

# 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

**Field Operations Protocol**

**EOHSI-AP-209-040**

**Title:** Human Biological Markers: Blood and Urine Sample Collection  
and Analysis

**Source:** Environmental and Occupational Health Sciences Institute

U.S. Environmental Protection Agency  
Office of Research and Development  
Human Exposure & Atmospheric Sciences Division  
Human Exposure Research Branch

**Notice:** The U.S. Environmental Protection Agency (EPA), through its Office of Research and Development (ORD), partially funded and collaborated in the research described here. This protocol is part of the Quality Systems Implementation Plan (QSIP) that was reviewed by the EPA and approved for use in this demonstration/scoping study. Mention of trade names or commercial products does not constitute endorsement or recommendation by EPA for use.

**TITLE:** HUMAN BIOLOGICAL MARKERS: BLOOD AND URINE SAMPLE  
COLLECTION AND ANALYSES

**SOURCE:** Environmental and Occupational Health Sciences Institute  
Post Office Box 1179  
681 Frelinghuysen Road  
Piscataway, NJ 08855-1179

**AUTHOR(s):**

*Kent W. Thumm* Date: 4/8/96  
*Debra Fossim* Date: 4/19/96  
Date: \_\_\_\_\_

**APPROVED BY:**

Principal Investigator: *E. Pellipen* Date: 5/6/96

QA Officer: *W. J. Smith* Date: 4/11/96

|                       |                |                                     |
|-----------------------|----------------|-------------------------------------|
| <b><u>STATUS:</u></b> | IN PROGRESS:   | <input type="checkbox"/>            |
|                       | DRAFT:         | <input type="checkbox"/>            |
|                       | FINAL VERSION: | <input checked="" type="checkbox"/> |

**REVISIONS:**

| No. | Date   | No. | Date |
|-----|--------|-----|------|
| 0   | 5/6/96 | 6   |      |
| 1   | †      | 7   |      |
| 2   |        | 8   |      |
| 3   |        | 9   |      |
| 4   |        | 10  |      |
| 5   |        | 11  |      |

† Effective date of this version is the date of the last approval signature;  
revision 0 is the original version.

HUMAN BIOLOGICAL MARKERS:  
BLOOD AND URINE SAMPLE COLLECTION AND ANALYSES

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## 1.0 SCOPE AND APPLICATION

The chief objectives of NHEXAS are (a) to establish relationships among environmental concentrations, exposures, and doses, (b) to determine the incidence and causes of high exposures, and (c) to produce reliable estimates of status and trends in these determinations. Among the chief goals of the Pilot/Scoping field studies are to test methodologies and to acquire environmental samples (multimedia), population information (activity, diet, etc.), and human biomarkers. These data are intended to furnish the bases of exposure assessments on a population-based scale for the target contaminants.

Human biological sample collection and analyses are included in NHEXAS to support these program objectives and goals. The presence of chemical contaminants in biological specimens, such as blood, urine, and hair represent a measure of the internal dose or *body burden*, for a given individual, derived from their environmental exposures. The occurrences of measurable levels in biological samples are, at the least, verification of exposure and uptake. That is, it serves as a reality check for environmental media and human characteristic and activity data collected in the field: if we measure relatively high exposure, then we expect to find a similarly higher-than-average body burden; if a person has a minimal body burden, then this should correspond to a minimally exposed individual. There are limitations in the state-of-the-science for quantitatively linking measurements for exposure and body burden. Various models are under development, and the NHEXAS results will be used in their development and validation.

Human blood and urine samples collected in the NHEXAS Pilot/Scoping Study are expected to have specific utility in the following areas: (i) To provide basis of comparisons of the exposure monitoring data with body burden data for individual and group results; (ii) To initiate (or add to) biomarker databases for population-based survey; (iii) To provide data (individual and range) for PBPK model evaluation; and (iv) To supply specimens for tissue archiving and future analyses.

## 2.0\* SUMMARY OF METHOD

A set of venous blood and urine samples will be collected from each compliant participant in the RTI/EOHSI NHEXAS Pilot/Scoping Study. The specific constituents in

biological specimens to be analyzed are as follows: (a) Lead and cadmium in blood; (b) Benzene and other VOCs in blood; and (c) Arsenic in urine. Human blood and urine samples will be analyzed by the Centers for Disease Control and Prevention/National Center for Environmental Health (CDC/NCEH) Division of Environmental Health Service in Atlanta, GA. Detailed procedures are given in the Appendices for blood and urine sample collection, handling, storage and shipment. Furthermore, the RTI/EOHSI consortium will work with CDC/NCEH in coordination and implementation of QA/QC procedures related to collection and analyses of blood and urine samples.

Willing subjects will provide one set of blood and two urine samples during the weeklong monitoring period. When available, phlebotomists from local Health Departments will draw the blood samples; otherwise, local health care workers with appropriate expertise will be hired. The blood samples will be drawn on the last day (Day 7) of the monitoring period. Participants will give urine samples (morning void) on Days 3 and 7; specimen containers will be supplied to them and the samples will be stored in their freezer until the following technician visit. Thereafter, the RTI field staff will be responsible for sample storage, handling and shipment.

### 3.0 MATERIALS

3.1 Supplies for collection and shipment of blood and urine samples will be supplied by CDC/NCEH to RTI in ready-to-use form.

#### 3.2 Blood Samples

3.2.1 Three blood sample *vacutainers* will be used for collecting venous blood into separate sub-samples: (a) a 3-mL purple-top (EDTA) for metals, (b) a 10-mL gray-top for VOCs, and (c) a 10-mL or 15-mL purple-top (EDTA) for an archived specimen (likely to be for hemoglobin adducts). Only CDC-supplied equipment (e.g., vacutainers, needle, crimper, etc.) will be used to draw and collect venous blood samples.

3.2.2 A portable cooler with ice packs (. 4EC) will be used to store blood samples from the time of collection while in transit to the field laboratory. A refrigerator may be used for short-term storage of blood samples.

- 3.2.3\* Samples will be sent to Atlanta in shipping materials supplied to RTI by CDC. These consist of small foam boxes, which hold up to 4 vacutainers, and larger shipping containers, which hold at least 9 boxes with ice packs.

### 3.3 Urine Samples

- 3.3.1 Urine specimen containers will be 150-mL capacity plastic containers with a snap-top; they will be supplied by CDC to RTI in their original wrapping. The containers will be unwrapped and labeled before the collection days and provided to the subjects in clean zip-lock bags.
- 3.3.2 RTI-supplied freezer storage boxes will be given to participants to hold filled containers in their home freezer.
- 3.3.3 Samples will be sent to Atlanta in shipping materials supplied to RTI by CDC. Sufficient *dry ice* will be used to keep samples frozen during transport, using approximately equal volumes (dry ice-to-specimen containers) inside the shipment box.

3.4 Sample codes will be assigned uniquely to each sample by RTI. Sample collection information described in Figures 1 and 2 will be entered by the field technician into the electronic sample collection data record for each participant. Custody records will be initiated in the field and a custody form will accompany each sample as it is transmitted for analysis or archival.

## 4.0 PARTICIPANTS AND SCHEDULES

4.1\* All participants will be asked to provide samples of blood and urine. Their permission or refusal will not affect their participation in any other part of NHEXAS protocols. A \$5 incentive will be offered for providing the urine samples. For providing the blood sample(s), the subjects will be offered \$20 cash payment.

4.2 Willing donors among NHEXAS participants will be visited at their home on Day 7 by a phlebotomist to collect the blood samples. The scheduling for the home visit for collection of the blood sample will correspond with the final monitoring visit.

4.3 Willing participants will provide first morning void urine samples on Days 3 and 7.

## 5.0 SAMPLE COLLECTION

### 5.1 Blood Samples

CDC and EOHSI will provide instructional materials to outline and give guidance for the requirements in blood sample collection and handling for the phlebotomists and RTI field personnel. Detailed description of the blood collection procedure is provided in Appendix A.

### 5.2 Urine Samples

Participants will collect urine during their first-morning voids on the two scheduled days. At the first monitoring visit (Day 1) they will receive an instruction sheet (see Figure 3) with the set of pre-labeled collection containers. The participants will be asked to provide information requested on the instruction form for each sample. Detailed procedures for urine collection are described in Appendix B.

## 6.0 SAMPLE STORAGE AND SHIPMENTS

### 6.1 Blood Samples

- 6.1.1\* From the time of the venipuncture procedure, whole blood samples in vacutainers will be stored cold (. 4EC) until shipment. An ice chest with ice packs will be used to store vacutainers from the time of collection; storage in a refrigerator will be used, when available. Samples must not be frozen.
- 6.1.2 A field technician will retrieve the blood samples from the household or from the phlebotomist. Upon retrieving the vacutainers, the field technician must verify that the vacutainer labels have been affixed, and that the sample collection information has been entered in the data file.
- 6.1.3\* The samples will be express shipped, packed with frozen ice packs (sufficient to stay cold) until delivery to CDC/Atlanta (metals and VOCs) and to RTI (archival). Samples should be shipped within three days of collection whenever possible and must be shipped within five days.
- 6.1.4\* A shipping summary form and an individual custody record for each sample will be completed and included in each shipment of blood samples.
- 6.1.5 The CDC contact address and detail description of shipment procedures are included in Appendix A.



## 6.2 Urine Samples

- 6.2.1 From the time of the morning void collection by the participant (or caregiver), urine samples will be stored frozen (<-2EC), until shipment to CDC. The participant will be instructed to put the specimen container(s) directly into the household freezer.
- 6.2.2 The field technician will retrieve urine specimen containers for transport to the field staging area in an ice chest with ice packs. Samples will then be stored in a freezer or on dry ice.
- 6.2.3 At the time of retrieval of urine samples, the field technician will also examine the participant's Urine Collection Instruction Sheet (Figure 3). Before leaving the household, the field technician must verify that both the form and the specimen container labels have been properly completed.
- 6.2.4 The samples will be shipped in dry ice (sufficient to stay frozen) for delivery to CDC/Atlanta. A shipping summary form and an individual custody record for each sample will be completed and included in the shipment of urine samples.
- 6.2.5 The CDC contact address and detail description of shipment procedures are included in Appendix B.

## 7.0 QA/QC PROCEDURES

### 7.1 Blood Quality Control

#### 7.1.1 Sample Code

- 7.1.1.1 A unique sample code will be assigned to each sample (i.e. for metals, VOCs, and archive) in the RTI/EOHSI NHEXAS sample collection record.
- 7.1.1.2 The vacutainers will have barcode labels affixed to them with sample codes identical to the code in the sample collection record.

#### 7.1.2 Custody

- 7.1.2.1 The field technician will take the blood specimens from the phlebotomists and log their entry in the sample collection record.
- 7.1.2.2 A custody record will be prepared for each of the blood samples. This record will be included with each sample when shipped to CDC.

### 7.1.3 Field Blanks

7.1.3.1 Field blanks will be prepared and provided by CDC to assess sample contamination from materials and methods. In the event that a suitable clean matrix can not be found for blood samples, empty containers will be used as field blanks.

7.1.3.2 A set of field blanks will be prepared for each county of the study. These will be sent to the field, where they will be stored, labeled and handled, then shipped following the same procedures as samples.

### 7.1.4 Collocated (duplicate) Sample Collection

7.1.4.1 Collocated samples will be collected to assess collection and analysis precision. Collocated samples will be collected, stored, and shipped following the same procedures as samples.

7.1.4.2 Collocated samples will be collected as scheduled by the field supervisor, based on the numbers and timing specified in the QSIP. No more than one type blood sample collection will include a collocated sample for a given participant. For example, if a collocated VOC blood sample is collected, collocated metals and archival blood samples may not be collected from that participant.

### 7.1.5 Field Controls

7.1.5.1 When possible, field controls will be prepared and provided by CDC to assess recovery of target analytes through storage, shipment, and analysis. Field controls will be stored and shipped following the same procedures as samples.

7.1.5.2 Field controls will be prepared by the CDC/NCEH or NIST laboratories by adding a known amount of the target analytes to a suitable matrix in an actual sample collection container. Field controls may not be available for archival blood samples or VOC blood samples. The availability and schedule of field controls for blood will be decided in discussion with CDC scientists.

## 7.2 Urine Quality Control

### 7.2.1 Sample Code

7.2.1.1 A unique sample code will be assigned to each sample in the RTI/EOHSI NHEXAS sample collection record.

7.1.1.2 The urine specimen containers will have barcode labels affixed to them with sample codes identical to the code in the sample collection record.

7.2.2 Custody

7.2.2.1 The field technician will take the urine specimens from the participants and log their entry in the sample collection record.

7.2.2.2 A custody record will be prepared for each of the urine samples. This record will be included with each sample when shipped to CDC.

7.2.3 Field Blanks

7.2.3.1 Field blanks will be prepared and provided by CDC to assess sample contamination from materials and methods. In the event that a suitable clean matrix can not be found for urine samples, empty containers will be used as field blanks.

7.2.3.2 A field blank will be prepared for each county of the study. These will be sent to the field, where they will be stored, labeled and handled, then shipped following the same procedures as samples.

7.2.4 Collocated (duplicate) Sample Collection

7.2.4.1 Collocated samples will be collected to assess collection and analysis precision. Collocated urine samples will be collected from one participant in each county.

7.2.4.2 For the collocated samples, a participant will be given two containers and requested to split their urine specimen into the two containers. Collocated samples will have separate sample codes and will be collected, stored, and shipped following the same procedures as samples.

7.2.5 Field Controls

7.2.5.1 When possible, field controls will be prepared and provided by CDC to assess recovery of target analytes through storage, shipment, and analysis. Field controls will be stored and shipped following the same procedures as samples.

7.2.5.2 Field controls will be prepared by the CDC/NCEH or laboratories by adding a known amount of the target analytes to a suitable matrix in an actual sample collection container. The availability and schedule of field controls for urine will be decided in discussion with CDC scientists.

## 8.0 REFERENCES

CDC/NCEH "Biomarkers of Exposure Measured at the NCEH/CDC", July 1993.

## BLOOD SAMPLE INFORMATION

|                  |  |
|------------------|--|
| SAMPLE TYPE:     | Blood, VOC, Metals, or Archive                                   |
| SAMPLE CODE:     | Same as label on sample container                                |
| PARTICIPANT ID:  | Three digit participant i.d. number                              |
| COLLECTION DATE: | Date sample collected  |
| COLLECTION TIME: | Time sample collected  |
| COLLECTOR ID:    | ID of staff member present at the collection                     |
| COMMENT CODE:    | Default = 0 for No; change to 1 or 2 if a comment is added below |
| COMMENT:         | Comment text associated with this particular sample              |

Figure 1. Blood sample collection information to be included in the sample collection record.

## URINE SAMPLE INFORMATION

|                     |  |
|---------------------|--|
| SAMPLE TYPE:        | Default is Urine, Day 3 or Day 7; change if different      |
| SAMPLE CODE:        | Same as label on sample container                          |
| PARTICIPANT ID:     | Three digit participant i.d. number                        |
| COLLECTION DATE:    | Date sample collected by participant                       |
| COLLECTION TIME:    | Time sample collected by participant                       |
| PREVIOUS VOID TIME: | Time of participant's last void prior to collection        |
| DATE RETRIEVED:     | The date the staff retrieves the sample                    |
| COLLECTOR ID:       | ID of staff that retrieves and inspects the sample         |
| COMMENT CODE:       | Default = 0; change to 1 or 2 if a comment is added below. |
| COMMENT:            | Comment text associated with this particular sample        |

Figure 2. Urine sample collection information to be included in the sample collection record.

## INSTRUCTIONS FOR COLLECTING URINE SAMPLES

### HOW MANY

We would like you to collect a urine sample on two days. You will collect a sample from your first morning void on each of the following two days:

FIRST SAMPLE: \_\_\_\_\_

SECOND SAMPLE: \_\_\_\_\_

### TIME OF DAY

We want you to collect samples from your first morning void; that is, the time you first wake up in the morning to begin your day. (If you have a sleep schedule other than the usual overnight time period, please discuss the collection time with our staff).

### HOW TO COLLECT THE SAMPLE

It is very important to collect the sample using the following instructions so that the samples will not be contaminated with dust or dirt:

1. The night before, bring the urine sample cup and spare to the bathroom.
2. In the morning, before collecting the sample, wash your hands thoroughly with soap and water. (Remember, collect your water sample first, if scheduled).
3. Remove the sample cup from the plastic bag.  
Remove the cap from the cup, put down the cap with the inside of the lid facing up.
4. Be careful not to touch the inside of the cup or the cap with your hands, clothing, or other material. If this happens, please use the second cup.
5. Urinate directly into the cup. Do not fill past the topmost line on the side of the cup.
6. Immediately place the cap on the collection cup. Again, do not touch the inside of the cap or collection cup.
7. Place the cup back into the plastic bag and seal the plastic bag.  
Put the collected sample into the plastic storage box in your freezer within 5 minutes.
8. Please complete the information for the urine samples.

|                                      | First Day | Second Day |
|--------------------------------------|-----------|------------|
| Date Collected                       | _____     | _____      |
| Time Collected                       | _____     | _____      |
| Time of last void before this sample | _____     | _____      |

Figure 3. Participant urine collection instruction sheet.

## APPENDIX A

### BLOOD COLLECTION PROCEDURES

A.1 Materials. Blood collection materials used must be provided by CDC unless denoted (\*).

- 3 mL purple-top (EDTA) vacutainer tubes - one per subject plus QCs
- 10 mL gray-top (heparin) vacutainer tubes - one per subject plus QCs
- 10 mL or 15 mL purple-top (EDTA) vacutainer tubes - one per subject plus QCs
- Butterfly assembly with tubing, sample luer adapter, and needle holder
- Tourniquet \*
- Vacutainer holder \*
- Shipment boxes
- Protective gloves
- Gauze squares
- Alcohol wipes
- Band-aids \*
- Sharps disposal container for used needles \*
- Cooler with cold packs or crushed ice \*

A.2 Venipuncture Procedure

- Enter the sample codes from the blood tube labels in the RTI/EOHSI NHEXAS sample spreadsheet (hereafter referred to as the Spreadsheet).
- Locate a suitable table and chair for blood collecting and lay out blood collection supplies.
- If the participant is a child, have a parent or other caretaker assist holding and comforting the child.
- Locate the puncture site. Hold with two fingers on one side of the "alcohol wipe" so that only the other side touches the puncture site. Wipe the area in a circular motion beginning with a narrow radius and moving outward so as not to cross over the area already cleaned. Repeat with a second alcohol wipe. Wipe off excess alcohol with a sterile gauze square; make certain the alcohol is dry.
- Fix the vein by pressing down on the vein about 1 inch below the proposed point of entry into the skin and pull the skin taut.
- Approach the vein in the same direction the vein is running, holding the needle so that a 15° angle with the participant's arm is attained.



- Push the needle, with bevel facing up, firmly and deliberately into the vein. Activate the first (purple top) vacuum collection tube. If the needle is in the vein, blood will flow freely into the tube. If no blood enters the tube, probe for the vein until entry is indicated by blood flowing into the tube.
- For collection, loosen the tourniquet immediately after blood flow is established and release entirely as the last tube fills. Collect the blood samples in the following order:
  - 3 mL purple-top tube for trace metals sample
  - 10 mL gray-top tube for VOCs sample
  - 10 mL or 15 mL purple-top tube for the archival sample
- Withdraw the needle and dispose of properly in the sharps disposal container.
- When the needle is out of the arm, press gauze firmly on the puncture. Heavy pressure as the needle is being withdrawn should be avoided because it may cause the sharp point of the needle to cut the vein.
- Have the participant raise their arm (not bend it) and continue to hold the gauze in place for several minutes. This will help prevent hematomas.
- Place a bandaid on the participant's arm.
- Mix the tubes to dissolve the anticoagulants by gently inverting the tubes 30 times.
- Immediately place the tubes into a cooler with sufficient ice packs to keep the samples chilled until they are returned to the field laboratory. Do not allow the samples to freeze, e.g. do not store in a vehicle in sub-freezing temperatures.
- Add any needed information about the sample collection to the sample collection record.
- Store the samples in a refrigerator at the field laboratory (or store on wet ice if refrigeration is not available) until shipment. Do not allow the samples to freeze.

#### A.3\* Shipment to CDC

- Metals and VOC blood samples for participants in the study county will be shipped within 3 days of collection when possible, 5 days maximum, using shipment containers provided by CDC. Pre-addressed labels for express shipment (e.g., FedEx) will be sent to the field along with the shippers. The following address should be used (unless noted otherwise at later date):

Dr. David Ashley, Chamblee Bldg. 17, Loading Dock  
Centers for Disease Control  
4770 Buford Highway  
Atlanta, GA 30341  
404-488-7962

- The shipment container will be packed with frozen blue ice packs. The container should be packed as close to pickup time and sent for delivery to CDC on Monday through Friday, excluding non-delivery holidays.

A.4\* Shipment to RTI

- Archival blood samples will be shipped within 3 days of collection when possible, 5 days maximum, using shipment containers provided by RTI.
- The shipment container will be packed with frozen ice packs, and sent for delivery to RTI on Monday through Friday.

## APPENDIX B

### URINE COLLECTION PROCEDURES

B.1 Materials. Urine specimen containers used must be provided by CDC.

- Pre-labeled urine specimen containers (150 mL plastic)
- Resealable plastic bags
- Protective gloves
- Plastic freezer storage box and lid
- Written forms: INSTRUCTIONS FOR COLLECTING URINE SAMPLES
- Freezer with adequate space for storage of . 20 urine specimen containers
- Transport cooler
- Dry ice, approximately 1 kg per 5-6 urine specimen containers

B.2 Identify participant. During the first visit, identify the participant who will be giving urine sample. For a child, determine whether a parent or caretaker will be responsible for urine sample collection.

- If the participant is older than 13 years old, they may collect the urine samples without adult assistance, provided that they demonstrate a willingness and understanding of the instructions.
- For participants between 7 and 12 years of age, and older children that may not be able to correctly collect the samples, a parent or other responsible care giver should assist or supervise the sample collection and ensure that the instructions are followed.
- For participants younger than 7 years of age, the parent or care giver must supervise collection of samples.

B.3 Instructions. During the first visit with the participant, provide a copy of the written instructions (Figure 3) to the participant or the participant's care giver and then read the instructions to the participant or care giver. The following instructions should be emphasized with the participant or care giver during the first visit:

- It is important to collect the first urination after arising in the morning, even if you plan to return to bed.
- If the participant does not have a typical sleep schedule (e.g, he or she works a night shift), explain that we want them to collect the urine samples at the end of their longest sleep period.
- It is very important that the inside of the container and the cap **not be touched in any way**. Exposure to air should be minimized.

- It is very important that the sample be frozen shortly after collection.
- Hands should be washed with soap and water before collection.
- The collection cup should not be opened until just before voiding.
- Leave the cap turned up while voiding, then recap the filled container immediately.
- If dirt gets into the container or onto the inside of the lid, use the spare container.
- After the sample is collected, replace the cap immediately.
- Return the filled specimen container to the resealable plastic bag.
- Place the container into the storage box in your freezer.
- Fill in the Information Sheet: **TIME COLLECTED, DATE COLLECTED, and TIME OF LAST VOID BEFORE *THIS* SAMPLE.**
- Ask the participant or care giver if they have any questions about the procedure. Provide additional instruction and reassurance as necessary.

B.4 Set-up Tasks. During the visit at the start of the monitoring week, the field technician should:

- Demonstrate the uncapping, capping, and sealing of the container in the bag and freezer storage box, using an example container.
- Write the names of the days on the space provided on the instruction sheet. The collection days will be Day 3 and Day 7.
- Ask the participant or care giver to place a freezer storage box in their freezer.
- Leave three (3) pre-labeled containers with the participant or care giver.

B.5 Mid-week Visit Tasks. During the visit on Day 4, the field technician should:

- Retrieve the Day 3 urine sample from the participant's freezer. Check the condition of the sample (i.e. frozen, label intact, no spillage, etc.).
- Check that the Information Sheet is correctly and completely filled. Inquire about any missing, incomplete, or questionable information.

- Ask the participant or care giver if the collection went well and whether they were able to follow the instructions. Record any relevant comments on the information sheet.
- Provide additional instruction to the participant or care giver, if necessary.
- Make sure that the participant has two remaining unused urine containers, one for sample collection and the second as a spare.
- Remind the participant or care giver the day on which we want them to collect the second sample.
- Place the collected urine in a cooler with sufficient ice packs to keep the sample frozen until the sample can be returned to the field laboratory.

B.6 End of Week Visit. On the visit on Day 7, repeat steps in B.5 above.

- In addition, take with you the freezer storage container from the participant's freezer.
- At the field laboratory, place the frozen urine sample in a freezer at a temperature of -2EC or lower. If a freezer is unavailable, dry ice may be used; or, if the storage area ambient temperature will not go above freezing, the sample may be stored in the area.

B.7 Shipment to CDC

- All urine samples for participants in the study county will be shipped to CDC at one time, using shipment containers provided by CDC. Pre-addressed labels for express shipment (e.g., FedEx) will be sent to the field along with the shippers. Until notified otherwise, the following address will be used:

Charles Dodson, Chamblee Bldg.17, Loading Dock  
Centers for Disease Control  
4770 Buford Highway  
Atlanta, GA 30341  
404-488-4305

- The shipment container will be packed with Dry Ice, in approximate equal volumes to the specimen containers, that is, 1 kg per 5-6 containers. Affix the DRY ICE label and fill out the amount of dry ice contained.
- The container should be packed on the same day as shipment and sent for deliver to CDC on Monday through Friday, excluding holidays.

## EXPLANATION OF REVISIONS

Revisions Made 4/96; Denoted by \*

### Section 2.0

Revised to indicate lead and cadmium as analytes in whole blood and arsenic in urine. Also, reference to collection of urine samples in the longitudinal studies was deleted.

### Shipment of Archival Blood Samples

CDC will no longer accept archival blood samples. These will now be shipped directly to RTI for processing and archival storage. Sections 3.2.3, 6.1.1, 6.1.3, 6.1.4, A.3, and A.4 were revised or included to reflect this change.

### Section 4.1

Based on discussions with OMB, the incentive for providing blood samples was lowered from \$50 to \$20.