

# Quality Procedure (QP) Interim Change Notice (ICN)

Effective Date: **10/6/05**

1 Page(s)

## Section 1: Description of Change (Requester completes)

1. Document Catalog No.: **ER2005-0745**

2. QP & Rev. No.: **4.1, R5**

3. ICN No.: **1**

4. QP Title: **Quality Procedure Development**

### 5. Description of Change:

All pages – update programmatic and organizational changes.

Section 6.4.3 change to read– The DCC shall ensure that no more than **four (4)** ICNs are issued against a particular procedural revision.

Section 6.4.4 change to read- If **four (4)** ICNs are already issued, the DCC shall inform the author that a revision is required, following section 6.3 of this procedure.

### Section 6.6

#### Add Note:

Effective October 6, 2005, the review period for QPs has been extended for one (1) year. The extension is to institute a new process for document review and control. Training to the procedures is still required for both new hires and for requalification. If a new or revised procedure is instituted, training requirements will be addressed at that time to ensure effective transition.

6.6.2 The author, or the responsible PL, shall submit the procedure review form along with the associated document signature form to the DCC for processing in accordance with QP-4.5, Document Control and Distribution.

Attachments B&C – Sample Flow charts - deleted

6. Attachments Modified, Added, or Removed:  Yes  No

### 7. ICN Justification:

Review period extension increased for one year to institute a new process for document review and control.

Number of allowable ICNs increased to prevent unnecessary revisions.

8. Requester: Cheri Vidlak (Signature on file)

(Print name, then sign.)

(Date)

10/5/05

## Section 2: Evaluation and Approval (PTL, Technical Reviewer, and QPPL complete)

9. Evaluation Remarks: (If none, enter N/A)

10. Team Leader: Phil Noll (Signature on file)

(Print name, then sign.)

(Date)

10/5/05

11. Technical Reviewer: Jackie Kolakowski (Signature on file)

(Print name, then sign.)

(Date)

10/5/05

12. QPPL: Fred Briggs (Signature on file)

(Print name, then sign.)

(Date)

20/5/05

**QP-4.1, R5**

**Los Alamos National Laboratory  
RRES-Remediation Services**

Identifier: <b>QP-4.1</b>	Revision: <b>5</b>	Effective Date: <b>12/10/02</b>	Reviewed Date: <b>05/06/2004</b>
ER Document Catalog Number: <b>ER2002-0577</b>			
Author: <b>Andrew E. Gallegos</b>			
<p><b>Environmental Restoration Project Quality Procedure</b></p> <p>for: <b>Quality Procedure Development</b></p>			
 <p>Los Alamos NATIONAL LABORATORY</p> <hr/> <p>Los Alamos NM 87545</p>	<p>Los Alamos National Laboratory, an affirmative action/equal opportunity employer, is operated by the University of California for the United States Department of Energy under contract W-7405-ENG-36.</p>		

## Revision Log

Revision No.	Effective Date	Prepared By	Description of Changes	Affected Pages
R0	12/16/97	John L. Day	New quality procedure (QP); replaces administrative procedures (APs) AP-01.1 and AP-01.5	All
R1	2/23/98	John L. Day	Format and process changes	All
R2	8/21/98	John L. Day	Format and process changes	All
R3	8/27/99	John L. Day	Format and process changes	All
R4	5/09/01	Andrew E. Gallegos	Revised to incorporate revision log page; section 2.0, Scope; section 3.0, References; new sections to address interim change notices (ICNs), lessons learned, Price-Anderson Amendments Act of 1988 (PAAA) and integrated safety management (ISM) requirements, and periodic procedure review requirements.	All
R5	12/10/02	Andrew E. Gallegos	Revised to incorporate ICN ER2001-0480, use of process flow charts, and format changes. Added Attachment B, "Quality Procedure Deletion Action Request," and information about development and submission of forms. Format changes include deletion of ER logo, table of contents page, and use of <i>shall</i> , <i>will</i> , <i>must</i> , and <i>should</i> . QP template and QP rewritten and restructured so that QP functions as instructions for template..	All
Reviewed	05/06/2004	Phil Noll	Process deemed adequate.	
R5,ICN1	10/6/05	C. Vidlak	Extend review period 1 year, change number of allowable ICNs to 4, organizational and programmatic updates. Delete Attachments B & C, Sample flow charts.	Pages 10, 12, & 16-18. All pages for org. & prog. changes

# Quality Procedure Development

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## List of Acronyms and Abbreviations

AP	administrative procedure	LANL	Los Alamos National Laboratory
DCC	Document Control Coordinator	PAAA	Price Anderson Amendments Act
ECR	Environmental Characterization and Remediation Group	PL	Project Leader
ER	environmental restoration	QP	quality procedure
ERS	Environmental Remediation and Surveillance Program	QPPL	Quality Program Project Leader
ENV	Environmental Stewardship Division	RPF	records processing facility
ICN	interim change notice	SOP	standard operating procedure
ISM	integrated safety management	TL	team leader

# Quality Procedure Development

## 1.0 PURPOSE

This Quality Procedure (QP) states the responsibilities and describes the process for developing, revising, periodically reviewing, creating interim change notices (ICNs), or deleting QPs for the Los Alamos National Laboratory (LANL) Environmental Stewardship (ENV) Division-Environmental Characterization and Remediation (ECR) Group.

**Note:** The same process for requesting a Standard Operating Procedure (SOP) actions is covered in QP-4.2, "Standard Operating Procedure Development."

## 2.0 SCOPE

- 2.1.1 All ECR participants shall implement this mandatory QP for the ECR Group.
- 2.1.2 **Subcontractors** performing work under the ECR Group's quality program shall follow this QP.

## 3.0 TRAINING

- 3.1.1 All **participants** shall train (i.e., read only training) to and use the current version of this QP. Contact the author of this QP if the text is unclear.
- 3.1.2 All **participants** using this QP shall document training in accordance with QP-2.2, "Personnel Training Management," using the training documentation link at the end of this document if they possess a CRYPTOCARD and administrative authority to the Laboratory, employee development system (EDS), or using the Training Documentation Form located in the forms section of the ENV-ECR web page.
- 3.1.3 The responsible **project leader (PL)** shall monitor the proper implementation of this procedure and ensure that the appropriate personnel complete all applicable training assignments.

## 4.0 DEFINITIONS

- 4.1.1 *Action step*—A procedure element that provides instruction for performing a specific process action or task.
- 4.1.2 *Action substeps*—Detailed actions that make up the upper-level action step or that describe how to perform the action step.

- 4.1.3 *Author*—The technical expert who owns the process described within the QP and who retains ultimate responsibility for the technical content.
- 4.1.4 *Document Control Coordinator (DCC)*—The person responsible for maintaining and managing the ER Project document control master list, formatting controlled electronic files for web publication, and ensuring that each QP is reviewed every two years.
- 4.1.5 *Effective date*—The date on which a procedure is sent for web publication.
- 4.1.6 *Identifier*—A unique number assigned to a procedure by the DCC to categorize, identify, and control the procedure.
- 4.1.7 *Interim Change Notice (ICN)*— Notification of procedure changes that are more narrow in scope than those of a major revision.
- 4.1.8 *Major revision*—Changes to a procedure that affect the technical content or process of the work.
- 4.1.9 *Minor revision*—Changes to a procedure (e.g., grammar or spelling corrections, renumbering sections or attachments, changing the title or document number, or updating organizational changes, etc.) that do not affect the technical content or process of the work.
- 4.1.10 *Process flow chart*—A tool used in complex procedures to enable the user to visually track action steps within the procedure or move on to other documents.
- 4.1.11 *Quality procedure (QP)*—Within the ER Project, a document that describes the process for performing any activity governed by the ECR Group Quality Management Plan.

## 5.0 RESPONSIBLE PERSONNEL

The following personnel are responsible for activities identified in this procedure:

- Author
- Document Control Coordinator
- Participant
- Peer Review Task Leader
- Project Leader

- Quality Program Project Leader
- Requester
- Reviewer
- Subcontractor
- Supervisor

## 6.0 PROCEDURE

### 6.1 QP Action Request

**Participants** shall request the development, revision, or deletion of a QP by contacting the ECR Quality Program Project Leader (QPPL).

### 6.2 New QP Development

6.2.1 The responsible QPPL shall assign an author to develop the QP.

6.2.2 The author shall obtain a new QP number (its identifier) from the DCC, providing the QP title and document catalog number from the Document Signature Form generated at <http://erinternal.lanl.gov/DocCatalog/home.asp>.

6.2.3 Before developing a QP, the author should review the following documents to ensure that applicable safety requirements are identified and addressed in the QP:

- The LANL ISM description document, LA-UR-98-2837, located at [http://int.lanl.gov/safety/pdf/desc\\_doc.pdf](http://int.lanl.gov/safety/pdf/desc_doc.pdf)
- The Price Anderson Amendments Act (PAAA), located at <http://aea.genlaw.lanl.gov/PAAA/index.html>.

6.2.4 The **author** shall work with a technical editor assigned to the author's focus area/organization, if applicable, to ensure that the QP is readable, coherent, and in compliance with ECR and LANL guidelines.

6.2.5 The **author** shall make a copy of the MS Word template provided at <http://erinternal.lanl.gov/WritingGuide.shtml> or <http://erinternal.lanl.gov/Quality/user/qps.asp> by opening the template and saving it with a file name that contains its document catalog number, the QP identifying number, and the revision number (e.g., ER2002-0577QP-4.1R3.doc [no spaces]). (The template contains proper formatting, headings, and boilerplate text.)

6.2.6 The **author** shall write the QP according to the general guidelines below:

- 6.2.6.1 Replace or delete the template bracketed text; the remaining text is mandatory, boilerplate text.
- 6.2.6.2 Express required actions by using *shall* in declarative sentences (e.g., “The **manager** shall approve the completed work order” instead of “Completed work orders are approved by the manager”). Use imperative sentences (direct commands) as illustrated throughout this QP.
- 6.2.6.3 Use acronyms and abbreviations as defined in the acronym and abbreviation list located at <http://erinternal.lanl.gov/WritingGuide.shtml>.
- Spell out acronyms and abbreviations at their first use in text, or;
  - Make an alphabetical list of the acronyms and abbreviations.

**Note:** An alphabetical list of acronyms and abbreviations is optional based upon the author’s preferences.

- Insert the list just after the table of contents if the list is shorter than one page. If the list is longer, provide the list as an attachment to the QP.

6.2.6.4 If a procedure is complex, consider incorporating one or more process flow charts under the following conditions:

- The chart does not replace procedural text.
- The chart helps the user better understand the action steps and subaction steps within the procedure.
- The chart is made up of standard flow chart symbols and processes (see Attachment C for examples).
- The chart is an attachment.

**Note:** The use of flow charts is not mandatory.

6.2.7 The **author** shall create QP sections as described below, leaving the template’s boilerplate text intact (the boxed text indicates a required section heading).

6.2.7.1 1.0 PURPOSE

Insert a clear and concise description of the task or operation governed by the procedure.

#### 6.2.7.2 2.0 SCOPE

Insert scope requirements as addressed in the QP template, however, if action step 2.3 does not apply do not enter it in the QP.

#### 6.2.7.3 3.0 TRAINING

Insert training requirements and describe how to meet those requirements (e.g., read only, OJT or classroom).

#### 6.2.7.4 4.0 DEFINITIONS

- Do not include “how-to” instructions or cite references for defined terms.
- Add any QP-related terms that are unique to the QP and any terms that may be unfamiliar to the QP user.
- Use the ENV-ERS Program glossary at <http://erinternal.lanl.gov/resources/docs/glossary.pdf> for writing definitions.

**Note:** If a term’s definition is revised and/or a new definition developed, submit the definition to an ER Project editor for incorporation into the ENV-ERS Program glossary.

- Order the terms and definitions alphabetically and follow the template’s numbering style.

#### 6.2.7.5 5.0 RESPONSIBLE PERSONNEL

List personnel alphabetically (by title or role) with responsibilities described in the QP.

#### 6.2.7.6 6.0 PROCEDURE

- Describe the required work in clear and concise action steps, giving one action per numbered section. If the procedure is complex, group action steps together and add a descriptive subheading, as done in this document. Apply the template’s “level2text TOC” style to these subheadings and create more subheadings, as needed, to show nested subactions.
- Identify by boldfaced title the person (from the section 5.0, RESPONSIBLE PERSONNEL) who performs each step.
- Include descriptions of applicable quality assurance and quality control management processes, and

include any safety requirements that are unique to the QP.

- Include references to any existing documents (e.g., QP-3.4, Managing Nonconformance, Deficiencies, and Corrective Actions) that should be used to demonstrate quality or control.

#### 6.2.7.7 7.0 LESSONS LEARNED

Add lessons learned boilerplate text and web locations as addressed in the template.

#### 6.2.7.8 8.0 RECORDS

- Insert the title or role of the person responsible for record submittal.
- List the QP-generated records that require transmittal to the ER Project Records Processing Facility (RPF).

#### 6.2.7.9 9.0 REFERENCES

- List all documents that are cited in the QP and all those needed for process clarity. (The QP template already contains a set of standard documents and their online location).
- When adding a document that is available from a different web location, provide the URL.

#### 6.2.7.10 10.0 ATTACHMENTS

- Include the template's wording, "The user of this QP may locate all forms associated with this procedure at <http://erinternal.lanl.gov/Quality/user/forms.asp>," only if all forms are online.
- Update the list of attachments in the QP template.
- Add new attachments. If one is an online form, add it by following the example of Attachment A in the QP template and using the appropriate watermark.
- If an attachment is a database-generated form, note that in the section 10.0 list.

6.2.8 The **author** shall ensure that the new QP is developed, reviewed, and approved in accordance with QP-4.9 and QP-3.5.

- 6.2.9 The **author** shall sign and date the Document Signature Form, forwarding a hardcopy of the QP, an electronic copy of the QP, and the signature form to the QPPL for review and approval.
  - 6.2.10 When satisfied that the QP meets the requirements of this procedure, the **QPPL** signs and dates the Document Signature Form.
  - 6.2.11 The **QPPL** shall complete the process by following QP-4.5.
- 6.3 QP Revision
- 6.3.1 If a QP requires major revision (see Section 4.8), the **QPPL** shall ensure that the author initiates the revision by following the appropriate requirements in section 6.2 above and in QP-4.9.
  - 6.3.2 If a QP requires only minor revisions (see section 4.9) that do not affect the technical content or process of the work, the **QPPL** shall ensure that the author follows QP-4.10.
- 6.4 Interim Change Notice (ICN)
- 6.4.1 Before creating an ICN, the **requester** shall consult the author or the QPPL to determine if an ICN is appropriate.
  - 6.4.2 The **requester** shall acquire the ICN number from the DCC, following QP-4.5, "Document Control and Distribution," and a Document Catalog Number in accordance with QP-4.9, "Document Development and Approval Process."
  - 6.4.3 The **DCC** shall ensure that no more than four (4) ICNs are issued against a particular procedural revision.
  - 6.4.4 If four (4) ICNs are already issued, the **DCC** shall inform the author that a revision is required, following section 6.3 of this document.
  - 6.4.5 If an ICN is appropriate, the **requester** shall fill out a QP ICN form located at <http://erinternal.lanl.gov/Quality/users/forms.asp> (see Attachment A).
  - 6.4.6 The **requester** shall enter a justification for the ICN in block 7 of the form and ensure that the justification is consistent with the definition of ICN in section 4.7 of this document.
  - 6.4.7 The **requester** shall obtain review and concurrence from at least one technical reviewer, as well as from the QPPL.
  - 6.4.8 The **reviewer** shall consider the changed portion of the procedure, the effects of the changes on the procedure, and the results of implementing the changed procedure.

6.4.9 After reviewing and approving the ICN, the **QPPL** shall forward an electronic copy of the ICN and the completed Document Signature Form to the **DCC** for processing.

6.4.10 The **DCC** shall process the ICN in accordance with QP-4.5.

## 6.5 QP Deletion

6.5.1 The **requester** of the deletion shall help the QPPL determine if the procedure is eligible for deletion by providing key information, for example:

- the relevant procedural requirements are no longer addressed in upper-tier documents such as 10 CFR, Part 830, Subpart A; Department of Energy Order 414.1; or Laboratory Implementation Requirements;
- a particular procedure's requirements will be, or are currently, integrated into another procedure(s);
- the ENVERS Program is no longer required to implement the processes addressed in the procedure; and/or
- the procedure requires total revision and/or is replaced by another procedure or form.

6.5.2 After obtaining the information addressed in action step 6.5.1, and a determination has been made to delete the QP, the **QPPL** shall send a global email to all participants addressing the deletion.

6.5.3 If a procedure user objects to the deletion, that procedure **user** shall notify the **QPPL** within ten working days of receiving the deletion notification.

6.5.4 After ten days, if no objection is made, the **QPPL** notifies the DCC to delete the procedure.

6.5.5 The **DCC** processes the deleted procedure in accordance with QP-4.5.

## 6.6 Periodic Review of Procedures

Note: Effective October 6, 2005, the review period for QPs has been extended for one (1) year. The extension is to institute a new process for document review and control. Training to the procedures is still required for both new hires and for requalification. If a new or revised procedure is instituted, training requirements will be addressed at that time to ensure effective transition.

6.6.1 The **author** or the **QPPL** shall review each QP within his/her purview at least every two years in accordance with QP-4.5 to

ensure that the QP meets current requirements, processes, regulations, standards, and/or laws.

- 6.6.2 The **author**, or the responsible **PL**, shall submit the procedure review form along with the associated document signature form to the DCC for processing.

## 7.0 LESSONS LEARNED

Before performing the work described in this QP, **participants** should go to the Department of Energy Lessons Learned Information Services home page, located at <http://www.tis.eh.doe.gov/ll.ll.html>, and/or the LANL Lessons Learned Resources web page, located at [http://www.lanl.gov/projects/lessons\\_learned/](http://www.lanl.gov/projects/lessons_learned/) and search for applicable lessons.

## 8.0 RECORDS

The **author** and **DCC** shall submit, as applicable, the following records to the RPF in accordance with QP-4.4:

- A hard copy of the approved new or revised QP
- A signed hard copy of the completed Document Signature Form
- A signed hard copy of the completed ICN form, if applicable
- A signed hard copy of the completed Quality Procedure Deletion Action Request form, if applicable
- An electronic copy of the approved new or revised procedure

## 9.0 REFERENCES

To properly implement this QP, **participants** should become familiar with the contents of the following documents located at [http://erinternal.lanl.gov/home\\_links/Library\\_proc.shtml](http://erinternal.lanl.gov/home_links/Library_proc.shtml):

- ER Project Quality Management Plan
- QP-2.2, Personnel Orientation and Training
- QP-2.3, Personnel Exit and Entry Process
- QP-3.5, Peer Review Process
- QP-4.2, Standard Operating Procedure Development
- QP-4.4, Record Transmittal to the Records Processing Facility
- QP-4.5, Document Control

- QP-4.9, Document Development and Approval Process: Peer Review Required
- Editing and Composition Guidelines for Preparing ER Project Documents, located at <http://erinternal.lanl.gov/WritingGuide.shtml>
- Los Alamos National Laboratory Integrated Safety Management Description Document, LA-UR-98-2837, located at [http://int.lanl.gov/safety/pdf/desc\\_doc.pdf](http://int.lanl.gov/safety/pdf/desc_doc.pdf)
- Price Anderson Amendments Act, located at <http://aea.genlaw.lanl.gov/PAAA/index.html>

## 10.0 ATTACHMENTS

The user of this QP may locate all forms associated with this procedure at <http://erinternal.lanl.gov/Quality/user/forms.asp>.

Attachment A: Quality Procedure Interim Change Notice form and instructions (2 pages)

[Using a token card, click \(+control key\) here to record "self-study" training to this procedure.](#)

If you do not possess a token card or encounter problems, contact the ENV-ECR training specialist.

# Quality Procedure (QP) Interim Change Notice (ICN)

Effective Date: \_\_\_\_\_  
Page(s)

## Section 1: Description of Change (Requester completes)

1. Document Catalog No.: **ER200 -**

2. QP & Rev. No.:

3. ICN No.:

4. QP Title:

5. Description of Change:

6. Attachments Modified, Added, or Removed:

Yes

No

7. ICN Justification:

8. Requester: \_\_\_\_\_

(Print name, then sign.)

(Date)

## Section 2: Evaluation and Approval (PTL, Technical Reviewer, and QPPL complete)

9. Evaluation Remarks: (If none, enter N/A)

10. Project Team Leader: \_\_\_\_\_

(Print name, then sign.)

(Date)

11. Technical Reviewer: \_\_\_\_\_

(Print name, then sign.)

(Date)

12. QPPL: \_\_\_\_\_

(Print name, then sign.)

(Date)

**QP-4.1, R5**

**Los Alamos National Laboratory  
Environmental Restoration**

## ICN Form Instructions

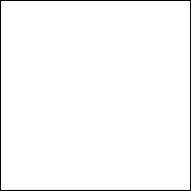
### **Section 1: Description of Change** (Requester completes.)

1. Enter the document catalog number for this ICN acquired from <http://erinternal.lanl.gov/DocCatalog/home.asp>.
2. Record the QP number and revision number.
3. Record the current ICN number acquired from DCC.
4. Record the procedure title.
5. Describe the changes in detail. Provide marked-up copies of the procedure or attach additional sheets, as necessary.
6. Were procedure attachments modified, added, or removed? Check *yes* or *no*. If *yes*, identify the affected attachments.
7. Provide a clear and concise justification for the change(s).
8. Print your name, then sign and date the form.

### **Section 2: Evaluation and Approval** (QPPL, Technical Reviewer, and PTL complete.)

9. Either the PTL or the QPPL records any evaluation remarks; if there are none, enter *N/A*.
10. The PTL prints name, then signs and dates the form.
11. The technical reviewer prints name, then signs and dates the form.
12. The QPPL prints name, then signs and dates the form.

Example



**t.)**