

# National Human Exposure Assessment Survey (NHEXAS)

## *Region 5 Study*

### Quality Systems and Implementation Plan for Human Exposure Assessment

Research Triangle Institute  
Research Triangle Park, NC 27079

Cooperative Agreement CR 821902

**Quality Systems Implementation Plan**

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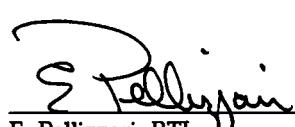
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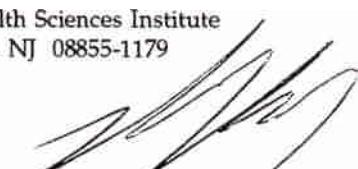
## QUALITY SYSTEMS AND IMPLEMENTATION PLAN FOR HUMAN EXPOSURE ASSESSMENT STUDY (Cooperative Agreement CR 821902-01-0) VOLUME 1

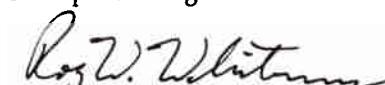
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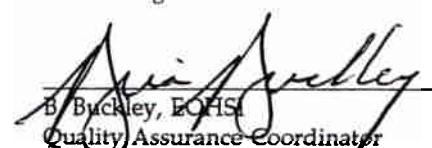
  
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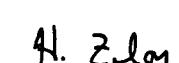
  
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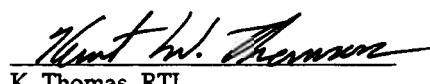
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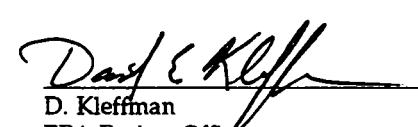
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## GENERAL OVERVIEW OF NHEXAS PROGRAM

The RTI/EOHSI Consortium scoping studies were designed to be part of the total NHEXAS framework which was developed as a result of a series scientific discussions and workshops conducted by the US EPA from 1992 through 1993. These led to a program document that defined the purpose and specific aims of the population survey. The NHEXAS will examine total human exposure and is structured to include: Phases I: Evaluation, pilot or scoping studies, Phase II: a full National Exposure Survey, and Phase III: a series of highly focused characterization modules. The Phase III studies could involve high end exposure groups, source apportionment and epidemiology. The EPA NHEXAS program document discussed scientific issues that needed to be evaluated prior to Phase II investigation. Included were methods evaluation, population and statistical sampling, selection of data quality objectives, and pathway identification for total exposure. The research program developed by the RTI/EOHSI Consortium Cooperative Agreement is a Phase I scoping or pilot study that attempts to achieve all of the above and will be supported by the techniques and protocols outlined in the current and future versions of the QSIP. In order to determine the feasibility of the NHEXAS to characterize total human exposure, the consortium will test a number of hypotheses using specific contaminants. The contaminants of concern in the RTI/EOHSI scoping study were selected from the NHEXAS program document and include selected metals, pesticides, volatile organic compounds and Polycyclic Aromatic Hydrocarbons. From these classes the first tier contaminants to be measured are: lead and arsenic; chlorpyrifos; benzene, chloroform and halocarbons; and benzo(a)pyrene (BaP) and benzo(a)anthracene, respectively.

The central hypothesis of the RTI/EOHSI program is: that individual and population exposures determined by modelled or extant data will be significantly different from those determined directly from multi-pathway and multi-media measurements. In addition there are a series of sub-hypotheses which presented in our original proposal. These range from pollutant specific exposure measurement and body burden hypotheses to the optimization of exposure models. A number of organizations have been identified as potential users of the data collected by the scoping and full NHEXAS program.

Sample collection will be performed by RTI/EOHSI consortium. Analyses of the external marker and biological marker samples will be completed by RTI/EOHSI or Federal laboratories associated with the CDC, FDA, and EPA. A data management system will be implemented for these data. This will be augmented by a data management system for data collected by the two other consortia conducting a scoping study. In keeping with the NHEXAS framework, the cooperative agreement will examine a probability based population sample for total exposure and the field study will be conducted in counties located throughout EPA Region V. The units for sampling are households and the individuals residing within each household.

Because specific features of the cooperative agreement requires evaluation of the protocols for use in the Phase II NHEXAS study all contaminants selected for examination potentially have multi-media and multiple routes of exposure. In addition, the protocols and analytical techniques to be employed will be the best available for total exposure assessment at this time. As the study progresses; however, new techniques will be introduced after they have been satisfactorily tested and protocols finalized for inclusion within the QSIP. The nature of the scoping study provides opportunities for developing new techniques and/or protocols, and we only intend to include these within the study after research has been conducted and tests completed in the field.

## SECTION 1 PROJECT PLANNING AND ORGANIZATION

### **1.1 PROJECT SCOPE, HYPOTHESES AND OBJECTIVES**

#### **1.1.1 General Goals of NHEXAS**

A Primary benefit of NHEXAS will be to reduce uncertainties in exposure and risk assessments, allowing toxicants and their sources to be reliably prioritized with regard to relative risk (1). The general goals of the NHEXAS program can be summarized as follows:

- a. to establish relationships between environmental concentrations, exposure, dose, and health response.
- b. to determine the incidence and causes of high exposures, especially for biologically susceptible persons, and
- c. to produce reliable estimates of status and trends in human exposures to potentially harmful environmental agents,

The planning and implementation of NHEXAS has been divided into three phases. The aims of the first phase of NHEXAS can be described as:

- a. to field test survey and measurement methodology for Phase II,
- b. to collect data useful for addressing an environmental problem of at least regional importance, and
- c. to collect information on cost (survey, monitoring, and analytical) and variance components for optimizing the Phase II sample design.

NHEXAS Phase II program aims can be summarized as:

- a. to estimate the distribution of exposures, especially the mean, median and 90th percentile for the general population and for subsets of special interest (e.g., biologically susceptible persons; geographical regions; subpopulations defined by race, ethnicity, and socioeconomic status),
- b. to identify the characteristics and exposure levels of the persons with the highest exposures in the general population and in the subpopulation of biologically susceptible persons to facilitate further investigation of these real-life "worst-case" situations,
- c. to collect data that can be used to calibrate and test models for human exposure so that the uncertainty in model-based exposure assessments can be reduced and better quantified;

- d. to determine relative risks for different compounds and different routes of exposure so that they can be appropriately prioritized for regulatory action, and
- e. to estimate trends in population exposures to identify emerging problems and to determine the effectiveness of regulations in actually reducing human exposures.

Subsets of the Phase II national sample (e.g., biologically susceptible or highly exposed persons) may be monitored more extensively in Phase III to identify in greater detail sources of exposure, linkages to health effects, etc.

#### **1.1.2 Definition of the Phase I Study**

##### **a. Phase I Study Hypotheses**

A brief synopsis of a few typical categories of hypotheses to be tested in the proposed Phase I Study is described here.

##### **b. Central Hypothesis**

The individual and population exposures (and potential dose) determined from modelled extant data (the initial exposure assessment) will be significantly different than that determined directly from multi-pathway and multi-media measurements (i.e., this Phase I Study). The central hypothesis is directed at the objective of testing for adequacy of initial exposure assessments, i.e., "checking the reality of modelled exposure assessments."

##### **c. Other Research Hypotheses and Objectives**

Lead, arsenic and other metals will be the primary focus of this Phase I study, while a nested design will also permit obtaining exposure distributions for benzene and other VOCs. Information on exposure monitoring for chloropyrifos/pesticides, and benzo[a]pyrene and other polycyclic aromatic hydrocarbons (BaP/PAHs) will be acquired in a special study module involving approximately 50 homes to use in planning future study designs.

Hypotheses that exemplify testing for selected subpopulation differences, effects of sources, for associations, for apportionment among pathways and improving exposure models and later phases of NHEXAS are additional categories of hypotheses and objectives to be examined in this Phase I Study.

#### ***Identifying Existing and Emerging Unacceptable Risks--***

1. The proportion of the population with exposures exceeding health-based exposure thresholds is the same for the general population and for biologically sensitive subpopulations.

2. There are no significant differences in exposures for the study toxicants (e.g., means, medians, or 90th percentiles) by region (e.g., Illinois versus the remainder of EPA Region V), race, ethnicity, and socioeconomic status (e.g., household income).

***Exposure-Environmental Related Hypotheses--***

1. The air exposure route for arsenic will be an insignificant component of total exposure, especially as compared to drinking water and food, and will not correlate with either route in those few settings demonstrating elevated air concentrations. Over 10% of the EPA Region V population is exposed to >10 µg/L of As in drinking water.
2. For aerosol mass, arsenic, lead and benzene, the ratios of personal measurements to microenvironmental measurements for the most exposed population are lognormally distributed and have a median of approximately 4.0 (upper 10%), with a geometric standard deviation of approximately 1.6.
3. Pathways leading to Pb exposure are not equivalent across all socioeconomic groups and age categories.
4. For benzene, personal sampling limited specifically to indoor or outdoor activities in occupational and residential settings provides a more complete picture of the source categories responsible for the most exposed portion of the study population, as compared to the total integrated exposure.
5. The capture of aerosols by the inspirable inlet will demonstrate an increased proportion of larger, retrained particles containing lead not collected by a PM10 inlet.

***Exposure-Body Burden Related Hypotheses--***

1. For a given level of environmental exposure, a variety of personal characteristics (e.g., age, race, sex, education, personal hygiene, etc.) will help predict the internal dose of the agent.
2. Doses estimated from biological specimens (i.e., blood, urine, and hair) will show a clearer gradient with regard to socioeconomic status than will estimates from environmental samples.
3. Dietary constituents (e.g., cruciferous vegetables) that activate the aryl hydrocarbon hydroxylase detoxification enzyme system will be associated with higher BaP-hemoglobin adduct levels for a given level of environmental BaP exposure.
4. For lead and arsenic exposures, hair samples at a single point in time will give dose estimates comparable to estimates obtained from repeated environmental measurements over a period of several months.

5. For such adduct-forming chemicals as BaP and pesticides, hemoglobin adducts will give dose estimates comparable to integrated estimates of external exposures measured in all media and routes.

*Establishing and Comparing Relative Risk-based Priorities*--There are no differences in population risks for the different toxicants being studied or between the different routes of exposure for each toxicant.

*Developing, Improving and Testing Exposure Models*--The Phase I study data can be used to refine, calibrate, and test microenvironmental models for human exposure. There is no difference between the population exposure parameters estimated using models and those estimated directly from the exposure monitoring data.

*Exposure-Disease Related Hypotheses For Future Consideration*--The proposed Phase I Study's design can yield preliminary data and thus an opportunity to begin to explore future disease related hypotheses for later phases of NHEXAS. For example, the following hypotheses might be considered:

1. Quantification of the relationship between human contact with contaminants and health is significantly improved by complementary measurement of internal dose and markers of early expression of disease.
2. Exposures to lead, arsenic, and pesticides measured from biological specimens and environmental samples will be associated with adverse reproductive outcomes.
3. Exposures to BaP measured from biological specimens and environmental samples will be associated with coronary heart disease.
4. Exposures to arsenic and other metals will be associated with cancer morbidity and mortality.
5. Questionnaire-based exposure classification groups and estimates are consistent with those based on concentration, exposure, or body burden measurements.

#### **1.1.3 Public Health Issues and Rationale for Selection of Contaminants**

A procedure for setting health priorities can incorporate the exposure and health effects of contaminants into a framework that permits identifying the highest ranking problems using (a) the most elevated exposures (i.e., high exposures for a significant number of people) and (b) the most toxic contaminants (i.e., harmful at low dose) (2).

Regarding NHEXAS, environmental exposures with a known or suspected large etiologic fraction for serious diseases are of interest. Public health issues and environmental exposures for arsenic (As), lead (Pb), benzene, chlorpyrifos, and benzo[a]pyrene (BaP) that may have large etiologic fractions for serious chronic diseases are the focus of this Phase I Study. Because the endpoints of toxicity for these chemicals are chronic effects, the proposed exposure study is designed for achieving better long-term exposure estimates. The choice of contaminants and the geographical region for study in the NHEXAS Phase I Study considers

toxicity, potential human exposure (i.e., the prevalence of the contaminant) and other factors (e.g., multi-pathway, multi-media routes of exposure, and environmental equity). A brief discussion of these factors is provided in this section for each contaminant.

a. Lead

**Toxicity**--Lead affects a variety of physiologic systems, including the brain, the kidney, the hematopoietic system, the cardiovascular system, and the developing fetus.

There are subtle effects associated with low exposures levels (3). Meta-analyses indicate that low level exposure to Pb causes intelligence quotient (IQ) deficits. Some studies of school age children with Pb exposure find evidence of problems with speech and language processing, attention, reading, spelling and mathematics scores, perceptual motor integration, and reaction time (4). These neurobehavioral problems may persist beyond childhood.

In addition to neurobehavioral effects of low Pb exposure, such exposures are also associated with a variety of other outcomes, including low birth weight, decreased postnatal growth, miscarriages, and premature birth (5). Several studies have found minor hearing impairment associated with Pb exposure at low levels (6). Although some studies suggest that Pb exposure can cause chronic renal disease, this putative association remains controversial (7).

Experimental and epidemiologic studies have indicated that blood Pb levels in the range of 10-15 µg/dL, or possibly lower, are likely to produce subclinical toxicity (8). A discernible threshold has not been demonstrated and therefore, an RfD for Pb has not been developed; instead probabilistic dose-response functions have been used (9). The EPA has alternatively developed the uptake/biokinetic Pb model that provides a means for evaluating the relative contribution of various media to establishing blood Pb levels in children, since abatement strategies will need to deal with potential multi-pathway multimedia routes of exposures-air, diet, water, soil/dust (nondietary ingestion), and paint (10). Model predictions, based on appropriate environmental media concentrations, need to be evaluated (validated) relative to measured blood lead concentrations.

**Prevalence**--Studies indicate that Pb exposures in industrialized countries are about 100 times the exposure levels found in pre-industrialized countries. This ubiquitous contaminant can be found in air, food, water, soil, and household products, and exposure often occurs through complex interacting pathways (11). Lead-based paint is the primary cause of high exposure among U.S. children; among children without acute poisoning, Pb levels in household dust is a strong predictor of levels in blood (3). There are an estimated 40 million homes in the U.S. with lead-based paint; 12-13 million children are exposed to these homes (5).

In uncontaminated soil, Pb concentrations typically range from 10-50 ppm. Soil concentrations near major roads can reach 2,000 ppm, and soil levels of 60,000 have been found near smelters (12). Some crops, especially root vegetables, take up Pb, but most food contamination occurs during processing (e.g., from soldered cans). Exposure to Pb in food and beverages is believed to far exceed exposure to Pb in air, gastrointestinal absorption is the major avenue of Pb uptake (8). Lead from household plumbing is the major source in

drinking water (especially in corrosive or soft waters where the pH is acidic); the principal source is Pb solder (8). Another important source has been lead-based fuels that has led to multi-media contamination.

**Risk**--Data from the Second National Health and Nutrition Examination Survey (1976 to 1980) indicate that 1.5 million (9.1%) preschool children, had blood Pb levels of 25 µg/dL or more (8). As noted above an RfD for Pb has not been established, but instead probabilistic dose-effect and dose-response functions for lead-induced hemoglobin, intelligence quotient, and erythrocyte protoporphyrin decrements have been used (9).

b. Arsenic

**Toxicity**--Chronic As poisoning leads to a variety of symptoms including weakness and fatigue, hair loss, weight loss, and anemia (13). Kidneys, liver and other organs can be damaged along with peripheral vascular lesions and other cardiovascular diseases. Peripheral neuropathy, primarily in the arms and legs, can also occur (14). Ingested As causes a variety of benign and malignant skin lesions that are distributed in a characteristic pattern (15). Children may be especially susceptible to As toxicity from ingesting drinking water.

Animal studies indicate that As is a teratogen. Moreover, epidemiologic studies found an association between As exposure near a copper smelter and congenital malformations and spontaneous abortions (14). In a review of the literature that was weighted heavily by drinking water studies, the authors found strong evidence that ingested inorganic As causes cancer of the bladder, kidney, lung, and liver (16). EPA classifies As a human carcinogen (17,18).

A reference dose (RfD) for noncancer effects has been tentatively established by EPA for As, based upon human data, as 0.3 µg/kg/day (13).

**Prevalence**--Arsenic is ubiquitous in soil, water, air, plants, and animals. In addition to such natural emission sources as volcanoes and forest fires, major anthropogenic sources include metal production, fossil fuel combustion, and waste incineration. Inorganic As found widespread use as an agricultural pesticide; however, since the 1970's farmers have used only small amounts. Arsenic compounds are currently used in the glass and electronics industries, as wood preservatives, and as food additives for farm animals to promote growth (14).

Several small surveys conducted in the 1980's have reported average As levels of 10-14 µg/L in groundwater of community and rural supplies, with ranges of 2.5 to 82 µg/L (19). Several towns and larger areas have had levels in drinking water reaching hundreds of µg/L to even a few mg/L (20,21).

Because sulphhydryl groups bind trivalent As, concentrations are high in nails and hair. A single dose of As appears at the nail tip in about 4 months. Arsenic deposited in nail roots migrates distally about 0.12 mm per day in growing nails, and about 0.35 mm per day in growing hair. Both materials provide potential markers of exposure. Arsenic is cleared rapidly from the blood (within about 10 hrs). Urine levels are often used for monitoring

occupational 8 hr exposures (14). Urine measurements of inorganic As and its metabolites (monomethyl arsenic and dimethylarsenic acids) are preferable to measurements of total As; the latter can include substantial amounts of organoarsenicals from seafood and other sources, which have low toxicity (22).

Prevalence data for As in ambient air is sparse, since it is not routinely measured in the National Air Sampling Network. The reported range is from non-detectable to 83 ng/M<sub>3</sub> (23). A limited study in Washington has reported personal and indoor air levels of 0.5-70.6 ng/M<sub>3</sub> and 0.8-34 ng/M<sub>3</sub>, respectively (24). Arsenic is present in soil at levels ranging from 0.2 to 40 µg/g (24).

The main exposure to inorganic As generally occurs via ingestion. Current dietary intake of total As in U.S. adults, excluding tap water, is estimated at about 45-50 µg/day (25). Approximately 80% of the As derives from seafood, meat, and poultry and about 17% from grains and cereals. The EPA has estimated the average total intake of inorganic As from food, water and other beverages to be about 17 µg/day with 5 µg/day from drinking water (25). On this basis the majority of the U.S. population is ingesting about 30% of ingested inorganic As from drinking water.

**Risk**--The potency of As a human carcinogen is relatively high. Several estimates for lifetime risk of dying of cancer (Liver, lung, bladder, kidney, and skin) from As ingestion exposure to 1 µg/kg-day have been made. These risks range from 0.001 to 0.048 (13-25). EPA's estimate for skin cancer is 0.002 (13).

Although there are no accurate data on the average As levels in drinking water for the U.S., estimates range from 2.0-2.5 µg/L (25). The lifetime risk of dying from liver, lung, bladder or kidney cancer due to drinking 1.6 L/day of water containing 2.5 µg/L of As has been estimated to be 1/1000 (25). Based on these calculated risks, Smith et al. (25) concluded that increased cancer risks from As in drinking water may be comparable to those from exposure to radon (3/1000,) and environmental tobacco smoke (4-10/1000,) in the United States.

The EPA has estimated that the national average level of inorganic As in drinking water is below 5 µg/L; however, it is estimated that approximately 350,000 persons might be ingesting water with levels above 50 µg/L, and about 2,500,000 persons drink water containing 25 µg/L of As (25).

c. Benzene

**Toxicity**--High doses of benzene affect the nervous system, while long-term exposure to low levels apparently impairs blood cell formation and bone marrow function, damages the central nervous system, and causes some types of cancer and leukemia (27).

**Prevalence**--Benzene is a widely used industrial solvent and is a by-product of combustion processes including forest fires, burning of wastes, and in cigarette smoke. Although environmental exposure levels vary from place to place, they are typically very low. The review and modeling by Eeg-Frey et al. (28) indicates that indoor benzene levels exceed outdoor levels, and that cigarette smoke is the largest anthropogenic benzene source.

The authors concluded that 99% of benzene in the environment can be found in air, with much smaller amounts in water, soil, water, and biota; it shows little accumulation in the food chain.

Gasoline station attendants, automobile mechanics, and drivers of tanker trucks experience modest benzene exposure levels that substantially exceed those in persons without occupational exposures (27). People who frequently fill their own automobile gas tanks, especially those in hot climates, probably have intermediate exposure levels. Because gasoline from leaking underground storage tanks can contaminate groundwater, some individuals using contaminated drinking water sources could have substantially higher benzene exposure levels, especially if they also bathe using contaminated water.

**Risk**--Exposure levels as low as 1 ppm are reported to have a relative risk of 1.7 for leukemia (28). The Cal-EPA has estimated a risk factor of  $3.9 \times 10^{-4}$  for exposure to benzene (13.6  $\mu\text{g}/\text{M}^3$ ) from indoor sources alone (29).

d. Chlorpyrifos

**Toxicity**--Reports suggest that chlorpyrifos use can cause headaches, allergic reactions (e.g., skin rash and asthma), and liver or kidney disease, and an excess of reported dizziness, malaise, and fatigue in exposed manufacturing workers (30).

High doses of chlorpyrifos cause acute organophosphate toxicity, and some evidence suggests that toxicity can occur from routine use for pest control in office buildings and homes (31). Infants are especially susceptible to home exposures, because they receive higher doses than adults, and have lower body tolerances.

**Prevalence**--Chlorpyrifos has broad-spectrum activity against several common pests (30). It is used agriculturally in different countries on such crops as corn, cotton, and citrus; structural treatments are used to control termites. Home pesticide applications for fleas are a potentially important exposure source (32). Chlorpyrifos was the second most frequently encountered pesticide residue found in food and feed samples in the Los Angeles District of the U.S. Food and Drug Administration (33), and it was the ninth most frequently encountered residue in the FDA Total Diet Study (34). Because plasma cholinesterase activity is more susceptible to inhibition from chlorpyrifos than is erythrocyte cholinesterase, the former is more commonly used for biologically monitoring of exposed workers (30). A chlorpyrifos metabolite is rapidly excreted in the urine.

**Risk**--Of concern is the residential use of chlorpyrifos to control flea infestations and other applications leading to dermal contact with treated surfaces or inhalation exposures following product use. Infants could have substantial dermal and inhalational exposures. Doses to infants of 1.2-5.2 times the No Observable Effect Level (NOEL) level have been estimated (32).

e. Benzo[a]pyrene

**Toxicity**--Studies of workers and others exposed to BaP and other PAHs (e.g., coke oven workers, foundry workers, and cigarette smokers) have found an increased risk of lung

cancer (35). A review of studies of aluminum plant workers, who are exposed to BaP and other chemicals, found evidence of excess lung, bladder, kidney, brain, and pancreatic cancers and leukemia (36), but the specific etiologic agents are unclear. Additionally, Everson et al. (37) found an inverse association between placental levels of a smoking-related (and presumably aromatic) DNA adduct and birth weight. Supporters of the monoclonal theory of atherogenesis propose that such mutagenic chemicals as BaP cause atherosclerosis by transforming smooth muscle cells in the arterial intima (38).

As with many chemicals, a BaP metabolite (BPDE-1) rather than BaP itself is the toxic agent. Because the human placenta and fetal liver can metabolically activate BaP and other PAHs, the fetus may suffer damage from reactive metabolites (39). Animal studies indicate that genetic differences in fetal metabolism can influence the toxicity and teratogenicity of PAHs (39). The induction of detoxification enzyme systems from such dietary components as cruciferous vegetables and from environmental chemical exposures also helps determine the metabolic fate of PAHs in exposed persons. Therefore, genetic as well as environmental determinants apparently influence the toxicity of BaP and other PAHs.

*Prevalence*--Benzo[a]pyrene (BaP) results from incomplete combustion of various organic materials such as fossil fuels and tobacco. It is abundantly produced during the frying/barbecuing of meats.

This ubiquitous contaminant is found in virtually all environmental media and food. Eeg-Frey and Travis (40) estimate that 82% of BaP is found in soil and 17% in sediment. Because of its lipophilic properties, BaP accumulates in the food chain, which accounts for about 97% of BaP intake by humans (40). Because BaP typically occurs in mixtures with other PAHs, its independent role in human disease is difficult to ascertain from epidemiologic studies. BaP is often used as a surrogate or index for all PAHs in a mixture.

#### **1.1.4 Relevance of Proposed Phase I Study**

Recently a report from the National Academy of Sciences (Science and Judgement in Risk Assessment) and several other publications have critically evaluated the strengths, weaknesses, and ideal exposure data bases for use in exposure assessment and epidemiological studies (41-44). The NHEXAS Phase I Study would develop information that is optimally suited for making an exposure assessments in the context of risk analysis and for establishing status and trends (44). Within this context the planned Phase I Study will yield exposure data that may be used specifically for the testing the hypotheses discussed earlier.

### **1.2 PROJECT DESCRIPTION**

#### **1.2.1 Geographical Area and Study Population**

The principal focus and optimal design for the Phase I Study will be to determine a series of exposure distributions for this population to As and Pb. In addition, a study of population exposure to Benzene and VOCs is nested in the proposed design.

The geographical area selected for study is EPA Region V. The proportion of races and ethnic groups, the socio-economic distribution and other demographic characteristics in this region are similar to and reasonably representative of the national level.

EPA Region V was specifically chosen for its suspected elevated levels of Pb in all pathways (routes) of exposure, i.e., air, drinking water, food, and household dust. Arsenic in drinking water and food are expected. Volatile organic chemicals (VOCs, e.g., benzene) are emitted from many commercial solvents and combustion sources (e.g., cigarette burning, etc.). Also the prevalence of wood burning in the Northern states suggests the potential exists for exposure to high levels of benzene and other VOCs. Petroleum refineries, coking ovens, chemical plants, and motor fuel handling can also lead to significant VOC air exposures in the general population. Groundwater contamination is increasing from waste sites and from leaking underground storage tanks that contained gasoline and other fuels.

Another chemical class of particular concern are polynuclear aromatic hydrocarbons (PAHs, e.g., BaP). The wide-spread prevalence of wood burning stoves and fireplaces are known to occur in the Northern states, where the levels of BaP have been reported to be elevated in both indoor and ambient air (45). PAHs are also emitted from a variety of other combustion sources such as coking ovens, steel mills, internal combustion engines, power plants, kerosene space heaters, charcoal/wood cooking, candles and cigarette smoke. In addition, PAHs are commonly formed in various cooking practices-charbroiling, frying, etc., and exposure can occur through ingestion of certain cooked foods (45).

Pesticide usage in the home and on crops is a widespread phenomenon in the U.S.

### **1.2.2 Contaminants Selected for Study**

As indicated above, Pb and As are the principal metals of interest. Two additional important metals, cadmium and chromium, will also be measured. The study design permits the inclusion of benzene and other VOCs with the same set of participants. In a separate module exposure measurements will be made in study participants for chlorpyrifos and other pesticides (47), and BaP and other PAHs (45,48). Table 1 lists the contaminants to be measured in this Phase I Study.

### **1.2.3 Environmental Pathways and Exposure**

#### **a. Routes For Study**

The primary objective is to acquire exposure data that may be used for making risk assessments for contaminants that produce chronic health-effects. An ingredient in the exposure assessment is estimating life-time exposure; however, most extant data are not readily suitable for this estimation since much of it was collected over short durations (e.g. 12-24 hr) in only one season and may not be representative of chronic exposure. We plan to make 6 day time-weighted exposure and environmental measurements (4 days for food) for a variety of environmental pathways and exposure routes for each study participant. The study will cover all seasons and some participants will also furnish selected samples in multiple seasons.

b. Lead, Arsenic, Cadmium, and Chromium

Lead, As, Cd, and Cr can occur in all media; we plan to collect personal, indoor and outdoor residential air, drinking water, food, and household dust. In addition, blood, urine and hair samples will be collected from all subjects to assess body burden and long-term exposure. Drinking water, household dust, urine, and hair will be obtained in two additional seasons of the year in a sub-set of participants. Inclusion of these pathways and media are important in understanding the relative importance of pathway exposure and for assessing total exposure through both environmental and biological measurements for these ~~four~~ important metals.

**Personal, Indoor, and Outdoor Air**—Inhalation of Pb, As, Cd, and Cr in air particulate represents one of several exposure routes. Personal, residential indoor, and outdoor particulate air samples will be collected from the subjects to obtain a 6 day time-weighted average concentration measurement. Personal samples will provide exposure data obtained in the breathing zone of the subject. Indoor and outdoor measurements for metals will provide data for use in models that attempt to calculate people's exposure by linking personal activity patterns with environmental measurements.

**Drinking Water**—First draw and extended flush water samples will be collected from all study participants and analyzed.

**Food**—The levels of As and Pb have been reported in total diet studies by the FDA (34). However, an exposure study of subjects should be performed to determine whether cooking practices and sanitary conditions in a home contribute to additional contaminant intake via food. For example, food, in addition to containing As or Pb from the marketplace, may become contaminated during its preparation by the water used. It is not known the extent that food material extracts contaminants from contaminated water. Also, home grown items, fish or food caught/hunted locally could differ in contaminant content than marketplace items. For these reasons, personal dietary exposure for As and Pb is planned in this Phase I Study. From each study participant, we would plan to collect food over the course of 4 days with compositing to obtain a 4 day exposure estimate to As, Pb, Cd, and Cr. Based upon our previous work with food collection, 4 days of dietary collection appears to be a reasonable and tolerable burden to the participant, (49-51).

**Housedust**—The prevalence of metals in air and soil outside of the home represents an important potential for exposure since dust from outside penetrates and is tracked into the home. Once the contaminant enters the home there are several pathways of exposure: resuspension of dust and subsequent inhalation; children's dermal exposure from track-in dust; sanitary practices, non-dietary ingestion, pica exposure in children, etc. General cleaning practices and surface deposition rates (from indoor and outdoor sources) are believed to be related to level of exposure.

It is essential to obtain samples of the particles that have been deposited on flat surfaces. Past experiences have suggested that the maximum concentrations (ug/g) for a dust generated outdoors and deposited indoors are found on the window sill and near entrances. However, the best locations for acquiring data for exposure assessment are surfaces which are commonly available for contact by an adult or child. These would include

the family or living room floor or a bedroom/living room surface, where much of the activities occur.

c. Benzene and Other VOCs

As indicated earlier benzene and other VOCs have a multitude of sources and are important toxic chemicals. Based upon previous studies for benzene, inhalation exposure is believed to the major route of exposure, its ingestion from water is minor. However, chloroform occurs in air and drinking water and exposure may be nearly equivalent (52). From the same set of subjects monitored for As and Pb exposure we plan to examine two media, air and drinking water, as pathways of exposure. The methods we have chosen present essentially no additional burden to the subject, and permits seasonal follow-up monitoring in two additional seasons of the year without the need of a re-visit by the field staff. Since the survey design and field costs are already borne by the primary visit, a wealth of data can be collected at only the cost of sample analyses.

*Personal, Indoor, and Outdoor Air*--We plan to collect 6 day time-weighted personal, residential indoor, and outdoor air samples on all primary study participants. In addition in a sub-set of subjects, two time-weighted personal air samples will be collected one to represent non-occupational and the other occupational exposure to allow a differentiation of these two major categories.

*Drinking Water*--The occurrence of benzene in drinking water is generally negligible. However, under ground leaking tanks has led to the contamination of drinking water with benzene (53). Trihalomethanes (THMs) are ubiquitous in drinking water; we plan to estimate exposure to chloroform in the general population.

d. Chlorpyrifos and Other Pesticides

As indicated above there is some emerging evidence on the toxicity and its prevalence in air and dust (47,54,55). This pesticide is commonly used in residential environments to control many types of insects, a common one being fleas. The number of people exposed and the magnitude of exposure to this pesticide is not very well understood despite its widespread use. Its occurrence in water has not been widely studied. Likewise, contaminated food eaten in the home with chlorpyrifos has not been adequately examined.

We plan to conduct a preliminary study on 50 subjects for the purpose of making an assessment of the magnitude of potential exposure to chlorpyrifos. These subjects will be from a separate home than those chosen for the primary study on metals and VOCs.

*Drinking Water*--We plan to determine the extent of exposure to Chlorpyrifos in drinking water. Other pesticides are reported by the multi-contaminant method chosen for analysis.

*Food*--From each study participant, we plan to collect food over the course of 4 days. Chloropyrifos and other pesticides have been reported in the total diet studies by FDA (33,34). For the same reasons given above for metals, we do not know the extent of food contamination resulting from home practices, and people's actual exposure through their diet.

**Housedust**--The outside and in-home usage of pesticides leads to these contaminants appearing in house dust where children (toddlers) may experience higher exposure than adults. As such, this medium can lead to human exposure through inhalation and ingestion as described above for As and Pb. The collection of housedust will utilize the same sampling strategy as for metals.

**Dermal Sampling**--To assess the extent of dermal exposure by pesticides, we plan to employ a sampling method(s) on these 50 subjects that will provide a time-weighted average concentration per unit surface area of skin coverage ( $\mu\text{g}/\text{cm}^2$ ).

e. Benzo[a]pyrene and Other PAHs

BaP and other PAHs occur in several media-particulate matter, housedust, and food. Exposure primarily occurs through inhalation and ingestion pathways. Furthermore, the extensive use of woodburning for heating in the colder climate of the Northern states along with other combustion sources suggests extensive exposure to BaP. A multi-class multi-contaminant method for collecting and analyzing pesticides and PAHs will be used which allows the inclusion of PAHs in a nested study with the same 50 subjects for pesticides described earlier. The results of this investigation would be useful for planning purposes in Phase II of NHEXAS.

**Personal, Indoor and Outdoor Air**--See description for pesticides.

**Food**--An aliquot of the food collected for chloropyrifos analysis would be available for analysis of BaP and other PAHs.

**Housedust**--As a compliment to indoor and outdoor inspirable air particulate samples collected for BaP and other PAHs, housedust provides a measure of the magnitude of BaP in this medium. Housedust can be a significant medium leading to exposure via ingestion in children. Similarly to metals, housedust can be resuspended into the air leading to inhalation exposure. The sampling strategy will be the same as for metals described earlier.

#### 1.2.4 Biological Markers

The potential for adverse health effects from environmental contaminants is most directly associated with biological effective dose (BED) to sensitive target organs, as this is the most relevant parameter for evaluating dose-response relationships. One goal of exposure assessment is to make accurate inferences of BED from measurements of environmental and exposure media, via modeling. However, it is often not possible or practical to measure the active toxin at the target site. Nonetheless, it is possible in many cases to quantitate the presence of a contaminant in human tissue (i.e., a biological marker of internal dose). This provides the next step toward BED with which to evaluate measurements of external dose (56).

While the biological marker is preferable, it is not always possible or practical for the larger populations needed for epidemiological studies or for risk assessments. We plan to use biological marker measurements to validate the external exposure data. This presupposes sufficient toxicological information (e.g. PBPK) on the mechanism of action and

fate. For example, it is imperative that metabolic interferences which may occur be identified and the analytical technique also have known sensitivity and specificity. Likewise, the biological (and sample) lifetimes must be sufficiently long (or known) to allow quantification.

Direct measures of the study toxicants or its metabolites in blood, urine, and hair will be performed in this NHEXAS Phase I population. These data will be compared to the exposure indices based on measurements in environmental and exposure media and questionnaire/history information.

#### ***Arsenic and Lead***

A biological marker for inorganic As will be measured in urine samples. The biological half-life of As in urine after exposure is 1-2 days. When exposure is solely to inorganic As, the excreted forms are principally the uncharged inorganic arsenic plus methylated species (22). However, organoarsenicals may be found in some marine fish or shellfish at very high concentrations. These compounds are of negligible toxicity, but are also rapidly excreted without substantial transformation (14). Analyses of total As may, therefore, be highly biased by diet. However, quantitation of the inorganic As and its methylated derivatives are not affected.

Hair and nail growth are also easily accessible biological material for determining arsenic. Arsenic is absorbed over the growth period, and these media are a better indices of chronic exposure levels than urine. We propose hair since it is possible to obtain growth that closer represents our environmental monitoring time-frame; nails would reflect exposure of several months prior.

Blood lead is considered to be the best and most sensitive indicator of concentration of the internal dose of lead. Lead in urine is effected much more by recent exposure, although it can be altered by recent changes in the exposure rate as well as the ingestion of a chelating agent (such as EDTA). Lead in hair, as for arsenic, can be determined and represents more the long-term exposure level. However, for both metals, it is difficult to distinguish between the endogenous and exogenously absorbed metal using only biological data. Furthermore, the route or pathway of exposure is not discernible.

#### ***Benzene and VOCs***

Blood samples will be collected for VOC measurements. Since the residence time for VOCs in humans is relatively short, on the order of 10 to 20 hours (57,58), the levels observed would reflect recent acute exposure.

Phenol is the main urinary metabolite of benzene, although it may not always be sensitive or specific enough for the parent component.

Correction of urinary metabolite concentrations with creatinine will be used.

### *Chloropyrifos and Pesticides*

We plan to collect urine samples twice in 50 subjects during the 6 day period to measure the metabolite of chloropyrifos. The measurement of body burden for pesticides permits an assessment of the total exposure to a subject.

Most of the lipid-soluble pesticides are readily absorbed by tissues, and they tend to be persistent, with biological half lives lasting as long as years. Frequently, the parent compound can be monitored in blood and urine.

### *Benzo[a]pyrene and PAHs*

Blood samples collected from 50 subjects will be analyzed for BaP adducts to protein and DNA. This strategy provides a unique opportunity to demonstrate the relationship, if any, between 4 & 6 day time-weighted environmental measurements for BaP in food and air, respectively, BaP levels in housedust, time activity data, and a biological marker with an integration time of 3 mo. in humans.

## **1.2.5 Questionnaires**

### *Descriptive and Baseline*

Descriptive and Baseline Questionnaires will be administered to each participant. Data items useful for predicting participation will be employed because these types of items can be used to model the probability of responding. A good model for the probability of responding can greatly reduce nonresponse bias (59). The Baseline Questionnaire examines the long-term history about a person's personal exposure related activities.

### *Time/Activity Diary, Technician Questionnaire, and Followup Questionnaire*

These questionnaires make important contributions to our understanding of an individual's exposure to contaminants during a specified period over which environmental and biological measurements are made. These instruments can identify the activities and use of sources that contribute to exposure (60-63). A multi-component time/activity diary can be used effectively across a wide range of demographic groups including individuals who differ in age, residential location, SES, educational background, occupation, and primary language to determine residential and occupational opportunities for exposure.

The underlying purpose of these questionnaires are to provide reliable information that identifies activity and location that may assist in identifying factors contributing to chronic and acute exposure to targeted contaminants. This information will be used in models for exposure and risk assessments, and for validating existing models (64).

### *Dietary Intake Diary*

The participant will also be asked to maintain a simple diary listing the foods eaten during the period of environmental and biological contaminant measurements (49,50). The diary is intended to capture descriptions of the type and amount of foods consumed so that

the monitoring personnel may qualitatively verify that the food collection is complete and probe the participant concerning missing items. These data will also be used in testing one of our hypotheses.

#### **1.2.6 Personal, Indoor, and Outdoor Air**

The air exposure route for each contaminant will be monitored using personal samplers and stationary samplers located inside and outside the home. Personal samplers will be both active, using a pump, passive, relying on diffusion for the collection substrate. Utilization of the new SKC, Inc. "total inspirable" aerosol inlet designed by the Institute of Occupational Medicine (IOM) to mimic total oral/nasal penetration (65) will be evaluated prior to the Field Study to validate the reproducibility and reliability of the sampling system. This validation will occur through laboratory pre-testing and during the Dress Rehearsals of all the NHEXAS methodologies (See Section 3.5.1 for description of pretest and Dress Rehearsal activities). The larger aerosol fraction collected by the inspirable cutpoint is proposed as a better indicator than PM10 of the total air exposure available for uptake. The value of comparisons with existing PM10 data bases (e.g. 24 hour average ambient air NAAQS and PTEAM data) will require limited comparability measurements with collocated indoor and outdoor PM10 samplers.

Benzene and other VOCs will be collected for long term exposures with passive badges (66). These badges provide acceptable accuracy, pose a minor subject burden, reduce data collection costs and provide for flexible study designs (67). The performance of the passive badges over 6 day periods will require only minor validation testing prior to the study to verify the calculated diffusion rates. The performance of this method will be assessed during the pretest phase and optimization and validation will be conducted as necessary, and again further tested under field conditions during the Dress Rehearsals.

Contaminant measurement methods with poor detection limits, relative to expected levels, will produce a substantial undefined set of non-quantifiable values. This may require robust statistical analyses. A 6-day integrated sample for chronic exposure, substantially increases the quantity of sample (compared to more typical 24 hour samples).

### **1.3 PERSONNEL QUALIFICATIONS**

#### **1.3.1 Survey Staff**

Survey staff working on the NHEXAS survey will include both survey specialists based at RTI and field interviewers located in the sample county areas. RTI survey specialists are experienced staff who have served in similar roles on previous exposure studies involving developing questionnaires and training materials, obtaining OMB and Protection of Human Subjects Committee approvals, recruiting and training interviewers, and supervising field data collection. The survey managers will be assisted by experienced support staff.

The experience of the field interviewers is a key factor for the success of the data collection. We will attempt to hire staff who have worked for RTI before, giving first priority to staff who have worked on projects similar to NHEXAS. Our National Interviewer File

(NIF) currently lists over 3,000 interviewers, located in all 50 states, who have previous RTI experience. We will use the NIF to identify potential interviewers for NHEXAS. If we can not identify sufficient candidates, located in the sample counties, who have time available and who are interested in NHEXAS, we will continue the recruiting effort using standard procedures to identify other candidates with interviewing experience.

Standard procedures for recruiting field staff after exhausting leads from the National Interviewer File (NIF) include contacts with current field interviewers and supervisors who may know staff in the areas of interest, contacts with other firms who use field staff, newspaper advertisements, and contacts with unemployment offices, and temporary agencies. In addition, if we are recruiting staff with special skills, we often contact local community colleges and other training agencies to recruit recent graduates or current students.

The current NIF contains 441 listings for staff in the six states of Region 5. Of these, 308 have RTI experience, and the remainder have some experience in interviewing, but not with RTI.

We seek experienced interviewers for several reasons. Successful, experienced interviewers are self motivated and understand the commitment required to complete their assignment on time, and on budget. Experienced interviewers require less training, and can use their previous experience to quickly become familiar with the activities involved in the current survey. Experienced interviewers also bring an understanding of their assigned area to the effort and can suggest changes in the survey approach to tailor the effort in their county, ensuring success.

The changes that experienced interviewers recommend often deal with community contacts that are necessary to support the field effort, and which vary from county to county. Local knowledge of interested community groups, awareness of other projects in the same area, and contacts with agencies or individuals who can help the interviewer or the field team complete their assignment is useful. There will be no changes in the specific data collection procedures and the information provided to the respondents. All suggestions will be reviewed at RTI prior to implementation, and information of value will be used in the current site and reviewed for utility in future sites.

### 1.3.2 Field Technicians

Sample collection procedures planned for the NHEXAS Phase I study are complex, and in some cases will require scientific and technical education or experience. Minimum project staff qualifications will include a bachelor's degree in a scientific, technical, or medical/social field of study. Candidates with degrees in chemistry will be selected first, if available. As a second qualification, candidates must be willing and able to spend a majority of their time on travel in EPA Region 5 states during the study period. Additional qualifications include the ability to drive, the ability to lift and carry boxes and equipment up to 40 lbs., the ability to communicate successfully with study participants, and the willingness to work on a nonstandard and shifting schedule.

### **1.3.3 Field Study Supervisor**

The field study supervisor will be responsible for all aspects of collecting personal and environmental samples for subsequent chemical analysis. Minimal educational qualifications require a Bachelor of Science degree in a chemistry or environmental sciences major. More important, the position requires extensive experience conducting, planning, and supervising human exposure studies. The field supervisor will have at least five years of experience developing methodology for, and conducting human exposure and residential field monitoring studies, and at least three years experience planning and supervising human exposure assessment field studies.

### **1.3.4 Laboratory Staff**

Minimum staff qualifications for laboratory analysts will include a bachelor's degree in chemistry or a closely related scientific field, with experience or applied training in the specific analysis they will perform. Minimum staff qualifications for laboratory sample processing personnel will include a bachelor's degree in chemistry or a closely related scientific field. Laboratory sample processing personnel may also be qualified if they have completed some college education in a science field (i.e., summer interns) as long as they work under direct supervision of qualified personnel. In either case, laboratory sample processing personnel will have experience or applied training in the specific sample processing tasks they will perform.

### **1.3.5 Data Management Staff**

NHEXAS data managers will include the survey operations supervisor and the database manager. Both of these positions minimally require a bachelor's degree in a science, social science, statistical, or computer field of study. The survey operations supervisor must have direct project experience in the collection, transmission, data entry, and validation of survey data. In addition, he or she must have experience with software used to transmit and process collected data. The database manager must have direct project experience in the collection, transmission, and processing of sample collection and analysis data. In addition, he or she must have software design and programming experience. High school diplomas are the minimal requirement for data entry technicians.

### **1.3.6 Federal and Federal-Contractor Staff**

Personnel qualifications have not been supplied by EPA for Federal or Federal-contractor staff members that will process samples, analyze samples, or perform data management tasks.

## **1.4 TRAINING REQUIRED**

### **1.4.1 Survey Staff**

Each field interviewer will be trained in all aspects of her job. RTI project staff will prepare an interviewer's manual which will detail all of the activities the interviewer will accomplish. We will include question-by-question specifications for each of the data

collection instruments. These specifications can provide information on the purpose of the question, alternative wording the interviewer is allowed to use if the respondent is having difficulty, and the range of acceptable answers, as well as edit procedures to be followed at the end of the interview. The interviewer's manual will be supplemented with the RTI General Interviewer's Manual and the standard training guide for counting and listing. These two standards provide training on activities common to all projects, allowing the project-specific interviewer's manual to remain focused.

We will prepare a training guide which will direct the interviewer's home study of the interviewer's manual. The guide will contain study exercises and self-tests. After the interviewer has completed the home study and returned the tests, an RTI project staff member will review the material with the interviewer and conduct a final test. This review and test will be conducted by telephone and will use a standard script and test to ensure consistency among the interviewers. Each interviewer will be allowed to begin work only after successfully completing the telephone review and test. The evaluation material will be maintained with the interviewer's other administrative material. Additional home study will be required for any interviewer whose performance is determined to be unsatisfactory.

#### 1.4.2 Field Technicians

All initial project staff members will undergo six to eight weeks of training that covers all aspects of the planned sample and data collection activities. Training topics and activities will include (but are not limited to) the following:

- Reading and understanding all sample collection protocols.
- Reading and understanding the overall study design.
- Reading and understanding the specific field study script and logistics.
- Laboratory training and practice for all sample collection equipment.
- Training with computer-aided data collection systems and software.
- Training and practice with all technician administered survey instruments.
- Training on all mobile laboratory operations, shipping procedures, and equipment maintenance.
- Training on all aspects of travel, decorum, communications, and safety procedures.
- Self-completion of all study activities.
- Practice of procedures on fellow project staff members.
- Full scale training with the complete study design on other Institute staff members.

In addition to the training described above, the initial two to four weeks of field sample collection activities will be performed under the direction of a supervisor with extensive experience in conducting exposure monitoring studies. If new staff members are hired after the study commences, they will receive an abbreviated training session with supervised on-the-job training in the field. All field technician training activities will be documented in a training file maintained for each technician.

The field study supervisor will conduct periodic inspections of operations at the field sites. Continuing compliance with written protocols will be evaluated during these visits.

Additional training and corrective actions will be performed, as necessary, and problems with implementing written procedures will be noted and reported to the Principal Investigator and for significant cases, to the EPA Principal Collaborator (PC).

#### **1.4.3 Field Study Supervisor**

The field study supervisor will not undergo a planned schedule of training activities. However, it will be the field supervisor's responsibility to train the field technicians, assist in designing the sample collection plan, and to help develop and test the sample collection protocols. It is, therefore, important that the field supervisor have a thorough understanding of overall NHEXAS program objectives and of the specific RTI/EOHSI consortium study design, hypotheses, and objectives. The field study supervisor will read all NHEXAS background and study design documents made available to the consortium. The supervisor will attend and participate in most pertinent consortium planning meetings. If possible, the supervisor will attend or participate in several of the NHEXAS workgroups and workshops planned prior to initiating study activities. These may include the questionnaire, dermal, and NIST/QA workshops and the biomarker discussion group. Attendance or participation in workshop or workgroup discussions will be documented in a NHEXAS training file for the field supervisor.

#### **1.4.4 Laboratory Staff**

All project laboratory analysts will be required to read and understand analytical protocols and perform the analysis methods using calibration, control, test, or other materials before analyzing study samples. Laboratory sample processing personnel will be required to read and understand sample processing protocols and perform the processing methods using control or other test materials before processing study samples.

#### **1.4.5 Data Management Staff**

The survey operations manager and database manager will not undergo a planned schedule of training activities since they are responsible for understanding all methods and writing the appropriate protocols. The supervisor and manager will be responsible for reading all associated NHEXAS material relevant to their areas of responsibilities, and will attend pertinent planning meetings. Data entry technicians will be trained by supervisory staff using the applicable NHEXAS questionnaires and sample data, and must demonstrate acceptable data entry skills.

#### **1.4.6 Federal and Federal-Contractor Staff**

Personnel training requirements have not been supplied by EPA for Federal or Federal-contractor staff members that will process samples, analyze samples, or perform data management tasks.

## 1.5 EXPERIMENTAL DESIGN

### 1.5.1 Survey Objectives

Broadly stated, the goals of the Phase I Study are twofold:

- (i) to demonstrate and evaluate methodology and field procedures for carrying out a nationwide NHEXAS program, and
- (ii) to produce exposure and exposure-related data which, through statistical analysis and exposure modeling, can produce meaningful inferences for EPA's Region V and which can potentially aid in the design of later phases of NHEXAS.

The discussion below relates to the types of hypotheses associated with (ii), which are listed as follows:

1. To test the adequacy of initial (i.e., pre-study) exposure assessments.
2. To test for subpopulation differences (e.g., biologically sensitive subgroups).
3. To test for effects of toxicant sources.
4. To test for associations (e.g., between environmental media concentrations and measures of exposure).
5. To apportion exposures among (measured) pathways.
6. To improve or develop exposure models (for extrapolation to long-term exposures, and for understanding media/exposure/dose relationships).
7. To improve the design of later phases of NHEXAS.

These hypotheses, objectives and the associated data analytic methods are briefly described below; more detail is provided in Section 3.4.

The above seven hypothesis categories are restated in Table 2. Within each major type, the table lists the more specific types of hypotheses to be investigated; for each type, the table indicates the relevant chemical classes (the X in the tabular cell indicates that at least the primary chemicals in the class will be examined).

Specific data analysis will include statistical estimation of the overall target population's exposure distributions and associated biomarker and environmental media concentration distributions, as well as similar estimated distributions for relevant subpopulations. These estimates will be used to assess the adequacy of initial (i.e., pre-study) exposure assessments (Hypothesis Type 1) and to assess exposure and concentration differences among subpopulations (e.g., different age groups, persons or homes with different activities or potential sources – i.e., Hypothesis Types 2 and 3). These analyses will involve producing pertinent descriptive statistics associated with the measured quantities (e.g., means, standard deviations, percentiles), along with standard errors of the estimates.

Other analyses (Hypothesis Types 4 and 5) will be used to examine associations of toxicant levels – for example, associations between exposure and biological markers, between exposure and environmental media measurements, or between two (or more) exposure pathways. These analyses will be useful for understanding the relative contributions of the

various pathways, understanding the degree to which the pathways are dependent upon one another, and understanding how alternative ways of measuring exposure-related quantities relate to one another (e.g., indoor air vs. personal air).

Evaluating (testing) and improving, or developing, exposure models will be another major use of the data (Hypothesis Type 6). One type of model development, which will be possible only for those quantities measured both in the initial monitoring period and in the followup periods, will examine direct estimation of long-term (e.g., annual) exposure distributions from the short-term (e.g., weekly) measurements. This will require analysis of the temporal relationships among the short-term physical measurements (e.g., seasonal adjustments, estimation of autocorrelations). This type of analysis is extremely important in understanding how, and to what extent, short-term measures can be used in exposure assessments of chemicals with chronic effects -- for instance, in obtaining an estimate of the 90th percentile of a long-term distribution. A second type of model to be investigated will involve relating the physical measurements to questionnaire and/or diary data (and possibly to other physical measurements). If such models are viable, future studies (including later phases of NHEXAS) may be able to use double sampling approaches in which a large sample of participants provides data on the predictor variables (i.e., the less expensive measurements) and only a small subsample is needed to provide data on the more expensive and burdensome direct measures.

It should be noted that Hypothesis Types 2 through 6 go beyond the Phase I Study; similar hypotheses will be of interest in later phases of NHEXAS. As such, their results can and should here be viewed as intermediate and exploratory in nature, both within the context of the Phase I as well as within the overall NHEXAS program. For instance, comparing exposure for different subpopulations, as is involved in Hypothesis Types 2 or 3, may facilitate the development of exposure-related models (Type 6 Hypotheses) during the Phase I. They, or the Phase I-Study models resulting from them, may also influence the focus of data collection and/or model development used in later phases. The same applies to Hypothesis Types 4 and 5. For example, correlation estimates between media concentrations and exposure for the Phase I Study data, and other similar measures of association, should be viewed as representing precursors to model development in the Phase I Phase and to analyses in later phases of the program (when the sample sizes should be more adequate to explore the generally complex dose/exposure/source and activity relationships). Even so, care must be exercised in making such judgments, since a nonsignificant association may simply be indicative of short contact times, of a correlation between activities and concentration level (so that measured concentrations do not reflect concentrations during periods of contact), or of effects of confounding variables.

Another use of the data is to address Hypothesis Type 7 -- to improve later phases of NHEXAS. Some analyses will be aimed at improving the sampling design directly. The sample for later phases can be allocated more efficiently by using estimates of cost components and variance components by stages of sampling for specific compounds and routes of exposure. Other types of analyses will estimate response rates and identify factors and sampling stages that seem to have the most influence on the rates. As a result of such analyses, changes in field procedures (e.g., ways of enrolling participants, ways of administering survey instruments) may be indicated for subsequent phases of the study.

### ***Key Survey Variables***

Based upon the above discussion it is clear that the key variables for the NHEXAS Phase I Study are the direct physical measurements of exposure and dose and of the related environmental media concentrations, since estimated regional (and ultimately, national) distributions of these types of quantities are part of the focus of NHEXAS. The primary chemicals of interest in each class were given in Table 1. Those questionnaire items needed to define important analysis domains may also be regarded as key. These include variables such as age and education level that may be used to identify susceptible subpopulations (e.g., children, low socioeconomic status), at least in later phases of the study. It may also include a few variables that identify strong sources of the toxicants that may tend to dominate the high-end portion of the exposure distribution (e.g., personal air benzene exposures from combustion sources such as tobacco smokers or auto exhaust).

#### **1.5.2 Survey Design**

Given the above study hypotheses and objectives, important study design features are:

- selecting a probability sample from persons residing in EPA Region 5 to ensure that the sample supports design-unbiased inferences to the residents of that region;
- selecting a large enough sample of primary sampling units (PSUs) that the first stage of sampling supports reliable estimation of the sampling variances of survey statistics, as well as adequate representation of the survey population;
- selecting a probability sample at each stage of sampling that supports estimation of the variance component due to that stage of sampling;
- selecting a large enough sample of persons to achieve sufficiently small sampling variances for survey statistics, accounting for the variance inflation effects of multistage sampling and unequal probabilities of selection; and
- achieving a response rate that is as high as possible to minimize the potential for nonresponse bias.

The details of the proposed probability sampling design are presented in Section 2.1. The precision we expect to achieve for important survey statistics is presented in Section 2.2.

Briefly, we propose a stratified, four-stage probability sampling design. (1) A sample of 35 counties selected with probabilities proportional to 1990 Census counts of occupied housing units is proposed at the first stage of sampling, unless additional funds become available for increasing the sample size. A sample of 30 to 50 counties is considered

minimally sufficient to support inferences to EPA Region 5.<sup>1</sup> (2) Four sample areas (area segments) defined from 1990 Census blocks will be selected within each sample county with probabilities, again, proportional to 1990 Census counts of occupied housing units. This design supports equal overall probabilities of selection for housing units by taking a fixed number of sample housing units per area segment. (3) A simple random sample of housing units will be worked sequentially in each area segment at the third stage of sampling until (4) a fixed number of study participants (either two or three) has been selected at the fourth stage of sampling in each area segment. A total of nine participants will be selected in each sample county for a total of 315 persons who agree to participate in the monitoring phase of the RTI/EOHSI NHEXAS Phase I study, unless funds become available for increasing the sample size.

In addition, two experimental designs are imbedded into the RTI/EOHSI survey design for the NHEXAS Phase I study. One experiment is designed to test potential differences in response rates by testing two alternative modes of presenting the monitoring program to sample subjects and by testing two levels of monetary incentives. The other experiment is for selection of persons for longitudinal followup. The longitudinal component of the study is needed to estimate autocorrelations over time within sample persons to enable model-based extrapolation to longer-term exposure distributions (e.g., annual or lifetime).

### ***Response Rate Experiment***

Two aspects of the NHEXAS communications strategy are expected to have a positive impact on response rates. First, we will be meeting with representatives of all communities in which sample households will be selected. We will explain the nature of the study in their community and request their endorsement. Ideally, the interviewer will be able to carry a letter of endorsement from a local official and/or a statement of endorsement from the local newspaper. We have found that endorsement, of lack of it, at the local level can have a major effect on response rates.

Second, we will offer to send a report regarding the results of the monitoring in their home to each participant. The report will put their results in perspective with regard to the remainder of the sample (e.g., percentile and comparison to the highest, lowest, and median values). In addition, if any health effect levels have been established at the national, state, or local level, those reference values will be reported. People may be particularly interested in

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The number of degrees of freedom available for estimating the sampling variance in a stratified multi-stage survey is the number of PSUs minus the number of strata. Hence, the number of sample PSUs must be relatively large to obtain reliable estimates of precision. Hansen et al. (1953, p. 134) recommend a sample of at least 50 observations to estimate the variance of a characteristic that is Normally distributed, more for non-Normal observations. Moreover, the cost-efficient allocation to the first stage of sampling increases as the cost per ultimate observation increases (Hansen et al., 1953, p. 408), which will be relatively large for the NHEXAS. Therefore, fewer than 50 sample PSUs is difficult to justify statistically.

REFERENCE: Hansen, M.H., Hurwitz, W.G., and Madow, W.G. (1953). *Sample Survey Methods and Theory*, Volume 1. Wiley, New York, NY.

the results for certain compounds, like lead. Hence, the study results may be a valuable incentive for some people to participate.

We are concentrating on achieving high response rates primarily for monitoring procedures that are essential for the national Phase II NHEXAS. A minimal Phase II study would be one that achieves high response rates for "screening" methods that can be used to identify people with high total exposures (for follow-up in Phase III). These methods need not be the most sensitive analytical methods available so long as they capture total exposure, are sensitive enough to identify highly exposed individuals, and can be implemented with high response rates (e.g., around 70 percent, overall).

We think the passive VOC monitoring plus the monitoring of biologicals (blood, urine, and hair) is an appropriate minimal set of monitoring activities for Phase II. Since VOC exposure occurs primarily through inhalation, the passive VOC monitoring is essentially total exposure monitoring for VOCs. Since all routes of exposure are potentially important for metals, and they have long half-lives in the body, the biologicals are excellent for screening for high exposures. Some metals are found primarily in the blood, while others are found primarily in the urine; hence, both are needed to screen for high exposures. Since there is relatively low burden associated with collecting hair samples and they are also useful for detecting exposure to certain metals, they may also be included in the minimal set of monitoring activities for Phase II. We note that these types of minimal screening activities with their emphasis on biological and passive monitoring could easily be melded into the NHANES data collection regimen, if that would enhance either NHEXAS or NHANES in the future.

Although a screening set of data items would be minimally sufficient for Phase II, as described above, our hope is that the Phase I field study can develop and validate a methodology for presentation of all the proposed monitoring techniques, including incentives for participation, such that the response rate for each exposure monitoring activity will be sufficient for inclusion in Phase II. One approach to this objective would be to randomly assign half the sample counties to each of two sets of incentives. However, given that similar exposure monitoring studies have often produced overall population response rates in the 50 to 60 percent range, we could easily be testing two sets of incentives, neither of which is sufficient, and not be able to detect that problem until over half of the sample counties had been completed.

Therefore, we have decided to begin implementation of Phase I with an aggressive incentive scheme that we expect has a good chance of producing satisfactory response rates, monitor its success, and modify the package if response rates do not appear to be satisfactory. If modifying participant incentives and program presentation do not appear to be sufficient, we will consider modifying the data collection procedures to make them less burdensome. For example, we could reduce the number of days of aerosol monitoring with the active pump from 6 days to 3 days. Similarly, the number of days of collection of food samples could be reduced (e.g., from 4 days to 2 days).

If we are forced to implement two quite different monitoring schemes (e.g., integrating over different numbers of days) to improve response rates, we will gain valuable information for designing the Phase II study at the expense of potential statistical analysis

results for Phase I. Similarly, if two different incentive schemes produce quite different response rates (e.g., 65 percent versus 45 percent), it may be inappropriate to combine the data produced with these two methods for inference to EPA Region V. In the latter case, relationships could be analyzed within the context of the sample itself. Whereas, in the former case (different data collection protocols), even those analyses may not be possible.

We propose a separate cash incentive for participation in each set of activities. The incentive for participation in food monitoring (\$90) is considered to be \$60 reimbursement for 4 days of food specimens and \$30 actual participation incentive. Because the aerosol and food monitoring are expected to impose the greatest burden on participants, each person who participates in one of these activities will also be given a raffle ticket (pursuant to compliance with local regulations, if any). Those who participate in both activities will receive two raffle tickets. Raffle winners will be selected quarterly from the tickets of participants during that quarter. The winners will receive their choice of \$500 cash or a selected item that we can obtain for approximately \$500. We will attempt to select items that are likely to appeal to different age groups (e.g., Sego game system, stereo system, television, etc.).

We feel that the above strategy of a decent cash incentive (e.g., \$30 to \$40) combined with a raffle may be the most cost-effective way to get participation for the most burdensome monitoring activities. If the funds required for the raffle described above were to be used to instead increase the cash incentives, the incentives for aerosol and food monitoring would be increased by only about \$10 each. We expect that the raffle with odds of about 1-in-50 of winning with one raffle ticket, or 1-in-25 with two raffle tickets, will have a greater impact than would an additional \$10 in cash incentive.

In addition, the monitoring team will carry with them a selection of nominal "Thank You" gifts to give to children under the age of 13 who agree to participate (e.g., toys, games, or t-shirts). We expect that some immediate, non-cash award is important for obtaining the full cooperation of children who participate.

In addition to making the concerted effort described above to develop and validate data collection procedures in Phase I that can produce acceptable response rates for Phase II, we will debrief each person who completes the Baseline Questionnaire. For each set of monitoring activities in which they do not participate, they will be asked what it was about those activities that most influenced their decision not to participate. The types of information to be collected in the debriefing, or post-refusal, questions include the following:

- Common reasons for refusals for refusals to surveys, in general.
- Levels of burden for this study, both real and perceived.
- Perceived value of incentives.
- Provision of sufficient information during introductions and transitions between phases.
- Effect of the order of presentation of the components of the study.

- Expected effects of potential reductions in burden.
- Reasons that respondents start the process and then decide not to continue, either between phases or during a phase.

Finally, the sets of monitoring activities will be presented to participants in a manner that will allow us to infer the response rates to expect if the VOC and aerosol monitoring were conducted with separate samples of participants in Phase II. In each county, half the participants will be randomly selected to be asked about participation in the Core (VOC) monitoring activities first. The other half of the participants will first be asked about participation in the aerosol monitoring activities. Each half-sample can be used to estimate the response rate that would be achieved if sample members were asked to participate only in the set of activities presented first.

### *Longitudinal Monitoring Design*

The basic reason for acquiring some temporal information (i.e., several weeks of exposure-related data) for the NHEXAS participants is the need to understand the magnitude of temporal changes and how such changes affect long-term (e.g., annual or lifetime) exposure distributions. One important aspect of the data analysis is to examine the feasibility of estimating long-term exposures because the primary endpoints for many toxicants of interest are of a chronic nature. Estimation of an exposure distribution having a person-week as its basic unit can be done directly (i.e., without resort to a model) if one obtains weekly exposure measurements from a valid probability sample of individuals and weeks. The mean of this distribution also is meaningful in terms of a longer time frame -- for instance, an annual mean may be estimated by multiplying the weekly mean by 52, if we sample with known probabilities from a frame representing all weeks in a year. However, other aspects of the annual distribution (e.g., the 90th percentile) cannot be directly associated with the points on the distribution of weekly exposures. To have the potential for developing exposure models that can produce exposure (or exposure-related) percentile estimates for time frames longer than those associated with the monitoring period requires that the participants furnish data for multiple monitoring periods. At a minimum, this information will indicate the degree of autocorrelation among the measurements, and thereby indicate the likelihood that a "high" toxicant level in a given week can reasonably be used as an indicator that the individual is among the highly exposed population over the course of a year. If the autocorrelation is high, intra-person variability will tend to be small relative to inter-person variability. In that case, future phases of NHEXAS may be able to rely on less frequent sampling in the temporal dimension; if not, including frequent temporal sampling may be necessary in later phases of NHEXAS if the distributions of long-term exposures must be estimated.

Therefore, an integral part of the RTI/EOHSI NHEXAS design is an investigation of autocorrelations between one-week exposures at several different lag intervals. Lag times between one and eight months will be investigated. This will enable sufficient sample sizes for each lag interval (in months) to produce reasonably stable estimates of the autocorrelations for these lag intervals. Autocorrelations will not be directly estimated for longer lag times because of the need to complete field data collection within about 15 months and because the autocorrelations for these longer-term lags should be small. Moreover, they

can be modeled by extrapolating from a plot of autocorrelation as a function of lag times. The function should be relatively flat and stable for longer lag times.

Each participant in about the first 22 sample counties will be asked (after completing the primary data collection activities) to participate in the longitudinal followup for two different lag times (e.g., 1 month and 6 months). The followup will be conducted by mail and will consist of the core monitoring activities listed in Table 3 for the second and third visits. As also shown in this table we expect about 150 (80 percent) of the participants to complete the first followup and about 135 (90 percent) of these to also complete the second followup.

The assignment to lag times will be stratified so that participants during the first 15 to 17 months are assigned to the full range of potential lag times from 1 to 8 months and participants in the last 5 to 7 months are assigned only to shorter lag times. This will enable all the followup data collection activities to be completed approximately at the same time that primary data collection activities are being completed in the final sample county.

Although each person who participates during the first 15 to 17 months will be assigned two follow-up appointments, pairs of months will be assigned to persons in a controlled random manner so that all lags from 1 to 8 months are approximately equally represented. Hence, we will not be producing cross-sectional estimates based on the follow-up participants.

Instead, the primary purpose of the proposed longitudinal follow-up study is to estimate intra-personal autocorrelations for lag times from 1 to 8 months. These estimated autocorrelations will be used to model the autocorrelations as a function of time and thereby enable model-based estimation of long-term exposure distributions (e.g., distributions of total annual exposures). From this standpoint it would be desirable to collect all sample types during the longitudinal monitoring. However, some sample types, including blood, good, dust wipe samples, and air aerosol samples will not be collected as part of the longitudinal monitoring. Given the fixed funding availability, having the field technicians return two times to the homes would require reducing the initial population sample size to levels that would introduce unacceptable imprecision in exposure distribution estimates. A second purpose of the longitudinal monitoring results from the limited resources that are available for performing follow-up visits by the field technicians. We are using this phase 1 study to help learn whether some types of samples can be effectively collected and returned to the laboratory by study participants. This option will be very attractive when a national study is conducted, particularly if multiple sample collection periods are needed. Some sample types, including blood, dietary, and active pump aerosol collection are not suitable for collection by the participants and were not included in our follow-up design.

Non-response bias is not expected to be a major consideration for estimating autocorrelations. However, maintaining as high a longitudinal participation rate as possible remains important. Therefore, the following panel maintenance procedures will be implemented.

In addition to the soil collection mat and dust collection plate, each subject who agrees to participate in the longitudinal follow-up study will be provided with a toll-free

(800) telephone number for calling RTI if they will not be able to keep their scheduled appointment or if they have any questions about the study. They will also be provided with a pre-paid postcard addressed to RTI, should that be a more convenient mode of communication for some participants.

The lag times between appointments (either the initial visit and the first follow-up or between the two follow-up appointments) will range from 1 to 7 months, about half being 4 to 7 months. Whenever the lag time is 2 months or more, a reminder postcard will be mailed to the participant 3 to 4 weeks before the scheduled appointment. The postcard will remind the participant to call the toll-free RTI telephone number if they need to re-schedule their appointment or if they have any questions.

#### *Pesticide/PAH Module*

Because of a limitation of funds until fiscal year '95, a 50-home Phase I test of data collection methods for assessing human exposures to pesticides and polynuclear aromatic hydrocarbons (PAHs) (the pesticide/PAH module) will be conducted separately from the 315-home Phase I test for metals and VOCs. Children will be oversampled in this module because they are a sensitive subpopulation for exposures to pesticides. The pesticide/PAH study will be conducted after all data collection for the primary investigation has been completed. The module will be conducted in a one- or two-county area within EPA Region 5, possibly the Cooke County, Illinois area. In this case, a probability sample of households and participants will be selected much as described above, except that the selection of area segments becomes the first stage of sampling. Therefore, the sample would be based on approximately 25 primary sampling units (area segments constructed from 1990 Census blocks), which would support limited inferences to the one- or two-county target population for the pesticide/PAH module.

The results of testing the sampling and analysis methodologies in this module will be important for the design of Phase II of the NHEXAS because Phase II is expected to include assessment of human exposures to pesticides and PAHs.

**Table 1. ANALYTES AND POLLUTANT CLASSES TO BE MONITORED  
IN RTI/EOHSI CONSORTIUM**

	Metals	VOCs	Pesticides	PAHs
Primary	Lead Arsenic	Benzene Chloroform Perchloroethylene Trichloroethylene	Chlorpyrifos Diazinon Atrazine Malathion	Benzo(a)pyrene Benzo(a)anthracene
Secondary	Cadmium Chromium	Methylchloroform Styrene Toluene Xylenes <i>p</i> -Dichlorobenzene	Chlordane Dieldrin Heptachlor 4,4'-DDE 4,4'-DDD DDT	Acenaphthylene Anthracene Benzo(ghi)perylene Fluoranthene Phenanthrene Pyrene Indeno(123-c,d)pyrene

Table 2. HYPOTHESES FOR NHEXAS REGION V

Hypothesis Type	Metals	Particles	VOCs	Pest.	PAHs	Comments
<b>1. TEST FOR ADEQUACY OF INITIAL EXPOSURE ASSESSMENTS</b>	X		X			Weighted data analysis is used to furnish population estimates.
1A. Exposure or concentration distribution from initial EA is/is not comparable to Pilot Study results.						
1B. Exposure or concentration data from the Pilot Study can/cannot be used to improve EA results.	X		X			Initial EA models rerun using Pilot Study data.
<b>2. TEST FOR SUBPOPULATION DIFFERENCES</b>	X					Questionnaire/diary data are used to define BS subpopulations. Weighted data analysis is used to furnish (sub)population estimates.
2A. Biologically sensitive (BS) subpopulations have/do not have total exposures like those of the general population.						
2B. Exposures for certain segments of the population are/are not different than those of the general population.	X	X	X			Questionnaire/diary data are used to define domains. Weighted data analysis is used to furnish (sub)population estimates.

Table 2. HYPOTHESES FOR NHEXAS REGION V (CONTINUED)

Hypothesis Type	Metals	Particles	VOCs	Pest.	PAHs	Comments
2C. Biological marker measurements for certain segments of the population are/are not different than those for the general population.	X		X			Questionnaire/diary data are used to define domains. Weighted data analysis is used to furnish (sub)population estimates.
2D. Environmental media concentrations for certain segments of the population are/are not different than those for the general population.	X	X	X			Questionnaire/diary data are used to define domains. Weighted data analysis is used to furnish (sub)population estimates.
<b>3. TEST FOR EFFECTS OF SOURCES</b>						
3A. Exposures for segments of the population having certain sources are/are not different from those of the general population.	X	X	X			Questionnaire/diary data are used to identify participants with potential sources/activities. Weighted data analysis is used to furnish (sub)population estimates.
3B. Environmental media concentrations for segments of the population having certain sources are/are not different from those of the general population.	X	X	X			Questionnaire/diary data are used to identify homes with potential sources/activities. Weighted data analysis is used to furnish (sub)population estimates.

**Table 2. HYPOTHESES FOR NHEXAS REGION V (CONTINUED)**

Hypothesis Type	Metals	Particles	VOCs	Pest.	PAHs	Comments
3C. Personal exposure measurements do/do not correlate with measures of source intensity.	X	X	X	X	X	Questionnaire/diary data are used to define measures of source intensity.
3D. Environmental media concentration measurements do/do not correlate with measures of source intensity.	X	X	X	X	X	Questionnaire/diary data are used to define measures of source intensity.
<b>4. TEST FOR ASSOCIATIONS</b>						
4A. Personal exposure measurements do/do not correlate with biological markers.	X		X	X	X	
4B. Personal exposure measurements do/do not correlate with environmental media concentration measurements.	X	X	X	X	X	
4C. Alternative media measurements are/are not correlated.	X	X	X	X	X	

Table 2. HYPOTHESES FOR NHEXAS REGION V (CONTINUED)

Hypothesis Type	Metals	Particles	VOCs	Pest.	PAHs	Comments
<b>5. APPORTION EXPOSURES AMONG PATHWAYS</b>	X		X			
5A. All measured pathways contribute equally/unequally to exposures.						
5B. Pathway contributions are/are not independent.	X		X	X	X	
<b>6. IMPROVE OR DEVELOP EXPOSURE MODELS</b>	X			X		Food diary data are used to provide consumption data. Toxicant concentrations for food items derived from Total Diet Study.
6A. Individuals' food exposures estimated by combining consumption data with concentration data from the Total Diet Study are/are not different from the measured food exposures.						
6B. Individuals' air exposures estimated from dispersion models are/are not different from the measured air exposures.	X	X	X			Extant dispersion models are used to estimate exposures for selected individuals.

Table 2. HYPOTHESES FOR NHEXAS REGION V (CONTINUED)

Hypothesis Type	Metals	Particles	VOCs	Pest.	PAHs	Comments
6C. Distributions of long-term measurements (exposures, doses, and environmental media concentrations) can/cannot be estimated directly from short-term measurements (i.e., using only physical measurements).	X		X			Duan-Wallace methodology is adapted to provide annual estimates for those media with longitudinal data. Weighted data analysis used to provide estimates of population parameters used as input to models.
6D. Personal exposures can/cannot be estimated by applying dose reconstruction models to biological marker data.	X		X	X	X	Pharmacokinetic models are developed and evaluated.
6E. Questionnaire/activity data (perhaps along with environmental media measurements) can/cannot be used to predict individuals' exposures.	X	X	X	X	X	Regression-type models are developed and evaluated.
6F. Modeling of indirect dermal exposure measurements can/cannot be used to predict actual dermal exposures.				X	X	Model-based estimate of dermal exposure is compared to direct measurements.

Table 2. HYPOTHESES FOR NHEXAS REGION V (CONTINUED)

Hypothesis Type	Metals	Particles	VOCs	Pest.	PAHs	Comments
<b>7. IMPROVE DESIGN OF LATER PHASES OF NHEXAS</b>	X	X	X			Questionnaire data are used to define domains with potentially different response rates. Response rates are computed for each stage of participation both overall and by these domains.
7A. Response rates are/are not sufficient to use the Pilot Study methodology in Phase II.						
7B. Respondents are/are not a biased subset of the sample subjects.	X	X	X			For each level of participation, respondents and nonrespondents are compared based on characteristics known for all participants at the previous level(s).
7C. Variance- and cost-component estimates from the Pilot Study are/are not useful for optimizing Phase II designs.	X	X	X			Cost- and variance-components from the Pilot Study are used to determine the minimum sample allocations for Phase II.

Table 3. RTI/EOHSI NHEXAS Design: Incentives and Expected Total Participants by Data Elements

Data Elements	Analytes Monitored <sup>a</sup>	Incentive Payment	Expected Participants (Response Rate)		
			1st Visit	2nd Visit	3rd Visit
A. Participant Recruitment					
Sample Line (Potential Housing Unit)	--	--	620	--	--
Occupied Sample Housing Unit	--	--	546(88%) <sup>b</sup>	--	--
Descriptive Questionnaire	--	--	513(94%) <sup>b</sup>	--	--
Participant Selected	--	--	374	--	--
Baseline Questionnaire	--	\$5	337(90%)	--	--
B. Core Monitoring Group		\$20 <sup>c</sup>			
Indoor Air (1 week; passive)	V		300(89%) <sup>d</sup>	150(80%) <sup>e</sup>	135(90%) <sup>f</sup>
Outdoor Air (1 week; passive)	V		100	85	77
Total Personal Air (1 week; passive)	V		300	150	135
Non-Work Personal Air (1 week; passive)	V		50(NA)	--	--
Time Diary/Activity Chart (1 week; daily)	--		300	150	135
Followup Questionnaire (1 week)	--		300	150	135
Tap Water (initial)	M		300	150	135
Tap Water (flushed)	M,V <sup>g</sup>		300	150	135
Urine (2 timed samples; item nonresponse allowed)	M	\$5	280(83%) <sup>d</sup>	140(93%) <sup>h</sup>	126(93%) <sup>h</sup>
Blood (3 vials; item nonresponse allowed)	M,V	\$50	280(83%) <sup>d</sup>	--	--
Hair	M				

Table 3. RTI/EOHSI NHEXAS Design: Incentives and Expected Total Participants by Data Elements

Data Elements	Analytes Monitored <sup>a</sup>	Incentive Payment	Expected Participants (Response Rate)		
			1st Visit	2nd Visit	3rd Visit
C. Core-Plus Monitoring Group					
Indoor Air (1 week; active) (Item nonresponse allowed)	M,PAR		239(71%) <sup>d</sup>	--	--
Outdoor Air (1 week; active) (Item nonresponse allowed)	M,PAR		100	--	--
Total Personnel Air (1 week; active) (Item nonresponse allowed)	M,PAR	\$40	239	--	--
Window Sill Dust	M,PAR		239	--	--
Primary Living Area Dust	M,PAR		239	--	--
Dust Collection Plate	M,PAR		----->	150 ----->	135
Main Entrance Floor Mat	M		----->	150 ----->	135
Entranceway and Yard Soil	M		50(NA)	--	--
Food and Beverages (4-day composite; item nonresponse allowed)	M	\$90 <sup>i</sup>	259(77%)		
Food Diary (4 days)	--		259		

<sup>a</sup> M=Metals; PAR = Particulates; V=VOCs.

<sup>b</sup> 94% of the 653 occupied sample housing units.

<sup>c</sup> Plus \$10 for first followup and \$20 for second followup.

<sup>d</sup> Percentage of the 337 persons completing the baseline questionnaire.

<sup>e</sup> 80% of the 188 core group participants asked to participate in the followups.

<sup>f</sup> 90% of the 150 first-followup participants.

<sup>g</sup> VOCs in water will not be analyzed in followup.

<sup>h</sup> 93% of the followup participants will collect urine.

<sup>i</sup> \$30 incentive plus \$15/day reimbursement for food samples.

## SECTION 2 PROJECT IMPLEMENTATION PLAN

### 2.1 PROJECT DESIGN CRITERIA

#### 2.1.1 Population Sampling Design

##### *Target Population and Coverage*

In addition to the criteria discussed earlier, the geographical area to be studied in the RTI/EOHSI NHEXAS investigation was selected to be an area that would result in a mini-national study to provide a realistic field test of field procedures being developed for the national, Phase II NHEXAS. Another criterion was to select a target area where the statistical inferences for the study toxicants would be of independent scientific interest for the target population selected for the Phase I Phase I study itself.

Given these considerations, EPA Region 5, which consists of the States of Minnesota, Wisconsin, Michigan, Illinois, Indiana, and Ohio, was selected as the geographic target area for the RTI/EOHSI NHEXAS Phase I investigation. This area is a relatively large population that provides a realistic test of NHEXAS field procedures as they could be implemented in a national study.

Other aspects of the definition of the target population for the RTI/EOHSI NHEXAS investigation are summarized in Table 4.

As is true for most environmental monitoring studies, exposures to the NHEXAS target toxicants vary almost continually in time. Therefore, the population units sampled and observed must be defined in terms of both spatial and temporal units (68). For the RTI/EOHSI NHEXAS investigation the target population consists of all person-weeks in EPA Region 5 during the approximately 15-month data collection period that satisfy all the criteria listed in Table 3.

##### *Sample Design*

The sampling design proposed for the RTI/EOHSI NHEXAS investigation is a stratified, four-stage probability sampling design. A first-stage sample of 35 counties designed to yield 315 persons (nine per county) agreeing to participate in the monitoring phase of the research program is currently planned. As demonstrated later, the precision of survey estimates based on these sample sizes is minimal. Therefore, if sufficient additional resources become available, the sample size will be increased by adding additional sample counties with nine persons per county agreeing to participate.

Thirty-five counties will be selected from EPA Region 5 at the first stage of sampling. Four sample area segments defined from 1990 Census blocks will be selected within sample counties at the second stage of sampling. Approximately 3 to 6 sample households will be selected within each sample segment at the third stage of sampling. Finally, after each sample household has completed a short Descriptive Questionnaire, including a roster of all members of the household, at most one sample person will be selected at the fourth stage of

sampling for monitoring within the sample household. One- and two-persons households will be subsampled to achieve approximately equal person-level probabilities of selection in spite of unequal number of persons in sample households. The third-stage sample will be released in waves to achieve approximately three participants per area segment, resulting in 315 persons who agree to participate in the monitoring program. Each stage of sampling is described in the subsections that follow.

### *First-Stage Sample of Counties*

#### (i) Sampling frame

The sampling frame for the first-stage sample will be constructed from the 1990 Census Summary Tape File 1A (STF 1A). The sampling units will consist of county-level records from this data base, with one possible exception. Some counties with large populations and large geographic extent that is likely to make intra-county travel time-consuming for the field monitoring team (e.g., Cooke County, Illinois) may be subdivided into two primary sampling units (PSUs) based on Census tracts. Counties with small populations will not be combined to form larger PSUs because of the increased travel cost and logistical difficulties of traveling between three sample homes on a given day when they are spread across a large geographic area.

#### (ii) Sample size

A NHEXAS survey design study by Clickner et al. (69), recommends a relatively large sample of PSUs (counties) because of the high cost of collecting and analyzing environmental samples and because of the possibility of high intraclass correlations (i.e., tendency for measurements to be more alike within counties). Therefore, the RTI/EOHSI consortium has developed a field data collection protocol intended to maximize the number of sample counties while maintaining a relatively efficient field data collection protocol within sample counties. Given the NHEXAS budgetary constraints, a sample of 35 counties is planned.

As previously noted, a sample of 50 or more counties would provide more defensible estimates of precision for survey statistics. However, efficient field logistics require approximately nine participants per county, and cost limitations, hence, limited the number of PSUs to no more than 35.

#### (iii) Stratification variables

The NHEXAS survey design study by Clickner et al. (69), recommends that environmental data not be used for disproportionate stratification in the NHEXAS. Oversampling of selected strata would produce a major increase in the precision of the estimate of the percentage of the population with high exposures to a selected toxicant only if the following two conditions both applied: (1) the percentage of persons with high exposures was much higher in the oversampled strata and (2) the oversampled strata contained a high proportion (say, 75% or more) of the highly exposed population. In practice, it is difficult to satisfy both of these conditions simultaneously. Any gains in precision for one toxicant are likely to be offset by losses in precision for other toxicants, especially those in different chemical classes. Moreover, the uncertainty in estimates used to

determine optimum sampling rates for a toxicant usually results in less gain in precision than theoretically expected and can even lead to loss in precision for the target toxicant. Therefore, we propose stratification based only on general population characteristics likely to be related to analysis domains and/or general population differences in exposures to toxicants with proportionate sampling rates, as recommended by Clickner et al. (69).

The RTI/EOHSI consortium will implement temporal stratification by selecting two independent samples of counties (PSUs): 17 counties will be selected for the first temporal sample and 18 counties for the second. The monitoring program will be completed in the first 17 counties before beginning monitoring in the second 18 counties. The first sample of 17 counties will form the core of the longitudinal followup study so that valid inferences can be obtained regarding autocorrelations of environmental measurements among the population of persons residing in the target geographic area.

Proportionate geographical stratification will be based on State (the 6 States in Region 5) and size of the PSU (1990 Census count of occupied housing units). This will guarantee that the sample will be spread across Region 5, giving geographical representation. In addition, it will help ensure that small PSUs are selected proportionately to their population. This could lead to increases in precision if there are geographical differences in exposures by State or between counties with large and small populations.

(iv) Sampling method

The RTI/EOHSI consortium will select sample PSUs (counties) with probabilities proportional to size (pps) using a sequential probability minimum replacement (pmr) sampling algorithm (70). Use of pps sampling facilitates an approximately equal probability sample of housing units with equal numbers of sample housing units per county. The frame units will be sorted by State in a geographical order<sup>1</sup> and by size within State in a serpentine manner (i.e., small to large in State 1, large to small in State 2, etc.). This will result in implicit stratification with exactly proportionate sampling rates based on the frame ordering because of the sequential nature of the sampling method (71).

Sampling in time will be achieved for each of the two explicit temporal sampling strata (the first 17 sample PSUs and the next 18) by randomly ordering the sample PSUs in each temporal stratum for sample administration. This random ordering accomplishes a random assignment of counties to field data collection periods (months and seasons). However, some compromises (e.g., trading months for one or more pairs of counties) to the randomization will be allowed to achieve a feasible travel schedule for the field monitoring crew. Dr. Edo Pellizzari, the RTI Project Director, will make the final decision regarding these compromises in consultation with his field staff directors and the project statisticians.

### *Second Stage Sample of Area Segments*

#### (i) Sampling frame

The sampling frame for the second-stage sample will be constructed from the 1990 Census Summary Tape File 1B (STF 1B) block-level data records. The sampling units will be constructed by combining blocks, as needed, to construct second-stage sampling units (SSUs) of a minimal size (e.g., 20 or more occupied housing units in 1990). In no case will the combination of blocks forming an SSU cross county boundaries. Also, the occurrence of SSUs that cross block group or block numbering area (tract) boundaries will be minimized.

#### (ii) Sample size

The NHEXAS survey design study by Clickner et al. (69) recommends minimizing sample clustering because of the high cost of collecting and analyzing environmental samples and because of the possibility of high intracluster correlations (i.e., tendency for the measurements of some chemicals in some media to be more alike within counties and within areas segments). Therefore, the RTI/EOHSI consortium will select four area segments per sample county (PSU). Since the field monitoring protocol accommodates nine sample homes per county, consideration was given to selecting three segments with three participants each. However, the potential for relatively high intracluster correlations suggests that this degree of clustering may be inefficient. Therefore, we will select four area segments per county with two participants from all but one segment, which will be designated for recruiting three participants. Hence, the total number of secondary sampling units (SSUs), or sample segments, will be 140 (four in each of 35 counties).

Insufficient data are available to determine the optimum cluster size, but the available evidence suggests that smaller cluster sizes (e.g., two homes per segment instead of three) are preferable. One purpose of the NHEXAS Phase I study will be to estimate intracluster correlations for specific chemicals and media to determine the optimum cluster sizes for the national, Phase II NHEXAS. This objective is another reason for using four sample segments per county. With four sample segments per county, the eight degrees of freedom resulting from the nine participants per county result in three degrees of freedom for the between SSU variance component and five for the within SSU component, whereas three clusters of three participants each would only provide two degrees of freedom for the between SSU variance component and six for within SSUs.

Often the number of sample homes per segment is varied to compensate for the disparity between the number of housing units counted in the 1990 Census and the number of housing units listed in the field to achieve more nearly equal probabilities of selection for the sample housing units. However, since estimation of variance components is important for the RTI/EOHSI NHEXAS Phase I study, we want no fewer than two participating households per segment. Therefore, we will use the pre-specified numbers of sample participants (2 or 3) per segment, as described above.

#### (iii) Stratification variables

In keeping with the spirit of the recommendations from the NHEXAS design study by Clickner et al. (69), the RTI/EOHSI sample will be proportionately stratified by general

population characteristics that may be related to analysis domains and/or general prevalence of exposure to toxicants with proportionate allocation of the sample to the strata. Four variables from the Census STF 1B data base will be used to construct second-stage sampling strata: (1) percent urban population; (2) percent Afro-American population; (3) average housing unit value; and (4) percent single family residences. The distributions of these variables will be examined within each of the 35 sample counties to construct appropriate strata for each county. Stratification by urbanization will help to ensure that some sample homes are located in rural areas. Stratification by percentage Afro-American population will help ensure proportionate representation of the Afro-American population to enable analysis of environmental equity. Stratification by average housing unit value and by percent single-family homes will help to ensure representation of both low and high socioeconomic households, again facilitating analysis of environmental equity. Increased precision will result to the extent that exposures are more homogeneous within strata based on urbanization, percentage Afro-American households, housing unit value, and single-family versus multi-family dwellings.

(iv) Sampling method

The same sequential pmr sampling algorithm used to select sample PSUs (counties) will be used to select the four sample SSUs (area segments) within each sample PSU with probabilities proportional to size (pps) (occupied housing units in the 1990 Census). Use of pps sampling facilitates an approximately equal probability sample of housing units with equal numbers of sample housing units per segment. The second-stage sampling frame will be sorted by the stratification variables and by size within strata in a serpentine manner. This sampling method ensures proportionate representation of the strata, as well as proportionate representation of SSUs containing relatively large and small numbers of housing units.

Temporal sampling will not be attempted within sample counties because all nine participants will be monitored during essentially the same week. Participants will only have a choice of at most three consecutive start days for overlapping one-week monitoring periods. Since each monitoring period will be a full week, this choice results in little potential for self-selection bias due to starting day, although the duration of sampling may exclude some potential subjects who might be unavailable on all of the visit days.

*Third-Stage Sample of Households*

(i) Sampling frame

The sampling frame for the third-stage sample of households within each sample area segment (SSU) will be the list of all potential housing units in the area segment, as compiled by the field interviewer assigned to the county. The procedures described in detail in RTI's general field interviewer's manual will be used to produce each list of housing units. These procedures prescribe the starting point and listing order in a manner that ensures completeness and reproducibility. Each list of housing units will be sent to RTI for in-house verification of completeness and conformance with the prescribed procedures. Field staff will be consulted, as needed, to correct any errors or omissions detected. The half-open interval sampling rule described below ensures complete coverage of the household population even when individual housing units are sporadically missed in the housing unit lists.

(ii) Sample size

A negative binomial sampling procedure will be implemented in each sample segment to achieve a pre-assigned number of participants in each segment. Hence, the sample size will be a random variable, the number of sample housing units needed to produce "m" successes (participants).

One of the four area segments in each sample county will be randomly selected to have three participants recruited. Two participants will be recruited from each of the other three area segments. Thus, the total number of sample households yielding a participant in the monitoring phase of the study will be 315 (nine in each of 35 counties).<sup>2</sup>

(iii) Stratification variables

There will be no stratification of sample households within sample segments.

(iv) Sampling method

Use of the negative binomial sampling procedure requires that all housing units listed for each sample segment first be placed in a random order so that the first "x" sample housing units constitute a simple random sample of size "x," for every integral value "x." A pseudo-random number generator will be used to generate a randomly ordered set of line numbers for each sample segment once the number of housing units (lines) listed is known. To achieve "m" participants in a segment, we will begin by fielding the first "m" housing units on the randomly ordered list (a simple random sample of size "m"). When the final result for one of these sample housing units is that they have refused, are ineligible, or are considered incapable of participating, the field supervisor will increase the size of the simple random sample by one housing unit by activating the next housing unit on the randomly ordered list (a supplemental sample of size one).

The third stage sample size for each segment will be the number of sample housing units activated for data collection. Each refusal or other non-interview at a survey-eligible sample housing unit will count against the survey response rate. Therefore, sample housing units beyond the initial "m" housing units will be activated only by the field supervisor who has verified that all possible attempts to obtain a response have been completed. Inability to contact the members of an occupied housing unit after repeated attempts will not be sufficient reason to activate an additional sample housing unit.

Whenever a sample housing unit is released for contact, the interviewer will check for missed housing units within the sample housing unit as well as between the sample housing unit and the next listed housing unit. Each missed housing unit identified in this manner will be included in the sample unless a call to the sampling staff at RTI results in selection of a subsample of the missed housing units when more than one missed housing unit is found between a sample housing unit and the next listed housing unit. Each missed housing unit that produces a study participant will count toward the requisite number of participants in

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Unless funding becomes available for selecting a larger sample.

the sample segment. This procedure ensures nearly complete coverage of occupied housing units in the target population.

*Fourth-Stage Sample of Persons for Monitoring*

(i) Sampling frame

The sampling frame for the fourth stage of sampling will be the roster of household members complied in the Descriptive Questionnaire for each household in the third-stage sample. The interviewer will use appropriate probes to check for completeness of the roster (e.g., "Does anyone else live here now?"). The interviewer will also remove any household members not eligible for the RTI/EOHSI Phase I study, based on the eligibility criteria listed in Table 4, before implementing the selection of a household member for the fourth-stage sample.

(ii) Sample size

No more than one participant will be selected from a sample household for the RTI/EOHSI NHEXAS investigation. Personal exposures have usually been found to be highly correlated with environmental conditions in the home. Therefore, the exposure measurements for multiple participants in a home would be expected to be highly correlated as well. Hence, these additional observations would be expected to contribute little to the overall effective sample size, unless separate analyses were planned where each analysis domain would contain no more than one household member (e.g., age-specific analyses). Two additional reasons to recruit no more than one participant per sample household are cost and respondent burden. The loss of effective sample size would be inconsequential if the additional data were available at little additional cost. However, just the opposite is true. Chemical analysis of the additional environmental and biological specimens would be expensive. Finally, these considerations do not justify the potentially large increase in respondent burden for a participating household (e.g., collecting and storing food samples for more than one person) if more than one participant were selected.

We are concerned that requiring each participant to participate in all facets of the RTI/EOHSI environmental monitoring program would result in response rates that would be unacceptably low for a national, Phase II survey (e.g., less than 50 percent). Since a major purpose of the NHEXAS Phase I study is to demonstrate a methodology that can be implemented nationally in Phase II, we felt that including an option for participation in which a relatively high response rate could be expected was very important. Therefore, we have partitioned the RTI/EOHSI monitoring activities into a core group and a "core-plus" group, as shown in Table 3. The anticipated response rates are based entirely on the professional judgement of the RTI researchers based on our experience with similar studies. We will attempt to get every sample subject to participate in all aspects of the monitoring program. The differential monetary incentives shown in Table 3 increase as the participant burden increases and are intended to encourage full participation. A person who participates in only the core monitoring program, electing not to provide a blood sample, will receive an incentive payment of only \$30. However, a person who agrees to all facets of the monitoring program will receive a \$210 incentive payment, \$60 of which is considered compensation for food samples provided for chemical analysis, plus two chances at a raffle prize worth approximately \$500.

We expect that 89 percent of the persons recruited to participate in the RTI/EOHSI NHEXAS investigation will agree to participate in at least the core monitoring program. Therefore, we expect to ask 337 persons to participate in order to yield 315 respondents who agree to participate in at least the core monitoring program (nine per county). In addition, we expect that about 15 persons who initially agree to participate in the monitoring program will become non-participants because of equipment failure, unforeseen circumstances that prevent their full participation, or refusal to complete the program because of respondent burden. Hence, the total number of persons expected to complete at least the core monitoring program is shown in Table 3 to be 300.

The anticipated response rates are based entirely on the professional judgement of the RTI research staff. Since the third-stage sample of households will be fielded in waves until the requisite number of core group participants has been recruited, deviations from the anticipated response rates will affect primarily the total number of sample housing units that must be contacted and participation beyond the core (e.g., for food monitoring and/or particulate monitoring).

The potential for nonresponse bias will be investigated for each stage of participation by comparing the characteristics of the participants to the non-participants (e.g., demographics and potential for occupational exposure) using the data at the previous stage(s) of participation (e.g., Descriptive Questionnaire, Baseline Questionnaire, core monitoring group, food monitoring group, etc.). Individuals who agreed to participate but for whom data were not successfully collected because of circumstances beyond their control (e.g., equipment failure) may be counted as participants for the purpose of these analyses.

(iii) Stratification variables

Selection of the participant within a sample household will not be stratified because all participants are to be selected with approximately equal probabilities, as discussed previously.

(iv) Sampling method

If one person were selected at random from every sample household, the survey design effect, or variance inflation factor, due to unequal probabilities of selection within households of different sizes would be approximately 1.3. Therefore, we will select a person from one-third of the one-person households, from two-thirds of the two-person households, and from all other households. This reduces the survey design effect for unequal person-level probabilities of selection to less than 1.1. Within those households chosen to have a sample member recruited, one eligible household member will be selected at random.

A pre-printed label for each sample housing unit will be used to accomplish this sample selection in a very simple manner. A randomly generated roster line number will be printed for every possible household size (up to 12, say). For households with three or fewer survey-eligible members, line numbers 1, 2, and 3 will be generated with equal probabilities. For a household with only one eligible person, no one will be selected if the random line number is 2 or 3. Similarly, for a two-person household, no one will be selected if the random line number is 3.

The sample sizes that we expect to achieve using this unequal probability selection of households for monitoring is shown in Table 5 by household size. Both person-level and household-level sampling weights that are the reciprocals of the person-level and household-level probabilities of selection, respectively, will be computed to enable unbiased estimation of population parameters from a sample with unequal probabilities of selection. The proposed design is a compromise between equal probabilities of selection for monitored households and for monitored persons with an unequal weighting design effect of about 1.1 expected in each case.

Ideally, each person would be randomly assigned to a start day within a sample week that was randomly selected for the area segment in which the person resides (within a randomly selected county-month) to avoid potential bias with regard to selection of the sampled 6-day monitoring periods. Controlled random selection or other controlled selection methods that force equal numbers of subjects to begin their 6-days of monitoring on each day of the week, is another approach to this same problem. The approach planned for the NHEXAS Phase I study in Region 5 is the following.

The method for scheduling the nine sample persons to be monitored in each sample county will be to begin monitoring three people on each of three consecutive days (e.g., Monday, Tuesday, and Wednesday). Then, 2 to 5 days will be allowed for take-down, travel, and set-up before beginning monitoring in the next county, except for occasional holiday breaks. Hence, the start days will be haphazardly allocated to days of the week, and we expect no bias toward any specific days of the week. We will monitor the distribution of start dates by day-of-week and use that information to help ensure an equal distribution.

## 2.2 DATA QUALITY INDICATORS

One dichotomy of survey errors is between sampling errors and nonsampling errors. Sampling errors are those errors that result from observing only a sample of units from the survey population, rather than the entire population. All other errors in the survey measurement process are nonsampling errors.

The precision that we expect to achieve with the sample selected from the survey population in Region 5 is addressed in Section 2.2.1 below. Section 2.2.2 addresses such nonsampling errors as noncoverage of the target population by the sampling frames, potential for bias resulting from survey nonresponse, measurement errors for questionnaire data, and measurement errors for chemical analysis data.

### 2.2.1 Survey Precision Targets

The precision of statistics based on a given sampling design is often discussed in terms of estimates of population proportions (e.g., frequency of occurrence of elevated levels of VOCs in air or arsenic in water) because the standard errors of proportions depend only on (1) the population proportion being estimated, (2) the sample size available for the estimate, and (3) the survey design effect for the estimate. In particular, no independent sources of information regarding population variability are needed for estimates of proportions.

The survey design effect for a statistic is the ratio of the sampling variance for the statistic under the actual sampling design divided by the variance that would have been achieved with a simple random sample of the same size. It can be factored into components associated with the effects of (1) stratification, (2) multistage sampling (clustering), and (3) unequal weighting (unequal probabilities of selection and weight adjustments for unit nonresponse). Stratification tends to decrease the design effect (increase precision), whereas multistage sampling and unequal weighting increase the design effect. Multistage sampling effects usually predominate.

The precision of estimates for EPA Region 5 based on the proposed RTI/EOHSI Phase I study design is addressed from several perspectives. One EPA requirement is for the sample size to be sufficiently large to be almost certain that at least one sample observation will be from the upper 10 percent of the population distribution. Table 6 presents the sample sizes needed to be from 98 to 99.9 percent confident that the sample contains at least one observation from the upper 1 to 10 percent of the population distribution for estimates with survey design effects up to three. Sample sizes that correspond approximately to those being proposed for the RTI/EOHSI NHEXAS Phase I study are shaded in Table 6. Because of unequal probabilities of selection and intracluster correlations, the survey design effects are expected to be on the order of 1.5 or greater for most estimates produced by the RTI/EOHSI NHEXAS Phase I study. We see from Table 6 that we can be about 99.9 percent certain that the total sample will include at least one observation from the upper 4 percent of the population distribution for those statistics for which the survey design effect is 1.5. Of course, this is not true for subpopulations represented by smaller sample sizes.

We can also compute the probability that specific upper population percentiles will lie within the range of sample observations based on the expected number of participants for the different types of data to be collected in the RTI/EOHSI NHEXAS Phase I study. The results for the 90th, 95th, and 98th percentiles are presented in Tables 7-9 for metals, VOCs, and particles, respectively. In each case, a survey design effect of 1.5 is assumed. Our professional experience suggests that this design effect is a reasonable expectation for most analyses, given that the design effect due to unequal probabilities of selection will be approximately 1.1. The design effect is likely to be larger for some media/compound combinations that exhibit high intracluster correlations (e.g., heavy metals in tap water). Each table presents the probabilities of including the specified percentile of the population distribution in samples from the full population, in samples from domains containing 25 percent of the population members (such as the household residents of Region 5 under 18 years of age), and in samples from domains containing 10 percent of the population members (e.g., Afro-American members of the household population in Region 5 or the household population members under seven years of age). In each case, we see that the expected numbers of respondents are generally sufficient to be almost certain that the sample size for the full population will be sufficient to include the 95th percentile of the population distribution. However, for a domain containing 25 percent of the population members, the sample size within this domain will be sufficient only to be nearly certain that the 90th percentile of the distribution for the subpopulation is included in the sample range. Finally, for domains containing only 10 percent of the population members, the sample size within that domain will not be sufficient to ensure that even the 90th percentile of the distribution within that domain is included in the sample range.

Estimating upper population percentiles (e.g., 90th percentile or greater) will be an important objective for the Phase II national NHEXAS study. Hence, the precision of estimates of upper percentiles of population distributions is also of interest for the Phase I study. The NHEXAS survey design report by Clickner et al. (69) shows in Appendix A that designing the NHEXAS to produce adequate estimates of population percentages will result in correspondingly adequate estimates of the corresponding population percentiles. For example, if a 10 percent population prevalence can be estimated well (e.g., with a 15 percent relative standard error), then the estimate of the 90th percentile of the population distribution will also be reasonably accurate. Hence, Tables 10-12 present relative standard errors (RSEs) for estimates of population proportions of 50 percent, 25 percent, and 10 percent. When the sample sizes are sufficient to produce adequate estimates of these percentages then the estimates of the population median, 75th percentile, and 90th percentile, respectively, will also be adequate. Cells with RSEs of 20 percent or less are shaded and may be interpreted as producing reasonably precise estimates. RSEs between 21 and 30 percent are underlined to indicate cells for which the precision of estimates will be marginal. The cells for which the RSE is expected to exceed 30 percent may be regarded as producing only poor estimates of the population percentages and percentiles. We see that the 90th percentile of the full population distribution will generally be estimated only with marginal precision (i.e., RSEs between 21 and 30). However, reasonably precise estimates will generally be obtained for the overall population median and the 75th percentile. For domains containing 25 percent of the population (e.g., a low socio-economic domain), the median will generally be estimated reasonably well, and the 75th percentile can be estimated with marginal precision. However, for domains containing only 10 percent of the population (e.g., the Afro-American population in Region 5), only the median will usually be estimated with marginal precision.

Tables 13-15 provide the standard errors of the estimated population percentages corresponding to the cells of Tables 10-12. These standard error estimates are provided for the benefit of any reviewer who may be more comfortable using them, rather than RSEs, to make the decision about which estimated population percentages (and corresponding population percentiles) will be estimated with sufficient precision.

Minimum detectable differences for estimates of population percentages (e.g., percent above a common threshold in two domains) are developed and presented in Appendix E.

Some analyses will be restricted to the non-smoking population because the survey procedures will not be able to capture the true personal exposures of smokers to substances inhaled directly in the tobacco smoke (e.g., particulated, benzene, and cadmium). However, the 1992 National Household Survey on Drug Abuse estimates that 26 percent of the civilian, noninstitutionalized population of the U.S. age 12 or older have smoked cigarettes in the past month. Since the target population for the NHEXAS includes children and infants, the percentage of the target population who are active smokers is expected to be less than 25 percent. Hence, the standard errors and relative standard errors for the domain of non-smokers are expected to be 10 to 15 percent greater than the values shown in Tables 10 through 15 for the "full population." These 10 to 15 percent increases leave the conclusions regarding which population parameters can be estimated reasonably well virtually unchanged. Therefore, the columns of Tables 10 through 15 for the "full population" can be safely regarded as applying to the domain of all non-smokers, also.

## 2.2.2 Survey Nonsampling Error

### *Noncoverage Error*

Noncoverage occurs when the sampling frame(s) fail to include some members of the target population. The use of area sampling frames for the first two stages of the RTI/EOHSI sampling design provides theoretically complete coverage at those stages of sampling. Some noncoverage can occur in the third-stage sample of housing units if the lists of current housing units compiled by the household interviewers are imperfect. Errors may occur because of problems accurately locating the boundaries of the sampled Census blocks in the field, especially if redevelopment has occurred since the 1990 Census. Errors may also occur because some housing units are not immediately apparent (e.g., garage apartments or apartments off a common entry hall). RTI sampling staff will be available to assist interviewers having difficulty locating the boundaries of sample segments by extracting additional information from the Census TIGER files and/or interpreting the information provided. In addition, the third-stage sampling procedure includes techniques to search for and include in the sample any missed housing units within the sample housing units or between them and the next listed housing unit. Given these field procedures, nearly complete coverage of the target population of household residents in EPA Region 5 should be obtained.

Another potential source of noncoverage occurs for the fourth-stage sample if the household respondent does not tell the interviewer about all of the eligible members of the household. The respondent may prefer not to acknowledge that a particular individual is living at the residence or may not consider an unrelated member of the household as belonging to the household. Therefore, the interviewer will be trained to probe for completeness of the household roster, including unrelated persons residing in the same housing unit. Given this training, coverage of the household population should be as good as practically possible.

### *Unit Nonresponse Error*

Unit nonresponse can occur at several levels in the RTI/EOHSI NHEXAS Phase I study design. The first opportunity for nonresponse is to the Descriptive Questionnaire, which we expect to complete for about 94 percent of the occupied sample housing units, as shown in Table 3. We also expect to complete a few "key" items on the Descriptive Questionnaire (e.g., the household roster with sex, race, and approximate age of each household member) for nearly all (say, 98 percent) of the occupied sample housing units by using information from neighbors and other sources. We will test for significant differences between respondents and nonrespondents for all characteristics known for both, such as the "key" Descriptive Questionnaire items. Sample subjects for whom data were not collected because of reasons beyond their control, such as equipment failure, may be treated as respondents for these analyses.

We will also compute weight adjustments to reduce the potential for nonresponse bias for each stage of nonresponse to the NHEXAS. The ability to make meaningful weight adjustments to compensate for the potential bias due to nonresponse depends heavily on the availability of sufficient data for the nonrespondent to adequately model the response propensity (probability of responding). Therefore, we are collecting as much data as

practically possible to characterize the nonrespondents. As noted above, as few "key" questionnaire items will be collected for virtually all households. These data will be available to model nonresponse to the Descriptive Questionnaire. All sample subjects selected for environmental monitoring will be asked to complete the Baseline Questionnaire, which contains extensive information regarding their potential for exposures, before asking them to consent to the monitoring program. Therefore, we will have the Descriptive Questionnaire data to model nonresponse to the Baseline Questionnaire, and we will have the Baseline Questionnaire data to model nonresponse to the monitoring phase of the study. We expect that standard weighting-class nonresponse adjustments will be sufficient to compensate for the lower levels of nonresponse to the Descriptive Questionnaire and the Baseline Questionnaire (72). However, logistic regression models for the probability of responding will also be explored for nonresponse in the monitoring phase because these models have the potential to make greater use of the data available in the Baseline Questionnaire and produce greater reduction of nonresponse bias (73).

#### *Item Nonresponse Error*

Item nonresponse occurs when less than the full set of environmental monitoring data are obtained from a participant for any reason (e.g., refusal to provide biological specimens, equipment failure, etc). Item nonresponse also occurs within questionnaires whenever a participant answers some, but not all, of the questions.

Methods for analyzing data containing item nonresponse include the following approaches:

- (1) treat item nonresponse as a separate level of response (e.g., yes, no, and don't know)
- (2) analyze only the set of records for which responses are obtained, preferably using an item-specific analysis weight adjusted for the item nonresponse
- (3) statistically impute substitute values for the missing data.

Statistical imputation has not been budgeted and is not planned at the present time. A combination of the first two approaches is planned. Tabulations of questionnaire data will generally include "don't know" as a separate level of response. Analyses of environmental and biological samples (e.g., percent measurable and means) will generally be restricted to the respondent records with a statistical weight adjustment within weighting classes to extrapolate inferences to the target population.

#### *Questionnaire Measurement Error*

Bias has been shown to occur in survey instruments (questionnaires) due to such factors as question wording, question structure (e.g., open-ended versus pre-specified response categories), question order, interviewer effects, and response errors. Respondents, even when doing their best to provide accurate responses, do not always fully understand the intent of a question or do not recall their activities accurately (74). One protection against these types of questionnaire measurement errors is extensive testing of the questionnaire, including administration of the questionnaire in a laboratory setting in which the understanding of each question and process of recall can be ascertained (75). The NHEXAS

Phase I study questionnaires will be pretested in both laboratory and field settings to guard against biased results.

We will attempt to hire mostly experienced interviewers, who are familiar with proper procedures for administering questionnaires. We will provide additional training for new and inexperienced interviewers. The interviewers will be trained to ask the questions exactly as written and not use leading probes.

Each interviewer will report to a supervisor at RTI approximately every two to three days when doing field data collection. Interviewers whose performance is unsatisfactory will be retrained or replaced. A portion (e.g., 10 to 20 percent) of each interviewer's sample housing units that do not result in a monitoring appointment will be independently verified. The monitoring appointments themselves serve as validation of the appointments scheduled.

### **2.2.3 Analytical Chemistry and Sampling Method Measurement Error**

National Institute of Science and Technology (NIST) performance evaluation samples and standards, replicate sample extract analyses, etc., will be used to quantify analytical measurement error variance and bias for the collection and analysis methods employed in the Phase I study. Sample collection and analysis precision will be measured, whenever possible, by collection and analysis of collocated (duplicate) samples. Sampling method bias will be more difficult to measure. Field blanks or container will be used to assess contamination, and field controls will be used, when available, to assess analyte recovery.

We expect to find that each field and laboratory measurement procedure has no significant bias. Standard errors of survey statistics will be based on the estimated total survey variance, which includes all sources of variation. Components of variance will be separately estimated for use in optimizing the Phase II design.

## **2.3 PROJECT RESPONSIBILITIES**

The Principal and Co-Principal Investigators of this consortium are Dr. E. D. Pellizzari (RTI) and Dr. P. Lioy (EOHSI), respectively. The EPA Principal Collaborator is Mr. J. Quackenboss. Dr Pellizzari has the prime authority to negotiate any changes in the technical effort with the EPA Project Officer. He also has overall responsibility for the study design within the consortium. Drs. Pellizzari and Lioy work closely on internal issues and with Mr. Quackenboss regarding external issues that impact on the Consortia and overall NHEXAS program.

Communications between Drs. Pellizzari and Lioy will be frequent and at a minimum of weekly telephone conversations, a routine practice that they have established in their past and current project collaborations. In addition, they will meet at one of the organizations or in Washington every two months to plan activities, review program elements and resolve program issues. The RTI-EOHSI team will meet once a year or more often, if needed, for program review. Other communications include E-mail and FAX regarding routine review of prepared materials and technical feedback.

Within the RTI team, Dr. Pellizzari is assisted by several Co-Principal Investigators and collaborators. Dr. R. Whitmore, Co-Principal Investigator, is responsible for the survey sampling design and for developing weights for the survey data. Mr. H. Zelon, Co-Investigator, is the lead for field survey operations. Dr. C. Rodes, Co-Principal Investigator, is responsible for aerosol contaminant methodologies. Mr. C. A. Clayton, Co-Principal Investigator, oversees statistical analysis of weighted data. Dr. Pellizzari is assisted by Mr. K. Thomas, Co-Investigator, who is in charge of all field monitoring activities. Other collaborators are Mr. J. Keever (VOC analysis), Drs. M. Goldberg and R. Fernando (metals analysis), Mr. L. Michael (database management). Figure 1 depicts the investigator relationships and their general areas of study.

The RTI team is patterned after other previous successful working relationships, i.e., they meet periodically as an entire group and more often ad hoc as needed between symbiotic parties. We also meet with the EPA Principal collaborator and on a frequent basis, about once a month for a few days.

Within the EOHSI team, Dr. Lioy serves as Co-Principal investigator and leads the EOHSI-EMAD scientific team (Figure 1). There are five components to the EOHSI activities: 1) activity pattern questionnaire development and analysis led by Dr. N. Freeman, 2) biological monitoring led by Dr. J. Waldman and Dr. C. Weisel, 3) surface dust collection techniques and analysis led by Dr. P. Lioy, (4) food analysis by Dr. A. Greenberg (Rutgers U.) and 5) mathematical modeling of exposure and dose reconstruction under the auspices of Drs. P. Georgopoulos and Lioy.

Since the team has experience in each area, and meet regularly within the Division to discuss topics of overlapping interest and concern, the coordination of efforts with in the NHEXAS will just be an expansion of current activities. However, to coordinate efforts and achieve deadlines, the UMDNJ team meets regularly to discuss field activities, data analysis, and the integration of results with Dr. Pellizzari's group at RTI. Patterned after previous working relationships, management includes periodic telephone calls and meetings on the design and implementation of the field and laboratory research efforts. In addition, the UMDNJ investigators participate in both conference calls and periodic individual or group meeting with RTI investigators, consultants, and EPA collaborators.

Ms. D. Smith (RTI) will serve as the Quality Assurance Officer within RTI and will oversee the overall RTI-EOHSI consortium. She can provide independent and objective assessment of project data quality. She will prepare a final QSIP and have the authority to implement the Plan in a manner necessary to insure and maintain the highest level of data quality. She will have the authority to review and assess all aspects of project performance; any inadequacies will receive Corrective Action.

Dr. B. Buckley will be the QA Officer for EOHSI's activities. He will coordinate and collaborate with Ms. Smith.

Table 4. DEFINITION OF THE TARGET POPULATION FOR THE  
RTI/EOHSI NHEXAS PILOT STUDY

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- (1) Geographical area: EPA Region 5.
  - (2) Military bases: excluded for the same reasons.
  - (3) Type of residence: Housing units occupied as primary residences (i.e., not vacation or temporary residences), excluding group quarters (e.g., institutions -- hospitals, prisons, etc. -- and residences occupied by more than 9 unrelated persons). A separate study would be necessary to characterize the exposures of group quarters residents, if there were sufficient interest.
  - (4) Type of residents: All permanent residents and those with no permanent residence elsewhere, except those who are absent for an extended period of time (e.g., students away at school, sailors at sea, etc.). Homeless persons are excluded because of the difficulty of selecting a valid probability sample and because week-long monitoring would be infeasible for this population.
  - (5) Age range: No restrictions. Small children are difficult to monitor, but they are likely to be a sensitive subpopulation for many compounds, so we feel that it is better to institute special procedures for monitoring children than to exclude them. Monitoring the elderly is less important in terms of monitoring for long-term, chronic health effects simply because they do not have as long to live. One could argue for excluding them to increase the pilot survey sample size for other age groups, but we prefer to include them to gain experience dealing with them for the national Phase II survey, in which they must be included.
  - (6) Smoking status: No restrictions. Although the personal exposures of smokers cannot be measured for some toxicants (e.g., particles and benzene), they can be monitored for others (e.g., arsenic). Therefore, we do not propose excluding smokers from the target population; they can be excluded from the analyses for specific toxicants, as appropriate.
  - (7) Temporal dimension: All weeks in the approximately 15-month data collection period.
-

**Table 5. Expected Sample Distribution by Household Size**

Household Size	Region 5 Percentage	Descriptive Q. Respondents	Asked to Participate	Participate in At Least Core
1-Person	24.7	127	42	34
2-Persons	31.7	163	109	87
3 or More	43.6	223	223	179
Total	100.0	513	374	300

**Table 6. Sample Size Required to Be K% Sure that the Sample Contains at Least One Observation From a Domain Consisting of P% of the Population**

K	P	SURVEY DESIGN EFFECT				
		1.00	1.25	1.50	2.00	3.00
99.9%	1%	687	859	1,031	1,375	2,062
	2%	342	427	513	684	1,026
	3%	227	283	340	454	680
	4%	169	212	254	338	508
	5%	135	168	202	269	404
	10%	66	82	98	131	197
99%	1%	458	573	687	916	1,375
	2%	228	285	342	456	684
	3%	151	189	227	302	454
	4%	113	141	169	226	338
	5%	90	112	135	180	269
	10%	44	55	66	87	131
98%	1%	389	487	584	778	1,168
	2%	194	242	290	387	581
	3%	128	161	193	257	385
	4%	96	120	144	192	287
	5%	76	95	114	153	229
	10%	37	46	56	74	111

$$n = d \log(1-K) / \log(1-P)$$

1. Design effect  $\approx 1.5$  for measures with low intracluster correlations, possibly VOCs in blood.
2. Design effect  $> 1.5$  for measures with high intracluster correlation, possibly lead in tap water.
3. To apply to subpopulations, the indicated sample size is needed in each subpopulation.

Table 7. RTI/EOHSI Design: Probability that the Sample Range Includes the P-th Percentile of the Population Distribution of Measured Concentrations for Selected Domains, Assuming a Survey Design Effect of 1.5: METALS

Media	Sample Size	Units <sup>a</sup>	Full Population			25% Domain			10% Domain		
			P=.90	P=.95	P=.98	P=.90	P=.95	P=.98	P=.90	P=.95	P=.98
AIR (6-day active samplers)	239	hh-wk	1.00	1.00	0.96	0.98	0.87	0.55	0.81	0.56	0.28
	100	hh-wk	1.00	0.97	0.74	0.83	0.57	0.29	0.50	0.29	0.13
	Total Personal	person-wk	1.00	1.00	0.96	0.98	0.87	0.55	0.81	0.56	0.28
TAP WATER (residential)	300	hh-WK	1.00	1.00	0.98	0.99	0.92	0.64	0.88	0.64	0.33
	135	person-3WK	1.00	0.99	0.84	0.91	0.68	0.37	0.61	0.37	0.17
FOOD/BEVERAGES (4-d comp)	259	person-WK	1.00	1.00	0.97	0.99	0.89	0.58	0.84	0.59	0.29
<b>DUST &amp; SOIL (residential)</b>											
Window Sill	239	hh-WK	1.00	1.00	0.96	0.98	0.87	0.55	0.81	0.56	0.28
	239	hh-WK	1.00	1.00	0.96	0.98	0.87	0.55	0.81	0.56	0.28
	135	hh->3wk	1.00	0.99	0.84	0.91	0.68	0.37	0.61	0.37	0.17
	135	hh->3wk	1.00	0.99	0.84	0.91	0.68	0.37	0.61	0.37	0.17
Yard Soil	50 <sup>b</sup>	hh-WK	0.97	0.82	0.49	0.58	0.35	0.15	0.30	0.16	0.07
<b>BIOLOGICALS</b>											
Urine (2 timed samples)	280	person-WK	1.00	1.00	0.98	0.99	0.91	0.61	0.86	0.62	0.31
	126	person-3WK	1.00	0.99	0.82	0.89	0.66	0.35	0.59	0.35	0.16
	280	person-WK	1.00	1.00	0.98	0.99	0.91	0.61	0.86	0.62	0.31

Prob =  $1 - (1 - P)^{n/d} - P^{n/d}$ , where n = sample size and d = survey design effect.

<sup>a</sup>wk → Measurements are integrated weekly exposures or concentrations

WK → one or more concentration measurements are made during the week

<sup>b</sup>Purposive sample. Population inferences not supported.

Table 8. RTI/EOHSI Design: Probability that the Sample Range Includes the P-th Percentile of the Population Distribution of Measured Concentrations for Selected Domains, Assuming a Survey Design Effect of 1.5: VOCs

Media	Sample Size	Units <sup>a</sup>	Full Population			25% Domain			10% Domain		
			P=.90	P=.95	P=.98	P=.90	P=.95	P=.98	P=.90	P=.95	P=.98
AIR (6-day active samplers)	300	hh-wk	1.00	1.00	0.98	0.99	0.92	0.64	0.88	0.64	0.33
			135	hh-3wk	1.00	0.99	0.84	0.91	0.68	0.37	0.61
Outdoor Residential	100	hh-wk	1.00	0.97	0.74	0.83	0.57	0.29	0.50	0.29	0.13
			77	hh-3wk	1.00	0.93	0.65	0.74	0.48	0.23	0.42
Total Personal	300	person-wk	1.00	1.00	0.98	0.99	0.92	0.64	0.88	0.64	0.33
			135	person-3wk	1.00	0.99	0.84	0.91	0.68	0.37	0.61
Non-Work Personal	50 <sup>b</sup>	person-wk	0.97	0.82	0.49	0.58	0.35	0.15	0.30	0.16	0.07
Work Personal (by subtr)	50 <sup>b</sup>	person-wk	0.97	0.82	0.49	0.58	0.35	0.15	0.30	0.16	0.07
TAP WATER (residential)	300	hh-WK	1.00	1.00	0.98	0.99	0.92	0.64	0.88	0.64	0.33
Flushed											
BIOLOGICALS	280	person-WK	1.00	1.00	0.98	0.99	0.91	0.61	0.86	0.62	0.31
Blood											

Prob =  $1 - (1 - P)^{n/d} - P^{n/d}$ , where n = sample size and d = survey design effect.

<sup>a</sup>wk → Measurements are integrated weekly exposures or concentrations

WK → one or more concentration measurements are made during the week

<sup>b</sup>Purposive sample. Population inferences not supported.

Table 9. RTI/EOHSI Design: Probability that the Sample Range Includes the P-th Percentile of the Population Distribution of Measured Concentrations for Selected Domains, Assuming a Survey Design Effect of 1.5: PARTICLES

Media	Sample Size	Units <sup>a</sup>	Full Population			25% Domain			10% Domain		
			P=.90	P=.95	P=.98	P=.90	P=.95	P=.98	P=.90	P=.95	P=.98
AIR (6-day active samplers)											
Indoor Residential	239	hh-wk	1.00	1.00	0.96	0.98	0.87	0.55	0.81	0.56	0.28
Outdoor Residential	100	hh-wk	1.00	0.97	0.74	0.83	0.57	0.29	0.50	0.29	0.13
Total Personal	239	person-wk	1.00	1.00	0.96	0.98	0.87	0.55	0.81	0.56	0.28
DUST & SOIL (residential)											
Window Sill	239	hh-WK	1.00	1.00	0.96	0.98	0.87	0.55	0.81	0.56	0.28
Primary Living Area	239	hh-WK	1.00	1.00	0.96	0.98	0.87	0.55	0.81	0.56	0.28
Collection Plate	135	hh - > 3wk	1.00	0.99	0.84	0.91	0.68	0.37	0.61	0.37	0.17

Prob =  $1 - (1 - P)^{n/d} - P^{n/d}$ , where n = sample size and d = survey design effect.

<sup>a</sup>wk → Measurements are integrated weekly exposures or concentrations

WK → one or more concentration measurements are made during the week

Table 10. Estimated Percent Relative Standard Errors for Estimates of Population Proportions, P, within Domains of Different Sizes, Assuming a Survey Design Effect of 1.5: METALS

Media	Sample Size	Units <sup>a</sup>	Full Population			25% Domain			10% Domain		
			P=.50	P=.25	P=.10	P=.50	P=.25	P=.10	P=.50	P=.25	P=.10
AIR (6-day active samplers)											
Indoor Residential	239	hh-wk	8	14	<u>24</u>	16	27	48	25	43	75
Outdoor Residential	100	hh-wk	12	<u>21</u>	37	<u>24</u>	42	73	39	67	116
Total Personal	239	person-wk	8	14	<u>24</u>	16	27	48	25	43	75
TAP WATER (residential)											
Initial or Flushed	300	hh-WK	7	12	<u>21</u>	14	24	42	22	39	67
	135	hh-3WK	11	18	32	<u>21</u>	37	63	33	58	100
FOOD/BEVERAGES (4-d comp)	259	person-WK	8	13	<u>23</u>	15	26	46	24	42	72
DUST & SOIL (residential)											
Window Sill	239	hh-WK	8	14	<u>24</u>	16	27	48	25	43	75
Primary Living Area	239	hh-WK	8	14	<u>24</u>	16	27	48	25	43	75
Collection Plate	135	hh- > 3wk	11	18	32	<u>21</u>	37	63	33	58	100
Entrance Floor Mat	135	hh- >3wk	11	18	32	<u>21</u>	37	63	33	58	100
Outdoor Soil	50 <sup>b</sup>	hh-WK	17	<u>30</u>	52	35	60	104	55	95	164
BIOLOGICALS											
Urine (2 timed samples)	280	person-WK	7	13	<u>22</u>	15	25	44	23	40	69
	126	person-3WK	11	19	33	<u>22</u>	38	65	35	60	104
Blood	210	person-WK	7	13	<u>22</u>	15	25	44	23	40	69

$$RSE = [P(1-P) / (n/d)]^{1/2} \div P.$$

<sup>a</sup> wk ==> measurements are intergrated weekly exposures or concentrations.

WK ==> one or more measurements are made during the week.

<sup>b</sup> Purposive subsample. Population inferences not supported.

Table 11. Estimated Percent Relative Standard Errors for Estimates of Population Proportions, P, within Domains of Different Sizes, Assuming a Survey Design Effect of 1.5: VOCs

Media	Sample Size	Units <sup>a</sup>	Full Population			25% Domain			10% Domain		
			P=.50	P=.25	P=.10	P=.50	P=.25	P=.10	P=.50	P=.25	P=.10
AIR (6-day passive samplers)	300	hh-wk	7	12	<u>21</u>	14	<u>24</u>	42	<u>22</u>	39	67
			135	hh-3wk	11	18	32	<u>21</u>	37	63	58
Outdoor Residential	100	hh-wk	12	<u>21</u>	37	<u>24</u>	42	73	39	67	116
			77	hh-3wk	14	<u>24</u>	42	<u>28</u>	48	84	44
Total Personal	300	person-wk	7	12	<u>21</u>	14	<u>24</u>	42	<u>22</u>	39	67
			135	person-3wk	11	18	32	<u>21</u>	37	63	33
Non-Work Personal	50 <sup>b</sup>	person-wk	17	<u>30</u>	52	35	60	104	55	95	164
Work Personal (by subtr)	50 <sup>b</sup>	person-wk	17	<u>30</u>	52	35	60	104	55	95	164
TAP WATER (residential)	300	hh-WK				14	<u>24</u>	42	<u>22</u>	38	65
Flushed			7	12	<u>21</u>						
BIOLOGICALS	280	person-WK				15	<u>25</u>	44	<u>23</u>	40	69
Blood			7	13	<u>22</u>						

$$RSE = [P(1-P) / (n/d)]^{1/2} \div P.$$

<sup>a</sup> wk ==> measurements are intergrated weekly exposures or concentrations.

WK ==> one or more measurements are made during the week.

<sup>b</sup> Purposive subsample. Population inferences not supported.

Table 12. Estimated Percent Relative Standard Errors for Estimates of Population Proportions, P, within Domains of Different Sizes, Assuming a Survey Design Effect of 1.5: PARTICLES

Media	Sample Size	Units <sup>a</sup>	Full Population			25% Domain			10% Domain		
			P=.50	P=.25	P=.10	P=.50	P=.25	P=.10	P=.50	P=.25	P=.10
AIR (6-day active samplers)											
Indoor Residential	239	hh-3wk	8	14	<u>24</u>	16	<u>27</u>	48	<u>25</u>	43	75
Outdoor Residential	100	hh-wk	12	<u>21</u>	37	<u>24</u>	42	73	39	67	116
Total Personal	239	person-wk	8	14	<u>24</u>	16	<u>27</u>	48	<u>25</u>	43	75
DUST & SOIL (residential)											
Window Sill	239	hh-WK	8	14	<u>24</u>	16	<u>27</u>	48	<u>25</u>	43	75
Primary Living Area	239	hh-WK	8	14	<u>24</u>	16	<u>27</u>	48	<u>25</u>	43	75
Collection Plate	135	hh - > 3wk	11	18	32	<u>21</u>	37	63	33	58	100

$$RSE = [P(1-P) / (n/d)]^{1/2} \div P.$$

<sup>a</sup> wk ==> measurements are intergrated weekly exposures or concentrations.

WK ==> one or more measurements are made during the week.

Table 13. Estimated Standard Errors for Estimates of Population Proportions, P, within Domains of Different Sizes, Assuming a Survey Design Effect of 1.5: METALS

Media	Sample Size	Units <sup>a</sup>	Full Population			25% Domain			10% Domain		
			P=.50	P=.25	P=.10	P=.50	P=.25	P=.10	P=.50	P=.25	P=.10
AIR (6-day active samplers)											
Indoor Residential	239	hh-wk	.04	.03	.02	.08	.07	.05	.13	.11	.08
Outdoor Residential	100	hh-wk	.06	.05	.04	.12	.11	.07	.19	.17	.12
Total Personal	239	person-wk	.04	.03	.02	.08	.07	.05	.13	.11	.08
TAP WATER (residential)											
Initial or Flushed	300	hh-WK	.04	.03	.02	.07	.06	.04	.11	.10	.07
	135	hh-3WK	.05	.05	.03	.11	.09	.06	.17	.14	.10
FOOD/BEVERAGES (4-d comp)	259	person-WK	.04	.03	.02	.08	.07	.05	.12	.10	.07
DUST & SOIL (residential)											
Window Sill	239	hh-WK	.04	.03	.02	.08	.07	.05	.13	.11	.08
Primary Living Area	239	hh-WK	.04	.03	.02	.08	.07	.05	.13	.11	.08
Collection Plate	135	hh->3wk	.05	.05	.03	.11	.09	.06	.17	.14	.10
Entrance Floor Mat	135	hh->3wk	.05	.05	.03	.11	.09	.06	.17	.14	.10
Outdoor Soil	50 <sup>b</sup>	hh-WK	.09	.08	.05	.17	.15	.10	.27	.24	.16
BIOLOGICALS											
Urine (2 timed samples)	280	person-WK	.04	.03	.02	.07	.06	.04	.12	.10	.07
	126	person-3WK	.05	.05	.03	.11	.09	.07	.17	.15	.10
Blood	280	person-WK	.04	.03	.02	.07	.06	.04	.12	.10	.07

$$\text{Standard Error} = [P(1-P) / (n/d)]^{1/2}$$

<sup>a</sup> wk ==> measurements are intergrated weekly exposures or concentrations.

WK ==> one or more measurements are made during the week.

<sup>b</sup> Purposive subsample. Population inferences not supported.

Table 14. Estimated Standard Errors for Estimates of Population Proportions, P, by Sample Size and Domain Size, Assuming a Survey Design  
Effect of 1.5: VOCs

Media	Sample Size	Units <sup>a</sup>	Full Population			25% Domain			10% Domain		
			P=.50	P=.25	P=.10	P=.50	P=.25	P=.10	P=.50	P=.25	P=.10
AIR (6-day passive samplers)	300	hh-wk	.04	.03	.02	.07	.06	.04	.11	.10	.07
			.05	.05	.03	.11	.09	.06	.17	.14	.10
Outdoor Residential	100	hh-wk	.06	.05	.04	.12	.11	.07	.19	.17	.12
			.07	.06	.04	.14	.12	.08	.22	.19	.13
Total Personal	300	person-wk	.04	.03	.02	.07	.06	.04	.11	.10	.07
			.05	.05	.03	.11	.09	.06	.17	.14	.10
Non-Work Personal	50 <sup>b</sup>	person-wk	.09	.08	.05	.17	.15	.10	.27	.24	.16
Work Personal (by subtr)	50 <sup>b</sup>	person-wk	.09	.08	.05	.17	.15	.10	.27	.24	.16
TAP WATER (residential)	Flushed	hh-WK	.04	.03	.02	.07	.06	.04	.11	.10	.07
BIOLOGICALS											
Blood	280	person-WK	.04	.03	.02	.07	.06	.04	.12	.10	.07

$$\text{Standard Error} = [P(1-P) / (n/d)]^{1/2}$$

<sup>a</sup> wk ==> measurements are intergrated weekly exposures or concentrations.  
 WK ==> one or more measurements are made during the week.

<sup>b</sup> Purposive subsample. Population inferences not supported.

Table 15. Estimated Standard Errors for Estimates of Population Proportions, P, within Domains of Different Sizes, Assuming a Survey Design Effect of 1.5: PARTICLES

Media	Sample Size	Units <sup>a</sup>	Full Population			25% Domain			10% Domain		
			P=.50	P=.25	P=.10	P=.50	P=.25	P=.10	P=.50	P=.25	P=.10
AIR (6-day active samplers)											
Indoor Residential	239	hh-wk	.04	.03	.02	.08	.07	.05	.13	.11	.08
Outdoor Residential	100	hh-wk	.06	.05	.04	.12	.11	.07	.19	.17	.12
Total Personal	239	person-wk	.04	.03	.02	.08	.07	.05	.13	.11	.08
DUST & SOIL (residential)											
Window Sill	239	hh-WK	.04	.03	.02	.08	.07	.05	.13	.11	.08
Primary Living Area	239	hh-WK	.03	.03	.02	.08	.07	.05	.13	.11	.08
Collection Plate	135	hh - > 3wk	.05	.05	.03	.11	.09	.06	.17	.14	.10

$$\text{Standard Error} = [P(1-P) / (n/d)]^{1/2}$$

<sup>a</sup> wk ==> measurements are intergrated weekly exposures or concentrations.

WK ==> one or more measurements are made during the week.

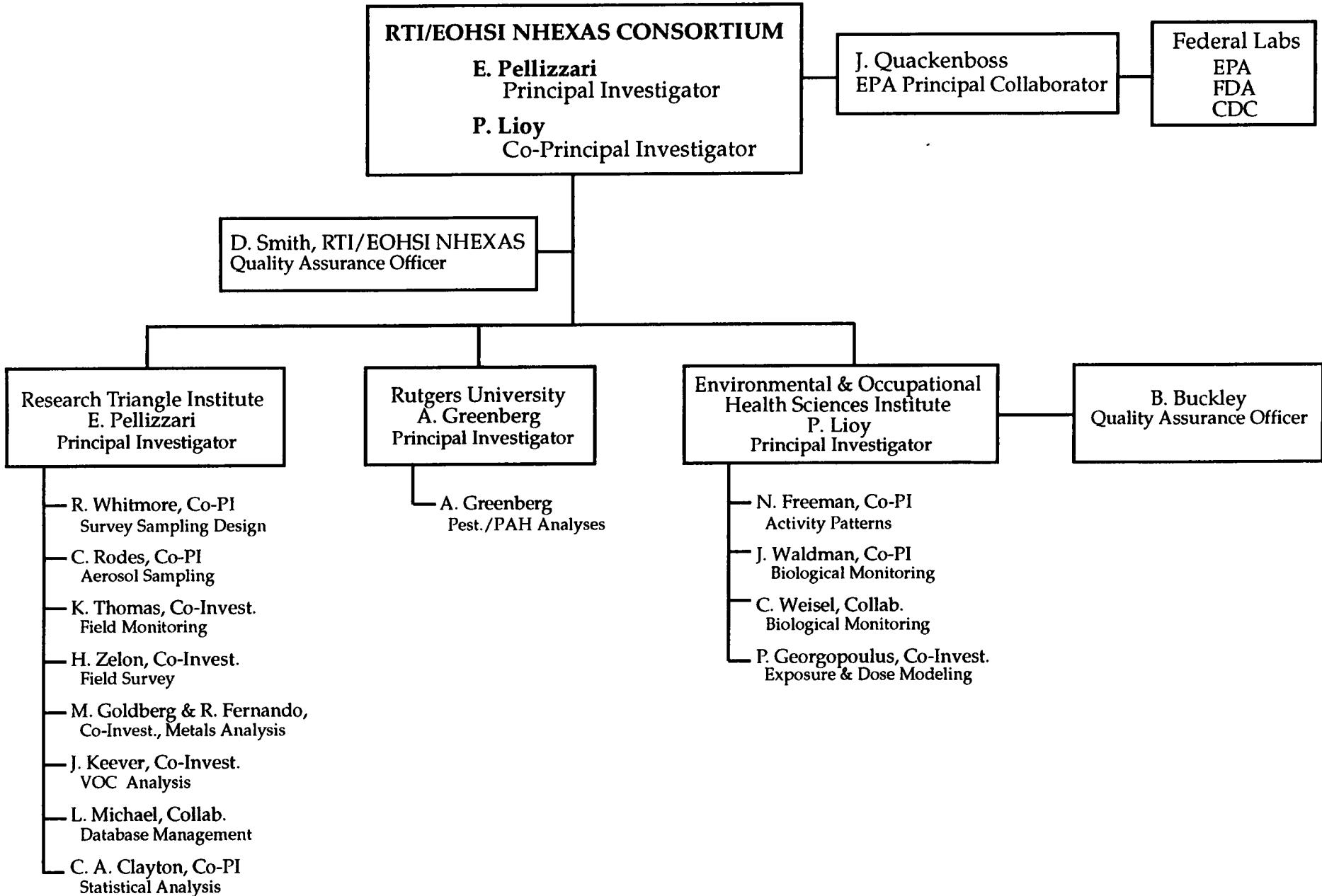


Figure 1. Overview of RTI/EOHSI NHEXAS Consortium Responsibilities.

## SECTION 3 DATA ACQUISITION AND MANAGEMENT

### 3.1 CONTROL AND CALIBRATION OF MEASUREMENT AND TESTING EQUIPMENT

Measurement and testing equipment to be used in the NHEXAS Phase I study fall into two categories, field equipment and laboratory equipment. In general, most of the procedures used for personal and environmental sample collection in the field have been selected to minimize time and difficulty burdens. Therefore, equipment that requires control and calibration is limited to sample collection pump systems and their flow check measurement devices, and a sample weighing balance or balances. Control and calibration for each of these devices will be discussed briefly below, with detailed procedures described in the sample collection protocol for each method. The remaining personal and environmental samples will be collected on or in the appropriate media (bottle, container, tube, etc.) that requires no calibration or system maintenance. Selection and cleaning methods for these materials are described in the sample collection protocol for each method. A list of all current and proposed collection and analysis protocols appears in Appendices A and B.

#### 3.1.1 Field Sampling Equipment

##### *Sampling Pumps*

Portable battery operated sampling systems will be used to collect aerosol samples or combined pesticide/PAH samples. Each sampling system and collection substrate (aerosol inlet with Teflon filter or pesticide/PAH collection cartridge) will be identified separately with a bar coded identification label, and the identification number recorded with the sample collection data. The flow rate will be measured and recorded for each sample at the initial deployment of the sampling system in the field. If the 2.0 lpm flowrate is out of range ( $> 5\%$ ), the flow will be adjusted or another sampling system substituted. The flow rate will be measured and recorded again at the end of the sample collection period. An integral interrogation sub-system in the sampling system will monitor and store in a memory unit, performance variables, including pressure drop across the filter, battery voltage and sampled air temperature. Any malfunctions or unusual conditions will be noted with the data collection record. Those sampling systems identified to be operating improperly will be segregated for further examination and be returned to the project headquarters for corrective service. Sampling system operation problems and repairs will be noted in a field notebook. The field supervisor will examine sample collection records and the notebook for systematic problems with individual units.

##### *Flow Measurement Devices*

A critical orifice meter/pressure transducer combination will be used to measure the aerosol and pesticide/PAH air sample collection flow rates. An initial calibration of the flow measuring devices will be performed in the laboratory at five or more flow rates centered around the target pumping rate (2.0 lpm), and across a  $\pm 35\%$  range, using a reference method (NIST traceable bubble flow device) to verify the accuracy at each calibration level.

Accuracy must be within  $\pm 5\%$  at all calibration levels. Calibration data will be recorded in a laboratory notebook and tracked using control charts. All flow checks and problem comments will be recorded in a field notebook. Any devices found to be out-of-calibration will be returned to the project headquarters for thorough laboratory calibration, adjustment or repair, as necessary. Detailed procedures will be described in NHEXAS Protocols "Personal, Indoor and Outdoor Air Sampling Procedures for Total Inspirable and PM10 Aerosols" RTI/ACS-AP-209-010.

### ***Food Balance***

A Mettler BD-6000 (or equivalent) portable field balance will be used to weigh food and beverage samples in the field. A calibration check will be performed on the balance one time each day the balance will be used. This balance check may be performed at the field office prior to visiting the homes. A 1000 g and a 100 g standard weight (ASTM Class 1 or NIST Class 5) will be weighed separately, and the result will be recorded in the field notebook. Values of  $1000 \pm 20$  g and  $100 \pm 2$  g will be considered acceptable. Any problems or out of range calibration checks will be noted in the field notebook. If the balance needs adjustment or repair, it will be shipped to project headquarters or repair facility, and the project supervisor will notify the analytical lab to weigh the samples upon receipt until a replacement or repaired balance can be shipped to the field.

#### **3.1.2 Laboratory Analytical Equipment**

Many different analytical methods will be used to measure target analyte concentrations across the types of personal and environmental samples that are to be collected. It is also important to note that different laboratories will analyze samples from different media. The proposed analytical laboratories, and the samples to be analyzed at each are:

1. Research Triangle Institute -
  - a. VOCs in air by solvent extraction and gas chromatography/mass spectrometry (GC/MS)
  - b. metals in air by acid extraction/digestion and graphite furnace atomic absorption spectrometry (GFAAS), and by hydride-generation graphite furnace atomic absorption spectrometry (HGFAAS)
  - c. aerosol mass by microbalance weighing pre- and post-weighing
  - d. pesticides and PAHs in air by solvent extraction and GC/MS
  - e. arsenic in dust, soil, and dermal samples by acid extraction and HGFAAS
2. Environmental and Occupational Health Sciences Institute -
  - a. lead, cadmium, and chromium in dust, soil, and dermal samples by acid extraction and inductively coupled plasma/mass spectrometry analysis (ICP/MS)
3. Rutgers University -
  - a. PAH in food samples using base extraction and high performance liquid chromatography with ultraviolet and fluorescence detectors (HPLC/UV/FL)
  - b. Pesticides in food samples using solvent extraction, GC/MS

4. EPA/EMSL-Cincinnati Contract Laboratories -
  - a. metals in tap or drinking water by EPA method 200.8, ICP/MS
  - b. VOCs in drinking water by EPA method 524.2, GC/MS
  - c. arsenic in drinking water, with MDL <0.2 µg/L (EPA has not supplied a written method for arsenic at this MDL as of this QSIP revision)
  - d. pesticides and PAHs in drinking water by method 525.2, GC/MS
5. Food and Drug Administration, Washington DC Laboratory -
  - a. metals in foods and beverages by total diet study methods (with modifications by FDA to improve detection limits)
6. Centers for Disease Control -
  - a. metals in blood
  - b. VOCs in blood
  - c. pesticides (or their metabolites) in blood
  - d. metals in urine
  - e. pesticides (or their metabolites) in urine
7. EPA/HERL - RTP
  - a. PAHs (or their metabolites) in blood and urine

In most cases, several different analytical systems will be used in each laboratory. It is critical that control and calibration procedures be defined for each instrument prior to initiating sample analysis. In addition, each laboratory is responsible for preparing and following an analytical protocol (AP) or a standard operating procedure (SOP) for each analytical method. The AP or SOP defines the calibration and control criteria for each method. Because the calibration and control procedures are detailed and complex, and because many methods will be used, the reader is referred to the protocol for specific information. A list of protocols and standard operating procedures (SOPs) for specific analytical and general laboratory procedures appears in Appendices A and B.

### **3.2 IDENTIFICATION OF DATA**

#### **3.2.1 Survey Data**

All data collected will be labeled with unique identification numbers. Each housing unit selected for contact will be assigned a unique number, based on the segment number and the line number of the housing unit on the list of housing units created for the segment. The identification number assigned to the respondents will include the housing unit identification number and a roster number for the selected individual. The roster number is obtained from the list of household residents created during the administration of the descriptive questionnaire. The combination of the housing unit ID and the respondent's roster number creates a unique ID for each respondent, and links the respondent to the sampling statistics, allowing the correct assignment of weights.

Each document used in the study will have a space for the household or respondent ID number. These numbers, and any numbers applied by the monitoring team, will be the only identifying information on data collection instruments containing respondent

information. ID numbers will also be placed on forms containing names and addresses, but these forms will not contain any data, and will be separated from questionnaires. The forms containing personal identifying information will be stored in limited access files and access to the linkage between names and data limited to maintain confidentiality.

### 3.2.2 Environmental Sample Collection and Analysis Data

Each sample collected or produced during the NHEXAS study will be labeled with a unique code number. The code number will be the link between any collection or custody data and the sample. The proposed coding format for samples to be collected in the 300-person portion of the study are described below. Codes for samples to be collected in the 50-person pesticide/PAH module will be assigned as part of an appendix to be prepared to the QSIP. These codes will be used to track the sample through collection, storage, shipment, processing, and analysis.

A nondescriptive sample code will be used for NHEXAS samples collected or prepared by the RTI/EOHSI consortium. The code will contain minimal information to identify the sample type to ensure shipment to the correct analysis laboratory, and a unique four-digit identification number. The proposed coding format is described as follows:

General Code Format: AAXXX

where:

AA      Sample type designator:

AV	= air passive badges, VOCs	TM	= dust wipe, WWT method, metals
AA	= air filters for aerosols	TA	= dust wipe, WWT method
AT	= PM10 filters for aerosols	WM	= water for metals
DP	= dust deposition, plate	SE	= soil from entrance way
DC	= dust deposition, carpet	SY	= soil from yard
WM	= water for metals	DD	= duplicate diet food or beverage
WA	= water for arsenic	UR	= urine
WV	= water for VOCs	BA	= whole blood, archive
BM	= whole blood, metals	HR	= hair
BV	= whole blood, VOCs		
LM	= dust wipe, metals,LWW dust method, metals		
LA	= dust wipe, LWW method, arsenic		

XXXX Sample identification numbers, from 0001 to 9999

Nondescriptive codes will simplify label preparation and the creation of unique computer file names. Only six characters are used in the code so that the analysis laboratory may add an additional two characters to specify aliquot number, replicate analysis number, etc. Nondescriptive codes will require that some information must be linked to the codes in data

and custody records. For example, the food analysis laboratory will need to combine and homogenize the food from four bottles for each participant. Participant identification numbers (three digit numbers) must be linked to each sample record. More detailed description of coding and labeling is provided in RTI/ACS-AP-209-070 in Appendix A.

Each participant will be assigned a unique three-digit identification code to be used for sample tracking. This ID code will be linked to the Survey participant ID code (Section 3.2.1). More detailed description of coding and labeling is provided in RTI/ACS-AP-209-070 in Appendix A.

### **3.3 CONTROL OF ERRONEOUS DATA**

Insurance of data integrity is of critical importance to the NHEXAS program. To this end, procedures will be implemented to minimize erroneous data at every step of the data collection, transmission and manipulation processes. Initial data recording, either by hand or computerized, will be executed so as to minimize inaccuracies. Handwritten entries of original data (e.g. into a laboratory notebook) will be subjected to thorough inspection and review by laboratory and/or field supervisors. Transcription also represents a significant source for incorporation of errors into the data. Data transcription, such as would occur during manual entry of analytical results into the NHEXAS database, will be verified by duplicate entry of the data. Visual screening of data, either handwritten or computer-entered, will be conducted at each step in the data handling process to identify blatant errors, illogical values and omissions. Where feasible, electronic data transmissions will employ copy and/or send qualifiers to insure that the files at source and destination locations are exact duplicates of one another. If grounds for rejection or modification of data are uncovered, the original and corrected copies of the data will be carefully labeled and the reason for the editorial documented.

All sample and questionnaire data will be input to a data management system, either by manual keying or, where feasible, by electronic transfer to the host computer using a modem or physical floppy disk transfer. All data will be manually screened prior to transfer for the correct range (i.e., >minimum; <maximum values for ordinal and interval data) and type (i.e., character, string, integer, or real) of each field; and to identify/flag potential illogical (inconsistent) entries (e.g., non-smokers who report active smoking). Additionally, transmission errors will be identified following electronic transfer by comparing the original and transmitted file versions. Retention of the original data in its original form will be required to insure the accuracy of transmitted or processed data.

### **3.4 DATA EVALUATION**

An important component in assuring data quality is mathematical and statistical evaluation. This will be implemented at various stages of the data handling and records assembly processes. Consistency (presence of questionable data requiring further investigation), completeness (absence of missing values), and agreement between associated (e.g. duplicate) samples will be evaluated as part of the quality assurance procedures. The univariate procedure in SAS (SAS Institute, Cary, NC) provides a convenient and accessible means of obtaining these analyses. Data records will be examined for range (maximum, minimum, missing, out-of-range), duplication, and type (numeric or alpha) prior to further

data analysis operations. Identification of potential erroneous values within the dataset will require that the original data be inspected and appropriate editorials made to the dataset file. Previous file versions will be maintained with accurate documentation of any changes implemented.

Data evaluation will be conducted by the Quality Assurance Officer with the support of the Data Manager using appropriate software tools. This will include review of distributions (continuous variables) and frequencies (discrete variables) for each measurement, calculated result, and questionnaire variable to identify outliers for further followup. In addition, bivariate plots and cross-tabulations will be used to evaluate the data for internal consistency.

Additional data analyses will be performed in five main phases:

- i. Preliminary analyses to assess data completeness and accuracy.
- ii. Development of sampling weights.
- iii. Non-model based analyses.
- iv. Model-based analyses.
- v. Analyses for aiding the design of phase II.

These analyses are described briefly in the following paragraphs. In addition, for Types iii, iv, and v, a series of detailed tables is provided to indicate the types of hypotheses (previously identified in Table 2) that will be addressed. These tables are indexed to Table 2 by hypothesis type and chemical class, and utilize the notation defined in Table 17. Each table (Tables 18-38) corresponds to a given major hypothesis type for a given chemical class and indicates, for each such case, the method(s) of analysis and the scope of application (e.g., which media), along with the principal organization within the consortium that will be responsible for carrying out the analysis. An index to these tables is as follows:

Hypothesis Type	Pollutant Class			
	Metals	Particles	VOCs	Pesticides and PAHs
1	18		28	
2	19	24	29	
3	20	25	30	34
4	21	26	31	35
5	22		32	36
6	23	27	33	37
7		38 (applies to all classes)		

### **3.4.1 Preliminary Analyses to Assess Data Completeness and Accuracy**

These analyses will be performed first. They will involve producing tabulations and/or plots of all data items (both questionnaire and direct physical measurements). The intent is to ensure, to the extent possible, that the data are accurate and are as complete as possible. Peculiar patterns, unexplained missing values, potential outliers, and inconsistencies in the data will be identified and then referred to the appropriate staff for review and possible rectification. For the physical measurements, the percent detected (percentage exceeding limits of detection) will be determined, with the intent of eliminating those combinations of chemicals and media having low percent detected from further analysis. The preliminary tabulations (e.g., histograms) of the physical measurements will also serve to indicate general shapes of distributions that may suggest the desirability of making data transformations (e.g., taking logarithms) prior to performing other types of statistical analysis or modeling. The raw tabulations of questionnaire items will serve to indicate those items which will be of marginal (or no) use in subsequent statistical analyses and modeling efforts (e.g., if all or almost all participants or homes fall into a single response category) or items that may need transformation to be of use (e.g., collapsing a multi-category item into one with only two or three levels).

### **3.4.2 Development of Sampling Weights**

Sampling weights applicable to the population during the data collection period will be developed, using weighting class nonresponse adjustments, as indicated in Section 2.2.2. These weights will allow inferences to be made to the population of person-weeks or household-weeks during the time frame of data collection. Since that time frame is not expected to cover exactly a 12 (or 24) month period, however, a set of annualized person- and household-level weights will also be developed that avoids the overrepresentation of any particular season of the year (i.e., seasons will be used to form weighting classes, each of which will be forced to be equally represented). These latter weights will be used to produce annualized estimates that should be more comparable, for instance, to estimates from external exposure assessments or to another region's estimates (assuming that they, too, are appropriately annualized).

### **3.4.3 Non-Model-Based Analyses**

These analyses will include estimation of the overall target population's exposure distributions and associated dose and environmental media concentration distributions, as well as similar estimated distributions for relevant subpopulations. In particular, they will involve generating pertinent descriptive statistics associated with the measured quantities such as means, standard deviations, and selected percentiles. Such estimates will be used to assess the adequacy of initial (i.e., pre-study) exposure assessments and to assess exposure and concentration differences among subpopulations (e.g., different age groups, persons or homes with different activities or potential sources). Sampling weights will be employed in these data analyses so that the resultant estimates will apply to the survey population of person-weeks (if person-level sampling weights are used) or of household-weeks (if household-level sampling weights are used). Both sampling weights applicable to the population during the data collection period (i.e., inferences to person-weeks or

household-weeks during that time frame) and the annualized person- and household-level weights will be employed. The latter are expected to be more appropriate for external comparisons, but are anticipated to be less precise than the former due to the greater variability in the annualized sampling weights. SUDAAN (Survey DAta Analysis), a software product designed for analysis of data from complex sample survey designs, will be used to produce such estimates, along with their standard errors (see SUDAAN, 77,78). Approximate precision of population and subpopulation proportions (e.g., proportion of the target population with exposures exceeding a given threshold level) was given in Tables 10 through 16. Appendix E shows minimum detectable differences in proportions for various samples sizes. Tables 18-20 indicate the planned analyses of these types for metals; Tables 24 and 25, for particles; Tables 28-30 for VOCs; and Table 34, for pesticides and PAHs.

Other analyses will be used to examine associations of analyte levels – for example, associations between exposure and biological markers, between exposure and environmental media measurements, or between two (or more) exposure pathways. These analyses will be useful for understanding the relative contributions of the various pathways, understanding the degree to which the pathways are dependent upon one another, and understanding how alternative ways of measuring exposure-related quantities relate to one another (e.g., indoor air vs. personal air). The first step in these analyses will be to estimate correlations; both Spearman correlations and Pearson correlations will be used, the latter being applied where necessary on a transformed (e.g., logarithmic) scale. Regression models may also be used as a part of this analysis. Both weighted and unweighted correlations and regressions can be performed, as needed. As noted in Section 1.5.1, these simple associations and regressions (as well as the above-described subpopulation comparisons) cannot be expected to provide a complete understanding of complex dose/exposure/concentration relationships; rather, these results will be used to help guide the modeling efforts described below. Details can be found in Tables 21 and 22 (metals), in Table 26 (particles), in Tables 31 and 32 (VOCs), and in Tables 34 and 35 (pesticides and PAHs).

#### **3.4.4 Model-Based Analyses**

The next phase of the data analysis will be aimed at improving or developing physical models of exposure (see Tables 23, 27, 33, and 37, respectively, for metals, particles, VOCs, and pesticides/PAHs). One type of model development, which will be possible only for those quantities measured both in the initial monitoring period and in the followup periods, will examine direct estimation of long-term (e.g., annual) exposure distributions from the short-term (e.g., weekly) measurements. This will require analysis of the temporal relationships among the short-term physical measurements (e.g., seasonal adjustments, estimation of autocorrelations). This type of analysis is extremely important in understanding how, and to what extent, short-term measures can be used in exposure assessments of chemicals with chronic effects -- for instance, in obtaining an estimate of the 90th percentile of a long-term distribution. The methods of Duan and Wallace will adapted for this analysis (80).

A second type of exposure modeling to be investigated will involve using regression models to relate the environmental concentration measurements to questionnaire and/or

diary data (and possibly to other concentration measurements). If such models are viable, future studies (including later phases of NHEXAS) may be able to use double sampling approaches in which a large sample of participants provides data on the predictor variables (i.e., the less expensive measurements) and only a small subsample is needed to provide data on the more expensive and burdensome direct measures (81).

Other model-based analyses include (a) evaluation of the feasibility of combining extant data on contaminant concentrations in foods with the Phase I Study's food consumption data (from individuals' food diaries) to estimate food-related exposures to metals and pesticides, and (b) evaluation of the feasibility of predicting individuals' air exposures via existing dispersion models.

### **3.4.5 Analyses for Aiding the Design of Phase II**

Table 38 indicates the types of analyses that will be used for improving later phases of NHEXAS. These analyses include those aimed at improving the sampling design directly – for example, by achieving an improved sample allocation due to having better estimates of cost and variance components. They also include analyses that estimate response rates and identify factors and sampling stages that seem to have the most influence on the rates. As a result of such analyses, changes in field procedures (e.g., ways of enrolling participants, ways of administering survey instruments) may be indicated for subsequent phases of NHEXAS. It should be noted that some of the aforementioned types of hypotheses are also associated with design improvements – for example, use of correlations and associations to demonstrate the suitability, or lack of suitability, of various physical measurement methods.

## **3.5 PROCEDURES**

The overall scheme for providing data to perform the analyses described above is comprised of three primary activities: selection of the study participants, the acquisition of environmental and biological samples and survey information from the study participants, and chemical analysis of the environmental samples at the analytical laboratories.

### **3.5.1 Pretest and Dress Rehearsal**

Prior to undertaking this Phase I Study, the RTI/EOHSI Consortium will conduct a pretest and two dress rehearsals with all survey instruments and environmental collection systems to be used. The purpose of the pretesting has been to refine and validate the survey instruments, and methods for collection and analysis of samples for particles, metals and VOCs. The pretesting will occur from September, 1993 to about August, 1994. Subsequently, two dress rehearsals will be conducted. The first dress rehearsal will be performed in approximately August, 1994 time-frame using three homes to exercise and assess the scripting and performance of all protocols (collection, analysis and database construction). Based upon what is learned from this dress rehearsal, the scripting of field logistics, collection, analysis and data management protocols will be revised, where necessary, to incorporate needed improvements. A second dress rehearsal will be conducted after OMB Clearance has been granted and just a few weeks before beginning the main field study.

This dress rehearsal will be performed on 3 or 6 homes to familiarize all personnel with the logistics of conducting the work at a home using the combination of sampling systems, and to organize/streamline personnel duties into an efficient set of operations at the home. This process, i.e., a pretest and dress rehearsal, will also be performed before conducting the pesticide/PAH module in the field which is scheduled after the Main Study has been completed.

### ***Questionnaires***

Pretesting of NHEXAS survey instruments will be conducted in three phases. The first two phases of pretesting -- simulated interviews with RTI staff members and interviews with selected volunteers from the general population in the Research Triangle Park (RTP) area of North Carolina -- will be conducted inhouse at RTI's Laboratory for Survey Methods and Measurement. The third phase of pretesting will be full dress rehearsals of all data collection procedures at a few homes in the RTP area. Each phase of pretesting will cover all aspects of survey data collection: the interviewer script, lead letter, and study brochure; the screening instrument and selection of a study subject; and all instruments to be administered to the study subject -- demographic questionnaire, food frequency questionnaire, time-activity diary; and consent form. During each pretest, the time required to complete each section of the interview will be recorded and any problems with administration of the instruments will be noted. After each phase of testing, the problems encountered will be discussed with project and EPA staff and revisions will be incorporated for the next level of testing. If the first two phases of pretesting result in major changes, those phases may be repeated with the revised instruments before the dress rehearsal. The purpose of the dress rehearsals will be to test the logistics of conducting all the separate study procedures under actual field conditions, to identify problems with individual components of the data collection procedures.

### ***Chemical and Physical Methods***

Pretest--Several specific tests and minor developmental efforts (in addition to preparation of sampling protocols as part of this QSIP) for the field sampling component have been identified as necessary during the NHEXAS Pretest period. The ultimate focus of these activities is reduction in respondent burden, resulting in an improved response rates. These include: (a) validating the performance of the Inspirable inlet relative to the PM10 inlet used for PTEAM, preparing SOPs and developing specific QC procedures; (b) evaluation of the expected filter loading histories produced by extended, 7-day chronic exposure sampling for aerosols in selected activity scenarios, and development of strategies to minimize loss of data from overloading situations; (c) Designing, packaging and testing the miniature controller/interval timer for the personal samplers, specifically to meet NHEXAS requirements; (d) Analysis of expected real-time concentration histories for specific contaminants to determine if interval sampling can provide integrated samples that are sufficiently representative of the true air exposure for 7 days; (e) evaluation of the passive VOC badge in terms face velocity effects on constants of sampling rate, optimizing solvent recovery and analysis parameters for VOCs from badges, determining the method detection limits for each VOC, intrusion of VOCs into capped badges for occupational/-nonoccupational exposure differentiation, effect of storage time on recovery of VOCs from badges, and assessment of burden, and collection and analysis (e.g., detection limits, interferences) performance for benzene and the other VOCs as worn by at least nine respondents; (f) Testing the degree of respondent burden and acceptance imposed by

various personal sampling configurations in a focus group-style setting; and (g) development of creative field sampling strategies to optimize and reduce the very substantial labor and per diem costs projected for NHEXAS, without significantly affecting data quality or study hypothesis testing.

Dress Rehearsals--The NHEXAS Dress Rehearsals are especially important to identify problems in sampling procedures and hardware not previously used for collection of extended samples for chronic exposures. A concern involves conscious or unconscious changes in respondent activities resulting from the extended intrusion of the sampling and data collection processes over a 7 day period. Reduction of the burden from active samplers and procedures that are too burdensome, large, heavy or noisy will be critical, especially if exposure information is expected from children. Since significant methods development activities are not encouraged by the RFP, and personal sampling technologies have only modestly advanced in recent years, the limits of application of existing procedures for exposures (especially air) must be established. Of the proposed contaminants for NHEXAS, only benzene has available a minimally intrusive (passive) measurement technology. For short (e.g., 12 or 24-hour) periods, respondents may "endure" an obtrusive exposure measurement device. Longer periods may result in samplers being used incorrectly (e.g., set aside for certain activities) or cause subjects to drop out of the study after only a few days. Food collection procedures must be optimized to provide representative collections and eliminate atypical diets to accommodate the study

The dress rehearsals will not only be used to determine if the sampling hardware and procedures are appropriate, but to determine if the measured exposures are truly representative. The rehearsal is expected to involve two 7 day test periods in the Research Triangle Park area, with a total of 6 to 9 respondents (RTI employees or acquaintances not associated directly with the NHEXAS program), incorporating at least a six week review period between sampling periods for assessment. All field procedures expected to be used in the full scale study would be employed, including: respondent questionnaires and sampling location selection, fixed location sampler installation and take-down, personal monitor respondent training, contaminant sample collection (all media), data entry, filter weighing, sample storage and shipment, biomarker sample collection, storage and documentation, and QA procedure review. A complete analysis of the dress rehearsal findings will be performed and reported in a report or a seminar, to document the expected routine performance and provide a basis for methodological improvements prior to the full-scale study.

In addition, all samples collected as part of the first dress rehearsal will be processed through the analysis laboratories. This activity will test the analytical protocols and the electronic transfer procedures for moving the data into, and merging data within, the database. Revisions in the protocols will be made as needed based upon the performance results obtained.

### 3.5.2 Survey

Study participants will provide information on both interviewer and self-administered questionnaires and diaries. In the tiered study design, some participants may not complete all of the listed survey instruments. Survey instruments to be completed include:

1. Descriptive questionnaire (interviewer administered)
2. Baseline questionnaire (interviewer administered)
3. Technician questionnaire (completed by field staff from observation)
4. Followup questionnaire, first sample collection week (interviewer administered)
5. Time/activity diary (self administered with technician followup)
6. Dietary intake diary (self administered with interviewer followup)
7. Followup questionnaire, second sample collection week (self administered)
8. Followup questionnaire, third sample collection week (self administered)
9. Time/activity diary, second sample collection week (self administered)
10. Time/activity diary, third sample collection week (self administered)

Field interviewers will be involved in six activities in each county. (1<sup>st</sup>) The first step in each selected area is the process of counting and listing each possible housing unit in the sample area. Following standard procedures, the interviewer will locate the sample area, will identify the boundaries and an appropriate starting point, and will count the number of housing units on each street segment. The interviewer will sum the number of housing units. If the number is too large (to be determined), the segment sketch and housing unit counts will be returned to RTI where the statisticians will divide the segment into subsegments and select one subsegment for listing with probability proportional to its housing unit count. The procedures described in detail in RTI's general field interviewer's manual will be used to construct the list of all housing units in the area segment or subsegment. These procedures ensure that a complete list is developed in a prescribed, repeatable manner. The interviewer will list an address or unique description for each housing unit. RTI's sampling statisticians will use this list to select the sample housing units to be contacted.

(2<sup>nd</sup>) The interviewer's second step is to contact each housing unit selected, in the order specified. The interviewer must determine that the selected unit is a housing unit and is not a group quarters, a unit occupied by ten or more unrelated persons. If a selected unit is ineligible, the interviewer will document the reason, and will contact the next unit on the list.

(3<sup>rd</sup>) The interviewer will next attempt to complete a descriptive questionnaire at each eligible housing unit. The screening respondent must be a resident of the household who is at least 18 years of age. After completing the descriptive questionnaire, the interviewer will consult the pre-printed sample selection matrix for the sample housing unit, which will indicate the randomly selected roster line number, if any, to identify the sample person from the household roster. If no one is selected or if the residents of the household refuse to complete the descriptive questionnaire, the field supervisor will increase the sample size by

assigning the next housing unit on the ordered list to the field, unless a nonresponse follow-up contact may be appropriate. (Completeness goal for this stage = 94%).

(4<sup>th</sup>) The fourth step is the administration of the baseline questionnaire. The interviewer will explain the basic components of the NHEXAS study and ask the respondent to participate in the baseline interview. The interviewer will administer the questionnaire and record the respondent's answers. (Completeness goal = 90%).

(5<sup>th</sup>) The interviewer's next step is to explain the rest of the study, detailing the components of the environmental and personal sample collection. The interviewer will attempt to get each respondent to provide as full a set of the samples as possible, explaining the importance of full participation, and telling the respondent of the increased incentive associated with each level of participation.

(6<sup>th</sup>) The final step is to select a starting date and time for the environmental and personal sampling. The interviewer will tell the respondent which days the team will be working in the area, and will help the respondent select one of the three starting dates. After the interviewer has three respondents for each date, he or she will call the respondents and determine the time that the monitoring team will meet the respondent. The appointment dates and times, locations of the respondent's homes, and other data from the descriptive and baseline interviews will be compiled and left for the sampling team, prior to their arrival at their hotel. Shortly before the scheduled monitoring dates, the interviewer will call the respondents to remind them of the visits.

In the follow-up monitoring the participants will be contacted by phone reminding them of this scheduled activity and to answer any questions that may arise.

### 3.5.3 Procedures for Personal and Environmental Sample Collection and Analysis

Many different kinds of personal, environmental, and biological samples will be collected and analyzed under the NHEXAS Phase I study design (Table 16). Sample collection protocols (SCPs) will be used to guide the sample collection, storage, and shipping of all samples during the field study. Analytical protocols (APs), or standard operating procedures (SOPs) where they exist, will be used to guide the analysis of all NHEXAS samples. Any changes in the SCPs, APs, or SOPs will be documented and approved by the PI and QA officer, and the revised procedure will be identified by a new revision number and date. Each sample collection and analysis procedure is described briefly below; the reader is referred to the protocols for detailed procedures. An overview of sampling methods, sample processing and shipment is given in Tables 39 and 40, respectively. Tables 41 and 42 provide an overview of the laboratory methods. A list of all protocols and SOPs appears in Appendix A. Exhibit A depicts the overall sampling and analysis logistical flow between organizations and field operations.

Environmental and personal exposure sample collection methods have been selected to measure the extent of an individual's exposure to specific toxic chemicals. Personal sample collection methods (air, diet, dermal) will be used to assess the total exposure to a selected list of metals, and the exposure through primary pathways for selected volatile organic chemicals (VOCs), pesticides, and polyaromatic hydrocarbons (PAHs). Environmental sample collection methods have been selected to provide information about the source of the chemicals and the exposures and the relative importance of the media and

location to exposure, dose, and risk. Some of the planned samples (standing water, dietary, urine) will be collected by the participants, while the remainder will be collected or setup by the field technicians (personal, indoor, and outdoor aerosol and VOC air monitors, tap and drinking water, dust, soil) or by a trained nurse or phlebotomist (blood). The stratified sample collection design, defining the number of samples to be collected, is presented elsewhere in this document.

Methods for pesticide and PAH collection and analysis are described briefly in this document. Since the 50-person module for pesticides and PAHs will be conducted at or near the end of the 300-person study, detailed protocols have not been written for all methods. The planned protocols are described in Appendix B. Protocols and other documents, describing the pesticide and PAH methods in detail, will be prepared and submitted for EPA review before the 50-person module is begun.

#### *Aerosols in Air (metals and aerosol mass)*

A personal sample will be collected for inspirable aerosols over a period of approximately 144 hours to measure inhalation exposure to mass and metals. The inspirable aerosol fraction includes the total aerosol matter that can result in chemical exposure, and therefore best represents the inhalation pathway for total exposure assessment. A battery operated personal sampling system will be used to collect aerosols at 2.0 lpm through an IOM (Institute of Occupational Medicine) size selective inlet with a 25 mm, 3 µm porosity Teflon filter. This inlet collects the total inspirable aerosol fraction (approximately a D50 of 50 µm). The participant will carry a personal sampling system consisting of the pump, flow controller, DP cell (Delta Pressure sensor), thermistor, interval timer, data system, battery pack, and aerosol inlet, all packaged in a specially designed carrying pack. The sampling system will be contained in a soft "fanny" pack, while the inlet will be located near the breathing zone on a padded shoulder strap. The approximate total personal sampling system weight is expected to be just over 2 pounds (~990 g). The pack portion is expected to be ~12 inches long, 3-1/2" high and 3" deep. The potential influence of the bulkiness of the personal sampling system on the daily activity patterns of the participant will be addressed during the Dress Rehearsal.

An interval timer will be used to extend battery life and reduce filter blinding. This timer will sequentially turn the pump ON and OFF with an ON-cycle time of 60 seconds and an OFF-cycle time of 120 seconds to provide a total sample of 2880 minutes over 6 days. A preliminary evaluation of this cycle against real-time aerosol data has shown that over a 6 day period the cycled sample integrated average is essentially identical to a sampler operating continuously. The mass collected is computed to provide a minimum detection limit of 20 µg/m<sup>3</sup> using a 5-place analytical balance with a resolution of 15 µg. The interval operation also extends the total sampling "window", such that the system will easily collect a sample over a 3 day period on one set of 4 AA alkaline batteries (for personal sampling), or over 6 days with a set of 4 D alkaline batteries (for indoor and outdoor, fixed-location sampling). One battery pack change will be required during the 6 day period for personal sampling.

Flow rates will be measured at deployment and pick-up, and an integral miniature data logger will be used to record elapsed sampling time and other collection parameters. Aerosol samples will also be collected inside all homes (main living area) with personal aerosol monitoring, and outdoors at a subset of participant homes to assess sources of

exposure. Filter samples will be weighed for aerosol mass at RTI. Indoor and outdoor samples will be collected using PM10 size-selective inlets at a subset of homes to provide data to assess comparability between IOM and PM10 measurements. Metals will be analyzed, after acid extraction, by graphite furnace atomic absorption spectrophotometry (GFAAS) for lead, cadmium and chromium. Hydride method coupled with atomic fluorescence (HAF) will be used for arsenic analysis. Detailed procedures will be described in NHEXAS Protocols (Appendix A - RTI/ACS-AP-209-010, RTI/ACS-AP-209-011, RTI/ACS-AP-209-110, RTI/ACS-AP-209-111, NHX-SOP-171-005, and NHX-SOP-171-006).

#### *VOCs in Air*

A personal sample will be collected over a period of approximately 144 hours to measure VOC exposure from the inhalation pathway. A 3-M 3520 (dual stage) passive charcoal badge will be used to minimize participant burden. A second badge will be used for a subset of participants to assess the contribution of occupational exposure to the total exposure to selected VOCs. (Occupational exposure will be measured by difference - the second badge will be covered during working hours). Those participants using a second badge for occupational monitoring will be asked to write down each day the number of hours that their second badge was covered. Badges will also be deployed inside all homes (main living area) and outside of a subset of participant homes to assess the sources of exposure. Total elapsed sampling time will be calculated from the uncapping and capping times recorded by the field staff. Badges will be resealed in their cans for storage and shipment. Collected VOCs will be solvent extracted and analyzed by gas chromatography/mass spectrometry (GC/MS) operated in the selected ion monitoring (SIM) mode. Collection and analysis protocols describe the procedures in detail (Appendix A--RTI/ACS-AP-209-012, RTI/ACS-AP-209-112, NHX-SOP-184-001, NHX-SOP-184-002).

#### *Pesticide and PAHs in Air*

A personal sample will be collected for selected pesticides and PAHs in air to assess exposure through the inhalation pathway. Both chemical types will be collected on, and analyzed from, the same filter. A battery operated pump will be used to pull air through a cartridge with a quartz fiber filter and bed of XAD-2 resin at 1 or 2 L/min. Interval timing may be used over the collection period of approximately 144 hours to prolong battery life. Pesticide and PAH samples will be collected indoors and outdoors at the participant home to asses sources of exposure. The total volume to be collected may be as low as 4 m<sup>3</sup> (at 1 L/min for 72 hours out of 144) up to 17 m<sup>3</sup> (at 2 L/min for 144 hours). Testing of flow rates and run times will be performed prior to initiating the work to obtain the optimum sample volume. Samples will be stored frozen and shipped cold to the laboratory. Filters and the XAD-2 sorbent will be extracted together with solvents. Extracts will be analyzed by GC/MS/SIM. Collection and analysis protocols will describe the procedures in detail (Appendix B-RTI/ACS-AP-209-013, RTI/ACS-AP-209-114, NHX-SOP-184-001, NHX-SOP-184-002).

#### *Standing Tap Water (metals)*

Water samples will be collected from the kitchen tap by the participant after the water in the pipes in the home has remained undisturbed for a period of four hours prior to collection. This sample is intended to assess the contribution of the home plumbing to exposure to metals, particularly lead from plumbing solder joints. We will request that the

participants collect the sample on the morning of the day prior to the second staff visit to the home. If they forget to collect the sample or forget not to use any water in the home until after the sample is collected, they have the opportunity to collect it on the morning of the day of the second visit. The sample may be collected at other times or on other days if necessary or because the participant has forgotten. Participants will be instructed to store the sample in their refrigerator immediately after collection and until retrieved by the field staff. Written and verbal instructions will be provided to guide the participant's collection of the sample (RTI/ACS-AP-209-001). Water will be collected one time in a 250-mL polyethylene container. Samples will be refrigerated and shipped cold to the EPA-designated contract laboratory. Samples will be acidified upon receipt at the lab. Metals analysis will be completed by inductively coupled plasma/mass spectrometry (ICP/MS) according to EPA Method 200.8. Collection and analysis protocols describe the procedures in detail (Appendix A-RTI/ACS-AP-209-001, EPA-Compendium of Methods for Analysis of Metals and VOCs in Water).

#### *Tap Water-Flushed System (metals)*

Water samples will be collected from the kitchen tap by the field technicians after water has been run through the pipes for three minutes. This sample will be collected to assess potential contamination with metals from the water source or supply. In most cases, where tap water is also the primary drinking water source, the flushed sample will also be used to assess exposure from water ingestion. Two samples (one for Pb, Cd, Cr and one for As) will be collected by the project staff members in 250 mL polyethylene containers. For participants that are not collecting duplicate diet samples, separate samples of drinking water will be collected if tap water is not the primary source of drinking water. Samples will be acidified upon receipt at the lab. Metals analysis will be completed for Pb, Cd, and Cr by ICP/MS. A separate analysis for arsenic may be required to obtain the necessary detection limit of 0.2 µg/L. Collection and analysis procedures are described in detail in the protocols (Appendix A-RTI/ACS-AP-209-002, EPA-Compendium of Methods for Analysis of Metals and VOCs in Water).

#### *Drinking Water (VOCs)*

Drinking water samples will be collected from the primary drinking water source by the field technicians. This may be either a flushed home piping system, when tap water is the source of drinking water, or from any other source such as bottled water. This sample is intended to assess the contribution to exposure that results from the drinking water. Samples for VOCs will be collected with no headspace in 40 mL glass vials with acid preservative and ascorbic acid to quench residual chlorine. All samples will be refrigerated in the field and shipped cold to the analysis laboratory. VOC analysis will be performed by GC/MS according to EPA Method 524.4. Collection and analysis procedures are described in protocols (Appendix A-RTI/ACS-AP-209-003, EPA-Compendium of Methods for Analysis of Metals and VOCs in Water).

#### *Drinking Water (pesticides and PAHs)*

One drinking water sample will be collected for pesticide and PAH analysis from each of the 50 homes in the 50-person pesticide/PAH study module. Samples of drinking water will be collected by the field staff in 1-L glass bottles. A chlorine quencher (sodium sulfite) will be added to the sample. An acid preservative will also be added if it is deemed

necessary for the specific target analytes. Water samples will be analyzed by GC/MS according to EPA Method 525.2. All samples will be refrigerated in the field and shipped cold to the EPA-specified contract laboratory. Collection and analysis procedures are described in protocols (Appendix B-RTI/ACS-AP-209-004, EPA-Method 525.2).

#### ***Food and Beverages (metals, pesticides and PAHs)***

Dietary samples will be collected to assess exposure of individuals through the ingestion pathway as an important component of measuring total exposure. Dietary samples will be collected for metals in the 300-person primary module and for pesticides and PAHs only in the 50-person module. Dietary samples will be collected from house study participants that agree to collect dietary samples on four consecutive days using duplicate diet methodology. This method requires that participants prepare or obtain duplicate portions of all foods and beverages they consume during the specified period. Drinking water is included in the dietary collection so that dietary ingestion of the target analytes from all sources can be measured. Participants will collect separate solid food and beverage samples in polyethylene (metals) or glass (pesticides/PAHs) containers. Solid foods and beverages will be collected separately to reduce sample handling problems and to reduce analyte dilution effects. The solid foods and beverages collected for metals analysis during each of the four one-day collection periods will be refrigerated and shipped cold to FDA, where they will be combined and homogenized. Beverage samples will also be combined and homogenized.

In order to evaluate intra-individual intake variability (for the purpose of assessing the optimum number of days of dietary sample collection) we will also ask FDA to prepare four daily food and beverage composites from 25 of the NHEXAS participants in addition to their 4-day composites. From these 25 sets of daily composites, 12 sets will be selected for analysis, with the selection criteria set to include a range of contaminant concentrations.

Analysis for metals will be performed using the FDA Total Diet Study methods. Collection and analysis procedures for metals are described in protocols (Appendix A-RTI/ACS-AP-209-030, FDA-Compendium of Methods for Analysis of Trace Metals in Dietary Samples). Food samples for pesticide and PAH analysis will first be submitted to FDA for homogenization. Aliquots of the homogenized samples will be shipped to Rutgers University for analysis for both pesticides and PAHs. NIST quality assurance samples for pesticides and PAHs in foods will be analyzed by Rutgers U. if available. Collection and analysis procedures will be described in protocols (Appendix B-RTI/ACS-AP-209-031, EOHSI-AP-209-133).

#### ***Dust Wipe Samples (metals, pesticides and PAHs)***

Dust wipe samples will be collected by the field technicians to assess potential residential sources of dermal and inhalation exposures and to examine relationships between analyte levels in dust and those in personal and biomarker samples. Dust samples will be collected for metals in the 300-person primary study module, and for pesticides and PAHs in the separate 50-person module. Dust samples will be collected on a window sill and in the participant's primary living area using the Lioy-Wainman-Weisel (LWW) wipe sampler. Samples will also be collected in a subset of homes using the Wet Wipe Towel (WWT) method for comparability testing because both methods are currently in use in other studies. Separate samples will be collected at each location; one for analysis of lead, cadmium and

chromium at EOHSI, and one for analysis of arsenic at RTI. Samples will be refrigerated and shipped cold to EOHSI. Dust samples for metals will be weighed to measure the collected mass, then acid extracted and digested, with analysis at EOHSI by ICP/MS and HAF at RTI. Pesticides and PAH samples will be weighed to measure the collected mass, then solvent extracted and analyzed by GC/MS or HPLC. Collection and analysis procedures are described in protocols (Appendix A--EOHSI-AP-209-020, EOHSI-AP-209-120, RTI/ACS-AP-209-121, and Appendix B--EOHSI-AP-209-022, RTI/ACS-AP-209-124, EOHSI-AP-209-125).

#### *Dust Deposition Samples (metals, pesticides and PAHs)*

Dust deposition samples will be collected to assess the incremental deposition of dust inside the residence and to examine relationship between this long term source and exposure. Dust samples will be collected for metals in the 300-person primary study module, and for pesticides and PAHs in the separate 50-person module. Two types of deposition sample will be collected. First, a clean, flat plate will be left on an exposed shelf. After a specified period of time, the participants will ship the plate to the laboratory. Second, a small pre-weighed section of carpet will be deployed in the participant's home. After a specified period of time, the participants will ship the carpet section back to the laboratory. After weighing, samples will be prepared for analysis of lead, cadmium, and chromium at EOHSI and for arsenic at RTI. The metals will be acid extracted and digested, with analysis by ICP/MS and HAF. Pesticides and PAHs will be solvent extracted and analyzed by GC/MS or HPLC. Collection and analysis procedures are described in protocols (Appendix A--EOHSI-AP-209-020, EOHSI-AP-209-120, RTI/ACS-AP-209-122, and Appendix B--EOHSI-AP-209-022, RTI/ACS-AP-209-124, EOHSI-AP-209-125).

#### *Soil Samples (metals)*

Soil samples will be collected to examine the source relationship between analyte levels in soil and those measured in personal, indoor, and biomarker samples. Soil will be collected by a sweeping method from the most heavily trafficked areas at the primary entrance to the home, and by a ring collection method from exposed soil in the primary outdoor activity areas as determined by discussion with the participants. Samples will be refrigerated and shipped cold to EOHSI. Samples will be acid extracted and digested, followed by ICP/MS and HAF analysis. Collection and analysis procedures are described in protocols (Appendix A--EOHSI-AP-209-121, EOHSI-AP-209-120, RTI/ACS-AP-209-123, and Appendix B--EOHSI-AP-209-023, EOHSI-AP-209-126, RTI/ACS-AP-209-127).

#### *Dermal Wipe/Rinse Samples*

Dermal samples will be collected for a subset of participants to better understand the dermal contact with toxic chemicals and the resulting potential for the internal dose as a result from the dermal absorption and nondietary ingestion. It is important to understand the contribution from the dermal pathway towards total exposure; however the collection methods and interpretation of measurements have not been widely used in total exposure assessment studies. The methodology for using indirect method to estimate dermal exposure will be developed in parallel with the NHEXAS Phase I study. A test of the methodology will be implemented by collecting dermal rinse and/or wipe samples from participants monitored during the final stages of the field effort for metals, or in the distinct pesticide/PAH sampling module. Optimal methods and timing for wipe and rinse sampling will be evaluated during the research phase, so methods are not included at this time.

Collection and analysis procedures are to be written (Appendix B--EOHSI-AP-209-050, EOHSI-AP-209-051, EOHSI-AP-209-150, EOHSI-AP-209-151, RTI/ACS-AP-209-152, RTI/ACS-AP-209-153).

#### ***Blood Samples (metals, VOCs, pesticides, PAH)***

Several biological media, including blood, urine, and hair will be collected to examine the relationships between personal exposure measurements, environmental measurements, and body burden. Although pharmacokinetic models may be used to help interpret the results of biomarker measurements, the study is not designed to generate information for development or detailed testing of PBPK models. For some chemicals (i.e. lead and benzene), blood is the best biomarker for evaluating relationships to exposure. Venous blood samples will be collected by venipuncture by a local health care worker at one time using three or four specially prepared Vacutainers supplied by the Centers for Disease Control (CDC). Whole blood will be collected in one Vacutainer for VOCs, one or two Vacutainers for metals, and one Vacutainer for archival (for possible future analysis of DNA or protein adducts). Whole blood samples will be refrigerated and shipped cold to CDC for analysis. During the pesticide/PAH study module, different vacutainers will be used (replacing one or more of the metal/VOC vacutainers) to collect whole blood. The serum will be separated by centrifugation and frozen in glass bottles. The samples will be returned frozen to CDC and to EPA-HERL. Samples will be analyzed by CDC for pesticide analytes and selected metabolites. Samples will be analyzed by EPA-HERL for PAH analytes or selected metabolites. Collection and analysis procedures are based on CDC methods and are described in protocols (Appendix A--EOHSI-AP-209-040, CDC-Compendium of Method Summaries for Collection and Analysis of Metals and VOCs in Blood and Urine, and Appendix B--EOHSI-AP-209-041).

#### ***Urine Samples (metals, pesticides)***

For some chemicals (i.e. arsenic) urine provides the best information about the relationship between exposure and body burden. Two samples will be collected during the one week monitoring period. Sample collection times will be optimized to provide information about the uptake or elimination of analytes measured in other personal and environmental samples collected during the week. The proposed collection times for metals are Day 3 and Day 7, but may be different for pesticides and PAHs. Morning void urine samples will be collected. Participants will store the samples in their freezer or in a cooler provided by the field staff. Samples will be shipped frozen to CDC. Samples will be analyzed by CDC for target metal or pesticide analytes and selected metabolites. Samples will be analyzed by EPA-HERL for target PAHs or selected metabolites. Collection and analysis procedures are described in protocols (Appendix A--EOHSI-AP-209-040, CDC-Compendium of Method Summaries for Collection and Analysis of Metals and VOCs in Blood and Urine, Appendix B--EOHSI-AP-209-041).

#### ***Hair Samples (metals)***

Hair may represent a useful biomarker for long-term exposure for some chemicals (i.e., arsenic). Since one NHEXAS objective is to characterize long-term exposures, hair could be an important assessment parameter. Some work is needed on the analytical methodology to eliminate exogenous sources of the target analytes prior to analysis. Because of the potential usefulness of hair to assess body burden and the low burden of collection, hair

samples will be collected and archived pending development of suitable sample clean-up procedures. Collection procedures are listed in Appendix A (RTI/ACS-AP-209-046).

### **3.5.4 Field Procedures For Collection of Environmental/Biological Samples**

Study participants will collect, or allow the project staff to collect, environmental and personal samples from multiple media. In the tiered study design, participants may choose not to participate in certain categories of sample collection. The three tiers in the 300-person module has been designated core, core+ and core++. Some samples will be collected only for a subset of study participants. Sampling during the three periods include:

**First Week - Environmental and Personal Sample Collection (Collected by, or assisted by project staff)**

1. Indoor VOC passive badge sample (6-day integrated) (core)
2. Outdoor VOC passive badge sample (6-day integrated) (core)
3. Personal VOC passive badge sample (6-day integrated) (core)
4. Non-occupational personal VOC passive badge (6-day work time integrated)
5. Indoor active pump sample (6-day integrated) (core+, and 50-person module)
6. Outdoor active pump sample (6-day integrated) (core+, and 50-person module)
7. Personal active pump sample (6-day integrated) (core+, and 50-person module)
8. Drinking water samples (core and 50-person module)
9. Standing tap water sample (core)
10. Dust wipe samples (core+ and 50-person module)
11. Plate deposition dust sample (core+ and 50-person module)
12. Carpet deposition dust sample (core+ and 50-person module)
13. Dermal wipe/rinse sample (50-person module)
14. Soil sample (subset of 50 participants)
15. Duplicate diet food and beverage samples (4-day total) (core++)
16. Blood samples (one time) (core and 50-person module)
17. Urine samples (2) (core and 50 person module)
18. Hair sample (core)

**Second Week - Environmental and Personal Sample Collection (Completed by participant) (subset of 300-person module only)**

1. Indoor VOC passive badge sample
2. Outdoor VOC passive badge sample
3. Personal VOC passive badge sample
4. Drinking water samples (2)
5. Standing tap water sample
6. Plate deposition dust sample
7. Carpet deposition dust sample
8. Urine samples (2)
9. Hair sample

**Third Week - Environmental and Personal Sample Collection (Completed by participant) (subset of 300-person module only)**

1. Indoor VOC passive badge sample
2. Outdoor VOC passive badge sample
3. Personal VOC passive badge sample
4. Drinking water samples (2)
5. Standing tap water sample
6. Urine samples (2)
7. Hair sample

#### ***Field Sample Collection***

All field sampling activities will be conducted or coordinated by RTI personnel. The field supervisor has extensive experience with multi-media field monitoring studies; the field technicians will be trained in all aspects of sample collection before monitoring begins.

Each field technician will be responsible for the proper implementation of the sampling SOPs and protocols. In addition, he/she will supervise a phlebotomist who collects blood samples from participants on the last day of the monitoring visit.

Table C-1 in Appendix C shows the estimated percentage of homes that will have environmental, personal and biomarker sample collection by tier (core, core+, core++). In addition, tables are included in Appendix D which detail the tasks which will be carried out for each visit to the study homes.

Questionnaires will be administered at each home to obtain information on time/activity patterns, and diet of the participant.

The acquisition of the required environmental and biological samples will be conducted according to written protocols or standard operating procedures (SOPs). The list of applicable protocols and SOPs is included as Appendix A. The sampling procedures are summarized in Table 39 for metals and VOCs. When the QSIP addendum is prepared for the 50-person pesticide/PAH module, summary tables will be included for pesticide/PAH methods.

#### ***Field Sample Processing and Shipping***

An important component of the study is coordination of sample storage in the field and shipment to the analytical laboratories. Each sample type has specific requirements for handling and storage. Samples will be shipped to a number of laboratories; each sample type/laboratory combination also has requirements for conditions and holding times. These are described in detail in the protocols and SOPs. An overview is shown in Table 40 for metals and VOCs. General laboratory analysis procedures are described for metals (Table 41) and for VOCs (Table 42).

#### ***Preparation of Sampling Materials/Supplies***

RTI is responsible for assembling the equipment necessary for the study. This includes identifying the equipment, assuring that it is inspected, tested, and configured properly. RTI is also responsible for assembling containers, documents and other materials necessary for conducting the study. Preparation includes four general categories:

- Preparation of survey instruments and associated documents,
- Preparation of field sampling equipment, collection media and supplies, record keeping forms and software
- Preparation of the mobile laboratory system and equipment, and
- Preparation of analytical measurement systems and supplies.

### ***Sample Management***

The conditions under which each sample is collected will be recorded in sample collection records. Sample collection records will be paper forms and/or computer files on which the field staff will enter sample collection and processing data. Sample custody procedures will be initiated when the sample is collected (Appendix A, RTI/ACS-AP-209-071). The individual assigned to collect specific samples will be required to fill in all of the appropriate sampling information and maintain this record.

Two primary types of codes will be prepared for tracking samples and participants during the field study. A unique 6-character sample code will be assigned to each sample (see 3.2.2). This code will be used to track the sample, or its subsequent collection and analysis data, from the initiation of sample collection through data analysis. The sample code will consist of two alpha characters to identify the sample type (and analysis laboratory), followed by four numbers that uniquely identify the sample. A series of computer generated sample code labels will be prepared and affixed to the sample or its container. This code will also be read into the sample data collection software using a bar code reader. This code will appear on all data collection records and custody records.

A second separate and unique three digit code (see 3.2.2) will be assigned to each participant for sample collection and data management purposes. This code will be included on all data collection records.

This coding system will require that some information be linked to codes in other records. For example, the food analysis laboratory must combine and homogenize food from four bottles for each participant. Thus, participant identification numbers (three digit number) must be linked to each sample record.

All sampling materials and supplies will be transported to the field by study personnel or carriers selected by the Field Supervisor.

Samples will be shipped by overnight carrier directly to the analysis laboratory or to RTI for further processing.

### **Collection Schedule - Overall Study**

As detailed later in this section, each respondent will be monitored over a seven-day period, encompassing approximately 144 hours. A total of nine respondents will be monitored in each county, requiring approximately 12 days per county to move, set-up, and complete all monitoring and shipping activities. After monitoring is completed, the monitoring team will ship samples and then move to the next county in the sample. Based

on receiving OMB approval in mid-summer, the first counties will be sampled in the early fall. The exact dates for the initiation of activities will be determined after the sample of counties has been selected, the sequence of travel determined and OMB approval has been received. If OMB approval is granted in late summer/early fall the initiation of the field sampling activities will be postponed until March/April of 1995.

A two phase study rehearsal will be used to test the methodology and logistics prior to beginning the 300-person study module. In the first phase, from 3 to 6 participants will be selected for the initial rehearsal during the summer of 1994. All sample collection, processing, and analysis methods are to be tested during this first rehearsal. Questionnaires will be administered to at least two of the participants, and more if their test slots are available. The primary purpose of this first rehearsal is as an initial shakedown of the procedures, equipment, logistics and burden (participant and staff). This will include assessment of participant training needs. Changes in the methodology and draft protocols will be implemented as needed based on the results of the first rehearsal. Participant training materials will be prepared or revised. At least one month, and preferable at least six weeks, will be allowed for modifications before the second rehearsal is performed. A second rehearsal, with 3 to 6 participants, will be performed after OMB approval is obtained and shortly before the 300-person study module is scheduled to begin. The purpose of this rehearsal is to provide a final exercise of the modified protocols, equipment, and participant training procedures. It will also serve to prepare the staff for the start of field collection activities. Any final changes will be made in the draft protocols, and the protocols will then be considered to be the initial working versions. Any subsequent changes in the protocols will be subject to documentation according to the appropriate standard operating procedure (NHX-SOP-100-002).

We will develop a schedule based on the timing of holidays and vacation periods. We will not schedule monitoring at Thanksgiving, between Christmas and New Years, and around other holidays since respondent availability and cooperation are diminished at these times, and the need to schedule vacation and holiday breaks for the monitoring team.

Prior to the collection of environmental and personal samples as described below, field interviewers will work in the county for approximately four weeks. Using segment maps and materials prepared by the sampling statisticians, the interviewer will complete the count and list process for each segment selected in the county. After conveying the count information to the statisticians, the interviewer will complete any required subsampling activities. Based on the counts and completed listings, the statisticians will select the ordered sample, and provide the listing to the interviewer. During the two weeks prior to monitoring, the interviewer will contact the assigned sample, and any replacements, and complete the descriptive questionnaire, identify the selected respondent, complete the baseline questionnaire, and determine the dates of the monitoring visits. Completing the respondent selection and enrollment during the two weeks prior to monitoring allows the interviewer and respondent flexibility in selecting dates for participation, but is not so far in advance that the respondent loses his motivation to participate.

Once the schedule for the environmental and personal monitoring is developed, we will develop the overlapping schedule for the interviewer's work in each county. We will recruit and train the field staff based on that schedule.

Personal and environmental sample collection activities will be conducted over periods of approximately 12 days in each selected county (Table 43). The project staff technicians will spend the first day preparing equipment and sample collection media for the approximately nine participants that have been recruited to complete sample collection activities in the county. On the second day, two members of the technical staff will initiate sample collection activities with three participants. A second visit will be made to each participant home, in most cases three days after the first visit. And the technical staff will make a final visit to each participant home six days after the initial visit. This schedule will be followed on staggered days for the remaining participants (Table 43 displays the scheduled visits). An interviewer or technical staff member will perform an additional short visit (between the second and third monitoring visit) to those participants collecting dietary samples. On the days after all participant visits have been completed, samples will be packed and shipped and the project staff will drive the mobile laboratory to the next county. Appendix D provides detailed sample collection activities for each home.

Personal and residential environmental samples will be collected for each participant during a one week period. Air samples will be collected over an integrated time period of approximately 144 hours. Participants will be trained to wear their personal air samplers, to collect dietary samples over four consecutive days, to collect two urine samples and a standing water sample at specified times during the one week period, and to complete their time-activity diary. The remaining personal and environmental samples will be collected by project staff during one of the three or four visits scheduled for each home.

A subset of participants in the 300-person module will be asked to provide a limited number of survey data, personal, and environmental samples during two additional weeks. All participants completing the first monitoring week in the first half (18 counties) of the study will be asked to participate in the temporal monitoring. The followup weeks will be scheduled to provide information on temporal variability over different time intervals, ranging from a few weeks in the same season to many weeks in different seasons.

### 3.5.5 Sample Custody

The field staff, under direction of the Field Supervisor, will have responsibility for sample custody in the field. He will be responsible for monitoring and tracking all collection, storage and shipment activities, including sample and document custody. The field technicians will serve as the field sample custodians. While in the field, the technicians will maintain custody of samples during acquisition, field processing, and storage in the field work room or laboratory(for those samples which are not shipped immediately). The technicians will also be responsible for shipping samples back to RTI or other laboratories (i.e., FDA, CDC, EPA) for processing and analysis. Samples, and associated electronic files, shipped to RTI will be checked for any problems upon receipt (i.e., broken containers;missing data) and then logged in on the custody form and in an electronic file. Samples will then be stored as specified until further processing or distribution. Custody procedures are described in more detail in RTI/ACS-AP-209-071 in Appendix A.

#### *Custody of Survey Documents*

The RTI field staff and interviewers will be responsible for custody of the survey documents (questionnaires and diaries) while they remain at the field site. They will review

the forms for completeness in the field, and retain custody of them until they are shipped to RTI. Confidentiality of this information will be maintained.

#### *Custody of Environmental Samples*

RTI field staff will be responsible for custody of all environmental samples collected in the field. The field staff will prepare, deploy, retrieve, and store all samples, and shall maintain records for these samples. The field staff will relinquish custody when the samples are shipped to the analytical laboratories. Custody records will be shipped with the samples to analytical laboratories. The analytical laboratories will be responsible for the samples from receipt until final disposition of the samples. The analytical laboratories will also be responsible for shipping completed custody records to RTI at the completion of the analytical phase.

#### *Field Data*

RTI field staff will be responsible for the generation, storage, and transmission of the sample collection and custody data associated with each sample. All sample collection data will be entered directly into computer files during collection. Paper records will be used only if the primary and backup computers both fail. Backup files of the sample collection data will be created on removable disk after each data collection session in each home, and full data backups of all files will also be periodically performed as work is completed in each county. Electronic copies of all data files will be transmitted to the field supervisor and subsequently to the or database manager at RTI. This transmission will be made at least once for each county, and more often as needed. Sample collection data needed at the analytical laboratories will accompany the samples as they are shipped. Where possible, the transmission will be in the form of electronic data files. If the an analytical labs is unable to process the computer files, then paper copies containing the sample collection information will be generated and shipped with the samples as part of the custody record.

Participants will be responsible for collecting samples during the second and third six-day sample collection periods that will be used at some homes. Participants will be asked to provide minimal sample collection data, including collection date and collection (start/stop) times. Participants will record this information on a simple paper form or label on the container, to be returned with the samples. RTI staff will enter the collection information into the appropriate computer files.

#### *Custody Documents and Procedures*

RTI field staff will initiate records for each environmental sample during the first six day monitoring period for each home during the field study. At a minimum, this field record will include sample codes, collection initiation and completion times and dates, and shipping date. Staff identification numbers (4 digit) will be associated with each procedure. Tracking records will be initiated at the laboratory for most quality control samples (field blank, for example).

When samples are shipped from the field to the analytical laboratory, a custody record will accompany the samples. An electronic file (sample collection data and custody data combined) will be supplied to the analytical laboratory as well, if the laboratory will support electronic tracking.

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Participants will be responsible for collecting and shipping samples during the second and third six-day sample collection periods that will be used at some homes. Participants will not maintain custody or tracking records. These records will be initiated when the samples are received at RTI for processing and shipment to the analytical laboratories.

Table 16. RTI/EOHSI NHEXAS Design: Number of Sample Persons by Medium and Type of Compound<sup>a</sup>

Medium	Metals			Particulates			VOCs		
	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3
AIR									
Indoor	239			239			300	150	135
Outdoor	100			100			100	85	77
Total Personal	239			239			300	150	135
Non-Work Personal							50 <sup>b</sup>		
TAP WATER									
Initial	300	150	135						
Flushed	300	150	135				300	?	?
FOOD & BEVERAGES	259								
DUST & SOIL									
Window Sill Dust	239			239					
Primary Living Area Dust	239			239					
Dust Collection Plate	----->	150----->	135	----->	150----->	135			
Entrance Floor Mat	----->	150----->	135						
Soil	50 <sup>b</sup>								
BIOLOGICALS									
Urine (2 samples)	280	140	126						
Blood (2 vials)	280						280		

<sup>a</sup>Estimates, based on projected response rates.

<sup>b</sup>Purposive subsample.

Table 16. RTI/EOHSI NHEXAS Design: Number of Sample Persons by Medium and Type of Compound<sup>a</sup>

Medium	Metals			Particulates			VOCs		
	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3	Week 1	Week 2	Week 3
AIR									
Indoor	239			239			300	150	135
Outdoor	100			100			100	85	77
Total Personal	239			239			300	150	135
Non-Work Personal							50 <sup>b</sup>		
TAP WATER									
Initial	300	150	135				300	?	?
Flushed	300	150	135						
FOOD & BEVERAGES	259								
DUST & SOIL									
Window Sill Dust	239			239					
Primary Living Area Dust	239			239					
Dust Collection Plate	----->	150----->	135	----->	150----->	135			
Entrance Floor Mat	----->	150----->	135						
Soil	50 <sup>b</sup>								
BIOLOGICALS									
Urine (2 samples)	280	140	126				280		
Blood (2 vials)	280								

<sup>a</sup>Estimates, based on projected response rates.

<sup>b</sup>Purposive subsample.

TABLE 17. TYPES OF PHYSICAL MEASUREMENTS FOR REGION V STUDY

TYPE OF MEDIA	300-Home Probability-Based Study			50-Home Special Study	
	Metals	Particles	VOCs	Pesticides	PAHs
Environmental	WI*		WF*	WF	WF
	WF*		AI*	AI	AI
	AI	AI	AO*	AO	AO
	AO	AO		DW	DW
	DW	DW		DL	DL
	DL	DL		DP	DP
	DP*	DP*		S	S
	DR*				
	S**				
Personal Exposures	F AP	AP	AP* APNW**	F AP KW KR	F AP KW KR
Biological Markers	B U*		B	B U	B U

\* = measured in 2 additional followup periods as well as in monitoring period

\*\* = measured only for purposive subsample of 50 homes or people

NOTATION:

B	= blood
U	= urine (U1 = first, U2 = second)
W	= tap water (WI = initial, WF = flushed)
AP	= personal air
APNW	= personal air while not at work
AI	= indoor residential air
AO	= outdoor residential air
D	= dust (DL = living area, DW = window sill, DP = plate, DR = rug)
F	= food/beverage
S	= soil
KW	= dermal wipe
KR	= dermal rinse

TABLE 18. HYPOTHESIS M1: METALS - TEST FOR ADEQUACY OF INITIAL EXPOSURE ASSESSMENTS (EAs)

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
M1A. Exposure or concentration distribution from initial EA is/is not comparable to Pilot Study results.	<p>Treat mean of weekly exposure or concentration from EA as constant m. Test estimated population mean from Pilot Study vs. m. Use day or week as standarized time unit.</p> <p>Treat 90th percentile from EA as a constant g. From Pilot Study, estimate proportion of pop. with exposure or concentration &lt; g, and compare to expected 0.9. Time units must be compatible from Pilot Study and EA.</p>	WI (Pb), WF (As), AP, F	RTI/TSG/ EOHSI
M1B. Exposure or concentration data from the Pilot Study can/cannot be used to improve EA results.	Rerun EA models using Pilot Study data. Compare estimated means and percentiles to prior estimates.	Pb and As, by pathway	HSPH

TABLE 19. HYPOTHESIS M2: METALS - TEST FOR SUBPOPULATION DIFFERENCES

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
M2A. Biologically sensitive (BS) subpopulations have/do not have total exposures or doses like those of the general population.	Use health-based threshold T. Define BS domain. Estimate proportions of the BS and non-BS domains that exceed T. Test for equality of the two proportions.	B (Pb) - Domain = children less than 10 years old U (As) - Domain = ?	RTI/EOHSI
M2B. Exposures for certain segments of the population are/are not different than those of the general population.	Define domain. Estimate mean exposure for the domain and its complement. Test for equality.  Estimate given percentile f (e.g., median, 90th) of overall population exposure distribution. Estimate proportion of domain with exposures exceeding f. Do same for complement and compare proportions.	AP, F  Domains defined by gender, socioeconomic status, race, home location (rural/urban and Great Lakes area/other), age, working status, time spent indoors, age of home, type of home,....	RTI
M2C. Biological marker measurements for certain segments of the population are/are not different than those for the general population.	Like M2B	B (Pb) U (As)  Domains as in M2B.	RTI
M2D. Environmental media concentrations for certain segments of the population are/are not different than those for the general population.	Like M2B	D, AI, AO, WI (Pb), WF (As)  Segments defined by SES, race (head of HH), age of home, water source, type of home, family size, home location,....	RTI

TABLE 20. HYPOTHESIS M3: METALS - TEST FOR EFFECTS OF SOURCES

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
M3A. Exposures for segments of the population having certain sources are/are not different from those of the general population.	Define domain in terms of persons or homes having/not having source. Estimate mean exposure for the domain and its complement. Test for equality.  Estimate given percentile $f$ (e.g., median, 90th) of overall population exposure distribution. Estimate proportion of domain with exposures exceeding $f$ . Do same for complement and compare proportions.	AP: Potential sources include home conditions (e.g., cleanliness, age of home, paint condition), indoor/outdoor pets, family size, specific hobbies or jobs,....  F: Potential sources include heavy consumption of specific food groups (e.g., root vegetables), home conditions, location of food preparation/consumption, water,....	RTI/EOHSI
M3B. Environmental media concentrations for segments of the population having certain sources are/are not different from those of the general population.	Like M3A	AI, AO: Potential sources as for AP in M3A.  W,D: Potential sources as for F in M3A.	RTI
M3C. Personal exposure measurements do/do not correlate with measures of source intensity.	Calculate Spearman correlations. Calculate Pearson correlations for original and log-transformed data. Form categories of responses for intensity measures and treat as in M3A.	AP vs. amount of cleaning, time indoors, no. of children, no. cigarettes smoked by self/others, proximity to roads,....  F vs. amounts of specific foods consumed, amount of cleaning,....	RTI
M3D. Environmental media concentration measurements do/do not correlate with measures of source intensity.	Like M3C	AI, AO, W, D - source intensities as for AP in M3C	RTI

TABLE 21. HYPOTHESIS M4: METALS - TEST FOR ASSOCIATIONS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
M4A. Personal exposure measurements do/do not correlate with biological markers.	Calculate Spearman correlations. Calculate Pearson correlations for original and log-transformed data. (Compare weighted & unweighted correlations.)	AP, F, KW, KR and WI vs. B (Pb) AP, F, KW, KR and WF vs. U (As)	RTI/EOHSI
M4B. Personal exposure and dose measurements do/do not correlate with environmental media concentration measurements.	Like M4A	AI, AO, D, and S vs. AP AI, D, W and S vs. F, KW, KR	RTI/EOHSI
M4C. Alternative media measurements are/are not correlated.	Like M4A	WI vs. WF; AI vs. AO, D, and S; DL vs. DW, DP, DR and S; DW vs. DP, DR, and S; DP vs. DR and S; DR vs. S	RTI

TABLE 22. HYPOTHESIS M5: METALS - APPORTION EXPOSURES AMONG PATHWAYS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
M5A. All measured pathways contribute equally/unequally to exposures.	Convert concentrations to average mass/day. Estimate population means and percentiles of these measures, and compare corresponding estimates across pathways.	AP vs. F	EOHSI/RTI
M5B. Pathway contributions are/are not independent.	Calculate inter-pathway correlations (Spearman, and Pearson [original and log-transformed])	AP vs. F, AP vs. D, F vs. D	RTI

TABLE 23. HYPOTHESIS M6: METALS - IMPROVE OR DEVELOP EXPOSURE MODELS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
M6A. Individuals' food exposures estimated by combining consumption data with concentration data from the Total Diet Study are/are not different from the measured food exposures.	Compute difference of measured and estimated exposures for each individual. Estimate mean (median) of differences and test whether zero. Also correlate measured and estimated exposures across individuals.	Selected individuals having high quality food diary data, and diverse types of food items in their diet.	RTI
M6B. Individuals' air exposures estimated from dispersion models are/are not different from the measured air exposures.	Like M6A.	Selected individuals in selected urban areas.	EPA
M6C. Distributions of long-term measurements can/cannot be estimated directly from short-term measurements (i.e., using only physical measurements).	Adapt Duan-Wallace method to extrapolate to annual exposures (pre-test lognormality assumption; perform estimation by domain if necessary).  Estimate autocorrelation functions of exposure measurements (concentration measurements) by grouping observations by months; perform seasonal adjustments.	U, W, DP, DR (i.e., those environmental measures with longitudinal data).	RTI/RAND/EOHSI
M6D. Personal exposures can/cannot be estimated by applying dose reconstruction models to biological marker data.	Use pharmacokinetic models to estimate exposures. Correlate results with measured exposures.	B - Pb U - As, Cd	EOHSI
M6E. Questionnaire/activity data (perhaps along with environmental media measurements) can/cannot be used to predict individuals' exposures.	Develop regression-type prediction models. Correlate predictions with measured exposures and biological markers (where possible).	Relate AP to AI, AO, times and activities.  Relate F to W,D, types of food consumed, age of home,....	RTI/RAND/EOHSI

TABLE 24. HYPOTHESIS A2: PARTICLES - TEST FOR SUBPOPULATION DIFFERENCES

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
A2B. Exposures for certain segments of the population are/are not different than those of the general population.	<p>Define domain. Estimate mean exposure for the domain and its complement. Test for equality.</p> <p>Estimate given percentile <math>f</math> (e.g., median, 90th) of overall population exposure distribution. Estimate proportion of domain with exposures exceeding <math>f</math>. Do same for complement and compare proportions.</p>	AP Domains defined by SES, race, location (rural/urban and Great Lakes area/other), age, working status, age of home, home type,....	RTI/EOHSI
A2D. Environmental media concentrations for certain segments of the population are/are not different than those for the general population.	Like A2B	AI, AO Segments defined by SES, race (head of HH), location, age of home, home type,....	RTI

TABLE 25. HYPOTHESIS A3: PARTICLES - TEST FOR EFFECTS OF SOURCES

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
A3A. Exposures for segments of the population having certain sources are/are not different from those of the general population.	Define domain in terms of persons or homes having/not having source. Estimate mean exposure for the domain and its complement. Test for equality.  Estimate given percentile f (e.g., median, 90th) of overall population exposure distribution. Estimate proportion of domain with exposures exceeding f. Do same for complement and compare proportions.	AP  Potential sources include combustion, cleanliness, type hobbies/jobs,....	RTI/EOHSI
A3B. Environmental media concentrations for segments of the population having certain sources are/are not different from those of the general population.	Like A3A	AI, AO  Potential sources as in A3A.	RTI
A3C. Personal exposure measurements do/do not correlate with measures of source intensity.	Calculate Spearman correlations. Calculate Pearson correlations for original and log-transformed data. Form categories of responses for intensity measures and treat as in A3A.	AP vs. no. cigarettes smoked by self/others, time spent indoors, frequency of cleaning/yard work,....	RTI
A3D. Environmental media concentration measurements do/do not correlate with measures of source intensity.	Like A3C	AI and AO - like A3C	RTI

TABLE 26. HYPOTHESIS A4: PARTICLES - TEST FOR ASSOCIATIONS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
A4B. Personal exposure measurements do/do not correlate with environmental media concentration measurements.	Calculate Spearman correlations. Calculate Pearson correlations for original and log-transformed data. (Compare weighted & unweighted correlations.)	AI and AO vs. AP	RTI
A4C. Alternative media measurements are/are not correlated.	Like A4B	AI vs. AO	RTI

TABLE 27. HYPOTHESIS A6: PARTICLES - IMPROVE OR DEVELOP EXPOSURE MODELS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
A6B. Individuals' air exposures estimated from dispersion models are/are not different from the measured air exposures.	Compute difference of measured and estimated exposures for each individual. Estimate mean (median) of differences and test whether zero. Also correlate measured and estimated exposures across individuals.	AP: Selected individuals in selected urban areas.	EPA
A6E. Questionnaire/activity data (perhaps along with environmental media measurements) can/cannot be used to predict individuals' exposures.	Develop regression-type prediction models. Correlate predictions with measured exposures and biological markers (where possible). Develop prognostic models from exposure to dose.	Relate AP to AI, AO, times and activities.	RTI/RAND/EOHSI

TABLE 28. HYPOTHESIS V1: VOCs - TEST FOR ADEQUACY OF INITIAL EXPOSURE ASSESSMENTS (EAs)

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
V1A. Exposure or concentration distribution from initial EA is/is not comparable to Pilot Study results.	<p>Treat mean of weekly exposure or concentration from EA as constant <math>m</math>. Test estimated population mean from Pilot Study vs. <math>m</math>. Use day or week as standarized time unit.</p> <p>Treat 90th percentile from EA as a constant <math>g</math>. From Pilot Study, estimate proportion of pop. with exposure or concentration <math>&lt; g</math>, and compare to expected 0.9. Time units must be compatible from Pilot Study and EA.</p>	Benzene: WF, AP	RTI/TSG/ EOHSI
V1B. Exposure or concentration data from the Pilot Study can/cannot be used to improve EA results.	Rerun EA models using Pilot Study data. Compare estimated means and percentiles to prior estimates.	Benzene, by pathway	HSPH

TABLE 29. HYPOTHESIS V2: VOCs - TEST FOR SUBPOPULATION DIFFERENCES

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
V2B. Exposures for certain segments of the population are/are not different than those of the general population.	Define domain. Estimate mean exposure for the domain and its complement. Test for equality.  Estimate given percentile $f$ (e.g., median, 90th) of overall population exposure distribution. Estimate proportion of domain with exposures exceeding $f$ . Do same for complement and compare proportions.	AP  Segments defined by SES, race, location (rural/urban and Great Lakes area/other), age, working status, smoking status,....	RTI/EOHSI
V2C. Biological marker measurements for certain segments of the population are/are not different than those for the general population.	Like V2B	B  Segments as in V2B.	RTI/EOHSI
V2D. Environmental media concentrations for certain segments of the population are/are not different than those for the general population.	Like V2B	WF, AI, AO  Segments defined by SES, race (head of HH), location, smoking in home,....	RTI

TABLE 30. HYPOTHESIS V3: VOCs - TEST FOR EFFECTS OF SOURCES

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
V3A. Exposures for segments of the population having certain sources are/are not different from those of the general population.	<p>Define domain in terms of persons or homes having/not having source. Estimate mean exposure for the domain and its complement. Test for equality.</p> <p>Estimate given percentile f (e.g., median, 90th) of overall population exposure distribution. Estimate proportion of domain with exposures exceeding f. Do same for complement and compare proportions.</p>	AP: Potential sources include tobacco smoke, petroleum products, gasoline engines, paint use/storage,....	RTI/EOHSI
V3B. Environmental media concentrations for segments of the population having certain sources are/are not different from those of the general population.	Like V3A	AI, AO: Potential sources as in V3A.	RTI
V3C. Personal exposure measurements do/do not correlate with measures of source intensity.	<p>Calculate Spearman correlations.</p> <p>Calculate Pearson correlations for original and log-transformed data.</p> <p>Form categories of responses for intensity measures and treat as in V3A.</p>	AP vs. no. cigarettes smoked by self/others, freq./duration of commuting, freq. of pumping gas, freq. of showers,....	RTI
V3D. Environmental media concentration measurements do/do not correlate with measures of source intensity.	Like V3C	AI - like V3C	RTI

TABLE 31. HYPOTHESIS V4: VOCs - TEST FOR ASSOCIATIONS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
V4A. Personal exposure measurements do/do not correlate with biological markers.	Calculate Spearman correlations. Calculate Pearson correlations for original and log-transformed data. (Compare weighted & unweighted correlations.)	AP and WF vs. B	RTI/EOHSI
V4B. Personal exposure measurements do/do not correlate with environmental media concentration measurements.	Like V4A	AI and AO vs. AP	RTI/EOHSI
V4C. Alternative media measurements are/are not correlated.	Like V4A	AI vs. AO and WF	RTI

TABLE 32. HYPOTHESIS V5: VOCs - APPORTION EXPOSURES AMONG PATHWAYS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
V5A. All measured pathways contribute equally/unequally to exposures.	Convert concentrations to average mass/day. Estimate population means and percentiles of these measures, and compare corresponding estimates across pathways.	AP vs. WF	EOHSI/RTI
V5B. Pathway contributions are/are not independent.	Calculate inter-pathway correlations (Spearman, and Pearson [original and log-transformed])	AP vs. WF	RTI

TABLE 33. HYPOTHESIS V6: VOCs - IMPROVE OR DEVELOP EXPOSURE MODELS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
V6B. Individuals' air exposures estimated from dispersion models are/are not different from the measured air exposures.	Compute difference of measured and estimated exposures for each individual. Estimate mean (median) of differences and test whether zero. Also correlate measured and estimated exposures across individuals.	Only for selected individuals in selected urban areas.	EOHSI/EPA
V6C. Distributions of long-term measurements can/cannot be estimated directly from short-term measurements (i.e., using only physical measurements).	Adapt Duan-Wallace method to extrapolate to annual exposures (pre-test lognormality assumption; perform estimation by domain if necessary).  Estimate autocorrelation functions of exposure measurements (concentration measurements) by grouping observations by months; perform seasonal adjustments.	AP, AI, AO, WF (i.e., those measures with longitudinal data).	RTI/RAND
V6D. Personal exposures can/cannot be estimated by applying dose reconstruction models to biological marker data.	Use pharmacokinetic models to estimate exposures. Correlate results with measured exposures.	B	EOHSI
V6E. Questionnaire/activity data (perhaps along with environmental media measurements) can/cannot be used to predict individuals' exposures.	Develop regression-type prediction models. Correlate predictions with measured exposures and biological markers (where possible).	Relate AP to AI, AO, times and activities.	RAND/RTI/EOHSI

TABLE 34. HYPOTHESIS P3: PESTICIDES AND PAHs - TEST FOR EFFECTS OF SOURCES

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
P3C. Personal exposure measurements do/do not correlate with measures of source intensity.	Calculate Spearman correlations. Calculate Pearson correlations for original and log-transformed data. Form categories of responses for intensity measures and treat as in P3A.	Pest.: AP, KW, KR vs. freq. of pesticide use; F vs. freq. of indoor pest. use,... PAHs: AP vs. wood combustion freq., cooking freq.; F vs. grilling freq.	RTI
P3D. Environmental media concentration measurements do/do not correlate with measures of source intensity.	Like P3C	AI vs. D and S; AO vs. S Pest.: Usuage freq. vs. D PAHs: Wood combustion freq. vs. D	RTI

TABLE 35. HYPOTHESIS P4: PESTICIDES AND PAHs - TEST FOR ASSOCIATIONS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
P4A. Personal exposure measurements do/do not correlate with biological markers.	Calculate Spearman correlations. Calculate Pearson correlations for original and log-transformed data. (Compare weighted & unweighted correlations.)	AP, KW, KR and F vs. B and U	RTI/EOHSI
P4B. Personal exposure measurements do/do not correlate with environmental media concentration measurements.	Like P4A	AI, AO, D and S vs. AP D and WF vs. F D vs. KW, KR	RTI
P4C. Alternative media measurements are/are not correlated.	Like P4A	AI vs. AO, D, and S AO vs. D and S D vs. S KW vs. KR	RTI

TABLE 36. HYPOTHESIS P5: PESTICIDES AND PAHs - APPORTION EXPOSURES AMONG PATHWAYS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
P5B. Pathway contributions are/are not independent.	Calculate inter-pathway correlations (Spearman, and Pearson [original and log-transformed])	AP vs. F, WF, and S F vs. WF and S KW and KR vs. WF and AP	RTI/EOHSI

TABLE 37. HYPOTHESIS P6: PESTICIDES AND PAHs - IMPROVE OR DEVELOP EXPOSURE MODELS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
P6A. Individuals' food exposures estimated by combining consumption data with concentration data from the Total Diet Study are/are not different from the measured food exposures.	Compute difference of measured and estimated exposures for each individual. Estimate mean (median) of differences and test whether zero. Also correlate measured and estimated exposures across individuals.	Pesticides only - Selected individuals having high quality food diary data, and diverse types of food items in their diet.	RTI
P6D. Personal exposures can/cannot be estimated by applying dose reconstruction models to biological marker data.	Use pharmacokinetic models to estimate exposures. Correlate results with measured exposures.	B,U vs. AP, F, KW/KR	EOHSI
P6E. Questionnaire/activity data (perhaps along with environmental media measurements) can/cannot be used to predict individuals' exposures.	Develop regression-type prediction models. Correlate predictions with measured exposures and biological markers (where possible).	Relate AP to AI, AO, times and activities.  Relate F to WF, types of food consumed, ....  Relate KW/KR to dermal activity questions, classify "high risk" activities vs. skin loading (dust) and concentrations	RAND/RTI/ EOHSI
P6F. Modeling of indirect dermal exposure measurements can/cannot be used to predict actual dermal exposures.	Develop exposure estimates by modeling of indirect measurements. Compare to direct measurements.	Relate estimates (functions of D measures and activity data) to KW and KR	EOHSI

TABLE 38. HYPOTHESIS 7: IMPROVE DESIGN OF LATER PHASES OF NHEXAS

HYPOTHESIS TYPE	METHOD FOR ESTIMATION/TESTING	SCOPE OF APPLICATION	RESPONSIBILITY
7A. Response rates are/are not sufficient to use the Pilot Study methodology in Phase II.	Compute response rates for each stage of participation both overall and for domains anticipated to have different response rates. Compare response rates for analysis domains (e.g., white vs. non-white)	Response rates computed for participation in Descriptive Questionnaire, Baseline Questionnaire, and monitoring groups (core, blood, urine, core-plus, and food monitoring groups)	RTI
7B. Respondents are/are not a biased subset of the sample subjects.	Estimate and compare the distributions of characteristics known for both responding (R) and nonresponding (NR) sample members (e.g., racial distributions) for each stage of participation.	Use "key" Descriptive data to compare Descriptive R and NR persons; use Descriptive data to compare Baseline R and NR persons; use both types of data to compare R and NR persons for monitoring groups.	RTI
7C. Variance- and cost-component estimates from the Pilot Study are/are not useful for optimizing Phase II designs.	Estimate costs per unit by stage of sampling (county, segment, person) based on the Pilot Study. Estimate variance components by stages of sampling (via analyses of variance) for key population estimates expected to drive the Phase II design. Derive intra-cluster correlations (ratios of variance components) and allocations to stages of sampling that achieve specified precision constraints on these estimates at minimum cost.	Toxicants selected based on Phase II objectives plus levels of occurrence and monitoring-phase response rates in Pilot Study. Major pathways determined from descriptive analyses.	RTI

**TABLE 39. OVERVIEW OF SAMPLING METHODS**

Sample Matrix/Analyte	Type	Sampling Method	Reference (Protocol/SOP)
Air /Metals and mass	I,O,P	144 h integrated sample; Personal sampler operated 2L/min with interval timer; IOM inlet with filter, (subset, PM <sub>10</sub> )	AP-209-010 AP-209-011
Air /VOCs	I,O,P, Occ.	144 h integrated sample; 3M 3500 passive charcoal badge	AP-209-012
Standing Tap Water/- Metals	I	One collection from kitchen tap; Collected in polyethylene containers	AP-209-001
Flush/Drinking Water/Metals, VOCs	I	Collected from kitchen tap or primary drinking water source; Polyethylene and glass containers	AP-209-002 AP-209-003
Food and Beverages/ Metals	P	Duplicate diet collected for 4 one-day periods; Polyethylene containers.	AP-209-030
Dust wipe/Metals (LWW)	I	Lioy-Wainman-Weisel (LWW) wipe samples; Collected from a windowsill and in primary living area	AP-209-020
Dust wipe/Metals (WWT)	I	Wet Wipe Towel (WWT) method; Collected from a windowsill and in primary living area	AP-209-020
Dust deposition/Metals	I	Two types: tared plate and tared carpet section exposed for time period.	AP-209-020
Soil/Metals	O	Composite sample; sweepings from surface in front and read high-traffic areas.	AP-209-021
Blood/Metals, VOCs	P	Venous blood collected in Vacutainers provided by CDC	AP-209-040
Urine/Metals	P	Two samples during the one week monitoring period.	AP-209-040
Hair/Metals	P	Scalp hair collected with thinning shears from occipital location.	AP-209-046

I = Indoor, O = Outdoor, P = Personal, Occ. = Occupational

TABLE 40. OVERVIEW OF SAMPLE PROCESSING AND SHIPMENT

Sample Matrix/ Analyte	Type	Processing/Shipment	Reference (Protocol)
Air /Metals, mass	I,O,P	Filters shipped to RTI at ambient temperature	AP-209-010
Air /VOCs	I,O,P, Occ.	Refrigerated in field, filters shipped to RTI at ambient temperature	AP-209-012
Standing Tap Water/- Metals	I	Refrigerated and shipped cold to lab designated by EPA within 7 days.	AP-209-001
Drinking Water /Metals, VOCs	I	Metals: collected in polyethylene bottles; VOCs: 40 mL vials with acid preservative and chlorine quencher (ascorbic acid). Refrigerated in the field and shipped cold to lab designated by EPA within 7 days.	AP-209-002 AP-209-003
Food and Beverages/ Metals	P	Refrigerated, shipped cold to FDA within 6 days	AP-209-030
Dust wipe/Metals (LWW)	I	Refrigerated, shipped cold to EOHSI	AP-209-020
Dust wipe/Metal (WWT)	I	Refrigerated, shipped cold to EOHSI	AP-209-020
Dust Deposition/Metals	I	Shipped to RTI; RTI ships to EOHSI	AP-209-020
Soil/Metals	O	Refrigerated, shipped cold to EOHSI	AP-209-021
Blood/Metals, VOCs	P	Refrigerated, shipped cold to CDC within 5 days	AP-209-040
Urine/Metals	P	Participants will store in freezer or cooler; shipped frozen to CDC	AP-209-040
Hair/Metals	P	Shipped to RTI	AP-209-046
Survey Documents		Shipped to RTI	AP-209-302

I = Indoor, O = Outdoor, P = Personal, Occ. = Occupational

**TABLE 41. SUMMARY OF LABORATORY METHODS**  
**-METALS-**

Storage	Preparation:	Analysis:	Reference
<b>METALS IN AIR SAMPLES</b>			
23 °C; up to 3 months	Sample filter extracted with acid	Hydride Method Atomic Fluorescence Spectrophotometry (HAF) for As, GFAA for Pb; (XRF)-other metals	AP-209-111 SOP-171-005 SOP-171-006
<b>METALS IN DUST AND SOIL SAMPLES</b>			
23 °C; up to 3 months	Housedust dispersed in HCl by sonication for Pb and HNO <sub>3</sub> for As; digestion with microwave and cool; centrifuge, decant, analyze supernatant	HAF for As and ICP/MS for Pb	AP-209-120 (Pb); AP-209-121, -122, -123 (As)
<b>METALS IN WATER SAMPLES</b>			
4 °C; up to 3 months	HNO <sub>3</sub> digestion; Closed vessel microwave heating used during acid digestion; For As: hydride generation (AsH <sub>3</sub> ) prior to GFAA.	GFAA	EPA Method 200.8 (Pb); not identified for As
<b>METALS IN FOOD SAMPLES</b>			
4 °C; frozen after homogenization	Pb: samples dry ashed. As: samples digested with nitric, perchloric, and sulfuric acids (4:1:1). For As: hydride generation (AsH <sub>3</sub> ) prior to GFAA	GFAA for Pb, HGFAA for As	FDA Total Diet Study Compendium
<b>METALS IN BIOLOGICAL SAMPLES</b>			
blood and urine at 4° or -20 °C.  hair at 4°C, archival	digested in HNO <sub>3</sub> ; digest evaporated. For As: hydride generation(AsH <sub>3</sub> ) prior to analysis	GFAA, HGFAA	CDC Compendium

**TABLE 42. SUMMARY OF LABORATORY METHODS**  
**-VOCs-**

Storage	Preparation:	Analysis:	Reference
<b>VOCs IN PERSONAL AND AIR SAMPLES</b>			
-20 °C up to 3 months	Sample extracted with 1.5 mL of solvent. Extract analyzed directly.	GC/MS in the selected ion monitoring mode	AP-209-112
<b>VOCs IN WATER SAMPLES</b>			
4 °C; 2 weeks maximum	Purge and trap of 5 mL sample	Capillary GC/MS	EPA Method 524.2
<b>VOCs IN BLOOD</b>			
4 °C; 2 weeks	Whole blood sample (10 mL) diluted with water; purge and trap of diluted sample at 30°C	GC/high resolution MS in the selected ion monitoring mode; isotope dilution used for quantitation	CDC Compendium

**TABLE 43. EXAMPLE VISIT SCHEDULE FOR NINE PARTICIPANTS IN A COUNTY**

Participant	Project Staff Set-Up	Sample Collection <sup>a,b</sup>										Ship Samples	Day Off	Travel
		Day: 1	2	3	4	5	6	7	8	9	10			
1		V <sup>c</sup>			V			V						
2		V			V			V						
3		V			V			V						
4			V			V			V					
5			V			V			V					
6			V			V			V					
7				V			V			V				
8				V			V			V				
9				V			V			V				

a Monitoring for each participant and home will be conducted over a period of approximately 144 hours.

b For participants with dietary collection - an additional short visit will be needed to pick up dietary samples.

c V - designates a visit by the project staff to the participant home.

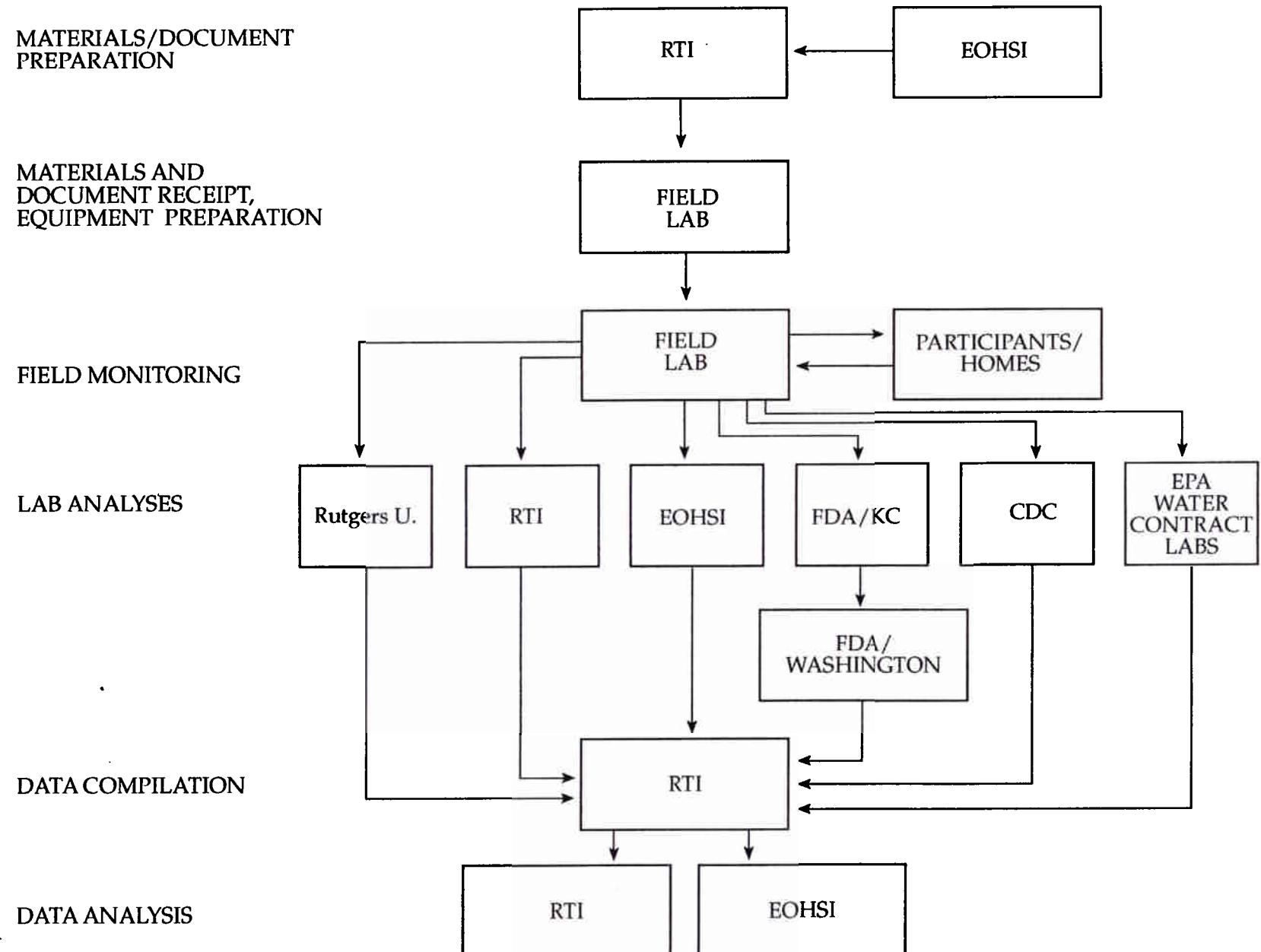


Exhibit A. Overall Sampling and Analysis Logistical Flow.

## SECTION 4 RECORDS USAGE AND MANAGEMENT

### 4.1 DATA RECORDS

A data record is a collection of information associated with a sample or group of samples and may include narrative or descriptive qualifying information. Such qualifiers subjectively identify events which occurred during collection of the sample that which might impact the data and/or which may prove useful in explaining the results of the data evaluation. Each data record, or observation, will be an assemblage of information (questionnaire and/or analytical results) linked together by various data "keys". The participant identification number on the questionnaires and the sample identification numbers associated with each sample will serve as two such keys. These keys will be used to associate data records from one source (e.g., the Time/Activity Diary) with another (e.g., results from VOC analysis). In order to be merged in this way, record "fragments" must reside on the same hardware platform, and preferably on the same software platform, as well. During data analysis, the record must contain all information pertinent to that analysis, but does not need to contain all available information for a given study participant. In practice, records will be assembled from individual database components resident on a VAX/VMS platform linked to a DOS/Windows environment by DEC PathWorks (Digital Equipment Corp., Maynard, MA)

The database will contain an "information shell" which is defined as the database residence for all descriptive information (e.g., sample flow rate, collection time, etc.) about the samples. The information shell is comprised of four principle file components: 1) a composite of all sample collection records for each participant, 2) the sample status summary for each participant, 3.) the data evaluation and certification file, and 4) the data dictionary which contains a complete characterization of all database variables. The purpose of the information shell is to contain all supporting information for the analytical data and, further, to serve as the basis for sample tracking and data credibility assessment. Records of specific significant events which occurred during sample collection will also be included in the information shell. Analytical results from a given instrument will be combined with descriptive information (e.g., sample volume) to produce the calculated concentrations pertinent to a particular analysis.

### 4.2 RECORDS MANAGEMENT SYSTEM

The records management system for the NHEXAS study will be a computer-based system and will encompass as many components of the study as feasible with study resources. The hardware and software backbone of this management system will support the following database functions:

- file import and export flexibility and translation;
- data entry verification;
- records access control and auditing processes;
- sample collection, processing, and shipping scheduling;
- records assembly, merging, and updating;

- database version control;
- mathematical and logical calculations;
- database documentation.

In this regard, Paradox (Borland International, Inc., Scotts Valley, CA) commercial relational database software will be used for data management on the NHEXAS study. A detailed description of this software is contained in the Data Management Protocol, however, all aspects of the data management design are subject to evaluation during the dress rehearsals. This is especially true for the data originating from the federal laboratories.

Given the number of analytical laboratories and the large number and types of samples to be collected, sample custody is an extremely important issue to the NHEXAS study. In this regard, the information shell will contain an inventory of all samples to be collected from a given study participant (i.e. the Sample Status Summary) and also, where available, the current status of all samples in the collection and analysis scheme, based on the samples scheduled for collection. For a given study participant, the information shell will initiate from the pre-collection data gathered from the participant by the interviewer. From this base, an accounting of samples can be made at each point in the movement of samples and data through the analytical processes.

#### **4.3 RECORDS VALIDATION**

Records validation begins with assurance that the NHEXAS database(s) contains results for each sample that was scheduled to be collected (initial completeness check). Since numerous analytical laboratories are involved in sample processing, sample/results custody outside of RTI will be at the pleasure of the participating labs or the U.S. EPA. However, it is extremely important that some information be incorporated into each of the database fields to avoid erroneous results from subsequent statistical analyses. In this regard, a principal function of the records management system will be to track sample custody from the collection schedule through the incorporation of results into the database. Within the constraints of the program, sample custody information will be compiled for each sample so that ongoing quality assurance procedures can assess completeness and results integrity of the database.

Since evaluation, augmentation, and modification are expected to be dynamic functions involving numerous individuals throughout the study, access control to the database(s) becomes a critical concern. For this reason, only the NHEXAS Database Manager, the ACS Quality Assurance Officer, and the Principal Investigator will have access to the developing databases. To insure rigorous access control, all NHEXAS files will be maintained under a password-protected status. File access will be enabled exclusively by the NHEXAS Database Manager. Management of multiple versions of each of the database components will be the exclusive responsibility of the Data Manager. The records management system will insure that the most current version of a database contains the accumulated additions and modifications to that module. An audit trail of database access will be implemented by the Database Manager to record all entries and revisions or updates into the databases.

#### **4.4 RECORDS IDENTIFICATION, INDEXING, AND RETENTION**

The participant identification and sample identification codes are the principal record identification tools. Each of these codes contains information which identifies a given study participant or sample. A non-descriptive sample code (e.g., sample code: 2863952) will be employed. Descriptive information is contained within each sample collection record to enable accurate and unique identification of the sample. Merging of records across datasets will be accomplished using either the sample code or the sample descriptors as "keys".

All raw data and dated copies of intermediate datasets will be retained for the duration of the study and can only be made available to the contributing laboratory with the approval of the Principal Investigator. These raw and intermediate files will be processed, and copies will be maintained, on a "batch" basis where each batch corresponds to a certain time period, or number of records or households/counties.

#### **4.5 RECORDS DISTRIBUTION AND STORAGE**

Contributions to the NHEXAS database will be submitted from numerous sources and probably in a diversity of file formats. Raw data will be transferred from the field site to the RTI-based host VAX computer either via modem or will be copied onto a floppy disk and physically transmitted to the NHEXAS database manager. All incoming results will reside in the custody of the NHEXAS database manager on a secured disk volume used exclusively for receipt and compilation of the study data on the host computer. A complete backup of the entire database will be conducted daily onto magnetic tape. A minimum of five successive daily backups will be maintained at all times. Raw data and tape backups are stored in different physical locations for protection against unauthorized access and accidental and malicious loss. At no time will only a single copy of the data exist.

Data will be stored in "modules" to permit allocation of selected records and/or fields for processing and evaluation by a contributing laboratory. These modules will be comprised of records from a particular sample type (e.g. VOCs) and record type (e.g. calibration data). Access to portions of the database will be controlled by the Database Manager and will maintain a log of individuals who enter the database, the database components that were allocated and the dates and times of the access. A Data Management Document will be prepared (Appendix A--RTI/ACS-AP-209-400).

## SECTION 5 QUALITY ASSURANCE GOALS

Data Quality Indicators are discussed for the population-based sample design in Section 2.2. Quality Assurance goals for survey data collection sample collection and sample analysis are included in this section. RTI will be responsible for collection of all personal, biological, and environmental samples for the RTI-EOHSI consortium, but analysis will be performed by several laboratories. Quality Assurance goals are based on previous experience with these analyte/matrix combinations. This experience is limited for some media and types of samples. One purpose of a Phase I study is to evaluate quality assurance results for each method to help determine usability and applicability of the method and to provide information for setting quality assurance goals in later phases of the study.

The quantification limit was one of several factors in the selection of analytical methods for measuring each chemical in various media. For example, it is important that the analytical method used for As in drinking water will have adequate sensitivity for the anticipated chemical levels in each medium. As indicated in Table 45, the quantification limits for the methods selected will have adequate sensitivity to obtain measurable values based upon the "typical" prevalence data reported in the literature. (The one exception is for As, since the method has not yet been specifically chosen and only the necessary QL is given). Thus, one of the quality assurance goals, the use of sufficiently sensitive methods to obtain measurable values, should be achievable and would permit the relatively accurate and precise determination of means and 90th percentiles.

Quality Assurance goals have not been included for the special study (pesticides and PAHs) which is scheduled to be conducted at the end of the field monitoring of the main study on metals and VOCs. This information will be appended to the QSIP.

### 5.1 COMPLETENESS

Response rate goals are summarized in Table 3, with 90% of the occupied housing units completing the descriptive questionnaire, 80% of the selected participants completing the baseline questionnaire, and 67% of the selected participants completing the monitoring. A high rate of completeness of the descriptive and baseline questionnaires is important for estimating potential non-response bias. As detailed in Section 2.2.1, estimated percent relative standard error tables have been developed to show the effects of sample sizes on the precision of population estimators. A cross reference for these tables is shown in Table 44 of this section. Thus, completeness of participating can affect the precision of population estimations while the response rate for participation in monitoring can affect potential bias in the estimations.

Completeness goals, *per se*, will not be developed for the other survey instruments, sample collection, or laboratory analysis. Survey data may be lost because of incomplete enumeration of the sample, inability to contact a prospective subject or surrogate (for the descriptive questionnaire), non-response, refusals, and failure to complete all instruments or questions. Information regarding the reasons for any incomplete samples will be recorded and tracked to permit evaluation of potential bias due to self-selection by subjects relative to other causes.

Samples may be lost due to the inability to collect the sample in the field, breakage, and loss. Similarly, in the laboratory, sample losses may occur due to breakage during storage or handling, and invalid analytical results.

## 5.2 ACCURACY AND PRECISION

The Quality Assurance goals for accuracy (bias) and precision are based on the expected performance of the methods. The major consideration is that these goals be consistent with the assumption that measurement errors will be small. Method performance will be monitored during pre-study activities. Some accuracy and precision goals may be revised based on information from Federal Labs or from testing but the overall goal of keeping measurement error small will be maintained.

Accuracy and precision evaluations of the survey instruments will not be performed in this Phase I study. Accuracy evaluations or external validation, require performance of objective measurements or the availability of a "standard" or "reference" survey method for comparison. Reference methods are generally not available for the survey instruments proposed for this study, and the cost and burden of objective measurements are precluded by the sample collection and monitoring components of the study. Precision of data collected with survey instruments is often evaluated by re-administration of the instrument at another time. The temporal nature of many questions on the questionnaire will prevent useful precision estimation using readministration. Readministration is not applicable to the time/activity or food diaries.

Table 45 indicates the precision and accuracy goals for sample collection and analyses. These goals, for the most part, are based on prior performance of the method. In some cases the objectives represent expected performance, based on limited experimental data. Revision of these goals may be recommended for future phases of NHEXAS based on evaluation of the data collected during this study.

The accuracy parameter can be expressed as % bias from known values. During this study, analytical bias will be evaluated by analysis of performance evaluation or reference materials provided by NIST. Since these materials probably will not be available for all sample type and analyte combinations, accuracy will be evaluated on a routine basis as percent recovery from spiked (fortified) samples. The percent recovery values reflect analyte losses during processing and analysis.

The precision measure is expressed as the percent relative standard deviation (%RSD) between replicate field samples. The %RSDs reflect the overall variability of sampling, shipping, storage, handling and analysis. Replicate samples will not be collected for food or personal aerosol samples. Sample preparations will be analyzed in duplicate for these sample types, where possible, to obtain an estimate of analytical precision. For dust and soil collection methods, the precision measured for replicate field samples may include a variability component for non-homogeneity in the original matrix.

Bias may result in dietary intake measurements due to changes in the participant's dietary intake, dietary pattern, or as a result of incomplete food collection. The most widely reported change in dietary behavior during duplicate diet studies is a decrease in caloric

intake of 5 to 25%. Participants in this study also will not be required to prepare duplicate portions by the weighing method because of the high burden and likelihood that up to a third of their meals will be consumed outside the home (usually with preparation by other people). Since people will prepare their duplicate portions using simple visual estimates, there may be a systematic bias in the amount of food that is collected. In order to assess the potential bias in the amount of ingested and collected food, we plan to have the dietary samples from approximately 50 participants analyzed for caloric content. We will compare their measured caloric intake to values calculated using NRC guidelines for usual intake that are adjusted for sex, age, weight, and activity level. We will also ask each participant whether there were foods they did not or could not collect (with addition of a portion to the sample if possible), and whether there were changes from usual intake in the amount or type of foods during the collection period.

### **5.3 REPRESENTATIVENESS**

There were several criteria for the selection of the geographical area to be studied in the RTI/EOHSI NHEXAS investigation (Phase I Phase I study). One criterion was that the area selected would result in a realistic field test of procedures being developed for the national study. Another criterion was that the statistical inferences for the study toxicants would be of independent scientific interest for the target population selected for the Phase I Phase I study.

A discussion of the geographical area, contaminants selected for study and the environmental media and pathways was provided in Section 1.2. Other issues concerning representativeness are discussed in Sections 2.1 and 2.2.

### **5.4 COMPARABILITY**

Comparability issues are being addressed in the planning process by EPA. These include, but are not limited to:

- Data comparability within each consortium,
- Data comparability among the consortia,
- Comparability of sample collection methods,
- Comparability of survey instruments (the same survey instruments will be used by all three consortia).

Some of the issues will be addressed through analysis of reference materials, and possibly analysis round-robin testing and collocated field monitoring. At this time, however, fiscal resources are not available and technical plans are not complete.

The data collected in this study will be according to the prescribed protocols and SOPs. Thus, the data collected at the beginning of the program will be comparable or contiguous in quality to that data collected in the middle and the end of the program.

## 5.5 METHOD QUANTIFICATION LIMITS

Specific procedures for setting and/or measuring method quantitation limits (MQLs) in the RTI/EOHSI laboratories have not been determined as of this QSIP revision. MQLs will be determined or specified separately for each type of analysis that is performed. In general, two approaches will be followed. In some cases the MQL will be defined as the lowest calibration level. In these cases the lowest calibration level will be set at or below the QLs defined in Table 45. In other cases it may be necessary to experimentally determine the MQL by analysis of sample matrix or sample extracts fortified at levels near the instrumental detection limit. At least seven replicates would be analyzed, with MQLs calculated from the standard deviation multiplied by the one-tailed t value for the appropriate degrees of freedom.

TABLE 44. CROSS-REFERENCES FOR SAMPLE SIZE EFFECTS

Analyte	Media	Table Number
Metals	Aerosols, Water, Food, Dust/Soil, Urine, Blood	10
VOCs	Air, Water, Blood	11
Particle Mass	Air, Dust/Soil	12

TABLE 45. QUALITY ASSURANCE GOALS FOR SAMPLE COLLECTION AND ANALYSIS

Matrix	Type/Location	Analysis Lab	Precision RSD	Bias	QL <sup>d</sup>	Reported Occurrence <sup>a</sup>
Air	Metals(Indoor)	RTI	<10%	<20%	<1 ng/m <sup>3</sup> (As) 10 ng/m <sup>3</sup> (Pb)	QL-80 ng/m <sup>3</sup> (<10) QL-50 ng/m <sup>3</sup> (20)
	Metals (Outdoor)	RTI				
	Metals (Personal) <sup>b</sup>	RTI				
Air	VOCs (Indoor)	RTI	<25%	<25%	1.0 µg/m <sup>3</sup> (Benzene)	1-44 µg/m <sup>3</sup> (8)
	VOCs (Outdoor)	RTI				
	VOCs (Personal)	RTI				
Air	Particles	RTI	<25%	<25%	-25 µg/m <sup>3</sup>	35-180 µg/m <sup>3</sup> (90)
Water	Metals	EPA-Ci	<10%	<15%	0.2 µg/L (As) 1 µg/L (Pb)	QL-80 µg/L (<5) QL-100 µg/L (4)
	VOCs	EPA-Ci	<25%	<25%	0.05 µg/L (Benzene)	?
Dust/ Soils	Metals	EOHSI	<20%	<20%	1 µg/g (As) 1 µg/g (Pb)	0.2-40 µg/g 18-16,000 µg/g (100)
Food <sup>b</sup>	Metals (Food & Beverage)	FDA	<20%	<20%	5 ng/g (As) 5 ng/g (Pb)	QL-100 ng/g (50) QL-20 ng/g (10)
Blood	Metals	CDC	<10%	<30%	6 µg (As) 10 µg/L (Pb)	- <sup>c</sup> 2-20 µg/dL
	VOCs	CDC	<25%	<25%	0.03 ng/mL (Benzene)	0.03-0.6 ng/mL (0.14)
Urine	Metals	CDC	<10%	<30%	6 µg/L (As) 2 µg/L (Pb)	QL-100 µg/L (25) QL-45 µg/L (?)
Air	Pesticides (Indoor)	RTI	e	e	e	e
	Pesticides (Outdoor)	RTI				
	Pesticides (Personal)	RTI				
Air	PAHs (Indoor)	RTI	e	e	e	e
	PAHs (Outdoor)	RTI				
	PAHs (Personal)	RTI				
Water Pesticides	EPA-CI	e	e	e	e	e
Dust/Soils Pesticides	RTI	e	e	e	e	e

(continued)

TABLE 45. (continued)

Matrix	Type/Location	Analysis Lab	Precision			QL <sup>d</sup>	Reported Occurrence <sup>a</sup>
			RSD	Bias	e		
Dust/Soils PAHs	RTI	e	e	e	e	e	e
Dermal Wipes Pesticides	RTI	e	e	e	e	e	e
Dermal Wipes PAHs	RTI	e	e	e	e	e	e
Dermal Wipes PAHs	RTI	e	e	e	e	e	e
Food Pesticides	RTI/Rutgers	e	e	e	e	e	e
Food PAHs	RTI/Rutgers	e	e	e	e	e	e
Blood Pesticides	CDC	e	e	e	e	e	e
Blood PAHs	CDC	e	e	e	e	e	e
Urine Pesticides	CDC	e	e	e	e	e	e
Urine PAHs	CDC	e	e	e	e	e	e

<sup>a</sup> Reported values are "typical" ranges found in monitoring studies performed throughout the U.S. Values in parentheses are typical averages or means.

<sup>b</sup> Replicate samples will not be collected; precision estimates will be based upon replicate analysis.

<sup>c</sup> Blood Arsenic is not considered by CDC to be a good indicator of exposure.

<sup>d</sup> QL = quantifiable limit (similar to method detection limit).

<sup>e</sup> Information will be provided when collection and analysis protocols are compiled; study design for pesticide/PAH module is in progress but will not be completed until about December 1995.

TABLE 46. SUMMARY OF ALL SAMPLE TYPES PROJECTED FOR STUDY<sup>a</sup>

	Samples (Field)						Proposed QC Samples (Laboratories) <sup>b</sup>					QA <sup>c</sup>			
	SA	DUP	FB	FC	CB	QS	Subtotal	RAA	REA	MS	MB	MC	PE	Subtotal	Total
<b>AIR</b>															
VOCs	1482	35	35	35	0	0	1587	0	35	0	35	35	35	140	1727
Metals (IOM)	578	35	35	0	0	0	648	0	35	0	35	35	35	140	788
Metals (PM <sub>10</sub> )	70	14	35	0	0	0	119	0	5	0	5	5	0	15	134
<b>WATER</b>															
Metals															
Pb,Cr,Cd	1190	35	35	35	0	0	1298	0	0	35	35	35	35	140	1438
As	605	35	35	35	0	0	713	0	0	35	35	35	35	140	853
VOCs	300	35	35	35	300	300	705	0	0	35	35	35	35	140	845
<b>DUST</b>															
LWW															
Pb,Cr,Cd	478	35	35	0	0		548	0	35	0	35	35	35	140	688
As	478	35	35	0	0		548	0	35	0	35	35	35	140	688
WWT															
Pb,Cr,Cd	120	7	7	0	0		134	0	7	0	7	7	0	21	155
As	120	7	7	0	0		134	0	7	0	7	7	0	21	155
Plate															
Pb,Cr,Cd	285	10	10	0	0		305	0	14	0	14	14	14	56	365
As	285	10	10	0	0		305	0	14	0	14	14	14	56	365
Carpet															
Pb,Cr,Cd	285	10	10	0	0		305	0	14	0	14	14	14	56	365
As	285	10	10	0	0		305	0	14	0	14	14	14	56	365

continued

TABLE 46. (continued)

	Samples (Field)						Proposed QC Samples (Labs) <sup>b</sup>					QA <sup>c</sup>			
	SA	DUP	FB	FC	CB	QS	Subtotal	RAA	REA	MS	MB	MC	PE	Subtotal	Total
<b>SOIL</b>															
Primary Entrance															
Pb,Cr,Cd	50	0	0	0	5		55	5	5	0	5	5	5	25	80
As	50	0	0	0	5		55	5	5	0	5	5	5	25	80
Primary Activity Area															
Pb, Cr, Cd	50	0	0	0	5		55	5	5	0	5	5	5	25	80
As	50	0	0	0	5		55	5	5	0	5	5	5	25	80
<b>FOOD</b>															
Food 4-Day Comp.	259	0	10	0	0		269	10	10	10	12	12	12	66	335
Bev. 4-Day Comp.	259	0	10	0	0		269	10	10	10	12	12	12	66	335
Food 1-Day Comp. <sup>d</sup>	48	0	0	0	0		48	0	0	0	0	0	0	0	48
Bev. 1-Day Comp. <sup>d</sup>	48	0	0	0	0		48	0	0	0	0	0	0	0	48
<b>BLOOD</b>															
Metals	280	10	35	10	0		335	0	10	0	0	35	35	80	415
VOCs	280	10	35	10	0		335	0	0	0	0	70	70	140	475
Archive	280	10	0	0	10		300	0	0	0	0	0	0	0	300
<b>URINE</b>															
Metals	1092	35	35	10	35		1207	0	35	0	0	60	60	155	1362
<b>HAIR</b>															
Metals	550	0	0	0	35		560	0	0	0	0	0	0	0	560

continued

TABLE 46. (continued)

## FOOTNOTES:

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**\*Sample Types:**

SA = Samples  
DUP = Duplicate Samples  
FB = Field Blank Samples  
FC = Field Control Samples  
CB = Container Blank Samples  
QS = Duplicate Sample for QC/QA

RAA = Replicate Aliquot Analysis  
REA = Replicate Analysis of Aliquot  
MS = Matrix Spike Sample  
MB = Method Blank Sample  
MC = Method Control Sample

<sup>b</sup>These are proposed laboratory QC samples and analyses; the actual numbers at the Federal laboratories will depend on their analysis schemes and QA/QC requirements.

<sup>c</sup>QA Samples = Performance Evaluation (PE) Samples to be supplied by NIST.

<sup>d</sup>From 12 participants, each of the 4 daily samples will be analyzed. This does not involve additional sample collection.

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## SECTION 6 QUALITY CONTROL AND PREVENTATIVE MAINTENANCE

### **6.1 QUALITY CONTROL**

The Quality Control program is not complete at this time. The quality control procedures for the field sampling effort have been established, but may be revised, based on evaluation of the pre-study "dress rehearsal". Quality Control for the analytical laboratories, especially the government laboratories, is not yet in place. Allocation of quality control samples (field controls and blanks, replicate samples) is based upon (1) the goal for QC samples to be approximately 5% of field samples, (2) the county as a "batch" for chemical analysis (approximately 35 counties will be sampled).

#### **6.1.1 Quality Control for Sample Selection**

The sampling design for the RTI/EOHSI NHEXAS investigation is a stratified, four-stage probability sampling design. The first stage sample of 35 PSUs and the second stage sample of area segments (SSUs, second-stage sampling units) will be selected using a systematic sample selection procedure developed and extensively tested by RTI that is imbedded as a SAS procedure supported and maintained by RTI. The third stage sample of households and the fourth stage sample of participants will be selected using standard random number generators. All field materials will be reviewed by supervisors before they are sent to the field.

#### **6.1.2 Quality Control for Survey Operations**

Survey Operations field activities are divided into three main categories. These are the count and list, the household screening and the field data collection.

Quality control for the count and list consists of interviewer training and maintaining close contact with the RTI survey staff. In this way the survey staff can monitor progress and correct any problems that occur before beginning in a new county. In addition, statistical clerks will check all completed check and list materials. This review will check for completeness of the listing, following of all rules governing starting points and path taken, determining the correct starting number, and correspondence between maps and the listing.

During the household screening process, several stages of review occur. The interviewer in each country will maintain regular contact with the RTI survey staff. The survey staff will also verify a percentage of the ineligibles.

In the field the completed study documents will be scanned for completeness, legibility and obvious problems. Appointment schedule, correct address and other items will be verified by the field team upon arrival at the participant's home. As questionnaires are returned to RTI, each will be subjected to an additional scan edit as they are being logged in and batched. All documents will be subject to a final complete edit and coding procedure. All data entry will be verified by re-key or percentage re-key procedures.

Additional details are being incorporated into the SOP for NHEXAS systems audits.

### 6.1.3 Quality Control Samples

An overview of the quality control samples planned is shown in Table 46. The sample types include blank samples, (fortified) control samples and replicate samples. These samples are intended to provide a measure of contamination, recovery and precision for the sampling and analysis procedures. All control sample types are not scheduled for all analyte/matrix combinations, however, due to technical and resource limitations. Procedures for the preparation of blanks and controls for use as quality control samples in the field study will be described in "Preparation of Quality Control Samples" (Appendix A - RTI/ACS-AP-209-191).

Other quality control samples, such as method controls and blanks, and replicate analysis of processed samples, are planned to provide quality control information for laboratory procedures. These are shown in Table 46 as well.

#### *Control and Blank Samples*

Control samples will be prepared to evaluate recovery of target analytes through all of the shipping, storage, processing, and analysis procedures. Blank samples will be used to assess contamination (or the potential for contamination) by target analytes through all of the shipping, storage, processing, and analysis procedures.

Sets of (fortified) control samples will be prepared for some sample matrices by adding known amounts of selected compounds to the sample matrix or sampling device. The control samples will be shipped to the collection site, handled, stored, and shipped back to RTI in the same manner as field samples. For some matrices (dust, soil, food, aerosol) it may not be feasible to prepare uniform fortified samples.

Analyte-free matrix blanks will also be prepared (blanks) for most sample matrices. As with the control samples, the blanks will be shipped to the collection site and treated in the same manner as field samples. In cases where analyte-free blanks cannot be prepared (blood archival samples, hair, soil, and perhaps solid foods) container blanks will be utilized.

A summary of the blank and control sample types is shown in Table 47.

#### *Replicate Samples*

Samples of selected matrix types will be collected in duplicate (co-located samples). Analysis of these samples will provide a measure of overall variability in the sampling and analysis methods. In some cases (dust and soil) non-homogeneity in the sample matrix may also be a component in the measurement precision.

The potential added burden to the participant of collecting duplicate blood samples will be minimized by collecting only a small total number of duplicates (Table 46), and

collecting no more than one type of duplicate blood sample from any one person. No additional needle sticks are involved; the duplicate sample will be collected from the same venipuncture as the other three sample tubes.

Samples of selected duplicate pairs or split aliquots of extracts will be sent to an external reference laboratory if other laboratories have the resources to perform the analyses (i.e., NIST and/or other NHEXAS collaborating laboratories).

The number of field QC samples scheduled depends on several factors, including the total number of samples scheduled, the use of batching for organizing sample analysis, and the resources available for collection and analysis. In many cases (air, water, LWW dust, blood metals and VOCs, and urine) the lab QC sample batching will be performed on the basis of sample collection in each county. For each batch of samples returned from one of the 35 scheduled counties, one or two QC samples will be applied for each of the sample types. Under this schedule, one or two QC samples to be applied to each group in terms of shipment to the field, storage in the field, shipment from the field, and storage and processing at the laboratory. This is particularly important for the field blanks, where contamination may be assessed by batch and across the entire study.

In other cases (WWT dust, plate and carpet dust, soil, food, and some types of blood QC samples) there will not be enough samples collected to justify the cost of using field QC samples for the samples associated with each county. For these sample types, field QC samples were scheduled at a rate of about 5 to 7%, with a minimum number of 5 samples or analyses. It must be recognized that the number and types scheduled for analysis at the Federal laboratories are only suggested; the actual types and numbers are not within control of the consortium.

#### **6.1.4 Quality Control for Field Activities**

Quality Control in the field consists of two main activities, (1) quality control for maintaining the integrity of survey instruments and other field documents, and (2) quality control for maintaining the integrity of environmental samples. A summary of QC checks for survey instruments and field documents is shown in Table 48. An example of QC checks for field samples is shown in Table 49.

#### **6.1.5 Laboratory Quality Control**

The Quality Control program for all of the analytical laboratories has been completed. An example of the QC parameters and criteria that have been established is shown in Table 50. Critical measurement parameters for QC are described in the analytical protocols.

##### *Quality Control Samples and Analyses*

Several types of quality control samples and analyses have been proposed for laboratory sample analysis laboratories (Table 46). Replicate aliquot analysis (RAA) requires the analysis of a second portion of a sample homogenate and has been proposed for the soil and food matrices to assess homogenization and analysis precision. Replicate extract analysis (REA) requires reanalysis of a sample extract and has been proposed to assess analytical

precision. Matrix spike (MS) samples require fortification of duplicate samples or from an aliquot of the original sample to assess recovery from actual sample matrices and have been proposed for water and food. Method blanks (MB) are used to assess contamination that occurs as a result of the extracting materials and method, and are prepared by taking the unfortified extraction or digestion liquids through the entire laboratory processing and analysis procedure. Method controls (MC) are used to assess analyte recovery through laboratory processing and analysis, and are prepared by taking fortified extraction or digestion liquids through the entire laboratory processing and analysis procedure. At some laboratories, method controls may be prepared by fortifying clean surrogate sample matrix materials.

Analysis of performance evaluation or reference materials has been proposed for most sample types (Table 46). The number and types of PE samples that are utilized in the Phase I study will ultimately depend on availability from NIST.

The number of laboratory QC and PE samples scheduled depends on several factors, including the total number of samples scheduled, the use of batching for organizing sample analysis, resources available, and quality control procedures followed in specific laboratories. In many cases (air, water, LWW dust, blood metals and VOCs, and urine) the lab QC sample batching will be performed on the basis of sample collection in each county (and the samples returned from longitudinal sampling during the same time period). For each batch of samples returned from one of the 35 scheduled counties (and the longitudinal samples received in the same time period), one or two QC samples or analyses will be applied for each of the sample types. In other cases (WWT dust, plate and carpet dust, soil, and food) there will not be enough samples collected to justify lab QC samples and analyses for the samples associated with each county. For these sample types, lab QC samples and analyses were scheduled at a rate of about 5 to 7%, with a minimum number of 5 samples or analyses. It must be recognized that the number and types scheduled for analysis at the Federal laboratories are only suggested; the actual types and numbers are not within control of the consortium.

## 6.2 PREVENTATIVE MAINTENANCE

A bound notebook will be maintained for recording the performance and calibration data for laboratory analytical instruments (NHX-SOP-120-002). Where applicable, the following information will be recorded:

- Results of performance tests,
- Instrument calibration information,
- Comments concerning the analysis as they are performed,
- Dates on which routine maintenance is performed and a detailed account of what was done,
- Record of all equipment repairs, changes and modifications which affect performance,

- Instrument failure, and
- Description of any problems encountered and steps taken to rectify them.

Records will be maintained in a field laboratory notebook for all calibration and maintenance for field measurement and storage equipment (e.g., sampling pumps) as well. Each piece of equipment will be identified with a unique code, and this code shall be used in all notebook entries. Specific procedures and time intervals will be included in the specific sample collection protocols; these procedures will be collated in two other protocols for ease of reference by the field staff (Appendix A - RTI/ACS-AP-209-081 and RTI/ACS-AP-209-082).

TABLE 47. PREPARATION OF QUALITY CONTROL SAMPLES

Sample Matrix/-Analyte	Sample Type	Sample Description
Air		
Metals	Field Blank	Unexposed filter
VOCs	Field Blank	Unexposed badge
	Field Control	Badge spiked with target analytes
Water		
Metals	Field Blank	Analyte-free reagent water
	Field Control	Analyte-free reagent water spiked with target analytes
VOCs	Field Blank	Analyte-free reagent water
	Field Control	Analyte-free reagent water spiked with target analytes
Dust		
Metals (LWW)	Field Blank	Analyte-free wipes
Metals (WWT)	Field Blank	Analyte-free Wet Wipe Towels
Plate	Field Blank	Unexposed plates
Carpet	Field Blank	Unexposed carpet
Soil		
Metals	Container Blank	Container without sample matrix
Food <sup>a</sup>		
Metals	Field Blank	Analyte-free water
Blood <sup>a</sup>		
Metals	Field Blank	Analyte-free water or known low-analyte sample matrix
	Field Control	Spiked analyte-free water or low-analyte sample matrix
VOCs	Field Blank	Analyte-free water or known low-analyte sample matrix
	Field Control	Spiked analyte-free water or low-analyte sample matrix
Urine <sup>a</sup>		
Metals	Field Blank	Analyte-free water or known low-analyte sample matrix
	Field Control	Spiked analyte-free water or low-analyte sample matrix

(continued)

TABLE 47. (continued)

Sample Matrix/- Analyte	Sample Type	Sample Description
Air	b	b
Pesticides		
PAHs		
Water	b	b
Pesticides		
Dust	b	b
Pesticides		
PAHs		
Soil		
Pesticides	b	b
PAHs		
Dermal Wipes	b	b
Pesticides		
PAHs		
Food	b	b
Pesticides		
PAHs		
Blood	b	b
Pesticides		
PAHs		
Urine	b	b
Pesticides		
PAHs		

a Proposed; Federal lab cooperation and input needed.

b Information will be provided when collection and analysis protocols are compiled; study design for pesticide/PAH module is in progress but will not be completed until about December 1995.

**TABLE 48. QUALITY CONTROL IN THE FIELD**

	Procedure	Responsibility
Survey Instruments	scan-edit for completeness and inconsistencies; cross check	field interviewers and technicians
Sample Collection Data	scan-edit for completeness, out-of-range values <sup>a</sup> ; cross check	field technicians and field supervisor
	file back-up	field technicians
Sample Storage	scheduled check and recording of storage conditions	field technicians
Sample Shipment	scan edit of shipped documents; remote check of documents and completeness	field technicians and field supervisor
Overall Procedures/SOPs	periodic audit of compliance with procedures	field supervisor
Sample Identification and Assignment	verify proper sample and participant ID codes and labels, and in data collection records; use bar code IDs and scanner	field technicians

<sup>a</sup>Electronic range checking may also be utilized.

TABLE 49. QUALITY CONTROL MEASUREMENTS FOR FIELD EQUIPMENT

Measurement	QC Procedure	Requirement
Balance (Food Weight)	Weigh check weight each weighing session.	within 2% for 100 g and 100 g weight
	Inspect balance before each weighing session	Must be clean,
	Re-weigh at least one sample each weighing session.	%RSD $\leq$ 10
Sample Volume (Metals in Air)	Measure flow rate at beginning and end of monitoring.	range at beginning of monitoring = TBD <sup>a</sup>
	If rotameters are used, check calibration vs. bubble flow meter before sampling in each county.	within 5% of calibration
Refrigerators	Daily temperature check during sample storage.	1°C to 6°C
Freezers	Daily temperature check during sample storage.	-20° to -7°C

<sup>a</sup>TBD = to be determined.

**TABLE 50. QUALITY CONTROL FOR ANALYSIS OF VOCs  
IN AIR SAMPLES (EXAMPLE)**

QC Procedure	Requirement
Analyze badges before shipment to field (one per batch/lot)	< 70 ng/mL of each target VOC in the extract
System Suitability	Acceptable chromatography (resolution, tailing factor)
Multipoint calibration	RSD for mean RRF for each target analyte must be $\leq 25\%$
Sensitivity	Lowest calibration standard must be within linear range; signal-to-noise ratio for lowest standard at least 10:1.
Check Standard (before analysis begins, and at intervals); independently-prepared standard	Bias $\leq 25\%$ .
Mid-point calibration check (each 8 h shift)	Calculated RRF must be within 25% of mean calibration RRF. Quantitation ion areas may not decrease more than 25% from most recent calibration check or 50% from initial calibration.
Duplicate analysis of one sample in each batch (~35 samples)	RSD for measureable target analytes $\leq 25\%$ .

## SECTION 7 DATA REDUCTION, VALIDATION, AND REPORTING

### 7.1 FIELD COLLECTION DATA

#### 7.1.1 Data Entry

Specific information about the sample must be recorded during collection. This information includes parameters like start and stop times and dates, flow rates, identification numbers, etc. Collection information items are specific to each kind of sample, and are defined in the collection protocols (Appendix A). Custody information is also recorded during collection, processing, and shipping activities. Wherever feasible, field sample collection and custody data will be entered directly into a Quattro Pro spreadsheet specifically created for this process. Bar-coded labels and scanners will be used for sample, participant, and ID code data entry into the spreadsheet in order to reduce transcription error. Files will be backed-up at the end of each session and the backup disks will be archived in a separate location daily to prevent catastrophic data loss. In a few cases, sample collection information will be recorded on paper forms.

#### 7.1.2 Data Transfer from Field

The field staff will be responsible for transferring sample collection and custody records to the analytical laboratories along with the samples. Custody records will be printed and will include information needed by the analytical laboratory for processing, analysis, or concentration calculation. Any original paper forms will be shipped with the samples after copies have been made. Diskette copies will be made of all electronic files and printed custody records. These copies will be batched by county and shipped to the field supervisor at the completion of sample collection activities in the country.

#### 7.1.3 Data Verification

Field staff will perform scan edits of data entered into the data collection spreadsheet before the termination of each data entry session. This initial review will include range checking and completeness verification. Upon arrival at RTI, all sample collection data will be carefully scrutinized by the Field Supervisor and again by the Database Manager after incorporation into the Information Shell. A field staff member will perform a final scan-edit of the collection and custody data from each home/participant after all collection activities have been completed and before final copies are prepared for transfer to the information shell by the Database Manager. Incorrect or incomplete entries will be modified if possible during scan-edits, otherwise brief explanatory text will be written to the comment field of the affected record(s). The field supervisor will, upon receipt of original or copies of the data, perform scan-edits of 100% of the field collection and custody records (electronic and paper) for completeness, compliance with field protocols (e.g., sample duration, flow rates, siting criteria), and consistency. The field supervisor will initiate corrective action for errors found in the data and will look for and correct systematic problems in data entry or transmission.

Field computers will be equipped with modems to allow real-time, remote examination of collection and custody data for verification, status, and tracking purposes by the supervisory staff.

#### **7.1.4 Validation of Data Collection, Calculation, Transfer**

Validation of the field data collection and transfer mechanism will be performed in two stages. In the first stage, prior to beginning the field study, all software functions will be manually verified, including hand calculation checks for all software calculations. Backup procedures will be checked by 100% comparison of printed output of the original and backup versions. During this initial phase, the test data set that is used for validation will be saved for later tests. At least two master copies of the validated software will be retained in separate locations, under control of the database manager. Multiple working copies of the base software will be sent to the field.

In the second stage, verification of software function will be ongoing through the field study. Field staff will use a backup copy of the software if their original version becomes corrupted. The field supervisor will perform test calculations on a subset of returned data sets. Finally, the test data set developed prior to the study will be periodically entered into the current working version of the software, with the output compared to the output during the original validation. Discrepancies will initiate corrective action in the form of examination and modification of contributing formulae. Modifications to the data collection software may only be made by the database manager or field supervisor, under the advisement of the Database Manager. All changes will be documented; new software versions will have a different name than the original. The database manager will archive master copies of each software version in two locations.

### **7.2 CHEMICAL ANALYSIS DATA**

#### **7.2.1 Rounding-off Rules**

In general, all arithmetic operations should be performed with all decimal places intact and the final result rounded off to correspond to the value with the fewer(est) significant figures. For most results, the minimum significant figures will be 2.

#### **7.2.2 Method Quantitation Limits**

See Section 5.5.

#### **7.2.3 Data Reduction**

Data reduction begins with analytical results. Concentration data are calculated from instrumental results, field sampling parameters (volume, weight, etc. found in the information shell) and calibration data. Instrumental result files, will be converted to ASCII format in order to be compatible with the data in the information shell. Analyte concentrations will be computed by dividing the analytical results by the sample size as found in the information shell. This processing step will be conducted in the database software. The Data Management Protocol outlines, in detail, the data reduction process for

each sample type and analyte. Individual calculation approaches and acceptance criteria are discussed in the respective protocols. If the analysis did not meet acceptable performance standards, corrective action is indicated (Section 9.0). In addition, the corresponding data record(s) will be flagged as being suspect or voided, depending on the specific limits for each parameter.

For samples analyzed at RTI or EOHSI, matrix concentrations will be calculated using field collection data (i.e. sample volumes or masses) from the Information Shell. An example for metals and VOC in air are shown below. Equivalent calculations will be performed to obtain food, dust and soil concentrations on a weight ( $\mu\text{g/g}$ ) basis, and on a surface loading basis ( $\mu\text{g/cm}^2$ ) for dust. Water, blood, and urine will be calculated on a weight/volume basis ( $\mu\text{g/L}$  or  $\text{ng/mL}$ ).

Metals in air:

$$\frac{\text{ng}}{\text{m}^3} = \frac{\text{ng}_T}{\text{Volume, L}} \times \frac{1000 \text{ L}}{\text{m}^3} \quad (1)$$

where Volume is the volume of air sampled, in L, and  
 $\text{ng}_T$  is the amount of target analyte in the sample, in ng.

VOCs in air:

$$\frac{\mu\text{g}}{\text{m}^3} = \frac{\mu\text{g}_T}{\text{Volume, L}} \times \frac{1000 \text{ L}}{\text{m}^3} \quad (2)$$

where Volume is a function of the effective sampling rate of the badge, and  $\mu\text{g}_T$  is the amount of target analyte in the sample, in  $\mu\text{g}$ .

In addition to the calculation of analyte concentrations, based on sample size, the VOC data will be subjected to further refinement with respect to occupational and non-occupational exposure. The following formula will be applied:

$$\text{occupational exposure} = \text{total exposure} - \text{nonoccupational exposure}$$

It is expected that results from participating laboratories will not require further calculations. They are expected to be reported in appropriate units as indicated in Figure 2.

The results will be reviewed for acceptability by the respective analytical laboratory manager. The criteria for "in-control" analytical conditions will be assessed, and a summary will be prepared for any data generated under analytical conditions judged to be "out-of-control". The data will be reviewed for completeness, and for invalid data (for example, sample integrity was compromised).

The data will then be transferred to the database manager by one of several mechanisms, depending on the source of the data (Figure 2). Analytical results generated at RTI will be transmitted from the analytical instrument to the database manager as ASCII files either via modem or on diskettes. These ASCII files will be imported into Quattro Pro (Borland International, Inc., Scotts Valley, CA) spreadsheet programs for post-analysis processing. Results from the spreadsheet processing will be exported directly to the secured database disk as worksheet files. EOHSI and Rutgers data will be requested in spreadsheet (preferable) or ASCII format and in hardcopy. A subset of the electronic data will be verified against hardcopy after incorporation into the database environment. Data originating from the federal labs (EPA, CDC, FDA) will also be transmitted electronically in EPA 2180.2 format. An overview of the data flow is shown in Figure 3.

### 7.3 DATA ENTRY

The RTI database manager will be responsible for compiling data into the NHEXAS database. The respective laboratory managers are responsible for transmitting data to the RTI database manager. The database manager will assemble the survey data, field collection data, and laboratory analysis data. Survey data will be provided by the survey operations supervisor, field data will be provided by the field supervisor, and chemical analysis data will be provided by the respective laboratory manager. Verification, validation and update procedures for external datafiles are significant concerns in the selection of the database software. Data transfer mechanisms, in their approximate order of preference, include

1. network file transfer,
2. modem file transfer,
3. data on floppy disk, or
4. hardcopy.

With the exception of hardcopy data, datafile are expected to encompass ASCII (tab-delimited; quote-delimited; space-delimited), spreadsheet (e.g., Lotus) and database (e.g., dBase IV) formats. Candidate hardware/software platforms are under consideration which offer input-file flexibility. Data received in hardcopy form will be manually keyed. Contributing laboratories will be requested to supply completed custody documents with the data, including calibration and QC sample results.

### 7.4 PREPARATION OF THE DATABASE

The database system, hardware and software, must meet two basic requirements:

1. The system must provide selective and controlled access to database records, and
2. The database system must be capable of successfully merging information from various sources.

The detailed data management plan is presented in the data management protocol (RTI/ACS-AP-209-400).

Field data will be in Quattro Pro (Windows) spreadsheets. The analytical data will be converted from its original, instrument-dependent format to delimited ASCII files for import into the database. Following data validation checks, all incoming data will be introduced to the database as tables of data records, where a record is defined as a collection of information associated with a sample or group of samples and may include narrative or descriptive qualifying information. Analytical data will be combined and reprocessed with field data from the information shell. Each data record, or observation, will be an assemblage of information linked together by various data "keys". The participant identification number on the questionnaires and the sample identification numbers associated with each sample will serve as two such keys. These keys will be used to associate data records from one source (e.g., the Time/Activity Diary) with another (e.g., results from VOC analysis).

Since analytical data will be contributed by a number laboratories, an accounting of information will be based on an inventory of all samples to be collected from the study participants. This inventory will be maintained in the information shell. From this perspective, an accounting of samples (completeness) can be made at each point in the analytical processes.

## 7.5 DATA VALIDATION

Data validation will begin after samples have been analyzed and during the period of data entry and review. The following checks on data quality will be made:

1. In-control field sample collection and analytical conditions will be verified and data generated under conditions judged to be out-of-control will be noted.
2. The mechanisms used to transmit data from the laboratory to the database manager will be reviewed. Verification of electronic data, prior to transmission, is the responsibility of the contributing laboratory. All transmissions will be accomplished with electronic verification, if possible. In addition, RTI will manually verify 10% (from each transmitted batch) of the transmitted, received, and reformatted data against original hardcopy or other appropriate original data format.
3. Completeness will be reviewed at least weekly, and the causes for missing data will be investigated. Completeness will be determined at various points in the data evolution process by electronic comparison against the schedule of samples to be collected. This operation will be the responsibility of the NHEXAS Database Manager.

Procedures 1 and 2 will be performed by the appropriate laboratory manager. The QA Officer will verify that all validation steps are complete.

After data entry, the QA Officer will perform additional checks:

1. The completeness of the database will be reviewed.
2. Quantitation limits will be verified.
3. The concentration calculations of a random subset of the raw data will be re-calculated.
4. Summary statistics will be generated and review with respect to distribution characteristics and potential outliers. Potential outliers will be investigated.
5. The content and proper coding of a sample of questionnaire and diary data will be verified relative to the original hard-copies and coding instructions.

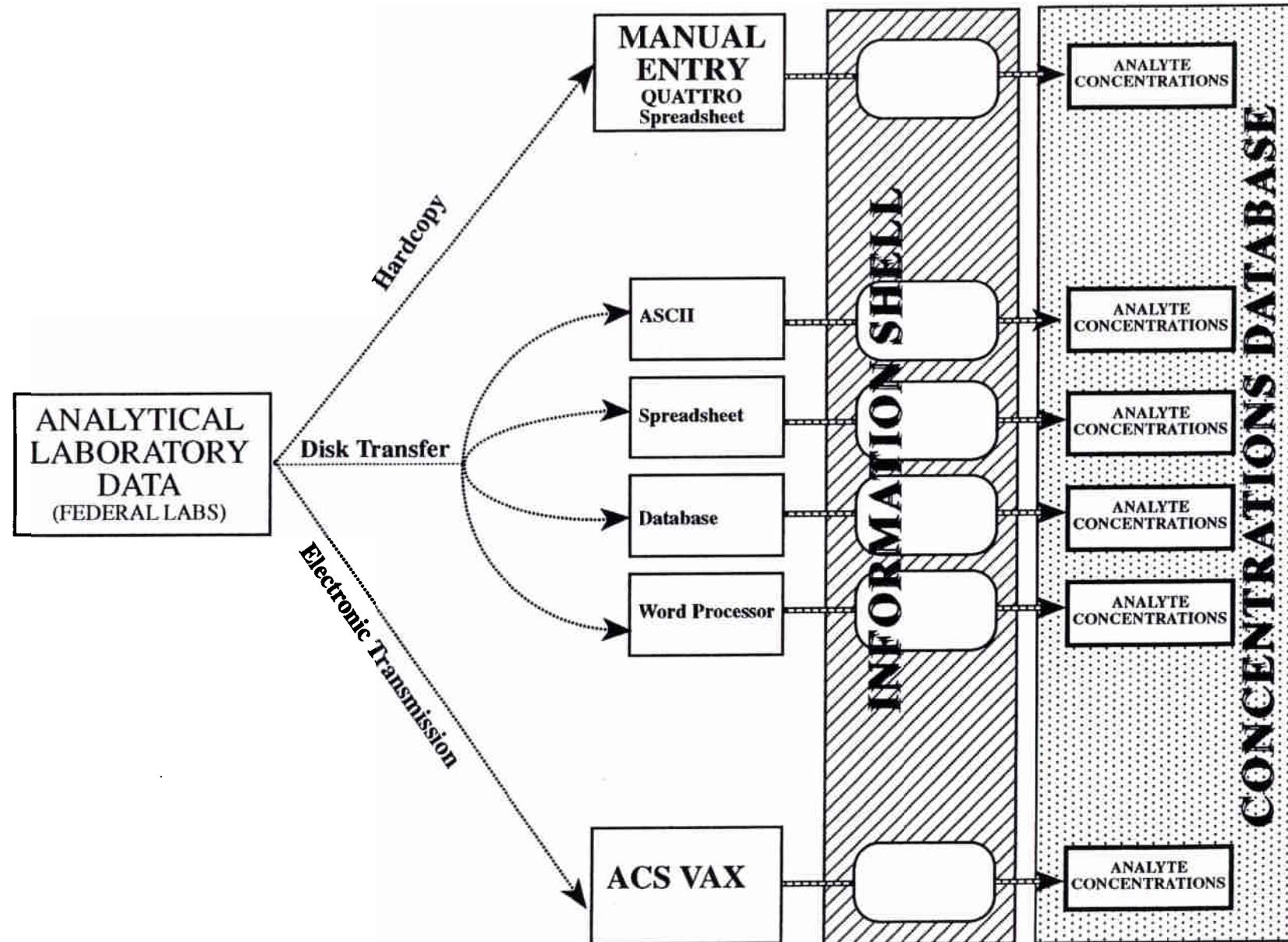


Figure 2. Overview of Analytical Laboratory Data Flow from Federal Labs.

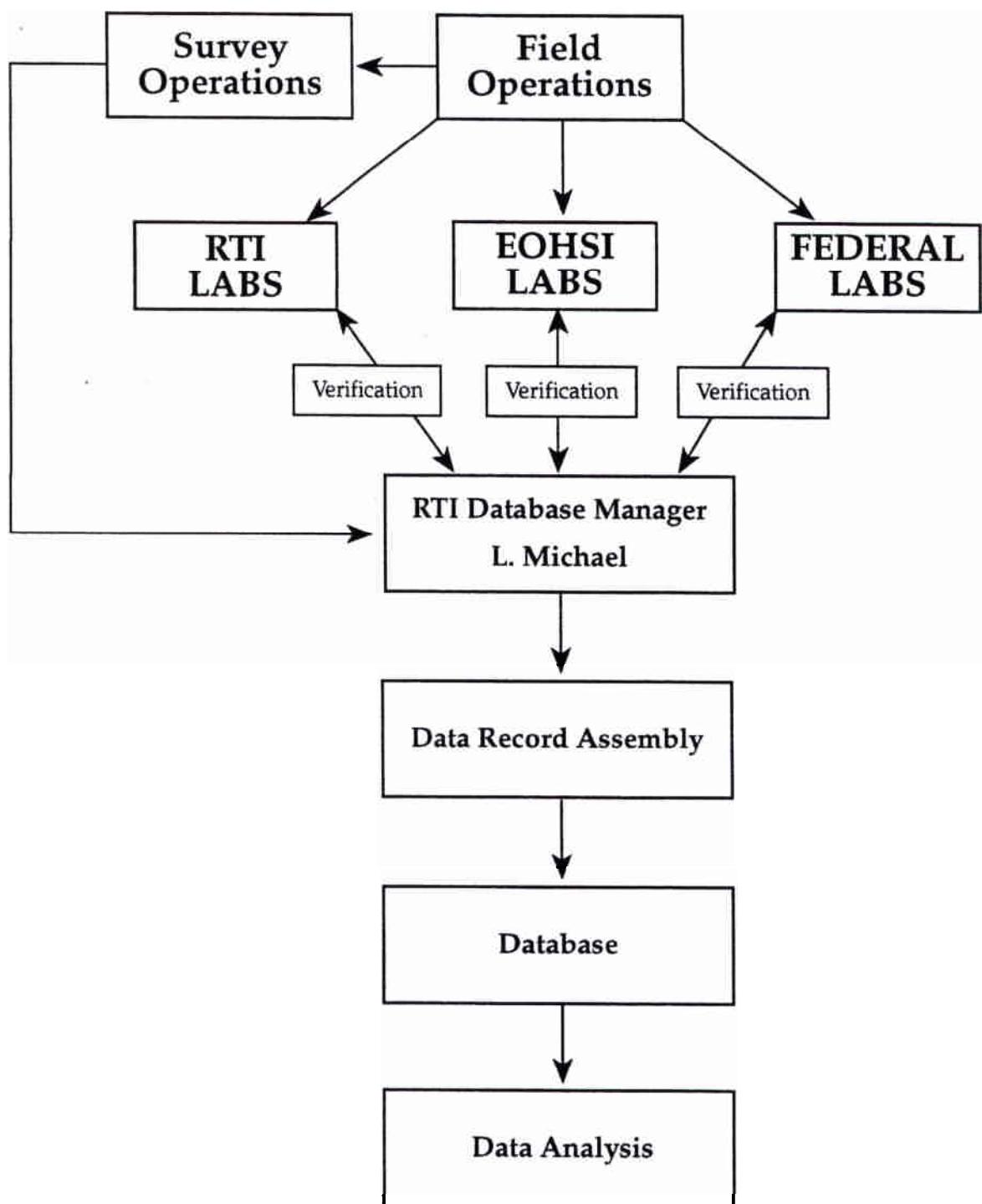


Figure 3. Overview of Chemical Analysis Data Flow.

## SECTION 8 SYSTEMS AND PERFORMANCE AUDITS

Systems and performance audits provide an independent assessment of adherence to policies and procedures and data quality. The RTI QA Officer is responsible for conducting systems audits of RTI activities and the EOHSI QA Officer is responsible for conducting systems audits of EOHSI activities. NIST will provide performance evaluation samples (see Appendix G for NIST statement of work). The program of systems and performance audits for other analytical laboratories (EPA-CI contractor laboratories, CDC and FDA) has not been finalized.

### **8.1 SYSTEMS AUDITS**

Major study components which will be audited are:

- Sample design,
- Survey operations,
- Preparation of sampling materials/supplies,
- Sample collection activities in the field,
- Sample processing and shipment,
- Analytical measurement systems,
- Data entry and processing.

A Quality Assurance Audit Checklist will be developed by the QA Officer to aid in the evaluation of the different work areas. These forms will be distributed to and discussed with appropriate work area leaders before the audits are conducted.

It will be the policy of this Quality Assurance Plan to avoid potential problems before they develop by disseminating QA information to and communicating with the work area leaders.

#### **8.1.1 Sample Design**

Audit of sample selection will be based on discussions with Dr. R. Whitmore, Co-Investigator for Survey Sampling Design, and RTI field personnel. The sample selection procedures will be evaluated with particular emphasis in the following areas:

- Use of tested software for first stage sample selection,
- Use of tested software for second stage sample selection,

- Use of standard random number generators for third and fourth stage sample selection,
- Review of materials before they are sent to the field,
- Resolution of problems.

A written audit report will be submitted to Dr. Whitmore within five working days of the audit.

#### **8.1.2 Survey Data Collection**

Audit of survey operations will be based on discussions with Mr. H. Zelon, Survey Operations Supervisor and the RTI field personnel. The field interview procedures will be evaluated with particular emphasis in the following areas:

- Listing (enumeration) procedures,
- Recruitment of participants,
- Administration of the questionnaires,
- Review, in the field, of completed documents,
- Receipt of documents at RTI,
- Effectiveness of training,
- Resolution of problems.

A written report will be submitted to the Mr. Zelon within 5 working days of the audit.

#### **8.1.3 Preparation of Sampling Materials/Supplies**

An audit checklist will be prepared, based upon appropriate protocols and SOPs. The audit will be conducted prior to the field sampling, if at all possible. The following system components will be assessed by the RTI QA Officer:

- Identification and tracking of samples to be collected.
- Preparation of equipment,
- Sample container preparation,
- Preparation of field data and custody records,
- Sampling pump calibration,

- Shipment to the field,
- Specific problem areas.

A written audit report will be submitted to Mr. K. Thomas, Field Supervisor, within 5 working days of the audit.

#### **8.1.4 Sample Collection Activities in the Field**

Internal review of sample collection activities in the field is an important component of this study. However, planning for systems audit(s) in the field is not complete at this time. A systems audit by the RTI QA Officer is planned for the second "dress rehearsal" which will be conducted prior to field monitoring. Particular attention will be paid to adherence to protocols and SOPs and documentation procedures. The following components will be assessed :

- Sample identification and tracking,
- Collection schedules,
- Sample collection methods,
- Collection and management of survey documents,
- Record keeping, and
- Specific problem areas.

In addition, the field supervisor, Mr. K. Thomas, will perform periodic inspections in the field to assess compliance with protocols and SOPs. He will initiate and document corrective action as necessary.

#### **8.1.5 Sample Processing and Shipment**

An audit will be conducted once during the sample processing activities of this study. Evaluation of documentation and custody procedures, sample and document storage and quality control procedures will be performed. Results will be submitted to Mr. K. Thomas.

#### **8.1.6 Analytical Measurement Systems**

The RTI analytical measurement systems will be audited once (at a minimum) during the course of sample analysis. The laboratory in which each matrix/analyte category (e.g., air/metals) is being analyzed will be evaluated for adherence to established protocols and general work performance. These audits will assess the following system components:

- Instrument(s) used and performance criteria,
- Custody procedures,

- Sample storage,
- Sample preparation methods,
- Internal QC protocols,
- Preventative maintenance,
- Assessment of accuracy and precision/control charts,
- Mechanisms for detecting and resolving analytical out-of-control situation,
- Data flow and tracking procedures,
- Problem areas.

Results will be submitted in writing to the Laboratory Manager and the Principal Investigator.

#### **8.1.7 Data Entry and Processing**

Periodic systems audits will be conducted on the data entry and processing phases of this study. Each phase will be audited once (at a minimum).

### **8.2 PERFORMANCE AUDITS**

Performance audits are scheduled as a part of this study. NIST will serve as the Analytical Reference Laboratory for the NHEXAS Phase I study. Specifically, NIST will serve as Reference Laboratory for all chemical measurements, working in behalf of EPA with the federal laboratories and our consortium to assess both intra- and inter-laboratory components of analytical bias. The work statement is included as Appendix G. The RTI/EOHSI consortium will participate in interlaboratory studies organized by NIST. This includes analysis of NIST SRMs or non-certified reference materials, analysis of QA (blind) samples and round-robin analyses.

Initially, a set of samples (analytes in solvent only) will be analyzed for VOCs and metals to assess the performance of the analytical laboratory prior to beginning the analysis of any samples collected from the field. Once the results of this exercise are within an acceptable range, a second set of solutions (consisting of a more complex mixture of chemicals in solutions simulating those found in extracts of field samples) will be analyzed. Finally, a set of samples that represent extracts of natural matrices will be analyzed. Successful completion of these analyses will precede the collection and analysis of any field samples. NIST will also provide performance audit samples as outlined in Appendix G.

## SECTION 9 CORRECTIVE ACTION

Every effort will be made in each phase of this study to anticipate and resolve potential problems before the quality of performance is compromised. One of the major objectives of this QSIP is to establish the mechanisms necessary to achieve this end.

For this study, the need for corrective action may be identified through audits (Section 8.0), internal QC checks, or observations during project activities by the project staff. Often the corrective action is straightforward. In other instances, identified problems will require investigation prior to corrective action. In these instances, the relevant task leader will be involved, as well as the RTI QA Officer.

All corrective actions will be documented on a Corrective Action Report Form such as the one presented in Figure 4. The Corrective Action Report Form will be routed to the relevant task leader and to the RTI QA Officer. If the task leader and RTI QA Officer determine that the problem may have impacted data quality, they will route the Corrective Action Report Form to the Principal Investigator, and after review has been completed and for significant issues, to the EPA Principle Collaborator.

## ACS PROJECT ACTIVITIES REQUIRING CORRECTIVE ACTION

RTI Project No.: \_\_\_\_\_; Lab Notebook Reference: \_\_\_\_\_  
RTI Project Title: \_\_\_\_\_

Nature of incident (include date):

Probable cause of incident:

Measures taken to prevent reoccurrence:

Study data affected by incident:

Comment/Recommendations:

\_\_\_\_\_  
Project Leader

\_\_\_\_\_  
Date

RTI/ACS-84/09

Figure 4. Corrective Action Report

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**APPENDIX A**

**LISTING OF PROTOCOLS AND SOPS  
FOR THE PRIMARY RTI/EOHSI NHEXAS PILOT STUDY**

**1. SAMPLE COLLECTION AND FIELD OPERATIONS PROTOCOLS AND SOPS**

- A1. RTI/ACS-AP-209-001, "Procedure for Collection, Storage, and Shipment of Standing Tap Water Samples for Metals By EPA Method 200.8", Research Triangle Institute, K. Thomas.
- A2. RTI/ACS-AP-209-002, "Procedure for Collection, Storage, and Shipment of Flush and Drinking Water or Drinking Water Samples for Metals by EPA Method 200.8", Research Triangle Institute, K. Thomas.
- A3. RTI/ACS-AP-209-003, "Procedure for Collection, Storage, and Shipment of Drinking Water Samples for VOCs by EPA Method 524.2", Research Triangle Institute, K. Thomas.
- A4. RTI/ACS-AP-209-010, "Personal, Indoor and Outdoor Air Sampling Procedures for Total Inspirable and PM<sub>10</sub> Aerosols", Research Triangle Institute, C. Rodes, P. Lawless, and R. Newsome.
- A5. RTI/ACS-AP-209-011, "NHEXAS Filter Handling, Weighing and Archiving Procedures for Aerosol Samples", Research Triangle Institute, C. Rodes.
- A6. RTI/ACS-AP-209-012, "Procedure for Collection, Storage, and Shipment of Samples for Volatile Organic Compounds in Personal, Indoor, Outdoor, and Occupational Air" Research Triangle Institute, K. Thomas.
- A7. EOHSI-AP-209-020, "Dust Sampling Workplan", Environmental and Occupational Health Sciences Institute, T. Wainman.
- A8. EOHSI-AP-209-021, "Soil/Street Sampling Workplan", Environmental and Occupational Health Sciences Institute, T. Wainman.
- A9. RTI/ACS-AP-209-030, "Procedure for Collection, Storage, and Shipment of Duplicate Diet Food and Beverage Samples", Research Triangle Institute, K. Thomas.
- A10. EOHSI-AP-209-040, "Human Biological Markers: Blood and Urine Sample Collection and Analyses", Environmental and Occupational Health Sciences Institute, K. Erstfeld, and K. Thomas.
- A11. RTI/ACS-AP-209-046, "Procedure for Collection, Storage, and Shipment of Hair Samples for Trace Metals and Arsenic", Research Triangle Institute, K. Thomas.
- A12. RTI/ACS-AP-209-070, "Sample Coding, Labeling, and Field Tracking Procedures", Research Triangle Institute, K. Thomas.
- A13. RTI/ACS-AP-209-071, "Sample Custody Procedures" Research Triangle Institute, K. Thomas.

- A14. RTI/ACS-AP-209-080, "NHEXAS Pilot Field Study Scripting and Logistics", Research Triangle Institute, K. Thomas.
- A15. RTI/ACS-AP-209-081, "Field Sample Storage Procedures", Research Triangle Institute, K. Thomas.
- A16. RTI/ACS-AP-209-082, "Procedures for Field Checks of Equipment", Research Triangle Institute, K. Thomas.
- A17. RTI/ACS-AP-209-083, "Sample Shipping Procedures", Research Triangle Institute, K. Thomas.
- A18. RTI/ACS-AP-209-084, "Vehicle Operations and Maintenance", Research Triangle Institute, K. Thomas.
- A19. RTI/ACS-AP-209-085, "Field Staff Safety and Decorum", Research Triangle Institute, K. Thomas.
- A20. RTI/ACS-AP-209-086, "Field Use of the Sample Collection and Custody Software", Research Triangle Institute, K. Thomas.
- A21. RTI/ACS-AP-209-087, "Participant Schedules and Training", Research Triangle Institute, K. Thomas.
- A22. RTI/ACS-AP-209-090, "Handling Quality Control Samples in the Field", Research Triangle Institute, K. Thomas.
- A23. RTI/ACS-AP-209-095, "Field Staff Training", Research Triangle Institute, K. Thomas.
- A24. NHX-SOP-190-002, "Standard Operating Procedure for Handling Human Blood and Other Body Fluids", Research Triangle Institute, C. Sparacino.

## 2. SAMPLE ANALYSIS PROTOCOLS AND SOPS

- A25. RTI/ACS-AP-209-111, "Analysis of Air Particulate for Lead, Arsenic, Cadmium, and Chromium", Research Triangle Institute, R. Fernando.
- A26. NHX-SOP-171-005, "Standard Operating Procedure for the Calibration of Perkin Elmer (PE) Model 5100 ZL Atomic Absorption Spectrometer: Graphite Furnace", Research Triangle Institute, M. Lang.
- A27. NHX-SOP-171-006, "Standard Operating Procedure for Maintenance of Perkin Elmer (PE) Model ZL5100 PC Atomic Absorption Spectrometer: Graphite Furnace", Research Triangle Institute, M. Lang.

- A28. RTI/ACS-AP-209-112, "Analysis of Volatile Organic Compounds from Charcoal Badges by Gas Chromatography/Mass Spectrometry", Research Triangle Institute, J. Keever.
- A29. NHX-SOP-184-001, "Standard Operating Procedure for Maintenance of the Hewlett-Packard 5988A GC/MS System", Research Triangle Institute, J. Keever.
- A30. NHX-SOP-184-002, "Standard Operating Procedure for Tuning of the HP-5988A Mass Spectrometer", Research Triangle Institute, J. Keever.
- A31. EOHSI-AP-209-120, "Analysis of Dust and Soil for Lead, Cadmium, and Chromium" Environmental and Occupational Health Sciences Institute, B. Buckley.
- A32. RTI/ACS-AP-209-121, "Analysis of House Dust for Arsenic", Research Triangle Institute, R. Fernando.
- A33. RTI/ACS-AP-209-122, "Analysis of Carpet Dust for Arsenic", Research Triangle Institute, R. Fernando.
- A34. RTI/ACS-AP-209-123, "Analysis of Soil for Arsenic", Research Triangle Institute, R. Fernando.
- A35. EPA - "Compendium of Methods for Analysis of Metals and VOCs in Water", U.S. Environmental Protection Agency, Environmental Monitoring Systems Laboratory.
- A36. FDA - "Compendium of Methods for Analysis of Trace Metals in Dietary Samples Using Total Diet Study Procedures", Food and Drug Administration, Total Diet Study Laboratory.
- A37. CDC - "Compendium of Method Summaries for Collection and Analysis of Metals and VOCs in Blood and Urine," Centers for Disease Control, National Center for Environmental Health, Division of Environmental Health Laboratory Sciences.

### 3. SOPs FOR RTI TRACE METALS FACILITY

- A38. NHX/SOP-300-001, "Standard Operating Procedure for Operation of PS Analytical Hydride Generation Atomic Fluorescence Spectrometer (HGAF)", Research Triangle Institute, R. Fernando.
- A39. NHX/SOP-300-002, "Standard Operating Procedures for Safety in the ACS Inorganic Clean Lab Facility", Research Triangle Institute, R. Fernando.

- A40. NHX/SOP-300-003, "Standard Operating Procedure for Purification of Reagents in the ACS Inorganic Clean Lab Facility for Trace/Ultratrace Metal Analysis", Research Triangle Institute, R. Fernando.
- A41. NHX/SOP-300-004, "Standard Operating Procedure for Monitoring and Maintaining Cleanliness of the ACS Inorganic Clean Lab Facility", Research Triangle Institute, R. Fernando.
- A42. NHX/SOP-300-005, "Standard Operating Procedure for the Maintenance of PS Analytical Hydride Generation Atomic Fluorescence Spectrometer (HGAF)", Research Triangle Institute, R. Fernando.
- A43. NHX/SOP-300-006, "Standard Operating Procedure for the ACS Inorganic Class 100/10,000 Clean Lab Facility", Research Triangle Institute, M. Lang.
- A44. NHX/SOP-300-007, "Standard Operating Procedure for Cleaning Labware in the ACS Inorganic Class 100/10,000 Clean Lab Facility", Research Triangle Institute, M. Lang.
- A45. NHX/SOP-300-008, "Standard Operating Procedure for the Mettler AT 261 Analytical Balance", Research Triangle Institute, R. Fernando.
- A46. NHX/SOP-300-009, "Standard Operating Procedure for the Hydro 'Picosystem Plus' Ultrapure Water System", Research Triangle Institute, R. Fernando.

#### **4. GENERAL LABORATORY SOPS**

- A47. NHX-SOP-120-001, "Standard Operating Procedure for Proper Use and Maintenance of Laboratory Notebooks", Research Triangle Institute, R. Handy, and G. McNeill.
- A48. NHX-SOP-120-002, "Standard Operating Procedure for Proper Use and Maintenance of Instrument Log Notebooks", Research Triangle Institute, D. Smith.
- A49. NHX-SOP-120-003, "Standard Operating Procedure for Proper Use and Maintenance of Chemical Log Notebooks", Research Triangle Institute, D. Smith.
- A50. NHX-SOP-150-001, "Standard Operating Procedure for Cleaning Glassware/Plasticware", Research Triangle Institute, R. Handy.
- A51. NHX-SOP-160-001, "Standard Operating Procedure for Calibration of a Mettler PL1200 Balance", Research Triangle Institute, D. Smith.
- A52. NHX-SOP-160-002, "Standard Operating Procedure for Calibration of a Mettler M5 Analytical Balance", Research Triangle Institute, D. Smith.

- A53. NHX-SOP-160-005, "Standard Operating Procedure for Cahn 29 Electrobalance", Research Triangle Institute, G. McNeill.
- A54. NHX-SOP-160-008, "Standard Operating Procedure for Mettler AE 163 and AE 240 Electronic Balance", Research Triangle Institute, C. Sparacino.
- A55. NHX-SOP-160-009, "Standard Operating Procedure for Mettler AE 160 Electronic Balance", Research Triangle Institute, C. Sparacino.
- A56. NHX-SOP-163-001, "Refrigerators and Freezers", Research Triangle Institute, C. Sparacino.
- A57. NHX-SOP-163-003, "Standard Operating Procedure for Drying Ovens", Research Triangle Institute, C. Sparacino.

## 5. QUALITY ASSURANCE SOPS

- A58. NHX-SOP-100-001, "Standard Operating Procedure for Preparation of a Standard Operating Procedure", Research Triangle Institute, D. Smith.
- A59. NHX-SOP-100-002, "Standard Operating Procedure for Revising Standard Operating Procedures", Research Triangle Institute, D. Smith.
- A60. NHX-SOP-100-003, "Standard Operating Procedure for Preparation of a Protocol", Research Triangle Institute, D. Smith.
- A61. NHX-SOP-110-002, "Standard Operating Procedure for RTI/EOHSI Quality Assurance Officer", Research Triangle Institute, D. Smith.
- A62. NHX-SOP-810-002, "Standard Operating Procedure for Preparation and Handling of Performance Evaluation Samples", Research Triangle Institute, D. Smith.
- A63. NHX-SOP-815-001, "Standard Operating Procedure for Conducting Systems Audits", Research Triangle Institute, D. Smith.
- A64. NHX-SOP-815-002, "Standard Operating Procedure for Conducting Laboratory Notebook Inspections", Research Triangle Institute, D. Smith.
- A65. NHX-SOP-815-003, "Standard Operating Procedure for Conducting Instrument Log Notebook Inspections", Research Triangle Institute, D. Smith.
- A66. NHX-SOP-815-004, "Training File Inspections", Research Triangle Institute, D. Smith.
- A67. NHX-SOP-820-001, "Standard Operating Procedure for Certification of Standard Weights", Research Triangle Institute, G. McNeill.

**6. SURVEY OPERATIONS PROCEDURES**

- A68. EOHSI-AP-209-300, "NHEXAS Time/Activity Diary Collection Protocol", Environmental and Occupational Health Sciences Institute, N. Freeman.
- A69. EOHSI-AP-209-301, "NHEXAS Time/Activity Diary Processing and Analysis Protocol", Environmental and Occupational Health Sciences Institute, N. Freeman.
- A70. RTI/CSUR-AP-209-302, "Field Interviewer Training Manual", Research Triangle Institute, H. Zelon and J. Snodgrass.

**7. DATA-BASE MANAGEMENT**

- A71. RTI/ACS-AP-209-400, "Procedure for Receipt, Processing, and Assembly of Analytical Results and Questionnaire Data into a Database", Research Triangle Institute, L. Michael.

**8. DATA ANALYSIS**

- A72. EOHSI-AP-209-600, "Exposure and Dose Assessment Modeling and Evaluation", Environmental and Occupational Health Sciences Institute, P. Georgopoulos.

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## APPENDIX B

### LISTING OF PROPOSED PROTOCOLS AND SOPS FOR THE RTI/EOHSI NHEXAS PILOT STUDY PESTICIDE/PAH 50-PARTICIPANT MODULE

NOTE: A 50-participant module is scheduled to be included in the third year of the NHEXAS Phase I pilot study performed by the RTI/EOHSI consortium. The proposed protocols and SOPs that will be used during this study module are listed below. Most sample collection and analysis protocols will not be written until the scope and scale of the study is defined. Also, there will be ongoing research and development of the dermal exposure assessment methodology during the first and second years of the three-year program. Sample collection and analysis protocols will be prepared based on the results of laboratory and small-scale test results. We plan to assemble all documentation for the 50-participant as an addendum to this QSIP at a later date.

## 1. SAMPLE COLLECTION PROTOCOLS

- B1. RTI/ACS-AP-209-004, "Procedure for Collection, Storage, and Shipment of Drinking Water Samples by EPA Method 525.2", Research Triangle Institute, M. Roberds, Draft, October 1993.
- B2. RTI/ACS-AP-209-013, "Procedure for the Collection of Polynuclear Aromatic Hydrocarbons (PAH) and Pesticides in Personal, Indoor, and Outdoor Air", Research Triangle Institute, M. Roberds, Draft, October 1993.
- B3. RTI/ACS-AP-209-031, "Procedure for Collection, Storage, and Shipment of Duplicate Diet Food and Beverage Samples for Pesticide and PAH Contaminants" work in progress.
- B4. EOHSI-AP-209-022, "Collection of Dust Samples for Pesticides and PAHs" work in progress.
- B5. EOHSI-AP-209-023, "Collection of Soil Samples for Pesticides and PAHs" work in progress.
- B6. EOHSI-AP-209-041, "Human Biological Markers -- Sample Collection for Pesticides and PAHs" work in progress.
- B7. EOHSI-AP-209-050, "Procedure for Collection, Storage, and Shipment of Dermal Wipe Samples for Pesticides and PAHs" work in progress.
- B8. EOHSI-AP-209-051, "Procedure for Collection, Storage, and Shipment of Dermal Rinse Samples for Pesticides and PAHs" work in progress.

## 2. SAMPLE ANALYSIS PROTOCOLS

- B9. EPA Method 525.2, "Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry", Environmental Monitoring Systems Laboratory, U.S. Environmental Protection Agency, J. Eichelberger, J. Munch, J. Shoemaker, Draft Revision 1.0, October 1993.

- B10. RTI/ACS-AP-209-114, "Extraction from Air Filter Samples and Analysis of Pesticides and PAHs by GC/MS" work in progress.
- B11. RTI/ACS-AP-209-124, "Analysis of Dust Samples for Pesticides" work in progress.
- B12. EOHSI-AP-209-125, "Analysis of Dust Samples for PAHs" work in progress.
- B13. EOHSI-AP-209-126, "Analysis of Soil Samples for PAHs" work in progress.
- B14. RTI/ACS-AP-209-127, "Analysis of Soil Samples for Pesticides" work in progress.
- B15. EOHSI-AP-209-133, "Analysis of Pesticides and PAHs in Food and Beverage Duplicate Diet Composite Samples" work in progress.
- B16. CDC - analysis of pesticides and metabolites in serum .... to be obtained
- B17. EPA - analysis of PAHs, metabolites, and adducts in serum .... to be obtained
- B18. CDC - analysis of pesticides, and metabolites in urine ..... to be obtained
- B19. EPA - analysis of PAHs and metabolites in urine ..... to be obtained
- B20. EOHSI-AP-209-150, "Analysis of PAHs in Dermal Wipe Samples" work in progress.
- B21. EOHSI-AP-209-151, "Analysis of PAHs in Dermal Rinse Samples" work in progress.
- B22. RTI/ACS-AP-209-152, "Analysis of Pesticides in Dermal Wipe Samples" work in progress.
- B23. RTI/ACS-AP-209-153, "Analysis of Pesticides in Dermal Rinse Samples" work in progress.

**APPENDIX C**  
**SUMMARY OF SAMPLES TO BE COLLECTED IN EACH HOME**

TABLE C-1. SUMMARY OF PROJECTED SAMPLE COLLECTION/ANALYSIS BY PARTICIPANT AND SAMPLE TYPE

Season	Percent of Homes					QC <sup>d</sup> Samples Percent	Total Samples (Est.)
	1			2	3		
	Core <sup>a</sup>	Core+ <sup>b</sup>	Core++ <sup>c</sup>				
Number of Homes:	22	58	220	150	135		
<b>AIR SAMPLES</b>							
VOCs in Air							
Personal	100	100	100	100	100	7	625
Indoor	100	100	100	100	100	7	625
Outdoor	33	33	33	57	57	7	282
Workplace	16.5	16.5	16.5	0	0	7	55
Subtotal							1587
Aerosols (IOM)							
Personal	0	33	100	0	0	12	309
Indoor	0	33	100	0	0	12	309
Outdoor	0	14	42	0	0	12	
Subtotal							648
Aerosols (PM <sub>10</sub> )							
Indoor	0	5	15	0	0	79	
Outdoor	0	5	15	0	0	79	
Subtotal							129
<b>WATER SAMPLES</b>							
Metals Initial/Pb	100	100	100	100	100	6	620
Flush/Pb	100	100	100	100	100	12	655
Flush/As	100	100	100	100	100	17	690
Drinking/Pb	5	5	5	0	0	0	15
Drinking/As	5	5	5	0	0	0	15
VOCs Drinking	100	100	100	0	0	135	705
Subtotal							2700

continued

TABLE C-1. SUMMARY OF PROJECTED SAMPLE COLLECTION/ANALYSIS BY PARTICIPANT AND SAMPLE TYPE (CONTINUED)

Season	Percent of Homes					QC <sup>d</sup> Samples Percent	Total Samples (Est.)
	1			2	3		
	Core <sup>a</sup>	Core+ <sup>b</sup>	Core++ <sup>c</sup>				
Number of Homes:	22	58	220	150	135		
<b>DUST SAMPLES</b>							
LWW Window/Pb	0	33	100	0	0	13	274
LWW Window/As	0	33	100	0	0	13	274
LWW Living/Pb	0	33	100	0	0	13	274
LWW Living/As	0	33	100	0	0	13	274
Plate/Pb	50	50	50	90	0	7	305
Plate/As	50	50	50	90	0	7	305
Carpet/Pb	50	50	50	90	0	7	305
Carpet/As	50	50	50	90	0	7	305
Subtotal							2236
WWT Window/Pb	0	9	25	0	0	12	67
WWT Window/As	0	9	25	0	0	12	67
WWT Living/Pb	0	9	25	0	0	12	67
WWT Living/As	0	9	25	0	0	12	67
Subtotal							268
<b>SOIL SAMPLES</b>							
Primary Entrance	0	18	18	0	0	10	55
Yard Soil	0	18	18	0	0	10	55
Subtotal							220

Continued

TABLE C-1. SUMMARY OF PROJECTED SAMPLE COLLECTION/ANALYSIS BY PARTICIPANT AND SAMPLE TYPE (CONCLUDED)

Season	Percent of Homes					QC <sup>d</sup> Samples Percent	Total Samples (Est.)
	1			2	3		
	Core <sup>a</sup>	Core+ <sup>b</sup>	Core++ <sup>c</sup>	150	135		
Number of Homes:	22	58	220	150	135		
<b>FOOD SAMPLES (FOODS AND BEVERAGES)</b>							
Metals (Foods Composite)	0	67	100	0	0	4	269
Metals (Bev. Composite)	0	67	100	0	0	4	269
Daily Samp. Anal. (food)	0	4	4	0	0	0	48
Daily Samp. Anal. (bev)	0	4	4	0	0	0	48
Subtotal							634
<b>BLOOD SAMPLES</b>							
Metals	93	93	93	0	0	20	335
VOCs	93	93	93	0	0	20	335
Archival	93	93	93	0	0	7	300
Subtotal							970
<b>URINE SAMPLES</b>							
Metals (2 per participant)	93	93	93	93	93	10	1207
Subtotal							1215
<b>HAIR SAMPLES</b>							
Metals	93	93	93	93	93	2	560

Tables Notes

<sup>a</sup>Core = These samples are collected at all homes.

<sup>b</sup>Core+ = Core samples + Dust Samples + Aerosol or Dietary Samples.

<sup>c</sup>Core++ = Core samples + Dust Samples + Aerosol and Dietary Samples.

<sup>d</sup>QC samples deployed/collected in field only. Does not include laboratory QC/QA samples or analyses.

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APPENDIX D  
SAMPLE COLLECTION ACTIVITIES FOR EACH HOME

NHEXAS - VISIT 1  
 ESTIMATED SAMPLE COLLECTION TIME  
 AT THE 3 TYPES OF HOMES

(Assumes 3 visits over a six day collection period two technicians working at each visit)

Home Type 1 = Core (Air VOC, Water VOC + Metals, Blood VOC and Metals, Urine Metals)

Home Type 2 = Core + Dust + Aerosol or Dietary

Home Type 3 = Core + Dust + Aerosol and Dietary

Staff Member	Visit and Activity	Est. Time Per Activity (min)	Percentage of Time Activity Performed at Each Type Home		
			Type 1 (n=22)	Type 2 (n=58)	Type 3 (n=220)
S1, S2	Drive to home	30	100	100	100
S1	Talk to participant(s), schedule	15	100	100	100
S1	Check daily activity log	8	100	100	100
S1	Train to collect standing water sample	5	100	100	100
S1	Train to collect urine and set up	10	85	85	85
S1	Train to wear workplace VOC monitor	5	16	16	16
S1	Train to collect food and set up	25	0	66	100
S1	Train for food diary	8	0	66	100
S1	Train to wear aerosol monitor (IOM)	5	0	33	100
S2	Deploy indoor VOC monitor	5	100	100	100
S2	Deploy outdoor VOC monitor	8	33	33	33
S2	Deploy personal VOC monitor	5	100	100	100
S2	Deploy workplace VOC monitor	5	17	17	17
S2	Deploy personal aerosol monitor (IOM)	10	0	33	100
S2	Deploy indoor aerosol monitor (IOM)	12	0	33	100
S2	Deploy outdoor aerosol monitor (IOM)	12	0	14	42
S2	Deploy indoor aerosol monitor (PM <sub>10</sub> )	10	0	5	15
S2	Deploy outdoor aerosol monitor (PM <sub>10</sub> )	10	0	5	15
S2	Problem solving time	10	100	100	100
Estimated Visit Time (min) MIN:			70	90	100
MAX:			80	120	140

NHEXAS - VISIT 2  
 ESTIMATED SAMPLE COLLECTION TIME  
 AT THE 3 TYPES OF HOMES

Staff Member	Visit and Activity	Est. Time Per Activity (min)	Percentage of Time Activity Performed at Each Type Home		
			Type 1 (n=22)	Type 2 (n=58)	Type 3 (n=220)
S1, S2	Drive to home	30	100	100	100
S1	Talk to participant(s)	10	100	100	100
S1	Time/activity log check	5	100	100	100
S1	Collect urine	5	93	93	93
S1	Pick up standing water sample	4	100	100	100
S1	Collect diet samples	15	0	66	100
S1	Food diary followup	10	0	66	100
S1	Diet questionnaires	5	0	66	100
S1 or S2	Technician quest/log	15	100	100	100
S2	Collect metals flush water sample	10	100	100	100
S2	Collect VOC water samples	8	100	100	100
S2	Collect LWW dust at 2 locations	25	0	33	100
S2	Collect WWT dust at 2 locations	20	0	9	25
S2	Collect soil	15	0	18	18
S2	Problem solving time	10	100	100	100
Estimated Visit Time (min)			MIN:	70	85
			MAX:	80	120
					145

NHEXAS - VISIT 3  
 ESTIMATED SAMPLE COLLECTION TIME  
 AT THE 3 TYPES OF HOMES

Staff Member	Visit and Activity	Est. Time Per Activity (min)	Percentage of Time Activity Performed at Each Type Home		
			Type 1 (n=22)	Type 2 (n=58)	Type 3 (n=220)
S1, S2	Drive to home	30	100	100	100
S1	Talk to participant(s)	5	100	100	100
S1	Time/activity log check	5	100	100	100
S1	Collect urine	5	93	93	93
S1	Collect blood	15	93	93	93
S1	Collect diet sample	15	0	66	100
S1	Food diary followup	10	0	66	100
S1	Diet questionnaires	10	0	66	100
S1	Collect hair	5	93	93	93
S1	Followup questionnaire	25	100	100	100
S1	Longitudinal sampling activities	20	50	50	50
S2	Collect indoor VOC monitor	5	100	100	100
S2	Collect outdoor VOC monitor	5	33	33	33
S2	Collect personal VOC monitor	5	100	100	100
S1, S2	Collect workplace VOC monitor	5	16	16	16
S2	Collect indoor aerosol monitor (IOM)	10	0	33	100
S2	Collect outdoor aerosol monitor (IOM)	12	0	14	42
S2	Collect personal aerosol monitor (IOM)	10	0	33	100
S2	Collect indoor aerosol monitor ( $PM_{10}$ )	10	0	5	15
S2	Collect outdoor aerosol monitor ( $PM_{10}$ )	10	0	5	15
S2	Problem solving time	5	100	100	100
S1, S2	Pack equipment	10	100	100	100
Estimated Visit Time (min) MIN:			70	85	100
MAX:			115	130	150

## APPENDIX E

### MINIMUM DETECTABLE DIFFERENCES IN POPULATION PERCENTAGES

## MINIMUM DETECTABLE DIFFERENCES IN POPULATION PERCENTAGES

To determine the minimum difference in population proportions, P, that can be detected with probability  $1 - \beta$  (power of the hypothesis test of no difference), it is convenient to transform the sample proportion, p, using the variance stabilizing transformation

$$t = 2 \arcsin \sqrt{p} .$$

The transformed variable, t, is approximately normally distributed when the sample size is sufficiently large. Its mean value is

$$E(t) = 2 \arcsin \sqrt{P} ,$$

where P is the population proportion estimated by p, and if the arcsin function is evaluated in radians, its variance is

$$\text{Var}(t) = (n/d)^{-1} ,$$

the reciprocal of the effective sample size, n/d.

The minimum difference,  $\Delta$ , that can be detected on the transformed scale with probability  $1 - \beta$  when testing with significance level  $\alpha$  can be shown to be

$$\Delta = (z_\alpha + z_\beta) \sqrt{d_1/n_1 + d_2/n_2} ,$$

where  $z_\alpha$  and  $z_\beta$  are critical points of a standard normal distribution with areas  $\alpha$  and  $\beta$  to the right, respectively,  $n_1$  and  $n_2$  are the sizes of the samples supporting the two estimated population proportions, and  $d_1$  and  $d_2$  are the survey design effects for these same estimates.

The symmetric interval,  $t \pm \Delta$ , representing the range of detectable differences on the transformed scale becomes a non-symmetric interval on the proportions scale. Thus, in Table E-1, we have presented the larger of the two population proportions and the minimum detectable decrease for various combinations of domain sample sizes, significance levels, and

powers of hypothesis tests. A survey design effect of 1.5 was assumed when calculating the minimum detectable differences for Table E-1, consistent with Tables 10-15 in Section 2.2.1

The first three sample size combinations shown in Table E-1 correspond to equal partitions (e.g., male and female) of samples of 300, 200, 100 participants. The last two sample size combinations correspond to 75%/25% partitions (e.g., high and low socio-economic status) and 90%/10% partitions (e.g., non-black and black population in EPA Region 5) of samples consisting of 300 participants.

Looking at the first row of Table E-1 and the column for the 75%/25% partition (225/75 participants), we see that if 50 percent of the population in the lowest 25% socio-economically had exposures above a given threshold, we would have a 50 percent chance (power) of detecting a significantly smaller percentage (at the 10% significance level) above the same threshold in the highest 75% socio-economically if their percentage above that threshold was 40 percent (50 - 10) or less. Similarly, we see that if 30 percent of the population in the lowest 25% socio-economically had exposures above a given threshold, we would have a 60 percent chance (power) of detecting a significantly smaller percentage (at the 10% significance level) above the same threshold in the highest 75% socio-economically if their percentage above that threshold was 19 percent (30 - 11) or less.

**Table E-1. Minimum Detectable Differences in Population Percentages Given the Domain Sample Sizes and the Larger Population Percentage, P**

Power of Hypothesis Test	One-Tail Significance Level <sup>a</sup>	Larger Percentage P	Domain Sample Sizes ( $n_1 / n_2$ )				
			150/150	100/100	50/50	225/75	270/30
50%	10%	50	9	11	15	10	15
		40	9	11	15	10	14
		30	8	10	13	9	13
		20	7	8	11	8	11
		10	5	6	7	5	7
	5%	50	12	14	20	13	18
		40	11	13	18	13	18
		30	10	12	16	11	16
		20	8	10	13	10	13
		10	6	7	9	7	8
60%	10%	50	11	13	18	12	18
		40	10	13	17	12	17
		30	9	11	15	11	15
		20	8	9	13	9	12
		10	6	6	8	6	8
	5%	50	13	16	22	15	22
		40	13	15	21	14	20
		30	11	14	18	13	18
		20	10	11	15	11	14
		10	7	8	9	7	9
70%	10%	50	13	15	21	15	21
		40	12	15	20	14	19
		30	11	13	18	12	17
		20	9	11	14	10	14
		10	6	7	9	7	9
	5%	50	15	18	25	17	24
		40	14	17	23	16	23
		30	13	15	20	15	20
		20	11	13	16	12	16
		10	7	8	10	8	10

<sup>a</sup> Double the significance level for a two-tail test (i.e., tabulated values are for two-tail tests at the 10% and 20% significance levels).

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**APPENDIX F**

**QUESTIONNAIRES**

NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

*DESCRIPTIVE QUESTIONNAIRE*

Identification Number

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(Record ID Here)

Public reporting burden for this collection of information is estimated to average 5 minutes per response, and to require 0 hours recordkeeping. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

August 2, 1995

## TOTAL VISITS:

SCREENING RESULT CODES (Circle Final Screening Code)	
<u>Pending Codes</u>	<u>Final Codes</u>
01 = No one at HU	10 = Vacant (1)
02 = Eligible Screening Respondent unavailable	11 = No one at HU after repeated visits
03 = Neighbor indicates occupancy	12 = Eligible Screening Respondent unavailable after repeated visits
04 = Physically/mentally incompetent	13 = Not primary residence (1)
06 = Language barrier	14 = Physically/mentally incompetent
07 = Refusal (CALL SUPERVISOR)	15 = Language barrier
08 = Unable to Locate HU	17 = Refusal (CALL SUPERVISOR)
09 = Other (Specify in Comments Section)	18 = Not a housing unit (1)
	19 = Group quarters
	21 = Other (Specify in Comments Section)
	29 = No one selected, minimal roster
	30 = No one selected for interview (1)
	31 = One selected

INTERVIEW RESULT CODES (Circle Final Interview Code)		
Pending Codes	Final Codes, Initial 9 Respondents	Final Codes, After Initial 9 Respondents
<u>Pending Codes</u> 51 = No one at HU 52 = Appointment broken 53 = Respondent unavailable, call back 54 = Break off (partial interview) 55 = Physically/mentally incompetent 57 = Language barrier 58 = Refusal (CALL SUPERVISOR) 60 = Other (Specify in Comments Section)	<u>Final Codes, Initial 9 Respondents</u> 70 = Baseline interview complete, agrees to monitoring (2) 71 = Baseline interview complete, refuse monitoring 72 = Refusal (CALL SUPERVISOR) 73 = Break off, partial interview/refusal (CALL SUPERVISOR) 74 = No one at HU after repeated visits 75 = Respondent unavailable after repeated visits 76 = Physically/mentally incompetent 77 = Language barrier 78 = Other (Specify in Comments Section)	<u>Final Codes, After Initial 9 Respondents</u> 80 = Baseline interview complete 82 = Refusal 83 = Break off, partial interview, refused to complete 86 = Physically/mentally incompetent 87 = Language Barrier 88 = Other (Specify in Comments Section)

- (1) Obtain verification information and terminate visit.
  - (2) Record monitoring appointments and complete Field Monitoring Appointment Sheet

# NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

## **DESCRIPTIVE QUESTIONNAIRE**

INTERVIEWER/TECHNICIAN ID: \_\_\_\_\_

Date Completed: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Hello. I'm (NAME) with Research Triangle Institute. We are conducting a study in cooperation with the Environmental Protection Agency on exposures to substances in the environment in and around your home. You have been selected at random to participate in this study. We mailed a letter to this address that explains the importance of your participation. Do you remember receiving this letter? IF LETTER NOT RECEIVED, HAND COPY TO RESPONDENT. ALLOW TIME FOR READING, ANSWER ANY QUESTIONS.

## **HOUSEHOLD ELIGIBILITY**

**D1. VERIFY ADDRESS FROM LIST OF DU'S AND RECORD ADDRESS BELOW.**

ADDRESS: \_\_\_\_\_ Street/RFD \_\_\_\_\_ Apt. # \_\_\_\_\_

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City	State	ZIP Code
------	-------	----------

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D2. VERIFY THAT THE RESPONDENT IS A PERMANENT RESIDENT OF THE HOUSEHOLD (NOT A VISITOR, BABY SITTER, HOUSE SITTER, ETC.), RESIDES WITH THE MEMBERS OF THE HOUSEHOLD AT LEAST HALF THE YEAR, AND IS AT LEAST 18 YEARS OLD. IF RESPONDENT IS NOT A RESIDENT OF THE HOUSEHOLD OR IS NOT 18 YEARS OR OLDER, REQUEST TO SPEAK TO SOMEONE ELIGIBLE TO ANSWER FOR THE HOUSEHOLD. IF AN ELIGIBLE SCREENING RESPONDENT IS OBTAINED, CIRCLE "1." IF NO ELIGIBLE SCREENING RESPONDENT IS AVAILABLE, CIRCLE "2."

ELIGIBLE SCREENING RESPONDENT ..... 1 ÷ CONTINUE

NO ELIGIBLE SCREENING RESPONDENT ..... 2 ÷ STOP. ENTER  
PENDING CODE 02  
ON RECORD OF  
CALLS AND  
THANK  
RESPONDENT.

D3. Is this property your primary residence or is it a vacation home or second home where you live less than half the year ? (CIRCLE ONE.)

PRIMARY RESIDENCE .....	1 ÷	CONTINUE
VACATION/SECOND HOME .....	2 ÷	GO TO D11

D4. Do 10 or more people live at this address? (CIRCLE "Y" OR "N.")

YES .....	Y ÷	CONTINUE
NO .....	N ÷	GO TO D6

D5. (PROBE FOR RELATIONSHIPS.) Is this (house/apartment) a group quarters? (CIRCLE "Y" OR "N.")

YES .....	Y ÷	GO TO D11
NO .....	N ÷	CONTINUE

## HOUSEHOLD ROSTER

D6a. First, I would like to ask a few general questions about you and the other people who live here now. Just to be sure I account for everyone, please tell me the first names of all the people who currently live here. Let's begin with the person or persons who own the residence or pay the rent. (ENTER FIRST NAMES IN COLUMN B OF THE ROSTER. ENTER RELATIONSHIP TO HEAD OF HOUSEHOLD IF FIRST NAMES ARE REFUSED.)

I have listed (NAMES). Is there anyone else living here now such as friends, roomers, or other people we might have overlooked? (IF SO, ADD THEM TO THE ROSTER.)

ASK QUESTION D6b. FOR EACH LISTED INDIVIDUAL.

D6b. Is (NAME) a full-time resident of this household, that is, a person who lives in the residence year round, except for short periods of time?

YES ..... Y ÷ CONTINUE  
NO ..... N ÷ DELETE FROM ROSTER

ASK QUESTIONS D6c-k FOR EACH LISTED INDIVIDUAL. RECORD RESPONSE IN ROSTER.

D6c. CIRCLE THE SEX ("M" FOR MALE OR "F" FOR FEMALE) OF EACH PERSON IN COLUMN C. ASK IF NOT OBVIOUS.

D6d. What is (NAME's) year of birth? (ENTER 2 DIGITS IN COLUMN D.)

D6e. What is (NAME's) race? (READ CHOICES AND CIRCLE ONE NUMBER IN COLUMN E.)

White .....	1
Black or African-American .....	2
American Indian .....	3
Eskimo or Aleut .....	4
Asian or Pacific Islander .....	5
Some other race (Specify: _____) .....	6
DON'T KNOW .....	DK
REFUSED .....	RE

D6f. Is (NAME) of Hispanic or Spanish origin? (CIRCLE RESPONSE IN COLUMN F.)

YES .....	Y
NO .....	N
DON'T KNOW .....	DK
REFUSED .....	RE

D6g. How much school has (NAME) completed? (READ CHOICES AND CIRCLE ONE NUMBER IN COLUMN G FOR THE HIGHEST LEVEL COMPLETED OR DEGREE RECEIVED. IF CURRENTLY ENROLLED, CIRCLE THE LEVEL OF THE PREVIOUS GRADE ATTENDED OR HIGHEST DEGREE RECEIVED.)

No schooling completed or kindergarten only . . . . .	1
Primary or middle school (Grade 1 through 8) . . . . .	2
Some high school (Grade 9 through 11) . . . . .	3
High school graduate (Grade 12 or GED) . . . . .	4
Some college or technical school . . . . .	5
College graduate . . . . .	6
Some post-college . . . . .	7
DON'T KNOW . . . . .	DK

D6h. Does (NAME) smoke tobacco products? (CIRCLE RESPONSE IN COLUMN H.)

YES . . . . .	Y ÷ CONTINUE
NO . . . . .	N ÷ GO TO D9j
DON'T KNOW . . . . .	DK ÷ GO TO D9j

D6i. Does (NAME) smoke inside the house? (CIRCLE RESPONSE IN COLUMN I.)

YES . . . . .	Y
NO . . . . .	N
DON'T KNOW . . . . .	DK

D6j. Does (NAME) work outside the home? (CIRCLE RESPONSE IN COLUMN J.)

YES . . . . .	Y
NO . . . . .	N
DON'T KNOW . . . . .	DK

D6k. Does (NAME) attend school or day care outside the home? (CIRCLE RESPONSE IN COLUMN K.)

YES . . . . .	Y
NO . . . . .	N
DON'T KNOW . . . . .	DK

## HOUSE CHARACTERISTICS

D7. I would now like to ask you a few questions about your home. Is your home... (READ CHOICES AND CIRCLE ONE. INCLUDE ALL APARTMENTS, FLATS, ETC., EVEN IF VACANT.)

- |  |    |
|--|----|
| A mobile home or trailer . . . . .                             | 1  |
| A one-family house detached from any<br>other house . . . . .  | 2  |
| A one-family house attached to one or<br>more houses . . . . . | 3  |
| A building with 2 apartments . . . . .                         | 4  |
| A building with 3 or 4 apartments . . . . .                    | 5  |
| A building with 5 to 9 apartments . . . . .                    | 6  |
| A building with 10 to 19 apartments . . . . .                  | 7  |
| A building with 20 to 49 apartments . . . . .                  | 8  |
| A building with 50 or more apartments . . . . .                | 9  |
| Other (Specify: _____)   | 10 |

D8. How many rooms are there in this house or apartment? Do NOT count bathrooms, porches, balconies, foyers, or halls.

\_\_\_\_\_ Rooms

D9. Is this house or apartment... (READ CHOICES AND CIRCLE ONE.)

- |  |    |
|--|----|
| Owning by you or someone in this household with<br>a mortgage or loan? . . . . .             | 1  |
| Owning by you or someone in this household free<br>and clear (without a mortgage)? . . . . . | 2  |
| Rented for cash rent? . . . . .  | 3  |
| Occupied without payment of cash rent? . . . . .   | 4  |
| DON'T KNOW . . . . .   | DK |

## **RESPONDENT SELECTION**

- D10. a. WHAT IS THE ROSTER LINE NUMBER OF THE SELECTED PARTICIPANT? ENTER "00" IF NO ONE IS SELECTED AND GO TO QUESTION D11.

<input type="text"/>	<input type="text"/>
----------------------	----------------------

- b. OBTAIN FULL NAME OF SELECTED PARTICIPANT.

FULL NAME OF PARTICIPANT

---

- c. IF PARTICIPANT IS UNDER 18, OBTAIN FULL NAME OF PARTICIPANT'S GUARDIAN.

FULL NAME OF GUARDIAN

---

- D11. My supervisor needs to call some of the people I talk with in order to verify my work.

- a. Do you have a telephone in this house or apartment?

YES .....	Y ÷	CONTINUE
NO .....	N ÷	GO TO D11c
DON'T KNOW .....	DK ÷	GO TO D11c
REFUSED .....	RE ÷	END OF SCREENING. ENTER FINAL RESULT CODE AND THANK RESPONDENT.

- b. What is the telephone number, starting with the area code?

(\_\_\_\_\_) - \_\_\_\_ - \_\_\_\_\_ . . . . . ÷ GO TO D12

c. Is there a telephone on which you can receive calls?

YES . . . . . Y ÷ CONTINUE

NO . . . . . N ÷ END OF  
SCREENING.

REFUSED . . . . . RE ÷ ENTER FINAL  
RESULT CODE  
AND THANK  
RESPONDENT

d. What is the telephone number, starting with the area code?

(\_\_\_\_\_) - \_\_\_\_ - \_\_\_\_\_

D12. When would be a good time to call you?

---

ENTER FINAL RESULT CODE AND THANK RESPONDENT.

## HOUSEHOLD ROSTER

NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

*BASELINE QUESTIONNAIRE*

Participant Identification Number

---

(Record ID Here)

Public reporting burden for this collection of information is estimated to average 25 minutes per response), and to require 0 hours recordkeeping. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

INTERVIEWER/TECHNICIAN ID: \_\_\_\_\_

Date Completed: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

August 2, 1995

# NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

## BASELINE QUESTIONNAIRE

=====

### DESIGNATED PARTICIPANT

(If the participant is less than 10 years old, what is the name of the individual who is providing the answers for the designated respondent?)

Name of Participant\_\_\_\_\_

Completed by\_\_\_\_\_ (if other than participant)

Relation to participant\_\_\_\_\_

Home Phone\_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_

=====

### LOCATION DATA (Technician Completed--address/ID label)

State\_\_\_\_\_ County\_\_\_\_\_

Census Tract\_\_\_\_\_ Block\_\_\_\_\_

Street Address\_\_\_\_\_ / \_\_\_\_\_

Apt./Space #

City, Zip\_\_\_\_\_ / \_\_\_\_\_

Zip code

=====

INTERVIEWER/TECHNICIAN ID: \_\_\_\_\_ Date Completed: \_\_\_/\_\_\_/\_\_\_

=====

## **DEMOGRAPHICS**

These first questions ask about (you/this child). (REMIND PARENT/GUARDIAN TO RESPOND FOR CHILD.)

- B1. What is the highest level of school (you have/this child has) completed? (READ CHOICES AND CIRCLE ONE. IF CURRENTLY ENROLLED, MARK THE LEVEL OF PREVIOUS GRADE COMPLETED OR HIGHEST DEGREE RECEIVED.)

No school completed or Kindergarten only . . . . .	1
Primary or middle school (Grade 1-8) . . . . .	2
Some high school (Grade 9-11) . . . . .	3
High school graduate (Grade 12 or GED) . . . . .	4
Some college or technical school . . . . .	5
College graduate . . . . .	6
Some post college . . . . .	7

- B2. CIRCLE SEX OF PARTICIPANT.

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

- B3. What is (your/his/her) date of birth? \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

- B4. How tall (are you/is he/she) without shoes? \_\_\_\_ ft \_\_\_\_ inches

- B5. How much (do you/does he/she) weigh? \_\_\_\_\_ pounds

ASK QUESTIONS B6 AND B7 ONLY IF RESPONDENT IS 10 YEARS OLD OR MORE. IF RESPONDENT IS LESS THAN 10, GO TO INTRODUCTION ABOVE B8.

- B6a. (Do you/Does he/she) currently smoke tobacco products or use smokeless tobacco products? (CIRCLE "Y" OR "N.")

YES . . . . .	Y ÷ GO TO B7a
NO . . . . .	N ÷ CONTINUE
DON'T KNOW . . . . .	DK ÷ CONTINUE

B6b. (Have you/Has he/she) ever smoked tobacco products or used smokeless tobacco products?  
(CIRCLE "Y" OR "N")

YES . . . . .	Y ÷	CONTINUE
NO . . . . .	N ÷	GO TO INTRODUCTION ABOVE B8
DON'T KNOW . . . . .	DK ÷	CONTINUE

B6c. How long ago did (you/he/she) stop using tobacco products? (ENTER NUMBER OR "DK")  
\_\_\_\_\_ ÷ GO TO INTRODUCTION ABOVE B8

B7a. On average, how many **cigarettes** (do you/does he/she) smoke *per day*? (READ CHOICES AND CIRCLE ONE.)

None . . . . .	1
Less than ½ pack . . . . .	2
½ pack or more, but less than 1 pack . . .	3
1 pack or more, but less than 1½ packs . . .	4
1½ packs or more, but less than 2 packs . . .	5
2 or more packs . . . . .	6
Occasional (social smoker) . . . . .	7
DON'T KNOW . . . . .	DK

B7b. On average, how many **cigars** (do you/does he/she) smoke per day? \_\_\_\_\_

B7c. On average, how many **pipefuls of tobacco** (do you/does he/she) smoke per day? \_\_\_\_\_

B7d. On average, how many times per day (do you/does he/she) use **smokeless tobacco products**?  
\_\_\_\_\_

## **PERSONAL EXPOSURE ACTIVITIES**

These next few questions are about things that happen at your home, on the job, or in school, and food (you/he/she) eat(s) that might put (you/him/her) in touch with the chemicals we are studying. Some of these questions ask about different periods of time. Some ask about the *past month*, some ask about the *past 3 months*, and some ask about the *past 6 months*. In order to help make these time periods clear, please think about something (you/he/she) did or which happened to (you/him/her) about *1 month ago*, *3 months ago*, and *6 months ago*. For example, finished school, got married, had a baby. Please tell me what each event was so that I can use them later. (RECORD EVENTS HERE AND USE AS NEEDED DURING INTERVIEW.)

1 MONTH EVENT: \_\_\_\_\_

3 MONTH EVENT: \_\_\_\_\_

6 MONTH EVENT: \_\_\_\_\_

- B8. On average for the *past month*, how many (hours/minutes) *per week* did (you/he/she) spend.... (IF LESS THAN 1 HOUR, ROUND TO THE NEAREST QUARTER HOUR; IF LESS THAN 10 HOURS, ROUND TO THE NEAREST HOUR; IF GREATER THAN 10 HOURS, ROUND TO THE NEAREST 10 HOURS, E.G., 10, 20, 30, 40, 50 HOURS. ENTER NUMBER AND CIRCLE MIN OR HR.)
- Inside (your/his/her) home with someone who was smoking tobacco? \_\_\_\_\_ (min/hr)
  - At work with someone who was smoking tobacco? \_\_\_\_\_ (min/hr)
  - In a car, bus, van, or other enclosed vehicle with someone who was smoking tobacco?  
\_\_\_\_\_ (min/hr)
  - In any other indoor or enclosed location with someone who was smoking tobacco?  
\_\_\_\_\_ (min/hr)

- B9. During the *past month*, has anyone, including you, smoked inside your home? (CIRCLE ONE.)

YES . . . . .	Y
NO . . . . .	N
DON'T KNOW . . . . .	DK

- B10a. On average for the *past month*, on how many days did (you/he/she) paint walls, furniture, cars or other objects? (READ CHOICES AND CIRCLE ONE.)

Never . . . . .	1
1-3 days per month . . . . .	2
1-2 days per week . . . . .	3
3-6 days per week . . . . .	4
Daily . . . . .	5
DON'T KNOW . . . . .	DK

- B10b. On average for the ***past month***, on how many days did (you/he/she) use chemical paint strippers to remove paint? (READ CHOICES AND CIRCLE ONE.)

Never . . . . .	1
1-3 days per month . . . . .	2
1-2 days per week . . . . .	3
3-6 days per week . . . . .	4
Daily . . . . .	5
DON'T KNOW . . . . .	DK

- B10c. On average for the ***past month***, on how many days did (you/he/she) remove paint by other methods such as scraping, heat gun or sanding? (READ CHOICES AND CIRCLE ONE.)

Never . . . . .	1
1-3 days per month . . . . .	2
1-2 days per week . . . . .	3
3-6 days per week . . . . .	4
Daily . . . . .	5
DON'T KNOW . . . . .	DK

- B10d. During the ***past three months***, on how many days (did you/did he/she) use lead solder to solder pipes, do electronic repairs, or join pieces of stained glass? (READ CHOICES AND CIRCLE ONE.)

Never . . . . .	1
1-3 days per month . . . . .	2
1-2 days per week . . . . .	3
3-6 days per week . . . . .	4
Daily . . . . .	5
DON'T KNOW . . . . .	DK

- B10e. During the ***past three months***, on how many days (did you/did he/she) use lead-based oil paint to paint pictures or jewelry? (READ CHOICES AND CIRCLE ONE.)

Never . . . . .	1
1-3 days per month . . . . .	2
1-2 days per week . . . . .	3
3-6 days per week . . . . .	4
Daily . . . . .	5
DON'T KNOW . . . . .	DK

- B10f. During the ***past three months***, on how many days (did you/did he/she) mold lead into fishing sinkers, bullets, or other objects? (READ CHOICES AND CIRCLE ONE.)

Never . . . . .	1
1-3 days per month . . . . .	2
1-2 days per week . . . . .	3
3-6 days per week . . . . .	4
Daily . . . . .	5
DON'T KNOW . . . . .	DK

- B11. During the ***past three months***, on how many days (did you/did he/she) eat fresh fruits or vegetables grown at your home? (READ CHOICES AND CIRCLE ONE.)

Never . . . . .	1
1-3 days per month . . . . .	2
1-2 days per week . . . . .	3
3-6 days per week . . . . .	4
Daily . . . . .	5
DON'T KNOW . . . . .	DK

- B12a. How often (do you/does he/she) eat fish caught by you or someone you know? (READ CHOICES AND CIRCLE ONE.)

Never . . . . .	1 ÷ GO TO B13
Less than once a year . . . . .	2 ÷ CONTINUE
Less than once a month . . . . .	3 ÷ CONTINUE
1 to 3 times a month . . . . .	4 ÷ CONTINUE
1 to 3 times a week . . . . .	5 ÷ CONTINUE
More than 3 times a week . . . . .	6 ÷ CONTINUE

- B12b. Where were these fish caught? (READ CHOICES AND CIRCLE ALL THAT APPLY)

Ocean . . . . .	1
Great Lakes . . . . .	2
Other lakes, ponds, rivers . . . . .	3
DON'T KNOW . . . . .	DK

- B13. Do you currently work full time or part time at any location away from your home? (CIRCLE "Y" OR "N." INCLUDE WORKING FOR OTHERS, SELF-EMPLOYED, AND VOLUNTEER WORK. INCLUDE THOSE WHO WORK OUT OF A HOME OFFICE IF THEY WORK PART OF THE TIME AWAY FROM HOME.)

YES . . . . .	Y ÷ CONTINUE
NO . . . . .	N ÷ GO TO B17a

- B14a. On average for the *past month*, how many hours *per week* did (you he/she) work at (your/his/her) primary job? (INCLUDE WEEKS WHERE TIME WAS TAKEN OFF FOR VACATION, SICKNESS, ETC. IF LESS THAN 10 HOURS, ROUND TO THE NEAREST HOUR; IF GREATER THAN 10 HOURS, ROUND TO THE NEAREST 10 HOURS; e.g., 10, 20, 30, 40, 50 HOURS.)

\_\_\_\_\_ hours per week

- i. On average, how many of these hours were spent working at home?

\_\_\_\_\_ hours per week

- B14b. What kind of business or industry is this? (For example, manufacturing, retail store, government, farm, school.)

\_\_\_\_\_

- B14c. What is (your/his/her) job title? (For example, electrical engineer, stock clerk, typist, farmer.)

\_\_\_\_\_

- B14d. What activities (do you/does he/she) perform most often as part of (your/his/her) duties at that job? (For example, typing, keeping account books, filing, selling cars, operating printing press, finished concrete.)

\_\_\_\_\_

- B14e. (Do you/Does he/she) wear protective clothing while at (your/his/her) primary job? (CIRCLE "Y" OR "N.")

YES ..... Y ÷ CONTINUE  
NO ..... N ÷ GO TO B14g

- B14f. Which types of protective clothing (do you/does he/she) wear while at (your/his/her) primary job? (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Gloves .....	1
Overalls .....	2
Overcoat (e.g., lab coat; smock) .....	3
Respirator .....	4
Other (SPECIFY: _____)	5
DON'T KNOW .....	DK

B14g. While at (your/his/her) primary job, (do you/does he/she) come into contact at least once a week with... (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Saw dust?	1
Road dust?	2
Fiberglass?	3
Silica (sand blasting)?	4
Mine dust?	5
Surface dust in office, classroom, store?	6
Other know type of dust? (SPECIFY: _____)	7
Unknown type of dust?	8
NO CONTACT WITH DUST	9

B14h. While at (your/his/her) primary job, (do you/does he/she) come into contact at least once a week with (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Welding fumes?	1
Solder or flux fumes?	2
Plastic fumes?	3
Paint fumes? (include varnish, shellac, etc.)	4
Gasoline or diesel fumes?	5
Other known type of fumes, smoke, gas, or vapors? (SPECIFY; _____)	6
Unknown type of fumes, smoke, gas, or vapors?	7
NO CONTACT WITH FUMES, SMOKE, GAS, OR VAPORS	8

B15. Do you have a second job? (CIRCLE "Y" OR "N.")

YES	Y ÷ CONTINUE
NO	N ÷ GO TO B17a

B16a. On average for the *past month*, how many hours *per week* did (you he/she) work at (your/his/her) second job? (INCLUDE WEEKS WHERE TIME WAS TAKEN OFF FOR VACATION, SICKNESS, ETC. IF LESS THAN 10 HOURS, ROUND TO THE NEAREST HOUR; IF GREATER THAN 10 HOURS, ROUND TO THE NEAREST 10 HOURS; e.g., 10, 20, 30, 40, 50 HOURS.)

\_\_\_\_\_ hours per week

i. On average, how many of these hours were spent working at home?

\_\_\_\_\_ hours per week

B16b. What kind of business or industry is this? (For example, manufacturing, retail store, government, farm, school.)

---

B16c. What is (your/his/her) job title? (For example, electrical engineer, stock clerk, typist, farmer.)

---

B16d. What activities (do you/does he/she) perform most often as part of (your/his/her) duties at that job? (For example, typing, keeping account books, filing, selling cars, operating printing press, finished concrete.)

---

B16e. (Do you/Does he/she) wear protective clothing while at (your/his/her) second job? (CIRCLE "Y" OR "N.")

YES ..... Y ÷ CONTINUE  
NO ..... N ÷ GO TO B16g

B16f. Which types of protective clothing (do you/does he/she) wear while at (your/his/her) second job? (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Gloves .....	1
Overalls .....	2
Overcoat (e.g., lab coat; smock) .....	3
Respirator .....	4
Other (SPECIFY: _____)	5
DON'T KNOW .....	DK

B16g. While at (your/his/her) second job, (do you/does he/she) come into contact at least once a week with (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Saw dust? .....	1
Road dust? .....	2
Fiberglass? .....	3
Silica (sand blasting)? .....	4
Mine dust? .....	5
Surface dust in office, classroom, store? .....	6
Other know type of dust? (SPECIFY: _____)	7
Unknown type of dust? .....	8
NO CONTACT WITH DUST .....	9

- B16h. While at (your/his/her) second job, (do you/does he/she) come into contact at least once a week with... (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Welding fumes? . . . . .	1
Solder or flux fumes? . . . . .	2
Plastic fumes? . . . . .	3
Paint fumes? (include varnish, shellac, etc.) . . . . .	4
Gasoline or diesel fumes? . . . . .	5
Other known type of fumes, smoke, gas, or vapors? (SPECIFY: _____)	6
Unknown type of fumes, smoke, gas, or vapors? . . . . .	7
NO CONTACT WITH FUMES, SMOKE, GAS, OR VAPORS . . . . .	8

- B17a. Do you attend classes as a student at any location away from your home? (CIRCLE "Y" OR "N." INCLUDE ELEMENTARY AND SECONDARY SCHOOLS, COLLEGES AND UNIVERSITIES, BUSINESS SCHOOL, TRADE AND VOCATIONAL SCHOOLS.)

YES . . . . .	Y ÷ CONTINUE
NO . . . . .	N ÷ GO TO B18

- B17b. On average for the *past month*, how many hours *per week* did (you/he/she) attend classes as a student? (INCLUDE WEEKS WHERE TIME WAS TAKEN OFF FOR VACATION, SICKNESS, ETC. IF LESS THAN 10 HOURS, ROUND TO THE NEAREST HOUR; IF GREATER THAN 10 HOURS, ROUND TO THE NEAREST 10 HOURS; e.g., 10, 20, 30, 40, 50 HOURS.)

\_\_\_\_\_ hours per week

- B18. FOR CHILDREN LESS THAN 6 YEARS OF AGE, CONTINUE WITH QUESTION B18a. OTHERWISE GO TO QUESTION B19.

- a. *On average*, how many hours *per week* does (he/she) spend away from the home, for example, at daycare, in a preschool, or at a neighbor's house? (IF LESS THAN 10 HOURS, ROUND TO THE NEAREST HOUR; IF GREATER THAN 10 HOURS, ROUND TO THE NEAREST 10 HOURS; e.g., 10, 20, 30, 40, 50 HOURS.)

\_\_\_\_\_ hours per week (IF ZERO, GO TO B19)

- b. Where does (he/she) spend this time away from home? (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Another home . . . . .	1
Daycare center, nursery school, or preschool . . . . .	2
Other school . . . . .	3
Other (SPECIFY: _____)	4

B19. What methods of transportation did (you/he/she) use to go to work, school, or daycare in the *past six months*? (READ CHOICES AND CIRCLE ALL THAT APPLY.)

- |  |   |
|--|---|
| Car, truck, van, or taxi cab . . . . .     | 1 |
| Bus, trolley bus, or trolley car . . . . . | 2 |
| Train, subway or elevated train . . . . .  | 3 |
| Motorcycle . . . . .                       | 4 |
| Bicycle . . . . .                          | 5 |
| Walk . . . . .                             | 6 |
| Other method (SPECIFY: _____) .            | 7 |

## **HEALTH STATUS**

B20. Overall, how would you describe (your/his/her) current health? (READ CHOICES AND CIRCLE ONE.)

- |                |   |
|----------------|---|
| Good . . . . . | 1 |
| Fair . . . . . | 2 |
| Poor . . . . . | 3 |

B21. (Have you/Has he/she) ever had any of the following? (READ CHOICES AND CIRCLE "Y" OR "N." IF YES, ASK SUB-QUESTIONS. IF PARTICIPANT IS UNCERTAIN, CIRCLE "N" AND CONTINUE WITH THE NEXT CONDITION.)

		Were you told (you/he/she) had this by a doctor or nurse?	(Do you/ he/she) have it now?	How old (were you/was he/she) when the doctor or nurse first told you?
a.	Diabetes?	Y ÷ N	Y ÷ N	Y ÷ N _____
b.	Neuromuscular disability, such as Polio, Multiple Sclerosis, Muscular Dystrophy?	Y ÷ N	Y ÷ N	Y ÷ N _____
c.	Asthma, allergies?	Y ÷ N	Y ÷ N	Y ÷ N _____
d.	Ulcer?	Y ÷ N	Y ÷ N	Y ÷ N _____
e.	Gastritis?	Y ÷ N	Y ÷ N	Y ÷ N _____
f.	FREQUENT indigestion?	Y ÷ N	Y ÷ N	Y ÷ N _____
g.	Any other stomach trouble?	Y ÷ N	Y ÷ N	Y ÷ N _____

IF YES, PLEASE SPECIFY: \_\_\_\_\_

h.	FREQUENT constipation?	Y ÷ N	Y ÷ N	Y ÷ N _____
i.	Cirrhosis of the liver?	Y ÷ N	Y ÷ N	Y ÷ N _____
j.	Fatty liver?	Y ÷ N	Y ÷ N	Y ÷ N _____
k.	Hepatitis?	Y ÷ N	Y ÷ N	Y ÷ N _____

		Were you told (you/he/she) had this by a doctor or nurse?	(Do you/ he/she) have it now?	How old (were you/was he/she) when the doctor or nurse first told you?
l. Yellow jaundice?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	_____
m. Nephritis	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	_____
n. Kidney stones?	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	<input type="checkbox"/> Y <input type="checkbox"/> N	_____
o. Any disease requiring chemotherapy?	<input type="checkbox"/> Y <input type="checkbox"/> N	How long ago did (you/he/she) last have chemotherapy? _____		

IF YES, PLEASE SPECIFY DISEASE: \_\_\_\_\_

## BASIC HOUSING CHARACTERISTICS

These next questions are about your (house/apartment). Please feel free to ask another member of your household for assistance if necessary.

B22. Is this property actively used as a farm or ranch? (CIRCLE "Y" OR "N.")

YES . . . . .	Y
NO . . . . .	N

B23. About when was this building first built? (READ CHOICES AND CIRCLE ONE.)

1990 TO PRESENT . . . . .	1
1985 TO 1989 . . . . .	2
1980 TO 1984 . . . . .	3
1970 TO 1979 . . . . .	4
1960 TO 1969 . . . . .	5
1950 TO 1959 . . . . .	6
1940 TO 1949 . . . . .	7
1939 OR EARLIER . . . . .	8
DON'T KNOW . . . . .	DK

B24. When did (you/he/she) move into this (house/apartment)? (READ CHOICES AND CIRCLE ONE.)

1990 TO PRESENT . . . . .	1
1985 TO 1989 . . . . .	2
1980 TO 1984 . . . . .	3
1970 TO 1979 . . . . .	4
1960 TO 1969 . . . . .	5
1950 TO 1959 . . . . .	6
1940 TO 1949 . . . . .	7
1939 OR EARLIER . . . . .	8
DON'T KNOW . . . . .	DK

B25. In the last six months, have any of the following been performed in this home? (CIRCLE "Y" OR "N.")

	<u>YES</u>	<u>NO</u>
Adding a room . . . . .	Y	N
Putting up or taking down a wall . . . . .	Y	N
Replacing windows . . . . .	Y	N
Refinishing floors . . . . .	Y	N
Exterior painting . . . . .	Y	N
Interior painting . . . . .	Y	N

B26a. Does this (house/apartment) have running water? (CIRCLE "Y" OR "N.")

YES . . . . . Y ÷ CONTINUE  
NO . . . . . N ÷ GO TO B26c

B26b. What is the source of the running water in your house/apartment? (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Public or commercial water system . . . . . 1  
(SPECIFY NAME \_\_\_\_\_)  
Private well . . . . . 2  
Cistern . . . . . 3  
Some other source (SPECIFY: \_\_\_\_\_) 4  
DON'T KNOW . . . . . DK

B26c. Which water source is used **most often** (more than half the time) for cooking? (READ CHOICES AND CIRCLE ONE.)

Tap water . . . . . 1  
Bottled water . . . . . 2  
Some other source (SPECIFY: \_\_\_\_\_) 3  
DON'T KNOW . . . . . DK

B26d. Which water source is used **most often** (more than half the time) for drinking? (READ CHOICES AND CIRCLE ONE.)

Tap water . . . . . 1  
Bottled water . . . . . 2  
Some other source (SPECIFY: \_\_\_\_\_) 3  
DON'T KNOW . . . . . DK

B26e. Do you use any of the following to treat your water at home? (CIRCLE "Y" or "N" FOR EACH TREATMENT TYPE.)

		YES	NO	DON'T KNOW
i.	Water Softener . . . . .	Y	N	DK
ii.	Charcoal Filter . . . . .	Y	N	DK
iii.	Reverse Osmosis . . . . .	Y	N	DK
iv.	Distilling . . . . .	Y	N	DK
v.	Other (SPECIFY: _____)	Y	N	DK

B27a. Is there an enclosed garage attached to this (house/apartment)? (CIRCLE "Y" OR "N.")

YES . . . . . Y ÷ CONTINUE  
NO . . . . . N ÷ GO TO B28

B27b. Where is the attached garage? (READ CHOICES AND CIRCLE ONE.)

Underneath the main living quarters . . . . .	1
Same level as the main living quarters . . . . .	2
Somewhere else; (SPECIFY: _____)	3

B27c. Is there a doorway leading directly from the garage into the living quarters? (CIRCLE "Y" OR "N.")

YES . . . . .	Y
NO . . . . .	N

B27d. Are automobiles, vans, trucks or other motor vehicles parked in this attached garage? (CIRCLE "Y" OR "N".)

YES . . . . .	Y
NO . . . . .	N

B28. Are any gas powered devices stored in any room, basement, or attached garage in this (house/apartment)? (CIRCLE ONE. DO NOT INCLUDE CARS, VANS, OR TRUCKS. DO INCLUDE MOTORCYCLES, GAS- POWERED LAWN MOWERS, TRIMMERS OR BLOWERS, BOAT ENGINES, ETC.)

YES . . . . .	Y
NO . . . . .	N
DON'T KNOW . . . . .	DK

B29a. Is air conditioning (refrigeration) used to cool this (house/apartment)? (CIRCLE "Y" OR "N.")

YES . . . . .	Y ÷ CONTINUE
NO . . . . .	N ÷ GO TO B30

B29b. Which types of air conditioning units do you use? (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Central unit/units . . . . .	1
Window or wall unit/units . . . . .	2
Portable unit/units . . . . .	3

- B29c. During which month (do you *usually*/would you) start using air conditioning to cool this (house/apartment)?

During which month (do you *usually*/would you) stop using air conditioning?  
(CIRCLE THE START AND STOP MONTHS.)

Start Month:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Stop Month:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec

- B30. Which fuels are used for heating this (house/apartment)? (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Gas: from underground pipes serving the neighborhood . . . . .	1
Gas: bottled, tank, or LP . . . . .	2
Electricity . . . . .	3
Fuel oil, kerosene, etc. . . . .	4
Coal or coke . . . . .	5
Wood . . . . .	6
Solar energy . . . . .	7
Other fuel (SPECIFY: _____) . . . . .	8
NO FUEL USED . . . . .	9
DON'T KNOW . . . . .	DK

- B31. Does this (house/apartment) have a central heating system with ducts that blow air into most rooms? (CIRCLE "Y" OR "N.")

YES . . . . .	Y
NO . . . . .	N

- B32. During which month (do you *usually*/would you) start using heating devices?

During which month (do you *usually*/would you) stop using heating devices? (CIRCLE THE START AND STOP MONTH.)

Start month:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Stop month:	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec

- B33a. During the months identified in the last question, do you use portable kerosene heaters in this (house/apartment)? (CIRCLE "Y" OR "N.")

YES . . . . .	Y ÷ CONTINUE
NO . . . . .	N ÷ GO TO B34

- B33b. How many kerosene heaters did you use *last year*? \_\_\_\_\_

B33c. How often do you use your kerosene heater *during the heating season*? (READ CHOICES AND CIRCLE ONE.)

- |  |   |
|--|---|
| Less than once a month . . . . .       | 1 |
| One to three times per month . . . . . | 2 |
| Once or twice a week . . . . .         | 3 |
| 3-5 times a week . . . . .             | 4 |
| More than 5 times a week . . . . .     | 5 |

B34a. *During the heating season*, is a portable or nonvented gas heater used in this (house/apartment)? (CIRCLE "Y" OR "N.")

- |               |               |
|---------------|---------------|
| YES . . . . . | Y ÷ CONTINUE  |
| NO . . . . .  | N ÷ GO TO B35 |

B34b. How many gas heaters? \_\_\_\_\_

B34c. How often is a portable or nonvented gas heater used? (READ CHOICES AND CIRCLE ONE.)

- |  |   |
|--|---|
| Less than once a month . . . . .       | 1 |
| One to three times per month . . . . . | 2 |
| Once or twice a week . . . . .         | 3 |
| 3-5 times a week . . . . .             | 4 |
| More than 5 times a week . . . . .     | 5 |

B35a. *During the heating season*, is a wood-burning or coal-burning stove used in this (house/apartment)? (CIRCLE "Y" OR "N.")

- |               |               |
|---------------|---------------|
| YES . . . . . | Y ÷ CONTINUE  |
| NO . . . . .  | N ÷ GO TO B36 |

B35b. How many wood or coal-burning stoves? \_\_\_\_\_

B35c. How often is a wood-burning or coal-burning stove used *during the heating season*? (READ CHOICES AND CIRCLE ONE.)

- |  |   |
|--|---|
| Less than once a month . . . . .       | 1 |
| One to three times per month . . . . . | 2 |
| Once or twice a week . . . . .         | 3 |
| 3-5 times a week . . . . .             | 4 |
| More than 5 times a week . . . . .     | 5 |

B35d. What is burned in the stove? (READ CHOICES AND CIRCLE ONE.)

Wood . . . . .	1
Coal . . . . .	2
Other: (SPECIFY: _____)	3

B36a. *During the heating season*, is a fireplace used in this (house/apartment)? (CIRCLE "Y" OR "N.")

YES . . . . .	Y ÷ CONTINUE
NO . . . . .	N ÷ GO TO B37

B36b. How many fireplaces? \_\_\_\_\_

B36c. How often is a fireplace used *during the heating season*? (READ CHOICES AND CIRCLE ONE.)

Less than once a month . . . . .	1
One to three times per month . . . . .	2
Once or twice a week . . . . .	3
3-5 times a week . . . . .	4
More than 5 times a week . . . . .	5

B36d. What is burned in the fireplace? (READ CHOICES AND CIRCLE ALL THAT APPLY.)

Wood . . . . .	1
Artificial logs . . . . .	2
Gas fire . . . . .	3
Other (SPECIFY: _____) . . .	4

B37. During the *past six months* have mothballs been used in this (house/apartment)? (CIRCLE "Y" OR "N.")

YES . . . . .	Y
NO . . . . .	N

B38. During the *past six months* have room deodorizers been used in this (house/apartment)? (CIRCLE "Y" OR "N.")

YES . . . . .	Y
NO . . . . .	N

B39a. Do you have house pets such as dogs, cats, gerbils, hamsters, rabbits, guinea pigs, or birds?  
(CIRCLE "Y" OR "N.")

YES . . . . . Y ÷ CONTINUE  
NO . . . . . N ÷ GO TO B40

B39b. How many of these pets are kept indoors most of the time? \_\_\_\_\_

B39c. How many of these pets are kept outdoors most of the time? \_\_\_\_\_

B39d. How many of these pets are kept both indoors AND outdoors? \_\_\_\_\_

## FAMILY INCOME

B40. Family income is often used in scientific studies to create groups of people who are similar. We do some analysis of the data using these groups. Please remember that all the data you provide is held in strict confidence.

Approximately what is the gross annual income for all family members in this household? (HAND SHOWCARD TO RESPONDENT.) Please tell me the number on this card. (IF RESPONDENT PROVIDES ANSWER DIRECTLY, CIRCLE NUMBER BELOW.

Less than \$9,999 . . . . .	1
\$ 10,000 - \$ 19,999 . . . . .	2
\$ 20,000 - \$ 29,999 . . . . .	3
\$ 30,000 - \$ 39,999 . . . . .	4
\$ 40,000 - \$ 49,999 . . . . .	5
\$ 50,000 - \$ 74,999 . . . . .	6
\$ 75,000 - \$ 99,999 . . . . .	7
\$100,000 or more . . . . .	8
DON'T KNOW . . . . .	DK
REFUSE . . . . .	RE

NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

*TIME DIARY AND ACTIVITY QUESTIONNAIRE*

Participant Identification Number

---

(Record ID Here)

Public reporting burden for this collection of information is estimated to average 1 hour, and to require 0 hours recordkeeping. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

INTERVIEWER/TECHNICIAN ID: \_\_\_\_\_

Date Completed: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

August 2, 1995

**NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY**

**TIME DIARY AND ACTIVITY QUESTIONNAIRE**

=====

**DESIGNATED PARTICIPANT**

(If the participant is less than 10 years old, what is the name of the individual who is providing the answers for the designated respondent?)

Name of Participant\_\_\_\_\_

Completed by\_\_\_\_\_ (if other than participant)

Relation to participant\_\_\_\_\_

Home Phone\_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_

=====

**LOCATION DATA (Technician Completed--address/ID label)**

State\_\_\_\_\_ County\_\_\_\_\_

Census Tract\_\_\_\_\_ Block \_\_\_\_\_

Street Address\_\_\_\_\_ / \_\_\_\_\_

Apt./Space #

City, Zip\_\_\_\_\_ / \_\_\_\_\_

Zip code

=====

**INTERVIEWER/TECHNICIAN ID:** \_\_\_\_\_

**Date Completed:** \_\_\_/\_\_\_/\_\_\_

=====

## NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

### TIME DIARY AND ACTIVITY QUESTIONNAIRE

At the end of each day, take a few minutes to record the time (you/your child) spent in each of the seven listed locations. There is one box for each day of the study. The numbers in the box stand for hours of the day. For example, 5 in the morning is 5:00 a.m. to 5:59 a.m. Complete the box by putting an X through each hour during which (you/your child) spent any time at any of the listed locations. These X's are to help you remember where (you were/your child was) throughout the day so you can estimate the total number of hours and minutes in each location. In the last column, write the total amount of time spent in each place. The numbers in the last column should add up to 24 hours. If the numbers don't add up to 24 hours, review your estimates of time spent in each location and correct errors.

The terms used in the time diary are defined as follows:

- Home: The house or apartment where (you live/your child lives); the location where we are collecting samples.
- Work: A place away from home where (you work/your child works).
- School: A place away from home where (you attend/your child attends) school.
- Transit: Any travel from one location to another, including all travel between such places as home, school, and shopping centers, as well as all other travel on roads, paths, or trails.
- Other: All other places (you spend/your child spends) time besides home, work, school, and in transit between locations.

	Location	Morning	Afternoon	Evening	Early Morning (Night time)	Amount of Time
Day 1 Day of Week	Inside at Home Inside at Work and School Inside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
DATE / /	Outside at Home Outside at Work and School Outside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
	In Transit	5 6 7 8 9 10 11	12 1 2 3 4 5	6 7 8 9 10 11	12 1 2 3 4	Hrs Min

PLEASE ALSO COMPLETE THE COLUMN FOR DAY 1 STARTING ON PAGE 6.

Total Daily Time Expenditure must add up to 24 Hrs

	Location	Morning	Afternoon	Evening	Early Morning (Night time)	Amount of Time
Day 2 Day of Week	Inside at Home Inside at Work and School Inside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
DATE / /	Outside at Home Outside at Work and School Outside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
	In Transit	5 6 7 8 9 10 11	12 1 2 3 4 5	6 7 8 9 10 11	12 1 2 3 4	Hrs Min

PLEASE ALSO COMPLETE THE COLUMN FOR DAY 2 STARTING ON PAGE 6.

Total Daily Time Expenditure must add up to 24 Hrs

	Location	Morning	Afternoon	Evening	Early Morning (Night time)	Amount of Time
Day 3 Day of Week	Inside at Home Inside at Work and School Inside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
DATE / /	Outside at Home Outside at Work and School Outside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
	In Transit	5 6 7 8 9 10 11	12 1 2 3 4 5	6 7 8 9 10 11	12 1 2 3 4	Hrs Min

PLEASE ALSO COMPLETE THE COLUMN FOR DAY 3 STARTING ON PAGE 6.

Total Daily Time Expenditure must add up to 24 Hrs

	Location	Morning	Afternoon	Evening	Early Morning (Night time)	Amount of Time
Day 4 Day of Week	Inside at Home Inside at Work and School Inside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
DATE / /	Outside at Home Outside at Work and School Outside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
	In Transit	5 6 7 8 9 10 11	12 1 2 3 4 5	6 7 8 9 10 11	12 1 2 3 4	Hrs Min

PLEASE ALSO COMPLETE THE COLUMN FOR DAY 4 STARTING ON PAGE 6.

Total Daily Time Expenditure must add up to 24 Hrs

	Location	Morning	Afternoon	Evening	Early Morning (Night time)	Amount of Time
Day 5 Day of Week	Inside at Home Inside at Work and School Inside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
DATE / /	Outside at Home Outside at Work and School Outside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
	In Transit	5 6 7 8 9 10 11	12 1 2 3 4 5	6 7 8 9 10 11	12 1 2 3 4	Hrs Min

PLEASE ALSO COMPLETE THE COLUMN FOR DAY 5 STARTING ON PAGE 6.

Total Daily Time Expenditure must add up to 24 Hrs

	Location	Morning	Afternoon	Evening	Early Morning (Night time)	Amount of Time
Day 6 Day of Week	Inside at Home Inside at Work and School Inside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
DATE / /	Outside at Home Outside at Work and School Outside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
	In Transit	5 6 7 8 9 10 11	12 1 2 3 4 5	6 7 8 9 10 11	12 1 2 3 4	Hrs Min

PLEASE ALSO COMPLETE THE COLUMN FOR DAY 6 STARTING ON PAGE 6.

Total Daily Time Expenditure must add up to 24 Hrs

	Location	Morning	Afternoon	Evening	Early Morning (Night time)	Amount of Time
Day 7 Day of Week	Inside at Home Inside at Work and School Inside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
DATE / /	Outside at Home Outside at Work and School Outside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
	In Transit	5 6 7 8 9 10 11	12 1 2 3 4 5	6 7 8 9 10 11	12 1 2 3 4	Hrs Min

PLEASE ALSO COMPLETE THE COLUMN FOR DAY 7 STARTING ON PAGE 6.

Total Daily Time Expenditure must add up to 24 Hrs

	Location	Morning	Afternoon	Evening	Early Morning (Night time)	Amount of Time
Day 8 Day of Week	Inside at Home Inside at Work and School Inside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
DATE / /	Outside at Home Outside at Work and School Outside at Other	5 6 7 8 9 10 11 5 6 7 8 9 10 11 5 6 7 8 9 10 11	12 1 2 3 4 5 12 1 2 3 4 5 12 1 2 3 4 5	6 7 8 9 10 11 6 7 8 9 10 11 6 7 8 9 10 11	12 1 2 3 4 12 1 2 3 4 12 1 2 3 4	____ Hrs ____ Min ____ Hrs ____ Min ____ Hrs ____ Min
	In Transit	5 6 7 8 9 10 11	12 1 2 3 4 5	6 7 8 9 10 11	12 1 2 3 4	Hrs Min

PLEASE ALSO COMPLETE THE COLUMN FOR DAY 8 STARTING ON PAGE 6.

Total Daily Time Expenditure must add up to 24 Hrs

DAILY ACTIVITY INFORMATION

	1	2	3	4	5	6	7	8
	Day _____							
	Date / /							
<b>Please circle "Y" for Yes or "N" for No for questions A1-A11.</b>								
A1. Did (you/your child) pump gas today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A2. Did (you/your child) have gasoline in contact with the skin today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A3. Did (you/your child) spend at least 15 minutes in an enclosed garage <u>with</u> a parked car today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A4. Did (you/your child) have soil or dirt in your yard in contact with the skin today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A5. Did (you/your child) have grass or leaves from your yard in contact with the skin today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A6. Did (you/your child) clean a fireplace or wood stove today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A7. Did (you/your child) start or tend a fire in a fireplace or wood stove today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A8. Did (you/your child) use an outdoor grill or burn wood, leaves, or trash today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A9. Were any tobacco products smoked in the home today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A10. Did (you/your child) take a shower today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
A11. Did (you/your child) take a bath today?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N

	1	2	3	4	5	6	7	8
	Day _____  Date / /							

**Please enter the number that answers questions A12-A16.**

A12. How many glasses or cups of water did (you/your child) drink today?	# drinks _____  # times _____  # times							
A13. How many cigarettes did (you/ your child) smoke today?	# cigarettes _____  # times _____  # times							
A14. How many cigars or pipefuls did (you/your child smoke today?	# cigars/- pipefuls _____  # times _____  # times							
A15. How many times did (you/your child) use smokeless tobacco today?	# times _____  # times _____  # times							
A16. How many times did (you/your child) wash (your/his/her) hands today?	# times _____  # times _____  # times							

**In questions A17-A22, please enter time spent. If the time was less than 1 hour, enter 15 min., 30 min., 45 min., or 1 hour, whichever is closest to time actually spent. If time was greater than 1 hour, round to the nearest hour. Circle either min. or hr.**

A17. (You/your child) traveled on roadways or highways today?	min/hr _____  min/hr _____  min/hr							
A18. (You/your child) spent indoors with someone who was smoking?	min/hr _____  min/hr _____  min/hr							
A19. (You/your child) spent in a vehicle with someone who was smoking?	min/hr _____  min/hr _____  min/hr							
A20. (You/your child) spent swimming in indoor or outdoor pools today?	min/hr _____  min/hr _____  min/hr							
A21. (You/your child) spent using cleaning supplies (cleaners, waxes, polishes) today?	min/hr _____  min/hr _____  min/hr							
A22. (You/your child) spent laying down or sitting on the carpet or rugs <b>at home</b> today?	min/hr _____  min/hr _____  min/hr							

	1	2	3	4	5	6	7	8
	Day _____ Date / /							

In questions A23-26, please enter time spent. If the time was less than 1 hour, enter 5 minutes, 10 minutes, 15 minutes, 30 minutes, 45 minutes, or 1 hour, whichever is closest to time actually spent. If time was greater than 1 hour, round to the nearest hour. Circle either min. or hr.

A23. (You/your child) spent in an enclosed workshop or garage used as a workshop today?	min/hr							
A24. Doors and windows <b>at your house</b> were left open for ventilation today?	min/hr							
A25. (You/your child) spent performing vigorous exercise like digging or other heavy manual labor, running, bicycling, aerobic dancing, playing basketball or soccer today?	min/hr							
A26. (You/your child) spent performing moderate exercise like walking, gardening, working while on your feet, or playing softball or golf today?	min/hr							
For Technician Use Only	Comp. <input type="checkbox"/> Asst. <input type="checkbox"/> Do <input type="checkbox"/>	Comp. <input type="checkbox"/> Asst. <input type="checkbox"/> Do <input type="checkbox"/>	Comp. <input type="checkbox"/> Asst. <input type="checkbox"/> Do <input type="checkbox"/>	Comp. <input type="checkbox"/> Asst. <input type="checkbox"/> Do <input type="checkbox"/>	Comp. <input type="checkbox"/> Asst. <input type="checkbox"/> Do <input type="checkbox"/>	Comp. <input type="checkbox"/> Asst. <input type="checkbox"/> Do <input type="checkbox"/>	Comp. <input type="checkbox"/> Asst. <input type="checkbox"/> Do <input type="checkbox"/>	Comp. <input type="checkbox"/> Asst. <input type="checkbox"/> Do <input type="checkbox"/>

NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

*TECHNICIAN WALK-THROUGH QUESTIONNAIRE*

Participant Identification Number

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(Record ID Here)

Public reporting burden for this collection of information is estimated to average 15 minutes per response, and to require 0 hours recordkeeping. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

INTERVIEWER/TECHNICIAN ID: \_\_\_\_\_

Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

August 2, 1995

**NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY**  
**TECHNICIAN WALK-THROUGH QUESTIONNAIRE**

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**LOCATION DATA (Technician Completed--address/ID label)**

State \_\_\_\_\_ County \_\_\_\_\_

Census Tract \_\_\_\_\_ Block \_\_\_\_\_

Street Address \_\_\_\_\_ / \_\_\_\_\_  
Apt./Space # \_\_\_\_\_

City, Zip \_\_\_\_\_ / \_\_\_\_\_

Zip code

---

INTERVIEWER/TECHNICIAN ID: \_\_\_\_\_ Date Completed: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

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NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY  
TECHNICIAN WALK-THROUGH QUESTIONNAIRE

COMPLETE THIS QUESTIONNAIRE BY OBSERVATION. YOU MAY ASK PARTICIPANT ANY QUESTIONS THAT ARE NOT APPARENT.

- T1. How many stories (floors) are in this building? (COUNT ONLY FLOORS WITH FINISHED ROOMS FOR LIVING PURPOSES OR FINISHED BASEMENTS.)

\_\_\_\_\_ Floors

IF MULTI-FAMILY BUILDING , CONTINUE. ELSE, GO TO QUESTION T3.

- T2. Which floor(s) do respondents live on? \_\_\_\_\_ floor(s).

- T3. How many rooms in the (house/apartment) are carpeted or have rugs covering most (> 50%) of their surface?

\_\_\_\_\_ Rooms

- T4. Using the following statements, how would you rate the overall dust level within the residence? (CIRCLE ONE.)

Very Dusty . . . . .	1
Some Dust -- obvious efforts to control dust . . . . .	2
"No" Dust -- extreme dust control, very clean . . . . .	3

Additional Comments on dust control: \_\_\_\_\_

\_\_\_\_\_

- T5. Indicate nearest major intersection: \_\_\_\_\_

## **EXTERIOR AND INTERIOR RESIDENTIAL CHARACTERISTICS**

T6a. Exterior siding material (including foundation): (CIRCLE ALL THAT APPLY.)

Wood . . . . .	1
Brick . . . . .	2
Vinyl/aluminum . . . . .	3
Concrete block . . . . .	4
Stucco . . . . .	5
Asbestos/asphalt . . . . .	6
Other (Specify: _____) . . . . .	7

T6b. Is there paint on any **exterior** surface that is chalking, chipping or peeling?

YES . . . . .	1
NO . . . . .	2
NOT PAINTED . . . . .	3

T6c. Is there paint on any **interior** surface that is chalking, chipping or peeling?

YES . . . . .	1
NO . . . . .	2
NOT PAINTED . . . . .	3

T6d. Dripline: (CIRCLE ONE.)

At wall . . . . .	1
Gutters -- no dripline . . . . .	2
_____ feet from wall . . . . .	3
Other (Specify: _____) . . . . .	4

T6e. Types of foundation: (CIRCLE ALL THAT APPLY.)

Slab . . . . .	1
Crawl space . . . . .	2
Combination crawl space/basement . . . . .	3
Full basement . . . . .	4
Other (Specify: _____) . . . . .	5
DON'T KNOW . . . . .	DK

T7a. Does this residence have a swimming pool?

YES . . . . .	Y ÷ CONTINUE
NO . . . . .	N ÷ GO TO T8

T7b. Where is the swimming pool located?

Inside . . . . .	1
Outside . . . . .	2

T8. Does this house or apartment have a hot tub or jacuzzi?

YES . . . . .	Y
NO . . . . .	N

NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

*FOLLOWUP QUESTIONNAIRE*

Participant Identification Number

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(Record ID Here)

Public reporting burden for this collection of information is estimated to average 20 minutes per response, and to require 0 hours recordkeeping. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

INTERVIEWER/TECHNICIAN ID: \_\_\_\_\_

Date Completed \_\_\_\_ / \_\_\_\_ / \_\_\_\_

August 2, 1995

**NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY**  
**FOLLOWUP QUESTIONNAIRE**

=====

**DESIGNATED PARTICIPANT**

(If the participant is less than 10 years old, what is the name of the individual who is providing the answers for the designated participant?)

Name of Participant\_\_\_\_\_

Completed by \_\_\_\_\_(if other than participant)

Relation to participant\_\_\_\_\_

Home Phone\_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_

=====

**LOCATION DATA (Technician Completed--address/ID label)**

State\_\_\_\_\_ County\_\_\_\_\_

Census Tract\_\_\_\_\_ Block\_\_\_\_\_

Street Address\_\_\_\_\_ /\_\_\_\_\_

Apt./Space #

City, Zip\_\_\_\_\_ /\_\_\_\_\_

Zip code

=====

**INTERVIEWER/TECHNICIAN ID: \_\_\_\_\_ Date Completed \_\_\_\_/\_\_\_\_/\_\_\_\_**

=====

These first questions are about things which may have happened in your home. They can be things (you do or see/he/she does or sees) or just normal activities. Please think about ***only the past week***, the time when you were taking part in this study.

F1. In the ***past week***, were any of the following items used in your home? (READ CHOICES AND CIRCLE "N" FOR NO AND "Y" FOR YES.)

		<u>No</u>	<u>Yes</u>
a. central air conditioner? .....	N      Y		
b. a window or wall air conditioning unit(s)? ..	N      Y		
	÷ b1. Was it set to... (READ CHOICES AND CIRCLE ONE.)		
		recirculate .....	1
		outdoor air .....	2
		DON'T KNOW ...	DK
c. a portable or ceiling fan? .....	N      Y		
d. a window fan? .....	N      Y		
e. an exhaust fan? .....	N      Y		

				How many days? (CIRCLE CORRECT NUMBER) ÷	When (you/he/she used (READ CHOICES), on how many days, if any, did you see or smell unusually heavy smoke or other fumes coming into the room? (ENTER 0 OR NUMBER OF DAYS)
		No	Yes	1 2 3 4 5 6 7 ÷	
f.	a wood-or coal-burning stove or furnace? . . .	N	Y	--> 1 2 3 4 5 6 7 ÷	_____ days
g.	an oil-burning furnace? . . . . .	N	Y	--> 1 2 3 4 5 6 7 ÷	_____ days
h.	a kerosene space heater? . . . . .	N	Y	--> 1 2 3 4 5 6 7 ÷	_____ days
i.	a gas-fired space heater? . . . . .	N	Y	--> 1 2 3 4 5 6 7 ÷	_____ days
j.	a fireplace? . . . . .	N	Y	--> 1 2 3 4 5 6 7 ÷	_____ days
k.	forced-air central heat? (not oil, wood,or coal burning) . . . . .	N	Y	--> 1 2 3 4 5 6 7 ÷	How often do you change or clean the filter on any of these devices? (READ CHOICES AND CIRCLE ONE.)
l.	electrostatic precipitators? . . . . .	N	Y	--> 1 2 3 4 5 6 7 ÷	
m.	ultrasonic humidifier? . . . . .	N	Y	--> 1 2 3 4 5 6 7 ÷	Less than once per month . . 1 Once per month . . . . . 2 More than once per month . . 3 DON'T KNOW . . . . . DK
n.	Other air filtering device Specify: _____ . . . . .	N	Y	--> 1 2 3 4 5 6 7 ÷	

			How many times in the <u><i>past week</i></u> ?	Number of days since last used?	How long (were you/was he/she) using or near the use of: (CIRCLE MIN OR HRS*)	Did (you/he/she) handle them (yourself/himself/herself)?		Did (you/he/she) wash hands after use?		Did (you/he/she) wear gloves, masks, or other protective equipment?						
	No	Yes				No	Yes	No	Yes	No	Yes					
F2.	In the <u><i>past week</i></u> , did (you/he/she) spend any time using or being near the use of: (ASK SUB-QUESTIONS FOR EACH YES RESPONSE.)										No	Yes	No	Yes	No	Yes
a.	paints or solvents (thinners and removers)? . . . . .	N	Y÷	____ times	____ days	____ min/hr	N	Y÷	N	Y	N	Y				
b.	glues or adhesives, such as contact cements, super glues, and aerosol adhesives, that contain chemical solvents? . . . . .	N	Y÷	____ times	____ days	____ min/hr	N	Y÷	N	Y	N	Y				
c.	petroleum products (kerosene, fuel oil) (not pumping gas)? . . . . .	N	Y÷	____ times	____ days	____ min/hr	N	Y÷	N	Y	N	Y				
d.	gas-powered lawn mower? . . . . .	N	Y÷	____ times	____ days	____ min/hr	N	Y÷	N	Y	N	Y				
e.	chain saw or other gas-powered equipment? . . . . .	N	Y÷	____ times	____ days	____ min/hr	N	Y÷	N	Y	N	Y				
f.	sander? . . . . .	N	Y÷	____ times	____ days	____ min/hr	N	Y÷	N	Y	N	Y				

(\*IF THE TIME WAS LESS THAN 1 HOUR, ENTER 15 MIN., 30 MIN., 45 MIN., OR 1 HOUR, WHICHEVER IS CLOSEST. IF TIME WAS GREATER THAN 1 HOUR, ROUND TO THE NEAREST HOUR. CIRCLE EITHER MIN. OR HR.)

F3. In the *past week*, did (you/he/she) spend any time, or (were you/was he/she) near anyone who was... (READ THE QUESTION, USING EACH CHOICE. IF RESPONDENT ANSWERS YES TO ANY CHOICE, CIRCLE "Y" AND ASK DETAILED SUB-QUESTIONS. CIRCLE "N" FOR NO.)

			<u>No</u>	<u>Yes</u>	How many times <u>in past week?</u>	Number of <u>days</u> since last done?	How long did (you/he/she) spend.... or (were you/was he/she) near someone else .... ? <u>(CIRCLE MIN OR HR*)</u>	Did you do this yourself?	<u>Yes</u>	<u>No</u>
a.	Vacuuming?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N
b.	Sweeping indoors?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N
c.	Dusting?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N
d.	Lawn mowing or edging?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N
e.	Gardening?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N
f.	Woodworking?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N
g.	Metal working/welding?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N

(\*IF THE TIME WAS LESS THAN 1 HOUR, ENTER 15 MIN., 30 MIN., 45 MIN., OR 1 HOUR, WHICHEVER IS CLOSEST. IF TIME WAS GREATER THAN 1 HOUR, ROUND TO THE NEAREST HOUR. CIRCLE EITHER MIN. OR HR.)

F4. In the *past week*, did (you/he/she) or anyone (you were/he/she was) close to: (READ THE QUESTION, USING EACH CHOICE. IF RESPONDENT ANSWERS YES TO ANY CHOICE, CIRCLE "Y" AND ASK DETAILED SUB-QUESTIONS. CIRCLE "N" FOR NO.)

			<u>No</u>	<u>Yes</u>	How many times <u>in past week?</u>	Number of <u>days</u> since last done?	How long did (you/he/she) spend .... or (were you/was he/she) near someone else .... ? <u>(CIRCLE MIN OR HR*)</u>	Did you do this yourself?	<u>Yes</u>	<u>No</u>
a.	Broil, smoke, grill, or barbecue food?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N
b.	Accidentally burn food while cooking?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N
c.	Grill with charcoal or gas?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N
d.	Cook with a wood-burning or coal-burning stove?		N	Y ÷	_____ times	_____ days	_____ min/hr		Y	N

(\*IF THE TIME WAS LESS THAN 1 HOUR, ENTER 15 MIN., 30 MIN., 45 MIN., OR 1 HOUR, WHICHEVER IS CLOSEST. IF TIME WAS GREATER THAN 1 HOUR, ROUND TO THE NEAREST HOUR. CIRCLE EITHER MIN. OR HR.)

F5. *During the past week*, did you or anyone else park a car or other motor vehicle in: (READ CHOICES AND CIRCLE "Y" OR "N.")

	<u>YES</u>	<u>NO</u>	<u>NOT APPLICABLE</u>
a. a garage attached to your home? . . . . .	Y	N	NA
b. a detached garage at your home? . . . . .	Y	N	NA
c. a carport attached to your home? . . . . .	Y	N	NA

The next questions are about the food (you/he/she) ate, any medicines (you/he/she) took, and other health concerns. Again, we only want to know about the *past week*, while (you were/he/she was) taking part in the study.

- F6. Please tell me the names of any medications (you/he/she) took during the *past week*. Include those drugs which a doctor prescribed, any (you choose/he/she chooses) (yourself/himself/herself) "over the counter," and any herbal or home medications. (PROBE FOR MEDICATIONS IN THE CATEGORIES LISTED. (CIRCLE "N" FOR NO AND "Y" FOR YES. IF RESPONDENT ANSWERS YES TO ANY CHOICE, LIST TYPES OF MEDICATIONS, INCLUDING BRAND NAMES, IN FIRST COLUMN, AND ASK DETAILED SUB-QUESTIONS. ASK TO SEE MEDICATION CONTAINERS AND FILL IN PRESCRIBED OR RECOMMENDED DOSE IN MG. IF NO WRITTEN INFORMATION IS AVAILABLE, PROBE FOR DOSE IN MG OR OTHER APPROPRIATE UNITS.)

Medication	No	Yes	How many times in past week?	Average Dose
a. Diuretics? _____ _____ _____	N	Y ÷	___ times ___ times ___ times	_____
b. Chelating Agents (EDTA, Calcium Disodium, Versenate, Succimer, or Chemet)? _____ _____ _____	N	Y ÷	___ times ___ times ___ times	_____
c. Antacids (Tums, Rolaids)? _____ _____ _____	N	Y ÷	___ times ___ times ___ times	_____
d. Hormones (thyroid medication, birth control pills)? _____ _____ _____	N	Y ÷	___ times ___ times ___ times	_____
e. Other? _____ _____ _____	N	Y ÷	___ times ___ times ___ times ___ times ___ times ___ times	_____

F7. Please tell me whether (you/he/she) took any vitamins or mineral supplements *during the past week* (PROBE FOR MINERAL SUPPLEMENTS IN THE CATEGORIES LISTED AND ANY OTHER VITAMINS OR MINERAL SUPPLEMENTS. CIRCLE "N" FOR NO AND "Y" FOR YES. IF RESPONDENT ANSWERS YES TO ANY CHOICE, LIST TYPES OF VITAMINS AND MINERALS, INCLUDING BRAND NAMES, IN FIRST COLUMN, AND ASK DETAILED SUB-QUESTIONS. ASK TO SEE VITAMIN CONTAINERS AND FILL IN PRESCRIBED OR RECOMMENDED DOSE IN MG. IF NO WRITTEN INFORMATION IS AVAILABLE, PROBE FOR DOSE IN MG OR OTHER APPROPRIATE UNITS.)

Vitamin and mineral supplements:	No	Yes	How many times in past week?	Average Dose
a. Calcium supplement? _____	N	Y ÷	____ times	_____
b. Selenium supplement? _____	N	Y ÷	____ times	_____
c. Chromium supplement? _____	N	Y ÷	____ times	_____
d. Multivitamins and all other vitamin and mineral supplements? _____ _____ _____ _____ _____ _____ _____ _____ _____	N	Y ÷	____ times ____ times ____ times ____ times ____ times ____ times ____ times ____ times _____	_____

ASK ONLY FOR FEMALES OVER 12. OTHERS GO TO F9.

F8. Are you currently expecting a baby or nursing a baby? (CIRCLE "Y" OR "N.")

Yes . . . . . Y  
No . . . . . N

ASK F9 ONLY IF RESPONDENT IS NOT MAINTAINING A FOOD DIARY. OTHERWISE GO TO QUESTION F10.

F9. Did (you/he/she) eat the following foods *last week*, that is, while (you were/he/she was) participating in this study? (CIRCLE "N" FOR NO AND "Y" FOR YES. IF RESPONDENT ANSWERS YES TO ANY CHOICE, ASK DETAILED SUB-QUESTIONS.)

	NO	YES	How many times in past week?	Average Portion Size
a. Broccoli cauliflower, or Brussels sprouts?	N	Y ÷	_____ times	_____ # cups
b. Cabbage, cole slaw, or sauerkraut?	N	Y ÷	_____ times	_____ # cups
c. Mustard greens, collards, or Swiss chard?	N	Y ÷	_____ times	_____ # cups
d. Turnips, or rutabagas?	N	Y ÷	_____ times	_____ # cups
e. Grapefruit or grapefruit juice? (IF RESPONDENT IS LESS THAN 21 YEARS OLD, GO TO g.)	N	Y ÷	_____ times	_____ # ounces
f. Alcoholic drinks (beer, wine, liquor)?	N	Y ÷	_____ times	_____ # drinks
g. Any foods that have been grilled, barbecued, flame broiled, smoked, charred, or blackened by burning?	N	Y ÷	_____ times	_____ # ounces

F10. During the *past week* (were you/was he/she) on any kind of diet either to lose weight or for any other reason? (CIRCLE "Y" OR "N.")

YES ..... Y ÷ CONTINUE  
 NO ..... N ÷ STOP

F11. What diet or diets (were you/was he/she) on? (READ CHOICES AND CIRCLE ALL THAT APPLY.)

- Weight loss or low calorie diet? ..... 1
- Low fat or cholesterol diet? ..... 2
- Low salt or sodium diet? ..... 3
- Sugar free or low sugar diet? ..... 4
- Low fiber diet? ..... 5
- High fiber diet? ..... 6
- Diabetic diet? ..... 7
- Any kind of vegetarian diet? ..... 8
- Other (Specify: \_\_\_\_\_) ... 9

NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

***24-HOUR FOOD DIARY***

Participant Identification Number

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(Record ID Here)

Public reporting burden for this collection of information is estimated to average 1 hour, and to require 0 hours recordkeeping. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

August 2, 1995

## HOW TO USE THE 24-HOUR FOOD DIARY

**FOR PARTICIPANTS LESS THAN 10 YEARS OLD, A PARENT OR GUARDIAN SHOULD PROVIDE ASSISTANCE, AS NEEDED, IN COMPLETING THE FOOD DIARY.**

### INSTRUCTIONS

- (1) We want you to list all of the foods, beverages, drinking water, and non-prescription medicines or vitamins you or this child eat(s) or drink(s) from midnight to midnight.
- (2) Every time you or this child eat(s), write down the name of the meal (breakfast, lunch, dinner, snack).
- (3) Then write down on a separate line the (brand/generic) name of every food, beverage, or non-prescription medicine or vitamin that you or this child eat(s) or drink(s).
- (4) For food mixtures such as stews or potpies, please write down the major kinds of foods in the mixture. Use the lines immediately below the one on which the name of the mixture is entered. In food mixtures, the component ingredients can be identified, for example—the type of meat in a stew—beef, lamb, venison, etc.
- (5) For beverages (including water), write down how many cups or glasses that you or this child drink(s)). Estimate equivalent measures of water or other beverages taken from a fountain or large container. Don't forget your second and third cups of coffee or tea, or refills at a restaurant.

**NHEXAS FOOD DIARY FOLLOW-UP - DAY 1 [NOTE: THE 24-HOUR FOOD DIARY CONTAINS SIMILAR PAGES FOR EACH DAY ON WHICH DUPLICATE DIET SAMPLES ARE COLLECTED.]**

**CONTINUE ON BACK IF YOU HAVE MORE FOODS TO LIST.**

## NHEXAS FOOD DIARY FOLLOW-UP - DAY 1

FOR  
INTERVIEWER  
USE ONLY

## NHEXAS FOOD DIARY FOLLOW-UP - DAY 2

**CONTINUE ON BACK IF YOU HAVE MORE FOODS TO LIST.**

NHEXAS FOOD DIARY FOLLOW-UP - DAY 2

NHEXAS FOOD DIARY FOLLOW-UP - DAY 3

**CONTINUE ON BACK IF YOU HAVE MORE FOODS TO LIST.**

NHEXAS FOOD DIARY FOLLOW-UP - DAY 3

**FOR  
INTERVIEWER  
USE ONLY**

NHEXAS FOOD DIARY FOLLOW-UP - DAY 4

CONTINUE ON BACK IF YOU HAVE MORE FOODS TO LIST.

NHEXAS FOOD DIARY FOLLOW-UP - DAY 4

**FOR  
INTERVIEWER  
USE ONLY**

NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY

*FOOD DIARY FOLLOWUP*

Participant Identification Number

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(Record ID Here)

Public reporting burden for this collection of information is estimated to average 1 hour, and to require 0 hours recordkeeping. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

August 2, 1995

COMPLETE ON SAME DAY SAMPLES ARE COLLECTED	DAY: DATE: / /	1 / /	2 / /	3 / /	4 / /
FD1. Was breakfast eaten? (OBSERVE FROM DIARY AND CIRCLE "Y" OR "N". IF "N," GO TO FD4.)	Y N	Y N	Y N	Y N	
FD2. Where was (your/his/her) breakfast prepared? (READ CHOICES.) a. Home ..... b. Restaurant ..... c. Work site or work cafeteria ..... d. School or day care center ..... e. Other ....	a b c d e	a b c d e	a b c d e	a b c d e	a b c d e
FD3. How often (do you/does he/does she) eat a breakfast like the one you described in the diary? (READ CHOICES AND ENTER ONE RESPONSE LETTER FOR EACH DAY OF FOOD COLLECTION.) a. 4 to 7 times per week b. 1 to 3 times per week c. 1 to 3 times per month d. Less than once a month	_____	_____	_____	_____	
FD4. Was lunch eaten? (OBSERVE FROM DIARY AND CIRCLE "Y" OR "N." IF "N," GO TO FD7.)	Y N	Y N	Y N	Y N	
FD5. Where was (your/his/her) lunch prepared? (READ CHOICES.) a. Home ..... b. Restaurant ..... c. Work site or work cafeteria ..... d. School or day care ..... e. Other _____	a b c d e	a b c d e	a b c d e	a b c d e	a b c d e
FD6. How often (do you/does he/does she) eat a lunch like the one you described in the diary? (READ CHOICES AND ENTER ONE RESPONSE LETTER FOR EACH DAY OF FOOD COLLECTION.) a. 4 to 7 times per week b. 1 to 3 times per week c. 1 to 3 times per month d. Less than once a month	_____	_____	_____	_____	
FD7. Was dinner eaten? (OBSERVE FROM DIARY AND CIRCLE "Y" OR "N." IF "N," GO TO FD10.)	Y N	Y N	Y N	Y N	

COMPLETE ON SAME DAY SAMPLES ARE COLLECTED	DAY: DATE:	1 / /	2 / /	3 / /	4 / /
FD8. Where was (your/his/her) dinner prepared? (READ CHOICES.) a. Home ..... b. Restaurant ..... c. Work site or work cafeteria ..... d. School or day care ..... e. Other .....		a b c d e	a b c d e	a b c d e	a b c d e
FD9. How often (do you/does he/does she) eat a dinner like the one you described in the diary? (READ CHOICES AND ENTER ONE RESPONSE LETTER FOR EACH DAY OF FOOD COLLECTION.) a. 4 to 7 times per week b. 1 to 3 times per week c. 1 to 3 times per month d. Less than once a month		—	—	—	—
FD10. Please think back. Were there any foods or beverages that you could not or did not collect for use? (LIST IDENTITY, SOURCE, AND AMOUNT OF EACH MISSING FOOD AND THE DAY IT WAS NOT COLLECTED.) a. At Breakfast _____ _____ _____ _____ b. At Lunch _____ _____ _____ _____ c. At Dinner _____ _____ _____ _____ d. For Snacks - include beverages such as coffee or tea _____ _____ _____		Y N	Y N	Y N	Y N

COMPLETE ON SAME DAY SAMPLES ARE COLLECTED	DAY: DATE: / /	1 / /	2 / /	3 / /	4 / /
FD11. Did (you/he/she), for any reason, eat more or less food than usual? (READ CHOICES AND ENTER a b, OR c .) a. More food than usual ÷ CONTINUE b. Less food than usual ÷ CONTINUE c. Same as usual ÷ GO TO FD13					
FD12. Because of: (READ CHOICES AND CIRCLE ALL THAT APPLY.) a. Travel or vacation ..... b. Weight control diet ..... c. Illness or medical condition ..... d. Work or school schedule ..... e. Entertainment or social occasion ..... f. Because of the food collection study ..... g. Ease/quickness of preparation ..... h. Other ..... Day 1: _____ Day 2: _____ Day 3: _____ Day 4: _____	a b c d e f g h	a b c d e f g h	a b c d e f g h	a b c d e f g h	a b c d e f g h
FD13. Did (you/he/she), for any reason, eat different foods than (your/his/her) usual diet? (CIRCLE "Y" OR "N") .....	Y N	Y N	Y N	Y N	
FD14. If yes, was that because of: (READ CHOICES AND CIRCLE ALL THAT APPLY.) a. Travel or vacation ..... b. Weight control diet ..... c. Illness or medical condition ..... d. Work or school schedule ..... e. Entertainment or social occasion ..... f. Because of the food collection study ..... g. Ease/quickness of preparation ..... h. Other: ..... Day 1: _____ Day 2: _____ Day 3: _____ Day 4: _____	a b c d e f g h	a b c d e f g h	a b c d e f g h	a b c d e f g h	a b c d e f g h

May 22, 1995  
NHEXAS QSIP  
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**APPENDIX G**  
**NIST WORK STATEMENT**



**NIST**

**UNITED STATES DEPARTMENT OF COMMERCE**  
**National Institute of Standards and Technology**  
Gaithersburg, Maryland 20899-0001

April 28, 1994

**RECEIVED**

**MAY 8 1994**

**ACS**

Dr. Edo Pellizzari  
Research Triangle Institute  
Analytical and Chemical Sciences  
P.O. Box 12194  
3040 Cornwallis Rd.  
Research Triangle Park, NC 27709

Dear Dr. Pellizzari:

NIST has been asked to serve as the Analytical Reference Laboratory for the NHEXAS pilot programs. A copy of the program description is attached. As discussed at the NHEXAS QA workshop held January 11 and 12, NIST will be providing intercomparison samples to interested laboratories according to the following timetable:

**May 1994      Solutions of:**

1. Benzene, toluene, 1,1,1-trichloroethylene, and trans-dichloroethene in carbon disulfide.
2. Arsenic and lead in water.
3. Chlordpyrifos, diazinon, atrazine, malathion, and carbaryl in hexane.
4. Fifteen chlorinated pesticides, including cis-chlordane, dieldrin, heptachlor, 4,4'-DDE, 4,4'-DDD, and 4,4'-DDT.
5. Twenty four polycyclic aromatic hydrocarbons (PAH), benzo[a]pyrene, and benz[a]anthracene, in hexane/toluene.

If the results of these exercises are within an acceptable range (determined in conjunction with EPA) of the gravimetric concentrations corrected for purities of the neat compounds and the NIST- and consensus-determined concentrations, the next set of solutions will be sent as follows:

**July 1994**

1. Complex mixture of volatile organic compounds (VOCs) in carbon disulfide.
2. Mixture of trace metals simulating those found in extracts from air particulates, household dust, and soil.
3. Real extracts of air particulate and soil containing PAH and pesticides.

If the results of these exercises are within an acceptable range (determined in conjunction with EPA) of the NIST- and consensus- determined concentrations, the next set of samples will be sent as follows:

September 1994

1. VOCs charged on collection medium
2. Natural matrices for the trace elements and PAH and pesticides
  - a. Air particulate matter
  - b. Indoor dust
  - c. Soil

This will be a performance-based approach for intercomparison studies, i.e., participants are encouraged to use their "own" methods for analysis of the samples.

Since not everyone is analyzing the same analytes in the same matrices, please indicate by May 13 which exercises your laboratory is interested in participating in. If you have any questions, please contact me at 301/975-3106, FAX 301/926-8617.

Sincerely,



Michele M. Schantz, Ph.D.  
Research Chemist  
Organic Analytical Research Division  
Chemical Science and Technology Laboratory

Attachment

cc: L. Bryan, EPA  
T. Buckley, EPA  
R. Evans, EPA  
K. Hammerstrom, EPA  
L. Porter, EPA  
J. Quackenboss, EPA  
W. May, NIST

## NIST NHEXAS WORKPLAN

The NIST Chemical Science and Technology Laboratory will assist the EPA in providing analytical measurement quality assurance for the NHEXAS Program. Specifically, NIST will serve as Reference Laboratory for all chemical measurements, working in behalf of EPA with the federal laboratories and "EPA Collaborators" to assess both intra- and inter-laboratory components of bias among the various measurement technologies used for acquiring NHEXAS data.

**TASK 1 (Workshops):** NIST will convene a workshop in FY-94 to discuss analysis methods and issues. Key measurement technologists and Quality Assurance Managers from all institutions will be invited to attend and discuss analytical methodologies (including internal QA plans) proposed for use in NHEXAS. The Product of this initial Workshop will be the design of a series of interlaboratory exercises on common samples to evaluate the performance of the various methodologies being proposed and a consensus concerning short term reference material needs. Additional workshops would be held periodically to discuss analytical measurement problems and issues that arise during the pilot studies. Longer term reference material needs will also be discussed at subsequent workshops.

**TASK 2 (NHEXAS Reference Laboratory Program):** Interlaboratory studies will be established to provide a basis for use of performance-based methods throughout the pilot and future NHEXAS studies. The data collected from such studies will be used to document interlaboratory comparability prior to the beginning of NHEXAS, to provide an external assessment of laboratory performance throughout the study, and to a lesser extent indicate the need for corrective action. Data from the interlaboratory studies would also be used in making decisions regarding the introduction and use of new laboratories and/or measurement methods during the course of the study. This approach would also provide NHEXAS flexibility and not be locked into 1993/94 measurement methods and technology; comparability of new measurement approaches which might be used to provide data can be documented. This is not to suggest that new laboratories should be brought into the program nor that measurement methods should be changed in a haphazard fashion, but rather that when new measurement methods are introduced for whatever reason, quality assessment can be made on data so generated.

NIST will conduct interlaboratory studies among laboratories designated to measure trace metals, pesticides, volatile organic compounds (VOCs) and polycyclic aromatic compounds (PAH) in NHEXAS air, dust and soil samples according to the following schedule:

May 1994 - distribute simple solutions containing NHEXAS analytes

- \* trace metals in water
- \* mixture of pesticides in hexane
- \* NHEXAS VOCs in carbon disulfide
- \* NHEXAS PAH in hexane/toluene

After analysis of data and feedback to labs, these solutions will be value assigned and provided to NHEXAS labs for use in their internal QC programs for calibration purposes.

July 1994 - distribute real or simulated extracts containing NHEXAS analytes

- \* mixture of trace metals
- \* pesticides and PAH
- \* complex mixture of VOCs in carbon disulfide

After analysis of data and feedback to labs, these extracts will be value assigned and provided to NHEXAS labs for use as control materials in their internal QC programs.

Sept. 1994 - distribute natural matrices to NHEXAS labs for analysis

- \* air particulate matter
- \* indoor dust
- \* soil
- \* collection medium (charged with VOCs)

After analysis of data and sufficient interactions to achieve the desired measurement comparability, matrices will be value assigned based on both NIST and interlaboratory data. Once an acceptable level of agreement is achieved among laboratories, measurements of NHEXAS samples would begin following internal QA/QC protocols instituted by each laboratory with these value-assigned materials being available for use as "Control Materials."

In FY95, NIST will collaborate with the designated Federal Laboratory for food analysis to validate measurement methods for use in NHEXAS. Initially, this collaboration will consist of joint analysis of common samples, analysis and critical evaluation of data. Analysis of NHEXAS samples should begin only after concurrence from NIST and EPA QA Team Leader. Further collaborations would involve joint certification of Reference Materials for use in future NHEXAS studies.

EPA-EMSL Cincinnati will be responsible for analysis of NHEXAS water samples through its contract laboratory network. EPA-EMSL conducts several QA exercises per year for its drinking water labs. NIST will participate in three of these exercises per year and will request that EPA Cincinnati share data from these studies with NIST. Since EPA Cincinnati has an extensive and ongoing QA program in place for its drinking water laboratories, analyses of NHEXAS samples should be allowed to commence as soon as possible. NIST will collaborate with EPA-Cincinnati to define reference material needs for future NHEXAS studies.

CDC has extensive experience in analysis of biomarkers in samples of biological origin. NIST will collaborate with CDC in identifying biological reference materials needs for future NHEXAS studies.

**TASK 3 (Analytical Support):** NIST will provide analytical measurement support for sampling intercomparison studies schedules for the spring or summer of 1995.

During the course of the pilot studies, NIST will provide analytical support requested by EPA to address comparability issues among the collaborating laboratories including, but not limited to sampling intercomparison studies.

**TASK 4 (Reference Materials):** The successful use of performance based analytical methods will require the availability and use of reference materials. The specific reference materials needed to support NHEXAS activities will be identified and discussed during the first and subsequent Analytical Measurement/QA Workshops. Not all reference material needs will be readily apparent; some needs will be established through and during the pilot studies. The pilot studies should give a clear indication of the types and quantities of reference materials needed for conducting any future NHEXAS studies.

A number of Standard Reference Materials (SRMs, the registered trade mark used by NIST to identify it's certified reference materials) currently exist that might be useful in NHEXAS pilot studies. Where the matrix is appropriate, but no data currently exists, NIST will conduct studies to provide estimated values for analytes of interest to NHEXAS and report the same at one of the Analytical Methods/QA Workshops. If the concentration levels are appropriate and a supply sufficient to serve NHEXAS purposes exists, NIST would perform analyses for value assigning the analytes of interest. These SRM's would be available to NHEXAS laboratories through purchase from the NIST Standard Reference Materials Program.

For the long term, it would be appropriate to develop additional "control materials" for exclusive use in the NHEXAS program. We propose that NIST provide value-assignment for these materials via a collaborative effort with NHEXAS laboratories. NIST would provide measurements by a single method (where possible, one that has been benchmarked against an independent method on a similar matrix during prior NIST SRM certification activities). The methodologies employed by the NHEXAS laboratories will be validated through the interlaboratory studies prior to use in reference material value assignment studies. NIST would maintain these materials and provide them to NHEXAS laboratories at no cost. Small portions of these materials would be set aside for studies to determine optimum conditions for storing such samples. If NIST and EPA deem it appropriate, these materials could be upgraded to SRM status and made available to the entire scientific community.

Throughout the pilot studies, matrixed QA samples will be distributed for analysis on a semi-annual basis. NIST will establish and maintain a performance database based on results from interlaboratory analysis of these samples in order to evaluate and qualify historical information as the project proceeds. NIST will work with NHEXAS laboratories to identify and resolve any methodological problems indicated by data generated in the interlaboratory studies. This performance database would allow critical evaluation (including possible flagging) of NHEXAS sample analysis data prior to it's being archived within NHEXAS databases.