906 KAR 1:040. Blood establishment inspection.

RELATES TO: KRS 216B.010-216B.055, 333.120, 21 C.F.R. Chapter 1, Part 601
STATUTORY AUTHORITY: KRS 214.020, 214.450-214.464, 214.468, 214.990(7), EO 96-862
NECESSITY, FUNCTION, AND CONFORMITY: KRS 214.452 mandates that the Cabinet for Health Services promulgate administrative regulations to establish fees for the cost of regular inspections of all blood establishments to determine their compliance with KRS 214.450 to 214.464 and 214.468. KRS 214.452(1) requires blood establishments to be licensed by the United States Food and Drug Administration. Federal regulation 21 CFR Chapter 1, Part 601, does not require Kentucky to conduct the federal inspection required for licensure. This administrative regulation does not conflict with those federal requirements because its purpose is to establish fees for the cost of inspections necessary to determine compliance with KRS 214.450 to 214.464 and 214.468. Executive Order 96-862, effective July 2, 1996, reorganizes the Cabinet for Human Resources and places the Office of Inspector General and its Programs under the Cabinet for Health Services.

Section 1. Definitions. "Blood establishment" is defined in KRS 214.450(2).

Section 2. Annual Inspection. The Office of Inspector General shall conduct an annual inspection of all blood establishments to determine their compliance with KRS 214.450 to 214.464 and 214.468.

Section 3. Fees for Inspections. For inspections conducted by the Office of Inspector General to determine compliance with KRS 214.450 to 214.464 and 214.468, blood establishments shall pay an annual inspection fee in the amount of $100.

Section 4. Payment of Fees. The annual inspection fee shall be due and payable on January 1, 1997, and on January 1 of each succeeding year thereafter. A check for the amount of the fee shall be made payable to the Kentucky State Treasurer and sent to the Division of Licensing and Regulation, Office of Inspector General, Cabinet for Health Services, 275 East Main Street, Frankfort, Kentucky 40621.

Section 5. Enforcement Notification. If the Office of Inspector General (OIG) ascertains that a blood establishment is not meeting the requirements of this administrative regulation, the OIG shall inform the Office of the Attorney General of a potential violation of KRS 214.452 to 214.464. (15 Ky.R. 767; eff. 11-4-1988; 23 Ky.R. 2320; eff. 12-18-1996; Crt eff. 4-30-2019.)