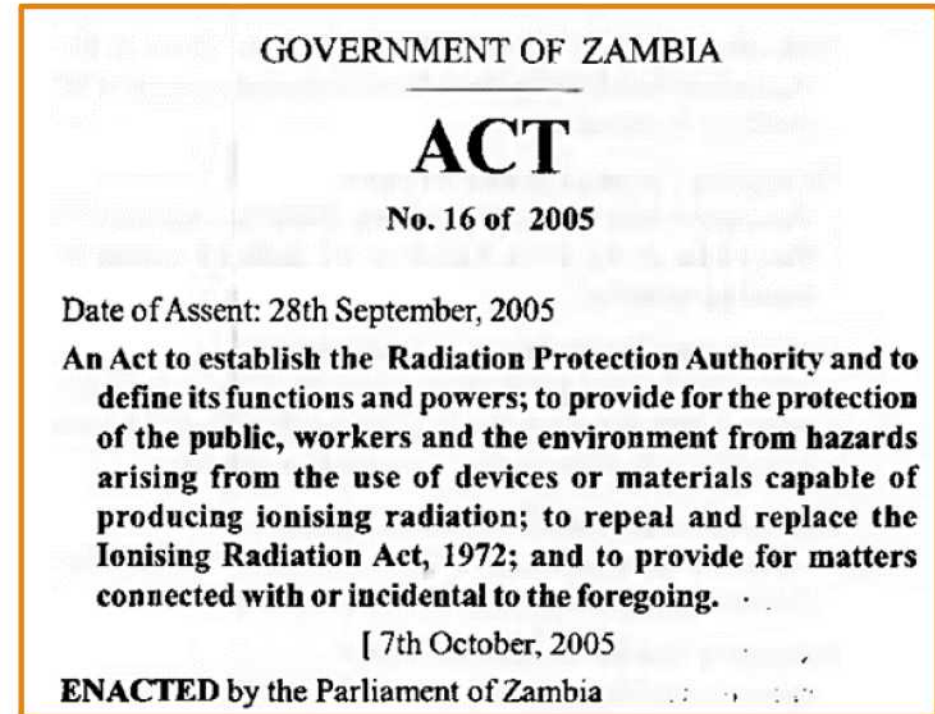


Medical equipment standards in Zambian hospitals

- Application of Radiation Protection Board standards during the life cycle of x-ray equipment
- Zambian Bureau of Standards standards during life cycle of scales

17.5.7 The usefulness of standards in Zambian hospitals is clearly explained, and examples of scenarios in which they would be helpful are provided.



17.5.7 Medical equipment standards in Zambian hospitals

Unit C 17.5 Adhering to Medical Equipment Standards

Module 279-17-C Regulations, Standards and Ethics

Zambia Bureau of Standards for Safety and Quality Standards

The Zambia Bureau of Standards (ZABS) is the Statutory National Standards Body for Zambia established under an Act of Parliament, the Standards Act, Cap 416 of **1994** of the Laws of Zambia for the preparation and promulgation of Zambian Standards

ZABS is a specialized organization of National importance serving the country in the field of **standardization, standards formulation, quality control, quality assurance, import and export quality inspections, certification and removal of technical barriers to trade.**



<http://www.zabs.org.zm/>

Radiation Protection Board: Standards for X-ray equipment

GOVERNMENT OF ZAMBIA

ACT

No. 16 of 2005

Date of Assent: 28th September, 2005

An Act to establish the Radiation Protection Authority and to define its functions and powers; to provide for the protection of the public, workers and the environment from hazards arising from the use of devices or materials capable of producing ionising radiation; to repeal and replace the Ionising Radiation Act, 1972; and to provide for matters connected with or incidental to the foregoing.

[7th October, 2005

ENACTED by the Parliament of Zambia

Zambia Ionizing Radiation Protection Act, 2005

Part II: establishes a Radiation Protection Authority, with a **Radiation Protection Authority Board**

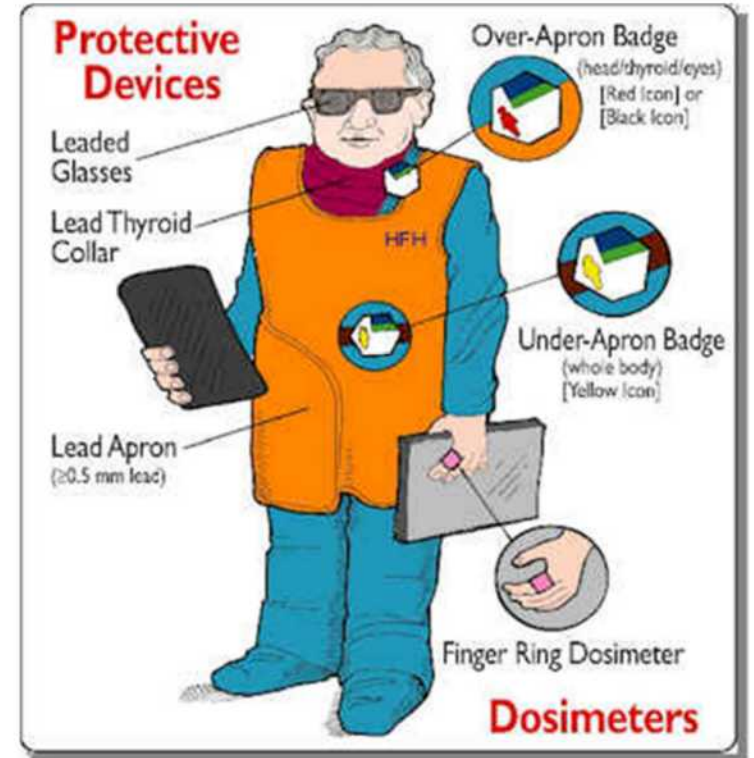
- consisting of 19 members, mostly representatives of various ministries
- main tasks:
 - **advise government on policies**, etc. related to radiation protection
 - **implement government policies** related to protection of public, workers, etc.
 - **issue licenses** and authorizations
- the board shall meet at least once every three months
- decision making is by majority of members present
- participants are not allowed to communicate on information that is acquired in this function

a selection of items only...

Zambia Ionizing Radiation Protection Act, 2005

Part III: The Secretariat

- will implement decisions of the board
- will set Radiation exposure limits
- shall maintain a **personnel radiation dosimetry service**
 - to provide personal **radiation measuring devices** to be worn by an individual likely to be exposed to radiation
 - to provide a **reporting service**.... adequate records of personal radiation exposure measurements
 - warn the public in case of actual or potential radiation exposure ...
 - monitor imported and local food stuff to detect any contamination with radioactive material
 - conduct assessments of radioactivity in underground mines ...
- an Executive Director will be appointed; (s)he is Secretary of the Board



Zambia Ionizing Radiation Protection Act, 2005

Part IV: Licences

- anybody dealing with radio-active materials (etc.) shall to apply to the Board for a license
- the radiation safety requirements prescribed by this act
 - **do not extend to patients undergoing medical treatment** by exposure to radiation by or under the supervision of a medical practitioner if such treatment is in accordance with and approved code of practice established by the relevant medical professional bodies
 - **do apply to the safety of medical and technical staff** working with the radioactive material or source of harmful ionising radiation and to the protection of all other persons, other than the patient undergoing treatment.
- every licensee shall appoint a competent person as **radiation protection officer**, who shall liaise with the Secretariat to ensure compliance with the Act.
- where a licensee intends to **decommission** an ionising radiation device, the licensee shall, at least six months before decommissioning the device, inform the Director....
a selection of items only...

Zambia Ionizing Radiation Protection Act, 2005

Part VI: Inspections

- the Board shall appoint **radiation safety officers** to monitor, inspect and enforce the provisions of this Act.
- A radiation safety officer shall have power at all reasonable times to enter,, to take samples of materials, take measurements,

a selection of items only...

Standards in Zambia

Further health related standards in Zambia:

- metrology on weights and scales
- Regulations on Medicines

Zambian Bureau of Standards: standards during life cycle of scales

Zambia Bureau of Standards Accredited

Zambia Bureau of Standards (ZABS) has been accredited by SADCAS in the scope of Mass Metrology and Volume Metrology in accordance with ISO/IEC 17025. Zambia Bureau of Standards accreditation covers mass pieces: 1-20mg, 20-50mg, 50-100mg, 100-200mg, 200-500mg, 100mg-1g, 1-2g, 2-5 g, 5-10g, 10-20g, 20-50g, 50g, 100g, 200g-2kg, 5kg, 10kg and 20kg; weighing instruments self – indicating: 0-5g, >5-100g, >100-200g, >200g-1kg, >1-2kg, >2-5kg, >5-10kg, >10-20kg, >20-40kg, >40-2000kg; and on-site calibration for item 2 and volume measures: micropipettes, volumetric flask and volumetric dispenser. Through this accreditation, Zambia Bureau of Standards has been granted the unique accreditation number CAL-8 003 and CAL-9 002 indicating that Zambia Bureau of Standards is a SADCAS calibration accredited Laboratory for Mass Metrology and Volume Metrology respectively. The ZABS is the second facility in Zambia to be accredited by SADCAS.



The certificate was handed over during a ceremony held on 16 August 2013 at the Southern Sun Hotel in Lusaka, Zambia. In his opening remarks the Director of ZABS, Mr Manuel Mutale gave a background to the establishment of the ZABS, the services that ZABS offers highlighting its status as the national standards body of Zambia which offers a one stop shop for Standardization, quality assurance and metrology services. He also briefed the delegates present on the ZABS accreditation roadmap and plans for the future.

The Chairperson of the ZABS Standards Council Dr David Nama, welcomed guests to the cocktail party

Zambian Bureau of Standards: standards during life cycle of scales

ZABS METROLOGY LABORATORIES CALIBRATION FEES

I. MASS METROLOGY

Number	Instrument	Charges (ZMK)	Charges (ZMKR)
1.1	Weight set 1 mg – 10 kg	1, 000, 000	1, 000
1.2	Weight set 1 mg – 1 kg	925, 000	925
1.3	Weight set 1 mg – 200 g	650, 000	650
1.4	Single weight	150, 000	150
1.5	Scale > 2000 kg – 4000 kg	3, 000, 000	3, 000
1.6	Scale > 1000 kg – 2000 kg	1, 500, 000	1, 500
1.7	Scale > 500 kg – 1000 kg	1, 000, 000	1, 000
1.8	Scale > 150 kg – 500 kg	700, 000	700
1.9	Scale > 30 kg – 150 kg	500, 000	500
1.10	Scale > 5 kg – 30 kg	400, 000	400
1.11	Spring balance	300, 000	300
1.12	Analytical balance 1 mg – 5 kg	400, 000	400
1.13	Magnetic susceptibility	50, 000	50

<http://www.zabs.org.zm/>

Zambia Medicines Regulatory Authority

The **Zambia Medicines Regulatory Authority** formerly the Pharmaceutical Regulatory Authority is the Statutory National Medicines Regulatory Body for Zambia established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia to regulate and control **the manufacture, importation, storage distribution, supply, sale and use of medicines and allied substances.**

The main objective of the Authority is to ensure that all medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy.



ZAMBIA MEDICINES REGULATORY AUTHORITY

Regulating Medicines For Public Health Protection



<http://www.zamra.org.zm/>

Zambia Medicines Regulatory Authority (2015-05-07)

The screenshot displays the Zambia Medicines Regulatory Authority (ZAMRA) website. On the left is a vertical navigation menu with the following items: HOME, FUNCTIONS, NDQCL, MARKETING AUTH., INSPECTORATE & LICENSING, ADMINISTRATION, FORMS & GUIDELINES, PROCEDURES, USEFUL LINKS, MEDIA CENTRE, CONTACT, and a green button for FAQ. The central area features a photograph of the inauguration of the new ZAMRA board on May 7, 2015. A banner in the background reads 'ZAMBIA MEDICINES REGULATORY AUTHORITY INAUGURATION OF THE NEW BOARD' and 'Regulating Medicines for Public Health Protection'. A group of people is seated around a conference table, with a man in a suit speaking into a microphone. To the right of the photo is a green sidebar with the headline 'ZAMRA BOARD UNVEILED' and a sub-headline: 'Government unveils a 14 member ZAMRA board to be headed by Hon Christina Muludika .'. At the bottom of the page, there are four red text links: 'About Us', 'Vision Statement', 'Mission Statement', and 'Pharmacovigilance (links)'.

Further development / adoption of standards for Med. Equipment in Zambia...

Set up community..... (association ?)

END

The creation of this presentation was supported by a grant from THET:

see <https://www.thet.org/>

