

Electronic Health Records and Electronic Health Archives: An Archival Examination of the ISO Health Informatics Standards



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I. Motive

93 standards + 30 technical reports of health informatics
by the International Organization on Standardization (ISO)

facilitating “capture, interchange and use of health-related data,
information, and knowledge to support and enable all aspects of the
health system”

also address { electronic health record (EHR)
eArchiving process

- Q1: Do these standards reflect what is the focus of
the records field??
- Q2: Are there any concerns that are critical to the health
industry but overlooked by the records field?
- The similarities or differences between what is
shaped by these standards and what is theorized
and practiced in the records management field

II. Methods

2-step analysis

1st Stage Analysis

2nd Stage Analysis

Expected
Outcomes

Data
Selection

Most
Relevant

- ISO/TS 21547:2010 - Reviewed and Confirmed in 2017 Health informatics --
Security requirements for archiving of electronic health records -- Principles
- ISO/HL7 10781 - Electronic Health Record System Functional Model, Release 2
- ISO 15489-1:2016 Information and documentation -- Records management --
Part 1: Concepts and principles
- ISO 16175-3:2010 Information and documentation -- Principles and functional
requirements for records in electronic office environments -- Part 3: Guidelines
and functional requirements for records in business systems

- Integrated business
process
- Integrated system design
- Streamlined managerial
framework

III. Preliminary findings

Conceptual comparison

ISO 15489-1 record(s)
information created, received and maintained as
evidence and as an asset by **an organization or person**,
in pursuit of legal obligations or in the transaction of
business.

ISO/TS 21547 EHR
comprehensive, structured set of clinical, demographic,
environmental, social and financial **data and information**
in electronic form, documenting the healthcare given to a
single individual.

At the conceptual level, the definition of record(s) in
ISO 15489-1 covers the definition of EHR in ISO/TS
21547.

Major Functionality Comparison

Examples:
ISO 15489-1 **9.4** & ISO 16175-3 **3.1.4 Records classification**
ISO/TS 21547 **3.2.26 Secure classification**

ISO 16175-3 **3.4 Retaining** and disposing of records as required
ISO/TS 21547 10.4.1 The EHR-archive must preserve
information(...**retention time**...)

ISO 15489-1 **9.9 Disposition** & ISO 16175-3 **2.4.1 Disposing of
records**
ISO/TS 21547 **10.3.6 Deletion of the HER**

The core concerns about functionality are covered in all listed
standards.
However, ISO 15489-1 and ISO 16175-3 focuse on high-level
generalization, while ISO/TS 21547 and ISO/HL7 10781 is
specific to the business activities in health industry.

Conclusion

- In the field of record or archival science, standards, policies and regulations can be formulated more
specifically. Therefore they can align with the standards for records management in a specific
industry in a more relevant, effective and systematic way.
- The result of the 2nd stage analysis could facilitate system integration and professional cooperation.