PREPARATION, REVIEW, AND APPROVAL OF PROCEDURES

Purpose

This Meteorology and Air Quality Group (MAQ) procedure describes the process for initiating, reviewing, approving, revising, and deleting a group procedure.

Scope

This procedure applies to the preparation, revision, and deletion of all procedures developed by MAQ group personnel or contractors working under the criteria of the MAQ Quality Management Plan.

In this procedure

This procedure addresses the following major topics:

Topic	See Page
General Information About this Procedure	2
Who Requires Training to this Procedure?	2
Preparing and Revising a Procedure	4
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Finalizing a Procedure	8
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Hazard Control Plan

The hazards associated with the work described in this procedure are documented in HCP-MAQ-Office Work.

Signatures

Prepared by: (Signed) Terry Morgan, QA Officer	Date: 8/20/03
Approved by: (Signed) Jean Dewart, MAQ Group Leader	Date: 8/21/03

01/26/04

CONTROLLED DOCUMENT
This copy is uncontrolled if no red stamp is present on printed copies.
Users are responsible for ensuring they work to the latest approved revision.

General information about this procedure

Attachments

This procedure has the following attachments:

Attach. Number	Attachment Title	No. of pages
1	Procedure Traveler	1
2	Guidance and Format for Writing a Procedure	8

History of Revision

Revision	Date	Description of Changes
0	3/15/95	New document.
1	4/16/96	Added steps and space on traveler for safety review determination.
2	2/20/97	Corrected reference to ESH-5 for safety reviews, removed required approval by ES&H groups, and changed “teams” and “programs” to “projects.”
3	7/20/98	Added steps on incorporating safety review as required by new LIR on Safe Work Practices. Added new required block for reference to Hazard Control Plan. Revised part 3 of traveler.
4	6/29/99	Replaced “minor changes” with “quick-change revisions” and added new checkbox to traveler.
5	8/13/99	Changed to integrate hazard control plan documentation into procedures and added chapter *Annual Review of Procedures*.
6	4/15/02	Quick-change revision to change name of division/ group designator.
7	8/21/03	Quick-change revision to add instruction on integration of security requirements.

Who requires training to this procedure?
(continued on next page)

The following personnel require training before implementing this procedure:

- group leader
- QA officer
- project leaders
- preparer

Not required to be trained to this procedure are:

- originators of procedure travelers
- reviewers of procedures
- document control coordinator

General information, continued

Who requires training to this procedure?, *continued*

Personnel previously trained to revision 6 of this procedure do not require retraining.

Training method

Training to this procedure will be by **"self-study" (reading)** and will be documented in accordance with the procedure for training (MAQ-024).

Prerequisites

In addition to training to this procedure, the following training is also required prior to performing this procedure:

- MAQ-035, "Work Safety Review and Authorization"

In lieu of training to MAQ-035, another individual who is trained to that procedure may conduct the hazard analysis and prepare the Hazard Control Plan.

Definitions specific to this procedure

Procedure: A procedure is a document that describes the methods to perform and implement critical administrative and technical processes within the group.

Quick-change revisions: changes to a procedure that do not affect the safety aspects of the process, do not substantially affect the technical aspects of the procedure, and do not substantially affect those who follow the procedure or use the procedure's results.

References

The following documents are referenced in this procedure:

- MAQ-024, "Personnel Training"
- MAQ-030, "Document Distribution"
- MAQ-035, "Work Safety Review and Authorization"
- LIR300-00-01, "Safe Work Practices," Laboratory Implementation Requirements, issued January 16, 1998
- LIR300-00-02, "Documentation of Safe Work Practices," Laboratory Implementation Requirements, issued August 19, 1998

Note

Actions specified within this procedure, unless preceded with "should" or "may," are to be considered mandatory instruction (i.e., "shall").

Preparing and revising a procedure

Who may originate action on a procedure?

The originator is **any employee** within the group who may request a

- new procedure,
- revision to any existing procedure, or
- deletion of an existing procedure.

Steps to request a change

To request a new procedure, a procedure revision, or a procedure deletion:

Who	Actions
Originator	• Complete part 1 of a procedure traveler (Attachment 1). • Forward the procedure traveler to the responsible manager (either a project leader or the group leader).

Steps to delete a procedure

If deletion of a procedure is requested:

Who	Actions
Responsible manager	• Approve the deletion of the procedure by signing part 2 and by marking "N/A" in parts 3, 4, and 5 of the procedure traveler. • Notify the group leader, QA officer, and the group document control coordinator that the procedure is to be deleted and forward the procedure traveler to the group document control coordinator. • Review other procedures to ensure no other impacts result from the deletion (e.g., references to deleted procedure).

No further actions are performed for deletions of procedures.

Making a quick-change revision to an existing procedure

Changes that meet the definition of a "quick-change revision" do not require the same approval and review steps as revisions. No formal review is performed. The procedure receives the next revision number and a revision of any applicable hazard control plan is prepared (so revision numbers match).

NOTE: Agreement that the proposed changes meet the definition of a quick-change revision will be indicated by signatures of the QA officer and Group Leader on the final title page of the procedure.

Continued on next page.

Preparing and revising a procedure, continued

Who	Actions
Responsible manager	• Complete part 2 of the procedure traveler; enter "no review necessary" in middle of part 2. • Mark "N/A" in parts 3 and 5 of the procedure traveler. • Designate a preparer to make the quick-change revisions.
Preparer	• Make the changes to the procedure, including incrementing the revision number. • Mark the changes with change bars (see the block "Indicating where changes were made"). • Update the History of Revision table. • Print a revision of any applicable hazard control plan with the new procedure's revision number and obtain approval of the HCP according to RRES-MAQ-035. • Skip to the chapter *Finalizing the Procedure.*

Steps to initiate a new or revised procedure

After the form is completed by the originator and received by the responsible manager:

Who	Actions

Responsible manager	• Complete part 2 of the procedure traveler.
	• Designate a preparer to perform the requested action.
	• Determine who *must* review the procedure and enter this information on the traveler (required reviewers). This includes, if applicable:
	  • at least one group employee who will perform the procedure (if not the preparer)
	  • external or internal experts on the subject or process of the procedure, if determined necessary
	  • a representative of any organization outside the group who performs actions specified in the procedure
	• Determine who *should* review the procedure and enter this information on the traveler (optional reviewers). This may include additional technical experts and/or those who provide the input data or information to the process.
	• Forward the procedure traveler to the preparer.

Getting a new procedure number

For new procedures, the **preparer** contacts the QA officer to obtain a number for the new procedure.

Preparing and revising a procedure, continued

Steps to prepare or revise a procedure

After the preparer is assigned responsibility to revise a procedure or to prepare a new procedure:

Who	Actions
Preparer	• Refer to copies of applicable requirements documents. • Consider any requirements given in the group Quality Management Plan that must be addressed by the procedure. • Prepare the procedure in accordance with Attachment 2 (*Guidance and Format for Writing Procedures*) (request assistance from the group QA team). • If the procedure process involves any work other than office and computer work, prepare a Hazard Control Plan in accordance with MAQ-035 and include the plan as Attachment 1. • If the procedure process involves office and computer work, include a reference to the hazard control plan that documents the hazards of this work. • After the Hazard Control Plan is completed, the preparer incorporates all required administrative and engineering controls, that were identified in the Hazard Control Plan, into the procedural steps in the appropriate locations. Also include any emergency steps to take, if appropriate. See NOTE in next block below. • Mark the procedure "DRAFT" when it is ready for review.

Note on incorporating ES&H and security requirements

It is group policy that environment, safety, health, and security considerations should be integrated into procedures at the point or points where the user needs to be aware of such issues and/or take specific related steps. Separate "ES&H procedures" are not recommended except for general safety knowledge topics. Separate "activity security plans" are not recommended except in special cases where no procedure or stand-alone HCP exists.

Indicating where changes were made

For revised procedures, it often speeds review and retraining if reviewers and users can easily determine what was changed from the previous revision. *Change bars* or *shading* may be used for this purpose.

The **preparer** indicates revised portions of the procedure by placing a vertical line in the right margin beside the affected text or by shading the text. Revision marks are unnecessary if most of the text is revised.

Reviewing a procedure

When the procedure is ready to be reviewed

After the draft procedure is ready:

Who	Actions
Preparer	• Forward copies of the draft procedure to the affected organization's managers, to those listed in part 2 of the traveler (if any), and a copy to the group QA team for review. • If environment, safety, and health groups must also review the procedure for environment, safety, and health considerations, send a copy to the safety group's coordinator with the appropriate form requesting review.
Leaders of projects affected by procedure	• Assign at least one qualified reviewer from within the project to perform a review of the procedure. • Review the appropriate QA project plan and determine whether revision of the plan is necessary. **NOTE**: The project leader may be the reviewer.
Reviewers	• Review the draft procedure and record comments on the copy of the draft procedure or on a separate sheet. • Return the comments to the preparer on or before the due date. If unable to complete the review in the allotted time, the reviewer should contact the preparer to arrange an agreeable review time.
Preparer	• Contact the reviewer to confer, either by phone or meeting, and resolve all comments. • If the reviewer and the preparer cannot come to an agreement on requirements, either person may elevate resolution to the project leader or to successively higher levels of group management. • If there are substantial changes to the procedure as a result of the review process, consider redistributing the procedure for review. • After comments are resolved, obtain the signatures of reviewers on the procedure traveler. (This provides a record of the review process and eliminates the need to keep other records of the review and comment resolution. Copies of reviewers' comments may be kept as records at the discretion of the project leader or preparer.)

Finalizing a procedure

Assistance available

The group **QA team** will be available to assist the preparer in formatting and printing the final copy.

Steps to prepare the final copy

After comments are resolved:

Who	Actions
Preparer	• Incorporate final comment resolutions into the procedure. • Ensure the procedure pages are properly formatted (according to Attachment 2). • Ensure that all associated attachments are included. • Mark the forms attached to the procedure “Example” and retain an original set of unmarked forms without headers. • Sign the first page of the procedure. • Forward the final procedure to the team leader(s), if necessary; the QA team leader; and the group leader for approval.

Who approves the procedure?

For procedures that apply to the whole group, the **QA officer** and the **group leader** will approve.

For procedures that apply to one or more projects but not to the group as a whole, the **project leader(s)**, the **QA officer**, and **group leader** will approve.

Another manager, such as a **project leader** or **program manager** from another organization, may also approve, depending on the applicability of the procedure.

Finalizing a procedure, continued

Approving the procedure

Upon receipt of the final version of the procedure:

Who	Actions
Approvers	Approve the procedure by signing in the approval block when assured that • all applicable requirements have been addressed; • reviewer comments have been adequately resolved; • the procedure sufficiently covers the subject matter; • environment, safety, and health groups, if required by the required safety review (see MAQ-035), either have approved or are expected to approve the procedure.
Responsible manager(s)	Prepare an initial distribution list of individuals who may need the procedure and forward the approved procedure to the group document control coordinator for processing and distribution.
Group safety officer or **group leader**	Sign part 4 of the traveler to indicate that the safety review process (MAQ-035) was followed (including development and approval of any required hazard control plan) and to authorize trained workers to perform the procedure.

Distribution of the completed procedure

After receiving the procedure, the **group document control coordinator** enters the effective date (the date of anticipated distribution) on the title page and in the History of Revisions table and distributes the procedure in accordance with the procedure for procedure control (MAQ-030).

Submitting records

After the procedure has been distributed, the **preparer** submits the records listed in *Records resulting from this procedure* to the group records coordinator.

Annual review of procedures

Tracking need for annual review

The **QA officer** tracks the effective dates and ensures each procedure is reviewed annually by the process owner.

Conducting annual reviews

The **QA officer** requests each process owner to review the procedure to determine if the procedure accurately describes the process followed.

If the procedure has a Hazard Control Plan, the **QA officer** ensures the group safety officer or safety committee reviews the plan and that this review is included with the documentation of the review of the procedure (see block below).

If either the procedure or the HCP needs revision, initiate a Procedure Traveler for the revision.

Documenting annual reviews

The **QA officer** documents the annual review of the procedure and, if applicable, the Hazard Control Plan, in an appropriate record (such as a memo to file).

Records resulting from this procedure

Records

The following records generated as a result of this procedure are to be submitted **within two weeks of the effective date** to the group records coordinator:

- Procedure Traveler
- copy of first draft of procedure (unnecessary if revision is for quick-change revisions or deletions of procedures)
- if required, ESH form requesting review by environment, safety, and health groups
- copy of approved procedure (unnecessary for deletions of procedures)
- documentation of annual reviews
- **optional**: reviewers' comments and comment resolutions

Click here to record "self-study" training to this procedure.

Meteorology and Air Quality Group

PROCEDURE TRAVELER

This form is from RRES-MAQ-022

Part 1 (completed by any group employee)

Procedure number: _____ Revision: _____

Procedure title: _____

Action Requested: ☐ New procedure ☐ Major revision of existing procedure ☐ Deletion of existing procedure

Description of and reason for action: ☐ Quick-change revision of existing procedure (parts 3 and 5 N/A)

Signature	Name (print)	Date

Part 2 (completed by appropriate manager)

I agree with the action requested: ☐ Yes ☐ No If No, enter reasons below.

If Yes, assigned preparer: _____. Affected teams, programs, groups, or individuals required to review this procedure and others who should review it (see procedure page 5):

Required reviewers: Optional reviewers:

Signature	Name (print)	Date

Sample

Part 3 (completed by preparer or other qualified safety reviewer)

I have evaluated, according to MAQ-035 and LIR300-00-01, the risks inherent in performing this procedure and have documented them on the Hazard Control Plan form, or referred to a plan that covers this type of work.

Preparer	Name (print)	Date

Draft prepared and sent for formal review on: _____. Comments resolved on: _____. After comments have been resolved with each reviewer, obtain signatures of the reviewers in part 5.

Part 4 (signed by safety officer or group leader)

I agree that the appropriate safety-related activities and appropriate risk level were identified during the hazard evaluation:

Safety officer or group leader	Name (print)	Date

Part 5 (signed by required reviewers: NA for quick-change revisions)

I attest that all my comments and concerns have been satisfactorily discussed, resolved, and/or incorporated into the final version of the procedure.

Signature	Name (print)	Date

Preparer: After all reviewers have signed above section, submit this form with copy of draft and final procedure to records coordinator.

GUIDANCE AND FORMAT FOR WRITING A PROCEDURE

Purpose of these guidelines

This attachment provides guidance to preparers of procedures so they can develop effective procedures that include required elements. The users of the procedures will find a professional and consistent format advantageous because similar information can be found in the same place from procedure to procedure.

NOTE: The QA team can take responsibility for the final formatting of the procedure for the preparer. The specifications for fonts, page headers, etc., are provided herein for completeness. A Word template file is available on the network.

Elements of the format

The format used is based on a method called *information mapping*. The major elements of the format are:

Term	Description
Block	A *block* is a "chunk" of information about one part of a subject. A block is characterized by the homogeneous nature of its contents. Each block has a descriptive label in the left column, is separated from other blocks with a horizontal line, and contains one or more paragraphs. The block format allows the reader to easily locate and comprehend information.
Tables	A table, like this one, is a graphic summary of similar information. Tables can be used in many ways and formats.
Chapter	Each chapter of the procedure presents a major topic. Each new chapter starts on a new page and is titled with the topic. A number may be used (optional) to identify the chapters.

Developing a procedure

Hints for developing a procedure

As a starting point for developing or revising a procedure, a flow chart of the process to be described is highly recommended. The flow chart will clearly show the steps and order of the process. It will also help identify the major topics that will form the chapters of the procedure. It may be included as an attachment to the procedure to assist the reader, but ensure that it stays accurate when the procedure process is revised during reviews and revisions.

Writing style

State the specific actions and what is to be done in clear, concise, step-by-step instructions, in the order the steps are to be completed. The procedure must include the essential or critical steps, but additional steps may be necessary to fill out or fully describe the process. Such steps may be included and qualified with “should” or “may.” When the order is not critical, you may include a note to indicate that certain steps may be performed before or after other steps.

For technical processes (generally performed by one person), each instructional step should start with a verb describing the step.

For procedures describing administrative processes (generally performed by several people), each step should start with the position or job title in **bold** print followed by a verb describing the step. A table can also be used to list the responsible position in one column and the steps in another column.

Separate the instructional steps from informational or descriptive text, preferably by using a separate block.

When required, an “if” or “when” clause at the beginning of the sentence may be used to qualify the performance of an instructional step.

Suggested process blocks

For procedures that describe technical processes, provide blocks to

- describe the need for the process,
- state the intent,
- present the principles upon which the process is based,
- present precautions and other prerequisite information,
- list any special permits or approvals that must be obtained before initiating the process, and
- list equipment needed to perform the tasks.

Developing a procedure, continued

Block titles

The following are examples of recommended block titles for some of the blocks suggested above:

- Introduction
- Equipment needed
- Steps to ....
- Before you begin
- How to ....
- Warning
- Caution
- Note

Example procedure steps

Procedural steps to accomplish a task can be presented in a table like the following example:

Follow these steps to delete a file from the database:

Step	Action
1	Pull up the file on the screen. Is it the correct file? If yes, go to step 2. If no, call your supervisor.
2	Copy down the file number. It will have 17 digits.
3	Erase the screen by pressing the *erase screen* key.
4	Do you want to print a copy of the file before you delete it from the database? If yes, go to Step 5. If no, go to Step 7.
5	etc...

Elements of all procedures

Procedure number

The procedure number is a unique alphanumeric identifier configured as follows:

RRES-MAQ-yyy, Rn; where

- RRES-MAQ indicates a Los Alamos National Laboratory Air Quality Group document (this identifier may change but will not refer to a different procedure and will not require revision of the procedure)
- yyy is the number of the procedure
- R indicates a revision
- n is the procedure revision number (0 indicates the initial procedure)

The group QA team will issue new numbers.

If the *title*, *scope*, or *purpose* of a procedure is significantly changed (i.e., other than minor editorial changes), consider it a new procedure rather than a revision and give it a new number.

Page specifications

Set the page margins at 1.2 inches at top and 1 inch on left, right, and bottom. If desired, forms (attachments) may have smaller margins to maximize space usage and provide for borders.

Place the block labels in the left column (about 1 1/8 inch wide) in bold type.

Type font

The type font should be 12 point Times New Roman or equivalent.

For the procedure title on page one and for the chapter headings, Arial or Helvetica 17 point may be used.

Elements of all procedures, continued

Headers

Each header contains the procedure number, revision, and pagination, in the format used in this procedure. Attachments have similar headers that indicate the attachment number.

The procedures are double-sided, with odd and even page headers for the body of the procedure and for each attachment. This allows the page numbers and document number to be on the unbound edges.

The first page header has "Effective date" in the middle box. The group document control coordinator enters the effective date of the procedure just before first distribution.

First page of the procedure

The first page contains the following blocks:

Block	Description
Purpose	State what the procedure is designed to do.
Scope	Define the limits of application of the procedure: affected activities, organizations within the division or group, and/or personnel (for clarity, specific exclusions may be stated).
In this procedure	In a table, list the major topics that are addressed in the procedure and give the page number in the second column of the table. This block may be moved to page 2 if this block plus the signatures block do not fit on the page.
Hazard Control Plan	For procedures that require an HCP, insert the text: "The hazard evaluation associated with this work is documented in Attachment 1: Initial risk = _____. Residual risk = ____. Work permits required: ____. First authorization review date is one year from group leader signature below; subsequent authorizations are on file in group office." For procedures that are covered by the HCP for office work, insert the following text: "The hazard evaluation associated with this work is documented in HCP-MAQ-Office Work."

Continued on next page.

Elements of all procedures, continued

Block	Description
Signatures	Provide a signature table with rows for the preparer, the QA officer, and for the group leader. If other project leaders must approve, add extra rows. If environment, safety, and health groups must review and approve, add extra rows. If all signatures do not fit on first page, leave preparer's and group leader's on first page, move others to second page.

Second page of the procedure

The second page of the procedure is labeled "**General information about this procedure**" and contains the following blocks:

Block	Description
Attach-ments	If there are attachments, list in a table the attachment number, title, and number of pages for each attachment to the procedure.
History of Revision	List all the revision numbers (beginning with 0), effective dates, brief descriptions of the revisions, and, if appropriate, information regarding superseded procedures.
Who requires training to this procedure?	Specify the individuals (by position or job title) who must be trained before performing the activities described in the procedure. Specific personnel who do not need to be trained to the procedure may also be listed.
Training method	Describe the type of training, as described in the training procedure (either "self-study [reading]," "classroom," or "on-the-job"), that is required for the procedure.
Prerequi-sites	(Optional) List any training prerequisites for the performance of the procedure. Example: "The following courses are also required before conducting field work: • First Aid (recertification annually), • Cardiopulmonary Resuscitation (recertification annually), and • Field Survival (one time only)."

Elements of all procedures, continued

Third page of the procedure

The third page is labeled "**General information**, continued" and contains the following blocks.
NOTE: For short procedures, these blocks may be moved to the second page.

Block	Description
Definitions specific to this procedure	If any, provide definitions for terms and items that are specific to the procedure.
References	If any, list the documents cited in the procedure.
Note	The note should state "Actions specified within this procedure, unless preceded with 'should' or 'may,' are to be considered mandatory instruction (i.e., 'shall')."

Fourth and following pages of the procedure

Title the page with the description of the first major topic of the procedure. Make appropriate blocks with titles to describe what is to be done and to provide additional information on safety, suggestions, notes, and warnings.

For each major topic, start a new page with the description of the topic as the title of the page. A number may be added to the front of the topic title to help orient the readers within the document.

Records

The last page and chapter of the procedure should be *Records Resulting from this Procedure.*

List the documents that are to be generated as a result of the performance of the procedure and state where the record is to be submitted. The records that are to be kept should provide objective evidence to an independent observer that the procedure was properly followed.

Elements of all procedures, continued

Attachments

For procedures that require an HCP, include it as Attachment 1.

Include forms, figures, examples, and supplementary documents to the procedure as "Attachments." Title with the same titles as those listed in the attachments block of the procedure. Number attachments sequentially (i.e., "Attachment 1," "Attachment 2") and place in order after the last page of the procedure.

Each attachment is paginated separately from the procedure (e.g., the first page of a three-page attachment would be labeled "Page 1 of 3"). Similarly to the procedure body, each attachment's header contains the procedure number and revision, attachment number, and pagination in the upper corner, as in the following example:

RRES-MAQ-002, R0
Attachment 4, Page 1 of 2

Stamp each form "**EXAMPLE**" when distributed as attachments in the procedure. Attachments that provide supplementary information (e.g., this attachment) should not be stamped.

Meteorology and Air Quality Group

PROCEDURE TRAVELER

This form is from MAQ-022

Part 1 (completed by any group employee)

Procedure number: _____ Revision: _____

Procedure title: _____

Action Requested: ☐ New procedure ☐ Major revision of existing procedure ☐ Deletion of existing procedure

Description of and reason for action: ☐ Quick-change revision of existing procedure (parts 3 and 5 N/A)

Signature	Name (print)	Date

Part 2 (completed by appropriate manager)

I agree with the action requested: ☐ Yes ☐ No If No, enter reasons below.

If Yes, assigned preparer: _____. Affected teams, programs, groups, or individuals required to review this procedure and others who should review it (see procedure page 5):

Required reviewers: Optional reviewers:

Signature	Name (print)	Date

Part 3 (completed by preparer or other qualified safety reviewer)

I have evaluated, according to MAQ-035 and LIR300-00-01, the risks inherent in performing this procedure and have documented them on the Hazard Control Plan form, or referred to a plan that covers this type of work.

Preparer	Name (print)	Date

Draft prepared and sent for formal review on: _____. Comments resolved on: _____. After comments have been resolved with each reviewer, obtain signatures of the reviewers in part 5.

Part 4 (signed by safety officer or group leader)

I agree that the appropriate safety-related activities and appropriate risk level were identified during the hazard evaluation:

Safety officer or group leader	Name (print)	Date

Part 5 (signed by required reviewers: NA for quick-change revisions)

I attest that all my comments and concerns have been satisfactorily discussed, resolved, and/or incorporated into the final version of the procedure.

Signature	Name (print)	Date

Preparer: After all reviewers have signed above section, submit this form with copy of draft and final procedure to records coordinator.