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Implementation Guide for CDA Release 2: Imaging Integration

Levels 1, 2, and 3

Basic Imaging Reports in CDA and DICOM Diagnostic Imaging Reports (DIR) – Universal Realm

Based on HL7 CDA Release 2.0

Release 1.0

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1 INTRODUCTION

1.1 Purpose

The purpose of this Implementation Guide (IG) is to describe constraints on the CDA Header and Body elements for Diagnostic Imaging Reports. A Diagnostic Imaging Report contains a consulting specialist's interpretation of image data. It is intended to convey the interpretation to the referring (ordering) physician and become part of the patient's medical record. It is intended for use in Radiology, Endoscopy, Cardiology, and other imaging specialties.

1.2 Audience

The audience for this document is software developers and consultants responsible for implementation of Radiology Information Systems, Radiology Reporting Systems, Picture Archiving and Communications Systems (PACS), other image and imaging management systems, and dictation/transcription and document management systems. A secondary audience is developers of specifications for health information networks, both governmental and non-governmental, who may specify use of this Implementation Guide for Diagnostic Imaging Reports. These systems are expected to transmit results of Electronic Health Record (EHR) systems or health information exchange networks as CDA documents created according to this IG.

1.3 Approach

The approach taken in the development of this IG was to review existing relevant Digital Imaging and Communications in Medicine (DICOM) standards and Integrating the Healthcare Enterprise (IHE) Implementation Profiles and to review CDA Header and Body elements and attributes with domain experts and, on that basis, constrain the CDA Header and Body elements.

Most of the constraints in this IG have been inherited from the DICOM Supplement 135: "SR Diagnostic Imaging Report Transformation Guide". This document, to be referred to in this IG as the *Transformation Guide*, has been made available for official comment within the DICOM Standards Development Organization. It is distributed with this specification for reference so that both documents will continue to receive the required review and so that changes will be harmonized across both specifications. A Diagnostic Imaging CDA report may contain more content than is present in DICOM, and only content that is specified in the *Transformation Guide* will be backwards-compatible.

1.4 Use of Templates

Templates are collections of constraints that specify and validate agreed-to requirements for exchange. Collecting individual constraints and assigning a unique template identifier (`templateId`) to the collection establishes a shorthand mechanism for the instance creator to assert conformance to those constraints. The template

identifier itself carries no semantics. Validation errors against a template must not be construed as anything other than failure to meet the exact requirements of the template, and absence of a template identifier need not be construed as failure to meet the constraints required by the template.

1.4.1 Originator Responsibilities: General Case

An originator can apply a `templateId` if there is a desire to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a `templateId` for every template that an object in an instance document conforms to. The IG shall assert whenever `templateIds` are required for conformance.

1.4.2 Recipient Responsibilities: General Case

A recipient may reject an instance that does not contain a particular `templateId` (e.g., a recipient looking to only receive CCD documents can reject an instance without the appropriate `templateId`).

A recipient may process objects in an instance document that do not contain a `templateId` (e.g., a recipient can process entries that contain `substanceAdministration` acts within a Medications section, even if the entries do not have `templateId`s).

If an object does not have a `templateId`, a recipient shall not report a conformance error about a failure to conform to a particular template on classes that do not claim conformance to that template and that are not required to be conformant by other templates.

1.5 Conventions Used in This Guide

This IG is a conformance profile, as described in the Refinement and Localization section of the HL7 Version 3 standards. The base standard for this IG is the HL7 Clinical Document Architecture, Release 2.0. As defined in that document, this IG is both an annotation profile and a localization profile. Every aspect of CDA R2 may not be described in this IG.

The mapping profile for SR to CDA is based on DICOM Template 2000 Basic Diagnostic Imaging Report, NEMA PS3.16-2008.

1.5.1 Explanatory Statements

As an annotation profile, portions of this IG summarize or explain the base standard; therefore, not all requirements stated here are original to this IG. Some, like the requirement for `typeId`, originate in the base specification. Those requirements that do not add further constraints to the base standard and that can be validated through CDA.xsd do not have corresponding conformance statements. (See, for example, Section 2.10 ClinicalDocument/confidentialityCode.)

1.5.2 Keywords

The keywords **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT**, **MAY**, and **NEED NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide. Keywords are used only in the context of formal conformance requirements.

1.5.3 Conformance Requirements

Conformance requirements within this IG are labeled as `CONF-DIR-nn`, where `DIR` represents Digital Imaging Report, and appear in the format illustrated below:

CONF-DIR-1 Here's an example of a conformance requirement for conformance to Level 1 requirements.

CONF-DIR-2 Here's another conformance statement. It might say that something **SHALL** include some specifically referenced thing using a keyword conformance verb.

1.5.4 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this document uses XPath notation in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. The purpose of using this notation is to provide a mechanism that will be familiar to developers for identifying parts of an XML document.

1.5.5 XML Examples

XML examples appear in various figures in this document in `this fixed-width style`. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (…) as shown in the example below.

Figure XX-1: ClinicalDocument example

```
<ClinicalDocument xmins='urn:h17-org:v3'>
  ...
</ClinicalDocument>
```

Within the narrative, XML element and attribute names will appear in `this fixed-width style`.

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

1.5.6 Constrained CDA RMIM and DICOM CMET Illustrations

Constrained RMIM and DICOM SR CMET figures are used throughout this document for illustrative purposes only. These illustrations do not represent the actual normative constraints of this specification. In particular, the names of the many of the classes in the diagrams do not match the element names available in CDA. Please refer to

"Supplement 135: SR Diagnostic Imaging Report Transformation Guide", for a complete description of the reasons behind the class/element name mapping.

1.5.7 DICOM Samples

DICOM Samples appear in the table format used in the DICOM Standard, listing each DICOM Attribute as a single line with columns denoting the Attribute Tag, Name, Value Representation, and usage description.

DICOM Images referenced in the samples may be presented here in DICOM tabular form followed by a rendering of the pixel data into the publishing format of this document. The DICOM binary-encoded form is included in the ballot package.

1.5.8 Content of the Implementation Guide Package

The Implementation Guide package contains the files listed in Table 1: Content of the Implementation Guide Package.

Table 1: Content of the Implementation Guide Package

Filename	Description
CDA IG Diagnostic Imaging Report.doc	This Implementation Guide
DIR.xml	Sample CDA XML instance conforming to this Implementation Guide
CDA-DIR.xsl	Display stylesheet for HTML

The CDA DIR RMIM (POCD_RM000040_constrained_pc.vsd) is currently used for illustration of the domain, and does not represent the actual constraints of this IG. The files listed in Table 2 are included with this package for reference.

Table 2: The DICOM SR Transformation Guide and Supplementary Material

Filename	Description
Supplement135_pc.doc	Supplement 135 Version 4 updated *Transformation Guide* for public comment..
EnhancedSR.dcm	Enhanced SR X-Ray Report Sample Document
POCD_RM000040_constrained_pc.vsd	Constrained Refined Message Information Model (RMIM) for CDA Diagnostic Imaging Reports. Only applies to transformed DICOM SR documents, not to documents originally authored in CDA

In addition, the image files referenced in the *Transformation Guide* are available online:

Table 3: External Image Samples from the DICOM SR Transformation Guide

Filename	Description	URL
SampleChestXR_PA.dcm	XR Posterior-Anterior Chest-Xray	http://www.hl7.org/Library/Committees/structure/SampleChestXR%5FPA%2Ezip
SampleChestXR_Lat.dcm	XR Lateral Chest-Xray	http://www.hl7.org/Library/Committees/structure/SampleChestXR%5FLat%2Ezip

1.6 Scope

This specification defines constraints on CDA Header and Body elements used in a Diagnostic Imaging Report document in the universal realm, and provides examples of conforming fragments in the Body of the document. An example of a conforming XML instance is provided as a separate XML instance: DIR.xml.

1.6.1 Levels of Constraint

This IG specifies three levels of conformance requirements:

- Level 1 requirements specify constraints upon the CDA Header and the clinical (nonstructured) content of the document.
- Level 2 requirements specify constraints upon the sections within the `structuredBody` of the `ClinicalDocument` element of the CDA document.
- Level 3 requirements describe a limited set of structured entries for the purpose of referencing and annotating images from within the report.

This specification is intended for global use (universal realm). The specification of workflows, messages, or procedures used in performing imaging procedures is outside the scope of this specification.

CDA provides a mechanism to reference a template or implementation guide that has been assigned a unique identifier. The following example shows how to formally assert the use of this IG. Use of the `templateId` indicates that the CDA instance not only conforms to the CDA specification, but also conforms to the constraints specified in this IG.

Figure 1: Use of the templateId element to indicate use of this guide

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:voc="urn:hl7-org:v3/voc"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
 <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
 <templateId root="2.16.840.1.113883.10.20.6"/>
  :
</ClinicalDocument>
```

Within this IG, the required and optional content within the Body is identified. This IG describes the informational content of each section, but the information in the CDA narrative block cannot be verified by software.

1.6.2 Future Work

If desired for implementation, a CDA XML Schema and/or a Schematron schema constrained to the elements allowed in this IG may be developed. Either schema would be informative, and implementers would be cautioned that not all constraints in this IG are represented.

Further work may include incorporation of templates for expressing and validating the clinical content requirements of specific diagnostic report types. This work will be done in conjunction with DICOM.

2 CDA HEADER CONSTRAINTS

2.1 Rendering Header Information for Human Presentation

Metadata carried in the Header may already be available for rendering from EHRs or other sources external to the document; therefore, there is no strict requirement to render directly from the document. An example of this would be a doctor using an EHR that already contains the patient's name, date of birth, current address, and phone number. When a CDA document is rendered within that EHR, those pieces of information may not need to be displayed since they are already known and displayed within the EHR's user interface.

Good practice recommends that the following be present whenever the document is viewed:

- Document title and document date
- Document version, if present
- Service and encounter types, and date ranges as appropriate
- All persons named along with their roles and participations. This includes, but is not limited to:
  - Author
  - Legal Authenticator
  - Physician Reading Study
  - Physician of Record
- The custodian of the document
- Selected organizations named along with roles and participations
- `recordTarget` (patient) name, identifier, and date of birth

2.2 ClinicalDocument

The namespace for CDA R2 is `urn:hl7-org:v3`. The appropriate namespace must be used in the XML instance of the Clinical Document. In the examples in this specification, all elements are shown unprefixed, assuming that the default namespace is declared to be `urn:hl7-org:v3`. This specification does not require use of any specific namespace prefix. Instances should not include the `xsi:schemaLocation`[1] element.

CONF-DIR-1: The root of a Diagnostic Imaging Report **SHALL** be a `ClinicalDocument` element from the `urn:hl7-org:v3` namespace.

[1] The `xsi:schemaLocation` element is not recommended by the XML ITS because of security risks. Receivers who choose to perform validation should use a locally cached schema.

2.3 Name, Address, Telephone Number, and Time Constraints

To support communication between the receiver of the document and the patient or any other person or organization mentioned within it, the elements representing them will be named. The following constraints are necessary to the wholeness of the document, which may cross organizational and realm boundaries.

CONF-DIR-2: All `patient`, `guardianPerson`, `assignedPerson`, `maintainingPerson`, `relatedPerson`, `intendedRecipient/informationRecipient`, `associatedPerson`, and `relatedSubject/subject` elements **SHALL** have a name.

CONF-DIR-3: All `patientRole`, `assignedAuthor`, `assignedEntity`[not(`parent::dataEnterer`)], and `associatedEntity` elements **SHALL** have an `addr` and `telecom` element.

CONF-DIR-4: All `guardian`, `dataEnterer/assignedEntity`, `relatedEntity`, `intendedRecipient`, `relatedSubject`, and `participantRole` elements **SHOULD** have an `addr` and `telecom` element.

CONF-DIR-5: All `guardianOrganization`, `providerOrganization`, `wholeOrganization`, `representedOrganization`, `representedCustodianOrganization`, `receivedOrganization`, `scopingOrganization`, and `serviceProviderOrganization` elements **SHALL** have `name`, `addr`, and `telecom` elements and **SHOULD** have `Id` elements.

When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance, if the information is unknown, these elements will be represented using an appropriate value for the `nullFlavor` attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary.

Figure 2: Various uses of nullFlavor

```
<assignedEntity>
  <id extension='3' root='2.16.840.1.113883.19'/>
  <addr nullFlavor='UNK'/>
  <telecom nullFlavor='ASKU' use='WP'/>
  <assignedPerson>
    <name nullFlavor='NAV'/>
  </assignedPerson>
</assignedEntity>
```

Events occurring at a single point in time that are represented in the Clinical Document Header will in general be precise to the day. These point-in-time events are the time of creation of the document; the starting time of a participation by an author, data enterer, authenticator, or legal authenticator; or the starting and ending time of an encounter.

CONF-DIR-6: Times or time intervals found in the `ClinicalDocument/effectiveTime`, `author/time`, `dataEnterer/time`, `legalAuthenticator/time`, `authenticator/time`, `encompassingEncounter/effectiveTime`, and `documentationOf/effectiveTime` elements **SHALL** be precise to the day, **SHALL** include an offset from UTC if the time

is more precise than to the day[2] and the offset is known, and **SHOULD** be precise to the second.

CONF-DIR-7: Times or time intervals found in the `asOrganizationPartOf/effectiveTime`, `asMaintainedEntity/effectiveTime`, `relatedEntity/effectiveTime`, `serviceEvent/effectiveTime`, `ClinicalDocument/participant/time`, `serviceEvent/performer/time`, and `encounterParticipant/time` elements **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone.

In CDA-conformant documents, all telephone numbers are to be encoded using a restricted form of the `tel:` URL scheme as described below.

The `telecom` element provides a contact telephone number for the various participants that require it. The value attribute of this element is a URL that specifies the telephone number, as indicated by the `TEL` data type.

Within the specification, all telephone numbers are to be encoded using the grammar shown in Figure 3: Restricted URL grammar for telephone communications, which is a restriction on the `TEL` data type and RFC 2806[3]. It simplifies interchange between applications, as it removes optional URL components found in RFC 2806 that applications typically do not know how to process such as ISDN subaddress, phone context, or other dialing parameters.

A telephone number used for voice calls begins with the URL scheme `tel:`. If the number is a global phone number, it starts with a plus (+) sign. The remaining number is made up of the dialing digits and an optional extension and may also contain visual separators.

Figure 3: Restricted URL grammar for telephone communications

```
telephone-url = telephone-scheme ':' telephone-subscriber
telephone-scheme = 'tel'
telephone-subscriber = global-phone-number  [ extension ]
global-phone-number = '+' phone-number
phone-number = digits
digits = phonedigit | digits phonedigit
phonedigit = DIGIT | visual-separator
extension = ';ext=' digits
visual-separator = '-' | '.' | '(' | ')'
```

CONF-DIR-8: Telephone numbers **SHALL** match the regular expression pattern `tel:\+?[-0-9().]+`

CONF-DIR-9: At least one dialing digit **SHALL** be present in the phone number after visual separators are removed.

---

[2] The XML ITS precludes the use of time zone unless the timestamp is more precise than to the day.

[3] Note that RFC 3966 obsoletes RFC 2806, but is backwards-compatible. The restricted grammar is compatible with both RFC 3966 and RFC 2806 by virtue of Section 2.5.11 of RFC 2806, which provides for additional parameters, e.g., "`;ext=,`" to be added as future extensions.

Figure 4: Valid telecom example

```
<!-- U.S. telephone number for HL7 headquarters -->
<telecom value="tel:+17346777777"/>
```

CONF-DIR-10: If the `telecom` is unknown, it **SHALL** be represented using the appropriate flavor of null.

Figure 5: Unknown telephone number example

```
<telecom nullFlavor='UNK'>
```

2.4 ClinicalDocument/typeId

The `ClinicalDocument/typeId` element identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier. The `@root` and `@extension` values of this element are specified as shown below.

CONF-DIR-11: The `root` attribute of the `typeId` element **SHALL** be `2.16.840.1.113883.1.3` and extension attribute **SHALL** be `POCD_HD000040`.

Figure 6: ClinicalDocument/typeId example

```
<typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
```

2.5 ClinicalDocument/templateId

The `ClinicalDocument/templateId` element identifies the template that defines constraints on the content. The `ClinicalDocument/templateId` with the content shown below indicates conformance to this specification.

CONF-DIR-12: A `ClinicalDocument/templateId` element **SHALL** be present with the value `2.16.840.1.113883.10.20.6`.

Figure 7: ClinicalDocument/templateId example

```
<templateId root='2.16.840.1.113883.10.20.6'/> <!-- conforms to the Implementation
Guide  -->
```

2.6 ClinicalDocument/id

The `ClinicalDocument/id` element is an instance identifier data type (see HL7 Version 3 Abstract Data Types). For compatibility with DICOM-SR, this specification constrains the `root` attribute to an OID, and UUIDs are prohibited. Since every UUID has an OID representation (see ITU-T X.667), this constraint should not pose an exceptional burden on implementers. If an extension is present, the root uniquely identifies the scope of the extension. The `root` and `extension` attributes uniquely identify the document.

OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and IGs.

CONF-DIR-13: The `ClinicalDocument/id` element **SHALL** be present. The `ClinicalDocument/id/@root` attribute **SHALL** be a syntactically correct OID, and **SHALL NOT** be a UUID.

CONF-DIR-14: OIDs **SHALL** be represented in dotted decimal notation, where each decimal number is either 0 or starts with a nonzero digit. More formally, an OID **SHALL** be in the form `([0-2])(.([1-9][0-9]*|0))+`

CONF-DIR-15: OIDs **SHALL** be no more than 64 characters in length.

Figure 8: ClinicalDocument/id example

```
<id extension='999021'  root='2.16.840.1.113883.19'/>
```

Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: http://www.hl7.org/oid.

Another useful resource lists the many ways to obtain a registered OID root for free or a small fee anywhere in the world and is located at:

http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration

The manner in which the OID root is obtained is not constrained by this IG.

When a DICOM SR report is transformed to a CDA Diagnostic Imaging Report, a new `ClinicalDocument/id` is created by the transforming application, and DICOM Attribute (`0008,0018`) `SopInstance` UID of the original document is used as a reference to the parent document (see 2.18 relatedDocument).

2.7 ClinicalDocument/code

CONF-DIR-16: The `ClinicalDocument/code` element **SHALL** be present and specifies the type of the clinical document.

Given that reports generated according to this IG may be transformed from established collections of imaging reports already stored with their own type codes, this IG does not prescribe a closed, static set of Document Type codes. The set of LOINC codes listed here may be extended by additions to LOINC and supplemented by local codes as translations.

CONF-DIR-17: The value for `ClinicalDocument/code` **SHOULD** be selected from Table 4: LOINC® Document Type Codes `2.16.840.1.113883.6.1 LOINC` **DYNAMIC** and **SHOULD** be `18748-4 "Diagnostic Imaging Report" 2.16.840.1.113883.6.1 LOINC` **STATIC**.

Figure 9: ClinicalDocument/code example

```
<code code="18748-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Diagnostic Imaging Report"/>
```

2.7.1 Use of Local Document Type Codes

CONF-DIR-18: Implementations **MAY** use local codes in `translation` elements to further refine the document type.

An example of the use of local document type codes is shown below.

Figure 10: Use of the translation element to include local codes for document type

```
<code code="18748-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Diagnostic Imaging Report"
<translation code='XRPEDS' displayName='Pediatric Radiography Report'
codeSystem='2.16.840.1.123456.78.9'/>
</code>
```

2.7.2 Precoordinated Document Type Codes

The LOINC® document hierarchy listed in Table 4 is a list of document type codes supported under this specification. Some of these codes (those not in boldface), are pre-coordinated with either the imaging modality, body part examined, or specific imaging method such as the view. Use of these codes is not recommended, as this duplicates information potentially present with the CDA document Header.

CONF-DIR-19: When pre-coordinated document type codes are used, they **SHALL NOT** conflict with the other information present in the document.

Table 4: LOINC® Document Type Codes

LOINC® Code	Display Name	Modality
18748-4	**Diagnostic Imaging Report**	**Any**
18747-6	CT Report	Computed Tomography
18755-9	MRI Report	Magnetic Resonance Imaging
18760-9	Ultrasound Report	Ultrasound
18757-5	Nuclear Medicine Report	Nuclear Medicine
18758-3	PET Scan Report	Positron Emission Tomography
18745-0	Cardiac Catheterization Report	Cardiac Radiography/Fluoroscopy
11522-0	Echocardiography Report	Cardiac Ultrasound
18746-8	Colonoscopy Report	Magnetic Resonance Imaging
18751-8	Endoscopy Report	Magnetic Resonance Imaging
18750-0	Electrophysiology Report	Cardiac Radiography/Fluoroscopy
11525-3	Obstetrical Ultrasound Report	Ultrasound

This table is drawn from LOINC® Version 2.26, January 10, 2008, and consists of codes whose scale is DOC and that refer to reports for diagnostic imaging procedures.

CONF-DIR-20: If pre-coordinated document type codes are used, values used in imaging procedure code `ClinicalDocument/documentationOf/serviceEvent/code` **SHALL NOT** conflict with `ClinicalDocument/code`.

2.8 ClinicalDocument/title

CONF-DIR-21: The `title` element **SHALL** be present and specifies the local name used for the document.

Figure 11: ClinicalDocument/title example

```
<title>Diagnostic Imaging Report</title>
```

Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "`DIAGNOSTIC IMAGING REPORT`." The title can be localized as appropriate (see the figure above). If there is no title in a transformed DICOM SR report, then it is suggested to use the LOINC® display name to populate this required field.

2.9 ClinicalDocument/effectiveTime

CONF-DIR-22: The `ClinicalDocument/effectiveTime` element **SHALL** be present and specifies the creation time of the document. All Diagnostic Imaging Report documents authored by direct input to a computer system **SHOULD** record an `effectiveTime` that is precise to the second.

In case the CDA was transformed from a DICOM SR, the `effectiveTime` is the creation time of the SR document.

Figure 12: CinicalDocument/effectiveTime example

```
<effectiveTime value='20050303171504+0500'/>
```

2.10 ClinicalDocument/confidentialityCode

CDA R2 requires that the `ClinicalDocument/confidentialityCode` be present. It specifies the confidentiality assigned to the document. This specification provides no further guidance on documents with respect to the vocabulary used for `confidentialityCode`, nor treatment, nor implementation of confidentiality. A CDA R2-conforming example is shown below:

Figure 13: ClinicalDocument/confidentialityCode example

```
<confidentialityCode code='N' codeSystem='2.16.840.1.113883.5.25'/>
```

2.11 ClinicalDocument/languageCode

The `ClinicalDocument/languageCode` specifies the language of the report. Diagnostic Imaging Reports must be readable by medical practitioners, caregivers, and patients.

CONF-DIR-23: `ClinicalDocument/languageCode` **SHALL** be present.

CONF-DIR-24: `ClinicalDocument/languageCode` **SHALL** be in the form `nn`, or `nn-CC`.

CONF-DIR-25: The `nn` portion of `ClinicalDocument/languageCode` **SHALL** be a legal ISO-639-1 language code in lower case.

CONF-DIR-26: The `CC` portion `ClinicalDocument/languageCode`, if present, **SHALL** be an ISO-3166 country code in upper case.

Figure 14: ClinicalDocument/languageCode example with language only

```
<languageCode code='en'/>
```

Figure 15: ClinicalDocument/languageCode example with language and country

```
<languageCode code='en-US'/>
```

2.12 ClinicalDocument/setId and ClinicalDocument/versionNumber

The `ClinicalDocument/setId` element uses the instance identifier (II) data type. The `root` attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the `extension` attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions, and Addenda in Section 4.2.3.1 of the HL7 CDA Release 2.0 Specification for some examples showing the use of the `setId` element.

CONF-DIR-27: Both `ClinicalDocument/setId` and `ClinicalDocument/versionNumber` **SHALL** be present or both **SHALL** be absent.

CONF-DIR-28: The `clinicalDocument/setId` element **SHALL** be different from `ClinicalDocument/id` when both are present (i.e., either the root or extension must be different).

Note that `setId` and version number will not be present in transformed DICOM SR documents.

Figure 16: ClinicalDocument/setId and ClinicalDocument/versionNumber example

```
<setId extension='s-999021'  root='2.16.840.1.113883.19'/>
<versionNumber value='1'/>
```

2.13 ClinicalDocument/copyTime

The `ClinicalDocument/copyTime` element has been deprecated in CDA R2.

CONF-DIR-29: A `ClinicalDocument/copyTime` element **SHALL NOT** be present.

2.14 Participants

This section describes the general constraints placed upon CDA participants.

The HL7 CDA Release 2.0 Specification, Section 4.2.2.1.3 describes various participant scenarios where a single person can participate in several roles. In these cases, the person needs to be listed for each role.

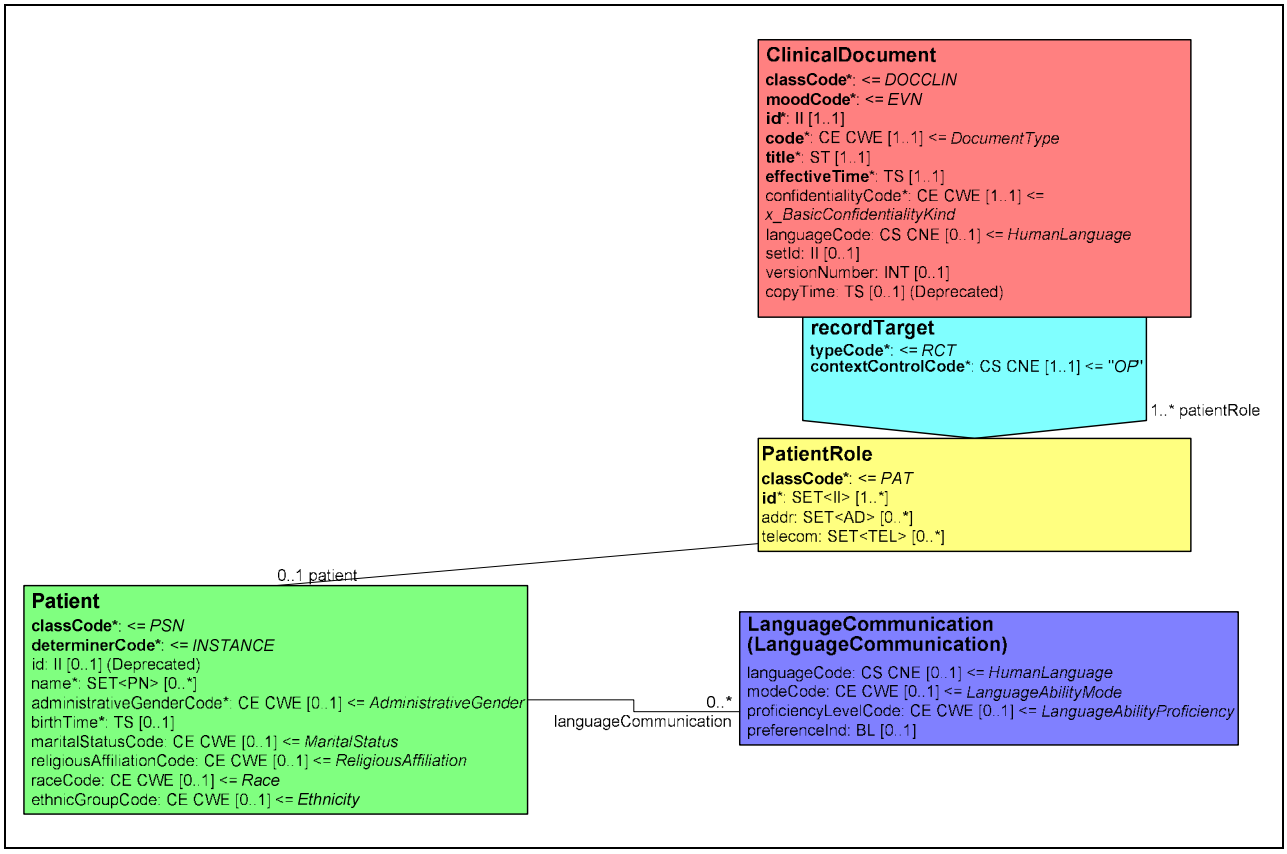
Note that Authentication requires that the participant be able to verify the accuracy of the document and Legal Authentication requires that the participant has the privilege to legally authenticate the document. Patients or other persons such as a guardian or parent may not have these privileges, depending upon local policy.

The participants are listed below in the order in which they appear in CDA R2.

2.14.1 recordTarget

The `recordTarget` element must be present. It records the patient or patients whose health information is described by the clinical document.

Figure 17: Patient Context illustration (non-normative)



CONF-DIR-30: At least one `recordTarget/patientRole` element **SHALL** be present.

CONF-DIR-31: A `patient/birthTime` element **SHALL** be present. The `patient/birthTime` element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null.

CONF-DIR-32: A `patient/administrativeGenderCode` element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for `administrativeGenderCode` **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary.

CONF-DIR-33: The `maritalStatusCode`, `religiousAffiliationCode`, `raceCode`, and `ethnicGroupCode` element **MAY** be present. If `maritalStatusCode`, `religiousAffiliationCode`, `raceCode`, and `ethnicGroupCode` elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies.

CONF-DIR-34: The `guardian` element **SHOULD** be present when the patient is a minor child.

CONF-DIR-35: The `providerOrganization` element **MAY** be present.

Figure 18: recordTarget example

```
<recordTarget>
 <patientRole>
  <id root="1.2.840.113619.2.62.994044785528.10" extension="0000680029"/>
  <addr nullFlavor="NI"/>
  <telecom nullFlavor="NI"/>
  <patient>
   <name>
    <given>Adam</given>
    <family>Everyman</family>
   </name>
   <administrativeGenderCode codeSystem="2.16.840.1.113883.5.1" code="M"/>
   <birthTime value="19641128"/>
  </patient>
 </patientRole>
</recordTarget>
```

2.14.2 author

The `author` element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship. The DICOM author date (based on the DICOM attributes Content Date and Content Time) is unchanged in a transformed SR document.

CONF-DIR-36: The `author/time` element represents the start time of the author's participation in the creation of the content of the clinical document. The `author/time` element **SHALL** be present.

CONF-DIR-37: The `assignedAuthor/id` element **SHALL** be present.

CONF-DIR-38: An `assignedAuthor` element **SHALL** contain at least one `assignedPerson` or `assignedAuthoringDevice` element.

Figure 19: author example

```
<author>
 <time value="20060823224352"/>
 <assignedAuthor>
  <id extension="121008" root="2.16.840.1.113883.19.5"/>
  <addr nullFlavor="NI"/>
  <telecom nullFlavor="NI"/>
  <assignedPerson>
   <name>
     <given>Christine</given>
      <family>Curie</family>
      <suffix>MD</suffix>
  </name>
  </assignedPerson>
 </assignedAuthor>
</author>
```

Figure 20: assignedAuthoringDevice example

```
<author>
 <time value="20060823224352"/>
 <assignedAuthor>
  <id root="86562fe5-b509-4ce9-b976-176fd376e477"/>
  <addr nullFlavor="NI"/>
  <telecom nullFlavor="NI"/>
  <assignedAuthoringDevice>
   <softwareName>Good Health Software Application</softwareName>
  </assignedAuthoringDevice>
 </assignedAuthor>
</author>
```

2.14.3 dataEnterer

The `dataEnterer` element represents the person who transferred the information from other sources into the clinical document where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the Header or Body of the document, subject to their own interpretation. The `dataEnterer` adds information to the electronic system. A person can participate as both `author` and `dataEnterer`.

A `dataEnterer` is a person entering the data into the originating system. The data entry person is collected optionally for internal quality control purposes. This includes the transcriptionist for dictated text.

CONF-DIR-39: When `dataEnterer` is present, an `assignedEntity/assignedPerson` element **SHALL** be present.

CONF-DIR-40: The `time` element **MAY** be present. If present, it represents the starting time of entry of the data.

Figure 21: dataEnterer example

```
<dataEnterer>
  <time value="20060823224352"/>
  <assignedEntity>
    <id extension='2' root='2.16.840.1.113883.19'/>
    <addr nullFlavor="NI"/>
    <telecom nullFlavor="NI"/>
    <assignedPerson>
      <name>
        <prefix>Mrs.</prefix>
        <given>Ellen</given>
        <family>Enter</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</dataEnterer>
```

2.14.4 informant

The use case for a Diagnostic Imaging Report does not include informants in the Header and there is no equivalent in DICOM SR used in Diagnostic Imaging Report templates.

CONF-DIR-41: The `informant` element **SHALL NOT** be present.

2.14.5 custodian

Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA specification), the `custodian` element is required and is the custodian of the clinical document.

The custodian is optional in DICOM SR documents. When transforming from SR to CDA, if `custodian` is not present in the source document, it must be set according to local organizational policies.

Figure 22: custodian example

```
<custodian>
<assignedCustodian>
  <representedCustodianOrganization>
    <id root="2.16.840.1.113883.19.5"/>
    <name>World University Hospital</name>
    <telecom nullFlavor="NI"/>
    <addr nullFlavor="NI"/>
  </representedCustodianOrganization> </assignedCustodian>
</custodian>
```

2.14.6 informationRecipient

The `informationRecipient` element records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the `receivedOrganization` is the scoping organization of that chart.

CONF-DIR-42: The `ClinicalDocument/informationRecipient` element **MAY** be present . When `informationRecipient` is used, at least one

informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization element **SHALL** be present.

The Referring Physician (the physician requesting the imaging procedure) typically receives a copy of the Diagnostic Imaging Report. The referring physician is also the ordering physician in DICOM[4].

CONF-DIR-43: The physician requesting the imaging procedure (ClincalDocument/participant[@typeCode=REF]/associatedEntity), if present, **SHOULD** also be recorded as an informationRecipient, unless in the local setting another physician (such as the attending physician for an inpatient) is known to be the appropriate recipient of the report.

CONF-DIR-44: When no referring physician is present, as in the case of self-referred screening examinations allowed by law, the intendedRecipient **MAY** be null with a nullFlavor of OTH. The intendedRecipient **MAY** also be the health chart of the patient, in which case the receivedOrganization **SHALL** be the scoping organization of that chart.

Figure 23: informationRecipient example

```
<informationRecipient>
 <intendedRecipient>
  <id extension='4' root='2.16.840.1.113883.19'/>
  <addr>
   <streetAddressLine>1030 Healthcare Drive</streetAddressLine>
   <city>Burlington</city>
   <state>MA</state>
   <postalCode>01803</postalCode>
   <country>USA</country>
  </addr>
  <telecom value='tel:(555)555-1032' use='WP'/>
  <informationRecipient>
   <name>
    <prefix>Dr.</prefix>
    <given>Fay</given>
    <family>Family</family>
   </name>
  </informationRecipient>
  <receivedOrganization>
   <name>Good Health Clinic</name>
   <telecom nullFlavor="NI"/>
   <addr nullFlavor="NI"/>
  </receivedOrganization>
 </intendedRecipient>
</informationRecipient>
```

[4] Currently, CDA does not allow participants in the "order" class. This will likely be addressed in the next release of CDA.

2.14.7 legalAuthenticator

The `legalAuthenticator` element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.

The act of legal authentication requires that a certain privilege be granted to the legal authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.

Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

CONF-DIR-45: If the document has been signed, `legalAuthenticator` **SHALL** be present.

CONF-DIR-46: The `assignedEntity/assignedPerson` element **SHALL** be present in `legalAuthenticator`.

Figure 24: legalAuthenticator example

```
<legalAuthenticator>
 <time value="20060827141500"/>
 <signatureCode code="S"/>
 <assignedEntity>
  <id extension="121008" root="2.16.840.1.113883.19.5"/>
  <addr nullFlavor="NI"/>
  <telecom nullFlavor="NI"/>
  <assignedPerson>
   <name>
    <given>Christine</given>
    <family>Curie</family>
    <suffix>MD</suffix>
   </name>
  </assignedPerson>
 </assignedEntity>
</legalAuthenticator>
```

2.14.8 authenticator

The `authenticator` identifies the participant who attested to the accuracy of the information in the document.

In radiology reporting environments, the authenticator would typically be a resident who dictated the initial report and reviewed and approved the transcribed version, but the report would still need to be legally authenticated by an attending radiologist.

CONF-DIR-47: An `authenticator` element **MAY** be present. The `assignedEntity/assignedPerson` element **SHALL** be present in an `authenticator` element.

Figure 25: authenticator example

```
<authenticator>
 <time value='20050329224512+0500'/>
 <signatureCode code='S'/>
 <assignedEntity>
  <id extension="4" root="2.16.840.1.113883.19"/>
  <addr>
   <streetAddressLine>1030 Healthcare Drive</streetAddressLine>
   <city>Burlington</city>
   <state>MA</state>
   <postalCode>01803</postalCode>
   <country>USA</country>
  </addr>
 <telecom value="tel:(555)555-1032" use="WP"/>
  <assignedPerson>
   <name>
    <prefix>Dr.</prefix>
    <given>Fay</given>
    <family>Family</family>
   </name>
  </assignedPerson>
 </assignedEntity>
</authenticator>
```

Automated systems, such as EHRs, that allow a clinical document to be generated need to give special consideration to authentication permissions because the information contained in the document may come from sources or contain information that the author cannot validate.

2.14.9 participant

CONF-DIR-48: The `participant` element **MAY** be present. If `participant` is present, the `assignedEntity/assignedPerson` element **SHALL** be present and **SHALL** represent the physician requesting the imaging procedure (the referring physician `AssociatedEntity` that is the target of `ClincalDocument/participant@typeCode=REF`).

Figure 26: participant example

```
<participant typeCode="REF">
 <associatedEntity classCode="PROV">
  <id nullFlavor="NI"/>
  <addr nullFlavor="NI"/>
  <telecom nullFlavor="NI"/>
  <associatedPerson>
   <name>
    <given>Amanda</given>
    <family>Assigned</family>
    <suffix>MD</suffix>
   </name>
  </associatedPerson>
 </associatedEntity>
</participant>
```

2.15 inFullfillmentOf

CONF-DIR-49: One or more `inFullfillmentOf` elements **MAY** be present. They represent the Placer Order that was fulfilled by the imaging procedure(s) covered by this report document.

The Placer Order is either a group of orders (modeled as PlacerGroup in the Placer Order RMIM of the Orders & Observations domain) or a single order item (modeled as ObservationRequest in the same RMIM). This optionality reflects two major approaches to the grouping of procedures as implemented in the installed base of imaging information systems. These approaches differ in their handling of grouped procedures and how they are mapped to identifiers in the DICOM image and structured reporting data. The example of a CT examination covering chest, abdomen, and pelvis will be used in the discussion below.

In the IHE Scheduled Workflow model, the Chest CT, Abdomen CT, and Pelvis CT each represent a Requested Procedure, and all three procedures are grouped under a single Filler Order. The Filler Order number maps directly to the DICOM Accession Number in the DICOM imaging and report data.

A widely deployed alternative approach maps the requested procedure identifiers directly to the DICOM Accession Number. The Requested Procedure ID in such implementations may or may not be different from the Accession Number, but is of little identifying importance because there is only one Requested Procedure per Accession Number. There is no identifier that formally connects the requested procedures ordered in this group.

In both cases, `inFullfillmentOf/order/id` is mapped to the DICOM Accession Number in the imaging data.

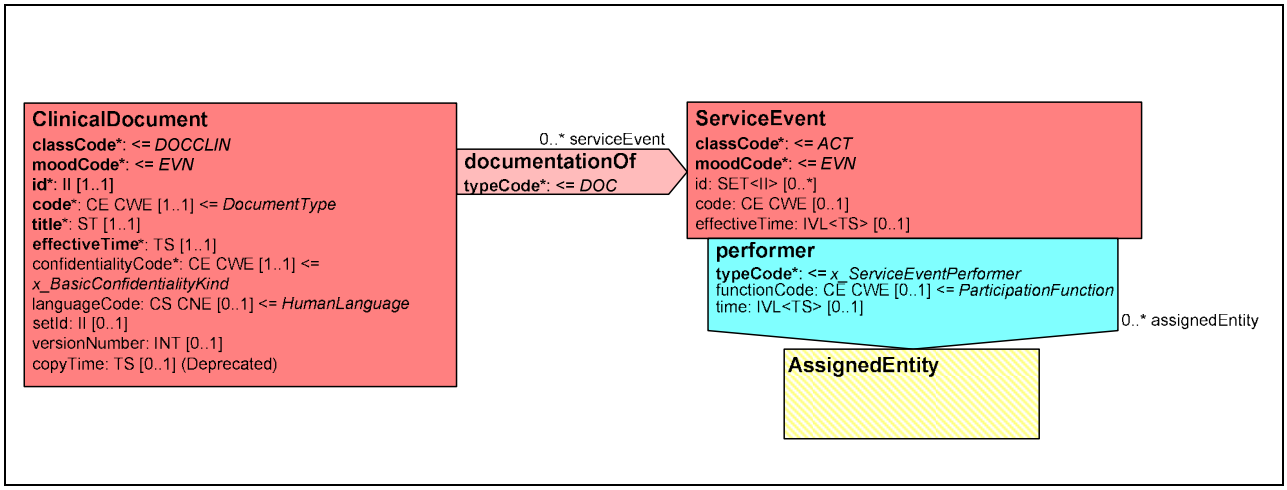
Figure 27: inFulfillmentOf example

```
<inFulfillmentOf>
  <order>
    <id extension="10523475" root="2.16.840.1.113883.19.4.27"/>
    <!--  {root}.27= accession number list *-->
  </order>
</inFulfillmentOf>
```

2.16 documentationOf

Each `documentationOf/ServiceEvent` indicates an imaging procedure that the provider describes and interprets in the content of the Diagnostic Imaging Report. The main activity being described by this document is the interpretation of the imaging procedure. This is shown by setting the value of the `@classCode` attribute of the `serviceEvent` element to `ACT`, and indicating the duration over which care was provided in the `effectiveTime` element. Within each `documentationOf` element, there is one `serviceEvent` element. This event is the unit imaging procedure corresponding to a billable item. The type of imaging procedure may be further described in the `serviceEvent/code` element. This IG makes no specific recommendations about the vocabulary to use for describing this event.

Figure 28: Procedure context (CDA Header) illustration (non-normative)



CONF-DIR-50: One or more `ClinicalDocument/documentationOf/serviceEvent` elements **SHALL** be present.

CONF-DIR-51: The value of the `serviceEvent/@classCode` attribute **SHALL** be `ACT` (a Healthcare Service).

CONF-DIR-52: One or more `serviceEvent/id` elements **SHOULD** be present.

In IHE Scheduled Workflow environments, one `serviceEvent/id` element contains the DICOM Study Instance UID from the Modality Worklist, and the second `serviceEvent/id` element contains the DICOM Requested Procedure ID from the Modality Worklist.

CONF-DIR-53: A `serviceEvent/code` element **SHALL** be present representing the procedure code sequence or the procedure code. The value of `serviceEvent/code` **SHALL NOT** conflict with the `ClininicalDocument/code`. When transforming from DICOM SR documents that do not contain a procedure code, an appropriate nullFlavor **SHALL** be used on serviceEvent/code.

The `effectiveTime` for the `serviceEvent` covers the duration of the imaging procedure being reported. This event should have one or more performers, which may participate at the same or different periods of time.

Service events map to DICOM Requested Procedures. That is, `documentationOf/ServiceEvent/id` is the ID of the Requested Procedure.

CONF-DIR-54: The `effectiveTime` element of the `serviceEvent` element **SHOULD** be present.

CONF-DIR-55: If present, the `effectiveTime` element **SHALL** contain a `value` attribute and **SHALL NOT** contain `low` and `high` elements.

CONF-DIR-56: A `serviceEvent` **SHOULD** contain at least one Physician Reading Study Performer (`templateId 2.16.840.1.113883.10.20.6.2.1`) listing the persons performing the procedure(s) being reported. There are cases where no performers might be listed, for example, in cases where the information is not available.

Figure 29: documentationOf example

```
<documentationOf>
 <serviceEvent classCode="ACT">
  <id root="1.2.840.113619.2.62.994044785528.114289542805"/>
  <!-- study instance UID -->
  <id extension="123453" root="1.2.840.113619.2.62.994044785528.26"/>
  <!-- requested procedure ID , {root}.26 = procedure ID Namespace-->
  <effectiveTime value="20060823222400"/>
  <performer typeCode="PRF">
   <templateId root="2.16.840.1.113883.10.20.6.2.1"/>
   <assignedEntity>
    <id extension="121008" root="2.16.840.1.113883.19.5"/>
    <code code="2085R0202X" codeSystem="2.16.840.1.113883.11.19465"
codeSystemName="NUCC" displayName="Diagnostic Radiology"/>
    <addr nullFlavor="NI"/>
   <telecom nullFlavor="NI"/>
    <assignedPerson>
     <name>
      <given>Christine</given>
      <family>Cure</family>
      <suffix>MD</suffix>
     </name>
    </assignedPerson>
   </assignedEntity>
  </performer>
 </serviceEvent>
</documentationOf>
```

2.16.1 Physician Reading Study Performer

CONF-DIR-57: The `templateId` for Physician Reading Study Performer **SHALL** be `2.16.840.1.113883.10.20.6.2.1`.

CONF-DIR-58: Physician Reading Study Performer **SHALL** be represented with a `performer` element where `@typeCode` is `PRF`.

CONF-DIR-59: A `time` element **MAY** be present representing the time span over which health care services are provided, if different from that of the service event.

The specific type of performer may be described in `performer/assignedEntity/code`.

CONF-DIR-60: A `assignedEntity/code` element **SHALL** be present and **SHALL** contain a valid DICOM personal identification code sequence (`@codeSystem` is `1.2.840.10008.2.16.4`) or an appropriate national health care provider coding system (e.g., NUCC in the U.S., where `@code` is `2.16.840.1.113883.11.19465`).

CONF-DIR-61: Every `assignedEntity` element **SHALL** have at least one `assignedPerson` or `representedOrganization`.

2.17 authorization

The `authorization` elements may be present. This document provides no guidance on the encoding of `authorization` elements.

2.18 relatedDocument

A Diagnostic Imaging Report may have three types of parent document:

- A superseded version that the present document wholly replaces (`typeCode` = `RPLC`). Diagnostic Imaging Reports may go through stages of revision prior to being legally authenticated. Such early stages may be drafts from transcription, those created by residents, or other preliminary versions. Policies not covered by this specification may govern requirements for retention of such earlier versions. Except for forensic purposes, the latest version in a chain of revisions represents the complete and current report.
- An original version that the present document appends (`typeCode` = `APND`). When a Diagnostic Imaging Report is legally authenticated, it can be amended by a separate addendum document that references the original.
- A source document from which the present document is transformed (`typeCode` = XFRM). A Diagnostic Imaging Report may be created by transformation from a DICOM SR document or from another Diagnostic Imaging Report. An example of the latter case is the creation of a derived document for inclusion of imaging results in a clinical document.

CONF-DIR-62: One or more `relatedDocument` elements **MAY** be present.

CONF-DIR-63: When a Diagnostic Imaging Report has been transformed from a DICOM SR document, `relatedDocument/@typeCode` **SHALL** be `XFRM`, and `relatedDocument/parentDocument/id` **SHALL** contain the SOP Instance UID of the original DICOM SR document.

Figure 30: relatedDocument example

```
<!-- transformation of a DICOM SR -->
<relatedDocument typeCode="XFRM">
  <parentDocument>
    <id root="1.2.840.113619.2.62.994044785528.20060823.200608232232322.9"/>
    <!-- SOP Instance UID (0008,0018) of SR sample document-->
  </parentDocument>
</relatedDocument>
```

2.19 componentOf

CONF-DIR-64: The `componentOf/encompassingEncounter` element **MAY** be present.

The `id` element of the `encompassingEncounter` represents the identifier for the encounter. When the diagnostic imaging procedure is performed in the context of a hospital stay or an outpatient visit for which there is an Encounter Number, that number should be present as the ID of the `encompassingEncounter`.

CONF-DIR-65: The `encompassingEncounter` element **SHALL** have an `id` element. In the case of transformed DICOM SR documents, an appropriate null flavor **MAY** be used if the `id` is unavailable.

The effectiveTime represents the time interval or point in time in which the encounter took place. The encompassing encounter might be that of the hospital or office visit in which the diagnostic imaging procedure was ordered. If the effective time is unknown, a nullFlavor attribute can be used.

CONF-DIR-66: The encompassingEncounter element **SHALL** have an effectiveTime element.

The responsibleParty element represents only the party responsible for the encounter, not necessarily the entire episode of care.

CONF-DIR-67: The responsibleParty element **MAY** be present. If present, responsibleParty/assignedEntity **SHALL** have at least one assignedPerson or representedOrganization element present.

CONF-DIR-68: A Physician of Record Participant (templateId 2.16.840.1.113883.10.20.6.2.2) **SHOULD** be present.

Figure 31: componentOf example

```
<componentOf>
  <encompassingEncounter>
   <id extension="9937012" root="1.3.6.4.1.4.1.4.1.2835.12"/>
   <effectiveTime value="20060828170821"/>
   <encounterParticipant typeCode="ATND">
    <templateId root="2.16.840.1.113883.10.20.6.2.2"/>
    <assignedEntity>
     <id extension="4" root="2.16.840.1.113883.19"/>
     <code code="208D00000X" codeSystem="2.16.840.1.113883.11.19465"
codeSystemName="NUCC" displayName="General Practice"/>
     <addr nullFlavor="NI"/>
     <telecom nullFlavor="NI"/>
     <assignedPerson>
      <name>
       <prefix>Dr.</prefix>
       <given>Fay </given>
       <family>Family</family>
      </name>
     </assignedPerson>
    </assignedEntity>
   </encounterParticipant>
  </encompassingEncounter>
</componentOf>
```

2.19.1 Physician of Record Participant

This participant is the attending physician and is usually different from the Physician Reading Study Performer defined in documentationOf/serviceEvent.

CONF-DIR-69: The templateId for a Physician of Record Participant **SHALL** be 2.16.840.1.113883.10.20.6.2.2.

CONF-DIR-70: A Physician of Record Participant **SHALL** be represented with an encounterParticipant element where @typeCode is ATND.

CONF-DIR-71: An `encounterParticipant/assignedEntity/id` element **SHALL** be present containing the `id` of the physician of record.

CONF-DIR-72: A `encounterParticipant/assignedEntity/code` element **SHALL** be present and **SHALL** contain a valid DICOM personal identification code sequence (`@codeSystem` is `1.2.840.10008.2.16.4`) or an appropriate national health care provider coding system (e.g., NUCC in the U.S., where `@codeSystem` is `2.16.840.1.113883.11.19465`).

CONF-DIR-73: An `assignedPerson/name` element **SHOULD** be present containing the name of the physician of record.

3 BODY

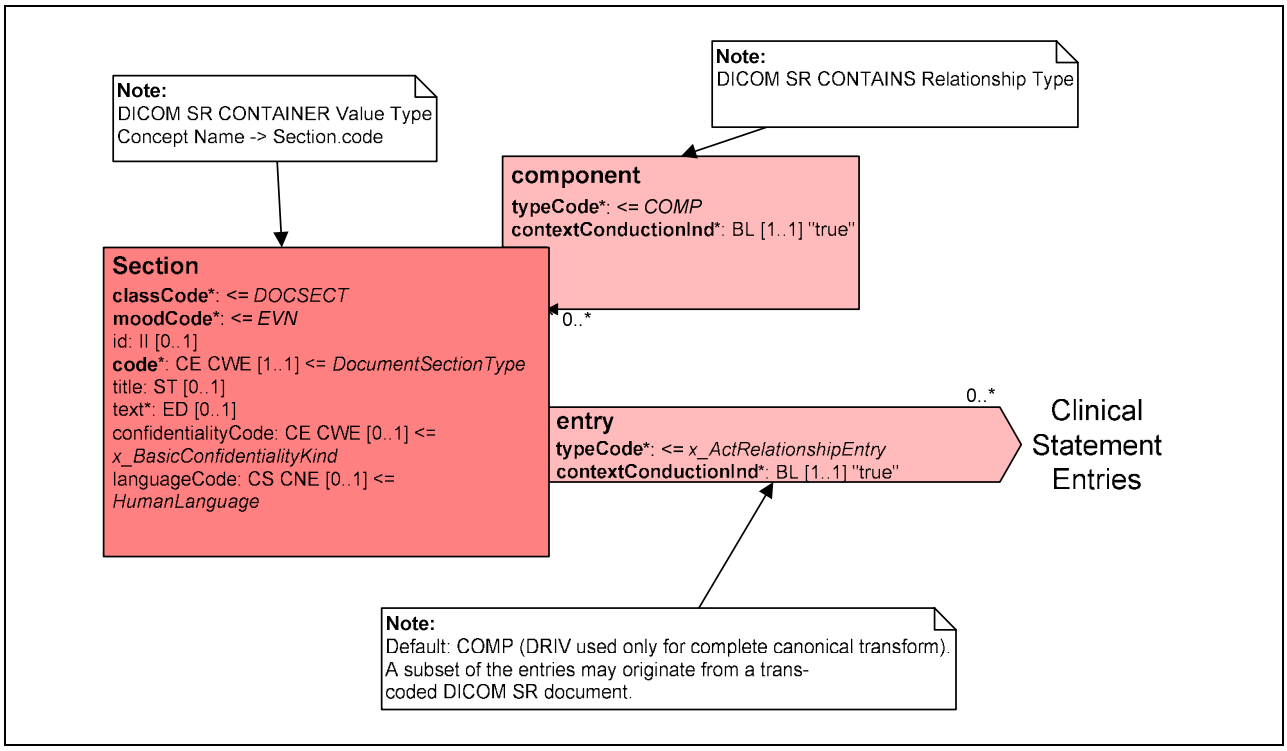
CONF-DIR-74: A Diagnostic Imaging Report **SHALL** have a `structuredBody` element. The content of this element makes up the human-readable text of the document.

3.1 Section Descriptions

This IG defines required and optional sections.

All section elements in the Body of the document must have a code. With the exception of the DICOM Object Catalog section that is based on the CMET A DICOMSEQUENCE MINIMAL(COCT_RM830110UV), some nonblank text or one or more subsections must be present, even if the purpose of the text is only to indicate that information is unknown.

Figure 32: Section illustration (non-normative)



3.1.1 Generic Section Constraints

The Section Type codes used in this IG are described below in Table 5. All section codes shown in this table describe narrative document sections[5].

The column headings of this table are described below:

[5] `SCALE_TYP = 'NAR'` in the LOINC tables.

DCM Code:	The code of the section in DICOM (Context Group CID 7001).
DCM Code Meaning:	The display name of the section in DICOM (Context Group CID 7001)..
LOINC® Code:	The code of the section in LOINC®.
LOINC® Component Name:	The display name of the section in LOINC®.
Use:	The use column indicates that a section in a Diagnostic Imaging Report is: R – required C – conditionally required O – optional

Table 5: Section Type Codes

DICOM Code	DICOM Code meaning	LOINC® Code	LOINC® Code Meaning	Use
121181	DICOM Object Catalog	N/A	N/A	C
121060	History	11329-0	HISTORY GENERAL	O
121062	Request	55115-0	REQUESTED IMAGING STUDIES INFORMATION	O
121064	Current Procedure Descriptions	55111-9	CURRENT IMAGING PROCEDURE DESCRIPTIONS	O
121066	Prior Procedure Descriptions	55114-3	PRIOR IMAGING PROCEDURE DESCRIPTIONS	O
121068	Previous Findings	18834-2	RADIOLOGY COMPARISON STUDY - OBSERVATION	O
121070	Findings	18782-3	RADIOLOGY STUDY OBSERVATION	R
121072	Impressions	19005-8	RADIOLOGY - IMPRESSION	O
121074	Recommendations	18783-1	RADIOLOGY STUDY - RECOMMENDATION	O
121076	Conclusions	55110-1	CONCLUSIONS	O
121078	Addendum	55107-7	ADDENDUM	O
121109	Indications for Procedure	18785-6	RADIOLOGY REASON FOR STUDY	O
121110	Patient Presentation	55108-5	CLINICAL PRESENTATION	O
121113	Complications	55109-3	COMPLICATIONS	O
121111	Summary	55112-7	DOCUMENT SUMMARY	O
121180	Key Images	55113-5	KEY IMAGES	O

CONF-DIR-75: The DICOM Object Catalog section (see Section 3.2.1 DICOM Object Catalog – DCM 121181), if present, **SHALL** be the first section in the document Body.

CONF-DIR-76: With the exception of the DICOM Object Catalog (`templateId 2.16.840.1.113883.10.20.6.1.1`), all sections within the Diagnostic Imaging Report content **SHOULD** contain a `title` element.

CONF-DIR-77: For sections not listed in Table 5, the `section/code` **SHOULD** be selected from LOINC® or DICOM.

The remainder of the examples in this section all show sample content that would appear in the `structuredBody` element.

For Level 2 conformance, all `section` elements that are present in the Body of the document must have a `code` and some nonblank text or one or more subsections, even if the purpose of the text is only to indicate that information is unknown.

CONF-DIR-78: All sections defined in Table 5: Section Type Codes **SHALL** be top-level sections.

CONF-DIR-79: A `section` element **SHALL** have a `code` element which **SHALL** contain a LOINC® code if available, or DCM code for sections which have no LOINC® equivalent. This only applies to sections described in Table 5: Section Type Codes.

CONF-DIR-80: Apart from the DICOM Object Catalog, all other instances of `section` **SHALL** contain at least one `text` element or one or more `component` elements.

CONF-DIR-81: All `text` or `component` elements **SHALL** contain content. `text` elements **SHALL** contain `PCDATA` or `child` elements, and `component` elements **SHALL** contain `child` elements.

CONF-DIR-82: The `text` elements (and their children) **MAY** contain Web Access to DICOM Persistent Object (WADO) references to DICOM objects by including a `linkHtml` element where `@href` is a valid WADO URL and the text content of `linkHtml` is the visible text of the hyperlink.

Figure 33: WADO reference using linkHtml example

```
<text>
  ...
  <paragraph>
    <caption>Source of Measurement</caption>
    <linkHtml
href="http://www.example.org/wado?requestType=WADO&amp;studyUID=1.2.840.113619.2.62.99
4044785528.114289542805&amp;seriesUID=1.2.840.113619.2.62.994044785528.200608232231424
85051&amp;objectUID=1.2.840.113619.2.62.994044785528.20060823.200608232232322.3&amp;co
ntentType=application/dicom">Chest_PA</linkHtml>
  </paragraph>
  ...
</text>
```

There is no equivalent to `section/title` in DICOM SR, so for a CDA to SR transformation, the `section/code` will be transferred and the `title` element will be dropped.

CONF-DIR-83: If clinical statements are present, the `section/text` **SHALL** represent faithfully all such statements and **MAY** contain additional text.

CONF-DIR-84: If the service context of a section is different from the value specified in `documentationOf/serviceEvent`, then the section **SHALL** contain one or more entries containing Procedure Context (`templateId 2.16.840.1.113883.10.20.6.2.5`), which will reset the context for any clinical statements nested within those elements.

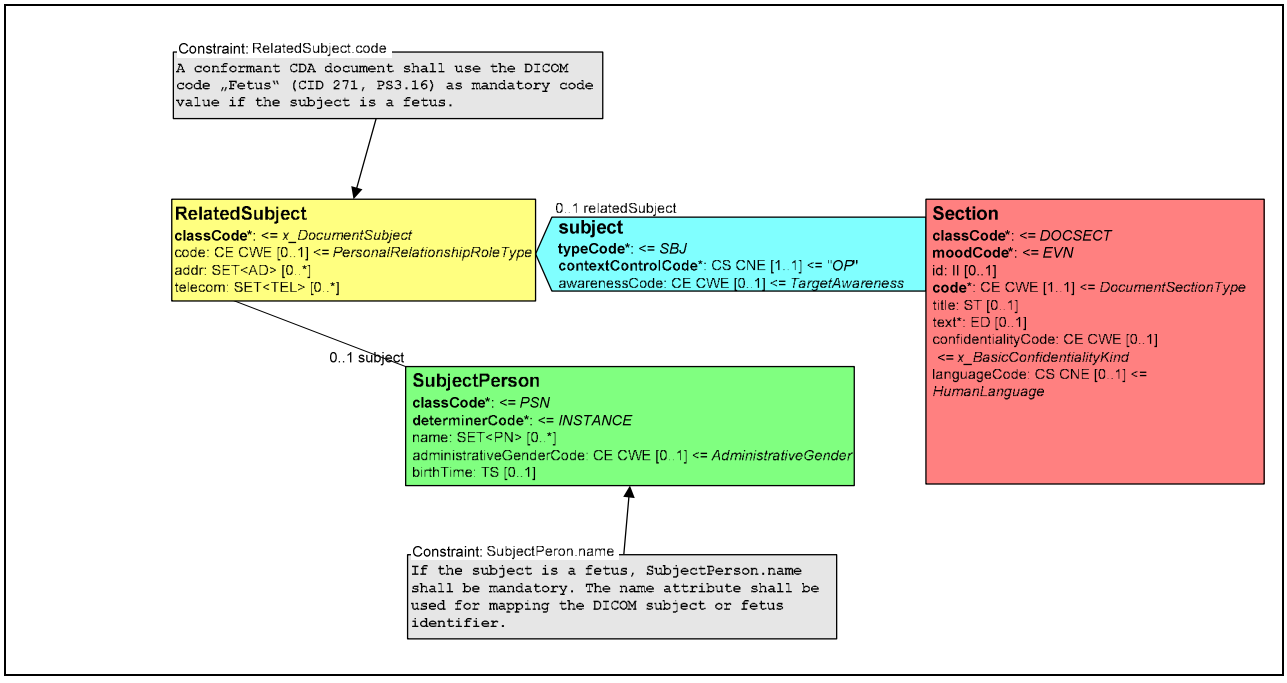
CONF-DIR-85: If the subject of a section is a fetus, the section **SHALL** contain a `subject` element containing a Fetus Subject Context (`templateId 2.16.840.1.113883.10.20.6.2.3`).

CONF-DIR-86: If the author of a section is different from the author(s) listed in the Header, an `author` element **SHALL** be present containing Observer Context (`templateId 2.16.840.1.113883.10.20.6.2.4`).

3.1.2 Fetus Subject Context

For reports on mothers and their fetus(es), information on a mother is mapped to `recordTarget`, `PatientRole`, and `Patient`. Information on the fetus is mapped to `subject`, `relatedSubject`, and `SubjectPerson` at the CDA section level. Both context information on the mother and fetus must be included in the document if observations on fetus(es) are contained in the document.

Figure 34: Fetus Subject Context illustration (non-normative)



CONF-DIR-87: The `templateId` for a Fetus Subject Context **SHALL** be `2.16.840.1.113883.10.20.6.2.3`.

CONF-DIR-88: A Fetus Subject Context **SHALL** be represented with a `relatedSubject` element.

CONF-DIR-89: A `code` element **SHALL** be present where `@code` is `121026` and `@codeSystem` is `1.2.840.10008.2.16.4`, identifying the subject as a fetus.

CONF-DIR-90: A `subject` element **SHALL** be present.

CONF-DIR-91: The `subject` element **SHALL** contain a `name` element, which is used to store the DICOM fetus ID, typically a pseudonym such as `fetus_1`.

Figure 35: Fetus Subject Context example

```
<relatedSubject>
 <templateId root="2.16.840.1.113883.10.20.6.2.3"/>
 <code code="121026" codeSystem="1.2.840.10008.2.16.4" displayName="Fetus"/>
 <subject>
  <name>fetus_1</name>
 </subject>
</relatedSubject>
```

3.1.3 Observer Context

The Observer Context is used to override the author specified in the CDA Header. It is valid as a direct `child` element of a section.

CONF-DIR-92: The `templateId` for an Observer Context **SHALL** be `2.16.840.1.113883.10.20.6.2.4`.

CONF-DIR-93: Observer Context **SHALL** be represented with `assignedAuthor`.

CONF-DIR-94: An `id` element **SHALL** be present containing author's `id` or the DICOM device observer UID.

CONF-DIR-95: Either `assignedPerson` or `assignedAuthoringDevice` **SHALL** be present.

Figure 36: Observer Context example

```
 <assignedAuthor>
  <templateId root="2.16.840.1.113883.10.20.6.2.4"/>
  <id extension="121008" root="2.16.840.1.113883.19.5"/>
  <assignedPerson>
   <name>
    <given>Richard</given>
    <family>Blitz</family>
    <suffix>MD</suffix>
   </name>
  </assignedPerson>
 </assignedAuthor>
```

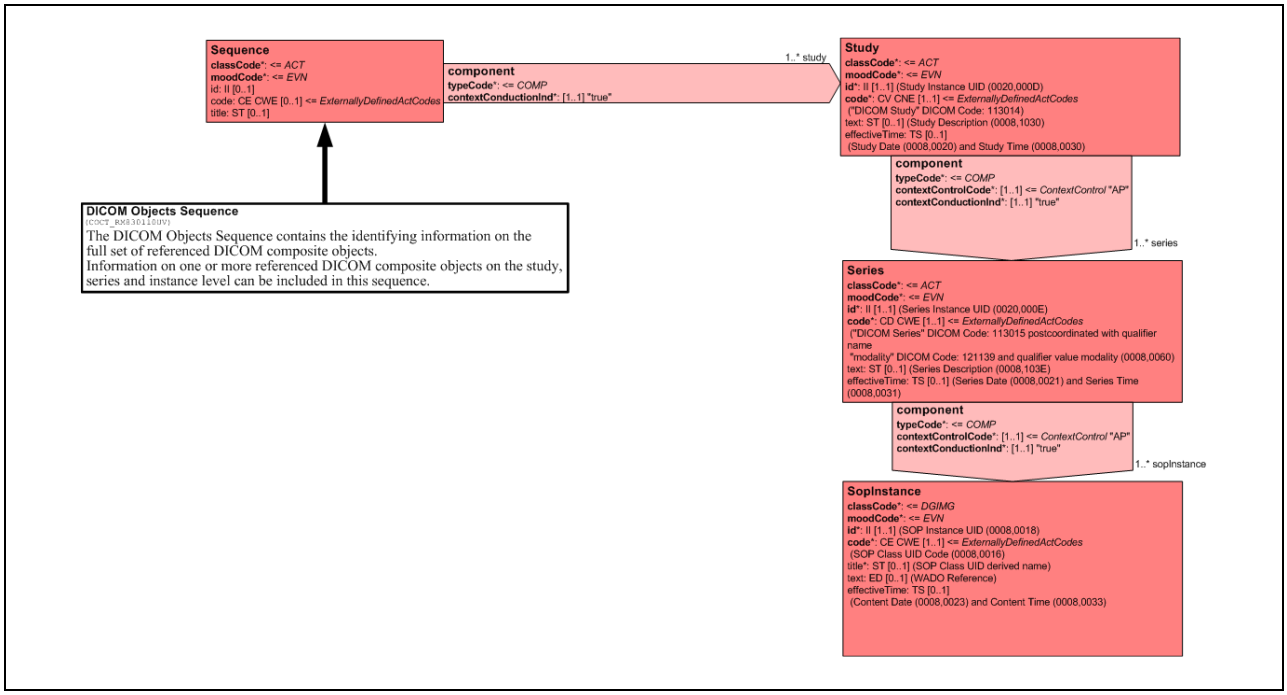
3.2 Imaging Report Sections

3.2.1 DICOM Object Catalog – DCM 121181

DICOM Object Catalog lists all referenced objects and their parent Series and Studies, plus other DICOM attributes required for retrieving the objects.

DICOM Object Catalog sections are not intended for viewing and contain empty section text.

Figure 37: DICOM Object Catalog illustration (non-normative)



CONF-DIR-96: The `templateId` for a DICOM Object Catalog section **SHALL** be `2.16.840.1.113883.10.20.6.1.1`.

CONF-DIR-97: A DICOM Object Catalog **SHALL** be present if the document contains references to DICOM Images. If present, it **SHALL** be the first section in the document.

CONF-DIR-98: A `code` element **SHALL** be present where `@code` is `121181` from code system `1.2.840.10008.2.16.4 DCM` **STATIC**.

CONF-DIR-99: Since the DICOM Object Catalog section is only intended to contain machine-readable content, it **SHALL NOT** contain a `title` element and **SHALL NOT** contain a `text` element.

CONF-DIR-100: One or more entry elements **SHALL** be present, each containing a Study Act (`templateId 2.16.840.1.113883.10.20.6.2.6`).

A sample of a DICOM Object Catalog section is shown below.

Figure 38: DICOM Object Catalog example

```
<section classCode="DOCSECT" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.6.1.1"/>
 <code code="121181" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
displayName="DICOM Object Catalog"/>
 <entry>
<!--
**********************************************************************
Study
**********************************************************************
-->
   <act classCode="ACT" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.6.2.6"/>
    <id root="1.2.840.113619.2.62.994044785528.114289542805"/>
    <code code="113014" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
displayName="Study"/>
<!--
**************************************************************
Series
**************************************************************
-->
    <entryRelationship typeCode="COMP">
     <act classCode="ACT" moodCode="EVN">
      <id root="1.2.840.113619.2.62.994044785528.20060823223142485051"/>
      <code code="113015" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
displayName="Series">
       <qualifier>
        <name code="121139" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
displayName="Modality"> </name>
        <value code="CR" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
displayName="Computed Radiography"> </value>
       </qualifier>
      </code>
<!--
**************************************************************
SopInstance UID
**************************************************************
-->
      <!-- 2 References (chest PA and LAT) -->
      <entryRelationship typeCode="COMP">
       <observation classCode="DGIMG" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.6.2.8"/>
        <id root="1.2.840.113619.2.62.994044785528.20060823.200608232232322.3"/>
        <code code="1.2.840.10008.5.1.4.1.1.1" codeSystem="1.2.840.10008.2.6.1"
codeSystemName="DCMUID" displayName="Computed Radiography Image Storage">
        </code>
        <text mediaType="application/dicom">
         <reference
value="http://www.example.org/wado?requestType=WADO&amp;studyUID=1.2.840.113619.2.62.9
94044785528.114289542805&amp;seriesUID=1.2.840.113619.2.62.994044785528.20060823223142
485051&amp;objectUID=1.2.840.113619.2.62.994044785528.20060823.200608232232322.3&amp;c
ontentType=application/dicom"/>
          <!--reference to image 1 (PA) -->
        </text>
        <effectiveTime value="20060823223232"/>
       </observation>
      </entryRelationship>
      <entryRelationship typeCode="COMP">
```

```
        <observation classCode="DGIMG" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.6.2.8"/>
          <id root="1.2.840.113619.2.62.994044785528.20060823.200608232231422.3"/>
          <code code="1.2.840.10008.5.1.4.1.1.1" codeSystem="1.2.840.10008.2.6.1"
codeSystemName="DCMUID" displayName="Computed Radiography Image Storage">
          </code>
          <text mediaType="application/dicom">
            <reference
value="http://www.example.org/wado?requestType=WADO&amp;studyUID=1.2.840.113619.2.62.9
94044785528.114289542805&amp;seriesUID=1.2.840.113619.2.62.994044785528.20060823223142
485051&amp;objectUID=1.2.840.113619.2.62.994044785528.20060823.200608232231422.3&amp;c
ontentType=application/dicom"/>
            <!--reference to image 2 (LAT) -->
          </text>
          <effectiveTime value="20060823223142"/>
        </observation>
      </entryRelationship>
     </act>
    </entryRelationship>
   </act>
  </entry>
</section>
```

3.2.2 Findings – LOINC® 18782-3

The Findings section contains the main narrative body of the report. While not an absolute requirement for transformed DICOM SR reports, it is suggested that Diagnostic Imaging Reports authored in CDA follow Term Info guidelines for the codes in the various observations and procedures recorded in this section.

CONF-DIR-101: A Findings section **SHALL** be present.

CONF-DIR-102: The `templateId` for a Findings section **SHALL** be `2.16.840.1.113883.10.20.6.1.2`.

CONF-DIR-103: This section **SHOULD** contain only the direct observations in the report, with topics such as Reason for Study, History, and Impression placed in separate sections. However, in cases where the source of report content provides a single block of text not separated into these sections, that text **SHALL** be placed in the Findings section.

3.2.2.1 Rendering of Paragraphs and Paragraph Sections

Paragraphs and paragraph captions may be present to improve rendering of the document as in the example below. See section 1.2.3, “Human Readability and Rendering CDA Documents”, in HL7’s “Clinical Document Architecture” specification for more information.

Figure 39: Findings example, including Level 3 content

```
    <section>
     <templateId root="2.16.840.1.113883.10.20.6.1.2"/>
      <code code="121070" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
       displayName="Findings"/>
      <title>Findings</title>
      <text>
       <paragraph>
        <caption>Finding</caption>
        <content ID="Fndng2">The cardiomediastinum is within normal limits. The
         trachea is midline. The previously described opacity at the medial
         right lung base has cleared. There are no new infiltrates. There is
         a new round density at the left hilus, superiorly (diameter about
         45mm). A CT scan is recommended for further evaluation. The pleural
         spaces are clear. The visualized musculoskeletal structures and the
         upper abdomen are stable and unremarkable.</content>
       </paragraph>
       <paragraph>
        <caption>Diameter</caption>
        <content ID="Diam2">45mm</content>
       </paragraph>
       <paragraph>
        <caption>Source of Measurement</caption>
        <content ID="SrceOfMeas2">
         <linkHtml

 href="http://www.example.org/wado?requestType=WADO&amp;studyUID=1.2.840.113619.2.62.9
94044785528.114289542805&amp;seriesUID=1.2.840.113619.2.62.994044785528.20060823223142
485051&amp;objectUID=1.2.840.113619.2.62.994044785528.20060823.200608232232322.3&amp;c
ontentType=application/dicom"
           >Chest_PA </linkHtml>
        </content>
       </paragraph>
      </text>
      <entry>
       <observation classCode="OBS" moodCode="EVN">
        <!-- Text Observation -->
        <templateId root="2.16.840.1.113883.10.20.6.2.12"/>
        <code code="121071" codeSystem="1.2.840.10008.2.16.4"
         codeSystemName="DCM" displayName="Finding"/>
        <value xsi:type="ED">
         <reference value="#Fndng2"/>
        </value>
        <!-- inferred from measurement -->
        <entryRelationship typeCode="SPRT">
         <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.6.2.14"/>
          <code code="246120007" codeSystem="2.16.840.1.113883.6.96"
                                  codeSystemName="SNOMED" displayName="Nodule size">
           <originalText>
            <reference value="#Diam2"/>
           </originalText>
          </code>
          <!-- no DICOM attribute  <statusCode code="completed"/> -->
          <effectiveTime value="20060823223912"/>
          <value xsi:type="PQ" value="45" unit="mm">
```

```
              <translation code="mm" codeSystem="2.16.840.1.113883.6.8"
                codeSystemName="UCUM" codeSystemVersion="1.5"/>
             </value>
             <!-- inferred from image -->
             <entryRelationship typeCode="SUBJ">
              <observation classCode="DGIMG" moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.6.2.8"/>
               <!-- (0008,1155) Referenced SOP Instance UID-->
               <id
                root="1.2.840.113619.2.62.994044785528.20060823.200608232232322.3"/>
               <!-- (0008,1150) Referenced SOP Class UID -->
               <code code="1.2.840.10008.5.1.4.1.1.1"
                codeSystem="1.2.840.10008.2.6.1"
                codeSystemName="DCMUID"
                displayName="Computed Radiography Image Storage"> </code>
               <text mediaType="application/dicom">
                <!--reference to CR DICOM image (PA view) -->
                <reference

 value="http://www.example.org/wado?requestType=WADO&amp;studyUID=1.2.840.113619.2.62.
994044785528.114289542805&amp;seriesUID=1.2.840.113619.2.62.994044785528.2006082322314
2485051&amp;objectUID=1.2.840.113619.2.62.994044785528.20060823.200608232232322.3&amp;
contentType=application/dicom"
                 />
               </text>
               <effectiveTime value="20060823223232"/>
               <!-- Referenced Frames -->
               <entryRelationship typeCode="COMP">
                <observation classCode="ROIBND" moodCode="EVN">
                <templateId
                root="2.16.840.1.113883.10.20.6.2.10"/>
                <code code="121190"
                codeSystem="1.2.840.10008.2.16.4"
                displayName="Referenced Frames"/>
                <entryRelationship typeCode="COMP">
                <!-- Boundary Observation -->
                <observation classCode="OBS" moodCode="EVN">
                <templateId
                root="2.16.840.1.113883.10.20.6.2.11"/>
                <code code="113036"
                codeSystem="1.2.840.10008.2.16.4"
                displayName="Group of Frames for Display"/>
                <value xsi:type="INT" value="1"/>
                </observation>
                </entryRelationship>
                </observation>
               </entryRelationship>
               <!-- Purpose of Reference -->
               <entryRelationship typeCode="RSON">
                <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.6.2.9"/>
                <code code="ASSERTION"
                codeSystem="2.16.840.1.113883.5.4"/>
                <value xsi:type="CD" code="121112"
                codeSystem="1.2.840.10008.2.16.4"
                codeSystemName="DCM"
                displayName="Source of Measurement">
                <originalText>
```

```
                <reference value="#SrceOfMeas2"/>
                </originalText>
                </value>
                </observation>
              </entryRelationship>
            </observation>
          </entryRelationship>
        </observation>
      </entryRelationship>
    </observation>
  </entry>
 </section>
```

3.2.3 Optional Sections

A Diagnostic Imaging Report can contain many optional sections. These sections have no additional constraints beyond those described under Section 3.1.1 Generic Section Constraints.

CONF-DIR-104: A Diagnostic Imaging Report **MAY** contain additional sections that provide additional information. The figures below "Reason for Study," "History" and "Impressions" are three examples of optional sections. Others, as set forth in Table 5: Section Type Codes, **MAY** also be present.

Figure 40: Reason for Study example

```
    <component>
     <section>
      <code code="18785-6" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Reason for study"/>
       <title>Reason for Study</title>
       <text>Suspected lung tumor</text>
     </section>
    </component>
```

Figure 41: History example

```
    <component>
     <section>
      <code code="11329-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="History"/>
       <title>History</title>
       <text>Sore throat.</text>
     </section>
    </component>
```

Figure 42: Impressions example

```
    <component>
      <section>
        <code code="19005-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="X-ray impression"/>
        <title>Impressions</title>
        <text>No acute cardiopulmonary process. Round density in left superior hilus,
further evaluation with CT is recommended as underlying malignancy is not
excluded.</text>
      </section>
    </component>
```

3.3 Clinical Statements

A Diagnostic Imaging Report may contain CDA entries that represent, in coded form findings, image references, annotation, and numeric measurements based on DICOM Basic Diagnostic Imaging Report (Template 2000) and Transcribed Diagnostic Imaging Report (Template 2005). Most of the constraints in this IG have been inherited from the *Transformation Guide*.

This IG and the companion *Transformation Guide* further constrain the transformation because image Spatial Coordinates region of interest (SCOORD) for linear, area, and volume measurements are not encoded in the CDA document. If it is desired to show images with such graphical annotations, the annotations should be encoded in DICOM Softcopy Presentation State objects that reference the image. Report applications that display referenced images and annotation should retrieve a rendered image using a WADO reference, including the image and Presentation State, or other DICOM retrieval and rendering methods. This approach avoids the risks of errors in registering a region of interest annotation with DICOM images.

DICOM Template 2000 defines imaging report documents that are comprised of a number of optional sections, including those defined above in Section 3.1.1 Generic Section Constraints. Each section contains:

- Text Observations (Text Elements in DICOM SR), optionally inferred from Quantity Measurement Observation or Image references
- Code Observations (Code Elements in DICOM SR), optionally inferred from Quantity Measurement Observation or Image references
- Quantity Measurement Observation (Numeric Elements in DICOM SR) with a coded measurement type, optionally inferred from an image reference
- Service Object Pair (SOP) Instance Observations containing image references

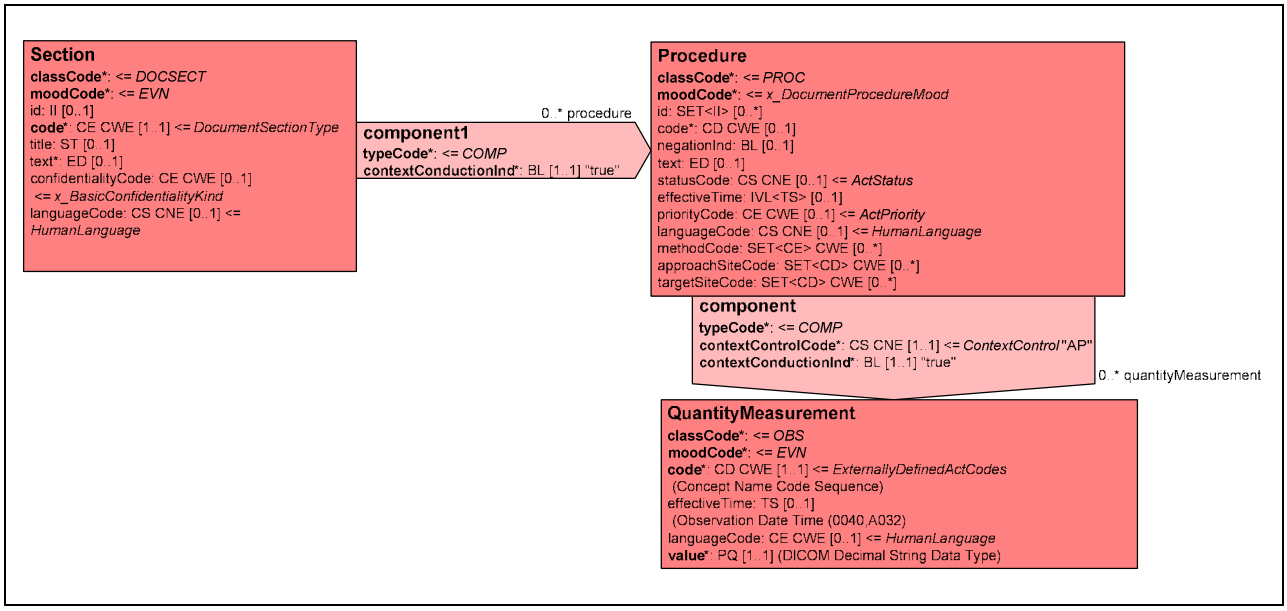
The number or order of the Observations and image references in the above bullet points are not constrained in a Section.

3.3.1 Procedure Context

The `ServiceEvent` Procedure Context of the document Header may be overridden in the CDA structured Body if there is a need to refer to multiple imaging procedures or

acts. The selection of the Procedure or Act entry from the clinical statement choice box depends on the nature of the imaging service that has been performed. The Procedure entry shall be used for image-guided interventions and minimal invasive imaging services, whereas the Act entry shall be used for diagnostic imaging services.

Figure 43: Procedure context (CDA Body) illustration (non-normative)



CONF-DIR-105: The templateId for a Procedure Context **SHALL** be 2.16.840.1.113883.10.20.6.2.5.

CONF-DIR-106: Procedure Context **SHALL** be represented with the procedure or act elements depending on the nature of the procedure (see above).

CONF-DIR-107: A code element **SHALL** be present containing the procedure code. The procedure code display name **SHALL** be present if available..

CONF-DIR-108: An effectiveTime element **SHOULD** be present indicating the time of the procedure.

CONF-DIR-109: If effectiveTime is present, @value **SHALL** be present and nested low and high elements **SHALL NOT** be present.

3.3.2 Study Act

A Study Act contains the DICOM study information that defines the characteristics of a referenced medical study performed on a patient. A study is a collection of one or more series of medical images, presentation states, SR documents, overlays, and/or curves that are logically related for the purpose of diagnosing a patient. Each study is associated with exactly one patient. A study may include composite instances that are created by a single modality, multiple modalities, or by multiple devices of the same modality. The study information is modality-independent. Study Act clinical statements are only instantiated in the DICOM Library section; in other sections, the SopInstance Observation is included directly.

CONF-DIR-110: The templateId for a Study Act **SHALL** be 2.16.840.1.113883.10.20.6.2.6.

CONF-DIR-111: A Study Act **SHALL** be represented with an act element where @classCode is ACT and @moodCode is EVN.

CONF-DIR-112: An id element **SHALL** be present where @root contains the OID of the study instance UID, and @extension **SHALL NOT** be present, since DICOM study ids consist only of an OID.

CONF-DIR-113: A code element **SHALL** be present where @code is 113014 (DICOM Study) and @codeSystem is 1.2.840.10008.2.16.4.

CONF-DIR-114: A text element **MAY** be present containing a description of the study.

CONF-DIR-115: An effectiveTime element **SHOULD** be present containing the time the study was started.

CONF-DIR-116: A component element where @typeCode is COMP **SHALL** be present containing a Series Act.

A Series Act contains the DICOM series information for referenced DICOM composite objects. The series information defines the attributes that are used to group composite instances into distinct logical sets. Each series is associated with exactly one study. Series Act clinical statements are only instantiated in the DICOM Library section inside a Study Act, and thus do not require a separate templateId; in other sections, the SopInstance Observation is included directly.

CONF-DIR-117: A Series Act **SHALL** be represented with an act element where @classCode is ACT and @moodCode is EVN.

CONF-DIR-118: An id element **SHALL** be present where @root contains the OID of the series instance UID, and @extension **SHALL NOT** be present, since DICOM series ids consist only of an OID.

CONF-DIR-119: A code element **SHALL** be present where @code is 113015 (DICOM Series) and @codeSystem is 1.2.840.10008.2.16.4.

CONF-DIR-120: The code element **SHALL** contain a qualifier element.

CONF-DIR-121: The qualifier element **SHALL** contain a name element where @code is 121139 (Modality) and @codeSystem is 1.2.840.10008.2.16.4.

CONF-DIR-122: The qualifier element **SHALL** also contain a value element where @code contains a modality code and @codeSystem is 1.2.840.10008.2.16.4.

CONF-DIR-123: A text element **MAY** be present containing a description of the series.

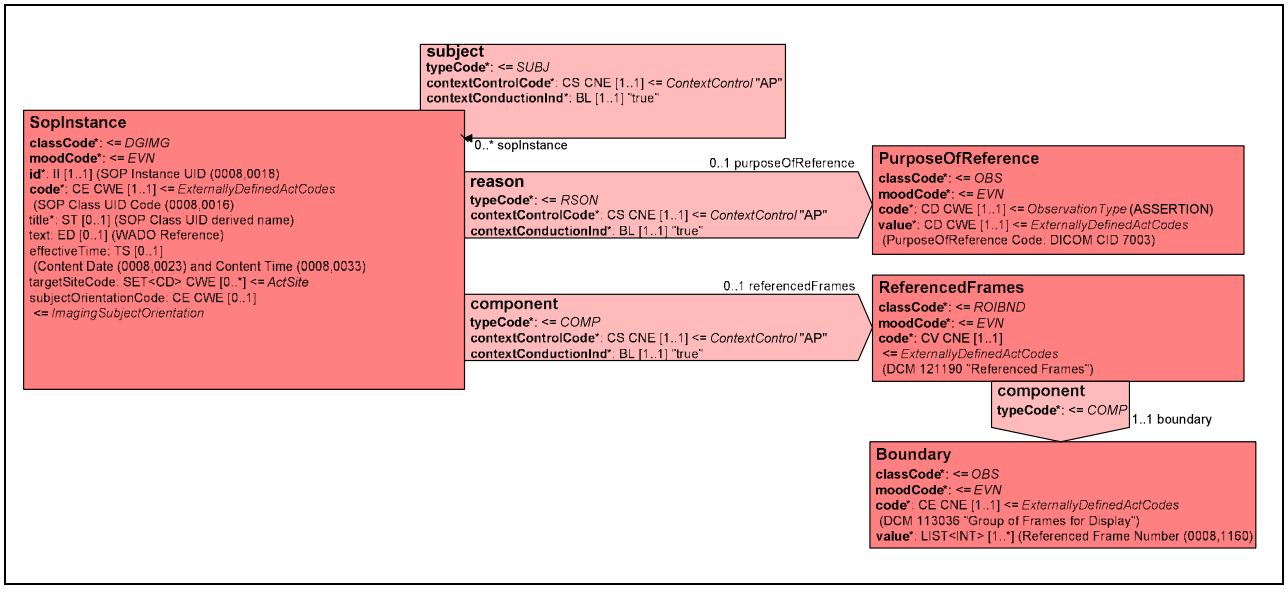
CONF-DIR-124: An effectiveTime element **SHOULD** be present containing the time the study was started.

CONF-DIR-125: A component element where @typeCode is COMP **SHALL** be present containing a SopInstance Observation (templateId 2.16.840.1.113883.10.20.6.2.8).

3.3.3 SopInstance Observation

A `SopInstance` Observation contains the DICOM Service Object Pair (SOP) Instance information for referenced DICOM composite objects. The `SopInstance` act class is used to reference both image and non-image DICOM instances. The `text` attribute contains the DICOM WADO reference.

Figure 44: SopInstance Observation illustration (non-normative)



CONF-DIR-126: The `templateId` for a `SopInstance` Observation **SHALL** be `2.16.840.1.113883.10.20.6.2.8`.

CONF-DIR-127: A `SopInstance` observation **SHALL** be represented with an `observation` element where `@classCode` is `DGIMG` and `@moodCode` is `EVN`.

CONF-DIR-128: An `id` element **SHALL** be present where `@root` contains an OID representing the DICOM SOP Instance UID.

CONF-DIR-129: A `code` element **SHALL** be present where `@codeSystem` is `1.2.840.10008.2.6.1 DCMUID` and `@code` is an OID for a valid SOP class name UID.

CONF-DIR-130: A `text` element **SHOULD** be present where `@mediaType` is `application/dicom`.

CONF-DIR-131: If a `text` element is present, it **SHALL** contain a `reference` element where `@value` contains a WADO reference as a URI.

CONF-DIR-132: An `effectiveTime` element **SHOULD** be present containing the content creation time.

CONF-DIR-133: If `effectiveTime` is present, it **SHALL** contain a `value` attribute and **SHALL NOT** contain `low` and `high` elements.

CONF-DIR-134: Zero or more `entryRelationship` elements where `@typeCode` is `SUBJ` **MAY** be present containing additional `SopInstance` Observations.

CONF-DIR-135: An `entryRelationship` element where `@typeCode` is `RSON` **MAY** be present containing a Purpose of Reference Observation (`templateId 2.16.840.1.113883.10.20.6.2.9`).

CONF-DIR-136: If the referenced DICOM object is a multiframe object and the reference does not apply to all frames, a `component` element where `@typeCode` is `COMP` **SHALL** be present containing a Referenced Frames Observation (`templateId 2.16.840.1.113883.10.20.6.2.10`).

Figure 45: SopInstance Observation example

```
<observation classCode="DGIMG" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.6.2.8"/>
 <!-- (0008,1155) Referenced SOP Instance UID-->
 <id root="1.2.840.113619.2.62.994044785528.20060823.200608232232322.3"/>
 <!-- (0008,1150) Referenced SOP Class UID -->
 <code code="1.2.840.10008.5.1.4.1.1.1" codeSystem="1.2.840.10008.2.6.1"
codeSystemName="DCMUID" displayName="Computed Radiography Image Storage">
 </code>
 <text mediaType="application/dicom">
  <!--reference to CR DICOM image (PA view) -->
  <reference
value="http://www.example.org/wado?requestType=WADO&amp;studyUID=1.2.840.113619.2.62.9
94044785528.114289542805&amp;seriesUID=1.2.840.113619.2.62.994044785528.20060823223142
485051&amp;objectUID=1.2.840.113619.2.62.994044785528.20060823.200608232232322.3&amp;c
ontentType=application/dicom"/>
 </text>
 <effectiveTime value="20060823223232"/>
 <!-- entryRelationship elements containing Purpose of Reference or Referenced Frames
observations may go here -->
</observation>
```

3.3.4 Purpose of Reference Observation

A Purpose of Reference Observation describes the purpose of the DICOM composite object reference. Appropriate codes, such as externally defined DICOM codes, may be used to specify the semantics of the purpose of reference. When absent, it implies that the reason for the reference is unknown.

CONF-DIR-137: The `templateId` for a Purpose of Reference Observation **SHALL** be `2.16.840.1.113883.10.20.6.2.9`.

CONF-DIR-138: A Purpose of Reference Observation **SHALL** be represented with an `observation` element where `@classCode` is `OBS` and `@moodCode` is `EVN`.

CONF-DIR-139: A `code` element **SHALL** be present where `code/@code` **SHOULD** be `ASSERTION` and `code/@codeSystem` **SHALL** be `2.16.840.1.113883.5.4 HL7 ActCode Complete` **STATIC**, but for backwards compatibility with the DICOM CMET, it **MAY** be drawn from Table 6: Purpose of Reference (DICOM CID 7003).

CONF-DIR-140: A `value` element **SHOULD** be present, but for backwards compatibility with the DICOM CMET, it may be absent.

CONF-DIR-141: If present, the values for `value/@code` and `value/@codeSystem` **SHOULD** be drawn from Table 6: Purpose of Reference (DICOM CID 7003).

Note that the use of `ASSERTION` for the code differs from the DICOM CMET. This is intentional. The DICOM CMET was created before the Term Info guidelines describing the use of the assertion pattern were released. It was determined that this IG should follow the latest Term Info guidelines. Implementers using both this IG and the DICOM CMET will need to be aware of this difference and apply appropriate transformations.

The table below shows codes for Purpose of Reference when an image reference is made without a measurement.

Table 6: Purpose of Reference (DICOM CID 7003)

Code	Code System Name	Code System OID	Display Name
121079	DCM	1.2.840.10008.2.16.4	Baseline
121080	DCM	1.2.840.10008.2.16.4	Best illustration of finding
121112	DCM	1.2.840.10008.2.16.4	Source of Measurement

Figure 46: Purpose of Reference example

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.6.2.9"/>
  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
  <value xsi:type="CD" code="121112" codeSystem="1.2.840.10008.2.16.4"
codeSystemName="DCM" displayName="Source of Measurement"/>
</observation>
```

3.3.5 Referenced Frames Observation

A Referenced Frames Observation is used if the referenced DICOM SOP instance is a multiframe image and the reference does not apply to all frames. The list of integer values for the referenced frames of a DICOM multiframe image SOP instance is contained in a Boundary Observation nested inside this class.

CONF-DIR-142: The `templateId` for a Referenced Frames Observation **SHALL** be `2.16.840.1.113883.10.20.6.2.10`.

CONF-DIR-143: A Referenced Frames Observation **SHALL** be represented with an `observation` element where `@classCode` is `ROIBND` and `@moodCode` is `EVN`.

CONF-DIR-144: A `code` element **SHALL** be present where `@code` is `121190` (referenced frames) and `@codeSystem` is `1.2.840.10008.2.16.4`.

CONF-DIR-145: An `entryRelationship` element where `@typeCode` is `COMP` **SHALL** be present containing a Boundary Observation (`templateId 2.16.840.1.113883.10.20.6.2.11`).

Figure 47: Referenced Frames Observation example

```
<observation classCode="ROIBND" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.6.2.10"/>
 <code code="121190" codeSystem="1.2.840.10008.2.16.4" displayName="Referenced
Frames"/>
 <entryRelationship typeCode="COMP">
  <!-- Boundary Observation -->
  <observation classCode="OBS" moodCode="EVN">
   <templateId root="2.16.840.1.113883.10.20.6.2.11"/>
   <code code="113036" codeSystem="1.2.840.10008.2.16.4" displayName="Group of Frames
for Display"/>
   <value xsi:type="INT" value="1"/>
  </observation>
 </entryRelationship>
</observation>
```

3.3.6 Boundary Observation

A Boundary Observation contains a list of integer values for the referenced frames of a DICOM multiframe image SOP instance. It identifies the frame numbers within the referenced SOP instance to which the reference applies. The CDA boundary observation numbers frames using the same convention as DICOM, with the first frame in the referenced object being Frame 1. A Boundary Observation must be used if a referenced DICOM SOP instance is a multiframe image and the reference does not apply to all frames.

CONF-DIR-146: The `templateId` for a Boundary Observation **SHALL** be 2.16.840.1.113883.10.20.6.2.11.

CONF-DIR-147: A Boundary Observation **SHALL** be represented with an `observation` element where `@classCode` is OBS and @moodCode is EVN.

CONF-DIR-148: A `code` element **SHALL** be present where `@code` is `113036` (Group of Frames for Display) and `@codeSystem` is `1.2.840.10008.2.16.4`.

CONF-DIR-149: One or more value element **SHALL** be present where `@xsi:type` is `INT` (`V3 type LIST<INT>`), each representing a frame for display.

Figure 48: Boundary Observation example

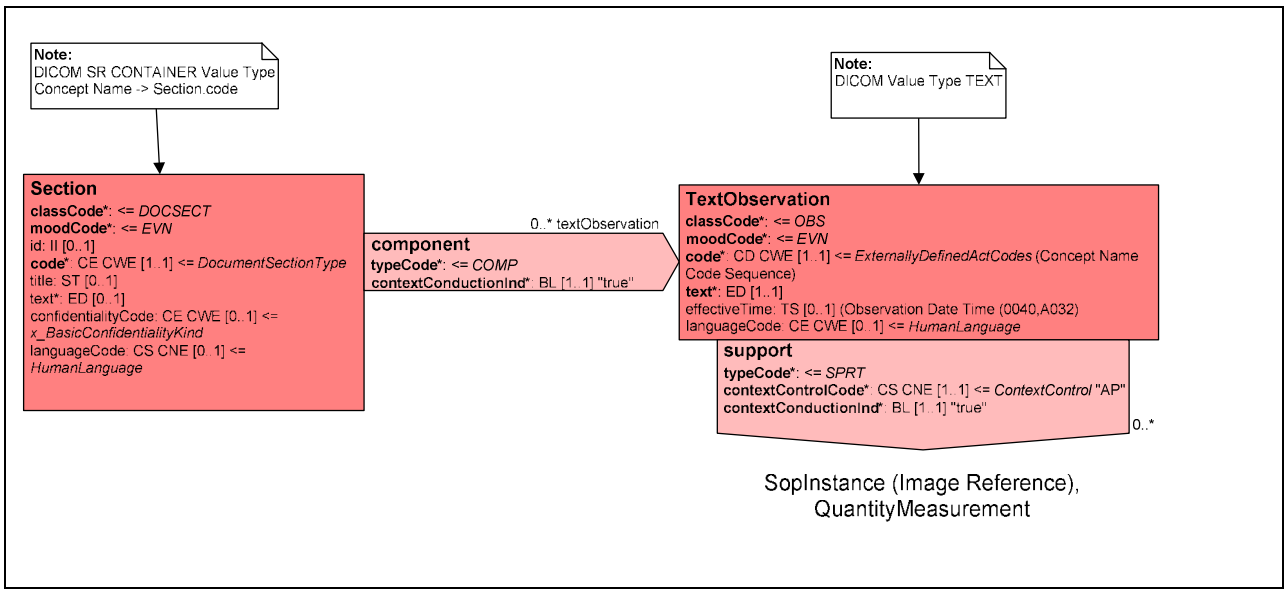
```
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.6.2.11"/>
 <code code="113036" codeSystem="1.2.840.10008.2.16.4" displayName="Group of Frames
for Display"/>
 <value xsi:type="INT" value="1"/>
</observation>
```

3.3.7 Text Observation

DICOM Template 2000 specifies that Imaging Report Elements of Value Type Text are contained in sections. The Imaging Report Elements are inferred from Basic Diagnostic

Imaging Report Observations that consist of image references and measurements (linear, area, volume, and numeric). Text DICOM Imaging Report Elements in this context are mapped to CDA text observations that are section components and are related to the `SopInstance` Observations (`templateId` 2.16.840.1.113883.10.20.6.2.8) or Quantity Measurement Observations (`templateId` 2.16.840.1.113883.10.20.6.2.14) by the SPRT (Support) act relationship.

Figure 49: Text Observation illustration (non-normative)



CONF-DIR-150: The `templateId` for a Text Observation **SHALL** be `2.16.840.1.113883.10.20.6.2.12`.

CONF-DIR-151: Text observations **SHALL** be represented with the `observation` element where `@classCode` is `OBS` and `@moodCode` is `EVN`.

CONF-DIR-152: A `code` element **SHALL** be present.

CONF-DIR-153: A `value` element **SHALL** be present where `@xsi:type` **SHALL** be ED.

CONF-DIR-154: An `effectiveTime` element **SHOULD** be present.

CONF-DIR-155: The `text` element **MAY** contain a `reference` element pointing to the equivalent content in `section/text`, or it **MAY** simply duplicate the appropriate text.

CONF-DIR-156: Zero or more `entryRelationship` elements where `@typeCode` is `SPRT` **MAY** be present, each containing a `SopInstance` Observation (`templateId 2.16.840.1.113883.10.20.6.2.8`), or a Quantity Measurement Observation (`templateId 2.16.840.1.113883.10.20.6.2.14`).

A Text Observation is required if the findings in the section text are represented as inferred from `SopInstance` Observations.

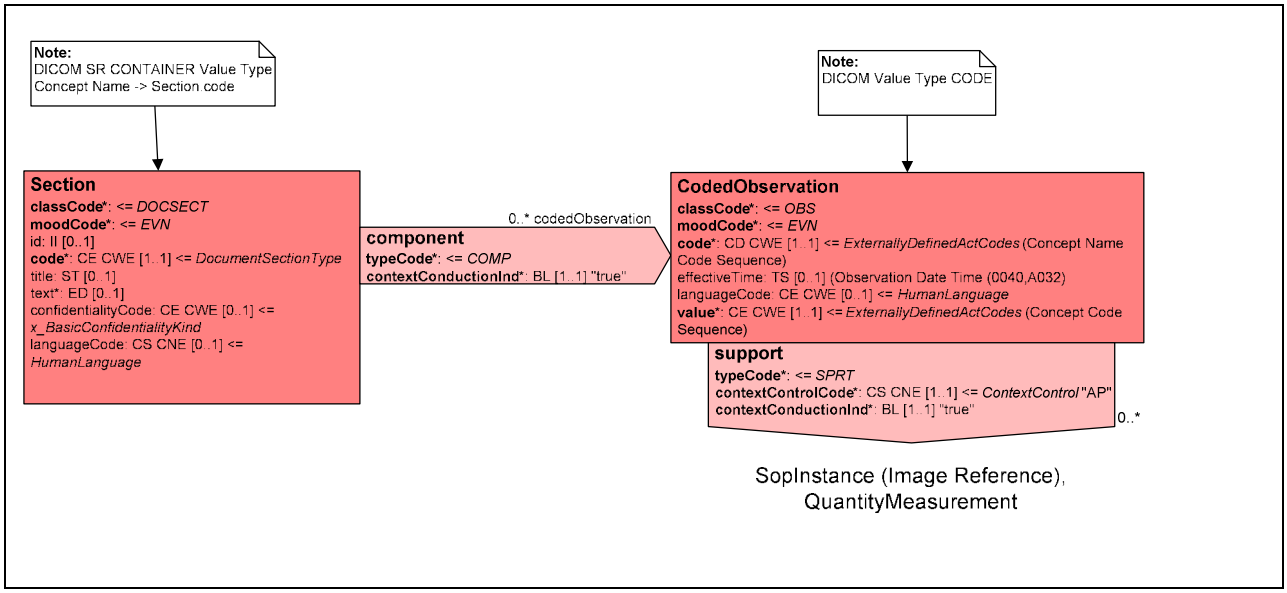
Figure 50: Section/text and Text Observation with Reference example

```
<text>
  <paragraph>
    <caption>Finding</caption>
    <content ID="Fndng2">The cardiomediastinum is within normal limits. The trachea is
midline. The previously described opacity at the medial right lung base has cleared.
There are no new infiltrates. There is a new round density at the left hilus,
superiorly (diameter about 45mm). A CT scan is recommended for further evaluation. The
pleural spaces are clear. The visualized musculoskeletal structures and the upper
abdomen are stable and unremarkable.</content>
  </paragraph>
  ...
</text>
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <!-- Text Observation -->
    <templateId root="2.16.840.1.113883.10.20.6.2.12"/>
    <code code="121071" codeSystem="1.2.840.10008.2.16.4" codeSystemName="DCM"
displayName="Finding"/>
    <value xsi:type="ED"><reference value="#Fndng2"/></value>
    ...
    <!-- entryRelationships to SopInstance Observations and Quantity Measurement
Observations may go here -->
  </observation>
</entry>
```

3.3.8 Code Observations

DICOM Template 2000 specifies that Imaging Report Elements of Value Type Code are contained in sections. The Imaging Report Elements are inferred from Basic Diagnostic Imaging Report Observations that consist of image references and measurements (linear, area, volume, and numeric). Coded DICOM Imaging Report Elements in this context are mapped to CDA-coded observations that are section components and are related to the `SopInstance` Observations (`templateId 2.16.840.1.113883.10.20.6.2.8`) or Quantity Measurement Observations (`templateId 2.16.840.1.113883.10.20.6.2.14`) by the `SPRT` (Support) act relationship.

Figure 51: Code Observation illustration (non-normative)



CONF-DIR-157: The `templateId` for a Code Observation **SHALL** be `2.16.840.1.113883.10.20.6.2.13`.

CONF-DIR-158: Code Observations **SHALL** be represented as `observation` elements where `@classCode` is `OBS` and `@moodCode` is `EVN`.

CONF-DIR-159: A `code` element **SHALL** be present.

CONF-DIR-160: A `value` element **SHALL** be present.

CONF-DIR-161: An `effectiveTime` element **SHOULD** be present.

CONF-DIR-162: Code Observations **SHALL** be rendered into `section/text` in separate paragraphs.

CONF-DIR-163: Zero or more `entryRelationship` elements where `@typeCode` is `SPRT` **MAY** be present, each containing a `SopInstance` Observation (`templateId 2.16.840.1.113883.10.20.6.2.8`), or a Quantity Measurement Observation (`templateId 2.16.840.1.113883.10.20.6.2.14`).

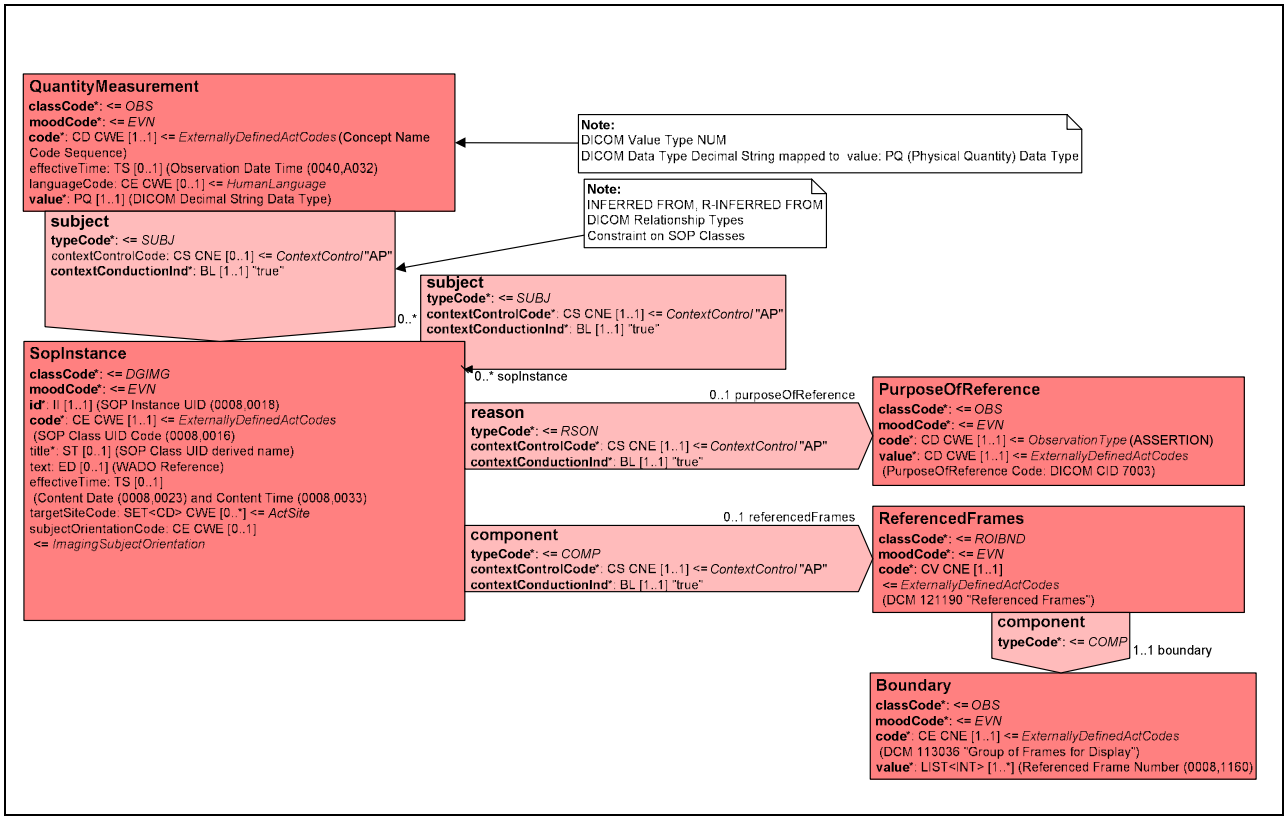
Figure 52: Code Observation example

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.6.2.13"/>
  <code code="18782-3" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Study observation"/>
  <statusCode code="completed"/>
  <value xsi:type="CD" code="309530007" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT" displayName="Hilar mass"/>
  <!-- entryRelationship elements referring to SopInstance Observations or Quantity
Measurement Observations may appear here -->
</observation>
```

3.3.9 Quantity Measurement Observation

A Quantity Measurement Observation is used to record quantity measurements based on image data such as linear, area, volume, and numeric measurements. The SNOMED CT® codes in Table 7: SNOMED CT® Quantity Measurement Type Codes are from the qualifier hierarchy and are not valid for `observation/code` according to the Term Info guidelines. These codes can be used for backwards compatibility, but going forward, codes from the observable entity hierarchy will be requested and used.

Figure 53: Quantity Measurement Observation illustration (non-normative)



CONF-DIR-164: The `templateId` for Quantity Measurement observations **SHALL** be `2.16.840.1.113883.10.20.6.2.14`.

CONF-DIR-165: A Quantity Measurement Observation **SHALL** be represented with an `observation` element.

CONF-DIR-166: A `code` element **SHALL** be present.

CONF-DIR-167: The value of `code/@code` and `code/@codeSystem` **SHOULD** be selected from the codes listed in Table 7: SNOMED CT® Quantity Measurement Type Codes or in Table 8: DICOM Quantity Measurement Type Codes **DYNAMIC.**

Note that CDA and DICOM SR have different conventions for the use of SNOMED identifiers. DICOM uses the old style SNOMED ID, while CDA uses the new concept ID format. This distinction is especially important when transforming from one standard to another.

CONF-DIR-168: In a CDA Diagnostic Imaging Report, SNOMED CT® concept IDs **SHOULD** be used.

CONF-DIR-169: A `value` element **SHALL** be present where `@xsi:type` **SHALL** be `PQ` (physical quantity), `@value` **SHALL** contain a numeric measurement, and `@unit` **SHALL** contain a valid UCUM expression.

CONF-DIR-170: An `effectiveTime` element **SHOULD** be present.

CONF-DIR-171: Zero or more `entryRelationship` elements where `@typeCode` is `SPRT` **MAY** be present, each containing a `SopInstance` Observation.

The value set of the `observation/code` includes numeric measurement types for linear dimensions, areas, volumes, and other numeric measurements. This value set is extensible and comprises the union of SNOMED codes for observable entities as reproduced in Table 7: SNOMED CT® Quantity Measurement Type Codes and DICOM codes contained in the Context Groups 7470 and 7472,as listed in Table 8: DICOM Quantity Measurement Type Codes.

Table 7: SNOMED CT® Quantity Measurement Type Codes

SNOMED CT® Quantity Measurement Observation Codes **Code System OID 2.16.840.1.113883.6.96**		
Concept ID	**Original SNOMED ID**	**Display Name**
439932008	F-00721	Length of structure
440357003	F-0072A	Width of structure
439934009	F-00723	Depth of structure
439984002	F-00726	Diameter of structure
439933003	F-00722	Long axis length of structure
439428006	F-00719	Short axis length of structure
439982003	F-00724	Major axis length of structure
439983008	F-00725	Minor axis length of structure
440356007	F-00729	Perpendicular axis length of structure
439429003	F-0071A	Radius of structure
440433004	F-0072B	Perimeter of non-circular structure
439747008	F-0071E	Circumference of circular structure
439748003	F-0071F	Diameter of circular structure
439746004	F-0071D	Area of structure
439985001	F-00727	Area of body region
439749006	F-00720	Volume of structure

Table 8: DICOM Quantity Measurement Type Codes

DICOM (DCM) Quantity Measurement Observation Codes **Code System OID 1.2.840.10008.2.16.4**			
Code	**Display Name**	**DICOM Context Group ID (CID)**	**Description**
121211	Path length	7470	Linear Measurements
121206	Distance	7470	Linear Measurements
121207	Height	7470	Linear Measurements
121216	Volume estimated from single 2D region	7472	Volume Measurements
121218	Volume estimated from two non-coplanar 2D regions	7472	Volume Measurements
121217	Volume estimated from three or more non-coplanar 2D regions	7472	Volume Measurements
121222	Volume of sphere	7472	Volume Measurements
121221	Volume of ellipsoid	7472	Volume Measurements
121220	Volume of circumscribed sphere	7472	Volume Measurements
121219	Volume of bounding three dimensional region	7472	Volume Measurements

A Quantity Measurement without a reference to images is illustrated below:

Figure 54: Quantity Measurement Observation example

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.6.2.14"/>
  <code code="439984002" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNM3"
displayName="Diameter of structure">
    <originalText>
      <reference value="#Diam2"/>
    </originalText>
  </code>
  <statusCode code="completed"/>
  <effectiveTime value="20060823223912"/>
  <value xsi:type="PQ" value="45" unit="mm">
  codeSystemVersion="1.5"/>
  </value>
  <!-- entryRelationships to SopInstance Observations may go here -->
</observation>
```

4 REFERENCES

- CDA Release 2.0: Clinical Document Architecture, Release 2.0, 2005, Health Level Seven, Inc.
- DICOM Template 2000 Basic Diagnostic Imaging Report, NEMA PS3.16-2008
- ISO-3166-1: Codes for the representation of names of countries and their subdivisions -- Part 1: Country codes, 1997, International Organization for Standardization
- ISO-639-1: Codes for the representation of names of languages--Part 1: Alpha-2 code, 2002, International Organization for Standardization
- LOINC®: Logical Observation Identifiers Names and Codes, Regenstrief Institute
- RFC 2806: URLs for Telephone Calls, 2000, A. Vaha-Sipila, The Internet Society
- RFC 2119: Key words for use in RFCs to Indicate Requirement Levels
- RFC 3066: Tags for the Identification of Languages, 2001, H. Alvestrand, The Internet Society
- Schematron: The Schematron Assertion Language 1.5, 2002, Rick Jelliffe, Academia Sinica Computing Centre
- SNOMED CT®: SNOMED Clinical Terms, 2002, SNOMED International Organization
- ITU-T X.667: International Telecommunication Union Series X: Data Networks and Open System Communications
- NUCC :Health Care Provider Taxonomy Code Set
- WADO Web Access to Persistent DICOM Objects, DICOM Standard PS 3.18
- DICOM CMET: HL7 V3 DICOM Common Message Element Type (CMET) with artifact id: COCT_RM830120UV.

APPENDIX A — VOCABULARY

This appendix describes the vocabularies used or defined by this specification and the Schematron schema that may be used to validate the content of the CDA Header for Diagnostic Imaging Report documents.

Administrative Gender

Administrative Gender codes used to describe the gender of the patient should come from the HL7 AdministrativeGender vocabulary. The OID for this vocabulary domain is `2.16.840.1.113883.5.1`.

Table 9: Administrative Gender

Code	Display Name	Description
F	Female	Female
M	Male	Male
UN	Undifferentiated	The gender of a person could not be uniquely defined as male or female, such as hermaphrodite.

Additional DICOM Utilized Code Systems

The code systems listed in Table 10 are used in DICOM and thus may be found in CDA Diagnostic Imaging Reports. OIDs listed as "TBD" are currently being requested by DICOM Working Group 6.

Table 10: Additional DICOM Utilized Code Systems

Code System	Full Name	OID
BARI	Bypass Angiography [6]Revascularization Investigation	TBD
BI[7]	ACR Breast Imaging Reporting and Data System (BI-RADS®BIRADS®[8]	TBD
MDNS	Universal Medical Device (UMD) Nomenclature System	2.16.840.1.113883.6.75
NCDR	American College of Cardiology National Cardiovascular Data Registry(TM) Cath Lab Module[9]	TBD
SCPECG	Standard Communications Protocol for Computer-Assisted Electrocardiography, Draft proposal for ISO Standard, AAMI, Revision 1.3	TBD

Null Flavors

Null Flavors are used to indicate why a required data element does not contain any information. The complete list is shown below for reference.

[6] Alderman,EL and Stadius, M, Coronary Artery Disease 1992,3:1189-1207;endorsed by ACC/AHA Guidelines for Coronary Angiography, J Am Coll Cardiol 1999,33:179.

[7] In the HL7 registry, the abbreviation BI is assigned to a different coding scheme, specifically the Beth Israel problem list.

[8] ACR Breast Imaging Reporting and Data System (BI-RADS®BIRAD®), Coding Scheme Version (0008,0103) is required; code values are section and paragraph identifiers within the publication where the code meaning is defined (e.g., "I.D.1", where I = Breast Imaging Lexicon, D = Special Cases, 1 = Tubular Density, as the code value for "Tubular Density").

[9] American College of Cardiology National Cardiovascular Data Registry(TM) Cath Lab Module Version 1.1, 1997; Version 2.0b, 1999.

Table 11: Null Flavor

Code	Display Name	Description
NI	NoInformation	No information whatsoever can be inferred from this exceptional value. This is the most general exceptional value. It is also the default exceptional value.
OTH	other	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).
NINF	negative infinity	Negative infinity of numbers.
PINF	positive infinity	Positive infinity of numbers.
UNK	unknown	A proper value is applicable, but not known.
ASKU	asked but unknown	Information was sought but not found (e.g., patient was asked but didn't know).
NAV	temporarily unavailable	Information is not available at this time but it is expected that it will be available later.
NASK	not asked	This information has not been sought (e.g., patient was not asked).
TRC	trace	The content is greater than zero, but too small to be quantified.
MSK	masked	There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information. Note: using this null flavor does provide information that may be a breach of confidentiality, even though no detail data is provided. Its primary purpose is for those circumstances where it is necessary to inform the receiver that the information does exist without providing any detail.
NA	not applicable	No proper value is applicable in this context (e.g., last menstrual period for a male).
NP	not present	Value is not present in a message. This is only defined in messages, never in application data! All values not present in the message must be replaced by the applicable default, or no-information (NI) as the default of all defaults.

Race

Race codes used to describe the race of the patient should come from the HL7 Race vocabulary. This vocabulary is too extensive to list in this document. The OID for this vocabulary domain is `2.16.840.1.113883.5.104`.

In the diagnostic reporting context, Race or Ethnicity as a CDA Header component is a confirming demographic attribute usually inherited from information systems providing orders or ADT information. In any circumstance where race or ethnicity is clinically relevant to report content, Race or Ethnicity shall be explicitly mentioned in the report narrative.

APPENDIX B — TEMPLATE IDS DEFINED IN THIS GUIDE

Template ID	Description
2.16.840.1.113883.10.20.6	CDA R2 Diagnostic Imaging Report (DIR) Implementation Guide
2.16.840.1.113883.10.20.6.1	DIR Section Template IDs
2.16.840.1.113883.10.20.6.1.1	DICOM Object Catalog Section (3.2.1)
2.16.840.1.113883.10.20.6.1.2	Findings Section (3.2.2)
2.16.840.1.113883.10.20.6.2	DIR Level 3 Content Template IDs
2.16.840.1.113883.10.20.6.2.1	Physician Reading Study Performer (2.16.1)
2.16.840.1.113883.10.20.6.2.2	Physician of Record Participant (2.19.1)
2.16.840.1.113883.10.20.6.2.3	Fetus Subject Context (3.1.2)
2.16.840.1.113883.10.20.6.2.4	Observer Context (3.1.3)
2.16.840.1.113883.10.20.6.2.5	Procedure Context (3.3.1)
2.16.840.1.113883.10.20.6.2.6	Study Act (3.3.2)
2.16.840.1.113883.10.20.6.2.8	SopInstance Observation (3.3.3)
2.16.840.1.113883.10.20.6.2.9	Purpose of Reference Observation (3.3.4)
2.16.840.1.113883.10.20.6.2.10	Referenced Frames Observation (3.3.5)
2.16.840.1.113883.10.20.6.2.11	Boundary Observation (3.3.6)
2.16.840.1.113883.10.20.6.2.12	Text Observation (3.3.7)
2.16.840.1.113883.10.20.6.2.13	Code Observation (3.3.8)
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