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Title 19—DEPARTMENT OF HEALTH

Division 25—Division of Administration Chapter 32—Milk-Testing Laboratories

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PURPOSE: Laboratories which perform examinations of milk required by the "Grade A Pasteurized Milk Ordinance" and by the cooperative State—United States Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers must be approved by the Department of Health, which is the official agency for approval of milk-testing laboratories. This rule establishes up-to-date minimum requirements for laboratory approval, using the current recommendations of the federal Food and Drug Administration.

PUBLISHER'S NOTE: The secretary of state has determined that publication of this rule in its entirety would be unduly cumbersome or expensive. The entire text of the rule has been filed with the secretary of state. Section (2) of this rule-the only part of the rule not published in its entirety-requires that laboratories be in compliance with the publication. Evaluation of Milk Laboratories, and the official Milk Laboratory Education Forms (FD-2400 series); these have been filed with the secretary of state. The entire text of the rule is also available at the office of the director, State Public Health Laboratory, Department of Health and is available to any interested person at a cost established by state law.

(1) Application for evaluation and approval of a laboratory must be made to the director, section of laboratory services, Department of Health by the director of the applying laboratory. To be eligible for evaluation, a laboratory must routinely analyze samples for either interstate or intrastate milk shippers.

(2) To be eligible for approval, a laboratory must be in substantial compliance with the United States Public Health Service/Food and Drug Administration's *Evaluation of Milk Laboratories* and official Milk Laboratory Evaluation Forms (FD-2400 series).

(3) An on-site evaluation of the applying laboratory shall be made by the state milk laboratory evaluation officer for a review of facilities, equipment, materials, procedures, test results and records. The evaluation shall be made using the official Milk Laboratory Evaluation Forms (FD-2400 series). The evaluation officer shall determine whether the laboratory techniques of analysts of the applying laboratory are in compliance with the procedures as described on the official Milk Laboratory Evaluation Forms (FD-2400 series). An on-site evaluation to determine compliance of a laboratory shall be made at least every two (2) years.

(4) Analysts must participate at least annually in the examination of split samples for those specific procedures for which they are certified. Failure without cause to participate in this annual Proficiency Testing Program or failure to meet established performance criteria will result in an analyst being placed on provisional certified status. Failure of analysts on provisional certified status to participate in the examination of split samples or to meet satisfactory performance levels on the next set of split samples will result in withdrawal of certification.

(5) An analyst who has lost certification must participate in a training program acceptable to the state milk laboratory evaluation officer before requesting recertification.

(6) The Department of Health shall issue a certificate of approval to each official laboratory and officially designated laboratory which has been approved. The certificate shall be returned to the Department of Health upon expiration or revocation.

(7) Approval of a laboratory may be revoked or suspended for failure to successfully participate in the Proficiency Testing Program as described in section (4) of this rule, for lack of certified analysts, for changes in quarters, personnel, equipment or supplies, which result in procedures and practices not in compliance with *Evaluation of Milk Laboratories* or for other reasons.

AUTHORITY: section 196.045, RSMo (1986). This rule was previously 13 CSR 50-141.010 and 19 CSR 20-32.010. Original rule filed Jan. 31, 1966, effective Feb. 10, 1966. Rescinded and readopted: Filed Oct. 15, 1981, effective Feb. 11, 1982. Changed to 19 CSR 25-32.010 Jan. 1, 1995.