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TITLE: SAMPLE CODING, LABELING, AND FIELD TRACKING PROCEDURES

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SAMPLE CODING, LABELING, AND FIELD TRACKING PROCEDURES

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1.0 SCOPE AND APPLICATION

This protocol is intended to define the coding scheme, labeling procedures, and field tracking for samples collected in the National Human Exposure Assessment Survey Phase I field monitoring study. Unique sample codes will be assigned to all personal, environmental, biological, and quality control samples. A label bearing the code in both bar code and alpha-numeric character formats will be affixed to all samples or sample containers. The purpose of the code is to allow identification and tracking of each sample throughout its lifetime. Sample codes will be only partially descriptive, with two letters to identify sample type followed by four digits to provide a unique number for each sample. Only six characters will be used in the code to facilitate the creation of computer file names that include the sample code. Bar codes will be used to allow sample code entry into electronic format both at the field site and in laboratories equipped to read the labels.

Participant identification codes (unique three-digit numbers) will be printed on labels with both bar codes and alpha-numeric characters. These labels will be applied to study documents and some types of sample collection containers.

Labels with unique codes (bar codes and alpha-numeric characters) will also be applied to most equipment (pumps, balances, flow measuring devices, etc.) used at the field site for sample collection or measurement.

The Field Supervisor will be responsible for the development, preparation, and application of labels to sample containers and equipment. Field staff may also be assigned these tasks under the direction of the Field Supervisor. Field staff will be responsible for adding participant identification codes to all field study documents.

2.0 SUMMARY OF THE METHOD

Sample, participant, and equipment labels will be prepared at RTI and distributed to the specific locations where they will be applied to sample containers, documents, and sample collection equipment. Sample labels will be comprised of six characters. The first two characters will be letters that designate the sample type. This two letter combination will be repeated for all samples of the same type. The final four characters will be a unique

combination of four numbers. In a few cases, more than one container of the same sample will be collected from a participant. In this case, a one-character suffix will be appended to the sample code. Labels will be affixed to the sample containers or equipment at the specified locations.

Participant identification code labels will be affixed to a defined group of sample containers and all study documents associated with each participant (questionnaires, diaries, diagrams, etc.).

Equipment codes will usually consist of one or two letters that define the type of equipment, and numbers that uniquely identify each piece of equipment.

The sample and equipment codes will be entered into the sample collection record as necessary, using either the bar code scanner or directly using the keyboard. Participant identification codes will be entered into the sample collection record software at one point and will be electronically assigned to all sample data records.

Records of sample transfer or disposition will be provided to the RTI Database Manager to allow sample tracking from the point of collection up to and including the submission of the analysis data.

3.0 MATERIALS AND EQUIPMENT

3.1 Computer, 486SX or higher, 8MB RAM or higher, 3.5" 1.44MB floppy disk drive, DOS 6.0 or higher, Windows 3.1, LabelWorks for Windows.

3.2 Custom created sample collection and custody record software. This software will form a computer file that will be used by the field staff to enter the all of the sample, participant, and equipment codes (see RTI/ACS-AP-209-086).

3.3 Laser printer

3.4 Self-adhesive labels, assorted sizes

3.5 Bar code scanner capable of reading code 128

4.0 CODE DEFINITIONS

4.1 Sample Codes

4.1.1 Each sample collected or produced during the NHEXAS study will be labeled with an unique code number. The code number will be the link between any collection or custody data and the sample.

4.1.2 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: WWXXYY(Z)

where:

WW = Sample type designator

AA	=	air filters for aerosols, IOM
AT	=	air filters for aerosols, PM_{10}
AV	=	air passive badges, VOCs
BA	=	whole blood, archival
BM	=	whole blood, metals
BV	=	whole blood, VOCs
DC	=	dust deposition, carpet
DD	=	duplicate diet food or beverage
DP	=	dust deposition, plate
HR	=	hair
LA	=	LWW dust wipe, arsenic
LM	=	LWW dust wipe, metals
SE	=	soil from entranceway
SY	=	soil from yard
TA	=	dust wipe arsenic, WWT
TM	=	dust wipe metals, WWT method
UR	=	urine
WA	=	water for arsenic
WM	=	water for metals
WV	=	water for VOCs

XX = a) Unique sample identification numbers, from 01 to 79

b) Extra labels kept on-site numbered from 80-89

c) Lab-prepared quality control samples, unique numbers from 90 to 91

YY = Unique sample identification numbers from 01 to 99

(Z) = Identifier for multiple containers of the same sample (dietary, water VOC). This identifier will be a letter starting with "A".

4.1.3 The four-digit sample identifications numbers may include special number sets to help define certain types of samples or sample collection locations. For example, the first two digits might be used to designate a particular county. Or, a combination of digits may be used to identify, for example, quality control samples In all cases, the four-digit code must remain a unique identifier. Any specific coding sequences must be recorded in a laboratory notebook maintained by the RTI Field Supervisor.

4.1.4 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. and still meet the eight-character limit used for many computer software file names. One extra character will be used to identify multiple samples of the same matrix.

4.1.5 Nondescriptive codes will require that information associated with the samples 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 included in each sample record, and thus, linked to the sample code.

4.1.6 Dietary sample coding is more complex, particularly for the aliquots that will be created after samples are homogenized at the FDA laboratory. The dietary sample and sample aliquot coding schemes are described in Figures 1 and 2. The Field Supervisor will be responsible for supplying dietary sample aliquot labels to FDA-Kansas City personnel.

4.2 Participant Identification Codes

4.2.1 A unique three digit identification code will be assigned to each participant by the Field Supervisor, or by the field staff under the direction of the Field Supervisor. This number will be independent of, but linked to, any other identification numbers assigned by the survey operations staff.

4.2.2 A three digit code is needed so that the field staff can easily recognize documents, samples, file names, etc.

4.2.3 The code is defined as follows:

General Code Format: XXX

where the three digits range from 001 to 999

4.3 Equipment Identification Codes

4.3.1 Equipment used to collect or process samples in the field will be assigned an equipment code. The equipment code will be entered into the sample collection and custody record to provide a link between the equipment and individual samples.

4.3.2 The code is defined as follows:

General Code Format: XXYY

where

XX = a two letter code defining equipment type as follows:

- FD = flow measuring device
- MB = Mettler BD6000 balance
- TC = thermoelectric cooler
- RF = field refrigerator
- FR = field freezer

YY = a two digit code that uniquely identifies each device, 01 to 99

5.0 PREPARING LABELS

5.1 Sample Code Labels

5.1.1 All original sample labels will be prepared at RTI for distribution to the location where they will be applied to the sample containers. The Field Supervisor will be responsible for the code labels during all phases of preparation and field activities.

5.1.2 In most cases, only one copy of each label will be prepared for field use so that there will be no chance of having two samples labeled with the same code. If cases arise where a second label, identical to the original, must be used to continue sample identification after some action, a confirmation check will be employed to ensure that the correct label is used.

5.1.3 Quality control samples (blanks, controls, etc.) prepared at the laboratory will be identified using labels that have a "9" as the third character. Field blanks will have "90" as the third and fourth characters. Field controls will have "91" as the third and fourth characters.

5.1.4 A set of labels will be prepared for each sample type that can be applied in the field in case, for some reason, the original label can not be used. The third and fourth characters in these labels shall be "80" so the supervisory staff will be able to identify those samples that were relabeled in the field. These labels will be designated "Field Extra Labels" and will be maintained by the field staff. Some of these labels will remain at the field laboratory and some will accompany the field team to the homes in case a sample must be relabeled or a replacement sampler or sample container must be used during the home visit.

5.1.5 The Field Supervisor will maintain custody of all labels until they are distributed to the point of application. It will be the Field Supervisor's responsibility to make sure that all sample code labels are unique.

5.1.6 The individual analysis laboratories will be responsible for preparing labels and applying the correct code to processed samples (extracts, digests, homogenates, etc.) with the exception of the FDA-KC food homogenization laboratory. Laboratory Supervisors may request that the Field Supervisor provide labels with the correct sample codes to be affixed to post-processing containers.

5.1.7 All sample code labels will be prepared with six alpha-numeric characters (seven for dietary and water VOC samples) and a Code 128 bar code appearing on the label. If there is sufficient room, the label will also include "NHEXAS RTI/EOHSI".

5.2 Participant ID Code Labels

5.2.1 Sets of three digit participant ID code labels will be prepared for application by the field staff and laboratory staff to sample containers and documentation.

5.2.2 Multiple sheets of labels will be prepared for each participant.

5.2.3 All participant code labels will be prepared with three alpha-numeric characters on the label. These labels should be kept small, so no other information will appear on the label.

5.3 Equipment ID Code Labels

5.3.1 Duplicate sets of equipment ID labels will be prepared prior to the study.

5.3.2 One set of labels will be applied to the equipment.

5.3.3 The other set of labels will be sent to the field in case of damage or loss of the original label.

5.3.4 All equipment codes will be prepared with four alpha-numeric characters.

6.0 APPLICATION OF LABELS

6.1 Sample Code Labels

6.1.1 Labels for the water bottles will be affixed to the bottles at RTI. Clear tape will be placed over the label and will be wrapped around the entire bottle.

6.1.2 Labels for the food bottles will be affixed to the bottles at RTI. Clear tape will be placed over the label and will be wrapped around the entire bottle.

6.1.3 Labels for the VOC badges will be sent to the field along with the badges, and will be affixed to the back sides of the badges as they are removed from their cans at the participant home. A piece of clear tape will be placed over the labels to protect them from abrasion while being worn by the participants.

6.1.4 Labels for soil collection bags will be affixed to the bags at RTI.

6.1.5 Labels for the LWW dust sample filters will be sent to EOHSI. Personnel there will affix the labels to the filter packaging before or during filter weighing.

6.1.6 Labels for the WWT dust samples will be affixed at RTI to the bags in which the wet towels will be placed after sampling.

6.1.7 Labels for the aerosol filters/cassettes will be placed on the cassette holder at RTI before or during the sample weighing procedure. Clear tape will be placed over the label to protect from abrasion while being worn by the participant.

6.1.8* Labels for the plate dust deposition samplers will be sent to EOHSI to identify samples when they have been returned by the participant.

6.1.9* Labels for the carpet dust deposition samples will be sent to EOHSI to identify samples when they have been returned by the participant.

6.1.10 Labels for the urine samples will be affixed to the containers at RTI after receipt from CDC. Clear tape will be placed over the label.

6.1.11 Labels for the blood Vacutainers will be affixed to the containers at RTI after receipt from CDC. Clear tape will be placed over the label.

6.2 <u>Participant ID Labels</u>

6.2.1 Participant ID labels will be affixed to the following documents.

Time and Activity Diary

24-hour Food Diary

Food Diary Followup Questionnaire

Technician Questionnaire

Soil Sample Collection Diagram

Participant Information/Appointment Sheets

Descriptive and Baseline Questionnaires -- if these are given to the field staff for return to RTI.

6.2.2 It is imperative that the ID code labels be affixed to the survey documents listed above so that there is a record linking the survey ID with the participant ID.

6.3 Equipment ID Labels

6.3.1 Labels for aerosol collection pumps, the food balance, the aerosol sample filter balance, pump flow measuring devices, and any other field equipment will be affixed to the equipment at RTI prior to being used in the field. Whenever possible, the labels will be covered with clear tape for protection.

6.3.2 Any equipment purchased or obtained after the study begins may be labeled either at the laboratory or at the field site.

7.0 SAMPLE TRACKING

7.1 Field Sample Tracking

7.1.1 Field staff will be responsible for custody of all samples from the time of collection until the time they are shipped.

7.1.2 The sample code on each sample will be identical to the code that appears in the appropriate field in the data collection record.

7.1.3 Field staff will ascertain that all samples are accounted for, using the sample shipping software, prior to shipping samples to the analysis laboratory.

7.1.4 Missing samples will be reported to the Field Supervisor as soon as possible.

7.1.5 Field staff will transmit copies of the shipping summary sheets for each sample type to the Field Supervisor after work is completed in each country.

7.1.6 Field staff will transmit a copy of the computer shipping file for each sample type to the Field Supervisor after work is completed in each country.

EXPLANATAION OF RTI/EOHSI NHEXAS DIETARY SAMPLE CODES

General Format: DDXXXXWY

Where:

DD = Duplicate diet sample (can be either solid food or beverage)

XXXX = Unique 4-digit sample identification number. A single number will be used on all bottles of solid food collected for a given participant. A single, but different number will be used on all bottles of beverage collected from a given participant.

W = A letter to indicate the collection day, where:
- A = Day 1
- B = Day 2
- C = Day 3
- D = Day 4
- Z = The composite prepared by combining the four daily samples

Y = A letter to designate each individual aliquot of a homogenized sample. This character will not appear on the samples collected in the field.

NOTES:

1. The sample label will include the text: NHEXAS - RTI/EOHSI

2. Samples sent from the field site by RTI staff that are intended for preparation of both daily and 4-day sample aliquots will have a second label on each bottle to alert FDA staff. This label will read:
   FOR DAILY SAMPLE PREPARATION

Figure 1. NHEXAS dietary sample coding scheme.

NHEXAS RTI/EOHSI DIETARY SAMPLE CODING AND ALIQUOT PREPARATION (EXAMPLES)

DIETARY SAMPLES FOR 4-DAY COMPOSITE ANALYSIS

Daily Samples (Collected in the field)		Aliquots of Homogenized 4-Day Composite	
DD7004A (Day 1 sample)		DD7004ZA	FDA 50g
		DD7004ZB	FDA 50g
DD7004B (Day 2 sample)		DD7004ZC	FDA 50g
		DD7004ZD	RTI 50g
	>	DD7004ZE	RTI 50g
DD7004C (Day 3 sample)		DD7004ZF	RTI 125g
		DD7004ZG	EPA 50g
DD7004D (Day 4 sample)		DD7004ZH	EPA 125g

DIETARY SAMPLES FOR DAILY AND 4-DAY COMPOSITE ANALYSIS

Aliquots of Homogenized Daily Samples			Daily Samples (Collected in the field)		Aliquots of Homogenized 4-Day Composite	
FDA 50g	DD7002AA					
FDA 50g	DD7002AB					
FDA 50g	DD7002AC	<	DD7002A (Day 1 sample)			
RTI 50 g	DD7002AD					
RTI 50 g	DD7002AE					
EPA 50g	DD7002AF					
FDA 50g	DD7002BA					
FDA 50g	DD7002BB					
FDA 50g	DD7002BC	<	DD7002B (Day 2 sample)		DD7002ZA	FDA 50g
RTI 50 g	DD7002BD				DD7002ZB	FDA 50g
RTI 50 g	DD7002BE				DD7002ZC	FDA 50g
EPA 50g	DD7002BF			>	DD7002ZD	RTI 50g
FDA 50g	DD7002CA				DD7002ZE	RTI 50g
FDA 50g	DD7002CB				DD7002ZF	RTI 125g
FDA 50g	DD7002CC	<	DD7002C (Day 3 sample)		DD7002ZG	EPA 50g
RTI 50 g	DD7002CD				DD7002ZH	EPA 125g
RTI 50 g	DD7002CE					
EPA 50g	DD7002CF					
FDA 50g	DD7002DA					
FDA 50g	DD7002DB					
FDA 50g	DD7002DC	<	DD7002D (Day 4 sample)			
RTI 50 g	DD7002DD					
RTI 50 g	DD7002DE					
EPA 50g	DD7002DF					

Figure 2. NHEXAS dietary sample aliquot coding scheme.

EXPLANATION OF REVISIONS

Revisions Made 4/96; Denoted by *

Sections 6.1.8 and 6.1.9

We found that labels might not adhere to the carpet and plate dust collectors after several months in a home. The procedure was modified to have EOHSI label the samples immediately upon return by the participant.