Abstract
This document describes a list of requirements that should be respected during the definition of CDA R2 Templates [7] using the HL7 Templates Standard DSTU R1 [5]. This document represents a complete interpretation of IHE Europe / gazelle team of the standard; any improvements or remarks may be followed to the writer of the document Abderrazek Boufahja [abderrazek.boufahja@ihe-europe.net] or to the technical manager of IHE Europe [eric.poiseau@ihe-europe.net].

Keywords: HL7 CDA R2, H7 Templates Standard

Introduction
This document describes the CDA requirements which should be respected by CDA specifications during the writing of the CDA specification into the HL7 Templates standard structure [5]. This specification can be interpreted as a kind of restriction of the HL7 Templates Standard when used to define CDA templates. IHE Gazelle team use this specification to verify the conformity of the HL7 Template DTSU exchange format (ie the XML produced), in order to use it for import of requirements from the exchange format to Gazelle ObjectsChecker validation tool [7] [8]. The validation of the HL7 Templates exchange format is a prerequisite for the import.

The requirements described allows to verify that the HL7 Templates exchange format contains valid information regarding the CDA model, and these requirements were listed during the development of the import from HL7 Templates exchange format to Gazelle ObjectsChecker. Some of the requirements are directly related to the CDA model (ie the CDA schema), some other requirements comes from the CDA normative description of the standard.

December 24, 2015
1. Errors Level

- Fatal Error : The error may be related to a problem on the specification, the specification is not conform at all to CDA standard, this may disturb the export from HL7 Templates to Gazelle ObjectsChecker

- Error : There are a problem in the specification or the description into the HL7 Templates format, however this may not disturb the export from HL7 Templates to Gazelle ObjectsChecker

- Warning : There are a problem which may be acceptable if well described ad analysed in the specification

2. HL7 Templates Standard DSTU R1 Requirements

The requirements are regrouped by elements type coming from HL7 Templates Standard.

2.1. TemplateDefinition requirements

- CDATEMP-001 : When a template contains context with path='/', and the template describe a CDA template, it shall be a ClinicalDocument template

2.2. RuleDefinition requirements

- CDATEMP-002 : An element SHALL have be distinguishable

- CDATEMP-003 : An element SHALL be from CDA model

- CDATEMP-005 : The maximum multiplicity SHALL be lower or equals to the maximum multiplicity from the CDA model

- CDATEMP-006 : isMandatory element SHALL not be set to false when it is equal to true from the CDA model

- CDATEMP-007 : When a datatype is specified it shall be from CDA datatypes

- CDATEMP-008 : When a datatype is specified it shall be equal or an extension of the original element datatype
- CDATEMP-036: When `act/statusCode/@code` has a value, it SHALL be from the valueSet `ActStatus`.

- CDATEMP-037: When `encounter/statusCode/@code` has a value, it SHALL be from the valueSet `ActStatus`.

- CDATEMP-038: When `observation/statusCode/@code` has a value, it SHALL be from the valueSet `ActStatus`.

- CDATEMP-039: When `procedure/statusCode/@code` has a value, it SHALL be from the valueSet `ActStatus`.

- CDATEMP-040: When `substanceAdministration/statusCode/@code` has a value, it SHALL be from the valueSet `ActStatus`.

- CDATEMP-041: When `supply/statusCode/@code` has a value, it SHALL be from the valueSet `ActStatus`.

- CDATEMP-042: When `consent/statusCode/@code` has a value, it SHALL be from the valueSet `ActStatus`.

- CDATEMP-043: When `authenticator/signatureCode/@code` has a value, it SHALL be from the valueSet `ParticipationSignature`.

- CDATEMP-044: When `legalAuthenticator/signatureCode/@code` has a value, it SHALL be from the valueSet `ParticipationSignature`.

- CDATEMP-045: When `OrganizationPartOf/statusCode/@code` has a value, it SHALL be from the valueSet `RoleStatus`.

- CDATEMP-046: In `observation/value`, CS datatype SHALL NOT be used as datatype.

- CDATEMP-047: When `observation/interpretationCode/@code` has a value, it SHALL be from the valueSet `ObservationInterpretation`.

- CDATEMP-048: The code of `RegionOfInterest` if present SHALL be from the valueSet `ROIOverlayShape`.

- CDATEMP-049: In `observationRange/value`, CS datatype SHALL NOT be used as datatype.
• CDATEMP-050: When observationRange/interpretationCode/@code has a value, it SHALL be from the valueSet ObservationInterpretation

• CDATEMP-051: In criterion/value, CS datatype SHALL NOT be used as datatype

• CDATEMP-052: consent.statusCode SHALL have the value ‘completed’ (or nothing)

• CDATEMP-055: whe PN/@qualifier has specific values, they SHALL NOT include LS as value

2.3. Attribute requirements
• CDATEMP-009: When an attribute is specified, it SHALL be from CDA attributes model for the parent CDA element

• CDATEMP-010: When the datatype of an attribute is set cs, the max attribute SHALL be *

• CDATEMP-011: When vocabulary is specified, the constrained attribute SHOULD not be a boolean

• CDATEMP-012: If isOptional attribute is specified with the value true, the original CDA attribute SHALL not be mandatory

• CDATEMP-013: If isOptional attribute is specified with the value false, and the original CDA attribute have a default value, the <attribute> element SHOULD have a value different than the default one

• CDATEMP-014: When datatype is specified for <attribute> element, it SHALL be a valid CDA datatype

• CDATEMP-015: When datatype is specified for <attribute> element, it SHALL be specified from a supported by the CDA attribute

• CDATEMP-016: if isProhibited is specified to true, then the original CDA attribute SHALL NOT be a mandatory element

• CDATEMP-017: When a value is specified in <attribute>, it SHALL reference a valid value for the current attribute’s name
• CDATEMP-018: When a name is specified in `<attribute>`, the parent element SHALL reference to the CDA element that contains the referenced name as an attribute

• CDATEMP-053: NP value of nullFlavor is not used for nullFlavor attribute

2.4. Vocabulary requirements
• CDATEMP-019: When a valueset is specified, and the referenced attribute is an enumeration, the content of the valueset SHALL be a restriction of the referenced attribute

• CDATEMP-020: When a valueset is specified, and the referenced attribute is an enumeration, the content of the @code SHALL be from the accepted enumeration values

2.5. Text requirements
• CDATEMP-021: When `<Text>` is specified, the `<element>` SHALL reference a CDA mixed element (i.e. can contain text)

2.6. Property requirements
• CDATEMP-022: In `<property>`, unit SHALL be from UCUM value set

• CDATEMP-023: In `<property>`, currency SHALL be from ISO 4217 [9]

• CDATEMP-024: When a `<property>` is declared, if it is for unit declaration, the parent element SHALL have a 'unit' attribute

• CDATEMP-025: When a `<property>` is declared, if it is for a monetary declaration, the parent element SHALL have 'currency' attribute

• CDATEMP-026: When a `<property>` is declared, if it is for a string length declaration, the parent element SHALL describe a string (like ST datatype)

• CDATEMP-027: When a `<property>` is declared, if it is for a value declaration, the parent element SHALL have a 'value' attribute
2.7. IncludeDefinition requirements

- **CDATEMP-028**: When `<Include>` used, its minimumMultiplicity SHALL be bigger or equals to the minimum multiplicity from the CDA model for all the included elements

- **CDATEMP-029**: When `<Include>` used, its maximum multiplicity SHALL be lower or equals to the minimum multiplicity from the CDA model for all the included elements

- **CDATEMP-030**: When `<Include>` used, isMandatory element SHALL not be set to false when it is equal to true from the CDA model for all the included elements

2.8. ChoiceDefinition requirements

- **CDATEMP-031**: When `<choice>` is specified and there are the same choice in CDA model, its maximumMultiplicity SHALL not be bigger than the default one from CDA model

- **CDATEMP-032**: When `<choice>` is specified and there are the same choice in CDA model, its minimumMultiplicity SHALL not be lower than the default one from CDA model

- **CDATEMP-033**: When `<choice>` is specified, it shall contain valid `<element>` from CDA model

- **CDATEMP-034**: When `<choice>` contains `<include>` element, the `<element>` elements of include SHALL be valid regarding the CDA model

2.9. ValueSet exception requirements

- **CDATEMP-035**: `<exception>` SHALL contains codes coming from NullFlavor enumeration

- **CDATEMP-054**: NP value of nullFlavor is not used for exception of value sets
3. Requirements Properties

Here for each requirement we describe the criticity and the domain from where the requirement was derived:

- CDA Model Specification: the requirement is related directly to the CDA model (ie the CDA schema)

The Keywords used in this table are like this:

- ID: the identifier of the requirement
- FE: Fatal error
- ER: Error
- WA: Warning
- CM: requirement related to CDA Model description
- CN: requirement related to a CDA normative requirement
- CR: the related CDA normative requirement

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