

D3001

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§493.1101 Standard: Facilities

(a) The laboratory must be constructed, arranged, and maintained to ensure the following:

(a)(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.

Interpretive Guidelines §493.1101(a)(1)

Work areas should be arranged to minimize problems in specimen handling, examination and testing, and the reporting of test results.

Workbench space should be sufficient for test performance, well lit, and have water, gas, suction, and, electrical outlets as necessary. Instruments, equipment, and computer systems should be placed in locations where their operation is not affected adversely by physical or chemical factors, such as heat, direct sunlight, vibrations, power fluctuations or fumes from acid or alkaline solutions. Equipment tops should not be used as workbench space.

Determination of proper lighting is subjective since the regulations do not specify the foot-candles or other measures of light intensity required. Ensure that lighting or background is appropriate for visual interpretation of test results (e.g., macroscopic evaluation of hemagglutination reactions or strep screen; dark background with reflected light for reading K-B disk diffusion AST). When citing deficiencies, document the circumstances in which lighting adversely or may adversely affect test performance or personnel safety.

Determine that the laboratory has a system to ensure its ventilation system properly removes vapors, fumes, and excessive heat, when appropriate, for the type of testing done in the laboratory.

Ensure that an adequate, stable electrical source is maintained at each location (e.g. outlets, not extension cords) and meets the power requirements for each piece of equipment.