South African Health Products
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GUIDELINE FOR RADIATION MONITORING REQUIREMENTS AND RADIATION OCCURRENCES

This guideline sets out requirements and recommendations for monitoring of radiation workers and reporting of radiation occurrences by holders of license issued in terms the Hazardous Substances Act, 1973 (Act 15 of 1973) and Regulations (No R1332 of 3 August 1973).

Document History

Final Version	Reason for Amendment	Effective Date
0	First issue and implementation	September 2012
1	- Content structured on the new SAHPRA Guideline Template - A unique document number SAHPGL-RDN-XR-10 allocated to this Guideline - Form RC008 changed to GLF-RDN-XR-02F, and Form RC010 also changed to GLF-RDN-XR-10A	August 2022

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Glossary

Abbreviation/ Term	Meaning
ALARA	As Low As Reasonable Achievable
ICRP	International Commission of Radiation Protection
mSv	Millie-Sieverts
PRMD	Personal Radiation Monitoring Devices
SABS	South African Bureau of Standards
SAHPRA	South African Health Products Regulatory Authority
Occupational Dose limits	Regulated annual dose limits for radiation workers
Ionizing Radiation	means radiation emanating from a listed electronic product, capable of producing ions directly or indirectly in its passage through matter
License Holders	Any individual holding the license issued in terms of the HS Act 15 of 1973
Radiation Protection Service	Approved service/lab providing monitoring devices to license holders
Radiation Worker	means any person who is potentially exposed to ionising radiation because of his occupation and who has been registered in terms of regulation
Regulations	Regulations relating to the Control of Electronic Products (No R1332 of 3 August 1973)

1. INTRODUCTION

REGULATIONS CONCERNING THE CONTROL OF ELECTRONIC PRODUCTS No. R.1332 stipulate the provision regarding radiation workers in section III.4. Every holder shall keep a register (hereinafter referred to as his "register") in which all persons who because of their occupation are potentially exposed to radiation from a listed electronic product for which he holds the licence and who, in accordance with the latest applicable recommendations of the ICRP: are regarded by the holder as radiation workers or trainee radiation workers shall be registered.

1.1 Purpose

The purpose of monitoring radiation workers is to ensure that annual occupational dose limits are within regulatory limits and to provide early reporting when exposure has occurred to ensure the principle of ALARA is maintained. Section III.5.c of the regulation no R.1332 every license holder should ensure that all radiation workers are monitored by an approved personnel monitoring service.

1.2 Scope

This guideline sets out requirements and recommendations for monitoring of radiation workers and reporting of radiation occurrences by holders of license to use a listed electronic product generating ionizing radiation.

2. LEGAL PROVISION

The guideline is implemented in promulgating the Hazardous Substances Act 15, 1973 (Act15 of 1973) the related Regulations R.1332

3. MONITORING OF RADIATION WORKERS

a) Every licence holder must ensure that the following three steps are taken in respect of any person who may, by virtue of his/her occupation, be exposed to more than three tenths of the occupational dose limit (20mSv/annum).

- Such a person must be registered as a radiation worker
- He/she must undergo the prescribed medical examination
- His/her exposure to radiation must be monitored

b) The three sets of records resulting from the above actions are best kept in a separate register. The record of each action mentioned above must be kept for at least ten years after the date of the action. These records must be available on site for inspection.

3.1 Registration of radiation workers (new Form No.: GLF-RDN-XR-02F, replaced old Form RC008)

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

3.2 Medical examinations of radiation workers

a) Before a person is registered / appointed as a radiation worker he/she must undergo a medical examination.

b) Medical examinations for radiation workers should follow general occupational medical practice for determining fitness for work.

c) The results must be kept in the licence holder's register.

d) In addition to the initial medical examination every radiation worker will be required to undergo a medical examination in the event of the following:

- Where a radiation occurrence has been confirmed or an incident resulting in an abnormal exposure is suspected
- Where the appointed medical practitioner deems it necessary
- Where such an examination is considered necessary either by the regulatory authority or the holder of the license.
- Where the radiation worker believes that his/her health has been or will be adversely affected by the factors relating to his/her occupation.

Annual medical examinations and those pertaining to de-registration are no longer required by the regulator, but it remains the prerogative of the license holder should he/she deems it necessary.

3.3 Monitoring service of radiation workers

a) The licence holder must ensure that all the registered radiation workers are issued with personal radiation monitoring devices (PRMD).

b) Application forms for PRMD's can be obtained directly from the following approved Radiation Protection Service Provider(s):

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) Records of the radiation doses to which workers have been exposed will be furnished to the licence holder by the SABS monthly or after a radiation occurrence (see 3.6 below). The records must be kept for 10 years.

3.4 Termination of registration as radiation worker

a) Record keeping in respect of the worker in question will now cease, but the file must be preserved in the licence holder's register for a period of 10 years from the date of the last entry in the file.

b) Licence holders are no longer required to submit GLF-RDN-XR-02F forms (replaced old RC008 forms) or inform the regulator of any change in the register as stipulated in Regulation III.4 b & c.

c) 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/Dosimeter Services on request.

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

3.5 Re-registration of a person as radiation worker

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

b) The procedures outlined in paragraphs 3.1 must then be followed with respect to the registration of this person as a radiation worker.

3.6 Radiation Occurrences (new Form No.: GLF-RDN-XR-10A, replaced old Form RC010)

a) Details of any radiation occurrence or suspected radiation occurrence must immediately be reported to SAHPRA radiation control on form GLF-RDN-XR-010A.

b) The workers concerned must immediately submit their personal dosimeters to the dosimetry service provider. The licence holder must liaise with Radiation Control on what action to be taken after such occurrence.

The attention of the reader is drawn to the fact that this guide is intended and was compiled merely to simplify and assist holders in the modus operandi with respect to the registration and monitoring of radiation workers.

4. REFERENCES

The following related documents are referenced:

4.1 South Africa, 1973. Hazardous Substances Act, 1973 (Act of 15 of 1973). https://www.sahpra.org.za/radiation-control-acts-and-regulations/

4.2 South Africa, 1973. Regulations Concerning the Control of Electronic Products. Regulation Gazette No 3991. https://www.sahpra.org.za/radiation-control-acts-and-regulations/

4.3 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

5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline for Radiation Monitoring Requirements and Radiation Occurrences - DOH, revision Sept 2012. It will be reviewed on this timeframe or as and when required.