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Standard Operating Procedure **NHX/SOP-815-003**

Title: Conducting Instrument Log 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 INSTRUMENT LOG NOTEBOOK INSPECTIONS

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CONDUCTING INSTRUMENT LOG NOTEBOOK INSPECTIONS

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1.0 SCOPE AND APPLICATION

Instrument Log 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 ACS Center Director (for programs originating within his/her Center) or Vice-President (for programs originating outside a Center).

2.0 APPLICATION

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

2.2 Instrument Log Notebook inspections will be conducted at six month intervals.

2.3 The Instrument Log Notebooks for each instrument or piece of equipment will be inspected.

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

3.0 LABORATORY NOTEBOOK RESPONSIBILITIES

3.1 All Instrument Log Notebooks must be used and maintained according to RTI/ACS-SOP-120-002 (current revision) Standard Operating Procedure for the Proper Use and Maintenance of Instrument Log Notebooks.

3.2 The Laboratory Manager is responsible for informing the QA Officer which Instrument Log Notebooks have been issued for each instrument and to whom they were assigned.

3.3 The QA Officer is responsible for monitoring and assessing ACS staff adherence to ACS-SOP-120-002 and reporting the assessment results to the Center Director and Vice-President.

4.0 INSTRUMENT LOG NOTEBOOK INSPECTION

4.1 The QA Officer or a member of the QA Office staff shall inspect the Instrument Log Notebook or Notebooks assigned to each instrument or piece of equipment.

NOTE: Included are all equipment used in the generation, measurement, or assessment of data.

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 NHX/SOP-120-002.

4.3.2 Current work will be reviewed in each notebook, that is, entries since the last inspection.

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

5.0 REPORT TO MANAGEMENT

5.1 A written report of inspection results shall be prepared and submitted to the Laboratory Manager (or Supervisor).

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

5.3 Summary results will be reported to the ACS Center Director (for programs originating within his/her center) or Vice-President (for programs originating outside a center) 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 odenticide Act (FIFRA), Federal Register (48 FR 53946) November 29, 1983, amended (54 FR 34051) August 17, 1989.

QA INSTRUMENT LOG NOTEBOOK INSPECTION

Inspection Date:

Notebook #:

Issuee Identity:

User Identity(s):

Instrument:

Location:

Notebook Accessibility:

Loose Pages:

Legibility:

Pages Dated and Signed:

Blank Space X'd out:

Handling of errors:

Content:

Analytical System:

Daily Log:

Sample Log:

Maintenance Log:

Figure 1. Instrument Log Notebook Inspection Form.

INSTRUMENT LOG NOTEBOOK INSPECTION REPORT

To: Supervisor

Notebook No.	Instrument	Location	Primary User	Major Deficiency	Other Factors	Comments	Inspector & Date

Major Deficiency Codes:

1. Insufficient Analytical Section
2. Insufficient Daily Log
3. Insufficient Sample Log
4. Insufficient Maintenance Section
5. Entries not current
6. Entries not coplete or note sufficently descriptive
7. Improper correction of errors/omissions

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.

INSTRUMENT LOG NOTEBOOK INSPECTION REPORT

To: Vice-President

Notebook No.	Instrument	Location	Primary User	Major Deficiency	Other Factors	Comments	Inspector & Date

Major Deficiency Codes:
1. Insufficient Analytical Section
2. Insufficient Daily Log
3. Insufficient Sample Log
4. Insufficient Maintenance Section
5. Entries not current
6. Entries not coplete or note sufficently descriptive
7. Improper correction of errors/omissions

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

Figure 3. Summar 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