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National Human Exposure Assessment Survey (NHEXAS)

Region 5 Study

Quality Systems and Implementation Plan for Human Exposure Assessment

Research Triangle Institute
Research Triangle Park, NC 27079

Cooperative Agreement CR 821902

Standard Operating Procedure **NHX/SOP-815-001**

Title: Conducting Systems Audits

Source: Research Triangle Institute

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.*

TITLE: STANDARD OPERATING PROCEDURE FOR CONDUCTING SYSTEMS AUDITS

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5		11	

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CONDUCTING SYSTEMS AUDITS

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1.0 SCOPE AND APPLICATION

Systems audits provide an independent assessment of adherence to policies and procedures and other factors affecting data quality. The RTI and EOHSI QA Officers are responsible for conducting systems audits. The results are reported to the appropriate Co-Principal Investigator and Principal Investigator.

2.0 SUMMARY

A summary of major study components which will be audited and the frequency are shown in the table below.

Study Component	Frequency
Study Design	Once
Survey Operations	Twice; beginning of field monitoring and later in field monitoring phase
Preparation of sampling materials/supplies	Twice; prior to field monitoring and after field monitoring has begun
Sample collection activities in the field	*
Sample processing and shipment	Once
Analytical measurement systems	At 6 month intervals
Data entry and processing	Twice

* No systems audit of sample collection activities in the field is planned.

3.0 RESPONSIBILITIES

3.1 The QA Officer will develop Systems Audit Checklists to aid in the evaluation of the program components. These forms will be distributed to and discussed with the appropriate Co-Principal Investigators before the audits are conducted.

3.2 In general, the systems audits will take place in two phases; the QA Officer will interview the Co-Principal Investigator or appropriate laboratory manager and then review records or inspect the laboratory.

3.3 The QA Officer will pay particular attention to adherence to SOPs and protocols.

3.4 (RTI) A written report of audit results will be prepared and submitted to the Co-Principal Investigator (or laboratory manager) and the RTI Principal Investigator.

3.5 (EOHSI) A written report of audit results will be prepared and submitted to the Co-Principal Investigator (or laboratory manager) and EOHSI Principal Investigator. A summary report will be submitted to the RTI QA Officer.

4.0 SYSTEMS AUDIT OF SAMPLING DESIGN

4.1 This audit will be based on discussions with Dr. R. Whitmore, Co-Principal Investigator. The extent to which sample design objectives were achieved during the delineation of the study population will be evaluated.

4.2 An audit checklist will be developed which will address the following subject areas:

- Construction of target population area frame,
- Stratification with respect to potential exposure and socioeconomic status,
- Selection of PSUs for first phase sample,
- Selection of potential study participants,
- Internal QC protocols,
- Resolution of special problem areas.

4.3 A written audit report will be submitted to Dr. Whitmore within 5 working days.

4.4 A summary report will be submitted to the Principal Investigator in the Quarterly QA Report.

5.0 SYSTEMS AUDIT OF SURVEY OPERATIONS

5.1 This audit will be based on discussions with Mr. H. Zelon, Co-Investigator, interviews with field personnel, and review of survey documents.

5.2 Audit checklists will be developed which will address the following subject areas:

- Administration of questionnaires,
- Review, in the field, of completed documents,
- Transfer of information from interviewers to RTI,
- Receipt and storage of documents at RTI,
- Completeness and quality of returned survey documents and QC checks,
- Custody of survey instruments,
- Coordination with field technical staff,
- Procedures for maintaining participant confidentiality,
- Effectiveness of training,
- Resolution of problems.

5.3 The survey operations study component will be audited twice - once soon after the field monitoring begins, and approximately six months later.

5.4 A written audit report will be submitted to Mr. Zelon within 5 working days of the systems audit.

5.5 A summary report will be submitted to the Principal Investigator in the Quarterly QA Report.

6.0 SYSTEMS AUDIT OF PREPARATION OF SAMPLING MATERIALS/SUPPLIES

This systems audit is conducted to evaluate adherence to protocols and SOPs. Two audits are planned; the first should be conducted, if possible, before the start of field sampling, and the second should be conducted after field sampling has been in progress.

6.1 This audit will be based on the appropriate protocols and SOPs.

6.2 Audit checklists will be developed which will address the following subject areas:

- Preparation of survey documents, including forms, maps, questionnaires,
- Preparation of equipment,
- Sample container preparation,
- Preparation of field blanks and controls,
- Preparation of field recordkeeping forms and software,
- Shipment to the field,

- Resolution of problems.

6.3 A written audit report will be submitted to Mr. K. Thomas, Field Supervisor, within 5 working days of the audit.

6.4 A summary report will be submitted to the Principal Investigator in the Quarterly QA Report.

7.0 SYSTEMS AUDIT OF SAMPLE COLLECTION ACTIVITIES IN THE FIELD

No systems audit of sample collection activities in the field by the RTI QA Officer is planned. Should this systems audit be added to the program, the RTI QA Officer will conduct the field systems audit according to RTI/ACS-SOP-812-001, Conducting a QA Systems Audit of Sample and Data Collection in the Field.

The RTI QA Officer will conduct a pre-study audit during the "dress rehearsal" conducted prior to field monitoring.

The QA Officer will confer with Mr. K. Thomas, the Field Supervisor, who will perform periodic inspections in the field to assess compliance with protocols and SOPs, and will report results to the QA Officer. Mr. Thomas will initiate and document corrective action, when necessary.

8.0 SYSTEMS AUDIT OF SAMPLE PROCESSING AND SHIPMENT

This systems audit is conducted to evaluate adherence to applicable protocols and SOPs. The QA Officer will pay particular attention to documentation and custody procedures, sample and document storage and quality control procedures.

8.1 This audit will be based on discussions with Mr. K. Thomas, Field Supervisor, interviews with field personnel, and review of documents.

8.2 Audit checklists will be developed which will address the following subject areas:

- Sample receipt from the field and log-in procedures,
- Sample distribution procedures,
- Sample tracking procedures,
- Record tracking and storage procedures,

- "Inventory control" procedures,
- Internal QC procedures,
- Resolution of problems

8.3 Sample Processing and Shipment will be audited once, as soon after the field monitoring begins as practical.

8.4 A written audit report will be submitted to Mr. K. Thomas within 5 working days of the systems audit.

8.5 A summary report will be submitted to the Principal Investigator in the Quarterly QA Report.

9.0 SYSTEMS AUDIT OF ANALYTICAL MEASUREMENT SYSTEMS

The analytical measurement systems (RTI, EOHSI) will be audited once (at a minimum) during the course of sample analysis. Follow-up audits should be conducted at six-month intervals. The laboratory in which each matrix/analyte category (e.g., air/metals) is being analyzed will be evaluated for adherence to protocols and SOPs and general work performance. The follow-up audits will evaluate continued adherence to protocols and SOPs.

9.1 These systems audits will be conducted by the RTI QA Officer at RTI and the EOHSI QA Officer at EOHSI.

9.2 Audit checklist(s) will be developed which will address the following subject areas:

- Instrument(s) used and performance criteria,
- Custody procedures,
- Sample storage,
- Sample preparation methods,
- Internal QC protocols,
- Preventative maintenance,
- Assessment of accuracy and precision,
- Mechanisms for detecting and resolving analytical out-of-control situations,
- Data flow and tracking procedures,
- Resolution of problems.

9.3 Reports

9.3.1 Results will be submitted in writing to the respective laboratory manager within five working days of the audit.

9.3.2 Summary results will be reported to the Principal Investigator.

9.3.3 The EOHSI QA Officer will submit summary reports to the RTI QA Officer quarterly.

10.0 SYSTEMS AUDIT OF DATA ENTRY AND PROCESSING

The QA Officer will conduct an audit of the data entry and processing component of this study. Evaluation of transcription of error rate, document storage, adherence to protocols and SOPs, and quality control procedures will be performed.

10.1 Scope

Data entry and processing includes a number of processes Each will be audited separately, if possible. Specific processes and key items for each are summarized in the following sections.

10.1.1 Survey Data Entry

Audit checklists will be developed which address the following areas:

- Batching procedures,
- Effectiveness of rekey procedures,
- Resolution of discrepancies,
- Internal QC procedures,
- Document storage procedures,
- Procedures for maintaining participant confidentiality,
- Resolution of problems.

The audit will be based, in part, on interviews with the data entry supervisor and review of documents and procedures.

10.1.2 Preparation of the NHEXAS Database

Audit checklists will be developed which address the following areas:

- Data transfer mechanisms,
- Verification procedures for data transfer,

- Control of access to database records,
- Procedures for assessing completeness,
- Internal QC procedures,
- Resolution of problems.

The audit will be based on interviews with the NHEXAS Database Manager and review of records and procedures.

10.1.3 Data Processing

Audit checklists will be developed which address the following areas:

- Procedures for assessing completeness,
- Internal QC procedures,
- Procedures for corrections to database,
- Security and back-up procedures,
- Procedures for maintaining participant confidentiality,
- Resolution of problems.

10.2 Reports

10.2.1 A written report will be submitted to the NHEXAS Database Manager within 5 working days of the audit.

10.2.2 Summary results will be reported to the Principal Investigator.

11.0 AUDIT REPORTS

11.1 A written report will be sent to the Co-Principal Investigator (or laboratory manager) and will include

- date of the systems audit,
- scope (study component under review),
- name and signature of the individual(s) performing the audit,
- names of individuals participating n the audit,
- results of the audit, include both favorable and adverse findings,
- action recommended and taken to resolve problems,
- scheduled date for the next inspection.

An example of a suitable report form is attached.

11.2 A summary report will be submitted to the Principal Investigator. This may be a brief summary report or a status chart which is updated periodically (quarterly, at a minimum). All items which may adversely affect data quality must be reported to the Principal Investigator.

NHEXAS Systems Audit Report

Audit Information:

Study Component _____

Audit Date(s) _____

Audit location _____

Individuals Participating:

Individual	Responsibility

Audit Summary:

Recommended Actions:

Attachments:

Submitted to: _____

Submitted by: _____ _____
QA Officer Date