Sections in This Document

1. Purpose

The purpose of this procedure is to establish and define an internal training program and to ensure the competency of laboratory personnel. Training and training verification are key factors for successful laboratory operations.

2. Scope

This training procedure is used to ensure that training has taken place with each employee for procedures and methods that the employee performs. The procedure applies to on-the-job training, in-house training, and training of employees new to ORA/ORS. The training is verified and recorded. The training procedure is applicable to new employees, for the introduction of new procedures and methods, for retraining of employees, and for reverification of employee performance.

3. Responsibility

A. Laboratory Management

1. Ensures implementation of training procedure.
2. Ensures resources are allocated for identified training within budgetary constraints.
3. Responsible for the evaluation, training, and growth of the technical and quality related skills of employees by establishing training schedule and rotation for all new employees and by ensuring personnel receive training and demonstrate competence.
4. Maintains employee training records as accurate and current.
5. Ensures proper supervision of trainees until training completed.
6. Ensures training records are complete.
7. Monitors employee performance to identify the need for retraining or additional continuing education.
8. Identifies training needs resulting from new or revised procedures and processes.
9. Authorizes personnel to perform specific laboratory activities.
10. Ensures and records continued competency of employees.

11. Has relevant knowledge of the technology, methods and procedures used, purpose of each test, and an understanding of the significance of deviations found regarding the normal use of the items, materials, products, etc. concerned within their area of responsibility.

B. Quality System Manager (QSM):

1. Ensures training is conducted and recorded for quality management system policies and procedures.

C. ORS Employees:

1. Complete required training within specified timeframe(s).
2. Ensure all agency mandated training, such as, but not limited to, annual ethics and computer security awareness, is successfully completed and a digital copy of the certificate submitted to the supervisor as a record of training completion which is maintained locally and is available upon request for internal or third-party audits.
3. Become aware and stay knowledgeable in all procedures and methods they are or will be expected to perform NOTE: Employees are responsible for self-training, through reading current literature, technical papers, publishing technical papers, exploring HHS Portal and FDA University training resources, etc.
4. Read and comply with all standards, regulations, policies, procedures, and work instructions.

4. Background

None

5. References

A. FDA staff manual. Guide 3120.1 Personnel – Staff Development and Training

B. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 6.2.

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. Training and Competency Requirements

Before starting any work-related duties, the employee will be familiar with work related documents. These documents include procedures, work instructions, applicable manuals, and regulations. Employees undergoing training are supervised until training is completed and competency demonstrated on an initial and continuing basis.

A. Training requirements are outlined and documented based on the position description of duties and responsibilities.

B. Training and competency is determined by the employee's educational qualifications, experience, complexity of the test method, and knowledge of the test method performed.

C. The employee will not perform any procedure, inspection, or method until all applicable training has been completed and competency demonstrated.

D. Employees may request training related to their duties. The agency communicates training resources and development services for staff throughout the year. Included in these resources and services are synchronous and asynchronous courses, learning enrichment events, webinars, lunch-and-learn, technical symposia, as well as resources for professional development and leadership programs, continuing education information, and web-based self-paced content.

E. Employees submit digital copy of records to their supervisor for filing and maintenance upon completion of training.

F. Training and competency records shall be maintained according to agency, organizational, and local policy.

G. The effectiveness of training is evaluated by, but not limited to, reviews performed by management, performance audits, and performance evaluations.

6.2. Training Technique

A. The training process for technical procedures such as laboratory analysis consists of the following steps:

1. Trainee reads the laboratory procedures, work instructions, or other applicable documents.

2. Trainee observes demonstration of the procedure by a trainer.
3. Trainee performs the procedure under observation by a trainer.
4. Trainee successfully completes the procedure independently.

B. The training process for non-technical procedures includes, but is not limited to:

1. Reading laboratory procedures,
2. Instructions,
3. Demonstrations,
4. Lectures and discussions,
5. Self-study,
6. Computer-based training,
7. Viewing videos, and
8. Manufacturer's training or demonstration.

C. An employee's performance is verified by measurement against a defined performance standard. The measures used to verify an employee's performance are assessment tools.

6.3. Assessment tools

A. Administration of a Written Evaluation: Written evaluations can be used in areas where verification of a participant's knowledge is desired. Knowledge of theory or principles, problem-solving ability, logical sequence used, and independent or group decision making may be ascertained.

B. Observation of Procedure, Process, or Outcome: Observation by a trainer of an employee performing or demonstrating a procedure.

C. Verification of Response to Situational Problems or Calculations Related to the Procedure: Example circumstances include resolution of a posed and procedure-related situational problem or recommendation of procedure-related course of action that is consistent with policies and regulations.

D. Response to Oral Queries Related to a Step or Procedure: Answers provided by the employee to questions asked by trainer.

E. Testing Blind QC Samples: Employees are unaware when blind test samples are assigned. They appear identical to other samples, are in

routinely used containers, and are from a similar source. The intent is to provide simulated samples to measure realistic analytic conditions. This tool assesses all phases of laboratory performance.

F. Testing of Known Samples: Participants know and often plan for known testing events, such as external proficiency surveys and commercially prepared quality control samples. Samples for quality assurance or quality control purposes are identified immediately upon receipt in the laboratory. It is considered a waste of time and resources to conduct more careful handling and analysis on these samples or perform duplicate testing. This tool assesses the analytical phase only.

G. Testing Previously Analyzed Samples: Duplicate or replicate testing provides accessible internal comparisons and contributes to the validation of the analytic phase. These sources may be previously tested samples, samples of known constituents, and already reported proficiency testing samples. This tool assesses the analytical phase only.

6.4. Demonstration of Competency

A. Competency assessment is one method to verify that analysts are competent to perform testing and report accurate and timely results.

B. To be competent, a laboratory analyst must know how to perform a test, can perform the test properly without supervision, and know when there is a problem with the test that must be solved prior to reporting results.

C. The major technologies (at minimum the items on accreditation scope) and methods being performed require demonstration of initial and ongoing competency by any of the following tools:

Competency Demonstration Examples

Assessment Item	Item Description	Examples
Direct observation of test performance and instrument maintenance and function checks	This is the actual observation of the analysis and maintenance procedures and checks of instruments as it is being performed by the analyst	On-site review

Monitoring the recording and reporting of results	Review of results for the proper and correct recording and reporting	Worksheet review & FACTS entries
Review of intermediate checks, QC results, proficiency test results, FV/PM charts	This is as it is implied, review of checks, QC results, PT results, FV/PM charts	QA spreadsheets (chem.) & Pos/Neg controls (micro); Control within acceptable limits; Worksheet review, PT review, Completion of FV/PM charts properly
Assessment of test performance through external/internal PT's	Unknown samples	Evaluate results obtained with known results
Samples analyzed; Method validations; Accuracy/Precision on lab control samples	This is as it is implied: number of samples analyzed; method validations performed; QC charting for accuracy/precision.	FACTS reports of samples by analyst; satisfactory completion of samples; satisfactory completion of method validation packet; QC charts with criteria

6.5. Authorization of Personnel

A. Laboratory management authorizes personnel to perform specific laboratory activities as defined in local policies and procedures, including analytical test methods and operation of major technologies use for laboratory analyses.

B. When personnel are authorized for a portion of an analytical test method or a portion of the operations for a major laboratory analysis technology, then training records must enumerate the specific parts of the method or major technology operations for which the employee has received training, is considered competent, and therefore lab management is authorizing that employee to perform.

6.6. Training and Competency Records

A. Training and competency records are maintained by local management as current and accurate.

B. Training records must include a description of the training, the trainee's legal name, the trainer's legal name, dates of received training, and

identify whether successful completion has been achieved by the named trainee. Training records are archived for exiting employees. Examples of training records:

1. Completed training checklist prepared internally for procedure.
2. Completed blind quality control (QC) samples, proficiency surveys, acceptable preparation, and analysis of QC samples.
3. Completed written evaluations.
4. Signed acknowledgment of reading procedural documents.
5. Attendance sign-in sheets for in-house training.
6. A certificate from manufacturer's training courses, computer-based classes, and committees/technical groups served.
7. Submission of technical papers and handouts of presentations given.
8. College transcripts for courses taken, licenses, memberships held, and special conferences attended.
9. Completed paperwork on safety briefing, orientation modules, and in- or out-processing steps for new hires and those employees leaving the organizational unit.
10. Memorandums on additional appointments or duties.

6.7. Retraining and Reverification

6.7.1. Retraining:

A. Employees will be retrained whenever significant changes occur in policies, values, goals, procedures, processes, and methods or instruments.

B. Employees will be retrained when the level of performance is unsatisfactory.

6.7.2. Reverification:

A. Reverification occurs when employees attend required courses, continuing education, presentations, workshops, conferences, and scheduled training either in house or manufacturer's training.

B. Performance reverification occurs when proficiency surveys, blind QC samples, or duplicate testing are submitted.

6.8. Required Training

All analysts and laboratory staff members are to undergo training in several procedures, policies, and practices upon entry of employment and during their career with FDA.

To best prepare laboratory analysts for the analytical work which they will be expected to perform, all analysts new to ORS must complete an ORS regulatory science-focused training process during which they demonstrate competence in their core lab functions in accordance with both enterprise and ORS local program office/lab processes. Laboratory analysts include, but are not limited to, all the following positions: biologists, chemists, engineers, entomologists, interdisciplinary scientists, microbiologists, physicists, etc. ORA/ORS management may use Level I Analyst Certification as part of the demonstration of competence for laboratory accreditation purposes.

However, Level I Analyst Certification is not all that is needed for laboratory analysts to achieve ISO demonstrated competence. Codified in the ORA Laboratory Manual (LM) are specifications on requirements for assessment and documentation of "demonstration of competency" in ORA/ORS laboratories to meet ISO 17025 requirements.

To meet ISO 17025 competence requirements, all laboratory analysts must demonstrate initial and ongoing competency in all the major technologies and methods which they will be expected to perform. Therefore, regardless of education level or prior laboratory experience. all analysts must complete additional training above and beyond that which is specified for ORA Level I Analyst Certification.

The current ORS supported and approved regulatory science-focused training process is composed of both Level I Analyst Certification and the specific laboratory activities defined in ORS enterprise and local lab policies and procedures. Upon successful completion of ORA's Level I Analyst curriculum, the laboratory analyst becomes eligible for Level I Analyst Certification.

What follows are types of required training, which may vary from employee to employee based upon duties and core functions specified in the job position description.

6.8.1. Facility Orientation for all Employees

A. New employees complete required administrative forms and procedures as part of initial agency and organizational onboarding process.

B. Introduction to co-workers, personnel policies, working conditions, daily routine, issuance of manuals, quality assurance system and any miscellaneous matters.

6.8.2. **Agency-mandated Training for all Employees (includes, but is not limited to, the topics below. For additional information, refer to** FDA Mandatory Training intranet website.

A. Annual Ethics Training

B. Computer Security Awareness Training

C. Records Management Training

6.8.3. Training of Laboratory Analysts new to ORS

A. Quality Management System (see 6.8.5)

B. ORA Laboratory Manual

C. ORS documents and procedures

D. Local program office/lab documents and procedures

E. Foundational concepts and scientific technical courses for laboratory analysts ORA Level I Analyst Certification

1. Level I Certificates are issued by the Office of Training, Education, and Development (OTED) which is one component of ORA's Office of Regulatory Management Operations. OTED's issuance of a Level I Analyst Certificate reflects that OTED staff have verified the laboratory analyst has successfully completed a curriculum of defined regulatory science-focused analyst training supported by ORS and that OTED has received materials endorsed by aboratory management which indicates that the analyst has successfully demonstrated the technical skills to pass the Level I Analyst performance audit.
2. Laboratory analysts hired after January 1, 2002, are required to complete a standard training curriculum, along with local laboratory training, and must achieve Level I Analyst Certification regardless of education level or prior laboratory experience. To that end, local management must assure the appropriate first-line supervisor confirms and verifies their lab analyst has successfully completed all pertinent training and documents in QMiS as part of the initial competency demonstration. See MAN-000054 ORA Lab Manual Vol. IV Section 1 - Laboratory Orientation for reference.

3. For those laboratory analysts hired prior to January 2002, there is a process for experienced analysts to achieve Level I Analyst Certification. The supervisory analyst, along with the local branch director (if any), and the lab director must complete and submit the "Experienced Analyst Level I Certification Concurrence Form" to ORA's Office of Training, Education, and Development (OTED). The experienced analyst must have demonstrated competency in the elements identified in the Level I Analyst Certification Program Performance Audit criteria.

3. Laboratory science technicians are not eligible to attain Level I Analyst Certification.

4. To achieve Level I Analyst Certification, the laboratory analyst must also pass the Level I Analyst performance audit. Level I Analyst Auditors are those supervisors and managers at the local laboratory who have listed on their OTED transcript the successful completion of OTED's specified auditor training. As of October 2022, OTED auditor training is as follows: Basics of Auditing (ID: MP150) course and associated exam, followed by the Level I Analyst Certification Performance Auditor (ID: MG122R100) course. If earlier versions of the Level I Analyst Certification Performance Auditor course appear on transcripts (Ex. MG122, MG122L100, etc.), then completion of such should be sufficient to be considered equivalent. Prior to evaluating an analyst on Level I Analyst performance audit criteria, laboratory management must ensure that supervisory staff have successfully completed the training required to achieve the Level I Analyst Auditor designation. Laboratory management must also actively monitor and track the status of all their supervisors/managers to assure those staff members will be available to evaluate Level I Analyst performance audits in a timely manner. Analysts must work with their immediate supervisor and local management to schedule that audit.

5. To pass the performance audit, analysts must demonstrate competency in all elements of the analyst audit criteria. The sample analysis selected for the performance audit must reflect the work covered during the candidate's new hire Level I Analyst Curriculum and ORS program office/local laboratory training. Once ORS local lab management concurs that the candidate has met all requirements for Level I Analyst Certification, including satisfactory completion of the analyst performance audit, the candidate's laboratory management must submit the performance Level I

Analyst certification package audit results and any supporting materials to OTED along with their endorsement of completion. OTED will issue Level I Analyst Certification after they verify successful completion of Level I Analyst training and the Level I Analyst performance audit.

6. However, laboratory analysts must still successfully demonstrate initial competency in specific local laboratory activities which do not appear on ORA's Level I Analyst curriculum in order to meet ISO 17025 competency requirements so that laboratory management can authorize them to perform local laboratory work. Refer to Sections 6.1 through 6.6 in this document, the other volumes of the ORA Laboratory Manual, and all local laboratory policies and procedures, to find specifications on how to assess and document training activities to achieve ISO 17025 demonstrated competence.

6.8.4. Safety Training as applicable per assigned duty location (may include the following topics):

A. Blood-borne pathogen standard,

B. Hazard communication standard (Right to Know),

C. Universal precautions,

D. Exposure control plan,

E. Medical surveillance program,

F. Personal protective equipment,

G. Security briefing,

H. Safety briefing,

I. Radiation protection training,

J. Fire extinguisher training,

K. Emergency evacuation,

L. Safety practices in the laboratory,

M. Chemical Hygiene, and

N. Hazardous Waste Management that includes annual training on handling, storage, and disposal of hazardous materials

6.8.5. Quality Management System training

Examples include:

A. Course-1436 Introduction to ORA's Quality Management System (in QMiS Training Module)

B. Auditor training

C. Root Cause and Corrective Action procedures

D. Quality Management Information System (QMiS) training

6.8.6. Technical training

A. Managers and employees will work together to identify training needs in accordance with core job function and per the employee's job position description of duties.

B. Supervisors will discuss local or external training on policies, regulations, procedures, methods, and instruments based on position description of duties and responsibilities.

6.8.7. Other Training

Laboratory staff may have an opportunity to attend auxiliary training which is not core scientific technical training for ORS if such auxiliary training is available and resources permitting. This type of training includes:

A. Attendance at presentations, courses, learning events, and special emphasis group meetings or conferences

B. Computer courses such as in-house training, instructional, and manufacturer's training for business software use such as Microsoft business products.

C. Interpersonal communications and communications upskilling.

7. Glossary/Definitions

A. FV/PM – Function Verification/Preventive Maintenance.

B. Procedure – This is a description of the sequence of steps leading to a defined outcome or product. A procedure can be technical or administrative.

C. Retraining – Retraining is required when assessments show less than satisfactory performance or whenever significant changes occur in procedures or processes.

D. Reverification – This is a process that ensures employees remain at an acceptable level of performance.

E. Trainer – Trainers are persons that are knowledgeable in and regularly perform the procedures in which they instruct others. Necessary attributes include good verbal skills, demonstrated attention to detail, and objectivity.

F. Training Methods - The process of training and criteria for success are defined.

G. Training checklist – The training checklist is prepared from the procedure by defining all steps to perform a procedure for the verification of employee's competency.

H. Training Verification – This is a systematic approach to demonstrate that the training outcome is successful.

8. Records

Training and competency management files and records

9. Supporting Documents

None

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.2	R	11/16/05	LMEB	LMEB
1.3	R	02/02/10	LMEB	LMEB
02	R	05/15/2019	LMEB	LMEB
03	R	REFER TO QMIS	Rebecca Shelby, ORS/ORCET Training Coordinator	LMEB

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

11. Change History

Revision #	Change
02	Revisions made to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were also made.
03	Specific language added for L1 analyst certification and Training/Competency records management. Clarified which sections relate to all ORS employees vs. analysts only. Other changes are highlighted. Document was transferred to ORA SOP template and formatting updated.

12. Attachments

None