United States Environmental Protection Agency

Office of Research and Development

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 **RTI/ACS-AP-209-071**

Title: Sample Custody Procedures

Source: Research Triangle Institute

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

FIELD OPERATIONS PROTOCOL	RESEARCH TRIANGLE INSTITUTE POST OFFICE BOX 12194 RESEARCH TRIANGLE PARK, NC 27709-2194	RTI/ACS-AP-209-071 Page 1 of 10

TITLE: SAMPLE CUSTODY PROCEDURES

SOURCE: Research Triangle Institute
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STATUS:

IN PROGRESS: ☐

DRAFT: ☐

FINAL VERSION: ☒

REVISIONS:

No.	Date	No.	Date
0	4/23/96	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.

SAMPLE CUSTODY PROCEDURES

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1.0 SCOPE AND APPLICATION

This protocol is intended to define custody procedures for samples and quality control samples collected in the National Human Exposure Assessment Survey Phase I field monitoring study. Samples for which custody must be documented include all personal, environmental, biological, and quality control samples. Custody records will provide a mechanism for tracking samples and assessing sample collection and processing completeness. Custody records will document the date and person responsible for collection, transfer, and sample handling steps associated with each sample. Custody records will also provide a reviewable trail for quality assurance purposes. The scope of generating and maintaining custody records is limited in this study and is not intended to be implemented at the level of complete chain of custody that would be required for regulatory measurements.

2.0 SUMMARY OF THE METHOD

Sample collection and custody records will be initiated in an electronic format at the field site to facilitate data entry, data transfer, sample tracking, and to provide remote review capability. The field staff member responsible for initiating sample collection, completing sample collection, or retrieving samples collected by participants will enter the date, sample identification code, time (for most sample types), and operation performed into the sample collection and custody electronic record for each sample. Shipping of samples from the field site will be recorded in the shipping and custody form generation software. A paper custody record (example in Figure 1) will be printed and will accompany each sample as it is shipped from the field to the analysis or archival laboratory. RTI/EOHSI consortium staff will be responsible for maintaining and continuing the custody record for each sample, documenting all receipt, processing, and analysis steps. The Federal laboratories will be strongly encouraged to use the paper custody records provided with the sample, and to return the custody record to RTI along with the analytical data.

3.0 MATERIALS AND EQUIPMENT

3.1* Portable field computer, 486SX, 8MB RAM, 200MB hard drive, 3.5" 1.44MB floppy disk drive, 9600/2400 FAX/modem, DOS 6.0, Windows 3.1, Quattro Pro 5.0 or higher.

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

3.3 Printer for Computer Output

3.4 Portable Copier

3.5 Printer and Copier Paper

3.6 3.5" 1.44MB DOS-formatted Floppy Diskettes

4.0 CUSTODY PROCEDURES: FIELD

4.1 Sample custody will be initiated at the point of collection for personal, environmental, and biological samples.

4.2 The field staff member responsible for initiating sample collection, completing sample collection, or retrieving samples collected by the participant or phlebotomist will enter their employment ID code, date, and time of day (for most sample types), and activity performed into the electronic sample collection and custody data record. The type of custody information to be collected for each particular sample is defined in the sample collection protocols. (In some cases the activity will have a default value in the software. The staff member may use the default or modify if a different activity was performed.)

4.3 Additional appropriate information will be recorded in the electronic data record at the time samples undergo any additional processing at the field laboratory.

4.4 After sample collection and field processing activities have been completed, and before sample shipment, a field staff member will review all sample collection and custody records for obvious errors and omissions. The person performing this review will write their initials and the review date in the data review log section of the field notebook. Any questions about the data will be resolved at the field site; unresolvable errors and corrective action will be noted in a field notebook.

4.5 The field staff member responsible for shipping the sample to the analysis or archival laboratory will enter their ID code, shipping date, and shipping destination into the electronic sample shipping and custody software as samples are being prepared for shipment.

4.6 Before shipping the sample, a paper copy of the custody information will be printed. This paper copy will accompany the sample to its destination. This copy will include sufficient space for the receiving laboratory to document custody of receipt and internal processing and analysis procedures and transfers. The paper copy will also include any sample collection information needed by the laboratory for processing, analysis, or calculation purposes.

4.7 Copies of the electronic version of the sample collection and shipping records will be returned to RTI at the end of the monitoring period in each county.

4.8 The Field Supervisor, or his qualified designee, will examine the records for obvious errors or omissions. The Field Supervisor or his designee will write his or her initials and the review date in the data review log section of the laboratory notebook. Any questions about the information will be resolved through conversation with the field staff, and errors and corrective action will be documented in a laboratory notebook.

4.9 Electronic data and custody record copies will be archived in a locked file cabinet under the control of the Field Supervisor.

4.10* <u>Backup of Sample Collection Records in the Field</u>

- 4.10.1 Field staff members will make two electronic copies, an original and a backup, any time an electronic sample collection data record is accessed.
- 4.10.2 The original version will reside on the hard disk drive of the laptop computer.
- 4.10.3 The backup copy will be written to a removable diskette.
- 4.10.4 The backup copy of each file will be made before each data entry session is terminated. Termination is defined as turning the computer off or discontinuing work for 30 minutes or more.
- 4.10.5 Backup diskettes will be stored, by a field staff member, in a location different than the computer to prevent total loss of data.
- 4.10.6 A second complete copy of all of the sample collection records will be made on a Bernoulli disk for return to the Field Supervisor at RTI when the work in a county is completed. A second Bernoulli disk will be used for field archival of

complete sample collection records. At this point, there will be three copies of each file; one on the backup diskette, one on the Bernoulli that remains in the field, and one on the Bernoulli that is transferred to the laboratory.

5.0 CUSTODY PROCEDURES: LABORATORY

5.1 Samples collected at the field site will be shipped to the following laboratories for analysis, processing, or archival:

1. Research Triangle Institute
2. Environmental and Occupational Health Sciences Institute
3. Centers for Disease Control
4. Food and Drug Administration
5. EPA-designated water analysis contract laboratory(ies)

Custody procedures within RTI and EOHSI laboratories are specified in this protocol. We strongly urge participating Federal and Federal-contract laboratories to follow these procedures. If the Federal and Federal-contract laboratories do not follow these procedures, they must use their own custody records that can be traced directly to the sample through the sample ID code.

5.2 One person will be identified at each laboratory who is responsible for receiving samples from the field site. This person, or their qualified designee, will inspect each sample as it arrives. Any problems or comments will be noted on the paper sample collection and custody record that arrives with the sample. The person will add initials and date of receipt in the appropriate columns, and the comment "received" under the "Operation Performed" heading.

5.3 Any problems with the samples, noted on receipt, that could compromise integrity of the data derived from the sample is to be reported in writing to the RTI Field Supervisor within one week. Examples of such problems include, but are not limited to: missing sample, damaged sample, loose or open sample container cap, missing or unreadable sample code label, missing or unreadable sample collection and custody record, or the arrival of warm or thawed samples when they are supposed to be shipped cold or frozen.

5.4 The person responsible for sample receipt may either place the sample in proper storage or immediately transfer custody to the laboratory staff member responsible for the next stage of processing or analysis.

5.5 The laboratory staff member will receive the sample and the sample collection and custody record from the person responsible for sample receipt. The laboratory staff member will initial the custody record, add the receipt date, and add the comment "received" under the "Operation Performed" heading. The laboratory staff member will be responsible for maintaining the sample under the correct conditions and will be responsible for the custody record while the sample is under his or her custody.

5.6 Any processing or analysis step will require updating the custody record with the initials of the person performing the activity, the date on which the activity is performed, and the operation performed.

5.7 Steps 5.5 and 5.6 will be followed if any activity is performed on the sample or processed sample by other laboratory staff members.

5.8 Upon completion of sample analysis, the person responsible for the analysis must return the original custody record to the RTI Field Supervisor. If a sample is not analyzed, but is archived, the original custody record should stay with the sample with a copy sent to the Field Supervisor.

5.9 In the course of sample processing, it may be necessary to create one or more new samples from the original sample. In these cases the laboratory is responsible for creating and maintaining a new custody record for each sample or group of samples. There must be a direct link between the new and original sample based on the original sample code. Upon completion of all sample processing and analysis activities at the laboratory, the person responsible for the final activity must return the original, or a copy, of the original sample custody records and laboratory-created custody records to the RTI Field Supervisor.

5.10 The RTI Field Supervisor or his designee is responsible for assembling and maintaining files of all custody records as they are submitted. These files will be locked and access shall be provided only through the RTI Field Supervisor or his designee. The Field Supervisor may distribute copies of the originals upon request, but may not release the originals except by written request through the Principal Investigator.

5.11 The RTI Field Supervisor will maintain a written record of missing or incomplete custody records. Laboratory supervisors will be contacted to obtain or complete the records. A report of missing or incomplete custody records and samples will be provided to the RTI Quality Assurance Officer.

6.0* CUSTODY PROCEDURE: QUALITY CONTROL SAMPLES

6.1 Quality control samples may include duplicate (collocated) samples, field blanks, field controls, container blanks, and a variety of laboratory blanks, controls, duplicates, replicates, spikes, and method evaluation samples.

6.2 Custody procedures described in Sections 4.0 and 5.0 must be followed for all quality control samples that are either sent to the field or originate outside of the analytical laboratory. Custody procedures should also be followed for internal laboratory quality control and quality assurance samples.

NATIONAL HUMAN EXPOSURE ASSESSMENT SURVEY
SAMPLE COLLECTION AND CUSTODY RECORD
RTI/EOHSI CONSORTIUM

SAMPLE CODE:	PARTICIPANT I.D.:	COUNTY I.D.:

SAMPLE TYPE:	VOC Badge
TO BE ANALYZED FOR:	VOCs

COLLECTION COMMENTS: _____

PROCESSING COMMENTS: _____

CUSTODY RECORD				
--CUSTODY OF--				
ORG.	INITIALS	ID	DATE	OPERATION PERFORMED
RTI				Sample Collected
RTI				Sample Shipped to RTI

Research Triangle Institute, Analytical and Chemical Sciences, P.O. Box 12194, RTP, NC 27709

Figure 1. Example of a printed custody record.

EXPLANATION OF REVISIONS

Revisions Made 4/96; Denoted by *

Section 3.1

Revised to indicate later versions of computer and software can be used.

Section 4.10.6

Original 4.10.6 deleted. The backup diskettes will be kept at the field site until it is convenient to return them.

Section 6.0

The original Section 6.3 described procedures for initiating custody records for laboratory-prepared QC samples. The Federal labs were not following this procedure, and it was found at RTI that it was better to record preparation information in a laboratory notebook. Section 6.3 was deleted.