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GUIDELINE FOR CODE OF PRACTICE FOR USERS OF NON - MEDICAL X-RAY EQUIPMENT - FORENSIC

This guideline is intended to help healthcare professionals in the forensic field who are tasked with acquiring rays of deceased individuals to protect themselves from the dangers of ionizing radiation.

Document History

Final Version	Reason for Amendment	Effective Date
0	First issue and published for implementation	November 2014
1	<ul style="list-style-type: none"> - Content structured on the new SAHPRA Guideline Template - A unique document number SAHPGL-RDN-XR-09 allocated to this Guideline - Form RC002 changed to GLF-RDN-XR-02A; Form RC001 changed to GLF-RDN-XR-02B; Form RC008 changed to GLF-RDN-XR-02F; Form RC-DEALER changed to GLF-RDN-XR-02G and Form RC010 also changed to GLF-RDN-XR-10A 	August 2022

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Glossary

Abbreviation/ Term	Meaning
ACT	Hazardous Substances Act, 1973 (Act 15 of 1973)
DOH	Department of Health
mSv	milliSievert
TLD	Thermo Luminescent Dosimeter
NTP	Nuclear Technology Products
PRMD	Personal Radiation Monitoring Device
SABS	South African Bureau of Standards
Actinic marking	Permanent transfer of patient data / identification on to the film prior to processing
ALARA	As Low As Reasonably Achievable
Controlled area	A controlled area is a limited access area in which the occupational exposure of personnel to radiation is under the supervision of an individual in charge of radiation protection. This implies that access, occupancy and working conditions are controlled for radiation protection purposes
Radiation worker	Any person who is potentially exposed to radiation as a result of his/her occupation to more than three tenths of the occupational dose limit (20mSv per annum)
Regulations	Regulations relating to the Control of Electronic Products (No R1332 of 3 August 1973)
Supervision	The supervisor accepts and shares with the supervisee responsibility for ensuring that the supervisee's work is professional and ethical, operating within whatever legal requirements and organizational norms apply
Non - Medical	X-Ray units by virtue of use do not require quality assurance testing and cannot be used for clinical applications.
X-Ray unit	An electronic product that is designed, manufactured, or assembled with the primary purpose of producing X-Rays

1. INTRODUCTION

This Code sets out requirements and recommendations for radiation safety associated with the use of non - medical forensic X-Ray equipment.

The Hazardous Substances Act, 1973 (Act 15 of 1973) and Regulations (No R1332 of 3 August 1973) govern the safe use of X-Ray equipment in South Africa.

Requirements from the Act and Regulations are incorporated in this Code. Further requirements are taken from source material listed in the section of References.

Whenever compliance with a requirement in this Code is mandated, the word 'must / shall' is used. The word 'should' indicate a practice that is recommended but not mandatory at this stage.

Where a given technology or practice is not specifically covered by this Code, guidance in matters of radiation protection should be sought from SAHPRA: Radiation Control.

The Licensee must be responsible for ensuring that corrective action takes place on items of non-compliance with this Code.

The Act does not allow any person to use radiation equipment unless he/she holds a licence under the Act for that purpose.

This Code does not cover the use of X-Rays for medical, dental, and veterinary diagnosis.

This Code must be read in conjunction with SAHPRA: Radiation Control Guideline documents as listed in **Annexure A** of this Code.

NOTE: All forms and guidelines are available at: <https://www.sahpra.org.za>

1.1 Purpose

The purpose of this guideline is to educate users of non-medical forensic X-Ray equipment on the correct use of this equipment to ensure their own and the public's safety.

Obtaining X-Rays is intended for the sole purpose of collecting information from deceased people for forensic purposes. In this scenario, the main concern is for the operator and public as the X-Rays are being performed on deceased individuals.

1.2 Scope

This guideline is meant to assist operators of forensic X-Ray equipment to safely execute their duties. The focus is on protection of the operator and the public from ionizing radiation.

2. LEGAL PROVISION

The Hazardous Substances Act, 1973 (Act 15 of 1973) and Regulations (No R1332 of 3 August 1973) govern the safe use of X-Ray equipment in South Africa.

3. REQUIREMENTS AND RECOMMENDATIONS

3.1 Licensing

3.1.1 The Regulations concerning to the Control of Electronic Products require that a joint product and premises licence be obtained for X-Ray equipment before it may be installed and commissioned.

- a) Licences are not transferable and are issued:
 - To a specific person or institution.
 - For specific equipment and its application, and
 - For a specific premises.
- b) Licences are issued subject to the Regulations concerning the Control of Electronic Products and the application of specific conditions.
- c) Licence holders must verify the accuracy of the information displayed on the licence issued and communicate any inaccuracies to SAHPRA: Radiation Control.

3.1.2 Application for licenses

It is the responsibility of the prospective user of an X-Ray unit to be in possession of a licence from Radiation Control prior to installation of the unit.

- a) New units Form **GLF-RDN-XR-02G** (old Form RC-DEALER)

A **GLF-RDN-XR-02G** (old Form RC-DEALER) application form is a combined form to be completed by both the supplier and the end user of a new X-Ray unit. The prospective user must obtain the **GLF-RDN-XR-02G** (old Form RC-DEALER) form from the supplier of the X-Ray unit. The section applicable to the user must be completed and the form returned to the supplier.

The supplier is responsible for the submission of the completed form to Radiation Control for processing.

- b) Pre-owned units Form **GLF-RDN-XR-02B** (old Form RC001)

Form **GLF-RDN-XR-02B** (old Form RC001) must be completed for a pre-owned X-Ray unit. It is the responsibility of the prospective user to submit the completed application form **GLF-RDN-XR-02B** (old Form RC001) to Radiation Control.

Allow 30 days for processing of applications.

3.1.3 Installations

The installation of an X-Ray unit may only commence after a licence to install the unit has been issued.

3.1.4 Disposal / modification of X-Ray equipment Form **GLF-RDN-XR-02A** (old Form RC002)

- a) The licence holder must apply for and obtain permission from Radiation Control by submitting a completed form **GLF-RDN-XR-02A** (old Form RC002) prior to cancellation, modification, disposal and/or sale of X-Ray equipment.

- b) Particulars regarding the type of disposal, eg. sale, dismantling, disappearance or storage of a unit, must be furnished to Radiation Control before the cancellation of the licence will be effected.

3.1.5 New / modified premises Form GLF-RDN-XR-02A (old Form RC002)

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

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

3.1.6 Responsible person

- a) The licence holder must appoint a responsible person that has adequate knowledge and experience in the field of radiation protection in general. The appointed person is responsible to the licence holder for the safe use of the X-Ray equipment (see also par 4).
 - The person appointed must be qualified in either of the following:
 - Radiography
 - Radiology; and
- b) Appropriately trained Forensic personnel.
- c) The responsible person must be appointed in writing indicating the scope of the actions delegated by the licence holder.

3.1.7 Change of responsible person Form GLF-RDN-XR-02A (old Form RC002)

The licence holder must notify Radiation Control of a change in responsible person by submitting a completed form **GLF-RDN-XR-02A** (old Form RC002)

3.2 Responsibilities of Licence Holders / Responsible Persons

3.2.1 The licence holder of a non-medical X-Ray facility is ultimately responsible for:

- a) The entire scope of radiation safety, for the equipment and premises for which he/she holds a licence.
- b) Fulfilment of all related statutory requirements, and
- c) Compliance to the Act, Forensic Code and Conditions specified in the licence.

3.2.2 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.

- 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 issued with personal radiation monitoring devices (PRMD's).
- The appropriate protective clothing, devices and equipment is provided to personnel and properly used.
- Radiation safety rules are communicated to and followed by all personnel.
- Operational procedures are established and maintained to ensure that the radiation exposure to workers, is kept as low as reasonably achievable (ALARA) without compromising the efficiency of the result, and
- Workers are educated in the hazards and risks of ionising radiation.

3.2.3 Keeping of forensic records

- a) Records must be kept and available for inspection purposes by Radiation Control.
- b) A record / register must be kept of all corpses undergoing X-Ray examinations. The record / register must be preserved as per legal requirements of South Africa and contain the following information:
 - surname, name.
 - date of examination.
 - brief indication of the examination.
 - fluoroscopy time, dose results (if available) and the name of the person performing the fluoroscopy procedure.

3.2.4 Keeping of equipment records

- a) Records must be kept of service and maintenance.
- b) Records must be kept of verification of bi-annual check of Protective clothing.

3.3 Operators

Only the following persons who are appropriately trained, may operate X-Ray equipment and perform examinations:

- Radiographer.
- Radiologist and
- Appropriately trained forensic personnel.

3.4 Radiation Workers

3.4.1 Dose limits for radiation workers and public

Table 1 Dose Limits for Radiation

Application	Occupational	Public
Effective dose	20 mSv per annum, not more than 100 mSv over a period of 5 years (not more than 50 mSv in	1 mSv per annum
<u>Annual equivalent dose to the</u>		
lens of the eye	20 mSv	1 mSv
skin	500 mSv	50 mSv
hands and feet	500 mSv	-----

- A radiation worker must be older than 18 years. However, if a radiation worker in training is younger than 18, but older than 16, such worker must work under direct supervision.
- The holder of the licence must keep record of the following for a period of 10 years for each radiation worker:
- The monthly dose reports furnished by the monitoring service provider (SABS) and results of medical examinations.

3.4.2 Pregnant radiation workers

When pregnancy has been diagnosed the women shall not be allowed to work under working conditions where the maximum equivalent dose limit of 2 mSv to the women's abdomen (lower trunk) for the remainder of the pregnancy could be exceeded. Pregnant radiographers shall continue to be monitored in the prescribed manner. Taking into account the specific working conditions and must be issued with a direct reading pocket alarm dosimeter, and in so doing prevent that such women are unwittingly exposed to radiation.

- The employer should provide continuous education as to the risks to the foetus and actual dose levels in the various working environments.
- Radiation workers, especially young females, must always and not only when pregnant, be well versed in the uses of ionisation radiation.

(Refer to Guideline document on Radiation Control website(<https://www.sahpra.org.za>) - see Annexure A.2 in this Code).

3.4.3 Appointment of radiation workers

NOTE: Licence holders are no longer required to submit form **GLF-RDN-XR-02F** (old Form RC008) or inform Radiation Control of any change in the register as stipulated in Regulation III.4 (b) & (c).

3.4.4 Medical examinations of radiation workers

- a) Before any person is appointed / classified as a radiation worker, he/she must undergo a medical examination.

- b) Medical examinations for radiation workers should follow general pre- employment occupational medical practice for determining fitness for work.
- c) In addition to the pre-employment medical examination a radiation worker may be required to undergo a medical examination in the event of the following:
- When a radiation occurrence / incident resulting in an abnormally high dose is suspected to have taken place or has been confirmed.
 - When a medical practitioner deems it necessary.
 - When such an examination is considered necessary either by the regulatory authority or the holder of the licence and
 - When the radiation worker suspects that his/her health has been, or will be, adversely affected by occupational factors.

NOTE: Annual medical examinations and those pertaining to de-registration are no longer required by SAHPRA: Radiation Control but it remains the prerogative of the licence holder should he/she deems it necessary.

3.4.5 Monitoring of radiation workers

- a) The licence holder must ensure that all radiation workers, are issued with a personal radiation monitoring device (PRMD).
- For correct positioning of the PRMD refer to guideline document on Radiation Control website - see **Annexure A.3** in this Code.
- b) Application forms for a PRMD can be obtained directly from the following current monitoring service provider:

Name of Service	Contact No.	Email Address
SABS Holdings	012 428 6199	rps@sabs.co.za
Dosimeter Services (Pty) Ltd	012 677 8074	nds@netcare.co.za

- c) The service provider will forward the radiation dose records to the licence holder on a monthly basis, or after a radiation occurrence. The dose records must be kept for 10 years.
- d) The licence holder must ensure that the service provider replaces PRMD's at regular intervals not exceeding 32 days.

3.4.6 Termination of employment as a radiation worker

- a) When a radiation worker ceases to be employed by the licence holder, the holder must provide that worker with a copy of his/her complete dose record. Such complete records can be obtained from the SABS on request.

NOTE: Licence holders are no longer required to inform Radiation Control of any change in the register as stipulated in Regulation III.4 (c).

3.4.7 Appointment of radiation workers by a new employer

- a) The licence holder must obtain from the SABS the previous dose records of the newly appointed radiation worker.

3.4.8 Radiation occurrences form GLF-RDN-XR-10A (old Form RC010)

- a) Details of any radiation occurrence or suspected radiation occurrence must immediately be reported to the Director: Radiation Control on form GLF-RDN-XR-10A (old Form RC010).

3.5 Radiation Protection

3.5.1 Basic radiation protection principles are based on:

- *The justification of the practice*

All radiation examinations must be justified.

- *The optimization of protection*

Radiation doses and those received by the public and occupationally exposed persons must be kept as low as reasonably achievable (ALARA), economic and social factors taken into account.

- *Limitation of individual dose and risk*

All non- medical applications of ionizing radiation must be managed in such a way that radiation doses to occupationally exposed person and members of the public do not exceed the specified dose limits (see par 6.1).

Pulsed fluoroscopy should be routinely used. During fluoroscopy, radiation time is minimized by pulsing the beam. At low-pulsed frequencies, major dose savings are made while ensuring useful images.

3.5.2 Protection of persons holding corpse or image receptors

- a) No person shall hold a corpse, X-Ray film cassette, or other imaging equipment or X-Ray tube head in position during exposures unless it is otherwise impossible to obtain a useful image and not merely that it is a matter of convenience.
- b) Any persons holding corpse or film cassettes in position during an X-Ray examination shall wear a lead rubber apron, lead rubber gloves thyroid protection and protective glasses. No part of the holder's body shall be in the primary beam, even if covered with protective clothing.

3.5.3 Protective clothing

- a) Any person who cannot remain in the protected area during X-Ray examinations must wear a protective apron of at least 0,25mm lead equivalence.
- b) Any person standing within 1 metre of the X-Ray tube or corpse during fluoroscopy examinations must wear eye protection (leaded glasses), thyroid protection and a protective apron of at least 0.35mm lead equivalent.
- c) Protective gloves shall be at least 0.35mm lead equivalence.
- d) Full frontal Pb lead rubber apron to be worn when operating handheld portable dental units.

(Refer to the Guideline documents on Radiation Control website - see Annexure A.3, A.8 & A.10 in this Code)

3.5.4 Record and Report Radiation Injuries

The licence holder shall ensure that all suspected radiation occurrences are immediately reported to the Director: Radiation Control. A "radiation occurrence" means a single event or series of events occurring in the course of the use of a listed electronic product which has resulted in injurious or potentially injurious exposure of any person to ionising radiation as a direct result of the use of that product. The licence holder must investigate the circumstances of the exposure, the possible effects on a person(s) concerned and decide on the action to be taken. The outcome of this investigation must be documented.

3.6 Premises Requirements

Refer to guideline document on Radiation Control website: General Guidelines with regard to the design of X-Ray rooms (see **Annexure A.6** in this Code)

3.7 Radiation Warning Signs, Notices and Lights at Entrances to X-Ray Rooms

Appropriate radiation warning signs and notices must be displayed and required warning lights in working order:

a) Fixed units:

A radiation warning sign and warning notice, "X-RAYS - NO UNAUTHORISED ENTRY" must be displayed at all entrances leading to the rooms where X-Ray units are installed.

b) Mobile units:

A radiation warning sign and warning notice, "X-RAYS - NO UNAUTHORISED USE" must be displayed on the control panel of the X-Ray units.

c) Lodox scan units

Warning signs, "**UNOFFICIAL ENTRY NOT ALLOWED WHEN IRRADIATION IS IN PROGRESS**" must be visible.

Radiation warning sign and warning notice, "**X-RAYS - NO UNAUTHORISED USE**" must be displayed on the control panel of the X-Ray units.

(Refer to Guideline document on Radiation Control website - see Annexure A.7 in this Code)

4 REFERENCES

This included all other related documents that should read with guide or forms or template that will be used

- 4.1 Australian Government. Australian Radiation Protection and Nuclear Safety Agency, 2008. Radiation Protection in Medical Applications of Ionizing Radiation. Publication No. 14, <http://www.arpsa.gov.au>
- 4.2 International Commission on Radiological Protection, 1991, 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60 Vol 21/1-3. Pergamon Press. <http://www.icrp.org>

- 4.3 International Commission on Radiological Protection, 2000. Pregnancy and Medical Radiation. ICRP Publication 84 vol 30/1. Pergamon Press. <http://www.icrp.org>
- 4.4 New Zealand Ministry of Health, National Radiation Laboratory, 1994. Code of Safe Practice for the use of X-Rays in Medical Diagnosis. NRL C5. <http://nrl.moh.govt.nz>
- 4.5 South Africa, 1973. Hazardous Substances Act, 1973 (Act of 15 of 1973). <https://www.sahpra.org.za/radiation-control-acts-and-regulations/>
- 4.6 South Africa, 1973. Regulations Concerning the Control of Electronic Products. Regulation Gazette No 3991. <https://www.sahpra.org.za/radiation-control-acts-and-regulations/>
- 4.7 International Commission on Radiological Protection, 73. Radiological Protection and Safety in Medicine. Annals of the ICRP Volume 26/2. Elsevier B.V. <http://www.icrp.org>
- 4.8 ICRP ref 4825-3093-1464 (21 April 2011).

5 VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old Code of Practice for Users of Non-Medical X-Ray Equipment – Forensic, revised November 2014. It will be reviewed on this timeframe or as and when required.

6 ANNEXURES

6.1 Annexure A

1. Code: Forensic use.
2. Management of pregnant radiographers and other staff members.
3. Personal monitoring when a lead rubber apron is worn - medical and veterinary use of X-Ray equipment.
4. Display and format of radiation warning signs at entrances to rooms containing X-Ray units.
5. Guidelines - Protective Clothing.
6. Radiation Protection of personnel in theatre

Guideline documents available on Radiation Control website: <https://www.sahpra.org.za>