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**Minimum Standards for Approval of
Public Health Laboratories**

Minimum standards 19-4-1

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Sec. 19-4-1. Minimum standards

Section 19a-36-A33 provides that a registered laboratory may be given a certificate of approval for making certain specified public health laboratory examinations, determinations or tests in a manner conforming with the requirements and standards required by the state department of health. In accepting approval, heads of laboratories shall agree to abide by these minimum standards upon which approval of public health laboratories is based, as follows:

(1) Adequate housing of the laboratory as determined by inspection before the certificate of approval is issued and by reinspection at any time.

(2) Equipment complete and in good order at all times as considered necessary for making each examination, determination or test for which approval is extended according to the method or methods which the person in charge has agreed to follow under subparagraph (b) of subdivision (4).

(3) Operation of the laboratory under the direct supervision of an individual designated by the owner of the laboratory to be in charge of the work for which approval is extended.

(4) Agreement on the part of the person, firm or corporation operating or maintaining the laboratory, or of the duly authorized agent thereof, that the individual designated by the owner to be in charge of the laboratory shall: (a) Conduct the laboratory strictly in accordance with recognized standards and to carry out the provisions of the general statutes and of the public health code pertaining to the performance and reporting of the examinations, determinations or tests for which approval has been extended; (b) report no public health laboratory examination, determination or test unless based upon a method or procedure which meets the approval of the state department of health and, upon request, to furnish the state department of health with a complete description of any method used in making any specified examination, determination or test for which approval is extended or requested; (c) notify the state department of health before undertaking any new type of public health laboratory examination, determination or test not already included in the list for which approval has been extended; (d) assume responsibility for the reliability of the laboratory findings made by any person employed in the laboratory, and for any interpretation based upon those findings.

(5) Agreement on the part of the person, firm or corporation operating or maintaining the laboratory, or of the duly authorized agent thereof: (a) To notify the state department of health in writing without delay if the person designated by the owner to be in charge of the laboratory severs or is about to sever connection with the laboratory and to surrender the certificate of approval on or before the day such person leaves; to give notice in writing prior to the taking of a leave-of-absence of more than four weeks' duration by such person; if approval has been conditioned upon the performance of a given type of test by a specified person, to give prompt notice in writing when the specified person severs or is about to sever connection with the laboratory; (b) to inform the state department of health without delay and in writing; (i) Of any change in the amount of time given to his position by the person designated by the owner to be in charge of the laboratory; (ii) of any contemplated removal of the laboratory to new quarters; (iii) of any major changes, alterations or additions to the laboratory quarters; (iv) of any change in ownership of the laboratory; (v) of any changes in personnel of the laboratory; (c) to permit

the use of no statement, made orally or appearing on any advertising or laboratory forms, which expresses or implies that approval of the state department of health is extended beyond that specified on the certificate of approval.

(Effective October 25, 1989)