South African Health Products
Regulatory Authority
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GENERAL GUIDELINE FOR CABINET AND CONVEYER BELT X-RAY

A cabinet or conveyer belt X-Ray scanner is primarily used for security screening of mail, baggage, cargo contents, etc. Other common names are X-Ray Screening Systems, X- Ray Security Systems, and scanners for the Inspection of Cargo contents. Even though cabinet and conveyer belt X-Ray scanners are designed to provide safe and efficient operation, they must be operated with safety in mind. It represents South African Health Products Regulatory Authority's (SAHPRA's) current thinking on the safety, quality, and efficacy of medicines It is not intended as an exclusive approach.

SAHPRA reserves the right to request any additional information to establish the safety, quality and efficacy of medicines and may make amendments in keeping with the knowledge which is current at the time of consideration of safety data.

Document History

Final Version	Reason for Amendment	Effective Date
0	First issue and implementation	September 2017
1	– Content structured on the new SAHPRA Guideline Template – A unique document number SAHPGL-RDN-XR-05 allocated to this Guideline – Form RC002 changed to **GLF-RDN-XR-02A**; Form RC001 changed to **GLF-RDN-XR-02B** and Form RC005 also changed to **GLF-RDN-XR-02C**	August 2022

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Glossary

Abbreviation/ Term	Meaning
ACT	Hazardous Substance Act 15 of 1973
SAHPRA	South African Health Products Regulatory Authority

1. INTRODUCTION

This guideline will provide you with all safety information needed in Cabinet and Conveyor Belt X-Ray Scanners. In terms of the Hazardous Substances Act, Act 15 of 1973, no person shall Import and/or Purchase and/or Use a listed electronic product unless such a product has been licensed. The product licence number, as issued by the - SAHPRA: Radiation Control must be displayed in/on an easily accessible area of each unit. The identification plate, permanently affixed to the unit, should contain information regarding the manufacturer, model designation, serial number, and place of manufacture for the device

1.1 Purpose

The purpose of this guideline is for license holders and users of cabinets and conveyer belts that uses X-ray source, and it provides regulatory requirements for the safe use of such equipment's.

1.2 Scope

The scope of this guideline is to provide you with proper regulatory standards, as well as to guide you with important information that should be displayed, such as Radiation warning signs and notices on the scanner. It will also provide radiation safety requirements for operators, maintenance personnel and the public.

2. LEGAL PROVISION

In terms of the Hazardous Substances Act, Act 15 of 1973, no person shall Import and/ or Purchase and/ or Use a listed electronic product unless such a product has been licensed.

3. LICENSING

3.1 New Equipment

- Licensing must be done through the supplier, but in conjunction with the user of the equipment.
- RC dealer must be completed by the supplier, signed by the license holder, and submitted before any installation

3.2 Pre-Owned/ Used

A GLF-RDN-XR-02B (old RC001) form is to be fully completed by the user and GLF-RDN-XR-02A (old RC002) form completed by the previous owner/seller. Both forms must be forwarded, to the relevant office in application of a licence.

3.3 Changes

- Normal Responsible person - A GLF-RDN-XR-02C (old RC005) form is to be fully completed by the user and forwarded to the relevant office
- If the responsible person leaves the position/ or is changed, a new responsible person must be appointed by completion and submission of the GLF-RDN-XR-02C (old RC005)
- Premises changes or disposal of scanner - A GLF-RDN-XR-02A (old RC002) form is to be fully completed by the user and forwarded to the relevant SAHPRA regional office.

4. INFORMATION TO BE DISPLAYED

The product licence number, as issued by SAHPRA: Radiation Control must be displayed in/ on an easily accessible area of each unit. The identification plate, permanently affixed to the unit, should contain information regarding the manufacturer, model designation, serial number, and place of manufacture for the device.

5. RADIATION SIGNS OR NOTICES SHALL BE DISPLAYED ON THE X-RAY SCANNER:

(a) Radiation warning sign (trefoil)

- Is shown in two contrasting colours.
- Is clearly visible and identifiable from a distance of 1 meter.
- On/Near the control panel of the unit in clear view of the operator.
- On the external surface of the device.

(b) Radiation warning notice

Radiation warning notices must bear the words below and must be permanently affixed or displayed.

- "CAUTION X-RAYS PRODUCED WHEN ACTIVATED".
- "TO BE USED BY AUTHORISED PERSONS ONLY".
- At all access openings where items are inserted or removed:

"DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ACTIVATED - X-RAY HAZARD".

6. RADIATION SAFETY REQUIREMENTS

Leakage radiation shall be ≤5µSv/h at any point 5cm from the external surface.

(a) Pregnancy

- The public dose limit is 1mSv per year (ICRP 103). Studies have shown that operators of X-Ray scanner machines for security purposes receive well below 1mSv of radiation dose per year from workplace activities.

(b) Items passing through

- Items passing through an X-Ray screening machine, will receive ionizing radiation exposure; but the exposure is too low to cause any damage to them.

7. OPERATORS AND MAINTENANCE PERSONNEL

Personnel, that use or perform maintenance on X-Ray scanners, must receive training, authorised by the original manufacturer on the operation and X-Ray safety relevant to the x- ray scanner intended for use.

(a) Use

- For regulatory purposes, operators of X-Ray scanners for security purposes, are exempted from being monitored as Radiation Workers.

(b) Maintenance

- All persons involved in the maintenance of these units, should be monitored as Radiation Workers.

8. OPERATIONAL SAFETY

X-Ray Inspection Systems are designed to provide safe and efficient operation however the systems have inherent dangers and must be operated with safety in mind.

(a) Conveyer Belt Unit

- Key actuated control so that X-Rays cannot be produced when the key is removed.
- Clearly visible reliable light/beam-on indication.
- No X-Rays shall be produced when the conveyer is stationary.

- Manual control of X-Ray production should be provided in case of an emergency.
- For exposures exceeding 0.5 seconds, two independent means to indicate when x- rays are being produced. (e.g mA meter and X-Ray ON light).
- Emergency buttons at either end of the units.
- Please note - X-Rays are switched on and off automatically, by activation or deactivation of conveyor belt.

(b) Cabinet Type

- Key actuated control so that X-Rays cannot be produced when the key is removed.
- Clearly visible reliable light/beam-on indication.
- Manual control of X-Ray production in case of an emergency.
- Accessible emergency buttons.

(c) Additional Requirements

The exposure switch must be a "dead-man" type. A safety interlock to prevent the production of X-Rays while any door or access panel leading to the interior of the cabinet or conveyer belt unit is open, must be present.

9. OTHER IMPORTANT SAFETY MEASURES

(a) DO

- Adhere to the operation manual/instructions as prescribed by the manufacturer.
- Ensure that curtains are hanging down and in a good condition.
- Ensure that warning signs, lamps and signals are installed.
- Ensure notices are clearly legible.
- Ensure that lights are in a good working condition before operating the unit.
- Use a solid push stick to remove items that are stuck on the conveyor belt.
- Turn the system OFF before reaching or crawling inside.

- Follow the procedure established at your facility when dangerous objects or weapons are identified on the screen.
- All maintenance functions must be performed by a qualified technician.
- Maintenance reports must be filed for future reference.

(b) DO NOT

- Insert any part of the body into the inspection tunnel while X-Rays are on.
- Operate the X-Ray system with lead curtains broken or removed.
- Displace the curtains while X-Ray lights are on.

10. REFERENCES

10.1 Hazardous Substances Act, Act 15 of 1973.

10.2 Regulations Concerning the Control of Electronic Products, R.1332. Code of practice for users of medical X-Ray equipment 01-2015.

10.3 ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4).

10.4 Health Physics Society. Airport Screening Fact Sheet. http://hps.org/documents/airport_screening_fact_sheet.pdf

10.5 Health Physics Society. Security Screening. http://hps.org/publicinformation/ate/faqs/securityscreening.html

11. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old Guidelines for Cabinet and Conveyor Belt X-Ray Scanners, revised September 2017. It will be reviewed on this timeframe or as and when required.