

# **National Human Exposure Assessment Survey (NHEXAS)**

## ***Maryland Study***

### **Quality Systems and Implementation Plan for Human Exposure Assessment**

Emory University  
Atlanta, GA 30322

Cooperative Agreement CR 822038

**Standard Operating Procedure**

**NHX/SOP-G06**

**Title:** Problem Management

**Source:** Harvard University/Johns Hopkins University

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.

1 Title of Standard Operating Procedure

Harvard University/Johns Hopkins University Standard Operating Procedures:  
**G06 Problem Management, Rev. 1.0**

2 Overview and Purpose

The purpose of this standard operating procedure (SOP) is to define a set of reporting actions to take in the case that a problem should arise during any phase of the study.

3 Discussion

Problem management is crucial to a study that involves many different people and sites, as well as a large quantity of data of many types. Problems are classified based on when they arise or are identified:

**Routine problems** arise during the course of normal study operations.

**Quality problems** arise during the course of regular internal quality assurance review procedures.

This procedure outlines the steps for making a problem known in order that it may be systematically resolved by the appropriate decision makers of the study.

If the solution to a particular problem is not identified in the appropriate SOP, the problem should be reported. Problems should be reported and documented in order to avoid inappropriate actions, to prevent future occurrences, and to add checks to weak points; alternative solutions to the problem and overall analytical needs of the study should be properly considered. After the problem is reported and solved, the SOP should be revised in order to ensure that the problem does not recur.

It is important to note that any modifications must be checked and validated prior to implementation. This will minimize negative effects on the collection of data. It will also assure that the data collected through the lifetime of the project are consistent in that they are not measuring different variables at different times of the project.

4 Personnel Responsibilities

Routine and quality problems are to be reported to the Study Coordinator through proper channels, outlined in section 6.1.6 and 6.2.3.

The following table lists the key personnel mentioned in this SOP, as of the date of this SOP.

<b>Title</b>	<b>Name</b>	<b>Affiliation</b>	<b>Responsibilities</b>
Principal Investigator	P. Barry Ryan	Emory	Oversee all aspects of NHEXAS study.
Study Coordinator	Carol Botteron	HSPH	Coordinate collaborating groups.
Quality Assurance (QA) Officer	Robert Weker	HSPH	Quality of field and laboratory work.
Field Coordinator	Robert Clickner	Westat	Coordinate field work.
Field Supervisor	Rotraut Bockstahler	Westat	Assign field staff to homes, etc.
Resource Specialist	Rick Rinehart Jill Weiner Rotraut Bockstahler	Westat	Supervise preparation for sampling, answer questions from field staff.
Co-PI	Thomas Burke	JHU	Supervise blood and urine division at JHU laboratory.
SwRI Laboratory Supervisor	David Camann	SwRI	SwRI work, coordination with Emory and HSPH, data review.
Emory Laboratory Supervisor	Bryan Burnette	Emory	Emory Trace Metals Laboratory.
Project Data Coordinator	David MacIntosh	Emory	Supervise all data entry, coding, and analysis.
Data Entry Supervisor	Keri Dailey	Emory	Accuracy of data entry & coding.

## 5 Required Equipment and Reagents

### Problem Reporting Forms

## 6 Procedures

### 6.1 Routine Problems

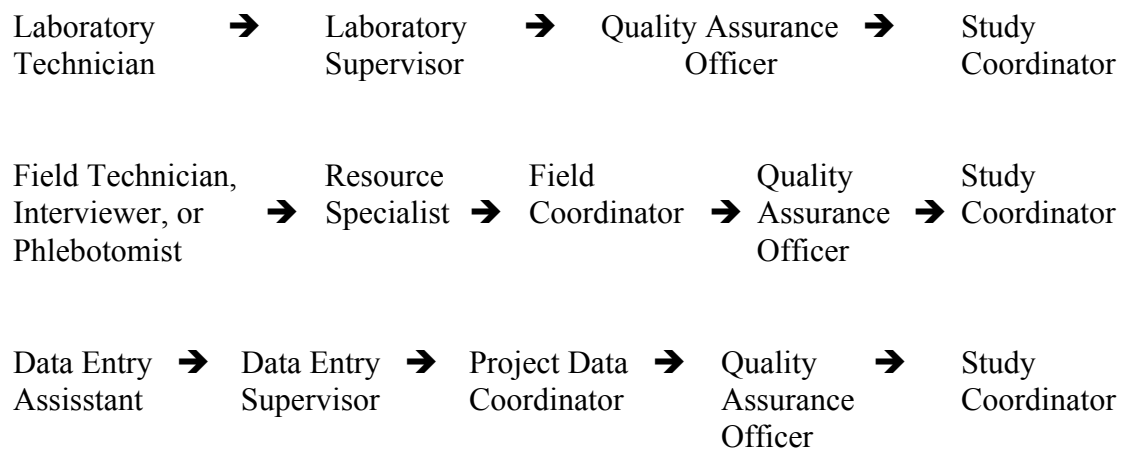
- 6.1.1 The employee encountering the problem should consult the appropriate SOP, as it may address common problems and their solutions explicitly. Field staff will be given a list of telephone numbers to call regarding problems.
- 6.1.2 If the SOP is not helpful, field staff should call the Resource Specialist for the appropriate medium. Field staff will be given a list of telephone numbers.
- 6.1.3 If consulting the SOP and the Resource Specialist does not solve the problem, report it by completing a Problem Reporting Form (see last page of this SOP). If you are able to solve the problem, describe your solution.
- 6.1.4 The employee encountering the problem should turn in the Problem Reporting Form

to the next person in the flow of problem reporting, usually a supervisor (see section 6.1.8).

- 6.1.5 If the supervisor can solve the problem, s/he should discuss the solution with the employee who encountered the problem, and describe the solution on the form. Confidential information regarding any possible personnel matters of a specific employee should not be included on Problem Reporting Forms.

**Note:** Once a problem is identified, a Problem Reporting Form must be filled out and sent through the proper channels, even if the problem has been solved. This is to ensure that everyone who might be affected by the problem knows about the problem and its potential solution.

- 6.1.6 The supervisor should forward the Problem Reporting Form to the Quality Assurance Officer, who will examine the problem and its solution in terms of QA. The QA Officer will discuss the problem with any appropriate personnel, note any action on the Problem Reporting Form, and forward the form to the Study Coordinator.
- 6.1.7 If the problem has been solved, the Study Coordinator will make sure that any necessary changes are made in SOPs, and that all personnel who need to know about the problem are informed. If the problem has not been solved, the Study Coordinator will contact the necessary personnel to resolve it. The Study Coordinator will make copies of the Problem Reporting Form for any other person(s) who might be involved in the problem's resolution.
- 6.1.8 The typical flow of reporting is as follows:



- 6.1.7 Each study site (FCC, laboratory, etc.) will maintain a central file or logbook for Problem Reporting Forms and related documents.

## 6.2 Quality Problems

- 6.2.1 The Problem Reporting Form should be completed by the Quality Assurance Officer and forwarded to the Study Coordinator who will contact the necessary personnel to resolve the problem.
- 6.2.2 The Study Coordinator will make copies of the Problem Reporting Form for any other person(s) who might be involved in the problem's resolution.
- 6.2.3 The typical flow of reporting is as follows:

Laboratory   ➔   Laboratory   ➔   Quality Assurance   ➔   Study  
Technician   Supervisor   Officer   Coordinator

## 6.3 Problem Followup

- 6.3.1 After a problem is resolved, the Study Coordinator should complete the Problem Reporting Form by describing the action taken.
- 6.3.2 A copy of this final completed Problem Reporting Form and copies of any updated standard operating procedure(s) that may have resulted will be distributed to all persons in that flow of reporting who will be affected.
- 6.3.3 If necessary to prevent further problems, the relevant SOP(s) will be modified and copies of the new versions distributed. If changes to an SOP are needed, the EPA will be notified in accordance with NHEXAS Approval Process (update of Sept. 17, 1994 version.)

## 7 Quality Assurance Procedures

This standard operating procedure is inherently part of the quality assurance procedures for the Study.

## 8 References

None.

**Problem Reporting Form**  
NHEXAS Phase I Study

Person reporting problem:	Affiliation and position:	Date:
Description of problem, suggested action, etc.:		
Forwarded to:	Affiliation and position:	Date:
Action:		
Forwarded to:	Affiliation and position:	Date:
Action:		