Sections in This Document

1. Purpose

To control all documents that form part of the quality management system (either internally generated or from external sources). Document control assures that quality system documents used by employees are properly developed, approved, contain current information, and are located where needed.

Quality system documents include, but are not limited to items defined as manuals, procedures, work instructions (WIs), test methods, templates, policies, regulations, standards, other normative documents, as well as drawings, software, and specifications.

2. Scope

This procedure applies to the Office of Regulatory Science (ORS) laboratories' quality assurance program pertaining to their work products and processes.

3. Responsibility

The responsibility section for this procedure is intended to be general to allow for the assignment of roles and responsibilities at each laboratory in accordance with their specific staffing resources.

A. Laboratory Management:

1. Reviews and approves policies and procedures in their area of responsibility and verifies the technical accuracy.
2. Identifies and ensures training needs are met.
3. Resolves conflict between the reviewer and preparer of the procedure.
4. Ensures resources are provided.

B. Quality System Manager (QSM):

1. Ensures document control system is implemented and maintained.
2. Coordinates reviews and revisions of quality system documents.
3. Archives superseded or obsolete documents.
4. Provides notification to impacted users when changes are made to local documents.

C. Staff:

1. Verifies the official version of the document is used by checking QMiS each time the document is used.
2. Reviews document content for clarity and accuracy to determine need for new procedures or modification to procedures.
3. Initiates Document Change Requests.

4. Background

Document Control is a requirement in accredited Quality Systems to ensure use and availability of only authorized editions of appropriate documents with periodic reviews to guarantee continuing suitability and compliance with applicable standard requirements. Documents enable communication of intent and consistency of action.

5. References

A. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Sections 8.2 and 8.3.

B. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals; An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

C. SOP-000104 Document Control and Management (ORA-Level)

D. WI-000061 How to Create and Send A Transmittal Notice (ORA-Level)

E. WI-000422 DCR Work Instruction for the Initiator and Approver (ORA-level)

6. Procedure

The laboratories use the Quality Management Information System (QMiS) for document control. QMiS allows access and organization of documents; collaboration for development, revision, and review; approvals; and archiving of old versions. For assistance using QMiS refer to the user manual and help features or contact your local QSM.

All documents issued to personnel in the laboratory as part of the management system are reviewed and approved for use by authorized personnel prior to use. Authorized editions of appropriate documents are made available at all locations where operations essential to the effective function of the laboratory are performed.

6.1. Internal Documents

6.1.1. Quality Management Information System (QMiS)

Internal laboratory documents are controlled in QMiS. Internal documents include procedures, work instructions, templates, forms, checklists, lists, organization charts, multiuser calculation spreadsheets, databases, etc.

In summary, all documents used prior and during the process of reporting data or completing quality management processes must be controlled.

The QMiS document InfoCard uniquely identifies the document number and includes the current revision number, issue date, title, and approval. Laboratory staff can only access current revisions of the documents in QMiS. Organizers and current document lists are maintained to ensure access to required documents at the point of use.

Documents printed from QMiS are Uncontrolled Documents and are automatically identified as uncontrolled.

6.1.2. Document Identification

Documents are uniquely numbered according to ORA policy and numbers are assigned by QMiS. Drafts outside QMiS, if used, are identified as DRAFT.

6.1.3. Document Formatting

Documents are formatted according to ORA policy/guidance for each of the document types.

Documents have a header indicating the document's unique identifier, date of issue and/or revision, page numbering, the total number of pages.

6.1.4. Document Change Request

A. The Document Change Request (DCR) form, in QMiS, is used to initiate and facilitate document change requests for creation of new documents or revisions to approved published document. Refer to WI-000422 DCR Work Instruction for the Initiator and Approver.

B. The standard approval routing for the DCR form goes from the Initiator to the Initiator's Supervisor and/or owner of the process affected by the document, and finally to the QSM.

6.1.5. Archiving

QSM archives documents in QMiS. Electronic copies in QMiS are "Archived," removed from open access, and retained in the system. Physical copies are removed from distributed locations.

Notification is required to affected users when a document is archived and no longer available.

6.1.6. Document Review:

A. The assigned reviewer examines the document for adequacy within the scope of their expertise. The reviewer uses reference documents and other pertinent information upon which to base their review.

B. The reviewer evaluates the document for technical accuracy; conflict with policies or procedures in other areas of the laboratory or ORS and ORA programs; if known, training needs, additional resources, and any impact to customers. Concerns and changes are noted, discussed, and reconciled with authors or other subject matter experts (SMEs).

C. The QSM reviews the document to ensure the requirements of the Quality Management System are met.

6.1.7. Development or Revision

A. Amendments or changes to documents by hand are not permitted.

B. New documents or changes to existing documents will be requested with a DCR in accordance with section 6.1.4.

C. QSMs will initiate and coordinate a collaboration task within QMiS for approved DCRs.

D. Authors, reviewers, and approvers are identified by laboratory management.

E. Documents should be drafted at the user level by staff familiar with the topic or process.

F. Document changes are indicated in the change history section of the document.

G. Minor changes may be made, reviewed, and approved by the QSM.

6.1.8. Document Approval:

A. Documents are approved by designated managers for adequacy prior to issue.

B. The approver reviews the document for accuracy and fitness for use. The approver uses reference documents and other pertinent information upon which to base their approval.

C. The approver ensures it does not conflict with other procedures.

D. The approver identifies need for training and resources.

E. Approvers sign off on the document indicating their review and approval.

F. Once sign offs are obtained, the document is issued by the QSM.

6.1.9. Notification

A. Notification of new, revised, or archived documents are provided to affected personnel, according to ORA policy/procedures.

B. New or revised documents are not used until approved and issued.

6.1.10. Periodic Review

A. Documents are reviewed periodically at a minimum of every two years, more frequently as determined by the laboratory, or as determined by ORA policy according to document type.

B. The assigned reviewer ensures the continued accuracy and fitness for use of the document.

6.2. External Documents

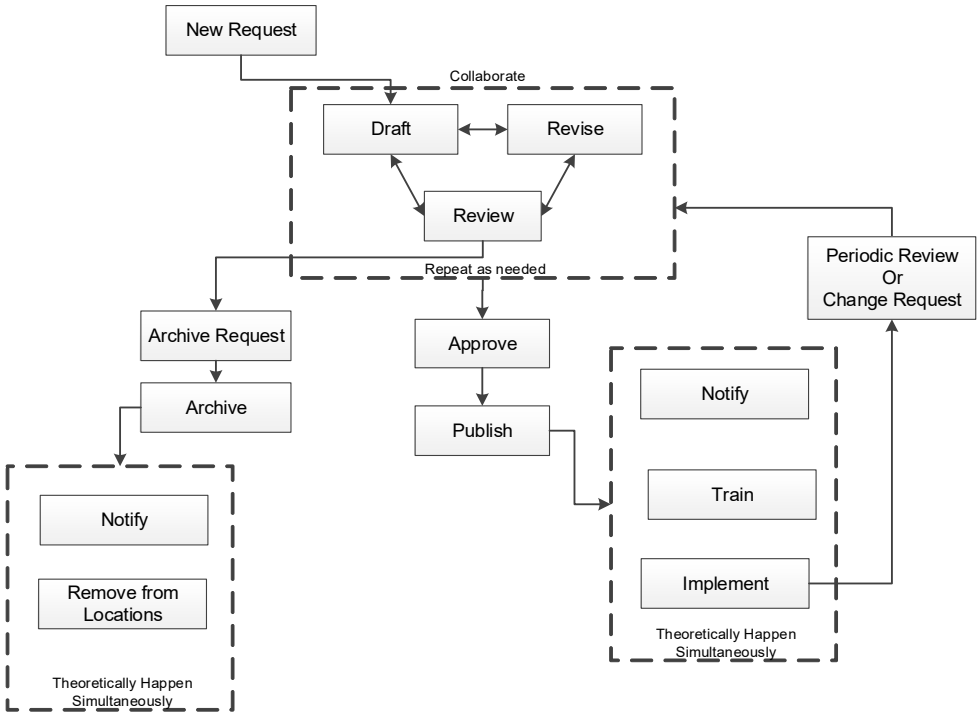
Documents from external sources are tracked using controlled lists to ensure they are available and current. External documents may include testing kit instructions, instrument manuals, instrument software, journal articles, laboratory information bulletins, standards, accreditation body resources, etc. These lists include the source of the document (when available), and, if relevant, page numbers (i.e. a method outlined in a scientific journal). The lists are reviewed and updated periodically. Revisions made to external documents are reviewed and incorporated into internal documents accordingly.

6.3. Document Retention and Archival

A. Documents are retained and archived according to the procedures, MAN-000032 ORA-LAB.4.13, Record and Data Management.

B. The QMiS system retains drafts, current, and archived documents created and issued in the system.

6.4. Process Map



7. Glossary/Definitions

A. Document control - Document control ensures “cradle-to-grave” management of documents in the management system and 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. And when obsolete, are either revised or removed from use.

B. Controlled copy - A controlled copy is an authorized 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, or removed to assure that users have access to only current revisions.

C. 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 is responsible for determining if the document is active prior to use.

D. Minor changes- Those changes that do not affect the content of quality of the action being prescribed in the document, such as typographical or

grammatical changes, formatting or small changes within the document that will not invalidate or negate previously issued content.

8. Records

A. Master lists

B. Document change requests
C. Transmittal Notices
D. Current and archived QMiS files and metadata

9. Supporting Documents

A. MAN-000032 ORA-LAB.4.13, Record and Data Management.

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.3	R	11/16/05	LMEB	LMEB
1.4	R	06/06/08	LMEB	LMEB
1.5	R	02/02/10	LMEB	LMEB
1.6	R	02/06/12	LMEB	LMEB
1.7	R	01/22/13	LMEB	LMEB
02	R	05/15/2019	LMEB	LMEB
03	R	Refer to QMiS InfoCard	LMEB	LMEB
* - D: Draft, I: Initial, R: Revision				

11. Change History

Revision #	Change
1.3	In document.
1.4	In document.
1.5	In document.
1.6	In document.
1.7	In document.

Revision #	Change
02	Changed 1st – 3rd level Manager responsibilities to "Laboratory Management"; added Background & References information; referred to OQMS-level document for formatting instructions; specified use of QMiS DCR; Development & review process streamlined; 2-year review added; added requirements/inclusions for external master list; updated process chart. Other revisions made to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were made.
03	Removed requirement for DCR to archive documents. Added requirement of notification for archived documents. Added clarification of types of documents that require control.

12. **Attachments**

NONE