

<p style="text-align: center;"><b>FOOD AND DRUG ADMINISTRATION</b>  <b>OFFICE OF REGULATORY AFFAIRS</b>  <i>ORA Laboratory Manual Volume II</i></p>	<p style="text-align: center;"><b>Document Number:</b>  ORA-LAB.5.2</p>	<p style="text-align: center;"><b>Revision #: 02</b>  <b>Revised:</b>  05/15/2019</p>
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## 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.

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## 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 new-hire training. 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.

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## 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.
  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
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of deviations found with regard to 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. Staff:

1. Completes required training within specified timeframe.
2. Becomes and stays knowledgeable in procedures and methods performed, NOTE: Employees are responsible for self-training, through reading current literature, technical papers, publishing technical papers;
3. Ensures all FDA mandated training, i.e. annual ethics, computer security, etc., is completed and certificate submitted to local training coordinator.
4. Reads and complies with standards, regulations, policies, procedures, and work instructions.

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**4. Background**

None

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**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.

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## 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.

- A. Training requirements are outlined and documented on the basis of the position description of duties and responsibilities.
- B. New hires complete applicable Office of Training, Education, and Development (OTED) New Analyst Training Curriculum.
- C. Training and competency is determined by the employee's educational qualifications, experience, complexity of the test method, and knowledge of the test method performed.
- D. The employee will not perform any procedure, inspection, or method until all applicable training has been completed and competency demonstrated.
- E. Employees may request training related to their duties. OTED posts training and development services for ORS staff on an annual basis. Included in these services are classroom courses, downlinks, lending library, certification and web-based courses.
- F. Employees submit records to supervisor and/or training coordinator for filing upon completion of training.
- G. Training and competency records shall be maintained according to local policy.
- H. The effectiveness of training is evaluated by but not limited to reviews performed by management 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.

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- 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

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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, an analyst must know how to perform a test, have the ability to perform the test, be able to perform the test properly without supervision, and know when there is a problem with the test that must be solved before reporting results.
- C. The major technologies (at minimum the items on accreditation scope) 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,	This is as it is implied, review of checks, QC results, PT results,	QA spreadsheets (chem.) & Pos/Neg controls (micro); Control within acceptable limits;

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FV/PM charts	FV/PM charts	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.
- B. When personnel are authorized for a portion of a method, the training records must indicate which parts of the method the employee has received training.

#### 6.6. Training and Competency Records

- A. Training and competency records are maintained
- B. Training records should include a description of the training, the trainee name, the trainer, dates of training, and indication of successful completion. 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 assigned procedural documents.
  5. Attendance sign-in sheets for in-house training.
  6. A certificate from manufacturer's training courses, computer-based classes, and committees served.

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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 or those 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 a number of procedures, policies and practices upon entry of employment and during their career with FDA. What follows are types of required training and they may vary from employee to employee based on duties.

### **6.8.1. Facility Orientation**

- A. New employees completing required administrative forms as part of initial processing; and
- 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**

- A. Annual Ethics Training



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B. Computer Security Awareness Training

C. Records Management Training

**6.8.3. New-Hire Training often includes:**

A. Basic Food and Drug Law,

B. Evidence Development Course,

C. Quality Systems and Audit Workshop,

D. Investigative Interviewing Course, and

E. OTED/ORA U computer-based training modules (See Volume IV Laboratory Training).

**6.8.4. Safety Training (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. Introduction to the Quality Management System

B. Auditor training

C. Root Cause and Corrective Action procedures

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D. Quality Management Information System training

**6.8.6. On-the-job (OJT) training, Office of Regulatory Affairs national training courses and manufacturer’s training**

A. Managers and employees will work together to identify OJT training needs and attendance in national trainings.

B. Local or external training on policies, regulations, procedures, methods, and instruments.

**6.8.7. Other Training**

Often laboratory staff has an opportunity to attend auxiliary training when available and resources permitting. This type of training includes:

A. Attendance at presentations, courses and conferences; and

B. Computer courses such as in-house training, instructional, and manufacturer’s training on software in use such as Microsoft Word and Excel, ChemStation, and Outlook.

**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.

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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

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## 9. Supporting Documents

None

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## 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

\* - 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.

## 12. Attachments

None