Kenya Bureau of Standards

Standards for quality life

KENYA STANDARDS AND CONFORMITY ASSESSMENT FOR MEDICAL DEVICES

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Outline

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- KEBS in brief
- Definition of standards
- Objectives of standardization
- Stages of development of Kenya Standards
- Fields, types and hierarchy of standards
- Sale of standards
- Standards on Medical Devices
- Conformity Assessment of Medical Devices

Establishment

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- KEBS is the National Standards body in Kenya; established through "The Standards Act" Cap. 496 of the Laws of Kenya; Legal Notices (LNs) have expanded our scope
- KEBS started its operations on 12th July 1974;
- Currently reports to the Ministry of Investments, Trade and Industry
- Operations are guided by the Strategic Plan, yearly Performance Contract with the Government
- Operates a performance management system based on a Balanced Scorecard
- KEBS operates an integrated infrastructure that encompasses Standards, Metrology and Conformity Assessment (SMCA) under one organization

KEBS Mandate

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KEBS is mandated (Standards Act CAP 496 and LNs) to provide standardization and conformity assessment services through:-

- Promotion of standardization in commerce and industry
- Provision of testing and calibration facilities
- Product and system certification
- Undertaking educational work in standardization and practical application of standards
- Maintenance and dissemination of International System of Units (SI) of measurements

KEBS Services

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- Standardization Services
  - Development of Standards (Company, National, Regional & International)
  - Maintenance of Measurement Standards (Metrology)
  - Technical support for multilateral and bilateral trade agreements
- Conformity Assessment Services
  - Inspection (Import and Export)
  - Quality Assurance (Product certification)
  - Market Surveillance
  - System Certification
  - Testing services
  - Calibration Services
- Training and Education
- Information Services (Library and Enquiry Point)

Definition — What is a standard?

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The output of the merger is an authoritative document called a **“standard”**

Standards give **requirements**, **rules** and **guidelines** for a process, product or service

Definition — What is a Standard?

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ISO/IEC Guide 2

*a **document**, established by **consensus** and approved by a **recognized body,** that provides for common and repeated use, rules, guidelines or characteristics for activities or their results aimed at the achievement of the optimum degree of order in a given context.*

Note:

Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits

Definition — What is standardization?

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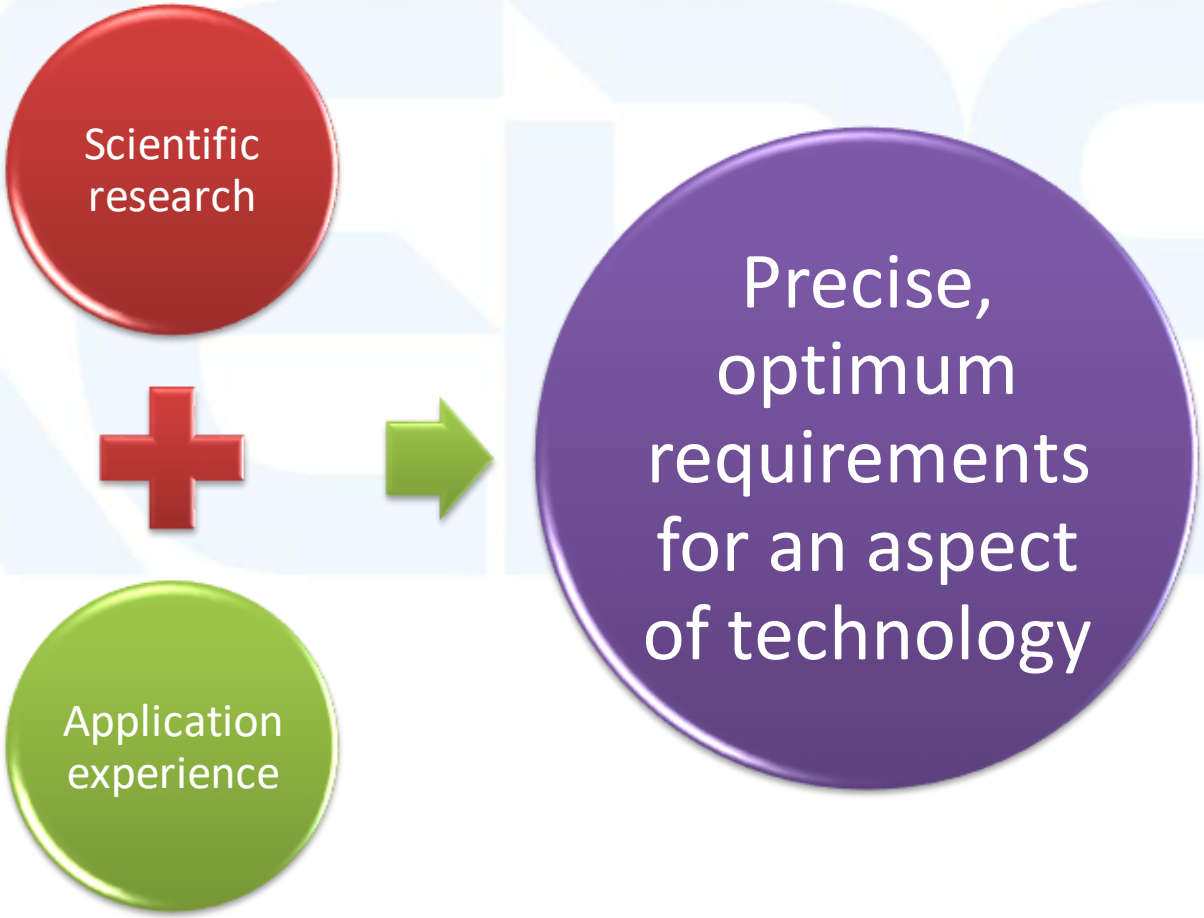
Standardization is the process that encompasses the initiation, development and application of standards



Definition — What is standardization?

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ISO/IEC GUIDE 2:

An activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context.

- Note 1: In particular, the activity consists of the processes of formulating, issuing and implementing standards.
- Note 2. Important benefits of standardization are improvement of the suitability of products, processes and services for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation.

Objectives of Standardization

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Objectives of Standardization

- Standardization makes things run **smoother!**
- **Compatibility** – Tyres & rims
- **Interchangeability** – Bulbs & holders, syringe & needles
- **Interconnectivity** - Phones & chargers
- **Interoperability -** Sim cards on any phone

Standards

How are standards developed?

Decision Making Process for Development of Kenya Standards

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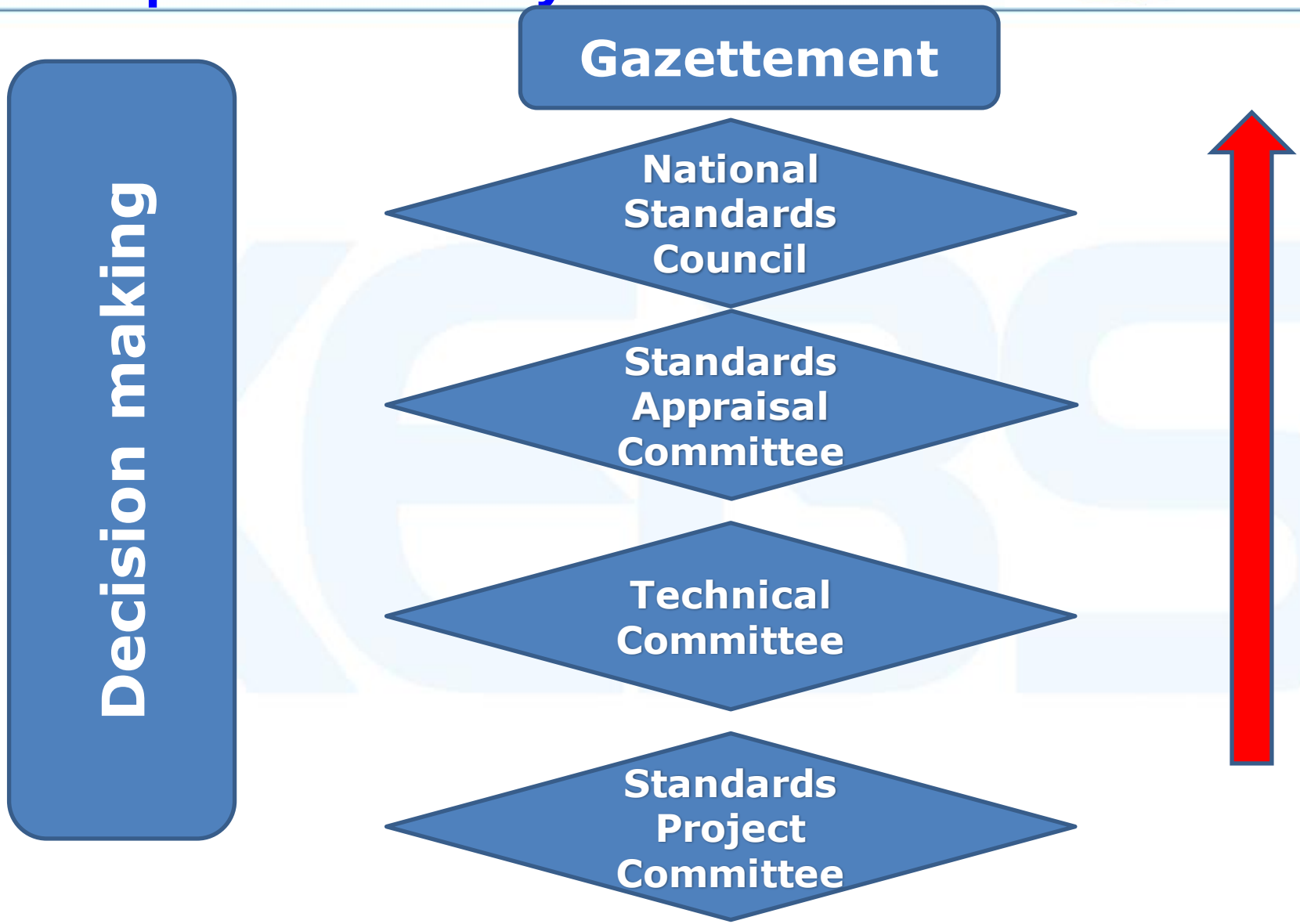
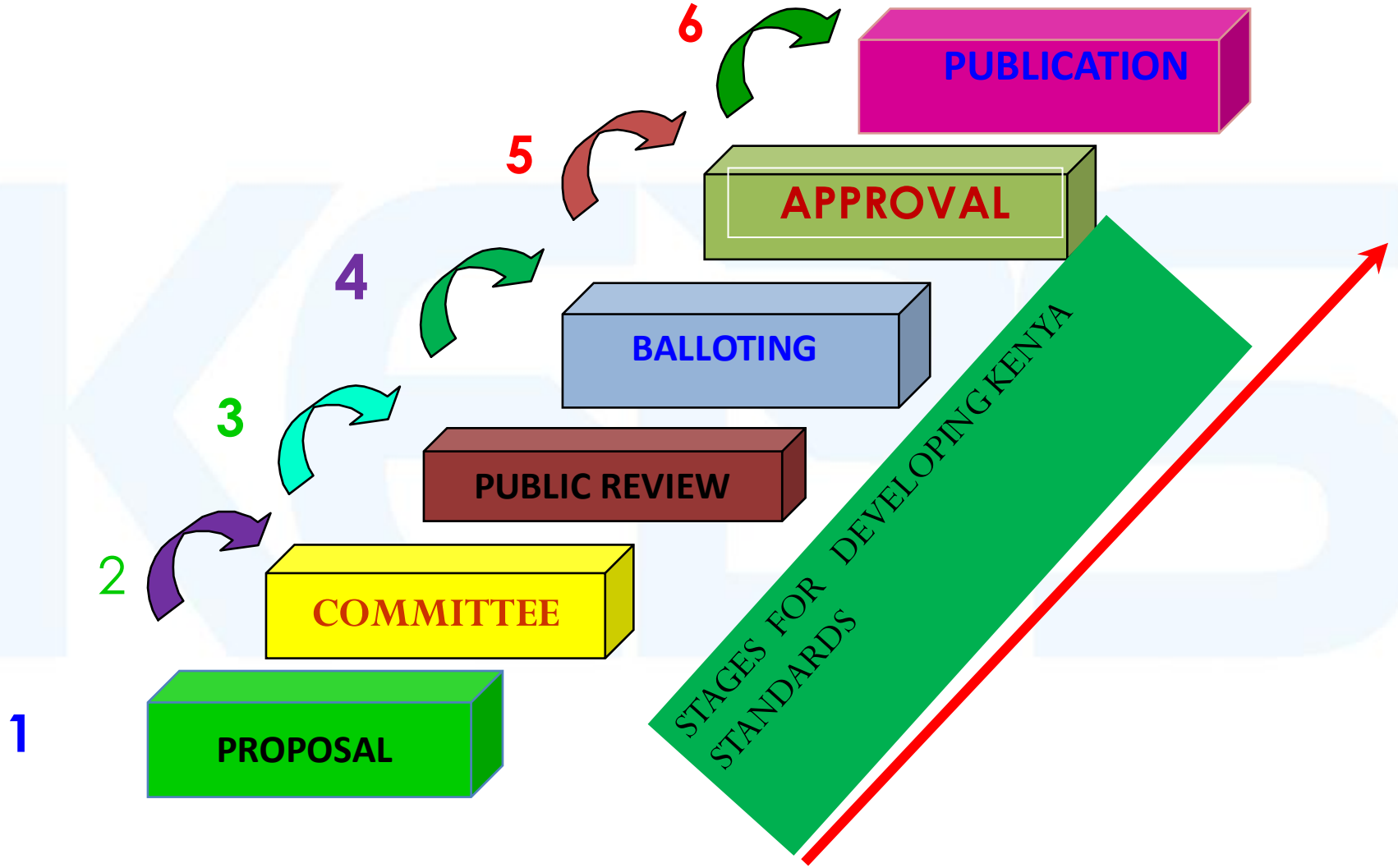


Stages of Development of Kenya Standards



Fields of standardization

KEBS is the Secretariat to more than 200 Technical Committees that develop standards in the following sectors:

- Chemical
- Food
- Agriculture
- Civil & Mechanical Engineering
- Electrotechnical
- Leather & Textiles
- Services

Constitution of Technical Committees

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The TC members are key stakeholders in standards development.
Categories include:

a) Government Lead Agency or regulator
b) Manufacturers or service providers
c) Major corporate consumers of the product/service
d) University , Research and other Technical Institutions
e) Industry Association
f) Trade Association
g) Professional Body
h) Consumer Organization
i) Non Governmental Organization, NGO
j) Renown Professionals
k) Firms co-opted for a project by TC
l) Secretariat.

Prioritization of standards

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Prioritization of the adoption/development of international, regional and national standards is done based on:

- Importance of economic field
- Degree of economic benefit
- Importance as export item
- Capacity as import substitute
- Level of consumer protection
- Availability of reference material
- Availability of testing facilities
- Volume of production or operation
- Ease of adoption and implementation
- Transfer of technology

Types of standards

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i. Basic Standard

ii. Terminology Standard

iii. Product Standard

iv. Testing Standard

v. Procedure

vi. Code of practice

vii. Service Standard

Hierarchy of standards

International Linkages

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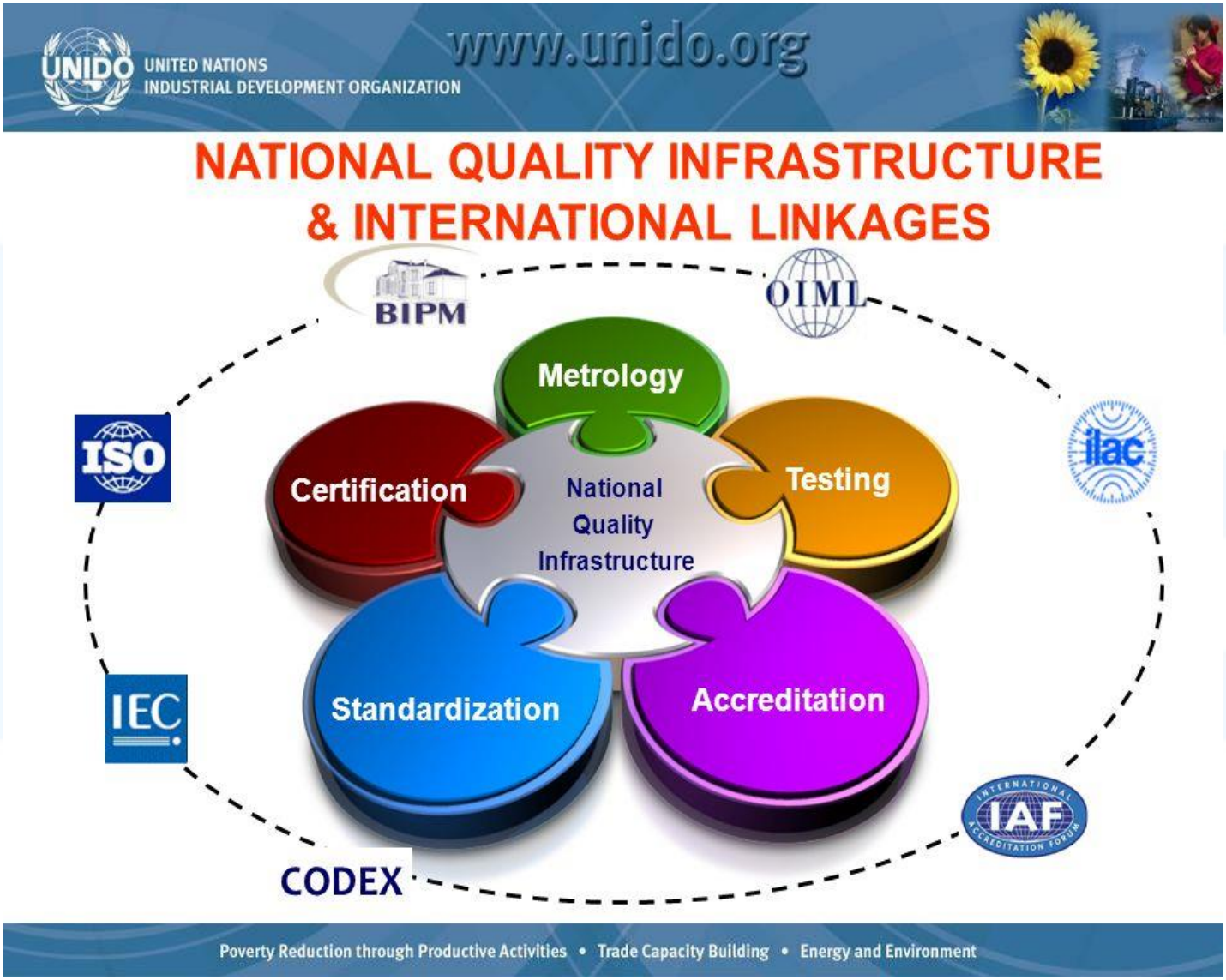

Standardization space

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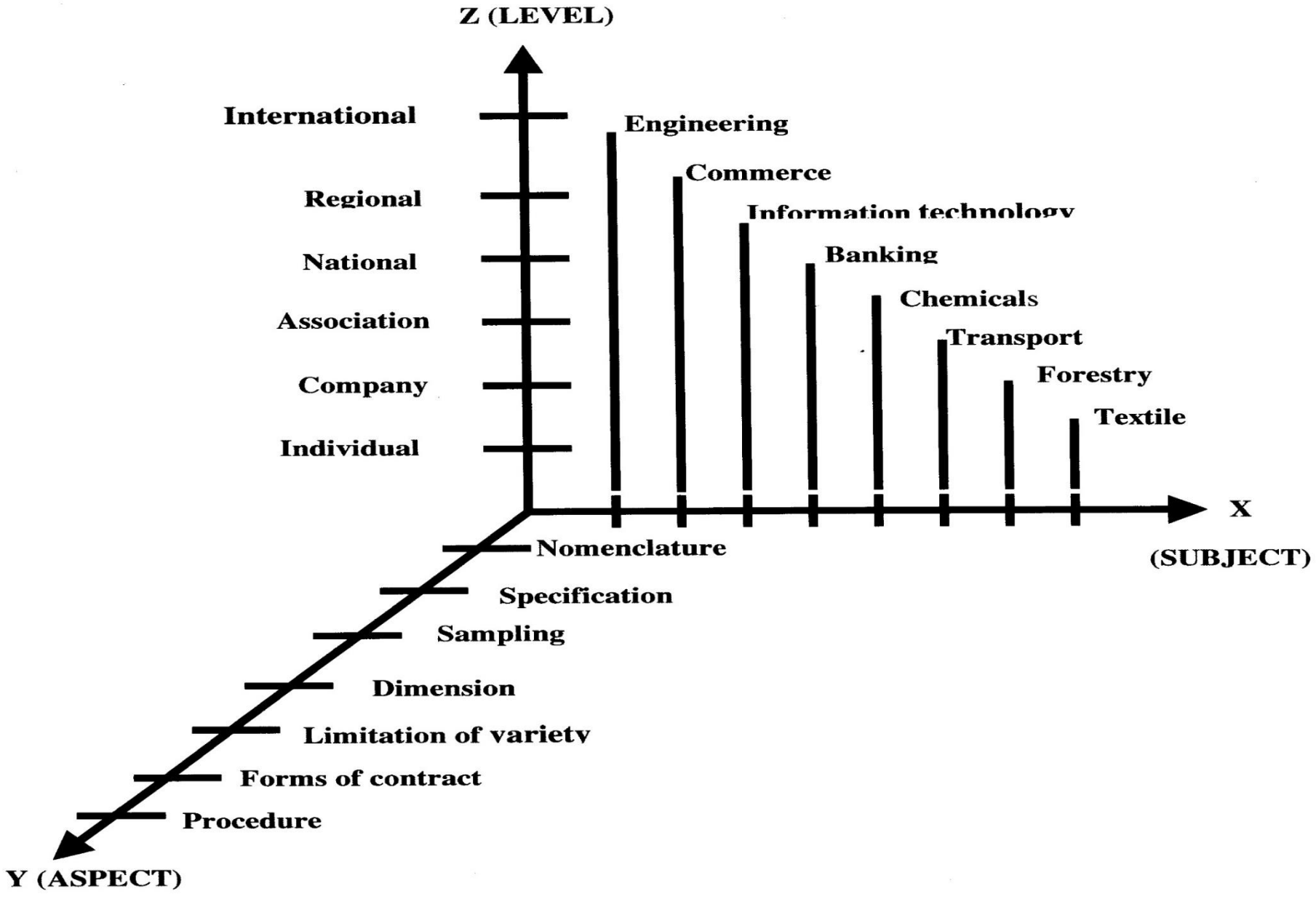

Points to note

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- Standards seek to address functionality, health & safety, and environmental aspects
- All products must meet the relevant Kenya Standard irrespective of:
  - Size of the company (large or SME)
  - Method of production (synthetic or natural)
  - Source of the product (locally manufactured or imported)
- For the product to be placed on the market or for sale to the public, the manufacturer/importer has to apply to KEBS for a Standardization Mark or CoC for imported products respectively
- It is the responsibility of the manufacturer/ importer to ensure the product functions and is safe

Catalogue of Kenya Standards

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- KEBS has an online catalogue of Kenya Standards which is accessible at https://www.kebs.org/ or URL http://onlinecatalogue.kebs.org

- The catalogue is searchable through several ways:
  - Keyword,
  - Standard number (all Kenya Standards are numbered),
  - Subject,
  - Advanced search.

Sale of Standards

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KEBS Webstore

- KEBS facilitates online sale of standards (through a Webstore) in response to customer demand for fast and convenient access to standards.
- The Webstore allows immediate delivery of standards in PDF format

- The Webstore is accessible from the KEBS Website at https://www.kebs.org or URL https://webstore.kebs.org

STANDARDS ON MEDICAL DEVICES

STANDARDS ON MEDICAL DEVICES

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- Standards on Medical Devices are developed/adopted through KEBS/TC 136 on Hospital devices, Tools and Equipment.
- So far, 195 international standards have been adopted, mainly ISO.
- KEBS is also actively involved in ARSO Technical Committees and is in the process of adopting the Regional Harmonized standards

STANDARDS ON MEDICAL DEVICES

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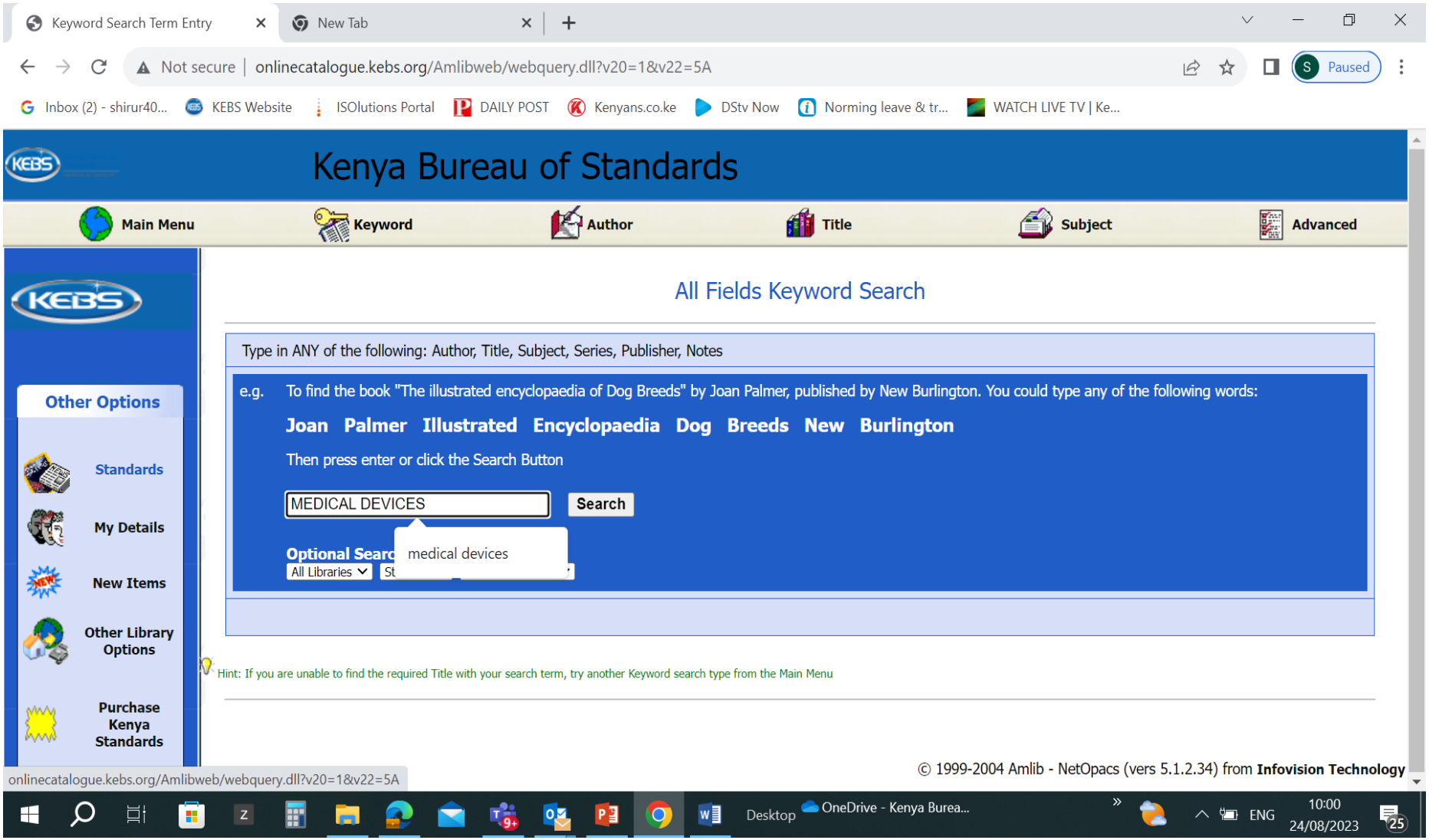

STANDARDS ON MEDICAL DEVICES

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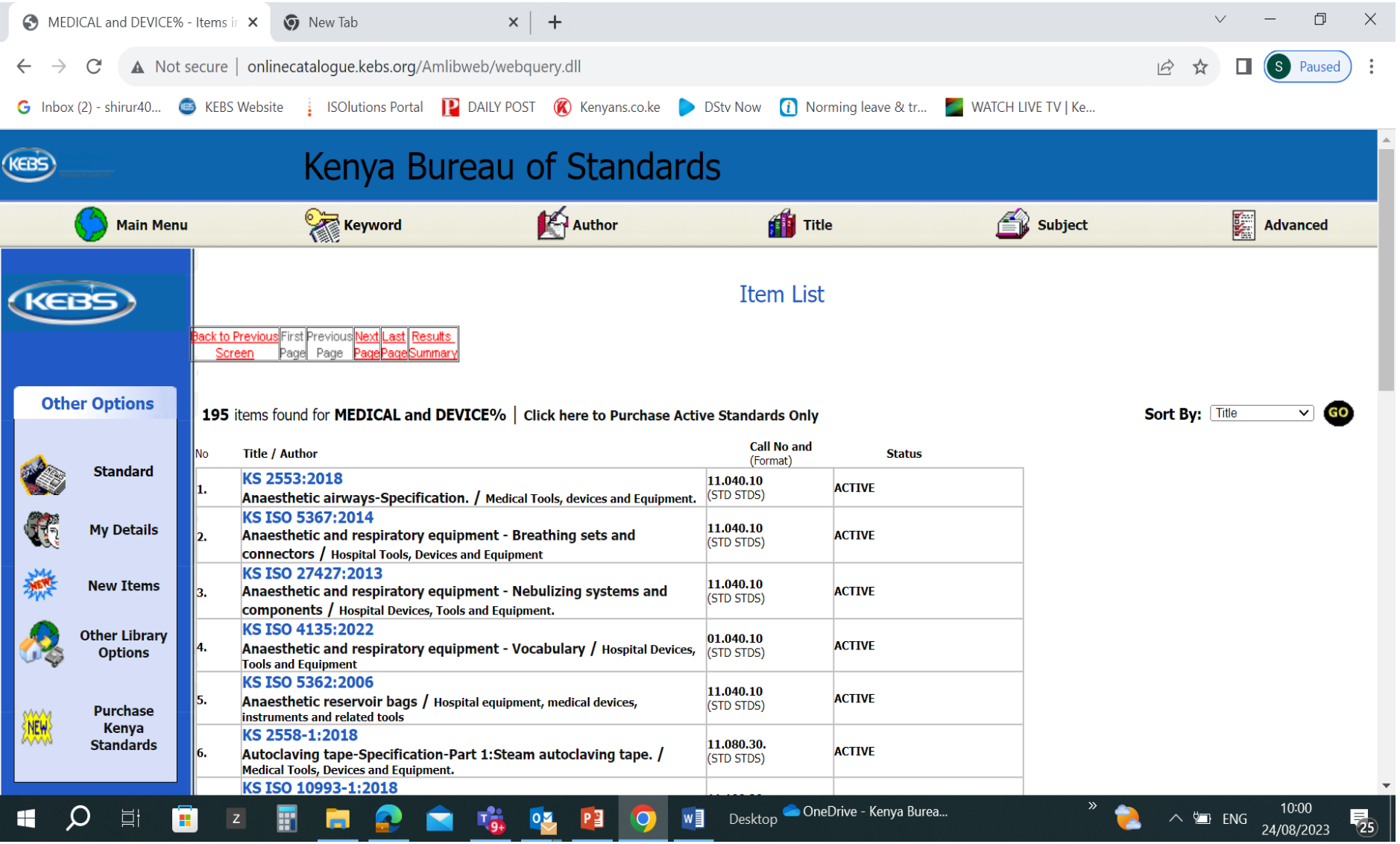

Regulation

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- Regulation of Medical Devices is done by the regulator, Pharmacy and Poisons Board in conjunction with KEBS (NSB)
- To improve the ease of doing business, the Government placed the responsibility of coordinating inspection of all imported products on KEBS
- KEBS plays a role in the importation process through the Pre –Export Verification of Conformity Program
- PPB and KEBS have developed Guidelines for Inspection of imported Medical Devices

Conformity Assessment

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Inspection

- To initiate importation of medical devices, the importer is required to apply for an import permit from PPB
- An importer shall apply and obtain a Unique Consignment Reference (UCR) number from Kenya Electronic Single Window System;
- The importer, through the exporter, shall then submit an inspection request to KEBS appointed inspection agent operating in the country of supply using the UCR as the reference for the consignment and pay requisite fees for the same.
- KEBS appointed inspection agent shall undertake inspection in the country of supply as provided for in the PVoC Manual and issue a CoC for products meeting the requirements of the relevant Kenya Standards or approved specification.

Conformity Assessment

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- Products not meeting the requirements of the relevant Kenya Standards or approved specifications shall be issued with a Non- Conformity Report (NCR) and shall not be eligible for exportation to Kenya.
- The Inspection agent shall provide CoC/NCR data to KEBS
- KEBS makes CoC data available to PPB through Kenya Electronic Single Window
- The importer shall produce the PPB import permit and CoC to PPB and KEBS for clearance of cargo at the port of entry

Conformity Assessment

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- During the inspection process, test reports are recognized for manufacturers who are certified to ISO 13485: 2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- Market Surveillance and monitoring is done by the Pharmacy and Poisons Board, given that the medical facilities where such equipment are placed are under their jurisdiction (hospitals)

THANK YOU

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