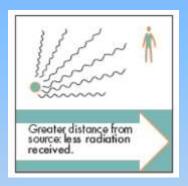


# **Radiation Control**



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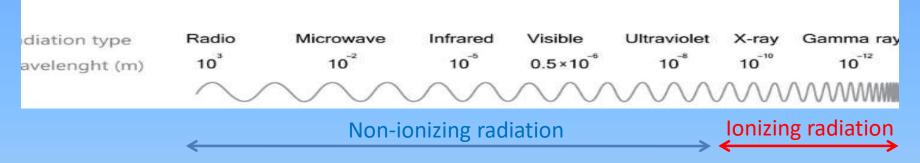


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### **lonising and non-ionising radiation**

### Electromagnetic Spectrum



### Ionizing radiation

#### Low risk

- CT-scanners
- Dental X-rays
- Mammography Units
- General radiography equipment
- Security scanners

### High risk

- Cyclotrons, manufacturers, research
- Irradiators
- Gamma Knife, Cyber Knife
- Linear Accelerators
- Blood irradiators
- Body scanners in mines
- Interventional radiology



#### **Mission**

To protect radiation workers, patients, members of the public and the environment from harmful effects of ionizing radiation without unduly limiting the operation of facilities or the conduct of activities that give rise to radiation risks.

#### NOTE:

- Most health-related matters are regulated according to norms and standards set by the World Health Organisation (WHO)
- All aspects of ionizing radiation are regulated according to the international standards of the International Atomic Energy Agency (IAEA)



### **Mandate**

# 1. **Public Health Amendment Act, 1971** (Act 42 of 1971) Regulations:

R1332 of 1973 – Control of Electronic Products referred to as Group III
hazardous substances (generally referred to as X-rays) - Radiation Protection

### 2. Hazardous Substance Act 15 (of 1973)

#### Regulations:

- R246 and R247 of 1993 related to Group IV hazardous substances (Radionuclides) - Radiation Protection
- R690 of 1989 Group III hazardous substances (electronic generators of ionising radiation and devices emitting radiation) - Devices
- R1302 of 1991 Schedule of listed electronic products Devices
- R326 of 1979 Provide for the institution of a national advisory committee on electronic products

### **Organizational Structure**

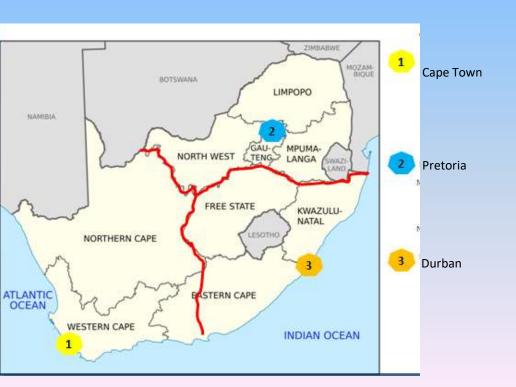
#### **Directorate: Radiation Control**

Sub-Directorate: lonizing Radiation

Sub-Directorate: Radionuclides

Sub-Directorate: Inspectorate

Sub-Directorate:
Non-ionizing Radiation and
Electro-Medical Devices



- Head office of DirectorateRadiation Control: Cape Town
- For the purpose of INSPECTIONS only, the country is divided in 3 sub-regions, each with a branch of the Inspectorate



#### 1. Electronic Generators of Ionising Radiation

Number of license holders: > 9 100

Number of licensed units: > 20 000

License: Sale, lease, install, use, operate, apply

- Compliance management: Radiation Safety of equipment, facilities and activities
- Enforcement
- Complaints, incidents/accidents involving X-ray generators
- Overexposures of radiation workers
- Monitor Patient Dose Reference Levels (DRLs)
- Import of devices (devise control validation for use in RSAD RA

#### Sub-Directorate: Electronic Generators of Ionizing Radiation

- Medical applications (69% of AH; ≈ 71% units)
  - Research institutions:
    - iThemba LABS open-sector cyclotron & Van der Graaff generator
    - Research & Training institutions
  - Radiation Oncology: Linear accelerators, CT scanners, Simulators, Ortho-voltage machines
  - Blood irradiators

#### **Diagnostic radiology:**

- Fluoroscopy Equipment
- Computed Tomography (CT) Scanners
- Mammography Units
- General radiography equipment
- Processor & hardcopy devices
- CR Readers, film viewers, reporting monitors
- Dental X-rays
- Digital Diagnostic Radiology (DDR) Systems



### Sub-Directorate: Ionizing Radiation (continued)

- Industrial applications (31% of AH; ≈ 29% Units)
  - Mining
  - Security
  - Veterinarian
  - Industrial radiography
  - Research
  - Manufacturers & distributors
  - Mortuaries & forensics laboratories







#### 2. Radionuclides

Number of license holders: ~ 2 400

Number of licensed units: > 15 00

License: Manufacture, acquire, possess, use, transfer, import, export, transport, dispose of (sell and discard)

- Cradle to grave tracking serial numbers
- Compliance management: Radiation safety of equipement, facilities and activities
- Enforcement
- Incidents/accidents involving radionuclides
- Overexposures of radiation workers
- Source exchanges



- RPO and medical physicist changes
- Reconcile monthly reports submitted by distributors
- Annual returns
- Import/export license (> 65 countries)
- Disposal of radionuclides
- Security of radioactive sources
- Emergency Preparedness and Response

Requires cooperate governance, MOU's

- Cooperate governance with SAPS (Explosives Unit, Priority Crime Unit), SARS Customs, Disaster Management, DoE, SACAA, etc.
- Involves several international conventions

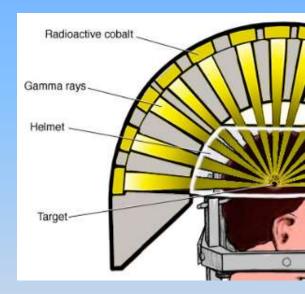


#### Sub-Directorate: Radionuclides

- Medical applications (≈ 10% of AH)
  - Gamma Knife
  - 22 High Dose Rate (HDR) Afterloaders
  - Radiation Oncology: ~ 190, including 3 x Co-60 therapy units
  - Nuclear Medicine: ~80, including 10 PET/CT scanners
  - Tertiary Training Centers: 6
  - Other smaller applications: Pathology labs, etc.

#### Industrial applications (≈ 90% of AH

- Manufacturers (2 Large, 1 small) exporting to > 65 countries
- Irradiators (5 industrial, 6 sample, 4 blood, etc.)
- Industrial radiography: (> 70 of AH, > 700 sources)
- > 35 Distributors (some with branches in other countries)
- Borehole logging: (11 of AH)
- Measure & Control Gauges in wide range of industries (> 950 DL, 750 SG authority holders)
   (Density-, Level-, Thickness gauges, Soil- & moisture gauges, etc.)
- Research, and Education & Training institutions
- Off-shore vessels (density gauges, well-logging, industrial radiography)
- Transport
- Long-term storage for radioactive waste (radioactive sources & materials)





#### 3. Inspectorate

- Inspector of ALL X-ray & radionuclide licence holders
- Compliance verification, targeted inspections, audits -
- Enforcement in collaboration with licensing staff

#### **Challenges:**

- Only 10 posts, of which 5 vacancies
- No competence to inspect high risk facilities & activities
- No equipment to perform job
- No regular meetings with licensing staff

#### Solutions:

- Two post levels: competency for high and low risk inspections
- More posts
- Modern communication media



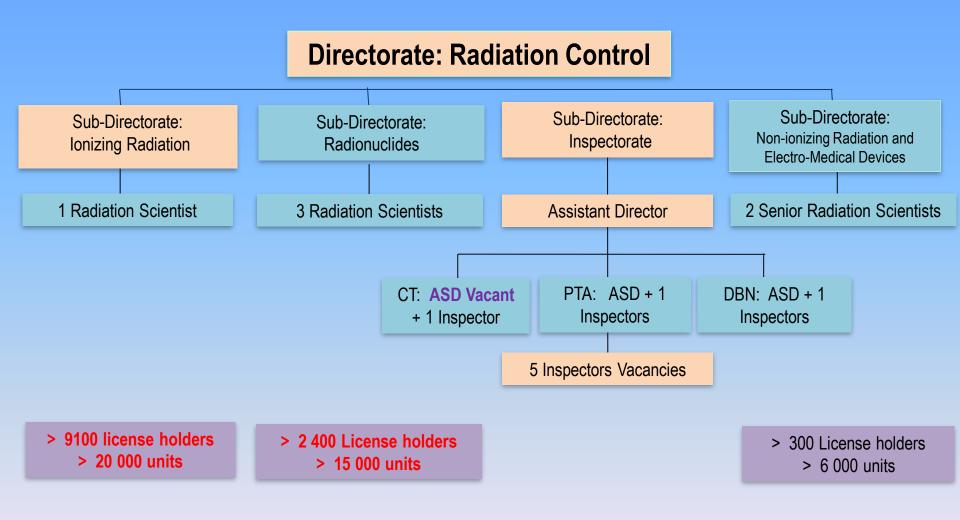
#### 4. NIRMED

Regulates ≈ 300 license holders, ≈ 6 000 makes & models

- Schedule of listed electronic products (R1302 of 1991) old, outdated;
   new technologies not included
- Includes, but not limited to devices that emit ionizing & non-ionizing radiation
- Medical and industrial devices
- Importation: Validation and registration for use in RSA



### **Staffing**





## **Thank You**



