Environmental Programs Directorate

Standard Operating Procedure

for **PROCEDURE DEVELOPMENT**

APPROVAL SIGNATURES:

Subject Matter Expert:	Organization	Signature	Date
Ellena Martinez	WES-RS	Signature on File	11/3/08
Responsible Line/Manager:	**Organization**	**Signature**	**Date**
Perry D. Farley	WES-RS	Signature on File	11/4/08

1.0   PURPOSE AND SCOPE

This procedure states the responsibilities and describes the process for development, review, validation, approval, and revision of administrative and standard operating procedures (SOP) for the Los Alamos National Laboratory (LANL) Environmental Programs (EP) Directorate. This procedure integrates the criteria of the Quality Assurance Plan for the EP Directorate.

This document is to be used by personnel involved in developing and writing procedures: writers, reviewers, administrators, subject matter experts, support personnel, and users. It provides a step-by-step process for developing new, or revising existing procedures, as well as the cancellation or deactivation of procedures.

2.0   BACKGROUND AND PRECAUTIONS

2.1   Background

This procedure provides guidance for developing accurate, complete, clear and consistent procedures. The information provided in this procedure is compliant with the LANL Conduct of Operations Manual, ISD 315-1, Chapter 16.0, Tier 3 Operations Procedures
http://policy.lanl.gov/pods/policies.nsf/MainFrameset?ReadForm&DocNum=ISD315-1&FileName=ISD315-1.pdf.

2.2   Precautions

2.2.1   New and revised procedures require an unreviewed safety question (USQ) screening in accordance with procedure EP-DIR-SOP-4001, Document Control, as part of a completed document history file to defining the work (including hazards, locations, etc.) prior to actual performance of the work.

2.2.2   This procedure applies to development of a new or revised procedure into the standard operating procedure (SOP) format or the cancellation/deactivation of a procedure. It does not provide guidance, nor does it include the process for scheduling, developing, editing, formatting, reviewing signing, controlling, producing, distributing, and archiving documents such as letters, reports, and work plans. For information pertaining to these activities, refer to procedure SOP-4006, Document Development and Deliverable Compliance Process.

2.2.3   This procedure is not intended to replace the Document Control process. It provides specific information pertaining to a procedure package (new or existing procedure and applicable forms) required by the Document Control Office in accordance with the LANL Conduct of Operations Manual, ISD 315-1, Chapter 16.0, Tier 3 Operations Procedure. Reference procedure EP-DIR-SOP-4001, Document Control, for additional information on the document control process and requirements.

2.2.4   This procedure applies to the EP Directorate activities, such as sampling, dose and risk evaluation, data collection, assessment and management, waste acceptance, and waste certification. All other facility-specific procedures must be coordinated through the Environment & Waste Management Operations (EWMO) Division. The EWMO Document Development and Maintenance process may be used for the EP activities as determined by the appropriate EP management.

2.2.5   It is the employee's responsibility to ensure they are working to the most current version of a procedure and form referenced within a procedure. SOPs can be found in the Waste Environmental Services (WES) web page at http://int.lanl.gov/environment/all/qa/adep.shtml .

3.0   STEP-BY-STEP PROCESS DESCRIPTION

3.1   Preparing New Procedures

Procedure Owner or designated Procedure Manager	1.	Contact the Procedure Manager to discuss the need for a new, revised, cancelled, or deactivated procedure and arrange for support for preparation.
		Note: The procedure owner is the originator who identifies the need for a new or revised document and initiates the formal request to proceed. The procedure owner may designate the processing and preparation of the document to the procedure manager. The procedure manager will assist in preparing required forms, coordinating review and concurrence, and responsible for circulating the procedure package for review and approval.
	2.	Review the criteria specified in the LANL Conduct of Operations Manual, ISD 315.1, Chapter 16.0, Tier 3 Operations procedures prior to developing a new procedure and the Document Control, EP-DIR-SOP-4001, procedure.
	3.	Initiate the procedure development process by completing the Procedure Request Form (Attachment 1).
	4.	Send the form via email to procedure_help@lanl.gov.
Procedure Manager	5.	Prepare a Procedure Change Request (PCR) form, Attachment 2.
	6.	Circulate the completed form to the appropriate manager for pre-approval (Responsible Line Manager or Program Director), prior to beginning the procedure development process.
		NOTE: Use of the terms "Responsible Line Manager" and "Responsible Functional Manager" are both used within the EP Directorate. For purposes of procedure ownership, responsibility, and signature either title is currently acceptable for signature and approval.
	7.	Track procedure status through completion.
	8.	Send an email request (if approved by appropriate manager) that includes the following information, to the Document Control Coordinator at ep-doccontrol@lanl.gov, to request a new document control number for the procedure:
		• title of procedure,
		• type of document (Administrative Procedure, Building Emergency Plan, and Standard Operating Procedures, etc.),
		• quality criterion, and
		• identification if the procedure is a "new procedure" or a "revision".
	9.	Save a copy of the SOP template under the new document control number and title and email the document to the Procedure Owner or Author.
		NOTE: This template is available on the WES-Division Office (DO) homepage at http://int.lanl.gov/environment/all/qa/adep.shtml.

Procedure Owner	10.	Complete each section of the SOP template. If the section does not apply, mark the section as Not Applicable (NA), i.e., flow charts not used within the procedure. • Purpose and Scope • Background and Precautions • Equipment and Tools • Step-by-Step Process Description • Process Flow Chart • Revision History • Attachments.
	11.	Include the periodic review date on the cover page of the procedure, not to exceed the required 5-year review.
	12.	If the procedure is new (not superseding an existing procedure), the procedure is designated as "Revision 0."
	13.	Specify changes to be made to the procedure in the Revision History section.
	14.	E-mail the draft procedure to the Procedure Manager at procedure_help@lanl.gov. The Procedure Manager will convert file from pdf to Word, if necessary, format, acquire a new Document Control identifier, coordinate update, review, and signature coordination.
Procedure Manager	15.	Review the draft document and ensure that each section of the SOP template is complete, in accordance with the requirements of the LANL Conduct of Operations Manual, ISD 315-1, Chapter 16.0, Tier 3 Operations Procedures.
	16.	Verify that the procedure meets the requirements specified in procedure EP-DIR-SOP-4001, Document Control.
	17.	Perform quality check to ensure the procedure contains: document title, appropriate signature reviews, a page number on each page, attachments, forms, etc.
	18.	Facilitate a peer review when the Procedure Owner specifies a peer review on the procedure request form, in compliance with procedure EP-ERSS-SOP-4005, Peer Review.
Procedure Owner	19.	Provide names of individuals to be included in the peer review of the document (i.e., Subject Matter Expert (SME), Quality Assurance (QA), Industrial Hygienist (IH), and Safety).
Procedure Manager	20.	Ensure each reviewer has completed a Procedure Review and Concurrence Form (Attachment 3), within the procedure document package.
Peer Reviewer	21.	Evaluate the procedure content related to their area of expertise for accuracy, clarity, and compliance with established requirements.
	22.	Complete each section of the Procedure Review and Concurrence form by numbering each comment sequentially, and providing a brief description of the comment.
	23.	If there are no comments on the procedure, specify "No comments" in the comment section of the form.

Cont.	24.	Sign the Procedure Review and Concurrence Form (Attachment 3), attesting to completion.
Procedure Owner	25.	E-mail the final draft document to the Procedure Manager for closure, when all reviews are completed and comments resolved.
Procedure Manager	26.	Complete Part # 1 of the Procedure Validation Checklist (Attachment 4), as required by the LANL Conduct of Operations Manual, ISD 315-1, Chapter 16.0, Tier 3 Operations Procedures, Section I. and F.
	27.	Include the Procedure Validation Checklist with the procedure document package to be sent to the Document Control Coordinator.
Procedure Owner	28.	Identify SME(s) that will complete Part #3 and Part #4 of the final Procedure Validation Checklist.
	29.	Contact the EP Training Office at eptraining@lanl.gov to schedule training review to complete the training level determination form.
Procedure Manager	30.	Review contents of procedure document package to ensure that the document meets the specifications of the LANL Conduct of Operations Manual, ISD 315-1, Chapter 16.0, Tier 3 Operations Procedures, and document control requirements.
	31.	Circulate the final procedure package for approval signatures on the PCR form to designated reviewers and designated approval personnel: • SME(s), • Procedure Owner • Responsible Line/Functional Manager • Derivative Classifier (DC) Review • Quality Assurance Team Leader (optional) • USQ Review • EP Training Team Leader or designee.
	32.	Allow each reviewer five (5) working days to review and sign the PCR form from date of circulation.
Procedure Manager Cont.	33.	Deliver the final procedure package, which includes the following documents, to the Document Control Coordinator: • Final Approved Procedure • Procedure Review and Concurrence Form(s) • Procedure Validation Checklist • Procedure Change Request Form • A Training Level Determination Form is required for all new or revised procedures (refer to EP-DIR-SOP-2011 Personnel Training and Qualification procedure) • and any other related documents.
	34.	Obtain the signature of the SME, QA, and the Responsible Line/Functional Manager on the cover page of the final procedure.

Cont.	35.	Ensure each form included in the procedure package is completed, including the required signatures.
	36.	Send a final email to the Document Control Coordinator at ep-doccontrol@lanl.gov, attaching the final Word version of the new procedure.

3.2 Revising Existing Procedures

Procedure Owner	1.	Contact the Procedure Manager to discuss the need for a revision to a procedure.
	2.	Review the LANL Conduct of Operations Manual, ISD 315-1, Chapter 16.0, Tier 3 Operations Procedures prior to revising an existing procedure.
	3.	Determine if the revision is a technical (i.e., major) or editorial (i.e., minor) change (see Section 3.1, step 13).
	4.	Contact the EP Training Office at eptraining@lanl.gov to schedule training review to complete training level determination form.
	5.	Send a completed procedure request form to the Procedure Manager or email to procedure_help@lanl.gov to request assistance in updating the procedure.
Procedure Manager	6.	When a procedure falls within the required schedule review period, and the Procedure Owner has changed, identify a new Procedure Owner based on reassignment by the Responsible Line Manager.
	7.	Use the information on the Procedure Request Form, prepare a Procedure Change Request form and forward to the Responsible Line Manager for approval to update and revise the procedure. *NOTE: In the absence of the Responsible Line Manager, the Program Director may also approve.*
	8.	Upon approval for procedure update, send an email request to the Document Control Coordinator at ep-doccontrol@lanl.gov to request a copy of the electronic word version of the procedure.
	9.	If an electronic version is not available from Document Control, convert the latest revision copy of the Adobe Acrobat procedure posted on the web into a Word version.
	10.	Include the procedure title and the document control number that is being superseded.
	11.	Change the revision numbers as follows: • Technical Revision – number will increase one whole number (e.g., Revision 0 goes to Revision 1.0); • Editorial Revision – number will increase by .1 (e.g., Revision 0 goes to 0.1). Determine the type of changes to be made using the following criteria: • Minor Change includes: correcting grammar or spelling, without changing the meaning, renumber sections or attachments, updating organizational titles without changing assigned responsibilities, update number or titles of other documents referenced in document, and revising or reformatting forms. • Major Change includes: any document change, including cancellation that cannot be characterized as a Minor Change or Immediate Document Change.
	12.	Prepare a PCR Form to update the procedure.

Procedure Manager Cont.	13.	Provide the Review and Concurrence Form and Procedure Checklist Validation Form to the Procedure Owner to complete.
	14.	Send a copy of the "final draft" electronic word version of the procedure to the Procedure Owner to distribute to selected reviewers [SME(s), QA, IH, Safety, etc.] for review and concurrence.
Peer Reviewer	15.	Review procedure for adequacy, technical accuracy, and completeness prior to approval for issue.
	16.	Complete each section of the Review and Concurrence form (Attachment 3) by numbering each comment sequentially, and provide a brief description of the comment. *NOTE: Reference the Environmental Peer Review process for further details.*
	17.	Indicate "No comments" if there are no comments on the procedure, in the comment section of the Review and Concurrence form.
	18.	Return the signed and completed Review and Concurrence form to the Procedure Owner.
Procedure Owner	19.	Perform comment resolution on comments received from all Peer Reviewers prior to approval of procedure. *NOTE: Concurrence must be reached on comments prior to closing the review process prior to closing the review process. .If resolution or concurrence can not be achieved the issue can be elevated to the Responsible Line Manager for documented resolution and closure of the issue.*
	20.	Close the peer review process by signing and dating the Procedure Change Request, Review and Concurrence, and the Procedure Validation Checklist forms.
	21.	Send the final procedure and applicable forms to the Procedure Manager.
Procedure Manager	22.	Deliver the final procedure package, which includes the following documents, to the Document Control Office (located at the Pueblo Complex, Room 109): - Final Procedure - Procedure Review and Concurrence Form(s) - Procedure Validation Checklist - Procedure Change Request Form - A Training Level Determination Form - and any other related documents.
	23.	Retain the hard-copy Procedure Request form documenting completion of the procedure package.
	24.	Ensure the cover page of the final procedure is signed by the SME or Procedure Owner, and the Responsible Line Manager. **Note**: Verify signatures obtained in the former procedure. The PCR form prepared for the revised document must obtain the same signatures.
	25.	Send an email containing the electronic version of the final procedure to the Document Control Coordinator (ep-doccontrol@lanl.gov).

3.3 Initiating an Immediate Document Change Request

Procedure Owner	1.	Follow the process described in the LANL Conduct of Operations Manual, ISD 315-1, Chapter 16.0, Tier 3 Operations Procedures, Subsection II, Immediate Document Change (IDC). [NOTE: An IDC is a minor change to an issued procedure made to address urgent operational needs that require expedited processing.]
	2.	Deliver the document and IDC form directly to the Document Control Coordinator for immediate posting of the changed procedure on the Web Site in accordance with procedure EP-DIR-SOP-4001, Document Control.

3.4 Cancelling or Deactivation of Procedures

Procedure Owner	1.	Send an email request, including the following information, to the Procedure Manager at procedure_help@lanl.gov stating your request to cancel a procedure: • name of the procedure • document control number • reason for cancellation.
Procedure Manager	2.	Forward the email request to cancel or deactivate a procedure to the Responsible Line Manager and the Quality Assurance Team Leader for concurrence.
	3.	If cancellation or deactivation is approved, process in accordance with procedure EP-DIR-SOP-4001, Document Control.
Procedure Owner	4.	Complete a PCR Form (Attachment 2), obtain appropriate signatures, and deliver the PCR form and procedure to the Document Control Coordinator for processing.

3.5 Records

Procedure Manager	1.	Transmit the records generated by this procedure, including the following, to the Document Control Coordinator for management and control of the procedure and forms until the procedure is superseded, cancelled, or deactivated: • Final procedure, • Procedure Change Review form, • Review and Concurrence form, • Procedure Validation Checklist form, • Training Level Determination Form, and • any additional documents generated by this procedure. Note: The procedure package is an active document that is maintained in the Document Control Office until the procedure is superseded, cancelled, or deactivated. Refer to the next step.
All	2.	Refer to procedure EP-DIR-SOP-4001, Document Control, for more information on final record submittal to the Records Processing Facility.

4.0 PROCESS FLOW CHART

None

5.0   ATTACHMENTS

[NOTE: Attachment 2, 3 and 4 are examples, only. Copies of these forms can be obtained from the LANL Conduct of Operations Manual, ISD 315-1, Chapter 16.0, Tier 3 Operations Procedures at this link:
http://policy.lanl.gov/pods/policies.nsf/MainFrameset?ReadForm&DocNum=ISD315-1&FileName=ISD315-1.pdf

Attachment 1   Procedure Request Form

Attachment 2   Procedure Change Review Form

Attachment 3   Review and Concurrence Form

Attachment 4   Procedure Validation Checklist

6.0   REVISION HISTORY

Revision No. *[Enter current revision number, beginning with Rev.0]*	Effective Date *[DCC inserts effective date for revision]*	Description of Changes *[List specific changes made since the previous revision]*	Type of Change *[Technical (T) or Editorial (E)]*
0	1/4/08	New Document	E

Using a CRYPTOCard, click here to record "self-study" training to this procedure.
If you do not possess a CRYPTOCard or encounter problems, contact the EP training specialist.

ATTACHMENT 1	
SOP-4007-1 **PROCEDURE REQUEST FORM**	Records Use only • **Los Alamos** NATIONAL LABORATORY — EST.1943 —

Doc Control Assigned SOP No: _____

Procedure Request Form

Request Date: _____ **Proposed Procedure Completion Date:** _____

Author/Owner: _____ **If needed, new owner assigned by FM:** _____

☐ **New Procedure**   ☐ **Revision**   ☐ **Cancellation**   ☐ **Deactivation**
Current No. _____

Procedure Title: _____

Charge Codes: _____

List a brief description of changes: ☐ Major ☐ Minor

_____

Service(s) and Signature Coordination Requested (work you wish Procedure Manager to perform):

☐ Retrieve electronic document   ☐ Request DC number   ☐ Process/New Template
☐ PCR Form   ☐ Review & Concurrence Form   ☐ Procedure Validation Checklist

Publication Services coordinated by Procedure Development Manager (optional)

☐ Peer Review/Comments Due_____   ☐ Proof Read/Edit
List Peer Reviewers: _____

Consideration of additional reviewers:

☐ Associate Director   ☐ Program Director   ☐ Other: _____

This section to be completed by Procedure Development Manager, only

Sub Assigned:_____
Date provided to Sub: _____
Date returned to PDM: _____
Date sent to RFM: _____
Date sent to Owner: _____
Date sent to SME(s):_____
Date sent to QA: _____
Date sent to ADC: _____
Date sent to USQ:_____
Date sent to CT:_____

If more than one procedure is included in this request, list the numbers assigned by DCC:
Doc Control #: _____
Supersedes #: _____
Doc Control #: _____
Supersedes #: _____
Doc Control #: _____
Supersedes #: _____

Date procedure package delivered to Doc Control: _____
☐ Sent final word version
Date posted on web:_____
Date procedure notification email sent: _____
Comments: _____
_____
_____

Example

SOP-4007 (9/08)

ATTACHMENT 2

SOP-4007-2 PROCEDURE CHANGE REQUEST	Records Use only **Los Alamos** NATIONAL LABORATORY — EST.1943 —

Conduct of Operations Manual
Los Alamos National Laboratory

Section 16.1 Attachment 3 – Procedure Change Request

Procedure Change Request

Section #1 - Type of Request

Manual/Procedure No. (if known): _____ Revision: _____

Title: _____

Detailed description of requested change (Attach additional sheets if needed. Number additional sheets):

Requestor Signature: _____ Print Name: _____ Phone: _____ Date: _____

Section #2 – Procedure Owner Supervisor Approval For Processing

☐ New Procedure ☐ Major Revision ☐ Minor Revision ☐ Special Procedure

☐ IPC ☐ Deactivation ☐ Cancellation ☐ IPC Rollup

☐ Approved ☐ Disapproved (Return to originator) Priority:

Procedure Owner Supervisor Signature: _____ Print Name: _____ Date: _____

Section #3 – Review and Concurrence

IPC # _____ IPCs Incorporated: _____ Affected Pages: _____

Other affected facilities or N/A: _____ Obtain Concurrence all facilities/organizations affected by this change

Review and Concurrence: Review organizations (N/A if not required); document additional review organizations, if needed, on continuation sheet. CSE approval required for all technical procedures except minor revisions, IPC Rollup, and non-AB related cancellations/deactivations. CSE approval always required for changes affecting safety basis steps.

Department:	Print Name:	Signature:	Date:

CSE USQ Number (As applicable): _____ ADC: ☐ Unclassified ☐ OUO: ☐ UCNI ☐ Classified

Print Name _____ Signature _____

Section #4 - Final Approval By Procedure Owner

Validation Required? ☐ Yes ☐ No	Document is Authorized to serve as Part 1 of the IWD	☐ Yes ☐ No	Periodic Review requirements Satisfied? ☐ Yes ☐ No

Training Required:
☐ Yes ☐ No   ☐ Classroom/Briefing   ☐ Just-in -Time   ☐ Hold for Completion of Training
☐ On the Job   ☐ Required Reading   ☐ Release Procedure to field

Approval Signature:	Print Name:	Z Number:	Date :	Phone:

LANL
ISD 315-1.2

ATTACHMENT 3	
SOP-4007-3 **REVIEW AND CONCURRENCE FORM**	Records Use only • Los Alamos NATIONAL LABORATORY — EST 1943 —

Conduct of Operations Manual
Los Alamos National Laboratory

Section 16.1 Attachment 5 – Procedure Review and Concurrence

Procedure Review and Concurrence

Page 1 of _

To:	Dept:	Review Due Date:	Concurrence Due Date:
From:	Dept:	Date Sent: (Review)	(Concurrence)
Procedure No:	Rev:	Draft:	
Procedure Title:			

Comments entered on the form are required to be
- Legible
- Numbered sequentially
- In black or blue permanent ink

Check if no comments:

☐ No comments

Comment Number	Paragraph, Section, or Step	Comment (Use additional sheets as necessary. Number sheets 1 of x)	Disposition

Example

Reviewer Print Name:	Reviewer Signature:	Date:	Phone:
Dispositioner Name:	Dispositioner Signature:	Date:	Phone:
Reviewer Concurrence Name:	Concurrence Signature*:	Date:	

* Concurrence Signature indicates concurrence with comment disposition for all comments.

ATTACHMENT 4

SOP-4007-4

PROCEDURE VALIDATION CHECKLIST

Records Use only

Los Alamos
NATIONAL LABORATORY

Conduct of Operations Manual
Los Alamos National Laboratory

Section 16.1 Attachment 6 – Procedure Validation Checklist

Procedure Validation Checklist					
Part #1 -- To Be Completed by the Procedure Organization					
Title:		Number:	Rev:	Draft:	
Procedure Writer:		Location:		Phone:	
Date:	Return by (date):				
Part #2 -- To Be Completed by the Procedure Owner					
Group responsible for Validation:		Scope of Procedure Validation to be performed on this Procedure: ☐ Entire Procedure ☐ Changes Only ☐ Waive			
		Indicate Validation Method: ☐ Walkdown ☐ Tabletop ☐ First Time Use ☐ Waived			
Owner Signature:		Print Name:		Date:	

Part #3 -- To Be Completed by the Procedure Validator(s)			
Instructions: For each "No" answer, provide comment(s) on comment sheet or markup the procedure to reflect necessary changes.			
Part 3, Section A – User Compatibility	Yes	No	N/A
Can the instructional steps be performed in sequence as written?			
Does each step provide sufficient detail to complete the activity?			
Are any steps or information omitted that are needed to perform the activity?			
Are steps - sequential - limited to one action per step where possible - easily read & un...			
Are required actions and responsibilities clearly defined?			
Are references to other steps within the procedure correct?			
Are instructions to branch to other procedures correct?			
Are tolerances and units of measure provided where needed?			
For time-critical actions, can steps be performed...			
If an activity is performed by more than one ... ...ction provided for communication and coordination?			
Are stop action limits ...vided for ... which ... ...ments to accomplish a task?			
...Section B – Plant Compatibility	Yes	No	N/A
Are location... ...by the pro...dure consistent with field installation?			
Do specified ... ...match those indicated on the instrumentation?			
Are equipment ...nts identified clearly and reflect the exact equipment field nomenclature?			
Are tools, instruments, or materials needed to complete the task specified?			
Is necessary personnel protective clothing or equipment specified?			
Can steps be performed safely (hazards to personnel & equipment identified)?			
Are protective measures adequate to protect personnel			
Part 3, Section C – ARP/AOP/EOP Validation (Mark N/A if this section is not applicable)	Yes	No	N/A
User Compatibility			
Are appropriate corrective actions to alarms specified?			
Are entry and exit points clearly specified?			
Plant Compatibility			
Is the correct alarm identification provided (matches the panel alarm window CRT/PLC display screen exactly)?			
Part 4 – To be Completed by the Procedure Validator			
Validator's Signature:	Validator's Printed Name:		
Location:	Phone:		Date:

Forward completed form to the Procedure Organization