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-G01**

Title: Preparation of Standard Operating Procedures

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:
G01 Preparation of Standard Operating Procedures, Rev. 1.0

2 Overview and Purpose

The purpose of this standard operating procedure is to develop a consistent method and style for all Harvard University/Johns Hopkins University standard operating procedures (SOPs).

3 Discussion

Standard operating procedures are necessary to document all procedures, methods, and techniques used in the NHEXAS investigations. Development of a standard style for such SOPs ensures that all necessary components will be in the SOP and that such components can be easily found and identified.

4 Personnel Responsibilities

The Principal Investigator has final responsibility for all SOPs developed under the Harvard/Johns Hopkins Consortium. Harvard, Johns Hopkins, SwRI, and Westat staff will prepare all SOPs under the ultimate direction of the Principal Investigator and under the direct supervision of the Co-Principal Investigator or Co-Investigator in charge. Changes to existing SOPs must be approved by the Co-Principal Investigator or Co-Investigator in charge and, finally, by the Principal Investigator. All changes must be documented.

5 Required Equipment and Reagents

None required.

6 Procedure

All SOPs are assigned a unique descriptive title and a Revision Number. Initial Revision numbers are all Rev. 1.0. A major change in protocol will be denoted by a change in the first number (e.g., Rev. 2.0). A minor revision in protocol will be denoted by a change in the second number (e.g., Rev. 1.1). A change reflecting a very small modification (e.g., change in beaker size for mixing) would be denoted with a letter (e.g., Rev. 1.1a).

If changes to an SOP are needed, the EPA will be notified in accordance with NHEXAS Approval Process (update of Sept. 17, 1994 version).

The essential components of the SOP can be found in the attached template document. For certain SOPs, not all sections will be applicable. If this is the case, note such by using such terms as: None Required, Not Applicable, etc. The SOP should not be overburdened with technical jargon. Accurate, scientific terms should be used when needed, but not in a manner that will decrease the understandability of the document.
All SOPs and revisions must be filed and maintained for the duration of the cooperative agreement plus an additional seven years unless specifically released from this requirement by the

Principal Investigator and the Environmental Protection Agency. Each institution in the consortium will maintain a notebook with all current SOPs on site.

The major headings for all SOPs should include the following:

1) Title

   Develop a unique, descriptive title for the SOP.

2) Overview and Purpose

   This section should describe briefly the purpose of the procedure. Concisely state the reason for developing this particular SOP in terms of project need.

3) Discussion

   A short description of where this activity fits with the NHEXAS program will give the activity firm grounding. A sentence or two on when to apply this procedure is also of use here.

4) Personnel Responsibilities

   The purpose of this section is to identify which consortium institutions and which individuals within the institution are responsible for the activities outlined in the SOP.

5) Required Materials and Reagents

   Itemize the required material, equipment, and reagents needed to undertake the activities described in the SOP. If there is more than one location or procedure, put the materials in separate subsections.

6) Procedure

   This is the essence of the SOP itself. All procedures to be undertaken must be described in a concise, step-by-step manner which would allow a trained individual not familiar with the process to replicate it. The actual format will vary according to the procedure to be described. The following points may be considered typical:

   6.1 Preparation for Collection
   In this section, describe any special conditions and preparations of sampling or other apparatus necessary prior to field collection.

   6.2 Selection of Sampling Location
   Describe the location for sampling (e.g., water samples are taken from the primary drinking water source as identified by the respondent).

   6.3 Sample Collection Procedure
   Describe the actual collection steps to be taken. Discussion should include who takes

the sample, when the sample should be taken, what container the sample will be taken in, the quantity of sample, a description of the sampling apparatus, and any other relevant information which would enable the reader to undertake the sampling.

6.4 Labeling of Sample
In this section, use the following language with any necessary modifications:
A unique ID number will be assigned for each sample (see HSPH SOP G03 "Identification Numbers for Samples and Forms"). Printed labels will show the ID number in bar-code and human-readable format. The field technician will affix identical labels to the sample container, the logsheet, and the chain-of-custody form.

6.5 Preservation and Storage
Address any special handling such as the addition of sample preservatives or storage under special conditions.

6.6 Handling and Shipping
Discuss special handling and shipping requirements for the preserved sample. See SOP G05 "Storage and Shipping of Samples."

6.7 Laboratory Analysis
Discuss the analytical laboratory analysis procedures. If the procedures are very involved or to be used in many different SOPs, a separate SOP describing such activities should be generated and referenced at this point.

6.8 Data Workup
See HSPH SOP D01 "Data Flow." In this section, use the following language with any necessary modifications:

Field and laboratory data will be returned to Harvard in both magnetic and hardcopy format. Data will be coded and checked, computer entry verified, and discrepancies resolved. Analytical results will then be merged with questionnaires and other data, using the ID number as the merge parameter.

6.9 Sample Tracking
See HSPH SOP G04 "Chain-of-Custody and Sample Tracking." In this section, use the following language with any necessary modifications:

The ID number will allow tracking of each sample. A data base management system will ensure knowledge of the status and location of any sample at any time including retrospectively.

The chain-of-custody form will accompany the sample wherever it goes. Anyone who receives, transfers, or ships the sample will sign and date it, and keep a photocopy. It must clearly contain all necessary information so that the custody of the sample can be determined at any time. Airbills, bills of lading, etc., are acceptable substitutes when a commercial or government carrier is used; copies of such bills will be attached to the chain-of-custody form.

2 Quality Assurance Procedures

This section should include the discussion of quality assurance procedures implemented for

this SOP. Examples of such procedures include:

2.1 Use of Laboratory and Field Blanks
Describe the use of laboratory and field blanks. In particular, what fractions of the total number of samples will be reserved for each.

2.2 Duplicate Sampling
Similarly, describe the fraction of side-by-side duplicate samples that will be done. The standard for this investigation will be 10% duplicate sampling.

2.3 Tolerance Limits, Detection Limits, and Sensitivity Limits
Describe here the expected minimum detection limit, expected or default control limits for apparatus, and sensitivity limits for the procedure being described.

3 References

List any references, including other SOPs, as shown below.

7 Quality Assurance Procedures

Each SOP will be read by all personnel involved in the aspect of the project covered by the SOP, including the EPA Principal Collaborator and Westat and SwRI personnel. Versions of the SOPs responding to their comments will be prepared before field work begins. During the study, problems will be handled according to HSPH SOP G06 "Problem Management."

8 References

Harvard University/Johns Hopkins University Standard Operating Procedures:
G03 Identification Numbers for Samples and Forms
G04 Chain-of-Custody and Sample Tracking
G05 Storage and Shipping of Samples
G06 Problem Management
D01 Data Flow

Linda Porter, EPA: NHEXAS Approval Process (update of Sept. 17, 1994 version).