United States Environmental Protection Agency

Office of Research and Development

# 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-100-002**

**Title:** Revising Standard Operating Procedures and Protocols

**Source:** Research Triangle Institute

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

**TITLE:** STANDARD OPERATING PROCEDURE FOR REVISING STANDARD OPERATING PROCEDURES AND PROTOCOLS

**SOURCE:** Research Triangle Institute
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**REVISIONS:**

| No. | Date | No. | Date |
|---|---|---|---|
| 0 | ‡ | 6 | |
| 1 | | 7 | |
| 2 | | 8 | |
| 3 | | 9 | |
| 4 | | 10 | |
| 5 | | 11 | |

‡ Effective date of this version is the date of the last approval signature; revision 0 is the original version.

# REVISING STANDARD OPERATING PROCEDURES AND PROTOCOLS

## TABLE OF CONTENTS

## 1.0 SCOPE AND APPLICATION

Well-written, correct procedures are an integral part of a good quality assurance program. SOPs and protocols represent approved methodology, but must also reflect improvements or changes in methodology. Once an SOP (or protocol) has been approved for use (issued), it may be revised only by one of the procedures described here.

## 2.0 SUMMARY

All changes in SOPs and Protocols must be documented and approved. An SOP or protocol approved for use (issued) may be revised only by one of the alternatives described below.

### 2.1 Revision

Revisions are made to the document and approved. A memo describing the change will be issued with the revised document, or a change log will be attached to the document.

### 2.2 New SOP or Protocol

If many changes are to be made, consideration should be given to preparing a new SOP or protocol. The original should be kept for future use.

### 2.3 Proposed SOP Revision Form

This alternative is designed for cases where temporary, short-term modifications are needed or for cases where the changes must be approved for use as soon as possible.

### 2.4 Field Revisions

Additions or corrections to approved SOPs and protocols may be initiated by the field staff with approval by the Field Supervisor. Careful documentation is required.

The following sections describe the procedure for each alternative and other procedures relating to document revision.

## 3.0 SOP/PROTOCOL REVISION

### 3.1 Recommended Use

3.1.1 Original document was incomplete.

3.1.2 Original document was in error.

3.1.3 Modifications or improvements in methodology require changes in the document.

3.1.4 Proposed revisions (Section 5.0) should remain in effect and be incorporated into the SOP.

### 3.2 Preparation

3.2.1 The appropriate Co-Principal Investigator or Supervisor will coordinate revisions.

3.2.2 The revised text will be submitted with changes incorporated with explanation to the QA Officer and Principal Investigator. The explanation of changes may be

- memo containing a complete summary of modifications, including deleted material,
- Proposed SOP Revision Form (Section 5.0),
- Change log.

3.2.3 The effective date of the original document (Revision 0 in the case of the first revision) will be added under "REVISIONS" on the Title Page. The symbol "‡" will be moved to the next line.

### 3.3 Approval

Revisions to SOPs and protocols require review and approval. The approval signatures required are the same as for the original document.

### 3.4 Documentation

All superseded SOPs and protocols which described procedures which, at one time, were approved methodology, must be retained for the record.

## 4.0 NEW SOP/PROTOCOL

### 4.1 Recommended Use

4.1.1 Original document is technically sound and should be kept for future use.

4.1.2 Many modifications are required or major modifications have been made to the procedure(s) described in the document.

4.1.3 Substantial changes have been made by an individual who is not the author or co-author of the document.

### 4.2 Preparation

Follow NHX-SOP-100-001.

### 4.3 Documentation

All original, signed SOPs and protocols will be maintained in a secure file.

## 5.0 PROPOSED SOP REVISION FORM

### 5.1 Recommended Use

5.1.1 Temporary, short-term modification is needed.

5.1.2 Changes in the SOP or protocol must be approved for use as soon as possible.

### 5.2 Procedure

5.2.1 Complete Proposed SOP Revision Form (attached).

NOTE: Form may be used for protocols as well as SOPs.

5.2.2 Revised SOP sections must be attached to the form. They may be handwritten.

5.2.3 Revision becomes effective upon approval (QA Officer, Principal Investigator).

5.2.4 Revision remains in effect for 30 days. If the 30-day period passes without further action, the original (or latest revision) becomes effective again.

5.2.5 Proposed revisions may be initiated by staff members implementing an SOP or protocol or by the supervisor responsible for the implementation of the SOP or protocol.

5.3 Documentation

5.3.1 The first time this approach is used for revision of a particular SOP or Protocol, the letter A will be used to identify the revision. Succeeding proposed revisions of the SOP will be labeled B, C, etc.

5.3.2 The original, signed copy of the Proposed SOP Revision Form must be kept with the original document in secure files.

## 6.0 FIELD REVISIONS

This alternative should only be used when it is not possible to utilize one of the other procedures. Careful and complete documentation is required when utilizing this alternative procedure. Close consultation with the Field Supervisor is required.

6.1 Recommended Use

6.1.1 Errors are found in the document after it is implemented in the field.

6.1.2 Items are incomplete, or need further explanation.

6.1.3 Modifications in methodology require changes in the document.

6.2 Preparation

6.2.1 The revisions or changes must be approved by the Field Supervisor prior to implementing the revision. Field staff must convey the nature of the problem and the proposed revision to the Field Supervisor.

6.2.2 Revisions or changes must be made to a single set of documents maintained in the field.

6.2.3 Revisions or changes must be initialed and dated by the individual making the changes.

6.3 Documentation

6.3.1 The set of documents containing field revisions must be retained as a part of the program SOP/Protocol file.

6.3.2 The Field Supervisor is responsible for maintaining the documentation for the field changes.

6.3.3 The Field Supervisor will use one of the other three revision methods to formalize the field revision as an updated or new SOP or protocol.

6.3.4 The updated or new SOP or protocol will be transmitted to the field staff after approval by the QA Officer and Principal Investigator.

## 7.0 SOP/PROTOCOL FILE

All documentation regarding SOP and protocol revisions will be maintained in a secure location. The QA Officer, or designee, is responsible for maintaining the SOP/protocol fields. The Field Supervisor is responsible for maintaining field revision documentation until these documents are entered in the NHEXAS SOP/protocol files.

The NHEXAS SOP/protocol fill will contain

- Original, signed copies of current and superceded SOP and protocol versions,
- Memos, proposed SOP revision forms, change logs for SOP revisions,
- field revision documentation.

## Proposed SOP Revision

**Proposed Revision Suffix (A-Z):** _____

**SOP No:** _____ **SOP Revision No:** _____

**SOP Title:** _____

**Laboratory Notebook Reference:** _____

**SOP section no(s). modified or deleted by proposed revision:**

Brief description of proposed revision:

(Attach original SOP text to this form for reference, if applicable.)

**Effective Date*:** _____ **Initiated by:**

**Termination Date**:** _____ _____

**Resolution:**

( ) SOP revised
( ) New SOP written
( ) Approval expired

**Approved by:**

_____
RTI QA Officer/Date

_____
Principal Investigator/Date

* The proposed revision is approved and in effect when the revised SOP has been attached and the approval signatures are in place.

** If not indicated, thirty days following "Effective Date". If no action has been taken after 30 days to revise the SOP or to issue a new one, the approval expires and the revision is no longer in effect.