Sections Included in this Document/(Change 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 System Manager (QSM):

- 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- archives superseded or obsolete documents.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 or initiating a revision in a web application, and
- ensures correct formatting conventions are followed.

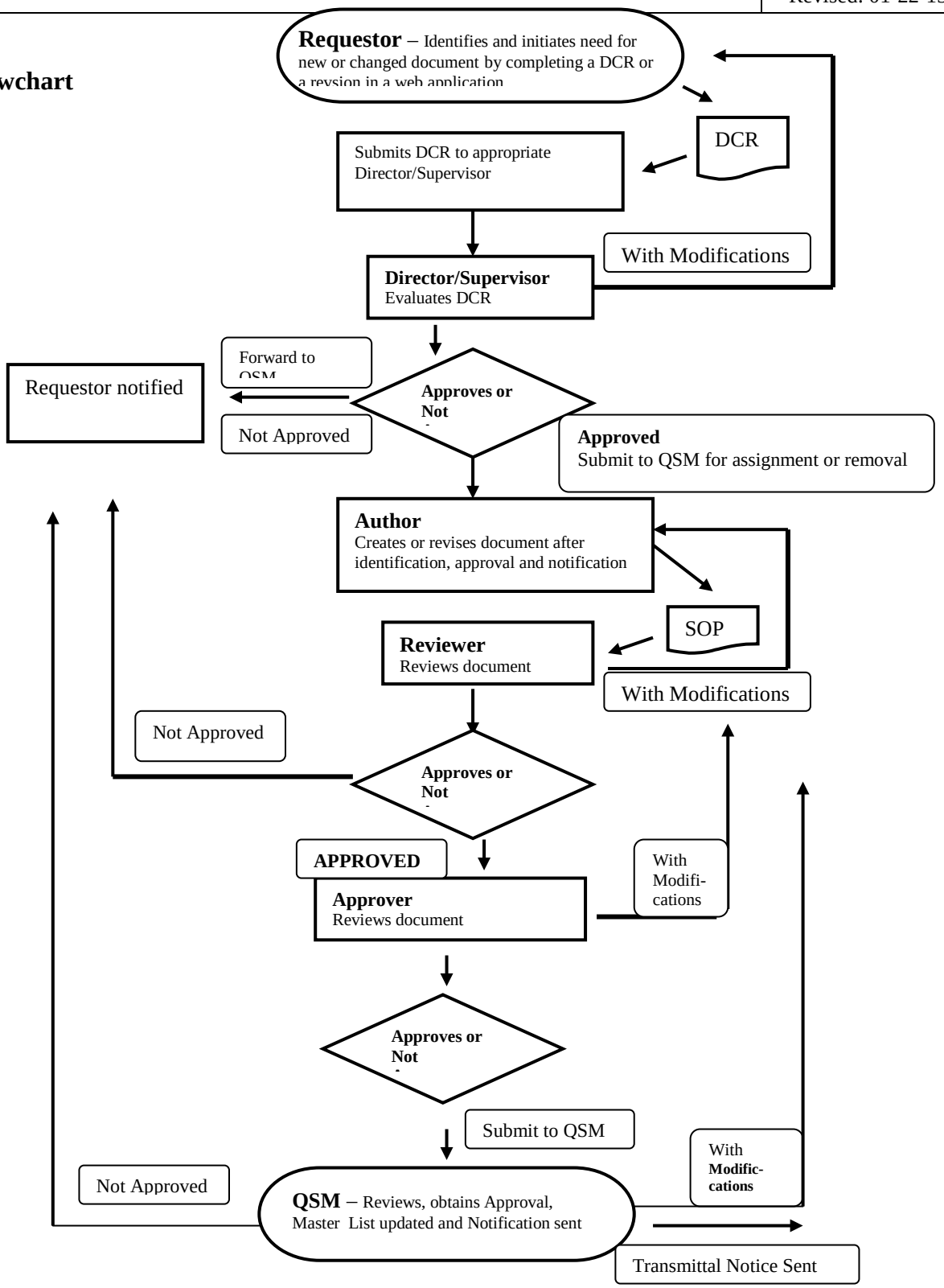
4. Background

None

5. References None

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.007 and [Name]-LB.7.001.

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, if used, are identified as DRAFT with a letter (A, B, C) to indicate the sequential revisions of the document. Drafts may be identified with a watermark or noted as "DRAFT" in the header. Drafts are not to be logged or tracked.

D. The QSM or computer program/web application assigns and maintains document numbers.

6.3 Document Formatting

A. Documents are formatted according to ORA-QMS.001. See document template on the [Location].

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;
- action to be taken, date and by whom.

B. The DCR is submitted by the QSM or computer program/web application to the {First Level Manger], [Second Level Manager] for action and evaluation. The QSM or computer program/web application maintains and tracks the DCR to ensure process is completed within 30 days. The QSM or computer program/web application 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 QSM removes and the QSM or computer program/web application archives the document and the Master List is updated.

2. For document creation or revision, the authors, reviewers and approvers will be identified by the QSM 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 QSM 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 the document is submitted 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 submitted to the QSM 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 QSM, the document will then be submitted to the Third Level Manager who is the final approving authority.

5. Once all sign offs are obtained, the document is issued.

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

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 QSM (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:

Using non-electronic and electronic systems:

- transmittal date,
- document affected,
- distribution.

Include if using non-electronic systems

- 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. For intranet posting, the QSM will notify the [Name] Regional Computer Center to post the document and create the links only after the document has completed the final review and approval.

6.7 Monitoring

A. The QSM or computer program/web application maintains the listing of quality documents which include the document number, document title, revision, effective date, date released, date reviewed and due date for next scheduled review for continuing relevance.

B. Documents are reviewed periodically [frequency] by the [Second Level Manager] or designee based on the latest date and reviews will be coordinated by the QSM or computer program/web application. 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 or web application revision 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 procedures, ORA-LAB.4.13, Record and Data Management and ORA-QMS.001, Record Control.

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.4.13 Record and Data Management
ORA-QMS.002, Control of Records
ORA-QMS.001, Document Control and Management
Staff Manual Guide 3291

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
1.4	R	6/6/08	In Document	LMEB	LMEB
1.5	R	02/02/10	In Document	LMEB	LMEB
1.6	R	02/06/12	In Document	LMEB	LMEB
1.7		01/22/13	In Document	LMEB	LMEB

Approving Official's Signature: _____ Date: _____

Document Change Request

ID Number:

Initiated By:

Date Created:

Quality Unit:

Short Title:

Action Requested:

Reason for Change Request:

Action To Be Taken:

Non-electronic system:

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:

Electronic system:

[Date:]
[To:]

The following documents have been modified:

[Document Number, revision – Document Title]

[url address of electronic system]

STEP 1: Initiate a DCR form at [Location].

STEP 2: Complete the sections on the DCR form. Indicated action requested (new, revision, removal, or review)

STEP 3: Submit the DCR form..

STEP 4: The [First or Second Level Manager] is notified of task 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 action (review, create, revise, remove), 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 QSM is notified that the action has been completed by submission of the form. The QSM will:

1. Remove the document, archive and update Master List, *or* the request is submitted to assign authors, reviewers and approvers.

2. Requestor is notified 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* retrieve the Word document to be changed.

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. Submit the document to the assigned approvers.
2. If the document is not approved, identify the reason and submit. 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 submit to the QSM.

2. If the document is not approved, identify the reason and submit to the QSM 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. After [First Level Manager] approval or non-approval, the Master List is updated, approved document released and affected staff is notified with a document transmittal via email .