



DEPARTMENT OF HEALTH
DIRECTORATE: RADIATION CONTROL



GUIDELINES

ORGANISATIONAL REQUIREMENTS FOR LICENCE HOLDERS AND RESPONSIBLE PERSONS IN RESPECT OF MEDICAL APPLICATIONS

GENERAL

Good radiation safety practice and the achievement of satisfactory working conditions depend on the effective organisation of health physics and safety. The holder of the licence for the use of x-ray equipment is responsible for the radiological safety of employees, patients and members of the public liable to radiation exposure as a result of the use of x-ray equipment.

RESPONSIBILITIES OF LICENCE HOLDER / RESPONSIBLE PERSON

1. The LICENCE HOLDER is ultimately responsible for:

- The entire scope of radiation safety, for the equipment and premises for which he/she holds a licence
- Fulfilment of all related statutory requirements
- Compliance to conditions specified in the licence

2. RESPONSIBLE PERSON

(a) The licence holder must nominate / appoint a responsible person that has adequate knowledge and experience regarding:

- Basic principles of radiation protection in general, as well as
- Specific aspects of radiation protection as applicable to the radiation equipment under his / her control

(b) The responsible person must be qualified in either of the following categories registered with the Health Professions Council of South Africa (HPCSA):

- Radiography
- Radiology
- Medical Physics
- Chiropractics

(c) The responsible person must be appointed in writing indicating the scope of actions delegated by the licence holder.

3. THE LICENCE HOLDER / RESPONSIBLE PERSON MUST ENSURE THAT:

- The equipment and the facilities, in which such equipment is installed and used, meet all applicable radiation safety standards
- The equipment is maintained and functions properly

- The equipment is used and maintained only by competent and appropriately trained persons / personnel
- Applicable Quality Control (QC) tests are performed at the prescribed frequencies as stipulated in the Licence Conditions
- The required QC equipment is provided
- Ensure that radiation surveys to monitor safe performance of equipment and to monitor radiation levels in work areas are undertaken
- Radiation workers (occupationally exposed persons) are identified and registered
- Radiation workers are issued with personal radiation monitoring devices (PRMD's)
- The appropriate protective clothing and equipment are provided to personnel and is properly used
- Radiation safety rules are communicated to and followed by all personnel
- Operational procedures are established and maintained for the purpose of keeping radiation exposure to workers, patients and public is kept as low as possible without compromising the diagnostic efficiency of the result (ALARA)
- Workers are educated in the hazards and risks of ionising radiation

(Policies and Guidelines are available on Radiation Control website <https://sites.google.com/site/radiationcontroldoh/>- Codes of Practice / Electronic products)

4. BASIC RADIATION PROTECTION PRINCIPLES

- (a) The *Justification* of the practice
No practice shall be adopted unless its introduction produces a positive net benefit to the exposed individuals or to society.
- (b) The *Optimisation* of protection
In relation to a particular practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposure shall be kept as low as reasonably achievable, economic and social factors being taken into account.
- (c) *Limitation* of individual dose and risk
The risk either from a dose or potential dose to a class of individuals shall not exceed the limits set for that class.

5. LICENSING

5.1 LICENCES

- (a) The Regulations concerning the Control of Electronic Products, require that a joint product / premises licence be obtained for x-ray equipment **before** it may be delivered, installed and commissioned.
- (b) Licences are not transferable and are issued:
 - To a specific person / persons / institution
 - For specific equipment and its application
 - For specific premises (building, room)
- (c) Licences are issued subject to the Regulations relating to Group III Hazardous Substances and the application of specific conditions.
- (d) Licence holders are required to verify the accuracy of the information displayed on the licence issued and to communicate any inaccuracies to the Department.

5.2 APPLICATION FOR LICENCES

(a) Application Forms

- It is the responsibility of the prospective licence holder to apply for a licence by completing and submitting an application form. Accurately completed forms will ensure processing of the applications without undue delay.
- The sales licence number and technical information required on the form must be obtained from the supplier/distributor of the x-ray equipment.
- An application should be submitted **at least 90 days prior** to delivery, installation and the commissioning of the equipment.
- **Allow 30 days for processing of applications.**

(b) Installations

- The installation of an x-ray unit may only commence if the prospective user is in possession of a licence to install such a unit.

(c) Acceptance tests

New Units

- If a new unit is installed "Acceptance Tests" must be performed and the results recorded on the prescribed form and filed in the IER (Individual Equipment Record) of the unit.

Pre-owned units

- Acceptance Tests must be performed and the results submitted to DOH on the prescribed form. Granting of a user licence is subject to the submission of Acceptance Test results.
- When an existing licensed unit is moved to a new premises (building) or room, Acceptance Tests must be performed on such unit and submitted to the DOH, prior to use.

(d) Disposal / modification of x-ray equipment (Form RC002)

- The licence holder must apply for and obtain permission from the Department by submitting a completed form RC002 prior to:
- Cancellation / modification and/or disposal / sale of x-ray equipment (Particulars regarding the type of disposal, e.g. sale, dismantling, disappearance or storage, must be furnished before the cancellation of the licence will be effected).

(e) New / modified premises (Form RC002)

The licence holder must apply for and obtain permission prior to:

- Modification of any licensed premises or layout of equipment on such premises
- Change of licensed premises (building) or equipment moved to other rooms within the same building.

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