Special Studies

Hair Mercury Component

Public Health Objectives:

The objective of the NHANES hair mercury component is to document total mercury levels in hair. Relationships have been established between the concentrations of mercury in human scalp hair and dietary methylmercury exposure. The purpose of the hair sample collection is to obtain a suitable biological sample that can be used for the determination of total mercury levels in hair. The sample should include the 3 cm segment of hair closest to the occipital region (back portion) of the scalp. The 3 cm segment of hair can be used to characterize recent exposure to methylmercury over a relatively uniform time interval (approximately 2.5 months.)

Staff:

A phlebotomist or trained health technician will collect the hair specimen.

Protocol:

Methods:

Approximately 100 strands (100 mg) of hair will be cut and collected from the occipital position (back) of the scalp. Blunt-tipped scissors will be used to minimize chances of personal injury.

Time Allotment:

The amount of time required to prepare the hair specimen for collection is estimated to be five minutes.

Health Measures:

Laboratory analysis will be performed to determine the total mercury content of the hair specimen.

Eligibility:

Males and females aged 1-5 years and females aged 16-49 years are eligible for this component. Hair samples will be collected during the first three (3) years of NHANES.

Exclusion Criteria:

Survey participants who lack hair due to their hairstyle, *alopecia totalis*, or chemotherapy treatment will be excluded; persons who have religious or cultural beliefs that hair should not be cut will also be excluded. Persons wearing wigs will be excluded unless they volunteer to remove the wig.

Justification for using vulnerable populations:

- Minors are included in this component because they are an important target population group for the assessment of mercury levels.
- Mentally impaired individuals will be included.

Risks:

Minimal risk. Potential exists for mishandling of scissors resulting in laceration.

Report of Findings:

Reported in the MEC: None

Reported from NCHS:

Level 1:	None
Level 2:	Mercury levels > 50 ppm
Level 3/Routine:	None

Household Lead Exposure

Laboratory Measure:

Lead in dust
Lead in blood

Public health objective:

Lead is a known environmental toxin that has been shown to deleteriously affect the nervous, hematopoietic, endocrine, renal and reproductive systems. In young children, lead exposure is a particular hazard because children more readily absorb lead than do adults, and children's developing nervous systems also make them more susceptible to the effects of lead. The risk for lead exposure is disproportionately higher for children who are poor, non-Hispanic black, living in large metropolitan areas, or living in older housing. The primary sources of exposure for children are lead-laden paint chips and dust as a result of deteriorating lead-based paint. Among adults, the most common high exposure sources are occupational.

Blood lead levels measured in previous NHANES programs have been the cornerstone of lead exposure surveillance in the U.S. The data have been used to document the burden of and dramatic decline of elevated blood lead levels; to promote the reduction of lead use; and to help to redefine national lead poisoning prevention guidelines, standards and abatement activities. No national data exist, however, on the prevalence of lead dust hazards in the nation's housing.

Staff:

Household interviewers: lead dust collection in the home.
Lab technicians: venipuncture for blood lead in the MEC.

Protocol:

Methods:

- Lead dust: Environmental samples of settled household dust will be taken at the time of the household interview for analysis of lead concentration. The interviewer will obtain written consent on the form that follows. A wipe sample will be collected from the floor and from the sill area of a window in the room where the child spends most of his/her time. The samples will be collected using a standard wipe protocol outlined in the HUD Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing.
- Blood lead: see venipuncture collection methods.

Time allotment:

- Lead dust: 5 minutes per household.
- Blood lead: part of venipuncture.

Eligibility:

- Lead dust: Households with children 1 - 5 years of age.
- Blood lead: Examinees 1 year of age and older who do not meet the exclusion criteria for venipuncture.

Exclusion criteria:

- Lead dust: none.
- Blood lead: No exclusions beyond those for venipuncture.

Justification for using vulnerable populations:

Not applicable.

Risks:

No risks.

Report of findings:

Reported in the MEC: None

Reported from NCHS : Lead dust

Level 1:	None
Level 2:	Dust levels above Federal guidelines: floor lead dust >100mg window lead dust >500mg
Level 3/Routine:	None

Attachment 36 is a copy of the EPA and HUD Real Estate Notification and Disclosure Rule.

Tuberculin skin test

Public Health Objectives:

To support public health programs in the control, prevention and eventual elimination of tuberculosis (TB), accurate and comprehensive data are needed about the extent of the TB burden in the community. The currently available data on TB morbidity are limited to reports of active disease and do not provide sufficient information for monitoring the extent of TB infection in the population and in population subgroups although the annual risk of infection and its trend are considered to be the best current indicators of magnitude of the TB burden. To determine the prevalence of TB infection, NHANES participants one year of age and older will be skin tested with a tuberculin purified protein derivative (PPD) product, PPD S-1, the U.S. standard antigen. To help distinguish reactions due to *Mycobacterium tuberculosis* from cross reactions due to nontuberculous mycobacteria, participants will also be skin tested with nontuberculous mycobacterial antigen PPD-B (Battey strain lot 100616, also called the Boone strain, of *Mycobacterium intracellulare*). The two products to be used are not commercially licensed but have received IND approval (BB-IND-7596) from the Food and Drug Administration for this and a number of previous large surveys in the U.S., including NHANES I.

To aid in the interpretation of skin test results and provide for risk factor analysis, as part of the household interview, participants will be asked questions about country of birth and length of residence in the U.S. (for persons not born in the U.S.), occupation, and prior TB skin testing, disease and exposure to *Mycobacterium tuberculosis*.

These data will be used to: 1) estimate the number and proportion of persons with *Mycobacterium tuberculosis* infection in the U.S. population and in demographic and geographic subgroups; 2) estimate trends in *Mycobacterium tuberculosis* infection in the U.S. population and in demographic and geographic subgroups; and 3) analyze demographic, geographic, socioeconomic and other risk factors for *Mycobacterium tuberculosis* infection.

Staff:

Certified Phlebotomist; two trained full-time skin test readers

Protocol: (completed protocol submitted to FDA and approval letter for IND attached as Attachment 28)

Methods and Health Measures:

- The TB skin test will be applied in the NHANES Mobile Examination Center (MEC), at which time the SP's arms will be examined for a BCG scar. The two PPD products will be administered intradermally using standard Mantoux technique to all consenting NHANES participants over the age of one year not reporting a previous adverse reaction to a tuberculin skin test (see **Attachment 37**).
- Each antigen will be administered in the volar surface of different arm, with WESTAT computer software instructing the phlebotomist on which arm each antigen should be applied for each SP according to a random allocation program. The antigen vials will have coded labels so that the placer will be blinded to the identity of the antigen being placed on either arm. SP's with only one arm available will have the antigens randomly allocated to the upper and lower volar surface of the available arm. Each respondent will be given an appointment to return to the field office for the skin test reading, or to the MEC in the case of SP's participating in the VOC study. If the SP is unwilling to accept the appointment or does not return at the specified time, Westat field staff will go to the respondent's home or workplace to do the reading. TB skin test results will be read by trained readers 48-76 hours after administration of the antigens. Readers will not be aware of the placement of the specific antigens when reading the test. As far as possible, twenty-five percent of SP's will have their skin tests read by two readers for quality control purposes.

Time Allotment:

5 minutes to inject, 10 minutes to read.

Eligibility:

Sample persons aged one year and over who do not meet the exclusion criteria.

Exclusion Criteria:

- Positive response to screening question: "Have you ever had a severe reaction to a TB skin test?".
- Severe skin conditions such as burns or active eczema over both arms.

Justification for using vulnerable populations:

- Minors over the age of one year are included in this component because they are an important target population group. Tuberculin findings are linked to other household interview and health component data and are used to monitor trends for infection.
- Mentally impaired individuals will be included

Risks:

Minimal risk. Commonly reported side effect includes skin redness and itching at the site of application. Ulceration and sloughing of skin extremely rare.

Report of Findings:

Reported in the MEC and/or Field Office:

Level 1:	None
Level 2:	Induration > 5 mm in either arm will result in referral to community physician or local health department.
Level 3/Routine:	Report of findings, see **Attachment 24**

Special training issues:

The Tuberculin skin test protocol involves two products not commercially licensed, but with IND approval (BB-IND-7596) from the Food and Drug Administration. These are PPD S-1, the U.S. standard antigen and nontuberculous mycobacterial antigen PPD-B (Battey strain lot 100616, also called the Boone strain, of *Mycobacterium intracellulare*). Because of this a special informed consent document for Tuberculin skin test training was developed (attachment XX).

The TB training will first be conducted in January 1999 for the field office staff. In February, two additional trainings will occur--one for skin test readers and placers and another to confirm standardization of trainers' reading and placing. Volunteers will be actively recruited for training from NCHS personnel, family member, contractors and by paid advertising. Non Federal employees will be remunerated $25 for volunteering. All skin test results will be reported according to the standard Report of Findings indicated above. All training will be conducted by the CDC TB Elimination Branch physician and nurses. The consent form (attachment XX) will be used for all training unless a portion of the training is limited to one or the other antigen. In those cases the references to the antigen not used will be omitted.

Additional training for the purpose of updating currently employed TB skin test readers and placers, training new readers and placers, and confirming standardization of trainers' reading and placing techniques will be conducted as required at NCHS, WESTAT, CDC, or in academic or clinical settings where TB skin testing courses are regularly conducted.

Volatile Organic Compounds Exposure Monitoring

Public health objective:

Nearly 200 air toxics have been associated with adverse health effects in occupational studies or laboratory studies, but have not been monitored in general population groups. Information on levels of exposure to these compounds is essential to determine the need for regulatory mechanisms to reduce the levels of hazardous air pollutants to which the general population is exposed.

The data will be used to: 1) characterize the distribution of personal exposures to selected volatile organic compounds; 2) characterize the distribution of blood levels of selected volatile organic compounds; 3) characterize the distribution of levels of selected volatile organic compounds in home tap water samples; 4) examine the relationship between personal exposure measures and blood levels and the relationship between water levels and blood levels of selected volatile organic compounds; 5) examine the relationship between measures of volatile organic compounds and demographic, economic, and behavioral characteristics; and 6) investigate possible associations between measures of volatile organic compounds and selected measures of health status.

Staff:

Certified phlebotomist

Protocol:

Methods:

- Personal exposure assessments will be obtained with small lightweight passive sampling badges worn by sample persons for a 48-hour period. Examinees will begin wearing the badges when they leave the MEC and will return the badges 48-72 hours later when they return to have their TB skin test read. Examinees participating in this assessment will be asked to return to the MEC to have their TB skin test read.

- Examinees selected for this component will be asked to collect a sample of tap water from their home and bring it with them on their return visit.

- A second blood draw will be obtained from participants on their return visit. Two 7 ml vials of blood (approximately one tablespoon) will be drawn. Blood levels of selected volatile organic compounds will be measured in this sample.

- Information that will be needed to interpret exposure information, including activity data for the exposure measurement period, will be obtained by a short questionnaire administered at the time the badges are returned. See **Attachment 38**, VOC Exposure Questionnaire.

Time allotment:

- Describing component and providing instructions for using badges and collecting water sample: 5 minutes
- Administering questionnaire about exposures: 5 minutes
- Blood draw: 5 minutes

Health measures:

- Personal exposure to air levels of the following volatile organic compounds:
  - benzene
  - 1,3-butadiene
  - carbon tetrachloride
  - chloroform
  - 1,4-dichlorobenzene

ethyl benzene
methylene chloride
methyl tertiary-butyl ether
styrene
tetrachloroethylene
toluene
trichloroethylene
xylenes

- Blood levels of the following organic compounds:
  1,1,1-Trichloroethane
  1,1,2,2-Tetrachloroethane
  1,1,2-Trichloroethane
  1,1-Dichloroethane
  1,1-Dichloroethene
  1,2-Dichlorobenzene
  1,2-Dichloroethane
  1,2-Dichloropropane
  1,3-Dichlorobenzene
  1,4-Dichlorobenzene
  2-Butanone
  Acetone
  Benzene
  Bromodichloromethane
  Bromoform
  Carbon Tetrachloride
  Chlorobenzene
  Chloroform
  cis-1,2-Dichloroethene
  Dibromochloromethane
  Dibromomethane
  Ethylbenzene
  Hexachloroethane
  m-/p-Xylene
  Methylene chloride
  Methyl tertiary-butyl ether
  o-Xylene
  Styrene
  Tetrachloroethene
  Toluene
  trans-1,2-Dichloroethene
  Trichloroethene
- Levels of the following volatile organic compounds in the home water sample:
  Chloroform
  Bromodichloromethane
  Chlorodibromomethane
  Bromoform
  Methyl tertiary-butyl ether

Eligibility:

A random subsample of persons 20-59 years old (expected sample size:1,000)

Exclusion criteria:

None

Justification for using vulnerable populations:

Not applicable

Risk:

The following are known risks for venipuncture:

- Hematoma
- Swelling, tenderness and inflammation at the site
- Persistent bleeding
- Vasovagal response - dizziness, sweating, coldness of skin, numbness and tingling of hands and feet, nausea, vomiting, possible visual disturbance, syncope and injury from fainting
- Rare adverse effects:
  Thrombosis
  Infection which results in thrombophlebitis

Special Precautions:

- Sterile equipment issued with all sample persons
- Physician on call in case an adverse affect occurs

Report of findings:

Reported from NCHS:

- Personal exposure levels:
  Sample persons will be contacted by telephone if the results for any of the chemicals that are monitored show exposure levels that are at or above the levels indicated below. These levels are based on the permissible time-weighted exposure levels as regulated by the Occupational Safety and Health Administration (OSHA) or exposure limits that are recommended by the National Institute for Occupational Safety and Health (NIOSH) if lower than the OSHA levels. These levels were further reduced by a factor of 10 to account for potential exposures not just limited to working hours and other potential inaccuracies. These levels are as follows:

benzene	0.01 ppm
1,3-butadiene	100 ppm
carbon tetrachloride	0.2 ppm
chloroform	0.2 ppm
1,4-dichlorobenzene	7.5 ppm
ethyl benzene	10 ppm
methylene chloride	2.5 ppm
styrene	10 ppm
tetrachloroethylene	2.5 ppm
toluene	10 ppm
trichloroethylene	5 ppm
xylenes	10 ppm

- There are no occupational regulations covering exposure to methyl tertiary-butyl ether and there will be no report of findings for this substance.

- Water measures
  The Environmental Protection Agency has proposed to define the maximum contaminant level (MCL) for total trihalomethanes to 0.08 mg/L. Total trihalomethanes are chloroform, bromodichloromethane, dibromochloremethane, and bromoform concentrations. Participants will be notified if the sum of concentrations for these compounds execedes the proposed MCL. There are no regulations covering concentration of methyl tertiary-butyl ether and there will be no report of findings for this substance.

- The telephone script that will be used for informing sample persons high personal exposure levels is as follows:

  The results from the sampling badge that you wore to monitor your exposure to several hazardous air pollutants showed that your exposure to (chemical) was at the level or higher than level that is allowable in work place settings. I have information about what this chemical is, how you might be exposed to it, and what the potential harmful affects of the chemical are. This information is summarized in a public health statement prepared by the Agency for Toxic Substances and Disease Registry (ATSDR). I will review this information with you and will also send you a written copy of this information. This level of exposure is only likely to occur from certain work place settings or from certain hobbies. The information from the ATSDR public health statement may help you understand where you may have been exposed to this chemical. If you are exposed to this level of the chemical over a long period of time, it may cause an adverse health effect. We can not tell you if this exposure has affected your health, only a doctor can determine that. If you wish to follow up with a medical doctor, I can give you the name of a doctor who specializes in environmental and occupational exposures.

- Blood levels of volatile organic compounds

  These findings will not be reported to participants. See **Attachment 30**, Strategy for Reporting Environmental Analytes.