National Human Exposure Assessment Survey (NHEXAS)

Maryland Study

Quality Systems and Implementation Plan for Human Exposure Assessment

Emory University
Atlanta, GA 30322

Cooperative Agreement CR 822038

Standard Operating Procedure **NHX/SOP-G05**

Title: Storage and Shipping of Samples

Source: Harvard University/Johns Hopkins University

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.*

1 Title of Standard Operating Procedure

NHEXAS Harvard/Emory/Johns Hopkins Standard Operating Procedures:
G05 Storage and Shipping of Samples, Rev. 1.0

2 Overview and Purpose

For the NHEXAS project many different kinds of samples will be collected, some of which will require particularly careful storage and shipping in order to preserve the sample's integrity. This SOP is intended to provide the guidelines necessary for safe and accurate sample storage, tracking, and shipment.

3 Discussion

Some of the samples to be collected for metal, pesticide, or PAH analysis may be unstable. Special storage and shipping techniques must be employed to keep contaminants from degrading, evaporating, or being irretrievably lost to the walls of the storage container.

Materials being stored and shipped during the course of the study include samples being shipped to outside laboratories for analysis, QA/QC samples for analysis, and sampling instruments and materials. This SOP applies to all items except those that need specialized instructions; in that case, this procedure would be superseded by the more specific SOP.

4 Personnel Responsibilities

- The person collecting a sample (Field Technician 1 or 2, Interviewer, or Phlebotomist) will be responsible for ensuring that it is obtained, handled, and transported to the Field Coordination Center (FCC) so that sample integrity is not compromised.

- The FCC Supervisor (or his designate) and the FCC Clerk will be responsible for storage of samples at the FCC and shipping to the laboratory.

- The FCC Clerk is responsible for ordering and maintaining packing supplies, cold packs, and dry ice.

- At the analyzing laboratory, the Laboratory Technician or Sample Custodian will be responsible for ensuring that all samples received are placed into the properly designated storage area.

- All staff handling a sample or other item being stored or shipped are responsible for maintaining chain-of-custody forms, the computer database, and other tracking forms as appropriate.

5 Required Equipment and Reagents

5.1 Storage

- Containers for sample collection and storage will be designated in the appropriate SOPs. Many will be glass or plastic containers with Teflon lined silicone seals.

- All storage containers will be pretreated as specified in the appropriate SOPs; the only possible exception will be supplier guaranteed containers, which will be spot tested prior to usage.

- Transportation from the field to the FCC or other shipping location: Coolers with cold packs will be used, except for "air for metals" and "dermal wipe for metals" samples, which can be transported at ambient temperature. (See Table 1 in section 6.3.)

- Storage: Refrigerators will be used for storage of food, water, dust, and soil samples. Approved biological refrigerators will be used for the storage of urine and blood. Air and dermal wipe samples to be extracted for pesticides and PAHs will be stored in a freezer. Samples to be frozen will be kept at -20°C or colder.

5.2 Shipping

5.2.1 Packing Materials

plastic bags, resealable (Ziplok or equivalent)
CDC specimen boxes (for urine and blood samples)
bubble packing
shipping containers, uninsulated (for shipping samples at ambient temperature)
shipping containers, insulated (for shipping samples with dry ice and with cold packs)
shipping tape: approved tape, plastic or filament
labels: DRY ICE
cold packs, frozen, one per "cold pack" shipping container
dry ice, slabs (1" x 7" x 10" or to fit container), one per "frozen" shipping container

5.2.2 Sample Tracking

computer with database software & printer
bar code reader and labels
photocopier
inventory forms
software to prepare CDC Specimen Shipping Lists (for urine and blood samples)
and shipping lists for other samples
disks with Westat's address on the label
(as a reminder to the recipient to return the disk after copying the file)
copies of logsheets
prepared airbills for Federal Express and other carriers
chain-of-custody forms

6 Procedure

6.1 Receiving, Storage, and Shipping Areas

The Field Coordination Center (FCC) will have designated areas for:

- receiving samples from the field, spiked samples from laboratories, equipment, supplies, etc.
- storage of samples awaiting processing (e.g. Harvard Impactors to be dismantled) or shipping.
- shipping to laboratories.

All areas should be clean and orderly to prevent accidents and misplacement of samples. No samples, materials, or equipment from other studies will be stored, used, or handled there.

The receiving and shipping areas will be distinct to prevent mixups. They will have supplies of forms, packaging materials, etc., and will have access to a photocopier and a computer with a bar code reader and database software.

The storage area will have a refrigerator-freezer and an insulated container for dry ice. Each shelf, drawer, box, and bin will be labeled for the type of sample or other material to be kept there. The labels will be specific to separate categories of equipment, for example:

- filters to be assembled into Harvard Impactors
- Harvard Impactors ready to go to the field
- exposed Harvard Impactors to be disassembled and cleaned
- exposed filters to be shipped
- pumps needing repair

Precautions will be taken to prevent cross contamination.

6.2 Receiving

Any staff member receiving samples, equipment, or supplies will:

- sign a chain-of-custody form with the person delivering the item (for exposed media and prepared unexposed media such as PUF samplers).
- read the bar code on the ID label (if any) with the bar code reader, and log the item into the computer database.
- store the item in the appropriate location.

6.3 Storage

Storage procedures are initiated as soon as a sample is collected. Table 1 shows the conditions, particularly temperature, required during transportation, storage, and shipping. All samples will be kept sealed, and will be shipped with appropriate padding.

Page 11 is a flow chart for biological samples, including storage conditions.

Table 1 -- Sample Storage Conditions
"FCC" includes satellite FCCs and transfer sites (in the case of urine and blood).
"Laboratory" includes SwRI (dust and soil), FDA (food), and CDC (urine and blood).

Sample		**Transportation to FCC**	**Storage at FCC**	**Shipping to Laboratory**	**Storage at Laboratory**
Air - metals (indoor, outdoor, personal)		no special conditions	no special conditions	no special conditions	no special conditions
Air - pesticides, PAHs (indoor) -- can be stored at room temp. before use		cold pack	freezer	dry ice	freezer
Dust and Soil	Before division	cold pack	refrigerator	cold pack	refrigerator
	Metals fraction	---	---	no special conditions	no special conditions
	Pesticide/PAH fraction	---	---	---	refrigerator
Dermal wipe - metals		no special conditions	no special conditions	no special conditions	no special conditions
Dermal wipe - pesticides		cold pack	freezer	dry ice	freezer
Water		cold pack	refrigerator	cold pack	refrigerator
Food (duplicate and mini-market basket)		cold pack	refrigerator	cold pack	refrigerator
Urine	Before division	cold pack	refrigerator	cold pack (to JHU)	refrigerator
	Fractions	---	freezer	dry ice	freezer
Blood	Whole blood	cold pack	refrigerator	cold pack (to JHU)	refrigerator
	Serum	---	freezer	dry ice	freezer

6.4 Shipping

Most field samples will be shipped from the FCC.
Processed samples will be shipped from SwRI (dust, soil, extracts) and the FDA (food).

6.4.1 Preparation

At the beginning of each month, the FCC Supervisor (Brian Dingwall) will prepare a

two-month shipping schedule that will indicate for each sample type:

- when the type of sample will be shipped, e.g. PUF samplers to SwRI on Wednesday of the pickup week (15 samplers) and the following Monday (12 samplers). The schedule will take into account sample requirements and the days on which the laboratory can receive samples.
- recommended carriers and speed (e.g. overnight) based on sample requirements.

The shipping documentation is prepared prior to packing the samples and includes the completed airbill for the carrier.

The sample documentation that accompanies the sample includes:
- inventory forms
- chain-of-custody forms
- special instructions if needed, e.g. analysis instructions for food

6.4.2 Sample Tracking

The FCC Clerk or other person doing shipping must properly complete chain-of-custody forms and enter the sample ID numbers by bar code into the tracking system.

Check to make sure that all individual samples are clearly labeled. Field staff should seal each labeled sample container into a plastic bag before transporting samples to the FCC.

(1) If the bar code identification for the sample is damaged or if one sample has no label, identify the sample and affix the appropriate label. (A spare label may be used or a new one printed.) Explain the problem in the "Comments" section of the chain-of-custody form. The sample may be sent for analysis.

(2) If there are two or more samples of the same type without readable labels, see if they can be identified unequivocally. If they can, proceed as in (1). If they cannot, mark them "Do not analyze" and send. Explain on the chain-of-custody form. These samples must be flagged in the computer system.

Check to make sure that any sample batches to be shipped are complete. If a sample is missing, ship the remainder of samples and flag the missing sample in the tracking system. This sample can be shipped separately when it is located.

The occurrence of any of the above problems should be extremely rare. If such a problem should occur, an additional internal audit must be completed to determine the cause and check the procedures used by personnel.

6.4.3 Inventory of Samples to Be Shipped

Before packing and shipping, an inventory will be made of samples to be shipped in order that all samples are accounted for and documented before shipping. The FCC Clerk (at the laboratory where blood is spun and serum and urine are split, the laboratory clerk) will:

- Assemble the samples that will be packed into one shipping container. If more than one container of samples will be sent to the same person at the same time, assemble all the samples and label the containers, e.g "1 of 3."

- Scan the ID labels with the bar code reader. Print a Specimen Shipping List. (For urine and blood samples, this will be in established CDC format.) If more than one container of samples will be sent to the same person at the same time, the list will include all the samples but indicate which container each sample is in.

- Give the Specimen Shipping List to the FCC Supervisor (or laboratory supervisor) or his/her designate. If the samples are cold or frozen, place the container in the refrigerator or freezer until the paperwork is completed.

- Notify the recipient by telephone or electronic mail at least 24 hours before the shipment will arrive. For most shipments this means before 2:30 PM the day of shipping.

The FCC Supervisor or designate will:

- Review the list and inspect the samples to make sure that the samples to be shipped are accounted for, that no undesignated samples have been packed, and that the properly completed chain-of-custody forms are enclosed. Sign the approved list.

- Check the logsheets and chain-of-custody forms for the samples. If there are any problems that might affect the integrity of a sample, make sure that there is a note on the chain-of-custody form.

The FCC Clerk or laboratory clerk will:

- When the FCC Supervisor or designate has inspected the samples and approved the list, pack the samples into the shipping container as shown in section 6.4.5.

- Photocopy the completed Specimen Shipping List. Initial the original and copy, and file the copy. This list, along with the copy of the airbill, serves as the shipping record to be maintained by the Field Coordinator.

- Seal the original Specimen Shipping List in a 9" x 12" plastic bag and place it with the shipment.

- Copy the Specimen Shipping List onto a disk with Westat's address on the label. Enclose the disk with the shipment. (If there is more than one container, put it in

container 1.)

- Send the Specimen Shipping List to the recipient by electronic mail. (This may be combined with notification if done at least 24 hours before the shipment will arrive.)

6.4.4 Packing Sample Documentation

All documents to be shipped shall have numbered pages, using the format that shows the page number and the total pages, e.g., "page 1 of 3," so that missing pages will be easily identified. Documents that will be transported to the analysis site in sealed plastic bags inside the package with the samples include the following:

- Disk containing the Specimen Shipping List;
- Chain-of-Custody form;
- Any special handling precautions and procedures required immediately upon arrival at the analysis site, e.g., "sample needs to be refrigerated at 4°C", etc.

6.4.5 Packing Samples

All necessary and prescribed safety precautions will be taken, including safe handling of samples, using appropriate personal safety equipment, and making sure that all samples are properly packed and labeled as to any potential hazard.

The FCC Clerk or JHU Clerk will:

- Package the samples to be shipped in one or more appropriate containers. Samples are to be securely packaged. For samples contained in glass, the containers will be cushioned first with plastic "bubble wrap" and then with styrofoam "peanuts." The outer packaging will be double corrugated (at minimum) cardboard boxing.

- Refrigerated and frozen samples will be shipped in polyfoam containers as follows:

  → Frozen urine or serum samples: place in CDC specimen boxes (white cardboard freezer boxes). Place each box inside a plastic bag and seal the bag.

  → Whole blood: place the tubes in a CDC specimen box. Place the box inside a plastic bag and seal the bag.

  → Frozen urine or serum, or whole blood: Pack the boxes into the designated shipping container. Frozen urine and serum may be shipped together but frozen samples and whole blood may not be mixed. If necessary, use sheets of bubble-pack material to keep the tubes or bottles vertical. Put one layer of bubble-pack on top.

  → Air PUF samplers, dust, soil, dermal wipe (pesticides), water, and food: Pack into the shipping container with appropriate cushioning. Put one layer of bubble-pack on top.

  → Place a frozen ice pack or a slab of dry ice (as appropriate) in the shipping container.

→ Use more bubble-pack material to even the top of the container. Place the polyfoam lid on top of the shipping container.

- Make sure that the Specimen Shipping List is complete. Seal it into a 9" x 12" plastic bag. If using an insulated container, secure the bag to the top of the polyfoam lid with postal tape. If using an uninsulated container, put the bag under the bubble wrap.

- Secure the outer cardboard lid onto the shipping container with postal tape.

- Label which end should be the "UP" end of the package. Mark "FRAGILE." Include a DRY ICE label if appropriate.

- Complete the Federal Express (or other carrier) form.

- Call Federal Express (or other carrier) and arrange for pickup.

6.4.6 Shipping Frequency and Conditions

When samples are packed safely and ready to be shipped with complete documentation, send out by the appropriate carrier (per the Field Coordinator's instructions). Completed chain-of-custody forms will be signed before shipment and upon receipt of samples.

The following tables show how samples are to be shipped to the laboratory or other destination. "Shipping Frequency" refers to the number of shipments per 2-week subcycle. Samples will be shipped during week 2 of the subcycle when samples are collected, and on the following Monday.

Most samples will be shipped by standard overnight delivery, to arrive by 2:30 PM the next day. Samples being shipped overnight will not be shipped on a Friday or the day before a holiday. Samples being shipped overnight will not be shipped on Thursday for Friday delivery without approval from the recipient. See Table 6 for addresses.

Table 2 -- Shipping from FCC

Sample	Destination	Shipping Frequency	Carrier	Special Packaging	Maximum Transit Time
Air - filters for metals (indoor, outdoor, personal)	Emory	1: end of subcycle	UPS	N/A	5 days
Air - PUF for pesticides, PAHs (indoor)	SwRI	2: Wed. , Mon.	Fedex	dry ice	overnight
Dust and Soil	SwRI	2: Wed. , Mon.	Fedex	cold packs	overnight
Dermal wipe -- metals	Emory	1	UPS	N/A	5 days
Dermal wipe--pesticides	SwRI	1	Fedex	dry ice	overnight

Water	EPA-EMSL	1	Fedex	cold packs	overnight
Food (duplicate and mini-market basket)	FDA	2: Wed. , Mon.	Fedex	cold packs	overnight

Urine and blood samples will be shipped with input from the analytical laboratory (CDC). Samples will be shipped using Federal Express or similar carrier on an overnight basis. Typically, samples will be shipped on Tuesday and Thursday (if approved by recipient) of the first week of sampling, and the following Monday, to ensure that no Saturday, Sunday, or holiday deliveries will occur.

Table 3 -- Shipping Blood Samples from FCC [RAW -- check Randy Watts]

Medium	Analyte and Sample Type	Container	Destination	Special Packaging
Whole Blood	PAHs: 83	10 mL purple top tube	Randy Watts	cold pack
	Metals: 81	3 mL purple top tube	David Ashley, CDC	cold pack
	VOCs: 84	10 mL gray top tube	David Ashley, CDC	cold pack

Table 4 -- Shipping Urine and Serum Samples from Laboratory

Medium	Analyte and Sample Type	Container	Destination	Special Packaging
Urine	Metals: 62, 72	15 mL blue capped tube	Charles Dodson, CDC	dry ice
	Pesticides: 63, 73	60 mL glass Wheaton bottle	Charles Dodson, CDC	dry ice
	Creatinine: 65, 75	2 mL cryovial	Charles Dodson, CDC	dry ice
Serum	Pesticides: 85	10 mL glass Wheaton bottle	Charles Dodson, CDC	dry ice
	Lipids: 86	5 mL glass Wheaton bottle	Charles Dodson, CDC	dry ice

Table 5 -- Shipping from SwRI

Sample	Destination	Shipping Frequency	Carrier	Special Packaging	Maximum Transit Time
Dust & soil fractions for metals analysis	Emory	turnaround time $\leq$ 1 week	UPS	N/A	5 days

Table 6 -- Shipping of Food Daughter Samples from FDA

		Shipping		Special	Maximum

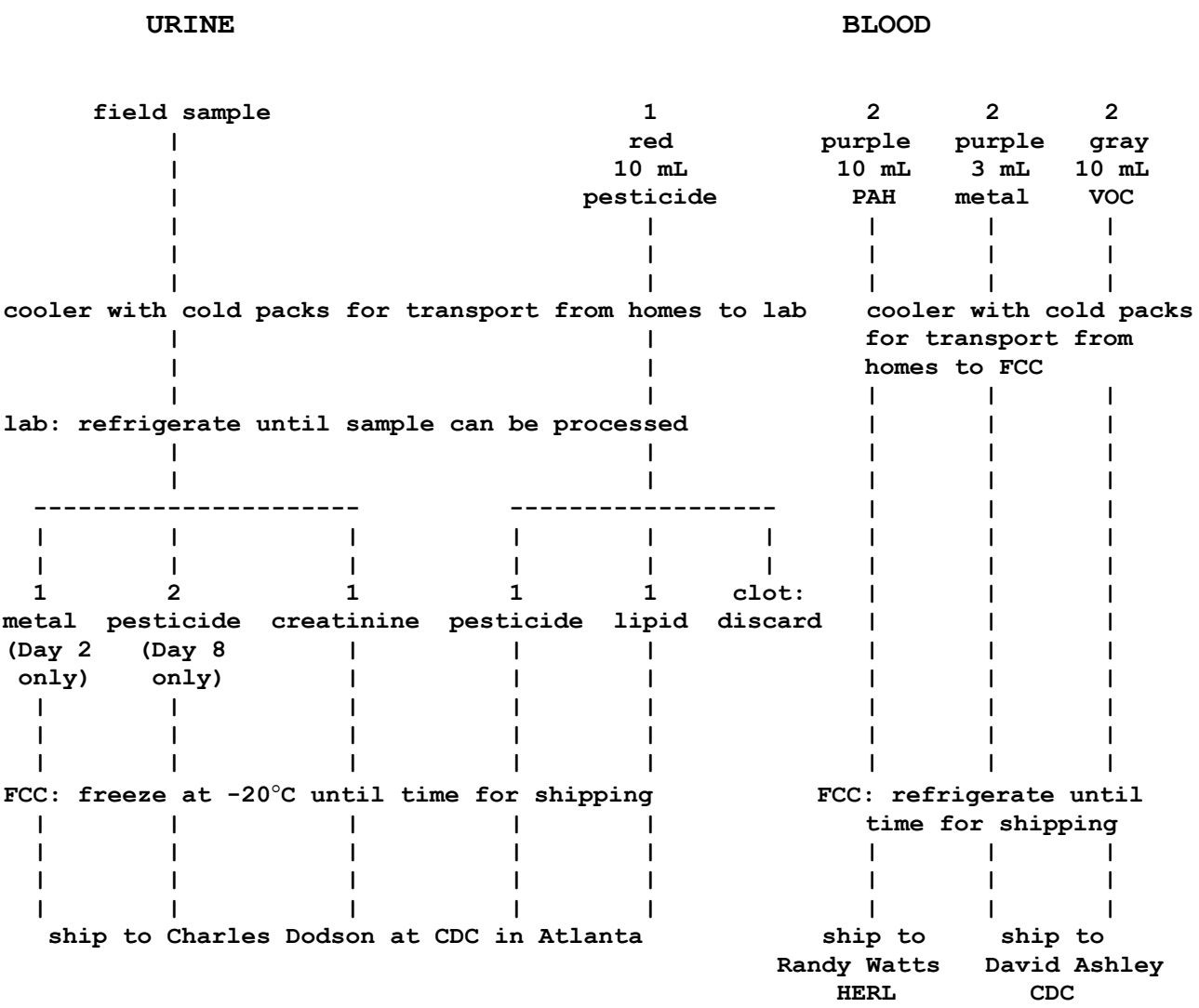
Purpose	Destination	Frequency	Carrier	Packaging	Transit Time
metals analysis			Fedex	cold pack	overnight
pesticides analysis			Fedex	cold pack	overnight
PAHs analysis			Fedex	cold pack	overnight
archive			Fedex	cold pack	overnight

Table 6 -- Addresses [RAW -- do you have any other email addresses for these people?]

Sample Type	Address	Phone & Email
Air for metals (outdoor, indoor, personal) Dermal wipe for metals Dust and soil fractions for metals	Bryan Burnette Rollins School of Public Health 1518 Clifton Rd, NE Room L37 Atlanta, GA 30322	404-727-9259
Dust Soil Dermal wipe for pesticides	David Camann / JoAnn Boyd Southwest Research Institute 6220 Culebra Road San Antonio, TX 78238	DC 210-522-2673 dcamann@swri.edu JAB 210-522-2169 fax 210-522-3649
Water for metals	Attn. Husein Sitabkhan, Lab Director Trans Enviro, Inc. 19701 South Miles Road Warrensville Heights, OH 44128	216-663-0808
Water for pesticides	Attn. Pete Youll, Project Manager (or Rick Bauer) Aqua Tech Environmental Laboratories, Inc. 6878 South St. Route 100 Melmore, OH 44885	1-800-783-5991
Water, food/beverages, urine, blood: photocopies of chain-of-custody forms	Lisa Melnyk Research Containment Facility Andrew Breidenbach Environmental Research Center 26 Martin Luther King Dr. Cincinnati, OH 45286	513-569-7494 MELNYK.LISA@ epamail.epa.gov Maurice Berry 513-569-7284 BERRY.MAURICE@ epamail.epa.gov
Food/beverages (field samples for splitting)	Kevin Cline Food & Drug Administration Kansas City District Office 11630 W. 80th St. Lenexa, KS 66214	913-752-2158 fax 913-572-3649
Urine and serum samples	Charles Dodson Chamblee Bldg. 17, Loading Dock Centers for Disease Control and Prevention 4770 Buford Highway Atlanta, GA 30341	404-488-4305
Whole blood samples to be analyzed for PAHs	Randy Watts / Joellen Lewtas [RAW -- check] U.S. Human Studies Facility	RW 919-966-0649

	MD-58C 104 Mason Farm Road Chapel Hill, NC 27599-7315	JL 919-966-0658 fax 919-966-0655
Whole blood samples to be analyzed for metals and VOCs	Dr. David L. Ashley Chamblee Bldg. 17, Loading Dock Centers for Disease Control and Prevention 4770 Buford Highway Atlanta, GA 30341	404-488-7962

Flow Chart for Biological Samples



[RAW - check]

7 Quality Assurance Procedures

To ensure that the storage and shipping procedures are valid, samples with known values will be carried through the entire storage and shipping procedure and percent recovery determined. In some cases, e.g. house dust, there may not be an acceptable standard but all attempts will be made to provide a reasonable substitute.

[RAW - you asked WHEN? Didn't you write this section?]

These test samples will be analyzed initially, then at the time of analysis of the collected samples. Acceptable recoveries will be in accordance with standard procedures for each medium, where such information already exists, e.g., NIST 1643c for metals in water. Otherwise, acceptable recoveries will be established.

8 References

NHEXAS Harvard/Emory/Johns Hopkins Standard Operating Procedures:

G03 Identification Numbers for Samples and Forms
G04 Chain-of-Custody and Sample Tracking
G06 Problem Management
G07 Training of Field Technicians
F01 Field Sampling -- General Information
F02 Collection, Storage, and Shipment of Indoor and Outdoor Air Samples for Metal, Pesticide, and PAH Analysis
F03 Collection, Storage, and Shipment of Personal Air Samples for Metal Analysis
F04 Collection, Storage, and Shipment of House Dust Samples for Metal, Pesticide, and PAH Analysis
F05 Collection, Storage, and Shipment of Soil Samples for Metal, Pesticide, and PAH Analysis
F06 Collection, Storage, and Shipment of Dermal Wipe Samples for Metal and Pesticide Analysis
F07 Collection, Storage, and Shipment of Drinking or Tap Water Samples for Metal and Pesticide Analysis
F08 Collection, Storage, and Shipment of Duplicate Diet Samples for Metal, Pesticide, and PAH Analysis
F09 Administration and Analysis of Food Checklist and Purchase of Mini-Market Basket Food
F10 Collection, Storage, and Shipment of Urine Samples for Metal, Pesticide, and Creatinine Analysis
F11 Collection, Storage, and Shipment of Blood Samples for Metal, Pesticide, PAH, VOC, and Lipid Analysis
F12 Duplicate Sampling
D01 Data Flow Procedures

Specimen Collection and Shipping Protocol (NHEXAS). Division of Environmental Health Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention, Atlanta, Georgia 30333. (Prepared: 4/19/91. Revised: 05/01/95.)

Standard Operating Procedures for Storage and Custody of NHEXAS Food or Beverage Composites. U.S. Food and Drug Adminstration, Center for Food Safety and Applied Nutrition, Elemental Research Branch, Washington, DC. (Revision: 0, Issue Date: June 1, 1995)