

## Standards Category: Functional Standards

**Functional Standards** describe the requirements for a software application from the user perspectives as defined by a qualified group of users (domain experts/stakeholders). The Functional Requirement Analysis Document (FRAD) is the format for representing users' requirements in the Functional Standard.

### Functional Requirement Analysis Document (FRAD) Outline Components

(Source: Bruegge B and Dutoit AH. Object-Oriented Software Engineering)

Component	Definition
Application Title	Title given to a software application/information system for a Use Case
Introduction	Description of a health problem/domain to be addressed using the means of health information technology (HIT) application
	Overview and scope of the proposed information system, i.e. Realization Scenarios within the Use Case
	Goal of the proposed information system
	Objectives and success criteria of the project
Actors	Business Actors (people) involved
	Technical Actors (information systems) involved
System Requirements	Functional and interoperability requirements (see list below)
	Non-functional requirements
Use Cases and Systems Models	Use Case/Realization Scenario Description (workflow and data flow)
	Use Case/Realization Scenario Diagrams (UML* Diagrams)
	High-Level System Architecture with systems components within an organization and across organizations
Hardware and Software Requirements	Description of the hardware and software needed to support user needs for information capture, management, analysis, sharing and use
Testing / Evaluation Plan	Scenarios for testing HIT applications, and evaluation metrics to validate that the information system meets user needs. Includes test strategy, plan, scenarios, scripts and tools
Project Development Timeline and Documentation	Project management timeline with the specific documentation developed at each phase of the project, e.g., FRAD at the requirement elicitation phase, design document at the design phase, test report at the testing phase etc.

\*UML-Unified Modeling Language. URL: <http://www.uml.org/>

**Functional requirements for a software application/information system** are derived from the description of user's business activities (business requirements: workflow and data flow) to support the following five functions of the information system:

- **Collect/Input Data**, i.e., enter/upload/update data into the application/information system
- **Manage Data**, i.e., verify data, store data, dispose data
- **Analyze Data**, i.e., group data by similar attributes (location, condition, etc.)
- **Integrate Data**, i.e. send/receive data to/from information systems (data sources)
- **Generate Output**, i.e., display reports, summaries, alerts, notifications, etc.

### Resources

Orlova A. Health Information Technology Standards and Systems Interoperability Course. *Lecture 5: Functional Standards*. Johns Hopkins School of Public Health (JHSPH) OpenCourseware. Johns Hopkins University.

URL: <http://ocw.jhsph.edu/index.cfm/go/viewCourse/course/InfStandards/coursePage/index/>

Orlova A, Bourquard K, Charles P. Understanding User Needs for Interoperability: Standards for Use Cases in eHealth. JAHIMA. 2017. 88(9): 40-44. URL: <http://bok.ahima.org/doc?oid=302252#.WcAR9bKGO00>

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### ISO Technical Committee 215 Health Informatics (ISO/TC215)

Established in 1998, **International Organization for Standardization, Technical Committee 215, Health Informatics (ISO/TC215)** has over 70 member countries and liaison organizations representing millions of healthcare stakeholders worldwide. **The ISO/TC215 mission** is *standardization in the field of health informatics to facilitate the capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.*

The **US delegation** at ISO/TC215 is represented by the **Technical Advisory Group (ISO/TC215 USTAG)** – a committee accredited by American National Standards Institute – that develops US national positions on international standards. Since 2011 AHIMA provides Secretariat to ISO/TC215 and serves as Administrator to the USTAG at ISO/TC215.

**ISO/TC215** develops international standards for semantic (shared content), technical (shared infrastructure) and functional (shared rules) interoperability. ISO/TC215 product portfolio contains **over 200 standards** including those under development. Functional standards are part of functional interoperability standards portfolio.

### ISO/TC 215 Privacy and Security Standards Examples

(IS – International Standard, TS – Technical Specification, TR – Technical Report, PWI – Preliminary Work Item)

ISO Number	Title
ISO/TR 21089	Trusted end-to-end information flows
ISO/TR 22221	Good principles and practices for a clinical data warehouse
ISO/TS 29585	Deployment of a clinical data warehouse
ISO/IS 27789	Audit trails for electronic health records
ISO/IS 21091	Directory services for healthcare providers, subjects of care and other entities
ISO/TS 17975	Principles and data requirements for consent in the collection, use or disclosure of personal health information
IEC 80001	Application of risk management for IT-networks incorporating medical devices
ISO/HL7 16527	HL7 Personal health record system functional model, Release 1 (PHRS FM)
ISO/HL7 10781	HL7 Electronic health records-system functional model, Release 2 (EHR FM)
<b>Under Development</b>	
ISO/TR 19669	Re-usable component strategy for use case development
ISO/PWI 22689	Quality management requirements for patient registries

### Resources

ISO/TC215 Standards and Projects Catalog: <http://www.ahima.org/~media/AHIMA/Files/AHIMA-and-Our-Work/ISOTC215StandardsCatalog2017.ashx?la=en>

ISO/TC215 Website at ISO: <https://www.iso.org/committee/54960.html>

ISO/TC215 Website at AHIMA: <http://www.ahima.org/about/global?tabid=ISO>