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Health informatics — Re-usable component strategy for use case development

Informatique de santé — Stratégie de composants réutilisables pour le développement de cas pratiques

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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This document is based in part on ISO/TR 21089 and ISO/HL7 10781.

Introduction

Use cases are often utilized to establish key objectives and requirements for software design and development, system testing, certification and implementation. This document offers a methodology for use case development that discovers common components of use case scenarios, then establishes a component catalogue for subsequent re-use and re-purposing of those components in new use case scenarios. The methodology establishes re-use as a key foundation for consistent infrastructure and build-out of software application systems in healthcare (and potentially other industries). Re-use of requirements often leads to re-use of software solutions (to those requirements). The methodology leads to uniformity in, and optimization of, requirement specification, standards and implementation guidance, software development, testing and certification and ultimately implementation. The methodology establishes the basis for requirements traceability, at each progression step, and end-to-end (use case to implementation).

Health informatics — Re-usable component strategy for use case development

1 Scope

This document specifies a use case development methodology, facilitated by a dynamic catalogue of re-usable components. Use cases are a basic tool in describing requirements for health and healthcare settings, service provision, information technology and software products. Use case development often follows a uniform template with components such as actors, roles, scenarios, event steps, actions, data objects/elements and requirements statements. This document includes a basic use case template and the methods of component identification, capture, cataloguing and re-use. This document also includes guidance for software designed to implement the methodology in the form of a use case authoring tool.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
action
activity or task performed by an entity at a given point in time

Note 1 to entry: A use case event is comprised of one or more actions occurring in sequence.

Note 2 to entry: It can also be defined as an element of an event (step) that a user performs during a procedure (see ISO/IEC 26514).

3.2
actor
health professional, healthcare employee, patient/consumer, sponsored healthcare provider, healthcare organisation, subject of care, device, system or application that acts (performs a role) in a health related communication or service

[SOURCE: ISO 17090-1:2013, 3.1.3, modified]

3.3
assumption
condition that is accepted as true

Note 1 to entry: It can also be defined as factors that, for planning purposes, are considered to be true, real, or certain without proof or demonstration (see ISO/IEC/IEEE 24765) or a statement that describes the expected behaviours of a system or actors who will use the system (see Reference [20]).

3.4
data element
data concept represented by a specific value domain and that describes a single atomic property about an object class

[SOURCE: ISO 14817-1:2015, 4.17, modified - Note 1 to entry deleted]

3.5
data object
collection of data that has a natural grouping and may be identified as a complete entity

Note 1 to entry: It can also be defined as a collection (set) of logically related data elements, e.g. "patient vital signs typically comprise heart rate, respiration rate, temperature and blood pressure".

[SOURCE: ISO/TS 27790:2009, 3.20, modified - Note 1 to entry has been added]

3.6
electronic health record
repository of information regarding the health of a subject of care, in computer processable form

Note 1 to entry: It can also be defined as comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information in electronic form, documenting the health care given to a single individual (ASTM 1769) or information relevant to the wellness, health and healthcare of an individual, in computer-processable form and represented according to a standardized information model (ISO 18308).

[SOURCE: ISO 13606-2:2008, 4.7, modified - Note 1 to entry replaced]

3.7
event
performance of a specified set of functions or operations

Note 1 to entry: It can also be defined as a health care interaction that involves a patient and that may be delivered by a health care provider or be provided as a service[21].

[SOURCE: ISO/IEC 23006-2:2016, 3.1.6, modified - Note 1 to entry has been added]

3.8
entity
legal (e.g. a corporation, labour union, state or nation) or natural person or system (e.g. device, software)

[SOURCE: ISO 15782-1:2009, 3.35, modified - text has been added to the definition and the example has been deleted]

3.9
health/care
health and/or healthcare

EXAMPLE Health/care providers support individual health and provide healthcare services.

3.10
initiative
collaboration of business/clinical experts to develop one or more use cases

3.11
pre-condition
condition which must be true prior to undertaking use case action(s)

3.12
post-condition
condition which must be true after undertaking use case action(s)

3.13
requirement
requirement statement
declaration of necessary condition(s)

Note 1 to entry: "specified requirement" is a need or expectation that is stated (*requirements are intended to define some feature of a real implementation and offer the possibility of testing)* (see ISO/IEC 17007:2009, 3.4).

3.14
re-usable component
element of the use case description that can be excerpted, labelled, catalogued and retained (in a persistent file) for selection and inclusion in a future use case or scenario

3.15
scenario
sequence of event (steps) necessary to complete a business/clinical process

Note 1 to entry: It can also be defined as a description of high level business activities defining process and requirements (see ISO/IEC 19501:2005).

3.16
subject of care
one or more persons scheduled to receive, receiving, or having received a health service

Note 1 to entry: It can also be defined as any person who uses, or is a potential user of, a health care service (see ISO/TS 22220:2011).

[SOURCE: ISO 18308:2011, 3.47, modified - definition has been amended and Note 1 to entry added]

3.17
use case
set of scenarios which address a particular business/clinical domain or topic

Note 1 to entry: It can also be defined as a specification of interactions between external actors and the system to attain particular goals (technopedia.com) or methodology used in system analysis to identify, clarify, and organize system requirements (whatis.com).

3.18
user story
simple narrative illustrating the user goals that a software function will satisfy

[SOURCE: ISO/IEC/IEEE 26515:2011, 4.16]

4 Symbols and abbreviated terms

EHR	electronic health record
EHR-S	electronic health record system
HIT	health information technology
SKMT	ISO TC215 Standards Knowledge Management Tool
SME	subject matter expert
UCR	use case requirements
UCA	use case analyst
UCAT	use case authoring tool

5 Objectives for the re-usable component strategy

The re-usable component strategy (for use case development) is based on the following objectives.

a) To formalize a process of identifying and cataloguing common use case components and patterns of re-use from developing use cases.

b) To save new resource investment by allowing business requirements analysts to quickly identify and re-use catalogued use case components already specified or to add new ones, when appropriate.

c) To formalize a process of identifying and cataloguing implementable software modules and data objects, either commercial or open source, which implement various aspects of required use case-identified software functionality, data/record management and exchange.

d) To save new resource investment by allowing software developers to readily identify and re-use catalogued software modules and data objects in their solutions.

e) To facilitate and promote uniformity in requirement specification, standards and implementation guidance.

f) To lay the foundation for uniform and consistent information infrastructure and build-out.

g) To ensure requirements traceability step-by-step and end-to-end (use case to implementation).

6 Use case basics

6.1 General

In healthcare, use cases typically describe scenarios involving patient flows (with the patient as an actor), provider/work flows (with provider(s) as actor(s)) and information flows [with systems or devices as actor(s)]. Use cases resolve to actors taking actions in sequence, as a progression of steps. EHR (or other) systems capture record entries resulting from actions taken, as persistent evidence of their occurrence.

6.2 Use case scenarios, events and actions

A use case has (is specified in terms of) one or more scenarios. Each scenario has (is specified in terms of) one or more events (in step-wise sequence) to support individual health and to provide healthcare. Each event/event step has (is specified in terms of) one or more actions (in step-wise sequence).

6.3 Use case actors

Use cases have business and clinical actors, as individuals or organizations acting in roles (e.g. performer, assistant, observer, author, scribe, attester). Use cases have technical actors, as systems and devices, also acting in roles (e.g. originator, sender or receiver).

7 Use case component candidates

7.1 General

Use case components are a vital part of a typical use case narrative, but don't necessarily include all elements (e.g. all sections of the use case requirements template). As specified in this document, use case components candidates have four distinctions, in arbitrary order: 1) identify-ability, 2) catalogue-ability, 3) commonality and potential for re-use, 4) computability.

7.2 Identify-ability

The use case component is consistently evident (identifiable) in the use case scenario or narrative. (Clause 10).

7.3 Catalogue-ability

The use case component is readily captured and retained as entry in a catalogue or registry, allowing it to be queried and selected then re-used or re-purposed in subsequent use cases.

7.4 Commonality

The use case component is evident in existing use case scenarios and has a significant potential for re-use in new or revised scenarios. Note that re-use often extends to the solution and thus, once a requirement has a designated software or dataset solution re-selecting that same component in a new use case or scenario offers potential for re-use of the same solution.

7.5 Computability

The use case component has characteristics which may be computable and thus may be implemented as standard software modules and/or data constructs.

8 Use case components

8.1 General

Based on distinctions identified in Clause 7 and review of the use case template in Clause 10, four basic categories of use case components are evident: 1) requirements, 2) actors and roles, 3) scenarios, events and actions, 4) data objects and elements.

8.2 Requirements

Use case requirements are statements of necessary conditions, which must be determined “true” to satisfy fulfilment. Use case requirements may be offered as proof statements and/or conformance criteria. (See examples in Tables 6 and 7.)

a) Requirements state necessary conditions which occur before, during and/or after each use case scenario.

b) Requirements may take the form of assumptions (10.5), pre-conditions (10.6), post conditions (10.7) or system functional requirements (10.13.3).

c) Requirements may be applicable (and accountable) to particular actors, at specific event steps or actions.

d) As a result, discrete requirements may be fulfilled by, and are thus traceable to, particular use case actors and actions.

e) Requirements are typically stated as SHALL (required), SHOULD (preferred) or MAY (optional).

f) Common requirements statements are catalogued as *re-usable components*.

8.3 Actors and roles

In the use case requirements template (Clause 10), use case actors are enumerated (10.8) and shown taking/performing actions in scenario events (10.10). (See examples in Table 8.)

a) Actors are individuals or organizations whose actions are often facilitated by EHR or other system software.

b) Actors (in roles) perform (and are typically accountable for) use case actions.

c) In separate actions, an actor may play a different role.

d) Actors may fulfil established requirements by performing specific actions (showing requirements traceability).

e) Common actors and roles are catalogued as *re-usable components.*

8.4 Scenarios, events and actions

In the use case requirements template, use case scenarios, events and actions are specified in 10.10. (See examples in Tables 10 and 11.)

a) Scenarios are comprised of discrete event steps in a typical sequence.

b) Scenarios have a base flow and may have one or more alternate flows.

c) Event steps are broken into discrete action(s) taken.

d) Actions are taken/performed by actor(s) in role(s).

e) Actors and actions may invoke EHR or other system functions.

f) Actions may be auditable at each occurrence.

g) Actions may be attestable (with signature).

h) Events and actions have discrete data inputs and outputs.

i) Inputs and outputs may be specified in terms of required data objects and elements (8.5).

j) Common actions are catalogued as *re-usable components.*

8.5 Data objects and elements

In the use case requirements template (Clause 10), data requirements are specified in 10.15. (See examples in Table 11.)

a) Data requirements resolve to data objects and elements essential to undertake events and actions in use case scenarios.

b) Data requirements typically include data objects and elements specified as, data/record inputs to and/or outputs from, use case events and actions.

c) Common data objects and elements are catalogued as *re-usable components.*

