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National Human Exposure Assessment Survey (NHEXAS)

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Quality Systems and Implementation Plan for Human Exposure Assessment

Research Triangle Institute
Research Triangle Park, NC 27079

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Standard Operating Procedure **NHX/SOP-815-002**

Title: Conducting Laboratory Notebook Inspections

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 CONDUCTING LABORATORY NOTEBOOK INSPECTIONS

SOURCE: Research Triangle Institute
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5		11	

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CONDUCTING LABORATORY NOTEBOOK INSPECTIONS

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1.0 SCOPE AND APPLICATION

Laboratory Notebook inspections are performed by the Quality Assurance Office Staff to document compliance with ACS Good Laboratory Practices (GLP). These GLPs are based on regulations promulgated by the FDA (1) and EPA (2). The inspections are conducted every six months using checklists developed for that purpose. The results are reported to the Laboratory Manager. A report is also sent to the Center Director (for programs originating within a Center) or Vice-President (for programs originating outside a Center).

2.0 APPLICATION

2.1 Laboratory Notebook inspections will be conducted by the Quality Assurance Office Staff.

2.2 Laboratory Notebook inspections will be conducted at six month intervals.

2.3 One or more Laboratory Notebooks in use by each individual will be inspected.

2.4 Checklists will be used during the inspection and report forms will be used for reporting results to management.

3.0 LABORATORY NOTEBOOK RESPONSIBILITIES

3.1 All Laboratory Notebooks must be used and maintained according to RTI/ACS-SOP-120-001 (current revision), Standard Operating Procedure for the Proper Use and Maintenance of Laboratory Notebooks.

3.2 The Laboratory Manager (or Project Leader) is responsible for informing the QA Officer which Laboratory Notebooks have been issued for each project and to whom they were assigned.

3.3 The QA Officer is responsible for monitoring and assessing ACS staff adherence to ACS-SOP-120-001 and reporting to the Center Director and Vice- President.

4.0 LABORATORY NOTEBOOK INSPECTION

4.1 The QA Officer or a member of the QA Office staff shall inspect at least one Laboratory Notebook in use by each individual involved in Laboratory work.

4.1.1 The QA Officer will designate the Notebook(s) to be inspected if there are several.

4.1.2 Current Laboratory Notebooks will be inspected whenever possible.

4.2 The Notebooks will not be removed from the laboratory or office area. All inspections will be carried out in the laboratory or office where the notebooks reside.

4.3 The inspection will be carried out using checklists developed for this purpose.

4.3.1 The basis for the inspection is ACS-SOP-120-001.

4.3.2 Current work will be reviewed in each notebook.

4.3.3 Comments will be made on the QA Notebook Inspection Form (Figure 1).

5.0 REPORTS TO MANAGEMENT

5.1 A written report of inspection results shall be prepared and submitted to the Laboratory Manger.

5.2 The summary form (Laboratory Notebook Inspection Report) shown in Figure 2 will be used for this purpose. Items requiring corrective action will be indicated.

5.3 Results will be reported to the Center Director and Vice-President in the Quarterly Quality Assurance Report using the form shown in Figure 3.

6.0 CORRECTIVE ACTION

The Laboratory Manager 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 Corrective Action Form (RTI/ACS-84-09) must be used for this purpose (Figure 4). Reports will be sent to the ACS Vice-President or Center Director when

- corrective action response has not been received by the QA Officer 14 days after notice that corrective action was required,
- corrective action cannot be agreed upon by the Laboratory Manager and QA Officer.

7.0 REFERENCES

1 FDA Final Rule - Good Laboratory Practice Regulations, Federal Register (43 FR 60013, December 22, 1978). Amended (52 FR 33780) September 4, 1987.

2 EPA Final Rule - Good Laboratory Practice Standards for Toxic Substances Control Act (TSCA), Federal Register (48 FR 53922) November 29, 1983, amended (54 FR 34033) August 17, 1989.

3 EPA Final Rule - Good Laboratory Practice Standards for Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Federal Register (48 FR 53946) November 29, 1983, amended (54 FR 34051) August 17, 1989.

QA NOTEBOOK INSPECTION

INSPECTION DATE:

NOTEBOOK #:

ISSUEE IDENTITY:

USER IDENTITY(S):

PROJECT # ISSUED:

PROJECT # USED:

CATAGORY OF NOTEBOOK:
(type of project/technique)

NOTEBOOK ACCESSIBILITY:

TABLE OF CONTENTS:

LOOSE PAGES:

LEGIBILITY:

PAGES DATED AND SIGNED:

BLANK SPACE X'd OUT:

HANDLING OF ERRORS:

CONTENT:
(sample entry/cross referencing, etc.)

Figure 1. Laboratory Notebook Inspection Form

LABORATORY NOTEBOOK INSPECTION REPORT

To Supervisor:

Notebook No.	Primary User	Primary Project	Major Deficiency	Other Factors	Comments	Inspected Date	Inspected By

Major Deficiency Codes

1. Entries not recorded same day of lab work.
2. Entries not complete or not sufficently descriptive.
3. Significant number of pages not signed and dated.
4. Entries not recorded in chronological order.
5. Poor organization of recorded material.
6. Inadequate or no Table of Contents.
7. Improper correction of errors/omissions.
8. Inadequate or improper cross-referencing.

Other Factors Codes:

1. Writing not legible.
2. Use of nonblack ink.
3. Notebook inaccessible.
4. Loose papers in notebook.

Figure 2. Summary Report to Laboratory Managers

LABORATORY NOTEBOOK INSPECTION REPORT

To Vice-President:

Notebook No.	Primary User	Primary Project	Major Deficiency	Other Factors	Comments	Inspected Date	Inspected By

Major Deficiency Codes

1. Entries not recorded same day of lab work.
2. Entries not complete or not sufficently descriptive.
3. Significant number of pages not signed and dated.
4. Entries not recorded in chronological order.
5. Poor organization of recorded material.
6. Inadequate or no Table of Contents.
7. Improper correction of errors/omissions.
8. Inadequate or improper cross-referencing.

Other Factors Codes:

1. Writing not legible.
2. Use of nonblack ink.
3. Notebook inaccessible.
4. Loose papers in notebook.

Figure 3. Summary Report to Center Director and Vice-President.

ACS PROJECT ACTIVITES REQUIRING CORRECTIVE ACTION

RTI Project No.:_____; Lab Notebook Reference:_____

RTI Project Title:_____

Nature of incident (include dates):

Probable cause of incident:

Measures taken to prevent reoccurrence:

Study data affected by incident:

Comment/Recommendations:

_____ _____

Project (Task) Leader Date

RTI/ACS-84/09

Figure 4. Corrective Action Form