The Arizona Border Study

An Extension of the
Arizona National Human Exposure Assessment Survey (NHEXAS)Study
Sponsored by the Environmental Health Workgroup of the Border XXI Program

Quality Systems and Implementation Plan for Human Exposure Assessment

The University of Arizona
Tucson, Arizona 85721

Cooperative Agreement CR 824719

Standard Operating Procedure **SOP-UA-G-1.0**

Title: Preparation of Standard Operating Procedures (SOPs)

Source: The University of Arizona

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

Environmental Protection Agency
Contract Number: CR821560

NHEXAS Arizona Project

Title: **Preparation of Standard Operating procedures (SOPS)**

Document No. UA-G-1.0

APPROVALS

☒ Full SOP ☐ Working SOP #pages 7

On Site Principal Investigator:

Issue Date: 8-12-94

Project QA Director:

Revision No. 0

Independent Reviewer:

Revision No: 1
Revision Date: June 30, 1997
Revision Made:
1. Generalize SOP use in multiple projects
2. Revise title Page + remove project specific info
3. Liberalize Pagination for appendices.

On Site PI:

Project QA Director:

Independent Reviewer:

Revision No:
Revision Date:
Revision Made:

On Site PI:

Project QA Director:

Independent Reviewer:

Distributed To:	Revision No. 1	2	3	4	5	6

Form TP-1

PREPARATION OF STANDARD OPERATING PROCEDURES (SOPS)

1.0 Purpose and Applicability

The purpose of this SOP is to establish a uniform format for the preparation of Standard Operating Procedures (SOPs) for the EPA NHEXAS, Border and any other Health and Environment projects undertaken. Use of these protocols ensures consistent implementation of project tasks, documents the preparation and implementation of the procedures used, describes quality control measures and the limits of the procedure.

2.0 Definitions

SOP: Standard Operating Procedure

3.0 References

None

4.0 Discussion

SOPs, as a minimum will contain appropriate and relevant information for valid completion of the task. Preparation of SOPs using the format defined in this procedure ensures that major sections of different SOPs are consistently labeled and easily identified.

5.0 Responsibilities

5.1 The local Co-Principal Investigator will be responsible for final review and approval of each procedure.

5.2 Members of the project-team with first-hand knowledge of the procedure will prepare the SOP as assigned by the local Co-Principal Investigator in the format outlined in this procedure.

5.3 Any person who amends or alters a procedure is responsible for ensuring that the changes have been properly documented, the SOP changed, reviewed, and reissued.

6.0 Materials and Equipment

None

7.0 Procedure

7.1 Procedure Identification and Control

7.1.1 Assign each procedure a unique identification code of two sets of letters and one set of numbers as follows:

The first set of letters indicates the Applicable Consortium Member:

UA - University of Arizona
BCO - Battelle Columbus
IIT - Illinois Institute of Technology

The second set of letters indicates the Project Area of Applicability:

G - General
T - Training of Personnel
F - Field and Field Packet Preparation
L - Laboratory Methods and Equipment Calibration
C - Custody of Samples and Data
D - Data
A - Statistical Data Analysis
M - Other Miscellaneous as Needed

Numbers following each Project Area designation will be in consecutive order with the decimal place indicating the revision of the SOP. NOTE that for first issue of SOPS, the decimal is "n.0".

EXAMPLE: SOP #UA-G-2.1 where:
UA : University of Arizona
G : General procedure
2. : The second issued SOP in the General Category,
1 : Indicates the first revision of the SOP

7.1.2 Assign every procedure a unique title.

7.1.3 Include in the heading of each page: unique SOP ID number, revision number and effective date of the procedure.

7.1.4 Paginate every page of the SOP "Page X of X." This includes Tables and Figures. Addenda can be numbered as part of the SOP but this is optional. If addenda are attached to the SOP and not numbered as part of it, then they should have at least internal, sequential page numbers.

7.2 Title Page

Each SOP will include a title page (Figure 1 Form TP-2) which will serve as a record of the SOP from its original issue date through any revisions. The Title Page shall include at a minimum the following information:

a) Unique ID Number
b) Revision Number
c) Reviewers' Dated Signatures
d) Issue Date
e) Description of Revisions and affected pages
f) Indication of Control

7.3 Format of Text

The recommended format of the body of the SOP will be as outlined below. This is meant as a guide. The writer has the latitude to alter the format to meet the needs of the protocol development. Develop each heading as much as needed to make clear what is happening in the SOP. Use the word "none" or "N/A" for any subject heading not required in the SOP. Adjust tab spacing as seems appropriate, but keep it consistent within a given SOP.

7.3.1 Purpose and Applicability

Describe the purpose and scope of the procedure. Define when and where the procedure should be used.

7.3.2 Definitions

Define words and phrases having a special meaning or application within the SOP. Definitions will be alphabetized and sequentially numbered.

7.3.3 References

Cite relevant SOPs necessary to carry out the work. Cite other sources of work as applicable. Alphabetize by author and year. Use a bibliographic reference style of your choice.

7.3.4 Discussion

Include background or contextual information as applicable to make SOP more understandable.

7.3.5 Responsibilities

Identify the organizational positions and responsibilities of the people who

are charged with implementing the procedure.

7.3.6 Materials and Reagents

a) Materials: Itemize equipment (e.g., pipettes, glassware) and major Instrumentation (e.g. HPLC, water bath) needed to perform SOP. Identify supplier or manufacturer of any non-stock item.

b) Reagents: Itemize reagents (e.g. gases, solutions) needed to perform SOP. Identify supplier or manufacturer of any non-stock item.

7.3.7 Procedure

Identify, list and label specific tasks in a step-by-step sequence. Be specific in context and scope, using short, declarative statements. The following is a suggested format: (see outline Table 1)

a) Preparation

1. Field Site Selection Criteria
2. Reagents
3. Standards/Blanks
4. Samples

b) Steps followed (Field Procedures/Lab Analyses/Data Procedures)

1. Standards/Blanks
2. Samples

c) Calculations

d) Quality Control

1. Tolerance Limits
2. Detection Limits
3. Corrective Actions

7.3.8 Records

a) Define clearly and concisely what data (e.g. reagent Lot #s instrumental parameters) need to be recorded.

b) Define where data are to be recorded. Attach forms or tables as appropriate.

c) Define where completed data forms/logbooks will be archived.

7.4 Attachments

7.4.1 Figures

Figures include forms, charts or graphs that are referenced in the SOP. They will follow the text of the SOP and be labeled and paginated as part of the SOP. Figures will be numbered sequentially.

7.4.1 Appendices

Appendices or other addenda can be numbered as part of the SOP but this is optional. If addenda are attached to the SOP and not numbered as part of it, then they should have at least internal, sequential page numbers.

NOTE: If figures and appendices are referenced in a different SOP, the figure or appendix label must include the SOP #, e.g. "SOP #UA-G-1.0-Figure 1."

8.0 Records

SOP's including any and all revisions shall be archived and retained for no less than 5 years unless otherwise specified by the Project Director and the Sponsor.

Figure 1. The SOP Title Page. Enter the names receiving Revision 0 and the date when each person has been given subsequent revisions.

Title:	
Document No.	APPROVALS
☐ Full SOP ☐ Working SOP #pages ___	On Site Principal Investigator:
Issue Date:	Project QA Director:
Revision No.	Independent Reviewer:
Revision No:	On Site PI:
Revision Date:	Project QA Director:
Revision Made:	Independent Reviewer:
Revision No:	On Site PI:
Revision Date:	Project QA Director:
Revision Made:	Independent Reviewer:

Distributed To:	Revision No. 1	2	3	4	5	6

Form TP-2

Figure 2. An Outline of the SOP Format.

TITLE OF THE SOP

1.0 Purpose and Applicability

2.0 Definitions
2.1 Def # 1
2.2 Def # 2

3.0 References
3.1 Ref # 1
3.2 Ref # 2

4.0 Discussion

5.0 Responsibilities

6.0 Materials and Reagents

6.1 Materials:

6.2 Reagents:

7.0 Procedure

7.1 Preparation
- 7.1.1 or a. Field Site Selection Criteria
- 7.1.2 or b. Reagents
- 7.1.3 or c. Standards/Blanks
- 7.1.4 or d. Samplers

7.2 Steps followed (Field Procedures/Lab Analyses/Data Procedures)
- 7.2.1 or a. Standards/Blanks deployed or used
- 7.2.2 or b. Samples

7.3 Calculations

7.4 Quality Control
- 7.4.1 or a. Tolerance Limits
- 7.4.2 or b. Detection Limits
- 7.4.3 or c. Corrective Actions

8.0 Records
- Tables
- Figures
- Appendices