

FOOD AND DRUG ADMINISTRATION OFFICE OF REGULATORY AFFAIRS <i>Office of Regulatory Science</i>	Document Number: MAN-000066	Revision #: 03 Revised: 10 Aug 2022
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1. Purpose

The purpose of this document is to outline the general training program to ensure engineering personnel competence.

2. Scope

This procedure is an introductory and general training outline for analysts working in an Engineering Laboratory.

3. Responsibility

A. Supervisor

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1. Ensures implementation of this procedure.
2. Ensures resources are adequately allocated to complete necessary training.
3. Ensures all training records are updated and complete.
4. Identifies training needs individually and on an ongoing basis.

B. Trainer

1. Prepares, coordinates, and implements training to analysts as needed/directed.
2. Ensures analyst meets all applicable requirements of directed training.
3. Ensures applicable training is documented and reported correctly.

C. Analyst - Trainee

1. Completes required training within given timeframes.
2. Becomes and stays knowledgeable in procedures and methods performed.
3. Participates, reads and complies with standards, regulations, policies, procedures and work instructions as part of training.
4. Documents and reports all training received as directed.

4. Background

It is understood that an analyst has a basic knowledge of engineering, scientific, and laboratory principles. This procedure serves only to provide guidance on specific methods and procedures within a regulatory engineering laboratory environment. Responsibility for the scientific background material and actual topics covered is left to the individual, the trainer, and the supervisor.

Because of the great diversity of disciplines and the multitude of instruments used by analysts, no specific laboratory sample information is presented here. Instead, a broad program is outlined to introduce or refresh knowledge in several engineering fields. A major portion of the program is the introduction of the new employee to specific laboratory practices, equipment, techniques, and concepts.

Not every topic is required to be covered for all analysts and may be tailored to suit laboratory and individual needs. Specialized training will be given as identified and needed.

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5. Supporting Documents

- A. Specific user and technical manuals as needed
- B. Applicable published standards, test methods and regulations
- C. MAN-000035 ORA Lab Manual Vol. II Personnel Training and Competency Management (ORA-LAB.5.2)

6. Procedure

6.1. New Hire or Previous Training

Prior to beginning the activities outlined within this procedure, it is expected that the analyst will have started or completed required laboratory training as part of the on-board process.

6.2. Engineering Laboratory General Training

In addition to higher level training on various systems, new analysts will be trained in specific practices within the engineering laboratory environment.

6.3. Local Systems

Analysts will be trained on various systems, subsystems, and forms specific to engineering lab practices. This may include but is not limited to:

- A. FACTS
- B. LIMS
- C. QMiS
- D. Access and use of local quality procedures, documents, and forms
- E. Lab specific worksheets and forms
- F. Lab specific safety and environmental procedures

6.4. Engineering Laboratory Methods/Procedures/Techniques

Analysts will be trained on various engineering methods, procedures and techniques that are specific to their engineering laboratory. These may include but are not limited to:

- A. Test methods/methodology
- B. Use of standards (e.g., weights, pin gauges, calibrators)
- C. Method validation and/or verification

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- D. Instrument verification/calibration
- E. Creating and using memos of analysis (MOA)
- F. Use of consensus and/or published standards and CFRs

6.5. Engineering Laboratory Instrumentation

Analysts will be trained on various engineering instrumentation and equipment, as needed. This may include but is not limited to:

- A. Cameras and lighting
- B. Microscopes and magnifiers (for visual inspection)
- C. Force measurement equipment (e.g., for tensile, compression, adhesion)
- D. Dimensional measurement equipment (e.g., for lengths, diameters, geometric dimensioning)
- E. Conditioning / environmental equipment (e.g., environmental chamber, temperature, humidity, water bath)
- F. Electronic instruments (e.g., multimeters, oscilloscopes, simulators)

6.6. Engineering Laboratory Sample Training

Analysts will be trained on specific methods and practices associated with engineering regulatory samples. This will involve a variety of training techniques such as reading/reviewing procedures, observation/shadowing, and/or hands-on practice. This may include but is not limited to:

- A. Attend/review presentations, methods, procedures, and/or forms.
- B. Observe demonstrations or watch a trained analyst perform testing on a regulatory sample.
- C. Hands-on testing using a practice sample.
- D. Test a regulatory sample under Trainer supervision.
- E. Perform a regulatory analysis with Trainer review.

6.7. Scope or Program Analyses

Analysts are trained to perform analyses specific to a variety of ongoing programs. These programs may require specific training, certification, and/or the use of specific methodologies to established standards or regulations. This may include but is not limited to:

- D. Medical gloves
- E. Clinical thermometers

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F. Laser devices

7. Glossary/Definitions

None

8. Records

Training files and documentation

9. References

None

10. Document History

Revision #	I	Date	Author Name and Title	Approving Official Name and Title
1.2	R	02/02/2010	LMEB	LMEB
1.3	R	02/14/2013	LMEB	LMEB
02	R	See QMiS	LMEB	LMEB
03	R	See QMiS	LMEB	LMEB

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

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11. Change History

Revision #	Change
1.2	Contents – added section 3.15 13.1 – minor revision to paragraphs 1 and 3. 13.2 B. – deleted 3 topic bullets and 2 equipment bullets 13.5 B. – deleted “including mercury-in-glass” 13.6 B – added “and temperature” to third bullet 13.8 B and 13.9 B – changed “will” to “may” 13.9 B. – deleted last two bullets; revised fifth bullet 13.11.5 A – added “digital and film radiography” 13.11.5 B. – added “may” to first sentence; deleted last paragraph 13.12.1 B. – deleted last part of second paragraph 13.12.7 B. – deleted equipment list 13.12.8 B – deleted second sentence 13.15 – section added Footer - updated
1.3	Header – Division of Field Science changed to Office of Regulatory Science
02	Complete rewrite to restructure and more accurately reflect current training practices within Engineering.
03	Grammar and format corrections made. No changes to process content with this revision.

12. Attachments

None