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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-120-001**

Title: Proper Use and Maintenance of Laboratory Notebooks

Source: Research Triangle Institute

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

Notice: *The U.S. Environmental Protection Agency (EPA), through its Office of Research and Development (ORD), partially funded and collaborated in the research described here. This protocol is part of the Quality Systems Implementation Plan (QSIP) that was reviewed by the EPA and approved for use in this demonstration/scoping study. Mention of trade names or commercial products does not constitute endorsement or recommendation by EPA for use.*

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

SOURCE: Research Triangle Institute
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Proper Use and Maintenance of Laboratory Notebooks
NHX-SOP-120-001

1.0 INTRODUCTION

The purpose of laboratory Notebooks is to provide a permanent legal record of experimental procedures and results. Thus, the laboratory Notebook serves as the principal means for documenting and evaluating project performance and data quality.

2.0 SCOPE OF PROCEDURE

This standard operating procedure describes in detail the rules and regulations which govern the proper use and maintenance of laboratory Notebooks in the performance of all ACS projects.

3.0 LABORATORY NOTEBOOK RULES AND REGULATIONS

3.1 Notebook Assignments

3.1.1 Request Notebooks by dialing Ext. 6210 (Hanes Building). Give name of individual to whom the Notebook should be issued and the RTI project number for which data will be recorded.

NOTE: The Notebook should be issued to the chemist performing the work and not to the Project Leader or supervisor.

3.1.2 Request and use a different Notebook for each assigned project.

NOTE: If the staff member is involved in several concurrent, low level-of-effort programs (e.g., projects involving commercial clients who periodically submit analytical requests), the experimental work performed on these projects may be described in the same Notebook. Consult with supervisor.

3.1.3 Issue a Notebook to all staff members assigned to work on a specific project.

NOTE: Staff members who are assigned a temporary, short-term task may record that data in the project Notebook issued to a co-worker. Consult with supervisor.

3.2 Recording of Data

3.2.1 All project work which results in the generation of data must be recorded in the Notebook of the chemist who performed the work.

NOTE: If a team of individuals are assigned to a common task, the project activity may be recorded either in a separate project Notebook issued for that purpose or in one of the co-workers Notebooks. In either case, the participating analysts must sign and date each entry. Consult with supervisor.

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

3.2.3 All entries must be recorded in black ink. Do not use nonpermanent inks.

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

3.2.5 All entries must be written directly in the Notebook and not on separate pieces of paper to be copied later. In the event that it is not possible or practical to record data directly into the Notebook, "bench books" can be used in the following manner: 1) use smaller bound Notebooks as bench books and appended to the laboratory Notebook; 2) sign and date each page of "bench book" and append to laboratory Notebook by pasting in each sheet used at the end of the day or have the sheets bound periodically.

3.2.6 "Bench books" may only be used when it is not possible to use the laboratory Notebook, such as when working in a hood. Consult with supervisor.

3.2.7 All complete and partial pages not used in recording data must be voided by placing an "X" or "Z" on the unused portion of the page.

3.2.8 Start and maintain a Table of Contents to facilitate retrieval of specific project data. Update the Table of Contents after every entry.

3.2.9 Witnessing data entries is not necessary unless the Project Director or QA Officer requires this action.

3.2.10 If project Notebook contains confidential data, prior approval must be obtained from Project Leader before copying pages.

3.2.11 Staff members assigned to off-site project duties (e.g., sample collection) will not need to record their daily activity in a laboratory Notebook. The Project or Task Leader will identify project staff assigned to off-site duty and their schedule by memo to the QA Officer.

3.3 Notebook Storage

3.3.1 All Notebooks must be easily accessible; e.g., on a desk or bookshelf.

NOTE: If a Notebook contains confidential data for a commercial client or for a program requiring security, a special Notebook storage area will be designated by the Project Leader.

3.3.2 Do not remove the Notebook from the building unless it is necessary to document a legitimate off-site project activity.

NOTE: The use of a Notebook for this purpose must be approved by the Project Leader.

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 laboratory Notebooks contain project raw data and must be retained in a safe and secure location after they are full. At this point, they are technically part of the Analytical and Chemical Sciences (ACS) archives.

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

3.5.1 When the project has been completed, return the Notebook(s) to the Project Leader or your supervisor.

3.5.2 When a Notebook is full, request a new one and retain it for reference or return it to Project Leader.

3.5.3 Upon termination of an employee's employment at RTI, all Notebooks assigned to the employee shall be transferred to the Office of the Vice-President.

NOTE: Approval for release of the final paycheck will be subject to this transfer; an assessment is made by the Office of Personnel during the termination interview that notebooks, building keys among other items have been properly transferred or returned.

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 Offices of Personnel and of the Vice-President.

3.7 Responsibility

3.7.1 The individual to whom the Notebook was assigned shall be responsible for the safekeeping of the Notebook.

3.7.2 The supervisor (or Project Leader) shall be responsible for informing the QA Officer which laboratory Notebooks have been issued for each project and to whom they were assigned.

3.7.3 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. In addition, unannounced checks on upkeep of Notebooks may be conducted by the Vice-President.

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

4.0 OUTLINE OF A TYPICAL NOTEBOOK ENTRY

NOTE: Several examples of Notebook entries are included in this SOP.

4.1 Place a heading (title) at the top of the page describing the nature of the work to be done.

4.2 Write a brief statement of purpose or intent of work.

4.2.1 Include pertinent Notebook and literature references.

4.3 Describe in detail the project activity performed.

4.3.1 Reference description of same procedure carried out previously only if the writeup is in the same Notebook presently being used. If the description is in another Notebook, the methodology must be described again.

4.3.2 Do not copy verbatim or paraphrase the procedure followed from a SOP, protocol, or other written document. Describe the operation performed in your own words.

4.3.3 Give particular attention to a description of the equipment and instrumentation used. Specify Model number, location, and the instrument log Notebook in which entries were made for the analysis. It is not necessary to give the individual log numbers for each analytical run unless this information is relevant to the results and conclusion of the experiment.

4.3.4 Examples of experimental <u>details</u> which must be recorded:

4.3.4.1 All chemicals used as standards, reagents, or solvents must be referenced in Notebook along with source, lot or batch number, and purity, if known.

4.3.4.2 Record gross weights and tares; specify balance used by the identification number affixed to each unit.

4.3.4.3 Preparation of calibration solutions.

4.3.4.4 Instrumental conditions used.

4.3.4.5 QA/QC measures followed.

NOTE: Emphasis is placed on specific details.

4.3.4.6 Results of calculations generated through the use of electronic or mechanical devices, e.g., calculators, computers, or sliderule.

4.4 Describe results of work performed

4.4.1 Indicate in the Notebook the storage location of raw data not included in the Notebook (e.g., spectra, computer printouts).

4.4.2 Label raw data described in 4.4.1 such that these items can be traced to the Notebook number and page containing the experimental writeup. To accomplish this goal, label the raw data either directly with the Notebook citation or indirectly with some unique code which can be used to trace the material to the laboratory Notebook entry.

NOTE: For example, one possible way that the raw data might be linked indirectly to the laboratory Notebook would be by entering this information in the instrument log notebook.

4.4.3 If copies of such data are put into Notebook, indicate where the original is located.

4.4.4 Identify all electronic data in the Notebook and indicate where the data are located.

4.4.5 Record not only all observations which were a normal consequence of performing the work but also any unusual or unexpected behavior. The use of Tables and Summaries for presentation of results is encouraged.

4.5 Conclusions/Recommendations

Examples of topics suitable for discussion in this Section.

4.5.1 State conclusions as they relate to objectives of work.

4.5.2 Suggest ideas for future work.

4.5.3 Identify problem areas.

4.5.4 Indicate likely or recommended course of investigation, if applicable.

4.5.5 How will information or product obtained from this effort be utilized? For example, (1) the measured breakthrough volumes will be used in quantitating target compounds in breath samples or (2) Tenax cartridges with loaded standards will be processed by GC/MS.

5.0 REFERENCE

Laboratory Notebooks, RTI Policy and Procedures Manual, Memorandum No. 911.

PROJECT NO. 3128-74

SUBJECT Calculation of Purity (% Acetic Acid) in B74A - Formic Acid DATE 6/2/86

FROM PAGE

Purpose: To estimate the % acetic acid in the sample B74A from NMR since no acetic acid peak showed up in qc analysis of the sample.

Procedure:
- NMR run 4/9/86 (p. 97, this nb).

10µl formic acid, 98% (nominal purity in sample can)
d = 1.220
10µl x 1.220 mg/µl = 12.20 mg x 0.98 = 11.96 mg

MW formic acid = 46.03 g/mole

$$W_s \times \left(\frac{A_u}{A_s}\right) \times \left(\frac{E_u}{E_s}\right) = W_u$$

$E_u = E_{HOAc}$*
= 60.05 ÷ 3
= 20.02

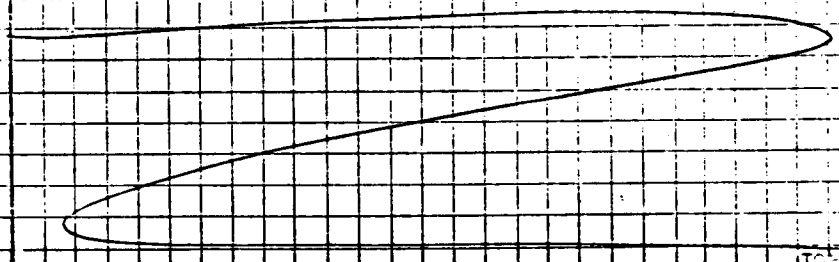
$$11.96 \left(\frac{1.6}{77.3}\right) \times \left(\frac{20.02}{46.03}\right) = W_u$$

$$0.108 = W_u \text{ (mg)}$$

0.108 mg acetic acid / 11.96 x 100% = 0.9% impurity

E_u = Proton equivalent weight, which is the MW ÷ # of protons giving rise to the peak

Conclusion: The level of acetic acid present in the sample is approximately 0.9%, by proton NMR.



WITNESSED AND UNDERSTOOD BY | DATE | SIGNATURE Phyllis D. Ellkins | DATE 6/2/86

Example of Laboratory Notebook Entry