



Manual on how a person can
**APPLY FOR A LICENSE TO
OPERATE A RADIOLOGY CLINIC**

BASIC INFORMATION

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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 Radiology clinics to make sure that these clinics meet fundamental standards of quality and safety. The names of licensed Radiology clinics 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 Radiology clinic.

2. General information

- a. In Malta, the use of Ionising Radiation producing equipment in Radiology Clinics is regulated through [Legal Notice 210 "Basic Safety Standards for Ionising Radiation Regulations, 2018"](#).
- b. Radiology Clinic services are to be performed **ONLY** by registered radiologists and radiographers, after being requested by a registered medical practitioner or dental surgeon;
- c. As stipulated by the [Medical and Kindred Professions Ordinance \(Chapter 31\)](#), the premises within which a Radiology Clinic can operate needs to have a valid license issued through the Superintendence of Public Health;
- d. Radiology Clinics also need a license from the Commission for the Protection from Ionising and Non-Ionising Radiation
- e. The licensing office for Radiology Clinics is within the Health Care Standards Directorate at the Health (HCSD) Regulation Department;
- f. Opening Hours are from 7am till 2.45 pm Monday to Friday;

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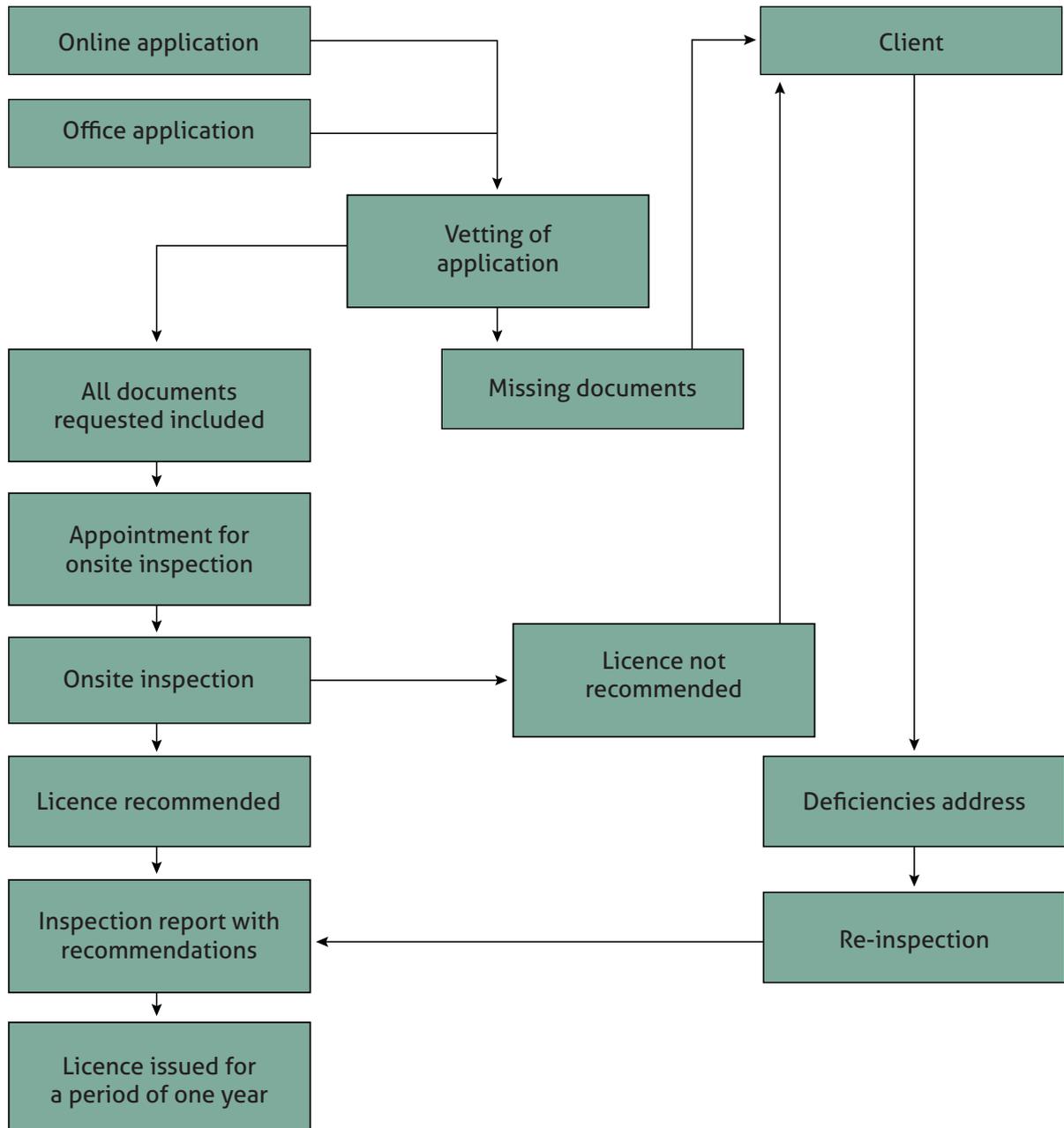
3. Applying for a license

- a. A person interested in providing Radiology services, must apply for a license through the Health Care Standards Directorate.
- 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 Radiology clinics license, the following documents must be submitted:
 - A duly filled-out [application form](#);
 - A copy of the registration certificate of all radiographers and radiologists who will be working within the Radiology clinic;
 - 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 Radiology clinic;
 - 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 radiology clinics 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 and register with the Council for professionals complimentary to medicine (CPCM);

- 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 Radiology clinic 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 advise 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 collect the license from the HCSD licensing office or may opt to 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 Radiology clinic

- a. Radiology clinic must have the license displayed in a prominent place where it can be easily observed by the public upon entering the waiting room;
- b. The premises must be kept clean, in good condition and state of repair;
- c. The Radiology clinic must have all the necessary equipment;
- d. The Radiology clinic must have adequate lighting and ventilation (Natural or mechanical);
- e. The area where Xrays are 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 Radiology clinic must have a separate waiting room and when the Radiology clinic is being planned, a changing area should have access through the waiting room;
- i. The Radiology clinic walls must be painted with water repellent paint for easy cleaning;
- j. 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 Radiology 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 radiology procedures

- a. Before installing new radiology equipment, reference shall be made to the Commission for Protection against Ionising and Non-ionising radiation;
- b. Depending on the equipment installed, a radiation protection expert and/or medical physicist expert may need to be consulted;
- c. Radiology and consumables equipment shall have all the requirements as mentioned in the **Legal Notice 210**, including a CE mark.
- d. Radiology clinic 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;
- e. 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.

