

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-C-3.0

Title: Packet Assembly, Custody, and Transfer to Data Section

Source: The University of Arizona

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

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Packet Assembly, Custody, and Transfer to Data Section

1.0 PURPOSE AND APPLICABILITY

This SOP outlines HH packet assembly, custody, and transfer to the data section in preparation for data entry into the electronic database as it exists 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 Border and other Health + Environment)

2.0 DEFINITIONS

- ESG 7.14.97
- 2.1 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.
 - 2.2 DATA COORDINATOR = The employee of the research project who supervises data entry and verification.
 - 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.
 - 2.5 FIELD KIT = A sampling tool-box carried by Field Team Members containing appropriate collection and storage utensils.
 - 2.6 FIELD COORDINATOR = The employee of the research project who supervises field data collection. 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.
 - 2.7 FORM, PHYSICAL = The paper or "hard copy" original of the data which is collected in the field. Form is also a generic term for any piece of paper data, such as records and check sheets, questionnaires, etc., which are collected for analysis.
 - 2.8 HOUSEHOLD(HH) = The residence occupied by study respondents.
 - 2.9 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 by the household.
 - 2.10 MATERIALS TECHNICIAN = The employee of the research project who is responsible for assembling and assigning field forms, questionnaires, samples and sampling equipment for field use.

- 2.11 N/A = Not Applicable.
- 2.12 PACKET = A sturdy envelope-like container that can be fully closed and is large enough to hold the physical data forms generated from sampling and surveying a study household.
- 2.13 QUALITY ASSURANCE(QA) = All those planned and systematic actions necessary for ensuring the accuracy, validity, integrity, preservation and utility of collected data.
- 2.14 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.
- 2.15 SAMPLE = A physical collection of media obtained from the study participants for the purpose of scientific analysis.
- 2.16 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.
- 2.17 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.
- 2.18 TRACKING SYSTEM = A data tracking system containing status information on all sampled houses: it tracks custody, transfer and storage of hard copy data, electronic data, field samples, and field sample aliquots.
- 2.19 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 assembling field forms, data sheets and questionnaires collected in a HH and collating those forms into the relevant HH packet after thorough QC and QA checks have been performed. The Team Leader is responsible for the safe and timely transport of forms from the sampling environment (HH) to the Field Office.
- 4.2 The Field Coordinator accepts custody of the forms after the Team Leader has performed a thorough QC check. The Field Coordinator performs a QA check, collates and arranges the forms into packets by HH, and upon completion of all sampling for that home in that stage, forwards the packet to the Data Coordinator.

- 4.3 The contents of the HH packet are listed in the HHID Report form (Fig.1) which is generated by the Tracking Database and accompanies the HH packet to the Data Coordinator. The Data Coordinator verifies the contents of the HH Packet against the report generated by the Tracking Database upon acceptance of the HH packet. The transfer of packet custody is recorded on the Household Packet Transfer Log (Fig. 2).

5.0 RESPONSIBILITIES

- 5.1 The Team Leader is responsible for:

- (a) forwarding individual field forms which have undergone extensive QC checks to the Field Coordinator for QA check within 24 hours of field form completion\collection,
- (b) rectifying any noted discrepancies within 24 hours of QA check by Field Coordinator, and
- (c) obtaining and archiving a photocopy of the HHID Report for their own records. The HHID Report is generated by the Field Coordinator when the packet is ready for transfer to the Data Section at the end of a given sampling stage.

- 5.2 The Field Coordinator (or delegate) is responsible for:

- (a) QA check of all forms submitted by Team Leaders within 24 hours of submission,
- (b) insuring Team Leader rectifies errata as necessary and re-submits each form within 24 hours of QA check,
- (c) filing each completed and QA checked form in the appropriate HH packet within 48 hours of data collection,
- (d) accepting custody of each form and annotating the receipt status and consignment of each form to its respective HH packet in the tracking system,
- (e) generating a HHID Report from the tracking system when all forms are accounted for,
- (f) transferring the HH packet to the Data Coordinator for batching,
- (g) recording the transfer on a Household Packet Transfer Log (Fig.2).
- (h) forwarding a copy of the HHID Report to the respective Team Leader for their records.

- 5.3 The Data Coordinator (or delegate) is responsible for:

- (a) receipt and handling of each packet transferred,
- (b) recording the receipt and custody of the HH packet on the HH Packet Transfer Log, and
- (c) batching of field packets in accordance with SOP #UA-C-4.0.

6.0 MATERIALS AND REAGENTS

- 6.1 Materials

Materials required include all appropriate packets, HHID Report forms and Household Packet Transfer Logs.

6.2 Reagents - N/A

7.0 PROCEDURE

7.1 Preparation

7.1.1 Form Preparation

The Team Leader is responsible for QC of forms collected in the field. Each form undergoes a QC check at the time of collection and upon return to the Field Office by the responsible Team Leader. The Team Leader corrects all discrepancies in accordance with SOP #UA-C-2.0, and forwards the original form to the Field Coordinator for QA check.

7.1.2 Packet Preparation

Once the Field Coordinator schedules a series of visits for data collection, they create a packet to house the forms to be collected from the HH. The packet is secured in the Field Coordinator's office awaiting incoming field forms.

7.2 Field Form Collection and Packet Generation.

7.2.1 Standards/Blanks - N/A

7.2.2 Actions

Data (including questionnaires) must be recorded on forms according to relevant protocol. All Team members share in this responsibility. The Team Leader is held responsible for custody and completion of each form.

- (a) Custody of the field form after sample collection is the responsibility of the Team Leader.
- (b) The form must be labeled with HHID, DATE of collection, collecting Team Members INITIALS, and other data / responses must be completed as prescribed in the appropriate protocol.
- (c) The Team Leader accepts custody of the form once it has passed an in-field QC audit after which it is securely stored in the HH bucket.
- (d) The form will be transported to the Field Office by the Team Leader at the conclusion of the HH visit.
- (e) Once the form has undergone QC checks in the Field Office, it is forwarded to the Field Coordinator for immediate QA check. The maximum time allowed between collection of the form and forwarding for QA check is 24 hours.
- (f) The Field Coordinator QA checks the form in accordance with SOP # UA-C-2.0 immediately, notes any discrepancies, and returns it to the appropriate Team Leader for correction as necessary. The

maximum time allowed between submission of a field form and QA check is 24 hours. The Team Leader is allowed 24 hours to correct the discrepancy and resubmit as necessary.

- (g) Once QA checks are complete, the form is filed in the appropriate HH packet. Addition of each form to the HH packet is annotated in the tracking database by the Field Coordinator and documented at the base of each form on the Chain of Custody Record on all data forms signature block (Fig. 3).
- (h) This process is repeated for each form submitted until the HH Packet contains all forms collected in the residence during that phase of sampling.

7.3 Custody and Transfer of Packets

The Field Coordinator will arrange for immediate transfer of all packets to the Data Coordinator once all sampling is accomplished and all forms have been submitted, QA checked, corrected, collated and filed in their respective HH packets.

- (a) The packet will be checked by the Field Coordinator to insure that it contains all relevant forms and that they correspond with the forms listed on the HHID Report (Fig. 1) which is produced by the Tracking System.
- (b) The Field Coordinator will record the assembled packet on the Household Packet Transfer Log (Fig. 2) and transfer the HH packet to the Data Coordinator.
- (c) The Data Coordinator will verify the presence of all forms listed on the HHID Report and will accept custody of the packet by annotating the chain of custody portion at the bottom of the HHID Report (Fig. 1) and the Household Packet Transfer Log (Fig. 2)
- (d) The Data Coordinator will batch the packets according to SOP #UA-C-4.0 and arrange for data entry, verification and cleaning.

7.4 Calculations - N/A

7.5 Quality Control

7.5.1 Tolerance Limits

In the HH sampling environment the Team Leader supervises all work and form completion. 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 and completion of all forms collected. The Field Coordinator is responsible for post-field collection QA. All forms will be 100% QC and QA checked.

7.5.2 Detection Limits

Each form is thoroughly QA and QC checked on at least three separate occasions before the packet is forwarded to the Data Coordinator. Special attention is paid to critical or key variables by the Team

Leader and Field Coordinator where unnoticed errors specific to in-field procedure might be undetectable to the Data Coordinator in later QC\QA checks.

7.5.3 Corrective Actions

Apparent mis-labeling and other assorted problems detected on field forms may be corrected by the Team Members when appropriate and in accordance with SOP #UA-C-2.0. All Team Members will notify the Field Coordinator in writing of all errata which might affect existing databases or alter any data which has already been transferred from the Field Teams to the Field Coordinator. The Data Coordinator and Data Manager will be notified by the Field Coordinator as appropriate. In cases where QA checks are left incomplete after transfer, the Data Coordinator will return the HH packet to the Field Coordinator for review/further action.

8.0 RECORDS

- 8.1 The HHID Report (Fig.1) is produced by the tracking system and is used as a summary checksheet of all forms collected in any given household. This report is transferred with the packet to the Data Coordinator. The Team Leader who supervised the sampling at the given household also receives a HHID Report for their records.
- 8.2 The Household Packet Transfer Log (Fig.2) is jointly maintained by the Field and Data Coordinator as a record of packets which have been forwarded to the Data Coordinator.
- 8.3 The Chain of Custody Signature Block (Fig.3) at the base of each form is completed by field personnel prior to consignment of the form to a HH packet.

Figure 1. HHID Report

HHID REPORT

PROJECT ID : _____	STAGE # _____	HHID # _____ Team Leader ID # _____
FORM ID : UA- C3.0 - 1.0	V1____/____/____ by_____.	
REPORT DATE 19____/____/____	V2____/____/____ by_____.	
	V3____/____/____ by_____.	
	V4____/____/____ by_____.	

IRN level Sampling

IRN #	Birth Name	Relates to IRN	Status Δ	Con- sent	Base Line	Active Diary	PEF Diary	Follow Up	Diet Diary	Diet √-list	Active Pump	Derm wipe	Urine	Blood	Diet samples
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]
[]			Y N	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]	[]

Household Level Sampling

PID Indoors	[]	In VOC by Badge	[]	Chain of Custody initiated (sig.) : _____ Consigned to packet : [] on ____/____/____ Box UA G4-2.0
PID Outdoors	[]	Out VOC by Badge	[]	
Sentinel Hi-Vol	[]	In Pump (PM)	[]	
Dust Floors	[]	Out Pump (PM)	[]	
Soil Composite	[]	In Pump (VOC)	[]	
Soil Foundation	[]	Out Pump (VOC)	[]	
Soil Thin Film	[]	Dust Surface (wipe)	[]	
Water - Tap Flush	[]	Dust Thin Film	[]	
Water - Drinking	[]		[]	
Tech Qx	[]	Descriptive Qx	[]	

Form ID = UA - C3.0 - 1.0.

Household Packet Transfer Log

[illegible]

Figure 3. Chain of Custody Record at the base of all Data Forms.

Data form
or questionnaire

Chain of Custody process initiated and recorded (sig.)
consigned to HH Packet [] Date ____/____/____

FORM: UA-G4.0-2.0