National Human Exposure Assessment Survey (NHEXAS)

Arizona Study

Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 821560

Standard Operating Procedure **SOP-UA-G-5.0**

Title: Receipt of Equipment and Field Implementation Supplies

Source: The University of Arizona

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.*

Receipt of Equipment and Field Implementation Supplies

1.0 PURPOSE AND APPLICABILITY

This SOP outlines procedures for the receipt of equipment and field implementation supplies at the NHEXAS Arizona Research Project. This procedure must be followed to ensure consistent data custody, storage, transfer 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 ESG 7-14-97

2.0 DEFINITIONS

2.1 BCO = Battelle Memorial Institute in Columbus Ohio, a NHEXAS Collaborator.

2.2 EQUIPMENT = Multiple or special use devices such as pumps, chemical reagents, high volume samplers, vacuums and other sample collection machinery or equipment used to collect sample media for the purposes of analysis at the NHEXAS Arizona project. These items are frequently referred to as "samplers".

2.3 FIELD = The sampling environment or the site at which data will be collected. This is almost always at the residence of the primary respondent.

2.4 FIELD COORDINATOR = The employee of the research project who supervises field data collection and operations. The Field Coordinator collates individual data into HH packets, and upon completion of all visits, sampling, and QA checks, forwards the packet to the Data Coordinator for processing.

2.5 FIELD IMPLEMENTATION SUPPLIES = Non capital equipment single use field sample tubes, filters, and other physical sample collection media used to collect data from participating study respondents and houses in the NHEXAS Arizona project. These items are frequently referred to as "samples".

2.6 MATERIALS TECHNICIAN = The employee of the research project who is responsible for receipt and initial inspection of field implementation supplies and equipment. The Materials Technician also logs the receipt of equipment and supplies into the NHEXAS Tracking System.

2.7 N/A = Not Applicable.

2.8 QUALITY ASSURANCE(QA) = All those planned and systematic actions necessary for ensuring the accuracy, validity, integrity, preservation and utility of collected data.

2.9 QUALITY CONTROL(QC) = Those quality assurance actions providing a means to control and measure the characteristics of a datum, process, or the adherence to established parameters.

2.10 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.

2.11 TEAM MEMBER = The member of a field team responsible for assisting the team leader in the collection of data and quality control checks in the field.

2.12 TRACKING SYSTEM = A data tracking system containing status information on all sampled houses. It tracks the custody, transfer and storage of hard copy data, electronic data, field samples and field sample aliquots.

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 the receipt and tracking of equipment and field implementation supplies used by the NHEXAS Arizona research project. The Materials Technician inspects field implementation supplies and equipment upon receipt, completes any paperwork and follows instructions requested by the sender to acknowledge receipt of the shipped items. Unique sample identification numbers are generated from the tracking system and assigned by the Materials Technician to each item received.

4.2 Each field implementation supply item is then logged into the tracking system and stored or processed as outlined in the appropriate protocol. Each piece of equipment is forwarded to the appropriate section coordinator for further inspection, testing and calibration as necessary.

5.0 RESPONSIBILITIES

5.1 The Materials Technician is responsible for:

(a) receiving materials shipped from BCO or elsewhere and acknowledging receipt of same to sending agency,
(b) assessing the integrity of materials through visual inspection at the time of receipt,
(c) assigning a unique identification number to each item (e.g. filters, badges, pumps, etc..) and logging them into the tracking system,
(d) recording each item as being either field-worthy or voiding materials that lost their integrity during shipping,
(e) assigning samples an initial Chain of Custody Record (Fig. 1). (this includes field blanks, lab blanks, valid and non-valid field implementation supplies) if one has not already been created,

(f) forwarding samplers (equipment) to the appropriate section coordinator and logging sample assignments in the tracking system,
(g) consulting the tracking system routinely to check expiration dates of shelved\stored samples,
(h) notifying the Laboratory Coordinator and the Field Coordinator of current and projected sample stock levels and shipment\receipt problems encountered.

5.2 The Section Coordinators are responsible for;
(a) performing a visual and operational test of all received samplers and recording the results on the Equipment/ Sampler Receipt Log (Fig. 2),
(b) performing an initial calibration test against standards according to the relevant protocol and documenting the results in the Equipment/ Sampler Receipt Log,
(c) notifying the sending agency of any problems encountered with the equipment,
(d) filing the Equipment/ Sampler Receipt Log in the appropriate equipment folder with the accompanying documentation for that sampler.

6.0 MATERIALS AND REAGENTS

6.1 Materials

Materials appropriate to this protocol include all relevant samples and samplers, NHEXAS Tracking System, Chain of Custody Records, and appropriate sample storage facilities

6.2 Reagents - N/A

7.0 PROCEDURE

7.1 Preparation

7.1.1 Site Selection Criteria

All samples have a designated storage site determined by the relevant SOP. Storage location and conditions are clearly defined in relevant protocols.

7.1.2 Reagents - N/A

7.1.3 Standards and Blanks - N/A

7.1.4 Sampler Preparation

All samplers must be logged in to the tracking system upon receipt and stored in the conditions outlined in the appropriate protocol. Specific preparation will vary by sample type before implementation in the field.

7.2 Receipt Procedures

7.2.1 Standards and blanks deployed or used

All samples, including standards and blanks, are assigned a unique identification number upon receipt. Standards and blanks designated by BCO or other shipping agency are treated according to the relevant protocol. Ten percent of all samples received will be randomly selected and designated a Laboratory or Field Blank. This status will be recorded in the tracking system. The sample will be labeled as a "blank" and will be randomly assigned to a household by the Materials Technician in the case of a field blank, or forwarded to the Lab Coordinator in the case of a lab blank. Spiked samples will be processed according to relevant protocol.

All standards and blanks received by the Materials Technician for the purpose of sampler standardization or calibration will be forwarded to the appropriate section coordinator.

7.2.2 Receipt of Field Implementation Supplies (Samples)

(a) The Materials Technician is notified of an impending shipment, the estimated arrival date, type and quantity of samples by BCO or other shipping agency.
(b) The Materials Technician or delegate accepts custody of the shipment upon arrival and assesses the integrity of materials upon the time of receipt. Those items shipped on ice are temporarily stored in a refrigerator or freezer according to relevant protocol.
(c) A unique identification number drawn from the tracking system is assigned to each item as it is logged-in the tracking system.
(d) Each item is carefully inspected for defects, flaws or punctures etc., both on the sample itself and on the sample packaging which would indicate a loss of integrity during shipment leaving that sample void and unusable. All suspect or void samples are coded as void in the tracking system.
(e) The Materials Technician assigns all field blanks, lab blanks, spike samples, valid and non-valid(void) field implementation supplies or samples an initial Chain of Custody Record (Fig. 1).
(f) Ten percent of all samples received are randomly labeled as blanks by the Materials Technician. This designation is recorded in the tracking system.
(g) Samples are stored in appropriate containers under carefully controlled conditions according to the parameters outlined in the respective protocol.
(h) The Laboratory Coordinator and the Field Coordinator are notified of the receipt of the samples through a photocopy of the shipment inventory or "acknowledgment of receipt" form. Information regarding sample integrity, spoilage and blank sample designation for each shipment is also forwarded.

(i) Current sample stock levels and earliest expiration dates logged in the tracking system are provided weekly to the Field and Lab Coordinators. As a Tracking System automated report generated by the Materials Technician.

7.2.3 Receipt of equipment (samplers)

(a) The Materials Technician is notified of an impending shipment, the estimated arrival date, type and quantity of samplers by BCO or other shipping agency.
(b) The Materials Technician or delegate accepts custody of the shipment upon arrival and assesses the integrity of the equipment @through visual inspection upon receipt.
(c) A unique identification number drawn from the tracking system is assigned to each sampler(equipment) as it is logged-in to the tracking system.
(d) Each sampler is carefully inspected for obvious defects, flaws or missing pieces etc., in addition to an inspection of the sampler packaging.
(e) The Materials Technician forwards the sampler, packaging and any accompanying documentation to the appropriate section coordinator.
(f) The appropriate section coordinator or delegate visually reinspects the sampler and packaging for any obvious defects, and documents any missing components or suspected problems on the Equipment/ Sampler Receipt Log (Fig. 2).
(g) The section coordinator or delegate performs an operational test of the sampler according to procedures outlined in the accompanying documentation or the respective protocol. Test results are recorded in the Equipment/ Sampler Receipt Log (Fig 2).
(h) The section coordinator or delegate performs a calibration test on the sampler according to procedures outlined in the accompanying documentation or the respective protocol. Test results are recorded in the Equipment/ Sampler Receipt Log (Fig. 2).
(i) The Equipment/ Sampler Receipt log is filed in the appropriate equipment folder with the accompanying documentation for that sampler.
(j) Dates for periodic and routine maintenance of samplers are noted by the section coordinator.
(k) The section coordinator notifies the sending agency of the receipt of the sampler and any problems encountered.

7.3 Calculations - N/A

7.4 Quality Control

7.4.1 Tolerance Limits - N/A

7.4.2 Detection Limits - N/A

7.4.3 Corrective Actions

Apparent mis-labeling and other assorted problems detected by NHEXAS Arizona staff may be corrected by the staff when appropriate and in accordance with SOP #UA-C-2.0.

The sending agency will be immediately notified if any trends in sample breakage during shipment are observed. If a piece of equipment(sampler) is malfunctioning upon receipt the sending agency is notified and corrective actions are taken in accordance with SOP #UA-G-2.0.

8.0 RECORDS

8.1 The Chain of Custody Record

The Chain of Custody form (Fig. 1) serves as the primary record of sample custody once it is received by the Materials Technician. This record remains with the sample at all times and documents custody of the sample at any given moment.

8.2 The Equipment/ Sampler Receipt Log (Fig.2)

The Sampler Receipt Log is completed by the responsible section coordinator or delegate. This log documents the condition and appearance of the sampler upon receipt. This log is filed with any technical documentation in the Equipment Documentation File Cabinet at the NHEXAS Arizona Field Office.

8.3 The Equipment Maintenance Sheet is used to document the repair, maintenance and operational history of all equipment used in the NHEXAS AX Project. Status information, oil or fluid changes, inspections or periodic maintenance should be documented on this form. The form is initiated by the Materials Technician once the sampler is received from the distributor. Additional copies are added as needed.

Figure 1. CHAIN OF CUSTODY RECORD

This form was updated and replaced 9/15/95 (old form deleted) MLO

Chain of Custody Record
NHEXAS Arizona Project (CR-821560)
Respiratory Sciences
1435 N. Fremont Ave
Tucson, AZ 85719
(520) 626 - 4226

Sample Type: ______________________. **page ____ of ____.**

Generated by: ______________________/______________________
print name *signature*

Date Generated	Time	Sample ID	# of Containers	Remarks
___/___/___	___:___			

History of Sample Handling and Custody

Relinquished or Received	Signature	Date mo / day / yr	Time	Action
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	
[Rel] or [Rec]		___/___/___	___:___	

FORM = UA-G4.0 - 1.2 **Attach Additional Pages as Necessary**

Figure 2. EQUIPMENT / SAMPLER RECEIPT LOG

EQUIPMENT / SAMPLER RECEIPT LOG

Date of Receipt ____/____/____. By :_____

Sampler Type _____. From: _____

Sampler ID Number:_____.

Y N
[ ] [ ] Visual Inspection Date ____/____/____
comments:

Y N
[ ] [ ] Operational Inspection Date ____/____/____
comments:

Y N
[ ] [ ] Calibration Date ____/____/____
comments:

SENDING PARTY NOTIFIED OF RECEIPT ON : Date ____/____/____

comments:

Form = UA-G5.0-1.0

Figure 3. The Equipment Maintenance Sheet.

EQUIPMENT MAINTENANCE SHEET

ID #:_____

Date	By	Remarks/Corrective Actions

FORM = UA- G5.0 - 2.0