

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

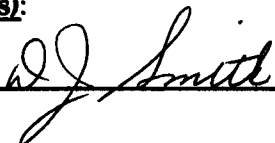
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Title: Training File Inspections

Source: Research Triangle Institute

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

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TITLE: STANDARD OPERATING PROCEDURE FOR TRAINING FILE INSPECTIONS**SOURCE:** Research Triangle Institute
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APPROVED BY:Principal Investigator: 

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TRAINING FILE INSPECTIONS

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1.0 SCOPE AND APPLICATION

Training file inspections will be performed primarily to assure that the program requirements are being met and that a current summary of training and experience is being maintained for each individual engaged in the RTI/EOSHI NHEXAS Program.

Training files must be maintained for all management, supervisory and technical staff working on this program.

2.0 SUMMARY

Training File Inspections will be conducted at six month intervals during the program. The first Inspection should be performed prior to the "Dress Rehearsal". The Inspections will be conducted by the QA Officer, or designee. Results will be reported to Co-Principal Investigators. A summary report will be sent to the Principal Investigator.

3.0 RESPONSIBILITIES

3.1 Management is responsible for maintaining training files. Files must be maintained for all current program staff and previous staff members and temporary staff. Training files for RTI staff will be maintained at RTI; training files for EOHSI staff will be maintained at EOHSI.

3.2 The QA Officer is responsible for conducting the Training File Inspections and reporting results to the program management. The EOHSI QA Officer will also prepare a summary report for the RTI QA Officer.

4.0 TRAINING FILE INSPECTION

4.1 The items that must be included in each Training File are:

- Current CV,
- Job Description,
- Documentation for training on applicable SOPs and protocols,

- Documentation of training and experience.

4.2 Develop Staff Training List

A list of required training and experience must be prepared for program staff members. This should be done in consultation with Co-Principal Investigators and other supervisory staff.

4.3 Prepare an Inspection Checklist

An example checklist is shown in Figure 1. The checklist must include:

- All current program staff,
- All items listed in Section 4.1,
- Other relevant items, such as safety training,
- Place for QA Officer signature and date,
- Notification of items requiring corrective action.

5.0 REPORTS TO MANAGEMENT

5.1 A written report of inspection results shall be prepared and submitted to the appropriate Co-Principal Investigator. A copy of the Inspection Checklist may be used for this purpose.

5.2 The report must include:

- Date and signature of the QA Officer conducting the inspection,
- Summary of results,
- Date of the next scheduled inspection,
- Notice of items requiring corrective action.

5.3 Results must be reported to the appropriate Co-Principal Investigator within 10 working days of the Inspection.

5.4 The EOHSI QA Officer shall submit a summary report to the RTI QA Officer.

5.4.1 The summary report must include the date and signature of the QA Officer conducting the Inspection.

5.4.2 The summary report should list the items included in the Inspection and status.

5.4.3 The summary report should be submitted to the RTI QA Officer by the end of the current Quarter (March 31, June 30, September 30, December 31).

5.5 Summary results will be reported to the Principal Investigator. The summary must include date of the Inspection, list of items included in the Inspection and items requiring corrective action. Summary results may be reported in the Quarterly QA report.

6.0 CORRECTIVE ACTION

The Co-Principal Investigator or supervisor must respond in writing to all inspection items requiring corrective action. The response must be sent to the QA Officer within 14 days of notice that corrective action is required. The ACS Corrective Action Form (RTI/ACS-84-09) shown in Figure 2 may be used for this purpose.

Reports will be sent to the Principal Investigator when

- a corrective action response has not been received by the QA Officer as required,
- corrective action cannot be agreed upon by the Co-Principal Investigator and QA Officer.

TRAINING FILE INSPECTION CHECKLIST

NAME	EDUCATION/EXPERIENCE		TRAINING/PROFICIENCY				
	Current CV	Job Description	SOPs	Training	Safety	QA	Other

Inspector/Date

✓ = suitable documentation; X = Corrective Action required.
RTI/ACS-QA-94-04

Figure 1. Example Training File Inspection Checklist.

ACS PROJECT ACTIVITIES REQUIRING CORRECTIVE ACTION

RTI Project No.: _____ Notebook Reference: _____

Project Title: _____

Nature of Incident (include dates):

Probable Cause of Incident:

Measures Taken to Prevent Reoccurrence:

Study Data Affected by Incident:

Comments/Recommendations:

Co-Principal Investigator

Date

Figure 2. Corrective Action Report Form.