South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

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GUIDELINE FOR THE SEALING AND UNSEALING OF HAZARDOUS SUBSTANCES

The above guideline intends to narrate the critical framework of sealing and unsealing hazardous substances. It stipulates all enforcement actions necessary, according to the Hazardous Substance Act, 15 of 1973 with respect to Grouped Hazardous Substances, related regulations and prescribed licence conditions, that may be imposed by the Inspectors under the Inspectorate division of Radiation Control.

Document History

Final Version	Reason for Amendment	Effective Date [dd Month yyyy]
0	First issue and publish for implementation	November 2014
1	Content structured on the latest SAHPRA Guideline Template	November 2024

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

Contents

Glossary

Abbreviation/ Term	Meaning
ES	Electronic Submission
HPCSA	Health Profession Council of South Africa
IB	Inspection Body
TECH Unseal	Technicians unseal letter
kVp	Kilovoltage Peak
POPI Act	Protection of Personal Information Act
QC	Quality Control
Regulation R1332	Regulations concerning the control of electronic products
SAHPRA	South African Health Product Regulatory Authority
SANAS	South African National Accreditation System

1. INTRODUCTION

The South African Health Products Regulatory Authority (SAHPRA) is responsible for the regulation of group III and IV products used in medical, industrial, veterinary, research and security applications. The aim is to protect patients, radiation workers, the public and the environment against over-exposure to ionizing radiation without limiting its beneficial use.

This guideline document describes the framework for the sealing and unsealing of hazardous substances. It defines the standards and actions required by Inspectors in the radiation control inspectorate sub-unit. It complies with the Hazardous Substance Act, 15 of 1973 with respect to Grouped Hazardous Substances and related regulations and licence conditions.

The sealing of hazardous substances may happen during announced and unannounced routine inspections or reported incidents/accidents relating to Grouped Hazardous Substances.

The sealing of a hazardous substances is an enforcement action therefore performing QC tests or services does not mean that the licence holder should resume using the unit. Licence Holders are encouraged to observe the instructions outlined on the sealing letter (GLF-RDN-INSP-01C) or do a follow up after the sealing of the hazardous substances.

It should be noted as per the Protection of Personal Information Act (POPIA) and the Hazardous Substances Act, that a licence holder's information will not be disseminated to a third party except when the information is required for legal proceedings.

1.1 Purpose

To establish clear and effective mandatory practices to enforce outlined procedures regarding sealing and unsealing of grouped hazardous substances. To ascertain safety and optimal functioning of radiation emitting devices.

1.2 Scope

The guideline covers the sealing and unsealing of Group III and IV hazardous substances used in medical, industrial, veterinary, research and security applications.

2. LEGAL PROVISION

The guideline is implemented in promulgating the Hazardous Substances Act, 15 of 1973, related regulations, SAHPRA guidelines and prescribed licence conditions.

3. GENERAL REQUIREMENTS

The related Regulation concerning the control of electronic products require that a joint product and premises licence must be obtained for Group III and IV before it may be installed and commissioned.

- It is the responsibility of the prospective user of these electronic products to be in possession of a licence from SAHPRA prior to the delivery and installation of these electronic products.
- Licenses are issued subject to the Regulations concerning the control of electronic products and the application of specific licence conditions.
- The licence holder must ensure that the room design shielding calculations and commissioning is performed by a qualified Medical Physicist registered with HPCSA after completion of the training program for Medical Physicist as prescribed on the HPCSA document CMS 03 PH Facility Based Intern Training Program.
- An Inspection Body (IB) approved by SAHPRA, OR an appropriately trained medical professional as per the South African National Accreditation System (SANAS) (ISO/IEC 17020 and TR78) standard and registered with the HPCSA as a Medical Physicist / Radiographer must be used to perform all the diagnostics X-rays acceptance tests as well as the routine tests.
- The applicable quality control (QC) tests are performed thereafter at the frequencies specified in, “Requirements for licence holders with respect to quality control tests for diagnostic x-ray imaging systems / dental diagnostic x-ray imaging systems”.
- A formal contract by SANAS Inspection Body (ISO/IEC 17020 and TR78) is required to perform these tests as listed on the *Code: Diagnostic QC – Requirements for licence holders with respect to Quality Control tests for Diagnostic x-ray imaging systems.*
- The licence holder shall ensure that only an IB approved by SAHPRA is used to perform all the acceptance tests as well as the annual/routine quality control tests.

4. SEALING OF ELECTRONIC PRODUCTS

- The decision to take urgent measures such as sealing is recorded in the inspection report OF-RDN-INSP-06B and verbal notification must be given immediately to the license holder or representative. A written SEAL letter GLF-RDN-INSP-01C with the same content must be provided within 24 hours. (Subject to whether the Inspector is working locally or out)

- **Electronic products will be sealed under the following conditions:**

- ❖ Unlicensed product
- ❖ Unqualified operators
- ❖ Illegal imports of products / components
- ❖ Annual QC tests not performed (outstanding for more than 3 months within the prescribed cycle)
- ❖ X-ray units to be stored / out of order / not to be used
- ❖ Supplementary radiographers not supervised by qualified radiographers.
- ❖ Mammography phantom for image quality not available
- ❖ Dental intra/extra oral phantom for image quality not available
- ❖ Dental x-ray units operating below 50 kVp.
- ❖ When no response to outstanding inspection report requirements have been received following a 30 days email reminder and telephonic follow-up confirmed by email.

5. UNSEALING OF ELECTRONIC PRODUCTS

- A seal may only be removed by an Inspector from SAHPRA.
- If it is not possible for an Inspector to remove the seal, the licence holder may only remove the seal following written confirmation UNSEAL letter GLF-RDN-INSP-01A from SAHPRA.
- Inspectors must grant permission in writing by providing the unseal letter for the seal to be removed from an electronic product.
- If an Inspector is not available, SAHPRA will forward an UNSEAL letter (GLF-RDN-INSP-01A) to the licence holder in order to remove the seal.
- No sealed electronic product should be tested or serviced without a technician unseal letter TECH UNSEAL (GLF-RDN-INSP-01B).
- If a IB Technician requires the unit to be unsealed, the TECH Unseal letter should be requested from the SAHPRA Inspector who sealed the unit. The letter will be addressed to the inspection body and

the technician's details will be listed on the letter. The letter will indicate that the unit is not licensed for "clinical use".

- The IB Technician must reseal the x-ray unit after the test/service was completed and the test results must be uploaded in the electronic submission (ES) template.

- Permission to unseal and permission to use the x-ray unit is granted to the licence holder once the QC tests are reflecting on the SAHPRA database, and the responsible Inspector confirms no other outstanding non-conformances.

6. REFERENCES

6.1 Related Articles

6.1.1 Hazardous Substance Act 15 of 1973 (Act 15, of 1973), https://www.sahpra.org.za/radiation-control-acts-and-regulations/

6.1.2 Regulation concerning the control of electronic products, (R1332) https://www.sahpra.org.za/radiation-control-acts-and-regulations/.

6.1.3 Schedule of listed electronic devices, Hazardous Substances Act 15, 1973, Regulation No. R.1302. https://www.sahpra.org.za/radiation-control-acts-and-regulations/

6.1.4 Regulations relating to Group IV Hazardous Substances, made in terms of section(s) 6 to 11, 25 and 26 of the Hazardous Substances Act 15 of 1973 and published under Government Notice R247 in Government Gazette 14596, dated 26 February 1993 (R247) https://www.sahpra.org.za/radiation-control-acts-and-regulations/

6.1.5 Template for the development of a facility-based intern training program: Medical Physicist, CMS 03 PH https://www.hpcsa.co.za/Uploads/professional_boards/mdb/guidelines/

6.1.6 South African Health Products Regulatory Authority (SAHPRA) and SANAS technical requirements for the application of ISO/IEC 17020: 2012 for testing of diagnostic x-ray imaging systems by inspection bodies TR 78-08.

6.2 Related Documents

6.2.1 Code: Diagnostic QC – Requirements for licence holders with respect to Quality Control tests for

Diagnostic x-ray imaging systems. https://www.sahpra.org.za/radiation-control-guidelines-and-codes-of-practice/

6.2.2 Guidelines for users of of electronic therapeutic devices emitting ionizing radiation, SAHPGL-RDN-XR 25_v2 https://www.sahpra.org.za/wp-content/uploads/

6.2.3 SAHPRA IB Sealing and Unsealing, 11/04/2023, https://www.sahpra.org.za/communication-to-industry/

6.2.4 Unseal letter, GLF-RDN-INSP-01A

6.2.5 Tech unseal letter, GLF-RDN-INSP-01B

6.2.6 Seal letter, GLF-RDN-INSP-01C

7. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision. It will be reviewed in this timeframe or as and when required.