

Secretary considers necessary to assure to the citizens of the State these safe and reliable laboratory or health services and shall adopt and promulgate rules and regulations for this purpose. Any person, partnership, association, or corporation desiring to open or maintain such a laboratory or tissue bank, except a physician or group of not more than three individual physicians performing laboratory examinations on his or their own patients, shall file with the Secretary an application setting forth the name of the owner, the types of laboratory or health services to be performed, and such other information as the Secretary may require. The Secretary shall cause an inspection to be made and, if in compliance with the minimum standards and qualifications, and upon payment of the fees herein authorized, he shall issue a permit to operate. The Secretary shall conduct periodic inspections to assure continuing compliance. THE SECRETARY MAY ENTER INTO AGREEMENTS WITH AN ORGANIZATION APPROVED BY THE SECRETARY TO CONDUCT THE PERIODIC INSPECTIONS AT NO COST TO THE STATE. No person, partnership, association or corporation may operate such a laboratory or tissue bank without this permit. The Secretary may refuse to issue, suspend or revoke a permit to operate, if, after inspection and due notice, a laboratory or tissue bank fails to comply with the minimum standards or qualifications or with the provisions of any rules or regulations regularly adopted by the Secretary. No person, partnership, association or corporation may represent or service or maintain in this State any office, representative or other facilities for the representation or servicing of any laboratory or tissue bank situated in this State or any other state which makes examinations in connection with the diagnosis and control of human disease or which procures, processes, distributes or sells human tissue, unless the laboratory or tissue bank so represented or serviced meets or exceeds the minimum standards and qualifications adopted by the Secretary under and pursuant to this section, and before representing or servicing any laboratory or tissue bank not situated within this State, each person, partnership, association or corporation shall make appropriate annual application to the Secretary on such terms and conditions as are adopted by the Secretary, the application to show by satisfactory evidence that any such laboratory or tissue bank not located within this State meets or exceeds the minimum standards and qualifications adopted by the Secretary pursuant to this section for similar laboratories or tissue banks located and operated within the State of Maryland. The term "tissue bank" as used in this section includes blood bank and the term "tissue" includes blood. Physicians exempt from licensing and inspection under this section are nevertheless required to demonstrate satisfactory performance in a proficiency testing program in applicable laboratory procedures. The State Department of Health and Mental Hygiene shall establish standards and criteria for demonstrating satisfactory performance in a proficiency testing program [and for conducting the programs]. THE PROFICIENCY TESTING PROGRAM SHALL BE CONDUCTED BY THE