Sections Included in this Document/(Change History)

1. Purpose

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 new-hire training. The training is verified and documented. 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. Responsibilities

A. [Second Level Manager]:

- ensures implementation of training procedure,
- ensures resources are allocated for identified training within budgetary constraints,
- 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,
- ensures training is accomplished,
- submits documentation for completed training for entry into

training database or Integrated Management of Personnel Administration through Computer Technology (IMPACT), and

- identifies training needs and courses and submits to the District Director prior to fiscal year budget.

B. [First Level Manager]:

- implements training and maintains employee training files,
- ensures proper supervision of trainees until training completed,
- reviews training received and ensures training files are complete,
- submits documentation for training completed,
- monitors employee performance to identify the need for retraining or additional continual education, and
- identifies training needs resulting from new or revised procedures and processes.

C. Quality Management Systems (QMS) Manager:

- trains employees in quality control and quality assurance procedures.

D. Staff:

- completes required training within specified timeframe;
- 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;
- reports all training received and submits documentation for training received; and
- reads and complies with standards, regulations, policies, procedures, and work instructions.

4. Background

None

5. References

*National clinical chemistry laboratory standard*s (NCCLS). (1995). Training Verification Approved Guideline.

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

6. Procedure

A. Before starting any work related duties, the employee should be familiar with all work related documents. These documents include procedures, work instructions, applicable manuals and regulations.

B. Training requirements are outlined and documented on the basis of the position description of duties and responsibilities.

C. New hires should complete all ORA U web-based modules for ORA Training and Development for New Hires.

D. The level of training is determined by the employee's educational qualifications, experience, complexity of the test method, and knowledge of the test method performed.

E. The employee will not perform any procedure, inspection, or method until all applicable training has been completed and competency demonstrated. Employees undergoing training are supervised until training is completed and competency demonstrated.

F. Employees may request training related to their job. ORA U posts the training and development services for ORA staff on an annual basis. Included in these services are classroom courses, downlinks, lending library, certification and web-based courses.

G. Upon completion of training submit documentation such as sign-in sheets for entry into training database.

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

6.1 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.

Documentation of these tasks is submitted for filing in the employee's training file.

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

- reading laboratory and district procedures,
- instructions,
- demonstrations,
- lectures and discussions,
- self study,
- computer-based training,
- viewing videotapes, and
- manufacturer's training or demonstration.

Documentation of these tasks is submitted for filing in the employee's training file.

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.

D. Assessment tools include the following:

- *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.

- *Observation of Procedure, Process, or Outcome:* Observation by a

trainer of an employee performing or demonstrating a procedure.

- *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.

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

- *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.

- *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.

- *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.

6.2 Documentation

Examples of Training Verification Records includes any of the following but is not limited to:

- completion of training checklists prepared internally for all procedures that an employee performs;

- completion of the procedure with submission of written evidence;

- completion of blind quality control (QC) samples, proficiency surveys,

QC samples, and duplicate testing with submission of results that are within acceptable criteria limits;

- completion of written evaluations, signing acknowledgment of reading assigned work instructions;
- attendance sign-in sheets (See Attachment A) on in-house training, certificates from manufacturer's training courses and computer classes, and committees served on;
- submission of technical papers and handouts of presentations given, college transcripts for courses taken, licenses and memberships held and special conferences attended;
- completed paperwork on safety briefing, orientation modules, and in- or out-processing steps for new hires or those leaving the organizational unit; and
- memorandums on additional appointments or duties.

NOTE: Social security numbers are not to appear on documentation in employee training files.

6.3 Retraining and Reverifica-tion

A. Retraining:

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

2. Employees will be retrained when the level of performance is unsatisfactory as shown by any to the assessment tools in section 6.1 C.

B. Reverification:

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

2. Performance reverification occurs whenever proficiency surveys, blind QC samples, or duplicate testing are submitted.

6.4 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.

A. Facility Orientation includes:

1. New employees completing required administrative forms as part of initial processing; and

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

B. New-Hire Training often includes:

- Basic Food and Drug Law,
- Evidence Development Course,
- Quality Systems and Audit Workshop,
- Investigative Interviewing Course, and
- ORA U computer-based training modules (See Volume IV Laboratory Training).

C. Safety Training may include the topics of:

- blood-borne pathogen standard,
- hazard communication standard (*Right to Know*),
- universal precautions (e.g. hand washing and aids awareness),
- exposure control plan,
- medical surveillance program,
- personal protective equipment,
- Security briefing,
- safety briefing,
- radiation protection training,
- fire extinguisher training,
- emergency evacuation, and
- safety practices in the laboratory

D. Chemical Hygiene

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

F. Quality Assurance including annual training on quality control (QC), quality assurance (QA), the ORA Quality Management System (QMS) and related procedures.

G. On-the-job training, Office of Regulatory Affairs national training courses and manufacturer's training

H. Training on policies, regulations, procedures, methods, and instruments.

6.5 Other Training

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

- attendance at presentations, courses and conferences; and
- 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.

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7. Definitions

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.

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

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

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

Trainer – Trainiers 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.

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

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

8. Records	Training files and documentation
9. Supporting Documents	None
10. Attachments	Attachment A: Training Sign-In Sheet

Document History

Version No.	Status (I, R, C)	Date Approved	Location of Change History	Name & Title	
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