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-110-002**

Title: RTI/EOHSI Quality Assurance Officer

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 RTI/EOHSI QUALITY ASSURANCE OFFICER

SOURCE: Research Triangle Institute
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RTI/EOHSI QUALITY ASSURANCE OFFICER

TABLE OF CONTENTS

1.0 SCOPE AND APPLICATION

The RTI/EOHSI NHEXAS Quality Assurance Officer will oversee quality assurance activities within the consortium, will oversee QA activities within RTI and collaborate with the EOHSI QA Officer. The Quality Assurance Officer is responsible for monitoring this study to assure management that the facilities, equipment, personnel, methods, practices, records and controls are in conformance with the program requirements.

The QA Officer is the individual designated by the Principal Investigator to be responsible for the conduct of the RTI/EOHSI QA Office.

2.0 SUMMARY

The specific duties of the Quality Assurance Officer fall into two main categories: (1) general activities, and (2) specific project activities. These activities are described in Sections 3.0 (General Activities) and 4.0 (Program Activities).

3.0 GENERAL ACTIVITIES

The Quality Assurance Officer provides support for this program to insure and maintain the highest level of data quality. These activities are described below.

3.1 SOP Preparation and Revision

3.1.1 The Quality Assurance Officer will prepare SOPs for review, inspection and audit activities.

3.1.2 The ACS QA Officer will review and approve all SOPs and protocols.

3.1.3 A complete master listing and file of all protocols and SOPs will be maintained in the QA Office.

Reference: NHX-SOP-100-001

3.2 Document Review

3.2.1 The QA Officer will review all project documents to assure that quality is maintained.

3.2.2 This includes, but may not be limited to SOPs and protocols and project reports.

3.3 Reports to Management

3.3.1 The QA Officer will submit reports to the Principal Investigator on a quarterly basis (more often, if needed).

3.3.2 These QA reports shall contain, but are not limited to, the following.

3.3.2.1 Work completed during the report period. Emphasis will be placed on inspections, reviews, and audits conducted during the report period. The report should contain (1) program component reviewed or audited, (2) type of review or audit, (3) items reviewed and findings, and (4) time expended by QA Office staff.

3.3.2.2 Work projected. Emphasis will be placed on scheduled activities such as systems or performance audits and training.

3.3.2.3 Updated status charts. These status charts will include, but not be limited to (1) status charts showing program component, Co-Principal Investigator, QA Officer, status of required reports and QA activities, (2) inspection chart showing status of all scheduled systems audits, including date for next inspection, (3) summary of documents reviewed during the report period, and (4) summary of data audits.

3.4 QA Document Files

The QA Officer shall be responsible for maintaining QA documents and files.

3.4.1 The QA Officer shall maintain a master listing of all project SOPs and protocols and copies of all current and superseded versions.

3.4.2 The QA Officer shall maintain the project SOP/protocol file. This is a limited access file containing original, signed copies of current and superseded versions.

3.4.3 The QA Officer shall maintain copies of all program protocols and approved amendments and revisions.

3.4.4 The QA Officer will be responsible for the maintenance of training (personnel) files for each RTI project staff. The file will contain a current curriculum vitae and a summary of training experience (minimum requirement).

3.4.5 The QA Officer will maintain a file containing results of all reviews, inspections and audits.

3.5 Corrective Action

3.5.1 Corrective action may be required as a result of a review, inspection or audit.

3.5.2 Corrective action may be initiated when an unexpected problem arises which may affect the work on the program. This might be a product recall, a problem with laboratory facilities or a QA/QC problem.

3.5.3 Work may not resume until the problem has been satisfactorily resolved and the QA Officer has acknowledged approval.

3.5.4 Troubleshooting may be required for some situations involving QA/QC problems. A significant effort may be devoted to determining the source of and corrective actions for these problems.

3.6 Development of QA Concepts

3.6.1 The QA Officer will be responsible for investigating and testing alternative QA procedures and developing QA methodology for new or unique analytical techniques.

3.6.2 The QA Officer is responsible for advising staff in quality assurance matters.

3.6.3 The QA Officer will advise management in reviewing technology, methods, equipment, and facilities with respect to their quality assurance aspects.

3.6.4 The QA Officer will be responsible for evaluating new ideas and current developments in the field of quality assurance. Recommendations for implementation of these new procedures will be made, when appropriate.

3.7 Training

3.7.1 The QA Officer shall be responsible for staff training in QA matters.

3.7.2 Each new RTI employee receives QA information as part of the new employee orientation packet. The supervisor is responsible for this orientation.

3.8 Certified Standards

The Quality Assurance Officer will encourage the use of Standard References Materials (SRMs) and Certified Reference Material (CRMs) for all analytical studies and will assist in the selection and procurement of them.

The QA program staff will maintain Certified Standards needed to assure high quality data. The most important are those required for instrument calibration (or routine check or calibration). Presently Certified Weights and UV standards are maintained; others may be added.

3.8.1 Certified Weights

A set of certified weights will be maintained by the QA program staff in a secure location. All applicable SOPs will be followed.

3.8.2 Certified UV Standards

A set of Certified UV standards for calibration of UV/Vis spectrophotometers will be maintained by the QA program staff. All applicable SOPs will be followed.

3.8.3 Other

The QA Officer will recommend and obtain other certified materials or equipment, where required.

Reference: NHX-SOP-820-001
NHX-SOP-820-002

4.0 PROGRAM ACTIVITIES

There are specific program responsibilities for the QA Officer. These are outlined in the QSIP. The RTI QA Officer is responsible for activities conducted at RTI (Systems Audits, for example). The EOHSI QA Officer is responsible for activities conducted at EOHSI. There are no responsibilities for QA oversight at other institutions (Federal laboratories).

4.1 Pre-Study Systems Audit

4.1.1 The pre-study audit will be performed during one or both of the scheduled dress rehearsals.

4.1.2 The pre-study audit will be initiated by the ACS QA Officer and based on requirements in the RTI/EOHSI QSIP and draft protocols and SOPs.

4.2 Quality Assurance Plans

4.2.1 Quality assurance planning shall be a pre-study activity for the NHEXAS program. The QA Officer will confer with the program leaders to determine the level of quality assurance required.

4.2.2 The QA Officer shall prepare or assist in the preparation of the QSIP.

4.3 Systems Audits

The QA Officer shall periodically conduct systems audits of program components studies and maintain written and properly signed records of each inspection. Pertinent information shall include: (1) the study component under review, (2) the date of the inspection, (3) the individual(s) performing the audit, (4) results of the audit including both favorable and adverse findings, (5) action recommended and taken to resolve problems, and (6) a scheduled date for next inspection.

4.3.1 The Quality Assurance Officer will use checklists to aid in the evaluation of different work areas.

4.3.2 Specialized SOPs and checklists developed for specific work areas will be used when appropriate. An example of an SOP is

RTI/ACS-SOP-812-001 Conducting a QA System Audit of Field Sample and Data Collection in the Field.

4.3.3 The systems audit will usually include an interview with the Co-Principal Investigator and an inspection of study records and documentation.

4.3.4 A technical systems audit will be conducted concurrent with the systems audit when appropriate, for example, analytical systems. The overall quality of the data generated during the study will be evaluated, including monitoring the in- or out-of-control status of the analytical system(s) and assessing precision and accuracy estimates.

4.3.5 A written report will be sent to the Co-Principal Investigator and will contain the date of the systems audit, scope of the audit, results of the audit, recommendations for remedial action, individuals participating in the audit. Reference: NHX-SOP-815-001

4.4 Performance Evaluation Samples

4.4.1 The Quality Assurance Officer will be responsible for the receipt or preparation, documentation, and submission of performance evaluation samples for analysis by the laboratory.

4.4.2 SOPs will be used which describe responsibilities for sample handling and data reporting.

Reference: NHX-SOP-810-002 Preparation and Handling of Performance Audit Samples

4.5 Quality Assurance Samples

4.5.1 The Quality Assurance Office will support participation in collaborative tests and use of referee or independent QA Laboratories in all analytical studies.

4.5.2 Where appropriate, SOPs will be used for these activities. For example,

RTI/ACS-SOP-881-001 Submission QA samples to and
882-001 Receipt of Data from A QA Laboratory
887-001

4.6 Project Quality Assurance Reports

The QA Officer will prepare reports as required by the Cooperative Agreement.

4.6.1 QA Statement

The Quality Assurance Officer will prepare and sign a statement to be included in the final report summarizing inspections and audits performed and include dates of the inspections and audits and dates reported to management.

4.6.2 QA Final

Where required, the Quality Assurance Office will prepare a QA final report or QA contribution to the final report. The report will include, but not be limited to, the following:

Statement of QA objectives,

Summary of all reviews, inspections and audits,

Results of performance evaluation sample analysis,

Summary of situations requiring corrective action and actions taken,

Evaluation of data quality, including in-control status of the analytical system(s), assessment of precision and accuracy estimates,

Evaluation of quality control procedures, and

Recommendations.

4.6.3 Other

Where required, the Quality Assurance Officer will prepare contributions to monthly, interim, and other reports.

5.0 LIAISON

5.1 The QA Officer will cooperate with other consortium quality assurance personnel on matters of mutual interest.

5.2 The QA Officer will cooperate with other RTI personnel concerned with compliance with government regulations (for example, the Safety Office).

5.3 The QA Officer will participate in site visits when QA representation is required and is responsible for hosting federal agency audits at RTI.