

Title: Good Documentation Practices

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Reference: SOP 270: Laboratory Non-Conformances, Including Corrective and Preventative Actions
SOP 2270: Data Archival

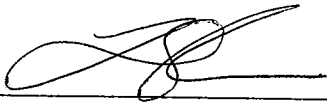
<u>Rev. No.</u>	<u>Effective Date</u>	<u>Revision Summary</u>
1.	06-03-96	Original version
2.	09-01-99	Converted to LWP format. Appendix B: added.
3.	08-21-00	Appendix I: Error Code S example corrected.
4.	12-09-08	SOP revised to comply with current version of SOP 101. Title and scope changed. Reworded throughout. Sec. 2.1: Electronic data clarified. Sec. 2.3, 2.4: moved to SOP 270 (NCR). Sec. 3.1: Added (moved from SOP 2260). Sec. 3.2.3 expanded. Sec. 3.2.8-3.2.9, 4.1, 4.3, 4.4: Added.
5.	JAN 28 2010	Sec. 3.1.2.1, 3.1.2.2, 3.1.9, 3.2.2.1, 3.2.2.2: added. Sec. 3.1.5, 4.1.2: expanded. Appendix II: Revised. Sec. 3.2.4: Additional error codes D and L added.

Prepared by

Date

Technical Review

Date



12/23/09



12-23-09

QA Approval/Date:

 01-28-2010

1.0 SCOPE

To ensure that good documentation practices are followed and documentation errors are properly corrected and noted as to their nature. Corrected information is documented in ink as close to the error as possible, initialed, and dated. The entry correction is accompanied with an explanation of the error, usually in the form of an error code.

2.0 DEFINITIONS

2.1 Raw Data: Any worksheet, record, memo, note, chromatogram, integral, spectrum, or result from original measurements, observations, and activities associated with the generation of sample results which may be needed to verify and evaluate the test procedure. Raw data also includes maintenance and calibration records for instruments, receipt and distribution records for test, control and reference substances and samples. Electronic data is considered raw data, however the laboratory uses a hybrid documentation system where critical electronic data is printed, reviewed, and archived in addition to being backed up on electronic media per SOP 2270.

2.2 Computer Generated Data: Any data obtained from an instrument's data collection system.

3.0 PROCEDURE FOR RAW DATA

3.1 Entering data into logbooks, notebooks, and worksheets

3.1.1 Enter raw data in chronological order as the observations are made. Under no circumstances are observations to be recorded onto "scratch paper" and then later transcribed.

3.1.2 Cross out empty space at the bottom of a page with a single line, with initials and date. It is also recommended that the end of each instrument sequence be indicated with the word "END" following the last sample of that sequence.

3.1.2.1 Render empty fields of forms or custom logbooks unusable with a dash, line-out, or N/A, as appropriate.

3.1.2.2 Comments or Notes fields do not need to be N/A'ed

- 3.1.3 Each worksheet or page of the logbook will be initialed (or signed) and dated by the analyst.
 - 3.1.3.1 A master list of each employee's signature and initials is kept in the QA files.
 - 3.1.3.2 It is the responsibility of the employee to notify QA of any changes to their initials or signature.
- 3.1.4 Make entries in indelible (water-resistant) black or blue ink. Pencils are not to be used under any circumstances.
- 3.1.5 Documentation is to be complete and legible. Data, observations, calculations, and conclusions or interpretations should be recorded in a manner that may be clearly understood by an outside auditor without additional interpretation or explanation. Show calculations performed in connection with testing, including units of measure, conversion factors, and equivalency factors.
- 3.1.6 Initial and date additional notations to raw data made by the data reviewer, comments or calculations added to instrument printouts by the analyst, or subsequent entries made on a page. This does not include check marks, underlining, circling, or otherwise highlighting data.
- 3.1.7 Do not use “ditto” marks or other indications of repetitive content, except in the case of client names, which are not an official part of sample identification.
- 3.1.8 Attach instrument printouts or other loose items to logbook pages with adhesive tape. Sign and date across the point of attachment so it is evident if the attachment is removed.
- 3.1.9 Manually recorded dates are written in the format MM/DD/YY or MM-DD-YY. Manually recorded times are written in military format (24 hour).
- 3.1.10 **“Backdating”(i.e. recording a date other than the current date when signing/initialing and dating a document) is grounds for immediate dismissal.** If a missing signature or initials needs to be added to a document, the current date is to be recorded, with an annotation of the date that the work actually occurred.

3.2 Changes made to raw data must be performed in the following manner:

- 3.2.1 Make a single line in ink through the error. The original entry should still be legible.
- 3.2.2 Record the correct entry on the document above or next to the original entry. If corrections will distort the readability of data or require additional space, use an asterisk or number to indicate what entry is being annotated and enter the information at the bottom of the page or in a margin.
- 3.2.3 Record your initials and the date the correction was made for each error.
 - 3.2.3.1 Do not use "X2" or "X3" to indicate multiple errors. Each error must be initialed, dated, and explained individually.
 - 3.2.3.2 If a large number of entry errors are present on a single page during the time the observations are being made, a line through the entire page (or reagent prep entry) may be made and initialed/dated. Record an explanation.
- 3.2.4 Annotate the correction with an error code for the change. To simplify the explanation of errors, Table 1 lists error codes to be used. Examples of the proper use of error codes are given in Appendix I.
- 3.2.5 If further explanation is needed, annotate the error correction(s) with an asterisk (or number) and explain the reason for the correction on the same page.

Example: ppm Ammonium

~~0.145~~ * 0.290 SS 12/12/09

~~0.130~~ * 0.260 SS 12/12/09

~~0.125~~ * 0.250 SS 12/12/09

* - Data has been corrected to account for a dilution factor of two due to the sample preparation procedure. SS 12/12/09

- 3.2.6 Do not use "white out" or correction tape. **Intentionally obscuring original data is grounds for immediate dismissal.**
- 3.2.7 Do not write over data (e.g., attempt to make a 5 into a 6). If this accidentally occurs, line out the write-over, record the correct entry, annotate the error with a "W", and initial/date the correction.

- 3.2.8 If an error correction is used to indicate that data or a series of data is not used, an explanation must be recorded on that page.
- 3.2.9 Reweighing or repipetting samples, standards, or reagents is not to be treated as a documentation error. Instead, if a preparation error is made, line out the entry, indicate the reason the data was not used (e.g. “weighing error”, “wrong chemical used”) and initial/date the entry. If a weighed sample aliquot or prepared reagent is not used, line out the entry, initial/date, and indicate “not used”.

TABLE 1

STANDARD ERROR CODES

Revised 01/2010

ERROR CODE	EXPLANATION
E	Entry or Recording Error
C	Calculation Error
S	Spelling Error
W	Wording Change or Write-over error
R	Rounding Error
D	Date Error
L	Rewritten to Improve Legibility

4.0 CORRECTION OR REVISION OF FINAL REPORTS

- 4.1 Once a final report has been issued to the client, requests to correct or revise the report are made using the form in Appendix II. Indicate whether the request is due to a “correction” or “revision”, as defined below:
 - 4.1.1 Correction is a change to any analytical result due to laboratory error. If a correction is made to a report, Client Services will submit a copy of the Laboratory Report Change Control Form (Appendix II) to QA for entry into the NCR/CAPA program (SOP 270). The NCR number is entered on the form.
 - 4.1.2 Revision is a customization of the report format to suit a client’s preferences, addition of additional details or specifications, or correction of typographic errors that do not impact the results or data (sample identification, for example).

- 4.2 Create a cover letter for the revised report which clearly identifies which part of the report is being changed and why. Use the information from the Corrected/Revised Laboratory Report form (Appendix II) to create this cover letter.
- 4.3 The report date of revised reports will reflect the date the revised report was generated and not the original report date.
- 4.4 The job number on the corrected or revised report will be stated as "#####-R1", with any additional revisions annotated -R2, -R3, etc. Include the "Original report issued" date on the first page of the revised report.
- 4.5 The original of the Laboratory Report Change Control Form will be filed in the Job Envelope. A copy is filed in Client Services.

APPENDIX I

ERROR CODE - E: "An error was made in recording the number"

pH = ~~8.6~~ 8.9 E SS 12/12/09

ERROR CODE - C: "A mistake was made in calculation by a factor of 2"

mg Vitamin C = $\frac{15.0 \text{ mL} \times 0.085}{0.200} \times 1 = \frac{12.8}{6.4}$
C SS 11/11/09

ERROR CODE - S: "A spelling error was made"

received S SS 12/12/09
...recieved...

ERROR CODE - W: "A number has been overwritten".

~~600~~ 600 W SS 12/12/09

ERROR CODE - R: "The number was rounded to the appropriate number of significant figures".

~~12.85 mg~~ 13 mg R SS 12/12/09

ERROR CODE - D: "The date was recorded incorrectly".

~~12/11/09~~ 12/12/09 D SS 12/12/09

ERROR CODE - L: "The entry was rewritten to improve legibility".

~~76~~ 79 L SS 12/12/09

**APPENDIX II
Laboratory Report Change Control**

Correction Revision

All corrections require NCR #: _____ and review by QA

Job Number: _____ Company: _____

Submitted By: _____ Date: _____

Change requested by: Client Contact: _____ Internally: _____

Reason for change: _____

Cover letter wording or information: _____

NCR must have been opened and QA Approval obtained for all corrected reports before submitting to client.

QA Approval of correction: N/A _____ Date: _____

Client has been sent: Emailed PDF of final signed changed report. Date: _____

Final signed changed report has been mailed. Date: _____

Original Form: File in job envelope Copy of Original Form: Client Services File