

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-4.0

Title: Archive Procedure for Study Samples

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.

Archive Procedure for Study Samples

1.0 PURPOSE AND APPLICABILITY

This SOP outlines archive/custody guidelines used by the NHEXAS Arizona research project. This procedure must be followed to maintain and locate samples, extracts, tracings and hard copy results after laboratory analysis for the NHEXAS ~~Arizona~~ projects of the University of Arizona/Battelle/Illinois Institute of Technology Consortium.

2.0 DEFINITIONS

- 2.1 BCO = Battelle Memorial Institute in <sup>Border and other Health
& Environment EST 7-14-97</sup> Columbus Ohio, a NHEXAS Collaborator. *9/14/95*
- 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 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).
- 2.3 HOUSEHOLD(HH) = The residence occupied by study respondents.
- 2.4 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.
- 2.5 LABORATORY ANALYSIS BY-PRODUCT = This category includes residual sample, sample extracts, analysis tracings and hard copies of analysis results.
- 2.6 N/A = Not Applicable.
- 2.7 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).
- 2.8 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.
- 2.9 QUALITY ASSURANCE(QA) = All those planned and systematic actions necessary for ensuring the accuracy, validity, integrity, preservation and utility of collected data.

- 2.10 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.
- 2.11 SAMPLE = That piece of physical data which is collected from the study participants for the purpose of scientific analysis.
- 2.12 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.
- 2.13 TEAM MEMBER = a field technician or interviewer who implements collection protocols in the field.
- 2.14 UA = University of Arizona, a NHEXAS Collaborator.
- 2.15 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 archiving samples and by-products of laboratory analysis for the NHEXAS Arizona Project. The Laboratory Supervisor at each institution (University of Arizona, Battelle Columbus, CDC, FDA and the contract Water laboratory) are responsible for maintaining the residual samples while they have integrity and the analysis records and by-products for up to three years after the completion of the project.
- 4.2 Custody records (Figure 1) must reside with each sample or be logged in a laboratory notebook if the sample is expended; this also applies to field and lab blanks.
- 4.3 All samples and analysis by-products are filed or stored in an organized manner that preserves their integrity. A sample retrieval mechanism will exist for the easy retrieval of any sample or analysis by-product.
- 4.4 The location custody sheets of expended samples, sample residuals, and analysis by-products are contained in the sample Tracking data base for Battelle and Arizona. Other laboratories must conform to these requirements.

4.5 All data and samples are kept in the locked project offices. Only project staff and University Security maintain keys. Access to samples and data is controlled. Access to archived samples and raw data must be approved by the appropriate supervisor (Laboratory Supervisor, Data Co-ordinator and Data Manager).

4.6 Access to electronic data is controlled through the LAN by the Data Manager employing electronic access levels and password accounts.

5.0 RESPONSIBILITIES

5.1 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) updating the NHEXAS Data Tracking System (UA and BCO only).

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 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, which 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, which ever comes first.
- d) All UA, BCO archive locations must be recorded in the electronic NHEXAS tracking data system.
- e) Access to any archived samples or data must be approved by the appropriate project officer and recorded on a log form that has the date and time of signout and the date and time of sample return. In general samples/data can be checked out for up to 2 weeks. An example of a log form is found in Figure 4. Specific steps are as follows:
 - 1. Determine where the sample is archived from the tracking system.
 - 2. Contact the appropriate supervisor for access.
 - 3. Log-out the sample on the appropriate form.
 - 4. Proceed with your needs while meeting criteria laid out in specific SOPs to maintain sample integrity.
 - 5. Inform the appropriate supervisor of sample return and obtain access. Log-in the sample when done (initials and date).
 - 6. The supervisor will check the log forms to make sure all samples/data are returned in a timely fashion.

7.7 Calculations - N/A

7.8 Quality Control & Corrective actions

- 7.8.1 A technician must be assigned the task of locating the sample based on the information on the Tracking database or the laboratory index. The item must be located and appropriately placed.
- 7.8.2 Supervisors must check on the status of checked-out samples at least every two weeks and recall any outstanding data/samples or extend the check-out for the next 2 week interval.

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 and must be kept with any extant sample or filed in the laboratory notebook after the sample is expended.

- b) The Laboratory Supervisor maintains a sequentially organized (by HHID) notebook location records of all archived materials.
 - c) The Archive location of all materials currated by UA and BCO is recorded in the NHEXAS tracking data system.
 - d) Other laboratories must have indexed records for the location of samples or analysis by-products.
- 8.2 Sample logs are kept in the appropriate storage area [lab (i.e., freezer logs, store room logs), data (data archive file cabinets)] in a location designated by the area supervisor. At the time of check-out the inquisitor will be apprised of the location.

Figure 1. Chain of Custody Record.

[illegible]

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

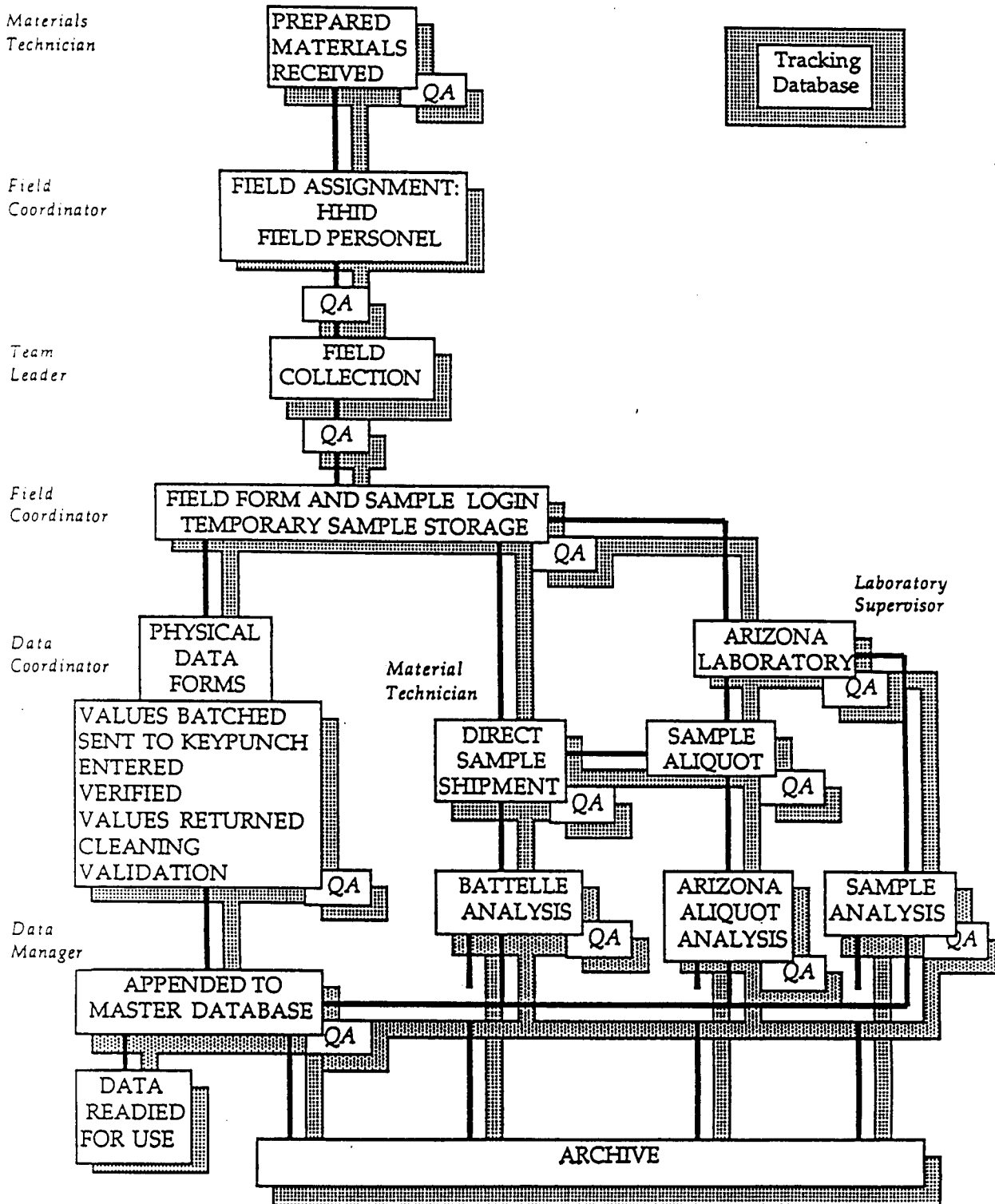
Form or Questionnaire

Chain of Custody process initiated and recorded (sig.) _____

Team Leader (QC) _____	Date: ____/____/____
Post Field QA & Custody _____	Date: ____/____/____
Consigned to Packet _____	Date: ____/____/____

Form UA-G4.0-2.0

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



POST FILING CUSTODY RECORD

FORM OR QUESTIONNAIRE NAME: _____

[illegible]