

Title: Control of Standard Operating Procedures and Test Methods

Filename: 101v8.lwp


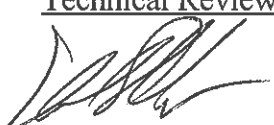
This document does not contain proprietary information.


Reference: Previous to 3-23-98, see SOP 100
SOP 140: Documentation of Training and Qualification of Employees
SOP 1000: File Storage and Retrieval

<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
1.	03-23-98	For WordPro version.
2.	03-26-99	Remove WordStar references, Sec. 3.2, 4.7: change Technical Director to Group Leader. Sec. 4.2: change "annually" to approx. once per calendar year. Sec. 4.4: change location of originals. Sec. 4.7, 5.1: change file name format. Add 4.11.
3.	03-09-00	File name changed to represent current version of Lotus 123. Sec. 3.1-3.3; Clarified. Sec. 4.10, 5.3: QAU makes SOP copies. Sec. 4.11: SOP Index now in hypertext PDF. FS1:\LWP changed to FS1:\QA, Current Revision deleted
4.	07-23-01	Sec. 5.4: Changed procedure about discarding older versions.
5.	08-14-03	
6.	08-12-08	2.1 Clarify access to index. 2.2 Change revision date to effective date. 3.0 Current organizational structure. 3.4 IT Coordinator responsibilities added. 4.2 Change review to every other year and add separate review page. 4.5 Change to Intranet access for SOPs. 4.8 Training signature page separated from text of SOP. 4.10 QAU controls master Word Pro files. 4.11 Markup Edits to be used. 4.11-4.19 New system for SOP control. 5.1 Limit access to Word Pro files. 5.3 Employees refer to Virtual Office version of SOP to perform work. 5.4 Deleted reference to Training Binders.
7.	02-25-09	Wording revised throughout for clarity, including title change. Sec. 2.3, 3.6, 5.4, 5.6: added. Sec. 4.20 moved to 5.3.

<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
8.	MAR 07 2011	Virtual Office references removed. Sec. 5.0: added. Sec. 6.0: reordered.

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<u>Prepared by</u>	<u>Date</u>	<u>Technical Review</u>	<u>Date</u>
	01/17/11		1-18-11

QA Approval/Date:  03/07/11

1.0 SCOPE AND APPLICATION

Essential, day-to-day operations of the laboratory and routine laboratory methods are described in a "Standard Operating Procedure" (SOP). This is designed to satisfy expectations of our profession, including Good Laboratory Practices (EPA FIFRA - 40 CFR Part 160 and FDA - 21 CFR Part 58), FDA CGMP (21CFR Part 211 and 820), and ISO 17025 standards.

Since our business is to supply our clients with analytical chemistry services, SOPs should cover elements required to supply consistently high quality services. Currently, SOPs do not address marketing and financial functions of the business. This SOP provides an outline of essential elements and format of SOPs. The format may vary as needed, but the essential elements must be present. The system used to control employee access to current SOPs is also described.

2.0 SUMMARY

- 2.1 The essential elements and format of an SOP are outlined in this document. An index with persons responsible for preparing and approving the documents as well as file names and status is kept in the Lotus 123 spreadsheet SOPINDEX3.123. Only the Quality Assurance Unit (QAU) has access to revise this spreadsheet.
- 2.2 The face page(s) documents the title, effective date, revision history, and approval of the document. Some SOPs refer to other procedures, published methods, or manuals, such as the Quality Assurance Manual or Safety Manual. These will be listed in the "Reference" section of the cover sheet.
- 2.3 Access to SOPs is controlled through the use of an Intranet system. Networked computers located throughout the laboratory provide password protected access to all employees. Standard methods, such as the USP and EP compendia and EPA methods are accessed through the use of the Internet.

3.0 RESPONSIBLE PARTIES

- 3.1 The Quality Assurance Officer (QAO) is responsible for the overall SOP process and quality system SOPs. The QA Chemist or other designees may assist the QAO. This team is referred to as the Quality Assurance Unit (QAU).
- 3.2 The General Manager is responsible for all non-technical SOPs (clerical and administrative).
- 3.3 The Technical Director is responsible for all technical SOPs. The Technical Director will routinely delegate review of technical SOPs to the Group Leaders.

- 3.4 The IT/IS Coordinator is responsible for maintaining appropriate access levels to the computer files described below.
- 3.5 Other employees may be assigned to prepare, revise, or approve SOPs by one of the individuals listed above.
- 3.6 When an SOP is revised, the department manager of the functional group that performed the original review will review and approve all changes.
- 3.7 The QAU is responsible for ensuring that appropriate review of the SOP has occurred and employee training, per SOP 140, is documented prior to final QA approval of the SOP.

4.0 PREPARING OR REVISING AN SOP

- 4.1 The SOP should document a procedure to the extent that the operation could be accomplished by someone with the necessary background with little or no supervision.
- 4.2 Each SOP will be reviewed every other calendar year to make sure that it is up-to-date and reflects current practices. No less than one month prior to the review due date, the QAU will inform the responsible party that the SOP is due for review. If there are no changes, the document is simply reviewed and signed on the SOP Review Log filed with the master hard copy of each SOP. This page is kept separate from the SOP and will not be paginated with the body of the SOP, although it will contain the SOP header text.
- 4.3 If a revision is necessary, a summary of revisions on the face page of the SOP should make it obvious to the reader which sections were changed and how they were changed. A “redline” copy of the revision may also be filed with the master copy to aid in the identification of changes. A justification of the change will be included in the revision history, if an explanation is needed.
- 4.4 Hard copies of retired SOPs (no longer in routine use) and SOPs replaced with revised versions are kept on file in the QAU office. These files may be archived in the locked storage bunkers or off-site (per SOP 1000) as space limitations require.
- 4.5 All original, current, official hard copies of SOPs are to be kept in a file cabinet in the QAU office. Their corresponding computer files are kept in the directory F:\QA\SOP\, with access limited to the QAU. Note that the computer files may not always contain all figures and appendices.
- 4.6 A PDF file is created for each SOP by scanning the approved hard copy which is then uploaded to a secure server (“V drive”) for read-only access by all employees.

4.7 Note the proprietary warning: many SOPs are considered company confidential and proprietary material. Non-confidential or proprietary SOPs may be posted to an Exova Internet site for the convenience of our clients and their auditors.

4.8 Revisions originate from overwrite protected, master file versions in F:\QA\SOP\subdirectories containing the latest version of the SOP in WordPro format.

\100_gen	100 General SOPs
\1_login	1000 Login and Admin SOPs
\2_genlab	2000 General Lab SOPs
\3_gc	3000 GC SOPs
\4_lc	4000 LC & IC SOPs
\5_gcms	5000 GCMS and LCMS SOPs
\6_iruv	6000 IR and NMR SOPs
\7_icpms	7000 ICPMS SOPs
\8wetchem	8000 Wet Chem SOPs

4.9 Each SOP contains a training documentation page. Employees responsible for conducting the operations documented in the SOP must sign this page after having read and understood the SOP, per SOP 140. This page is kept separate from the SOP and will not be paginated with the body of the SOP, although it will contain the SOP header text.

4.10 Note that the file contains a footer so that the document is paginated with the total number of pages. Appendices with figures, validations, and chromatograms may not be included in the total number of pages if they are not included in the computer file. However, scanning these appendices to an image file and importing them into the Word Pro file is preferred.

4.11 When changes are necessary, the person assigned to revise the SOP will draft modifications using the latest Word Pro version of the SOP file. Request the current file from the QAU, which will be issued in the format: XXXXvYdraft.lwp (where X is the SOP number and Y is the version) . This file will be watermarked "Draft". Save the file locally or in a folder on the R drive: R:\Draft Sops\

4.12 Any edits to the original file should be clearly marked by using the Edit/ Markup Edits command in Lotus WordPro.

4.13 Once the SOP has been revised to the satisfaction of the person revising the SOP and the appropriate group leader and/or Technical Director, send the electronic version of the new version of the SOP, with edits marked, to the QAU or notify the QAU that the version in the R:\Draft SOPs folder is ready for review.

- 4.14 Before accepting all edits to create a hard copy for signatures, the QAU will remove the “Draft” watermark and, if deemed appropriate, print a color copy of the file with edits indicated (“redline version”), to circulate with the SOP during training and to file in the SOP master file.
- 4.15 The QAU will “accept all edits” in the WordPro file, proofread and review formatting, print the revised SOP, and circulate the SOP for signatures. If acceptable, the revised SOP will be signed first by the preparer and then submitted to the appropriate department manager or the Technical Director for technical review. The persons assigned for review/preparation and technical review are identified in the SOPINDEX3.123 file and on the face page of the current version of the SOP. If the preparer is someone other than a Group Leader, the technical review of the SOP should be performed by the Group Leader
- 4.16 During the review process, signatories may request further revisions, requiring that the previous steps (4.11-4.15) be repeated. Correction of minor typographical or formatting errors does not require retraining on or resigning of a document.
- 4.17 The Group Leader is responsible for ensuring that everyone who conducts the procedure is trained on any procedural changes then reads and signs the SOP, after the technical review section has been signed. Once the SOP is signed by the appropriate persons, it is returned to the QAU.
- 4.18 When the signed version of the SOP is received, the QAU will update the SOP index (SOPINDEX3.123) and training records (TRAINING.123). After ensuring that all appropriate employees have read and signed the SOP, the QAU will sign the face page, stamp the SOP with an effective date, scan the signed SOP into a PDF file (stored in the protected directory F:\QA\SOP\SOPPDF\Approved), file the original with the master set (along with the print-out of the redline version, if present), upload the pdf copy of the SOP to the appropriate V drive folder, revise the file “sopindex.htm” with the current revision number, and preserve the final electronic Word Pro version in the protected directory.
- 4.18.1 Before loading the SOP into the V drive, the QAU will use Adobe Acrobat to add the following footer to the PDF file: “This document is uncontrolled when printed. For the current, official copy of this SOP, refer to Exova’s Intranet.”
- 4.18.2 Before loading the SOP into the V drive, the QAU will use Adobe Acrobat to add the following watermark to the PDF file: “Uncontrolled When Printed”. This watermark is set to only appear on the document when it is printed.
- 4.19 Once a month, the QAU will print the current SOPINDEX3.123 and identify SOPs scheduled for routine review. This printed copy will be kept with the master set of SOP’s and the prior month’s SOPINDEX3.123 copy will be discarded.

5.0 STYLE GUIDE FOR PROCEDURES

- 5.1 Margins/Headers/footers - Do not change the conditions.
- 5.2 There is no space after an open parenthesis or before a closed parenthesis.
- 5.3 Capitalize trade names (e.g. Teflon, Nalgene, NanoPure)
- 5.4 Tables - Tabs are for ease of viewing. Put them wherever it looks best. Paragraph indentation should be performed by using the “ruler” feature of Word Pro (“Set View Preferences” or “Show/Hide” under the “View” menu). Using the Create Table function makes for better looking tables.
- 5.5 Units - All the following call for a space after the number: 14 mL, 5 g, 23.2 kg. Use L for liter since “l” by itself can be mistaken for something else. Use the greek letter μ (Alt-230), not a lower case u. Use the symbol $^{\circ}$ (Alt-248), not a superscripted o or 0 to indicate degrees.
- 5.6 Symbol short cuts:
- $^{\circ}$ - hold down the <Alt> key and type the number 248
 - \pm - hold down the <Alt> key and type the number 241
 - μ - hold down the <Alt> key and type the number 230
 - 2 - hold down the <Alt> key and type the number 253
 - $\frac{1}{2}$ - hold down the <Alt> key and type the number 171
 - $\frac{1}{4}$ - hold down the <Alt> key and type the number 172
- For \leq or \geq , do not use underlines. Menu - Text - Insert Other - Symbol - Font Math B
- 5.7 Upper case vs. lower case - All compounds, elements, solvents, etc. should be lower case.
- 5.8 Abbreviations - Use only if the full word has been used earlier and followed by the abbreviation in parentheses.
- 5.9 Reagents: define the appropriate grade required, including water.

6.0 DOCUMENT CONTROL

- 6.1 To preserve the content of SOPs from corruption, the master computer copy of the SOP will be kept in a protected subdirectory (F:\QA\SOP\subdirectory) to which only the LAN supervisor and the QAU have access to files. SOP files contain the SOP number and the revision number as the file name. For example, "101v3.lwp" is the file for the third revision of this SOP. In this way, historical versions will be retained and will not be corrupted.
- 6.2 Once the updated version of the SOP has been prepared, reviewed and signed, at the time the original hard copy is being filed by the QAU, the current version of the WordPro will be copied to the protected directory. This directory is protected by network passwords.
- 6.3 Obsolete hard copies of SOPs will be stamped with a red stamp, "Obsolete" and archived. Obsolete PDF files will be removed from the V drive at the time that the new version is loaded. Revising the sopindex.htm file prevents access to obsolete PDF versions from the sop.htm web page.
- 6.4 Employees will refer to the V drive, on-line PDF version of an SOP to perform their work.
 - 6.4.1 An additional link to these same PDF files is provided by the HTM file located at F:\QA\SOP\SOPPDF\sop.htm. Employees may create a shortcut to this HTM file on their computer desktops.
 - 6.4.2 Printed copies of SOPs are considered uncontrolled. If an employee needs to print out an SOP to perform a detailed task at an instrument (for example), they may do so immediately before performing the work, but must discard the printed copy immediately after it is used.
- 6.5 Printed copies of an SOP, generated from the current PDF file, may be distributed by a member of the QAU to auditors or clients upon request or SOP PDF files may be posted to the company's website. They may be watermarked with the word "Copy" and a reference to their proprietary nature to indicate that they are an official, but uncontrolled, version of the SOP. SOPs of a proprietary nature may only be released to clients with whom Exova has a written confidentiality agreement and only with the permission of the General Manager or Technical Director.

- 6.6 Standard methods, such as the current USP and EP monographs and EPA methods, will be accessed from the website of the issuing body. Current passwords for subscription services are located in each department's folder in the V drive. Hard copies are also received of the USP and EP compendia. Previous versions are labeled, "For Reference Use Only" when a new version is received.
- 6.7 Client provided test methods and protocols will be scanned into the Job Tracking database by Client Services. The original will be filed in the job envelope.

APPENDIX I

Below is an SOP template for technical SOPs

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Title:

Filename: XXXXvY.lwp

This document contains proprietary information. It is provided to Exova employees only. Do not share this information verbally or otherwise with anyone without the express written consent of the General Manager or Technical Director.

References:

<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
1.	MM-DD-YY	Original version.
2.		<summary of revisions>

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Prepared by

Date

Technical Review

Date

QA Approval/Date: _____

1.0 SCOPE AND APPLICATION

2.0 SUMMARY

2.1 text

3.0 INTERFERENCES

4.0 APPARATUS AND MATERIALS

4.1 text

5.0 REAGENTS

5.1 text

6.0 SAMPLE HANDLING AND PRESERVATIONS

6.1

7.0 PROCEDURE

7.1 text

7.1.1 text

7.1.1.1 text

7.2 text

8.0 CALCULATIONS

8.1

9.0 QUALITY CONTROL

9.1 System suitability:

9.2 A duplicate and spike, or a spike and spike duplicate, should be performed on one sample in every twenty samples analyzed. The Relative Percent Difference (RPD) between the duplicates should be no greater than _____%. The Percent Recovery of the spiked sample should be within the range of _____%. RPD and Percent Recovery are calculated per the Quality Manual.

10.0 DETECTION LIMIT

11.0 SAFETY AND WASTE HANDLING

APPENDIX I

Include example copies of chromatograms, data system parameters, validation studies, detection limit studies, raw data, and calculations. Chromatograms may be captured using the Alt-Print Screen command, pasted into a graphics program document, and saved as a Bitmap or JPG file. This file can be imported into the WordPro document using the "Import picture" File menu option.

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

Signature

Date

EXAMPLE SIGNATURE PAGE
DO NOT SIGN

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SOP Review Log

<u>Reviewed by</u>	<u>Date</u>	<u>Approved by</u>	<u>Date</u>
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

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**EXAMPLE REVIEW PAGE
DO NOT SIGN**