

LLNL Environmental Restoration Division (ERD)  
Standard Operating Procedure (SOP)

ERD SOP 4.13: Standard Operating Procedure  
Process—Revision 1



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| APPROVALS:                              | Date           |
|---|----------------|
| <u>Albert Lamane</u><br>Division Leader | <u>6/20/00</u> |
| <u>[Signature]</u><br>EPD QA Manager    | <u>6/22/00</u> |

| CONCURRENCE:   | Date           |
|--|----------------|
| <u>[Signature]</u><br>QA Implementation<br>Coordinator | <u>6/20/00</u> |

### 1.0 PURPOSE

The purpose of this procedure is to establish the means for preparing and revising standard operating procedures (SOPs), and to ensure that they are reviewed for adequacy and approved by the appropriate personnel. Procedures are used by ERD personnel as a training tool and reference source.

### 2.0 APPLICABILITY

This procedure is applicable to ERD personnel that develop ERD SOPs.

### 3.0 REFERENCES

- 3.1 LLNL Environmental Protection Department, EPD Quality Assurance Management Plan (EPD QAMP).

## **4.0 DEFINITIONS**

See SOP Glossary.

## **5.0 RESPONSIBILITIES**

### **5.1 Division Leader**

The Division Leader's responsibility is to ensure that all activities performed by ERD are documented in a procedure as described by this SOP. The Division Leader approves all SOPs.

### **5.2 Group Leader or Manager**

The Group Leader or Manager who is responsible for the activity being addressed by the SOP approves the SOP and ensures that the SOP accurately reflects the processes in place and the requirements are implemented.

### **5.3 Reviewers**

ERD Personnel assigned as Reviewers are responsible for reviewing newly developed or revised SOPs that directly impact their work activity and ensuring that the SOPs reflect the processes in place and any new requirements are implemented.

### **5.4 ERD Quality Assurance Implementation Coordinator (QAIC)**

The QAIC is responsible for initiating and coordinating the SOP process for new SOPs and revisions. The QAIC concurs with all SOPs and controls their distribution.

### **5.5 Procedure Writer**

ERD personnel assigned as Procedure Writer or Author are responsible for developing or revising SOPs in their area of expertise, per this SOP, involving all personnel that are directly impacted in the writing/reviewing and ensuring that the review is documented.

## **6.0 PROCEDURES**

### **6.1 Initiation**

Procedures are required to document all ERD processes to ensure that work is done correctly, consistently, and safely. When a new procedure is required, the QAIC initiates the SOP process by requesting that the Group Leaders identify the appropriate Procedure Writer and Key Reviewers.

### **6.2 Preparation**

Procedures shall be prepared by the designated Procedure Writer per the requirements of this procedure.

### **6.3 Page Format**

The front page of each procedure shall contain the following:

1. Procedure title, number, and revision.

|                                      |                             |                    |
|--------------------------------------|-----------------------------|--------------------|
| <b>Procedure No.</b><br>ERD SOP-4.13 | <b>Revision Number</b><br>1 | <b>Page 3 of 5</b> |
|--------------------------------------|-----------------------------|--------------------|

2. Author(s).
3. Approval section which provides for signatures of the designated individuals and date, indicating approval of procedures.

#### **6.4 Page Headings**

Each subsequent page of a procedure shall have a page heading which includes the following information:

1. Procedure No.
2. Revision Number (e.g., Revision 0, Revision 1, etc.).
3. Page \_\_ of \_\_ (e.g., Page 1 of 10, 2 of 10, etc.).

#### **6.5 Outline and Content**

Procedures shall be divided into the following sections in the order presented:

##### **6.5.1 Section 1.0, *PURPOSE***

Briefly state why the procedure is being written and what activity is to be performed through the use of the procedure.

##### **6.5.2 Section 2.0, *APPLICABILITY***

Provide a concise description of to what or whom the procedure applies.

##### **6.5.3 Section 3.0, *REFERENCES***

List references. If there are no references, indicate “Not Applicable.”

##### **6.5.4 Section 4.0, *DEFINITIONS***

Provide definitions to clarify terminology used in the procedure. Definitions will be placed in the SOP Glossary in all SOP binders.

##### **6.5.5 Section 5.0, *RESPONSIBILITIES***

Identify the titles and major responsibilities of the individuals or organizations responsible for implementing the requirements of the procedure.

##### **6.5.6 Section 6.0, *PROCEDURE***

Section 6.0 should be as concise as possible, yet with enough detail that personnel with minimal working knowledge can perform a task by following the procedure. Provide a step-by-step sequence of operations required to perform the activity in a manner that is correct, safe, and fully responsive to applicable requirements.

##### **6.5.7 Section 7.0, *QUALITY ASSURANCE RECORDS***

Identify the QA Records that will be generated or completed as a result of implementing the procedure.

|                               |                      |             |
|-------------------------------|----------------------|-------------|
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|-------------------------------|----------------------|-------------|

### 6.5.8 Section 8.0, *ATTACHMENTS*

Any attachments, sample forms, etc., will be labeled “Attachment” followed by an upper case alpha code. Attachments shall be listed in this section. If there are no attachments, indicate “Not applicable.”

## 6.6 SOP Section Headings

Where necessary, SOPs shall be divided into Sections, Subsections, Sub-Subsections, and/or Sub-Sub-Subsections. Use sequential numbering (1.1, 1.1.1, 1.1.1.1, etc.) for all Section Headings (Note: Section Headings may vary per SOP). This guide will assist authors, compositors, and editors in preparing uniform ERD SOPs and is organized by the following examples:

### 1.0 SECTION HEADING 1—centered

Font = Century Schoolbook, Font Type = **bold**, ALL CAPS, Font Size = 12

### 1.1 Subsection Heading 2 (heading only)—left justified

Font = Century Schoolbook, Font Type = **bold**, Font Size = 12

### 1.1 Subsection Heading 2 (heading or text)—left justified

Font = Times, Font Type = plain, Font Size = 12.

### 1.1.1 Sub-Subsection Heading 3 (heading or text)—indent

Font = Times, Font Type = plain, Font Size = 12

### 1.1.1.1 Sub-Sub-Subsection Heading 4 (heading or text)—indent

Font = Times, Font Type = plain, Font Size = 12

- For numbering indented items or lists use Bullets (•); “En” Dashes (–); 1., 2., 3.; or A., B., C.

## 6.7 Review

Procedures, including revisions, shall be reviewed by ERD personnel whose work is directly related to the SOP. The Procedure Writer shall call a group meeting with those personnel to address their comments. The review shall be documented.

## 6.8 Approval

Procedures, subsequent revisions, or cancellations shall be approved by the Division Leader. The appropriate Group Leader approves these SOPs that fall in their field of expertise. SOPs that implement the requirements of the EPD QAMP do not require Group Leader approval.

## 6.9 Concurrence

Procedures shall be concurred to by the ERD QAIC. When an SOP implements the requirements of the EPD QAMP, the EPD Assurance Manager shall also concur.

## 6.10 Distribution

Procedures, including revisions, shall be assigned unique numbers by the QAIC and distributed as controlled documents.

## **6.11 Maintenance and Revisions**

6.11.1 Procedures shall be reviewed at least annually and documented by a review memorandum.

6.11.2 Any changes to the procedure shall constitute a revision.

6.11.3 Revisions to procedures shall be prepared, reviewed, approved, and distributed in the same manner as the original procedures.

## **7.0 QA RECORD**

7.1 The original approved procedure.

7.2 Revisions.

7.3 Review meeting signature sheet.

## **8.0 ATTACHMENTS**

Not applicable.