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1. Purpose

This document describes the guidelines for Office of Regulatory Science (ORS) laboratory facilities to ensure that the environmental conditions do not adversely affect or invalidate sample handling, instrumentation, analytical testing, and calibrations.

2. Scope

This procedure applies to all ORS laboratories.

3. Responsibility

A. Laboratory Management:

1. Ensures laboratory facilities meet the required environmental conditions, including any needed separation of work areas to ensure

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that analyses and calibrations will not be adversely affected within resources provided;

2. Ensures laboratory storage areas provide proper storage of samples, reagents, microbiological media, chemicals, select agents, standards and reference materials, and radioactive wastes and hazardous waste;
3. Ensures any additional laboratory conditions needed for specialized analyses are met, including structural, equipment needs and procedures for the handling and analysis of extremely hazardous materials within resources provided;
4. Ensures additional resources needed are identified and procured;
5. Ensures scheduled cleaning and maintenance service of the laboratory facility is accomplished;
6. Ensures a pest control program is in place;
7. Ensures modifications are made to the laboratory to accommodate new equipment, so the equipment does not interfere with the environmental controls in the laboratory;
8. Implements environmental control programs in the laboratory;
9. Performs continual laboratory surveillance to ensure proper conditions are being met, and
10. Recognizes when environmental conditions are not met and adversely affect test or calibration results.

B. Staff:

1. Plans and conducts laboratory operations in designated areas;
2. Monitors and records environmental conditions in their areas;
3. Identifies and implements any environmental controls needed to complete sampling, analysis and calibration, and ensure these factors do not adversely affect the quality of the work;
4. Practices good housekeeping practices; and
5. Practices proper handling and storage of hazardous waste, as defined in the Hazardous Waste Plan, so as not to adversely affect laboratory operations.

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4. Background

None

5. References

- A. Center for Disease Control, National Institutes of Health. Biosafety in microbiological and biomedical laboratories, current edition. Washington, DC: United States Department of Health and Human Services, Public Health Service.
- B. CRC Handbook of Laboratory Safety.
- C. Code of Federal Regulations. Title 29, Part 1910.1450. Washington DC: Government Printing Office.
- D. Code of Federal Regulations. Title 29, Part 1910.1000. Washington DC: Government Printing Office.
- E. American National Standards Institute/American Industrial Hygiene Association (ANSI/AIHA) Z9.5 Standard - Laboratory Ventilation Guidelines
- F. National Science Foundation (NSF)-ANSI 49 Class II (Laminar Flow) Biosafety Cabinetry
- G. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Section 6.3.
- H. 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. Environment

- A. The laboratories are designed to provide space, engineering controls, and proper environmental conditions for optimal sample storage, sample handling, analysis, and calibrations, in accordance with general laboratory practices, safety, and applicable Federal, State and local regulations.
- B. Facilities consist of laboratories, office areas, storage rooms, and special purpose areas. Laboratories are sectioned by testing

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compatibility and design capabilities. Floors in the laboratories are constructed from a material that is resistant to most chemical spills and easily disinfected. Microbiology labs are designed to minimize areas with cracks or fibers that could serve to accumulate debris and serve as an area for growth of microorganisms. Floors are clean, dry, and in sound condition so there are no tripping hazards.

- C. Laboratories are equipped with climate and ventilation control. The temperature and humidity within the laboratory are maintained within limits for the proper performance of each test or analysis and maintained according to the manufacturer's specifications for the proper operation of instruments. A comfortable working environment is considered 20 to 25° C with relative humidity of 35 to 50% depending on geographical area. In general, the work areas should be free of temperature extremes that are hazardous to health or which interfere with safe operations. Laboratories where toxic materials are handled are under negative pressure to adjoining areas with 8 to 12 air changes per hour. High hazard laboratories, clean rooms/isolators, animal facilities, and Biosafety Level III suites have unique working conditions. Work, storage areas, and restrooms are free of noxious odors. Exhaust ventilation is maintained for 24 hours per day in any area where chemicals are stored or used. No laboratory air is recycled through the building. The supply vents should not exceed 50 feet per minute (FPM) airflow.
- D. The laboratory maintains sufficient illumination for the procedure being performed and the noise levels conform with Occupational Health and Safety Administration (OSHA) guidelines. Lighting is at suggested level of 80 to 100 foot-candle intensity unless it affects the analysis and other lighting is needed. Specialized lighting may be needed in areas where direct sunlight can be deleterious to samples, reagents and media or can interfere with instrumentation or analysis.
- E. Workbench space is sufficient to perform operations and to prevent clutter. Benches are constructed of a material that is easily disinfected and impervious to most chemical spills. Bench space is convenient to sinks, water, gas, suction, and electrical outlets needed to properly carry out tests or analyses offered by the laboratory.
- F. The laboratories are equipped with chemical hoods to capture hazardous or odorous materials used or produced in the analyses and to protect employees from hazardous concentrations of airborne toxic substances. Class II biosafety cabinets (BSC) are provided for biohazardous analysis and sterility work. Laminar flow cabinets are not

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used because of the lack of employee protection. Sufficient hood space should be provided to laboratory employees. Face velocities for chemical hoods must be within 80 to 120 FPM with minimal distortion of air movement (cross-drafts) through the face of the hood from activities or sources in the room. Maintenance is performed routinely on these systems.

- G. Local utilities companies provide electricity and water. An auxiliary power generating system is in place to provide emergency power for hazardous or sensitive operations. Recommended parameters for electrical power include voltage regulation to within 5 to 10% of nominal with minimum line transients and a grounding system. Voltage regulation is important for instrumentation to maintain stable, drift-free operation. Constant-voltage transformers are in place to regulate voltage where line fluctuations occur. All instruments and equipment are grounded. Type I or Type II water is used for dilutions, preparation of reagent solutions and final rinsing of glassware. Ground fault interrupters are used in wet areas where there is a shock hazard. Electrical service is supplied, and circuit breakers are identified in electrical boxes.
- H. Separate storage areas of sufficient size are present in the laboratory to ensure that glassware, portable instrumentation, microbiological media, supplies, reagents, solvents, chemicals, hazardous or regulated wastes and reference standards and materials are properly stored. Separate storage areas prevent contamination or degradation, ensure the laboratory is in compliance with regulatory authorities, meet security needs, assure personnel safety, and minimize clutter. Chemicals and solvents are stored compatibly and in accordance with the manufacturer's guidance in the Material Safety Data Sheet (MSDS) and the fire code. Storage areas for samples are to accommodate retention of samples for the times and conditions needed to protect their integrity. Shelving units in storage areas are braced to prevent collapsing of the shelves.

6.2. Environmental Monitoring

NOTE: Calibrations or analysis of samples are not performed if monitoring reveals that required environmental conditions are not met.

- A. In laboratory rooms where temperature and relative humidity affect the analytical results, temperature and humidity are monitored and recorded. In some instances, the test is placed in a smaller controlled environment such as an incubator.

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- B. Chemical hoods and BSCs are visually checked for proper operation before each use. BSCs and chemical hoods are certified annually. As a minimum, airflow velocities in hoods are measured for the following two situations: (a) Hoods are measured annually, before use with a very toxic, low permissible exposure limit (PEL) or time weighted average (TWA) value material, and (b) whenever there is a fluctuation in performance. Biosafety cabinets are additionally monitored for particulates whenever there is a concern. A magnehelic gauge on the BSC monitors the static pressure on the high efficiency particulate HEPA filter to determine when the filter needs changing.
- C. Bench surfaces and hoods in microbiology laboratories are monitored periodically for microbiological contamination. Additionally, air sampling is performed periodically to monitor for microbiological contamination in these laboratories. Routinely, a series of antimicrobial cleansers are used in the microbiology laboratory at the end of an analysis, at the end of the day, or in the event of a spill to minimize any potential microbial contamination. In the chemical laboratories, air monitoring is conducted whenever there is a complaint of odors or other suspect indications of the presence of a chemical. Monitoring is mandatory when the chemical is regulated by Occupational Safety and Health Administration (OSHA) as a toxic air contaminant in 29 CFR, Part 1910.1000 and there is reasonable evidence of employee exposure.
- D. The laboratory shall define the use of water and ensure that the water is fit for that use. Distilled or de-ionized water systems are monitored at least monthly to ensure the water meets method specific quality attributes. Water used for microbiology analyses is verified monthly for acceptable levels of chlorine and aerobic plate count. Water used for pharmaceutical analyses is verified to meet the requirements of FDA Inspection Technical Guide, Number 46 Water for Pharmaceutical Use. Additional tests are performed on the water systems as defined by the laboratories to ensure the water is fit for use.
- E. In laboratories that perform metal analysis, benches, hoods and glassware are monitored periodically for metal contamination.
- F. Routine insertion of analytical and media blanks with sample analysis detects laboratory environmental contamination and any cross-contamination.

6.3. Segregation

- A. Separate areas are maintained for incompatible activities, and measures are taken to prevent cross-contamination. For example, no organics are used in a perchloric acid hood.

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- B. Sample receiving and storage is conducted in designated areas which are separate from the main part of the laboratory.
- C. The laboratory areas are separated from other sections in the building, such as Administrative Services, Investigation Branch, Compliance Branch, lunchroom and conference room facilities.
- D. Areas of specialized testing are separated from general work areas.
- E. Chemical, standards, reference materials and cultures are stored separately from samples.
- F. Microbiology media preparation and sterilization areas are separated from work areas to prevent contamination of clean media.
- G. Where feasible, volatile organic operations will be physically separated from solvent and sample handling areas and vented.

6.4. Housekeeping

- A. Laboratory areas are maintained sufficiently clean and orderly to prevent contamination of samples and to facilitate the efficiency of laboratory operations.

NOTE: Contractors perform a portion of the housekeeping responsibilities under the direction of the immediate supervisor or the principal analyst. Contractors are not allowed in certain laboratories without escort and guidance.

- B. Housekeeping, as a minimum, includes the following activities:
 1. sweeping or mopping floors, including walk-in refrigerators;
 2. cleaning up spills immediately;
 3. adequately decontaminating and cleansing glassware;
 4. cleaning contaminated equipment, removing all chemicals upon completion of analysis, removing all contaminants when the equipment is placed in surplus;
 5. disposing of radioactive, infectious, DEA-controlled, select agent, hazardous, and universal wastes properly;
 6. controlling pests; the use of aerosol agents to eliminate pests is discouraged as they can cause cross contamination to samples for several chemistry analysis, such as pesticides;
 7. emptying trash cans;
 8. vacuuming carpet;

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9. cleaning restrooms; and
10. monitoring storage areas to ensure storage conditions are clean and dry, there is no leakage of product, timely disposition of materials, and proper containment of offensive materials.

7. Glossary/Definitions

- A. Accommodation – This refers to space in the laboratory area and how it is suited for the work performed.
- B. Extremely hazardous – This is a characteristic of chemical compounds that are highly toxic or dangerous, such as arsenic or radioactive materials.
- C. Clutter – This refers to a crowded, confused, or messy collection of things.
- D. Incompatible - Activities or analyses which interfere or adversely affect other activities or analysis in the same area are considered incompatible.

8. Records

- A. Temperature and humidity records
- B. Maintenance, certification and performance records on chemical hoods and biosafety cabinets
- C. Surface and air sampling records for contamination
- D. Maintenance and performance records on water systems
- E. Pest inspections

9. Supporting Documents

- A. ORA Laboratory Manual, Volume III, Section 1 Environmental Health and Safety

10. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
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1.1	R		LMEB	LMEB
1.2	R	10/01/03	LMEB	LMEB
1.3	R	08/15/08	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