Kenya Bureau of Standards
Standards for quality life

APPENDIX DD
ADOPTION PROPOSAL FORM

CPR183/F12

Document Type:	**Adoption proposal**	
Dates:	Circulation date	Closing date
	16-01-2024	**16-02-2024**
TC Secretary	**This form shall be filled, signed and returned to Kenya Bureau of Standards for the attention of Micah Rachuonyo, rachuonyom@kebs.org**	

The Kenya Bureau of Standards intends to adopt the International Standards as detailed here below:

[1] Number: ISO 13008:2022

Title: Information and documentation — Digital records conversion and migration process

Scope
This standard specifies the planning issues, requirements and procedures for the conversion and/or migration of digital records in order to preserve the authenticity, reliability, integrity and usability of such records as evidence of business functions, processes, activities and transactions.

These procedures do not comprehensively cover:

— backup systems;

— preservation of digital records;

— functionality of trusted digital repositories;

— the process of converting analogue formats to digital formats and vice versa.

The adoption of this 2nd edition is intended to cancel and replace the 1st edition of 2012.

[2] Number: ISO 11798:

Title: Information and documentation — Permanence and durability of writing, printing and copying on paper — Requirements and test methods

Scope
This standard specifies requirements and test methods for evaluation of the permanence and durability of writing, printing and copying on paper stored in libraries, archives, and other protected environments for long periods of time, in which the information recorded on paper must be retained but not necessarily the full artistic quality.

It is applicable to:

— images on white permanent paper according to ISO 9706 or ISO 11108;

— recording obtained from pens, stamps, copying machines and printers (that can produce monocoloured and/or multicoloured images).

It does not apply to:

— documents stored under harmful conditions, such as high humidity that promotes microbiological attack, excessive heat, radiation (e.g. light), high levels of pollutants, or the risk of water damage (or water contact). Since documents might

be kept in non-protected environments before being transferred to protected environments, resistance to water and light is, however, of importance;

— legal documents, e.g. banking documents, where the authenticity is of primary interest;

— documents where the information contents are influenced by small colour changes;

— documents within the scope of ISO/TC 42, Photography.

This second edition cancels and replaces the first edition of 1999.

[3] Number: ISO 16245: 2023

Title: Information and documentation — Boxes, file covers and other enclosures, made from cellulosic materials, for storage of paper and parchment documents

Scope

This standard specifies requirements for boxes, file covers and other enclosures made of cellulosic material, to be used for long term storage of documents on paper or parchment. It is applicable to boxes made of solid or corrugated board and to file covers and other enclosures made of paper or board. The standard can also be applicable to other types of enclosures for long term storage such as cases, portfolios, tubes and envelopes made of cellulosic material. It however not applicable to storage of photographic materials.

This second edition cancels and replaces the first edition of 2009.

[4] Number: 13119:2022

Title: Health informatics — Clinical knowledge resources — Metadata

Scope

This standard specifies a number of metadata elements that describe resources containing medical knowledge, primarily digital documents provided as web resources, accessible from databases or via file transfer, but can be applicable also to paper documents, e.g. articles in the medical literature.

The metadata elements

— support unambiguous and international understanding of important aspects to describe a resource, e.g. purpose, issuer, intended audience, legal status and scientific background,

— are applicable to different kinds of digital resources, e.g. recommendation from consensus of a professional group, regulation by a governmental authority, clinical trial protocol from a pharmaceutical company, scientific manuscript from a research group, advice to patients with a specific disease, review article,

— are possible to present to human readers including health professionals as well as individuals/patients, and

— are potentially usable for automatic processing, e.g. to support search engines to restrict matches to documents of a certain type or quality level.

The metadata elements defined in this document are not intended to

— describe documents about a single patient, such as medical records,

— describe details of the medical content of the resource (but some idea of the content can be described via keywords or codes), or

— prescribe criteria for the quality of the resource content.

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[5] Number: ISO/TS 17975

Title: Health informatics — Principles and data requirements for consent in the collection, use or disclosure of personal health information

Scope

This standard defines the set of frameworks of consent for the collection, use and/or disclosure of personal information by healthcare practitioners or organizations that are frequently used to obtain agreement to process the personal health information of subjects of care. This is in order to provide an informational consent framework which can be specified and used by individual policy domains (e.g. healthcare organizations, regional health authorities, jurisdictions, countries) as an aid to the consistent management of information in the delivery of healthcare services and the communication of electronic health records across organizational and jurisdictional boundaries. This document is applicable to Personal Health Information (PHI).

[6] Number: ISO/TS 20440:2023

Title: Health informatics — Identification of medicinal products — Implementation guidelines for ISO 11239 data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

Scope

This standard describes data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging.

Based on the principles outlined in this document, harmonised controlled terminologies will be developed according to an agreed maintenance process, allowing users to consult the terminologies and locate the appropriate terms for the concepts that they wish to describe. Provisions to allow for the mapping of existing regional terminologies to the harmonised controlled terminologies will also be developed in order to facilitate the identification of the appropriate terms. The codes provided for the terms can then be used in the relevant fields in the Pharmaceutical product identification (PhPID), Physical Chemical Identifiers (PCID) and Medicinal Product Identifier (MPID) in order to identify those concepts.

This document is intended for use by:

— any organization that might be responsible for developing and maintaining such controlled vocabularies;

— any regional authorities or software vendors who want to use the controlled vocabularies in their own systems and need to understand how they are created;

— owners of databases who want to map their own terms to a standardized list of controlled vocabularies;

— other users who want to understand the hierarchy of the controlled vocabularies in order to help identify the most appropriate term to describe a particular concept.

[7] Number: ISO/TR 23358:2022

Title: Health informatics — A case study on establishing standardized measurement data in cardiac examination reports

Scope

This standard reposts a case study on how to establish and maintain standardized cardiac examination export measurement data (CE-EMD), especially for enabling its secondary use for medical research. The document includes information for CE-EMD on:

- Building a representative coalition of stakeholders to identify and establish specifications;

- Standardizing both the content and format in reports;
- Maintaining and extending the specifications over time.

Out-of-scope for this document are any requirements for specific CE-EMD content or formatting. Also, this document is limited to cardiac examination reporting, and does not encompass other clinical care areas or reporting that have been standardized.

[8] ISO/TR 11147:2023

Title: Health informatics – Personalized digital health – Digital therapeutics health software systems

Scope

This standard lists characteristics of a category of health software: digital therapeutics (DTx). DTx products generate and deliver medical interventions that are based on clinical evidence, have demonstrable positive therapeutic impacts on patient health, and produce real-world outcomes. Product use cases (see Annex B) demonstrate the variety of products represented in this quickly growing industry.

This standard provides an overview of how DTx relates to other ecosystem constructs, including medical devices, software as a medical device (SaMD), software in a medical device (SiMD), and other digital health technologies (DHT). It also addresses relevant health and medical device software standards that have various degrees of applicability to DTx.

The focus of this document is on therapeutic products that are used in the context of a disease, disorder, condition, or injury for human use. It does not address products that are intended for veterinary use or for general wellbeing. Additional exclusions of this document include DTx market access pathways (i.e. prescription, non-prescription pathways), medical device requirements, product risk assessment, clinical evidence requirements, data security, patient privacy considerations, and product authorization pathways.

[9] ISO/TS 17251:2023

Title: Health informatics — Business requirements for a syntax to exchange structured dose information for medicinal products

Scope

This standard specifies the business requirements for the structured content of structured or semi-structured dose instructions for recording dose instructions in the electronic health record (EHR), supporting clinical decision support, and in exchanging medication orders, as applicable to primary, secondary and tertiary care.

This standard is focused on the dose instructions as will be presented to the individual subject of care or caregiver. Comprehension of dose instructions by the subject of care or caregiver is an overarching consideration for subject of care safety and the best outcomes. Related factors are discussed but are not part of the primary scope.

The standard does not define an information model, except to the extent that those information model concepts are necessary to define business requirements.

Outside the scope of this document are:

- The implementation of dose instructions, i.e. assembling the structured elements into a form appropriate for the patient or caregiver;
- The content of a medication order beyond content related to dose instructions;
- The content of a record of dispense of a medicinal product;
- The functionality of health, clinical and/or pharmacy systems;
- Other kinds of content of health, clinical or pharmacy systems that are needed to support the whole process of health care providers, such as:
    - A drug knowledge database;
    - A decision support system;
    - A complete medical record (EHR);
    - A medicinal product dictionary;

- Verification of the medicinal product and dose being administered.
- — Some concepts from Identification of Medicinal Products are referenced, but not defined, in this document.

[10]ISO 22218-1:2023

Title: Health informatics — Ophthalmic examination device data — Part 1: General examination devices

Scope

This standard specifies the measurement data output formats for devices used in general ophthalmic examinations, including the following modalities:

- Refractometer (REF) – Refraction
- Keratometer (KM) – Corneal curvature
- Tonometer (TM) – Intraocular pressure
- Lensmeter (LM) – Spectacle lens power
- Phoroptor (PHOR) – Visual acuity

This standard only addresses text-based device reporting of ophthalmic examination device data (OEDD). Images generated as needed during an ophthalmic examination are outside the scope of this document.

[11]ISO 22218-2:2023

Title: Health informatics — Ophthalmic examination device data — Part 2: Specular microscope

Scope

This standard specifies the data output formats for the specular microscope. The data are usually sent from the specular microscope to either an ophthalmic information system (OIS) or a hospital information system (HIS).

This document addresses text-based analysis reporting of the specular microscope measured and analysed data such as the central corneal thickness, the density of endothelial cells per 1 mm^2, the coefficient variant, and the ratio of endothelial cells with a hexagonal shape.

[12]ISO/TS 21549-5:2023

Title: Health informatics — Patient healthcard data — Part 5: Identification data

Scope

This standard describes and defines the basic structure of the identification data objects held on healthcare data cards, but it does not specify particular data sets for storage on devices.

The standard does not apply to the detailed functions and mechanisms of the following services (although its structures can accommodate suitable data objects elsewhere specified):

- security functions and related services that are likely to be specified by users for data cards depending on their specific application, e.g. confidentiality protection, data integrity protection and authentication of persons and devices related to these functions;
- access control services;
- the initialization and issuing process (which begins the operating lifetime of an individual data card, and by which the data card is prepared for the data to be subsequently communicated to it according to this document).

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The standard does not cover:

- physical or logical solutions for the practical functioning of particular types of data card;
- the forms that data take for use outside the data card, or the way in which such data are visibly represented on the data card or elsewhere.

We are therefore seeking views from potential users in respect of the same. The Standard is available at the Kenya Bureau of Standards Information Centre. Please tick and fill your preference of the listed option. (If the spaces provided are not enough, please attach a separate sheet of paper).

☒ Adoption acceptable as presented

☐ Adoption proposal not acceptable because of the reason(s) below

Our Recommendations are as follows

Name of respondent:

Signature of respondent:

Position:

On behalf of

Date

NOTE: Absence of any reply or comments shall be deemed to be an acceptance of the proposal for adoption and **shall constitute an approval vote**.