WAC 16-309-130 Facilities, equipment, and maintenance. (1) Facilities where laboratory testing is performed must be designed for dealing with preanalytical, analytical, and postanalytical functions.

(2) The laboratory must monitor, control, and record environmental conditions as required by the relevant specifications, methods, and procedures where they influence the quality of the results. Due attention must be paid to biological sterility, dust, electromagnetic disturbances, humidity, electrical supply, temperature, and sound and vibration levels, as necessary to the technical activities concerned.

(3) Laboratories recycling solvents by roto-evaporator or similar equipment must have a procedure for evaluating recycled solvent performance prior to use in testing. This must be applied any time the laboratory recycles solvents.

(4) The laboratory must have space for the number of personnel and separation of work areas.

(5) The arrangement of space must allow for workflow, sampling, lab space, office space, and break areas.

(6) The laboratory must have eyewash stations, safety showers, and sinks within the laboratory in areas where exposure to corrosive chemicals or substances may occur. Eyewash facilities must be no greater than 10 seconds unobstructed travel distance from the area in the laboratory where hazardous chemicals are present.

(7) The laboratory must have chemical spill kits on-site and placed in locations that are well-labeled and easily available to personnel.

(8) The laboratory must have adequate electrical outlets, unobstructed, single-use, multiplug adaptors with surge control; single-use extension cords; ground fault circuit interrupters near wet areas.

(9) The laboratory must have sufficient numbers and types of safety equipment to minimize personnel exposure to biological hazards and toxic materials. There must be vacuum traps, ventilation for fume hoods and around solvent use or storage of solvents or waste. There must be storage cabinets for flammable solvent, acids, and bases. There must be vented hoods for any microbiological analysis (i.e., Class II Type A biosafety cabinets as applicable).

(10) The laboratory must assign a unique identifier to distinguish the individual test instrument and software version used. Each test result must be traceable back to the instrument used at the time of testing.

(11) The laboratory must comply with the scheduled maintenance and function checks recommended by the manufacturer at minimum and perform preventive maintenance and check critical operating characteristics of each instrument used in the testing process. Records must be retained for all instruments and equipment.

(12) For automated liquid handling equipment performing quantitative aliquoting, the laboratory must check the accuracy and precision of each system, perform a contamination check, and monitor and detect system issues or failures (e.g., drips or leaks, short sampling, bubbles, or air gaps in reagent dispensing lines) on a regular basis.

(13) The laboratory must verify the accuracy and precision of each pipette or pipetting device prior to placing it into service. Each device must be rechecked at least every six months. If the pipette or pipetting device is used to make measurements at different volumes, accuracy and precision must be checked at each volume used. Devices that do not meet stated precision and accuracy criteria must be removed from service.

(14) The laboratory must check and record temperatures on temperature sensitive devices (e.g., water baths, heating blocks, incubators, ovens, refrigerators, freezers, and refrigerated centrifuges) on a daily or when used basis. The laboratory must establish acceptance ranges to ensure proper storage conditions for samples, calibrator and control materials, test materials, and to ensure correct analytical conditions according to manufacturer and procedure requirements. Temperature records must be complete and clearly document the date and individual performing the check, and the laboratory must document corrective actions taken to address unacceptable temperature readings.

(15) Analytical balances must be mounted in accordance with manufacturer's instructions. They must be serviced and checked periodically over the relevant weight range using ANSI/ASTM Classes 1-3 or equivalent weights.

(16) The laboratory must verify instrument and equipment performance prior to initial use, after major maintenance or service, and after relocation to ensure that they run within defined tolerance limits and according to expectations.

(17) Instrument maintenance records and function check documents must be reviewed by technical supervisory staff or the scientific director at least monthly.

(18) Instruments that do not meet performance specifications must be placed out of service and labeled as "Not in Use" until it has been repaired and shown by verification that it will perform correctly.

(19) Laboratories must demonstrate, when possible, that calibrations of critical equipment and hence the measurement results generated by that equipment, relevant to their scope of accreditation, are traceable to the SI through an unbroken chain of calibrations.

(20) Laboratories must have breakrooms separate from the laboratory and ensure that food is not kept in refrigerators that have specimens, chemicals, or other laboratory related materials.

[Statutory Authority: RCW 15.150.030 and 2022 c 135. WSR 24-09-079, § 16-309-130, filed 4/17/24, effective 5/18/24.]