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Standard Operating Procedure **NHX/SOP-120-002**

Title: Proper Use and Maintenance of Instrument Log Notebooks

Source: Research Triangle Institute

U.S. Environmental Protection Agency
Office of Research and Development
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Human Exposure Research Branch

TITLE: STANDARD OPERATING PROCEDURE FOR PROPER USE AND MAINTENANCE OF INSTRUMENT LOG NOTEBOOKS

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PROPER USE AND MAINTENANCE OF INSTRUMENT LOG NOTEBOOKS

TABLE OF CONTENTS

LIST OF FIGURES

1.0 INTRODUCTION

The purpose of instrument log notebooks is to provide a record of the maintenance, daily use, and current status of a particular laboratory instrument.

2.0 SCOPE OF PROCEDURE

This Standard Operating Procedure describes in detail the guidelines which govern the proper use and maintenance of instrument log notebooks in the performance of all ACS projects.

3.0 INSTRUMENT LOG GUIDELINES

NOTE: Log notebook entries should contain no confidential information. Project numbers, rather than sponsor names should be used. Product names, and other confidential information should not be included in instrument log notebooks.

3.1 Notebook Assignments

3.1.1 Request Notebooks by dialing extension 6210 (Hanes Building). Give name of individual to whom the Notebook should be issued and the appropriate ACS overhead number for the laboratory in which the instrument is located.

NOTE: The Notebook should be issued to the individual responsible for the operation and upkeep of the instrument.

3.1.2 Request and use a different Notebook for each instrument. All instrumentation and equipment used in the generation, measurement or assessment of ACS project data must have a Notebook (1). Analytical instruments such as GC, HPLC, IR are included as well as balances, pH meters and computers.

3.1.3 Identify instrument on outside cover of notebook (Balance 042, for example).

3.1.4 Alternate recordkeeping procedures may be used if approved by the QA Officer. An example is log sheets used to record calibration and maintenance for some refrigerators, freezers and ovens.

3.2 Recording of Data

3.2.1 Written records must be maintained of all inspection, maintenance, testing, calibration, and/or standardization operations. The record must show in sufficient detail the methods and materials used and the schedules used in routine inspection, cleaning, maintenance, testing, calibration/standardization of the equipment. Remedial action taken to correct instrument failure or malfunction shall be documented.

3.2.2 All pages must be dated and signed on the day of recording the entry.

3.2.3 All entries must be legible and written in understandable prose.

3.2.4 All entries must be recorded promptly.

3.2.5 Black, permanent ink must be used for all entries.

3.3 Notebook Storage

3.3.1 All Notebooks must be easily accessible; e.g., on a desk or bookshelf and proximate to the instrument.

3.3.2 Do not remove the Notebook from the building.

3.4 Notebook Errors

3.4.1 Any errors or invalid data in the Notebook must be so designated by drawing a single line through the entry. The individual making this notation must initial the action and provide an explanation for the alteration, if appropriate.

3.4.2 If errors or omissions are noted at a later date, record the correction on the page currently being used and reference the page in error. On the latter page, indicate error and reference page with corrected entry.

3.5 Completed Notebooks

All instrument log notebooks when full are technically part of the Analytical and Chemical Sciences (ACS) Archives.

Regardless of who assumes custody of the completed Notebooks, the QA Officer must keep a record of their location.

3.5.1 When a Notebook is full, retain it for reference and request a new one.

3.5.2 When a Notebook is full, it may be kept with the instrument for reference or turned over to the QA Officer.

3.6 Lost Notebooks

3.6.1 If a Notebook has been misplaced, damaged, or lost, notify your supervisor (or Project Leader) who will inform the QA Officer, investigate the incident, and report in writing to the Office of Personnel and to the ACS Vice-President.

3.7 Responsibility

3.7.1 The Notebook should be issued to the individual responsible for the operation and upkeep of the instrument.

3.7.2 The individual to whom the Notebook is assigned shall be responsible for the safekeeping of the Notebook.

3.7.3 The Notebook assignee shall be responsible for informing the QA Officer which Laboratory Notebooks have been issued for each instrument.

3.7.4 The QA Officer shall be responsible for periodically monitoring and assessing ACS staff adherence to the regulations described in this SOP and submitting a report to the Vice-President and Center Director (ACS-SOP-815-003). In addition, unannounced checks on upkeep of Notebooks may be conducted by the Vice-President or Center Director.

3.7.5 The Vice-President shall be ultimately responsible for ensuring the proper maintenance of laboratory Notebooks.

4.0 OUTLINE OF A TYPICAL NOTEBOOK

The instrument log Notebook(s) shall contain three different types of information; analytical system identification, details of daily operation (use log), and written maintenance records (maintenance log).

4.1 Analytical System

The first page(s) of the Notebook shall be reserved for a description of the basic analytical system and all subsequent modifications.

4.1.1 Specify instrument model number, serial number and location. Instruments with component parts shall be identified by the major or most important component in the unit.

4.1.2 The component parts, configuration, and peripherals used shall be listed with their model numbers and serial numbers, if available.

4.1.3 Modifications to the system shall be included in this section. These would include addition of a module or detector, but not the changing of columns in a GC or HPLC.

4.1.4 An example of an analytical system page is shown in Figure 1.

NOTE: The analyst is responsible for identifying in his/her project notebook the analytical instrument(s) used.

4.2 Use Log

Several types of information comprise the use log. First, the daily log is a record of operational details for each analysis day. Second, the sample log is a record of all samples analyzed on the instrument. Usually these two types of information are combined in a single log, although they may be maintained separately.

4.2.1 An entry shall be made for each day of operation and should include the operator's name, the date, project and a description of the specific operating conditions of the day (temperatures, column, etc.). Comments on the type of samples run should be included (standards, clean samples, dirty samples, etc.).

4.2.2 If system performance runs are made or if a calibration is performed the data shall be included or referenced. Calibration data which are appropriately included in a project notebook must be referenced in the instrument log. Other calibration data, test runs, or performance runs shall be recorded in the use log or daily log section or in an accessible folder or binder which is referenced in the Notebook.

4.2.3 An example of a daily log page is shown in Figure 2.

4.2.4 A record of all samples analyzed on an instrument shall be maintained. The record may be maintained in a sample log section of the instrument log notebook. Alternately, the record of all analyzed samples may be included in the project notebook. In this case, the project notebook shall be referenced in the instrument log notebook, Section 4.2.1.

4.3 Instrument Maintenance Log

4.3.1 Written records must be maintained of all maintenance, routine and nonroutine.

4.3.2 Entries must contain the date of the operation.

4.3.3 Routine maintenance records must be kept and should include which standard operating procedures were followed.

4.3.4 Written records must be kept of nonroutine repairs performed on equipment as a result of instrument failure and malfunction. Such records must document the nature of the defect, remedial action taken to correct the defect, and resolution of the problem.

4.3.5 An example of instrument maintenance entries is shown in Figure 3.

5.0 REFERENCES

1. Good Laboratory Practices of the Analytical and Chemical Sciences Research Unit, October 1983.

2. GLP Regulations;

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

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.

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.

BAS 100A Electrochemical Analyzer

Model 100A	Serial No. 374
300A	Serial No. 7351597
KIB	Serial No. 591320
DMP40	Serial No. 207
PA-1	Serial No. 182
Pre Amp	Serial No. 182

Parts Description:

Model 100A (S/N 374) - Electrochemical analyzer; Z80A processor + program ROM.

Model 300A (S/N 7351597) - Amdek monitor, Q in amber

Model DMP40 (S/N 207) - Houston Instruments digital plotter

Model KIB (S/N 591320) - standard keyboard

Model PA-1 (S/N 182) - Low current pre-amplifier and Faraday cage

Figure 1. Example of an analytical system entry.

PROJECT NO.

SUBJECT

Date	Name	Proj. #	Use/Detector Type
2/25/95	P. Elkin	3807-014	Cond'n'd Col. 30-325@10°/min hold 30min at max. Decreased col. flow to 1.45ml/min. Changed H_2 tank. (Air ~700 psi) Ran Samples dwg 2-45ths Col. temp. 100-300°C@10°/min Other cond'ns as in 2/24/95 NB 8142
2/26/95	P. Elkin	3807-014	On last 3 runs, sample was not injected correctly. There was a smaller than usual solvent front & no peaks in the runs. - Changed to new syringe (metal plunger, as in FID) in autoinjector. - Reran last 13 samples, which were affected by this problem. Watched 1st couple inj's. They were okay. - gc parameters as in 2/25/95 NB 8142
3/3/95	N. Castillo	6069-004	Install Capillary DB-624 (30m × 0.53mm ID) 3 μ (S/N 2540686) same lines as in 2/22/95. Conditions same as 2/22/95 Column Flow: 6.5 mL/min

Figure 2. Example of a daily log entry.

PROJECT NO.

SUBJECT DATE

FROM PAGE

2-20-95

Gradient Performance Evaluation

Per ACS/SOP-165-003 rev. 1

Recorder 10mV (0.01 Volts full scale)
Detector:
Wavelength: 210 nm
AUFS Range: 0.5
Rise time: 1.0 sec
Output: 10mV

The more fine the scale is the more important the compressibility of the 1% Acetone in H_2O soln becomes. At the above listed settings and at ~24°C Lab temp. the compressibility was attempted at 46 (as for 100% H_2O). It was varied above and below this point to see what the proper setting should be. There is no calculation for estimating compressibility. It can be approached only by trial and error method. A certain mixture of a solution may have a compressibility outside the range of two pure solutions compressibility.

Soln
A Pump A = 100% H_2O (Hydro)

B Pump B = 99% H_2O 1% Acetone (B+S, HPLC Grade, Lot BC236)
990 mL H_2O (Grad cylinder) 10 mL Acetone (P-10 mL P. pettemer)
each soln degassed

Compressibility of Pump B was compared
At 46, 56, and 40

40 appears to be acceptable for these parameters

The Chromatograms of the three gradients are
Shown on p. 175

Terry W. Lack 2-20-95

Figure 3. Example of maintenance log.