Quartile
Prevalence - Females

	Number of Persons Reporting			
PCB* Level Range:	1st 0.38-2.64 n=113	2nd 2.65-3.90 n=112	3rd 3.91-6.46 n=112	4th 6.47-154.2 n=112
OBTAINING LOCAL SEAFOOD - CURRENT				
Catch own	4	6	3	7
Family/friends catch	16	9	11	20
Other local fishermen	2	1	3	-
Local fish retailers	14	12	15	11
Supermarkets	4	5	1	1
Restaurants	3	5	1	-
Get none	63	65	73	66
Don't know	7	9	5	7
OBTAINING LOCAL SEAFOOD - 10 YEARS AGO				
Catch own	4	9	3	7
Family/friends catch	15	14	12	23
Other local fishermen	-	1	1	-
Local fish retailers	12	10	12	12
Supermarkets	5	6	4	-
Restaurants	-	4	3	-
Get none	67	56	71	64
Don't know	10	12	6	6
HAS EATEN LOCALLY TRAPPED LOBSTER				
Five or more times -- yes	8	19	21	10
TIME OF LIFE ATE LOCALLY TRAPPED LOBSTER MOST FREQUENTLY				
Child	3	2	3	2
Teenager	1	9	2	-
Adult	4	8	15	8
Don't know	-	-	1	-
FREQUENCY OF EATING LOCAL LOBSTER				
Two or more times/week	1	-	1	-
At least once/week	-	1	5	-
Less than once/week, at least once/month	2	3	9	3
Less than once/month, at least once/year	5	14	6	6
Less than once/year	-	1	-	1

*PCB measured in parts per billion

PCB8 Level Range:	1st 0.38-2.64 n=113	2nd 2.65-3.90 n=112	3rd 3.91-6.46 n=112	4th 6.47-154.2 n=112
CONSUMPTION OF LOCALLY TRAPPED LOBSTER				
Increased	1	2	5	1
Same	1	5	7	4
Decreased	6	12	9	5
PARTS OF LOBSTER EATEN				
Claws and tail only	4	14	10	6
Also tomalley	4	5	11	4
SEAFOOD HARVESTED LOCALLY EVER EATEN				
Clams or Quahogs	20	26	25	24
Mussels	2	1	5	-
Eel	-	1	3	1
Blue Fish, Striped Bass or Mackerel	10	12	18	16
Scup, Tautog, Fluke, Cod, or Sea Trout	11	19	20	18

*PCB measured in parts per billion

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Among persons who have eaten locally trapped lobster, there was a generally even distribution throughout the four quartiles for both males and females. It is apparent from the reported frequency of consumption that those who do consume local lobster, do not do so with great frequency. This fact, coupled with small numbers in many of the cells, makes it difficult to see a relationship with serum PCB level. An observation that can be made from this quartile analysis, however, is that persons who reported eating local lobster most frequently as adults were more frequently in the upper quartiles for both men and women. This comment may not be particularly surprising since individuals who consumed lobster most frequently as adults experienced more recent exposure and may also have had a higher consumption rate.

In regard to whether trends in lobster consumption might affect serum PCB level, one can see that although more people reported decreased consumption levels as compared to those who either remained the same or increased their consumption, this fact did not lead to consistent trends toward greater numbers of persons as quartile levels decreased. Likewise, trends toward increasing numbers of persons in increasing quartile serum PCB level among those who reported increased consumption levels were also not noted. The most likely explanation for these findings is that frequency of consumption of local lobster is not high enough to affect serum PCB level.

An interesting issue, which continues to arise in regard to tolerance setting and regulation, is whether or not to consider the tomalley an edible portion of lobster, along with the claw and tail meat. PCBs are found in much higher concentrations in the tomalley. Questions were asked regarding consumption of tomalley and quartile analysis was used to see if

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respondents who ate tomalley along with the claws and tail meat might have higher serum PCB levels. Forty-two percent of people who eat lobster also consume the tomalley. However, no trends in level can be seen in this data. In addition to lobster, a number of other locally consumed species, i.e. clams, mussels, eels, blue fish, striped bass, mackerel, scup, tautog, fluke, cod, and sea trout, were also examined in relation to serum PCB level. Females who reported eating bluefish are disproportionately represented in the upper quartile. Again, small numbers in certain categories limit the usefulness of these data.

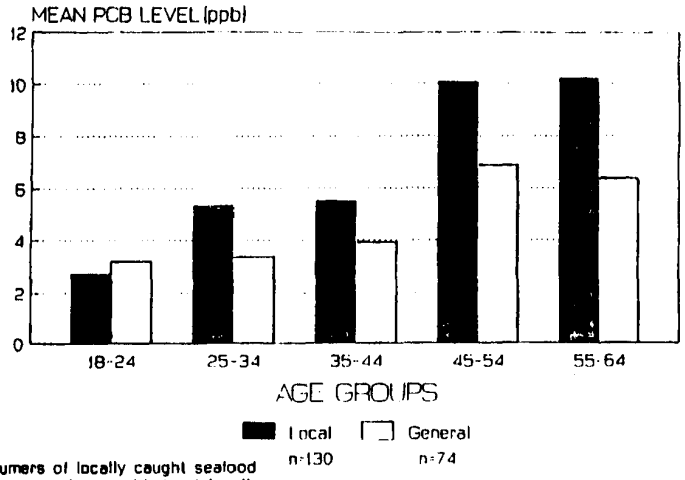
B. Comparison of Local and General Seafood Consumption.

To address the question of whether local seafood eaters have higher PCB levels than persons who do not consume local species, a comparison was made between these two groups. Mean serum PCB levels were examined within each age group so that age would not confound the findings. Consumers of local seafood have higher mean levels in every age group with the exception of ages 18 through 24 (Figure 10). It is clear from the data that consumers of local seafood are at higher risk of elevated PCB body burdens.

Local seafood consumers were also examined to see whether serum PCB levels increased with increasing frequency of consumption of local species. Slightly higher levels were found among very frequent consumers of local seafood as compared to infrequent consumers (Figure 11). It may be that if frequency of consumption were generally higher among consumers of local seafood in the prevalence population, greater differences in serum PCB level might have been noted.

FIGURE 10

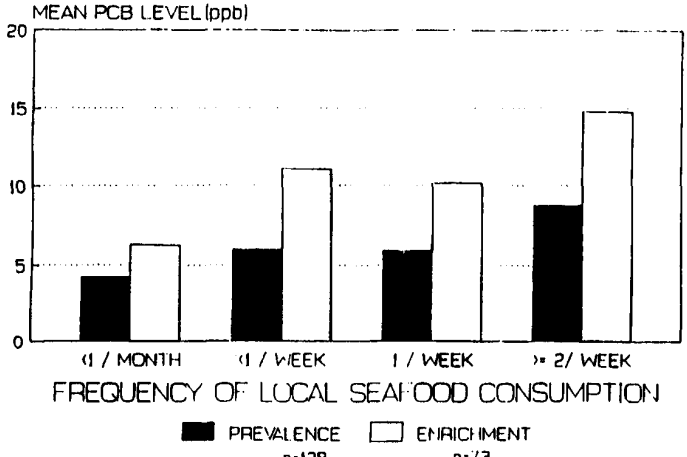
COMPARISON OF LOCAL AND GENERAL SEAFOOD CONSUMPTION FOR PREVALENCE SAMPLE



1 consumers of locally caught seafood
2 consumers of general but not locally caught seafood

FIGURE 11

DISTRIBUTION OF PCB LEVEL WITH FREQUENCY OF LOCAL SEAFOOD CONSUMPTION



Individuals reporting consumption of two or more species of seafood

Industrial and Occupational Exposure

Because PCBs were used in a number of manufacturing processes in the New Bedford area over an extended period of time, a large number of questions were included to gather information on occupational history and exposure to materials in which PCBs are known to have been used. Not only were detailed lists of various industries, type of manufacturing employment and specific materials described but these variables were all examined by quartile analysis for males, females, and the total group.

Industry of Employment

The results of the quartile analysis showed many gaps and some cells with very small numbers. However, some categories had high enough frequencies to make a few observations. After males and females had been combined, additional observations could sometimes be made (Table 17). The only category showing increased frequency in the upper quartile is for combined manufacturing industries. This finding is true for males and females separately and combined. An opposite trend is noted for persons employed in construction and the retail trades. Those who report employment in construction tend to be in the lower quartile ranges. This observation is true for both males alone and the total group. It is not possible to draw conclusions regarding females because of the small numbers in these cells. A similar observation can be made with employment in the retail trades. It would appear that for both males and females alone or combined, there is a disproportionate representation in the lower quartiles in the retail trade, not a surprising observation considering the unlikelihood of exposures to PCBs in this type of employment. No other trends could be made regarding frequency of high or low levels by industry

Table 17.

Industry of Employment by Quartile* Prevalence

	Number of Persons Reporting							
	1st		2nd		3rd		4th	
	M	F	M	F	M	F	M	F
n=	98	113	98	112	98	112	97	112
Agriculture, Forestry, Fishery	3	-	4	-	10	-	6	-
Mining	-	-	-	-	-	-	1	-
Construction	18	1	13	-	8	3	9	1
Manufacturing:								
[non-durable goods]	19	27	13	23	19	29	26	43
[durable goods]	13	10	11	6	9	5	22	5
[electrical machinery, equipment, supplies]	-	5	6	7	3	5	4	13
Transportation, Communication, Utilities	5	3	5	3	11	2	7	-
Wholesale trade	1	-	4	2	1	1	2	1
Retail trade	17	31	10	26	9	21	8	9
Finance, Insurance, Real Estate	4	5	-	5	2	5	3	2
Business and Repair services	2	1	6	2	3	4	1	1
Personal services	2	3	2	6	1	5	-	3
Entertainment and Recreational services	1	1	1	2	-	-	-	1
Professional and Related services	8	24	13	22	13	28	5	26
Public Administration	5	-	9	4	7	3	4	4
Not reported	-	2	1	4	2	1	-	3

*PCB Level Range	1st	2nd	3rd	4th
Males	0.5-2.68	2.69-3.93	3.94-6.84	6.85-60.92
Females	0.38-2.64	2.65-3.90	3.91-6.46	6.47-154.2

(PCB measured in parts per billion)

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of employment.

Selected Manufacturing Exposures

Again, results of the quartile analysis displayed in Table 18 showed many cells with low frequencies or gaps. Manufacture of hydraulic systems does seem to be reported with greater frequency in the upper quartiles for both males and the total sample. No statements could be made regarding females within this category because of low numbers. Although the numbers are also very small, weak evidence of greater frequency within higher quartiles may also be true for respondents in the manufacture of carbonless copy paper (total group) and for others in the manufacture of vacuum pumps (total group).

Exposure to Specific Materials

After a descriptive quartile analysis for each of the 21 materials which might contain PCBs, it was observed that, despite reasonably good frequencies in most of the cells, most categories of potential exposure did not show discernible trends. The data, displayed in Table 19, would seem to indicate that persons reporting exposure to lubricants (males only) and to rubber (males and total group) were more frequently found in the upper quartiles.

Blood Pressure

Blood pressure measurements (e.g., systolic and diastolic readings) were taken three times during the interview process. T-tests performed on systolic and diastolic readings indicated significant differences at the $p = .0001$ level. Therefore, all subsequent statistical analyses were completed with each of the three blood pressure readings.

Table 18.

Selected Manufacturing Exposure by Quartile* Prevalence

Number of Persons Reporting

	1st		2nd		3rd		4th	
n =	M 98	F 113	M 98	F 112	M 98	F 112	M 97	F 112
CARBONLESS COPY PAPER (manufacture only)	-	1	-	2	1	1	4	1
COATING ELECTRICAL CABLES WITH PLASTIC	4	3	5	3	3	1	4	2
FLOURESCENT LIGHTS (manufacture only)	-	-	-	-	-	-	-	-
GAS TRANSMISSION TURBINES	-	-	-	-	-	-	-	-
HEAT EXCHANGE UNITS OR HEAT TRANSFER SYSTEMS	4	-	2	2	1	2	2	1
HOME AIR CONDITIONERS (manufacture only)	-	-	-	-	-	-	-	2
HYDRAULIC SYSTEMS	8	1	4	-	10	2	13	-
INVESTMENT CASTING IN FOUNDRY	3	-	4	1	4	-	3	1
OLEFIN (manufacture only)	-	-	-	-	-	-	-	-
PAPER RECLAMATION	-	-	1	-	-	-	1	-
T.V. SETS (manufacture only)	-	1	1	-	-	1	-	-
SILK THREAD GLOSSING	-	-	-	3	-	1	-	2
VACUUM PUMPS	3	-	2	-	4	1	9	-

*PCB-Level Range	1st	2nd	3rd	4th
Males:	0.5-2.68	2.69-3.93	3.94-6.84	6.85-60.92
Females:	0.38-2.64	2.65-3.90	3.91-6.46	6.47-154.2

(PCB measured in parts per billion)

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Table 19.
Material Exposure by Quartile* Prevalence

	Number of Persons Reporting							
	1st		2nd		3rd		4th	
	M	F	M	F	M	F	M	F
n =	98	113	98	112	98	112	97	112
Adhesives	19	16	22	15	24	14	22	11
Compressor fluids	14	2	18	7	18	1	13	4
Caulking compounds	25	2	27	4	24	3	16	3
Cutting oils	20	5	32	8	26	4	37	10
Dedusting agents	10	3	11	7	9	1	9	2
Dyes	15	9	20	13	17	11	21	9
Flame retardants	10	7	11	10	14	6	9	2
Herbicides	5	-	7	1	7	2	4	-
Hydraulic fluids	27	3	32	7	39	3	34	1
Immersion oil	2	1	4	1	3	1	3	2
Lacquers	21	5	24	15	26	6	27	6
Lubricants	31	15	38	17	43	13	49	20
Paints	47	11	42	16	35	3	41	12
Plasticizers	9	-	10	8	14	3	9	1
Putty	27	1	27	2	20	-	17	1
Resins	15	3	19	4	21	7	18	7
Rubber	21	6	17	14	25	11	32	18
Sealants	20	5	23	10	20	3	18	5
Varnishes	20	6	22	6	22	2	14	2
Wax extenders	5	2	4	5	7	1	1	1
Wood preservatives	19	1	15	3	15	1	13	-
*PCB Level Range - Males	0.5-2.68		2.69-3.93		3.94-6.84		6.85-60.92	
Females	0.38-2.64		2.65-3.90		3.91-6.46		6.47-154.2	

(PCB measured in parts per billion)

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The mean systolic readings and standard deviations for the prevalence sample (n = 840) were 115.26 $\pm$18.85, 113.69 $\pm$17.62, and 114.28 $\pm$11.41. The mean diastolic readings for the prevalence sample were 72.19 $\pm$10.94, and 73.19 $\pm$10.95, and 73.17 $\pm$10.94, respectively. Systolic and diastolic values ranged from 69.00 to 228.00 and from 36.00 to 120.00. When the prevalence sample was examined by sex, there was no significant difference in systolic and diastolic blood pressure readings.

Pearson r correlations of specific independent variables were performed to help identify patterns and trends. These variables included serum PCB level, age, body mass, and systolic and diastolic readings. Age was moderately correlated with PCB level for all systolic and diastolic blood pressures. The correlations ranged from .33 to .51 (p = .0001). There was no relationship found between body mass and age. When the prevalence sample was examined by sex the same relationships were noted. In addition, there were significant moderate correlations for females (n = 449) and males (n = 391) between age and PCB levels (r = .30, r = .39, p = .0001). (Appendix II)

Therefore, it was apparent that the prevalence sample did not demonstrate significant patterns among the correlations of independent variables found to be predictive of serum PCB levels from the literature. The exception was the observed relationship of age and serum PCB level; however, age did not predict serum PCB level when regression models were used. Multivariate models using multiple regression and log linear models were attempted. None proved to be significant when using age, body mass, and systolic and diastolic blood pressure readings as the independent variables predicting serum PCB levels. In addition, age, body mass, and PCB level were used as independent variables with systolic and diastolic

blood pressure readings as the dependent variables. Again, no significant models were found. This result was not surprising, based on the lack of significant patterns found among the correlations.

Refusers

Of the 635 individuals who refused to participate, 560 (89.0%) completed the refusal questionnaire. Review of these data show the refusers and participant populations to be similar with regard to employment at a capacitor manufacturing firm. Of the refusers who completed the refusal questionnaire 17.9% ($\underline{n}$ = 102) reported past or present employment at one of the two local capacitor manufacturers, as compared to 21.1% ($\underline{n}$ = 177) of the prevalence study participants. Since there are no data on work history of refusers in the capacitor industry, it is impossible to compare duration of employment or specific occupation.

Limited data are available for comparing seafood consumption between the two populations. The survey instrument administered to actual study participants was quite detailed in this regard and provided extensive information on types of seafood consumed, seafood sources, and frequency of consumption for both general and local (contaminated) seafood. For the refusal questionnaire these questions were condensed into two: 1) "Do you eat a lot of fish and/or lobster (3X or more/week)?"; and in the event of a positive answer, the followup question, 2) "Where do you get your fish and lobster?". Given the differences in survey instruments, it is difficult to essess whether the two populations have an equal possibility of ingesting contaminated seafood. It is possible, however to offer a fair characterization of general seafood consumption habits among the refusers.

There were 101 (17.9%) refusers who reported eating "a lot" of fish and lobster. Of the participants, 128 (15.2%) reported eating seafood two or more times per week. Refusers were also asked how they obtained their local seafood. (It is important to note that this group of individuals were not offered a choice of responses [i.e., catch own, family/friends, etc.] but rather, self-reported their source of seafood.) Only 9.8% of the refusers reported "catch own" or "family/friends" as their means of obtaining locally caught seafood, compared to 25% of participants. This number may lend credence to an assumption that consumers of potentially contaminated seafood were not underrepresented in this investigation.

Medical conditions were also covered extensively in the survey instrument. The refusal questionnaire contained one question designed to pinpoint any chronic, recurring medical conditions. No association was found between the presence of medical conditions and refusal to participate. This supports the assumption that illness was not a deterrent to participation in the study.

Chi square tests were performed for association of refusal to participate and age, sex and residence. Occupational data other than employment in an electrical manufacturing plant was obtained largely from the local census. Therefore it was not included for comparison here. Age was significantly associated ($x^2 = 11.865$ with 4 d.f., $p = .018$) with refusal for females. This association was not significant among males who refused to participate. Neither sex nor city/town of residence was associated with refusal in both male and female subgroups.

A list of reasons individuals gave for refusing are listed in Appendix FF. The three predominant responses are: 1) no time (26.3%); 2) not interested (14.5%); and 3) no clear reason given (23.6%).

ENRICHMENT

As a result of the low serum PCB levels observed in the preliminary findings ($\underline{n}$ = 322) of the Phase I Prevalence Study, it became apparent that an exposed group of individuals (i.e. 150 people) would not be identified by random selection. On the basis of these findings, the MDPH and the CDC decided to conduct an enrichment study. Enrichment participants consisted of residents identified as being at greater risk of exposure to PCBs because of frequent intake of contaminated seafood.

The goal of the Enrichment Study was to identify the group of 150 individuals necessary for proceeding to Phase II of the GNBHES.

Enrichment Serum PCB Distribution: The distribution of levels among participants of the Enrichment Study are presented in Table 20. The range in levels for this sample was 1.40 ppb to 87.97 ppb with a median of 9.48 ppb and a mean of 13.34 ppb.

Enrichment PCB Level by Reported Ethnicity: Table 21 presents the distribution of serum PCB levels among Portuguese/Cape Verdean in comparison to non-Portuguese/Cape Verdean enrichment study participants. As was observed in the prevalence sample, participants reporting their ethnicity as either Portuguese or Cape Verdean had slightly higher mean serum PCB levels (17.1 ppb vs. 11.4 ppb).

Enrichment Serum PCB Level and Age: Figure 12 shows the relationship of serum PCB level to age among the enrichment study participants (n=110). In the three age groups into which enrichment participants were categorized

Table 20.

Distribution of Serum PCB Levels
Enrichment

Serum PCB Level*	MALES n=89 n	MALES n=89 %	FEMALES n=21 n	FEMALES n=21 %	TOTAL n=110 n	TOTAL n=110 %
0.0 - 1.49	-	-	1	4.8	1	.9
1.5 - 2.99	-	-	2	9.5	2	1.8
3.0 - 4.49	14	15.7	2	9.5	16	14.6
4.5 - 5.99	12	13.5	-	-	12	10.9
6.0 - 7.49	14	15.7	1	4.8	15	13.6
7.5 - 8.99	6	6.7	1	4.8	7	6.4
9.0 - 10.49	6	6.7	2	9.5	8	7.3
10.5 - 11.99	5	5.6	4	19.1	9	8.2
12.0 - 13.49	6	6.7	-	-	6	5.5
13.5 - 14.99	2	2.3	1	4.8	3	2.7
15.0 - 16.49	5	5.6	1	4.8	6	5.5
16.5 - 17.99	3	3.4	1	4.8	4	3.6
18.0 - 19.49	1	1.1	1	4.8	2	1.8
19.5 - 20.99	2	2.3	1	4.8	3	2.7
21.0 - 22.49	2	2.3	-	-	2	1.8
22.5 - 23.99	2	2.3	1	4.8	3	2.7
24.0 - 25.49	1	1.1	-	-	1	.9
25.5 - 26.99	2	2.3	-	-	2	1.8
27.0 - 28.49	1	1.1	-	-	1	.9
28.5 - 29.99	-	-	-	-	-	-
30.0 +	5	5.6	2	9.5	7	6.4
NEXT TO HIGHEST		63.76		55.70		83.99
HIGHEST		87.97		83.99		87.97
MEAN		12.63		16.34		13.34
MEDIAN		8.46		10.74		9.48
STANDARD DEVIATION		12.48		19.33		14.02
25TH PERCENTILE		5.57		5.39		5.59
75TH PERCENTILE		15.79		17.58		15.93

*PCB measured in parts per billion

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Table 21.

Serum PCB Level Distribution among Portuguese and Cape Verdean as Compared to All Others

Enrichment Participants

LEVEL	Portuguese N (N=37)	Portuguese % OF TOTAL	Non-Portuguese N (N=73)	Non-Portuguese % OF TOTAL
0 - 1.49	1	2.7	-	-
1.5 - 2.99	-	-	2	2.7
3.0 - 4.49	1	2.7	15	20.6
4.5 - 5.99	3	8.1	9	12.3
6.0 - 7.49	6	16.2	9	12.3
7.5 - 8.99	2	5.4	5	6.9
9.0 - 10.49	2	5.4	6	8.2
10.5 - 11.99	2	5.4	7	9.6
12.0 - 13.49	3	8.1	3	4.1
13.5 - 14.99	1	2.7	2	2.7
15.0 - 16.49	4	10.8	2	2.7
16.5 - 17.99	1	2.7	3	4.1
18.0 - 19.49	-	-	2	2.7
19.5 - 20.99	2	5.4	1	1.4
21.0 - 22.49	1	2.7	1	1.4
22.5 - 23.99	2	5.4	1	1.4
24.0 - 25.49	-	-	1	1.4
25.5 - 26.99	1	2.7	1	1.4
27.0 - 28.49	1	2.7	-	-
28.5 - 29.99	-	-	-	-
30.0 +	4	10.8	3	4.1
NEXT TO HIGHEST		55.70		63.76
HIGHEST		87.97		83.99
MEAN		17.14		11.41
MEDIAN		13.38		8.38
STANDARD DEVIATION		16.21		12.45
25TH PERCENTILE		7.00		4.64
75TH PERCENTILE		20.74		13.46

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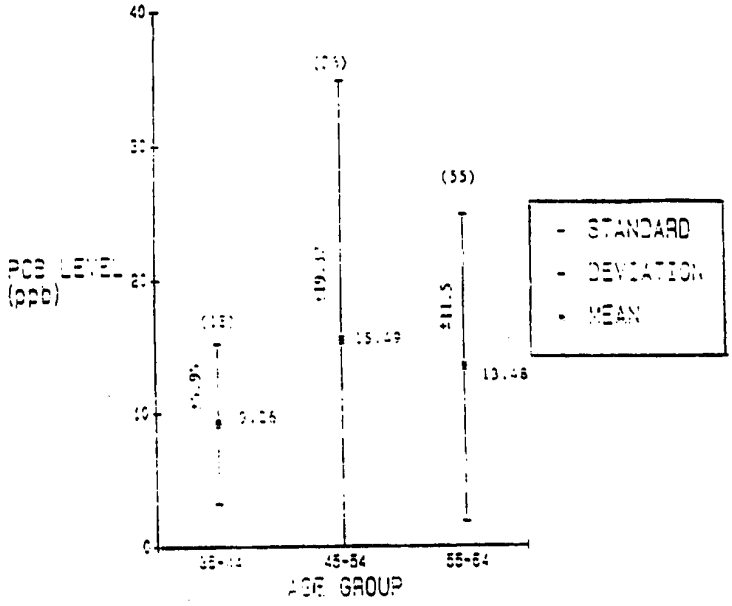
FIGURE 12

MEAN and STANDARD DEVIATION
SERUM PCB LEVEL[1] by AGE GROUP
ENRICHMENT



note: One participant was eliminated because they fell outside of these age groups.

1 PCB measured in parts per billion

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(i.e., 35-44, 45-54, 55-64) the mean serum PCB levels were: 9.26, 15.49, 13.48 ppb respectively.

Serum PCB Level range - Prevalence vs. Enrichment

To better assess the comparison of serum PCB levels of the randomly selected sample (i.e. prevalence) to the enrichment sample, the GNBHES programmer, using a random number generator program, selected a control group from the Prevalence Sample matched on age and sex. Figure 13 presents a comparison of the distribution of levels between these two groups.

It is not unexpected that the enrichment group (individuals at greater risk) shows greater numbers of people in the upper range of serum PCB levels because of the criteria set for entry into the Enrichment Study.

Seafood Consumption

Because the prevalence of elevated serum PCB levels was found to be low, and the frequency of consumption of local fish from areas of substantial PCB pollution was low among participants chosen by random sample, the enrichment group was recruited to see if more people could be found who consumed PCB contaminated species and had higher serum PCB levels.

Overall, marked differences in response to seafood consumption questions were noted between the enrichment and prevalence populations. Male and female responses were grouped for the analysis of enrichment data since these groups were small and did not show appreciable differences when results were examined separately.

FREQUENCY DISTRIBUTION TABLE COMPARING ENRICHMENT WITH PREVALENCE CONTROLS

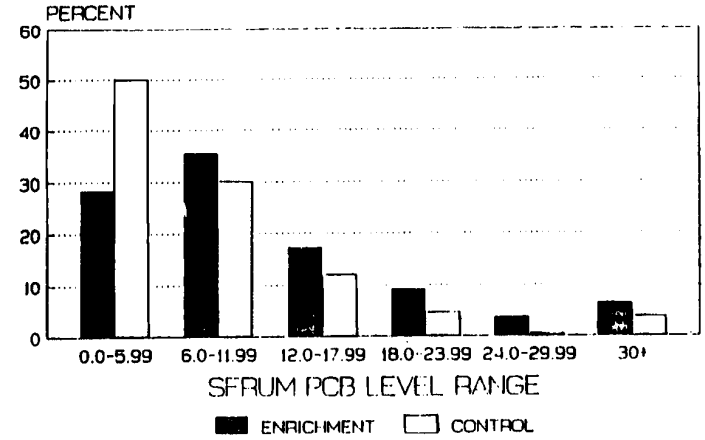

FIGURE 13

pcb measured in parts per billion n=110 n=110

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Seafood Source

The most frequently mentioned source from which people currently obtain seafood is from local fish retailers (Table 9). Fifty-four percent of the prevalence and 41% of the enrichment sample cited this source. The major difference regarding the source of seafood between the two study groups is the percentage of respondents who reported catching their own. Thirty-five percent of the enrichment population report catching their own fish as compared with only 4.2% in the prevalence population. This finding is not unexpected in light of the method by which the enrichment sample was selected. In looking to see whether the primary seafood source had changed since 10 years ago, one finds that the same sources are named by approximately the same relative percentages. Similar patterns are observed for local seafood consumption (Table 11 and 12). Again, the most important contrast between the two study populations is among those who report obtaining no seafood. Among those persons in the enrichment group who report getting no local seafood, one does see a drop of eight percentage points over the last 10 years, which may be an indication that the local fishing prohibitions have had some effect. It is, however, quite clear from Tables 11 and 12 that the enrichment population is more exposed to contaminated local seafood than is the Greater New Bedford population in general.

Trends in Seafood Consumption

The enrichment sample participants as well as those in the prevalence sample were asked whetner their general consumption of seafood as well as locally caught seafood had increased, decreased or remained about the same over the last 10 years (Table 13). The overwhelming response in both

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sample populations indicated that a very high percentage (85-89%) either increased this general consumption or it remained the same. Conversely, only a very small percentage of both groups reported a decrease. Among the persons in the enrichment sample who consumed at least two different species of local seafood, a much higher percentage reported a decrease. This decrease was substantially higher than that reported for general seafood consumption. This finding is again consistent with the fishing prohibitions. A decrease (61%) in consumption of local seafood is also seen in the prevalence population among those who report consumption of two or more local species. However, only about 20% of the prevalence group reports eating these local species, whereas approximately 75% of the enrichment sample does.

An even more important observation regarding trends among persons who report local seafood consumption might be that despite widespread public education regarding the local PCB contamination problems, 61.4% of the enrichment sample and 36.3% of prevalence sample indicated that their level of local consumption had either increased or been maintained. This finding would seem to indicate a need for both better enforcement activities and environmental health educational programs geared to recreational fishermen.

Preferred Species of Consumption

A list of specific species of fish was given to respondents of both enrichment and prevalence groups to ascertain the percentage of each group that consumed each species both in general and from defined local areas. Some species have been found to contain elevated levels of PCBs regardless of their source (30). Others are known to have been elevated if taken from contaminated areas.

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In examining the percentage of respondents in both the enrichment and prevalence samples who report eating each different species, it is quite apparent that a greater percentage of the enrichment sample consumes every species than does the prevalence group (Table 14 and 22). This is true for both general seafood consumption and for seafood obtained from local areas. Some species, such as clams, scup, tautog, fluke, flounder, cod, sea trout, lobster, are clearly more popular than others, such as mussels, eels, and fresh water species. Responses show markedly higher percentage consumption of species in which PCBs are routinely found among the enrichment than among the prevalence population. For this reason, further analysis was done to see if consumption of these species was more frequently reported among respondents with upper PCB quartile levels than in lower ones.

ENRICHMENT SERUM LEVELS OF PCB AND SEAFOOD CONSUMPTION

A. Patterns by Quartile

Patterns in local seafood consumption were examined by serum PCB level quartile to see whether any responses were more frequently reported in higher quartiles (Table 22). Specific types of seafood consumption, trends in local lobster consumption, and catching one's own seafood both now and 10 years ago were analyzed for the presence of trends by serum PCB level quartile. No obvious differences in frequencies were seen for specific species consumed; for individuals who currently or formerly trapped their own local lobster; for either increasing or decreasing trends in consumption; or for consumption of various edible portions of lobster. It is interesting to note that 56% of respondents who reported consuming locally trapped lobster consumed the tomalley.

Table 22.

Local Fish Consumption Patterns by Quartile

Enrichment

PCB Level Range*	Number of Persons Reporting			
	1st 1.4-5.61 n = 28	2nd 5.62-9.48 n = 27	3rd 9.49-15.7 n = 27	4th 15.71-87.97 n = 28
SPECIES CONSUMED				
Clams, quahogs	20	18	22	18
Mussels	7	1	9	4
Eels	5	5	7	10
Bluefish, striped bass and/or mackerel	17	18	24	18
Scup, tautog, fluke, flounder, cod, and/or sea trout	18	14	21	12
Lobster	19	13	21	16
PARTS LOBSTER				
Claws and tail	8	7	9	6
Also tomalley	11	6	12	10
PRIMARY SOURCE AS CATCH OWN FISH				
Now	14	12	19	13
Ten years ago	13	15	22	19
TRENDS IN LOCAL LOBSTER CONSUMPTION				
Increased or same	14	8	13	7
Decreased	5	5	8	9

*PCB measured in parts per billion

B. Frequency of Local and General Seafood Comparisons

Answers to the question of whether persons who report greater frequency of consumption of local species have higher serum PCB levels are presented in Figure 11. In the enrichment group, serum PCB levels increase with increasing frequency of consumption. This result is consistent with that seen for prevalence, only it is more pronounced in the enrichment sample.

Industrial and Occupational Exposure

Information on both industry of employment and specific occupation was collected. As in the prevalence group, occupational information reported was so widely scattered that few persons fell into any one category to be useful for in-depth analysis. Industry of employment, specific manufacturing employment and material exposures were analyzed descriptively by quartile frequency distributions by serum PCB levels. A quartile analysis approach was chosen to indicate whether persons with the highest serum PCB levels were disproportionately represented in certain types of industries, and, if so, whether those industries were likely to pose occupational exposure to PCBs. As in other enrichment analyses, males and females were grouped because of the small size of the groups.

Industry of Employment

Reported industries of employment were widely and rather evenly distributed among the enrichment population (Table 23). An examination of the quartile analysis showed no trends or clustering of persons with higher serum PCB levels by industry of employment, with the possible exception of the manufacture of electrical machinery and supplies. Persons reporting

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Table 23.

Industry of Employment by Quartile

Enrichment

	Number of Persons Reporting			
PCB* Level Range	1st 1.4-5.61 n = 28	2nd 5.62-9.48 n = 27	3rd 9.49-15.7 n = 27	4th 15.71-87.97 n = 28
Agriculture, Forestry, Fishery	2	0	1	2
Construction	4	2	4	4
Manufacturing:				
A. Non-Durable Goods	4	5	3	1
B. Durable Goods	3	2	3	3
C. Electrical machinery, equipment, supplies	0	1	3	7
Transportation, Communication, Utilities	2	3	0	5
Wholesale Trade	0	1	0	1
Retail Trade	5	2	3	1
Finance, Insurance, Real Estate	0	1	1	0
Business Repair Services	0	1	2	1
Professional & Related Services	7	4	4	0
Public Administration	1	5	3	3

*PCB measured in parts per billion

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employment in this industry were more frequently found in the upper two quartiles. This result is not unexpected when one considers the history of electrical capacitor manufacturing in New Bedford and the extensive, long term use of PCBs within that industry. It should also be noted that for workers reporting employment in the professional service category a disproportionate number seemed to be represented in the lower quartile ranges. A weak trend in this same direction might be also true for individuals in retail trade.

Selected Manufacturing Exposures

A number of specific manufacturing processes have been reported to present potential exposure to PCBs. Information on these processes was sought from respondents, and quartile levels were determined to show frequency in relation to the information. Data were examined to see whether persons in upper quartiles were more likely to report employment in these manufacturing categories. Results indicate that numbers in each category were so small that it was not possible to observe any trends (Table 24).

Exposure to Specific Materials

Another possible source of PCBs might be contact either through the use or manufacture of various types of materials that contain these compounds. It is well known that PCBs, because of their chemical and physical properties, found widespread application in a variety of products. For this reason, information was collected on contact with materials thought to potentially contain PCBs either now or in the past. One can see that many of these materials are frequently mentioned by the enrichment

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Table 24.

Selected Manufacturing Exposure by Quartile Enrichment

PCB* Level Range:	Number of Persons Reporting			
	1st 1.4-5.61 n =28	2nd 5.62-9.48 n = 27	3rd 9.49-15.7 n = 27	4th 15.71-87.97 n = 28
CARBONLESS COPY PAPER (manufacture only)	0	0	0	0
COATING ELECTRICAL CABLES WITH PLASTIC	3	2	3	1
FLOURESCENT LIGHTS (manufacture only)	1	0	0	1
GAS TRANSMISSION TURBINES	0	0	0	0
HEAT EXCHANGE UNITS OR HEAT TRANSFER SYSTEMS	2	0	0	1
HOME AIR CONDITIONERS (manufacture only)	0	1	0	1
HYDRAULIC SYSTEMS	4	3	3	2
INVESTMENT CASTING IN FOUNDRY	0	2	1	0
OLEFIN (manufacture only)	0	0	0	0
PAPER RECLAMATION	1	0	0	0
T.V. SETS (manufacture only)	0	1	0	0
SILK THREAD GLOSSING	0	0	0	0
VACUUM PUMPS	3	0	1	1

*PCB measured in parts per billion

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respondents (Table 25). Clearly, not all products within each category contains PCBs; therefore, simply reporting exposure to a particular material or group of materials is not synonomous with exposure to PCBs. However, since a percentage of materials within each material category contains PCBs, contact does increase the risk of exposure. Therefore, data were examined for a number of persons within each quartile who reported contact with each specific material, to see if certain types of exposures were disproportionately represented by persons having higher levels of PCBs. Certain material exposures did appear to be more frequently reported among higher quartiles such as exposures to putty, sealants, varnishes, and wood preservatives.

Blood Pressure

Blood pressure was also analyzed in the enrichment sample (n = 110). The first, second and third mean systolic readings were 128.45 $\pm$15.58, 124.69 $\pm$16.11, and 125.66 $\pm$16.55 (range = 96.00 - 186.00). The mean diastolic readings were 83.47 $\pm$9.43, 80.86 $\pm$9.74, and 81.16 $\pm$10.54 (range = 52.00 - 128.00). Correlations of systolic and diastolic readings, age, body mass, and serum PCB levels revealed no significant relationships among variables except for the second systolic blood pressure reading and PCB level (r = .53, p = .01) in females. However, there were also significant associations between the second and third systolic blood pressure readings and age (r = .55, p = .01; r = .46, p = .04). Because of the small sample size, these correlations are difficult to interpret. There may, in fact, be no relationship between serum PCB level and systolic blood pressure since the age variable may be confounding the interpretation of these

Table 25.
Materials Exposure by Quartile Enrichment

PCB* Level Range:	Number of Persons Reporting			
	1st 1.4-5.61 n = 28	2nd 5.62-9.48 n = 27	3rd 9.49-15.7 n = 27	4th 15.71-87.97 n = 28
ADHESIVES	8	5	8	9
COMPRESSOR FLUIDS	8	8	3	5
CAULKING COMPOUNDS	7	5	11	10
CUTTING OILS	11	12	14	15
DEDUSTING AGENTS	2	2	4	3
DYES	8	6	6	8
FLAME RETARDANTS	2	4	1	2
HERBICIDES	2	1	1	4
HYDRAULIC FLUIDS	11	9	7	14
IMMERSION OIL	1	2	0	1
LACQUERS	8	4	10	8
LUBRICANTS	13	13	11	16
PAINTS	11	12	15	14
PLASTICIZERS	3	5	2	4
PUTTY	3	5	8	12
RESINS	10	9	7	13
RUBBER	12	8	10	11
SEALANTS	5	4	8	12
VARNISHES	4	3	8	9
WAX EXTENDERS	1	3	1	4
WOOD PRESERVATIVES	2	3	8	8

*PCB measured in parts per billion

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variables. Multivariate models were not applied because of the size of the sample.

HEAVY METALS IN THE GREATER NEW BEDFORD POPULATION

Results of studies of sediments from the Acushnet River estuary and landfills in and around Greater New Bedford, Massachusetts, performed before the planning and design of the Greater New Bedford Health Effects Study, showed evidence of significant heavy metal contamination (31). Some of the known toxic effects from heavy metal exposure resemble the reported health effects of polychlorinated biphenyl (PCB) exposure. The health effects of exposure to inorganic lead, inorganic mercury, organic mercury, and the various inorganic and organic species of arsenic are summarized here. Inorganic arsenic can cause peripheral neuritis, myelitis, or motor paralysis. In contrast, arsenic in its dietary forms can be tolerated in humans without toxic effects even at relatively high levels. Inorganic lead causes encephalopathy and central nervous system damage and is positively correlated to blood pressure (32). Mercury is neurotoxic in both its inorganic and organic forms, with the organic moieties (e.g., methylmercury) having considerably greater toxicity (33).

The study design therefore included plans to measure these metals in a 10% subset of study participants. The findings could then be used to determine: 1) if a public health problem with regard to human exposure to these heavy metals existed in the Greater New Bedford community, and 2) if the effects of exposure to these metals produced a potentially confounding source of symptoms which might be interpreted as symptoms due to PCB exposure. Measurements in biological fluids could serve as markers for

undue absorption of these toxicants. This study chose to measure urine arsenic, urine mercury and blood lead on the basis of the known distribution and excretion patterns of these metals.

As the study progressed, it was decided to include measurements of speciated arsenic in any specimens with elevated total urinary arsenic, to clarify the presumed dietary origin of any elevated levels observed. Although urinary inorganic mercury is the analyte of choice for overall mercury exposure, the presence of alkylated forms of mercury, which might also be absorbed from dietary sources, was assessed by total mercury analyses on whole blood. Analyses were done on persons from the prevalence study with elevated urinary arsenic and on a small number of arbitrarily chosen specimens.. Findings with regard to exposure to these heavy metals are described in detail in Appendix BB and are summarized here.

Urine and whole blood specimens from a 10% subset of respondents in the Prevalence and Enrichment components of this study were examined for concentrations of blood lead, urinary total arsenic and urinary inorganic mercury. This subset consisted of 106 persons -- 96 persons from the Prevalence group and 10 persons from the Enrichment group. Ten samples from the total subset with urinary total arsenic >100 ng/mL were also tested fro arsenic speciation to determine the dietary (nontoxic) contribution to these elevations. In addition, 48 blood specimens from respondents were also tested for blood total mercury.

Results of this study of heavy metal exposure in residents of the Greater New Bedford area showed no evidence of excessive exposure to toxic forms of any of the elements tested. Levels of blood lead were within the expected range for nonoccupationally exposed adults and are typical of levels observed in urban adults in the United States. The urinary

inorganic mercury and blood total mercury levels measured were well below published exposure limits. This supports the conclusion that excessive exposure to elemental and organic forms of mercury did not occur in the persons tested. Total and speciated urinary arsenic measurements demonstrated that the only obvious exposure to arsenic was in the form of the relatively nontoxic dietary form of arsenic (predominately from seafood), and levels were well below action levels for this form of arsenic.

Elevated levels of certain heavy metals have been demonstrated in sediments from the Acushnet estuary and samples from local landfills and other sites; furthermore, the potential for industrial exposure is present among workers in the community. Results of this study of 106 New Bedford area residents, however, showed no evidence of excessive human exposure to lead, arsenic, or mercury in the community.

CHAPTER IV

DISCUSSION

After final disposition of all randomly selected participants of the Greater New Bedford Health Effects Study a response rate of 57% (Table 2) was observed in the prevalence sample. Although this figure may be considered low in comparison to clinical trials of a similar nature, discussions with scientists involved in investigations throughout the United States have indicated a decline in overall response rates. Some investigators are now compensating participants with hopes of achieving a response rate of 50% (35). In all cases it is necessary to obtain a sample with sufficient statistical power in order to draw meaningful conclusions from data collected. In the case of a prevalence study (like the GNBHES), it is of utmost importance that a representative sample is gained since we are making statements descriptive of a large population based on a statistical sample of the population. The GNBHES staff were able to meet original sample size estimates that enabled a test to be performed for a doubling of the expected prevalence of elevated serum PCB levels with a power of 80%.

It is clear from the data presented in Table 5 and Figure 8 that the prevalence of elevated serum PCB level among residents of Greater New Bedford is low. This observation remains true for both mele and female subgroups as well as the total prevalence study group. This event was not expected due to the high level of contamination that still exists in and around New Bedford harbor and the Acushnet River Estuary. For the most part, even the Greater New Bedford residents with highest risk of exposure from diet or occupation had serum PCB levels well within the range of CDC

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from diet or occupation had serum PCB levels well within the range of CDC estimates on a national basis for non-exposed U.S. residents that participated in other studies (1% $\geq$ 30 ppb).

It is also evident that residents of individual cities and towns within the study area (New Bedford, Acushnet, Dartmouth, and Fairhaven) do not differ greatly in regard to PCB serum levels and that no greater risk of exposure to PCBs exists in any one of the four cities and towns.

The data have shown (Figure 9) that the age of an individual is correlated with serum PCB level. A relationship between age and serum PCB level was observed among participants of the prevalence study. As data for each ascending prevalence age group was reviewed, the mean PCB levels increased proportionally among the five age intervals. It should be noted that although the relationship of age to serum PCB level was significantly correlated, age did not predict PCB level in the regression model. This relationship (age and serum PCB level) was supported in studies conducted by Kriess et al in 1982 (14) among farmers from Michigan.

In addition to this relationship, it is also noteworthy that in the general distribution of serum PCB levels, among those residents who reported having a Portuguese or Cape Verdean ethnicity, there exists a slightly higher mean PCB serum level. This observation held true for the total prevalence group and proportionally in each of the five age groups examined in this sample. After controlling for occupational and seafood consumption confounders as well as variability in laboratory analyses, this difference in levels diminished among ethnic groups.

The distribution of serum PCB levels among residents participating in the enrichment study (Table 20) show a higher mean and median level for this group of individuals. This finding was expected since this group was

recruited to participate largely on the basis of known seafood consumption exposures as well as an age confinement and a small number of people with previous known occupational exposures. It remains of interest that the utilization of the screening questionnaire enabled study staff to identify individuals with higher serum PCB levels due to a determination that these individuals were truly at higher risk of exposure to PCBs. The data collected in the enrichment study contribute greatly to more accurate assessments of exposure to PCBs among a high risk population. The mean serum PCB level for this group was 13.34 ppb which is almost three times greater than that of the prevalence (i.e. general population) group which was 5.84 ppb. Standard deviations were 14.02 and 7.78 respectively (Tables 5 and 20). Even though serum PCB levels were higher among enrichment participants, the ranges are very narrow and the standard deviations are broad. It is, therefore, true that although differences were noted between these two groups, these differences are not likely to be biologically important.

One of the major points of interest regarding data collected on the enrichment sample was that, compared to the prevalence sample, the relationship of serum PCB level to age diminished greatly. The age confinement for enrichment participants may have masked this relationship. It is possible that the greater the exposure an individual may have had to PCBs, the weaker the association with age may be (Figure 12).

The difference in serum PCB levels for Portuguese/Cape Verdean and Non-Portuguese/Cape Verdean was also examined for participants of the enrichment study. The observed difference was also evident in this sample of higher risk individuals (Table 21). Although the sample size was much smaller in the enrichment study (n = 37; n = 73) vs. the prevalence study

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(n = 415; n = 425), it is important to note that participants reporting their ethnicity as either Portuguese or Cape Verdean had a mean level of 17.1 ppb vs. 11.4 ppb for participants reporting their ethnicity as being other than Portuguese or Cape Verdean. However, variability of serum PCB levels in the Enrichment group was high (standard deviation ± 12.5) and like the prevalence group, these differences may be explained by occupation and seafood consumption.

In any case, although some sub-groups within each of the study samples (i.e. prevalence and enrichment) exhibited higher mean and median levels than others, it should be kept in mind that the levels in both groups were generally low. Data available on how rapidly PCBs disappear from human serum is quite limited. Six persons from the present study were participants of 1981 investigation. The PCB serum levels for all six individuals dropped over the time that elapsed. The approximate decline in levels in this limited number of people was forty percent.

One of the issues of continuing concern in New Bedford has been whether exposure to contaminated seafood from local areas has resulted in elevated body burdens of PCBs among area residents and the percentage of the population of this area is affected. Over the last ten years a number of governmental agencies have conducted PCB monitoring of seafood. This sampling has consistently shown levels of PCBs well above the FDA action level of 2.0 ppm (formerly 5.0 ppm) in a number of species taken from these areas. This tolerance was adopted as the rationale for the harbor closure by the MDPH in 1979. Recent monitoring has indicated that elevated levels of PCBs in seafood have not appreciably decreased. Prior to the 1979 regulations these waters were popular as a recreational fishing ground as well as a lucrative commercial lobster fishery. Before results from

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Phase I of the GNBHES were obtained, however, one could merely speculate as to the effectiveness of the prohibitions. It was clear from simple observation that fishing activities did not completely cease as a result of the ban. It was not possible, however, to estimate the decrease in terms of the number of people who formerly ate and no longer do, whether frequency of consumption has decreased among those who presently consume, and whether consumption has been high enough to be reflected in elevated body burdens. Because it is well recognized that there are some fish species which preferentially accumulate PCBs, information was sought to determine whether elevated serum PCB levels were associated with consumption of these.

Prevalence sample results have shown that serum PCB levels are low in general for the population of Greater New Bedford. It is also true that when questioned about seafood source only a small percentage of the greater New Bedford population is certain that they actually consumed fish from the closed areas. Even before the harbor closure this would seem to be the case. The majority of people in the New Bedford area seem to have had exposures to PCBs which have been similar to the general U.S. population. This is because the major route of exposure to PCBs today in the U.S. is from residues in commercial market fish. Because PCBs are stored in fatty tissue, body burdens gradually increase throughout life. This age trend has been shown in other studies (14) and is also seen in the Phase I Greater New Bedford Health Effects Study. Those who reported consumption of local seafood did have higher serum PCB levels in almost every age category (Figure 10) compared to those who did not consume. It should be stressed, however, that the range in levels is very small and most of those who consumed local species still had relatively low serum PCB levels. The

most likely explanation for this is that the frequency of consumption is not high. In other words, even though people report eating fish species from the contaminated areas, they do not eat large enough quantities of these species to markedly affect their overall body burden of PCB as reflected by serum PCB level. This infrequent consumption pattern was seen for lobster (Table 15), and is likely to be similar for other species. It was not possible to apply statistical tests for associations between serum PCB level and specific species since the cell numbers were small and the serum PCB level range was so narrow. This was the reason local seafood species were grouped for analyses.

In the enrichment population marked differences in seafood consumption patterns were noted. This, of course, was not surprising given the method of recruitment. This population clearly had a greater exposure to a variety of contaminated local seafood species (Tables 11 and 12), combined with a high general fish consumption. Some decreases in consumption were apparent as a result of fishery closures; however, nearly 62% still report continued or increased consumption of local species. As was seen with the prevalence sample, serum PCB levels increased with increasing frequency of consumption; however, serum PCB levels were still low in this group (Figure 11).

Because large numbers of persons were employed in the manufacture of electrical capacitors and other industries in which PCBs may have been used in New Bedford, information on industry of employment, selected types of manufacturing and exposure to specific materials was sought. Although some trends, (i.e., higher levels) among those employed in combined manufacturing industries were seen in quartile analyses, these were very weak. Observable trends in selected types of manufacturing and exposure to

specific materials were also weak and showed a lack of consistency between prevalence and enrichment responses. Low numbers of people in each data cell limit the ability to interpret these data.

The association of blood pressure and PCBs was examined in a study by Kreiss; diastolic blood pressure and PCB levels were significantly correlated.. However, the Kreiss et al study did not have a control group in its design; therefore, the high incidence of hypertension among the persons sampled confounded an explanation for the blood pressure and PCB association. In addition, there is a known relationship between age and blood pressure measurement; that is, blood pressure measurements, both systolic and diastolic, increase with age.

Other studies have demonstrated that serum PCB levels increase with age. It may be a spurious conclusion that blood pressure measurements (i.e. systolic and diastolic) are related to serum PCB levels since both tend to increase with age.

Other limitations to Kreiss et al.'s study include diagnosis of borderline or definite hypertension from single readings, unknown time of day when measurements were taken, and lack of control of the environment where the subjects' data were collected. In contrast, in the Greater New Bedford PCB Health Effects Study, blood pressure readings were taken at three times during the interview. (See Methods chapter for specific protocols.) The systolic and diastolic blood pressure readings for this study in the prevalence sample were significantly different from each other. This demonstrates the intermeasurement variability among blood pressure readings and the possible dependence of blood pressure on multiple external factors. While several multivariate techniques (e.g. multiple regression and log linear models) were applied to these data, no

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significant model was found using age, body mass, systolic and diastolic blood pressure readings as independent variables, and serum PCB level as the dependent variable. The analyses by Kreiss et al. included multiple regression and log linear models. Accordingly, age, body mass and serum PCB levels were utilized as independent variables, and systolic or diastolic blood pressure readings as the dependent variable. Again, no significant model was found. Therefore, the relationships demonstrated in Kreiss et al.'s work were not found in the Greater New Bedford PCB Health Effects Study. Perhaps the lack of significant models was due to the low serum PCB levels found in the residents of the Greater New Bedford area and the presence of a normotensive sample. Kreiss et al.'s study included a higher number of borderline and hypertensive individuals. It was not reported whether these individuals were treated with anti-hypertensive medications; thus, the systolic and diastolic readings may have been distorted (36). The data in this study demonstrated no significant relationship between blood pressure measurements and serum PCB levels. As stated previously, both blood pressure measurements and serum PCB levels increased with age. However, further study in this area might include experimental designs with comparison groups stratified by age, etc. which deliberately control for extraneous variables such as pesticide exposure and renal function as well as a variety of health habits such as diet and exercise.

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CHAPTER V

CONCLUSIONS

It is noteworthy that relatively few persons had elevated serum levels of PCB. This seems to indicate very little evidence of above normal exposure to PCBs among residents of the Greater New Bedford area. The findings suggest that the EPA ban of open-system use of PCBs in 1979 and the closure of New Bedford Harbor to fishing by MDPH in 1979, coupled with the considerable publicity over the hazards of eating locally-caught seafood have contributed to reductions of exposure via the food chain in recent years. It is also noteworthy that of those residents that were randomly selected (for determination of prevalence) less than 15% reported eating locally trapped lobster five or more times in their life and less than 2% report eating locally-caught eel; of those residents selected for participation for purposes of enrichment 63% reported eating locally-trapped lobster five or more times in their life and 25% reported eating locally-caught eel. These particular species were found to contain high levels of PCBs in the late 1970's (21), with concentrations in eels of up to 730 ppm and concentrations in lobster as high as 68 ppm and frequently greater than 10 ppm (2). Almost all individuals who were identified as being at the greatest risk of exposure via contaminated seafood intake, had relatively low serum PCB levels.

The risk of occupational exposure to PCBs has also greatly diminished since 1979. The serum PCB level analyses by quartile for occupational and material exposures for respondents of the enrichment study showed a higher frequency in the upper quartiles for those employed in electrical manufacturing. Exposure to certain types of materials are also seen with greater frequency in upper quartiles.

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Observations among participants of the prevalence sample indicated higher frequencies in upper quartiles for those employed in manufacturing Weak trends were also observed among males exposed to lubricants and rubber. Because there is little consistency between the two study groups and because data cells had very low frequencies, occupational exposures were not seen as an important contributor to elevated PCB body burdens in Greater New Bedford.

The conclusions to be drawn from the Greater New Bedford PCB prevalence investigation are: 1) that the prevalence of elevated serum PCB exposure among residents of Greater New Bedford is low; 2) even the residents at highest risk of PCB exposure from locally caught seafood consumption, for the most part, had levels within the typical range of the U.S. population; and 3) low and moderate serum levels of PCBs in this population do not appear to be associated with elevated blood pressure measurements. Enrichment sample analyses support the finding of the prevalence study with regard to decline in levels. It is possible that this group of individuals with "higher" PCB levels during the 85-86 investigation, may have had even greater levels if the investigation been conducted several years earlier, prior to the ban of open-system PCB use and fishing in and around the New Bedford harbor.

There are conflicting studies as to whether PCB exposure is related to blood pressure, independent of age and body mass. The Triana study showed a positive correlation after controlling for age, sex and Hollingshead index (2). The findings from that study differ from the New Bedford prevalence study in two important aspects:

(1) The levels of both blood pressure and serum PCB level were considerably higher in Triana than in New Bedford and,

(2) The rates of borderline and definite hypertension in Triana were

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30% higher than those found on the National Health Survey, while those in New Bedford were within the normal U.S. range.

In addition, 21.4% of the Triana subjects had PCB serum levels greater than 30 ppb. It would appear that if there is a relationship between serum PCB level and blood pressure it is possible that there exists a threshold for the level of PCB that effects blood pressure. Any variation in blood pressure levels among participants of both the prevalence study and the enrichment study may be explained by age and body mass.

Because the literature on the half-life of PCBs in humans is sparse, it is not posssible to estimate how much higher serum PCB levels may have been several years ago. We conclude that low and moderate serum levels of PCBs do not appear to be associated with increased blood pressure readings. It should be noted that the residents of Triana were also heavily exposed to DDT and that serum PCB levels were correlated strongly with DDT serum levels, although DDT showed no effect in the regression model. Other studies have shown correlations between exposure to organochlorine pesticides in association with higher levels of blood pressure (6). Further studies should be attempted in populations with heavier PCB exposure which is not confounded by pesticide exposure to rule out the effects on blood pressure at higher exposure levels than were seen in the Greater New Bedford PCB Health Effects Study.

Although some of our findings support positive trends with past occupational and industrial exposures among those in the highest quartile of PCB level, the majority of those respondents still had levels within the typical U.S. range and it is likely that these levels will decrease over time as well. The GNBHES has generated a large data base that merits continued analysis.

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RECOMMENDATIONS

(1) The current ban on fishing in and around the New Bedford harbor (i.e., the closure areas) should remain in effect until measurements in aquatic life decline to acceptable standards. Monitoring should be targeted on those species found to be consumed with the greatest frequency by the Greater New Bedford population.

(2) The Phase II study should not be conducted due to lack of a sufficient sample-size of 150 persons with PCB serum levels $\geq$ 30 ppb.

(3) Residents should refrain from obtaining and consuming recreationally caught seafood from the closure areas.

(4) Data collected for the GNBHES should be subjected to further analysis.

(5) Small scale follow-up studies should be designed by the MDPH to pursue certain areas of health research.

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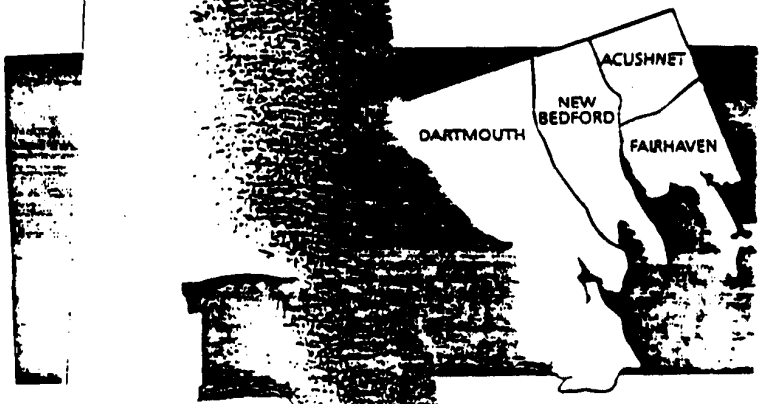
The Greater New Bedford PCB Health Effects Study 1984-1987

A P P E N D I C E S

A Collaborative effort of:

- The Massachusetts Depar ment of Public Health
- The Massachusetts Hea Research Institute
- The U.S. Centers for Dis Control



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APPENDIX A

STAFF

ACKNOWLEDGEMENTS

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Appendix A

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY STAFF

NAME	TITLE
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Greater New Bedford Health Effects Study

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617/996-8556 617/996-8571

Caro Sr.

O seu nome foi seleccionado para participar num Estudo sobre os Efeitos de Saúde na área de New Bedford. Foi escolhido, ao acaso, duma lista cientificamente próprio para constituir uma amostra representativa das pessoas residentes na área de New Bedford. O objectivo deste estudo é para investigar as possíveis problemas de saúde devidas à exposição aos produtos químicos bifenis policlorinados (vulgarmente conhecidos por PCB(s)) entre os residentes de New Bedford, Dartmouth, Fairhaven e Acushnat e possíveis efeitos adversos na saúde relacionados com esta exposição. Com certeza já ouviu falar da contaminação do porto de New Bedford por PCB(s) e da investigação que a Agência Federal de Protecção ao Ambiente (EPA) está a levar a efeito.

Aproximadamente uma pessoa em cada 30, de idades entre 18 e 64, residentes nas quatro cidades mencionadas, será seleccionada para participar no estudo. Para que o estudo seja o mais exacto possível, é necessário que todas as pessoas escolhidas para representar a comunidade respondam ao estudo e não se podem fazer substituições. A informação será utilizada unicamente para fins estatísticos e as pessoas que forem entrevistadas estarão a prestar um serviço importante contribuindo para um melhor conhecimento dos efeitos dos PCB(s) na área de New Bedford.

Vamos contactar as pessoas seleccionadas pelo telefone para informar que foram escolhidas para o estudo e para marcar uma entrevista nos nossos escritórios. Toda a informação fornecida pelas pessoas entrevistadas será confidencial e a entrevista deverá durar cerca de uma hora. Durante esta entrevista vamos fazer-lhe algumas perguntas, tirar amostras de sangue e fazer a urina e medir a tensão arterial, a altura e o peso. Os nossos escritórios vão estar abertos nas dias de semana à noite e nos fins de semana para que seja conveniente para as pessoas.

O Estudo sobre os Efeitos de Saúde fornecerá um melhor conhecimento sobre a exposição aos PCB(s) no ambiente de New Bedford e arredores e será informação a adicionar ao que já se sabe sobre este tipo de contaminação em geral. Nos próximos dias vamos contactar consigo pelo telefone para marcar uma entrevista. Se o seu número de telefone não faz parte de lista telefónica, por favor telefone para 996-8556 e peça para falar com Maria Medeiros.

Para mais informações sobre este inquérito, por favor telefone ou visite os nossos escritórios. Agradecemos desde já a sua participação neste importante estudo.

Julius Walker, Jr., Ph.D., M.P.H.
Comissário do Departamento de
Saúde Pública de Massachusetts

Renee Racine
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APPENDIX C

LETTER TO AREA PHYSICIANS

APPENDIX B
LETTER TO RESPONDENTS

Greater New Bedford Health Effects Study

46 Foster Street/Foster Hill Place
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617/996-8556 617/996-8571

Dear

You have been selected to participate in the Greater New Bedford Health Effects Study. Your name has been selected, entirely by chance, as part of a scientifically planned random sample of persons residing in the Greater New Bedford Area. The purpose of the study is to investigate human exposure to polychlorinated biphenyls (PCB) among residents of New Bedford, Dartmouth, Fairhaven and Acushnet and possible adverse health effects related to that exposure. You may have heard about PCB's in regard to the contamination of the New Bedford Harbor being investigated by the Environmental Protection Agency.

Approximately one in every 50 people aged 18 to 64 in the four towns will be requested to participate in the study. In order for this to remain an accurate sample, we need the responses of every resident that has been selected to represent the whole community, and so are not allowed to make substitutions. The information will be used only for statistical purposes and you and the others who are interviewed will be making an important contribution to current knowledge and effects of PCB's in the Greater New Bedford Area.

We will be contacting selected residents by telephone to request that they participate in the study, and to arrange a personal interview at our office. Information provided by study subjects will be confidential, and the interview should only take about one (1) hour. At this interview, a staff person will ask you to answer a set of survey questions, take blood and urine specimens, and measure the participant's blood pressure, height and weight. The project office will be open weeknights and weekends as a convenience to you.

The Health Effects Study will contribute important information about the extent of human exposure to PCB's in the environment of New Bedford and surrounding towns, and will add to the growing body of knowledge on this type of contamination in general. We will be trying to contact you by telephone within several days to set up an appointment. If your telephone number is unlisted or you do not have a telephone please contact us at 996-8556.

If you have any questions about this survey, please contact the Study office. We greatly appreciate your participation in this important study.

Bailus Walker, Jr., Ph.D., M.P.H.
Commissioner
Massachusetts Department of Public Health

Rene V. Racine
Acushnet Board of Health

Katherine Kirk Stern
Dartmouth Board of Health

Marcia Bueno, M.D.
Director, Department of Health
City of New Bedford

Edward J. Moe, D.D.S.
Fairhaven Board of Health

A cooperative effort of Massachusetts Department of Public Health and the Massachusetts Department of Public Health

MONS 027732

APPENDIX B

LETTER TO SELECTED RESPONDENTS



APPENDIX C
LETTER TO AREA PHYSICIANS

Greater New Bedford
alth Effects Study

April 25, 1989

Foster Street/Foster Hill Place
New Bedford, Massachusetts 02740-6601
617/996-8556 617/996-8871

Dear Doctor:

The Massachusetts Department of Public Health and the Centers for Disease Control, with funding from the Environmental Protection Agency Superfund, is conducting a health effects survey of persons living in New Bedford, Fairhaven, Acushnet, and Dartmouth. The purpose of the study is to investigate human exposure to polychlorinated biphenyls (PCB's) among residents of the New Bedford area and possible adverse effects related to that exposure.

Approximately one in every 50 persons aged 18 to 64 in the four towns will be selected at random and requested to participate in the study. In order to assure a valid outcome, we need the cooperation of every resident selected.

We will be sending chosen residents a letter, signed by the Commissioner of Health and representatives of the four local Boards of Health, informing them of their selection and requesting their participation in the study. A follow-up phone call will be made to arrange a personal interview at the study office. At this interview, trained staff members will ask a set of survey questions, take blood and urine specimens, and measure the participant's blood pressure, height and weight.

The question of a relationship between PCB level and diastolic blood pressure will be specifically investigated. We anticipate that some of the respondents in our study will be found to have elevated blood pressures. Using standards established by the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure, all respondents with borderline or definitely elevated blood pressure will be referred to their personal physician. Those without a personal physician will be urged to seek one immediately. Respondents with a systolic blood pressure of greater than 200 mm Hg or a diastolic greater than 115 mm Hg will be referred immediately to their personal physician.

Blood specimens will be analyzed for PCB levels by the Massachusetts Department of Public Health State Laboratory. The Centers for Disease Control is responsible for the maintenance of quality control procedures. In a sample of the respondents, the blood specimen will also be screened for lead, and the urine specimen used to determine arsenic and mercury levels.

This study will contribute important information about the extent of human exposure to PCB's in the Greater New Bedford area and add to the growing body of knowledge concerning the impact of environmental contamination on human health. We solicit your interest and support of this study and welcome any questions you may have concerning it or any of the participants who may also be your patients. We have enclosed a flyer announcing the study; we would appreciate your posting it in your waiting room or clinic. Please feel free to call me or Ms. Susan Ellis, the Project Director, at any time.

Sincerely yours,

Norman C. Tolles, M.D.
Medical Consultant

A cooperative effort of Massachusetts Department of Public Health and Massachusetts Health Research Institute, Inc.

APPENDIX D

LETTER TO AREA EMPLOYERS

APPENDIX D
LETTER TO AREA EMPLOYERS

Greater New Bedford Health Effects Study

0557 Street/Foster Hill Place
New Bedford, Massachusetts 02740-6601
617/990-0586 617/990-0571

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

The Massachusetts Department of Public Health, in cooperation with Massachusetts Health Research Institute, Inc. and the Centers for Disease Control in Atlanta, Georgia, will be conducting a health survey on persons living in New Bedford, Fairhaven, Acushnet, and Dartmouth. This study is designed to investigate possible adverse health effects of polychlorinated biphenyls (PCB's) pollution.

The PCB Health Effects Study is pleased to announce that the Board of Directors of the Greater New Bedford Area Chamber of Commerce has unanimously endorsed our study efforts. We welcome the opportunity to have local employers cooperate in our investigation of the health of the population.

The Greater New Bedford Area has a well-defined PCB pollution problem, principally due to contamination of the "Acushnet River." These PCB's have entered the food chain by contamination of lobster and other seafood, leading to potential exposure of many New Bedford area residents. Additionally, other area residents have had exposure via skin and respiratory absorption while employed at local capacitor manufacturing plants. Exposure to these sources of PCB's has been documented by previous investigations. As a result, there is public concern about possible long-term health effects.

The Health Effects Study will interview a representative sample of 1400 persons between the ages of 18 and 64, who have resided in the area for at least 5 years. Blood and urine testing will be done to determine the level of PCB contamination in the population, plus certain other environmental contaminants such as mercury and lead. Interview data will determine route of exposure, and blood pressure measurements will test the hypothesis of blood pressure correlation with the PCB blood level. A questionnaire will also provide information about the health status of the persons interviewed. Spanish and Portuguese translation will be provided to assure the participation of persons speaking these languages. Appointments for the interview and PCB measurement will be made with the randomly selected residents by direct or telephone contact by project staff.

PCB testing requires that subjects abstain from food for 12 hours before the blood sample is taken. To accomplish this the Greater New Bedford Health Effects Study project is seeking the cooperation and support of employers to allow any employees chosen by chance to participate in the program. The time needed to collect the data is expected to average one to one-half hours per respondent. For the reasons given above, it is essential to the integrity of the study that a high rate of participation be achieved. In this regard staff members from the project will occasionally call employers for their support. Such support may take the form of a request to allow an employee, for example, to arrive late at work, or to take an extended mid morning break on the day of the appointment.

Enclosed is a flyer about the study - similar posters are now being distributed in the New Bedford area. If there is a place at your company where this could be hung, we would appreciate your thoughtfulness.

MONS 027736

APPENDIX E

CERTIFIED LETTER

APPENDIX E
CERTIFIED LETTER

Greater New Bedford Health Effects Study

Foster Street/Foster Hill Place
New Bedford, Massachusetts 02740-6601
617/996-8556 617/996-8571

January 21, 1986

Dear Resident:

Our office has attempted to contact you, without success, on several occasions during the past several months. Perhaps you are unaware of our continuing efforts to determine the extent to which New Bedford residents may be at risk of possible exposure to the industrial toxin PCB, which has contaminated the New Bedford harbor and the Acushnet River Estuary.

The present phase of our study involves the random (computerized) selection of Greater New Bedford residents who are requested to donate one hour of their time for an interview concerning their health, residential and occupational history, and fish consumption. You were randomly selected and we sincerely need your help. If you choose not to participate, we cannot replace you: as a selected respondent, you represent many other residents as well. It will be very difficult for us to determine how widespread PCB exposure is among residents of the Greater New Bedford community if we do not get full co-operation from every randomly-selected respondent.

Even if you decide not to assist us, we would appreciate confirmation by either phone (996-8566) or by mail: Greater New Bedford Health Effects Study, 46 Foster St./Foster Hill Place, New Bedford, MA 02740-6601.

I urge you to participate in this very important study and thank you for you co-operation.

Sincerely,

Suzanne K. Conlon,
Project Director

MONS 027738

POR FAVOR AJUDANOS

PARA NOS PODER

OS AJUDAR

MONS 027739

Greater New Bedford
Health Effects Study

46 Pooter Street/Pooter Hill Place
New Bedford, Massachusetts 02740-6601
617/996-8556 617/996-8571

February 3, 1986

Caro (a) Residente,

Nos últimos meses e por várias ocasiões, o nosso escritório tentou entrar em contacto consigo, sem conseguir. Talvez você não tenha conhecimento dos nossos esforços contínuos para determinar a extensão dos riscos que correm os residentes de New Bedford se forem expostos ao toxina industrial PCB que contaminou o porto de New Bedford e o estuário do rio Acushnet.

A fase presente do nosso estudo envolve a selecção ao acaso (computorizada) de residentes de New Bedford e arredores que contribuirão, a nosso pedido, com uma hora do seu tempo para uma entrevista que tem a ver com a saúde, a história de suas residências e ocupações e o seu consumo de peixe. Você foi seleccionado (a) ao acaso e precisamos sinceramente de sua ajuda! Se você não quiser participar, não podemos substituí-lo (a); como respondente seleccionado, você representa muitos outros residentes também. Será muito difícil determinar qual a área de dispersão da exposição aos PCB's entre os residentes da comunidade de New Bedford e arredores, se nós não tivermos a cooperação absoluta de todos os respondentes seleccionados ao acaso.

Mesmo que você decida a não nos assistir, nós gostaríamos que confirmasse a sua resposta por telefone 996-8556 ou por correio: Greater New Bedford Health Effects Study, 46 Pooter St./Pooter Hill Place, New Bedford, MA 02740-6601.

Eu recomendo que participe neste estudo muito importante e agradeço a sua cooperação.

Sinceramente,

Suzanne K. Condon

Suzanne K. Condon,
Directora do Projecto

PLEASE HELP US TO

HELP YOU

MONS 027741

APPENDIX F

LETTER TO ENRICHMENT PARTICIPANTS

APPENDIX F
LETTER TO ENRICHMENT SAMPLE

Greater New Bedford
Health Effects Study

Foster Street/Foster Hill Place
...w Bedford, Massachusetts 02740-6601
617/996-8556 617/996-8571

January 23, 1986

Dear Resident,

You have been selected as a possible participant in the Greater New Bedford Health Effects Study, a scientifically planned study of Greater New Bedford residents who may have been exposed to polychlorinated biphenyls (PCB's). You may have heard about PCB's in regard to the contamination of the New Bedford Harbor and the Acushnet River Estuary, currently being investigated by the U.S. Environmental Protection Agency. The purpose of our study is to investigate human exposure to PCB's among the residents of Acushnet, Dartmouth, Fairhaven and New Bedford.

The information collected will be used only for statistical purposes, and you and other participants will be making an important contribution to our knowledge of the effects of PCB's in the Greater New Bedford area. We will be contacting you in regard to this matter in the near future. Information collected will be kept in strict confidence.

If you have questions regarding this letter or if your telephone number is not listed, won't you please call us at 996-8201.

Sincerely,

Suzanne K. Condon,
Director

MONS 027743

Greater New Bedford
Health Effects Study

4 ...ster Street/Foster Hill Place
New Bedford, Massachusetts 02740-6601
617/996-8556 617/996-8571

February 5, 1986

Caro (a) Residente,

Você foi seleccionado (a) como um (a) possível participante de um programa de estudo de saúde desta area (Greater New Bedford Health Effects Study). Este programa foi preparado cientificamente para estudar os residentes da área de New Bedford e arredores que possem ter sido expostos aos produtos toxinas PCB's (polychlorinated biphenyl's). Talvez já ouvisses falar dos PCB's em relação à contaminação do porto de New Bedford e do estuário do rio Acushnet, que presentemente estão a ser investigados pela Agência Americana de Protecção ao Meio-Ambiente (U.S. Environmental Protection Agency). O objectivo do nosso estudo é investigar a exposição humana aos PCB's entre os residentes de Acushnet, Dartmouth, Fairhaven e New Bedford.

A informação compilada será usada sómente para fins estatísticos, e você e outros participantes estarão a fazer uma contribuição importante para o nosso conhecimento dos efeitos dos PCB's na área de New Bedford e arredoras. Nós vamos contactá-lo (a) com referência a este assunto no futuro próximo. A informação compilada será guardada com absoluta confidência.

Se você tiver qualquer perguntas acerca desta carta ou se o seu telefone não está na lista, queira fazer o favor de nos chamar pelo número 996-8201.

Sinceramente,

Suzanne K. Condon

Suzanne K. Condon,
Directora

MONS 027744

APPENDIX G

ENRICHMENT SCREENING QUESTIONNAIRE

APPENDIX C

SCREENING

QUESTIONNAIRE

(1) Name: _____
Address: _____
Tel.#: _____

(2) Date of Birth: _____

(3) Length of Residence #yrs.:_____

(4) A/Have you ever worked at Cornell Dubilier, Aerovaux or any other company in which you may have been exposed to PCBs?

☐ yes ☐ no

B/If yes (1) company: _____ (2) # yrs: _____

(5) A/Do you consume any of the following types of seafood?
( ) check if yes

eel ☐ chub ☐ lobster ☐

catfish ☐ drum ☐

carp ☐ bluefish ☐

buffalo fish ☐ striped bass ☐

freshwater fish ☐ mackeral ☐

---

scup, tautog, fluke, flounder, or sea trout ☐

B/Are these types of seafood caught/trapped locally?
(check ( ) appropriate box)

☐ yes ☐ no

C/Can you estimate the total number of years you've been eating these types of fish?

#years = _____

If yes to any types of fish specify frequency:

Number days/week = _____

MONS 027746

(7) How do you obtain fresh seafood?
( ) check appropriate box)

- ☐ catch own
- ☐ family/friends caught
- ☐ other local fishermen
- ☐ supermarkets/grocery stores
- ☐ got none

Interviewer:

If resident is both age & residency eligible and high or moderate seafood consumption SCHEDULE APPOINTMENT.

Seafood Consumption:

High

Moderate

Low

QUESTIONNAIRE POINT SHEET

1) AGE
- 18-34.....0
- 35-39.....5
- 40-44.....10
- 45-49.....15
- 50-54.....20
- 55-59.....25
- 60-64.....30 _____

2) LENGTH OF RESIDENCE
- < 5 years.....0
- 5-9 years.....5
- 10-19 years.....10
- 20-29 years.....15
- 30-39 years.....20
- 40-49 years.....25
- 50-64 years.....30 _____

3) AEROVOX OR CORNELL
- No.....0
- < 5 years.....5
- > 5 years.....10 _____

4) FISH GROUPS
- Eel.....10
- Lobster.....10
- Each other group above line.....5
- Group below line...2 _____

5) CAUGHT LOCALLY
- No.....0
- Yes.....10 X 2=_____

6) YEARS OF FISH CONSUMPTION
- 0-9.....0
- 10-19.....5
- 20-29.....10
- 30-39.....15
- 40-49.....20
- 50-64.....25 _____

7) FREQUENCY OF CONSUMPTION
- less than once/week.....0
- 1-2 times/week.....5
- 3-4 times/week.....10
- 5-7 times/week.....15
- more than 7 times/week..20 _____

8) FISH SOURCE
- catch own.....10
- family/friends.....10
- local fishermen.....03
- supermarkets/fish markets.....03
- got none.....0 X 2=_____

SCORE
- LOW.....__to__points
- MODERATE.....__to__points
- HIGH.....__to__points

MONS 027748

SCREENING QUESTIONNAIRE
INSTRUCTION SHEET

I. Calling Instructions

-Verify the respondent's address.

-If R did not receive our letter, verify the address that you have, explain what the letter said, and offer to send a new one.

-If R asks how you got his/her name, an appropriate answer would be: "I'm a member of the scheduling staff. A number of different lists have been used, and I'm not sure which list your name came from. Names were selected at random.

-If R says that he/she has already been called for our main survey, an appropriate response would be: "I'm very sorry for the inconvenience. Thank you very much."

II. Questionnaire

1) This information should be pre-recorded on the sheet.

2) Ask: "What is your date of birth?" and record on line. For the point sheet, you will convert this date of birth to age.

Ask this question even if DOB or age were given in the original source; this will serve to verify the original information.

3) Ask: "How long have you been living in the Greater New Bedford area which includes New Bedford, Acushnet, Dartmouth, and Fairhaven?"

Do any calculations you need to do in the margin and just record the total number of Greater New Bedford years on the line.

Eligibility requirements for this sample are:
1) Age: 40-65
1) Residency: at least five years in the GNB area
If you find at the end of question #3 that R is not eligible, explain that they do not meet the requirements which we have established and thank them for their time.

4) Ask the question as written.
Possible follow-up probes:
"At which company do you/did you work?"
"For how many years did you work at X?"

You may get multiple spans at one company or work at several different companies. Record in margins if necessary.

If R gives you a company about which you (or R) is not sure (Isotronics, AFG, Epsc, etc.), record the information, and Susanne and Barbara will decide later whether to include it.

5A) Change the question to read as follows: "Have you consumed any of the following types of seafood five or more times in your lifetime?" Check each box to which R says yes. ("Do you" would only account for the present, and we are interested in lifelong patterns. If R questions what we mean by consumption, our criteri will be "five or more times in your lifetime" as in our main survey.

Thus: R: "I'm not sure about carp."
I: "Have you eaten carp five or more times in your lifetime?"
R: "Yes, I have."

5B) Change the question to read as follows: "Are any of these types of seafood caught/trapped locally?"

If you check the box, write in the types of fish which are caught locally.

"Locally" can be explained by using the map we use for the main survey and giving R the boundaries of the harbor area in terms of familiar landmarks: "From north of the Coggeshall Street Bridge due to the dike, including the area around Clark's Cove in the South End, to the Padanaram Bridge and all the way out to Mishaum Point i Nonquit and over to Rest Island in Fairhaven."

5C) Change the question to read as follows: "Can you estimate the total number of years you have been eating any of these types of fish?"

We want the longest time here. If they ate carp from 1929-1935, don't eat it now, but have eaten lobster from 1935-1985, the number of years would be 60.

If you get very vague answers, you may need to probe. Appropriate probes to determine total number of years are used in the main survey:

"How old were you when you first ate chub?"
"What was the last year in which you ate chub?"
Subtract the first year from the last year to get t number of years.

6) Ask: "How often do you eat/have you eaten any of th[illegible] of fish?"

The breakdowns on the point sheet could be used as appropriate probes: "Would you say it's less than once/ week, 1-2 times/week, 3-4 times/week...?", etc.

People who eat fish frequently will fall in the days/ week category; those who eat it infrequently will fall into the days/ month category. If you get information that does not fit neatly into one of these categories--"I eat fish once a year at my grandmother's"--write the information below the line.

7) Change the question to read as follows: "In the years you've been eating fish in the Greater New Bedford area, how have you obtained fresh seafood?" ("Do you" would only include the present, and we are interested in their lifetime fish-consumption habits.)

If R answers "restaurants" or "fish processing plant," write in this information.

"Supermarkets/grocery stores" should read "Fish markets/supermarkets/grocery stores." Any specific proper names--Shaw's, Captain Frank's, etc.,--will be recorded in this box.

At this point, you will schedule an appointment if you know you have an R whose fish consumption is quite high. Total the points. Uncertain cases--mainly "moderates" or "lows"--will be given to Suzanne or Barbara for evaluation.

If you have had a male respondent, you will ask here: "Is there anyone else in your household who eats a lot of fish?" You will then proceed to get the screening questionnaire information for other members of the household who might be potential respondents.

III. Point Sheet

1) Convert DOB to age; circle appropriate category and write in points on line.

2) Circle category and write in points on line.

3) Circle category and write in points on line.

4) For each group above the line, R will get 5 points; for the group below the line 2 points; for eel, 10 points; and for lobster 10 points. Add total and record on line.

5) "Caught locally" will be weighted (X 2) to 20 points.

6) Circle category and write in points on line.

7) Circle category and write in points on line.

8) The first two sources, "catch own" and "family/friends" will each be weighted (X 2). For example, if R gives both of these as sources, he/she would get 40 points.

APPENDIX II

REFUSAL QUESTIONNAIRE

MONS 027752

APPENDIX B

REFUSAL QUESTIONNAIRE

10/12/87

1. Age

   18-29.....1
   30-39.....2
   40-49.....3
   50-64.....4
   Missing.....7

2. Sex

   Male.....1
   Female.....2

3. Native Language

   English.....1
   Portuguese....2
   Spanish.....3
   Other Foreign
     Language....4
   Missing.....7

City/Town

   New Bedford.....001
   Acushnet.....002
   Dartmouth.....003
   Fairhaven.....004

Census Tract

   Missing.....9999

Occupation

   No Occupation
     Available.....997

   Specify Occupation.....

Main Reason for Refusal

	Reason	Date
A. Initial Call		
B. Follow-up Call #1		
C. Follow-up Call #2		
D. Follow-up Call #3		
E. Follow-up Call #4		

MONS 027753

I would like to ask you a few questions which would greatly assist us in better categorizing possible exposures that our refusers may have had.

Date for questions 8-10:.....

8. Have you worked at Aerovox or Cornell Dubilier or any other electrical manufacturing company?

Yes.....1
No.....2
Missing.....7 ——————————→ ☐

9. A. Do you eat a lot of fish and/or lobster?
(If the responding asks what "a lot" means, it means more than three times per week.)

Yes.....1
No.....2
Missing.....7 ——————————→ ☐

9. B. Where do you usually get fish and lobster?

Missing.....97 ——————————→ ☐☐

A. Do you have or have you had any recurring medical problems?

Yes.....1
No.....2
Missing.....7 ——————————→ ☐

B. (If Yes to 12 A)

What are those medical conditions?

1. ..... ☐☐☐☐

2. ..... ☐☐☐☐

3. ..... ☐☐☐☐

Retrieved Refusal

Yes.....1

No.....2 ——————————→ ☐

MONS 027754

CODES FOR MAIN REASON FOR REFUSAL (Q.8)

01 Too busy; No time ("I just don't have the time.")

02 Not interested ("I'm just not interested.")

03 Concern about privacy or confidentiality ("I just don't do surveys.")

04 Tired of surveys; Doesn't want to be a guinea pig

05 AIDS

06 Fear of giving blood (and/or fear of needles); Doesn't want to give blood

07 Physical/medical/emotional reasons

08 Cannot fast because of a physical condition

09 Physician advises against it

10 "I haven't had anything to do with PCB's anyway."

11 "There is nothing to do about PCB's anyway."

12 Information put out that there was not a problem

13 Logistical details: car, small children, invalid relatives, etc.

14 Cannot get time off from work

15 Spouse doesn't want Respondent to do it

16 The put-off ("Not now; maybe later.")

17 The hang-up with no reason

18 No clear reason given ("I just don't want to.")

19 Any other specific reason not listed above

20 People whom we declared Final Refusals after contact efforts produced no result. Contact efforts included 30 or more calls, 3 or more Home Visits scheduled for morning, evening, and Saturday, and/or 4 or more No Show appointments, in addition to certified letters. (6/3/86)

21 Initial Refusals who were declared Final Refusals with a second call because of the need to finalize all data (6/6/

APPENDIX I

MAIL-OUT REFUSAL QUESTIONNAIRE

APPENDIX I

MAIL-OUT REFUSAL QUESTIONNAIRE

Greater New Bedford
'ealth Effects Study

Foster Street/Foster Hill Place
v Bedford, Massachusetts 02740-6601
617/996-8556 617/996-8571

February 12, 1986

Dear

You were selected as a possible participant in the Greater New Bedford Health Effects Study, and at the time our staff contacted you, you decided not to participate.

I am enclosing a brief refusal questionnaire; I would appreciate it if yo would fill out the three questions and return it to us in the enclosed stamped self-addressed envelope. This information, which will be kept confidential, will enable us to better characterize the types of people that have not participated in our investigation (not individually but as a group) so that we may incorporate this into our final report on environmental contamination in the Greater New Bedford Community.

Please feel free to call me at 996-8556 should you have questions regarding the enclosed.

Sincerely,

Susanne K. Condon

Susanne K. Condon
Project Director

MONS 027757

MAIL-OUT REFUSAL QUESTIONNAIRE

Please check the appropriate box or fill in the applicable information:

1. Have you ever worked for Aerovox or Cornell-Dubilier or any other electrical manufacturing company?

YES ___ NO ____

2. A.
Do you eat a lot of fish and/or lobster? (i.e. 3 or more times per week)

YES ____ NO ____

B.
Where do you usually get fish and lobster?

---

3. Do you have or have you had any recurring medical problems?

YES ____ NO ____

(If yes to #3 only)

4. What are those medical conditions?

1) _____

2) _____

3) _____

APPENDIX J

COVER SHEET/CALL RECORD

APPENDIX J

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

(HARD COPY)

TOWN: _____ AGE ELIGIBLE: YES/NO

RANDOM #: _____ 5 YEARS ELIGIBLE: YES/NO

(WARD/) PRECINCT: _____ BATCH #: _____

SAMPLED RESPONDENT

FIRST	MIDDLE	LAST	DOB
NO.	STREET		OCCUPATION
TOWN/CITY		ZIP CODE	PHONE (HOME)

CURRENT ADDRESS (IF DIFFERENT FROM ABOVE):

NO.	STREET		
TOWN		ZIP CODE	PHONE

1. ASK FOR R BY FIRST AND LAST NAME. IF AVAILABLE, GO TO 2.

   IDENTIFY YOURSELF AND PROJECT: RETURN TIME? WORK NUMBER?

   AFTER FIVE CALLS, REVIEW WITH DATA MANAGER.

2. LETTER?: Hello, I am _____(name) from the PCB Health Effects Study. Did you receive a letter from the State and local Health Departments explaining that I would be calling?

   IF NO: Well, let me explain. We are working with the Massachusetts Department of Public Health to study the health effects of PCB's, the chemical that has contaminated the New Bedford Harbor. You and 1400 others have been chosen, entirely by chance, to help us find out about the health of residents of this area.

3. CHECK: (a) How old were you on your last birthday? _____
   IF <18 OR >64, TERMINATE.

   (b) CONFIRM ADDRESS DATA.

   (c) Have you lived in either Acushnet, Dartmouth, Fairhaven, or New Bedford for a total of five years at any time in your life?

   IF YES: IF R >44 ASK: Have you lived in this area for 5 years since 1940?

   IF NO: TERMINATE.

5/28/85

4. INTERVIEW TIME: Morning? A.M.: 7 8:30 10 11:30
Fasting
Do you smoke? (Can confirm with employer.

5 APPOINTMENT: (a) Questions about places you have lived in the NO area:
(b) Different jobs you have held;
(c) Urine specimen, to keep that in mind;
(d) Current medications? (bring bottles or tubes);
(e) Short-sleeved clothing/shirt);
(f) Fasting: Most importantly, in order to most accurately measure PSA's, we need you to not eat anything and drink only water for the 12 hours before you come in, that is, from _____, the night before - nothing but water.
(g) DIRECTIONS:
(h) REMINDER CALL: Can you on _____(DATE/TIME APPT)

CALL RECORD

/CALL/INT/CALL TIME/	/	/RESULT/	REASONS/COMMENTS/SUGGESTIONS
/__8__/__8__/__00__/__00__/__DATE__/__DAY__/__AM__/			
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/____/____/____/____/____/____/____/			
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/____/____/____/____/____/____/____/			

^WRITE "A" BEFORE CALL NUMBER IF MADE APPOINTMENT
^^USE THE FOLLOWING ABBREVIATIONS:

NA	= NO ANSWER	LM/PSO	= LANGUAGE REQUIRED	RC	= REMINDER CALL BACK
B	= BUSY SIGNAL	A	= APPOINTMENT MADE	IR	= INITIAL REFUSAL
NAH	= NOT AT HOME	I	= INTERVIEW	HV	= HOUSE VACANT
NAHH	= NAH, HOME VISIT	PR	= PHLEBOTOMY	VH	= VACATION/HOSPITAL
				DRC	= DECEASED/IN HH

^^^COMPLETE RECORD FOR EACH OF THE FOLLOWING INFORMATION AS POSSIBLE.
REFUSER_____ SEX_____ PSA#, FINAL(S) _____ AGE_____ (OR_____

MAILING RECORD_____ _____ ____ _____

APPENDIX K

CONSENT FORM

APPENDIX K

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
GREATER NEW BEDFORD PCB HEALTH STUDY
CONSENT FORM - PHASE I

I understand that the Massachusetts Department of Public Health is conducting a study in Greater New Bedford to determine whether blood levels of polychlorinated biphenyls (PCBs) are associated with alterations in the health status of exposed persons and that I have been asked to participate in this study.

A blood sample will be taken as part of this study to determine the level of PCB's or other environmental contaminants in the blood. The blood will be taken from a vein in the arm and will require the use of a hypodermic needle and syringe. Approximately 65 ml of blood will be drawn which is equal to slightly more than 4 tablespoons. This procedure usually involves little pain or discomfort, but occasionally some discomfort may occur after the blood sample is obtained. My blood sample will be tested for PCB's and a portion of my blood will be stored for future studies which may be indicated. In addition, some blood samples may also be tested for chlorinated hydrocarbons and/or blood lead.

An interview and questionnaire will be given by project staff. In addition, my height, weight, and blood pressure will be measured and a urine specimen collected by project medical staff. A portion of my urine specimen will be stored for future studies which may be indicated. Some urine samples may be tested for urinary mercury and urinary arsenic.

I am aware that the physicians who evaluate my test results will inform me and/or my physician of any unusual medical condition which in their opinion indicates the need for further evaluation by my physician.

I understand that the Massachusetts Department of Public Health and all persons who conduct this study will use information which I provide and the results of my tests only in accordance with the confidentiality provisions of the study protocol and will not make public any particular information which could readily be associated with me.

All results of my tests will be reported to me and/or to my physician within several months after laboratory analysis. I understand that my urine specimen may not be analyzed but may be stored for future analysis if that is indicated. However, I understand that I will not be notified of the results of my PCB blood tests (and chlorinated hydrocarbon tests, if performed) until after the completion of all Phase II blood collection. I also understand that this step is being taken to allow time for the laboratory tests to be completed and to insure the scientific integrity of the final study results by removing possible sources of bias.

I understand that I am not under any obligation to participate in the study and that I can end my participation at any time. I also consent to being recontacted for follow-up questions at a later date and for possible inclusion in Phase II of the study, which will involve a new consent participant agreement

I have read and understood the above statement, and I hereby agree to participate in the study

NAME . .. . DATE .....

If you have any questions about this study or reactions to tests, please contact Dr. David Guta of the ADPN [illegible]

WITNESS .... DATE ....

APPENDIX L

SURVEY INSTRUMENT

MONS 027765

APPENDIX I
SURVEY INSTRUMENT

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

CONSENT FORM SIGNED: _____ DATE: → [ ][ ] [ ][ ][ ][ ]
mo day yr

INTERVIEWER INITIALS: _____ TIME INTERVIEW STARTS: → [ ][ ] [ ][ ]

PHLEBOTOMY

INTRODUCTION:

I am going to be asking you some questions about your health and your experiences living in the New Bedford area. Some questions may not apply to you, but I have to ask them to be certain. In order for your answers to be most helpful to us, it is important that you try to be as accurate as you can. We are asking you to really think hard, take your time in answering, and to search your memory for the information I need. There are no right or wrong answers; I'm most concerned that my questions are clear and that you give exact answers. In order to most accurately record your answers, would you mind my using this tape.

1. How would you rate your health compared to persons your own age? Would you say it is _____(READ LIST)?

   Excellent.....1
   Very Good.....2
   Good.....3
   Fair.....4
   Poor.....5

   → [ ]

2. HEALTH STATUS:

A. What were you doing most of the past 12 months -- working at a job or business, keeping house, going to school, or something else?

   WORKING.....1 (GO TO B)
   KEEPING HOUSE.....2 (GO TO D)
   GOING TO SCHOOL.....3 (GO TO C)
   OTHER.....4 (GO TO C)

   → [ ]

B. Does any impairment or health problem NOW keep you from working at a job or business?

   YES.....1 (GO TO J)
   NO.....2 (GO TO C)

   → [ ]

C. Are you limited in the kind or amount of work you can do because of any impairment or health problem?

   YES.....1 (GO TO J)
   NO.....2 (GO TO I)

   → [ ]

(final: 5/7/85)

(Q2 CONT'D)

D Does any impairment or health problem now keep you from doing any housework at all?

YES.....1 (GO TO F) → ☐
NO.....2 (GO TO E)

E. Are you limited in the kind or amount of housework you can do because of any impairment or health problem?

YES.....1 (GO TO F) → ☐
NO.....2 (GO TO G)

F. About how long have you been limited in (unable to) _____?

_____ OR _____ _____ OR _____ CODE: YEARS ☐☐
DAYS WEEKS MONTHS YEARS

What is the main condition causing this limitation?

CONDITION: _____ CODE: ☐☐☐☐

Is this limitation caused by any other condition?

YES.....1 → ☐
NO.....2

IF YES, SECOND CONDITION: _____

GO TO G.

G. Does any impairment or health problem keep you from working at a job or business?

YES.....1 (GO TO J) → ☐
NO.....2 (GO TO H)

H. Are you limited in the kind or amount of work you could do because of any impairment or health problem?

YES.....1 (GO TO J) → ☐
NO.....2
IF NO: IF ENTRY IN F, GO TO Q3.
IF NO ENTRY IN F, GO TO I.

I. Are you limited in ~~SEX~~ any in ~~SEX ACTIVITIES~~ because of an impairment or health problem?

YES.....1 (GO TO J) → ☐
NO.....2 (GO TO Q3)

(Q2 CONT'D)

J. About how long have you been limited in (unable to) _____?

_____ DAYS OR _____ WEEKS _____ MONTHS OR _____ YEARS

CODE: YEARS

What is the main condition causing this limitation?

CONDITION: _____

CODE:

Is this limitation caused by any other condition?

YES.....1
NO.....2

IF YES, SECOND CONDITION: _____

3. SEX:

MALE.....1
FEMALE.....2

4. How old were you on your last birthday? _____
And the date of your birth is?

5. BLOOD PRESSURE #1:
I'm going to be measuring your blood pressure three times during this interview.

30 SEC RADIAL PULSE: _____ CODE I2:

IRREGULAR PULSE: YES.....1
NO.....2

SYSTOLIC: _____
DIASTOLIC: _____ RES: _____

CODE SYS:
CODE DIAS:

ARM: RIGHT.....1
LEFT.....2

TIME:

6 What city and state were you born in?

_____
CITY/STATE/COUNTRY

CODE: CITY

7. What nationality group would you say you belong in more than any other? (R's ancestors). (SHOW CARD #1) Please choose one from this card.

PORTUGUESE.....01
CAPE VERDEAN.....02
BRAZILIAN.....03
PUERTO RICAN.....05
MEXICAN.....06
CUBAN/CARIBBEAN/SO. AMERICAN.....07
SPANISH.....08
ENGLISH/SCOTTISH/WELSH.....10 → ☐
CANADIAN.....11
FRENCH.....12
FRENCH CANADIAN.....13
IRISH.....14
ITALIAN.....15
POLISH.....16
MIXED.....90
SPECIFY OTHER_____91
DON'T KNOW.....99

8. How many years of school have you completed?

NO FORMAL SCHOOLING.....00
GRAMMAR SCHOOL.....01
.
08
HIGH SCHOOL: FRESHMAN.....09
SOPHOMORE.....10
JUNIOR.....11
GRADUATE.....12 → ☐
COLLEGE: 1ST YEAR.....13
2ND YEAR.....14
3RD YEAR.....15
GRADUATE.....16
GRADUATE STUDIES.....17

RESIDENTIAL HISTORY

Now I need to find out about places you have lived. We're going to start with your current address and work backwards in time. Please include time spent in the military, away at school, job assignments out of this area, etc.

9. When did you move into your present house at _____ _____ (COVER SHEET)?
(no.) (street) (city/town)

_____/_____
MONTH YEAR

CODE: # of MONTHS ☐

10. PREVIOUS ADDRESSES:

ASK THE NEXT TWO QUESTIONS UNTIL NON-GMS AREA:
PUT ADDRESSES AND DATES IN TABLE

A. (1) What was your previous residence?

(2) When did you move into_____(Q10A(1) - address)?

WHEN NON-GMS-AREA, RECORD CITY/STATE

AND ASK: Previous to _____/_____(last date), did you live in Bluebe
month year
Acushnet, Dartmouth, Fairhaven, or New Bedford at any earlier time? (1940 Or

	ADDRESS/NO./STREET/CITY	DATE(MONTH/YEAR)	CODE: CT	/CODE: MN
1.				
2.				
3.				
4.				
5				
6.				
7.				
8.				
9				
10				
11				

B SUPPLEMENTAL RESIDENCE SHEET USED

YES. 1
NO. . . . . 2 → ☐

OCCUPATIONAL_HISTORY

Now I want to review your employment history and the types of industries you have worked for. I'm also interested in different positions you have had with each company.

11. Over the PREI_INS_SCENE, were you working either full time or part time?

WORKING FULL TIME.....1 (GO TO Q12)
WORKING PART TIME.....2 (GO TO A)
NOT WORKING.....3 (GO TO B)

A. WORKING PART TIME:
Are you a full-time student?

YES.....1 (GO TO Q12)
NO.....2 (GO TO Q12)

B. NOT WORKING:
Are you a full-time student?

YES.....1 (GO TO D)
NO.....2 (GO TO C)

C. What best describes your major activity over the PREI_INS_SCENE?

READ LIST:

Homemaker.....01
Retired.....02
Laid Off.....03
Unemployed.....04
Disabled Permanently.....05
Disabled Temporarily.....06
Other: SPECIFY: _____07

D. FOR HOMEMAKER, RETIRED, NON-WORKING STUDENT, UNEMPLOYED, DISABLED OR OTHER:
Have you ever had a full time or part time position for which you received an hourly wage or salary?

IF YES: How long ago did you leave this position?

_____ OR _____ OR _____
DAYS MONTHS YEARS

(30 DAYS.....1
30 DAYS - 5 MONTHS.....2
6 MONTHS - 11 MONTHS.....3
1 YEAR+.....4
NEVER EMPLOYED.....5 (GO TO Q21, PAGE 18)
LAID OFF OR RETIRED.....6
CURRENTLY EMPLOYED.....9

12. MOST RECENT EMPLOYER:

A. What company or business do (did) you work for?
(NAME OF COMPANY) _____

LOCAL C OF C LIST.....1-175
OTHER LOCAL.....250
OTHER MASS/R.I. IDENTIFIED CO.....300-399
OTHER MASS/R.I.....500.
OTHER OUT OF STATE.....600

B. What kind of business or industry is (was) this? (i.e., TV REPAIR SHOP, GARMENT FACTORY, RETAIL SUPERMARKET, ROAD CONSTRUCTION.)
(TYPE OF BUSINESS) _____
CODE: INDUSTRY

C. Is this mainly _____(READ LIST)?

Manufacturing.....1
Wholesale Trade.....2
Retail Trade.....3
Other.....4

13. MOST RECENT JOB:

A. What kind of work are (were) you doing?
PROBE: e.g., TV REPAIRMAN, SEWING MACHINE OPERATOR, CIVIL ENGINEER.
KIND OF WORK: _____

B What are (were) your most important activities or duties:
PROBE: e.g., KEEP ACCOUNT BOOKS, FILES, SELL CARS, OPERATE PRINTING PRESS.
DUTIES: _____

C. What is (was) your job title?
TITLE: _____
CODE: OCCUPATION

D. How many months/years have (did) you had this specific position with _____(COMPANY NAME - Q12A)? _____/_____
MONTHS YEARS
CODE: # of MONTHS

14. FOR RESPONDENT WHOSE CURRENT (LAST) JOB WITH LOCAL CATAGLIOS MANUFACTURER: GO TO A (PAGE 8)

FOR OTHERS, ASK: Have you ever worked at Aerovox or Cornell-Dubilier?

YES.....1 (GO TO B) (PAGE 9)
NO.....2 (GO TO Q15) (PAGE 11)

(Q14 CONT'D)

A. (1) COMPANY:

AEROVOX.....1

CORNELL/DUBILIER.....2

(2) When did you start at _____(A/CD)? _____/_____

MONTH YEAR CODE: # OF MONTHS

(3) Including your present position, what kinds of work (have you done/did you do) at _____(A/CD) during (the last/those) _____(Q14A(2)) (months/years)? RECORD BELOW EACH MENTIONED

(4) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) What were your most important activities or duties when you were _____(kind of work)?

(b) During the ____(Q14A(2))(months/years) you were at _____(A/CD), please estimate the total amount of time you _____(kind of work).

	KIND OF WORK	ACTIVITIES/DUTIES	TOTAL TIME (M/Y)	CODE: POSITION	CODE: NOM
a.			M / M / Y		
b.			M / M / Y		
c.			M / M / Y		
d.			M / M / Y		
e.			M / M / Y		
f.			M / M / Y		
g.			M / M / Y		
h.			M / M / Y		

IF A SECOND WORK SPAN AT A/CD, RECORD AT Q14C (PAGE 10).

THEN ASK: Did you ever work for _____(other CD/A)? IF YES, GO TO Q14C(P10)
IF NO, GO TO Q15(P11)

8. FOR PAST EMPLOYEES OF A/CD:

(1) COMPANY:
AEROVOX.....1
CORNELL/DUBILIER.....2 → [ ]

(2) When did you start at _____(A/CD)? _____/_____ → 19[ ][ ]
MONTH YEAR

(3) When did you leave _____(A/CD)? _____/_____ [ ][ ][ ]
MONTH YEAR
CODE: # OF MONTHS

(4) What KIND OF WORK did you do at _____(A/CD) during the last _____(Q14B(2&3))(months/years)? RECORD BELOW EACH MENTIONED

(5) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) What were your most important activities or duties when you were _____(kind of work)?

(b) During the ____(Q14B(2))(months/years) you were at _____(A/CD), please estimate the total amount of time you _____(kind of work).

	KIND OF WORK	ACTIVITIES/DUTIES	TOTAL TIME (M/Y)		CODE: POSITION	CODE: MONTHS
a.			M		[ ][ ][ ]	[ ][ ]
			D			
			Y			
b.			M		[ ][ ][ ]	[ ][ ]
			D			
			Y			
c.			M		[ ][ ][ ]	[ ][ ]
			D			
			Y			
d.			M		[ ][ ][ ]	[ ][ ]
			D			
			Y			
e.			M		[ ][ ][ ]	[ ][ ]
			D			
			Y			
f.			M		[ ][ ][ ]	[ ][ ]
			D			
			Y			
g.			M		[ ][ ][ ]	[ ][ ]
			D			
			Y			
h.			M		[ ][ ][ ]	[ ][ ]
			D			
			Y			

IF A SECOND WORK SPAN AT A/CD, RECORD AT Q14C (PAGE 10)

THEN ASK: Did you ever work for _____(other CD/A)? IF YES, GO TO Q14C(P10)
IF NO, GO TO Q15(P11)

C. SECOND WORK SPAN AT A/CD:

(1) COMPANY:

AEROFOX.....1
CORNELL/DUBILIER.....2 ⟶ ☐

(2) When did you start at _____(A/CD)? _____/_____ ⟶ 19☐
MONTH YEAR

(3) When did you leave _____(A/CD)? _____/_____
MONTH YEAR
CODE: 0 OF MONTHS ☐☐

(4) What KIND OF JOBS did you do at _____(A/CD) during the last _____(Q14C(2&3))(months/years)? RECORD BELOW EACH MENTIONED

(5) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) What were your most important activities or duties when you were _____(kind of work)?

(b) During the ____(Q14C(2))(months/years) you were at _____(A/CD), please estimate the total amount of time you _____(kind of work).

	KIND OF JOBS	ACTIVITIES/DUTIES	TOTAL TIME (M/Y)	CODE: POSITION/	COD NUM
a.			M / Y	☐☐☐	☐
b.			M / Y	☐☐☐	☐
c.			M / Y	☐☐☐	☐
d.			M / Y	☐☐☐	☐
e.			M / Y	☐☐☐	☐
f.			M / Y	☐☐☐	☐
g.			M / Y	☐☐☐	☐

IF A SECOND JOB SPAN AT A/CD, USE CAPACITOR SUPPLEMENTAL.

THEN ASK: Did you ever work for _____(other CD/A)? IF YES, USE SUPPLEMENT
IF NO, GO TO Q15

D SUPPLEMENTAL CAPACITOR SHEET USED:

YES.....1 ⟶
NO.....2

15. Now please think back through all jobs you have ever had or positions you have held with various companies. Include pieces of work that were jobs held in the summer, any military duty, temporary jobs like at Christmas time, part-time positions, as well as full time salaried or wage-based employment.

A. Have you ever employed at any (IF AT A/CD: other) company that manufactured electrical capacitors or transformers?

YES.....1 (GO TO B) ☐
NO.....2 (GO TO Q16) ——→

B. (1) COMPANY: GE, PITTSFIELD.....3 ——→ ☐
OTHER_____.....4

(2) When did you start at _____(Q15B(1))? _____/_____ MONTH YEAR 19☐☐

(3) When did you leave _____(Q15B(1))? _____/_____ MONTH YEAR
CODE: # OF MONTHS ☐☐☐

(4) What KINDS OF WORK did you do at _____(Q15B(1)) during the last _____(Q15B(2&3))(months/years)? RECORD BELOW EACH MENTIONED

(5) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) What were your most important activities or duties when you were _____(kind of work)?

(b) During the ____(Q15C(2))(months/years) you were at _____ (Q15B(1)), please estimate the total amount of time you _____(kind of work).

	KIND OF WORK	ACTIVITIES/DUTIES	TOTAL TIME (M/Y)	CODE: POSITION/	CODE: MONTHS
a.			M / Y	☐☐☐	☐☐
b.			M / Y	☐☐☐	☐☐
c.			M / Y	☐☐☐	☐☐
d.			M / Y	☐☐☐	☐☐

USE CAPACITOR SUPPLEMENTAL FOR ADDITIONAL KINDS OF WORK OR SECOND WORK SPAN

C Did you work at any other company that manufactured capacitors or transformers? _____ IF YES, USE CAPACITOR SUPPLEMENTAL

D. CAPACITOR SUPPLEMENTAL SHEET USED:
YES.....1 ——→ ☐
NO.....2

16. Were you ever in a position that involved the maintenance of electrical equipment?
YES.....1 (GO TO A)
NO.....2 (GO TO Q17)

A. CURRENT JOB: YES.....1
NO.....3
IF YES, PROBE FOR OTHER POSITIONS IN N OF EE. SAME COMP'Y: YES. GO TO (1). IF NO. GO TO (1).

(1) What company or business did you work for?
(NAME OF COMPANY)_____

(2) What kind of business or industry was this?. (i.e., TV REPAIR SHOP. HOME HEATING SYSTEM INSTALLATION.)
(TYPE OF BUSINESS)_____
CODE: INDUSTRY

(3) Was this solely _____(READ LIST)?
Manufacturing.....1
Wholesale Trade.....2
Retail Trade.....3
Other.....4

(4) What kind of work were you doing?_____ PROBE

(5) What were your most important RESPONSIBILITIES: DUTIES:_____ PROBE

(6) What was your job title?_____
CODE: OCCUPATION

(7) What year did you start this position? 19_____

(8) How many months/years did you have this specific position with _____(COMPANY NAME - Q16A(1))? _____/_____
MONTHS YEARS
CODE: # of MONTHS

B. PROBE: FOR ALL positions HELD AT THAT COMPANY.
THEN ASK: Did you work at another company where you were involved in the maintenance of electrical equipment? IF YES, GO TO C.

C. NAME OF COMPANY: _____
TYPE OF BUSINESS: _____ CODE: INDUSTRY

KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____
CODE: OCCUPATION

START YEAR: 19_____

MONTHS/YEARS: _____ OR _____
MONTHS YEARS CODE: # of MONTHS
PROBE FOR OTHER POSITIONS IN N OF EE. SAME OR DIFF'T COMP'Y: IF YES, GO TO SUP

D. SUPPLEMENTAL ELECTRICAL MAINTENANCE SHEET USED:
YES.....1
NO.....2

17. Have you ever worked at the City of New Bedford sewage treatment plant?

YES.....1 (GO TO A) → ☐
NO.....2 (GO TO Q18)

3

CODE: INDUSTRY ☐☐☐

A. (1) What kind of work were you doing?_____ PROBE

(2) What were your most important activities or duties:
DUTIES: _____ PROBE

(3) What was your job title?_____
CODE: OCCUPATION ☐☐☐

(4) What year did you start this position? 19_____ 19☐☐

(5) How many months/years did you have this specific position with the sewage treatment plant? _____/_____
MONTHS YEARS
CODE: # of MONTHS ☐☐☐

PROBE: FOR ALL positions HELD AT SEWAGE TREATMENT PLANT.

B. KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____

CODE: OCCUPATION ☐☐☐

START YEAR: 19_____ 19☐☐

MONTHS/YEARS: _____ OR _____
MONTHS YEARS
CODE: # of MONTHS ☐☐☐

C. PROBE: FOR ALL positions HELD AT SEWAGE TREATMENT PLANT.
USE WASTE TREATMENT SUPPLEMENTAL.

D. SUPPLEMENTAL WASTE TREATMENT SHEET USED:

YES.....1 → ☐
NO.....2

18. Have you ever worked at the New Bedford dump (NEAR AIRPORT)?

YES.....1 (GO TO A)
NO.....2 (GO TO Q19)

3

CODE: INDUSTRY

A. (1) What kind of work were you doing?_____
PROBE

(2) What were your most important activities or duties:
DUTIES: _____ PROBE

(3) What was your job title?_____
CODE: OCCUPATION

(4) What year did you start this position? 19_____ 19

(5) How many months/years did you have this specific position with the dump? _____/_____
MONTHS YEARS

CODE: # of MONTHS

PROBE: FOR ALL positions HELD AT DUMP.

B. KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____

CODE: OCCUPATION

START YEAR: 19_____ → 19

MONTHS/YEARS: _____ OR _____
MONTHS YEARS

CODE: # of MONTHS

C. PROBE: FOR ALL positions HELD AT DUMP.
USE WASTE TREATMENT SUPPLEMENTAL.

D. SUPPLEMENTAL WASTE TREATMENT SHEET USED:

YES.....1
NO.....2

19. Have you ever worked -- even temporarily -- at a job that brought you into contact with any of the following materials or have you worked in companies manufacturing or using the following materials? (READ LIST)

YES.....1
NO.....2

IF YES TO ANY, USE PAGE 16 (Q19A-Q19G) TO RECORD. THEN RETURN TO NEXT MATERIAL.

(1) Adhesives → ☐
(2) Compressor fluids → ☐
(3) Caulking compounds → ☐
(4) Cutting oils → ☐
(5) Dedusting agents → ☐
(6) Dyes → ☐
(7) Flame retardants → ☐
(8) Herbicides → ☐
(9) Hydraulic fluids → ☐
(10) Immersion oil for microscopes → ☐
(11) Lacquers → ☐
(12) Lubricants → ☐
(13) Paints → ☐
(14) Plasticisers → ☐
(15) Putty → ☐
(16) Resins → ☐
(17) Rubber → ☐
(18) Sealants → ☐
(19) Varnishes → ☐
(20) Wax extenders → ☐
(21) Wood preservatives → ☐

IF NO TO ALL OF ABOVE: ..... (GO TO Q20, PAGE 17)

(Q19 CONT'D)
IF YES TO ANY OF ABOVE. USE A TEROSGE.G TO RECORD.

TEEN ASK: Did you work at any other company that used this material or another job that brought you into contact with this material?

A. (1) MATERIAL: _____ CODE:
(2) What company or business did you work for?
(NAME OF COMPANY)_____ CODE:

(3) How many months/years did you have this job?_____MONTHS
YEARS

TEEN ASK: Did you work. CODE: # OF MONTHS

B. (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

C. (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

D. (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

E. (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

F (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

G. SUPPLEMENTAL EXPOSURE SHEET USED:
YES. 1
? →

20. Have you ever worked - temporarily, part time, or in a full time job - in any position in a manufacturing concern?

YES.....1
NO.....2 (GO TO Q21)

A. Have any of your jobs been in companies where any of the following materials were manufactured or these materials were used in the manufacture of other products? (READ LIST)

YES.....1
NO.....2

(1) Carbonless copy paper
(2) Coating electrical cables with plastic
(3) Fluorescent lights (manufacture only)
(4) Gas transmission turbines
(5) Heat exchange units or heat transfer systems
(6) Home air conditioners (manufacture only)
(7) Hydraulic systems
(8) Investment casting in foundry
(9) Olefin (manufacture only)
(10) Paper reclamation
(11) TV sets (manufacture only)
(12) Silk screen glassing
(13) Vacuum pumps

IF NO TO ALL OF ABOVE: _____ (GO TO Q21)

IF YES TO ANY OF ABOVE, USE B TO RECORD.
THEN ASK: Did you work at any other company that used this material or at another job that brought you into contact with these materials? USE C TO RECORD. THEN RETURN TO LISTING.

B. (1) PRODUCT: _____ CODE:
(2) What company or business did you work for?
(NAME OF COMPANY)_____ CODE:

(3) How many months/years did you have this job?_____MONTHS
_____YEARS
CODE: # OF MONTHS

C. (1) PRODUCT: _____ CODE:
(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

D. (1) PRODUCT: _____ CODE
(2) COMPANY: _____ CODE

(3) _____ _____
MONTHS YEARS CODE: # OF MONTHS

E. SUPPLEMENTAL EXPOSURE SHEET USED:
YES.....1
NO.....2

MONS 027782

21. Have you ever sprayed roads to keep down dust either as a job or on your own property (liquid other than water)?

JOB.....1 (GO TO A)
HOME.....2 (GO TO B)
BOTH JOB AND HOME.....3 (GO TO A AND B)
NO, NEITHER.....4 (GO TO Q22)

A. (1) What company or business did you work for?
(NAME OF COMPANY)_____ CODE:

(2) What kind of business or industry was this?
(TYPE OF BUSINESS)_____
CODE: INDUSTRY

(3) For many months/years did you have this job?_____MONTHS
YEARS
CODE: # OF MONTHS

B. HOME SPRAYING: For many years did you (spray/have this done)?

_____/_____
MONTHS YEARS CODE: # OF MONTHS

22. SECOND BLOOD PRESSURE:

30 SEC RADIAL PULSE: _____ CODE I2:

IRREGULAR PULSE: YES.....1
NO.....2

SYSTOLIC: _____ CODE SYS:
DIASTOLIC: _____ RES: _____ CODE DIAS:

ARM: RIGHT.....1
LEFT.....2

TIME:

[illegible]

23. OBTAINING FRESH SEAFOOD:

CATCH OWN.....01
FAMILY/FRIENDS CARGET.....02
OTHER LOCAL FISHERMEN.....03
LOCAL FISH RETAILERS.....10-30 34
SUPERMARKETS/GROCERIES.....50-76 [illegible]
GOT NONE.....90
Restaurants 60

A. How do you and your family obtain {CREB seafood?
PROBE USING CODES.

ANSWER 01: _____ CODE: PLACE

ANSWER 02: _____ CODE: PLACE

B. (IBB_YRBEF_BBQ, in 1975 / LAST YEAR LIVED IN GMB AREA).
How did you and your family obtain {CREB seafood?

ANSWER 01: _____ CODE: PLACE

ANSWER 02: _____ CODE: PLACE

24. My next question refers to all types of fish and seafood, and includes both locally caught seafood and all kinds bought for cooking at home or purchased in restaurants.

A. Would you say that QYRE_IBB_LABE_IBB_YRBEF, your consumption of BBY_IYBB of fish and seafood has increased, decreased, or remained about the same?

INCREASED.....1
SAME.....2 (GO TO Q25) ⟶
DECREASED.....3
NO SEAFOOD WHOLE TIME.....9 (GO TO QB5)

B. Can you think of one particular reason for this change?

ECONOMICS.....1
TASTE.....2
HEALTH REASONS (NO).....3
PCBs.....4
OTHER.....5
NO CHANGE.....9

CODE:

25. For each of the following types of seafood, have you eaten each five or more times in your lifetime? (READ LIST)

YES.....1
NO.....2

A. Clams and Quahogs? →

B. Mussels? →

C. Eel? →

D. Blue fish, striped bass, or mackerel? →

E. For each of the following groups of fish and seafood, have you eaten each five or more times in your lifetime? (READ LIST)

YES.....1
NO.....2

Scup, tautog, fluke, flounder, cod, or sea trout(weak fish)? →

F. Catfish, carp, buffalo fish, fresh water trout, chubs, or drum? →

G. (1) Lobster? (IF NO, GO TO Q26 OR Q27) →

(2) For lobster, was this usually the claws and tail, just the tomalley (green organs), or both?

CLAWS AND TAIL ONLY.....1
TOMALLEY ONLY.....2 →
BOTH.....3
NO LOBSTER.....9

IF NO TO ALL OF ABOVE: _____ (GO TO Q27)

26. IF YES TO ANY OF A THROUGH G, Q25:

A. CONSIDERING together all the types of (fish and) seafood you just mentioned having eaten - that is, _____ and _____(Q25) -- how frequently have you eaten ANY of these species IN_THE_LAST THREE_MONTHS? (READ CODES AND SHOW CARD 02)

Often=two or more times/week.....1
Occasionally=at least once/week.....2
Sometimes=(once/week, at least once/month.....3 →
Infrequently=(once/month, at least once/year.....4
RARELY OR NEVER=(ONCE/YEAR.....5

B For how many years have you been eating these types of seafood?

1-64 (EARS.....01 THROUGH 64 →
LESS THAN ONE YEAR.....91
NEVER ATE ANY.....99

(026 CONT'D)

C. Would you say your consumption of these fish and seafood GROUPED- that is, _____and_____(025) - has increased, decreased, or remained about the same over the last _____(026B) years?

INCREASED.....1
SAME.....2 → ☐
DECREASED.....3
NEVER ATE ANY.....9

27. The next set of questions has to do with recreational and fishing activities in the Acushnet River and New Bedford Harbor area. The area I'm referring to is (SHOW MAP AND LANDMARKS).

Have you ever done any of the following five times or more in this area?

YES.....1
NO.....2

A. Clamming or quahogging? → ☐
B. Picking mussels? → ☐
C. Catching or trapping eels? → ☐
D. Trapping lobsters? → ☐
E. Sports or commercial fishing? → ☐

28. About how much do you usually weigh without shoes or clothing?

---------- CODE: # of POUNDS ☐☐☐

29. TRICEPS SKIN FOLD:

A. ARM: RIGHT.....1 → ☐
LEFT.....2

B. 1st MEASUREMENT: CODE mm: ☐☐

B. 2nd MEASUREMENT: CODE mm: ☐☐

30. HEIGHT: --------/-------- CODE I 2.54: cm ☐☐
feet inches

31 HEIGHT: ---------- CODE lb ☐☐☐

32. OBTAINING LOCAL SEAFOOD:

CATCH OWN.....01
FAMILY/FRIENDS CAUGHT.....02
OTHER LOCAL FISHERMEN.....03
LOCAL FISH RETAILERS.....10-34,34
SUPERMARKETS/GROCERIES.....30-34,37
DON'T KNOW.....98
Restaurants 60

A. How do you and your family obtain seafood that has been caught locally in the river/harbor area (MAP)?

ANSWER 01: _____ CODE: PLACE

ANSWER 02: _____ CODE: PLACE

B. (IF 1978, in 1979 / LAST YEAR LIVED IN ONE AREA), how did you and your family obtain locally-caught (MAP) seafood?

ANSWER 01: _____ CODE: PLACE

ANSWER 02: _____ CODE: PLACE

33. You told me earlier that you have lived in the New Bedford area for more than five years. During that time, and again referring to the local river and harbor area (REMIND R OF MAP), I am going to ask you how frequently you consumed several types of local seafood that were caught in the New Bedford harbor by you or by friends, family, or neighbors.

LOBSTER: Have you eaten locally-caught lobster five or more times in your lifetime?

YES.....1 ——→
NO.....2 (GO TO Q34)

A. (1) How old were you when you first ate locally-caught lobster? _____

(2) What was the most recent year in which you ate local lobster? _____

CODE: # OF YEARS

B. During these _____(Q33A) years, please think back to the time of your life when you ate lobster caught in the New Bedford harbor the most frequently. Would that time have been when you were a child, teenager, or adult?

CHILD.....1
TEENAGER.....2 ——→
ADULT.....3
ALL THREE THE SAME.....4

(Q13 CONT'D)

C. When you were eating local lobster the most often, would you say you ate it two or more times per week, at least once a week, less than once a week but at least once a month, or less than once a month but at least once a year? (SHOW CARD 62 AGAIN)

Often=two or more times/week.....1
Occasionally=at least once/week.....2
Sometimes=(once/week, at least once/month.....3 → ☐
Infrequently=(once/month, at least once/year.....4
RARELY OR NEVER=(ONCE/YEAR.....5

D. Would you say your consumption of locally steamed lobster has increased, decreased, or remained about the same over the last _____(Q13A) years?

INCREASED.....1
SAME.....2
DECREASED.....3 → ☐
NEVER ATE LOBSTER.....9

E. Have you usually eaten the claws and tail, just the tomalley (green organs), or both from locally trapped lobster?

CLAWS AND TAIL ONLY.....1
TOMALLEY ONLY.....2
BOTH.....3 → ☐
NO LOBSTER.....9

34. IF YES TO Q33, AFTER 2nd 'YES' IN Q34, READ QUESTIONS 34(1)-(6) VERBATIM.
IF NO TO Q33, READ QUESTIONS 34(1)-(6) VERBATIM 1ST AND 4TH 'YES'.

(1) Have you eaten local _____ - (dug/picked/caught) in the harbor area by you or family, friends, or neighbors - five or more times in your lifetime?

YES.....1
NO.....2 (GO TO NEXT SEAFOOD)

(2) How old were you when you first ate locally (dug/picked/caught) _____?

(3) What was the most recent year in which you ate local _____?

(4) During these _____(Q34(1)&(2)) years, please think back to the time of your life when you ate _____ (dug/picked/caught the most frequently). Would that time have been when you were a child, teenager, or adult?

CHILD.....1
TEENAGER.....2
ADULT.....3
ALL THREE THE SAME.....4

(5) At this time when you were eating local _____ the most often, would you say you ate them two or more times per week, at least once a week, less than once a week but at least once a month, or less than once a month but at least once a year? (SHOW CARD #2 AGAIN)

Often=two or more times/week.....1
Occasionally=at least once/week.....2
Sometimes=<once/week, at least once/month.....3
Infrequently=<once/month, at least once/year...4
RARELY OR NEVER=<ONCE/YEAR.....5

(6) Would you say your consumption of locally (dug/picked/caught) _____ has increased, decreased, or remained about the same over the last _____(Q34(1)&(2)) years?

INCREASED.....1
SAME.....2
DECREASED.....3
NEVER ATE _____.....9

		(1) YES, NO.	(2) FIRST YEAR	(3) LAST YEAR	(4) MOST FREQ. YEARS	(5) FREQ-ENCY	F
A.	Clams or Quahogs						
B.	Mussels						
C	Eel						
D	Blue Fish, Striped Bass, or Mackerel						
E.	Scup, Tautog, Flukes, Cod, or Sea Trout(Weak Fish)						

35. IF YES TO TWO OR MORE SPECIES IN Q33 OR 34: CONTINUE
IF YES TO NONE OR ONLY ONE: GO TO Q36.

Combining together all the types of locally caught seafood - trapped or caught by you or family or friends in the harbor area - I have just mentioned, from lobster to eel to clams to striped bass to flounder:

A. (1) How old were you when you first ate any of these locally caught species? _____

(2) What was the most recent year in which you ate local seafood caught in the harbor area? _____

CODE: # OF YEARS

B. During these _____(Q35A) years, please think back to the time of your life when you ate any of these kinds of seafood that was caught in the Harbor Region the most frequently. Would that time have been when you were a child, teenager, or adult?

CHILD.....1
TEENAGER.....2
ADULT.....3
ALL THREE THE SAME.....4

C. At the time when you were eating local seafood the most often, would you say you ate it two or more times per week, at least once a week, less than once a week but at least once a month, or less than once a month but at least once a year? (SHOW CARD B2 AGAIN)

Often=two or more times/week.....1
Occasionally=at least once/week.....2
Sometimes=<once/week, at least once/month.....3
Infrequently=<once/month, at least once/year.....4
RARELY OR NEVER=<ONCE/YEAR.....5

D. Would you say your consumption of seafood locally caught in the harbor area by you or family, friends, or neighbors has increased, decreased, or remained about the same over the last _____(Q35A) years?

INCREASED.....1
SAME.....2
DECREASED.....3
NEVER ATE LOCAL SEAFOOD.....9

MEDICAL_HISTORY

36. SODIUM:

A. Over the last twelve months, HOW_OFTEN did you usually eat at LEAST_ONE of the following foods - dried cod fish, ham or cold cuts, fast food hamburgers or chicken, canned vegetables and soups, or salted snacks(e.g., potato chips) _____(READ LIST)?

Daily.....1
2-4 Times/Week.....2
About Once/Week.....3
<Once/Week.....4

B. In the preparation of food, do you usually, sometimes, or rarely add salt?

USUALLY.....1
SOMETIMES.....2
RARELY.....3

C. After food is served, do you usually, sometimes or rarely add salt at the table?

USUALLY.....1
SOMETIMES.....2
RARELY.....3

D. During the past 5 years, would you say the amount of salt from all sources in your diet has increased, decreased, or remained the same?

INCREASED.....1
SAME.....2
DECREASED.....3

E. (1) Are you on a low sodium diet?

YES.....1
NO.....2 (GO TO Q37)

(2) Was this diet recommended by a physician?

YES.....1
NO.....2
NO SODIUM DIET.....9

Now I will be asking some questions about your health:

37. CURRENT DOCTOR

A. Is there a regular doctor who would usually be seen or called concerning your health?

YES.....1 ⟶ ☐
NO.....2 (GO TO F)

B. What is his name?_____

C. What is his/her address?_____
_____
CODE: SPECIALTY ☐☐

D. At the end of this interview, I will be giving you a card indicating your blood pressure reading. Would you like me to send these results or your PCB blood measurement to Dr. _____(Q37A)?

YES.....1 (GO TO Q38) ⟶ ☐
NO.....2 (GO TO E)

E. Is there another physician you want me to report your blood pressure reading to?

YES.....1 (GO TO E(1)) ⟶ ☐
NO.....2 (GO TO Q38)

(1) What is his name?_____

(2) What is his/her address?_____
_____
CODE: SPECIALTY ☐☐

F. At the end of this interview, I will be giving you a card indicating your blood pressure reading. Is there a physician you would like me to send the blood pressure or PCB blood measurement results to?

YES.....1 (GO TO F(1)) ⟶ ☐
NO.....2 (GO TO Q38)

(1) What is his name?_____

(2) What is his/her address?_____
_____
CODE: SPECIALTY ☐☐

38. Are you CURRENTLY being treated by a physician for any health or medical condition?

YES.....1 → ☐
NO.....2 (GO TO Q39)

A. (1) What is this condition? _____ CODE: ☐☐☐☐

(2) What physician is treating you for _____(Q38A)?

_____

(3) When were you first diagnosed as having _____ (Q38A)?

_____/_____ CODE: YEARS ☐☐
MONTH YEAR

B. Is there another condition a physician is currently treating you for?

YES.....1 → ☐
NO.....2 (GO TO Q39)

(1) What is this condition? _____ CODE: ☐☐☐☐

(2) What physician is treating you for _____(Q38B)?

_____

(3) When were you first diagnosed as having _____ (Q38B)?

_____/_____ CODE: YEARS ☐☐
MONTH YEAR

C. And is there another condition a physician is currently treating you for?

YES.....1 → ☐
NO.....2 (GO TO Q39)

(1) CONDITION #3: _____
(2) CONDITION #4: _____
(3) CONDITION #5: _____
(4) CONDITION #6: _____

39. Are you CURRENTLY taking any medications - either ordered by a physician or bought over the counter?

YES.....1
NO.....2 (GO TO Q40) → ☐

IF YES, ASK: Please try to recall the medications you currently are taking, the physician who ordered them and the reason you're taking them.

	DRUG	PHYSICIAN	CONDITION	MO/YEAR IT BEGAN
a.				
b.				
c.				
d.				
e.				
f.				

8. PROBE: FOR ADDITIONAL RX'S AND OVER-THE COUNTER, INCLUDING SKIN PREPARATIONS, ANTI-HISTAMINES, ASPIRIN.

	DRUG	PHYSICIAN	CONDITION	MO/YEAR IT BEGAN
a.				
b.				
c.				

40. Are you currently taking any medicine in the following categories?
SKIP CATEGORY IF MENTIONED ABOVE

IF YES, ASK: For what condition are you using this medication?
In what month and year did you start using this medication?

	YES..1 NO...2	CONDITION	MO./YR. BEGUN	TOTAL MONTHS
(a) Blood pressure medicines?	☐	----------	___/☐☐	☐☐☐
(b) Anti-histamines?	☐	----------	___/☐☐	☐☐☐
(c) Heart medicines?	☐	----------	___/☐☐	☐☐☐
(d) Anti-coagulants (blood thinners)?	☐	----------	___/☐☐	☐☐☐
(e) Long-term antibiotics?	☐	----------	___/☐☐	☐☐☐
(f) Steroids (cortisone like medicines)?	☐	----------	___/☐☐	☐☐☐
(g) Diabetes pills or insulin?	☐	----------	___/☐☐	☐☐☐
(h) Sleeping pills?	☐	----------	___/☐☐	☐☐☐
(i) FOR FEMALES ONLY: Birth control pills?	☐	----------	___/☐☐	☐☐☐
(j) Multiple vitamin supplements?	☐	----------	___/☐☐	☐☐☐
(k) Thyroid medicine?	☐	----------	___/☐☐	☐☐☐
(l) Muscle relaxants?	☐	----------	___/☐☐	☐☐☐
(m) Sedative or tranquilizers?	☐	----------	___/☐☐	☐☐☐
(n) Are you currently receiving Radiation therapy?	☐	----------	___/☐☐	☐☐☐

41 RECENT BLOOD PRESSURE:

A. Before today, when was the last time you had your blood pressure taken?

_____ DAYS OR _____ MONTHS OR _____ YEARS

1-64 YEARS	01 through 64
< 1 MONTH	91
1-3 MONTHS	92
4-6 MONTHS	93
7-11 MONTHS	94
NEVER	95 (GO TO Q42)

B. What were you told about the level of your blood pressure? Was it_____(READ LIST)?

Below Normal	1
Normal	2
Above Normal	3
NEVER MEASURED	99

42. Have you ever been told by a doctor that you have any of the following conditions? (READ LIST)

IF YES, ASK: What month and year were you first told by a doctor that you had this condition?

	YES..1 NO...2	MO./YEAR QUEST
(a) High blood pressure?		___/
(b) Liver problems, i.e., cirrhosis, fatty liver, hepatitis, yellow jaundice? IF YES, PROBE: conditions and date: _____		___/
(c) Have you ever been told by a doctor that you have any of the following SKIN conditions?(READ LIST)		
(1) Psoriasis?		___/
(2) Dermatitis?		___/
(3) Eczema?		___/
(4) Acne?		___/
(5) Chloracne?		___/
(6) Darkening of skin & nails (except for tanning)?		___/
(7) Hives?		___/
(8) Excess facial hair?		___/
(9) Excess growth of hair on shoulders, upper body, or chest around nipples?		___/
(10) Other Skin Condition: PROBE _____		___/

(042 CONT'D)
IF YES, ASK: What month and year were you first told by a doctor that you had this condition?

YES..1 NO...2 MO./YEAR ONSET

(d) Have you ever been told by a doctor that you have any of the following circulatory conditions? (READ LIST)

(1) Blood problems, i.e., anemia or bleeding tendencies? ---/---
(2) Heart attack/failure? ---/---
(3) Angina? ---/---

(e) Have you ever been told by a doctor that you have any of the following eye conditions? (READ LIST)

(1) Cataracts? ---/---
(2) Eye infections, "pink eye", or conjunctivitis? ---/---
(3) Chronic excessive discharge or lid swelling? ---/---
(4) Glaucoma? ---/---
(5) Other Eye Condition: PROBE
---------- ---/---

(f) Have you ever been told by a doctor that you have any of the following nervous system conditions? (READ LIST)

(1) Seizures, Fits, Epilepsy? ---/---
(2) Stroke? ---/---
(3) Weakness or paralysis in arms or legs? ---/---
(4) Numbness in arms or legs? ---/---
(5) Tremors? ---/---
(6) Dizziness? ---/---
(7) Mental Illness? ---/---
(8) Chronic Memory Loss? ---/---
(9) Headaches >1/week? ---/---
IF-YES:
Generalized. . .1
Localized . . .2

(10) Other Neurological Condition: PROBE
---------- ---

(-Q42 CONT'D)
IF YES, ASK: What month and year were you first told by a doctor that you had this condition?

YES..1 MO./YEAR
NO....2 ONSET

(g) Have you ever been told by a doctor that you have any of the following respiratory conditions?(READ LIST)

(1) Bronchitis (more severe than ordinary colds: cough brings up thick sputum)? → ☐ ___/☐☐

(2) Asthma? → ☐ ___/☐☐

(3) Other chronic breathing or lung disorders? → ☐ ___/☐☐
PROBE CONDITION: _____

(h) Have you ever been told by a doctor that you have any of the following generalized disorders?

(1) Swelling in hands or feet? → ☐ ___/☐☐

(2) Rapid weight loss? → ☐ ___/☐☐
IF YES: reason:
DIETING.....1
OTHER ILLNESS.....2
UNKNOWN.....3

(3) Immune deficiencies or other immune disorders? → ☐ ___/☐☐

(4) Repeated or markedly prolonged infection? → ☐ ___/☐☐

(5) Diabetes or sugar? → ☐ ___/☐☐

(6) Thyroid disease? → ☐ ___/☐☐

(7) Other Generalized Condition: PROBE → ☐ ___/☐☐
_____

(i) Have you ever been told by a doctor that you have cancer? → ☐ ___/☐☐
IF YES, cancer of what?_____ _____

(j) OTHER: Have you had any other serious or chronic medical or surgical conditions that I have not mentioned?

YES.....1 → ☐
NO.....2

IF YES, PROBE: CONDITIONS AND DATES:
_____
_____
_____

43. Have you ever had any of the following symptoms for [DCESE_2000508 QC_1999SEC]? (READ LIST)

IF YES, ASK: (1) What month and year did _____ begin?

(2) Do you still have this symptom?
YES.....1
NO.....2

		YES..1 NO..2	ONSET MO./YEAR	CURRENT YES/NO
A.	Loss of Appetite?		___/___	
B.	Nausea?		___/___	
C.	Weakness?		___/___	
D.	Fatigue?		___/___	
E.	Numbness or Tingling in your Extremities?		___/___	

44. Over your lifetime, have you ever smoked more than a total of five packs of cigarettes?

YES.....1
NO.....2 (GO TO Q45)

A. Do you currently smoke cigarettes?

CURRENT SMOKER.....1
FORMER SMOKER.....2
NEVER SMOKED.....3

B. In an average day, how many cigarettes do (did) you smoke?

_____ OR _____
PACES CIGS

C. How long have you been smoking (did you smoke)?

_____ OR _____
MONTHS YEARS

CODE: # of PACKYEARS [ ]

45. Have you ever smoked a pipe, cigarillos, or cigars?

YES.....1
NO.....2 (GO TO Q46)

A Do you currently smoke a pipe, cigarillos, or cigars?

CURRENT SMOKER.....1
FORMER SMOKER.....2
NEVER SMOKED.....3

46. Over your lifetime, have you had more than a total of five alcoholic drinks?

YES.....1
NO.....2 (GO TO Q47) → ☐

A. Do you currently drink alcoholic beverages?

CURRENT DRINKER.....1
FORMER DRINKER.....2 → ☐
NEVER DRANK.....9

B. Using the numbers on this card, estimate on the average, how often you consume _____(type)? (SHOW CARD 83)

ONCE OR MORE/DAY.....1
2-6 TIMES/WEEK.....2
1/WEEK.....3
1-3 TIMES/MONTH.....4
<1/MONTH.....5
RARELY.....6
NEVER.....9

1. Cans or bottles of Beer:

FREQUENCY → ☐

2. Glasses of Wine:

FREQUENCY → ☐

3. Shots of Hard Liquor or Whiskey:

FREQUENCY → ☐

C. How many cans, glasses, and shots do (did) you usually have in one sitting?

ONE.....01
TWO.....02
THREE.....03
FOUR.....04
FIVE.....05 → ☐☐
SIX.....06
SEVEN OR MORE.....07
NEVER DRANK.....99

47. From this card, please tell me that number that indicates your racial background? (R'S ANCESTORS) SHOW CARD 84

WHITE.....1
BLACK.....2
AMERICAN INDIAN/ALASKAN NATIVE.....3 → ☐
ASIAN/PACIFIC ISLANDER.....4
OTHER.....5
SPECIFY: _____

48. Are you_____(READ LIST)?
Married.....1
Widowed.....2
Separated.....3
Divorced.....4
Never married.....5 → ☐

49. How could you tell me how many persons are CURRENTLY living in your household, including yourself? Please count anyone who usually lives there but is temporarily away, such as on vacation or in a hospital.

A. # of PERSONS (INCLUDE R) (IF ONE, GO TO Q50) → ☐☐

B. How many of these are aged 18 or older? _____ CODE: # >= 18 ☐☐

50. Please estimate the combined income for the past 12 months, (adding together income for all the persons you mentioned as living in your household). Include income from all sources such as wages, social security, retirement or unemployment benefits, interest, help from relatives, rent from property and so forth. Just read the number on this card (#5) next to your estimate.

$ 0 - 14,999.....1
15,000 - 29,999.....2
30,000 +.....3 → ☐

51. In case we have any follow-up questions or you have moved when our PCB test results are available and we want to get them to you, could you please tell me the name, address, and phone # of two people who will always be able to reach you but do not live with you.

NAME: _____

ADDRESS: _____PHONE: _____

NAME: _____

ADDRESS: _____ PHONE: _____

92. BLOOD PRESSURE #3

30 SEC RADIAL PULSE: _____ CODE I2: ☐☐

IRREGULAR? YES.....1
NO.....2 → ☐

SYSTOLIC: _____ CODE SYS: ☐☐☐
DIASTOLIC: _____ RES: _____ CODE DIAS: ☐☐☐

ARM: RIGHT.....1
LEFT.....2 → ☐

TIME: → ☐☐☐

COMPLETE BLOOD PRESSURE REPORT-SUBTRACT RANDOM ZERO. USE LOWEST OF 3 READINGS(P

INTERVIEWER SECTION

After the interview, complete the following questions:

56. What was the respondent's general attitude toward the interview?

VERY INTERESTED.....1
INTERESTED.....2 → ☐
DISINTERESTED.....3

57. Did respondent feel confident of responses?

YES, ALL THE TIME.....1
YES, MOST OF THE TIME.....2
ONLY SOME OF THE TIME.....3 → ☐
SELDOM.....4
NEVER.....5

EXIT THE SURVEY

58. FLAG if any call-backs or follow-ups needed for:

Blood	------
Urine	------
Skin fold	------
Residential	------
Occupational	------
Medical	------
Other:	
----------	------

CODE THE SURVEY

After coding, complete the following questions:

59. CURRENT ADDRESS:

A. CODE: CURRENT TOWN: → ☐☐☐

B. CODE: CURRENT CENSUS TRACT: → ☐☐☐☐

60. SAMPLED ADDRESS:

A. CODE: SAMPLED CENSUS TRACT: → ☐☐☐☐

B. CODE: SAMPLE ADDRESS=CURRENT.....1
SAMPLE=PAST, STILL GMB.....2 → ☐
SAMPLE=PAST, NON-GMB.....3

61. CODE: # OF GMB ADDRESSES: → ☐☐

CURRENT ALONE.....01

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

CONSENT FORM SIGNED: _____ DATE: → DD MMM YY

INTERVIEWER INITIALS: _____ TIME INTERVIEW STARTS: →

PHLEBOTOMY

INTRODUCTION:
Vou fazer-lhe algumas perguntas sobre a sua saúde e as experiências que tem passado desde que vive na área de New Bedford. No entanto, gostaria de realçar que é extremamente importante que teste ser o mais exacto possível nas suas respostas para que elas nos ajudem a compreender o efeito da presença de PCBs no ambiente da área de New Bedford. Pedimos-lhe que pense bem nas respostas que vai dar. Não há respostas certas ou erradas: o que é importante é que compreenda as minhas perguntas e que dê respostas exactas. Para melhor documentar as suas respostas, interessa-me que eu use esta fita magnética (tape)?

1. Como avalia a sua saúde comparada com pessoas da sua idade? Diria que é EXCELENTE, MUITO BOA, BOA, NORMAL, FRACA?

Excellent.....1
Very Good.....2 → ☐
Good.....3
Fair.....4
Poor.....5

2. HEALTH STATUS:

A. Descreva as suas actividades da SEMANA PASSADA OU ULTIMOS 12 MESES - Trabalhou num emprego ou negócio, dona de casa, estudante ou outra tarefa?

HOMEMAKING.....1 (GO TO B)
KEEPING HOUSE.....2 (GO TO D) → ☐
GOING TO SCHOOL.....3 (GO TO G)
OTHER.....4 (GO TO G)

B. Tem algum problema físico ou de saúde que lhe impeça de trabalhar presentemente num emprego ou negócio?

YES.....1 (GO TO J) → ☐
NO.....2 (GO TO C)

C. É limitado na qualidade ou quantidade de trabalho que pode fazer devido a qualquer problema físico ou de saúde?

YES.....1 (GO TO J) → ☐
NO.....2 (GO TO I)

(final: 7/27/85)

(Q2 CONT'D)

D. Presentemente tem algum problema físico ou de saúde que lhe impede de fazer qualquer trabalho de casa?

YES.....1 (GO TO F)
NO.....2 (GO TO E)

E. É limitado na qualidade ou quantidade de trabalho de casa que pode fazer devido a qualquer problema físico ou de saúde?

YES.....1 (GO TO F)
NO.....2 (GO TO G)

F. Há quanto tempo é que esta limitado _____?
_____ OR _____ _____ OR _____ CODE: YEARS
DAYS WEEKS MONTES YEARS

Qual é a condição maior que causa esta limitação?

CONDITION: _____ CODE:

Esta limitação é causada por outra condição?

YES.....1
NO.....2

IF YES, SECOND CONDITION: _____

GO TO G.

G. Tem algum problema físico ou de saúde que lhe impeça em qualquer quantidade de trabalho num emprego ou negócio?

YES.....1 (GO TO J)
NO.....2 (GO TO H)

H. É limitado na qualidade ou quantidade de trabalho que pode fazer devido a algum problema físico ou de saúde?

YES.....1 (GO TO J)
NO.....2
IF NO: IF ENTRY IN F, GO TO Q3.
IF NO ENTRY IN F, GO TO I.

I. É limitado de alguma maneira de tomar parte em qualquer actividade ou de saude?

YES.....1 (GO TO J)
NO.....2 (GO TO Q3)

(Q2 CONT'D)

J. Há quanto tempo é que está limitado _____?

_____ OR _____ _____ OR _____ CODE: YEARS
DAYS WEEKS MONTHS YEARS

Qual é a condição maior que causa esta limitação? CODE:

CONDITION: _____

Esta limitação é causada por outra condição?

YES.....1
NO.....2

IF YES, SECOND CONDITION: _____

3. SEX:

MALE.....1
FEMALE.....2

4. Que idade tem?_____
A data do seu nascimento é?

5. BLOOD PRESSURE #1:
Eu vou-lhe medir a tensão arterial tres vezes durante esta entrevista.

30 SEC RADIAL PULSE: _____ CODE I2:

IRREGULAR PULSE: YES.....1
NO.....2

SYSTOLIC: _____ CODE SYS:
DIASTOLIC: _____ RES: _____ CODE DIAS:

ARM: RIGHT.....1
LEFT.....2

TIME:

6 Em que cidade e estado é que nasceu?

_____ CODE: CITY
CITY/STATE/COUNTRY

7. Qual o grupo étnico com que mais se associa (ou qual a nacionalidade dos seus antepassados)? (R's ancestors.) (SHOW CARD #1)
Por favor escolha por este cartão.

PORTUGUES.....01
CABO VERDEANO.....02
BRASILEIRO.....03
PORTO RIQUENHO.....05
MEXICANO.....06
CUBANO/CARAIBAS/AMERICA DO SUL.....07
ESPANHOL.....08
INGLES/ESCOCES/GALES.....10 → [ ]
CANADIANO.....11
FRANCES.....12
FRANCES CANADIANO.....13
IRLANDES.....14
ITALIANO.....15
POLACO.....16
MULATO.....90
OUTRO.....91
DON'T KNOW.....97

8. Quantos anos de escola já completou?

NO FORMAL SCHOOLING.....00
GRAMMAR SCHOOL.....01

08
HIGH SCHOOL: FRESHMAN.....09
SOPHOMORE.....10
JUNIOR.....11
GRADUATE.....12
COLLEGE: 1ST YEAR.....13 → [ ]
2ND YEAR.....14
3RD YEAR.....15
GRADUATE.....16
GRADUATE STUDIES.....17

NOTE: Escola Primária: 1, 2, 3, 4a. classe
Liceu: 1, 2, 3, 4, 5, 6, 7o. ano
Universidade: 1, 2, 3, 4, 5o. ano
Estudos após graduação

RESIDENTIAL HISTORY

Agora preciso de saber os lugares que tem vivido. Vamos começar com a sua direcção mais recente à mais antiga. Por favor inclua o tempo que passou no serviço militar, na universidade, e outros trabalhos fora desta área, etc...

9 Quando é que se mudou para esta casa?
_____ _____ (COVER SHEET)? [ ]
(no.) (street) (city/town)

_____/_____
MONTH YEAR

CODE: 8 of MONTHS

MONS 027806

10. PREVIOUS ADDRESSES:

ASK THE NEXT TWO QUESTIONS UNTIL NON-GNB AREA:
PUT ADDRESSES AND DATES IN TABLE

A. (1) Qual era a sua direcção antes desta?

(2) Quando foi que se mudou para lá_____(Q10A(1) - address)?

WHEN NON-GNB-AREA, RECORD CITY/STATE

AND ASK: Antes de _____/_____(last date), morou em Acushnet, Dartmouth
month year
Fairhaven ou New Bedford em qualquer outra altura? (1940 ON)

	ADDRESS(No. STREET/CITY)	DATE(MONTH/YEAR)	CODE: CT	CODE: M
1.				
2.				
3.				
4.				
5				
6.				
7.				
8				
9.				
10.				
11				

B SUPPLEMENTAL RESIDENCE SHEET USED:

YES.....1
NO.....2 ⟶ ☐

OCCUPATIONAL_HISTORY

Agora vou rever os seus empregos e os tipos de indústria em que trabalhou. Também estou interessada nas posições que desempenhou em cada companhia.

11. Has_HUSBAND_EVER_WORKED tem trabalhado em regime de "full time" ou "part time"?

WORKING FULL TIME.....1 (GO TO Q12)
WORKING PART TIME.....2 (GO TO A)
NOT WORKING (DESEMPREGADO).....3 (GO TO B) ——→ ☐

A. WORKING PART TIME:
É estudante em regime de "full time"?

YES.....1 (GO TO Q12)
NO.....2 (GO TO Q12) ——→ ☐

B. NOT WORKING:
É estudante em regime de "full time"?

YES.....1 (GO TO D)
NO.....2 (GO TO C) ——→ ☐

C. Indique o que é que descreve as suas actividades nos últimos 5MOS_BEFORE.

READ LIST:

Homemaker (Doméstica(o))....1
Retired (Reformado(a))....2
Laid Off (Desempregado(a) Temporariamente)....3
Unemployed (Desempregado(a))....4
Disabled Permanently (Incapacitado(a) Permanentemente)....5
Disabled Temporarily (Incapacitado(a) Temporariamente....6
Other: SPECIFY: _____7 ——→ ☐

D. FOR HOMEMAKER, RETIRED, NON-WORKING STUDENT, UNEMPLOYED, DISABLED OR OTHER:
Já alguma vez trabalhou "full time" ou "part time" recebendo salário?

IF YES: A quanto tempo é que deixou esse emprego?
_____ OR _____ OR _____
DAYS MONTHS YEARS

<30 DAYS....1
30 DAYS - 5 MONTHS....2
6 MONTHS - 11 MONTHS....3
1 YEAR+....4 ——→ ☐
NEVER EMPLOYED....7 (GO TO Q21, PAGE 18)
LAID OFF OR RETIRED....8
CURRENTLY EMPLOYED....9

MONS 027808

12. MOST RECENT EMPLOYER:

A. Para que companhia ou negócio trabalha ou trabalhou?
(NAME OF COMPANY) _____

LOCAL C OF C LIST.....1-499
OTHER LOCAL.....250
OTHER MASS/R.I. IDENTIFIED CO.....300-399 CODE: ☐☐
OTHER MASS/R.I.....500
OTHER OUT OF STATE.....600

B. A que ramo de indústria pertence essa companhia? (por exemplo: oficina de reparações de televisões, fábrica de confecções, supermercado, construção de estradas.)

(TYPE OF BUSINESS) _____
CODE: INDUSTRY ☐☐

C. A companhia é principalmente _____(READ LIST)?

Manufacturing (Manufactura).....1
Wholesale Trade(Venda por atacado)....2
Retail Trade (Venda a retalho).....3 →
Other (Outro).....4

13. MOST RECENT JOB:

A. Que tipo de trabalho faz (fazia)?
PROBE: por exemplo, MECANICO DE REPARAÇÃO DE TELEVISÕES, OPERADOR DE MÁQUINAS, ENGENHEIRO CIVIL.
KIND OF WORK: _____

B. Quais são (foram) as suas funções e actividades mais importantes:
PROBE: por exemplo, FAZER A CONTABILIDADE, VENDER CARROS, MANOBRAR A MÁQUINA IMPRESSORA.
DUTIES: _____

C. Como se chama (chamava) o seu cargo?
TITLE: _____
CODE: OCCUPATION ☐☐

D. Há quantos meses/anos tem este cargo na companhia _____
(COMPANY NAME - Q12A)? _____/_____
MONTHS YEARS
CODE: # of MONTHS ☐☐

14. FOR RESPONDENT WHOSE CURRENT (LAST) JOB WITH LOCAL MANUFACTURER: GO TO A (PAGE 8)

FOR OTHERS, ASK: Já alguma vez trabalhou ao serviço ou Cornell Dubilier?

YES.....1 (GO TO B) (PAGE 9) →
NO.....2 (GO TO Q15) (PAGE 11)

(Q14 CONT'D)

A. (1) COMPANY:
AEROVOX.....1
CORNELL/DUBILIER.....2 → ☐

(2) Quando começou ao _____(A/CD)? _____/_____
MONTH YEAR CODE: # OF MONTHS ☐☐☐

(3) Incluindo a posição que presentemente ocupa, que OUTROS_EMPREGOS já foi ao_____(A/CD) durante os últimos_____(Q14A(2)) (months/years)? RECORD BELOW EACH MENTIONED

(4) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) Quais eram as suas funções e actividades mais importante quando trabalhava _____(kind of work)?

(b) Durante os ____(Q14A(2))(months/years) que esteve no _____ (A/CD), calcule por favor o tempo total que passou em cada trabalho _____(kind of work).

	KIND_OF_JOBS	ACTIVITIES/DUTIES	TOTAL_TIME_(M/Y)	CODE: POSITION/	CODE: MONTH
a.			_M_ / _M_ / _Y_	☐☐☐	☐☐
b.			_M_ / _M_ / _Y_	☐☐☐	☐☐
c.			_M_ / _M_ / _Y_	☐☐☐	☐☐
d.			_M_ / _M_ / _Y_	☐☐☐	☐☐
e.			_M_ / _M_ / _Y_	☐☐☐	☐☐
f.			_M_ / _M_ / _Y_	☐☐☐	☐☐
g.			_M_ / _M_ / _Y_	☐☐☐	☐☐
h.			_M_ / _M_ / _Y_	☐☐☐	☐☐

IF A SECOND WORK-SPAN AT A/CD, RECORD AT Q14C (PAGE 10).

THEN ASK: Trabalhou alguma vez para outra companhia _____(other CD/A)? IF YES, GO TO Q15(P 11) IF NO, GO TO 14C(P 10).

8. FOR PAST EMPLOYEES OF A/CD:

(1) COMPANY:

AEROVOZ.....1

CORNELL/DUBILIER.....2 ⟶ ☐

(2) Quando começou no _____(A/CD)? _____/_____ ⟶ 19☐☐
MONTH YEAR

(3) Quando é que saiu _____(A/CD)? _____/_____
MONTH YEAR
CODE: # OF MONTHS ☐☐

(4) Que tipo de trabalho é que fazia no _____(A/CD) durante os ultimos_____(Q14B(2&3))(months/years)? RECORD BELOW EACH MENTIONED

(5) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) Quais eram as suas funções e actividades mais importante quando trabalhava _____(kind of work)?

(b) Durante os ____(Q14B(2))(months/years) que esteve no _____ (A/CD), calcula por favor o tempo total que passou em cada trabalho _____(kind of work).

	KIND OF WORK	ACTIVITIES/DUTIES	TOTAL TIME (M/Y)	CODE: POSITION	CODE MONT
a.			M / Y	☐☐☐	☐
b.			M / Y	☐☐☐	☐
c.			M / Y	☐☐☐	☐
d.			M / Y	☐☐☐	☐
e.			M / Y	☐☐☐	☐
f.			M / Y	☐☐☐	☐
g.			M / Y	☐☐☐	☐
h.			M / Y	☐☐☐	☐

IF A SECOND WORK SPAN AT A/CD, RECORD AT Q14C (PAGE 10).

THEN ASK: Trabalhou alguma vez para outra companhia _____(other CD/A)? IF YES, GO TO Q15(P 11). IF NO, GO TO 14C(P 10).

C. SECOND MORE SPAN AT A/CD:

(1) COMPANY:
AEROVOX.....1
CORNELL/DUBILIER.....2 → ☐

(2) Quando começou no _____(A/CD)? _____/_____ → 19☐☐
MONTH YEAR

(3) Quando é que saiu _____(A/CD)? _____/_____ ☐☐☐
MONTH YEAR
CODE: # OF MONTHS

(4) Que tipo de trabalho é que fazia na _____(A/CD) durante os ultimos _____(Q14C(2&3))(months/years)? RECORD BELOW EACH MENTIONED

(5) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) Quais eram as suas funções e actividades mais importante quando trabalhava _____(kind of work)?

(b) Durante os ____(Q14C(2))(months/years) que esteve na _____ (A/CD), calcule por favor o tempo total que passou em cada trabalho _____(kind of work).

	KIND OF WORK	ACTIVITIES/DUTIES	TOTAL TIME (M/Y)	CODE: POSITION/	CODE: # MONTHS
a.			M / Y	☐☐☐	☐☐
b.			M / Y	☐☐☐	☐☐
c.			M / Y	☐☐☐	☐☐
d.			M / Y	☐☐☐	☐☐
e.			M / Y	☐☐☐	☐☐
f.			M / Y	☐☐☐	☐☐
g.			M / Y	☐☐☐	☐☐

IF A SECOND MORE SPAN AT A/CD, USE CAPACITOR SUPPLEMENTAL.

THEN ASK: Trabalhou alguma vez para outra companhia _____(other CD/A)? IF YES, USE SUPPLEMENT. IF NO, GO TO Q15.

D. SUPPLEMENTAL CAPACITOR SHEET USED:
YES.....1
NO.....2 → ☐

15. Agora, por favor, pense em todos os empregos que tem tido ou funções que tem desempenhado nas várias companhias. Inclua não só empregos assalariados em full time mas também trabalhos de verão, serviço militar, empregos temporários, por exemplo na época do Natal, empregos em part time, etc.

A. Trabalhou alguma vez para uma (IF AT A/CD: other) companhia que fabricasse condensadores (capacitors) eléctricos e transformadores?
YES.....1 (GO TO B) ——→ ☐
NO.....2 (GO TO Q16)

B. (1) COMPANY: GE, PITTSFIELD.....3
OTHER_____....4 ——→ ☐

(2) Quando começou ao _____(Q15B(1))? _____/_____ MONTH YEAR 19☐

(3) Quando é que saiu _____(Q15B(1))? _____/_____ MONTH YEAR
CODE: # OF MONTHS ☐☐

(4) Que tipo de trabalho é que fazia na _____(Q15B(1)) durante os ultimos _____(Q15B(2&3))(months/years)? RECORD BELOW EACH MENTIONED

(5) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) Quais eram as suas funções e actividades mais importantes quando trabalhava _____(kind of work)?

(b) Durante os ____(Q15C(2))(months/years) que esteve na _____ (Q15B(1)), calcule por favor o tempo total que passou em cada trabalho _____(kind of work).

	KIND OF WORK	ACTIVITIES/DUTIES	TOTAL TIME (M/Y)	CODE: POSITION/	COD NO
a.			M / M / Y		
b.			M / M / Y		
c.			M / M / Y		
d.			M / M / Y		

USE CAPACITOR SUPPLEMENTAL FOR ADDITIONAL KINDS OF WORK OR SECOND WORK SPAN

C. Trabalhou em alguma outra companhia que fabricasse condensadores e transformadores? _____ IF YES, USE CAPACITOR SUPPLEMENTAL

D. CAPACITOR SUPPLEMENTAL SHEET USED:
YES.....1 ——→
NO.....2

16. Alguma vez foi envolvido alguma posição pela manutenção de equipamento eléctrico?
YES.....1 (GO TO A)
NO.....2 (GO TO Q17) → ☐

A. CURRENT JOB: YES.....1 → ☐
NO.....2
IF YES, PROBE FOR OTHER POSITIONS IN N OF EE, SAME COMP'Y: YES, GO TO (1).
IF NO, GO TO (1).

(1) Qual companhia ou negocio que trabalhou?
(NAME OF COMPANY)_____

(2) Que tipo de companhia ou indústria era esta? (i.e., TV REPAIR SHOP, HOME HEATING SYSTEM INSTALLATION.)
(TYPE OF BUSINESS)_____
CODE: INDUSTRY ☐☐

(3) A companhia/indústria era principalmente_____(READ LIST)?
Manufacturing (Manufactura).....1
Wholesale Trade (Venda por atacado)...2
Retail Trade (Venda a retalho).....3
Other (Outro).....4

(4) Que tipo_de_trabalho fazia?_____ PROBE

(5) Quais eram as suas funções e actividades mais importante?
DUTIES:_____ PROBE

(6) Qual era o titulo do seu cargo?_____
CODE: OCCUPATION ☐☐

(7) Em que ano começou a desempenhar esta posição? 19_____ 19☐

(8) Quantos meses/anos desempenhou esta posição?
(COMPANY NAME - Q16A(1))? _____/_____
MONTHS YEARS
CODE: # of MONTHS ☐☐

B. PROBE: FOR ALL positions HELD AT THAT COMPANY.
THEN ASK: Trabalhou noutra companhia em que fosse envolvido pela alguma posição pela manutenção do equipamento eléctrico?
IF YES, GO TO C.

C. NAME OF COMPANY: _____
TYPE OF BUSINESS: _____ CODE: INDUSTRY ☐☐
KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____
CODE: OCCUPATION ☐☐
START YEAR: 19_____ 19☐
MONTHS/YEARS: _____ OR _____
MONTHS YEARS CODE: # of MONTHS ☐☐
PROBE FOR OTHER POSITIONS IN N OF EE, SAME OR DIFF'T COMP'Y: IF YES, GO TO SUPP

D. SUPPLEMENTAL ELECTRICAL MAINTENANCE SHEET USED:
YES.....1
NO.....2 → ☐

17. Já trabalhou alguma vez na "fabrica" de tratamento de esgotos em New Bedford?

YES.....1 (GO TO A) ⟶ ☐
NO.....2 (GO TO Q18)

CODE: INDUSTRY ☐☐

A. (1) Que tipo de trabalho é que fazia_____ PROBE

(2) Quais eram as suas funções e actividades mais importante?
DUTIES: _____ PROBE

(3) Qual era o titulo do seu cargo?_____
CODE: OCCUPATION ☐☐

(4) Em que ano começou a desempenhar este posição? 19_____ 19☐

(5) Quantos meses/anos desempenhou esta posição na "fabrica" de tratamento de esgotos? _____/_____
MONTHS YEARS
CODE: # of MONTHS ☐☐

PROBE: FOR ALL positions HELD AT SEWAGE TREATMENT PLANT.

B. KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____

CODE: OCCUPATION ☐☐

START YEAR: 19_____ 19☐

MONTHS/YEARS: _____ OR _____
MONTHS YEARS
CODE: # of MONTHS ☐☐

C. PROBE: FOR ALL positions HELD AT SEWAGE TREATMENT PLANT.
USE WASTE TREATMENT SUPPLEMENTAL.

D. SUPPLEMENTAL WASTE TREATMENT SHEET USED:

YES.....1 ⟶ ☐
NO.....2

18. Já alguma vez trabalhou no lugar do lixo da cidade de New Bedford (perto de aeroporto)?

YES.....1 (GO TO A) → ☐
NO.....2 (GO TO Q19)

CODE: INDUSTRY ☐☐☐

A. (1) Que tipo de trabalho fazia?_____
PROBE

(2) Quais eram as suas funções e actividades mais importante
DUTIES: _____ PROBE

(3) Qual era o titulo do seu cargo?_____
CODE: OCCUPATION ☐☐☐

(4) Em que ano começou a desempenhar esta posição? 19____ 19 ☐☐

(5) Quantos meses/anos desempenhou esta posição no lugar do lixo? _____/_____
MONTHS YEARS

CODE: # of MONTHS ☐☐☐

PROBE: FOR ALL positions HELD AT DUMP.

B. KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____

CODE: OCCUPATION ☐☐☐

START YEAR: 19____ → 19 ☐☐

MONTHS/YEARS: _____ OR _____
MONTHS YEARS

CODE: # of MONTHS ☐☐☐

C. PROBE: FOR ALL positions HELD AT DUMP.
USE WASTE TREATMENT SUPPLEMENTAL.

D. SUPPLEMENTAL WASTE TREATMENT SHEET USED:

YES.....1 → ☐
NO.....2

19. Já alguma vez trabalhou -- ate mesmo temporariamente -- em qualquer emprego que estivesse em contacto com algum dos seguintes materiais, ou já trabalhou em qualquer companhia que fabrica ou usam os seguintes materiais? (READ LIST)

YES.....1
NO.....2

IF YES TO ANY, USE PAGE 16 (Q19A-Q19G) TO RECORD. THEN RETURN TO NEXT MATERIAL

(1) Adesivos → ☐ ☐
(2) Fluidos de Compressores → ☐ ☐
(3) Substancias de calafetagem → ☐ ☐
(4) Óleos desengordursdores → ☐ ☐
(5) Agentes de retirar poeiras → ☐ ☐
(6) Tintas de tingir → ☐ ☐
(7) Retardadores de incendios → ☐ ☐
(8) Herbicidas → ☐ ☐
(9) Fluidos hidráulicos → ☐ ☐
(10) Óleo de imersão para microscópios → ☐ ☐
(11) Lacas → ☐ ☐
(12) Lubrificantes → ☐ ☐
(13) Tintas → ☐ ☐
(14) Plastificadores → ☐ ☐
(15) Massa de vidraça → ☐ ☐
(16) Resinas → ☐ ☐
(17) Borracha → ☐ ☐
(18) Vedadores → ☐ ☐
(19) Vernizes → ☐ ☐
(20) Aumentadores de cera → ☐ ☐
(21) Conservantes de madeira → ☐ ☐

IF NO TO ALL OF ABOVE: _____ (GO TO Q20, PAGE 17)

(Q19 CONT'D)
IF YES TO ANY OF ABOVE, USE A TEROUGE G TO RECORD.

THEN ASK: Já trabalhou em qualquer outra companhia que usa estes materiais ou qualquer outro emprego em que o pos em contacto com estas materias?

A. (1) MATERIAL: _____ CODE:
(2) Para que companhia ou negocio que trabalhou?
(NAME OF COMPANY)_____ CODE:

(3) Quantos meses/anos teve este trabalho?_____MONTHS
YEARS

THEN ASK: Ja trabalhou... CODE: # OF MONTHS

B. (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

C. (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

D. (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

E. (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

F. (1) MATERIAL: _____ CODE:

(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

G. SUPPLEMENTAL EXPOSURE SHEET USED:
YES.....1
NO.....2 ⟶

20. Já alguma vez trabalhou - ate mesmo temporariamente quer "part time" ou "full time" em QUALQUER posição em fábricas ou indústrias?

YES.....1
NO.....2 (GO TO Q21)

A. Já trabalhou em companhias em que os seguintes materiais eram fabricados ou eram usados para fabricar outros produtos?
(READ LIST)

YES.....1
NO.....2

(1) Papel Quimico
(2) Forrar fios eléctricos com plástico
(3) Lampadas fluorescentes (fabrico apenas)
(4) Turbinas de transmissão a gás
(5) Unidades de produção de calor ou sistemas de transferencias de calor
(6) Aparelhos de ar condicionado para uso caseiro (fabrico apenas)
(7) Sistemas hidráulicos
(8) Ferro fundido
(9) "Olefin" (fabrico apenas)
(10) Reciclagem de papel
(11) Aparelhos de televisão (fabrico apenas)
(12) Linha de seda
(13) Bombas de aspirador

IF NO TO ALL OF ABOVE: _____ (GO TO Q21)

IF YES TO ANY OF ABOVE, USE B TO RECORD.
THEN ASK: Já trabalhou noutra companhia que usava estes materiais ou em algum trabalho em que esteve em contacto directo com estes materiais? USE C TO RECORD. THEN RETURN TO LISTING.

B. (1) PRODUCT: _____ CODE:
(2) Para que companhia ou negocio trabalhou?
(NAME OF COMPANY)_____ CODE:

(3) Quantos meses/anos teve este trabalho?_____MONTHS
YEARS
CODE: # OF MONTHS

C. (1) PRODUCT: _____ CODE:
(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

D. (1) PRODUCT: _____ CODE:
(2) COMPANY: _____ CODE:

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS

E. SUPPLEMENTAL EXPOSURE SHEET USED:
YES.....1
NO.....2

21. Já alguma vez aguou ruas para não deixar levantar o pó, quer como trabalho, quer na sua propriedade (queria_ligação_que_não seja_água)?

JOB.....1 (GO TO A)
SOME.....2 (GO TO B) → ☐
BOTH JOB AND SOME.....3 (GO TO A AND B)
NO, NEITHER.....4 (GO TO Q23)

A. (1) Para que companhia ou negocio que trabalhou?
(NAME OF COMPANY) _____ CODE: ☐☐☐

(2) Que tipo de companhia ou industria era esta?
(TYPE OF BUSINESS) _____
CODE: INDUSTRY ☐☐☐

(3) Quantos meses/anos teve este trabalho?_____MONTHS
YEARS
CODE: # OF MONTHS ☐☐☐

B. ROAD SPRAYING: Por quantos anos é que fez este trabalho de aguar?

_____/_____
MONTHS YEARS CODE: # OF MONTHS ☐☐☐

22. SECOND BLOOD PRESSURE:

30 SEC RADIAL PULSE: _____ CODE I2: ☐☐☐

IRREGULAR PULSE: YES.....1 → ☐
NO.....2

SYSTOLIC: _____ CODE SYS: ☐☐☐
DIASTOLIC: _____ RES: _____ CODE DIAS: ☐☐☐

ARM: RIGHT.....1 → ☐
LEFT.....2

TIME: → ☐☐☐☐

[illegible]

23. OBTAINING LOCAL SEAFOOD:

CATCH OWN.....01
FAMILY/FRIENDS CAUGHT.....02
OTHER LOCAL FISHERMEN.....03
LOCAL FISH RETAILERS.....10-39
SUPERMARKETS/GROCERIES.....50-74
DOT KNOW.....98

A. Como é que você e sua família obtinha peixe e mariscos [1979]?
PROBE USING CODES.

ANSWER 01: _____ CODE: PLACE

ANSWER 02: _____ CODE: PLACE

B. ([Se_not_1979, em 1979/ O ÚLTIMO ANO QUE VIVEU NA ÁREA DE NEW BEDFORD ANTES DE 1979), como é que vosse e sua família obtinha peixe e mariscos [1979]?

ANSWER 01: _____ CODE: PLACE

ANSWER 02: _____ CODE: PLACE

24. Quero referer a seguinte pergunta a [todos] tipos de peixe e marisco, incluindo peixe e mariscos apanhado nas áreas local e todos tipos comprado para cozinhar em casa ou comprado em restaurantes.

A. Acha que [INCREASE_SINCE_NOT_KNOW] o consumo total de qualquer tipo de peixe e marisco tem AUMENTADO, DIMINUÍDO OU FICADO NA MESMA?

INCREASED.....1
SAME.....2 (GO TO Q25)
DECREASED.....3
NO SEAFOOD MEALS TIME.....9 (GO TO Q25)

B. Pensa que houve alguma razão para este mudanças?

ECONOMICS.....1
TASTE.....2
HEALTH REASONS (NO).....3
PCBs.....4
OTHER.....5
NO CHANGE.....9

CODE:

25. Dos seguintes tipos de peixe ou marisco, já comeu na sua vida cinco vezes ou mais? (READ LIST)

YES.....1
NO.....2

A. "Clams" ou "Quahogs"? →

B. Lapas? →

C. Saquis? →

D. Peixe azul, "Striped Bass" ou cavala? →

E. Dos seguintes tipos de peixe e marisco, já comeu na sua vida cinco vezes ou mais? (READ LIST)

YES.....1
NO.....2

"Scops", "tató", solha, bacalhau e truta do mar (peixe fraco)? →

F. Peixe gato, carpa, peixe "búfalo", truta de água doce, caboz? →

G. (1) Lagosta? (IF NO, GO TO Q26 OR Q27) →

(2) Como geralmente as bocas e o rabo da lagosta, só as "papas verdes" ou ambos?

CLAWS AND TAIL ONLY.....1
TOMALLEY ONLY.....2 →
BOTH.....3
NO LOBSTER.....9

IF NO TO ALL OF ABOVE: _____ (GO TO Q27)

26. IF YES TO ANY OF A THROUGH G, Q25:

A. Se [illegible] todos os tipos de (peixe e) marisco acima mencionados que já comeu -- isto é, _____ e _____(Q25) -- quantas vezes comeu qualquer destes espécies [illegible] 12 meses? (READ CODES AND SHOW CARD 92)

Muitas vezes=duas ou mais vezes por semana.....1
Ocasionalmente=pelo menos uma vez por semana....2
Algumas vezes=uma vez por semana, pelo menos uma vez por mês.....3 →
Poucas vezes=uma vez por mês, pelo menos uma vez por ano.....4
RARAMENTE OU NUNCA=UMA VEZ POR ANO.....5

B. Há quantos anos é que já vem comendo estes tipos de peixe ou mariscos?

1-64 YEARS.....01 THROUGH 64 →
LESS THAN ONE YEAR.....91
NEVER ATE ANY.....99

(Q26 CONT'D)

C. Acha que o consumo total destes peixes e mariscos são.
_____e_____(Q25) - tem AUMENTADO, DIMINUÍDO OU FICADO NA MESMA
os mesmos durante os ultimos _____(Q26B)anos?

INCREASED.....1
SAME.....2
DECREASED.....3 →
NEVER ATE ANY.....9

27. As seguintes perguntas estão relacionadas com passatempos, tais como pesca no rio Acushnet e nas partes da área do New Bedford. A área que me estou a referir é a seguinte (SHOW MAP AND LANDMARKS).

Já alguma vez fez as seguintes actividades nesta área cinco vezes ou mais?

YES.....1
NO.....2

A. Apanhando "clams" ou "quahogs"? →

B. Apanhando "lapas"? →

C. Apanhando enguia? →

D. Apanhando lagostas? →

E. Pescando como indústria ou desporto? →

28. Quantas libras pesa normalmente sem sapatos ou roupa?

_____ CODE: # of POUNDS

29. TRICEPS SKIN FOLD:

A. ARM: RIGHT.....1 →
LEFT.....2

B. 1st MEASUREMENT: CODE mm:

B. 2nd MEASUREMENT: CODE mm:

30. HEIGHT: _____/_____ CODE I 2.54: cm
feet inches

31 HEIGHT: _____ CODE. lb:

32. OBTAINING LOCAL SEAFOOD:

CATCH OWN.....01
FAMILY/FRIENDS CADGE.....02
OTHER LOCAL FISHERMEN.....03
LOCAL FISH RETAILERS.....10-39
SUPERMARKETS/GROCERIES.....50-74
OUT HOME.....90

A. Como é que voce e a sua familia obtinha peixe e mariscos apanhados @@ELA_ACHE, no rio ou porto(MAP)?

ANSWER 01: _____ CODE: PLACE

ANSWER 02: _____ CODE: PLACE

B. @É_QUE_ESSE, em 1975/O ULTIMO ANO QUE VIVEU NA AREA DE NEW BEDFORD ANTES DE 1975, como é que voce e a sua familia obtinha peixe e mariscos apanhados @@ELA_ACHE, no rio ou porto(MAP)?

ANSWER 01: _____ CODE: PLACE

ANSWER 02: _____ CODE: PLACE

33. Disse-me antes que já viveu na área de New Bedford por mais de cinco anos. Durante este tempo, e novamente referindo-me ao rio e ao porto local (REMIND R OF MAP), vou então perguntar-lhe quantas vezes é que @@EU certos tipos de mariscos locais que foram apanhados por si, por amigos, familiares ou vizinhos no porto de New Bedford.

LOBSTER: Comeu lagosta apanhada @@ELA_ACHE cinco ou mais vezes durante a sua vida?

YES.....1
NO.....2 (GO TO Q34) ——→

A. (1) Que idade tinha quando começou a comer lagosta apanhada aqui @@_ÁCHE? _____

(2) Qual é o ano mais recente que voce come lagosta apanhada na área? _____

CODE: # OF YEARS

B. Durante este__ _____(Q33A) anos, por favor lembre-se do tempo em que @@ELE_VOCE comeu lagosta apanhada_na_costa_de_New_Bedford. Isso foi quando era CRIANÇA, ADOLESCENTE OU ADULTO?

CHILD.....1
TEENAGER.....2
ADULT.....3 ——→
ALL THREE THE SAME.....4

(Q33 CONT'D)

C. Quando estava a comer lagosta, apanhado em_áreas, diria que comia duas ou mais vezes por semana, pelo menos uma vez por semana, menos do que uma vez por semana, mas pelo menos uma vez por mes, ou menos do que uma vez por mes, mas pelo menos uma vez por ano? (SHOW CARD 62 AGAIN)

Often=two or more times/week.....1
Occasionally=at least once/week.....2
Sometimes=(once/week, at least once/month.....3
Infrequently=(once/month, at least once/year.....4
RARELY OR NEVER=<ONCE/YEAR.....5

D. Acha que o seu consumo de lagosta apanhado em_áreas tem AUMENTADO, DIMINUÍDO, OU FICADO NA MESMA o mesmo de que os ultimos ____(Q33A) anos?

INCREASED.....1
SAME.....2
DECREASED.....3
NEVER ATE LOBSTER.....9

E. Geralmente come as bocas, o rabo, ou os dois orgão (papas verdes) ou ambos das lagostas apanhadas nesta área?

CLAWS AND TAIL ONLY.....1
TOMALLEY ONLY.....2
BOTH.....3
NO LOBSTER.....9

34. IF YES TO Q33, AFTER 3RD 'YES' IN Q34, READ QUESTIONS 34(1)-(6) VERBATIM.
IF NO TO Q33, READ QUESTIONS 34(1)-(6) VERBATIM 1ST AND 4TH 'YES'.

(1) Já comeu _____ - apanhados nesta área por si, membros da família, amigos ou vizinhos -- cinco ou mais vezes durante a sua vida?

YES.....1
NO.....2 (GO TO NEXT SEAFOOD)

(2) Que idade tinha quando começou a comer _____ apanhados nesse_área?

(3) Qual é o ano mais recente em que comeu _____ apanhados nesse_área?

(4) Durante estes _____(Q34(1)&(2)) anos, por favor lembre-se de coisas em que pode_estar comeu _____(apanhados_na_costa_de_New_England). Isso foi quando era CRIANÇA, ADOLESCENTE OU ADULTO?

CHILD.....1
TEENAGER.....2
ADULT.....3
ALL THREE THE SAME.....4

(5) Na altura que comia _____ apanhados nesse_área, diria que comia-os duas ou mais vezes por semana, pelo menos uma vez por semana, menos do que uma vez por semana, mas pelo menos uma vez por mês, ou menos do que uma vez por mês, mas pelo menos uma vez por ano? (SEE CARD 82 AGAIN)

Often=3 or more times/week.....1
Occasionally=at least once/week.....2
Sometimes=<once/week, at least once/month.....3
Infrequently=<once/month, at least once/year...4
RARELY OR NEVER=<ONCE/YEAR.....5

(6) Acha que o consumo total de _____ apanhados_nesta_área, tem AUMENTADO, DIMINUÍDO OU FICADO NA MESMA os menos durante os últimos _____ (Q34(1)&3)) anos?

INCREASED.....1
SAME.....2
DECREASED.....3
NEVER ATE _____.....9

	(1) YES, NO	(2) FIRST YEAR	(3) LAST YEAR	CODE: YEARS	(4) MOST FREQ	(5) FREQ-NEMCY	(6) FREQ-UENCY
A. "olano" ou "quebogo"							
B. Lapas							
C. Taquila							
D. Peixe azul, "Striped Bass", ou cavala							
E. "Scup", "tautó", peixe, baseiou o truta do mar (peixe fresco)							

35. IF YES TO TWO OR MORE SPECIES IN Q33 OR 34: CONTINUE
IF YES TO NONE OR ONLY ONE: GO TO Q36.

Se juntarmos todos os tipos de peixe e mariscos apanhados por si, família, ou amigos no porto local que mencionei desde a lagosta até ao caranguejo, os "clams" ao "striped bass" e salsa:

A. (1) Que idade tinha quando começou a comer estas espécies de peixe apanhadas nesse local? _____

(2) Qual é o seu mais recente ano que comeu mariscos apanhados no porto de área local? _____

CODE: # OF YEARS

B. Durante estes _____(Q35A) anos, por favor lembre-se do tempo em que mais vezes comeu qualquer tipo de mariscos apanhados no porto de Nova Redford. Isso foi quando era CRIANÇA, ADOLESCENTE OU ADULTO?

CHILD.....1
TEENAGER.....2
ADULT.....3
ALL THREE THE SAME.....4

C. Quando estava a comer mariscos apanhados no porto de Nova Redford, diria que comia duas ou mais vezes por semana, pelo menos uma vez por semana, menos do que uma vez por semana, mas pelo menos uma vez por mês, ou menos do que uma vez por mês, mas pelo menos uma vez por ano? (SHOW CARD 92 AGAIN)

Often=two or more times/week.....1
Occasionally=at least once/week.....2
Sometimes=<once/week, at least once/month.....3
Infrequently=<once/month, at least once/year.....4
RARELY OR NEVER=<ONCE/YEAR.....5

D. Acha que o seu consumo de marisco apanhado no área tem AUMENTADO, DIMINUÍDO, OU FICADO NA MESMA o mesmo do que os últimos _____(Q35A) anos?

INCREASED.....1
SAME.....2
DECREASED.....3
NEVER ATE LOCAL SEAFOOD.....9

MEDICAL_HISTORY

36. SODIUM:

A. Nos últimos 12 meses QUANTAS_VEZES comeu PEIXE_SECCO_NOS_VOS uma das seguintes comidas: bacalhau seco, presunto ou carnes frias, hamburgers ou galinha (i.e., McDonald's, Kentucky Fried Chicken), vegetais e sopas enlatadas ou salgadinhos (exemplo: batatas fritas) TODOS OS DIAS, 2 A 4 VEZES POR SEMANA, CERCA DE UMA VEZ POR SEMANA, MENOS DO QUE UMA VEZ POR SEMANA _____(READ LIST)?

Daily.....1
2-4 Times/Week.....2 ⟶ ☐
About Once/Week.....3
<Once/Week.....4

B. Quando prepara a comida, geralmente, de vez em quando ou raramente usa sal?

USUALLY.....1
SOMETIMES.....2 ⟶ ☐
RARELY.....3

C. Depois da comida pronta, geralmente, de vez em quando ou raramente usa sal a mesa?

USUALLY.....1
SOMETIMES.....2 ⟶ ☐
RARELY.....3

D. Nos últimos cinco anos, diria que a quantidade de sal que usa tem AUMENTADO, DIMINUIDO, FICADO NA MESMA?

INCREASED.....1
SAME.....2 ⟶ ☐
DECREASED.....3

E. (1) Voce está numa dieta de sal?

YES.....1
NO.....2 (GO TO Q37) ⟶ ☐

(2) Foi recomendada por um médico?

YES.....1
NO.....2 ⟶ ☐
NO SODIUM DIET.....9

Agora vou fazer algumas perguntas sobre a sua saúde:

37 CURRENT DOCTOR

A. Tem um médico que geralmente pode ser contactado àcerca da sua saúde?

YES.....1
NO.....2 (GO TO F) ——→ ☐

B. Qual é o seu nome?_____

C. Qual é a direcção?_____
_____

CODE: SPECIALTY ☐☐

D. No fim desta entrevista, vou entregar-lhe um cartão indicando a sua pressão arterial. Quer que eu envie estes resultados ou resultados do PCB ao Dr. _____(Q37A)?

YES.....1 (GO TO Q38)
NO.....2 (GO TO E) ——→ ☐

E. Tem outro medico que queira que eu mande o reporte da sua pressão arterial?

YES.....1 (GO TO E(1))
NO.....2 (GO TO Q38) ——→ ☐

(1) Qual e o seu nome?_____

(2) Qual e a direcção?_____
_____

CODE: SPECIALTY ☐☐

F. No fim desta entrevista, vou entregar-lhe um cartão indicando a sua pressão arterial. Tem um medico que deseje que eu envie o resultado da sua pressão arterial e os resultados do PCB?

YES.....1 (GO TO F(1)
NO.....2 (GO TO Q38) ——→ ☐

(1) Qual e o seu nome?_____

(2) Qual e a direcção?_____
_____

CODE: SPECIALTY ☐☐

38. Está ACTUALMENTE a ser tratado por um médico por qualquer razão física ou de saúde?

YES.....1 → ☐
NO.....2 (GO TO Q39)

A. (1) Qual é a condição? _____ CODE: ☐☐☐☐

(2) Qual é o Médico lhe está tratando _____(Q38A)?

_____

(3) Quando é que primeiro soube deste problema _____ (Q38A)?

_____/_____ CODE: YEARS ☐☐
MONTH YEAR

B. Tem qualquer outra condição que está sendo tratado pelo médico?

YES.....1 → ☐
NO.....2 (GO TO Q39)

(1) Qual é a condição? _____ CODE: ☐☐☐☐

(2) Qual é o Médico que lhe está tratando _____(Q38B)?

_____

(3) Quando é que primeiro soube deste condição _____ (Q38B)?

_____/_____ CODE: YEARS ☐☐
MONTH YEAR

C. Tem outra condição que estar ser tratado por um médico?

YES.....1 → ☐
NO.....2 (GO TO Q39) ☐

(1) CONDITION 03: _____
(2) CONDITION 04: _____
(3) CONDITION 05: _____
(4) CONDITION 06: _____

19. Está ACTUALMENTE a tomar qualquer remédios, quer receitado pelo médico ou comprado sem receita?

YES.....1
NO.....2 (GO TO Q40) → ☐

IF YES, ASK: Por favor tente lembra-se dos remédios que está presentemente a tomar, o médico que os receitou e a razão porque está a toma-los.

	DRUG	PHYSICIAN	CONDITION	NO/YES/DON'T KNOW
a.				
b.				
c.				
d.				
e.				
f.				

8. PROBE: FOR ADDITIONAL A'S AND OVER-THE COUNTER, INCLUDING SKIN PREPARATIONS, ANTI-HISTAMINES, ASPIRIN.

	DRUG	PHYSICIAN	CONDITION	NO/YES/DON'T KNOW
a.				
b.				
c.				

40. Está presentemente tomando algum remédio nas seguintes categorias?
SKIP CATEGORY IF MENTIONED ABOVE

IF YES, ASK: Porque razao esta tomando estes remedios?
Ea que nos e ano começou a tomar este remedio?

	YES..1 NO....2	CONDITION	MO./YR. BEGUN	TOTAL MONTHS
(a) Remédios para tensão alterial?	☐	----------	---/☐☐	☐☐☐
(b) Anti-histemines?	☐	----------	---/☐☐	☐☐☐
(c) Remédios para o coraçāo	☐	----------	---/☐☐	☐☐☐
(d) Anti-coqulantes (fazer o sangue mais fino)?	☐	----------	---/☐☐	☐☐☐
(e) Anti-bióticos para longo termo?	☐	----------	---/☐☐	☐☐☐
(f) Esteróides (remédios parecidos a cortisone)?	☐	----------	---/☐☐	☐☐☐
(g) Comprimidos para diabete ou insulina?	☐	----------	---/☐☐	☐☐☐
(h) Comprimidos para dormir?	☐	----------	---/☐☐	☐☐☐
(i) FOR FEMALES ONLY: Comprimidos para? controle de nascimento.	☐	----------	---/☐☐	☐☐☐
(j) Suplemento de vitaminas?	☐	----------	---/☐☐	☐☐☐
(k) Remédios para a tiróide?	☐	----------	---/☐☐	☐☐☐
(l) Relaxantes de musculos?	☐	----------	---/☐☐	☐☐☐
(m) Sedotivos ou tranquilizantes?	☐	----------	---/☐☐	☐☐☐
(n) Tratamento e "Radiaçāo"?	☐	----------	---/☐☐	☐☐☐

41. RECENT BLOOD PRESSURE:

A. Antes de hoje, quando foi a altura vez que mediu a sua tensão arterial?

_____ DAYS	OR	_____ MONTHS	OR	_____ YEARS

1-64 YEARS	01 through 64
< 1 MONTH	91
1-3 MONTHS	92
4-6 MONTHS	93
6-11 MONTHS	94
NEVER	95 (GO TO Q42)

B. Qual era a medida da sua tensão arterial? Era_____(READ LIST)?

ABAIXO DO NORMAL	1
NORMAL	2
ACIMA DO NORMAL	3
NEVER MEASURED	8

42. Já alguma vez foi-lhe dito por um médico que tem qualquer das seguintes condições? (READ LIST)

IF YES, ASK: Em que mes e ano é que lhe foi dito pela primeira vez por um médico que tinha esta condição?

	YES..1 NO...2	MO./YEAR QUEST
(a) Tensão alta?		___/___
(b) Problemas do fígado, isto é cirrose, fígado encharado, hepatite, "fel amarelo"? IF YES, PROBE: conditions and date: _____		___/___
(c) Já alguma vez foi dito por um médico que tinha algum das seguintes condições de pele (READ LIST)		
(1) Psoriase?		___/___
(2) Dermatite?		___/___
(3) Eczema?		___/___
(4) Acne?		___/___
(5) Cloracne?		___/___
(6) Escurecimento da pele e unhas (excepto quando apenas sol)?		___/___
(7) Cortes na pele?		___/___
(8) Excesso de cabelo na cara?		___/___
(9) Excesso de crescimento de cabelo nos ombros, parte superior do corpo, no peito à volta dos mamilos?		___
(10) Qualquer outra condição de pele: PROBE		

IF YES, ASK: Em que ano é que lhe foi dito pela primeira vez por um médico que tinha esta condição? YES..1 NO./YEAR
NO....2.....DON'T

(d) Já lhe foi dito por um médico alguma vez que tem algum dos seguintes condições circulatórias? (READ LIST)

(1) Problemas de sangue, isto é anemia, ou tendencia a sangrar? ---/

(2) Ataque de coração/falha? ---/

(3) Angina de peito? ---/

(e) Já lhe foi dito por um médico alguma vez que algum dos seguintes condições da vista? (READ LIST)

(1) Cataratas? ---/

(2) Infecções nos olhos (olhos cor de rosa)? ---/

(3) Constante lágrimas nos olhos ou inchaço? ---/

(4) Glaucoma? ---/

(5) Outros condições de olhos: PROBE ---/

(f) Já alguma vez foi-lhe dito por um médico que tem algum dos seguintes condições de sistema nervoso (READ LIST)

(1) Ataques, epilepsia? ---/

(2) Tremores? ---/

(3) Fraqueza ou paralisia dos braços ou pernas? ---/

(4) Pernas e braços dormentes? ---/

(5) Arrepios? ---/

(6) Vertigens? ---/

(7) Doença mental? ---/

(8) Constante perda de memória? ---/

(9) Dores de cabeça mais do que uma vez por semana?
IF YES:
Em geral. 1
Num lugar específico.....2

(10) Outras condições neurológicos: PROBE ---/

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(Q42 CONT'D)

IF YES, ASK: Em que ano é que lhe foi dito pela primeira vez por um médico que tinha esta condição? YES..1 NO./YEAR
NO....2_____ONSET

(g) Já lhe foi dito por algum médico que tem alguma das seguintes condições respiratórias?(READ LIST)

(1) Bronquite (mais severa do que constipações normais: a tosse faz sair a expectoração)? → ☐ ___/☐☐

(2) Asma? → ☐ ___/☐☐

(3) Outras doenças crónicas do respiração ou pulmões? PROBE CONDITION: _____ → ☐ ___/☐☐

(h) Já lhe foi alguma vez dito por algum médico que tem alguma das seguintes condições comuns?

(1) Inchaço dos pés ou asma? → ☐ ___/☐☐

(2) Rápida perda de peso? → ☐ ___
IF YES: razão:
DIETA.....1 → ☐
OUTRA DOENÇA....2
DESCONHECIDO....3

(3) Deficiencias de imunização ou outros problemas de imunização? → ☐ ___/☐☐

(4) Infecções repetidas ou que duram demais? → ☐ ___/☐☐

(5) Diabetes ou açúcar? → ☐ ___/☐☐

(6) Doenças de tiróide? → ☐ ___/☐☐

(7) Outras condicoes gerais: PROBE → ☐ ___/☐☐
_____

(i) Já lhe foi dito por algum médico que tem cancro? → ☐ ___/☐☐
IF YES, Cancro sonde?_____

(j) OTHER: Já teve outras doenças crónicas ou operações que eu não tenha mencionado?

YES.....1 → ☐
NO.....2

IF YES, PROBE: CONDITIONS AND DATES:

_____ _____
_____
_____

43. Já teve algum dos seguintes sintomas durante tres anos ou mais?
YES. ASK: (1) Em que mes e ano _____ começou?

(2) Ainda tem esse sintoma?
YES.....1
NO.....2

		YES..1 NO..2	NO./YEAR ONSET	CURRENT YES/NO
A.	Perda de apetite?		___/	
B.	Náusea?		___/	
C.	Fraqueza?		___/	
D.	Fatiga?		___/	
E.	Paralização ou "formigueiro" nas extremidades do corpo?		___/	

44. Já fumou mais do que cinco carteiras de cigarros durante a sua vida?

YES.....1
NO.....2 (GO TO Q45)

A. Fuma cigarros presentemente?

CURRENT SMOKER.....1
FORMER SMOKER.....2
NEVER SMOKED.....3

B. Num dia normal, quantos cigarros fuma (fumou)?

_____ OR _____
PACKS CIGS

C. Há quanto tempo é que fuma (fumou)?

_____ OR _____
MONTHS YEARS

CODE: # of PACKYEARS

45. Já alguma vez fumou cachimbo, cigarrilhas ou charutos?

YES.....1
NO.....2 (GO TO Q46)

A. Fuma presentemente cachimbo, cigarrilhas ou charutos?

CURRENT SMOKER.....1
FORMER SMOKER.....2
NEVER SMOKED.....3

46. Em total, Já tomou mais de cinco bebidas alcoólicas na sua vida inteira?

YES.....1
NO.....2 (GO TO Q47) ——→ ☐

A. Presentemente, bebe bebidas alcoólicas?

CURRENT DRINKER.....1
FORMER DRINKER.....2 ——→ ☐
NEVER DRANK.....3

B. Usando os números neste cartão, calcule quanta bebida consome _____(tipo)? (SHOW CARD 83)

UMA OU MAIS POR DIA.....1
DUAS A SEIS VEZES POR SEMANA.....2
UMA POR SEMANA.....3
DE UMA A TRES VEZES POR MES.....4
MENOS DO QUE UMA VEZ POR MES.....5
RARAMENTE.....6
NUNCA.....7

1. Latas ou garrafas de cerveja:

FREQUENCY ——→ ☐

2. Copos de vinho:

FREQUENCY ——→ ☐

3. Cálices de licor ou whiskey:

FREQUENCY ——→ ☐

C. Quantas latas, copos e cálices costuma beber de uma assentada?

ONE.....1
TWO.....2
THREE.....3
FOUR.....4
FIVE.....5 ——→ ☐
SIX.....6
SEVEN OR MORE.....7
NEVER DRANK.....8

47. Olhando para este cartão, diga-me qual número indica a sua raça? (R'S ANCESTORS) SHOW CARD 84

BRANCO.....1
PRETO.....2
INDIO AMERICANO/NATURAL DO ALASKA.....3 ——→ ☐
ASIATICO/ILHAS DO PACIFICO.....4
OUTRO.....5
SPECIFY: _____

48. Voce e_____(READ LIST)?
CASADO.....1
VIUVO.....2
SEPARADO.....3
DIVORCIADO.....4
SOLTEIRO(A).....5



49. Agora pode-me dizer quantas pessoas estão ACTUALMENTE a viver na sua casa, incluindo voce? Por favor conte todas as que aqui vivem, incluindo as que estão ausentes temporariamente, por exemplo em férias ou no hospital

A. # of PERSONS (INCLUDE R) (IF ONE, GO TO Q50)



B. Quantas destas pessoas tem mais de 18 anos? _____
CODE: # >= 18

50. Por favor faça uma estimativa do rendimento familiar, somando todos os ordenados dos ultimos 12 meses das pessoas que vivem consigo. Inclua todos os ordenados, salarios, pensões de seguro social e de reforma, juros, ajudas da familia, rendas de propriedades, beneficios de desemprego. Leia o numero neste cartao (05) que condiz com o seu ordenado.

$ 0 - 14,999.....1
15,000 - 29,999.....2
30,000 +.....3



51. Se caso que tenha mais algumas perguntas ou se mudar quando os resultados do PCS estiverem prontos e quisermos enviá-los a si, pode dar-me o nome, a direcção e o número de telefone de duas pessoas que conseguirão sempre estrar em contacto consigo, mas que não vivem consigo.

NAME: _____

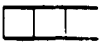
ADDRESS: _____PHONE: _____

NAME: _____

ADDRESS: _____ PHONE: _____

52: BLOOD PRESSURE #3

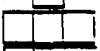
30 SEC RADIAL PULSE: _____ CODE 52:



IRREGULAR? YES.....1
NO.....2

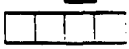


SYSTOLIC: _____ CODE SYS:
DIASTOLIC: _____ RES: _____ CODE DIAS:



ARM: RIGHT.....1
LEFT.....2





TIME: _____

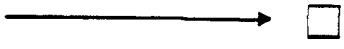
COMPLETE BLOOD PRESSURE REPORT-SUBTRACT RANDOM ZERO. USE LOWEST OF 3 READINGS(P. 3, 18.

INTERVIEWER SECTION

After the interview, complete the following questions:

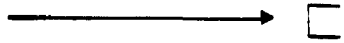
86. What was the respondent's general attitude toward the interview?

VERY INTERESTED.....1
INTERESTED.....2
DISINTERESTED.....3



87. Did respondent feel confident of responses?

YES, ALL THE TIME.....1
YES, MOST OF THE TIME.....2
ONLY SOME OF THE TIME.....3
SELDOM.....4
NEVER.....5



EDIT THE SERIES

88. FLAG if any call-backs or follow-ups needed for:

Blood	------
Urine	------
Skin fold	------
Residential	------
Occupational	------
Medical	------
Other:	
----------	------

CODE THE SERIES

After coding, complete the following questions:

89. CURRENT ADDRESS:

A. CODE: CURRENT TOWN:



B. CODE: CURRENT CENSUS TRACT:



90. SAMPLED ADDRESS:

A. CODE: SAMPLED CENSUS TRACT:



B. CODE: SAMPLE ADDRESS=CURRENT.....1
SAMPLE=PAST, STILL ONE.....2
SAMPLE=PAST, NON-ONE.....3



91. CODE: # OF ONE ADDRESSES:



CURRENT ALONE.....01

62. A. CODE: Total # of MONTHS in Greater New Bedford area: → [ ][ ][ ]

B. CODE: Interruption in sequences of Greater New Bedford area addresses for >12 months.

YES.....1
NO.....2 → [ ]

63. LANGUAGE INTERVIEW CONDUCTED IN:

ENGLISH.....1
PORTUGUESE.....2
SPANISH.....3
OTHER: _____.....4 → [ ]

64. TYPE OF INTERVIEW:

IN-OFFICE.....1
FIELD.....2
TELEPHONE.....3 → [ ]

65. A. PROXY RESPONDENT

YES.....1
NO.....2 → [ ]

B. Proxy responses began with Question #_____ → [ ][ ]

NO PROXY.....99

66. A. NUMBER OF CALLS → [ ][ ]

B. NUMBER OF VISITS TO HOUSE → [ ][ ]

C. NUMBER OF MAILINGS: → [ ][ ]

JUST INTRODUCTORY LETTER.....

67. NUMBER OF MINUTES to complete interview and blood pressure: → [ ][ ][ ]
Use last blood pressure measure as end of interview.

68. Day of week interview taken:

SUNDAY.....1
MONDAY.....2
TUESDAY.....3
WEDNESDAY.....4
THURSDAY.....5
FRIDAY.....6
SATURDAY.....7 → [ ]

69. INTERVIEWER #: _____ → [ ]

APPENDIX M

URINE SPECIMEN SHEET

APPENDIX H

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

URINE SPECIMEN

DATE OF BIRTH: _____ INTERVIEWER: →

DATE OF INTERVIEW/BP: _____ DATE: →

DIFFERENCE IN DATES: YES...1 →
NO....2

TIME: →

1.

A. During the last 24 hours, have you eaten any of the following foods? (CHECK ANY A SAYS 'YES')

Clams: _____
Quahogs: _____
Oysters: _____
Mussels: _____
Scallops: _____
Lobster: _____
Swordfish: _____
Flounder: _____
Tautog: _____

YES TO ANY.....1
NO TO ALL.....2 →
UNKNOWN.....3

B. During the last 24 hours, have you eaten any of these same foods? (CHECK ANY A SAYS 'YES')

Clams: _____
Quahogs: _____
Oysters: _____
Mussels: _____
Scallops: _____
Lobster: _____
Swordfish: _____
Flounder: _____
Tautog: _____

YES TO ANY.....1
NO TO ALL.....2 →
UNKNOWN.....3

I. RESULTS:

≥10cc OR MORE.....1
<10cc.....2 →
UNABLE TO OBTAIN.....3

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APPENDIX N

PHLEBOTOMY SHEET

APPENDIX A

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

PHLEBOTOMY

E [illegible] BIRTH: _____ PHLEBOTOMIST: → ☐

E [illegible] /INTERVIEW/BP: _____ DATE: → ☐☐ DAY ☐☐ YR ☐☐

DIFFERENCE IN DATES: YES....1 NO....2 → ☐

TIME: → ☐☐☐☐

A. When was the last time you ate any food?_____

<1 HOUR.....01	6-7 HOURS.....07
1-2 HOURS.....02	7-8 HOURS.....08
2-3 HOURS.....03	8-9 HOURS.....09
3-4 HOURS.....04	9-10 HOURS.....10
4-5 HOURS.....05	10-11 HOURS.....11
5-6 HOURS.....06	11-12 HOURS.....12
	>12 HOURS.....13

☐☐

B. When was the last time you had anything to drink other than water?_____

CODE: ☐☐

IF <12 HOURS TO EITHER A OR B:

(1) What did you eat/drink? _____

Liquid.....1
Snack.....2
Meal.....3 → ☐

(2) IF <12 HOURS, TRY TO RESCHEDULE:

DATE/TIME: _____ _____

Rescheduled.....1 (FILE)
Continued.....2 (GO TO 3)
>12 hours.....9 (GO TO 3) → ☐

For RESCHEDULED Respondents Only:

A. When was the last time you ate any food? _____ CODE: ☐☐

B. When was the last time you had anything to drink other than water? _____ CODE: ☐☐

IF <12 HOURS TO EITHER A OR B, ASK: What did you eat/drink?

_____

Liquid.....1
Snack.....2
Meal.....9 → ☐ CONTINUE

ARM: RIGHT.....1
LEFT.....2

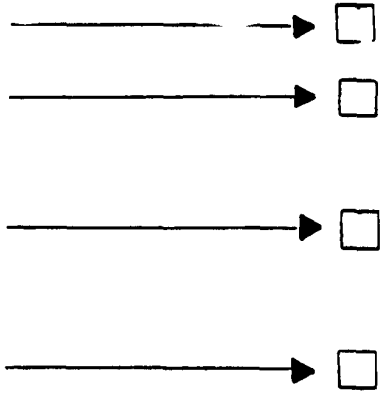
B. Second Site: RIGHT.....1
LEFT.....2
OTHER: _____.....8
FIRST SITE.....9

PROBLEMS ENCOUNTERED:

EXCESSIVE BLEEDING.....1
SYNCOPE(FAINTING).....2
DIZZINESS.....3
OTHER _____.....4

RESULTS:

ALL 5 TUBES, NO PROBLEMS.....1
<5 TUBES, NO PROBLEMS.....2
ALL 5 TUBES, ONE OR MORE PROBLEMS(Q4).3
<5 TUBES, ONE OR MORE PROBLEMS(Q4)....4
REFUSAL.....9



APPENDIX O

RESIDENTIAL SUPPLEMENT

MONS 027846

APPENDIX O

RESIDENTIAL SUPPLEMENT

PREVIOUS ADDRESSES:

ASK THE NEXT TWO QUESTIONS UNTIL NON-ONB AREA:
PUT ADDRESSES AND DATES IN TABLE

A. (1) What was your previous residence?

(2) When did you move into_____(Q10A(1) - address)?

WHEN NON-ONB-AREA, RECORD CITY/STATE

AND ASK: Previous to _____/_____(last date), did you live in either
month year
Newsheet, Dartmouth, Fairhaven, or New Bedford at any earlier time? (1940 ON)

	ADDRESS/No. STREET/CITY	DATE MONTH/YEAR	CODE: CT /CODE: MNTH
1		/	/
2.		/	/
		/	/
4.		/	/
5.		/	/
6.		/	/
7.		/	/
8.		/	/
9.		/	/
10.		/	/
		/	/

B. SUPPLEMENTAL RESIDENCE SHEET USED:

YES..... 1 → ☐
NO 2

APPENDIX P

CAPACITOR SUPPLEMENT

APPENDIX P

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

CAPACITOR SUPPLEMENTAL

Q14 & Q15 CONTINUED:

A. (1) COMPANY:
AEROVOX.....1
CORNELL/DUBILIER.....2
GE, PITTSFIELD.....3
OTHER _____.....4

(2) When did you start at _____(COMPANY)? _____/_____ → 19 ☐☐
MONTH YEAR

(3) When did you leave _____(COMPANY)? _____/_____
MONTH YEAR CODE: # OF MONTHS ☐☐☐

(4) What kinds_of_work did you do at _____(COMPANY) during those _____(2&3)(months/years)? RECORD BELOW EACH MENTIONED

(5) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) What were your most important activities or duties when you were _____(kind of work)?

(b) During the ____(2&3)(months/years) you were at _____(COMPANY), please estimate the total amount of time you _____(kind of work).

	KIND OF WORK	ACTIVITIES/DUTIES	TOTAL TIME (M/Y)	CODE: POSITION/	CODE: MONTHS
a.			M / Y	☐☐	☐☐
b.			M / Y	☐☐	☐☐
c.			M / Y	☐☐	☐☐
d.			M / Y	☐☐	☐☐
e.			M / Y	☐☐	☐☐
f.			M / Y	☐☐	☐☐

IF ANOTHER WORK SPAN AT SAME OR DIFFERENT COMPANY, CONTINUE.

THEN ASK: Did you ever work for _____(other CO/S OR another company making capacitors or transformers? IF YES, CONTINUE.

(1) COMPANY:
AEROVOX.....1
CORNELL/DUBILIER.....2
GE, PITTSFIELD.....3
OTHER _____.....4

(2) When did you start at _____(COMPANY)? _____/_____ MONTH YEAR → 19

(3) When did you leave _____(COMPANY)? _____/_____ MONTH YEAR CODE: # OF MONTHS

(4) What kinds of work did you do at _____(COMPANY) during these _____(2&3)(months/years)? RECORD BELOW EACH MENTIONED

(5) FOR EACH POSITION, ASK: (AND RECORD BELOW)

(a) What were your most important activities or duties when you were _____(kind of work)?

(b) During the ____(2&3)(months/years) you were at _____(COMPANY), please estimate the total amount of time you _____(kind of work).

	KIND OF WORK	ACTIVITIES/DUTIES	TOTAL TIME (M/Y)	CODE: POSITION/	CODE: # MONTHS
a.			M / Y		
b.			M / Y		
c.			M / Y		
d.			M / Y		
e.			M / Y		
f.			M / Y		

IF ANOTHER WORK SPAN AT SAME OR DIFFERENT COMPANY, CONTINUE.

THEN ASK: Did you ever work for _____(other CD/A OR another company making capacitors or transformers? IF YES, CONTINUE.

APPENDIX Q

ELECTRICAL EQUIPMENT WASTE TREATMENT SUPPLEMENT

APPENDIX O

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

ELECTRICAL EQUIPMENT MAINTENANCE/
WASTE TREATMENT SUPPLEMENT

Q16, Q17, & Q18 CONTINUED:

16. ELECTRICAL EQUIPMENT MAINTENANCE:

A. (1) What company or business did you work for?
(NAME OF COMPANY)_____

(2) What kind of business or industry was this? (i.e., TV REPAIR SHOP, HOME HEATING SYSTEM INSTALLATION.)
(TYPE OF BUSINESS)_____
CODE: INDUSTRY

(3) Was this mainly _____(READ LIST)?
Manufacturing.....1
Wholesale Trade.....2
Retail Trade.....3
Other.....4

GO TO B.

17 & 18. WASTE TREATMENT:

A. SEWAGE TREATMENT PLANT/DUMP CODE: INDUSTRY

PROBE: FOR ALL positions HELD AT THAT COMPANY.

GO TO B.

B. (1) What kind of work were you doing?_____ PROBE

(2) What were your most important activities or duties:
DUTIES:_____ PROBE

(3) What was your job title?_____
CODE: OCCUPATION

(4) What year did you start this position? 19____ 19

(5) How many months/years did you have this specific position with _____(COMPANY 16A(1), 17A, OR 18A)? _____/_____
MONTHS YEARS
CODE: # of MONTHS

PROBE: FOR ALL positions HELD AT THAT COMPANY. IF YES, GO TO C.

FOR Q16, THEN ASK: Did you work at another company where you were involved in the maintenance of electrical equipment? IF YES, GO TO C.

NAME OF COMPANY: _____
TYPE OF BUSINESS: _____ CODE: INDUSTRY

KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____
CODE: OCCUPATION

START YEAR: 19____ → 19

MONTHS/YEARS: _____ OR _____
MONTHS YEARS CODE: # of MONTHS

PROBE FOR OTHER POSITIONS IN W OF EE, SAME OR DIFF'T COMP'Y: IF YES, CONTINUE.
PROBE FOR OTHER POSITIONS IN SEWAGE TREATMENT PLANT AND/OR DUMP: IF YES, CONTINUE.

D. NAME OF COMPANY: _____
TYPE OF BUSINESS: _____ CODE: INDUSTRY

KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____
CODE: OCCUPATION

START YEAR: 19____ → 19

MONTHS/YEARS: _____ OR _____
MONTHS YEARS CODE: # of MONTHS

E. NAME OF COMPANY: _____
TYPE OF BUSINESS: _____ CODE: INDUSTRY

KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____
CODE: OCCUPATION

START YEAR: 19____ → 19

MONTHS/YEARS: _____ OR _____
MONTHS YEARS CODE: # of MONTHS

F. NAME OF COMPANY: _____
TYPE OF BUSINESS: _____ CODE: INDUSTRY

KIND OF WORK: _____
ACTIVITIES: _____
JOB TITLE: _____
CODE: OCCUPATION

START YEAR: 19____ → 19

MONTHS/YEARS: _____ OR _____
MONTHS YEARS CODE: # of MONTHS

APPENDIX R

MATERIAL PRODUCT EXPOSURE SUPPLEMENT

APPENDIX R

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

MATERIAL/PRODUCT
EXPOSURE SUPPLEMENT

Q19 & Q20 CONTINUED:

COMPLETE FOR MATERIALS(Q19) AND PRODUCTS(Q20):

THEN ASK: Did you work at any other company that used this material or another job that brought you into contact with this material?

A. (1) MATERIAL/PRODUCT: _____ CODE: ☐☐

(2) What company or business did you work for?
(NAME OF COMPANY)_____ CODE: ☐☐☐

(3) How many months/years did you have this job?_____MONTHS
_____YEARS
CODE: # OF MONTHS ☐☐☐

B. (1) MATERIAL/PRODUCT: _____ CODE: ☐☐

(2) COMPANY: _____ CODE: ☐☐☐

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS ☐☐☐

(1) MATERIAL/PRODUCT: _____ CODE: ☐☐

(2) COMPANY: _____ CODE: ☐☐☐

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS ☐☐☐

C. (1) MATERIAL/PRODUCT: _____ CODE: ☐☐

(2) COMPANY: _____ CODE: ☐☐☐

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS ☐☐☐

D. (1) MATERIAL/PRODUCT: _____ CODE: ☐☐

(2) COMPANY: _____ CODE: ☐☐☐

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS ☐☐☐

(1) MATERIAL/PRODUCT: _____ CODE: ☐☐

(2) COMPANY: _____ CODE: ☐☐☐

(3) _____/_____
MONTHS YEARS CODE: # OF MONTHS ☐☐☐

APPENDIX S

HOME VISIT SUPPLY LIST

APPENDIX S

HOME VISIT KIT SUPPLY LIST

STOP WATCH

STETHESCOPE

BLOOD PRESSURE CUFF

CARDS

MAP

NAPKINS OR TOWELS

BAG FOR DISPOSAL

BLOOD EQUIPMENT

TRICEPS MEASURE

URINE CUP

NEEDLE DISPOSER

NEWSPAPER OR TISSUE PAPER

SUPPLEMENTAL SHEETS

FLASHLIGHT

EMERGENCY TELEPHONE NUMBER (999-1212)

MONS 027857

APPENDIX T

BLOOD PRESSURE INSTRUCTION SHEET

APPENDIX T

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

RESPONDENT BLOOD PRESSURE INSTRUCTION SHEET

OUR BLOOD PRESSURE WAS MEASURED TO BE: ___ ___ ___/___ ___ ___

THIS MEASUREMENT SHOWS YOU HAVE: NORMAL BLOOD PRESSURE (<140/<90)

BORDERLINE BLOOD PRESSURE (140-159/90-104)

DEFINITE HIGH BLOOD PRESSURE (160+/105+)

IF YOU HAVE BORDERLINE OR DEFINITE HIGH BLOOD PRESSURE, YOU SHOULD ONSULT YOUR PHYSICIAN. IF YOUR BLOOD PRESSURE IS HIGH ON SEVERAL MEASURE-ENTS, YOU MAY BE ADVISED TO LOSE WEIGHT, TO AVOID SALTY FOODS, OR TO TAKE EDICATION TO LOWER YOUR BLOOD PRESSURE. FOR SOME PATIENTS, YOUR DOCTORS ILL FIND A CURABLE CAUSE OF HIGH BLOOD PRESSURE. FOR OTHER PATIENTS, NO AUSE WILL BE FOUND AND THE HIGH BLOOD PRESSURE WILL BE TREATED. IF YOU HAVE LOOD PRESSURE, YOU MAY FEEL PERFECTLY HEALTHY. HOWEVER, HIGH BLOOD ESSURE OVER MANY YEARS MAY DAMAGE YOUR KIDNEYS AND YOUR HEART OR CAUSE YOU AVE A STROKE. TREATMENT OF HIGH BLOOD PRESSURE WILL HELP YOU TO PREVENT ESE PROBLEMS.

IF YOU HAVE DEFINITE HIGH BLOOD PRESSURE, CHECK TO SEE IF THE FIRST NUMBER IGHER THAN 200. NOW CHECK TO SEE IF THE SECOND NUMBER IS HIGHER THAN 115. YOU CAN ANSWER YES TO EITHER OF THESE QUESTIONS, WE ADVISE YOU TO SEE A YSICIAN OR NURSE CLINICIAN WITHOUT DELAY.

TE: _____ INTERVIEWER: _____

THESE CLASSIFICATIONS HAVE BEEN ESTABLISHED BY THE JOINT NATIONAL COMMITTEE ETECTION, EVALUATION, AND TREATMENT OF HIGH BLOOD PRESSURE.

APPENDIX U

INTERVIEWERS MANUAL

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APPENDIX U

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY
INTERVIEWER'S MANUAL

I. BACKGROUND AND OBJECTIVES

The Greater New Bedford PCB Health Effects Study, Phase I, is a joint project among the Massachusetts Department of Public Health, Centers for Disease Control, and Massachusetts Health Research Institute, Inc. The primary objective of Phase I is to measure the prevalence (i.e., the distribution of individual levels) of PCB serum levels in a sample of the populations of the three towns of Acushnet, Dartmouth, Fairhaven, and the city of New Bedford, Massachusetts. Interest in determining the PCB prevalence arises from the uniqueness of the local situation in New Bedford: not only has there been occupational exposure to PCB's by persons working at the two local capacitor manufacturers, but also the whole population has been potentially exposed via the introduction of PCB's into the aquatic food chain.

Thus, in addition to measuring respondents' serum PCB levels, the Study will be conducting an interview which includes occupational and seafood dietary histories to see if there is an association between the PCB levels and routes of exposure. An abbreviated medical history will also be taken, focussing on specific diagnoses, in order to get an initial idea of any association between PCB levels and health status. Scientific evidence on a relationship between PCB levels and health effects is to-date unclear: in the Far East acute poisoning episodes, immediate physical effects were observed; long-term dermatological context in occupational settings has resulted in chloracne; and tests with laboratory animals have shown some carcinogenic and liver function toxic effects. One reason for this study being funded is to investigate whether there are observed health effects in humans who have been chronically exposed over a long period of time.

This manual contains the general guidelines and specific instructions for carrying out the interviewing tasks associated with collecting data for the Greater New Bedford PCB Health Effects Study. Other documents, such as the original proposal and updates, the sampling plan, and the instructions for collection of clinical data, detail other elements of the study.

In order to obtain useful and accurate data for analysis, the sample must be truly representative of the Greater New Bedford population, the interview questions must be asked in a uniform and standard fashion and the responses must be properly recorded and transmitted to the project staff. As an interviewer, you are responsible for these tasks and the success of the study depends upon the quality of your work.

II. SAMPLING PROCEDURES

The source lists used for sampling for the PCB Health Effects Study are the 1984 street listings for the City of New Bedford and the towns of Acushnet, Dartmouth, and Fairhaven. We must have the most current, and therefore, most accurate source list enumerating the population under study, and thus we are updating these lists with 1985 Commonwealth-required census data currently being compiled in each town registrar's office. The procedures for updating our 1984 listings to 1985 information appear with the Sampling Plan. Until we have every ward and precinct updated, we may have some difficulty in selected areas determining who the respondent is that we want to be contacting; however, this difficulty will be resolved as soon as possible in order to avoid adding any seasonal bias to the order in which we interview.

The sampling strategy being used is a proportional two-tiered stratification plan. The two variables being used to stratify are city/town and gender; proportional merely indicates that the number of respondents for each city/town and gender classification will be based on the percentage of these kinds of individuals (e.g., males in New Bedford) that were counted in the 1980 national census for the local area. By using the city/town lists of 1985 residents in the three towns and city, we will be sampling people, rather than households, and therefore must rigorously follow-up with each selected person to get full participation. The list of random numbers (page, column, line number) is not ordered hierarchically. Thus, with the exception of random numbers that are in New Bedford precincts still waiting 1985 update information, the respondents indicated by the random numbers will be chosen in the order their location designation appears in the sampling list.

The major point to be emphasized about the sampling is that the strategy has been designed carefully to maximize the desired end product of 1400 respondents who will constitute a representative cross-section of the Greater New Bedford population between the ages of 18 and 64. Each person listed in the sampling source lists had an equal chance of being included in our sample. Many respondents will wonder and ask "Why me?". You should emphasis that they were chosen completely by chance and NOT because of any unusual characteristics of that person or his/her family. We will also run into some people who will want to be in our sample, either because they want to know their PCB level or because they are particularly concerned about PCB's (e.g. they may be a commercial fisherman or have worked at one of the local capacitor manufacturers) or about environmental contamination in general. With these persons, thank them sincerely for their interest, explain carefully our randomization procedures and the necessity of creating a scientifically drawn cross-section of the population, and then refer them to the Health Education Office.

A. IDENTIFYING THE RESIDENTS:

After piloting and determination of how quickly we can collect our study data, the Data Manager will calculate how many random members

from each town will be used each week. The list of random numbers for each town will indicate those numbers that have already been used. Starting with the first non-used number, start filling out the "Random Number Assignment" Sheet that has the following column headings:

TOWN:

# PAGE	LINE	COLUMN	PRECINCT NAME (L, F, I)	ADDRESS (ZIP)	Y.O.B.	OCCUP.	ELIG. STATUS

Each row on the form is used for a random number, which goes under the Page/Line/Column headings. Precinct is for identification of the ward or precinct that random number leads you to; Name, Address, and Year of Birth are the critical information to be abstracted for that random number; if the specific line on the selected page denotes a vacant address or a blank line, indicate that here. Be sure to record any middle initials that will help us identify the correct respondent. Also, record zip code, needed for mailing purposes, and occupation for help in making the initial telephone calls.

Eligibility status is coded as: 1 = age eligible, 2 = >69, and 3 = <18. Since anyone 17 or older is listed in the Street Listings, use the cut-off years of 1920 and 1967 to establish the initial age eligibility. For persons with birthdays in these two years in which the respondents might or might not be eligible for sample inclusion, determination of final age eligibility will occur during the telephone contact.

8. INITIATING THE COVER SHEET:

For all persons on the "Random Number Assignment" sheet who might be included based upon the census data on year of birth, initiate a cover sheet. Do NOT yet assign a study number. Fill in the section at the top for town, random number, precinct, year of birth, and address.

Mail the Introductory letter, with the stamp "Address Correction Requested" on the envelope. Record the date of the mailing, with an "MI" in the result row.

On the day the Introductory letter is mailed, the search for the telephone number for that person needs to begin. Actually this is easiest to do when the person has been selected from the street listings because the street listing can lead you to phone numbers listed under other family member names. Initially try the local phone book. If not immediately located, try alternate spellings if they might be appropriate: for example, with a last name of Damadeiros, try DaMad, DaMed, DeMad, DeMed, as well as Mad and Med. If a phone number is not easily found, then place the form in the "Reverse Directory" pile. Weekly these forms will be checked in the "Criss-Cross" Blue Book at the City Library. The reason for checking the reverse directory before calling information is for instances of non-single person households. The phone may well be listed under a household member other than our respondent.

If neither directory yields a number, go back to the source lists, the city/town censuses, to double check the name and address. Then mail information. If information has no phone or an unlisted number, try to determine the number by calling neighbors and what may be other family members (leads will have been recorded from the "Reverse Directory"). If nothing yields success, place in the "No Phone" box. A household visit will then be necessary to complete the Cover Sheet portion of the respondent information and make an appointment.

person and try to get forwarding information (address and phone number). We will pursue such people that have moved within the Providence-Boston-Cape Cod area. We will try for both an interview and phlebotomy with these people (e.g., weekend visits to New Bedford and home visits to them). If no information is forthcoming from the current occupant, talk with the Data Manager about further search procedures.

D. Cover Sheet Interview:

Once you have contacted the chosen potential respondent, go through the introduction and eligibility questions. You can vary from the wording on the cover sheet provided that you communicate all the elements in the interview and any consistent variation you feel more comfortable with has been reviewed with the Data Manager. If there is hesitation about answering questions on the phone, offer the respondent our office number (on letterhead) to confirm our reason for calling. If the respondent seems to have a language other than English as his/her preferred language, exit using the phrase you have been taught, mark it on the call record, and give this cover sheet to one of the bilingual interviewers.

If the potential respondent is either age or residence ineligible, terminate the call after thanking them for their time. Indicate the reason for termination at the top of the Cover Sheet.

E. Appointment:

The impression to be given to the respondents is one of our flexibility to their schedules. On the other hand, we need to use our time best and keep as much as possible to a regular schedule that still allows us to get both the interview and the blood and urine specimens. Getting the blood - for which we need a 12-hour fasting (water only for 12 hours before phlebotomy is essential) - is going to be a snag in some instances. However, scheduling two visits, one for phlebotomy and one for interview, decreases the chance of our getting both pieces of data (only one invalidates the utility of the other) and creates a lot of work for ourselves in reminder and follow-up calls.

The schedule that we'll start out trying makes an effort to maximize our availability in the morning while having one interviewer and lab person present on some afternoons until 5. Wednesday night we can take appointments till 6:30 (open until 8), and on two Saturdays a month we'll be available from 8 to noon, with one or two interviewers and one lab person. We'll reassess the schedule on a regular basis, with the dual intents of meeting staff needs and getting as many interviews as possible.

Our initial attempt in making appointments will be to schedule one visit (interview, fasting blood, and urine specimen) in the morning. Then our afternoons will largely be spent on editing. Encourage the respondent to think about getting time off from work; though we do

not want anyone docked for pay, we have tried, through the Chamber of Commerce and our community outreach and publicity efforts, to make the whole population aware of our activities. Offer to call the employer if it seems appropriate. We mind don't want to have a full Saturday schedule. Schedule dual appointments for interviewing and phlebotomy only if this is the only way to get our data: try to schedule dual appointments with phlebotomy on the same morning as the post-work afternoon interview.

Do not make promises to the respondent, particularly regarding length of time. As our pretesting has shown us, the length of the interview substantially with the experiences of the respondent and other (non-quantifiable) characteristics of the respondent's personality. Thus, do not say, "It only takes an hour"; rather say "With the average person, it takes an hour to an hour and fifteen minutes." A forewarned respondent who knows how late he'll be for work is a better respondent than one who gets anxious about the length of time it is taking.

Finally, relay the information about preparation for the interview. When placing the scheduled interview in the appointment book, generally try to randomly assign the interview among people available at that time. There should only be exceptional cases where you can justify to the Project Director or Data Manager why it is essential that the person who made the initial call should also do the office interview. In particular, we want to stay away from having you interview people you know: this is not because your interviewing ability is doubted, but because people you know, especially casual acquaintances, may feel inhibited being asked personal questions (e.g., marital status) by someone who knows them. All of the AA's available time has been scheduled for interviewing to illustrate open time, but as a rule she will be spending half her time doing other essential work to keep everything flowing; so don't overbook the AA. Depending upon the span of time available between making the initial contact and the appointment, address a reminder card for mailing putting the date on the call record or schedule the reminder phone call.

Place the Cover Sheet in the appropriate week's file for preparation of an interview file. Record in the Master Appointment Book all appointments you made while calling the night before. If you were not calling, check the Master Appointment book to update your copy so that you know your own schedule and so you are prepared the next time you are responsible for making first contacts.

F. Refusals:

Occasionally you will encounter refusals. We are hoping that our modes of contact, publicity, and community interest will keep refusals to a minimum. Do not take refusals personally, if you have followed the proper contact procedures. Avoid accepting proxy refusals, i.e., refusals from family members other than the respondent, unless there is clear indication that the person to whom you wish to speak is mentally incompetent and the family member is the spokesperson. If there are physical limitations making the person housebound, get the pertinent

IV. GENERAL INSTRUCTIONS:

A. Write in pencil.

B. R means Respondent.

C. Items to be read to the R are in lower case type.

D. Instructions for the interviewer are in CAPITALS.

E. Lower case words in parenthesis are alternative ways of phrasing a question. Other information in parentheses may indicate from what previous question information is needed for you to complete the question.

F. CODING:

The boxes on the right hand side of each page are for use in data entry. In most cases you will enter the appropriate code in answer to the question directly into the box while conducting the interview.

If there is an arrow before the box, enter the code during the interview. In cases where there is no arrow, or the word CODE: appears to the left of the box, these data are to be completed when coding after the completion of the interview. In these instances, write the response on the blank line indicated or circle the response number. These data will then be coded using the editing materials, such as the Census Tract Coding Guide or the occupations manual.

When making entries in boxes, write the numbers legibly. Place answers as far to the right as possible, e.g., when two or more connected boxes are provided. Also zero fill on the left. For example, census tract # 1.0 = 0 1 0, and the fourth of June = 0 6 0 4.

G. LENGTH OF TIME:

There are some questions where respondents are asked how long they have been doing something or how long ago something happened. In cases where you are provided with a blank line followed by two options for unit of time, write down the answer and circle the appropriate unit of time. In other instances you are provided with multiple blanks with different units of time printed underneath: enter the response in only ONE interval of time, and code the information after the interview.

H. COMPLETE ANSWERS:

DO NOT leave blanks on the questionnaire where answers should be recorded. You will notice that the option of a "Don't Know" answer is generally not included on the questionnaire: during coding, however, you can use codes ending in 8 (i.e., "8", "98", "998") to signify "Don't Know". You may write in 'DK' on the form (but not in the box) when that is the only legitimate response.

We have not provided 'DK' as a possible response to emphasize that you cannot take 'Don't Know' as an 'easy-out'. Particularly in instances where we are asking a respondent to estimate how frequently they did something, sometimes the first response given is 'I don't know'. Do not accept a DK until you have paused, if appropriate repeated the question and/or the choice of answers provided, and done a minimum amount of probing. Probe in a manner that uses that data as we will be coding the responses (e.g., "Would you say that it is indeed closer to 25 or closer to 100?" and then "less than or more than 100 times?"). Only if the person continues to clearly not have any estimate do you accept a DK.

Of course we don't want to lead the respondents to incorrect or misleading answers, but often a person will have a fairly good idea of an answer but not respond immediately because he/she is not certain of the specific amount.

I. CONTINGENCY QUESTIONS:

Most sections of the questionnaire are specifically designed to incorporate many contingency questions; this was purposely done to economize the time needed to collect information from the average respondent. A contingency question is one that is asked only if the appropriate response is received to the preceding question (indicated on the schedule by 'GO TO' or 'IF YES...').

Any contingency question that does not need to be asked of a particular R is then 'inapplicable' for that respondent. During the interview, leave inapplicable responses blank. After the interview, while editing, code the inapplicables as '9': i.e., '9', '99', '999'

If you discover during editing that you forgot to ask a question, do not code with a '9' Later in the manual there are instructions as to what to do about missing information.

J. LISTS OF YES/NO:

In the Occupational Section of the schedule, there are two long lists of materials and products, and the Medical History section has many specific illnesses that have to be asked of each respondent. Each item does have to be read to the respondents. Yes is always 1 No is always 2 As you are reading the list of occupational items to the respondent, always record immediately any 'Yes' or '1' responses: when

there is a '1' response on these long lists, this is when additional information from the respondent is required to give us more detail about that particular exposure. Since most of the answers here will be 'No', you may find it more convenient to not write in the '2's' as you're interviewing. In those instances where the entire list yielded all 'No' answers, place a check next to the statement at the bottom of the list, 'IF NO TO ALL OF ABOVE:'. This then will provide a check for yourself that not only were all the answers 'No' (and therefore all blanks when you do the first edit), but you did not neglect to ask the items comprising the question.

K. COMMENTS:

Feel free to write on the schedule any comments either the respondent had as a condition or qualification to his/her answer or that you as the interviewer think of that you might need later for editing or for raising a concern with the Data Manager regarding the correct answer. If you must paraphrase a question to get an adequate answer, write on the schedule exactly how you recorded it. However, remember that you must get through the schedule efficiently and we must be collecting the data in a standardized fashion. Please do not write comments anywhere near the coding boxes, where they might confuse the data entry personnel.

V. STUDY NUMBERS:

All eligible respondents who initially agree to participate must be assigned a study number, including no shows and incomplete interviews. That is, once the outcome of the initial contact using the cover sheet and the accompanying interview instructions is that the potential respondent is both age and residence eligible for study inclusion, a study number must be assigned, even if the eventual result of contact with that respondent is a no-show or non-complier.

A. LABEL FORMAT:

There is about three-quarters of a computer sheet of labels for each study number. One out of every block of 20 numbers has already been omitted and sent seperately by CDC to the State Lab for their quality control program. We must note on the log sheet whenever we encounter such a 'missing number'. There are 40 labels for each respondent, of which 14 have been pre-printed as to the application they are intended for.

The last four digits (on 26 of the labels) in the first row of printing on each label constitute what we refer to as the study number. The first six digits are there for use by the CDC. The four items of information with blank lines trailing letters are data that we need to fill in as we use the labels. 'D' stands for date: use all numbers here, in the order of month (1-12), separated from day (1-31) by a dash (-), followed by the last two digits of the year(85). 'T' indicates time, and will generally only need to be used on the labels that are already pre-printed. Use time as a twenty-four hour clock, with the hour and the minute designations seperated by a colon(:): e.g., 13:10 means 1:10 p.m. in the afternoon. 'I' is where you place your initials on every label that you are assigning to a tube, cup, or piece of paper. Finally, 'DOB' is for Date of Birth of the respondent, and is to be filled in in a manner similar to 'D'. The purpose of having DOB on the labels is that it serves as a second level of labelling beyond the four-digit study number to avoid confusion between respondents. If only the four-digit study number were used for identification, since generally we will be interviewing respondents on the same day that have very similar study numbers (since study numbers will generally be assigned consecutively), the mere slip of a finger on the keyboard, or the transposition of a number could cause the mis-identification of respondents.

The top five labels are for the five tubes of blood to be taken during phlebotomy. Use these in the order in which they appear, so that the fifth and last one goes on the SST lead tube. If you end up taking more than five tubes (e.g., you had to try a second phlebotomy site), use one of the unassigned labels for that respondent located in the back of the R's file folder.

The first label in the second row, pre-printed with 'UR COLLECTION' is to be placed on the urine specimen collection cup by the receptionist (see next section).

The remaining eight pre-printed labels are to be used in the lab (see processing directions). The next row of five labels are to be sent to the State Lab, after DOB has been filled in.

The remaining 21 non-pre-printed labels were prepared for our internal use on documents here in the New Bedford facility. While there are not sufficient numbers to put one on every page of the questionnaire, there are plenty to meet our needs. The labels will be placed in the upper right corner of all documents related to that respondent, including the consent form, urine questionnaire, phlebotomy questionnaire, the interview questionnaire, any and all supplemental interview sheets required, and the respondent's final file folder.

B. NAMES AND LABELS:

The major purpose for using these labels is to enhance confidentiality of the data we are collecting by minimizing the number of places the respondents' actual names will appear. For example, neither MDPH (State Lab or Tremont Street) nor CDC wants to or needs to know the respondents' names. Here any questions to arise that would require re-contacting the respondents, that would be our responsibility. The respondents' names will thus appear in four places, all of which will remain in the N.B. office: the Random Number Assignment sheet, the Cover Sheet, a computer file for printing address labels, and a paper list (Study Number Log) duplicating the computer list where the name is matched to the assigned Study Number.

C. ASSIGNING STUDY NUMBER:

In the beginning, the assignment of study numbers, the initiation of each respondent's file, and the addition of that respondent to the computer mailing file will be the responsibility only of the Administrative Assistant. Once you have identified a respondent as both age and residency eligible, and the cover sheet is completed, return the cover sheet to the appropriate box. At this point, a study number will be assigned, a file folder will be initiated (identified by the study number), the respondent's name entered and a label affixed to the Study Number Log. The AA will then prepare a file folder for that respondent for use at the time of interviewing. For participants, the file will consist of the following pre-labelled forms: a consent form, urine questionnaire, phlebotomy form, interview schedule, blood pressure reporting form, and supplemental forms that could be needed.

VI. CONSENT, URINE COLLECTION, AND PHLEBOTOMY:

One thing we must all be very careful of: there must always be two people or more in the office whenever any respondent is expected, even if it is just for an early-morning phlebotomy appointment. There are several reasons for this requirement. The first is the general safety of all staff: we do not want someone alone in the office doing lab work or interviewing in a closed office and not have another responsible staff person out at the reception area watching for other respondents and generally monitoring for unexpected incidents or theft. Secondly, to help the flow of respondents, there are tasks that demand interaction with respondents that do not entail specialized knowledge or skills other than being knowledgeable about the study and being personable. When only two people are in the office and an interview is being conducted, the lab tech must keep tabs on the front to handle in-coming respondents or stray walk-ins.

A: DAILY PREPARATION.

The AA (or the Data Manager, in her absence) will pull the respondent files needed for the next day based on the appointment book. This underscores the importance of placing all appointments you have made in the Master Appointment Book.

B. CONSENT FORM:

When a respondent walks in the door, after greeting the person the receptionist will give him/her a consent form for perusal. This task is assigned to the receptionist since the consent form must be understood and signed before anything further occurs. The urine and blood specimens may well be collected before the actual interviewing begins, and these cannot be taken until after consent is given. The receptionist will answer any questions with regard to the Consent Form, and then sign and date it as the witness. Take this opportunity of witnessing the consent form to underscore to the respondent the confidential manner in which his/her information will be treated.

C. URINE COLLECTION:

The next task is to have the respondent give us a urine specimen. Remove the 'UR> COLLECTION' label from the panel attached to the urine questionnaire, and affix it to the cup, after snipping the plastic wrapping but before giving the specimen cup to the respondent. Briefly go through the instructions, emphasizing that the cap is to be placed inside facing up, the insides of the container and cap are not to be touched, and the specimen must be covered immediately after being filled. Mention that the instructions are posted in the lavatory

The question on fish consumption during the last 24 hours must be asked of each respondent, but the answer does not affect our wanting the urine specimen right then and there for all respondents The

information is merely for analysis purposes. When the respondent returns, take the five phlebotomy labels and the pre-labeled phlebotomy data sheet to the phlebotomist, and take the pre-labeled questionnaire and supplement sheets to the interviewer. Immediately go into the bathroom, collect the urine specimen, and take it to the lab technician.

If a respondent is not able to give us an adequate urine specimen, check with him/her after the interview if R thinks that at this point a specimen would be possible. If this does not work out, reschedule right then for a return visit for a urine specimen! If the rescheduled appointment is for later that day or the next day, put the urine form in R's folder and refile in the Respondents to be Interviewed' section of the cabinet. If they do not show for the rescheduled appointment, the cover sheet and urine form need to go with reminder calls. When a second urine appointment is necessary, use a new, sterile, unopened specimen collection cup, affixing a study number label from those available in the back of the respondent's folder.

C. PHLEBOTOMY:

For respondents whom are having the blood collection and interview at the same visit, the phlebotomy must be the first element of the interview process. This is for subject comfort. The phlebotomist will follow the procedures for blood collection detailed in the lab instructions, particularly noting any complications. Then offer the starved respondent some juice and crackers, and proceed with completing the interview while the blood samples are being processed.

VII. QUESTIONNAIRE:

Consider the interview schedule to be in its next-to-final form. While formatting refinements are still being ironed out with the word processor, we still be pre-testing the questionnaire following training. Some changes might be made as a result of pre-testing; these would be the result of group discussion with final say-so by the Project Director and MDPH.

The schedule is the result of a great deal of thought and work and consultation, and great care was taken in the choice of questions to be included and how they should be worded. Despite all this effort, the schedule may not be perfect, but PLEASE you MUST use it as it is. Your own thoughts on wording questions may be better - but not necessarily. And we must have standardization among all interviewers. So, if you detect something wrong with the wording, speak to the Data Manager and Project Director about it -- until and unless a decision is made on your suggestion, stay with the questionnaire exactly as it is.

The ordering of questions has also been carefully considered. If questions are asked in a sequence different from that of the schedule, you could end up leading the respondent to a different answer by prejudicing his/her knowledge or attitudes. As with wording, DO_NOT ever deviate from the schedule as it is presented to you, unless given specific written instructions to change. These instructions would come in the form of an 'Interviewer Update Sheet', which will be issued to all interviewers on a periodic basis when the PD or DM find consistent confusion or errors, omissions in instructions, or situations arise that had not been accounted for.

A. QUESTIONNAIRE FORMAT:

The schedule is organized into 8 sections: sections are usually indicated by headers in underlined capital letters to let you know the topic is changing. The physical measurements (blood pressure, skinfold, height and weight) are spaced throughout the questionnaire, to allow for three blood pressure measurements and for the other measurements to provide a break in the routine of asking questions.

I. Introduction/Initial Demographic
II. Residential History
III. Occupational History
IV. Harbor Exposure/General Seafood
V. Local Seafood Consumption
VI. Medical History
VII. Demographic
VIII. Interviewer Section

B. SPECIFIC QUESTIONS:

SECTION I

INTRODUCTION:

The purpose of this introduction is to get a tacit commitment from the respondent to actively participate in the interviewing process by trying to be accurate. We want to impress upon R that this is not just a telephone survey from a computer voice about use of toothpaste brands.

Taping the interview serves two purposes: a backup record of the interview for answering any questions we may have, and documentation of data quality. The tape contents will be erased as soon as its purpose has been served; it will not be retained as part of R's file.

In the beginning, all interviews will be monitored from the tapes for data quality. As the study progresses, all interviews will continue to be recorded but only randomly chosen portions of each interview will be reviewed for data quality. Taping is less intrusive than having a third person be a silent observer of the process. Also, if you were being monitored on a non-random basis, you might subtly change your own interviewing technique without deliberately doing so. The tapes can indicate to the PD and DM less than satisfactory interviewing techniques you may have slipped into, and identify consistent difficulties with the interview or the schedule that more than one interviewer is having; you may not be able to identify these on your own.

This technique of data quality control has worked quite well in other, similar studies. Respondents do not usually object when you associate the reason for taping with assuring the accuracy of the answers you have just asked them to consider carefully. If any R objects, first mention that the tapes are erased as soon as the forms have been edited, and that the tape is really providing a check on the interviewer. If R still objects, do not use the tape, and write in a note to this effect at the top of the schedule. Try it! - you might be surprised how accustomed you will become to this technique.

Q1:

This question is to get the interview started. Most respondents enjoy talking about their health. We want to know how R evaluates his/her health status, and not how their physician or neighbor or you rate it.

Q2, HEALTH STATUS:

You must follow the 'GO TO's very carefully in this question. The purpose of the question is to elicit more specific information from the R about any health problems that interfere with the conduct of his/her

usual activity and functioning. Three elements about the limitation or disability are being solicited: whether R has a limitation of his/her activities, the degree of the limitation, and the way in which R is limited in his/her ability to function.

Long-term or 'permanent' limitation is being sought in these questions. These do not include a pregnancy or delivery, or, in general, any injury, illness, or operation that occurred less than three months ago unless the effects of the injury or illness include a permanent limitation.

When the respondent mentions a condition, make sure that it is basically 'permanent' and/or occurred more than three months ago and the limiting effects are still present. For example, a sprained back, broken wrist, or 'the flu' does not constitute a valid answer. If R says "I sprained my back (or had a hernia operation) and haven't worked for two weeks," REPEAT the question, saying "Except for your sprained back (the hernia operation), are you limited...?" If the sprained back occurred more than three months ago and R says he is limited because of this condition, this situation meets the criteria.

If, *when you get to the point of recording the condition causing* the limitation, and the answer appears to not satisfactorily meet either the duration or permanency criteria, go back to the question where you received a 'yes' as to limitation, and repeat the questions from that point on, following the correct 'GO TO's. Again introduce the phrase "except for", erase your original code(s), and finish the section.

Examples of limitations are: can't climb stairs, can only work (do housework) with frequent interruptions for rest, can't do certain kinds of jobs, can't drive. Conditions include: absence of an extremity or organ, the name of a disease, a disabling symptom, or a condition resulting from an accidental injury. Also included in conditions are health problems such as alcoholism, depression, senility, and mental illness.

Limitation refers to what is normal for most persons in the age group of the respondent and the limitation prevents activities that could be undertaken in normal circumstances. When R names a limitation, if you have any doubt as to the legitimacy of the answer in relation to the purpose of the question, PROBE by asking, "Is this due to an impairment or health problem?" For example, R says "My husband has to do all the driving," PROBE to see if this is due to a health condition of R, and not just because R has never learned to drive or has had his/her license suspended.

Q2A tells you what their major activity was over the last year, and points you to the succeeding letter portion of the question to be asked based upon R's activity. If R gives more than one answer, ask "What did you spend the most time doing over the last 12 months?" If this does not yield an appropriate response, because equal time was spent on both, PROBE: "*Which do you consider the most important?*"

When you do get a positive response on limitation, record the condition (the cause(s) of the limitation) exactly as reported by R, unless you have run into one of the problems discussed above, e.g., the condition is not 'permanent' or has been present less than three months. Coding of conditions will be done at a very general level using the ICD-9-CM Classification of Diseases.

For length of time of the condition, carefully enter R's response on the correct option (days, weeks, months, or years) and code later using the editing sheet.

Q3, SEX:

This is completed by interviewer observation.

Q4, AGE:

Current age is to be recorded on the blank line. Now you have it available to you as a piece of information duration in the seafood consumption questions later in the schedule. You may want to write it on a scrap of paper next to you for later calculations. Age on last birthday also serves as a check on DOB.

Record Date of Birth as Month, Day, Year.

Q5, BLOOD PRESSURE #1:

Record pulse; code later, multiplying by 2. Use the right arm for measuring blood pressure when possible; stroke, a cast, other disability, or an adverse reaction to the taking of a blood specimen from the right arm would be reasons for using the left arm.

Record the systolic, diastolic, and random digit zero figures on the blank lines. Code systolic and diastolic later by subtracting the random digit zero number from both observed figures.

Record time using the 24-hour clock.

Q6, EDUCATION:

If R has never attended school, enter '00'.

The codes for two through seven years of school are available for your use; we just saved some room by not printing them all.

Generally, the education we are referring to here is academic, i.e., that leading to a high school diploma or a college, university, or professional degree. Thus business and trade schools are not to be counted, unless they were part of the regular school system and could have been eligible for credit in that system. Adult education classes

and correspondence courses also do not count unless their completion involves credit towards receiving an elementary school certificate, a high school diploma, or a college degree.

If you or R is unsure of the exact number of years, PROBE regarding such questions as kind of degree awarded or advancement towards a degree, and record in the margin the probe and the answer.

If the answer is junior high school, PROBE as to the years that would be equivalent to 7th, 8th, or 9th grades. For respondents who skipped or repeated grades, determine the last grade completed, regardless of the number of years involved. Post-high school courses that were not part of attending college would be recorded as 12, High School Graduate (if R did receive a diploma).

If the numbers of years of college cannot be determined because R has attended part time, PROBE for the number of credits completed, and we will code the answers later. Part-time attendance needs to be referenced to the number of years of courses completed, not the years R has been taking courses. For example, R has been attending SMU for ten years, taking one course per semester; PROBE to determine whether SMU classifies his/her currently as, e.g., a sophomore (code = 1), one year of college completed) or determine the number of credits completed.

If R completed four years of college but did not graduate, code as 15.

SECTION II. RESIDENTIAL HISTORY

Q10, PREVIOUS ADDRESSES:

Completing this question will be quite simple for many residents and tiring for some. Always remember the purpose of this question: we want to know where in the Greater New Bedford area the R has lived and for how long at each address.

All addresses and length of time at each will be coded when the interview is completed. Do concentrate in this section, though, to make sure the information you're receiving makes sense. You need to watch for unaccounted gaps in the data as the respondent is giving you the data.

Start with the current address (confirming it from the cover sheet) and ask for length of residence. Then work backwards in time, collecting address and length of residence (preferably both month and year) as well as R can recollect.

If R is having trouble with the months associated with moves, PROBE if he/she remembers the season of the year or can relate it to a significant event (e.g., the end of the academic school year or around Christmas). For longer histories of residence in this area, major

events such as WWII or national presidential elections might serve as useful probes.

As soon as you hear a residence or city/town which is not in the DNH area, record only the town (street address unimportant in this case) and length of residence. Then ask the OR question at the top of the page: "Previous to (that time), did you live in either Acushnet, Dartmouth, Fairhaven, or New Bedford at any earlier time?" We are not interested in place of residence prior to 1940, since that is the time exposure could have begun.

If you need more space for post-1940 residences than the ten available in the body of the questionnaire, put '1' in Q10B and use the supplemental sheet available in the back of R's folder. Don't forget during coding to then place a label on the supplemental sheet.

SECTION III, OCCUPATIONAL HISTORY

In this section, first we characterize the respondent's current (or most recent) means of employment. Then a series of conditional questions are asked about possible places or types of employment that are associated with exposure to PCBs. If any of these conditional questions are answered positively, we then want to record data about the place of employment, the kind of work R did there including all specific positions (e.g., welder vs. office clerk) in order to get an understanding of possible degree of exposure, when that specific employment began, and how long the potential exposure was.

The first of the two long lists of products is asked of all respondents who have ever been employed: rather than trying to characterize in detail the degree of exposure, for any positive response to a product listed, we merely need to know at what company they worked while having contact with the product and how long they worked there.

The second list is asked only of people who have been employed in places producing or using the products in the manufacturing process. Again, just company and length of employment are then recorded.

In questions where you have to record detailed information on employment, such as kinds of work performed and type of company, you must be certain to have obtained information sufficient to allow you to code the answers later. Frequently, just taking the respondent's first answer and turning it around into a PROBE will yield enough additional information: you can PROBE by, e.g., "What kind of accountant?" or "What type of mechanic?" Familiarize yourself intimately with the NCHS publication, Guidelines for Reporting Occupation and Industry on Death Certificates. In general, you must play incredibly dumb and never presume you understand what the respondent meant: always push for more and more specific information.

The Occupational Section concludes with a question on spraying of roads that is asked of everyone, regardless of current or past employ-

ment status.

Q11, CURRENT WORKING STATUS:

We want to be able to characterize what the respondent's current working status is, and the questions are ordered so as to follow a precedence of ordering that we want. Emphasize "the_past_two_weeks", i.e., the previous 14 days: if R started a full-time job one week or more ago, then we categorize R as working full-time. If R is working full-time, go to Q12.

If R is working part-time or not at all, you then need to ask Q11A(part-time) or Q11B(not working) to determine if he/she is a full-time student. Being a full-time student usually means taking four or more courses. If R is only a part-time student (anything less than four courses at the college level), consider this a 'NO' with respect to full-time student status and proceed accordingly.

Working full-time is 35 hours per week or more. If R is uncertain.

A person who is not working now but is starting a new job next week is not working: continue on to ask 11B and 11C to get activity over the past two weeks. A respondent who, during the preceding two weeks, was on sick leave or paid vacation from a full-time position is considered employed full-time.

For persons not currently working, record the answer to 11D on the blank provided and code. If R never was employed, skip to Q21.

Q12, CURRENT EMPLOYER:

Ask of all persons currently or ever employed: the reference point for persons not currently working is their most recent place of employment.

Record the name of the company, getting the most specific information possible. For example, if they say 'RCA', ask at what plant or office: each RCA location does different things -- some are manufacturers of products, others are regional distributors, others conduct direct retail sales, and others are purely management. If they say, e.g., the City of New Bedford, ask for department; apply this rule to all public or government workers. Coding will be done later, using the lists from the Chamber of Commerce and others for local companies.

Ask the type of business because for many persons the name of the company alone is not going to permit us to code the industry R works in. Just 'factory' or 'office' is nowhere near sufficient. PROBE with such questions as "What kind of factory?", "What does the factory produce?", or "What is the major business or activity of this office?"

Q12C does, in many instances, provide additional useful information for understanding the nature of the industry in which R is

employed. If IR has already given you sufficient information in explaining place of employment, DO NOT skip the manufacturing/retail/wholesale/other question. To avoid sounding stupid, you may introduce Q12C by saying, "This may sound redundant, but is this mainly...?" Do not belittle the importance of this question: certain enterprises, for example, may have manufacturing and wholesale divisions at the same location, and we need to know which division R is in.

Q13, CURRENT POSITION:

Parts A, B, and C are all necessary pieces of information that will be used to code current or most recent occupation. While the majority of people will give you an answer that is detailed enough, PROBE in order to have information that is as specific as possible. Review the NCPS document to give you examples of adequate and inadequate answers

For example, 'Manager' is a job title, but is not an adequate answer for Q13A or B. Additional information needed for Q13A might include administrator of the data processing division, and activities involved could be allocating workloads, supervising keypunch operators, budgeting, and providing project estimates. Sometimes you may end up getting identical answers for kind of work and job title: if this happens return to kind of work (Q13A) and reask this question to get a more appropriate answer.

For Q13D, record the length of time R has had this specific position with the company named above. You already know, for persons from whom you are collecting data on their most recent position, when they left it.

Q14, CAPACITOR MANUFACTURING:

An occupational history specific to work at Aerovox or Cornell Dubilier is being obtained here for both persons who are currently employed at either facility and for persons who ever worked there. Three pages are available for recording these histories: 14A is for current employees, 14B is for past employees, and 14C is included to allow space for employment at the OTHER company or for a second time span of work at the first plant. Thus, if R is currently an employee of Aerovox or CD, complete A. If, in answering A(2), he/she says "I started in June of '84, but I also worked there one summer when I was a teenager", record current information at 14A and then GO TO 14C to record start and stop dates and employment experience for his/her teenage work.

The work at these plants, except for very short-term employees and office workers, seems to be of a nature that specific job titles sometimes do not exist and employees rotate on a non-regular basis from task to task. Thus we are asking R to list KINDS of work -- in the plural -- he/she did while working at A or CD. Record these as

mentioned.

Then ask, for each 'kind of work', what their important activities or duties were associated with the kind of work and the total amount of time H can estimate he/she did that kind of work during his tenure at A or CD.

Circle 'W' or 'M' or 'Y' in the third column of each row of kind of work to indicate whether the total time span written is Weeks, Months, or Years.

Once you have completed the abbreviated job history at one of the two plants, ask if they ever worked at a previous time at the current plant and if they ever worked at the other local capacitor manufacturer. That is, if you have just recorded information about their job(s) at Aerovox, ask:"Did you ever work for Cornell Dubilier?" If so, record the CD job history at 14C.

Once you have repeated the three job questions about kind of work, most important activities, and total amount of time exactly as they appear at the top of each new page for sections of Q14, you can abbreviate the query to the most important words in the questions as first phrased. Use PROBES as discussed above to get adequate information. If the answers go beyond these kinds of work, repeat the questions verbatim again.

Use the Supplemental Capacitor sheet if the number of kinds of work or the number of continuous terms of employment exceeds the space available.

Q15, OTHER CAPACITOR PLANTS:

Ask this of all respondents, using the alternative phrasing based on whether they had local exposure at Aerovox or Cornell Dubilier (Q14) or not. The company most likely to be mentioned here is the G.E. Pittsfield facility: others would be outside of Massachusetts, but we do want to get information on any employment in any capacitor or transformer manufacturer.

Obtain employment histories for those companies for anyone responding 'YES', using the same questions and PROBES as for local capacitor manufacturing employment (Q14).

Before continuing, ascertain whether there might have been employment at yet a second or third company manufacturing capacitors or transformers. If so, use the Supplemental Capacitor Sheet.

Q16, ELECTRICAL EQUIPMENT MAINTENANCE:

Capcitors and transformers are used in electrical equipment and systems and thus anyone responsible for maintaining or repairing such items may have been directly exposed to cracked or broken capacitors

containing PCB oil. Thus we need to ask this question of all respondents whom have ever been employed.

- If respondent's current job fits this category, place a '1' in Q16A and ask about previous positions in the same company or employment at other companies that involved the maintenance of electrical equipment. If you get a positive answer to this PROBE, continue on to (1) If only the current position fills this criterion, go on to Q17; that is, if the current position is the only job R has ever had maintaining electrical equipment, you do not have to reask and rerecord that detailed information already obtained in Q12 and Q13.

This question's format is nearly identical to that of Q12 and Q13 combined. Use that set of instructions for direction in asking the questions, PROBING, and recording information here. Unlike the capacitor question (Q14), each block of data here is specific to one position, not to the entire work span with that company.

After completing Q16A for the first position in electrical equipment maintenance R mentions, PROBE as to other positions in that same company in which R was also responsible for electrical equipment maintenance, and PROBE for electrical equipment maintenance positions in other companies. If this probing yields another position, use Q16B to record the information, asking the questions as they are worded in Q16A. Then PROBE again regarding additional positions or positions in other companies.

Use the Supplemental Electrical Equipment Maintenance/Waste Treatment sheet if necessary; when coding later, remember to put a label on the supplement.

Examples of jobs that fall into the category of electrical equipment maintenance are: repairing television sets, high school maintenance janitor (as compared to cleaning), and installing and doing upkeep on cooling systems.

Q17, WASTE TREATMENT PLANT:
Q18, NEW BEDFORD DUMP:

Because samples of the sediment in the sewage discharge pipes and the dump area have tested positive for PCB's, we need to ask these two questions of all persons who have ever been employed. While asking the questions may seem offensive to some people, merely say something like "I need to ask all questions of everyone in order to double-check." You may, to placate the respondent, go on to say "...and many people have had part-time or summer jobs that are very different from their current careers."

Again, we have to collect data on the specific positions -- not just kinds of work -- that persons ever employed at the treatment plant or the dump. Use the instructions for Q16 for the flow between subsections and PROBES.

Q19. MATERIALS:

This list of materials is to be asked of all respondents ever employed. The emphasis in Q19 is on either of two types of exposure: actual contact with the material (e.g., as a cleanser) or any employment in companies that manufacture the materials or use the materials (in manufacture, production, or in a manner such as a cleanser).

Do not try to give explanations of what the materials are or what they do: these are common generic names, and most people who have worked with the materials will recognize them and therefore not ask. For persons who do ask for explanations, first try just repeating the question, substituting the specific item about which R asked for the word 'materials'

You do not have to, during the interview, write in all the '2's for 'NO' -- but be certain to immediately mark a '1' for any 'YES'. If the responses to all the materials are 'NO', you can place a check in the space provided at the end of the list. This check will then tell you when editing the survey later that you did ask the materials (rather than somehow accidentally skipping the question) and you can legitimately put a '2' in all the preceding coding boxes.

As soon as R says 'Yes' to any material, GO TO Q19A (or B, etc., the first unused space for recording job information). Write down the material, and then ask the two following questions on name of business concern and tenure with that company. It would be very difficult to try to rate all possible specific jobs as to the degree of exposure to PCB's each entails: thus we are only going to get company name and time with the company that brought the respondent into contact with the material or manufactured or used the material.

After recording the job information (material, company, and time) for the first 'Yes' you encounter, before returning to the list of materials you must ask the PROBE question, making it specific to the material you are currently dealing with: "Did you work at any other company that used (material, e.g., Lacquers) or another job that brought you into contact with (material)?" After the probe, and the completion of data in response to that probe, return to that material in the list (the last '1' you recorded), and continue with the list of materials. Record subsequent 'Yeses' and their associated exposure information (at Q19B through E) as each is encountered.

The respondent is very likely to mention, when you start the specific questions, if the job you're starting to record is the same as one already discussed on a preceding question. If it is the same as his/her current job, you must write down the material, the company (or write 'current'), and then ask the second question on months/years with that company. This second question must be repeated since under current job (Q12 and Q13) we only inquire about time in the current position, not total time with the company.

If you get two or more 'Yeses' to different materials, you may

find that some exposures were at the same company. You must be sensitive to this possibility, and if the data sound familiar, ask "Is this the same as...(previous company mentioned)?" After recording the material about which the R just responded positively, if the company is the same as the one directly above your current recording place, you may record 'same' for company name and length of employment. However, if you have recorded at Q19A 'X' company/tenure for Dyes, and 'Y' company/tenure for Hydraulic Fluids is recorded at Q19B, and the answer for Lacquers is company 'X' (two blocks above at A), you must rewrite at Q19C for Lacquers the information already recorded at A.

If the R, in answer to the question "How many months/years did you have this job?" gives you a start date (e.g., 12/83) and a termination date (e.g., 7/85), **do not** repeat the question. These dates are sufficient for you to later calculate the total number of months R was employed at that company

Space is provided for five materials and their related exposure data. Alternatively, this space could be filled with information about five different companies at which R was in contact with the same material. If more space is needed than is provided, so indicate at Q16F and use the Material/Product Exposure Supplement. Do not forget to label the supplement during editing.

Q20. MANUFACTURE OF PRODUCTS:

The second list of manufactured products is to be asked only of persons who have been employed in a company that manufactured products. While the contingency question that determines whether the list of products is asked of the respondents sounds similar to previous questions in the Occupational Section, it is different and therefore must be distinguished by the interviewer. In Q20, the emphasis is on employment in places **manufacturing** any of the products or using the products in manufacturing, and is **not** concerned with contact with a variety of materials (as in Q19) that can be manufactured, used in manufacturing, and used in wholesale, retail, and service industries.

If R has **never** been employed, in any capacity, in a manufacturing company, GO TO Q21. On the other hand, even if the respondent has already given you information on some manufacturing experience he has had in previous questions, you must ask the contingency question as it is phrased. A positive response then directs you to Q20A. Two kinds of exposure to the products would yield a 'Yes': involvement in the process of manufacturing these products or the use of these products while manufacturing a second, unnamed product.

The format of Q20 for asking, PROBING, and recording information are the same as Q19. Use those instructions in completing Q20. A critical element in both questions is remembering, after recording a positive response ('1') and the company and length of employment associated with that exposure, that the PROBE followup question **must** be asked before proceeding onto the next product. That is, we need to check if the respondent has been exposed to the manufacturing process

or use of the products at more than one place of employment.

Space is provided in the body of the questionnaire for four blocks of information on company and length of employment; use the Supplemental Materials/Products Exposure sheet if it is needed, labelling it during the editing process.

Q21, ROAD SPRAYING:

This is asked of all respondents, including those never employed. For never employed persons, this is the first question to follow the current activity status (Q11).

Two sources of exposure to road spraying using PCB-related oils are being asked about: at R's residence and employment activity conducting such spraying. However, in terms of employment, the question specifically focuses upon the act of spraying, not upon the passive circumstance of having it done in R's hometown. Residential spraying has to have been commissioned (or done by R) specifically on property where the respondent lived.

In the circumstances of a positive response or a query from R, use the phrase that has been placed in brackets for use by the interviewer at your discretion. Spraying with a liquid other than water for the purpose of reducing flying dust is the activity we are interested in.

Dependent upon the answer to Q21, section A or section B or both need to be completed. For persons doing the spraying as an occupation, we need the name of the company and the type of business or industry, and thirdly, the number of months or years R held this position. For residential spraying, only the number of years is needed. Do not forget, once you have recorded one exposure, to ask if there are other instances.

Since the spraying of roads is seasonal, do not ask the respondent to total up the number of months this was done, if the spraying occurred in multiple years.

Q22, SECOND BLOOD PRESSURE:

See Q5.

SECTION IV, HARBOR EXPOSURE/GENERAL SEAFOOD

Q23, OBTAINING FRESH SEAFOOD:

This question, along with a related question on the procurement of local seafood (Q32), constitute the only open-ended questions in the schedule. We want to get some information on buying and procurement patterns, but feel a bit restricted because of the legal issues involved and because we are really uncertain as to what the majority of

people's habits are and were for obtaining fish.

Fresh seafood -- if the respondent is confused -- refers to seafood that is either not frozen or is 'fresh frozen'. This question is to be distinguished from Q24 in that we do not here refer to consumption of the fresh seafood outside of the home, such as in restaurants.

Because personal buying habits as well as availability from different sources have changed over time, we are asking this question with reference to both the present and ten years ago. Q23A refers to the present. Q23B has two alternative phrasings provided: you must choose which one is most appropriate based upon the residential history obtained earlier. If R did not live in the GMB area ten years ago, instead of 1975 use from the residential history the most recent year before 1975 that R did live here. On the other hand, if R first moved into the GMB after 1975; do not ask Q23B; code as inapplicable.

We want to allow for a lot of information here, since it is a difficult question to get quantitative information on. First ask the question as completely open-ended, recording on the dash for 'ANSWER #1' the first answer that is forthcoming. If no answer is given or only a blank stare is received, PROBE using the general coding categories that are provided. However, if you do have to use the probes, and the respondent chooses either 'local fish retailers' or 'supermarkets', you need to PROBE further to see if a particular retailer is (was) patronized, e.g., Becks', Tavares, Almac's. Code the specifics later, using the list provided.

If only one source of fresh seafood is identified, PROBE with the following phrase (and the groups of codes, if appropriate): "And is (was) there another way you and your family obtain(ed) fresh seafood?" If more than two sources of fresh seafood are identified by R, record all of them. However, we can only preserve coding room for two, so record the first two sources mentioned on the spaces provided.

Q24, CHANGE IN CONSUMPTION:

Before asking about local seafood, we want to get an idea of the respondents' general consumption of all types of fish and seafood. In order to clarify that Q24 refers to fresh water fish and seafood, to local and non-locally caught seafood, and to both home and restaurant consumption, a lead-in is provided.

After the explanation, pause and then ask Q24A, emphasizing the two phrases that are underlined. It is possible that a respondent could have eaten absolutely no fish or seafood over the last ten years, so a fourth coding option is provided.

Continue on to Q24B for persons who answer that their consumption has either increased or decreased. Record the answer to Q24B verbatim on the dotted line provided. Do not try to lead the respondent into one of the coding options provided. The coding options are, at this

point. first thoughts as to what the possible answers might be. If, during coding, the verbatim answer does not seem to fit into one of the categories provided, mark this as a problem on the questionnaire front page.

Q25, GENERAL CONSUMPTION:

The fish and seafood included in Q26 are species that have been shown to be high in PCB's or in the metals we are testing for. Clearly some are not species that can be obtained locally, except in the frozen form in supermarkets or restaurants. Respondents could well have eaten these fish and seafood while living in the local area, obtaining them through these general methods. Respondents could also, while living elsewhere in the United States, have eaten substantial amounts of these species, perhaps even obtaining them by local catching.

Because of the many ways respondents could have consumed these fish and seafood, we are asking only a very general contingency-type question that has no follow-up on the particular species. Q25 is asking for a lifetime consumption of these species potentially high in PCB's at a minimal level of five times or more.

For sections D through F, the emphasis is on the word or. For example, if the respondent has never eaten striped bass or mackerel, but has eaten blue fish five or more times, the answer to be coded is 'YES'.

Do not try to explain or describe any species that the respondent queries you about. If they have not heard of the species, consider the answer a 'No' for that particular species, although not for the whole section, if the unrecognized species is in Q25D, E, or F.

The initial lead-in question is repeated in section E to remind the respondent of the frequency of consumption being asked.

Q25G has two subsections. If the respondent has not eaten lobster five or more times, continue on to Q26. If 'Yes' to Q25G(1), then ask the second question on lobster consumption referring to the part of the lobster usually consumed.

If R says 'No', or less than five times over R's lifetime, to all seven species or groups of species comprising Q25, skip the next question and continue on with Q27.

Q26, GENERAL CONSUMPTION COMBINED:

Q26 has several critical elements built into the question that must be communicated to the respondent through emphasis on the underscored words, combining', 'any', and 'in the last twelve months' In order to quantify, to some degree, the consumption of the fish and seafood mentioned in Q25 that are high in PCB's or heavy metals. Q26 has several questions relating to recent consumption patterns of all

the species just discussed in Q25.

The interviewer must fill in the blanks provided in Q26 with species of fish and seafood to which R responded positively in the preceding question. Merely glance above, noting in which sections of Q25 you marked a '1' for 'YES', and substitute the species for the blanks. If there was a yes for Q25D, Q25E, or Q25F, do not attempt to mention all these species -- rather, mention two from each group. The reason for filling in the blanks is to remind the respondent of exactly which species of fish and seafood among the ones we are interested in he has eaten to a minimal degree over his lifetime.

After highlighting the time-dependent phrase, 'in the last twelve months', show R Card #2, reading quickly through the codes and their definitions. Note that 'RARELY OR NEVER' is in capital letters on the schedule: it does not appear on Card #2, and is not to be read to the respondent. This last option is a code for your use only.

Sections B and C also refer to the combined fish and seafood mentioned in Q25. Some respondents will not give you a number of years in answer to Q26B, but rather give you information such as "My whole life" or "Since I was a child". In these instances, you will have to do a rough calculation based on the respondent's age and the application of age 3 to approximate the respondent's 'whole life' to estimate the actual answer in terms of years.

After recording the answer to B, continue on to C. In Q26C, the first group of blanks are to be filled in as you did for Q26A. The last blank is to be filled in with the answer you just calculated to Q26B. Here, after having determined for how many years the respondent has eaten the several varieties of fish and seafood, we need to determine whether the amount of consumption over the last twelve months, as reported in Q26A, is the result of an increase or decrease in a lifetime pattern of consumption, or is fairly representative.

Q27, OBTAINING LOCAL SEAFOOD:

Since this is the first time R is encountering 'local', before asking Q27, pull out the provided map and indicate some landmarks. Do not let the respondent rush you by saying "I've lived here a long time, and know the area." Continue with your explanation of the local purchase area as we must define it, to underscore the necessity of R grasping the boundaries.

Each of the five groups of local seafood must be asked. Respondents will have lived in the CMB area for periods of time ranging from barely five years to their whole lifetime, from birth to their current age of 64. Thus we want to know, accumulated over whatever time they have had the opportunity to catch the local seafood, if they have done each at least five times.

The reference point here is the respondent -- not family or friends, or neighbors. It is the activity of catching the seafood that

is of interest, and not the consumption of seafood. Each activity is then simply coded, as the question is asked, as "Yes"(=1) or "No" (=2).

Q28, USUAL WEIGHT:

Before we actually measure the respondent's weight, we want to get an idea of whether what we are going to empirically observe is a fairly typical weight of this respondent. Thus Q28 refers to R's USUAL weight. If it seems appropriate to PROBE based upon the respondent's initial answer, the definition of usual would be his/her weight before any recent (at a minimum, those occurring within the past 30 days) substantial changes in weight, either gains or reductions. The reference point for usual weight is not the respondent's ideal or desired body weight, nor is it the weight when they were a (usually thinner) teenager.

If the respondent does not at first give a response because he/she remembers that weight measurement is part of the Study protocol, PROBE for USUAL body weight by giving the above definition of usual.

Do not belabor a refusal or a 'Don't Know' answer here, since we will be measuring weight and we don't want to get a refusal to do the empirical measurement because of respondent antagonism.

Q29, 30, AND 31, PHYSICAL MEASUREMENTS:

Take the skinfold, height, and weight measurements according to the clinical protocols. Record the observations.

Measure height to the nearest one-quarter inch. During editing, transform the feet/inches measurement recorded into centimeters, by multiplying total inches by 2.54.

Record weight in quarter-pound units as it balances on the scale. When coding, round up to the nearest full pound; round 1/4 down (e.g., 134 and 1/4 = 134 lb.) and round 1/2 and 3/4 up to the next full pound.

Q32, OBTAINING LOCAL SEAFOOD:

Earlier we asked the respondent an open-ended question about sources from which he obtained fresh seafood; now we want the same kind of information with reference to locally caught seafood. See the instructions for Q23 on how to ask the questions, PROBING, and the recording of answers.

However, unlike the following three questions on the consumption of local seafood in which we are extremely specific and limiting in the definition of local, here we do want to refer back to the map of the boundaries we are using of the river/harbor area but not be as strict with respondent's lack of knowledge or uncertainty. Do emphasize the

r -lined work 'locally' and refer to the map, but do not use the nation of local fish as applied below (caught by R, or his/her n y, friends, or neighbors). Rather, for PROBING a 'Don't Know' hat stems from uncertainty by the respondent as to whether locally ought seafood was actually caught within the harbor confines, use: Seafood that you understand(understood) to be or are(were) told s(was) local.

The reason for allowing the respondent this leeway in the definition of 'local' in Q32 is because we are interested in procurement atterns and will be investigating whether these data do tell us nything about exposure. We do not know what markets do, and especially did ten years ago, carry seafood caught in the harbor.

Q33. LOCAL LOBSTER CONSUMPTION:

This is the first of the questions on the consumption of locally ught seafood. Q34 asks about other species of seafood known to be gh in PCBs or heavy metals that can be caught or trapped in the local rbor area, and Q35 asks about the consumption of any of these local ecies grouped together.

There are two concepts inherent in this question that must be mmunicated to the respondent. The first is that of our definition of seafood. Thus you start by underscoring to the R that he/she has in the GNB area for more than five years. The purpose of the minder is to emphasize the length of time R has lived in close oximity to the available seafood. Because there have been several tervening questions and a break for the physical measurements since e first time you explained what we mean by the river/harbor area, mind R of the map and its fishing boundaries again.

The second concept to be understood is that of eating seafood at the respondent knows was caught within the river/harbor area. We ve tried to communicate this concept by mentioning that seafood known be caught locally is that that the respondent actually caught, or s caught by members of R's family, or by friends or neighbors.

Attentive respondents may, upon hearing the question, respond that ey don't positively know whether the 'local' seafood they have eaten truly caught in the harbor boundaries because they bought what was belled as or presumed to be 'local' seafood at fish retailers in the ea. To help these respondents, repeat the phrase as to sources of taining local seafood that we have listed (caught by R, or R's mily, friends, or neighbors). If R persists that they never obtained cal seafood from acquaintances (the only circumstances under which ey could know that the seafood was caught in the harbor area), this a true 'Don't Know' response. Purchases at local markets were rately not listed as ways of obtaining local seafood, since ge of its source would not have always been generally avail- An alternative source of local seafood would be from strangers, h as children on the docks or casual peddlers, who are not retailers seafood or commercial fishermen, but are selling seafood as a

be getting just estimates. However, 'Don't Know's' really should not be occurring once R has said 'Yes' to consuming a total of five or more local lobsters.

Q34. LOCAL SPECIES CONSUMPTION:

The consumption of five species, or groups of species, of seafood that are high in PCBs or heavy metals and can be obtained in the local river/harbor area is the topic of Q33. A tabular format is provided for the recording of the responses. The actual questions that need to be asked for each variety of seafood appear at the beginning of the question. This format was done for your convenience and to be less tiresome for the respondents who answer 'Yes' to more than one of the contingency lead-in questions (i.e., five times or more lifetime consumption).

However, you must make sure that, at a minimum of the first time you get a 'Yes' to the contingency question with reference to a particular variety of local seafood, that you then ask the follow-up questions on number of years, frequency, and change in consumption pattern exactly as they appear at the beginning of Q34. For example, the R said 'No' to Q33 on lobster consumption, 'No' to Q34A on clams and quahogs, but responded affirmatively on eating five dozen or more locally picked mussels. Ask the three follow-up questions for mussels as they are worded at the beginning of Q34, substituting mussels for the dotted lines as you read them.

For respondents who answer positively to consumption of several varieties of locally caught seafood, you may abbreviate the follow-up questions the second and third times to just the critical phrases. For example, "At what time of your life did you eat eel most often?", and "At that time, how often did you eat local eel (Card #2)?". However, use these shorter versions of the questions carefully and only when you are certain that the respondent is still focussed correctly. In addition, for the fourth variety of seafood for which you end up asking the follow-up questions, return to the use of the exact wording: this is to remind the respondent of the exact intent of his/her answers.

Refer back to the instructions for Q33 for further guidance in gathering this information.

Q35. TOTAL LOCAL CONSUMPTION:

Here we are trying to get an idea of the R's consumption of any of the species of seafood high in PCBs or heavy metals that are available in the local harbor area. Thus we are summing across the species of seafood detailed in Q33 and all sections of Q34. Skip this question if R responded affirmatively with reference to lifetime consumption of quantities exceeding five to none or only one of the species in questions 33 and 34.

You ask this question when there were two or more species of local

Q 37 CURRENT DOCTOR

In this question, we are trying to determine R's current physician and if R would like us to send his/her PCB blood measurement results to this physician or, if not, if he/she would like them sent to another physician.

If R has a regular doctor, fill in the physician's name and address in Q 37B-C. When editing, you will use our code list of area physicians to code the speciality.

Part "D" has been changed to read as follows: "At the end of this interview...reading. Would you like me to send the results of your PCB blood measurment to Dr. _____?" (Fill in the blank with the name of the physician provided in Q 37A.) The same wording would then also be used for parts E or F.

Skips: (1) If R does not have a regular doctor, you skip from Q 37A to Q 37F. (2) If R does not wish his PCB results sent to his/her regular doctor, skip from Q 37D to Q 37E.

Q 38 MEDICAL CONDITIONS

In this question, we are looking for relevant health and/or medical conditions. Try to recall any limiting conditions R may have given you in Q 2; for example, if R said he/she couldn't work because of a bad back in Q 2, but then said "No" to Q 38, you might probe as follows: "At the beginning of the interview, you told me that you couldn't work because of a bad back. Are you currently being treated by a doctor for your back problem?"

If R says "Yes" to the first part of Q 38, record the name of the condition, the treating physician, and the date of the initial diagnosis of the condition. (Note that this date is not that of the onset of the condition, but of its initial diagnosis. R may have first experienced back problems in 1973, yet first gone to a doctor for diagnosis and treatment in 1975; use 1975 for the code "Year.")

Record the condition as R reports it, but probe if it is totally unfamiliar to you. Also, try to probe very vague complaints, i.e., back problems," "stomach problems," "trouble with my feet," "stress," "emotional problems," etc. Conditions will be coded by the medical consultant using the categories in the International Classification of Diseases (ninth revision, 1975); the more thorough and accurate the description, the more accurate our coding will be.

In this instance, we are using years, not months, for coding time, and you record the exact number of years since the initial diagnosis. Codes for less than a year for this questions are as follows:

seafood that R has eaten. You need to remind the respondent of the species he/she mentioned at the end of the first question in Q35. And the species, with regard to consumption, are being combined together here, and we are asking about consumption of any of the species. For example, if R ate local clams and quahogs when he was a child for the ages approximately 3 to 18, and five years ago took up sportsfishing for striped bass that he has been cooking at home, and R is now 50, the answers to Q35A(1) and Q35A(2) would be 3 and 50, respectively.

Refer back to Q33 for information on asking and PROBING for this question.

SECTION VI, MEDICAL HISTORY

Q36, SODIUM:

The purpose of the sodium question is to get some indication of the amount of salt in the respondent's diet. Sodium intake can be associated with hypertension.

Q36A is complicated with regard to the number of concepts involved, and therefore you must practice your phrasing of the question so that the respondents do not start to answer the question before you have finished. Do emphasize the underlined words, but do not ignore the time frame referenced in the first phrase, 'over the last twelve months'. Then keep your voice up when you reach the point where you must read the options of frequency of eating at least one of the mentioned foods (examples of highly salted foods).

The frequencies used in Q36B and Q36C are quite standard and should be easily comprehended by the respondents. Two common deviations from the choices presented are: "Always" and "Never". If one of these two deviations is reported, do not bother to repeat the question as originally phrased. A response of "Always" should be written down and then coded as 'Usually'; a response of "Never" should also be written down and then coded as 'Rarely'.

Most respondents will have an opinion as to whether the salt in their diet has changed in the last five years. If you at first get a "Don't Know", repeat the question. Even if the respondent does no cooking or does not know what foods are salty, he/she should at least have an idea as to whether the amount of salt he/she adds to food at the table has changed.

Regardless of the answer to Q36D about behavioral changes in salt consumption over the last five years, ask Q36E about a low sodium diet of all respondents. A R could have been on a low sodium diet for more than five years, and thus their behavior has not changed. Also, they could have had a 'diet' prescribed by their physician, and still not have changed their salt intake behavior. Ask Q36E(2) only of persons who say that they are on a low sodium diet (Q36E(1)).

< 1 month.....91
1-3 months.....92
4-6 months.....93
7-11 months.....94

The same procedures apply to Q 38B. For Q 38C, record the conditions on the lines provided. It would be helpful here if you would also write in the doctor's name and the initial year of treatment.

Pregnancy is not to be included as a medical condition in Q 38. Problems associated with pregnancy--toxemia, etc.,--should be included.

"Currently" in this question means "within the past two weeks."

Q 39 CURRENT MEDICATIONS

Q 39 and Q 40 both deal with medications. In Q 39, you are asking R what specific medications he/she is actually taking now; Q 40 is seeking information on general categories. In Q 39, we want both prescription and over-the-counter medications. Probe carefully for name (and accurate spelling) of the medication, physician, condition, and month/year begun. (The condition and physician may well be familiar to you from Q 38.) If R has mentioned a condition in Q 2 or Q 38 and says "No" to this question concerning medications, you would properly probe by asking "Are you taking any medication for your back problem...or your ulcers...?", etc.

We ask R in our initial calls to bring along to the interview any medications that he/she might be taking, but if R is taking medications, does not know their names, and has not brought them in, arrange for a call-back so that R can read you the information off the label.

Q 40 CURRENT MEDICATIONS: CATEGORIES

Q 40 may seem repetitious, but it serves to (1) double-check on information in Q 39 and to (2) jog R's memory for medications he/she may have forgotten in Q 39.

DO NOT skip the category if mentioned in Q 39 (as the instructions on the questionnaire state): you may re-word the question as you deem appropriate to avoid excessive repetition, for example: "You told me you were taking Dyazide ordered by Dr. Smith for high blood

pressure since 1985, so you are taking blood-pressure medicines." This re-wording confirms and verifies the accuracy of the information in both questions.

For each category of medications, you will record "Yes/No," the condition, and the month/year begun. Total months will be calculated during editing.

Q 40 i will be coded "9" (Inapplicable) for men.

If you have any question about drugs or classes of drugs (i.e., whether Sudafed is or is not an antihistamine, whether Valium is a muscle relaxant or a tranquilizer, etc.) flag these so that our medical consultant may analyse them and complete coding in this section.

If R gives you a specific medication in Q 39, but then says "No" to its corresponding general categories, flag these in turn for the attention of the medical consultant.

In Q 40 e, " long-term antibiotics" means any antibiotic taken for longer than one month.

If information in Q 40 should lead you to believe that R forgot a medication in Q 39, go back to Q 39 and record the medication he/she has just mentioned. (This seems to happen frequently.) Also, if R gives you names of prescription drugs, but has said that he/she is not being treated for any condition in Q 38, go back to Q 38 and probe: "Given that you are taking medication I from Dr. X, would you say you are currently being treated by a physician for any health or medical condition?" If the answer is positive, record at Q 38.

Questions 37-38-39-40 are very closely interrelated, and information obtained in one question may, in fact, give you information you will need to use for probing another in this series of questions.

Q 41 RECENT BLOOD PRESSURE MEASUREMENT

Record the date of R's most recent blood pressure measurement (i.e.,"1975," "six weeks ago," "last year") and transform it to fit one of the days/months/years categories. Record years as 01-44, using the exact number of years. Code months as indicated in the table.

In Q 41B, if R doesn't know or doesn't remember or wasn't told the results of his blood pressure measurement, code "8" for "Don't Know." You may code expressions such as "they said it was good," "It was fine," or "It was OK" to "2" (Normal).

Q 42 PAST MEDICAL CONDITIONS

This question on past medical conditions has 10 sub-sections (a-j). There are two criteria for a "Yes" response here: (1) that R has had the condition and (2) that R has seen a doctor about the condition or discussed the condition with a doctor. For each condition, record "Yes/No" and the month/year of initial diagnosis. It is important to read EVERY introductory question exactly as it appears. These introductory questions serve two purposes: they introduce a new category for R (skin, circulatory, eye, etc.), and they remind R that a doctor must have been contacted about this condition. If R gives you a condition and says that he/she has never seen a doctor about it, write it in, but do not code it.

For longer entries such as Q 42 b (liver problems), 42 d 1 (blood problems), 42 g 1 (bronchitis), read the whole entry, as the clue may be in the sub-category.

If R does not recognize the name of a condition, he/she has probably not had it; you do not need to explain these conditions. If, in a given category, R gives you a condition that you do not recognize, write it in and flag it for editing by our medical consultant; most of these will fit in the "other categories."

Time coding in this question is for month/year of initial diagnosis (not total number of years as in Q 18). Probe as you do in Q 10 (residential history) to help R remember dates by assisting him/her in associating these conditions with other life events.

In Q 42 a 5, glasses or contacts are not included as eye conditions. In Q 42 h 5, we are looking for diabetes or sugar in the urine, not hypoglycemia or low blood sugar. In Q 42 i, if R reports that he/she has had cancer, probe to find out what kind of cancer, and write this information on the line provided. In Q 42 j, record any other conditions that R mentions here and record the dates.

Q 43 SYMPTOMS

The symptoms listed in this question may all be associated with toxic exposures. The criteria for a "Yes" in this question are different from the criteria in Q 42: we are only interested here in knowing if R has ever experienced any symptom for three months or longer; the consultation with a doctor is not a factor. Here again you probe for year of onset, not total number of years; next, record whether or not R is currently experiencing the symptom with a "1" or a "2."

In this question, the occurrence of any of these symptoms as associated with pregnancy is not to be included.

Q 44 and Q 45 SMOKING

Packyears = number of packs x number of years: this calculation may be done during editing using the tables provided. If R answers "No" to Q 44, code Q 44A and B as "9" and skip to Q 45. In Q 44B, we are looking for both current and past smoking; if R is a former smoker, you ask "In an average day, how many cigarettes did you smoke?"

Q 46 ALCOHOL CONSUMPTION

Alcohol consumption may be related to alteration of certain liver function tests which are of concern in this study. As with smoking, we are interested in both current and past drinking.

If R answers "No" to Q 46, code Q 46A-C as "9," (Inapplicable).

If after a "Yes" in Q 46, R answers "No" to Q 46A, you are dealing with a former drinker, and thus, Q 46B (-) and Q 46C are all asked for past drinking, i.e., "estimate on the average how often you used to consume...." and "how many cans, glasses, and shots did you usually have in one sitting?"

In Q 46B 3, "shots of hard liquor or whiskey" includes mixed drinks.

SECTION VII DEMOGRAPHIC INFORMATION

Q 47 RACIAL BACKGROUND

Q 47 on racial background contrasts with Q 7, nationality group. If you have any problems coding a race that R may give you, flag it for the editors. If R gives "Cape Verdean" or "Puerto Rican" as a race, code it as "5," (Other).

Q 48 MARITAL STATUS

Record R's marital status.

Q 49 HOUSEHOLD SIZE

Read the whole question to be sure R includes himself/herself in this total calculation.

Include as household members: persons who are temporarily not physically present in the house, but who would usually live there, such as persons on vacation, in the hospital, or away on a business trip.

Include: unrelated household members who function with R as a family unit, i.e., foster children; unmarried couples living together as couples even though they are not actually married. "Living with a friend" can call for probing and task: ask if they are living as a couple and sharing expenses as a couple: if so, include.

Exclude: a household member who recently left to take up residence elsewhere, i.e., students living on-campus or students living off-campus who are paying rent at an address other than that of R. Exclude roomers, boarders, maids, butlers, etc.

If you have any doubt as to the inclusion of certain individuals in a household, probe to see how long the person has been living there and which expenses they share, and write in this information. Flag the question for consultation with the Data Manager or Project Director.

Q 50 INCOME

As there are many possible sources of income, read the whole question so that R is aware of all sources to be included in the answer. Include income of all individuals in Q 49; if there are two parents and three children working and earning money, the income recorded here is the family income of all five people, not the individual's income.

Income is often a sensitive question: the use of broad categories, rather than specific incomes, should reduce refusals. If R is reluctant to give you this information, assure him/her of the confidentiality of the data: if R still refuses, write in "Refusal" and record a "7" (Missing Information) in the box.

Q 51 OTHER CONTACTS

These two individuals should not be anyone in Q 49, that is, not anyone who is a member of R's household. Get as much information as you can here. If R refuses to give you this information, just write in "Refused."

Q 52 BLOOD PRESSURE #3

The pulse, blood pressure, and time will be recorded as in Q 5 (p. 3) and Q 22 (p. 18). The "Respondent Blood Pressure Instruction Sheet" will be completed using the lowest of the three blood pressures.

Q 56-Q 57 INTERVIEWER SECTION

This section allows you to evaluate the respondent in terms of attitude and confidence level; these are, of course, subjective ratings. If you have interviewed a particularly difficult or uncooperative respondent, write in this information here. If, in your judgment, you have interviewed a respondent for whom you doubt the validity of the data for whatever reason, consult with the Data Manager or the Project Director.

Q 58 EDITING

If you discover you have any missing information or procedures, check the appropriate box. Appropriate call-backs or follow-up visits (for Urine or Phlebotomy) should be planned at this point. If you are unsure whether certain missing information should have a call-back or should be recorded as missing (for instance, if you inadvertently skipped a question), contact the Data Manager before calling back. We do not want to have too many call-backs to the respondents. If you do call back for missing information, be sure to record this call on the Cover Sheet so that it will be recorded in the total number of calls in Q 66A.

Q 59-Q 69 FINAL CODING

At this point, go back through the whole questionnaire and edit it thoroughly for errors or inconsistencies. Add codes as necessary, using the coding materials provided. If you do have inconsistencies of which you are aware and which remain even after careful probing, you could note this for the editors in the margins. Such an inconsistency might be an R who told you in Q 2 that they were limited in work-related activities by migraines and then answered "No" to Q 42 f & about headaches. These inconsistencies do occur, particularly in the fish questions: in the final analysis, we have to accept what R said, not what we think they might more appropriately could have said or should have said. If you have particular problems in one area of the questionnaire, you might listen to the tape again while doing your final editing and coding.

Q 59-Q 62 ADDRESS AND CENSUS TRACT

This coding will be done from the residential history in Q 9 and Q 10 (pp. 4-8). The census tract codes will be added in final editing. It is important to check at this point (and in Q 9 and Q 10) the relationship of the address(es) in Q 9 and in Q 10A 1. Procedures for coding months in Q 9-10 and in Q 62A are in the Coding Sheet on Time (9/22/85).

Q 63 LANGUAGE

Record the language in which you conducted the interview.

Q 64 TYPE

Interviews conducted in the course of a Home Visit will be coded as "2," ("Field").

Q 65 PROXY

We have eliminated this question for Data Entry. If you have had a proxy situation, note it in writing here.

Q 66 CONTACT EFFORTS

The information in this section will enable us to analyze our search efforts for reaching respondents and setting up the actual interview.

In Q 66A, the number of calls will be taken directly from the Cover Sheet; include all calls (neighbor calls, no answers, follow-up calls for further information, etc.)

In Q 66B, "Number of Visits to the House," we will include only Home Visits for contact purposes. Exclude Home Visits for interview or any procedures in this figure.

In Q 66C, the number of mailings includes all mailings for contact purposes, including reminder postcards.

Q 67 NUMBER OF MINUTES

The total number of minutes for the interview will be calculated by subtracting the figure on the top of page 1, "Time Interview Starts," from the figure in Q 62 (p. 16). At this point, you should also check that you have consistently used the 24-hour system for any afternoon or evening interviews.

Q 68 DAY OF WEEK

This information will be useful to us for planning later schedules for interviews.

Q 69A INTERVIEWER NUMBER

Record your interviewer number

Q 69B BATCH NUMBER

A Q 69 B is added during the final editing to record batch number.

APPENDIX V

SPECIMEN COLLECTION & SHIPPING PROTOCOL

NEW BEDFORD, MA
CASE #84-0021
Phase I

SPECIMEN COLLECTION AND SHIPPING PROTOCOL

A. INTRODUCTION

The proper collection, processing, storage and shipment of physiologic specimens from participants in the Greater New Bedford PCB Health Effects Study is critical to the success of the study. The following sections describe the procedures which must be followed for all specimen collections in both Phase I and Phase II. These procedures must be strictly adhered to in order to avoid contamination, loss, or degradation of the specimens. Please familiarize yourself with the study protocol and insure that you understand the concept of the study, the role of all of the personnel involved, and your own role.

You must coordinate with the Project Director to establish a schedule for collection of specimens which meshes with the entire clinic visit and does not interfere with other testing which is planned. Arrangements must be made for the transfer of specimens to the MDPH Laboratory, Jamaica Plains, MA. for PCB analyses, and shipment to Atlanta. You must also coordinate with other laboratories in the New Bedford - Boston Area for the timely shipment of specimens for CBC and Immunologic testing at the times specified in the protocol (Phase II only). As a general rule, Urine collections should be performed when the subject first arrives at the clinic location. Keep in mind that urine collection procedures for this study will be somewhat time consuming and will require special preparation of supplies prior to clinic time (see section B.2).

Note also that subjects are to report to clinic in a fasting state and this will require that blood collection be accomplished early in the visit to avoid discomfort to the subject and an adverse impact on compliance. Blood and urine collection must be completed and processed on site under carefully controlled conditions of good laboratory practice. Blood separation and processing must be accomplished promptly (see section D.2) to avoid degradation of the specimen.

B. PREPARATION OF THE WORK AREA AND SUPPLIES

1. <u>Organization of Work Area and Supplies</u>
The following supplies should be prepared and well organized for easy access prior to each Phase I clinic visit. Note that quantities are the minimum number required for each subject to be examined, so allow for spare supplies.

a. Blood and Serum Collection

Expendable Items Needed per Person for Blood and Serum Collection:

- Gauze sponges, 2x2" (2)
- Alcohol wipe

- Bandaid
- 15 mL red-top vacutainer (4)
- 5 mL lavender top vacutainer with EDTA.
- 21 or 23 g butterfly
- Luer-adapter to adapt butterflies for use with vacutainers
- Wooden applicator sticks, sterile, to rim clot; (4)
* Pasteur pipettes (2)
* 5 mL Wheaton serum bottles, Cat No. 223738, (5)
* 30 mL Wheaton bottle (1)
* Teflon-lined stoppers for Wheaton bottles (6)
- Aluminum seals (5)
- Prenumbered labels

*These items must be rinsed with acetone and then hexane. See "Recommended Procedures for Cleaning Pasteur Pipets and Wheaton Bottles."

Additional Supplies:

- Tourniquets
- Vacutainer holders
- Pipette bulbs
- Crimpers to be used for securing aluminum cap on 5 mL vial
- Racks
- Centrifuge
- Teflon wash bottles

b. Urine Collection

Expendable Items Needed per Person for Urine Collection:

- 1 urine collection cup (250-ml, plastic, capped, wrapped)
- 1 conical-bottom, 15-ml plastic centrifuge tube for arsenic analysis (contains nitric acid)
- 1 conical-bottom, 15-ml plastic centrifuge tube for mercury analysis (contains triton and sulfamic acid). This tube is marked with a yellow dot.

Additional Supplies:

- deionized water
- garbage bags

2. <u>Special Preparation</u>

a. Recommended procedures for Cleaning Pasteur Pipets and Wheaton Bottles (These supplies are prepared in advance by MDPH Laboratory Institute)

Supplies and Equipment Needed:

- Teflon wash bottles - 125 or 250 ml capacity

- Acetone - "Nanograde Quality" or suitable for gas chromatography with electron capture detection.
- Hexane - same criteria as acetone.
- Kimwipes
- Large Beaker
- Laboratory hood

Procedures:

Hands should be washed and free of grease. The use of gloves is not recommended, unless it can be assured that they will not impart any detectable contamination to the supplies being washed. (In most instances this can't be guaranteed).

Pasteur Pipets - in a laboratory hood grasp a bundle of pipets so that the tips are pointing away toward a drain or waste bottle. Flush the insides by squirting acetone through the large opening and wash the tips as well. Repeat the procedure using hexane. Cover the bottom of a large beaker with a Kimwipe (R) Place the washed pipets (tip up) in the beaker and allow to air dry in the laboratory hood. Cover the tips with a large Kimwipe (R)

Wheaton Bottles, Silicone Closure (with Teflon (R) face) - in a laboratory hood rinse the vial with acetone. Discard acetone. Rinse the bottle with hexane. Discard hexane. Place hexane in the bottle, assemble (i.e., use silicone closure), gently swirl so as to make contact with Teflon(R) face of the silicone closure only. Do not allow the hexane to contact the non-teflon portion of the silicone closure. Discard hexane. In a laboratory hood allow bottle to drain onto Kimwipe and let silicone closure dry with Teflon (R) face up. Reassemble.

b. <u>Addition of nitric acid to arsenic tubes</u>

Supplies and Equipment Needed:

- powder-free lab gloves
- ultrapure concentrated nitric acid (G. Frederick Smith Chemical Co., Columbus, Ohio 43223, Catalogue No. 63, ultrex grade, or equivalent)
- lab apron
- safety glasses
- pipettor (Eppendorf or other precision 100 ul pipettor; Biorad BR-33 clear (metal-free) 1-100 ul disposable pipet tips, or equivalent)
- conical bottom, 15-ml plastic centrifuge tubes
- Laboratory hood

Procedure:

While wearing protective unpowdered gloves, apron and glasses, working under a laboratory hood, and using a pipettor, pipet 100 ul of ultrapure concentrated nitric acid into the bottom of

each of the 15-ml conical-bottom tubes which will be used for arsenic analyses. Process one tube at a time, removing the cap, adding the acid, and replacing and screwing the cap. Place the tube in a test tube rack and proceed to the next tube. Do not touch the interior of the cap or tube or place the cap or pipet tip on external surfaces which may be contaminated for trace elements.

Also, do not add nitric acid to more tubes than can be used in one day. In handling and transporting, conical-bottom tubes must be kept in an upright position so that the preservative will not run up the sides or touch the top.

c. Addition of Triton and Sulfamic acid to mercury tubes:
(These supplies are prepared in advance by MDPH Institute)

Supplies and Equipment Needed:

- powder-free lab gloves
- Triton X-100 (alkylaryl polyether alcohol), J.T. Baker Chemical Co., Phillipsburg, NJ 08865, Cat. NO. X-198, or equivalent.
- Sulfamic acid (J.T. Baker Chem. Co., Phillipsburg, NJ 08865, Cat. No. 7-V145, or equivalent). CAUTION - STRONG ACID!
- lab apron
- safety glasses
- pipettor (Eppendorf or other precision 10 ul pipettor; Diamed BR-33 clear (metal-free) 1-100 ul disposable pipet tips, or equivalent)
- yellow stick-on dots, 1/2" super-stick stock (Shamrock Specialty Systems, Post Office Box 143, Dellwood, IL 60104, or equivalent)
- conical bottom, 15-ml plastic centrifuge tubes
- Laboratory hood
- Analytical balance capable of weighing to .001g.

While wearing protective unpowdered gloves, apron and glasses, working under a laboratory hood, and using a precision pipettor, pipet 10 ul of Triton X-100 into the bottom of each of the 15-ml conical-bottom tubes which will be used for mercury analyses. Add 20 mg of sulfamic acid to each tube. Process one tube at a time, removing the cap, adding the Triton-X and sulfamic acid, and replacing and screwing the cap. Then mark the tube with a yellow stick-on dot, place the tube in a test tube rack and proceed to the next tube. Do not touch the interior of the cap or tube or place the cap or pipet tip on external surfaces which may be contaminated for trace elements.

In handling and transporting, conical-bottom tubes must be kept in an upright position so that the preservatives will not run up the sides or touch the top.

d. Preparation of laboratory blanks: (Deionized water is supplied by MDPH Institute). Still wearing protective clothing and working under a hood, prepare one arsenic tube laboratory blank and one

mercury tube laboratory blank for each day on which urine specimens are collected. Select one of the 15 mL plastic arsenic tubes to which 100uL of nitric acid has just been added and slowly pour 10 mL ± 1 mL of deionized water to the arsenic tube. Cap, label with the preprinted label 'LAB BLANK - As', seal, and invert the tube several times. Similarly, select one of the 15 ml plastic mercury tubes to which triton and sulfamic acid has been added (Yellow Dot) and add 10 ml ± 1 ml of deionized water as above. Cap, label with the preprinted label 'LAB BLANK - Hg', seal, and invert the tube several times. On each label and using a ballpoint pen, write the date collected and the initials of the laboratory technician preparing the lab blanks. Freeze the blanks in an upright position at -20°C and store them frozen until shipment to CDC with the urine specimens.

C. MANAGEMENT OF THE SUBJECT

1. Pre-Clinic Instructions to Subjects

Fast overnight (water only), approximately a 12-hour fast. Specimens will be drawn in the morning following the fast. Record time each subject last ate.

2. Scheduling of Events

Refer to the schedule for all clinic activities established by the Project Director. This schedule must consider the relationships among all testing to be performed, clinic logistical requirements, and the comfort of the individuals being tested.

3. Paper Work

It is extremely important that all records associated with each subject be maintained in an organized and complete manner to ensure that all information is properly collected and accurate. Specimens should be labeled promptly and processed as a unit or "run" and precautions must be taken to avoid patient - specimen - label - record mixups. This type of error is usually the most common error in the laboratory setting, but careful planning and a well organized work area will keep such errors at a minimum. Some of the information required for the specimen label and shipping list, described in section E.2 and Appendix 1, will be collected at the time of specimen collection. Problems in blood collection should be noted in the sample log and in the comments section of the shipping list.

4. Urine Collection

Expendable Items Needed per Person for Urine Collection:

- 1 urine collection cup (250-ml, sterile, plastic, capped, wrapped)
- 1 conical-bottom, 15-ml plastic centrifuge tube for arsenic analysis (contains nitric acid)
- 1 conical-bottom, 15-ml plastic centrifuge tube for mercury

analysis (contains triton and sulfamic acid). This tube is marked with a yellow dot.

Additional Supplies:

- deionized water

a. Instruct participants to wash hands with soap and water.

b. Instruct participants in how to collect urine to minimize trace element contamination:

- The cellophane wrapping of the urine container should not be opened until just before voiding.

- The person should leave the cap in the wrapping while voiding, then recap the filled container immediately.

- IT IS MOST IMPORTANT that the inside of the container and the cap not be touched or come into contact with any parts of the body or clothing or external surfaces. Exposure to air should be minimized.

- The person should leave the capped specimen in the bathroom or transport it with the cap on to the laboratory. The specimen will then be labelled with the gummed label marked with their study ID number (e.g. 84-0021-xxxx) and the words "Urine Collection".

NOTE: For this situation, and these analytes, strict adherence to the above precautions should minimize interferences, and it will not be necessary to obtain a clean-catch (midstream) specimen or prewash the genitalia.

5. Blood and Serum Collection

Expendable Items Needed per Person for Blood and Serum Collection:

- Gauze sponges, 2x2" (2)
- Alcohol wipe
- Bandaid
- 15 mL red-top vacutainer (4)
- 5 mL lavender top vacutainer with EDTA
- 21 or 23 g butterfly
- Luer-adapter to adapt butterflies for use with vacutainers
- Wooden applicator sticks, sterile, to rim clot; (4)
* Pasteur pipettes (2)
* 5 mL Wheaton serum bottles, Cat. No. 223738, (5)
* 30 mL Wheaton bottle (1) (or other suitable volume glass container with teflon-lined stopper)
* Teflon-lined stoppers for Wheaton bottles (6)
- Aluminum seals (5)
- Prenumbered labels

*These items must be rinsed with acetone and then hexane. See "Recommended Procedures for Cleaning Pasteur Pipets and Wheaton bottles."

Additional Supplies:

- Tourniquets
- Vacutainer holders
- Pipette bulbs
- Crimpers to be used for securing aluminum cap on 5 mL vial
- Racks
- Centrifuge

a. Preparation of Puncture Site

The anticipated puncture site and all necessary equipment, including needles, tubes, etc., must not only be kept sterile but must also remain free from contamination by those elements to be assayed for in trace amounts by the Clinical Chemistry Division of CDC. Extreme caution must be exercised throughout the collection of blood and pooling of sera for data to be valid.

Procedure: Locate the puncture site. Cleanse the area with the "alcohol prep" provided that has been found to be free of any contamination. Hold with 2 fingers on one side of the "alcohol prep" so that only the other side touches the puncture site. Wipe the area in a circular motion beginning with a narrow radius and moving outward so as not to cross over the area already cleaned. Repeat with a second alcohol prep.

b. Locate a suitable table and chair for blood drawing and lay out blood collection supplies.

c. Locate vein and cleanse in manner previously described, then apply the tourniquet. If it is necessary to feel the vein again, do so; but after you feel it, cleanse with alcohol prep again, and dry with a gauze square.

d. Use a butterfly needle to draw venous blood into vacutainer tubes (four 15-ml red tops, and a one 5-ml lavender top).

e. Fix the vein by pressing down on the vein about 1 inch below the proposed point of entry into the skin and pull the skin taut.

f. Approach the vein in the same direction the vein is running, holding the needle so that it makes a 15° angle with the examinee's arm.

g. Push the needle, with bevel facing up, firmly and deliberately into the vein. If the needle is in the vein, blood will flow freely into the tube. If no blood enters the tube, probe for the vein until entry is indicated by blood flowing into the tube.

h. For single tube collection, release the tourniquet while the tube is filling. For multiple-specimen collection, loosen the tourniquet immediately after blood flow is established and release entirely as the last tube fills.

i. Withdraw the needle with a slow but firm motion.

j. When the needle is out of the arm, press gauze firmly on the puncture. Heavy pressure as the needle is being withdrawn should be avoided because it may cause the sharp point of the needle to cut the vein.

k. Have the examinee raise his arm (not bend it) and continue to hold gauze in place for several minutes. This will help prevent hematomas.

l. Invert the lavender tubes several times to ensure proper mixing. Red top tubes should not be inverted or mixed. If multiple samples are drawn, tubes with anticoagulant may be mixed while succeeding tubes are filling.

m. All tubes should be completely filled. There must be a proper ratio of anticoagulant to blood. In the 5-mL lavender top tubes, a minimum amount of 3.75 ml blood must be drawn for accurate results.

n. Report to the physician any reaction experienced by the participant during the venipuncture procedure.

o. Label all tubes with the prenumbered labels provided, and use a ballpoint pen to add the date collected and your initials to the label. The lavender-top tube should be labelled with the label showing the subject's study ID number (e.g. 84-0021-xxxx-81) and the words "blood Lead-CDC". The red-top tubes should be labelled with the corresponding labels marked "blood for Serum".

p. Bandage the puncture hold in the subject's arm.

q. Place the lavender-top tubes upright in a rack in the refrigerator within 30 minutes after being drawn. Log in the specimens and keep refrigerated (not frozen) until picked up for shipment. For the CDC lavender top tube for lead analysis, note on the log sheet if a full draw is not obtained (minimum blood volume is 3.75 ml) or if the blood tube was not refrigerated within 30 minutes.

r. Place the red-top tubes upright in a rack and allow them to clot at room temperature for 30 - 45 minutes.

D. SPECIMEN PROCESSING

1. Urine

a. Divide the urine specimen into the appropriate tubes as follows:

- Wear the powder-free lab gloves and work over the bathroom or laboratory sink.

- Gently swirl the specimen in the capped container to resuspend any solids.

- Immediately after mixing, pour 10 ml ± 1 ml aliquots of the urine into each of two conical bottom, 15 ml centrifuge tubes: one to which Triton and sulfamic acid have been added for mercury analysis (yellow dot), and one to which nitric acid has been added for arsenic analysis.

- Process each tube individually, removing the cap just before pouring and returning it immediately after filling the tube. (DO NOT TOUCH the inside of the tube or cap or place the cap on a potentially contaminated external surface; minimize exposure to ambient air.) Tighten the cap, and mix each tube vigorously to dissolve the preservatives. Attach the gummed label marked with the subject's study ID number (e.g. 84-0021-xxxx-T1) and the words "Urine Hg - CDC" to the tube with the yellow dot, and the label with the words "Urine As - CDC" to the other tube.

- Using a ballpoint pen, add the date collected and your initials to the prenumbered labels of each of the two tubes.

- Pour any unused urine into the toilet, rinse the specimen cup, and dispose of it in the designated garbage bag.

- Immediately transport and freeze the tubes of urine in an upright position in a -20°C freezer. (If the urine is not placed in the freezer within 1 hour of collection, note this on the specimen shipping list. Also record on the shipping list any known contamination of the specimen.)

b. Collection of laboratory blanks for the mercury and arsenic tubes: Every day, one set of the two trace element tubes will be prepared as "lab blanks," using deionized water in place of urine.. Prepare these blanks under the same conditions as for processing specimens (whether in the bathroom, lab, etc.) as follows:

- Immediately after processing the preceding urine specimen, obtain one each of the mercury (yellow dot) and arsenic tubes. Using the deionized water provided, pour 10 ml ± 1 ml of water into each tube, recap mix as for urine specimens, and add the correct preprinted label (LAB BLANK-HG and LAB BLANK-AS).

- On the labels for the lab blanks, use a ballpoint pen to write the date and your initials.

- Freeze the blanks in an upright position at -20°C and store them frozen with the urine specimens.

NOTE: Specimens should be collected and aliquotted and blanks processed under as clean conditions as possible to minimize contamination from dust in the ambient air.

c. Log in all urine specimens and blanks and store them frozen at -20°C until they are prepared for shipment.

2. Blood and Serum

a. After they have been allowed to clot at room temperature for 30-45 minutes, centrifuge the red-top tubes for 10 minutes at the RPM necessary to attain a force of 1000 x g. To calculate the number of revolutions per minute (RPM) necessary to attain 1000 x g, use the following formula or refer to attached nomograph:

$$RPM = \frac{9450}{\sqrt{R}}$$ (where R is the distance in centimeters from the center of rotation to the bottom of a test tube when it is extended in the centrifuge head)

Example: for R=16 cm, RPM = approximately 2400.

b. Using the prenumbered labels provided for each participant, label one-30ml Wheaton vial and five-5ml Wheaton vials. Use a ballpoint pen to add the date collected and your initials to the labels on the Wheaton vials. To 30 ml Wheaton vial should be labelled with the label showing the subject's study ID number (e.g. 84-0021-xxxx) and the words "Pooled Serum". The 5-ml Wheaton vials should be labeled with the corresponding labels marked "PCB-MDPH", "PCB - CDC", "Archive - MDPH". "Chlor HC - CDC", and "Archive - CDC".

c. Using the transfer pipet provided, pipet the serum from each participant's four red-top tubes into the 30 ml Wheaton vial. Check to make sure that the numbers on the labels are the same. DO NOT ALLOW SERUM TO REMAIN IN CONTACT WITH THE CLOT FOR LONGER THAN 1 HOUR AFTER THE SPECIMEN IS COLLECTED.

d. Mix the pooled serum to insure a homogeneous sample. Use a second transfer pipet to aliquot 4.3 - 4.5 ml of the pooled serum into each of the five-5ml Wheaton vials.

e. Immediately cap, seal, and crimp the filled Wheaton vials and place them upright in a -20°C freezer. Time between collecting blood and freezing serum should not be more than 1 1/2 hours. Store the frozen serum at -20°C or less until the vials are packed for shipment.

f. Log in the specimens by placing a (✓) in the appropriate column of the specimen shipping list and note in the comments column the following conditions, if any occurred, by the specimen vial(s) affected:

Turbid = Serum is turbid.

Hemolysed = Serum is hemolyzed.

Low Volume = Serum volume in any vial is less than 4.3 ml. (Estimate the amount, for example, "Approx. 2 ml. of serum in vial 3.")

RBC Contact = Serum left in contact with red cells for more than 1 hour. (Record the amount of time, for example, "Time between blood collection and harvesting of serum was 2 hours.")

Time to Freezing = Time between blood collection and freezing of serum was greater than 90 minutes. (State the time, for example, "Serum left in vial at room temperature overnight before freezing.")

Thawed = Serum thawed during storage or handling. (Refreeze and note intervening time, for example, "Freezer failure; serum was thawed for approximately 5 hours before refreezing.")

E. SHIPMENT OF SPECIMENS TO CDC, ATLANTA, GA.

1. Beginning of study and general instructions

a. Determine from the local post office the times 'Express Mail' packages are picked up in order to connect with the best flights to Atlanta, Georgia. Shipments to Atlanta will be scheduled weekly and scheduled only Monday through Wednesday mornings. IMPORTANT: Since the materials packed in accordance with the instructions below will remain frozen or cool only about 2 1/2 days, shipments should not arrive in Atlanta on weekends or on Federal holidays.

Inquire about regulations in your area concerning shipment of serum and urine specimens with dry ice and the quantity of dry ice allowed per shipper. Also, make sure the specimens will be received at CDC with 24 hours.

Telephone the laboratory at CDC the day the shipment is mailed (area code 404, 452-4002). Speak with Brenda Lewis, Margie Sailors or Jim Gill.

b. For all shipments, do not pack the shippers with frozen specimens and dry ice or the shippers with whole blood and frozen coolant until just before transport to the postal drop.

c. Maintain a supply of dry ice from a local supplier for shipping specimens each week. A block should be sawed at the plant into 1" slabs. Then each of these should be sawed lengthwise. A 7" X 10"

slab would fit easily into the shipper without having to break the slab.

d. Shipments of whole blood require a coolant to keep the materials cool during the shipment (NOT FROZEN). The laboratory techs should keep 10-12 coolant packs in the freezer at all times; replace the ones used weekly to maintain the inventory for other unexpected demands for these items.

2. Paper Work

For each shipment, fill out the Specimen Shipping List provided by CDC. Please give the following information in the spaces provided:

- Page Number - e.g. 1 of 4
- Shipment Number - number shipments sequentially starting with 1
- No. frozen shippers: No. shippers containing frozen urine and serum specimens
- No. refrigerated shippers: No. shippers containing whole blood specimens
- Type of Specimens - blood, serum, or urine
- No. of Specimens - number of each type of specimen shipped
- Name, Title, Signature, and Phone Number of person sending shipment
- Date Shipped
- Specimen ID for each participant - e.g. 84-0021-0001
- Date Collected - e.g. 12-15-84
- For each participant, check ( ) each individual specimen type/aliquot included in this shipment

Comments -Specify any deviations from collection, storage, and shipment protocols, and date of occurrence.If the number of specimens in a shipment is too large to fit on one page of the Shipping list, please use the continuation sheets provided. See Appendix 1 for an example of a completed Specimen Shipping Lists. Xerox 2 extra copies. As will be described again later, the original will be shipped with the specimens, a copy mailed to CDC in a separate envelope, and a copy for your records.

3. Instructions for packing and shipping frozen serum and urine specimens to CDC

Supplies needed per shipper:

- 1 styrofoam shipper (each shipper will hold frozen specimens from approximately 20-24 participants)
- 10-12 lbs. dry ice
- 24 bubble-pack bags 4" x 5"
- Safety glasses or eye shield

- Strapping tape
- Gloves for handling dry ice and frozen specimens
- Sheets of bubble-pack packing material
- Preaddressed, franked CDC mailing label
- 'Express Mail' label, preaddressed by Centers for Disease Control personnel
- DRY ICE label
- HUMAN BLOOD label containing after hours delivery instructions
- CDC 'Specimen Shipping List' filled out (used for whole blood inventory also)
- Zip-lock bag
- Frozen serum specimens in 5-ml Wheaton vials labelled "PCB - CDC", "Chlor HC - CDC", and "Archive - CDC"
- Frozen urine specimens in 15-ml plastic centrifuge tubes labeled "Urine As - CDC", and "Urine Hg - CDC"

Packing specimens:

a. General safety precautions:
When packing the shippers, use gloves to handle the dry ice to avoid burning the hands. Glasses or an eye shield should also be worn if the dry ice cakes are to be broken into small pieces.

b. Fill each bubble-pack bag only with frozen specimens from one participant. Each bag should contain 2 frozen urine specimens (labeled urine AS-CDC and urine HG-CDC) and 3 frozen serum specimens (labeled PCB-CDC, CHLOR-HC-CDC, and Archive-CDC, all from the same participant. Seal each bag using the peel-off adhesive strip and return the bag to the freezer until all specimens are packed.

c. 20-24 filled bubble bags may be packed vertically in two rows in the bottom of the shipper:



d. Put 2-3 layers of sheet bubble-pack material on top of the specimens.

e. Fill the shipper with dry ice (probably will hold 10-12 lbs) and place the polyfoam lid on top of the shipper.

f. Secure the completed 'Specimen Shipping List' in a zip-lock bag and attach to the top of the polyfoam lid with filament tape. Only one 'Specimen Shipping List' is required/shipment even though several different shippers of the two types (dry ice and refrigerated) may be mailed at one time. However, mail a xerox copy of the 'Specimen Shipping List' in a separate envelope to the same CDC address. This is to insure against loss and considerable time lags in detecting missing shippers.

g. Secure the outer carton lid on the shipper with filiament tape.

h. Cover or remove previous address labels on all shippers. 'Express Mail' best accomplishes the required timely delivery of specimen shippers. Contact the postal service to determine the nearest branch offering 'Express Mail' and if service is available to Atlanta, Georgia. The local postmaster may require a letter outlining your schedule of shipments and destination along with the address and telephone number of the person responsible for receiving the specimens at CDC in case any questions arise regarding the shipment. The local post office will provide the appropriate 'Express Mail' labels for your use.

i. Label each shipper with the following:

(1) Preaddressed, franked CDC mailing label with the following address:

Dr. Jane Neese
Center for Environmental Health
Building 17, Rm 1115
Centers for Disease Control
Atlanta, GA 30333

(2) 'Express Mail' label with the same CDC address as above typed in.

(3) DRY ICE label with the weight of dry ice added.

(4) HUMAN BLOOD label containing after hours delivery instructions.

j. Deliver to the postal drop and check to be sure specimens will be received at CDC in 24 hours.

k. Telephone the laboratory at CDC the day the shipment is mailed (404) 452-4002. Speak with Brenda Lewis, Margie Sailors or Jim Gill.

4. Instructions for Packing and Shipping Refrigerated Blood Specimens to CDC

Supplies needed per shipper:

- 1 styrofoam shipper
- 2 foam racks each capable of holding 25-5 ml vacutainers
- 4-24 oz. cold packs (frozen before shipment)
- 6 layers of bubble-pack
- Strapping tape
- Gloves for handling frozen cold packs
- Preaddressed, franked CDC mailing label
- 'Express Mail' label, preaddressed by Centers for Disease Control personnel

- HUMAN BLOOD - THIS SIDE UP label containing after hours delivery instructions
- KEEP REFRIGERATED - DO NOT FREEZE label
- Zip-lock bag
- Refrigerated blood specimens in 3-ml lavender top vacutainers labeled "Blood Lead - CDC"

NOTE: Inventory of blood specimens should be included in 'specimen shipping list' enclosed with frozen specimens.

Packing specimens:

a. Place cold paks in a -20°C freezer the day before the shipment. Four 24 ounce paks will be needed for each shipper used. More cold packs may be needed if freezer does not attain -20°C. Up to 30 specimens can be shipped per shipper.

b. Working quickly, so that the blood will not be exposed to ambient temperature for more than 5 to 10 minutes, wrap each foam rack containing up to 30 tubes for blood lead analysis by CDC with bubble-pack material; secure with tape.

c. Place two ice paks in the bottom of the shipper. Cover with bubble paper before adding one or two wrapped foam racks; cover the racks with bubble paper before adding two additional ice paks. Fill the shipper with styrofoam packing pieces and place the polyfoam lid on top of the shipper.

d. Secure the outer carton lid on the shipper with filiament tape.

e. Cover or remove previous address labels on all shippers. 'Express Mail' best accomplishes the required timely delivery of specimen shippers. Contact the postal service to determine the nearest branch offering 'Express Mail' and if service is available to Atlanta, Georgia. The local postmaster may require a letter outlining your schedule of shipments and destination along with the address and telephone number of the person responsible for receiving the specimens at CDC in case any questions arise regarding the shipment. The local post office will provide the appropriate 'Express Mail' labels for your use.

f. Label each shipper with the following:

(1) Preaddressed, franked CDC mailing label with the following address:

Dr. Jane Neese
Center for Environmental Health
Building 17, Room 1115
Centers for Disease Control
Atlanta, GA 30333

(2) 'Express Mail' label with the same CDC address as above typed in.

(3) Place 'HUMAN BLOOD - THIS SIDE UP' and 'KEEP REFRIGERATED - DO NOT FREEZE' stickers on the shipper, so that the blood tubes will be kept upright and the shipper will be kept refrigerated if delayed in transit or delivered to CDC after hours.

g. Deliver to the postal drop and check to be sure specimens will be received at CDC in 24 hours.

h. Telephone the laboratory at CDC the day the shipment is mailed (404) 452-4002. Speak with Brenda Lewis, Margie Sallors or Jim Gill.

5. Distribution of Specimens to Locations Other than CDC

Follow directions provided by the Project Director for the transfer of appropriate specimens to laboratories other than CDC. CDC gummed labels are also provided for these specimens to maintain consistency. During Phase I, Specimens will be shipped to other laboratories as follows:

Specimens for PCB Analysis to MDPH Laboratory, Jamica Plains, MA.

Appendix 1

Example of Completed Specimen Shipping List

SPECIMEN INFORMATION SYSTEM
FORM 1 - NEW BEDFORD STUDY
SPECIMEN SHIPPING LIST

Case Number : 84-0021
Shipment Number : 1
No. Frozen Shippers : 1
No. Refrig. Shippers : 1

Shipped By: JANE McKEEL, MTA. I
Name Title
Jane McKeel
Signature
11-26-84 123 456
Date Shipped Phone

Type* of Specimens:	No. Specimens:
SERUM	61
URINE	37
BLOOD	21

Received By: MARK SMITH of NMEC
Name CDC Un
Mark Smith 11-
Signature Date

Specimen ID 84-0021 - Person	Type*/Aliquot No. (Mark Shipped Specimen) T1	T2	S2	S4	S5	B1	Date Collected MM-DD-YY	Comments (Specify any from collection, stora shipment protocols, ar of occurrence)
84-0021-XXXX	X	X	X	X	X	X	XX-XX-XX	
84-0021 0001	✓	✓	✓	✓	✓	✓	11-19-84	
84-0021 0002	✓		✓			✓		SHORT URINE AND B
84-0021 0003	✓	✓	✓	✓	✓	✓		
84-0021 0004	✓	✓	✓	✓	✓	✓		BLOOD VOLUME < 3 ml
84-0021 0005	✓	✓	✓	✓	✓	✓		
84-0021 0006	✓	✓	✓	✓	✓	✓	↓	
84-0021 0007	✓	✓	✓	✓	✓	✓	11-19-84	SERUM QUANTITY LO
84-0021 0008	✓	✓	✓	✓	✓		11-20-84	
84-0021 0009			✓	✓	✓	✓	↓	NO URINE SAMPLES
84-0021 0010	✓	✓	✓	✓		✓	11-20-84	

*Type of specimen: T = Urine (preserved), S = Serum, B = Whole Blood

Appendix 1 - Continued

Example of Completed Specimen Shipping List

SPECIMEN INFORMATION SYSTEM
FORM 1 - NEW BEDFORD STUDY
SPECIMEN SHIPPING LIST - Continued

Case Number : 84-0021
Shipment Number : 1

Initials of Shipper JM
Initials of Receiver MA

Specimen ID 84-0021 - Person	Type*/Aliquot No. (Mark Shipped Specimen) T1	T2	S2	S4	S5	B1	Date Collected MM-DD-YY	Comments (Specify any deviat from collection, storage, an shipment protocols, and date of occurrence)
84-0021-XXXX	X	X	X	X	X	X	XX-XX-XX	
84-0021 0001	✓	—	✓	✓	✓	✓	11-19-84	
84-0021 0013	✓	✓	✓	✓	✓	✓		
84-0021 0014	✓	✓	✓	✓	✓	✓	"	
84-0021 0015	✓	✓	✓	✓	✓	✓	11-20-84	
84-0021 0016	✓	—	✓	✓	✓	✓	11-21-84	
84-0021 0017	✓	✓	✓	✓	✓	✓	"	
84-0021 0018	✓	✓	✓	—	—	✓	"	SHORT SERUM SAMPLE
84-0021 0019	✓	✓	✓	✓	✓	✓	"	
84-0021 0020	—	—	✓	✓	✓	✓	"	NO URINE SAMPLE
84-0021 0021	✓	✓	✓	✓	✓	✓	"	
84-0021 0023	✓	✓	✓	✓	✓	✓	"	
84-0021 0024	✓	✓	✓	✓	✓	✓	11-21-84	
84-0021								
84-0021								
84-0021								
84-0021								
84-0021								
84-0021								
84-0021								
84-0021								

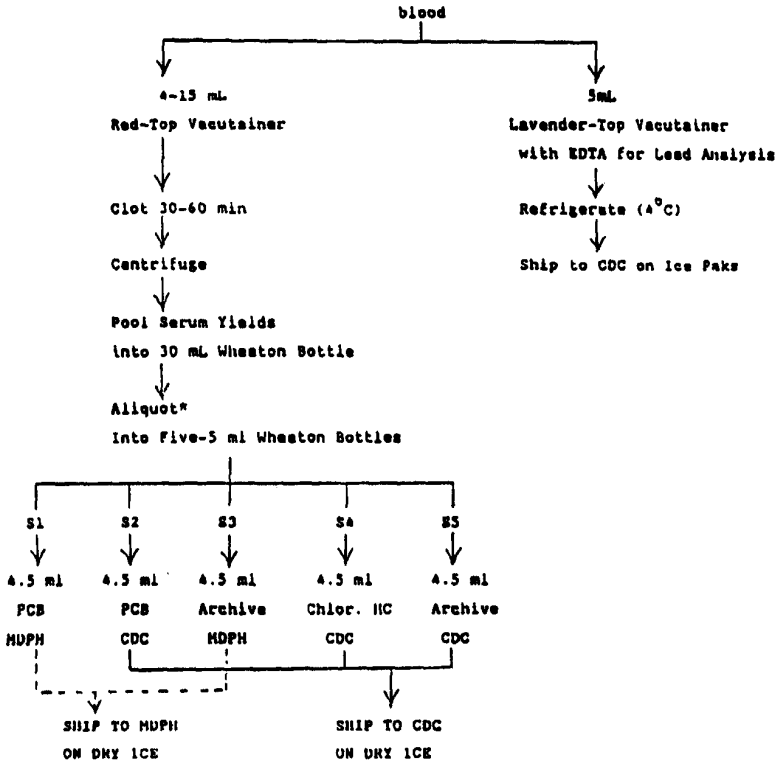
Type of specimen: T = Urine (preserved), S = Serum, B = Whole Blood

New Bedford, MA.

Case 84-0021

Phase - I

BLOOD AND SERUM COLLECTION



*Aliquot 4.3 - 4.5 ml/bottle using the following Priority:
(FIRST), S2 (SECOND), S3, S4, S5 (LAST)

New Bedford, MA.

Case 84-0021

Phase - I

URINE COLLECTION

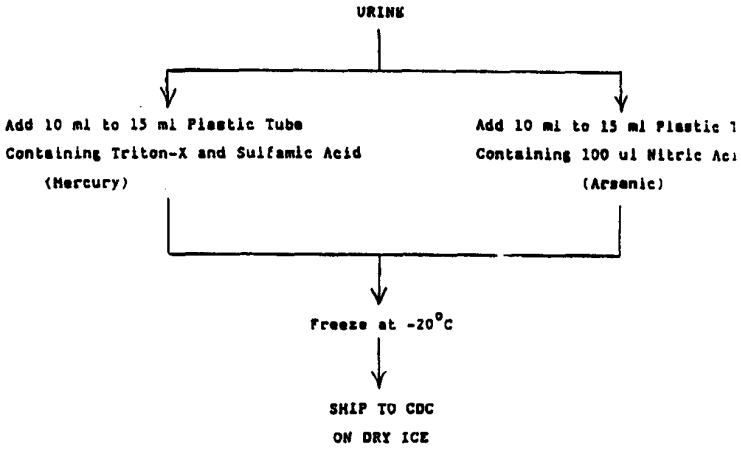
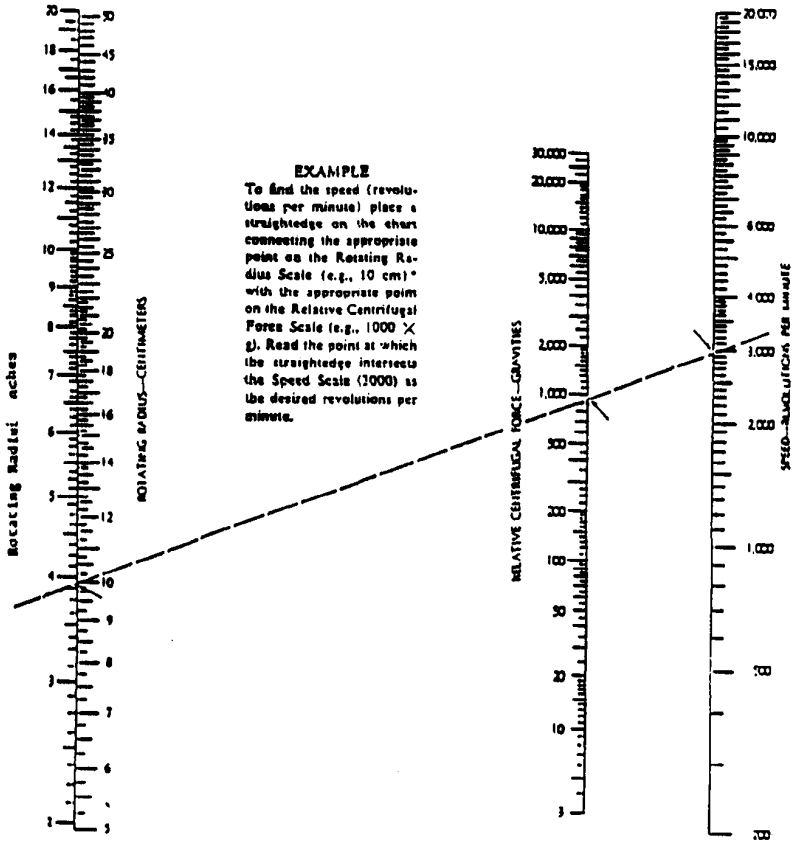


EXHIBIT 15-18

NOMOGRAPH FOR CALCULATING CENTRIFUGE SPEED



*To determine the rotating radius of the centrifuge head, measure—with the tube in the extended position—from the center of the drive shaft to the middle of the liquid column you are centrifuging.

APPENDIX W

SAMPLE SIZE POWER ESTIMATES

MONS 027925

APPENDIX W

SAMPLE SIZE POWER ESTIMATES

Boston University School of Public Health

School of Medicine — Epidemiology and Biostatistics Sec

80 East Concord Street
Boston, Massachusetts 02118

(617) 638-5172

July 16, 1986

Suzanne Condon
Greater New Bedford Health Effects Study
46-R Foster Hill Place
New Bedford, Massachusetts 02740

Dear Suzanne Condon:

I am writing in response to our conversations during the conference call on July 16, 1986 regarding the adequacy of a sample size of 840 persons for the PCB study in New Bedford. I have calculated the power for detecting a doubling of the proportion of persons with a PCB level greater than or equal to 30 ppb. Given the CDC estimate for unexposed populations of 1 percent, this would mean detecting a proportion of 2 percent or more. I base my calculations on the premise that the CDC estimate is constant or is estimated from an infinitely large population (i.e. one million persons). Using the normal approximation for a one-tailed test with an alpha level of 5%, I estimate the power to be 82% for a sample size of 840. Using the continuity correction suggested by Fleiss in Statistical Methods for Rates and Proportions, 2nd edition, pages 38-46, I estimate the power to be 78%.

These calculations indicate that the sample of size 840 closely matches your stated goals. If I can be of any further assistance, please give me a call.

Sincerely,

L. Adrienne Cupples

L. Adrienne Cupples, Ph.D.
Associate Professor of Public Health
(Epidemiology and Biostatistics)

...jk

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Contr

Memorandu

Date July 29, 1986

From Mathematical Statistician, Special Activities Branch, EHLS, CEH

Subject Sample size for Phase I of the Greater New Bedford PCB Health Effects Study

To Dayton Miller, Ph.D., Project Officer, Greater New Bedford PCB Health Effects Study

This memo is in regard to the question of the sample size to be completed in Phase I of the New Bedford PCB study. The objective stated in the sampling plan was to detect a doubling of the prevalence of elevated serum PCB's (defined as >30 ppb) above the expected prevalence of 1%, with 95% confidence and 80% power. The original sample size of 1400 was more than was needed to accomplish this objective and was since revised down to 850. Presently, 840 persons have been sampled according to Suzanne Condon. In order to increase that number to 850 would require that an additional sampling "batch" be used, which would entail considerable effort. The question of the adequacy of the 840 vs. 850 to accomplish the stated objective was discussed, as you know in the conference call of July 16, 1986. I have calculated the power to detect a doubling of the 1% prevalence with a sample size of 840 in two ways. Using the binomial distribution, I come up with a power of approximately 78%, while with the normal approximation the power is approximately 82%. Both of these calculations assume alpha=.05 and a 1-tailed test, as we discussed during the conference call. Adrienne Cupples (memo to Suzanne Condon of July 14, 1986) also came up with 82%, using the normal approximation. She also used a formula from Fleiss, Statistical Methods for Rates and Proportions, which employs a continuity correction and came up with 78% power.

There are a number of competing formulas for calculating power in this situation, and the relative merits of them can be debated. However, from the methods used by Dr. Cupples and myself it would seem that a sample size of 840 is sufficient to achieve a power of approximately 80% (give or take 2% depending on the formula) for the stated hypothesis.

Donald E. Phillips

Donald E. Phillips, Ph.D.

MONS 027927

APPENDIX X

COOPERATIVE AGREEMENT

APPENDIX X

1. DATE ISSUED: JUL [illegible], 1986
2. FEDERAL CATALOG NO.

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
Centers for Disease Control
Procurement and Grants Office
255 E. Paces Ferry Rd., N.E., Room 321
Atlanta, GA 30305

3. SUPERSEDES AWARD NOTICE dated 12/17/85
except that any additions or restrictions previously imposed remain in effect unless specifically rescinded.

NOTICE OF COOPERATIVE AGREEMENT AWARD

4. GRANT NO.: U61/CCU100711-02-3 Formerly:
5. ADMINISTRATIVE CODES: CCU61

6. PROJECT PERIOD: From 8/1/84 Through 3/31/89
7. BUDGET PERIOD: From 8/1/85 Through 3/31/87

AUTHORIZATION (Legislation/Regulation)
Section 104(d)(1) of P.L. 96-510 The Comprehensive Environmental Response, Compensation and Liability Act of 1980.

8. TITLE OF PROJECT (OR PROGRAM) (Limit to 55 spaces)
New Bedford PCB Health Survey

9. GRANTEE
a. Name: Massachusetts Health Research Institute, Inc.
b. Organizational Unit:
c. Street: 101 Tremont Street, Suite 600
d. City: e. State: f. Zip Code

10. DIRECTOR OF PROJECT (PROGRAM OR CENTER DIRECTOR, COORDINATOR OR PRINCIPAL INVESTIGATOR)
NAME: Condon (Last) Suzanne (First) (Initial)
ADDRESS: SAME AS #9

11. APPROVED BUDGET (Exclusive of PHS Direct Assistance)
I ☒ Grants Funds Only
II ☐ Total project costs including grant funds and all other financial participation

a. Personal Services	$ 183,157
b. Fringe Benefits	32,052
c. Consultants	
d. Travel	4,038
e. Equipment	2,600
f. Supplies	15,806
g. Contractual	
h. Patient Care	
i. Consumption (A&R)	
j. Tuition Costs	
k. Other	63,656
l. TOTAL DIRECT COSTS	$ 301,309
m. Indirect Costs (Rate 7.1% MTDC)	$ 21,979
n. TOTAL APPROVED BUDGET	$ 323,288
o. Federal Share	$ 323,288
p. Non-Federal Share*	$

*Must meet all matching or cost participation requirements. Subject to adjustment in accordance with PHS policy.

12. AWARD COMPUTATION FOR GRANT

a. Amount of PHS Financial Assistance (from 11.o)	$ 323,288
b. Less Unobligated Balance From Prior Budget Periods	$ 96,29[illegible]
c. Less Cumulative Prior Award(s) This Budget Period	$ 165,6[illegible]
d. AMOUNT OF THIS ACTION	$ 61,3[illegible]

13. RECOMMENDED FUTURE SUPPORT (SUBJECT TO THE AVAILABILITY OF FUNDS AND SATISFACTORY PROGRESS OF THE PROJECT)

BUDGET YEAR	TOTAL DIRECT COSTS	BUDGET YEAR	TOTAL DIRECT COSTS
a.		e.	
b.		f.	
c.		g.	
d.		h.	

14. APPROVED DIRECT ASSISTANCE BUDGET (IN LIEU OF CASH)

a. Personal Services	$
b. Travel	
c. Vaccine	
d. Other	
e. TOTAL DIRECT ASSISTANCE	$

15. PROGRAM INCOME SUBJECT TO 45 CFR 74.45 SHALL BE:
a. ☐ Used to further the objectives of the legislation under which the grant was made.
b. ☐ Deducted from total project costs for the purpose of determining the net costs on which the Federal share of costs shall be based.
c. ☐ Other - See Special Conditions
d. ☒

16. THIS GRANT IS SUBJECT TO THE TERMS AND CONDITIONS INCORPORATED EITHER DIRECTLY OR BY REFERENCE IN THE FOLLOWING:
a. The grant program legislation cited above.
b. The grant program regulation cited above.
c. This award notice including terms and conditions, if any, noted below under Remarks.
d. PHS Grants Administration Manual Chapters in effect as of the beginning date of the budget period.
e. PHS Grants Policy Statement in effect as of the beginning date of budget period.
f. 45 CFR Part 74.

In the event there are conflicting or otherwise inconsistent policies applicable to the grant, the above order of precedence shall prevail. Acceptance of the grant terms and conditions is acknowledged by the grantee when funds are drawn or otherwise obtained from the grant payment system.

REMARKS (Other Terms & Conditions Attached - ☒ Yes ☐ No) SPONSOR: Agency for Toxic Substance and Disease [illegible]
SEE ATTACHED

AGENCY OFFICIAL (Signature, Name and Title)
Leo [illegible] Sanders, Grants Management Officer

17 DOCUMENTATION CLASS: 41.51 18 CFDA: 13.161 19 ORGANIZATION DESCRIPTION

	ACCOUNTING CLASSIFICATION	FY	CLASS	AMOUNT
20 a.	[illegible]	CCU100711	[illegible]	[illegible]
21 a.	b.	c.	d.	e.

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NOTICE OF COOPERATIVE AGREEMENT

(Continuation Sheet)

PAGE	DATE ISSUED (Mo
2 of 6	JUL 31 198
GRANT NO.	
U61/CCU100711-02-3	

ITEM NO.

Award is revised to extend budget and project periods to 3/31/87. Additionally, supplemental funds in the amount of $61,386 are authorized regarding application dated May 8, 1986. The unobligated balance of funds in the amount of $9,947 from the 01 year is also authorized for use in the 02 year.

Revised work activites regerding the peer review of study results is hereby made a part of this award.

All other terms and conditions of prior awards remain in effect.

MONS 027930

Cooperative Agreement with
Massachusetts Health Research Institute, Inc.

I. Purpose and Cooperative Activities

A. Purpose

The purpose of this Cooperative Agreement is to assist in the design and conduct a health affects study of persons who reside in the Greater New Bedford, Massachusetts Community who are at risk to exposure to poly- chlorinated biphenyls (PCB's) from environmental contamination, contaminated aquatic local food supply, and occupational contact. The Study will be conducted in two phases, with Phase 1 consisting of a random sampling of approximately 1,400 residents of Greater New Bedford to determine the extent of PCB contamination in the population, route(s) of exposure, confounding exposure to chlorinated hydrocarbons and heavy metals, and blood pressure and will include limited collection of certain demographic information. Phase 2 will be a case controlled study of 150 persons with elevated blood PCB levels greater than 30 ppb and a matched control group of 150 persons with background levels of PCB's less than 10 ppb. Phase 2 will include biochemical measurements to address several known and suspect PCB health effects including liver enzyme induction, alteration of lipid metabolism, depressed immune function and neurotoxicity.

B. Massachusetts Health Research Institute, Inc. (MHRI)

The MHRI will:

1. Design and develop all aspects of the investigation.

2. Jointly with CDC, design and ensure the conduct of medical and laboratory examinations with adequate quality control including:

Phase 1 - (1,400 subjects)
blood PCB levels
blood pressure measurements
seven antigen skin test (immune function)

Phase 2 - (300 subjects)
blood PCB levels
complete blood count (CBC)
blood pressure
lymphocyte subset analysis (immune function)
seven antigen skin test (immune function)
neurologic and neurobehavioral evaluation

3. Participate in a CDC initiated quality assurance program for the measurement of PCB.

4. Develop and administer questionnaires, interviews, and followup examinations (e.g. for skin test) to uniformly collect and evaluate information from individual subjects with respect to demographic variables, limited dietary history, and possible occupational exposure.

5. Set up and maintain appropriate and secure recordkeeping and data processing system to maintain a central file of study subjects and their medical, laboratory and demographic information.

6. Develop with CDC, assurances and mechanisms for the timely and complete sharing and analysis of demographic, medical, epidemiologic, laboratory and quality control information.

7. Provide the necessary examining facilities and administrative support including secretarial staff, office space, equipment and supplies, medical materials, and specialized clinical equipment.

8. Results from investigations will not be released to the public until reviewed and approved by CDC.

9. Maintain confidentiality of all personal information and medical exam/laboratory tests results.

10. MHRI, with assistance from CDC, will conduct a peer review of the final draft report of the study. The peer review should be conducted by a scientific committee with appropriate representation to objectively evaluate the study findings. The peer review group should have three to seven disinterested scientific experts selected on the basis of their reputation f : scientific objectivity. Members of the committee must be outside individuals not employed by the grantee, CDC, or Agency Toxic Substance and Disease Registry (ATSDR) and must not have institutional ties with any person involved in the conduct of the study or research under review. The committee should be appointed by the grantee, with collaboration with CDC. As a part of the final report to be submitted to CDC, the peer review process should be documented, including peer reviewers' comments and the disposition of any issues raised.

C. CDC Activities

CDC will:

1. Provide reference laboratory and quality assurance services to the MHRI for the analysis of total PCB's to include:

   Assistance in the design and establishment of an internal bench quality control program, selection of appropriate equipment and definition and validation of methods for PCB analysis.

- Preparation and characterization of quality assurance material for both laboratories.
- Preparation and maintenance of stock PCB standard solutions for calibration for use in both laboratories and standard lots of certain chromatographic reagents.
- Additional training, if needed, for selected individuals from MDPH in the analysis of PCB's.
- Analysis of 10% of specimens collected in Phase 1 for total PCB's for confirmation of MDPH quality control.

2. Provide specific PCB isomer analysis on specimens from a subset (no more than 25 samples) of Phase 1 subjects with elevated PCB's.

3. Provide screening analysis for commonly occuring chlorinated hydrocarbons in approximately 5% of Phase 1 participants.

4. Perform heavy metal analysis on specimens from approximately 10% of Phase 1 subjects including blood lead, urinary arsenic and urinary mercury.

5. Provide clinical laboratory analysis on all subjects enrolled in Phase 2 including:

BUN	cholesterol
creatinine	triglyceride
t. bilirubin	high density lipoprotein cholesterol
LDH	urinary porphyrins
SGOT	urinary D - glucaric acid
SGPT	blood lead
gamma glutamyl transpeptidase	urinary arsenic
albumin	urinary mercury
total protein	alkaline phosphotase
urinary protein	

6. Participate in the development of research protocols and plans for all investigations.

7. Participate in defining the methods for identification of risk groups and comparable control groups for all investigations.

8. Provide administrative, scientific and statistical expertise and consultation in the management and technical performance of all investigations.

9. Participate in public awareness activities designed to encourage maximum participation by selected members of the New Bedford Community.

10. Participate in analyzing data submitted and determining results including preparation and publication of permanent reports.

11. Maintain liaison with and provide EPA with appropriate reports.

12. Collaborate with MHRI in organizing and conducting a peer review of the results of the study prior to publication and submission of the final report.

II. Scheduling and Reporting

A. Quarterly progress/status reports will be required and will be due 30 days after the initial due date i.e., the first quarterly report will be due December 1, 1984. As a minimum, quarterly progress reports will include progress information describing the current stage of the project schedule/plan and any problems that will affect the conduct of the investigation.

B. All statements concerning the conduct and the results of the project, including press releases, statements to the public, and statements to governmental agencies or private organizations, will emanate from a MHRI designated spokesperson, after review and consultation among officials of MHRI, CDC, and the national headquarter's office of EPA. MHRI will serve as the ultimate repository of all information originating from the project, but access to the information for purposes of analysis is to be provided to CDC. Reports and manuscripts drafted for publication in scientific journals describing the findings of this cooperative effort may be written by the principal investigators or by other professional staff involved in the study. All drafts will be reviewed by both MHRI and CDC prior to submission for publication.

C. The following is a schedule for submission of quarterly reports:

Quarter ending:	Report due CDC:
July 31, 1986	August 30, 1986
October 30, 1986	November 30, 1986
December 31, 1986	January 30, 1986
March 31, 1986	April 30, 1986

APPENDIX Y

SUMMARY OF PROPOSAL

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APPENDIX Y

Massachusetts Department of Public Health
Greater New Bedford PCB Health Study

SUMMARY

The study about to be undertaken cooperatively between the U.S. Centers for Disease Control and the Massachusetts Department of Public Health will study the health effects of persons that reside in the Greater New Bedford, Massachusetts community who are at risk of exposure to poly-chlorinated biphenyls (PCBs) from environmental contamination, contaminated aquatic local food supply, and occupational contact.

The study will be conducted in two phases. Phase I will involve recruitment of residents of the community. These 1400 people will be randomly selected from census lists throughout the Greater New Bedford area and blood samples will be taken. The Phase I study will also collect data to determine the extent of PCB contamination in the population, route(s) of exposure, confounding exposure to chlorinated hydrocarbons and heavy metals, and blood pressure and will include limited collection of certain demographic information.

Phase II of this study will be a case-controlled study comprising two groups of approximately 150. The majority of these people will come from the results of the Phase I study. One set of these 150 individuals will have PCB blood levels above 30 ppb which we will refer to as the exposed group. The second group of 150 people will consist of 150 people with PCB blood levels lower than 10 ppb. These two groups will be matched for age, sex and ethnicity.

Tha Phase II study will be much more involved and will test several specific hypotheses concerning PCB health effects including biochemical measurements which will address several known and suspect PCB health effects. These will include tests of liver enzyme induction, alteration of lipid metabolism, depressed immune function and neurotoxicity.

It is anticipated that this program will continue for up to three years. The first year will include recruitment and training of staff, a pre-test period to verify forms, procedures and laboratory quality control, followed by Phase I examination, questionnaires, laboratory analyses and data entry. The latter part of the first year will include preliminary statistical analysis of Phase I data and detailed planning and preparation for Phase 2. Phase 2 pretesting and initial examinations are projected to begin at thirteen to fourteen months into the study (possibly later if a sufficient number of individuals with elevated PCB levels are not identified during Phase I and must be recruited from individuals at higher risk). Detailed statistical analysis and final report writing will commence at approximately twenty-one months into the study and are anticipated to continue through the third year.

APPENDIX Z

PHASE I SAMPLING PLAN

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APPENDIX I

PHASE I SAMPLING PLAN:

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

The purpose of the Greater New Bedford PCB Health Effects Study, Phase I, is to determine the prevalence of serum levels of polychlorinated biphenyls (PCB's) in the local population and investigate the possible association of PCB serum levels with residential and occupational histories, dietary habits, health status, demographic characteristics, and blood pressure readings in sampled residents. The population under investigation consists of residents of the towns of Acushnet, Dartmouth, Fairhaven, and the City of New Bedford between the ages of 18 and 64. Only civilian, non-institutionalized adults in this age span, who have lived continuously or intermittently within the boundaries of the four towns for a minimum of five years since January 1, 1940, will be considered eligible as survey respondents.

Sample Size: A sample of the survey population will be drawn by process of random selection from updated town and city street listings of current voters and residents 17 years of age and older as of 1984. The total population count for the four municipalities in the Greater New Bedford area was approximately 140,000 inhabitants at the time of the 1980 federal census. The target of a completed sample size of 1400, roughly 1% of the total population and 2% of the 18-64 population, was established based on statistical considerations from previous

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studies. The Centers for Disease Control estimates that 1% of a population 'unexposed' to PCB contamination would be expected to have PCB levels of 30 ppb or greater. The completed sample size of 1400 is calculated as sufficient to detect an increase of 1% or more (i.e., a doubling) above the 1% estimate of background PCB levels in the Greater New Bedford population at a 5% significance level associated with 80% power to detect a true difference (one-tailed test).

Sampling Strategy: The determination of the sampling strategy to be employed was based on both practical and theoretical concerns. A review of available source lists (i.e., documents listing households, addresses, residents, etc.) from which a sample could be drawn was undertaken to evaluate the applicability and completeness of lists and the relevance of each to the study purpose. The utility of various source lists was then balanced against the theoretical issues of sampling strategy alternatives such as stratification and clustering to determine the maximally effective approach to adopt. The most appropriate and complete lists are annual individual town/city listings of residents 17 years of age and older. Since these source lists are in the form of Commonwealth-required 1985 censuses, and thus the study does not have to create its own lists of residents, the necessity to cluster the sample is eliminated. A two-level proportional stratification, by city/town and then by sex within communities, is proposed for the PCB Health Effects Study, Phase I.

Increased precision in study results are often observed when stratification in population sampling is employed due to the partiali-

sation of study response variation. The total variation of any study variable in a stratified random sample of participants may be conceived of as composed of two elements: variation between strata and variation within each stratum. In stratified random sampling, the variation between strata does not become an integral part of standard error calculation, i.e., the measurement of the precision of study results. By stratifying one ensures that the component of overall study variation in the population due to variation in the variable used to stratify is exactly reflected in the sample. Sampling, and therefore equal probability of selection given random sampling, only takes place within strata. Consequently, since only the variation within each stratum enters into calculation of the standard error, the greater the part of the total variation in a study population that is accounted for by the between strata variation, the greater will be the gain in precision due to stratification. Thus the principal objective of stratified sampling is to select a variable(s) for stratification so that the strata differ as widely as possible from each other yet are as homogeneous as can be within each stratum.

In the PCB Health Effects Study Phase I, two variables have been chosen for stratifying the sample selection: city/town of residence and sex of the respondents. City/town boundaries, while a practical variable for stratifying, were not thought to increase precision enough to comprise the only stratifying variable. Census tract of residence, a smaller geographical unit, was eliminated from contention as a variable by which to stratify because of the small numbers of respondents that would be selected from each tract. In examining the source

lists to be used for sampling, additional variables were found that would function as a second layer of stratification: age and sex. Given that response rates in population surveys do frequently vary by age, the use of age for stratification would most likely require the weighting of the contribution of each stratum to the total survey response in tabulations. On the other hand, the variable sex is available, it has been shown to have an association with our dependent variable of PCB serum level, and employing sex of the respondent as the second level of stratification may eliminate any need to weigh responses because of different response rates among the strata.

Choice of place of residence as the first level of stratification was dictated first by the availability of annual census reports for each city and town in the Greater New Bedford area as documents seperately compiled and presented in varying formats. Secondly, a review of the size of the residential population within each locality as enumerated in the 1980 U.S. Census showed substantial differences in the contribution of each city/town to the total study population. The total population of the four city/towns comprising the Greater New Bedford, MA area as defined in this study was 146,907. The reported town and city populations and percentage contributions for persons of all ages were: Acushnet 8,704 (5.9%); Dartmouth 23,966 (16.3%); Fairhaven 15,759 (10.7%); and New Bedford 98,478 (67.0%). By subtracting out persons reported in the 1980 census as 17 or less years of age and persons 65 years of age or greater, the remaining persons 18 through 64 represent the proportion of people in the Greater New Bedford area who in 1980 would have been considered potential survey

respondents. Due to differing age structures in each city/town population, the potential percentage contributions of the area towns and the city of New Bedford to the sample of persons 18-64 change slightly: Acushnet 6.2%; Dartmouth 17.3%; Fairhaven 10.9%; and New Bedford 65.6%. These revised percentages were then utilized in determining study estimates of the number of valid respondents from each of the four city/towns needed to reach the goal of a completed sample of 1400 persons. Thus, in addition to the fact that the census source lists enumerating the area population are available only for each city/town separately, the unbalanced contribution of each city/-town to the total survey population (range of 6.2% from Acushnet to nearly two-thirds from New Bedford) indicates that stratification by city/town residence is both practical and theoretically advisable. Each town or city will be a stratum with the number of randomly selected eligible study participants being proportionately selected according to the size of each town and city contribution to the final study sample size. Proportional sampling within the city/town strata is chosen because a hypothesis to the effect that the dependent variable (serum PCB levels) will vary according to town of residence is not being tested. Secondly, to do disproportional sampling and to test such a hypothesis, it would be necessary to sample many more residents aged 18-64 in each of the four localities than the proportional approach calls for, given sample size calculations. However, with the proportional sampling, some reduction in overall sample variation should be achieved; tabulations from the survey results will include comparisons of PCB levels among the sampled residents of the four

communities.

After statistical consultation, additional consideration was given as to what other steps might be taken to gain still greater accuracy and precision in study response results. A second layer of stratification was proposed, and variables available in the source lists were identified, such as age and sex. Then a review of previous studies was undertaken to determine if any of the available variables had shown an association with PCB levels. For designation as a stratifying variable, sex was preferable to age because of the different response rates appearing in many surveys among age groups. Reported(1) findings of a 1979 community-wide study in Triana, Alabama sponsored by the Chronic Disease Division, Bureau of Epidemiology and the Clinical Chemistry Division, Bureau of Laboratories, Centers for Disease Control that was designed to evaluate area population health effects from exposure to DDT environmental residues indicated that PCB contamination was also present. Subsequent analysis revealed age and sex differences in association with log PCB blood levels in the respondents: e.g., male subjects had a higher geometric mean PCB level than female subjects (23.8 vs 13.7 ug/l; p>0.0001). Results of a Greater New Bedford area volunteer non-randomized pilot study conducted in November of 1981 by the Massachusetts Department of Public Health in conjunction with the New Bedford Health Department gives further support to the idea that blood PCB accumulations may differ in occupationally exposed persons by sex: analyzed median PCB blood levels for males (17 ppb)

1KREISS, K., MD; Zack, M., MD; Kimbrough, R., MD; Needham, L., Ph.D.; Smrek, A.; Jones, B.: Association of Blood Pressure and Polychlorinated Biphenyl Levels. JAMA, June 26, 1981 - Vol. 245, No. 24.

were almost twice that observed in females (9 ppb) in this small sample of 51 volunteers. The latter observed differences by sex in median PCB levels should be interpreted with caution since there were more than three times more male volunteers (N=39) than female volunteers (N=12). To increase the likelihood of decreasing the response variation that will be observed in the PCB Health Effects Study and thus increasing the precision of the measurements, it was decided to employ a two-level stratification strategy: within the city/town geographic strata, the proportion of male and female respondents randomly selected are to equal the reported percentage of male and female adults between 18 and 64 years of age observed in the 1985 state census.

For sampling purposes the number of random numbers generated for selecting sample respondents has been adjusted to account for proportional representation of each city/town population. As the enrollment of sampled participants proceeds, monitoring of the sexual composition of respondents and non-respondents will be ongoing to assure proportional representation of males and females until estimated sample size study goals are reached within each sex and municipal stratum. Should the estimated proportional sexual stratum completed sample size be reached for one sex first within a city/town stratum as respondents corresponding to the random numbers are identified, only those new respondents whose sexual gender is to date under-represented in respect to final sample requirements will be contacted for inclusion. The estimated sample sizes by proportional municipal and sex strata are in Table 1.

Sampling Frame: The sampling frame to be used in drawing a random sample from a population should be that source list that is most complete, current, accurate, and has one record per unit of observation. City directories, consisting of a listing of dwellings and household units, compiled by independent organizations such as Polk, are perhaps the most commonly used source lists for survey sampling in urbanized areas. However, in Massachusetts under state law, each city and town is supposed to conduct an annual census of its population. The cities and towns then frequently publish the results of the census with regard to the persons tallied (usually only persons 17 years of age and older), labelling it a street or voter listing (the latter being a misnomer, since all adults, regardless of voting stuatus, are identified). As source lists for the PCB Health Effects Study, these censuses are considered preferable to city directories because of their quasi-legal nature, currency, expected accuracy, and inclusion of person-specific data.

The structural arrangement of the 1984 town lists of persons residing in Acushnet, Dartmouth, and Fairhaven are very similar in the manner in which population information is presented. The listings are ordered first by administrative precinct, and then within each precinct streets are listed in alphabetical order and specific addresses appear in ascending order, up either one side or both sides of a street in consecutive or odd-even numbering, depending upon where precinct boundaries are drawn. The listing of addresses within a precinct usually yields a partially printed page before the next precinct begins on a new page. In all three town listings, two completed columns of

addresses are printed on each page. The New Bedford listing differs from the three smaller town listings in two ways: the 57 precincts ar grouped into six wards, and thus the first level of organization is th ward; secondly, there is only one column of data per page. The characteristics of each of the town census listings that had to be taken into account in requesting computer-generated random numbers fo identifying sampled respondents are summarized in Table 1.

Prior to using the city/town census documents as a source list f identifying randomly selected respondents, the Acushnet, Dartmouth, Fairhaven, and New Bedford 1984 lists were up-dated by project staff in regard to address changes and additions as occuring from new residential building permits issued by each town between January 1, 1984 and January 1, 1985. This information was sought and compiled from various town or city offices such as town clerk, registrar of voters, assessor, building department, planning department, and water department. From whatever source(s) available updates of all changes in residential buildings based on permits for new, converted, or demolished buildings were obtainable, we then listed the modifi- cations by street location, unit type, and permit number. When available, new address assignments associated with new building perm were also accessed to update the 1984 listings. A complete populati census of the city of New Bedford had not actually been done since 1980; the available listing for New Bedford is based on 1980 addres with residential changes that occurred from the time of the 1980 Cen through January, 1984 based on sources such as voter registration, change of address notifications, and vital statistics. The determin

tion of building permits and concomitant address changes in New Bedford for 1980 through most of 1984 were graciously provided to us by the Pawtucket Heart Health Program in Rhode Island, which conducts periodic cross-sectional health surveys in New Bedford as a control measurement of the changes in the Pawtucket population resulting from their community cardiovascular disease prevention efforts. The total number of recorded residential housing changes for the three towns and city within the Greater New Bedford area are summarized in Table 3.

In researching the data gathering methodology of each of the four census listings with the responsible person in each municipality (town clerk or election registrar), difficulties with the New Bedford source list came to light. As mentioned above, a complete enumeration had not taken place since 1980; the basis of the available 1984 listing was the 1980 census with corrections and updates inserted as information was given to the Election Office. A completely non-random check of the directory for addresses at which we knew the status of the dwelling and the occupants yielded a major problem with the 1984 listing: apparently a substantial number of people were still listed in the directory who had left the city since the 1980 Census was taken, and new residents were not included unless they had registered to vote or the previous occupant was first identified as having vacated. Thus, not only was the majority of the New Bedford compilation out of synchronization with the other town listings with regard to the time period in which the data were gathered, but the city listing apparently incorporated a much larger number of errors than would normally be acceptable. However, it was learned that the Commonwealth of Massachu-

setts requires a state-wide mid-decade census of municipalities to be conducted in January of 1985. Updating with respect to accuracy and completeness the New Bedford street listing with the 1985 data was clearly desirable: to do the remaining one-third of the study population residing in the remaining three towns has also been undertaken in order to have comparability between the four towns. Not wanting to wait for the final printed versions of the 1985 census to be available (estimated May 1985), cooperation from each City Hall was sought with the intent of establishing a way for the Health Effects Study to get the 1985 census data before publication. Three of the four town registrars were extremely cooperative, and the decision was made to have project staff update the 1984 listings for Acushnet, Fairhaven, and New Bedford precinct by precinct as the census data were compiled at each City Hall. The end product of the updating work will be listings formatted as in 1984 with the most recently available 1985 data incorporated. Appendix A documents the procedures used for updating. After reviewing data on the first two completed New Bedford precincts and noting the large number of person deletions and person additions for given street addresses, it became apparent that one problem we encountered is that on some occasions page line adjustments would have to be done, i.e., in situations when the number of person additions on a given page and at a given street address exceed the number of deletions of persons on that same page. In order to retain a constant format with regard to number of lines per page, excess persons are placed in available empty lines on preceding pages of the precinct being updated. Statistical consultation gave assurance that this

procedure is legitimate since the randomization process by which survey respondents are identified is completely independent of the placement of specific addresses or persons within the directories. Thus, by updating the source lists to include 1985 Census data, we are not only using the most timely information available but also not changing the probability of a given person being a survey respondent in the sample to be drawn.

Any source list used in sampling should be evaluated by persons independent of the agency compiling the data in order to determine the accuracy and completeness of the list. Since we could find no other study that had conducted an evaluation, we are doing block verification. Survey consultants recommended that at least 100 residential addresses from each town and city under study should undergo on-site verification. Estimating that there are between two and ten dwellings or an average of five dwellings on urban block faces, it was calculated that 20 randomly selected census tract block faces from each stratum should be verified. Project staff listed the block numbers assigned by the U.S. Bureau of the Census, using 1980 census tract block maps for each of the four towns in the Greater New Bedford area; we renumbered the blocks consecutively to facilitate the block face random selection procedure. The number of census track blocks within each of the study strata are: Acushnet, 104 blocks; Dartmouth, 278 blocks; Fairhaven, 383 blocks; New Bedford, 1,474 blocks. Blocks were considered too large a unit for verification because potentially only five four-sided blocks could total 100 residences in each town. Thus it was decided to select one block side (face) per each of the randomly selected strata

blocks for verification of the 1985 census listings with regard to address, occupants, and inclusion of all residential buildings. Computer generated random numbers(2), consisting of 20 random numbers in the range of blocks specified for each municipal stratum and a second number ranging from one to four denoting block face, were used to select the 80 block/faces now being verified (Appendix B).

Eligible Respondent Selection: The sampling strategy to be followed in determining survey participants' selection is that of a three stage proportional probability sampling design (two stage in New Bedford) in which every eligible person 18-64 years of age within the designated strata of the Greater New Bedford area population has an equally random probability of being chosen for inclusion as a survey respondent. The first stage of the selection process for each town/city stratum will have as the primary sampling unit a random selection of pages out of each town or city listing; each selected page becomes the vehicle of the second stage of printed column designation (this step not necessary for New Bedford); the third probability is the random number indicating the selected line identifying possible individual respondents. No restrictions have been placed on the generation of these random numbers other than that the allowable ranges of page, column, and line numbers within each stratum list correspond to the structure of each city/town listing: thus every person listed on any given randomly selected page should have an equal probability of

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2SAS(Statistical Analysis System) random number generator, modified (using Syntax) by Mr. Bob Beattie of the Massachusetts Department of Public Health Division of Data Processing.

being selected for participation. Ascertainment of the second variable used in stratification, sex, will be confirmed at first contact with selected respondents, and thus the meeting of the proportionally-determined sample sizes for each town/sex stratum will be evaluated as the sampling progresses and Phase I nears conclusion.

Since the city/town census listings, unlike the more traditionally available Polk city directories, are compilations of individuals, we will be able to identify immediately the respondent that has been chosen by the random number. Thus our source lists enable us to sample persons instead of households within each stratum. By sampling persons instead of households it is unnecessary to follow the cumbersome procedures otherwise required that involve home visitation by survey personnel to list adults within sampled households and then randomly selecting one adult as the survey participant. Using lists of persons eliminates the necessity for correcting for overrepresentation of persons in small households in one-person per household sampling schemes. It is not desirable, given the objectives of the PCB Health Effects Survey, to deliberately sample households and collect data on all adults in the household because of the expected high correlation among household members in the areas of residential history and dietary patterns, two independent variables under investigation. The drawback to using lists of persons as the source documents, however, is that we cannot just take as selected respondents the member(s) of the household at the address at the time of the contact, as is frequently done in household-based sample surveys. No substitutions or replacements will be allowed: the only acceptable respondent will be the person listed

at the time of enumeration of the 1985 legal census (i.e., in the directory on the randomly chosen line). By our updating our source documents to conform to the 1985 data, we will be working with a source list that is only out-of-date by one to nine months. In the instances where the chosen listed resident is no longer at the census address, we will attempt to follow that respondent to his/her current address using established search procedures; if the respondent can be located in the Boston/Providence/Cape Cod area, we will conduct the interview and collect the clinical specimens.

The number of random numbers actually needed for each city/sex stratum in the PCB Health Effects Study are substantially higher than those shown in Table 1, which referred to the number of completed interviews and clinical measurements needed from the population of persons 18 to 64 years of age in order to achieve a proportional sample of 1400. Eligibility criteria (age between 18 and 64, five years or more residence in the Greater New Bedford area, and non-impairment) and anticipated non-response rates (refusals, no contacts, and drop-outs) must be accounted for in determining the number of random numbers. From the street listings (adults only), percentage estimates were calculated for each town/city of the number of households containing only adults 65 years of age or older, and thus ineligible as survey respondents. A marked variation among municipal strata in the percent of the population 65 or older and therefore ineligible due to age appeared: Acushnet 20.0%; Dartmouth 25.0%; Fairhaven 24.0%; and New Bedford 30.0% A second adjustment in the number of random numbers needed has been made for potential respondents who do not meet the

survey criterion of having lived in the Greater New Bedford area for at least five years between 1940 and 1984. A 20.0% ineligibility rate was estimated based on 1970 U.S. Bureau of the Census data on five-year (1965-1970) migration status: 23.7% of the U.S. population aged 25 and older resided in 1965 in a different geo-political unit than their reported location at the time of the federal Census. Since the five-year mobility question does not allow for life-time return migrants, an estimate of 20% is reasonable, and without other information, is used in the counts for each stratum. Finally, an expectation of less than 1% of selected respondents who are found to be too mentally or physically impaired (short-term acute care hospitalization does not equal ineligibility) to assume the role of a study participant was included in the calculations. The PCB Health Effects Study is aiming at a response rate, among eligible respondents, of 85%. However, in order to ensure the availability of a sufficient number of random numbers, we calculated in a response rate of 75% based on the Pawtucket Heart Health Program's experience of a 70% response rate in New Bedford. Based on the above calculations in number of random numbers needed for each city/town stratum, enough additional possible respondents were included to allow for a proportionally stratified piloting of up to 100 completed participants. Lastly, the numbers estimated to be needed were rounded up to allow for rejection of random numbers due to the appearance of duplicate numbers and for the designation of lines in the source lists that are blank (at the end of precincts or between the last address on one street and the beginning of a new street's addresses) and lines that are printed as street

names. The number of random numbers needed for the proportional sampling of males and females aged 18 to 64 years within each of the four municipalities to reach a completed sample size of 1400 appear in Table 4.

Respondent Contact: Based on random page, column, and line selection, possible study participants will be identified by name from the 1985 updated town or city census listings and a survey cover sheet initiated. Then a check will be made, from the census data, as to whether each meets study requirements in terms of being an adult between 18 and 64 years of age. For those that are age eligible, the local telephone directory will be cross-referenced to record a number for future telephone contact (a reverse telephone directory is available for determining if an unlisted telephone is due to differences in surname spelling). A personal letter (in English and Portuguese), signed by the Massachusetts Commissioner of Health and representatives of the four local Boards of Health, will be mailed to each chosen respondent, informing them of their being randomly selected to participate in the Greater New Bedford PCB Health Effects Study, the purpose of the study, rationale behind our investigation, and inherent methodology of study participation (Appendix C). Followup contact of the introductory study letter will be carried out (when telephone numbers are obtainable) to determine residence eligibility, solicit participation, answer questions, and set up an appointment time for those persons agreeing to become study respondents. For possible participants for whom we have a telephone number, up to five phone calls on

different days and at different times of the day (initial calls attempted between three and eight p.m.) will be placed over the two week period following the introductory study letter. When no phone contact has been made using this procedure, the situation will be reviewed by the Data Manager for other suggestions. If necessary, in order to contact a 'telephone available' person regarding participation in the study, three home visits by project staff are allowed. If, on the other hand, a potential respondent does not have a telephone or has an unlisted number (based on regular telephone directory, information, and reverse directory check), the field visit approach to the address found in the updated town or city listing will be followed in order to establish contact and follow through to scheduling with the appointment. In this circumstance, a minimum of five field visits to the home address of the identified person will be scheduled over the two week period following the introductory study letter. If no information as to how we can contact the potential respondent can be learned from other household members or neighbors, the Data Manager will review and an additional three field visit attempts to the home address of the selected person may occur. Field visits will also be scheduled at different times and different days of the week. All attempts at contact, via telephone or field visit, will be recorded on the cover sheet. Finally, individuals who agree to become study respondents will be sent confirmation letters from the PCB Health Effects Study office thanking them for their willingness to participate, confirmation of the date and time of office appointment, and iteration of the instructions for participation (fasting state, full bladder, and loose-sleeved

clothing).

For those randomly selected possible study participants who were found ineligible for entry into the study due to age or residence criteria, contact will end. Similarly, persons we cannot contact using the above procedures will be considered non-respondents for this reason after a review is made of all contacts attempted; the data file for non-respondents will consist of any demographic data obtainable from family members or neighbors. Refusals to participate and failures to keep scheduled appointments will cause recontact efforts by study staff to obtain a conversion or to reschedule following written communication. In the event of refusals that cannot be converted to participants, estimates of background information about that individual such as sex, age, race, ethnicity, and years of residence in the Greater New Bedford area will be recorded by the interviewers. Reason for refusing study entry will also be ascertained. From drop-outs, i.e., individuals initially agreeing to participate but then failing to keep scheduled appointments, reasons for non-appearance will be solicited. Thus cover sheets on all randomly selected residents will be initiated; ineligibility will be recorded for adults 65 and over or individuals living in the Greater New Bedford area less than five years. All attempts at contact and each outcome will be included. For initial refusals and failures to keep appointments, recontacts will be initiated and some basic demographic information estimated when attempts at conversion to a completed interview and clinical measurements are not successful.

RANDOMLY SELECTED STUDY STRATA CENSUS TRACT BLOCKS
AND BLOCK-FACES SELECTED FOR SITE VERIFICATION

ANDOVER			DARTMOUTH			FAIRHAVEN			NEW BEDFORD		
CENSUS TRACT NO.	CENSUS BLOCK NO.	FACE NO.	CENSUS TRACT NO.	CENSUS BLOCK NO.	FACE NO.	CENSUS TRACT NO.	CENSUS BLOCK NO.	FACE NO.	CENSUS TRACT NO.	CENSUS BLOCK NO.	FACE NO.
6541.0	110	3	6531.0	1h1	4	6551.0	231	2	6502.01	508	
6541.0	116	1	6531.0	221	3	6552.0	101	4	6505.0	302	1
6541.0	118	1	6531.0	403	3	6552.0	103	2	6505.0	401	1
6541.0	119	1	6531.0	609	3	6552.0	221	3	6509.0	416	2
6541.0	121	3	6531.0	808	2	6552.0	507	3	6510.02	210	4
6541.0	123	1	6531.0	928	3	6552.0	411	4	6510.02	325	3
6541.0	126	3	6532.0	228	3	6553.0	129	4	6510.02	405	1
6541.0	127	4	6532.0	331	1	6553.0	503	1	6511.0	205	1
6541.0	132	4	6532.0	331	1	6553.0	603	3	6511.0	305	1
6541.0	136	1	6532.0	332	1	6554.0	105	4	6512.0	201	2
6541.0	910	4	6532.0	425	2	6554.0	119	3	6513.0	210	2
6542.0	205	4	6532.0	427	3	6554.0	121	4	6513.0	302	4
6542.0	209	2	6532.0	509	3	6554.0	123	1	6513.0	214	1
6542.0	212	2	6532.0	521	4	6554.0	125	2	6516.0	203	1
6542.0	217	3	6532.0	613	4	6554.0	128	3	6516.0	208	1
6542.0	230	2	6532.0	925	3	6554.0	130	4	6522.0	106	4
6542.0	238	2	6533.0	303	2	6554.0	620	4	6526.0	111	4
6542.0	313	1	6533.0	601	2	6554.0	802	2	6526.0	211	4
6542.0	320	4	6533.0	607	4	6554.0	804	3	6528.0	219	1
6542.0	330	1	6533.0	942	4	6554.0	807	4	6528.0	422	1

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TABLE 1

ESTIMATED COMPLETED STUDY SAMPLE SIZE, BY CITY/TOWN AND SEX STRATA

SEX	AGENCOURT	OAKVILLE	CALEDONIA	NEW_REDFORD	TOTAL
MALES	43	117	75	430	665
FEMALES	44	125	78	488	735
TOTAL	87	242	153	918	1400

TABLE 2

STRUCTURAL CHARACTERISTICS OF THE 1984 TOWN AND CITY LISTINGS OF THE GREATER NEW BEDFORD AREA

STREET LISTING CHARACTERISTICS	ACUSHNET	DARTMOUTH	FAIRHAVEN	NEW_BEDFORD
# WARDS	0	0	0	6
# PRECINCTS	3	11	6	57
# COMPLETE LISTING PAGES	63	123	86	1177
# PARTIALLY-USED LISTING PAGES	2	6	6	42
# TOTAL LISTING PAGES	65	129	92	1219
# COLUMNS/PAGES	2	2	2	1
# LINES/COLUMN	154	158	154	70

TABLE 3

REPORTED NUMBER OF RESIDENTIAL HOUSEHOLD CHANGES
FOR THE TOWNS AND CITY OF THE GREATER NEW BEDFORD AREA

	ACUSHNET(1)	DARTMOUTH(1)	FAIRHAVEN(1)	NEW BEDFORD(2)
New single family dwelling	40	143	17	141
New multiple family dwelling	0	0	0	31
New additional apartments	-	-	-	280
Converted single to multiple family dwellings	0	2	3	0
Demolished single family dwellings	0	2	2	1
Demolished multiple family dwellings	0	0	0	220(3)

(1)Changes are for 1984.
(2)Changes are for 1980 through 1984.

3New Bedford Building Department uses tenements when referring to multiple family dwellings but does not distinguish number of apartments or family units involved. Tenements also refer to a single family apartment unit eliminated. Therefore, the total count reflects a combination of apartments and whole buildings that were demolished.

TABLE 4

NUMBER OF RANDOM NUMBERS GENERATED BY SEX AND TOWN OR CITY STRATA

	ACUSHNET	DARTMOUTH	FAIRHAVEN	NEW_BEDFORD	AREA_TOTAL(1)
MALES	148(49.2%)	290(48.4%)	197(49.3%)	1219(46.9%)	1854(47.5%)
FEMALES	152(50.7%)	310(51.6%)	203(50.7%)	1381(53.1%)	2046(52.5%)
TOTAL	300	600	400	2600	3900

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(1) Within strata and area totals reflect size adjustments incorporated for estimated non-response rate, adults 65 years of age or older, mentally or physically impaired persons, persons who have not resided in the Greater New Bedford area for a minimum of 5 years, piloting, and source list lines that are not persons.

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Appendix A

Updating New Bedford Census Lists for 1985

Protocol for Line Substitutions Assignments

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1) As each precinct of the New Bedford 1985 census is available to the project from the New Bedford Election Commission, a team will be assigned to:

a. Delete all red-lined-out residents from the N.B. 1984 census master copy and make other corrections as provided (i.e., spelling, Y.O.B., occupation, etc.) onto our copy (continuous computer printout sheet donated by the Election Commission).

b. Copy all new census address additions from the Census cards (be careful to keep cards in order for the census people), listing by columns:
/Ln. Assgnt. /New Addr. /Name(L. F. Mi.)/Y. O. B. /Old Addr. /Occup/

c. Transfer all red line deletions and corrections from our green sheet copy to the 70-line computer format sheets.

2) Line Substitution: In order to position Census card additions as close to the addresses that they represent:

a. Divide Additions Listing by address grouping for each of the 70-line format page's address grouping. Use the 70-line computer format page numbers for a guide on the additions listing pages. This will indicate to which page that line substitution belongs.

b. Beginning with the first available line of each 70-line format page, assign that line's number to the first addition of that address grouping. Continue to assign each available line to each available addition until you run out of additions or available lines for that grouping.

(1). If you run out of additions: Note the last available line used - you may come back there to utilize available lines for overflow from succeeding pages.

(2). If you run out of available lines: Return to the previous page and make use of available lines (if any) until additions are completed. Remember to use above protocol and start on that preceding page at the first line now available

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for reassignment. For unusually large overflows, continue to access preceding pages in succession until you have completed all additions for that address grouping.

^^^^^ Be certain to denote to what 70-line format page number these overflow additions have been assigned, as well as their line assignments.

c. Our goal is to create a master list for each precinct so that for any random sample selection one may go from the red-line on the 70-line computer format to the Additions Listing for that precinct, check page number and line number, and find the new line substitution assignment.

Please, if there are any questions - just ask!

3) As the project proceeded with the New Bedford census update, it became evident that there were still some discrepancies between the green computer sheets given to us by the Election Commission and the 70-line format sheets that we are using as the basis for the random selection.

a. The major difference is that the census green sheets also contain children (17 years or younger). Therefore as do not have any of the residents on our form that are about to turn eighteen or already have turned eighteen this year. As each of these are encountered, place a question mark next to them.

b. There are also rare occasions where residents have made the census lists before the green sheets were printed and yet were not listed before the 70-line format sheets were printed. These residents are also to be noted with a question mark.

c. After discussion with the Project Director it has been decided that the above two categories of questionable residents are to be picked up as a group (after individual review regarding inclusion) at the end of the line assignment of each precinct and assigned lines according to the above protocol. The difference is that they are to be assigned on the last page of the precinct where there are consistently a block of available lines due to precincts ending with a partial 70-line format page.

d. As mentioned in the sampling plan there is a lengthy list of new, converted, and demolished residences available for the years 1980 to 1984 from the New Bedford Building Department. Prior to the random selection of study respondents, compare the 70-line format sheet with this listing to assure that demolished addresses are not shown as occupied. Also compare the two lists to check that new address listings have made the 1985 census.

Appendix A

Updating Acushnet, Dartmouth, and Fairhaven Census Lists for 1985

Protocol for Line Substitution Assignments

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1) As each precinct of the Acushnet, Dartmouth, and Fairhaven 1985 census is available to the project from the Acushnet, Dartmouth, or Fairhaven Town Clerk/Registrar, a team will be assigned to:

a. Delete all D/M (delete/moved) residents from the Acushnet, Dartmouth, and Fairhaven 1984 census master copy and make other corrections as provided (i.e., spelling, Y.O.B., occupation, etc.) onto our copy of the 1984 census book.

b. Copy all new census address/resident additions recorded in red at the end of each street (be careful to keep sheets in order for the census people), listing by columns:
/Ln. Asgnmt. /Hse Addr. /Name(L. F. Mi.)/Y. O. B. /Old Addr. /Occup/

2) Line Substitution: In order to position address/resident additions as close to the addresses that they represent:

a. Divide Additions Listing by address grouping for each of the 77/78/77-line (respectively for Acushnet, Dartmouth, Fairhaven) format page's address grouping for each column (A or B) of each page of the 1984 Census book. Use the 77/78/77-line computer format page numbers for a guide on the additions listing pages. This will indicate to which page and column that line substitution belongs.

b. Beginning with the first available line of each 77/78/77-line format column, assign that line's number to the first addition of that address grouping. Continue to assign each available line to each available addition until you run out of additions or available lines for that grouping.

(1). If you run out of additions: Note the last available line used - you may come back there to utilize available lines for overflow from succeeding columns.

(2). If you run out of available lines: Return to the previous column and make use of available lines (if any) until additions are completed. Remember to use above protocol and start on that preceding column at the first line now available for reassignment. For unusually large overflows, continue to access preceding columns in succession

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until you have completed all additions for that address grouping.

***** Be certain to denote to what 77/79/77-line format page number and column letter these overflow additions have been assigned, as well as their line assignments.

c. Our goal is to create a master list for each precinct so that for any random sample selection one may go from the red-line on the 77/79/77-line computer format to the Additions Listing for that precinct, check page number, column letter, and line number, and find the new line substitution assignment.

Please, if there are any questions just ask!

3) The Building Departments of the three towns were accessed as done also in New Bedford. At that time a list was generated by staff of all new and converted residences and also of those that were demolished. Prior to the random selection for each precinct of each town, compare the updated census books to these listings to assure that demolished addressees are not shown as occupied. Also compare the two lists to check that new 1984 address listings have made the 1985 census.

APPENDIX AA

BLOOD PRESSURE, HEIGHT & WEIGHT, AND SKINFOLD THICKNESS MEASUREMENT PROTOCOL

APPENDIX AA

Methods

Blood Pressure Measurement

1. Assemble and check equipment. (Cuff must be completely deflated and the gauge must register zero).

2. Have the subject seated and have them roll up the sleeve to uncover the arm being used.

3. Wrap the wide portion of the cuff against the inner surface of the subject's upper arm.

4. Locate subject's pulse (brachial artery) by feeling in the bend of the elbow with the fingertips. (antecubital space).

5. Place stethoscope over pulse point. (Be sure the earpieces face forward when placing in ears).

6. Tighten thumbscrew of air bulb.

7. Inflate cuff by pumping bulb to a point about 20mm Hg above where pulse sounds were last heard. (Note: sounds called Korotkoff)

8. Loosen thumbscrew of the bulb and allow the air to escape slowly.

9. Watch the gauge when the first distinct sound is heard, note the number on the gauge; this is the systolic pressure. The number on the gauge at which the last distinct sound is heard is the diastolic pressure.

10. Open the valve completely, releasing all the air.

11. Remove cuff from subject's arm and rearrange subject's clothing.

12. Record results.

Note: In some subjects, sounds may be heard to extremely low levels, all the way to the bottom of the gauge. In such subjects, note the levels on the gauge at which the sound changes from a distinct tone to a dull, muffled beat. The diastolic pressure is recorded at the level at which the suund changes.

Wait at least 2 minutes before repeating reading on same arm. Clean the stethoscope with an alcohol pad daily.

Equipment: Stethoscope and sphygmomanometer.

Height

1. Record height to the nearest .25 of an inch.

2. Have subject remove his/her shoes.

3. The subject stands with ankles together, heels against the door, feet flat on the floor, and shoulders against the door

4. Have subject look straight ahead for correct head position by placing a pencil on either ear, making sure it is aligned with the eye.

5. Use a chair to stand on for subjects who are taller than yourself.

6. Put the triangle on the center of the subject's head, making sure one side of it is flat against the head and another side is flat against the door.

7. Mark the place on the right angle of the door. The mark should be placed on a piece of tape that can be removed from the door. The measurement will be taken from the measurement tape to the nearest 1/2 of an inch.

Weight

1. Have subject remove outer clothing (coats, sweaters, etc.), empty pockets and remove shoes.

2. Have subject stand on center of Detecto scale with arms by his/her side.

3. Balance weights on scale.

4. Make sure subject is standing still. Record weight.

* Scale checked by Dept. of Weights and Scales (City of New Bedford) January, 1985.

Caliper measurement of triceps

1. Individuals should be standing when measured. If long sleeve clothing is worn by subject have him/her remove the sleeve of the right arm.

2. Measurement is made between the acromial process (shoulder) and the olecranon process. (elbow)

3. The right side of the body should be used when measuring skin folds.

4. Consistency in locating a skin fold at its proper anatomic site can be improved by using a tape measure. Measure from the acromial process and olecranon process. A small mark should be made with a felt tip pen midway between these points. The skinfold will then be measured at the same location each time.

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5. The skinfold is picked up firmly with the thumb and forefinger of the left hand. A full fold should be pinched, lifted slightly away from the underlying tissue. The caliper is applied at the right angle to the fold. Once the caliper is applied, the pressure of the fingers should be released momentarily so that the pressure at the time of measurement is exerted by the caliper face-points and not by the fingers. The caliper should be held on the fold until the reading reaches a relatively stable value (about 3 seconds).

6. The caliper measurement should be done two (2) time recording the mm. Record both measurements.

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APPENDIX BB

HUMAN EXPOSURE TO LEAD, ARSENIC, AND MERCURY IN THE GREATER NEW BEDFORD POP

Appendix BB

to

Final Report

Greater New Bedford PCB Health Effects Study

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Human Exposure to Lead, Mercury, and Arsenic in The Greater New Bedford Population

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5/29/87

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This work was conducted by the Massachusetts Department of Public Health (MDPH) and the Massachusetts Health Research Institute (MHRI), with the assistance of the Center for Environmental Health, Centers for Disease Control, U.S. Public Health Service. Partial funding was provided by the Agency for Toxic Substances and Disease Registry (ATSDR), U.S. Public Health Service, from the Comprehensive Environmental Response, Compensation, and Liability Act trust fund (Superfund), through an interagency agreement with the Environmental Protection Agency (EPA).

Additional information on this project may be obtained by writing:

Greater New Bedford Health Effects Study
Massachusetts Department of Public Health
150 Tremont Street
Boston, Massachusetts 02111

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INTRODUCTION

Results of studies of sediments from the Acushnet River estuary and landfills in and around Greater New Bedford, Massachusetts, performed prior to the planning and design of the Greater New Bedford Health Effects Study showed evidence of significant heavy metal contamination (1). Some of the known toxic effects from heavy metal exposure resemble the reported health effects of polychlorinated biphenyl (PCB) exposure. Summarized here are the health effects of exposure to inorganic lead, inorganic mercury, organic mercury, and the various inorganic and organic species of arsenic. Inorganic arsenic can cause peripheral neuritis, myelitis or motor paralysis. In contrast, arsenic in its "dietary" form can be tolerated in humans without toxic effects even at relatively high levels. Inorganic lead causes encephalopathy and central nervous system damage and is positively correlated to blood pressure (2). Mercury is neurotoxic in both its inorganic and organic forms, with the organic moieties (e.g, methylmercury) having considerably greater toxicity (3).

Our study design therefore included plans to measure these metals in a 10% subset of study participants. The findings could then be used to determine: 1) if a public health problem of human exposure to these heavy metals existed in the New Bedford community, and 2) if the effects of exposure to these metals produced a potentially confounding source of symptoms that might be interpreted as symptoms due to PCB exposure. Measurements in biological fluids could serve as markers for undue absorption of these toxicants. In this study, we chose to measure urine arsenic, urine mercury, and blood lead because of the known distribution and excretion patterns of these metals.

As the study progressed, we decided to include measurements of speciated arsenic in any specimens with elevated total urinary arsenic, to clarify the presumed dietary origin of any elevated levels observed. Although urinary inorganic mercury is the analyte of choice for overall mercury exposure, the presence of alkylated forms of mercury, which might also be absorbed from dietary sources, was assessed by total mercury analyses on whole blood from a small number of arbitrarily chosen specimens from the New Bedford area residents and persons from the prevalence study with elevated urinary arsenic. Findings with regard to exposure to these heavy metals are the subject of this section of the final report.

DESIGN

We studied the prevalence of elevated serum PCBs and heavy metals in 840 randomly selected residents of the Greater New Bedford community (including the towns of New Bedford, Fairhaven, Dartmouth, and Acushnet) who had lived there a minimum of 5 years and who were 18 to 64 years of age. We also studied a separate component of 110 residents considered at high risk from dietary and occupational exposure in order to identify persons with high PCB levels who might be tested in a more detailed health study at a later date.

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Respondents in both components of the study were given detailed questionnaires about occupational and medical history and seafood consumption. Respondents were required to fast a minimum of 12 hours or overnight. We measured height, weight, and skinfold thickness. We also took three independent blood pressure readings at intervals during the examination with a Hawksley random zero sphygmomanometer (W.A. Baum Co., Copiague, N.Y.). The PCB portions of these studies are presented elsewhere in this report along with detailed descriptions of the sampling plan and recruitment process.

METHODS:

Sample collection: As respondents arrived at the examination center, they were given detailed instructions (in English or Portuguese, as appropriate) on the procedure to follow for contamination-free collection of urine for trace metals analysis and they were provided with sterile, plastic urine containers. Venous blood for blood lead and mercury analyses was collected and mixed with ethylenediaminetetraacetic acid (EDTA) by inversion in Vacutainer blood collection tubes (Becton Dickinson, Rutherford, N.J.). The anticoagulated whole blood was stored unopened in the collection tubes under refrigeration until shipment to CDC over ice. Under clean conditions, urine was transferred to separate specimen containers, with 1% v/v nitric acid used as a preservative for urinary total arsenic analysis or 0.1% v/v Triton X-100 and 0.2% w/v sulfamic acid used for urinary mercury and speciated arsenic analysis. Urine samples were frozen at minus 20°C until shipment to CDC over dry ice. Representative samples of specimen containers and glassware were prescreened by CDC for trace metal contamination.

Suitable specimens for trace metal analyses were collected from all respondents. As specified in the study design, however, measurements of blood lead, urine mercury, and urinary total arsenic were only performed on specimens from a 10% randomly selected subset. Arsenic speciation was performed on specimens from individuals in the 10% subset found to have total urinary arsenic above 100 ng/mL. Total blood mercury was measured on 48 arbitrarily chosen specimens from New Bedford area residents and a few persons in the prevalence study with elevated urinary arsenics.

ANALYTICAL METHODS

The Division of Environmental Health Laboratory Sciences (EHLS), Center for Environmental Health (CEH), CDC performed all analyses for heavy metals except for measurements of arsenic species which were done by the Environmental Health Laboratory, School of Public Health and Community Medicine, University of Washington, Seattle, Washington. All heavy metal analyses performed by the EHLS included a minimum of three bench quality control samples in each analytical run and, in most cases, at least one blind control.

Blood lead was measured by the method of Paschal et al. (4) by using established electrothermal atomic absorption techniques and a

Perkin-Elmer Model 372 Atomic Absorption Spectrometer equipped with autosampler and deuterium background correction. (Perkin Elmer, Inc., Norwalk, Connecticut). We verified the accuracy of this method during the study by analyzing blood pools whose target values were established by National Bureau of Standards (NBS) stable isotope dilution mass spectroscopy (SIDMS). The literature-based expected range for blood lead used by our laboratory in evaluating samples from adults is 0-40 µg/dL (5).

We measured urinary inorganic mercury by the Littlejohn et al. method (6), employing cold vapor atomic absorption spectroscopy on a Perkin Elmer Mercury Hydride System (MHS-20). Accuracy was verified during the study by the analysis of NBS Standard Reference Material (SRM) 2672a. The literature-based expected range for urinary inorganic mercury used by our laboratory in evaluating samples is 0-20 ng/mL (3).

We measured total urinary arsenic by the method of Paschal et al (7), using established electrothermal atomic absorption techniques and a Perkin-Elmer Zeeman/5000 Atomic Absorption Spectrometer equipped with an autosampler and Zeeman-effect background correction. Samples were diluted with a matrix modifier containing nickel nitrate and magnesium nitrate in nitric acid before being analysed. We verified the accuracy of the method during the study by the analysis of NBS SRM 2670. The literature-based expected range for total urinary arsenic used by our laboratory in evaluating samples is 0 - 100 ng/mL (8).

Speciated arsenic measurements were performed at the Environmental Health Laboratory, School of Public Health and Community Medicine, University of Washington, by the method of Braman and Foreback (9) for reduction and selective volatilization of the corresponding hydrides, followed by electrothermal atomic absorption with a Perkin Elmer Model 180 AA Spectrometer. Accuracy of this method was verified by daily analysis of bench mark urine pools whose target values were established by an interlaboratory comparison study. The literature-based expected range for speciated arsenic used in evaluating samples is 5 - 30 µg/L (10,11,12).

We measured total blood mercury by the method of Greenwood (13), using established cold vapor atomic absorption techniques with Magos' reagent to assess the different forms of mercury. We used a Laboratory Data Control (LDC) Mercury Monitor (Riviera Beach , Florida) for this work. We verified method accuracy during the study by the analysis of spiked bovine blood pools. The literature-based expected range for blood total mercury is 0-30 ng/mL, but the effects of mercury intoxication have not been reported below total blood mercury levels of 200 ng/mL. (3,14,15,16).

Quality control statistics for all CDC analytical methods are presented in Table I. In all cases, CDC data reported in this study are from analytical runs that met the quality control criteria for acceptable performance established by the laboratory.

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RESULTS

The 10% subset of respondents for heavy metals analyses yielded 96 persons in the randomly selected portion of the study, and 10 persons in the cohort that had been selected because of their high risk of exposure to PCBs. Because the distributions and ranges of values for all measurements for both cohorts were essentially identical, for the purposes of this discussion, the data from the total of 106 persons have been pooled for each analyte measured. These data, with the exception of speciated arsenic and total blood mercury, are presented in the form of frequency distributions (Figure 1) and are summarized in tabular format (Table 2). Findings are discussed in the order of increasing public health significance.

BLOOD LEAD

The data for lead in blood are the most straightforward to interpret, and we found no evidence of excessive exposure to lead in the persons sampled. As Table 2 shows, the mean and median blood lead values were 9.81 and 8.25 µg/dL, respectively. These data are typical of adult nonoccupationally exposed urban U.S. residents, and are comparable to data obtained in control areas of other CDC studies (17). In all cases, the levels found were below the level of 40 µg/dL set for adults by the Occupational Safety and Health Administration (OSHA) at which removal from the workplace exposure site is mandatory (5). It can be concluded, therefore, that lead does not represent a confounding variable in this study for the interpretation of PCB data, nor was there evidence of unusual lead exposure in the general New Bedford population.

URINE INORGANIC MERCURY

Urine is a primary excretory medium for absorbed inorganic mercury, and is the specimen of choice for evaluation of exposure (3,18). The World Health Organization (WHO) has set a "health based occupational exposure limit" for inorganic mercury in urine of 50 ug mercury per g creatinine (19). This is roughly equivalent to 50 ng/mL, assuming a concentration of 1 g/L creatinine in urine. In a large study by WHO, 95% of the subjects had urine mercury levels at or below 20 ng/mL (N=1107) (3). Only one specimen examined in the present New Bedford study had a value of greater than 20 ng/mL (24.8 ng/mL). These data are summarized in Table II. Inorganic mercury does not appear to be a public health issue in this New Bedford population nor a confounding variable in this study of PCB exposure.

URINARY TOTAL ARSENIC

Arsenic is excreted primarily in urine with a relatively short half-life of 1-3 days for most forms of inorganic arsenic (19). Evaluation of arsenic absorption via measurement of urine arsenic is, however, complicated by the presence of "dietary" arsenic. Dietary arsenic is speculated to be a complex molecule in which arsenic is bound to proteins (20). The toxicity of this form of arsenic low compared to

other forms of arsenic, particularly inorganic arsenic III or arsenic V. The analytical method used by CDC in this study quantitates total arsenic, which means that all forms of arsenic are measured, including dietary arsenic. Thus, the interpretation of the data is complicated by the inclusion of dietary (nontoxic) arsenic. To resolve the possible complication in interpretation, we submitted selected specimens, including all of those whose total arsenic was greater than 100 ng/mL, to the University of Washington for arsenic "speciation" analysis. The data provided by the University of Washington group give an accurate picture of the inorganic arsenic and its metabolites in urine.

Data obtained by the CDC method for total urinary arsenic are presented in Table II and are compared with data from the University of Washington for inorganic arsenic species in Table III. The most current action level or exposure standard for total arsenic is cited by several investigators (8) to be 100 ng/mL total arsenic. Studies cited by WHO (21) indicate that concentrations of up to 1000 ng/mL (1 mg/L) total arsenic can be observed in subjects consuming seafood within the previous 24 hours without any known adverse effects.

Ten specimens (9.4%) out of the 106 measured had total urinary arsenic levels greater than 100 ng/mL. Of the ten persons supplying these specimens, seven reported eating various species of seafood at least once a week or more, two reported eating seafood at least once a month, and one reported eating seafood at least once a year.

Sixty-nine persons answered questions about recent seafood consumption at the time of urine collection. Twenty-three percent (3 out of 13) of those who stated that they had eaten certain species of seafood in the past 48 hours had urinary total arsenic >100 ng/mL. In contrast, only 3.6% (2 out of 56) of the persons who said they had not eaten certain species of seafood in the past 48 hours had urinary total arsenic >100 ng/mL. The survey questions on seafood consumption were very specific about certain species of seafood. They did not, however, identify clearly those persons who may have eaten within the past 48 hours seafood species that were not specifically mentioned in the question. These data, when examined in the light of the speciated arsenic data for persons with urinary total arsenic >100 ng/mL, support the conclusion that recent seafood consumption, reported or otherwise, explains the elevated levels observed.

Interpretation of the concentrations of the various arsenic species is more difficult than that for total arsenic, since very few studies have been conducted with large populations. Data available from some studies indicate an expected range of 5 to 30 ng/mL of metabolites of inorganic (nondietary) arsenic in an unexposed population (Morin and Vahter, 1981; Fee et al [illegible] (10,11,12). More recent data from the University of Washington Laboratory indicate, however, that levels for some species of arsenic measured by this method are elevated after ingestion of clams, flounder, and other types of seafood, apparently without harmful effects (22). Specifically, the species dimethylarsinic acid (DMA) is elevated on ingestion of seafood (Figure 2). This observation is reflected in our data, in that those specimens with elevated speciated arsenic have elevated dimethylarsinic acid, along with

elevation in the "dietary" arsenic (See Table 3). These two findings together strongly suggest that the elevation in the speciated arsenic (sum of inorganic arsenic, and the arsenic content of monomethylarsonic acid and dimethylarsinic acid) is due to seafood ingestion.

BLOOD TOTAL MERCURY

To rule out the possibility that New Bedford Area residents had been exposed to the more toxic organic form of mercury, we decided to include measurement of blood total mercury on a small, arbitrarily selected group of blood specimens that had been collected originally from participants in the study for blood lead measurement. Dietary contributions to body burdens of mercury is of importance, because organic mercury, mostly as methylmercury, is present in significant amounts in seafood. Studies of populations known to consume relatively large quantities of fish have demonstrated absorption of methylmercury through seafood (14,15,16). Most of these reports, however, suggested only a slight probability of an adverse reaction. The primary measurement in such studies has been blood total mercury. Most population studies show levels of total mercury much lower than 200 ng/mL, the level at which adverse health effects are observed in the most susceptible members of a population (14,15,16). Data from 48 New Bedford area residents yielded a mean blood mercury of 8.4 ng/mL and a maximum value of 33.1 ng/mL. This limited study does not indicate any obvious or excessive exposure to organic forms of mercury in this population.

SUMMARY

In our study of heavy metal exposure in residents of the Greater New Bedford area we found no evidence of excessive exposure to toxic forms of any of the elements tested. Levels of blood lead were within the expected range for nonoccupationally exposed adults and are typical of levels observed in urban adults in the United States. The urinary inorganic mercury and blood total mercury levels measured were well below published exposure limits, which supports the conclusion that no excessive exposure to elemental and organic forms of mercury occurred in those tested. Total and speciated urinary arsenic measurements showed that the arsenic exposure was the relatively nontoxic dietary arsenic (predominately from seafood), and levels were well below action levels for this form of arsenic.

Although elevated levels of certain heavy metals have been found in samples from Acushnet estuary sediments, local landfills and other sites, and there is the potential for industrial exposure among workers in the community, this study of 106 New Bedford area residents gave no evidence of excessive human exposure to lead, arsenic, or mercury.

Use of trade names is for identification only and does not constitute endorsement by the Public Health Service or the U.S. Department of Health and Human Services.

ACKNOWLEDGMENTS

The authors recognize the contributions of the following people: (1) the MMRI staff who collected and processed specimens, conducted interviews and examinations of respondents, and gave administrative support; (2) the MDPH personnel who contributed to the processing of specimens and data; (3) the CDC personnel who performed analyses and gave logistical support in the area of heavy metals; and (4) the consultants who contributed during the planning, implementation, and data analysis phases of this study. Special thanks are due George Bailey, Brenda Lewis, and Phillip Stroud (CDC); Lynda Anastasio, Barbara Ford, Jane Masado, Mary Medeiros, and Lori Stevenson, (MMRI); Kathleen Gallagher, Paul George, David Gute, Rosemarie Kappes, and Elaine Krueger (MDPH) for their hard work on this portion of the Greater New Bedford PCB Health Effects Study; Susan Kutzner and Norman Telles

Greater New Bedford PCB Health Effects Study
1984 - 1987

TABLE 1

Quality Control Statistics
Heavy Metal Analyses

Analyte	Pool I.D.	Target Value	Achieved*		
			$\bar{x}$	s.d.	n
Blood lead (µg/dL)	DE7CS9	15.9	15.76	0.79	10
Urinary total arsenic (ng/mL)	SRM2670	480	460.1	37.6	12
Urinary inorganic mercury (ng/mL)	SRM2672a	105	102.4	12.4	16
Blood total mercury (ng/mL)	Bovine Pool	-	25.2	2.5	24

* Data are from representative quality control pools used by CDC during these analyses.

Greater New Bedford PCB Health Effects Study
1984 - 1987

TABLE 2

Heavy Metal Findings
Respondents in Prevalence and Enrichment Cohorts

Analyte	$\bar{x}$*	n	s.d.	range	median
Blood lead (µg/dL)	9.81	106	6.18	2-34.7	8.25
Urinary total arsenic (ng/mL)	38.2	106	**	<8-365	13
Urinary inorganic mercury (ng/mL)	3.43	106	**	<2-24.8	2.6
Blood total mercury (ng/mL)	8.38	48	7.00	0.5-33.1	6.65

* Values below the detection limit were counted as half the detection limit in computing means.

** Computation of standard deviation for this population is not valid because 37 mercury and 41 arsenic values were below the method detection limits.

Lower detection limits for Hg and As were 2.0 and 8.0 ng/mL, respectively.

Greater New Bedford PCB Health Effects Study
1984 - 1987

TABLE 3

Comparison of Urinary Total Arsenic to Speciated Arsenic

Subject No.	Total As ng/mL	Inorganic As ng/mL	Monomethylarsonic Acid ng/mL	Dimethylarsinic Acid ng/mL	Total[♦] Speciated As ng/mL	Dietary As ng/mL
1	234.6	1.4	1.8	22.6	25.8	208.8
2	150.1	1.2	1.2	6.9	9.3	140.8
3	213.2	2.4	2.6	33.1	38.2	175.0
4	255.7	2.5	3.2	89.4	95.1	160.6
5	201.9	1.0	2.6	85.8	89.4	112.5
6	326.4	0.7	1.1	7.2	9.0	317.4
7	136.9	1.2	<0.5	16.9	18.7	118.2
8	298.0	<0.5	<0.5	20.3	21.3	276.7
9	369.0	1.1	3.2	53.8	58.2	306.8
10	127.4	<0.5	<0.5	15.5	16.5	110.9
Mean[*]	230.9	1.2	1.7	35.2	38.2	192.8
s.d.	81.3	0.8	1.2	30.8	32.0	80.7
n	10	10	10	10	10	10
Range	127.4-365.0	<0.5-2.5	<0.5-3.2	6.9-89.4	9.0-95.1	110.9-192.8
Median	223.9	1.2	1.5	21.5	23.6	167.8

[*] Values below the detection limit of 0.5 ng/mL were counted as half the detection limit in computing means and standard deviations.

[♦] Total speciated arsenic is the sum of inorganic arsenic, and the arsenic in monomethylarsonic acid and dimethylarsinic acid

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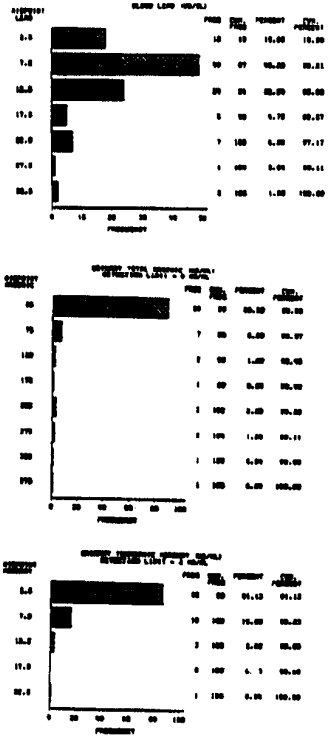
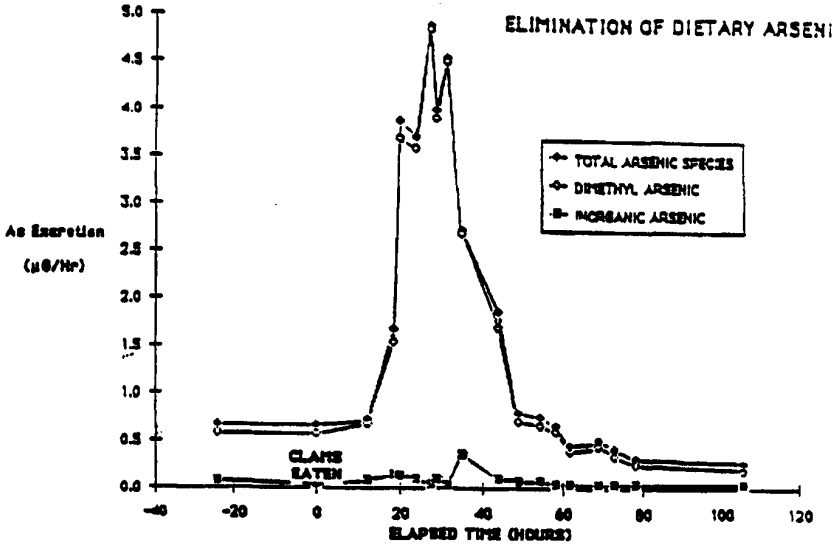
Figure 1

GREATER NEW BEDFORD PCB HEALTH EFFECTS STU



Distributions of blood lead urinary arsenic and urinary inorganic mercury levels, 106 persons, New Bedford, MA, 1984-1986.

Figure 2



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APPENDIX CC

HUMAN RESEARCH REVIEW COMMITTEE

APPENDIX CC

LEMUEL SHATTUCK HOSPITAL
HUMAN RESEARCH REVIEW COMMITTEE

APRIL 25, 1983

RECEIVED
MAY 16 1983
MASS. HEALTH RESEARCH

PRESENT: Dr. Cohen, Mr. Bloom, Mr. Davenport, Mr. Frauenhofer, Dr. Greco, Mr. Lally, Dr. Lewis, Mrs. McLaughlin, Dr. Paone, Dr. Rifkin

The minutes of the previous meeting were approved on motion.

Protocol #1: Health Effects of Polycholorinated biphenyl (PCB) Pollution

The investigator informed the committee that the protocol will also be submitted to the EPA Center for Disease Control for review and approval. The protocol which was submitted for review by this committee was not in its entirety.

The committee approved Phase I of the study with the following modifications:

1) The Blood Pressure Instruction Sheet is to be separated into three separate forms: one for normal blood pressure; one for borderline blood pressure; and one for definite high blood pressure. Each instruction sheet is to clearly indicate the medical attention advised for the particular blood pressure measurement.

2) To insure confidentiality, a separate cross file system is to be maintained for patient number and case number so that the data gatherers do not have access to both names and case numbers.

3) Any significant changes made by the EPA Center for Disease Control are to be submitted to this committee for review before proceeding with the project.

The committee approved Phase II in principle. The investigators are to return to the full committee with the data collected in the Phase I study before proceeding to Phase II.

The consent form for Phase I is to be rewritten to state the intent of the study. The following statement is to be deleted from the consent form: "Information obtained in this study is collected under Chapter 111, Section 24A of the Massachusetts General Laws, which legally protects the study's confidentiality.

The committee requested that two copies of the unabridged protocol be forwarded to this committee together with a copy of the amended consent form for Phase I.

APPENDIX DD

ANALYSIS PROTOCOL FOR PCB'S AND OTHER CHLORINATED HYDROCARBONS

APPENDIX DD

ANALYSIS PROTOCOL FOR PCBS AND OTHER CHLORINATED COMPOUNDS OF ENVIRONMENTAL CONCERN: CDC - NEW BEDFORD STUDY

PREPARED BY THE DIVISION OF ENVIRONMENTAL HEALTH
LABORATORY SCIENCES OF CEH, CDC

ANALYSIS PROTOCOL FOR PCBS AND OTHER CHLORINATED COMPOUNDS OF ENVIRONMENTAL CONCERN: CDC - NEW BEDFORD STUDY

INTRODUCTION

The following procedures will outline the Centers for Disease Control's (CDC) extent of involvement both analytically and with regard to quality assurance with the Massachusetts Department of Public Health (MDPH) in the assessment of serum levels of PCBs, and in a select number of samples - chlorinated hydrocarbons, in the residents of New Bedford, Massachusetts.

The concern of possible PCB exposure of these residents arises from two main sources: 1) Their consumption of lobster and other fish taken from the Acushnet River that is believed to be contaminated with PCBs, and 2) [illegible] occupational exposure through skin and respiratory absorption for these residents employed by a nearby capacitor plant. [illegible]

EXTENT OF CDC'S INVOLVEMENT [illegible]

The involvement of the Toxicology Branch of the Division of Environmental Health Laboratory Sciences (EHLS), Center for Environmental Health (CEH), CDC will be primarily related to, but not necessarily limited to:

1) Providing validated methods for the determination of all analytes that are stated in this protocol. For the PCBs determination, an intact method, including essential reagents and standards will be transferred from CDC to MDPH. For the chlorinated hydrocarbons (CHs) determination, a select number of analytes (pp'-DDE, Heptachlor epoxide, Trans nonachlor, Dieldrin, Oxychlordane, Endrin, B-HCCH, γ-HCCH and Hexachlorobenzene) will be screened for in ~5% of the New Bedford cohort.
2) Providing assistance in the design and maintenance of a quality control system to be utilized in an internal and external mode.

3) Providing characterized quality control material to be used in the establishment and maintenance of the quality control program.

4) Providing capillary gas chromatography electron capture and capillary gas chromatography mass spectrometry analysis of a select number of the New Bedford cohort that exhibit high levels of PCBs regardless of the exposure origin, i.e. environmental or occupational.

ACQUISITION OF SAMPLES AND SUBSEQUENT HANDLING

Field personnel from the MDPH will have the responsibility of obtaining the blood samples from the New Bedford cohorts. The following procedure has proven adequate:

1) Draw at least 4 tubes (10-12 ml per tube) of blood into 15 ml red top vacutainer tubes.

2) Let stand 20-30 minutes at room temperature.

3) Centrifuge 10 minutes at ~2400 rpm.

4) Pool the serum and pipette at least 4.5 ml of serum into the supplied *glass vials. *Glass vials should have, at the least, been rinsed with acetone, then hexane and allowed to dry. (These vials should be labeled and identified with the same number (or other symbol) used to identify the respective vacutainer tube and patient).

5) Cap, seal, and crimp the vial and secure the label with cellophane tape.

6) Place vial into a freezer maintained at approximately -20°C where they will remain until shipped. Samples to be stored for longer periods of time may require lower temperatures, i.e. -70°C.

7) The vials should be sealed in a bubble bags and placed in a container for transport to the state laboratory.

8) For those specimens that are to be shipped to CDC send by air with package addressed to: Ms Brenda Lewis, Centers for Disease Control (C 32/1503), Atlanta, GA 30333.

Field personnel from the MDPH will have the responsibility of racking the serum samples into analytical runs prior to transport to the laboratory. An analytical run will consist of 15 cohort specimens and a select number of the following controls (See Appendix A): 1) New Bedford Base Bovine serum (NBBBS); 2) New Bedford Chlorinated Hydrocarbon Spike (NBCHS); 3) New Bedford External Blind Control (High or Low) (NBEBC); and 4) New Bedford Bench Control (High or Low) (NBBC), and 5) Goat serum (AR 1242). In order for the "blind control" samples to be completely indistinguishable from the unknowns, it will be necessary for the field personnel to transfer the quality control material to a container identical with those used for the unknowns since the quality control material is stored in tube drawn, 15 ml, wide mouth bottles. Ms. Kathleen Gallagher (MDPH) will be responsible for transferring (at least 3 ml of a well mixed sample) the blind quality control materials from the tube drawn, 15 ml wide mouth bottles to a 5 ml Wheaton serum bottle and attaching the appropriate label. The label will be supplied by the Special Activities Branch (SAB) of EHLS, CEH, CDC, (Don Phillips). The resulting specimen should be indistinguishable from a cohort specimen. Other quality control materials will be inserted in the run by the bench chemist prior to initiating an analytical run. See Appendix A for additional information concerning quality control materials. It is suggested that Ms. Gallagher prepare a sufficient quantity of the blind quality control material to last for twenty runs.

ANALYTICAL METHOD

The analytical method to be used for the determination of PCBs in serum by MDPH and CDC is described in CDC Laboratory Update 81-108 "Polychlorinated Biphenyl Determination at Parts-Per-Billion Level in Serum"; however, the following changes must be noted: 1) Use of an internal standard (IS) for quantitation; and 2) Addition of a keeper solution prior to each evaporation step.

The use of an IS was initiated in an effort to reduce that part of the variation in the method attributed to gas chromatography, and therefore the IS is added to the sample just before analysis by gas chromatography. Decachlorobiphenyl (DCB) was chosen as the IS because it does not appear to interfere with the two most common Aroclor types found in the environment, namely Aroclors 1254 and 1260. The keeper solution is used to reduce the loss of more volatile PCBs and other exogenous compounds that are extracted.

The analytical method to be used for the determination of PCBs in serum is outlined below.

A. Apparatus, Reagents and Standards

1) Adsorption chromatography column -

Glass, 18 cm x 9 mm with or without stopcock but with 50 ml reservoir

2) Solvents -

n-hexane, methanol and ethyl ether (Distilled-in-glass quality) Nathan

3) Sodium Sulfate - (For Preparation see Appendix B) [illegible]

Anhydrous, reagent grade, washed with hexane and continuously [illegible] oven-dried at 130°C. Remove from oven and let cool in desiccator before use.

4) Silica Gel -

Weigh no more than 20 g of Woelm Silica Gel 70/150 mesh into a 250 ml beaker, cover with aluminum foil (shiny side out) (punch several holes in foil) and let stand in 130°C oven for at least 24 hrs. (We use a bench type gravity convection laboratory oven). Let silica gel cool in vacuum desiccator. Weigh dried gel into flask with Teflon-lined screw cap. Add water down sides of flask in an amount to constitute 3% of the total weight. Extract water beforehand 3 times with hexane (For Preparation see Appendix B). Shake wetted gel until there is no evidence of clumping. Rotate 3 hrs on mechanical rotator and let

stand tightly capped overnight before use. Silica gel prepared in this manner maintains its elution characteristics for at least 7 days.

5) Keeper solution -

1% (w/v) of Paraffin oil (Fisher paraffin oil, N.F., White, Light, domestic, viscosity 125/135) in hexane.

6) Aroclor standards - Aroclor 1254, Monsanto Lot AK 38; Aroclor 1242, Monsanto Lot KK-06-411

7) Decachlorobiphenyl Standard - Analabs, (RCS-051)

B. Extraction of Serum

Pipet 4 ml (ideally) of well mixed serum into a clean 16 x 125 mm culture tube. Add 2 ml of methanol (methanol volume is one-half serum volume) and mix by vortexing. Add 5 ml hexane-ethyl ether (1 + 1), mix by vortexing, rotate 15 min at 50-55 rpm on rotary mixer, centrifuge 6 min at 1800 rpm, and transfer supernatant to 20 x 150 mm culture tube. Repeat this extraction step twice being sure to vortex sample well prior to placing on rotary mixer. To the combined extracts, add 3 drops of keeper solution and reduce solvent volume to ~0.5 ml under a gentle stream of (pre-purified) nitrogen at room temperature.

C. Adsorption Chromatography

1) Prepare the adsorption chromatography column as follows: (1) Plug the 18 cm x 9 mm glass column with a small plug of silanized glass wool; (2) Add anhydrous sodium sulfate to a height of 10 mm; (3) Add 3.0 g of 3% deactivated silica gel; and (4) Add anhydrous sodium sulfate to a height of 10 mm.

2) Prewash the column with 20 ml hexane and just as the last of the hexane layer reaches the top of the top sodium sulfate layer, add the concentrated (0.5 ml) extract. Rinse the sample tube with three 0.5 ml portions of hexane and transfer each wash to the head of the column.

Elute the column with 5 ml hexane and discard the first 7 ml of eluate (0.5 ml concentrated sample +3 x(0.5 ml wash) + 5 ml eluate) [Note: This eluate may be combined with subsequent eluate if desired and collected in an appropriate vessel]. Just as the hexane layer reaches the top of the top sodium sulfate layer, add sufficient hexane in order to collect 15 ml of eluate in a calibrated 15 ml conical centrifuge tube. Add 5 drops of keeper solution and concentrate the eluate just to dryness (critical) in a 40°C water bath with a gentle stream of (pre-purified) nitrogen. Add 1.0 ml (Volumetric pipet) of DCB (at the same concentration level used in the GC standards). [Note: Use DCB to make all dilutions of samples when necessary].

D. Setting up the gas chromatograph (GC)

Pack a 6' x 1/8" (i.d.) glass column with 3% SE-30 (or equivalent) on 80/100 mesh Gas Chrom Q. Condition the packed column with a carrier gas flow rate of at least 30 ml/min by increasing the oven temperature 8°C/min. from ambient to 240°C and holding at least 72 hrs.

Prepare separate gas chromatographic standards in hexane of the Aroclor and decachlorobiphenyl (DCB) standards supplied, at concentrations of 100 and 30 ppb, respectively. [Note: Use a DCB concentration that produces a 50% full scale deflection, the concentration needed may be less than 30 ppb]. Use these standards to establish the best parameters for your gas chromatograph and data system. Set column temperature such that the retention time of DCB is $\leq$ 30 min. Suggested parameter setting based on the system we are using:

Column temperature	- 205°C
Injection temperature	- 250°C
Detection temperature	- 330°C (^{63}Ni)
Carrier flow (N_2)	- 20 ml/min

While it is desirable to keep the (GC) run time $\leq$ 30 min this should not be done at the sacrifice of resolution or sensitivity. Using your established parameters compare your GC trace with that published by Webb-McCall (J. Chro. Sci. 11 July, 1973). Injection of pp'-DDE for computation of relative retention times will facilitate this process.

Composition of AR 1254 and AR 1242 per Webb-McCall - J. Chrom Sci. 11 (July, 1973).

AR 1254		AR 1242	
(RT_{DDE} X 100)	Mean Weight Percent	(RT_{DDE} X 100)	Mean Weight Percent
47	6.2	11	1.1
54	2.9	16	2.9
58	1.4	21	11.3
70	13.2	28	11.0
84	17.2	32	6.1
98	7.2	37	11.3
104	13.6	40	11.1
128	15.0	47	8.8
146	10.4	54	6.8
160	1.3	58	3.6
174	8.4	70	10.3
203	1.8	78	3.6
232	1.0	84	2.7
		98	1.3
		104	2.3
		128	1.6
		146	1.0

Special Note: Although Webb-McCall report only two late eluting PCB peaks 203 and 232, at least five have been observed. In order to account for these additional peaks a grouping function in the data system (if available) is used (See Appendix C).

Prepare a series of Aroclor standards at four concentration levels: 25, 50, 100, and 200 ppb with DCB as the internal standard. Concentration of the DCB should be constant and provide a measurable peak, i.e. 30% full scale deflection. Using the data system available load retention times and concentrations for each Webb-McCall peak and the internal standard for each level of standard concentration. Through a series of at least three injections (1-3 microliter/injection) generate calibration factors for each Webb-McCall peak at each concentration level of the standard. Compute the mean, standard deviation and relative standard deviation (%) for the calibration factors within and among concentration levels. This information will provide an indication of the linearity of the system. A relative standard deviation of $\leq$ 10% should be achievable for most of the Webb-McCall peaks except 58, 160, 174 and 203-232 in AR 1254. Because of the elution characteristics of these peaks on non polar liquid phases and/or their areas, the relative standard deviation will most likely be higher. If unusually high relative standard deviations (%) occur, use of the grouping function in the data system (if available) will most likely lower them. A relative standard deviation (%) of $\leq$ 10 appears achievable for all of the peaks in Aroclor 1242 except Webb-McCall Peak 37 which we have found varies from 4 to 32 percent dependent upon the concentration.

RUN SEQUENCE

Once calibration factors have been established, an acceptable analysis sequence for the GC could be: Four unknowns (including bench QC) followed by a calibration update, four more unknowns followed by a calibration update.... The calibration updates should not be done in any particular sequence (with regard to standard concentration); however, it has been found more advantageous to update the lower concentration standards more often than the

high. The lower concentration standards are more difficult to calibrate and maintain in calibration and these low standards will be used more often in the analysis of general population samples. In the quantitation of unknowns use the concentration level of the standard that best matches the response of the unknown. It may be necessary to use the response of two standards if so, average the reported concentration.

QUALITY ASSURANCE AND COMPARABILITY AMONG LABORATORIES

Every effort must be made to obtain comparability among the two laboratories as a means of achieving quality assurance. While it is realized that exact duplication in two laboratories of apparatus, environment and analytical technique is impossible, an effort will be made toward getting the laboratories as comparable as possible. The measure of comparability will be comparison data obtained by the two laboratories on specially prepared material composed of base bovine serum in combination with in vivo and in vitro added PCBs and CHs.

CDC will prepare a series of pools that contain in vitro spiked PCBs only (AR 1254) at five concentration levels 0-100 ppb. CDC will also prepare three additional pools that contain in vitro spiked PCBs only (AR 1242) at 0, 15 and 30 ppb respectively. All material will be stack filtered prior to the addition of PCBs but not sterile filtered afterwards. The material in vitro spiked with Aroclor 1254 will be analyzed by both laboratories. In six separate analytical runs duplicate aliquots of each of five pools will be analyzed. The material in vitro spiked with Aroclor 1242 will also be analyzed by both laboratories. The [illegible] will analyze a single aliquot from each pool in ten separate analytical runs. The CDC will analyze a single aliquot from the 0 ppb pool and duplicate aliquots from the 15 and 30 ppb pools in six separate analytical runs. These analyses will constitute the

first step toward attaining laboratory comparability. At this step, lab comparability will be considered achieved if the mean value for PCB at each concentration level achieved by HDPH is within ± 25% of both the target value and CDC's mean, with a within-lab CV of ≤ 25% for concentrations ≤ 20 ppb. For concentrations > 20 ppb HDPH mean must be within ± 15% of both the target value and CDC's mean, with a within-lab CV of ≤ 15%.

CDC will also prepare a series of pools that contain in vivo PCBs (as AR 1254) and in vitro chlorinated hydrocarbons and a single pool that contains in vivo PCBs only (as AR 1242). The PCBs (1254) will be at four concentration levels and will vary from 0-100 ppb. The PCBs (1242) will be at one concentration level, 30 ppb. All materials containing in vivo PCBs will be sterile. They will be analyzed by CDC and HDPH in a series of 20 analytical runs. Each run will consist of analyzing a single aliquot from one vial of each pool. These analyses will serve a dual purpose. First, they will constitute the second step toward attaining laboratory comparability and second they will provide the initial quality control data for both laboratories. At this step laboratory comparability will be considered achieved when the bias between the laboratories is no greater than ± 25% for concentrations ≤ 20 ppb and ± 15% for concentrations > 20 ppb. In addition the within-lab CV must be ≤ 25% for concentrations ≤ 20 ppb and ≤ 15% for concentrations > 20 ppb.

While HDPH will have the responsibility of generating and maintaining its own quality control charts, CDC will generate and maintain quality control charts for both laboratories. Data for both laboratories will be entered into the computer for the five quality control pools (quality control limits will not be computed for pool HBBBB and HBCHB) with the following information: Year, Month, Day, Pool, Value, Analyst, Instrument, Run #.

The CDC computer program QCLIMIT will then generate for each of the five

quality control pools plots of the PCB values. Each plot will include the run mean, the overall QC mean, the upper and lower 95% confidence limits (UCL and LCL), and the upper and lower 99% confidence limits. These values will be used for determining if an analytical run is in or out of control for the first 20 analytical runs of unknowns. After 20 analytical runs of unknowns the means will be updated using only the data obtained during the 20 runs of unknowns. The means obtained for each pool from the 20 runs of unknowns will be compared to the initial means obtained during the 20 runs of characterization. If there is a significant difference ($\alpha = 0.05$) between the two sets of means the original characterization data will be dropped and new QC limits set from the 20 analytical runs of unknowns. If there is no significant difference data from the initial characterization and the 20 analytical runs of unknowns will be combined and new QC limits set. These limits will be used for the remainder of Phase 1. The updated quality control means must meet the same criteria for comparability as the initial characterization run means.

CONTROL RULES (REJECTION CRITERIA)

Although the MDPH personnel will maintain responsibility for plotting their own quality control data, they will transmit to CDC their quality control data as well as unknown run data as soon as possible. CDC personnel will then load MDPH and CDC quality control data into the computer. The quality control system will be declared out of control if any of the following events occur singly or in combination:

1. Values obtained from one or more quality control pools during a single run fall outside the 99% limits (upper or lower).
2. Two consecutive values of one control pool fall either both above the 95% UCL or below the 95% LCL.
3. Ten consecutive values for one pool fall either all above or all below the

means however, a scientific judgment will be made before categorically describing such a system as "out of control."

If the system is found to be out of control then some form of remedial action is required. Under no circumstance is there to be any deviation from the method as it was originally established in order to remedy the out of control situation. While there are possibly a number of alternatives to be checked during the "out of control" period the following five are probably the most expedient:

1. Determine if a clerical error has occurred, i.e. were the data simply transcribed wrong;
2. Has a sample mix up occurred , i.e. has a patient sample been substituted for a quality control sample;
3. Has an instrumentation error occurred, this can take two forms, either mechanical (bad septum, low gas pressure, bad injection, etc.) or electrical (data system, attenuation, thermal zones, etc.);
4. Determine if a change in the concentration of standards has occurred; and
5. Review the sample sequence in the analytical run to ensure that "carryover" from a concentrated sample did not contaminate the "out of control" QC sample.

If none of the previously mentioned alternatives prove viable for resolving the "out of control" situation, CDC should be notified and the matter discussed.

RECORD KEEPING

Another aspect of any laboratory effort involves record keeping. The importance of maintaining a notebook which chronicles all the events relating to the project is important. We have used the concept of one notebook per project and allowed all individuals working on the project to have access to it. In this way all information relating to solvents, adsorbents (Lot nos.)

standard preparation, GC problems are all kept in one place. Listed in Appendix D are codes to be used for indicating changes in methods as they relate to extraction, adsorption chromatography and gas chromatography.

AROCLORS TO BE MONITORED

Preliminary analysis of gas chromatographic peaks, produced by a composite sample from New Bedford residents, using principal components analysis indicates the presence of early and late eluting PCBs. These PCB patterns are most similar to Arocolors 1242 and 1254.

It will be necessary during the analysis of unknowns to be aware of the presence of unusually large peaks ≥ 25% full scale deflection eluting prior to p,p'-DDE. Generally exposure to AR 1254 does not result in significant PCB peaks that elute prior to p,p'-DDE. All PCB peaks observed in unknowns will be quantitated as AR 1254 except in those instances where unusually large early eluting peaks are observed. The early peaks (pre-DDE) will be quantitated as AR 1242 and the late peaks (post p,p'-DDE) will be quantitated as AR 1254.

SPECIFIC CONSUMER AND CHLORINATED HYDROCARBON ANALYSIS

CDC will analyze a subset of cohorts in Phase I for PCB specific congeners (not to exceed 25 specimens) and a select number of specimens for chlorinated hydrocarbons (not to exceed 75 specimens). It is proposed that this subset be selected on the basis of the original PCB determination made by MDPH. If the total PCB concentration is ≥ 30 ppb, then the specimen would be a candidate for these additional analyses. It is suggested that the specimens be selected on a run by run basis so that the ..... goes progress at an acceptable rate during Phase 1.

PILOT STUDY

The MDPH proposes two pilot studies. The first will involve at most ten

people and will evaluate, on a very preliminary basis, interviewing techniques specimen taking techniques, etc. No samples will be sent to CDC in this pilot.

The second pilot will be a more formal one and will involve at least 100 people. This pilot will evaluate the complete system in terms of interview techniques, specimen acquisition, specimen movement, laboratory analysis, etc. CDC will receive ten percent of these specimens for analysis. None of the data obtained during the second pilot will be included in the final data set for New Bedford.

SPECIMEN HANDLING AT CDC

CDC will be responsible for the analysis of at least 10% (blind duplicates) of the specimens received from the MDPH for PCBs using packed column, gas chromatography. The main objective is to provide check analysis of the MDPH data. CDC cannot commence analysis until MDPH has completed ten analytical runs. The SAB (CEH,EHLS) will be responsible for ranking of the unknown specimens and insertion of the blind quality control specimens. SAB will use a systematic approach in their selection of specimens to be analyzed by CDC, i.e., every tenth specimen. [Note: Once the analyses are complete if none of the specimens contain PCBs at concentrations > 30 ppb additional analyses will be done preferentially selecting specimens whose PCBs concentrations are > 30 ppb as reported by MDPH]. The bench quality control material will be inserted by the analyst. The make up of each analytical run at CDC will be the same as MDPH, i.e. number of unknown patient specimens, number of blind QC material and number of bench QC material for both Aroclors 1242 and 1254.

TRANSMISSION OF DATA VIA GENERAL COMMUNICATION BETWEEN LABORATORIES

A combination of two systems LOTUS-1-2-3 (File Structure) and SMARTCOM II (Data Transmission) will serve as a means of communication between MDPH and CDC. Transmissions at CDC will be received on an IBM PC XT. Communication

from MDPH will be initiated by Ms. Kathleen Gallagher. Once data have been generated and reviewed by MDPH they will be transmitted to CDC on a run basis for data review. The format used must include the following information: 1) I.D. # for cohort; 2) Lab sample I.D.; 3) date sample collected; 4) date sample received in lab; 5) Analysts name or initials; 6) Analysis date, Extraction and GC; 7) GC, I.D., 8) Total Aroclor results (ppb) 1242, 1254 and individual peak (ppb) (Webb-McCall ID); 9) Comments.

APPENDIX A

Quality Control Material Available for the New Bedford Project

Tool I.D.	Analytes (ppb) PCBs (as AR 1254)	Chlorinated Hydrocarbons[1]	Purpose	Frequency of use per Analytical Run
New Bedford BBB	No	No	Serves as a reagent blank for the analytical system	One sample per run
New Bedford CHB	No	Yes	Monitors the carryover of chlorinated hydrocarbons in the PCB fraction following adsorption chromatography	One sample per run
New Bedford Low Bench Control	25	Yes	Monitors the "recovery" of in vivo PCBs in the presence of chlorinated hydrocarbons	One sample in alternate runs
New Bedford High Bench Control	100	Yes	Monitors the "recovery" of in vivo PCBs in the presence of chlorinated hydrocarbons	One sample in alternate runs
New Bedford Low External Blind Control	10	Yes	Monitors the "recovery" of in vivo PCBs in the presence of chlorinated hydrocarbons	One sample in alternate runs
New Bedford High External Blind Control	50	Yes	Monitors the "recovery" of in vivo PCBs in the presence of chlorinated hydrocarbons	One sample in alternate runs
Goat Serum (AR 1242)	20	No	Monitors the "recovery" of in vivo PCBs	One sample per run

[1]HCB (0.6 ppb), g-HCCH (0.6 ppb), oxychlordane (0.5 ppb), Heptachlor Epoxide (0.5 ppb), trans-Nonachlor (0.6 ppb), pp'-DDE (19.1 ppb), Dieldrin (0.5 ppb) and pp'-DDT (1.0 ppb)

MONS 028007

Appendix B

Preparation of Select Reagents

Anhydrous Sodium Sulfate

Prerinse all glassware with acetone, then hexane and allow to air dry before use.

To a one liter beaker add approximately one half of its volume with sodium sulfate. Add an adequate amount of "nanograde" hexane to create a slurry. Stir with a glass stirring rod and decant the hexane. Repeat these steps for a total 6 washes. Using a wide diameter funnel, pour approximately equal amounts of the washed sodium sulfate into two 500 ml glass reagent bottles. Wash out beaker and funnel with small amounts of hexane . Stopper the bottles with DMCS treated glass wool and invert over a glass beaker until all excess hexane is drained. Remove the remaining hexane by placing the bottles in a vacuum Remove the remaining hexane by placing the bottles in a vacuum oven at 30°C overnight. Store the hexane washed sodium sulfate in 130°C oven. Remove as needed and allow sufficient time to cool in a vacuum dessicator before use.

Water for Reactivation of Silica Gel

Prerinse all glassware with acetone, then hexane and allow to air dry before use. To a 200 ml separatory funnel with glass stopper and teflon stopcock add 100 ml of deionized water and 25 ml of "nanograde" hexane. Extract the water by gentle (to avoid emulsion) inversion several times. Allow the phase to separate, and drain the water into another sepa.. -- funnel. Discard the hexane extract. Repeat the extraction two more times discarding the hexane extract after each extraction. After the third extraction drain the water into a clean container for storage. Monitor the water for signs of bacterial growth, at which time the water should be discarded.

MONS 028008

Appendix C

Quantitation of Peaks 203-232 in Aroclor 1254

The VISTA 402 data system being used by CDC has a grouping function that allows peaks to be grouped and the area reported as a group with the retention time reported as the midpoint.

The LC100 integrator being used by MDPH does not have a grouping function. In order that the treatment of peaks 203-232 be as comparable as possible among the laboratories, the following procedure will be used by MDPH for quantitation of these peaks:

Assign the mean weight percent value of 1.8 to the 203 peak, to the remaining peaks (four in most gas chromatographic systems) aliquot (equally) among the peaks the remaining 1 percent, i.e. each peak would be assigned a mean weight percent value of 0.25 (if 4 peaks are present).

APPENDIX D

Log Sheet Codes for Changes in Method

Extraction (changes in)

E1 = volume of serum
E2 = size of culture tube
E3 = volume of methanol
E4 = lot of methanol
E5 = volume of hexane-ethyl ether
E6 = ratio of hexane to ethyl ether
E7 = lot of ethyl ether
E8 = lot of hexane
E9 = extraction time
E10 = rate of rotary mixer
E11 = centrifuge conditions
E12 = number of extraction times
E13 = concentration method
E14 = glassware cleanup
E15 = miscellaneous; describe fully in notebook

Adsorption Chromatography (changes in)

AC1 = amount of silica gel
AC2 = size of column
AC3 = deactivation procedure
AC4 = lot of hexane
AC5 = volume of prewash
AC6 = volume of elution
AC7 = concentration method
AC8 = miscellaneous; describe fully in notebook

APPENDIX D - continued

Gas Chromatography (changes in)

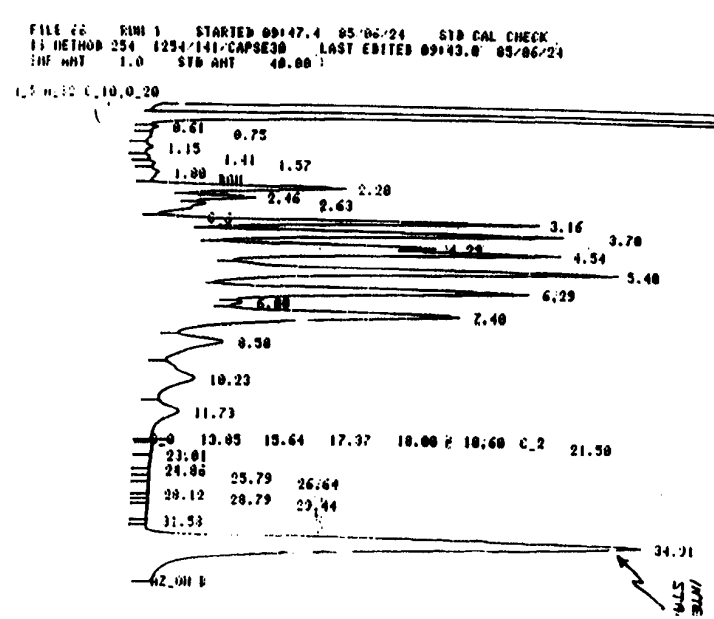
G1 = septum
G2 = carrier gas cylinder
G3 = rate of carrier gas
G4 = number of syringe washes
G5 = volume of syringe washes
G6 = syringe
G7 = marked change in base frequency
G8 = detector baked out
G9 = temperature program
G10 = marked change in retention time
G11 = from N_2 std to N_2 high
G12 = from N_2 high to N_2 std
G13 = current range change
G14 = column repacked
G15 = volume injected
G16 = detector temperature
G17 = injector temperature
G18 = miscellaneous; describe fully in notebook

Quantitation (changes in)

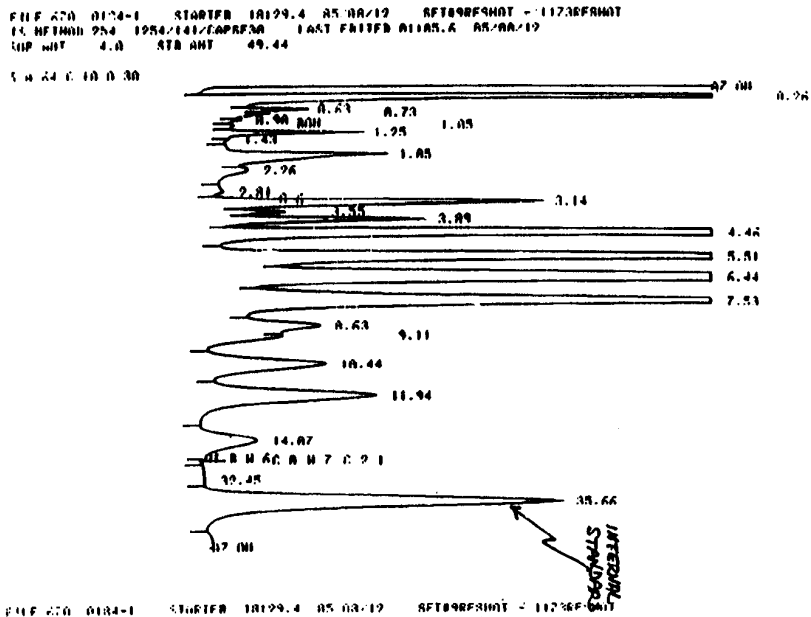
Q1 = number of standards/run
Q2 = method of calculating calibration factor
Q3 = order standards analyzed in run
Q4 = Data system conditions such as thresholds, forced baseline tie grouping etc.
Q5 = miscellaneous; describe fully in notebook

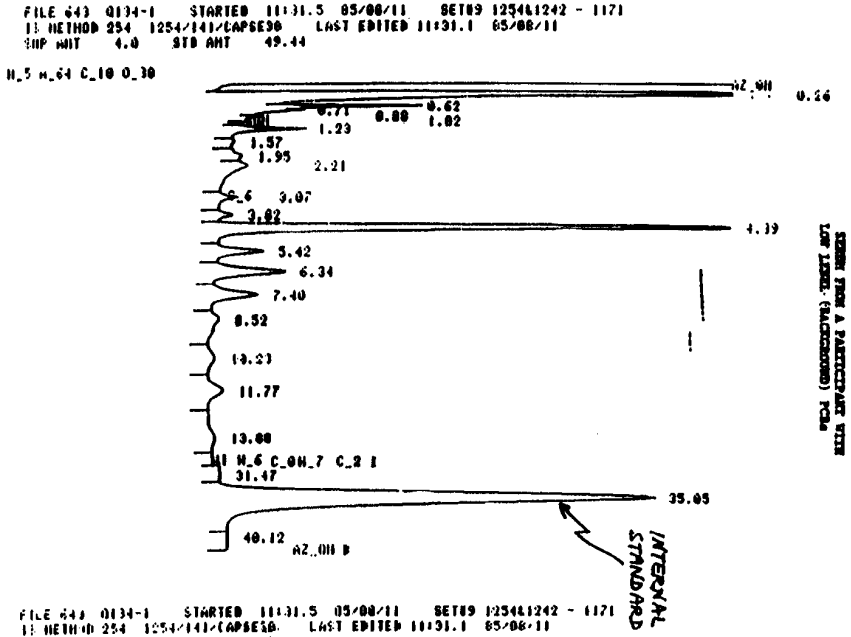
APPENDIX EE

CHROMATOGRAMS



CALIBRATION STANDARD FOR AROCLOR 1254


INTERNAL STANDARD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II METHOD 254 1254/141/CAPSE30 LAST EDITED 11:31.1 85/08/11
SHP WHT 4.0 STD AMT 49.44
H_5 H_64 C_10 O_30
AZ_00
0.26
0.71
0.80
0.62
1.02
1.23
1.57
1.95
2.21
3.07
3.82
4.39
5.42
6.34
7.40
8.52
10.23
11.77
13.60
31.47
35.05
40.12
AZ_00
INTERNAL STANDARD
FILE 644 0134-1 STARTED 11:31.5 85/08/11 SET#9 12544:1242 - 1171
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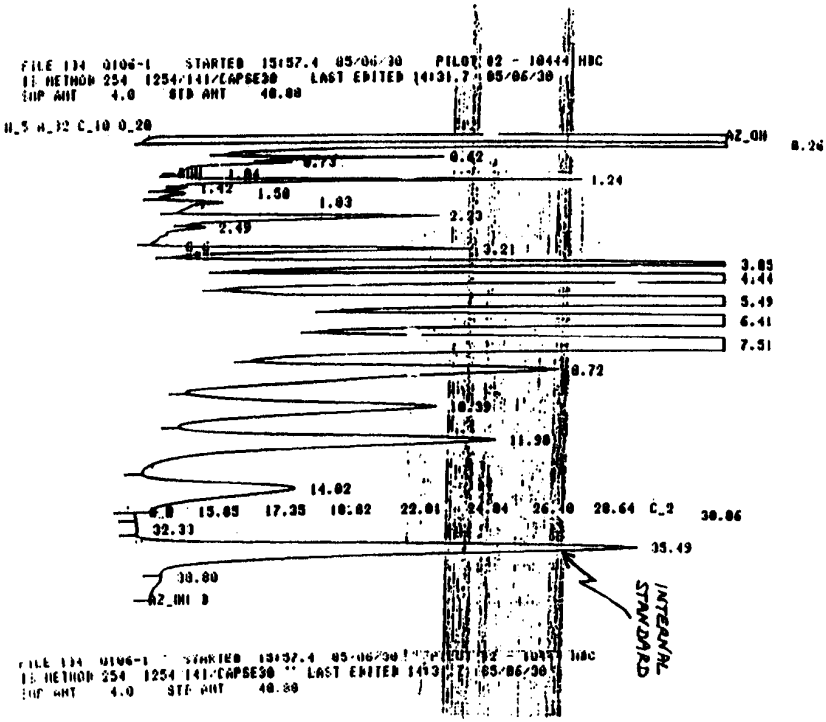
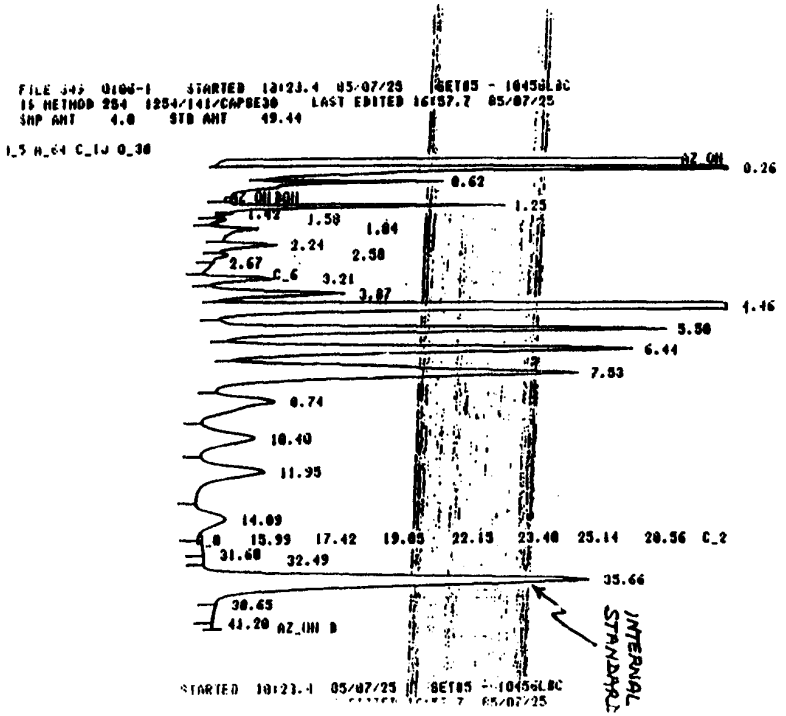
MONS 028015



FOR LEVEL FOR QUALITY CONTROL SAMPLE



LAW LEVEL PCB QUALITY CONTROL SAMPLE

APPENDIX FF

REASON FOR REFUSAL

APPENDIX FF

REASON FOR REFUSAL

01	Too busy: No time (I just don't have the time.")	167	=	26.3%
02	Not interested ("I'm just not interested.")	92	=	14.6%
03	Concern about privacy or confidentiality (I just don't do surveys.")	1	=	.2%
04	Tired of surveys; Doesn't want to be a guinea pig	1	=	.2%
05	Aids	1	=	.2%
06	Fear of giving blood (and/or fear of needles); Doesn't want to give blood	35	=	5.5%
07	Physical/medical/emotional reasons	54	=	8.5%
08	Cannot fast because of physical condition	2	=	.3%
09	Physician advises against it	1	=	.2%
10	"I haven't had anything to do with PCB's anyway."	1	=	.2%
11	"There is nothing to do about PCB's anyway."	2	=	.3%
12	Information put out that there was not a problem	0		
13	Logistical details: car, small children, invalid relatives, etc.	8	=	1.3%
14	Cannot get time off from work	0		
15	Spouse doesn't want respondent to do it	4	=	.6%
16	The put-off ("Not now; maybe later.")	5	=	.8%
17	The hang-up with no reason	5	=	.8%
18	No clear reason given ("I just don't want to.")	150	=	23.6%
19	Any other specific reason not listed above	48	=	7.6%
20	People whom we declared Final Refusals after contact efforts produced no result. Contact efforts included 10 or more calls, 3 or more Home Visits scheduled for morning, evening, and Saturday, and/or 4 or more No Show appointments, in addition to certified letters. (8/3/86)	28	=	4.4%
21	Initial Refusals who were declared Final Refusals without a second call because of the need to finalize all data. (8/6/86)	7	=	1.1%
	Missing reason	23	=	3.6%

APPENDIX GG

CHLORINATED PESTICIDES

APPENDIX GG

Prevalence of Chlorinated Pesticides in the Serum of a Subset of the New Bedford Cohort

Prevalence of Chlorinated Pesticides In the Serum of a Subset of the New Bedford Cohort

Introduction

The Greater New Bedford PCB Health Effects Study was designed to assess the prevalence of elevated serum levels ($\geq$ 30ppb) of PCBs among the residents of the Greater New Bedford area and to determine if PCBs concentration is associated with elevated blood pressure. In a cooperative agreement between the Massachusetts Department of Public Health (MDPH) and the Centers for Disease Control (CDC), CDC analyzed approximately 10% of the New Bedford cohort, comprising Phase 1, for PCBs.

In addition to determining PCBs, CDC also agreed to determine chlorinated pesticides. The chlorinated pesticides are another group of lipid soluble compounds known to accumulate in body tissues and fluids of the general population. Although these compounds were not implicated in the environmental assessment of the Acushnet River estuary it was decided that because of the possible confounding effects these compounds could have on the interpretation of PCB health effects, they should be determined. CDC agreed to analyze approximately 5% of the Phase 1 cohort for chlorinated pesticides.

The pesticides determined are those reported by the Environmental Protection Agency (EPA) as being present in the serum of the general population of the United States as indicated by the Health and Nutrition Examination Survey II Data, 1975-1980 (1).

The main objectives were: 1) To determine if the New Bedford cohort had undue exposure to chlorinated pesticides when compared to other populations; and 2) If there was a significant relationship between the serum concentration of PCBs and chlorinated pesticides in the New Bedford cohort.

Analytical Methods

The chlorinated pesticides determined were: hexachlorobenzene (HCB), p,p'-DDE (DDE), gamma-BHC (γ-BHC), beta-BHC (β-BHC), oxychlordane (OC), heptachlor epoxide (HE), trans nonachlor (TN), o,p'-DDT [DDT(op)], p,p' [(DDT(pp)], dieldrin (HEOD), and endrin (END). Residues of these compounds in serum would be an indication of either past or current exposure to them.

Specimens were analyzed in three seperate analytical runs. Each run contained one blind quality control specimen. This specimen was prepared to mimic general population sera in terms of concentration and presence of chlorinated pesticides. Two bench quality control specimens were added by the bench chemist to each analytical run. Chlorinated pesticides were determined using the following analytical method. Serum samples were denatured with methanol and extracted with a 1:1 mixture of hexane and ethyl ether. The extracts were cleaned up using adsorption chromatography (Florisil®). Two fractions were collected from Florisil, 6% ethyl ether in petroleum ether and 15% ethyl ether in petroleum ether. The 6% fraction was cleaned up using an acid wash and further adsorption chromatography(silica gel). Two fractions were collected from silica gel, hexane (Fraction I) and benzene (Fraction II). This analysis scheme resulted in three fractions that were analyzed by gas liquid chromatography using electron capture detection. The following analytes elute in these designated fractions:

Adsorbent	Fraction	Analytes
Florisil®	II	Dieldrin, Endrin
Silica Gel	I	Hexachlorobenzene, p,p'-DDE, PCBs
Silica Gel	II	γ-BHC, δ-BHC, Oxychlordane, Heptachlor Epoxide, Trans-Nonachlor, o,p'-DDT, pp'-DDT

Fractions were analyzed under the following gas chromatographic conditions:
1) Fraction II - Florisil® - Trans-Nonachlor used as an internal standard for gas chromatographic determination.

Instrument - Perkin-Elmer Sigma 1
GC Column - 6' x 2 mm (i.d.) glass column packed with 1.5% SP-2250/1.95% SP-2401 on 100/120 Supelcoport
GC Column temperature - 210°C
Carrier gas and flow - 95% Argon/5% Methane - 20 mL/min
Scavenger gas and flow - 95% Argon/5% methane - 20 mL/min
Injection Port - 225°C
ECD type-temperature ^{63}Ni - 325°C
Electrometer Range - 1
Attenuation - 1

2) Fraction I - Silica Gel - Decachlorobiphenyl used as an internal standard for gas chromatographic determination -

Instrument - Varian 3700 GC (CDS 111C)

GC Column - 6' x 2 mm (i.d.) glass column packed with 3% SE-30 on 80/100 Gas Chrom Q

GC Column temperature - 205°C

Carrier gas and flow - Nitrogen - 20 mL/min

Injection port - 250°

ECD type - temperature ^{63}Ni - 330°C

Electrometer Range - 10

Attenuation - 8

3) Fraction II - Silica Gel - Mirex used as an internal standard for gas chromatographic determination -

Instrument - Varian 6000 GC (VISTA)

GC Column - 6' x 2 mm (i.d.) glass column packed with 1.5% SP-2250/1.95% SP-2401 on 100/120 Supelcoport

GC Column temperature - 220°C

Carrier gas and flow - nitrogen - 30 mL/min

Injection port - 225°C

ECD type - temperature ^{63}Ni - 300°C

Electrometer Range - 10

Attenuation - 8

Results

Quality control statistics obtained during the analysis of the 5% subset of the New Bedford cohort for chlorinated pesticides are presented in Table 1. All values obtained on the quality control specimens were within the 99% control limits.

Analysis of approximately 5% of the New Bedford cohort in Phase 1 resulted in 45 sera to be evaluated for chlorinated pesticides. A summary of the pesticides found and their relationship to the general population - NHANES II Data (1) is shown in Table 2. Detectable amounts of HCB and DDE were found in all 45 specimens. B-BHC, OC TN, and DDT(pp) were detected in some of the specimens, while no detectable amounts of HE, HEOD END, γ-BHC, and DDT(op) were found in any of the specimens. While the percentages of specimens above

detection limits were considerably higher for HCB, OC, and TW in the New Bedford cohort than in the NHANES National survey, this may be attributed to differences in analytical methods that result in lower detection limits for the analytical method used in this study. Comparison of the percentages of specimens above the detection limits used for NHANES shows the New Bedford cohort to have lower prevalence of detectable amounts of all chlorinated hydrocarbons than did the NHANES cohort.

Conclusion

Although comparisons with the general population from NHANES II Data are confounded by differences in analytical techniques, the median concentration of the chlorinated pesticides in this subset would not be considered indicative of unusual exposure to these compounds. Dichlorodiphenyldichloroethylene (DDE) has the highest median concentration, 4.06 ppb, the median concentrations for the other pesticides are less than 1.0 ppb. The lack of detectable amounts of the various chlorinated hydrocarbons precluded correlation analyses with PCB levels, with the exception of HCB and DDE. The log of HCB and DDE concentrations were significantly correlated with the log of PCB concentration: $r = 0.372$ $p = 0.0118$, $n = 45$ for HCB; and $r = 0.494$, $p = 0.0006$, $n = 45$ for DDE. All chlorinated hydrocarbons examined did parallel the serum PCB concentration in that the prevalence of elevated levels is low.

References

1. Murphy, R., and Harvey, C. "Residues and Metabolites of Selected Persistent Halogenated Hydrocarbons in Blood Specimens from a General Population Survey" Environmental Health Perspectives 10, pp. 115-120, 1985.

Table 1. Quality Control Statistics for Chlorinated Hydrocarbon Pesticide Analyses

Analyte	Characterized Values (n=20)		ANALYTICAL RUN #1	ANALYTICAL RUN #2	ANALYTICAL RUN #3
	X	S.D.			
HCB	0.674	0.064	0.556	0.536	0.376
DDE	5.64	0.522	5.82	5.19	4.64
γ-BHC	0.530	0.104	0.426	0.682	0.340
β-BHC	0.601	0.142	0.436	0.685	0.380
OC	0.749	0.096	0.685	0.828	0.595
HE	0.999	0.147	0.718	0.862	0.644
TN	0.942	0.117	0.861	0.897	0.651
DDT (p,p')	2.00	0.706	1.73	1.74	0.628
HEOD	1.16	0.128	1.06	0.998	1.00
END	1.24	0.196	1.00	1.22	1.00

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Table 1. Results of chlorinated hydrocarbon pesticide analyses for 5% subset of Phase I. NHANES (National Health and Nutrition Examination Survey) reference ranges are given for comparison purposes (Murphy and Harvey, 1983, Environmental Health Perspectives, Vol. 60: 115-120). The last two columns show the % of the New Bedford samples which were above the detection limit used in NHANES, and the median of the values above that detection limit. These figures may be directly compared to the NHANES results in the previous two columns.

						NANES ref. ranges			
Analyte	n	min (ppb)	max (ppb)	median (ppb)	% > DL*	NHANES % > DL	NHANES median > DL (ppb)	% > NHANES DL	median >NHANES DL ppb
hexachloro-benzene	45	0.065	0.289	0.11	100	3.1%>1ppb	1.7	0%>1ppb	----
p,p -DDE	45	0.595	30.5	4.06	100	99%>1ppb	11.8	96%>1ppb	4.11
beta-BHC	45	<0.16	0.508	<0.24	20	14%>1ppb	1.7	0%>1ppb	----
oxychlor-dane	45	<0.12	0.445	<0.18	13	2.3%>1ppb	1.4	0%>1ppb	----
heptachlor epoxide	45	<0.11	<0.18	<0.17	0	2.3%>1ppb	1.3	0%>1ppb	----
trans-nonachlor	45	<0.146	0.977	<0.24	44	4.4%>1ppb	1.4	0%>1ppb	----
dieldrin	45	<0.21	<0.44	<0.29	0	8.6%>1ppb	1.4	0%>1ppb	----
endrin	45	<0.24	<0.53	<0.36	0	----------	---	--------	----
p,p -DDT	45	<0.35	3.71	<0.52	7	31%>2ppb	3.3	2%>2ppb	3.71
gamma-BHC	45	<0.05	<0.10	<0.07	0	----------	---	--------	----
o,p -DDT	45	<0.10	<0.44	<0.30	0	----------	---	--------	----

* DL = lower detection limit

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APPENDIX HH

1242 SERUM PCB LEVELS

APPENDIX HH

Aroclor 1242 Serum PCB Levels[1]

for Participants in the Prevalence Study

Serum PCB Level (ppb)	Number of Sera
< 2	656
2 - 9.9	62
10 - 19.9	3
20 - 29.9	0
≥ 30	2
	723 [2]

(1) Quantitation of serum PCBs as Aroclor 1242 was complicated by a "contaminant" peak often observed (approximately 70% of samples) in the area of gas chromatographic peaks designated as Webb-McCall peaks 37, 47, 54, and 58. Investigation of this broad "contaminant" peak determined that the peak was not introduced during shipping or handling of specimens. Mass spectral characterization and gas chromatographic analysis with electron capture detector and electrolytic conductivity detector determined that the peak was neither a PCB nor a chlorinated hydrocarbon compound. Inclusion of the Webb-McCall peaks 37 thru 58 in the quantitation scheme would have overestimated significantly actual PCB concentration when the contaminant peak was present in a sample. Therefore these peaks were not included in quantitation of the serum PCB levels as Aroclor 1242. On average, the exclusion of these peaks cause an estimated 10% underestimate of the serum PCB level.

(2) 723 of the 840 sera from participants in the Prevalence Study were quantitated for serum PCBs as Aroclor 1242. 116 sera were not quantitated because either an Aroclor 1242 control serum was not included in the analysis (5 analytical runs) or the AR 1242 control serum value fell outside the 99% confidence limits established for quality control (2 analytical runs). One serum was unable to be quantitated as AR 1242 as a result of instrument failure.

APPENDIX II

CORRELATIONS

APPENDIX I I

CORRELATION TABLE PREVALENCE DATA FOR BLOOD PRESSURES

VARIABLE	N	MEAN	STD DEV	SUM	MINIMUM	MAXIMUM
LEVEL	840	5.8760	7.78377	4938.16	0.3000	154.2000
MASS	774	25.9135	4.97756	20057.05	16.6819	50.0068
AGE	840	39.4487	13.37746	33136.00	18.0000	68.0000
SYSBP1	837	115.2567	18.63526	96460.00	70.0000	226.0000
SYSBP2	834	113.6611	17.62423	94810.00	76.0000	228.0000
SYSBP3	836	114.2679	17.33047	95528.00	69.0000	216.0000
DIABP1	837	73.4898	11.41429	61511.00	36.0000	120.0000
DIABP2	834	72.1799	10.94157	60178.00	40.0000	120.0000
DIABP3	836	73.1734	10.94676	61173.00	46.0000	112.0000

CORRELATION COEFFICIENTS / PROB > |R| UNDER HO:RHO=0 / NUMBER OF OBSERVATIONS

	LEVEL	MASS	AGE	SYSBP1	SYSBP2	SYSBP3	DIABP1	DIABP2	DI
LEVEL PCB LEVEL 1254	1.00000 0.0000 840	0.08785 0.0165 774	0.32627 0.0001 840	0.20046 0.0001 837	0.18746 0.0001 834	0.18627 0.0001 836	0.15837 0.0001 837	0.09485 0.0043 834	0.1 0.
MASS BODY MASS-METRIC	0.08785 0.0165 774	1.00000 0.0000 774	0.24361 0.0001 774	0.35126 0.0001 774	0.38484 0.0001 771	0.34966 0.0001 773	0.38488 0.0001 774	0.38576 0.0001 771	0.3 0.
AGE	0.32627 0.0001 840	0.24361 0.0001 774	1.00000 0.0000 840	0.50779 0.0001 837	0.48761 0.0001 834	0.48282 0.0001 836	0.36130 0.0001 837	0.33618 0.0001 834	0.3 0.
SYSBP1	0.20046 0.0001 837	0.35126 0.0001 774	0.50779 0.0001 837	1.00000 0.0000 837	0.80435 0.0001 834	0.64877 0.0001 836	0.72763 0.0001 837	0.65868 0.0001 834	0.6 0.
SYSBP2	0.18746 0.0001 834	0.38484 0.0001 771	0.48761 0.0001 834	0.80435 0.0001 834	1.00000 0.0000 834	0.67858 0.0001 834	0.67726 0.0001 834	0.78416 0.0001 834	0.6 0.
SYSBP3	0.18627 0.0001 836	0.34966 0.0001 773	0.48282 0.0001 836	0.64877 0.0001 836	0.67858 0.0001 834	1.00000 0.0000 836	0.66394 0.0001 836	0.66185 0.0001 834	0.7 0.
DIABP1	0.15837 0.0001 837	0.38488 0.0001 774	0.36130 0.0001 837	0.72763 0.0001 837	0.67726 0.0001 834	0.66394 0.0001 836	1.00000 0.0000 837	0.81244 0.0001 834	0.7 0.
DIABP2	0.09485 0.0043 834	0.38576 0.0001 771	0.33618 0.0001 834	0.65868 0.0001 834	0.78416 0.0001 834	0.66185 0.0001 834	0.81244 0.0001 834	1.00000 0.0000 834	0.7 0.
DIABP3	0.10929 0.0014 834	0.34448 0.0001 773	0.32139 0.0001 836	0.63641 0.0001 836	0.66237 0.0001 834	0.71242 0.0001 836	0.77171 0.0001 836	0.77918 0.0001 834	1.0 0.

APPENDIX JJ

DATA ANALYSIS

Appendix JJ

Data Analysis

The data analyses for the Greater New Badford Health Effects Study was programmed on the mainframe at the Massachusetts Department of Public Health. All programming for the study was completed using the Statistical Analysis System (SAS) software package. The following modules of SAS were used in the analyses.

1) Proc Freq.....Frequencies,Tables

2) Proc Univariate....Means,Medians,Standard Deviations,Range, Minimum,Maximum,N,Variance

3) Proc GLM.....Regression Analyses

4) Proc Corr.....Pearson Correlations

5) Proc Ttest.....Ttests,Standard Deviations,Standard Error

6) Proc Means.....Mean Values

7) Proc Sort.....Sort Values

8) Proc Print.....Print Values

APPENDIX KK

QUALITY CONTROL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

APPENDIX KK

April 9, 1987

Ralph Timperi
State Laboratory Institute
305 South Street
Jamaica Plain, MA 02130

Dear Ralph:

Here is the section for the New Bedford final report which summarizes the quality control from CDC's perspective. The analytical protocol is attached as an appendix to the report and gives details for anyone who might want to refer to it. The QC section simply summarizes the approach and gives the overall results of the inter-laboratory comparisons and QC monitoring.

In the QC section, references are made to the analytical protocol as an appendix, and to 6 figures which I left unnumbered, not knowing how the other figures for the final report were numbered. The first two are the MDPH QC means charts for 1254 and 1242. The next two are to be similar QC means charts for CDC. However, our plotter died just before getting these two figures, so I will have to send them to you later after it is fixed. The last two figures are scatter plots showing the comparison between CDC and MDPH for 1254 and 1242.

Per Dayton's request, Virlyn has also written up a brief paragraph about to be inserted at the appropriate place in the final report. I'm not sure that it fits in the QC section. Perhaps you can determine where it should best be placed.

I will be sending you the CDC QC charts as soon as I can get them plotted. We will be looking forward to receiving your laboratory portion of the final report to review. Let us know your comments on our portion.

Sincerely yours,

Don Phillips

Donald L. Phillips, Ph.D.
Supervisory Mathematical
Statistician
Special Activities Branch
Division of Environmental Health
Laboratory Sciences
Center for Environmental Health

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(Paragraph giving brief description of specific congener and chlorinated hydrocarbon analysis)

In addition, CDC has made a commitment to provide capillary gas chromatography analysis (congener specific) using electron capture detection and mass spectrometry confirmation for polychlorinated biphenyls in the twenty-five highest specimens of the New Bedford cohort.

CDC has also made a commitment to determine the concentration of the most commonly occurring chlorinated hydrocarbons (as determined by the Environmental Protection Agency from the National Health and Nutrition Examination Survey II) in the same group (twenty-five) in addition to determining these analytes in five percent of the New Bedford cohort included in the prevalence study. These determinations are pending and will be added to the report at a later date.

QUALITY CONTROL

validated analytical procedure for the determination of PCB's in serum was transferred from CDC to MDPH. Subsequent quality assurance for the MDPH analyses of PCB levels followed a multi-phase approach. First, the comparability of the MDPH and CDC laboratories was established using in vitro and in vivo spiked sera analyzed by both laboratories. Second, quality control limits were established for each laboratory from multiple analytical runs to characterize the QC materials used throughout the study. These limits were updated after an additional 20 analytical runs. Quality control rules were established to reject analytical runs when these limits were exceeded. Third, the CDC laboratory analyzed a subset of the specimens analyzed by the MDPH laboratory and comparability of results was monitored continuously throughout the study. Additional details on the QC procedures may be found in Appendix CD, Analysis Protocol for PCB's and Other Chlorinated Compounds of Environmental Concern: CDC - New Bedford.

The criteria for laboratory comparability for the in vitro and in vivo spiked pools were:

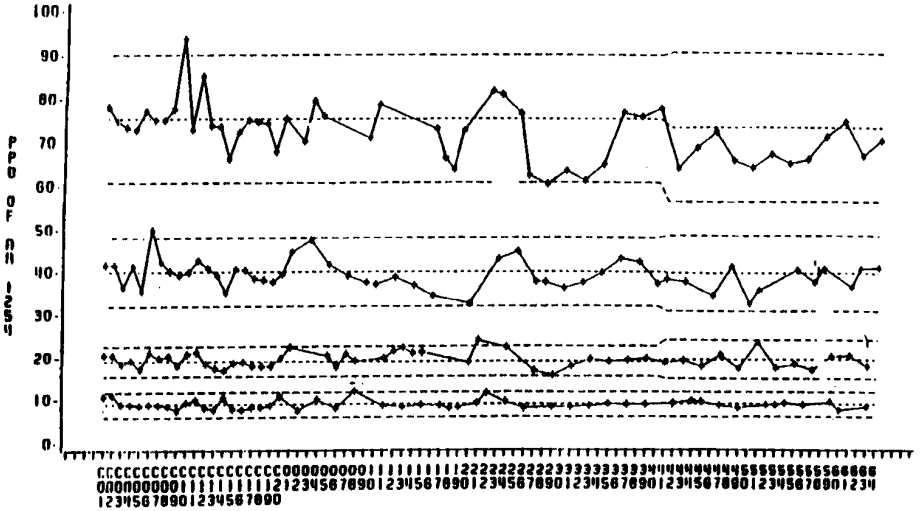
a) MDPH bias for the mean of less than 15% from the target value (in vitro only) and from the CDC mean for concentrations over 20 ppb
b) MDPH bias for the mean of less than 25% from the target value (in vitro only) and from the CDC mean for concentrations under 20 ppb
c) MDPH CV of less than 15% for concentrations over 20 ppb
d) MDPH CV of less than 25% for concentrations under 20 ppb

These levels of comparability were satisfactorily met for the in vitro and in vivo spiked serum pools for Aroclor 1254. These requirements were also essentially met for Aroclor 1242 as pre-DDE peaks 70 + 78/84 (MDPH biases from the target values and CDC means for the in vitro pools ranged from 24 to 27 %). Quality control limits were calculated for the in vivo pools which were used in the analytical runs during the study. These limits were updated after an additional 20 analytical runs. The limits and the observed values for these quality control pools for all MDPH analytical runs during the study are shown on Figure 1 for Aroclor 1254 and Figure 2 for Aroclor 1242. Runs C01 through C20 are the pre-study characterization runs used to set the QC limits. Runs 22 and 23 for Aroclor 1242 fell outside the QC limits and no Aroclor 1242 values were used from these runs. Runs 8 and 18-19 had no Aroclor 1242 QC pool included so no Aroclor 1242 values were used from these runs either. The limits and observed quality control pool values for the CDC analytical runs are shown on Figure 3 for Aroclor 1254 and Figure 4 for Aroclor 1242.

The CDC laboratory analyzed for PCB, in parallel with the MDPH laboratory, duplicate specimens from the pilot and a 10% random subset from Phase I and the Enrichment sample. In addition, specimens which were found to have greater than 15 ppb Aroclor 1254 by MDPH were also analyzed by CDC. For these specimens, the median bias and percent bias for MDPH values compared to CDC values were -1.12 ppb and -16.7 %, respectively for Aroclor 1254, and -0.33 ppb and -27.1 % for Aroclor 1242. Figures 5 and 6 show scatter plots of the MDPH values vs. the CDC values for the specimens analyzed by both laboratories for Aroclors 1254 and 1242, respectively.

GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY

AROCLOR 1254 IN VIVO POOLS QC MEANS CHART
MEANS AND 99% LIMITS ARE SHOWN
LIMITS ESTABLISHED FROM 20 CHARACTERIZATION (C) RUNS
LIMITS UPDATED AFTER 20 ADDITIONAL RUNS



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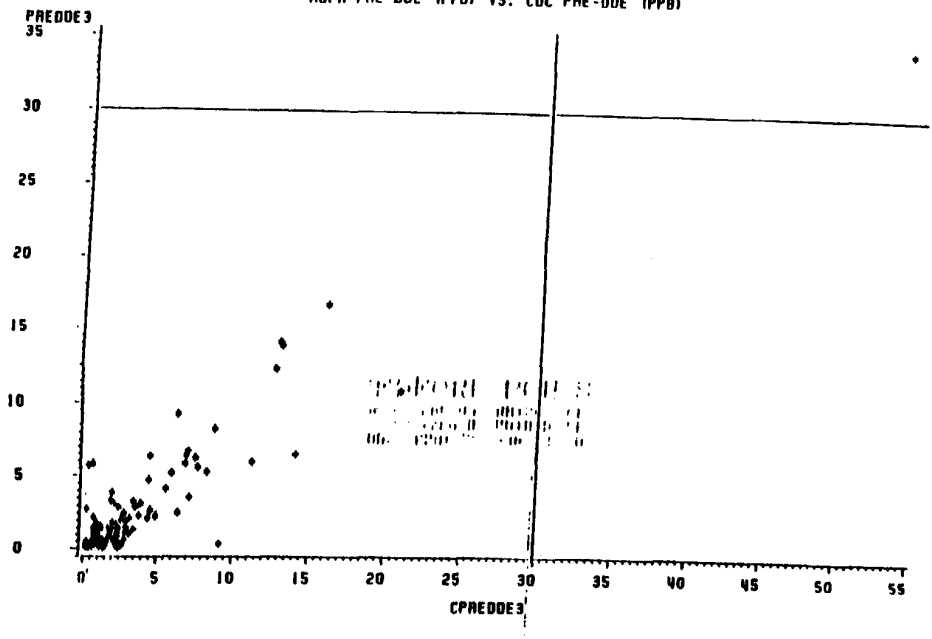
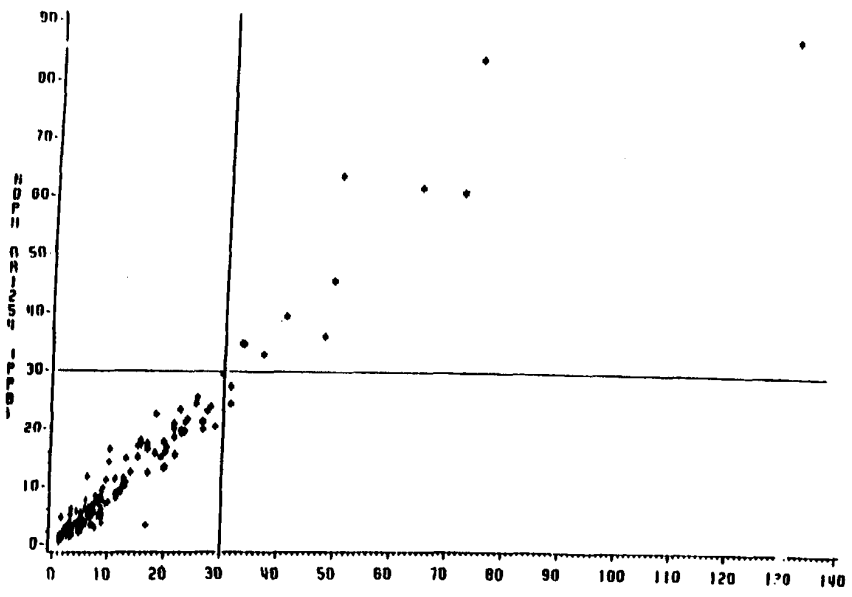
NEW BEDFORD PCB STUDY

COMPARISON OF PRE-DDE AR1242 VALUES FOR SPECIMENS ANALYZED BY BOTH NDPH AND CDC
NDPH PRE-DDE (PPB) VS. CDC PRE-DDE (PPB)



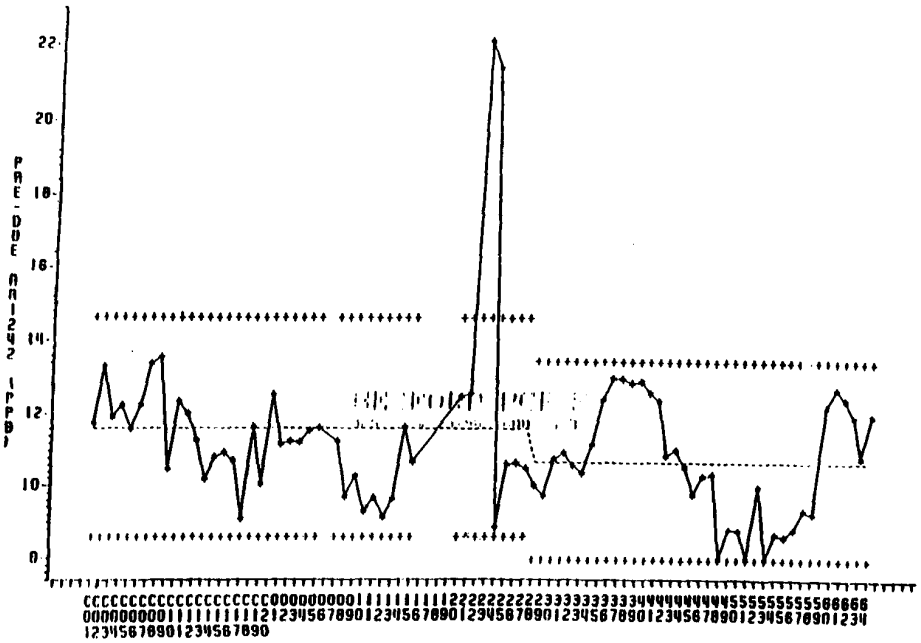
NEW BEDFORD PCB STUDY

COMPARISON OF AR1254 VALUES FOR
SPECIMENS ANALYZED BY BOTH MDPH AND CDC
MDPH AR1254 (PPB) VS. CDC AR1254 (PPB)



NEW BEDFORD PCB STUDY

MDPH PRE-DDE (PEAKS 70 & 78/80) GOAT SERUM QC MEANS CHART



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APPENDIX LL

PEER REVIEW

GREATER NEW BEDFORD HEALTH EFFECTS STUDY

Report of the Peer Review Committee

January 16, 1987

A six member peer review committee was established by the Massachusetts Health Research Institute (MHRI) to evaluate the preliminary draft report on the Greater New Bedford Health Effects Study project which was conducted collaboratively by the MHRI, the Massachusetts Department of Public Health and the Centers for Disease Control over the past two years. Disciplines represented by the peer committee include: medicine, toxicology, epidemiology, public health science, statistics, chemistry and laboratory science. Peer committee members are listed in Appendix A.

The Committee met December 15, 1986 in Boston MA, with staff of the collaborative agencies, briefed on the history and background of the New Bedford project, presented with a rough draft documentation report on work accomplished during phase I of the project and requested to professionally critique the work and documentation per the elements listed in the charge to the Committee shown in Appendix B. Following this meeting, the committee received a draft document titled "Dealing with Non Response: The Greater New Bedford Health Effects Study" to be included in the review.

The Committee reconvened January 15 and 16 1987 to discuss their deliberations, prepare and present a peer review report and discuss their findings with the collaborative agencies. The following report document; and fulfills the Committees' charge to professionally review the work accomplished to date as presented in the draft documents.

PEER REVIEW REPORT

1. Background Comments

The reviewers feel that the New Bedford Health Effects Study project has merit, was well designed was well planned and was competently carried out. The study protocol, procedures and forms were adequate and well documented. Contingencies were planned for potential problems areas and unexpected events handled adequately.

The technical competence behind the study effort was adequate and it is obvious that the local staff carried out this mission efficiently, enthusiastically and within the project design. The project was completed on time and the staff appeared to care about its performance and success as well as the broad need to get to the heart of the New Bedford contamination issue on behalf of the

citizens in the communities and the public health community at large.

The New Bedford study addressed a challenge which was not only difficult but controversial, emotional and highly visible (as is often the case in contemporary public health efforts). The collaborative project team is to be complemented on a thorough comprehensive job which has produced a voluminous and useful data base.

As a constructive note to the Centers for Disease Control and agencies which will perform similar efforts in the future, the peer panel regretted that its involvement came exclusively on completion of the project. Members felt that interaction at the completion of the study protocol design would have permitted constructive input prior to initiation of field and laboratory work which might have anticipated or eliminated certain output deficiencies.

II. Comments on the Specific Charges which the Review Committee considered:

1a. The peer panel feels that the project met the stated objected to determine the prevalence of PCB exposure in citizens in the greater New Bedford area. The draft report as it stands, does not clearly project this accomplishment. It is felt that the data is present but needs to be coaxed out and presented more clearly and efficiently.

1b. The peer panel does not believe that the report has presented data which determines whether or not a relationship exists between PCB serum levels and blood pressure. The panel has reservations concerning the ability to address this issue given the limited range of PCB exposure observed in this population.

2. There are additional analyses both laboratory and statistical which need to be performed. It is understood that some of these are underway. The data base appears adequate for additional manipulations which need to be performed and articulated in the report.

3. There are some missing data tables. It is important that a consistent format be chosen and used for all tables. Attention should be given to titles and table layout and labelling. The data has been collected - it needs to be organized and presented more clearly.

4. The literature citations are essentially adequate. Additional citations could be added in order to more fully explain findings, support discussion or reference general population comparisons.

5. Scientific improvement is required in terms of more thorough explanation of study findings. Additional proofs are needed

to describe analytical laboratory methodology and choice of statistical tests and to support discussions of epidemiological findings and sample selection.

6. The draft report as it stands is not ready for public release. The style and order of presentation needs reworking. Several areas of discussion need to be more thoroughly documented. findings and their comparisons more completely explained and details of omission clarification or addition described.

It is felt that the project was adequately designed, well run and established a voluminous data base. Therefore, it deserves the commitment required to produce a clear concise carefully prepared and edited report which fully presents this data. Ideally, the study findings should receive the scrutiny and acceptance of a referred medical journal prior to general release. It is recognized that public agencies may not be allowed the luxury of such an endorsement if it requires a long review period prior to publication.

As a minimum, public expectations must be met by producing an understandable and believable (documented) explanation of: what the problem was, what was done. what was found (past and present) and what all means. The project essentially provided this information. These findings must now be articulated in a forthright clear manner.

III. Broad Multi-disciplinary Comments

The report needs an executive summary understandable to non-scientists. The question of blood pressure correlation requires consideration of statistical approaches used in the literature citations, adoption of average readings rather than lowest readings and consideration of the use of hypertension medication. The pilot study needs to be considered and explained in terms of the current survey findings. Levels of contamination in harbor seafood need to be presented and the significance of eel consumption considered in data analyses. The issue of seafood consumption rates needs to be better defined with respect to serum PCB levels. The data set needs to be examined to determine whether or not the range of variation in PCB exposure found supports detailed evaluation of hypertension in this population. Blood pressure correlations with PCB exposure should consider that appearance of this toxicological effect is not linear but may have a threshold. Occupationally exposed persons and ethnic subgroups should be sorted out of the general population group for separate consideration. While the study essentially finds little evidence of excessive PCB exposure, the non response rate and non responder group characterization needs to be adequately worked up, explained, defended and factored into the overall conclusions. Statistical methods used need to be documented and defended against alternative approaches. A thorough discussion of selected analytical laboratory methodology needs to be presented. A comparison of the methodology used in 1981 and in the current study needs to be

presented and its impact explained. Analytical accuracy needs to be defined in terms of both bovine and human serum standards. Interferences found in Aroclor 1242 chromatograms need to be identified and explained as well as why PCB analyses on the basis of Aroclor 1242, 1254 or 1260 standards are adequate for human PCB exposure evaluation.

IV. Detailed Reviewer Comments

The above discussion presents broad based multi-disciplinary comments on the study findings and draft report. Detailed comments and explanation of points raised by the individual reviewers are presented in the reports in Appendix C.

APPENDIX A

MEMBERS OF NEW BEDFORD PCB HEALTH STUDY PEER REVIEW COMMITTEE

1) David Brown PhD
Epidemiologist/Toxicologist
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APPENDIX B

CHANGE TO THE REVIEW COMMITTEE

1. Does the report meet the objectives of the study as stated during the preliminary meeting?

   a. to determine the prevalence of PCB exposure among residents of Acushnet, Dartmouth, Fairhaven and New Bedford.

   b. to determine whether or not there exists a relationship between PCB serum level and blood pressure.

2. Are there additional data analyses that need to be conducted, and if so, what would you suggest needs to be added?

3. Do the tables, charts, and graphs accurately reflect the statements of the narrative report?

4. Are the reference and bibliography sections complete and are they appropriately referred to in the text?

5. What needs to be done to scientifically improve the report?

6. What needs to be done [illegible] to release the report to the Community?

APPENDIX C

Reports of Individual Review Committee Members

COMMENTS OF THE PEER REVIEW COMMITTEE
ON THE 12/86 INITIAL DRAFT OF
THE GREATER NEW BEDFORD PCB HEALTH EFFECTS STUDY
FINAL REPORT

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1) Relegate more material to the appendices.

2) Insufficient detail on a number of crucial issues including tha statistical and laboratory methodology. There needs to be a more thorough exposition of the data.

3) It is not clear what was done in the trend analyses.

4) Explain the rationale for the choice of a particular analyses.

5) Include a section on the limitations of the study.

6) The discussion and conclusion sections need to be expanded. Refer to the literature in the discussion and compare these results to the results of other studies.

7) The discussion section should relate the results to current thinking on the subject and to etiologic models if possible.

8) Provide and executive summary of not more than 10 pages to include relevant tables, background, methods, results, and conclusions.

9) Clearly state whether the investigators felt the goals of the study were met.

10) Clearly label all tables, arrange them to correspond with the text.

11) Include confidence limits or standard errors.

12) Include a reference for PCB half-life.

13) Eliminate "surprising".

14) Rather than defend a finding that was different than expected, the report should explain what was found, i.e.: relatively low serum PCB levels.

15) The study objective may be better stated as: To determine the prevalence of excess exposures to PCB's and to establish characteristics of those persons with excess exposures.

16) Table 9 and page 46, these suggest that PCB levels decrease over time?

17) Table 42 should appear earlier.

18) The protocol called for analytical tests on other chlorinated contaminants in a subset of the study group--these data are missing.

19) One cannot draw analytic conclusions from descriptive data.

20) The report should be accepted for publication by a peer reviewed journal before it is circulated to the community.

21) Additional analyses need to be performed to bolster the conclusion that the first objective was met.

22) The response rate and the non-responders need to be addressed further as there is a question of potential bias.

23) Would DPH involvement and DPH regulations promote bias?

24) The report may want to state that: Due to the way in which the study was presented to participants, i.e., that the study was of residents who may have been exposed to PCB's, it could have resulted in those with high PCB exposure being more likely to participate (indirect way of validating the null result).

25) Explain the differences in the methodologies used in the pilot study and in the current study. Did the lab over-estimate PCB levels?

26) Why was 1260 used in the pilot and 1254 used in the present study?

27) Show the contrast of levels between prevalence, enrichment and pilot participants (low, intermediate, and high consumers of local seafood).

28 Incorporate the Telles report since it appears to represent the upper boundary of consumers of local seafood.

29) The prevalence of PCB is representative only of the dates tested. On the other hand, if preliminary studies are correct then the rate of elimination seems to be over-stated. Is there an analytical problem?

30) Explain the relationship of 1254 and 1242 to total serum PCB level.

31) What is gained by separating 1254 and 1242? These are not specific compounds

32) Could the seasonal variation in seafood consumption (esp. lobster) make a difference in serum levels if the half-life for PCB was shorter than anticipated?

33) Emphasize that PCB is a group of substances.

34) Address the issue of accuracy of PCB extraction from serum samples.

35) Concern was noted over the odd peak in some of the 1242 analyses

36) Why was 30 ppb chosen as the cutoff, the report seems to have a fixation with this number.

37) It would be useful to see information on serum PCB levels by age group without being broken down by town since there is some indication of increasing levels with age, a relationship which may support the notion of long half-life for PCB and long-term bioaccumulation.

38) The slope with age suggests slow accumulation in either diet, environment or persons. In contrast, PBB Michigan and Yusho show no age trend, but PCB Michigan did show an age trend.

39) Isomers of PCB need to be identified since only certain isomers have biological activity.

40) Explain the reduction in sample size.

41) Why was a doubling of the prevalence set as a criteria for sample size estimation?

42) The estimation of PCB prevalence in some subgroups will be inadequate due to a small sample size in those subgroups.

43) Require more information about PCB as a continuous measure as well as the prevalence of levels above 30 ppb.

44) The association of PCB and blood pressure is not adequately addressed.

45) Define blood pressure variables.

46) Selecting the lowest blood pressure reading and not the mean of the readings is not the best approach clinically.

47) Smoking, drinking and dietary risk factors for high blood pressure need to be taken into account.

48) Address the issue of anti-hypertensive treatment. Generate a hypertension variable which considers those on hypertension medication to be definite hypertensives.

49) Logistic regression is inappropriate for blood pressure. Use log of bp and multiple linear regression.

50) Analyses are not the same as Kreiss/Triana nor are they comparable. Explain or redo the analyses in a like fashion to assess the PCB/blood pressure relationship.

51) It is unlikely that the effect of PCB on blood pressure is linear or that it is equivalent at all ages, it is necessary to weight the data as Kreiss does or the presence of extreme values will erfect the analyses. Kreiss corrected for this using geometric means.

52) Develop a chart which discusses all persons over the 40-64 age group. If one looks at the (preliminary) and the Kreiss reports excess blood pressure was found only in the young group in the preliminary and to less magnitude of effect in the Kreiss report at both ages.

53) What is the value of data comparing fish consumption among enrichment participants and prevalance participants? Fish consumption was chosen for so one would expect the differences.

54) Correlate the changes in fish PCB level measured with changes in human sera levels with time.

55) It would be informative to relate the prevalence rates to current models for PCB contamination with the possible implications for human beings.

56) Focus on the effects of eel ingestion.

57) What happens when composition workers, waste water workers and seafood eaters only are considered with respect to age?

58) Will inclusion of occupationally exposed persons confound the results? Since minimal changes in PCB mixture can create great differences in the type of exposure: Are the PCB's in fish the same as the PCB's in the industry? The mean and median serum PCB levels for wokers is several fold higher than for fish eaters.

59) Need to determine the prevalence for those persons with no occupational exposure

60) It would be scientifically useful if archived sera from 10-20 of the highest level participants were tested utilizing the Webb/McCall methodology used in Michigan. This provides a separation of the major PCB homologs present in the sera.

61) Women of childbearing age with elevated serum PCB levels should be warned of the risks of breast-feeding.

RESPONSE TO PEER REVIEW COMMENTS

1) Self-evident.

2) See chapter II--Methods.

3) No longer exists.

4) See chapter II--Data Analysis.

5) See chapter II--Limitations.

6) See revised Introduction, Discussion, and Conclusions.

7) See revised Discussion and Conclusions.

8) Enclosed.

9) See Conclusions.

10) See tables.

11) See chapter II--Data Analysis, also see tables and figures.

12) Discussion of PCB half-life deleted from report.

13) Done.

14) See revised chapter III--Results, chapter IV--Discussion.

15) Study objectives are clearly stated in chapter I--Introduction.

16) PCB half-life deleted from report.

17) See figures 11 and 12

18) A discussion of chlorinated hydrocarbon analyses and results are provided in appendix GG.

19) Agreed. No conclusions drawn. See chapter III--Results and chapter IV--Conclusions.

20) Papers describing major findings will be submitted prior to release of report. Report cannot be withheld from public while awaiting review and acceptance of papers.

21) See chapter II--Characteristics of the Participant Sample and chapter III--Results.

22) See chapter II--Limitations and Chapter III--Refusals.

23) See chapter II--Limitations.

24) See chapter III--Refusals.

25) Pilot study critique is not part of the objectives for the GNBHES. However, there were methodological differences in laboratory analysis The analytical methods used in 1981 and in 1985-86 differ with respect to the following: 1) Activation of silica gel; 2) deactivation of the silica gel; and 3) eluting solvent. The methods used in the 1981 study is reported in Burse et al. JAOAC 66 pp. 32-39 (1983). The method used in 1985-86 is reported in Burse et al. JAOAC 66 pp. 986-968 (1983). These two methods have been compared using the same specimens. As to the over-estimation of PCB, generally speaking a PCB residue calculated as AR 1260 would tend to be higher than the same residue calculated as AR 1254. However, this should not be a factor for those persons participating in both the 1981 and the 1985-86 studies. Their PCB level was determined again (as AR 1254) using specimens which had baen stored at CDC.

26) Present study patterns most closely resemble 1254. Rationale for choice of 1254 was not written up. In additon, without the use of analytical techniques more sophisticated then packed gas liquid chromatography, e.g. capillary gas liquid chromatography and/or Principal Component analysis the selection of an Aroclor to be used as a quantitative standard for comparison with a residue pattern is very subjective. Aroclor 1260 was chosen for the initial study in 1981 because: 1) No information was provided on suspected Aroclor exposure and 2) In our limited experience in studies involving the general population (i.e., persons without undue exposure) residue patterns look "most like" Aroclor 1260. Arclor 1254 was selected in the current study because MDPH informed CDC that this was the Aroclor against which the "fish" residues had been quantitated.

27) Pilot data were collected differently and are not comparable. However, enrichment sample is compared to prevalence controls (See figure 13).

28) Telles report was dissimilar in many ways to GNBHES. Seafood consumption was not quantified in Telles report. It is best to use data from GNBHES to estimate upper bounds.

29) See chapter II--Laboratory Measurements.

30) Quantitation of serum PCBs as Aroclor 1242 is done by comparing sample extract peaks that can be identified as Webb-McCall peaks 20 through 146. Quantitation as Aroclor 1254 is done using Webb-McCall peaks 47 through 232. Each peak has a weighted value that is related to its quantitative composition of PCB congeners. A "total PCB value" using the Aroclor 1242, 1254 standards is obtained by using AR 1242 peaks 28 84 and AR 1254 peaks 98/104 - 232, and assigning appropriate weights for each quantitation as total PCBs to either AR 1242 or AR 1254 is that weighted values are distributed over the range of possible Webb-McCall peaks 28 - 232.

31) The value of quantitating PCB levels by both AR 1242 and AR 1254 is that it allows examination of PCB trends using composite values that are indicative of more recent exposure (AR 1242) and longer term (diet?) exposure (AR 1254).

32) Cannot asnwer due to type of data collected

33) See chapter I--Introduction and chapter II--Laboratory Methods.

34) The accuracy of the serum PCB analyses in relation to Analyte recovery has been assessed using known in vivo standards of bovine and goal origin. Additional studies have been designed to examine the recovery of PCBs from in vitro spiked samples in order to assess any possible differences between bovine and human serum with regard to extraction of PCBs. Data will be reported on this study as soon as possible.

35) The presence of a contaminating peak found in the range of the Webb-McCall peaks 37 - 58 was examined by GC/MS, GC/ECD and GC with HEC. It was determined that the contaminant(s) were inherent in the serums and were neither PCBs nor chlorinated hydocarbons. The effect of this contaminating peak on quantitation was determined as potentially causing up to a 10% underestimate of the PCB level.

36) CDC estimates that 99% of the population has a serum level less than 30 ppb.The null hypothesis for the study was that the prevalence of elevated serum PCB levels (defined as $\geq$ 30 ppb) was equal to one percent , versus the altenate hypothesis that the prevalence that the prevalence was > one percent. It was necessary to choose a specific cutoff to denote elevated levels in order to formulate the null hypotheses and to perform sample size and power calculations. For consistency, this level was used throughout the report. Also health effects are more likely to be seen if levels higher in study group in contrast to general population.

37) See figures #9 and #12.

38) See chapter IV--Discussion.

39) Specific congener analyses are underway and will be reported as part of followup activities.

40) See chapter II--Characteristics of the Participant Sample.

41) * * * * * * * *

42) Agreed. See chapter III--Results.

43) See chapter III--Results.

44) See chapter III--Blood Pressure.

45) * * * * *

46) * * * * * Analyses were run for all combinations.

47) Ran all. Smoking was the only significant correlation with elevated blood pressure and after all variables were taken into account the numbers were too small for meaningful analysis.

48) This was analyzed for each age range, comparing mean, median, standard deviation, etc for those on anti-hypertensive medication and for those who were not. No differences in level were observed.

49) See chapter II--Data Analysis and chapter III--Blood Pressure.

50) See chapter II--Data Analysis, chapter III--Blood Pressure and chapter IV--Discussion.

51) See response to #48 also see chapter IV--Discussion. Weighted and unweighted data were run.

52) See response to #48. Also it is clear from rigorous statistical analysis of our data that no significant association between level of blood pressure and serum PCB level was found. Age and level and age and blood pressure are correlated. To do tables with age, blood pressure and PCB level could cause the public to draw misleading conclusions from the data. No association was found in older group with blood pressure and PCB level.

53) See chapter III--Enrichment Levels and Seafood Consumption. This is simply a descriptive measure between the two groups.

54) Environmental testing does not indicate a decreasing trend in seafood levels. The human PCB serum analyses were only measured at one point in time. Data from those reporting decreased consumption levels of local (contaminated) fish is described in table 13.

55) Sources of exposure for our sample are described. Much research regarding food-chain and other environmental models describing PCB cycling in environmental media are being developed for New Bedford Harbor but are not complete as yet. It would appear that these models are <u>very</u> site specific.

56) Looked at. Insufficient sample size to draw real conclusions only small percentage eat eels (table 14). Eel eaters also ate other species.

57 See chapter III--Results and chapter IV--Discussion.

response pg.5

58) See chapter III--Results and chapter IV--Discussion.

59) " " " " " " " "

60) Webb/McCall was utilized for all sera. See chapter II--Laboratory Measurements.

61) See Recommendations. Very few women of childbearing age with elevated levels in our sample. We will give advice on a case-by-case basis for this.

July 6, 1987

Ms. Suzanne K. Condon
Director, New Bedford Health Study
Massachusetts Department of Public Health
150 Tremont Street
Boston, Mass. 02111

Dear Ms. Condon:

The committee constituted to provide peer review for the Greater New Bedford PCB Health Effects Study has received and reviewed the final draft report on the project. The document adequately describes the project and the data base it created.

The committee was provided with a seven item charge upon which to judge the report. In terms of that charge (attached), the following represents the consensus opinion of the committee;

1a) The report adequately meets the objective to determine the prevalence of PCB exposure among residents of the four communities.

1b) The report adequately addresses observed blood pressure within the study group. As discussed, the lack of participants with significantly elevated PCB levels prevents a scientific test of the hypothesis that there exists a relationship between serum PCB levels and blood pressure.

2. No further data analyses are necessary to describe the study, its findings and the three major conclusions stated.

3. The Tables and Figures associated with the document are adequate and support the text.

4. The references and bibliography adequately support statements and references in the text.

5. Creation of a population data base provides the opportunity to expand the scope of the study in an attempt to further explore suggested associations, trends in time or additional details. As indicated throughout the report, this would require either additional participants for adequate statistical tests, collection

of additional information or specimens and/or repeated observations at a later point in time. Formulation and testing of hypotheses concerning blood pressure, PCB half life, or consumption trends for example, would require such an approach. The committee recommends that scientific conclusions beyond the major descriptive ones stated, should undergo the usual scrutiny of a scientific peer review journal prior to finalization.

6. The report is an adequate and understandable presentation of the study activities and findings. Its release to the community is a local institutional decision.

Sincerely,

Harold E.B. Humphrey, Ph.D.
Chairman

APPENDIX B

CHANGE TO THE REVIEW COMMITTEE

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5. What needs to be done to scientifically improve the report?

6. What needs to be done in order to release the report to the Community?

Greater New Bedford
Health Effects Study

46 Foster Street/Foster Hill Place
New Bedford, Massachusetts 02740-6601
617/996-8556 617/996-8571

MEMORANDUM

TO: Harold Humphrey, Ph.D.
Chairman, Peer Review Committee

FROM: Suzanne K. Condon SKC
Project Director/Co-Principal Investigator

RE: Final Comments of the New Bedford
Peer Review Committee

DATE: July 13, 1987

Thank you for providing me with the final comments of the Peer Review Committee established for the Greater New Bedford PCB Health Effects Study. We are pleased that we have met the objectives of the study and that the entire report in it's final form was acceptable to the Committee as stated in your letter dated July 7, 1987.

With regard to the Committee's fifth comment, we agree that there is a need for further examination of the data and for follow-up activities, as we have reflected in our own recommendations.

Once again, on behalf of the entire project team, I would like to thank you and the Committee for all your time and effort involved in the peer review process.