

UCD CSN Standard Operating Procedure #902

Laboratory Documentation Practices

*Chemical Speciation Network
Air Quality Research Center
University of California, Davis*

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1. PURPOSE AND APPLICABILITY

This Standard Operating Procedure (SOP) describes documentation requirements to ensure data integrity, traceability, and quality. The instructions herein apply to paper data and documentation supporting CSN laboratory activities.

2. SUMMARY OF THE METHOD

All written documentation should be made in ink and be clearly legible. All written marks must be accompanied by the author's initials and the date.

3. DEFINITIONS

- **AQRC:** Air Quality Research Center
- **Chemical Speciation Network (CSN):** EPA's PM_{2.5} sampling network, with sites located principally in urban areas.
- **EPA:** Environmental Protection Agency
- **Instrument Notebook:** A notebook used to record operational and maintenance observations related to an instrument. Instrument notebooks are assigned to specific instruments.
- **Laboratory Notebook:** A notebook used to record data and observations for laboratory operations. Typically used when electronic documentation or access-controlled worksheets are not available for a procedure.
- **NA or N/A:** Not applicable
- **UCD:** University of California, Davis

4. HEALTH AND SAFETY WARNINGS

Not applicable.

5. CAUTIONS

Not applicable.

6. INTERFERENCES

Not applicable.

7. PERSONNEL QUALIFICATIONS, DUTIES, AND TRAINING

All UCD AQRC Laboratory Group staff assigned to this project have the following responsibilities:

- Follow this SOP.
- Accurately record and document work.
- Keep records orderly and protected.

The UCD AQRC Laboratory Group Spectroscopist / Quality Assurance Analyst has the following responsibilities:

- Perform periodic review and inspection of laboratory documentation.
- Report findings from reviews to the Laboratory Group Manager.
- Ensure corrective actions for any findings are completed.

The UCD AQRC Laboratory Group Manager has the following responsibilities:

- Ensure that staff are trained on this SOP.
- Oversee records produced by the laboratory.
- Review QC findings and corrective actions.

8. PROCEDURAL STEPS

8.1 General Guidelines

- Record only true information and actual data.
- Entries shall contain sufficient detail to reconstruct the work performed and achieve similar results. Content of entries should include purpose of an experiment, equipment used, detailed description of methods used, preparation of reagents and standards and/or calculations performed.
- All raw data will be retained including rejected data.
- Inclusively paginate all multi-page documents (i.e. Page X of Y).

8.2 Entries

- Record all entries indelibly in ball point ink (no pencils or inks that bleed or smudge). Black or blue ink is preferred.
- All entries must be recorded at the time the work is performed by the person performing the work or making the initial observation.
 - Date and initial all entries.
 - See “Signatures” section for description of Data Recorder.
- Data should be entered directly into the applicable document (notebook, form, etc.) not recorded elsewhere and then transcribed.
- All handwriting must be clear and legible.
 - Decimal points, numbers, letters, symbols, footnotes, and special notations must be clear and easy to interpret.
- Avoid personalization of documentation, highlighting, and non-standard punctuation.

- Limit use of abbreviations, code names, trademarks, trade names, or numbers. If necessary, they must be defined at least once, preferably when first used in each notebook or document.
- Do not obliterate an entry with correction fluid/tape, tape, labels, write-overs, etc.
- All work requiring complex calculations must have the formula described in a SOP or TI. If calculated by hand, the calculations must be documented.
- Acceptable time and date formats:
 - Use 12-hour format and indicate AM or PM, or use 24-hour format with a leading zero for single digit hours (i.e. 8:15am is 0815).
 - Dates may be formatted as MM/DD/YYYY or YYYY-MM-DD.
 - Whichever time and date format is used, be consistent within a document or notebook.
- Repeat entries:
 - Do not use ditto marks.
 - For identical inputs recorded at the same time enter the data in the first box and draw a line through all boxes in which the input is identical, initial and date along the line.
- Correcting errors:
 - Correct all known mistakes and errors.
 - Do not obscure the original entry with the correction or notation.
 - Do not use correction fluid or tape to make corrections.
 - Draw a single line through the error, initial and date, and add a reason or correction for the error.
 - The following are typical examples of errors:
 - Late entry (entry not made on the day the work was performed).
 - Calculation or mathematical error.
 - Recording error (such as a typographical error or other incorrect information).
 - If a corrected entry requires a detailed explanation, comments or footnotes may be used as long as they are uniquely identified.
- Keep records free of spills:
 - If hazardous material spills on a document and the data are still legible, make a photocopy for the file and use appropriate contamination controls.
 - Record on the copy why it is being used in place of the original (e.g. “copy replaces original because of a chemical spill”).
 - Dispose of the contaminated pages in the appropriate hazardous waste container.
 - If data have been obliterated, promptly notify a supervisor who will decide how to reconstruct the data. If the data cannot be reconstructed, the supervisor will document the steps taken to correct the issue.
- All spaces must have an entry unless specified in the related SOP or TI.
- Make all entries in the spaces provided. If no space is provided, make the entry on another area of the page or worksheet and date and initial the entry.
- Blank spaces can be filled with “NA” or “N/A” if the entry is not applicable to a particular process. Date and initial the entry.

- On forms and notebook pages, draw a diagonal line through any unused portions of the page; date, initial, and indicate that the section is not applicable with “NA” or “N/A”

8.3 Signatures and Initials

- All initials and signatures must be legible, recognizable, and uniquely identified by the signer.
- Sign or initial after each step is performed or reviewed.
- If more than one person is performing a task, the additional person(s) will sign, date, and document their involvement in the task.

8.4 Notebooks

- Bound notebooks should only be used when other controlled forms are unavailable and when many pages of hand-written documentation are needed, or when long-term documentation is needed (e.g. instrument notebooks).
- Indicate on the inside front cover and/or first page of the notebook what the notebook will be used to document and uniquely identify the notebook.
 - For laboratory notebooks, the specific project must be identified as well as the date the notebook was started. If multiple people will work on the same project, they should use the same notebook.
 - For instrument notebooks, the instrument model and serial number must be identified as well as the common name the instrument (e.g. Panalytical Epsilon 5, serial #: DY0695, Baldur). Record the start date of the notebook. There should only be one active instrument notebook per instrument at any given time.
- Completed notebooks:
 - Draw a diagonal line through any unused pages, initial and date, and indicate that data entry is complete or not applicable.
 - On the inside front cover and/or first page of the notebook, indicate “data entry completed”, date, and initial.
 - Completed notebooks will be archived with other program materials.

8.5 Printouts of Electronic Documents

Printed electronic documents should be identified, dated, and initialed to document that it is a printed document, not a copy or original.

8.6 Verified Copies

- This applies only to copies of an original that are required to be “exact,” “certified,” or “verified”, such as:
 - A copy of an original document that was contaminated or damaged (must include explanation if the original has been destroyed and the copy will replace the original; this should be explained on the copy).
 - Requested by the EPA or AQRC management.

- Photocopy the original document. The person who makes the copy must sign or initial and date the copy to indicate it is complete and legible.
- Copies may be reduced in size as long as they remain clearly legible.
- A second person, typically the Laboratory Group Manager, must verify that the copy is an exact copy of the original and write “verified copy of original” on the copy with date and initial.

9. REFERENCES

Not applicable.