South African Health Products
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GUIDELINE FOR USERS OF ULTRA-PORTABLE X-RAY EQUIPMENT

This guideline sets out requirements and recommendations for radiation safety associated with the use of ultra-portable diagnostic X-ray equipment. It represents the South African Health Product Regulatory Authority's (SAHPRA) current thinking on the safety, efficacy, and quality of 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. The Medicines and Related Substances Act 101 of 1965 governs the regulation of all medical devices in South Africa.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue and implementation	14 November 2025
2		

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Contents

Glossary

Abbreviation/ Term	Meaning
Act	Hazardous Substances Act, 1973 (Act 15 of 1973)
ALARA	As Low as Reasonably Achievable
CE	Conformité Européenne
CAD	Computer Aided Detection
EU	European Union
HPCSA	Health Professions Council of South Africa
HSA	Hazardous Substances Act, 1973 (Act 15 of 1973)
IAEA	International Atomic Energy Agency
IER	Individual Equipment Record
kV	Kilo voltage
MDR	Medical Device Regulation (EU) 2017/745
MDD	Medical Device Directive 93/42/EEC
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
PPE	Personal protective equipment
SAHPRA	South African Health Products Regulatory Authority
SOP	Standard Operating Procedure
TB	Tuberculosis
UP-XR	Ultra-Portable X-Ray
WHO	World Health Organization

1. INTRODUCTION

This guideline sets out requirements for the importation and use of ultra-portable X-ray (UP-XR) and recommendations for radiation safety associated with the use thereof. The document emphasises the importance of radiation safety for UP-XR systems, while ensuring alignment with the World Health Organization's (WHO) and International Atomic Energy Agency (IAEA) principles of radiation protection.

Where a given technology or practice is not explicitly covered by this guideline, guidance in matters of radiation protection should be sought from the South African Health Products Regulatory Authority's (SAHPRA)'s Radiation Control Unit. The licensee shall be responsible for ensuring that corrective action takes place on items of non-compliance with this guideline. The Hazardous Substances Act (HSA) does not allow any person to use radiation equipment unless he/she holds a license under the HSA for that purpose, while the Medicines and Related Substances Act (MRSA) governs the regulation of all medical devices that enter South Africa. The use of ultra-portable X-ray equipment without proper licensing is strictly prohibited and may result in legal penalties. This guideline must be read in conjunction with the HSA, the MRSA, and related regulations. All relevant forms and guidelines are available at: https://www.sahpra.org.za/radiation-control-guidelines-and-codes-of-practice/.

1.1 Purpose

The purpose of this guideline is to guide importers, distributors, and users of ultra-portable digital X-rays (UP-XRs) to ensure the safe and effective use of the equipment for its intended purpose(s).

1.2 Scope

This guideline applies to all license holders of ultra-portable X-ray equipment in South Africa. It establishes the regulatory framework for the importation, installation, and use of UP-XR equipment. The use of an ultra-portable X-ray should be strictly justified for patients who cannot access a fixed X-ray unit due to their location or clinical condition.

1.3 Background

Radiography plays a critical role in the screening and diagnosis of tuberculosis (TB) and other pulmonary conditions in South Africa. The evolution of X-ray technology has progressed from analogue to digital systems, with further advancements leading to mobile and ultra-portable solutions.

Ultra-portable X-ray systems offer significant advantages in terms of mobility, accessibility, and reduced radiation exposure. Ultra-portable radiography systems differ from conventional fixed and mobile X-ray

systems in their reduced generator output power and intended use in non-dedicated settings, including field and community environments. This necessitates a tailored regulatory approach that adequately addresses safety and effectiveness, particularly regarding the unique questions posed to radiation safety and image quality. As per the IAEA for any activity involving radiation exposure, the three general principles of radiation protection are: justification, optimisation, and dose limitation. Therefore, the radiation exposure must have a net overall benefit.

1.4 Definition of ultra-portable radiography

The WHO and the IAEA classify ultra-portable radiography systems as a sub-type of portable radiographic digital equipment, defined as those "used in a variety of X-ray imaging applications to support out-of-hospital infrastructure screening, diagnostic, and monitoring interventions, applications and campaigns", including adult and paediatric applications/interventions as appropriate. The permitted level of use includes dedicated and non-dedicated settings, such as healthcare centres, temporary and/or emergency health centres, outreach and field interventions (mobile clinics, screening campaigns, home care), and/or teleradiology solutions in remote areas.

2. LEGAL PROVISION

The use of ultra-portable X-ray equipment in South Africa is governed by the:

- Hazardous Substances Act 15 of 1973
- Regulations R.1332 of 3 August 1973
- Regulations R.1302 14 June 1991
- Medicines and Related Substances Act 101 of 1965
- Medical device regulations

3. GENERAL REQUIREMENTS

3.1 EU-Based Reliance Approach

In accordance with SAHPGL-BAU-01_v4 and SAHPGL-RDN-XR-24, this guideline establishes a reliance-based regulatory pathway for the submission of ultra-portable chest radiography systems for market authorisation. Importers/Dealers must ensure that their devices have obtained Conformité Européenne (CE) marking under the European Union (EU)'s Medical Device Regulation (MDR 2017/745) or Medical Device Directorate (MDD 93/42/EEC), demonstrating compliance with all applicable EU requirements for safety and performance.

3.1.1 Alignment with International Standards

Ultra-portable radiography systems submitted for consideration by SAHPRA must further demonstrate compliance with the minimum technical specifications of the WHO and IAEA (Annex 1). For the intended purpose of chest X-rays system who do not comply with the technical specifications will be rejected.

3.1.2 Weight Variance Allowance

At the discretion of SAHPRA, the total system weight is permitted to vary by 5 kg over the permissible weight specified by WHO-IAEA. As a result, the total system weight must be no greater than 35 kg, including all essential components as defined in the minimum technical specifications.

4. REQUIREMENTS OF IMPORTERS AND DISTRIBUTORS OF UP-XR

4.1 Import Licensing

4.1.1 Applicant Eligibility

Entities applying to import UP-XR are required to:

- Hold a Medical Device Establishment License as mandated by the Medicines and Related Substances Act 101 of 1965 Section 22C and medical device regulations further detailed in guideline SAHPGL-MD-06_v3.
- Comply with the requirements for the importation of ionising radiation-emitting devices as mandated by the HSA and detailed per SAHPGL-RDN-XR-24.
- Appoint an Authorised Representative with responsibilities defined in the regulations relating to medical devices (Annexure 10).

4.1.2 Application

In accordance with SAHPGL-RDN-XR-24_v1, a Primary Importer is required for devices that are manufactured internationally to be imported into South Africa. The Primary Importer must comply with the requirements and regulations of SAHPGL-RDN-XR-24_v1 and ensure compliance with the HSA.

The Primary Importer must apply for an import license to SAHPRA in accordance with SAHPGL-RDN-XR-24_v1. The application must be submitted to the following email address: import.xrays@sahpra.org.za. All required documentation for import must be submitted within 50 working days to allow finalisation of the application.

4.1.3 Required Documentation

The documentation outlined in Section 3 of SAHPGL-RDN-XR-24_v1 must be submitted in support of the application for an import licence.

Eligibility must be clearly demonstrated by ensuring:

- Supporting documentation highlights compliance with the WHO-IAEA specifications
- The submission of both the Notified Body Certificate and Declaration of Conformity to demonstrate EU market authorisation.

4.1.4 Application Review and Approval

SAHPRA will review the application and may request additional information or clarification as necessary.

Upon approval, an Import Licence with conditions will be issued for the ultra-portable radiography system. This allows the Primary Importer to bring the device into South Africa. Additional licenses must be secured for installation and use.

4.2 Install and Use Licensing

4.2.1 Applicant Eligibility for Install and Use License

Prospective Licence Holders must apply in conjunction with an entity that holds a valid licence for the installation and operation of other modalities of diagnostic X-ray equipment in dedicated settings. The existing facility must be compliant with the Hazardous Substances Act, regulations and licence conditions, as well as the Medicines and Related Substances Act (Act No. 101 of 1965, as amended).

4.2.2 Application

The Primary Importer must apply for an "Install and Use" license to SAHPRA, utilising the GLF-RDN-XR-02G form. The ultra-portable nature of the equipment should be specified in the application, alongside justification for use in non-dedicated settings. The intended purpose of the equipment must be clearly specified and must not deviate from the manufacturer's labelling and instructions for use.

4.2.3 Application Review and Approval

SAHPRA will review the application and may request additional information or clarification as necessary.

Upon approval, an Install and Use license will be issued, allowing the installation of the ultra-portable radiography unit. Subsequently, a 'Use Licence' must be obtained by entities responsible for equipment operation.

4.3 Post Approval Requirements

4.3.1 Post-Market Surveillance

Equipment manufacturers and primary importers of ultra-portable radiography systems must align with the post-market surveillance measures for diagnostic X-ray systems outlined in SAHPGL-MD-03 and SAHPGL-INSP-RC-01_v3 and additional requirements for ultra-portable X-ray systems specified in Annex 4.

4.3.2 Vigilance and Adverse Event Reporting

Equipment manufacturers and primary importers are required to record and report all adverse events including investigations, root cause analysis, and corrective and preventative actions (CAPA) as outlined in SAHPGL-MD-03_v4.

5. REQUIREMENTS OF UP-XR USE LICENCE HOLDERS

5.1 Use Licensing

As ultra-portable X-ray systems form part of medical X-ray equipment, all aspects of SAHPGL-RDN-XR-02_v1 apply. Refer to this guideline for all regulations, forms, and installation/disposal procedures for medical X-ray equipment.

5.1.1 Individual Equipment Record (IER)

As per SAHPGL-RDN-XR-02_v1, the License Holder is required to establish an Individual Equipment Record (IER) for all new units. The IER must contain all information stipulated in SAHPGL-RDN-XR-01_v1.

5.1.2 Acceptance Testing

- Acceptance Testing by a SAHPRA-approved Inspection Body is required upon installation, before obtaining a Use License.
- Required tests are specified in SAHPGL-RDN-XR-01_v1 and following manufacturer-specific testing. Annex 4 outlines the required tests for ultra-portable equipment.
- Acceptance tests for radiation safety must be performed in both dedicated and non-dedicated

settings.

- Results from acceptance tests must be recorded on the prescribed form and filed in the IER of the unit.

5.1.3 Review and Approval

If the results of Acceptance Tests meet the expected performance standard, for both dedicated and non-dedicated settings, a Use License will be granted by SAHPRA for the equipment. This license must be connected to an existing facility which is already in possession of a licensed X-ray product. The use of ultra-portable devices will become the responsibility of the license holder to ensure that they are properly used and at any time SAHPRA may visit the facility and the license holder should know the whereabouts of the ultra-portable devices for which they have licenses.

5.2 Quality Assurance

After obtaining the Use License, the Licence Holder must conduct quality assurance testing aligned with SAHPGL-RDN-XR-01_v1 and any conditions that exist on their license.

Additional tests required for ultra-portable equipment are specified in Annex 4. Any specific tests indicated by manufacturers must be included in the periodic quality assurance schedule for the unit.

5.3 Premises Requirements

The requirements for premises where UP-XR equipment is used shall comply with Section 3.6 of SAHPGL-RDN-XR-02_v1, with specific adaptations for non-dedicated settings as outlined in Annex 4.

5.4 Operator Requirements

5.4.1 Radiography

Radiographers are qualified operators as accredited by the Health Professions Council of South Africa (HPCSA) and eligible to be appointed as responsible persons on behalf of a licence holder.

5.4.2 Radiologist

Radiologists are qualified medical specialists in radiology accredited by the HPCSA for reporting of images, interpretation, and diagnosis. A radiologist is also eligible to be an operator and appointed as responsible persons.

5.5 Radiation Worker Requirements

All radiation workers involved in the operation of UP-XR equipment must comply with the requirements specified in Regulation R.1332 Section III.5-6 and Section 3.4 of SAHPGL-RDN-XR-02_v1, including appropriate monitoring and training.

5.6 Radiation Management

Appropriate radiation management must be strictly adhered to in both dedicated and non-dedicated settings.

- The management of radiation workers must be followed as described in SAHPGL-RDN-XR-02_v1.
- Required radiation safety practices for non-dedicated settings are outlined in Annex 4 of this document.
- Any incident involving radiation overexposure, equipment malfunction, or accidental radiation exposure must be reported immediately to SAHPRA's Radiation Control Unit at radcon.incidence@sahpra.org.za.

5.7 Record Keeping

- IER and radiation worker records must be kept by the License Holder in accordance with SAHPGL-RDN-XR-02.
- Records should be readily available for inspection during audits or investigations by Radiation Control. The retention of patients' records must be done in accordance with the HCPCSA guidelines Booklet 9.

ULTRA-PORTABLE X-RAY DEVICES WITH CAD SOFTWARE

Where CAD or AI software is used for interpreting chest radiographs from ultra-portable X-ray devices in TB screening and triage, only software pre-qualified, or otherwise approved, by the WHO or certified by Stringent Regulatory Authorities (SRA) or WHO-listed Authorities (WLA; eligible authorities listed previously) for this specific indication shall be permitted. Implementation parameters and threshold configurations must align with local epidemiological context and designated clinical pathways. This provision shall be it operationalised in accordance with WHO's Policy on CAD for TB Screening (Annexure 8) and SAHPRA's regulatory requirements of Artificial Intelligence and Machine Learning Enabled Medical Devices (Annexure 9).

6. VALIDITY

This guideline is valid for a period of five (5) years from the effective date of publication. It will be reviewed within this timeframe or as and when required.

7. Acknowledgement

The South African Health Products Regulatory Authority (SAHPRA) and the National Department of Health (NDoH), supported by the Clinton Health Access Initiative (CHAI) and the Gates Foundation, work together to improve access to ultra-portable radiography systems.

8. REFERENCES

8.1 The following related documents are referenced

1. South Africa, 1973. Hazardous Substances Act, 1973 (Act 15 of 1973). https://www.sahpra.org.za/radiation-control-acts-and-regulations/
2. South Africa, 1973. Regulations Concerning the Control of Electronic Products. Regulation Gazette No. 1822 (Regulation R1332 of 1973). https://www.sahpra.org.za/radiation-control-acts-and-regulations/
3. South Africa, 1965. Medicines and Related Substances Act, 1965 (Act 101 of 1965) as amended. https://www.sahpra.org.za/acts/
4. International Atomic Energy Agency, International Safety Standards. https://www.iaea.org/resources/rpop/resources/international-safety-standards/justification-and-optimization
5. European Union, 2017. Regulation of the European Parliament and of the Council on Medical Devices (Regulation 2017/745 of 2017). (MDR 2017/745) https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng
6. European Union, 1993. Council Directive concerning Medical Devices (Council Directive 93/42/EEC of 1993). (MDD 93/42/EEC) https://eur-lex.europa.eu/eli/dir/1993/42/oj/eng

8.2 Related Guidelines

8.2.1 SAHPGL-MD-06: Guideline for a License to Manufacture, Import, Export, or Distribute Medical Devices and IVDs

8.2.2 SAHPGL-RDN-XR-01: Quality Control Tests for Diagnostic X-ray Imaging Systems

8.2.3 SAHPGL-RDN-XR-02: Code of Practice for Users of Medical X-ray Equipment

8.2.4 SAHPGL-RDN-XR-11: Requirements for Radiation Shielding of Rooms

8.2.5 SAHPGL-RDN-XR-24: Guideline for Import Applications of Electronic Devices Emitting Ionising Radiation

8.2.6 SAHPGL-BAU-01: Reliance Guideline

8.2.7 SAHPGL-INSP-RC-01_v3 – Guidelines for Post-Marketing Surveillance of Medicines and Health Products

8.2.8 SAHPGL-MD-03_v4 – Guideline for Medical Device Adverse Event Reporting

9. ANNEXURES

Annexure #	Title	Hyperlink
1	Minimum Technical Specifications for Ultra-Portable X-Ray Equipment (WHO-IAEA)	https://iris.who.int/bitstream/handle/10665/344514/9789240033818-eng.pdf?sequence=1
2	GLF-RDN-XR-02G – Application form for a License to Install and Use an X-Ray Device and Related Components	https://www.sahpra.org.za/wp-content/uploads/2023/02/GLF-RDN-XR-02G_v1-Application-form-for-a-Licence-to-Install-and-Use-an-X-Ray-Device-and-Related-Components-Old-RC-DEALER.docx
3	GLF-RDN-XR-02B – Application for A License to Use an X-ray Device	https://www.sahpra.org.za/wp-content/uploads/2022/06/GLF-RDN-XR-02B_v1-APPLICATION-FOR-A-LICENCE-TO-USE-AN-X-RAY-DEVICE-RC001-Form.docx
4	Operational procedures for radiation safety in a non-dedicated setting	Includes as Annexure 4
5	Template for Individual Equipment Record (IER)	Refer to SAHPRA's Guideline **for QC in Medical Diagnostic X-ray Imaging Systems SAHPGL-RDN-XR-01**
6	Site Assessment Form (for non-dedicated settings)	Included as annexure 6
7	Incident Reporting Template	• https://www.sahpra.org.za/document/reporting-national-radiation-occurrences/ • https://www.sahpra.org.za/document/guideline-for-radiation-monitoring-requirements-and-radiation-occurrences/
8	Use of computer-aided detection software for tuberculosis screening: WHO policy statement	https://www.who.int/publications/i/item/9789240110373
9	Regulatory Requirements of Artificial Intelligence and Machine Learning (AI/ML) Enabled Medical Devices	https://www.sahpra.org.za/document/regulatory-requirements-of-artificial-intelligence-and-machine-learning-ai-ml-enabled-medical-devices/

10	Regulations Relating to Medical Devices and In-Vitro Diagnostic Medical Devices (IVDs)	https://www.sahpra.org.za/document/regulations-relating-to-medical-devices-and-in-vitro-diagnostic-medical-devices-ivds/

Annexure 4: OPERATIONAL PROCEDURES FOR RADIATION SAFETY IN NON-DEDICATED SETTINGS

This addendum provides essential operational procedures for establishing and maintaining radiation safety in temporary X-ray facilities using UP-XR systems in non-dedicated settings. All procedures must comply with SAHPRA regulations and be performed by qualified personnel that has adequate knowledge and experience in the field of radiation protection and are registered with the HPCSA in one of the following categories: radiography, radiology, or medical physics.

1. SITE ESTABLISHMENT AND ASSESSMENT

Site Selection Requirements:

- **Minimum clear radius**: 10 meters in all directions from the UP-XR system
- Complete physical survey documenting open space, terrain, proximity to public areas, and natural barriers
- Environmental assessment, including weather conditions, ground stability, and potential interference sources
- **Documentation**: Site Assessment Form (GLF-RDN-XR-02H) and simple site plan with UP-XR placement and controlled zone boundaries
- **Approval**: Responsible person must approve the site assessment; complex sites require Radiation Protection Advisor (RPA) consultation

Demarcation: Use portable barriers, stakes with coloured tape, radiation warning signs, and physical barriers where possible.

2. SAFETY PROCEDURES

Operator Safety:

- **Positioning**: Stand as far as possible behind the X-ray tube, use a remote control when possible, or a wired switch no less than 2m in length, or according to manufacturer specifications. Never stand in the primary beam or hold the generator while operating.
- **PPE Requirements**: Lead apron (min 0.25mm Pb equivalent), thyroid shield, consider lead glasses for outdoor operations
- **Exposure Limits**: With lead apron - may operate inside controlled area; without lead apron - remain outside controlled zone

Patient Safety:

- Provide clear instructions and proper positioning to minimise repeat exposures
- Use appropriate exposure factors per established charts as available
- Restrict X-ray beam to area of interest using collimation
- Follow special procedures for pregnant patients and paediatric patients

Public Safety:

- **Exclusion**: No public allowed in controlled zone during exposures (exceptions for essential caregivers with PPE)
- **Waiting Areas**: Establish at least 10 meters from the X-ray tube
- **Post-Examination**: Remove barriers and conduct final survey when operations are complete

3. PERSONAL PROTECTIVE EQUIPMENT (PPE)

Required PPE:

- **Lead Aprons**: Min 0.25mm Pb equivalent, wrap-around style for operators, appropriately sized
- **Thyroid Shields**: Min 0.25mm Pb equivalent, required for all operators in non-dedicated settings
- **Lead Gloves**: Min 0.25mm Pb equivalent when hands might be near primary beam
- **Lead Glasses**: Min 0.5mm Pb equivalent with side protection, recommended for all operators
- **Portable Shields**: Min 0.5mm Pb equivalent, 1.7m height when available and practical

4. RADIATION MONITORING

Personnel Monitoring

- **Dosimetry**: All radiation workers are issued a personal dosimeter

Area Monitoring

- **Instruments**: Calibrated survey meters suitable for UP-XR energy range and field conditions
- **Frequency**:
  - <1-day sites: twice-daily surveys at setup and set down
  - 1–3-day sites: daily surveys
  - <3-day sites: once at setup
- **Protocol**: Conduct surveys during initial setup, verify controlled zone boundaries, document results

5. QUALITY CONTROL TESTING SCHEDULE

Daily Checks (Before First Use)

- Battery testing (≥50% charge), visual inspection of all components

- Check cords, exposure switch, laser positioning, field light, X-ray window
- Verify PPE availability and condition, check image quality, and initialisation process
- Confirm radiation warning signage and controlled area distances

Weekly/Monthly Checks

- **Weekly**: Solar panel cleaning
- **Monthly**: Solar panel output/capacity/charging tests, battery charger functionality

Quarterly Checks

- Exposure time range, kV range, software version verification
- Comprehensive performance evaluation by a qualified medical physicist

Six-Monthly Checks

- Battery capacity assessment, full charge verification, visual battery inspection
- Internal component inspection for damage, loose connections, oil leakage

Annual Checks

- High temperature simulation (35-40°C), standardised phantom testing
- WHO-IAEA parameter evaluation, leakage measurements, entrance skin dose assessment
- Total radiation assessment, exposure limit verification, distance confirmation

6. EQUIPMENT CONSIDERATIONS

Environmental Protection:

- Use protective covers during transport, shield electronics from sunlight
- Protect against dust/moisture, consider wind stabilisation
- **Operating Limits**: Temperature 5-45°C, Humidity 20-80% non-condensing

Battery Management:

- Maintain multiple charged batteries, follow manufacturer temperature recommendations
- Document performance and replacement schedule, consider solar charging for remote locations

Maintenance:

- Follow manufacturer's maintenance schedule with additional checks for environmental damage
- Clean external surfaces after each day of use, apply safety-related updates promptly
- Use only authorised personnel for repairs, verify radiation safety after repairs

Annexure 6: ULTRA-PORTABLE X-RAY (UP-XR) OUTDOOR SITE ASSESSMENT FORM

Reference: Based on SAHPRA Guideline for Code of Practice for Radiation Safety of UP-XR Equipment

1. Deployment Details (Site, Date, Operator)

Date of Survey:	
Time of Survey:	
Responsible Operator:	
Operator Contact #:	
UP-XR System Model:	
Serial Number:	
Deployment Location (Address/GPS:	
Expected Workload (Exams/Day):	

2. Minimum Space & Physical Requirements (Section 4.1.2)

☐ **Minimum Clear Radius**: Is there a clear radius of $\geq_{10}$ meters in all directions from the UP-XR placement?

☐ **Overhead Obstructions**: Are there any overhead obstructions that could interfere with equipment or operations?

(*If checked, STOP and reassess*).

☐ **Ground Stability**: Is the ground surface level and stable for system and patient positioning?

☐ **Proximity to Public**: Is the proposed location far enough from high-traffic public areas (e.g., pathways, markets)?

☐ **Natural Barriers**: Are natural barriers (e.g., large mounds, thick bushes) utilized to minimize public access?

3. Controlled Zone Establishment (Section 4.2)

Maximum Exposure Factors Considered: 90 kV, 2.5 mAs 120 kV, 5.0 mAs (Use this unless lower factors are justified)

Workload Adjustment (Section 4.2.4):

☐ Expected Workload $\leq_{30}$ examinations/day (Use standard dimensions below).

☐ Expected Workload $_{>30}$ examinations/day (Increase dimensions by 50%).

Controlled Zone Demarcation & Dimensions (Based on 120 kV, 5.0 mAs standard)

☐ Controlled zone boundaries marked using portable barriers/tape/rope.

☐ Radiation warning signs displayed at all potential entry points.

☐ Dedicated staff member assigned to control access, OR operator ensuring no unauthorized entry.

☐ **Distance check**: Actual measured distance is greater than the required minimum:

Back (towards X-ray tube): ≥ **7.0m** (*Required minimum*)

Sides (L/R of patient): ≥ **4.0m** (*Required minimum*)

Front (opposite X-ray tube): ≥ **4.0m** (*Required minimum*)

4. Environmental Assessment & Equipment Protection

Environmental Factor	Status (Yes/ No)	Mitigation/Comments
Adverse Weather (Rain/High Wind/Dust) is forecast.		
Ground is adequately dry and stable.		
Sun position avoids glare on display and patient setup.		
Equipment is protected from direct sunlight/moisture (e.g., covers, canopy).		

5. Pre-Operational Checklist

☐ All operators are wearing personal dosimeters (worn under the lead apron).

☐ All required PPE (Lead Apron ≥ 0.25mm Pb Eq., Thyroid Shield) is available, inspected, and free from damage/cracks.

☐ Remote control or maximum available cable length will be used for exposure.

☐ Waiting area for the public is established ≥8 meters from the X-ray tube.

☐ Clear instructions and signage are available for patients and the public (local languages used).

☐ A minimum of one portable shield (≥0.5mm Pb Eq., ≥1.7m height) is available and positioned for operator safety (if required).

6. Site Approval and Sign-Off

Declaration: I, the undersigned, confirm that the site meets all minimum requirements for establishing a temporary UP-XR facility, and that the required controlled and supervised areas have been established according to the protocol.

Operator	
Printed Name	
Date	
Signature	

Note: If **RPA Consultation** is required due to site complexity or workload exceeding 30 exams/day, the RPA must sign above.