Sections in This Document

1. Purpose

To provide guidance describing the audit program used to evaluate, monitor, and continually improve the quality management system. A properly

performed assessment of the quality management system demonstrates the level of compliance with applicable standards and regulatory requirements. The information collected is used towards continual improvement of the system.

2. Scope

This procedure applies to the Office of Regulatory Science (ORS) laboratories and laboratory work products and processes. This procedure directly concerns the laboratory's quality assurance program.

3. Responsibility

A. Laboratory Management:

1. May assign auditors within the laboratory for internal audits
2. Allocate appropriate resources to conduct internal audits.
3. Ensures information and access is provided to auditors.
4. Informs staff of audit schedule
5. Ensures corrective action process is implemented in a timely fashion to address identified nonconformances.

B. Quality System Manager (QSM):

1. May serve as the lead auditor within the laboratory.
2. Coordinates audits and ensures auditors have adequate training and guidance.
3. Monitors audit activities, assembles report, and ensures results of the audits are reported to relevant management.
4. Monitors continual improvement processes.
5. Ensures corrective action process is initiated for identified nonconformances.
6. Acts as the Laboratory Point of Contact (POC) for External audits performed.

C. Auditor:

1. Reviews background information in preparation for audit.
2. Conducts audit in accordance with audit procedures and within defined scope and/or established criteria.
3. Collects and documents objective evidence to support findings.
4. Coordinates schedule during audit with staff to be interviewed.

D. Staff:

1. Provide information as requested by auditors and participate in audits as necessary.
2. Provide input to responses for observations or non-conformances identified, as assigned.

4. Background

NONE

5. References

A. ISO 19011:2002, Guidelines for Quality and/or Environmental Management Systems Auditing.

B. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories Section 8.8.

C. 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

6. Procedure

6.1. Internal Audit Process

Internal quality system audits are performed on a predetermined schedule and as otherwise directed by management at the local level by trained staff from within the laboratory.

A. Audits shall be conducted in accordance with the local schedule outlined in the laboratory's local procedures.

B. The audit program shall address all elements of the management system, including laboratory activities and procedures.

C. Internal Audits shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and results of previous audits.

D. Audits should examine all aspects of the management system using both horizontal and vertical auditing techniques.

E. The QSM defines the audit criteria, scope, frequency, objectives, methods, etc. before the start of an audit using a risk-based approach.

F. Auditors conduct the audits and receive information through several means such as:

1. interviews with personnel,
2. examination of documentation,
3. observation of activities and conditions,
4. review of quality and technical records, and
5. use of checklists.

G. For all audits, objective evidence shall be obtained to support an observation.

H. When using a checklist, annotate it with specific objective evidence to support the evaluation of the satisfactory or unsatisfactory decision. The information collected on the checklist assists with report formulation and corrective action initiation.

I. The Quality Manager provides management with a summary report documenting the area of activity audited, the audit findings and on-the-spot corrections.

J. When evaluation of the audit findings cast doubt on the effectiveness of operations with its own management system or that the nonconforming work could reoccur, the laboratory shall take develop and implement timely corrective action.

K. Appropriate corrections and corrective actions are recorded and implemented without undue delay.

L. Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action plan.

6.2. Quality Management System Audits

A. Audits of the entire Quality Management System are conducted at a minimum of once per year. These internal system audits are planned and scheduled by the Quality System Manager. This may be accomplished by piecing together many internal branch/section audits that represent the whole system.

B. Areas audited include, but are not limited to:

1. laboratory information management systems
2. ISO/AOAC requirements.

3. methods and procedures.
4. personnel training and competency.
5. equipment management and maintenance.
6. laboratory proficiency testing.
7. quality control (QC) and QC charts.
8. workload and sample handling processes.
9. records and reports (work products).
10. standards, organisms, certified reference materials.
11. housekeeping; and
12. laboratory environment.

6.3. Process/Product Audits

The information from specific process/product audits supports the completion of the comprehensive internal audit and shows performance throughout the year instead of only at one sampling point. Process/Product audits allow for earlier detection of problems, reduce propagation of error, and provide data for trend analysis if necessary. Use audit criteria and quality factors from the relevant procedures being audited.

The process audits described below are performed at each laboratory, at a frequency and schedule defined in the laboratory's local procedure. A national quality factor checklist may be used to record the review. On the spot corrections are annotated on the form.

6.3.1. Worksheet Review Audits

The worksheet review audit is to verify the laboratory is following its procedures for the analysis and reporting of samples. This is a vertical audit in nature. A worksheet review audit may focus on a method; evaluate individual analyst performance; etc.

Worksheet review audits are carried out by the Branch Directors, Supervisors, and qualified analysts performing worksheet checks according to the laboratory sampling plan. The auditor should not have performed any part of the analysis or activities related to the worksheet(s) reviewed. The worksheet review audit frequency and schedule include both violative and non-violative samples.

6.3.2. On-Site Review

The purpose of the on-site review is to witness a process being performed. The review may focus on a method, evaluate individual analyst performance, observation of sample handling processes by the sample evidence specialist; etc. Laboratory management performs these audits.

The recommended frequency is at least one internal onsite review per analyst per year. The on-site review frequency and schedule takes into consideration the methods on the laboratory's scope of accreditation.

6.3.3. Oral Review (optional)

The purpose of oral worksheet review is to verify that Analysts will be able to testify about their analyses as competent fact witnesses. Using the worksheet, the Analyst reconstructs the test procedures and explains the results. Oral reviews should be performed by someone outside the supervisory group.

6.3.4. Sample Accountability Review

The purpose of the Sample Accountability Review is to ensure samples are handled correctly as they are processed through the laboratory. FACTS information is checked for accuracy and completeness. This includes the acceptance, storage, transfers, usage, and disposal. Laboratory management performs these audits.

The recommended frequency is at least once per year or more frequent based on management assessments.

6.3.5. Laboratory Controls Review Audits

Responsibility for performing these audits shall be defined by the laboratory.

Laboratory control reviews are horizontal in nature and includes multiple areas and items within the laboratory.

6.3.5.1. Equipment Record Review

The purpose of the equipment audit is to check that appropriate records are present and accessible for equipment.

The recommended frequency is to review each type of equipment on an annual basis.

6.3.5.2. Environmental Control Review

The purpose of these audits is to ensure the laboratory procedures pertaining to the laboratory environment are performed as prescribed. The processes audited may include, but are not limited to:

A. Engineering Controls (Chemical Fume Hoods, Biosafety Cabinets, Laminar Flow Hoods, etc.)

B. Water purification systems

C. Environmental monitoring

D. Access control

E. Sample and chemical storage conditions

The recommended frequency is at least once per year or more frequent based on management assessments.

6.3.5.3. Standards, Reagents, Media, Reference Standards/Materials

The purpose of this audit is to ensure appropriate records are available for standards, reagents, media, and physical reference standards/materials and that related procedures are being followed.

The recommended frequency is at least once per year or more frequent based on management assessments.

6.4. Internal Audit (Follow-up/Focused)

Follow-up or focused audits are based upon need. They may be in response to prior audits, detected nonconformances, complaints, or as effectiveness reviews for planned or completed corrective or preventive actions. These audits can be conducted without scheduling or prior notification.

6.5. Training Requirements

Audits shall be carried out by trained and qualified personnel who are, when resources permit, independent of the activity audited. Personnel conducting audits are trained and qualified based upon completion of one or more of the following criteria:

A. previous demonstration of performing audits (e.g., FDA inspections, ORA audits).

B. documented training conducted by laboratory QSM.

C. successful completion of a recognized auditing course or auditor certification.

6.6. External – Second Party Audits

Audit performed by personnel not from the local laboratory. For example, this might be an audit performed by another ORS laboratory quality system manager, other ORS personnel, etc.

If an external auditor or a team is utilized, the auditor or audit team may hold opening and closing meetings with management to outline the plan of action and discuss findings and whether the laboratory conforms to stated requirements.

6.7. External – Third Party Audits

Performed by accreditation organization auditors. All audit findings resulting from a third-party audit must be addressed using the corrective action process, including root cause analysis.

6.8. Nonconformances

Nonconformances may be corrected on the spot if the issue is minor, isolated, and can be easily corrected. These nonconformances are recorded in the final report with corrections noted.

Nonconformances that are not corrected “on-the-spot” shall be addressed using the Corrective Action procedure. (MAN-000030)

7. Glossary/Definitions

A. Audit – An audit is a planned and documented investigative evaluation of an item or process to determine the adequacy of and compliance with planned arrangements and whether these arrangements are implemented effectively and are doable to achieve objectives.

B. Audit report – An Audit Report is a summary of the audit scope and findings.

C. Quality factors – These criteria are quality elements needed for purposeful work. Work requests or compliance programs directing a piece of work or general guidance documents, such as the Laboratory Manual, the Quality Management System Manual, pertinent laboratory procedures and work instructions, contain quality elements.

D. Horizontal Audit – Examination of an element of the management system across multiple samples, people, equipment, departments, etc.

E. Monitor – To monitor is to observe and record activity to measure compliance with a standard of performance, routine, and ongoing collection of data about the indicator.

F. Non-conformity – A non-conformity is non-fulfillment of a specified or implied requirement of the quality management system or of a quality work product.

G. Objective evidence – Objective evidence is information, which can be proven true, based on facts obtained through observation, measurement, test, or other means. Objective evidence includes, but is not limited to staff interviews, direct observation, document review, or record review.

H. Observation – An observation is objective evidence that creates concern that may indicate future problems. Often these areas noted can be the basis for an Improvement action.

I. On-the-spot correction - This is an immediate step taken to correct or resolve a non-conformity.

J. Performance audit – a performance audit is an assessment of the technical activities of personnel and are categorized as a quantitative appraisal of quality.

K. Requirement – A requirement is a declared, implied, or routine need or expectation.

L. System audit – A system audit is an on-site assessment of the laboratory's quality management system and referred to as a qualitative appraisal of quality.

M. Vertical Audit – Examination of one sample through all aspects of handling.

8. Records

A. Completed audit checklists

B. Process forms in QMiS

- Lab Onsite Review Check List
- Lab Sample Accountability Quality Factor Checklist
- Lab Environmental Quality Factor Checklist
- Lab Equipment Quality Factor Checklist
- Lab Standards_Reagent_Media Quality Factor Checklist
- Lab Worksheet Review Quality Factor Checklist

C. Audit Report in QMiS

D. Corrective Action records in QMiS

9. Supporting Documents

A. MAN-000030 ORA Lab Manual Vol. II - Corrective Action (ORA-LAB.4.11)

B. WI-000238 How to Access and Complete the Laboratory Worksheet Review Quality Factor Checklist

C. JA-000230 Using the QMiS Worksheet Review Quality Factor Checklist (QFC) Process Form

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.4	R	12/31/07	LMEB	LMEB
1.5	R	02/06/12	LMEB	LMEB
02	R	06/06/2019	LMEB	LMEB
03	R	01/23/2020	LMEB	LMEB
04	R	REFER TO QMIS	LMEB	LMEB

* - D: Draft, I: Initial, R: Revision

11. Change History

Revision #	Change
02	Removed EAL-G3 reference because it was not mentioned in the rest of the document. Removed ORA-QMS references so that this document can stand alone. Revised example schedules. Other revisions made as needed to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were also made.
03	Revised "Responsibility" section as requested by ORS Management: • Laboratory Management: Added "May assign auditors within the laboratory for internal audits" • QSM: Changed "Serves as Lead Auditor within the laboratory" to "May serve as the lead auditor within the laboratory"
04	Formatting and minor language revisions made. Revised Responsibility section to further clarify roles. Added QMiS QFC process forms to Records Section. Updated References and Supporting Documents Sections. Section 7 Glossary: Clarified "Observation" can lead to Improvement Action. Other minor changes are highlighted throughout the document.

12. Attachments

List of Attachments

Attachment A - Example of how an audit schedule can be set up

The required amount columns are suggestions, not requirements. The requirement shall be set by the laboratory.

Review Activity	Reviewer	Frequency
Worksheet Review	Name	Annual - 2 per analyst Quarterly – 9 Class 1 and 2 each Quarterly- 7 Class 3
On-Site Review	Name	Annual – 1 per analyst Annual – 1 per method
Oral Review	Name	# Per year Every 4 years – 1 per analyst
Sample Accountability	Name	Quarterly – Random FACTS records, 5 active, 5 in process or unassigned; 5 completed.
Equipment Records	Name	Quarterly – 5 types each; equipment, measurement device, analytical instrument
Environmental Controls	Name	Quarterly - Defined %
Standards, Reagents, Media, Physical Reference Standards/Materials	Name	Quarterly – Defined %
Internal Audit (Comprehensive)	Name	Annual

Attachment B - Example of an audit schedule organized by ISO/IEC 17025:2017 elements broken up across a fiscal year

ISO/IEC 17025:2017 & AOAC Requirements	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP
4.1 – 4.2												
5.1 – 5.7												
8.8 – 8.9												
6.1 – 6.2												
6.3 – 6.4												
6.5 – 6.6												
7.1 – 7.3												
7.4 – 7.7												
7.8 – 7.11												
8.1 – 8.4												
8.5 – 8.7												
COMPLETED												