902 KAR 11:020. Reports and standards of health and safety.

RELATES TO: KRS Chapter 333
STATUTORY AUTHORITY: KRS 194.050
CERTIFICATION STATEMENT:
NECESSITY, FUNCTION, AND CONFORMITY: KRS Chapter 333 directs that the Cabinet for Human Resources may require medical laboratory directors to submit reports concerning selected test results and medical laboratory operations. KRS Chapter 333 authorizes the Secretary for Human Resources to adopt rules and regulations to effectuate the provisions of KRS Chapter 333, including standards of construction of medical laboratories, sanitary conditions within the medical laboratory and its surroundings, and licensure of medical laboratories. This administrative regulation sets out the contents of the required reports, standards of health and safety for medical laboratories, and a provision relating to licensure.

Section 1. Reporting of Information Concerning Operations. The medical laboratory director shall submit to the cabinet reports of operation as the cabinet may require.

Section 2. Medical Laboratory Space, Facilities, and Personnel Health. Conditions in the medical laboratory shall be adequate to ensure proper performance of services within the laboratory. The following requirements shall be met:

(1) Workbench space within the laboratory shall be ample, well-lighted, and situated to facilitate the use of necessary sinks, water, gas, suction, and electrical outlets.

(2) Work areas shall be arranged to minimize problems in transportation and communication.

(3) The laboratory shall be properly ventilated.

(4) Volatile chemicals and inflammable solvents shall be properly stored in areas where they are unlikely to ignite.

(5) Temperature and humidity within the laboratory shall be controlled within the limits required for proper performance of tests and operation of instruments affected by these variations.

(6) Fire precautions and occupational safety rules shall be posted and observed to avoid physical, chemical, and biological hazards.

(7) Appropriate sterilization and disinfection techniques shall be used for tests performed on potentially contaminated material. Pipettes, Petri dishes, and other disposable items shall be appropriately discarded immediately after use. Each sterilizing cycle shall contain a recording thermometer or other device indicating the point of proper sterilization. Records of temperature readings shall be kept at least two (2) years. Proper operation of the autoclave shall be checked monthly with viable spores or appropriate indicator.

Section 3. Provisions for Acceptance by National Licensing or other Accrediting Bodies. With the exception of 902 KAR 11:030 and Section 1 of this administrative regulation, medical laboratories inspected and certified pursuant to 42 USC 263a, Public Health Service Act, and medical laboratories which have been inspected and accredited by the commission on inspection and accreditation of the College of American Pathologists or by any other national accreditation body approved by the cabinet, shall be deemed to meet all of the requirements for licensure, if the standards applied by the commission or body in determining accreditation of the medical laboratory are equal to, or more stringent than, the provisions of KRS Chapter 333 and the rules and regulations issued pursuant to KRS Chapter 333; and there is adequate provision for assuring the standards continue to be met by the laboratory.

Section 4. Compliance with State, Federal, and Local Laws. All medical laboratories shall comply with any other applicable state, federal, and local laws and regulations.
(3 Ky.R. 197; 748; eff. 5-4-1977; 20 Ky.R. 2180; eff. 3-14-1994; eff. 3-22-2019; Crt eff 12-29-2025.)