Sections Included in this Document and Document History

1. Purpose

To assure that quality system documents used by [Name] employees are properly developed, approved, active and located where needed. Quality system documents include the following: manuals, procedures, Work Instructions (WIs), methods, policies and regulations.

2. Scope

This procedure applies to the control of documents including electronic and external, which calls for quality requirements or prescribes activities affecting quality such as methods, regulations, directives, procedures and instructions, pertaining to the [Name] Quality Management System (QMS).

3. Responsibilities

A. [Third Level Manager]:

- reviews policies and procedures in their area of responsibility,
- verifies the technical accuracy of the procedures in their area,
- identifies training needs resulting from new or revised procedures, and
- resolves any conflict between the reviewer and preparer of the procedure.

B. [Second Level Manager]:

- reviews and approves branch related procedures,
- ensures resources are provided to accomplish quality work, and
- ensures identified training is implemented.

C. [First Level Manager]:

- ensures implementation of document control system,
- is the final reviewing and approving authority for policies and procedures,
- ensures documents are revised and active, and
- performs clearance duties and assigns reviews as requested from other units.

D. Quality Management System (QMS) Manager:

- implements and maintains document control system,
- coordinates reviews and revisions of quality system documents,
- maintains electronic Master List to ensure active and revised documents are provided to staff, and
- archives superseded or obsolete documents.

E. Staff:

- is responsible for verifying that the official version of the document is used by checking the Master List located [Location],
- reviews and determines need for new procedures or modification of procedures,
- initiates changes by completing a Document Change Request (DCR) form, and
- ensures correct formatting conventions are followed.

4. Background	None

5. References

ORA-QMS.1.0 Document Control, Version 1, 10-01-2000

ORA-QMS.1.1 Document Numbering Conventions, Version 1.0, 10-01-2000

ORA-QMS.1.2 Document Formatting Conventions, Version 1.0, 10-01-2000

ORA-QMS.1.3 Document Change Request Requirements, Version 1.0, 10/01/2000

ORA-QMS.1.4 Document Development, Review and Approval Requirements, Version 1.0, 10-01-2000

ORA-QMS.1.5 Document Publication and Notification Requirements, Version 1.0, 10-01-2000

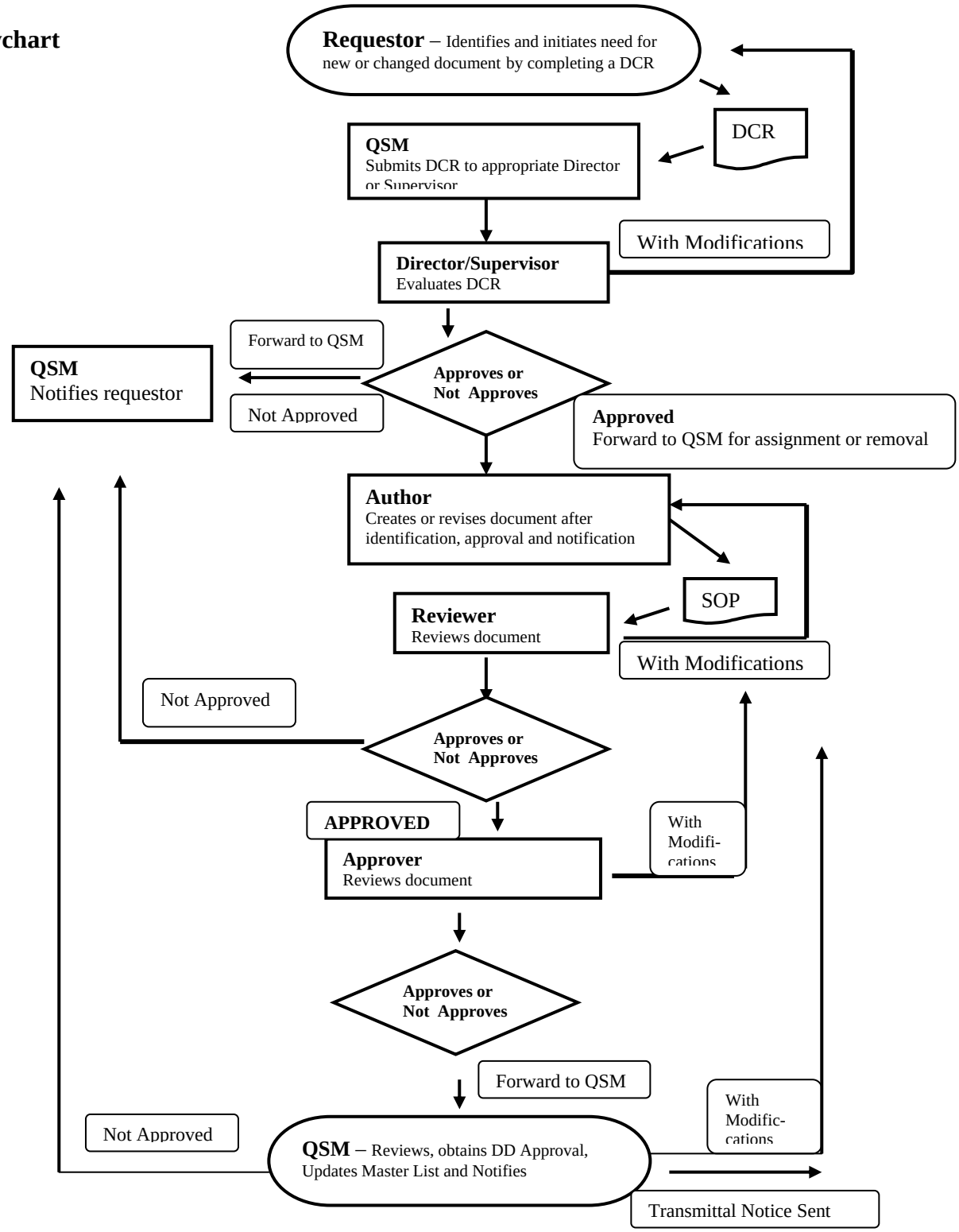
ORA-QMS.1.6 Document Template Use, Version 1.0, 10-01-2000

ORA-QMS.1.7 Document Monitoring for Continuing Relevance, Version 1.0, 10-01-2000

6. Procedure

Flowchart on next page.
See Attachment C for the step by step DCR Process.

6.1
Flowchart



6.2 Document Numbering

A. Numbering format will be alphanumeric, separated by a period, for example: XXX.# or XXX-XXX.#.#. Where XXX is the abbreviation for the district (i.e [Name]) and the second XXX is used if limited to an identified branch within the district (i.e. LB for Laboratory, IB for Investigations Branch, CB for Compliance Branch, ADM for Administration). A third XXX may be used to further specify within the section (i.e. [Name]-LB-EQ.1). Where # is the number of the document followed by the second # to group related documents, for example: [Name]-LB.7 and [Name]-LB.7.1.

B. Versions are numbered sequentially. The version number followed by a second sequential number (i.e. 1.1) notes minor revisions. Major revisions will result in a new version number, which will be the next sequential number (i.e. 2.0). See definitions for minor and major revision.

C. Drafts are identified as DRAFT with a letter (A, B, C) to indicate the sequential revisions of the document. Drafts will not be logged or tracked.

D. The QMS Manager assigns and maintains document numbers.

6.3 Document Formatting

A. Documents are formatted according to ORA-QMS.1.2. See document template on the [Location].

B. ORA-QMS.1.2 and ORA-QMS.1.6 contain instructions on format and use of the template.

6.4 Document Change Request

A. Document Change Request (DCR) form is used to initiate the development or change of procedural documents. The DCR form is located on [Location] or DCRFORM.doc. The DCR contains at least the following information:

- DCR#;
- date of request;
- requestor's name;
- contact information;
- document involved;
- comments and instructions with supporting documentation;
- follow-up and by whom; and
- final response, date and by whom.

B. The DCR is submitted by the QSM to the {First Level Manger], [Second Level Manager] for action and evaluation. The QMS Manager maintains and tracks the DCR to ensure process is completed within 30 days. The QSM notifies the requestor by email of the decision to create, revise, remove or take no action after completion of process.

6.5 Developing, Reviewing and Approving

A. Document Initiation:

1. If the decision was made to remove the document, the QMS Manager removes and archives the document and updates the Master List.

2. For document creation or revision, the authors, reviewers and approvers will be identified by the QMS Manager according to the organizational level and approved by the [First Level Manager]. Document revisions are reviewed and approved by the same persons of the branch or section identified in the original review unless designated otherwise on the form.

3. The authors can proceed with preparing the DRAFT of the new or changed document. Document changes will be summarized in, as well as, additional training or resources.

4. The QMS Manager monitors the timely completion of the project.

B. Document Review:

1. The author submits the new or revised completed document to the identified reviewer who examines it for adequacy within the scope of their expertise. The reviewer uses reference documents and other pertinent information upon which to base their review.

2. The reviewer evaluates the document for technical accuracy, conflict with other section policies or procedures, conflict with other branch policies or procedures, if known, training needs, additional resources, and any impact to customers. Concerns and changes are noted, discussed, and reconciled with authors.

3. After the changes have been made, the reviewer signs and forwards the document to the approver. Unresolved conflicts are noted.

C. Document Approval:

1. The approver reviews the document to ensure it contains all elements, identifies conflicts with other branches, and determines the need for training and resources identified. The approver uses reference documents and other pertinent information upon which to base their approval.

2. If additional changes or conflict resolution is needed, the approver determines the final action after discussion with the reviewer and author.

3. The document will then be forwarded to the QMS Manager who will perform a review of the process and makes any changes. The document may be sent back to the Second Level Manager for any clarifications.

4. After the review by the QMS Manager, the document will then be submitted to the Third Level Manager who is the final approving authority.

5. Once all signatures are obtained, the QMS Manager is responsible for issuance.

D. Minor changes may be made, reviewed and approved by the QMS Manager. A DCR will be generated and submitted to the [First Level Manager] for final approval.

E. Amendments or changes to documents by hand are not permitted. Minor changes identified are noted and made during the next review and revision. In cases of emergency issuance of changes, the DCR process can be accelerated by actions by the QMS Manager (i.e. personally walking the process through).

6.6 Notification

A. Before issuance and subsequent revisions, documents are reviewed and approved by Part 6.4 Document Change Request, A-C of this procedure.

B. If the document is a revision, the changes made are identified in the document on a cover page or attachments.

C. Notification of new, revised, or cancelled documents are publicized in a transmittal notice to affected personnel through email. The transmittal notice contains the following information:

- transmittal date,
- transmittal number,
- document affected,
- distribution,
- filing instructions,
- completed education or training requirements,
- changes made, and
- issued by and authority.

D. The use of new or revised documents occur only after notification through this transmittal and their appearance on the Master List located on the [Location].

E. The QMS Manager will notify the [Name] Regional Computer Center to post the document on the intranet and create the links only after the document has completed the final review and approval.

6.7 Monitoring

A. The QMS Manager maintains the listing of quality documents which include the date prepared, date revised, date reviewed and due date for next scheduled review for continuing relevance.

B. Documents are reviewed annually by the [Second Level Manager] or designee based on the latest date and reviews will be coordinated by the QMS Manager. External electronic documents available and maintained on-line are checked and controlled by periodically [frequency] checking the appropriate website, i.e. A2LA policy and requirements documents are checked by accessing www.a2la.org.

C. A document change request will be initiated and procedure followed for revisions.

6.8 External Documents

A. Documents from external sources are controlled using listings to track the use of versions as part of the quality system. The date, version and page number are to appear on these lists. Lists are maintained for the manufacturer's operator manuals and reference documents.

6.9 Document Retention and Archival

A. Documents are retained and archived according to the procedure, Record Management.

7. Definitions

Clearance - Clearance is granting permission to proceed with a proposed directive.

Document control - Document control ensures that documents are reviewed for adequacy, approved for release by authorized personnel and distributed to and used at the location where the prescribed activity is performed.

Controlled copy - A controlled copy is a formal copy of the latest, correct issue of a document; an identified issue of a document to an individual or location of record. The controlled copy is officially tracked, updated and destroyed to assure that it is current.

Uncontrolled copy - An informal copy of a document for which no attempt is made to update it after distribution; the document is marked "Uncontrolled" and the user determines if the document is active prior to use.

Minor changes or revisions - Those changes that do not affect the content of quality of the action being prescribed in the document, such as typographical or grammatical changes, template formatting or small changes within the document.

Major changes or revisions - Those changes which affect the content of quality of the action being prescribed in the document, such as updated technology resulting in change of procedure or multiple changes within the document.

8. Records

Master list
Document change requests
Listing of external documents

9. Supporting Documents

ORA-LAB.4.12 Record and Data Management

10. Attachments

Attachment A: Document Change Request Form
Attachment B: Document Transmittal Form
Attachment C: DCR Process in Eleven Steps

Document History					
Version No.	**Status (I, R, C)**	**Date Approved**	**Location of Change History**	**Name & Title**	
				Author	**Approving Official**
1.3	R	11/16/05	In Document	LMEB	LMEB

Approving Official's Signature: _____ Date: _____

ID#_____

FDA/ORA [Name]
DOCUMENT CHANGE REQUEST FORM

REQUESTOR
Requested by:_____Branch/Section_____Phone:_____Date:_____

Document Type: SOP ☐ Other ☐ | Type of Action Requested: NEW ☐

Organization Level: District ☐ Branch ☐ | REVISION ☐ REMOVAL ☐

Multi. Brchs ☐ Section ☐ Other ☐ | REVIEW ☐

Document Number
From: _____
To: _____

Revision Level
From: _____
To: _____

Document Title
From: _____
To: _____

Affected Document(s): _____
Summary Recommendation (include any supporting documentation):
_____
_____

ACTION TO BE TAKEN
Approved by: _____ CREATE ☐ REVISE ☐ REMOVE ☐

Not Approved: _____ No Changes Needed ☐ Date: _____

Reason for Not Approved _____

AUTHOR, REVIEWER, APPROVER ASSIGNED
Author: _____ Reviewer: _____ Approver: _____

Approved by: _____ Date Submitted: _____

DOCUMENT REVIEW
Approved by: _____ Date: _____ Not Approved: _____ Date: _____

Reason for Not Approved:_____

DOCUMENT APPROVAL
Approved by: _____ Date: _____ Not Approved:_____ Date: _____

Reason for Not Approved:_____

QUALITY SYSTEM REPRESENTATIVE-FINAL RELEASE
Insufficient Information: ☐ Returned to:_____ON:_____Change Implemented_____

Approved By: _____ Notification sent: _____ Effective Date: _____
Master List Update: _____ Quality System Representative:_____

Document Transmittal

Date:
Transmittal Number:

Document(s)

Number	Version	Title

Distribution List

Notification:
Controlled Copies:
Uncontrolled Copies:

Filing Instructions

Remove:
Insert:

Explanation/Education or Training Requirements

Change history:

Issued by QSM:

STEP 1: Obtain a DCR form at [Location] or DCRFORM.doc. Double click on selected file top open the database of the Word document.

STEP 2: Complete the REQUESTOR section on the DCR form.

STEP 3: Forward the DCR form to the QMS Manager *or* Notify the QMS Manager that a new request has been initiated in the database.

STEP 4: The QMS Manager notifies the [First or Second Level Manager] via email for action.

STEP 5: The [First or Second Level Manager] reviews the request and performs one of the following:

1. If more information is needed or the form needs changes, the requestor is contacted.
2. If the request is approved, mark the applicable box , enter name and date.
3. If the request is not approved, either mark that no changes were made or identify the reason.

STEP 6: The QMS Manager is notified that the action has been completed by submission of the form or via email. The QMS Manager will:

1. Remove the document, archive and update Master List, *or* identify and assign authors, reviewers and approvers *and* obtain approval of the [First Level Manager].
2. Notify the requestor by email of the decision whether to create, revise, remove or take no action; *and*, if applicable, notify the request of the assigned authors, reviewers and approvers.

STEP 7: Upon notification of approval of the request, the assigned author will:

1. Retrieve document template from [Location] *or* select the Word document to be changed. The documents are Read Only.
2. Type or revise the information. NOTE: When revising a document, make sure that Word tracks the changes.

STEP 8: After the document is written or revised, summarize the document changes and any training or resource needs and submit the document to the assigned reviewers.

STEP 9: The reviewer reads and evaluates the document. Concerns and changes are noted and discussed with the author. After changes and identification, if any, of additional training and resources or impact to customers, performs one of the following:

1. If the document is approved, enter in name and date. Forward the document to the assigned approvers.

2. If the document is not approved, identify the reason and notify the QSM who in turn will notify the author. Any conflicts will try to be resolved between both the author and reviewer.

STEP 10: Approver reads and reviews the document. Changes and concerns are noted and discussed with the reviewers and authors. The approver determines the final action. After changes and identification, if any, of additional training and resources or impact to customers or other branches, performs one of the following:

1. If the document is approved, enter in name and date and forward to the QMS Manager.

2. If the document is not approved, identify the reason and notify the QMS Manager who in turn will notify the author.

STEP 11: The QMS Manger performs a review of the process and the document. Changes may make changes (i.e. formatting). If clarifications are needed, the document is sent back to the approvers. The QMS Manager submits the DCR and document to the [First Level Manager] for approval. After his or her approval or non-approval, the QMS Manager updates the Master List, posts approved document and notifies affected staff with a document transmittal via email.