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-2.0**

Title: Form QA and QC Checks

Source: The University of Arizona

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

Form QA and QC Checks

1.0 PURPOSE AND APPLICABILITY

The purpose of this SOP is to outline the process of Field Quality Assurance and Quality Control checks in use at the NHEXAS Arizona Research Project. This procedure must be followed to insure consistent data collection, transport, storage, shipment and analysis of a high quality for the NHEXAS ~~Arizona~~ projects of the University of Arizona/Battelle/Illinois Institute of Technology Consortia.
Border and Other Health + Environment
ESC 4.14.97

2.0 DEFINITIONS

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 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 sample collection by field team members (see Fig. 1).

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 KIT = A sampling tool-box containing appropriate collection and storage utensils.

2.5 FORM, PHYSICAL = The paper or "hard copy" original of the data record which is collected in the field.

2.6 HOUSEHOLD(HH) = The residence occupied by study respondents.

2.7 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.

2.8 N/A = Not Applicable.

2.9 PACKET = This is a large (9.5" x 12.5") household specific manilla envelope which holds the physical "hardcopy" questionnaires and field sampling forms collected from a study household.

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

2.11 QUALITY CONTROL(QC) = Is the operationalization of the above listed quality assurance criteria to control and measure the characteristics of a datum, process, or the adherence to established parameters.

2.12 SAMPLE = That piece of physical data which is collected from the study participants for the purpose of scientific analysis.

2.13 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.

2.14 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 describes the scope and method of Field form QA and QC checks utilized by this study. All Field Team members share the responsibility of obtaining and recording data collected for this project at a high level of reliability, precision and accuracy. In the field, Team Members practice a form of continual feedback and double-checking of each others work against the set standard outlined in the relevant sampling SOP. The Team Leader is responsible for the QC checks of all forms, questionnaires, and samples collected in the field.

4.2 QA checks will be performed within 24 hours of data collection. The Team Leader will submit the data sheets, questionnaires, and records which have been collected in the field and undergone rigorous QC checks to the Field QA Coordinator. Discrepancies will be noted, recorded and the data will be returned for rectification as necessary.

4.3 Field Team Member quality is fundamentally tied to data quality. Team Members are evaluated by the Field Coordinator on the basis of Quality of data collected, recorded and entered into the study database.

5.0 RESPONSIBILITIES

5.1 The Team Leader is responsible for:

a) QC checks of forms and data collected in field.
b) Submission of forms, questionnaires, and data records to Field QA Coordinator within 24 hours of collection.
c) Rectification of outstanding errors of omission / commission identified by Field Coordinator during QA check.
d) Immediate update of "Trascking" database.

5.2 All team members are responsible for:

a) QC checks of each-other in data recording and sampling.
b) Notifying Team Leader immediately sampling/recording falls below designated standards.
c) Comprehensive and exhaustive completion of data records, forms and questionnaires.

5.3 The Field QA Coordinator is responsible for:

a) Thorough QA check of all data within 24 hours of submission.
b) Notifying Team Member of discrepancies in a timely fashion.
c) Documenting errata and enforcing QA standards in Field Team work.
d) Periodic reports to Principal Investigator regarding data quality

6.0 MATERIALS AND REAGENTS

6.1 Materials

Materials required to successfully execute a QC check of procedure or documentation are detailed in the particular SOP for that procedure. QA checks evaluate forms, questionnaires and data records submitted for accuracy, completion, and logical inconsistencies in responses.

6.2 Reagents - N/A

7.0 PROCEDURE

7.1 Preparation

7.1.1 Reagents - N/A

7.1.2 Standards & Blanks - N/A

7.1.3 Sampling Preparation

(a) Samples are prepared according to protocol. The Materials Technician QC checks of all materials prepared for use in the Field.

(b) Team Leader double checks Tracking database and "hardcopy" data for accuracy (if visit is in stage 2 or greater).

(c) Team members verify equipment and sample readiness and applicability.

7.2 Sample Collection

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

(a) Quality control during and after collection is the responsibility of the Team Leader primarily.

(b) All samples must be labeled with HHID, DATE of collection, Time of Collection, Type of Sample Collected, collecting Team Members Initials at a minimum. Other data must be added as prescribed in the appropriate protocol.

(c) The Team Leader is responsible for all issues relating to sample security and custody, and must complete the Chain of Custody Record (Fig.1).

(d) All samples and forms 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 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". This field is included on all data sheets. The Team leader must also perform and initial all relevant QC checks.

(f) The Team Leader will annotate any suspected interruptions in the chain of custody on the Chain of Custody Record, or note any issues compromising sampling quality, and will notify the Field Coordinator upon return to the Field office.

7.3 Post Field Issues

7.3.1 After the Team Members have completed their independent QC checks on samples, data forms and questionnaires, the Team leader must submit all data collected to the Field QA Coordinator for QA check within 24 hours of collection.

(a) Team Leaders will review comments made by QA coordinator and rectify as necessary.

(b) Corrections must be made within 24 hours of return to the Team leader and re-submitted.

(c) Once the form has met acceptable QA standards, the Field QA Coordinator initials the "Post Field QA & Custody" field on the data form, and files the record in the appropriate HH packet.

(d) The Field Coordinator and the Team members will hold periodic private counseling sessions where error rates and common errors of omission and commission will be addressed.

(e) Team members will update the Field electronic database as necessary.

7.4 Analyses - N/A

7.4.1 Standards/Blanks - N/A

7.4.2 Samples - N/A

7.5 Calculations - N/A

7.6 Quality Control

7.6.1 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 and for related quality control issues.

7.6.2 Tolerance Limits - N/A

7.6.3 Detection Limits - 100% of all data fields are checked.

7.6.4 Corrective Actions

Apparent mis-labeling problems detected in the field may be corrected by the Team Members when appropriate and in accordance with the Error Codes outlined in Figure 2.

8.0 RECORDS

8.1 Chain of Custody record

8.1.1 This data record (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. The chain of Custody Record is a fundamental element in the Quality Control and Assurance process.

8.1.2 Data to be recorded for correct handling and custody include:
(a) Sample Type
(b) Collection date
(c) Collection Time
(d) Sample ID Number
(e) Collectors Name
(f) Number of Sample Containers
(g) "Relinquished by and "Received by" tracking data.

8.1.3 The completed original Chain of Custody record will remain with the data sample. A copy of the Chain of Custody Record will be maintained and archived by the Field QA coordinator.

8.2 Error Codes

The Error Codes listed in Figure 2. represent the standard and only accepted codes for correcting errors in this research project. The Error Codes are utilized after the nature of the error has been determined. The Team Member will draw a single black line through the erroneous value and record the error code next to the previous value. The Team member will then record their initials and date next to the change.

8.3 Data Sample

The sample container will also have HHID, Date, Time, sample Type, and Team Member initials recorded upon it with indelible ink at the very minimum. Additional data may be recorded as indicated by protocol.

Fig.1 Chain of Custody Record.

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

Fig.2 Error Codes.

ERROR CODE

Data which are incorrectly entered will be noted and a code for changes used. The code will be entered with the initials of and dated by the person making the change.

Code	Explanation
A	Inadvertently entered incorrect original data.
B	Inadvertently transposed the wrong data or transposition error.
C	Inadvertently recorded data in wrong location or wrong data book.
D	Changed wording, sentence structure or description for greater clarity.
E	Spelling error.
F	Inadvertently not recorded at time of initial observation.
G	Incorrect calculation.
H	Extraneous characters from printer.
	NOTE: No "I" since it may be confused with a 1.
J	Inadvertently error-coded the wrong entry.