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13.1 Introduction

This section is an introductory and training outline for new employees having the equivalent of a bachelor's degree in engineering or related physical sciences. Responsibility for the scientific background material is left to the individual and the trainer.

Because of the great diversity of disciplines and the multitude of devices used by engineers or scientists, no sample information is presented here. Instead, a broad program is outlined to introduce and refresh knowledge in a number of engineering fields, with assignments to provide "hands on" experience using the type of equipment common to engineering analyses. A major portion of the program is the introduction of the new employee to laboratory equipment, the fundamentals of its use, and to the individuals who are familiar with the equipment and knowledgeable in the respective fields.

Specialized training will be given as identified and needed.

13.2 Photography

A. Objective

To review the basic principles of photography and to introduce photographic equipment to the trainee.

B. Assignment

The trainer will review the fundamentals of photography with the trainee. Topics to be covered include:

- f-stop,
- depth of field,
- film speed,
- filters,
- lighting,
- light meters, and
- film storage.

The trainer will introduce photographic equipment and instruct in its use and care. Equipment presented should include:

- 35 mm camera,
- digital camera,
- Polaroid camera,
- oscilloscope camera,
- close-up camera,
- microscope camera, and
- other equipment (scanners, color printers).

The trainee will be expected to gain practical experience using the photographic equipment to produce good quality photographs with complete and accurate detail.

13.3 Basic Electricity

A. Objective

To provide the trainee with a review of the fundamentals of electricity associated calculations, and other considerations.

B. Assignment

The trainer will present a fundamental review of electricity, including:

- direct-current (DC),
- alternating-current (AC),
- Ohm's Law,
- voltage dividers,
- capacitive effects,
- frequency response,
- input impedance,
- line regulation,
- grounding,
- "floating" equipment, and
- high-voltage measurements.

The trainee will be assigned calculations and exercises as needed to provide practical experience in the proper use of electricity and in the handling of problems associated with its use and measurement.

13.4 Electromagnetic Interference

A. Objective

To introduce the trainee to the fundamentals of electromagnetic interference and the methods and equipment used for its measurement.

B. Assignment

The trainer will review the fundamentals of electromagnetic waves, electromagnetic fields, and the electromagnetic spectrum. The trainer will present information on the three types of electromagnetic interference (conducted, static, and radiated) encountered, discuss examples of electromagnetic interference pertinent to the Agency's regulation of medical devices and radiation-emitting products, and present information on spectral analysis methods and equipment used to assess electromagnetic interference.

Through assigned exercises, the trainee will be expected to become familiar with the methods and equipment used to characterize electromagnetic fields and assess electromagnetic interference.

13.5 Temperature

A. Objective

To provide the trainee with the fundamentals of temperature and temperature measurement.

B. Assignment

The trainer will present basic information regarding temperature and temperature measuring equipment. Topics to be covered are:

- constant temperature baths,
- thermometers and their corrections (such as stem correction),
- thermistor-based temperature measuring equipment,
- calibration of temperature measuring equipment, and
- use of standard thermometers, including mercury-in-glass and platinum resistance thermometers.

The trainee will be expected to gain practical experience with laboratory equipment.

13.6 Relative Humidity

A. Objective

To provide the trainee with a review of the fundamentals of relative humidity and the measurement of relative humidity.

B. Assignment

The trainer will present a fundamental review of relative humidity and instrumentation (and instrument calibration techniques) used to measure relative humidity, including:

- sling psychrometers,
- hygrometers,
- electronic humidity sensors and instruments, and
- environmental chambers.

The trainee will be assigned calculations and exercises to provide practical experience in the measurement of relative humidity.

13.7 Mechanical Forces and Thickness

A. Objective

To provide the trainee with a review of mechanical force and thickness measurement fundamentals and to introduce measurement instruments.

B. Assignment

The trainee will review the fundamentals of force and thickness measurements and be instructed in the use and maintenance of measuring equipment. Some of the equipment and topics to be covered are:

- micrometers,
- vernier calipers,
- dial thickness gauges,
- linear displacement gauges,
- standard rules,
- push-pull force gauges,
- tension dynamometer,
- hardness testing equipment,
- piezoelectric crystal transducers,
- weighing scales and balances,
- stiffness testing,
- torque measurement, and
- shaker tables.

The trainee will be assigned practical exercises using laboratory equipment.

13.8 Pressure

A. Objective

To introduce the trainee to the fundamentals of air and fluid pressure and the methods and equipment used for their measurement.

B. Assignment

The trainer will review the basic principles of air and fluid pressure measurements and associated theoretical considerations, including the concept of fluid pressure "head" and its application.

The trainer will present and explain the pressure measuring equipment and will instruct in its use. Equipment to be presented will include:

- barometer and correction of readings,
- well manometers,
- "U" tube manometers,
- aneroid gauges,
- differential pressure devices,
- pressure transducers, and
- pressure standards.

The trainee will be expected to become familiar with the use and application of the equipment through exercises assigned by the trainer.

13.9 Air Flow

A. Objective

To introduce the trainee to the fundamentals of air flow and volume measurements.

B. Assignment

The trainer will present the basic principles of flow measurement and volume determinations.

The trainer will describe to the trainee the use of flow and volume instrumentation and the application of correction factors. The equipment involved will include:

- rotometers,
- regulators,
- orifice plates,
- volume standards,
- hot-wire anemometer,
- turbine anemometer, and
- pressure-drop anemometer.

In addition, maintenance of air-line filters and other ancillary equipment will be covered.

The trainee will be expected to become familiar with the use of airflow equipment through assigned exercises.

13.10 Sound

A. Objective

To introduce the trainee to the principles of sound and acoustic measurement.

B. Assignment

The trainer will present the fundamentals of sound and its detection and measurement. Areas to be covered include:

- acoustical transducers,
- decibels,
- frequency spectrum,
- "weighting" of sound measurements,
- measurement of sound pressure levels, and
- "noise" hazards and typical sound levels.

The trainee will be expected to become familiar with the use of sound measuring equipment through assigned exercises.

13.11 Radiation

13.11.1 Sources of Radiation Exposure

A. Objective

To introduce sources of radiation exposure, both natural and manmade, and to provide a background in radiation protection and safety to the trainee.

B. Assignment

The trainer will present information on radiation protection, safety rules and regulations, and various sources of radiation exposure.

The trainee will be expected to read assigned references and be able to apply radiation safety procedures, as instructed.

13.11.2 Radiobiology of Ionizing Radiation

A. Objective

To familiarize the trainee with the biological effects of ionizing radiation.

B. Assignment

The trainer will present the fundamentals of ionizing radiation radiobiology, to include:

- sequence of biological effects,
- determinants of biological effects, and
- carcinogenic, teratogenic, and genetic effects of ionizing radiation exposure.

13.11.3 Radiation Instrumentation

A. Objective

To introduce the trainee to the various types of instruments for radiation detection and measurement and to provide practical experience in their use.

B. Assignment

The trainer will present the various types of instruments, their preferred uses, their limitations, and the corrections needed to read actual (corrected) values for each type. Instrument types to be presented include:

- GM (Geiger Mueller) counters,
- ionization chambers,
- scintillation detectors,
- thermo luminescent dosimeters (TLD), and
- film dosimeters.

The trainee will perform measurement and/or calibration exercises assigned by the trainer.

13.11.4 Properties and Production of X-rays

A. Objective

To introduce the trainee to the basic properties and methods of x-ray production.

B. Assignment

The trainer will present the fundamental properties of x-rays and the basics of x-ray machines. This presentation will include:

1. X-rays
 - a. definition
 - b. production
 - c. properties

2. X-ray machines
 - a. set up
 - b. controls
 - c. production of x-rays

3. X-ray exposure variation
 - a. kVp
 - b. mA
 - c. mAs
 - d. time
 - e. distance

4. X-ray scatter

The trainee will become familiar with the operation, uses, and limitations of x-ray equipment.

13.11.5 Radiography and X-ray Film Processing

A. Objective

To acquaint the trainee with the fundamentals of taking a radiograph, processing the film to produce the desired results, and reading film using a densitometer.

B. Assignment

The trainer will present the fundamentals of radiography, which include:

1. Radiographic film
 - a. description
 - b. characteristics
 - c. image formation

2. Intensifying screens

3. Grids

4. Film developing
 - a. manual
 - b. automatic processing
 - c. variation with developer temperature

5. Film variation
 - a. kVp
 - b. mA
 - c. mAs
 - d. time
 - e. distance
 - f. large vs. small x-ray tube focal spots

6. Film densitometers and their use

Practical exercises will include use of an x-ray machine and variation of exposure factors.

The trainee will be expected to be capable of producing an acceptable radiograph deciding on exposure technique factors for the objects and developing the film.

13.12 Instrumentation

13.12.1 Soldering and Wiring

A. Objective

To review the fundamentals of good soldering techniques and good wiring practices.

B. Assignment

The trainer will introduce the various types of soldering equipment and will review the basic principles of good solder joint production and good wiring practices.

The trainer will present methods and precautions for soldering and working with semiconductor devices in general and with CMOS (complementary metal oxide semiconductor) devices in particular.

The trainee will be expected to perform practical exercises assigned by the trainer to gain experience in hardwiring components and circuits.

13.12.2 Analog and Digital Meters

A. Objective

To introduce the trainee to types of meters, their operating principles, what the meters actually measure, their use, and precautions regarding their use.

B. Assignment

The trainer will review the fundamentals of meters and their use. Included in the review will be the following:

1. Direct current meters
 - a. d'Arsonval movement
 - b. ammeter
 - c. voltmeter
2. Alternating current meters
 - a. voltmeter
 - b. ammeter
 - c. wattmeter
3. Ohmmeters
4. Multimeters
5. Peak reading voltmeter

The trainee will perform exercises with meters to gain practical experience in their use, the proper choice of meter for a given application, and interpretation of the manufacturer's specifications for individual meters.

13.12.3 Oscilloscopes

A. Objective

To acquaint the trainee with various oscilloscopes and accessories.

B. Assignment

The trainer will introduce oscilloscope equipment and will discuss equipment capabilities for given measurement applications. Among components to be discussed are:

- portable oscilloscopes—line and battery powered
- digital storage oscilloscopes
- vertical amplifiers
- time bases—normal and delaying
- differential comparators
- probes, their selection and use

The trainee will be expected to gain familiarity with oscilloscope equipment and its use through practical experiments assigned by the trainer. The trainee is also encouraged to experiment with the equipment independently—to learn how to select the proper equipment for a given measurement and to become aware of equipment strengths and limitations.

13.12.4 AC and DC Power Supplies

A. Objective

To introduce the trainee to AC and DC power supplies.

B. Assignment

The trainer will present the AC and DC power supplies, including transformers, batteries, generators, and solar cells, and will instruct the trainee in their applications and use.

The trainee will be expected to become familiar with these devices through practical exercises assigned by the trainer.

13.12.5 Pulse and Function Generators

A. Objective

To introduce the trainee to pulse and function generating equipment.

B. Assignment

The trainer will present the pulse and function generating equipment and will instruct the trainee in its use.

The trainee will be expected to become familiar with the equipment through practical exercises assigned by the trainer.

13.12.6 Calibrators and Standards for Electronic Instrumentation

A. Objective

To introduce the trainee to laboratory standard instruments, standard calibrators, and local operating procedures regarding their use.

B. Assignment

The trainer will present the calibration standards and standard electronic instrumentation. Types of standard instruments to be introduced will include:

- voltage standards
- current standards
- frequency standards
- time standards
- resistance/impedance standards

In addition, local policy, procedures, and constraints regarding their use will be covered.

13.12.7 Special Purpose Instrumentation

A. Objective

To introduce the trainee to instrumentation for making special purpose measurements and for acquiring/accumulating specialized data.

B. Assignment

The trainer will introduce the special purpose instrumentation and describe its use. Some of the equipment to be presented will include:

- instrumentation tape recorder
- memory voltmeter
- transient store unit

- line voltage monitors
- capacitance meters
- scaler timers
- chart recorders
- electrical safety leakage tester

The trainee will be expected to gain practical experience with the equipment through exercises assigned by the trainer.

13.12.8 Automated Data Collection Systems

A. Objectives

To provide the trainee with an introduction to the types of automated data collection systems and their use.

B. Assignment

The trainer will introduce automated data collection systems and their interface with data gathering sensor systems. Basic programmable calculator programming and "canned" programs will be presented.

13.13 Medical Device Standards

A. Objective

To introduce the trainee to sources of medical device standards and their use in the analyses of medical devices.

B. Assignment

The trainer will present information on medical device standards including policies, laws, and regulations prescribing the use of medical device standards by the Agency, sources of medical device standards, types of medical device standards (e.g., test methods, specifications, guides, and practices, etc.), and these standards in analyses of medical devices.

The trainee will be expected to become familiar with medical device standards and their use in medical device analyses through practical exercises assigned by the trainer.

13.14 References

1. User and technical manuals for local instruments and systems.
2. Other material as assigned by the trainer.