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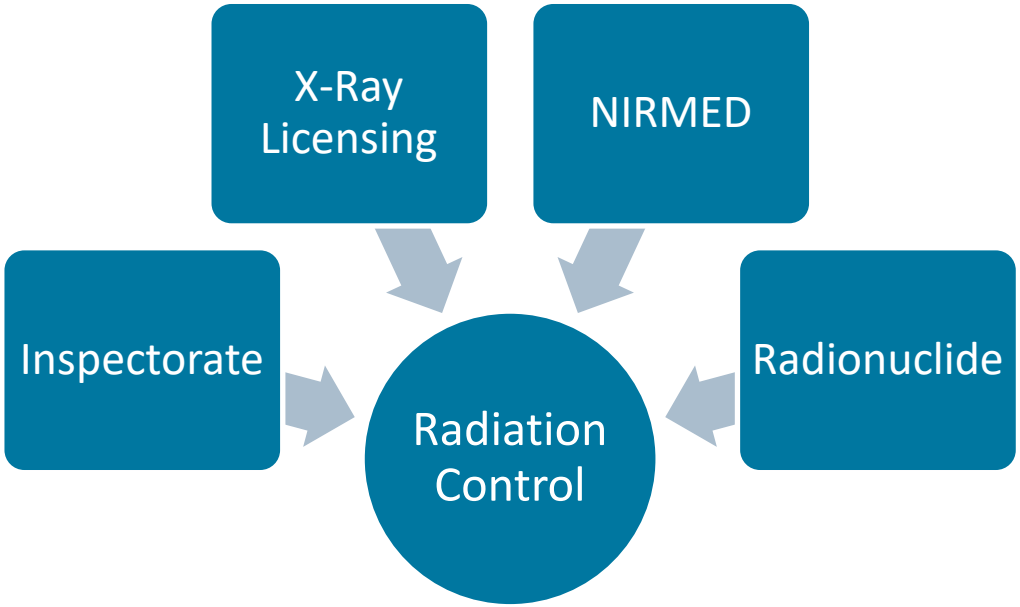
SAHPRA Compliance Requirement’s

M.A Maphophe

SAHPRA-Radiation Control Subunit's



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Hazardous Substance Act & Regulations

- https://www.sahpra.org.za/radiation-control-acts-and-regulations/
- HAZARDOUS SUBSTANCES ACT 15 OF 1973
- Regulations concerning the control of Electronic Products – R.1332
- R246 & R247 - Regulations under HAZ SUBS ACT 15 OF 1973
- Regulations relating to Group III Hazardous Substances (Regulation R690, 14 Apr 1989)
- Schedule of Listed Electronic Products (Regulation R1302, 14 June 1991)

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HAS-15 1973- provisions

3. Sale of Group 1 and Group. III, and letting, use, operation, application and installation of Group III, hazardous substances.

No Person Shall:-

b. Sell, let, use, operate or apply any Group Ill hazardous substance unless a license under section 4 (b) is in force in respect thereof, and otherwise than subject to the conditions prescribed or determined by the Director-General;

c. Install or keep installed any Group III hazardous substance on any premises unless a license under section 4 (c) is in force in respect of such premises, and otherwise than subject to the conditions prescribed or determined by the Director-General.

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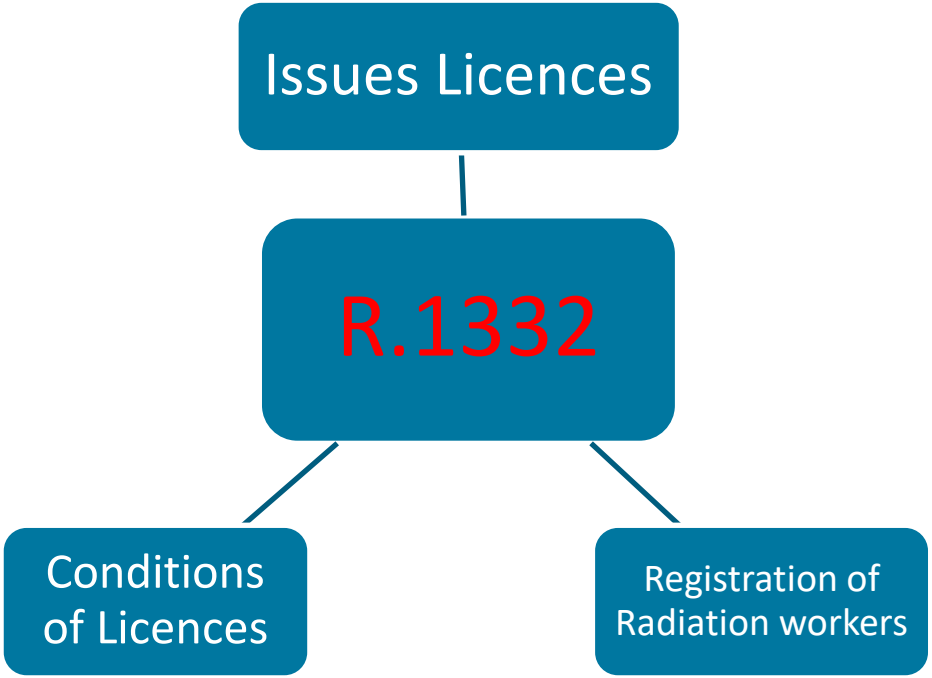
Regulation 1332-



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Regulation 1332-

III.3b. Provisions Regarding Applicant & Licence Holders

The holder shall be liable for the entire scope of radiation protection with regard to a listed electronic product or premises for which he holds a licence. Such liability shall relate to any aspect that could reasonably be included under radiation protection, and, in addition to other relevant responsibilities which the Secretary may specify in the licence,

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Regulation 1332-

III.5C. Provision of Monitoring of Radiation Working

Monitoring of radiation workers.- Every holder shall ensure that-

1. his radiation workers be monitored by a Personnel Monitoring Service previously approved by the Secretary and hereinafter referred to as the "Service" Information regarding the Service may be obtained from the Secretary

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Dose limits

Application	Occupational	Public
Effective dose	20 mSv per annum, not more than 100 mSv over a period of 5 years (not more than 50 mSv in any one year)	1 mSv per annum
Annual equivalent dose to the		
lens of the eye	20 mSv	1 mSv
skin	500 mSv	50 mSv
hands and feet	500 mSv	--------

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Regulation 1332-

III.6. Provisions regarding patients

a. exposure of human beings to a useful beam is permitted only for strictly necessary medical purposes and after asertaining that there has been no previous radiological examination which would make further examination unnecessary

b. the exposure of and the exposed area on the patient are limited to the lowest value compatible with successful diagnosis or therapy;

c. in all diagnostic and therapeutic irradiations every effort is made to keep the gonad skin and integral dose at the lowest possible values consistent with clinical requirements;

d. appropriate special precautions are taken in the irradiation of persons under the age of 18 years women of reproductive age and pregnant women on whom only essential examinations shall be done

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Regulation 1302 - Listed Electronic Products Import (dealer)

Licensing requirements apply to any person or company that either

- Imports any new or fully refurbished device,
- Manufactures x-ray device in RSA or
- Fully refurbish x-ray device in RSA

Documentation

- Application form 41BM-1(IMP)
- Color brochure (incl technical specifications)
- Letter of appointment of authorized representative of original manufacturer
- Copy of EC certificate(s) issued by a recognized Notified Body to original manufacturer

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Listed Electronic Products- Ionizing Radiation

- Diagnostic X-ray units.
- Therapeutic X-ray units.
- X-ray volts used for industrial, research, educational or am other purposes.
- Electron accelerators.
- Heavy particle accelerators.
- Neutron generators.

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Licensing

Regulations (R.1332) require that a joint product and premises licence be obtained for x-ray equipment before it may be installed and commissioned.

Licences are issued to:

Specific Institutions	• Medical institution; Dental Practice; Radiology Practice; Oncology etc
Specific Person	• Radiologists; Oncologist; Radiographers; Dentist; Veterinary etc
Specific Premises	• Linac Bunker's; Industrial Site; research facilities etc

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Licensing- Application New Unit

Import Licence condition 03:

- For installation and use, the dealer must submit the appropriate form to SAHPRA. User and Dealer Info
  - **RC-DEALER**: Diagnostic X-ray device and related components
  - **RC-DENT**: Dental X-ray device and related components
  - **RC003-1 and RC011-1** (rev 1): Therapy equipment
- Delivery or installation of any unit/component may commence only after the licence holder has received approval ("MAY INSTALL") from SAHPRA:

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Licensing- Application 2nd Hand Equipment

Applicable form:

APPLICATION DISPOSAL OF A LICENSED ELECTRONIC PRODUCT AND OR NEWMODIFIED PREMISES (RC002)	OF-RADCON-X RAY-02A
APPLICATION FOR A LICENCE TO USE AN X-RAY DEVICE (RC001)	OF-RADCON-X RAY-02B
CHANGE OF RESPONSIBLE PERSON ADDITIONAL RESPONSIBLE PERSON (RC005)	OF-RADCON-X RAY-02C
APPLICATION RE-ACTIVATE LICENCE FOR STORED CANCELLED ELECTRONIC PRODUCT (RC007)	OF-RADCON-X RAY-02D

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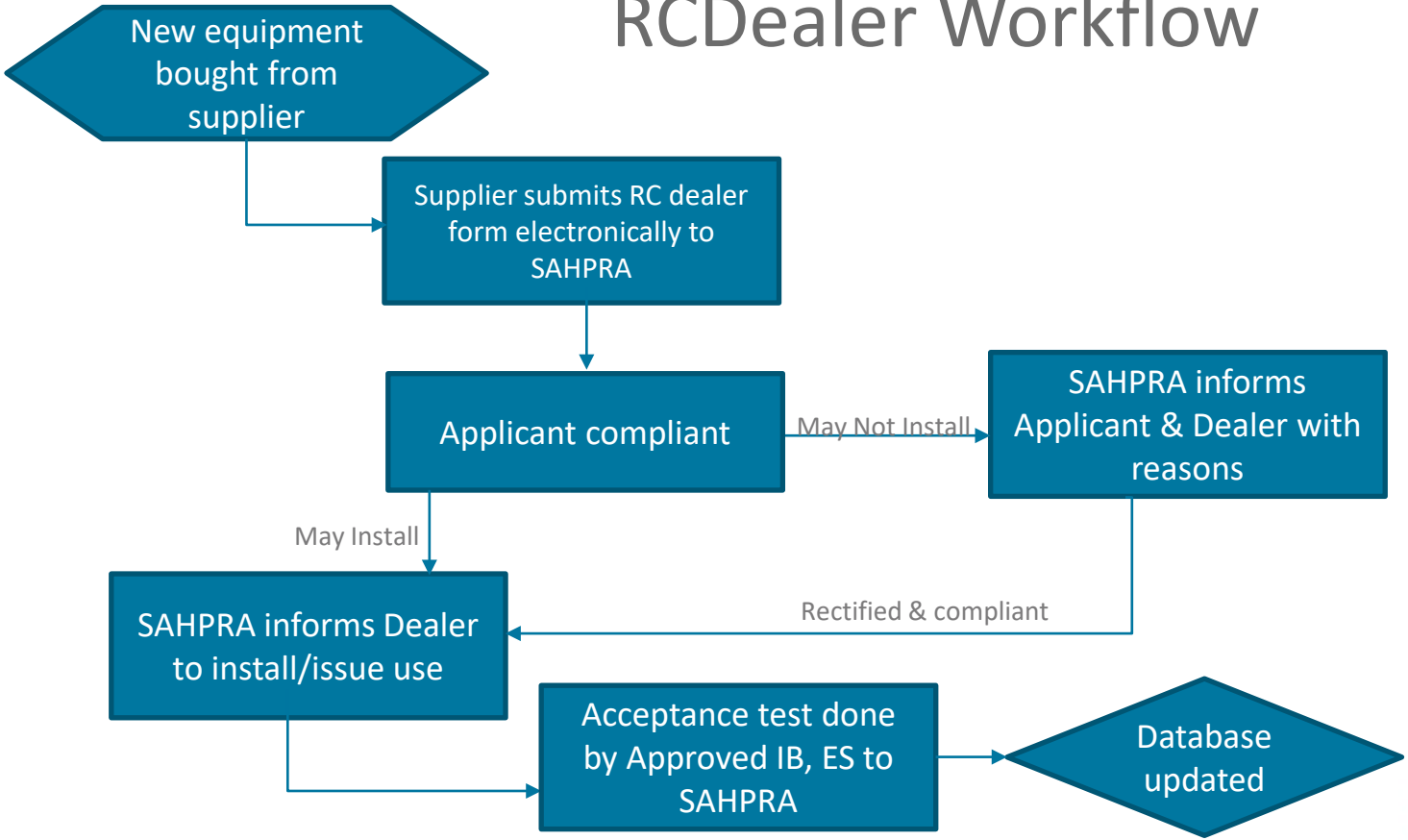
RCDealer Workflow



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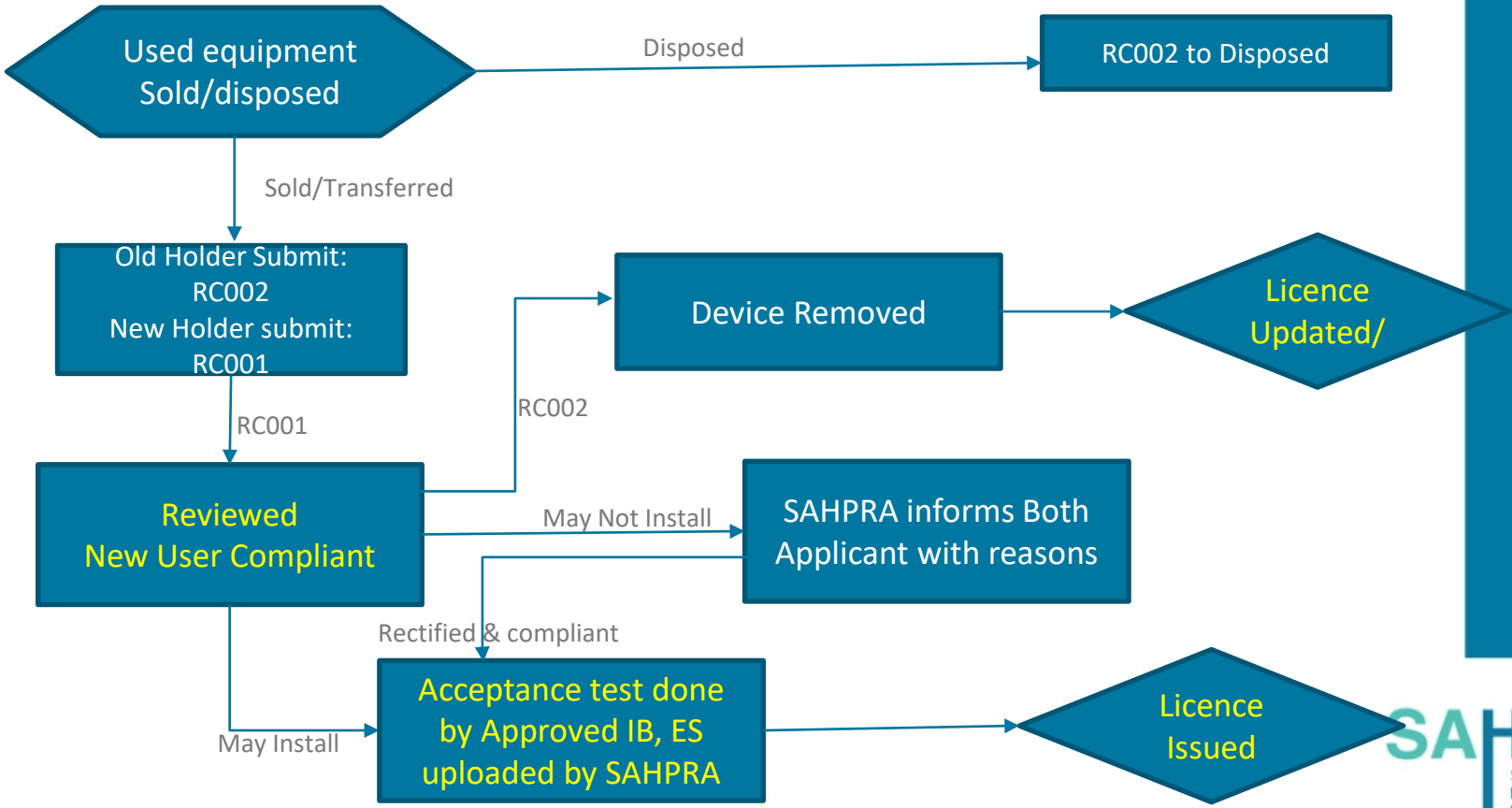
2nd Hand - Workflow



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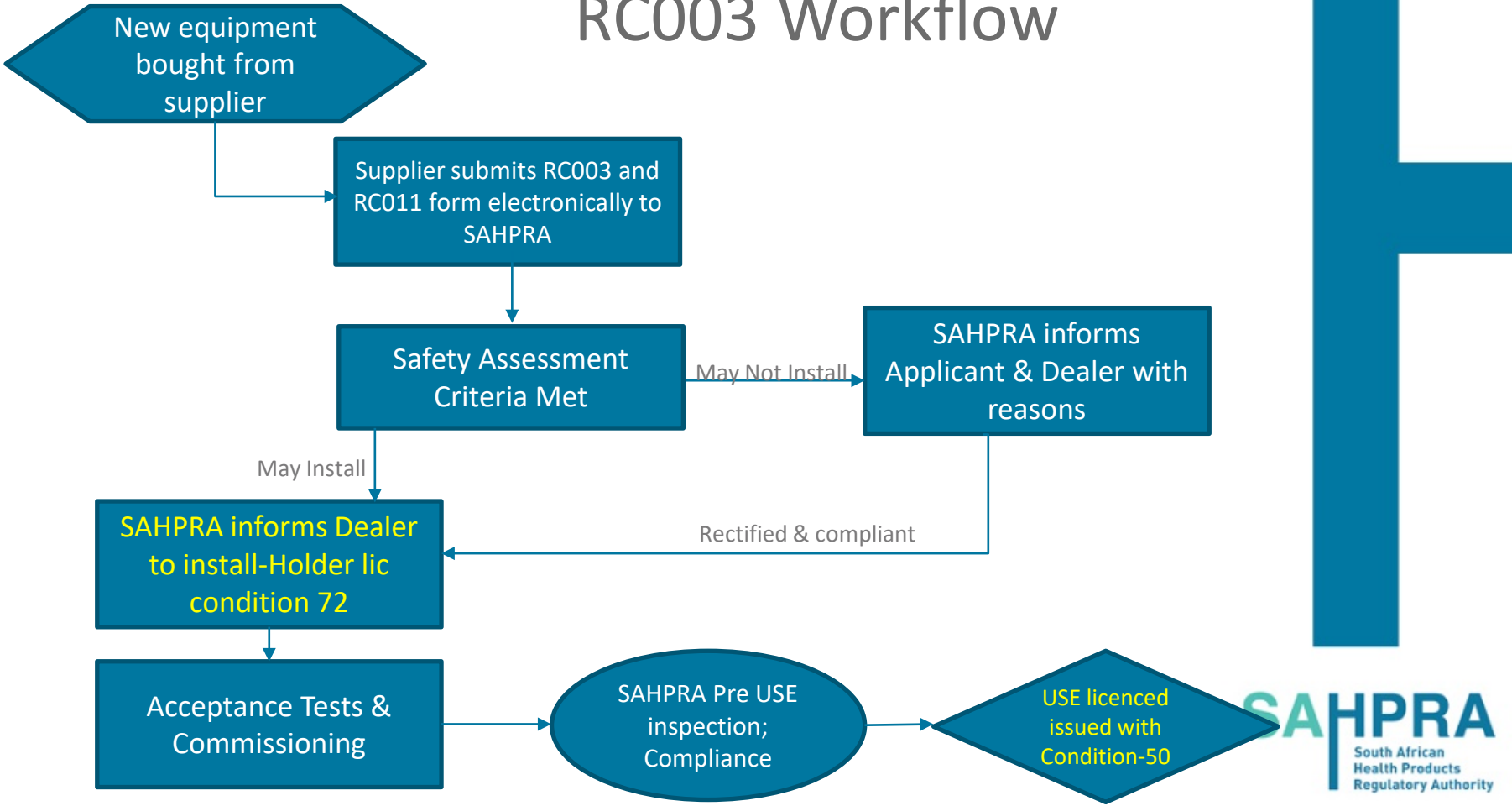
RC003 Workflow



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Available on Dealer import licence must match Brand & Model

3 INSTALLATION

Complete installation?	Upgrade or Modification?	Licence No. of user (Only for upgrade or modification):	Estimated Date of Installation:

4 INFORMATION CONCERNING THE SYSTEM – Individual components must be listed

	Import or Manufacture Licence No.	Date of Manufacture	Brand	Model	Serial no
System					
Generator					
Collimator					
Tube Assembly					
Table System					
Image Intensifier					
Erect Bucky					
DDR					
CR System					

If available
Compulsory dental & Vets

Specification document

5 TECHNIQUE FACTORS

Maximum kV:	kW	Maximum exposure time……s OR …….mAs

6 INSPECTION BODY THAT WILL PERFORM ACCEPTANCE TESTS (ONLY applicable to Medical X-ray Equipment)

Inspection Body:	SANAS Ref No.:

most dealers have IB lic

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8 PARTICULARS OF APPLICANT (USER)

Name and postal address of individual or organisation :		
		Postcode :
☎	Fax no.:	Email:
Name and postal address of contact person (*If different from above*):		
		Postcode
☎/Cell:	Fax no.:	Email:
DOH Reference Number (user):		

Licence belong to institution

CEO is the contact Licence

Existing holders and N/A for new holders

9 RESPONSIBLE PERSON (AS APPOINTED BY PURCHASER) - Must be completed in full.

Surname	Title	Initials	ID no.
Address			
☎/Cell	Email		
Professional Registration Number (Where applicable) :			
Designation	Qualification		
I am aware of my duties as responsible person♦	Signature	Date	

RP appointed/ RC005 to change

HPCSA etc

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Responsible person

- The person appointed must be qualified in either of the following categories and registered with the (HPCSA):
  - ✓ Radiography
  - ✓ Radiology
  - ✓ Medical Physics or
  - ✓ Chiropractic
- Responsible person must have adequate knowledge and experience in the field of radiation protection in general.

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Responsible person

DUTIES OF RESPONSIBLE PERSON

- 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;

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Responsible Person cont’

- 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 reasonable achievable (ALARA) without compromising the diagnostic efficiency of the result, and
- Workers are educated in the hazards and risks of ionising radiation.

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Medical Physics Role

- MP required in Interventional Radiology to establish and implement optimization procedures. (RC006)
- Medical physics and acting medical physics required in the USE of therapeutic or particle accelerator (RC003)

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14 TYPE OF INSTALLATION (PLEASE COMPLETE **EITHER** SECTION 14.1 OR 14.2)

14.1 Enclosed installation ***(X-ray equipment which is installed and used within the same enclosure or room.)***

Please attach a diagram or plan indicating the appropriate enclosure or room with special reference to:

(a) The normal location of the x-ray tube; the direction and extent of x-ray tube movement; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

(b) The structural composition and thickness (1/2 brick thickness) or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

(c) The dimensions of the room(s) concerned.

(d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

14.2 Open installation

State why an enclosed installation is not likely to be practicable. ***(e.g. Mobile / Portable X-ray equipment)***

.....

15 DOSIMETRY SERVICE

Name of dosimetry service that will be made use of

16 DECLARATION BY THE PURCHASER (USER)

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14. Type of Installation

- A diagram or plan must be attached as per 14.1 of the Rcdealer form
- Hand drawn diagram usually not clear in future they will be no longer acceptable
- Guideline with regard to the design of X-ray rooms is available on https://www.sahpra.org.za/radiation-control-guidelines-and-codes-of-practice/ **under review
- The guideline covers general and fluoroscopy rooms and some of the special procedure
- Radiotherapy bunker design as specified by NCRP 151
- Not applicable in mobile units and Portable hand held devices
- Not applicable when adding a component in existing device such as DDR or CR Systems

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15. Dosimetry Service

- Two Personnel monitoring service approved
  - SABS
  - Dosimeter Services (PTY) LTD
- Monitoring service are SANAS accredited and SAHPRA approved therefore have to legal documents.
- Both Monitoring services are subscribe to the national dose register.

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May or May not Install

- May install:-
  - Applicant compliant in all their existing equipment (N/A new applicant)
  - Applicant compliant with requirements for the device applied for
  - Installation may resume
  - USE may resume once acceptance performed
  - Responsible persons ensures Conditions/Code of practice/Acts and regulation is adhered to

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May not Install

- May not install:-
  - Is usually not a rejection of application
  - Reason if non-compliant (outstanding annual QC test, no HPCSA for Responsible person, Incorrect diagram, un approved Dosimetry service; incomplete sections of the form, inconsistencies etc)
  - May not install always communicated to applicant and dealer (Popi Act applies)

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IB Licence Document

- Acceptance and/or routine quality control tests must be performed in accordance with the requirements as listed in table 2 of document DIAGNOSTIC QC or DIAGNOSTIC ACCEPTANCE DENTAL.
- Results of the acceptance and/or routine quality control tests must be documented
- A copy of these results must be handed to the licence holder of the diagnostic x-ray imaging equipment for filing on the Individual Equipment Record;

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IB Licence Document (continue)

- Should any of the tests indicate non-compliance, the licence holder must be informed that corrective maintenance (repairs) should be implemented immediately, followed by re-testing;
- The Inspection Body must submit to SAHPRA, on a monthly basis all QC and repair tests which were performed during the preceding month.
- Acceptance tests must be submitted immediately after they have been completed

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Examples

LIST OF LICENCES

ELECTRONIC PRODUCTS - Page 4

A COPY OF THIS LIST MUST BE DISPLAYED ON THE PREMISES

Licence no.:
VILLA
APOLLO DRF
Serial no.:

Annexure: Conditions
95

Keep Installed Use,

Last QC date- 17-JUN-22

Licence no.:
PHILIPS
INGENUITY CT
Serial no.:

Annexure: Conditions
95

Keep Installed Use,

Last QC date- 18-NOV-21

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Examples

LIST OF LICENCES

ELECTRONIC PRODUCTS - Page 3

A COPY OF THIS LIST MUST BE DISPLAYED ON THE PREMISES

Responsible Person:

PRODUCT	PREMISES	CONDITIONS
Licence no.: ZIEHM VISION R Serial no.:		Annexure: Conditions 73, 95 Keep Installed Last QC date-

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CODE OF PRACTICE FOR USERS OF MEDICAL X-RAY EQUIPMENT

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Links

- https://www.sahpra.org.za/faqs-x-rays-radiation-control/
- https://www.sahpra.org.za/whistleblower/
- https://www.sahpra.org.za/radiation-control-acts-and-regulations/
- https://www.sahpra.org.za/radiation-control-application-and-report-forms/
- https://www.sahpra.org.za/radiation-control-guidelines-and-codes-of-practice/

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END

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