

The Arizona Border Study

*An Extension of the
Arizona National Human Exposure Assessment Survey (NHEXAS) Study
Sponsored by the Environmental Health Workgroup of the Border XXI Program*

Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 824719

Standard Operating Procedure

SOP-UA-C-1.0

Title: Custody of Field Samples

Source: The University of Arizona

U.S. Environmental Protection Agency
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APPROVALS

On Site Principal Investigator:

Project QA Director:

Independent Reviewer:

On Site PI:

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Custody of Field Samples

1.0 PURPOSE AND APPLICABILITY

This SOP outlines sample custody guidelines used by the NHEXAS Arizona research project. This procedure must be followed to maintain sample integrity and insure consistent data transport, storage, shipment and analysis of a high quality for the NHEXAS Arizona projects of the University of Arizona/Battelle/Illinois Institute of Technology Consortium. *Border and Other Health & Environment* *EXG 7.14.97*

2.0 DEFINITIONS

- 2.1 BCO = Battelle Memorial Institute in Coulombs Ohio, a NHEXAS Collaborator.
- 2.2 BUCKET = A plastic container with a buckle top. One bucket is assigned to each household to be visited. Household identification and stage numbers are listed on the outside of the container. The bucket contains all paperwork to be completed by field staff or household respondents. It serves as the primary vehicle for securing and transporting forms, data and samples to and from the field through the course of the study.
- 2.3 CHAIN OF CUSTODY RECORD = A vital data tracking and quality assurance form which is attached to every field sampling data sheet. Chain of custody commences with the point of origination (for filters or badges) or sample collection by field team members (for food, soils, water etc.) (see Figure 1 and 2).
- 2.4 FIELD = The sampling environment or the site at which data will be collected. This is almost always at the residence of the primary respondent.
- 2.5 FIELD KIT = A sampling tool-box containing appropriate collection and storage utensils.
- 2.6 FORM, PHYSICAL = The paper or "hard copy" original of the data record which is collected in the field.
- 2.7 HOUSEHOLD(HH) = The residence occupied by study respondents.
- 2.8 HOUSEHOLD IDENTIFICATION NUMBER(HHID) = A unique number and character combination which is assigned to each respondent household for identification purposes. This number must be recorded on all data (forms, samples, questionnaires and correspondence) generated within the household.
- 2.9 N/A = Not Applicable.
- 2.10 NHEXAS Tracking Data System = A data tracking system containing status information on all sampled houses. Household completion status, status of questionnaires, samples collected, current sample location, status

of laboratory analysis, status of database updates, custody transfers and data transfers will all be addressed in the Tracking Data System. The system will be composed of multiple relational databases connected through invisible programming. Programming applications will provide reports at key stages of the project (Figure 3).

- 2.11 PACKET = This is a large (9.5" x 12.5") manila envelope which holds the physical "hard copy" questionnaires and field sampling forms collected from a specific study household.
- 2.12 QUALITY ASSURANCE(QA) = All those planned and systematic actions necessary for ensuring the accuracy, validity, integrity, preservation and utility of collected data.
- 2.13 QUALITY CONTROL(QC) = measures implemented to evaluate the accuracy, validity, integrity and integrity of collected samples or data. Examples include field checks of all forms or questionnaires, re-interview of subjects, pre-evaluation of filters, lab blanks, field blanks and spiked samples.
- 2.14 SAMPLE = That piece of physical data which is collected from the study participants for the purpose of scientific analysis.
- 2.15 TEAM LEADER = The member of the field team who is primarily responsible for respondent contact, data collection, field form and questionnaire completion, and site QC checks of all data.
- 2.16 TEAM MEMBER = a field technician or interviewer who implements collection protocols in the field.
- 2.17 UA = University of Arizona, a NHEXAS Collaborator.
- 2.18 VISIT = A scheduled appointment with participating respondents at their place of residence (HH) for the collection of samples, questionnaires and other data.

3.0 REFERENCES

- 3.1 Lebowitz, M.D. 1993. Study Design (Revision of 31 Dec. 1993). EPA NHEXAS Cooperative Agreement.

4.0 DISCUSSION

- 4.1 This SOP outlines the correct procedure for obtaining and maintaining custody of field samples. The Team Leader is responsible for the safe and timely transport of samples from the field to the office or lab. The Field Coordinator then accepts custody of the sample and arranges for direct delivery, interim storage, or immediate delivery/shipment of samples for analysis.

- 4.2 Custody of every sample is recorded on the Chain of Custody Record (Fig.1) initiated at the point of sample or origin for items like filters and badges or by the Team Leader at the time of sample collection for items like soil, water or food samples.
- 4.3 Field and lab blanks are assigned to 10% of the houses sequentially by the Materials Technician. These samples originate at the laboratory or field office. The Materials Technician transfers lab blanks to the Laboratory Supervisor or the Team Leader (in the case of a field blank to be taken into the field). Field blank are employed as specified in the pertinent protocol. The Laboratory Supervisor maintains custody and analyzes lab blanks for some procedures. In other cases the lab blank is transferred to the Materials Technician and shipped to another laboratory for analysis.
- 4.4 Although it is the primary responsibility of the Team Leader to direct and secure sample custody, all Team Members are required to assist in sample custody as instructed by the Team Leader in the field. Sample integrity and custody are fundamental elements to this research project. If the chain of custody is broken, the integrity of the sample is lost along with data quality.
- 4.5 Major custody transfers of samples and current custody status will be recorded in the electronic NHEXAS Data Tracking System.

5.0 RESPONSIBILITIES

5.1 The Materials Technician is responsible for:

- a) receiving numbered materials shipped from Battelle,
- b) assessing integrity of materials at the time of receipt,
- c) logging in numbered materials (e.g., filters, badges etc.) and recording them as field assignable or voiding materials that have lost their integrity during shipping,
- d) assigning valid materials with an initial custody record form (Figure 1); (this includes field and lab blanks),
- e) logging sample assignments by location (HHID or lab blank),
- f) receiving materials with custody forms for shipment,
- g) completing custody record forms and copying them,
- h) shipping custody forms with samples, and
- i) updating the NHEXAS Data Tracking System.

5.2 The Team Leader is responsible for:

- a) arranging sample collection dates and times with the HH,
- b) selecting the sample sites at each HH,
- c) securing and maintaining custody of all samples collected,
- d) completing relevant sections of the Chain of Custody Record,
- e) assuring a continuous custody chain and notifying the Field Coordinator immediately if sample custody is jeopardized, and
- f) updating the NHEXAS Data Tracking System.

5.3 All Team Members are responsible for:

- a) sample collection according to protocol, and
- b) assuring custody chain and notifying Team Leader or Field Coordinator immediately if sample custody is jeopardized.

5.4 The Field Coordinator is responsible for:

- a) receiving custody of samples and blanks from the field and determining their integrity,
- b) voiding samples that have lost integrity,
- c) appropriately storing valid samples and their custody records,
- d) transferring custody of valid samples for analysis or shipment, &
- e) updating the NHEXAS Data Tracking System.

5.5 The appropriate Laboratory Supervisor is responsible for:

- a) receiving custody of samples and blanks from the Field Coordinator or the Materials Technician and determining their integrity,
- b) voiding samples that have lost integrity,
- c) appropriately storing valid samples and their custody records prior to analysis,
- d) treating, preparing or analyzing samples,
- e) appropriately archiving samples and maintaining custody, or
- f) transferring custody to the Materials Technician for shipment, and
- g) updating the NHEXAS Data Tracking System (UA and BCO only).

5.6 The appropriate Project Data Coordinator is responsible for:

- a) receiving custody of packets from the Field Coordinator.
- b) cleaning, verifying and validating data derived from physical forms,
- c) appropriately archiving and maintaining custody of forms, and
- d) updating the NHEXAS Data Tracking System.

6.0 MATERIALS AND REAGENTS

6.1 Materials

The chain of custody form and the pertinent SOP which describes issues addressing sample integrity including container specifications, storage requirements, transportation logistics, temporal parameters etc..

6.2 Reagents - N/A

7.0 PROCEDURE

7.1 Preparation

7.1.1 Reagents - N/A

7.1.2 Custody and Treatment of Standards & Blanks

A. Field Blanks:

- 1) On receipt of materials, the Materials Technician will assign field blanks and initiate the Chain of Custody Record (Fig.1).
- 2) The Team Leader or Laboratory Supervisor will accept custody of the blanks and complete the appropriate components of the custody form. The transfer is recorded in the NHEXAS Data Tracking System.
- 3) When a field blank is deployed at a sampling site, the custody form remains with the field Team Leader in the household bucket; otherwise the Chain of Custody Record will remain with the field blank at all times. Blanks will be transported by the Team Leader in the bucket, or the field kit as appropriate.
- 4) If the blank is to be left in the residence for a period of time the Team Leader will notify the respondent of such, and will record this time in residence in the remarks section on the Chain of Custody Record (Fig.1).
- 5) When the blank is collected, the date of collection will be recorded and the Team Leader will maintain custody of the sample until it is transferred to the Field Coordinator in the field office. The transfer is recorded in the NHEXAS Data Tracking System.
- 6) The Field Coordinator places the field blank with other samples in the appropriate storage area pending shipment for analysis.
- 7) The Field Coordinator transfers the sample and custody to the Materials Technician for shipment.
- 8) The Materials Technician assigns custody to the receiver at the time of shipment.
- 9) The annotated Chain of Custody Record is shipped with the sample, while the Materials Technician maintains a photocopy of the original. The transfer is recorded in the NHEXAS Data Tracking System.

B. Laboratory Blanks

- 1) On receipt of materials, the Materials Technician will assign laboratory blanks and initiate the Chain of Custody Record (Fig.1). This is the same form as used for Field Blanks (above 7.1.2 A 1).
- 2) Lab blanks are the responsibility of the Lab Supervisor until the blank sample is transferred/shipped for analysis.
- 3) Lab blanks are stored and analyzed precisely as all collected samples.
- 4) When ready for shipment, the Materials Technician accepts custody of the lab blank, annotates the Chain of Custody Record and arranges for immediate shipment.
- 5) The original Chain of Custody Record is shipped with the sample, the Materials Technician maintains a photocopy. The transfer is recorded in the NHEXAS Data Tracking System.

7.1.3 Sample Preparation

The Team Members must effectively preserve the integrity of all samples collected. The field kit and bucket must be stocked with appropriate materials, specifically - sample storage containers, sample transfer containers, blue ice and materials for correct sample collection and transport. The particular sample data sheet and Chain of Custody Record for the HH to be sampled should be in the HH bucket. Spare data sheets and Chain of Custody Record forms must be available in the field kit.

7.2 Sample Collection

7.2.1 Samples must be collected and transported according to relevant protocol. All Team Members share in this responsibility.

- a) Custody of the sample after collection is the responsibility of the Team Leader.
- b) The sample must be labeled with HHID, date of collection, time of collection, type of sample collected, collecting Team Members initials, and other data as prescribed in the appropriate protocol.
- c) The Team Leader will accept custody of the sample and will record acceptance on the Chain of Custody Record.
- d) The sample will be securely stored in the HH bucket, Field Kit or other special container as defined by appropriate protocol and will be transported to the Field Office/Laboratory by the Team Leader at the conclusion of the visit.
- e) The Team Leader will sign the section of the relevant data collection sheet which indicates that "Chain of Custody Process Initiated and Recorded" (see Fig.2). This field is included on all field data sheets.
- f) The Team Leader will annotate any suspected interruptions in the chain of custody on the Chain of Custody Record, and will notify the Field Coordinator of same upon return to the Field Office.
- g) On return from the field the Team Leader transfers sample custody to the Field Coordinator or his designee. The transfer is recorded in the NHEXAS Data Tracking System.
- h) The Field Coordinator or his designee arranges for interim storage, direct delivery or immediate shipment of the samples as specified in the appropriate SOP.

7.3 Custody and Transfer of Physical Data Forms

- a) Custody of the physical data forms after collection is the responsibility of the Team Leader.
- b) The physical data forms must be labeled with HHID, date of collection, time of collection, type of sample collected, collecting Team Members initials, and other data as prescribed in the appropriate protocol.
- c) The Team Leader will accept custody of the physical data forms and will record acceptance on the Chain of Custody Record.
- d) The physical data forms will be securely stored in the HH bucket.

- e) The Team Leader will sign the section of the relevant data collection sheet which indicates that "Chain of Custody Process Initiated and Recorded" (see Fig.2). This field is included on all field data sheets.
- f) The Team Leader will annotate any suspected interruptions in the chain of custody on the Chain of Custody Record, and will notify the Field Coordinator of same upon return to the Field Office.
- g) On return from the field the Team Leader transfers physical data form custody to the Field Coordinator or his designee. The transfer is recorded in the NHEXAS Data Tracking System.
- h) The Field Coordinator or his designee arranges for interim storage and placement of all forms in appropriate HH packets.
- i) Packets are transferred to the Project Data Coordinator. The transfer is recorded in the NHEXAS Data Tracking System.

7.4 Custody and Shipment of Samples

The Field Coordinator transfers sample custody to the Materials Technician for shipment. The transfer is recorded in the NHEXAS Data Tracking System. Custody transfer will be recorded on the forms. The samples will be shipped according to parameters set in the relevant protocol.

- 7.4.1 The Chain of Custody Record will reflect the time that the sample was sealed in a packing container awaiting imminent shipment.
- 7.4.2 The Materials Technician will maintain a photocopy of all Chain of Custody Records completed prior to sample shipment.
- 7.4.3 The Field Coordinator will notify the receiving lab of the date and time of shipment and the quantitative and qualitative characteristics of the shipment sent, with expected arrival time.

7.5 Custody & Analysis

- 7.5.1 Standards/Blanks: After initial assignment and deployment, standards and blanks are treated according to the same protocols as samples.
- 7.5.2 Custody of Laboratory Samples and Products:
 - a) At the time of sample receipt, either through shipment or direct transfer, the Lab Supervisor verifies sample integrity, accepts and signs the Custody form. UA and BCO will record the transfer of the NHEXAS Data Tracking System.
 - b) The sample is placed in storage compatible with the protocol storage requirements.
 - c) The lab supervisor may assign sample analysis to a technician. This will be documented by a custody transfer completion.

- d) After analysis multiple analysis products may exist each in the custody of the lab technician. The original custody form will remain with any residual, unexpended sample. New custody forms will be completed for any other products resulting from the analysis.
- e) If the complete sample is expended the custody form is marked 'sample expended' and filed in a retrievable area in the lab.
- f) Custody of unexpended samples, tracings, extracts and data is transferred to the Laboratory Supervisor who signs the custody forms.
- g) The Laboratory Supervisor transfers the paper or electronic data output to the Project Data Manager in an agreed upon format. Data transfer is NHEXAS Data Tracking System. Data will be treated in accordance with the project data protocols.

7.6 Custody & Archives

- a) The various Laboratory Supervisors (UA, BCO, CDC, FDA and Water) are responsible for curating unexpended samples under conditions described in the appropriate protocols for the duration of the sample integrity or 3 years after the completion of the project, whichever ever comes first. Samples must be organized, indexed and retrievable.
- b) Each Laboratory Supervisor is responsible for keeping all paper laboratory records in an organized format (notebooks or sequential files) with a key index describing the archive location of all output.
- c) Each Laboratory Supervisor is responsible for archiving any sample extracts under conditions preserving extract integrity. Extracts must be kept in an organized indexed and retrievable fashion. Extracts must be curated while they retain integrity or 3 years after the completion of the project, whichever ever comes first.
- d) All UA, BCO archive locations must be recorded in the electronic NHEXAS tracking data system.

7.7 Calculations - N/A

7.8 Quality Control

7.8.1 In the HH sampling site the Team Leader supervises all work and forms completed. Team Members work collectively and check each other's work for accuracy, precision and compliance with SOP procedure and policy. The Team leader is primarily responsible for the custody of all samples collected. The Project Field Coordinator is responsible for interim storage of the samples and the Materials Technician packages, stores, transports, delivers and ships all samples and physical data forms in accordance with the appropriate SOP.

7.8.2 Tolerance Limits: A break in sample custody compromises sample integrity and invalidates the sample. There is 0 tolerance of a break in sample custody.

7.8.3 Detection Limits - A break in custody is determinable at each stage of transfer and will be detectable at each transfer stage. Detection in this case will be 100%.

7.8.4 Corrective Actions

- a) Apparent mis-labeling problems detected in the field may be corrected by the Team Members when appropriate and in accordance with SOP #UA-C-2.0.
- b) Detected breaks in Custody will require documented retraining of the errant technician or employee. Repeated failure to maintain custody after remedial retraining will be cause for dismissal.
- c) If sample integrity is lost and if we are still sampling in the home, a second collection will be made.

8.0 RECORDS

8.1 Chain of Custody Records

- a) The chain of custody form (Fig.1) will serve as the primary record of sample custody after collection in the field. The Team Leader is responsible for the thorough completion of this form. Enter data in the appropriate fields on the form.
- b) The completed original chain of custody record will remain with the physical sample.
- c) The completion of the custody record is a variable that will be tracked in the "NHEXAS tracking database."
- d) The Materials Technician maintains a sequentially organized (by shipment date) notebook containing photocopies of custody forms of shipped samples.
- e) The Laboratory Supervisor maintains a sequentially organized (by HHID) notebook containing photocopies of custody forms of expended samples.
- f) Possession of custody is recorded in the NHEXAS tracking data system at major points of sample transfer.
- g) The Archive location of all materials curated by UA and BCO is recorded in the NHEXAS tracking data system.

8.2 Data Sample

- a) Technicians will record HHID, Date, Time, sample Type, and Team Member initials on the outside of the sample container using indelible ink.
- b) Sample containers will be processed for delivery, interim storage or immediate shipment for analysis upon return to the Field Office.

8.3 Archived Samples/Data

- a) The Laboratory Supervisor maintains a sequentially organized (by HHID) notebook location records of all archived materials.
- b) The Archive location of all materials curated by UA and BCO is recorded in the NHEXAS tracking data system.

Figure 1. Chain of Custody Record.

[illegible]

Figure 2. Chain of Custody Record on all Data Forms.

Form or Questionnaire

Chain of Custody process initiated and recorded (sig.) _____
Team Leader (QC) _____ Date: ____/____/____
Post Field QA & Custody _____ Date: ____/____/____
Consigned to Packet _____ Date: ____/____/____

Form UA-G-4.0-2.0

Figure 3. Generalized scheme of the NHEXAS Tracking Data System.

