



Manual on how a person can
**APPLY FOR A LICENSE TO
OPERATE A MEDICAL
DIAGNOSTIC LABORATORY**

BASIC INFORMATION

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BASIC INFORMATION

From time to time the process to apply for a license may change, so there will be regular updates of this manual. The aim is to provide increased access to online information.

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1. Introduction

The inspectorate within the Healthcare Standards Directorate monitors, inspects and regulates Medical diagnostic laboratories to make sure that these laboratories meet fundamental standards of quality and safety. The names of licensed laboratories are published on the website so that the public is aware as to which establishments are licensed and thus have reinforced procedures for patient safety. This list can be accessed through <https://deputyprimeminister.gov.mt/en/hcs/Pages/health-care-standards.aspx>.

The Directorate puts the health of the public at the centre of its work and strives to be rigorous, fair and consistent in its approach. The aim of this document is to provide basic information to any person applying for a license to operate a Medical diagnostic laboratory.

2. General information

- a. Medical diagnostic laboratories in Malta are regulated through the [*Licensing of Private Medical Diagnostic Laboratories \(S.L. 458.25\)*](#);
- b. Medical diagnostic laboratory procedures are to be performed **ONLY** by registered Medical laboratory scientists under the prescription of a registered pathologist;
- c. As stipulated by the [*Medical and Kindred Professions Ordinance*](#), the premises within which a Medical diagnostic laboratory can operate needs to have a valid license issued through the Superintendence of Public Health;
- d. The licensing office for Medical diagnostic laboratories is within the Health Care Standards Directorate at the Health Regulation Department;
- e. Opening Hours are from 7am till 2.45 pm Monday to Friday;

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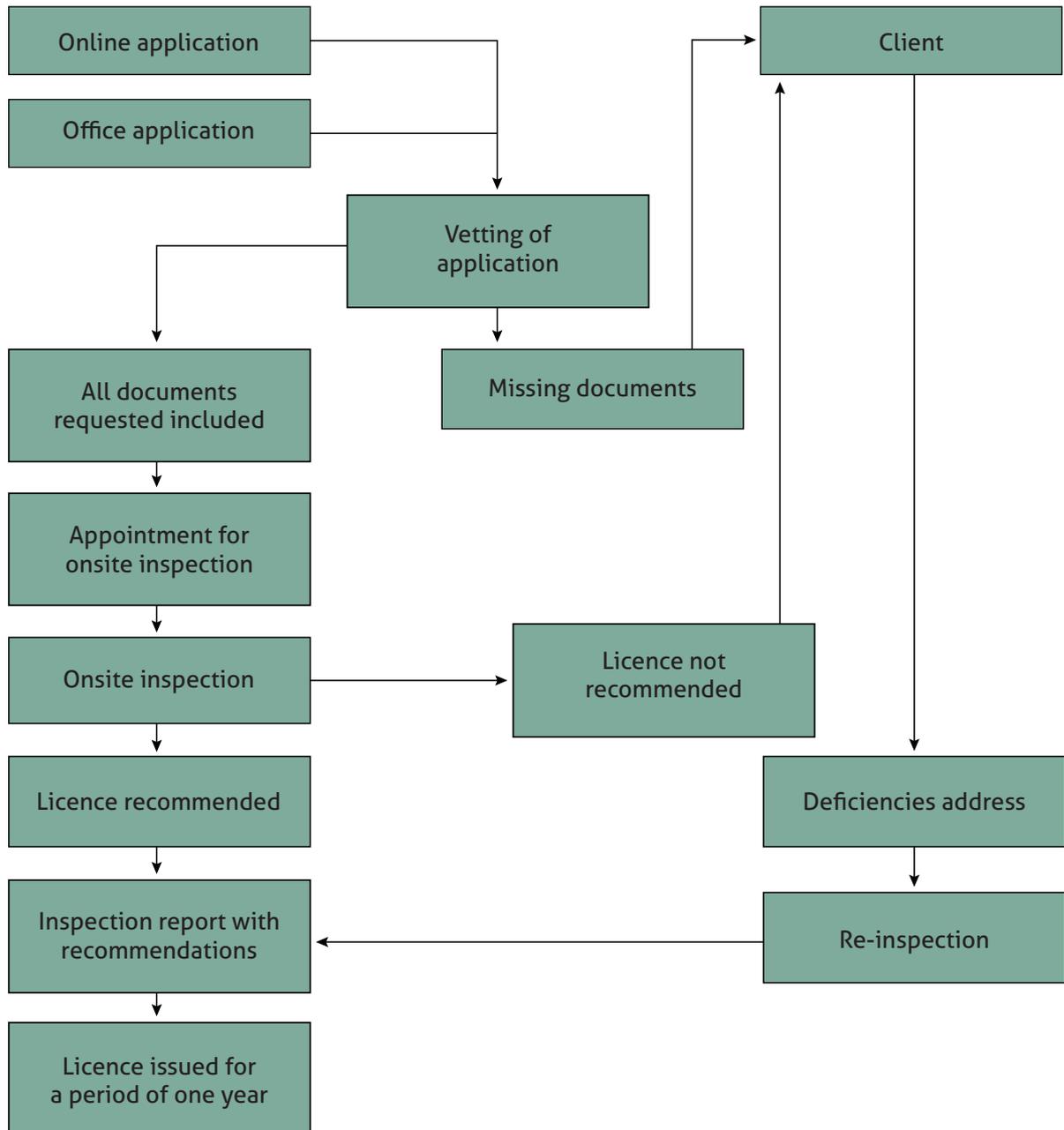
3. Applying for a license

- a. A person interested in providing diagnostic laboratories services must apply for a license as stipulated in Subsidiary legislation 458.25
- b. New applicants must be at least eighteen (18) years of age;
- c. One can apply for a license either by completing the [application form](#) or through the online application available at: <https://hcstandardsregistration.gov.mt/>
- d. When applying for a Medical diagnostic laboratory license, the following documents must be submitted:
 - A duly filled-out [application form](#);
 - A copy of the Medical Council of Malta/CPCM registration certificate of all pathologists and Medical laboratory scientists who will be working within the laboratory;
 - A permit showing the proposed premises including the site plan or a declaration by an architect certifying that the premises carry a PA permit for use as a Medical diagnostic laboratory;
 - If applying on behalf of a company, a copy of the Memorandum of Articles together with a declaration by the Director/s of the same company indicating that license is to be issued on the applicant's name;
 - For a third-country national to practice in a Medical diagnostic laboratory in Malta, one must apply for a work permit through Jobs Plus which can be reached on telephone number 22201290 or e-mail: jobsplus@gov.mt;

- e. Upon receiving the filled in application together with all the relevant documents, the licensing officer will vet the application accordingly;
- f. At this stage an onsite inspection is organised and the applicant is informed;
- g. An inspection team holding an authorisation badge will visit the premises. In case of a new establishment, a pre licensing visit may be requested by the applicant (recommended);
- h. A [*self-assessment*](#) check-list indicating the requirements to operate a Medical diagnostic laboratory will be sent to the applicant ten days prior to the inspection. This self-assessment will guide the applicant on what the inspection team will be expecting to find during the planned visit;
- i. During the inspection, the inspection team will verify if all conditions for licensing are satisfactory and will decide whether to recommend licensing or not;
- j. In cases where deficiencies are identified, a meeting with the applicant to advice and highlight the deficiencies needing attention will be held, this may necessitate a follow up visit;
- k. Once all conditions for licensing are satisfactory a license will be issued;
- l. The license includes a set of conditions. The licensee must understand and comply with these conditions;
- m. Once licensing is recommended, the applicant is advised to pay an annual license fee of €128.10 The applicant may opt to collect the license from the HCSD licensing office or receive it by registered post.

4. The licensing process

The following flow chart outlines the procedure followed by the client and the inspectorate during the licensing process.



5. The Medical diagnostic laboratory

- a. A Medical diagnostic laboratory must have the license displayed in a prominent place where it can be easily observed by the public upon entering the waiting area.
- b. The premises must be kept clean, in good condition and state of repair;
- c. The Medical diagnostic laboratory must have all the necessary equipment;
- d. The Medical diagnostic laboratory must have adequate lighting and ventilation (Natural or mechanical);
- e. The area where blood is taken must provide total client privacy;
- f. The premises must have an efficient drainage system connected to a main system;
- g. Fire-fighting equipment must consist of fire extinguishers with a valid expiry date and fire blankets;
- h. A laboratory must have a separate waiting room and when the laboratory is being planned, the work station should only have access through the waiting room;
- i. The area where blood is taken must provide total client privacy;
- j. The laboratory walls must be painted with water repellent paint for easy cleaning;
- k. Toilet facilities must be available.

6. The work station

- a. Work surfaces must be kept clean and well maintained and must be regularly washed with warm soapy water and wiped with a 70% alcohol solution. Work tops should be made of an impervious material for easy cleaning;
- b. Paper towels must always be available;
- c. There should be sufficient bench space to accommodate all the equipment used for laboratory procedures;
- d. A wash hand basin must be available within easy reach of the workstation/s and must be kept clean, well maintained and connected to the main drainage system. Single lever taps must have a supply of hot and cold water;
- e. Soap/suitable detergent and adequate drying facilities must be available near each wash hand basin;
- f. Client couches must be upholstered with an impervious type of material, which can be easily cleaned. Multiple couches must have a partition between them for adequate client privacy;
- g. A proper sharps container must be available within each work station;
- h. A foot operated pedal bin lined with a disposable garbage bag must be available in each working station.

7. Lavatory facilities

- a. Lavatory facilities must be connected with the main drainage system and must always be kept clean and well maintained;
- b. There must be a proper functioning flushing apparatus;
- c. The wash hand basin within the lavatory room must have a supply of hot and cold water;
- d. Adequate hand washing/drying facilities must always be available;
- e. Proper ventilation must be present within the lavatory facilities (natural or mechanical);
- f. The lavatory facilities must have adequate lighting;
- g. Where possible lavatory facilities are to be accessible from the waiting room.

8. Equipment used during Medical diagnostic laboratory procedures

- a. Medical diagnostic laboratory equipment must be operated, maintained and serviced as per manufacturer's instructions. All documentation relating to maintenance and servicing should be made available and stored properly;
- b. Medical diagnostic laboratory equipment and consumables must have a CE mark;
- c. All sharps must be disposed of in special sharps containers that are rigid, puncture-resistant, and leak-proof and must be kept upright. Clinical waste must be collected by an approved Class D waste collector.

9. Additional guidelines

- a. Maintain an updated Equipment Register complete with a scheduled Maintenance Program;
- b. Refrigerators, incubators and other equipment should be monitored through a calibrated temperature monitoring device;
- c. An adequate First Aid box is to be readily available;
- d. Participation in External Quality Assurance scheme/s is recommended for at least once a year for each test performed at the licensed laboratory;
- e. At least one back-up of all laboratory data generated must be stored 'off-site'.

