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Los Alamos
NATIONAL LABORATORY
— EST.1943 —

Environmental Programs Directorate

Standard Operating Procedure

for   **PROCEDURE DEVELOPMENT**

APPROVAL SIGNATURES:

Subject Matter Expert:	Organization	Signature	Date
Ellena Martinez	BPS-DO	Signature on File	3/30/2010
Responsible Line/Manager:	**Organization**	**Signature**	**Date**
Gail Toddings	BPS-DO	Signature on File	3/31/2010

1.0   PURPOSE AND SCOPE

This procedure states the responsibilities and describes the process for developing, reviewing, validating, approving, and revising administrative and technical standard operating procedures (SOP) and Plans for the Los Alamos National Laboratory (LANL) Environmental Programs (EP) Directorate. This document is to be used by personnel involved in developing and writing procedures including writers, reviewers, administrators, subject matter experts, support personnel, and users.

This procedure applies to the 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 Waste Disposition Project (WDP) Division. The WDP Document Development and Maintenance process may be used for the EP activities as determined by the appropriate EP management.

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.

1.1   Background and Precautions

1.1.1   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.

1.1.2   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, 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.

1.1.3   This procedure is not intended to replace the Document Control process. It provides specific information pertaining to the development of 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. Refer to EP-DIR-SOP-4001, Document Control, for additional information regarding the document control requirements.

1.1.4   It is the employee's responsibility to ensure they are working to the most current version of a procedure and form(s) referenced within a procedure. SOPs may be accessed through the Business & Project Services (BPS) Division web page at http://int.lanl.gov/environment/all/qa/adep.shtml or through the Controlled Documents cabinet in Domino http://idocmanage.lanl.gov/domdoc/RRESlib.nsf.

2.0 STEP-BY-STEP PROCESS DESCRIPTION

2.1 Preparing New Procedures

Procedure Owner or designated Point of Contact	1.	Contact the BPS Procedure Development team 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 development team. The team will assist in preparing required forms, coordinating review and concurrence, and responsible for circulating the procedure package for review, signature and final approvals of the procedure.
	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 Development Team	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 to the Document Control team at ep-doccontrol@lanl.gov, to request a new document control number for the procedure. Include the following information:
		title of procedure, author name, organization name
		type of document (Administrative Procedure, Building Emergency Plan, and Standard Operating Procedures, etc.),
	9.	Email the SOP template to document owner/author and ensure that the number assigned by document control is included in the document.
		NOTE: The SOP template is accessible on the BPS-Division web page: 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 (include changes made to document) • Attachments (list name of attachments).
	11.	Include the periodic review date on the cover page of the procedure, not to exceed the required 5-year review.
		NOTE: The new procedure is designated as "Revision 0."
	12.	E-mail the final draft procedure to the Procedure Development team at procedure_help@lanl.gov. The designated point of contact will convert the file from pdf to word format, if necessary, acquire a new Document Control identifier, and coordinate the revision with author, reviewers, and acquire final approval signatures.
	13.	Provide names of individuals to be included in the review and concurrence of the document (i.e., Subject Matter Expert (SME), Quality Assurance (QA), Industrial Hygienist (IH), and Safety).
Procedure Development Team	14.	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.
	15.	Perform quality check to ensure the procedure meets the requirements specified in procedure EP-DIR-SOP-4001, Document Control.
	16.	Verify that procedure contains the following information: document title, appropriate signature reviews, a page number on each page, attachments, forms, etc.
	17.	Facilitate and coordinate the Review and Concurrence (Attachment 3) with the list of reviewers specified by the Procedure Owner on the procedure request form.
	18.	Include the Review and Concurrence Form provided by reviewers in the procedure document package.
Procedure Reviewer(s)	19.	Evaluate the procedure content related to area of expertise for accuracy, clarity, and compliance with established requirements.
	20.	Complete each section of the Review and Concurrence form by numbering each comment sequentially, and providing a brief description of the comment.
	21.	If there are no comments on the procedure, specify "No comments" in the comment section of the form.
	22.	Sign the Procedure Review and Concurrence Form (Attachment 3), attesting to completion.

Procedure Owner	23.	Accept and/or reject comments from reviewers and update procedure as necessary. Send an e-mail to the Procedure Development Team including the final draft document.
Procedure Development Team	24.	Complete Part # 1 of the Procedure Validation Checklist (Attachment 4), if necessary, according to the LANL Conduct of Operations Manual, ISD 315-1, Chapter 16.0, Tier 3 Operations Procedures, Section I. and F. Include the Procedure Validation Checklist with the procedure document package to be sent to the Document Control Coordinator.
	25.	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.
	26.	Circulate the final draft procedure to the approving managers/reviewers in the sequential order as listed on the PCR/Dar form: Procedure Development Team Point of Contact Responsible Line/Functional Manager Designated Reviewers as specified by Procedure Owner Quality Assurance Team Leader (optional) USQ Review (allow 5-7 days) Derivative Classifier (DC) Review Central Training Review/Approval Procedure Owner/RLM **NOTE**: Allow reviewers 2 to 5 working days to review and sign, as appropriate.
	27.	The final signed procedure must be delivered to the Document Control team to include the following: Final Signed Procedure Procedure Review and Concurrence Form(s) Procedure Validation Checklist (if applicable) PCR or DAR Training Level Determination Form as specified in the EP-DIR-SOP-2011 Personnel Training and Qualification procedure and any other related documents. Complete the Document Control Quality Verification Checklist referenced in EP-DIR-SOP-4001, Document Control, procedure.
	28.	Send a final email to the Document Control Coordinator at ep-doccontrol@lanl.gov, attaching the final Word version of the new procedure and deliver hardcopy. Complete a Document Control Verification checklist. Refer to EP-DIR-4001, Document Control procedure, to access the checklist.

2.2   Revising Existing Procedures

Procedure Owner	1.	Contact the Procedure Development team 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.	Complete and send the procedure request form to the Procedure Development team at procedure_help@lanl.gov to initiate assistance in updating a procedure and/or plan.
Procedure Development Team	5.	Prepare a Procedure Change Request (PCR) 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.*
	6.	The approved PCR allows the procedure development team to initiate the 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.
	7.	If the electronic word version is not available, then convert the Adobe Acrobat pdf version posted on the web into a word version.
	8.	Move the data into the Standard Operating Procedure template. Include the procedure title, document control number and change the revision number.
	9.	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.
All	10.	Refer to Section 3.1. Follow Steps 19 through 32.

2.3   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.

2.4	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 • state the reason for cancellation.
Procedure Development Team	2.	Prepare a PCR or DAR form to cancel procedure. Acquire the following signatures on the form: • Responsible Line Manager • Procedure Owner
	3.	Send email to request USQ review.
	4.	Send the completed and signed PCR/DAR with a copy of the procedure or plan that will be cancelled to the Document Control Coordinator for processing.
2.5	Records	
Procedure Development Team	1.	Transmits 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 active procedure package is managed and maintained in the Document Control Office until the procedure is superseded, cancelled, or deactivated.
All	2.	Refer to procedure EP-DIR-SOP-4001, Document Control, for more information on final record submittal to the Records Processing Facility.

3.0   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

4.0   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
1	3/31/10	Moved section 2.2.4 precaution that states EWMO facilities are excluded from using this procedure to the Purpose and Scope Section 1.0. Removed references to Peer Review and made editorial changes.	T/E

Using a CRYPTO Card, click here for "Required Read" credit.

If you do not possess a CRYPTOCard or encounter problems, contact the EP Central Training Office.

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

LIMTs Action #_____   *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 new number   ☐ Process/New Template
☐ PCR Form   ☐ Review & Concurrence Form   ☐ Procedure Validation Checklist

Publication Services coordinated by Procedure Development Manager (optional)

☐ Review/Concurrence Due Date: _____   ☐ Proof Read/Edit
List Procedure 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: _____
_____
_____
_____

Return completed form to the Procedure Development Office (Room 110).

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

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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

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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

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

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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 & understood?			
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 within the limits?			
If an activity is performed by more than one person, is adequate direction provided for communication and coordination?			
Are stop action limits provided for steps which specify adjustments to accomplish a task?			
Part 3, Section B – Plant Compatibility	Yes	No	N/A
Are locations specified by the procedure consistent with field installation?			
Do specified units of measure match those indicated on the instrumentation?			
Are equipment/components 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			