DRI STANDARD OPERATING PROCEDURE

Creation, Revision, Distribution, and Archiving of SOPs

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1. INTRODUCTION

1.1 Purpose of procedure

This document describes Standard Operating Procedures (SOPs) followed by the Desert Research Institute (DRI). Its objectives are to:

1. Provide prescriptive and descriptive guidance for standard operations.
2. Assure continuity, uniformity, and improvement of measurement processes.
3. Allow external systems audits to verify DRI measurement processes.

As the second objective implies, these procedures are not static, and it is expected that they will be updated and revised to correct deficiencies, to incorporate better methods of accomplishing the same task, and to introduce new knowledge and innovation to the measurement process.

This SOP also provides a Microsoft Word template for subsequent SOPs, including first through fourth level headings, body text for paragraphs, list bullets, and list numbers. Not every heading will be applicable to every procedure, in which case a "Not applicable" entry should be made.

1.2 Measurement principle

The measurement process consists of measurement methods and procedures that detail the way in which those methods are carried out. Standard Operating Procedures (SOPs) are both prescriptive and descriptive. They are prescriptive in the sense that they guide the actions of the individual charged with carrying out the process, and that they allow an evaluation, by the independent systems audit, of the extent to which they are being properly executed. Procedures are descriptive in the sense that they report the measurement process in great enough detail that a scientist of ability equal to those performing the measurement could form an independent judgment of the correctness of the measurement process.

1.3 Measurement interferences and their minimization

Identify contaminants or co-pollutants that might positively or negatively bias the results and explain how these might be avoided, or at least minimized.

1.4 Ranges and typical values of measurements obtained by this procedure

State the maximum and minimum values to which the measurement methods apply and suggest how samples might be concentrated or diluted to obtain these values.

1.5 Typical lower quantifiable limits, precision, and accuracy

State the MDLs, LQLs, Precision, and accuracy, as defined below, expected from application of this procedure.

1.6 Responsibilities of personnel for carrying out portions of this procedure

Describe does what. Typical performance roles are: 1) Project manager; 2) field technical; 3) laboratory technician; 4) field operations supervisor; 5) laboratory operations

supervisor; 6) quality auditor; 7) quality assurance manager; 8) data manager; and 8) data analyst.

1.7 Definitions

- SOP=Standard Operating Procedure.
- MDL=Minimum Detectable Limit, the lowest value at which a response can be detected by the procedure.
- LQL=Lower Quantifiable Limit, the practical limit obtained by the entire sampling and analysis procedure, determined by two or three times the standard deviation of the field blank (a sample that goes through all processes except actual sampling) or two or three times the MDL, whichever is larger.
- Precision=The repeatability of measurements for the same sample, as determined from replicate analysis and propagation of errors.
- Accuracy=Deviations from independent quality auditing standards or standard reference materials.
- Primary standard=One traceable to a standard reference material or source.
- Transfer standard=One that is comparable to the primary standard but that can be easily reproduced for instrument calibration.
- Performance standard=One that is comparable to the primary standard, but independent of the calibration standard. It is used periodically (e.g., once every ten samples) to verify that the calibration has not drifted. Performance standards can be used to determine MDLs and instrument precision.
- Audit standard=One that is comparable to the primary standard, but independent of the calibration or performance standards. It is used in independent audits to determine accuracy.

1.8 Related procedures

List other procedures that relate to this one (e.g., a field sampling procedure might be associated with a laboratory procedure).

2. APPARATUS, INSTRUMENTATION, REAGENTS, AND FORMS

2.1 Apparatus and instrumentation

2.1.1 Description

Name the instruments, model numbers, and manufacturers for equipment used to implement the procedure.

2.1.2 Characterization

Describe typical stability, response times, and idiosyncrasies.

2.1.3 Maintenance

Describe routine maintenance, trouble-shooting tips, and references to operating manuals.

2.1.4 Spare parts

List spare parts and supplies that should be kept on hand for simple repairs and maintenance.

2.2 Reagents

This includes gases (e.g., gas cylinders) as well as liquids and solids. List the reagents, their purity grades, suppliers, storage requirements, and when to reorder (some reagents have a limited shelf-life. This includes gases as well as

2.3 Forms

Include examples of paperwork (e.g., data sheets, sample chain of custody forms), descriptions of the entries, and when to reorder.

3. CALIBRATION STANDARDS

3.1 Preparation of working standards, ranges of standard values, and traceability to primary standards

Explain what the calibration standards are and how they are prepared and related to the primary standard. Specify the number of standards spanning the range used to generate a calibration curve.

3.2 Use

Explain what instrument output (e.g., voltage, peak area) is compared with the calibration standards)

3.3 Typical accuracy of calibration standards

Specify the deviations from primary reference materials.

4. PROCEDURES

4.1 Start-up

Explain how to set up and begin operations. For creating SOPs, the following steps apply.

4.1.1 When to prepare a new SOP

New SOPs may need to be prepared when a new method or instrument is put into routine service. The preparer of the new SOP should be the person(s) most familiar with the initial use of the method or instrument and/or the one(s) who will most often use the SOP.

4.1.2 Obtain an SOP number

Each SOP is assigned a number by the Quality Assurance Manager in the form N-SnnrR where

N = one of seven major groups, as defined below.
R = identifies the revision number.
S= number of a sub-category, as defined below.
nn= unique number for that procedure.

4.1.3 Obtaining an SOP number

SOPs are divided into the following categories and sub-categories

1. **Field Procedures:** These includes procedures for routine maintenance, operation, and calibration of monitoring instrumentation, general procedures for monitoring station operation, and procedures for periodic intensive field activities. Subsets are:

- 1-001 to 1-099: General Procedures
- 1-101 to 1-199: Continuous Gas Analyzers
- 1-201 to 1-299: Particulate Samplers
- 1-301 to 1-399: Meteorological Instrumentation
- 1-401 to 1-499: Visibility Instrumentation
- 1-501 to 1-599: Data Recording Equipment
- 1-601 to 1-699: Other Field Procedures

2. **Laboratory Procedures:** Includes all routine laboratory procedures involved with processing of data, such as pre- and post-sampling filter processing or chemical analysis procedures. Does not include automated data processing procedures (Section 3.0) or laboratory procedures that are related to the verification of standards (Section 4.0). Subsets are:

- 2-001 to 2-099: General Procedures
- 2-101 to 2-199: Filter Processing Procedures
- 2-201 to 2-299: Chemical Analysis Procedures
- 2-301 to 2-399: Other Lab Procedures

3. **Data Processing and Data Validation Procedures**: Include procedures for computer processing of data, data file creation, data editing, data review and validation, data storage, and reporting. Subsets are:

3-001 to 3-099: General Procedures
3-101 to 3-199: Computer DP Procedures
3-201 to 3-299: Other DP Procedures

4. **Quality Assurance Procedures**: Include procedures related to performance and system audits and laboratory verification of transfer standards.

4-001 to 4-099: General Procedures
4-101 to 4-199: Audit Procedures
4-201 to 4-299: Standards Laboratory and Verification of Transfer Standards Procedures

5. **Modeling and Data Interpretation Procedures:** Include procedures for running computer models and for standard methods of data presentation (tabular and graphic).

5-001 to 5-099: General Procedures
5-101 to 5-199: Computer Modeling Procedures
5-201 to 5-299: Data Interpretation and Presentation Procedures

6. **Administrative Procedures:** Includes procedures for SOPs, document control, travel, report preparation formats, purchasing, and document control. No subsets

7. **Special Study Procedures**: Include all non-routine procedures, or procedures that cannot be categorized into any of the above categories. No subsets.

4.1.4 Create title page and header

Each page of a Standard Operating Procedure will have a heading the gives the title, page number, date of last revision (by month and year), SOP number and revision number (new SOPs have revision 0). The header for this SOP is an example. The title page includes the name of the procedure, its number, the DRI department that prepared, and signatures of the preparer, reviewer, and quality assurance manager.

4.1.5 Name and store the file

SOP files in Microsoft Word are labeled as follows:

ALPHADESRIPT_N-nnn_rR_yyyymmdd.doc, where

ALPHADESCRIPT=A shortened version of the procedure title
N-nnn= the procedure number
R=the revision number
Yyyymmdd=year, month, and day of the revision.

SOP files are stored on the eafmain server in the SOPs folder in a sub-folder for the categories defined above. Previous SOPs are moved into the directory marked OLD within each subfolder.

4.1.6 Review by Quality Assurance Manager

When the new SOP has been finalized and edited it should be given its final SOP number and effective date and sent to the QA Officer (and possibly others) for review. After the reviewer(s) have reviewed the document it must also be approved by the EAF Director. The preparer, reviewers, and EAF Director must sign and date the original cover page. The original, signed document will be archived electronically as a PDF file as well as a Word document. The original SOP, with original signatures, will be archived in a hardcopy file of SOPs maintained by the QA Officer. The original shall be labeled as an original and 2 hardcopies made to be included in the archive.

4.1.7 Distribution

The QA manager sends a notice (usually email) to all people using the procedure, noting important changes from previous revisions. The QA manager then verifies that operating personnel have obtained and read the procedure and have implemented the changes.

4.2 Routine operation

Describe steps to be followed for each sample.

4.2.1 Revising procedures

It may sometimes be necessary to revise an existing SOP for any of several reasons; modifications to an instrument or software, assessments or audits indicate an actual or potential problem. The procedure for making the revisions is the same as for preparing a new SOP, except that a new SOP number is not needed. The SOP revision number and effective date are changed. Also, the preparer must add a comment to the change documentation section of the SOP to state the date and brief reason or change for the revision.

At any time that laboratory procedures are changed from what appears in the approved, current SOP the SOP must be amended as expeditiously as possible, not to exceed 5 days. Any deviations from the SOP in the interim period before the SOP is revised must be documented.

Review and approval are the same as for a new SOP. However, when the revised SOP becomes effective, all hardcopies must be clearly marked as outdated and removed from working areas. The electronic versions of the old SOP revision are moved to the old folder and old is added to its title, as below:

SOPSOP_6-013_r0_07/07_OLD.doc

4.3 Follow-up or shut-down

Describe how to shot down the instrument after analyses have been performed. Not applicable to this procedure.

4.4 Checklists

Summarize procedure in one sentence steps that don't include all of the detail described above. Not applicable to this procedure.

5. QUANTIFICATION

5.1 Calibration procedures

Explain how calibrations are carried out. Not applicable to this procedure

5.2 Calculations (including background subtraction, interference corrections, and precision calculations)

Provide formulae and instructions for relating instrument output. Not applicable to this procedure.

6. QUALITY CONTROL

6.1 Performance testing

Describe frequency of blanks and standards)

6.2 Reproducibility testing

Describe selection, analysis schedule, and frequency of replicates.

6.3 Control charts, tolerances, and actions to be taken

Describe how control charts are to be kept, when deviations of blanks and replicates are too large, and what should be done. Not applicable to this procedure.

6.4 Flags for non-standard procedures

Include a table of data validation flags that indicate potentially suspect data. Not applicable to this procedure.

7. QUALITY AUDITING

Specify auditing or interlaboratory schedules and refer to specific procedures, if applicable. Not applicable to this procedure.

8. REFERENCES

Cite relevant references for the above categories. Not applicable to this procedure.

9. CHANGE DOCUMENTATION

Tabulate dates and revision numbers for prior procedures.

01/28/20 Added requirement for the SOP amendment to be created within 5 days when any laboratory procedures is changed from what is prescribed in the current SOP.