


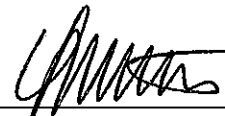
Title: Control and Use of Laboratory Notebooks, Logbooks, and Worksheets

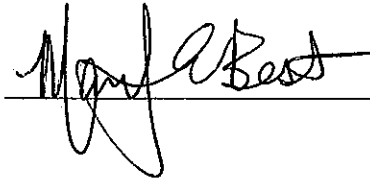
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Reference: SOP 2160: Laboratory Data Review and Generation of Reports
SOP 2240: Good Documentation Practices
SOP 250: Internal, External, and Third Party Audits.

<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
1.	03-11-99	Original version
2.	03-03-00	Sec. 4.4: SuperCalc file discontinued. Sec 4.5: updated. Sec 4.6: added. Sec 4.7.5: added. Sec. 4.9: expanded to include supervisor review of logbook entries.
3.	08-08-01	4.4: Changed database location to QA\Logbooks. 4.5: Added GC/GCMS and LC to list of sample prep logbooks.
4.	08-26-02	Sections 2.0, 4.9: Change periodic to quarterly. Sec. 4.1: Change two days to one week. Sec. 4.2: Add letterhead. Sec. 4.5: Minor wording changes.
5.	09-04-03	Expanded all sections to include Log-In Job books. Sec. 4.5: Moved GC/GCMS and IC/LC sample prep logbooks and wet chemistry logbooks to section 4.6. Removed page issuance and template storage by QAU for individual worksheets. Sec. 4.8: Added statement regarding signature and date to printout. Appendix I: Added label for Log-In Job book.
6.	AUG 19 2009	Revised to conform to current version of SOP 101. Scope expanded to include worksheets. Sec. 3.1-3.4: added. Sec. 4.4: added. Sec. 4.7, 4.8 Rev. 5 moved to SOP 2240. Sec. 4.11: Reference to SOP 250 added.

<u>Prepared by</u>	<u>Date</u>	<u>Technical Review</u>	<u>Date</u>
	07/15/09		7/15/09

QA Approval/Date:  08/19/09

1.0 SCOPE AND APPLICATION

This SOP outlines the procedures used for issuing and using laboratory notebooks (also referred to as logbooks) and worksheets intended for the recording of laboratory data and the Log-In book for job number assignment/tracking upon sample receipt. This SOP is designed to ensure that the recording of raw data is kept and preserved in a useable, permanent manner.

2.0 SUMMARY

- 2.1 Job numbers are sequentially assigned to samples received in Log-In and recorded in the Log-In Job book. Courier, client, and invoice information, analyses, group assignment, computer entry, and disposition are also entered into this book.
- 2.2 Raw data (excluding chromatograms and other instrument or computer data printouts) are recorded in bound laboratory notebooks or on controlled worksheets which contain instrument run and equipment information, reagent and sample preparation data, original observations, calculations, and other information associated with the analysis of samples. These notebooks and worksheets are kept with the appropriate functional group while in use and then archived. The Quality Assurance Unit (QAU) audits this data (per SOP 250) for accuracy, completeness, and compliance with SOP 2240: Good Documentation Practices. Review of notebooks for accuracy of calculations and conformance to test methods is performed with the review of data packages by a second qualified chemist (SOP 2160).

3.0 RESPONSIBLE PERSONS

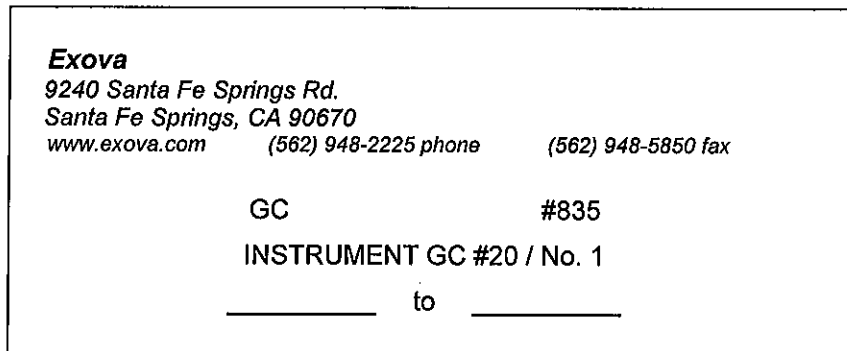
- 3.1 Each employee is responsible for keeping laboratory notebooks used in their area in order and in compliance with SOP 2240.
- 3.2 Log-In and Client Services personnel are responsible for maintaining the Log-In book with the appropriate information.
- 3.3 The QAU is responsible for issuing notebooks; designing, binding, and paginating custom logbooks; reviewing notebooks per SOP 250; archiving notebooks no longer in use; and maintaining a spreadsheet listing the status of all notebooks that have been issued.
- 3.4 The IT department is responsible for controlling the security and backup of issued worksheets, associated audit trails, and custom logbook templates.

4.0 PROCEDURE

- 4.1 Department managers or analysts are responsible for requesting a notebook when one is needed. Examples of types of logbooks include: standard preparation, instrument maintenance, instrument use, and sample preparation. Client Services or Log-In personnel are responsible for requesting a new Log-in book when needed. Request notebooks at least one week in advance of when the first entry into the logbook is expected to occur. Indicate the name of the group and the purpose for which the notebook/job book is to be used. A reference to the previous logbook number used for that purpose, if applicable, should be given.
- 4.2 Prior to issuing a notebook, QA will label the notebook with the following information on the front cover:

Functional Group (e.g., GC) Sequential Logbook number
Type of logbook/No. of this type of book (e.g., Instrument: GC #1/ No. 9)
Dates of use (e.g., 11/10/08 to 10/11/09, usually issued blank to be filled in
at the time of first use and the time of last use by the analyst)

EXAMPLE:



- 4.3 Prior to issuing a Log-in book, apply an adhesive label to the front cover with the following information:

Sequential number of this type of book (e.g., Job Log Book #17)
Range of job numbers associated with the book (usually issued blank to be filled
in at the time of first use and the time of last use)
Dates of use (usually issued blank to be filled in at the time of first use and the
time of last use)

Place the label on the front, center of the book. The label information is also written on the inside front cover in marker pen.

- 4.4 Before issuing a notebook, verify that the pages are adequately bound and sequentially numbered. Create a Tick Log Legend on the front page, adjacent to the front cover. Inside the front cover, record the date issued by QA and the initials of the issuing QA employee.
- 4.5 Attach an adhesive label to the inside front cover of each notebook and job book that lists the error codes to be used, according to SOP 2240. The text for this label is to be as follows (or equivalent):

STANDARD ERROR CODES	
<u>ERROR CODE</u>	<u>EXPLANATION</u>
E	Entry or Recording Error
C	Calculation Error
S	Spelling Error
W	Wording Change or Write-over error
R	Rounding Error

(Effective 12/09/08)

- 4.6 When a notebook or job book is issued, update the spreadsheet listing all notebooks or job books. This database is currently located in a protected directory accessible only by QA at: FS1:\QA\Logbooks\Logbook.wk4 (notebooks) and FS1:\QA\Logbooks\Log-In Logbook.wk4 (job books). Refer to this spreadsheet when determining the next logbook sequential number to be used.
- 4.7 Any employee who makes an entry into a notebook or job book must complete the tick log in the front of the book with their initials, name (printed and signed), and date.
- 4.8 Sample prep worksheets and wet chemistry miscellaneous analyses worksheets are issued as a series of sequentially numbered individual pages at the time of use. These are issued by an off-the-shelf computer database program (FoxPro) configured to automatically generate the next sequentially numbered worksheet and create an audit trail of worksheets printed.
 - 4.8.1 Worksheets are printed with a color logo, designating them as originals.
 - 4.8.2 Completed wet chemistry worksheets are filed with the data package for a particular job.
 - 4.8.2 Completed sample preparation pages are scanned into a controlled directory with read-only access and the originals filed with the job envelope.

- 4.9 Custom logbooks for a particular analysis or procedure may be created from an appropriate number of loose sheets designed by the QAU, with input from the appropriate department managers, employees, and/or Technical Director. These are coil bound (or equivalent) prior to being numerically paginated and issued by the QAU. Templates are kept in a secured directory accessible only by QA. The footer of the template references the file name of the template version used.
- 4.10 Notebooks are reviewed per SOP 250. Job Books are reviewed quarterly by the QAU. Worksheets are reviewed as part of data package review, per SOP 2160.
- 4.11 Controlled documents, including notebooks and worksheets, are not to leave the facility, except under exceptional circumstances pre-approved by the General Manager (by court subpoena, for example).
- 4.12 When a notebook or job book has been completed and is no longer needed for reference in the lab, it will be collected by or given to a member of the QAU, who will archive it in a secured area. The logbook spreadsheet will be updated to indicate that this book has been archived.
- 4.13 Archived notebooks may be scanned into one or more PDF files (depending on size) by the QAU for read-only access by employees through Virtual Office. The logbook database will be updated to indicate that this logbook or job book has been scanned.
- 4.14 Archived notebooks or job books may be requested from a member of the QAU for reference purposes. A record will be kept in the logbook tracking spreadsheet of the person who has borrowed the logbook or job book, when it was released, and when it was returned.

SOP Review Log

<u>Reviewed by</u>	<u>Date</u>	<u>Approved by</u>	<u>Date</u>
1.	_____	_____	_____
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9.	_____	_____	_____
10.	_____	_____	_____

The following people have read this SOP and are currently using these procedures in the laboratory:

<u>Signature</u>	<u>Date</u>	<u>Signature</u>	<u>Date</u>
	8/18/09	Theresa [unclear]	08/18/09
	8/18/09	Charles [unclear]	08-18-09
	08/18/09		8-18-09
	08/18/09	Mary [unclear]	8/18/09
Amanda Elchert	08/18/09	Me [unclear]	08/18/09
	08/18/09		08.18.09
	08/18/09		
	08/18/09		
Janet K. Harvey	8/18/09		
	8/18/09		
	08/18/09		
John [unclear]	08/18/09		
	8-18-09		
	08/18/09		
	08/18/09		
	8/18/09		
	08/18/09		
Murina A. [unclear]	08/18/09		
Joe [unclear]	8/18/09		
[unclear]	08/18/09		
	08/18/09		
	08/18/09		