



Doc Number: GLF-RDN-XR-02C [Old No. RC005] Revision 1.0	APPLICATION IN TERMS OF ARTICLE 4 OF THE HAZARDOUS SUBSTANCES ACT 15 OF 1973	 South African Health Products Regulatory Authority Effective date: 22 April 2022
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Section A. CHANGE OF RESPONSIBLE PERSON / ADDITIONAL RESPONSIBLE PERSON
Section B. RESIGNATION / TERMINATION OF RESPONSIBLE PERSON

NOTE: ALLOW 30 DAYS FOR ADMINISTRATION

PARTICULARS OF APPLICANT

For office use only
File no:
Licence no:
Code:

Name and postal address of licence holder:		
		Postcode:
	Fax no.:	E-mail:
Name and postal address of contact person (If different from above):		
		Postcode:
	Fax no.:	

DECLARATION (by the applicant):

I, (PLEASE PRINT):..... hereby declare that the information supplied is to the best of my knowledge true and correct.	
Signature:	Date:
Designation:	

Section A.: CHANGE OF RESPONSIBLE PERSON/ ADDITIONAL RESPONSIBLE PERSON

DETAILS OF NEW RESPONSIBLE PERSON

Surname:	Title:	Initials:	ID no:
Address:			
Email:		Cell.no:	
Experience regarding radiation protection:			
Designation:		Qualification:	
HPCSA Registration number:			
I am aware of my duties as responsible person ♦	Signature:		Date:

♦ SAHPRA Guidelines documents: <http://www.sahpra.org.za> >health products > radiation control Code - users of medical x-ray equipment → Pt. 4

APPOINTMENT OF RESPONSIBLE PERSON ¹

- The licence holder must appoint a responsible person that has
 - adequate knowledge and experience in the field of radiation protection in general; as well as specific aspects of radiation protection as applicable the installations under his/her control,

DUTIES OF RESPONSIBLE PERSON

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 "Diagnost QC" document on SAHPRA: Radiation Control website; (**medical use only**)
- The required QC equipment is provided; (**medical use only**)
- 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, patients and public is kept as low as reasonably achievable (ALARA) without compromising the diagnostic efficiency of the result, and
- Workers are educated in the hazards and risks of ionising radiation.

Section B.: RESIGNATION / TERMINATION OF RESPONSIBLE PERSON

Surname:	Title:	Initials:	ID no:
Address:			
Email:		Cell.no:	
Designation:		Qualification:	
I request removal of my details as Responsible person		Signature:	Date:

For office use only	
Type of modification/disposal	Generic code
Change of responsible person	DP010
Additional responsible person	DP011
Resignation/ Termination	DP012

¹ Refer to: <http://www.sahpra.org.za >health products > radiation control ->

- Regulations Concerning the Control of Electronic equipment.
- Code of practice for users of medical x-ray equipment.