Integrating the Healthcare Enterprise

IHE Cardiology
Technical Framework Supplement

Cath Report Content
(CRC)

Revision 2.1 – Trial Implementation

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Foreword

This is a supplement to the IHE Cardiology Technical Framework 5.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Framework.

This supplement is published on July 25, 2016 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Cardiology Technical Framework. Comments are invited and can be submitted at http://www.ihe.net/Cardiology_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at www.ihe.net.

Information about the IHE Cardiology domain can be found at ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE Cardiology Technical Framework can be found at http://ihe.net/Technical_Frameworks.

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Introduction to this Supplement

This content profile is motivated by cardiologists, who face an increasing demand from patient-care, data-quality and legislative perspectives to increase the usefulness and actionability of (discrete) clinical data across the various care-settings and stakeholders.

A solution for such interoperability is, however, not a simple undertaking. Unstructured textual data forms remains the predominate mechanism for information exchange among health care providers, and a good majority of data needed by physicians and other health care providers to make good clinical decisions is embedded in this free text. Efficient and effective interoperability therefore begins by identifying the most relevant clinical data.

Clinically-relevant Cardiac Cath lab data is the key value proposition of this profile. The approach is to:

1. reuse the distribution and structuring work from the XDS (ITI domain), Medical summaries (PCC domain), and the HL7®[1] Implementation Guide for CDA®[2] Release 2: IHE Health Story Consolidation, Release 1.1 DSTU (C-CDA) for exchangeable procedure notes (HL7/IHE).
2. extend it through adding and codifying the ACC-NCDR Cath/PCI dataset and the ACC NCDR Cath/PCI version 4.4.
3. leverage clinical data standards like ICD9/10, SNOMED and LOINC.
4. extend it through adding and codifying the STS/ACC TVT Registry dataset version 2.0
5. evaluate it as it applies to the ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the Cardiac Catheterization Laboratory.

The aim is to enable collection and distribution of the most clinically-relevant discrete data on the cardiac catheterization procedures common in cardiology. The usage of the discrete data is three-fold:

1. To enable individual diagnostic and interventional cath procedures to be more easily shared and used between care givers and systems.
2. To enable population-based outcomes-based research on procedure effectiveness.
3. To harmonize data collection for procedural reports with data registries for data exchange.

These diagnostic and interventional cath procedures are used as key constituents of the patient's treatment during cardiac encounters and disease management. Allowing for a means to extract and exchange key cardiac measures across providers and their systems will be a huge advantage

[1] HL7 is the registered trademark of Health Level Seven International.

[2] CDA is the registered trademark of Health Level Seven International.

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to delivery of a complete, accessible and actionable cardiac data set to all stakeholder in the healthcare continuum.

There are very successful quality-improvement programs in place by the professional bodies such as the ACC, AHA, and state registries concentrating on the most invasive, and expensive cardiac procedures. However, the effort in translating and extracting the discrete data required by these registries still involves significant manual work and inefficiencies due to the absence of a standardized structuring of information at the point of clinical reporting.

This supplement provides a framework to make progress in these areas. This profile codifies representative areas of procedure indications, procedures, medications, observations, complications and findings for cardiac catheterization diagnostic and interventional procedures and specifies how this discrete data can be organized to be used by both care-providers and automated data processing systems.

Relationship to Workflow Profiles

Cath Report Content (CRC) is a *content* profile – it is agnostic with respect to the workflow or data exchange mechanism in which the data is produced and handled.

Content Profiles define how the content used in a transaction is structured. The binding of the Content to an IHE transaction that is part of an IHE Workflow Profile specifies how this payload may influence the metadata or the behavior of the transaction. Content modules within the Content Profile then define the payloads. Content modules are transaction neutral, in that what they describe is independent of the transaction in which they are used, whereas content bindings explain how the payload influences the transaction metadata and/ or behavior.

The CRC content is intended to be deployed, for example in the Displayable Reports (DRPT) Workflow Profile for in-patient environments, or the Cross-Enterprise Document Sharing (XDS) Profile to propagate the content across organizational boundaries.

It is important to note that that key report-generation/distribution workflow aspects such as physician identification, insurance preauthorization, report routing and acknowledgement, and patient consent, are **out of scope** for this content profile.

Cath Report Content (CRC) Profile

The Cath Report Content (CRC) Profile specifies the content structure for a clinical report of a cardiac catheterization imaging exam, that may include a DICOM®[3] Study. Such exams include:

[3] DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

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Procedure
Diagnostic Cardiac Catheterizations
Temporary LV Mechanical Support
Endomyocardial Biopsy
Right Heart Catheterization
Pericardiocentesis
Percutaneous Coronary Intervention (PCI)
Transatrial Aortic Valve Replacement (TAVR)
Transatrial Mitral Valve Replacement (TMVR)
Mitral Valve Repair (Mitraclip)

The CRC Profile specifies the use of an HL7 Clinical Document Architecture (CDA) format for the report. This format supports both the human readable narrative historically used for clinical reports, as well as a substantial set of discrete data elements that may be used for longitudinal or population analysis or other computer processing.

There may be a DICOM Study associated with the exam. In addition to reference images, the DICOM Study data may include discrete data elements encoded in DICOM Structured Report information objects that may be transcoded into the discrete data elements specified in this Profile. (See the Evidence Documents Profile and its cardiology options in IHE Card TF-1:7.)

The CRC Profile does not presume to describe the complete content of a cardiac catheterization laboratory report. It does provide the framework of high level section titles and a set of discrete data elements. Within that framework reports can be created with the clinical content desired by their authors, including additional discrete data elements. In general, there are no constraints on the narrative text and figures that the cardiologist could include in the report document, although there are requirements on minimum data elements reflecting expert consensus (ACC-NCDR Cath/PCI, ACCF-AHA Cardiac Cath Reporting workgroup).

This profile also does not provide all of the details necessary to construct a CDA compliant document. Please refer to the HL7 CDA Release 2 Standard.

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Open Issues and Questions

#	Open Issue Description
63	Table 6.3.6.7-1: Procedure Indications 1.3.6.1.4.1.19376.1.4.1.5.37 STATIC: It has been suggested that this table be updated to be harmonized with the RCS-C Profile Section 6.5.4.2.2.3.1.1 Pre-procedure Indication (templateId 1.3.6.1.4.1.19376.1.4.1.6.4.52. This is part of the update needed for PCI and should be done after public comment for the Structural Heart Additions.
57	Table 6.3.6.8-1: Result Observation Constraints 1.3.6.1.4.1.19376.1.4.1.5.38 STATIC: There is no LOINC Code for "Total pacing time." This measurement is part of Structural Heart Interventions and refers to the total time the heart is placed is rapid fibrillation during device deployment.
55	Vocabulary Constraints for Indications without SNOMED or LOINC definitions from Table 6.3.6.7-1: Procedure Indications 1.3.6.1.4.1.19376.1.4.1.5.37 STATIC: 1. Hostile Chest 2. IMA at High Risk of Injury
54	Vocabulary Constraints for Planned Procedure without SNOMED or LOINC definitions from Table 6.3.6.10-1: Cardiac Activity Procedures 1.3.6.1.4.1.19376.1.4.1.5.40 STATIC: 1. Percutaneous replacement of mitral valve using fluoroscopic guidance
53	Table 6.3.6.16-1: Complications 1.3.6.1.4.1.19376.1.4.1.5.46 STATIC: There are no SNOMED codes for the following TVT complications: Device Embolization Left Ventricle, Device Embolization Aorta
47	6.3.4.2 Medical History – Cardiac Section: There is codification available for: Hospital admission, transfer from other hospital or health care facility (SNOMED: 4563007) Should we develop codification for patient preprocedure status to communication status of "transferred from other provider"?

Closed Issues

#	Closed Issue Description/ Resolution
1	*Which document do we use on which to base this profile,* HL7 Consolidated CDA DSTU or the IHE_CARD_Suppl_CIRC_Rev1.1_TI 2011-06-24 content profile? A: The committee agreed to use the HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, Release 1.1 DSTU (July 2012 edition).

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#	Closed Issue Description/ Resolution
2	Generally, certain concepts represented by SNOMED compositions have been submitted for pre-coordinated codes. In CIRC, compositional coding was used to represent some concepts and there are still some in this profile. Requests were submitted to SNOMED for pre-coordinated codes that represent these compositions with a single code and we're waiting for these single codes to be provided by SNOMED. A: This single code (mid right coronary artery) – is available (450960006).
2a	Need to handle multiple performers for header, including authors and legal authenticators. A: Header either has allowances for multiple performers and has been expanded to include multiple authors and authenticators as need but is limited to a single legal authenticator as constrained by CDA.
3	How do we associate medical equipment with Procedures? A: Medical devices are described in the Procedures Description Cardiac Section.
4	What to do with US realm race code (7263), ethnicity (5323), do we really need race or ethnicity? A: All US realm specifics should be reflected in section (or Volume?) 4 of this content profile which will be done at a later date.
5	How do we associate procedures and findings, particularly coronary segments? A: We are using a Lesion ID (as an instance of a result observation "id") to link findings to procedures. The Lesion ID is associated with a coronary segment.
6	In medical history, do we need past and present illness? A: NO. The ACCF-AHA Cardiac Cath Reporting - ReportTemplate does not separate illness by past and present, and committee experience shows no real reason to separate these out, especially since there is an allowance to record if a problem is active in the Medical History Section.
7	How do we record more than one piece of information for a data concept, like a table format versus straight text in the rendered report? A: We can have structured elements in the coded data and if these elements appear in the narrative, they must be accurately rendered. In the narrative text, any valid HTML markup can be used, including markup used to render a table in HTML.
8	Q - Does the text narrative for every CDA construct need to completely contain the full coded content. A: If the ACT relationship is DRIV, then the narrative is based solely on the coded content. But does this need to include all the coded content?

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#	Closed Issue Description/ Resolution
	Technically it is not required, but all coded content SHOULD be included in the narrative. There SHALL be no conflicts between the narrative and the coded content. The coded content may not be an equivalent of the narrative. This has been added as a note in Section 6.3.1.4 (Conventions).
8a	What do we do with data fields that have coded values potentially cover multiple SNOMED codes, for example New York Class and Angina Class. A: We can use multiple SNOMED codes to describe the value needed based on CCDA.
9	CIRC has an Indications and Planned Procedure section and CCDA separates these into separate sections. A: We have adopted the C-CDA approach and will have a separate Procedure Indications Section and a Planned Procedure Section.
10	Some of these concepts identified in the NCDR CathPCI Registry v4.4 Coder's Data Dictionary do not seem to be "Yes/No" valued. Do they belong in the Complications section? A: No, only concepts that are SNOMED CT "findings" should be included in this section. This also includes disorders (which are also findings). a. Concepts that are procedures should be included in other sections b. Items that are measurements should be associated with the appropriate procedures c. If there are appropriate findings concepts for these procedures, these will be included in the complications list i. Renal failure ii. Anemia due to blood loss
11	Is there a need to create a specialization of the Problem Observation entry to reflect that there will not be either a Health Status entry or an Age Observation entry? A: We created a specialization of the problem observation entry to also include severity so we can set the cardinality of these other entries as needed for this specific use.
12	Is this content profile for US realm only or for Universal realm? A: This CRC Profile is realm agnostic and could be further extended for US-realm, Universal realm or any national extension.

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#	Closed Issue Description/ Resolution
13	How do we link Procedure Findings.Result Observation and Procedures.Procedure Activity Procedure entries? A: There is a new lesion ID which is intended to be used to link a Procedure Findings.Result Observation and Procedures.Procedure Activity Procedure entries which are for the same lesion.
14	Q - Can we use the segmental wall analysis, from IHE_CARD_Suppl_CIRC_Rev1.1_TI 2011-06-24 in a revised format to fit drawings from ACCF-AHA Cardiac Cath Reporting - ReportTemplate and other drawings performed by vendors? A: Yes, it is possible to include graphical representations (e.g., drawings) of coronary anatomy and segmental wall analysis to be embedded in the CDA document to be either embedded in-line or referenced via a URL. These are allowed at the document summary level.
15	Q - Which document content section should be used to record bruits (femoral, carotid)? A: These are recorded in the Vital Signs Section, see Value Set 1.3.6.1.4.1.19376.1.4.1.5.36
16	Q - Do we need an anesthesia section (e.g., for aortic valve replacement done in cath lab under general anesthesia)? A: We have the ability to record Local anesthetics and sedation administration in the Medications Administered Section if needed and have included an Anesthesia section to handle all other types of anesthesia
17	Q - The ACCF-AHA Cardiac Cath Reporting - ReportTemplate shows ICD9 coding sections for both pre and post diagnosis. How are postprocedure diagnoses determined and are the ICD-9 codes actually available at the time of producing this procedure note? A: After discussion, it was determined that some systems will have this information available at the time of the Procedure Note, so we have included language in preprocedure and postprocedure diagnosis to allow the inclusion of ICD9 coding.

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#	Closed Issue Description/ Resolution
18	If grafts were performed, the ACC coding only requires stenosis to be recorded for each of these systems. In the real world, a methodology should be used that uniquely identifies a graft and its related stenosis which can then be used for both Cath Lab and OR cardiac procedures. Q – do you agree?, and is this addressed in the ACCF-AHA Cardiac Cath Reporting – ReportTemplate? A: The ACCF-AHA Cardiac Cath Reporting – ReportTemplate does not reflect grafts in the samples but discussion centered on including graft descriptions that include an origin, type of conduit, and insert site. This has been allowed for by including these descriptions in text format by the Content Creator as part of the narrative for the Procedure Description Section (or any other section).
19	Q - In the Medical History section, is “health status observation” for the patient required or used? Or is “problem status” sufficient for each problem observation? A: C-CDA 1.1 provides a new value set for health status observation that is meaningful. For this initial CRC version, this will be available for use, if needed/desired.
19a	Q – can we have a shared single code for identifying cath and PCI document types? A: We have adopted Cath, PCI, and Cath/PCI document types for this content profile.
20	In the Medical History Section, should prior procedures be moved to the history section of Procedures. Logically they fit in this section but CCDA has a section for history in the procedures area. Q – does it make most clinical sense to put prior procedures in the medical history section of the report? A: Prior procedures have been included in the Medical History section.
21	Q – is there a good source of Cath Procedure Findings you can recommend? A: We have created a list of Procedure Findings that is extensible, which means it can be expanded as needed.
22	Q - Is this the complete set of complications that should be included in this profile? Are there other specific complications that should be added? (Complication Section)? A: We have included ACC-NCDR Cath/PCI complication values as a starting point in this extensible table. Expansion to other complications is at the Content Creator's discretion.
23	Q -Is There a need for the Procedures Specimens Taken section? A: Yes, the Section has been added and is based on the C-CDA definition. It can be used to handle biopsy and other specimens.

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#	Closed Issue Description/ Resolution
24	Q - Is there a need for the Procedure Implants section? A: No. This is required for EP and is out of scope for this CRC Profile.
25	Q - For the Medical History section, is there a need to identify the "severity" of the problem? A: Yes, possibly so we have added a "Severity Observation" entry to the Problem Observation entry in this section.
26	We are working with draft documents from the ACCF-AHA Cardiac Cath Reporting - ReportTemplate. We will need to revise our profile when this document is final. Q - When is expected completion? A: Per discussions at the PC F2F @ACC it will be available in 6 months from 3/25/2012.
27	Q - How is Hematoma size best represented clinically? This is not a complication but could be related to a complication (Complication Section). A: This should be treated a result observation related to the particular Problem Observation in the Complication Section. This is out of scope for this profile version.
28	Vol 1 - Section 12.3.1 – Should there be a binding to the IEO Profile? Technically there could be a binding to IEO, but practically it is questionable. IEO is targeted for cardiology practice offices. A: This profile is not targeted for the ambulatory setting so there should not be a binding to the IEO Profile. Text referencing IEO has been removed.
29	Need to remove C-CDA sections/entries that are unchanged. Also need to harmonize definitions of entries across sections within this profile. A: Done
30	Need to assign IHE Card specific template IDs for new/changed entries and vocabulary constraints. Entries highlighted in Table 6.3.3-1 need IHE Card specific template IDs. A: New template IDs were created for the CRC specific sections and entries.
31	Need better xml samples for all sections/entries. It would be useful to create XML of a complete sample report. A: Done
32	IVUS/IVOCT procedures are mention in the intro section as being in scope. No specific measurements are described elsewhere in the content specification. Should there be additional specific measurements for IVUS/IVOCT or should the intro section be modified to remove this from the scope for this profile?

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#	Closed Issue Description/ Resolution
	A: Removed references to IVUS/IVOCT from this specification. It is believed that support for IVUS/IVOCT requires additional vocabulary which could be added (via a CP) after complete analysis is done.
33	Need to assign unique constraint IDs to CRC specific constraints. A: This will be done by tooling from MDHT (when available) as part of the CDA template development process.
34	The intention is to have the CRC specific vocabulary sets be extensible and also not be based on a specific version of the vocabulary standard (e.g., SNOMED). This profile specifies all the CRC specific vocabulary sets as STATIC. The value sets can be extended where they are designated for use for a specific element specified as a CWE data type.
35	There are problems with C-CDA specification that should be submitted to HL7 and addressed by HL7. Need to compile list of these problems and IHE Card will submit them. A: A list of C-CDA errata was developed and submitted to HL7.
36	Q: Should the cardinality for Legal Authenticator be [0..1] or [1..1]. A:[1..1] because this profile does not support the exchange of preliminary unapproved reports (non – legally authenticated).
37	There is no code in Table 6.3.6.11 selected for Antiarrhythmics: Azimilide A: this is a general class 3 Antiarrhythmics (potassium channel antagonist), but no specific code was found. This entry was removed from the table.
39	In the Procedure Device Organizer – Cardiac entry, should the participant/participantRole/playingDevice be specified as “DEV” or “MMAT”? A: The more general MMAT will be used to specify the participant since this includes devices as well as the more general manufactured material (e.g., drug-coated stents).
40	In the Plan of Care Activity Act entry the statusCode is included in the C–CDA example but there is no constraint for it. CRC had added a constraint for statusCode in the Plan of Care Activity Act - Cardiac entry but this constraint has been removed since the status of the care activity act is represented in the moodCode for the Act. The use of statusCode is allowed, but CRC is silent on whether this should be included or not.
41	In the Problems/Concerns vocabulary constraints (Section 6.3.61.) there were codes included for therapy for diabetes and angina that were not problems/concerns. These included diabetes control (diet, oral, insulin), CAD presentation, onset of illness, thrombolytic therapy, anginal class, anti-anginal medication (beta blockers, calcium channel blockers, long acting nitrates, ranolazine), and NYHA Class. These were

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#	Closed Issue Description/ Resolution
	removed from this vocabulary constraint set. How these are represented needs to be addressed – potentially leveraging the CIRC mechanism for diabetes and angina problem entries. This will be addressed when this profile is harmonized with CIRC and during development of the NCDR registry submission content profile.
42	The question was asked if the CRC Profile should support peripheral vascular diagnostic and interventional procedures since PCI and SHIP procedures may include interventional peripheral vascular procedures performed during procedures such as TAVR. Response: not during the current 2015 – 2016 development cycle
45	Should the Content Creator be required to support structural heart interventions reporting or should we create optionality? The author is concerned that optionality by document type (DIAG, PCI, TAVR, LAAO) is problematic. Response: Support for structural heart interventions is optional.
46	Should this version of the CRC Profile support peripheral vascular diagnostic and interventional procedures as SHIP procedures often include both diagnostic and interventional peripheral vascular procedure components. RESPONSE: This is not within the scope of this release of the CRC, but may be included in a future work item.
49	6.3.2 Cath Report Content Header Element Constraints: requires a Study Instance UID for DICOM imaging data. Practices vary between institutions, but at some there is no cine fluoroscopic imaging performed for biopsy or RHC. There is concern surrounding the need for medical-legal documentation of the procedure in light of aggressive limitation of cine for patient radiation safety. (State this as a solicitation for public comment.)
51	CLOSED: 6.3.4.16 Procedure Results – Cardiac Section 30954-2: Interventional procedure including PCI and structural heart interventions include measurements and observations done before (baseline) and after (post-procedure) the intervention. Separate Results Organizers for baseline and post-procedure measurements and observations can be used to organize the procedure results.
56	Section 12.2.1 Content Consumer Options: Modified to accommodate Diagnostic, PCI and Structural Heart Interventions. Needs to be reviewed by the committee for appropriate language and included constraints.
58	Table 6.3.6.8-1: Result Observation Constraints 1.3.6.1.4.1.19376.1.4.1.5.38 STATIC: Procedure Type Condition: StHrt-Int has been added for those measurement include in TAVR, TMVR and Mitral Clip procedures. This needs to be reviewed by the committee for accuracy.
62	Table 6.3.6.7-1: Procedure Indications 1.3.6.1.4.1.19376.1.4.1.5.37 STATIC: The following items were removed from the table: chest pain, Heart disease risk

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#	Closed Issue Description/ Resolution
	factors, Post PTCA, History of CABG, Abnormal ECG, Arrhythmia, Hypertension, Palpitation, Supraventricular Tachycardia, H/O myocardial infarction, LBBB, Heart disease, perioperative evaluation, structural disorder of heart, pericardial disease, liver disease, Occupational requirement.

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Volume 1 – Profiles

12 Cath Report Content Profile (CRC)

The Cath Report Content (CRC) Profile specifies the content structure for a clinical report of a cardiology procedure recorded in a Cardiac Cath Lab. Such procedures include:

Table 12-1: CRC Profile Supported Procedures

Procedure
Diagnostic Cardiac Catheterizations
Temporary LV Mechanical Support
Endomyocardial Biopsy
Right Heart Catheterization
Pericardiocentesis
Percutaneous Coronary Intervention (PCI)
Transatrial Aortic Valve Replacement (TAVR)
Transatrial Mitral Valve Replacement (TMVR)
Mitral Valve Repair (Mitraclip)

The CRC Profile specifies the use of an HL7 Clinical Document Architecture (CDA) format for the report.

Not included in the scope of this profile are imaging studies (e.g., echocardiography) and electrophysiology procedures.

This profile also does not provide all of the details necessary to construct a CDA compliant document. Please refer to the HL7 CDA Release 2 Standard.

12.1 CRC Actors, Transactions, and Content Modules

Figure 12.1-1 shows the actors directly involved in the CRC Profile and the relevant transactions between them. There are two actors in this profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of other IHE profiles, and is out of scope of this profile; hence there is no transaction per se defined for this profile.

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Figure 12.1-1: Cath Report Template Actor Diagram

Note: The primary intended transmission mechanism in the intra-institutional context is the IHE Displayable Reports Profile (DRPT), and in the inter-institutional context the IHE Portable Data for Imaging (PDI) or IHE Cross Enterprise Document Sharing Profiles (XDS, XDM, and XDR). A Report Creator, Document Source or a Portable Media Creator of those profiles may embody the Content Creator. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer.

12.1.1 Actor Descriptions and Actor Profile Requirements

12.1.1.1 Content Creator

1. A Content Creator shall be able to create a Cath Procedure Report according to the specifications for that content profile found in CARD TF-3 as defined in the optionality of Table 12.2-1: CRC Profile Options.
2. A Content Creator shall support at least one of the options of Table 12.2-1: CRC Profile Options.
3. A Content Creator shall be grouped with the Time Client and shall synchronize its clock with a Time Server.

12.1.1.2 Content Consumer

1. A Content Consumer shall be able to consume (receive and process) a Cath Procedure Report document.
2. A Content Consumer shall implement the View Option or Discrete Data Import Option, or both.
3. A Content Consumer that implements the Document Import or Section Import Option shall implement the View Option as well.
4. A Content Consumer that implements the View Option shall be able to:
   a. Demonstrate rendering of the document for display.
   b. Print the document.
   c. Display the document with its original style sheet.
   d. Support traversal of any links contained within the document.
5. A Content Consumer that implements the Document Import Option shall:
   a. Store the document.
   b. Demonstrate the ability to access the document again from that storage.

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6. A Content Consumer that implements the Section Import Option shall offer a means to import one or more document sections into the patient record as free text.
7. A Content Consumer that implements the Discrete Data Import Option shall offer a means to import structured data from one or more sections of the document.

12.2 CRC Actor Options

Options that may be selected for this Content Profile are listed in Table 12.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 12.2-1: CRC Profile Options

Actor	Option Name	Optionality	Section
Content Consumer	View Option	O (see 12.2.1)	PCC TF-2 :3.1.1
	Document Import Option	O (see 12.2.1)	PCC TF-2 :3.1.2
	Section Import Option	O (see 12.2.1)	PCC TF-2 :3.1.3
	Discrete Data Import Option	O (see 12.2.1)	PCC TF-2 :3.1.4
Content Creator	Diagnostic	O (see Note)	CARD TF-1:12.2.2
	PCI	O (see Note)	CARD TF-1:12.2.3
	Structural Heart Intervention	O (see Note)	CARD TF-1:12.2.4

Note: A Content Creator shall support at least one of these options.

Options have been specified for Content Creator based upon which of the procedure types the Content Creator is able to support. A conformant Content Consumer must be able to consume all procedure types. The Content Creator options vary only by procedure type supported. Content requirements and constraints apply to all procedure types unless explicitly stated otherwise. Within this specification the variation in content requirements are expressed in two ways:

1. **Conditional Constraint**: Constraints which are particular to one procedure type are preceded by the phrase “If procedure type=” followed by the code for the procedure type for which the conditional constraint applies: “Diagnostic”, “PCI” or “Structural Heart Intervention.” (Abbreviation StHrt-Int is used) By default the constraint applies to all procedure types.
2. **Value-set Member Scope**: Each member of a value set includes an indication as to which procedure type it applies: “Diagnostic”, “PCI” or “Structural Heart Intervention.” If “All” is specified, then the value set member applies to all procedure types.

12.2.1 Content Consumer Options

The Content Consumer is required to support at least one of the View or Discrete Data Import Options. The Document Import and Section Import Options, if implemented, also require the

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View Option. These options as specified in the PCC Technical Framework assume use of XDS or related profiles for transport; this profile specifies bindings to other workflow profiles (see Section IHE CARD TF-1:12.7), and these options should be interpreted as applicable with any binding.

12.2.2 Diagnostic Option

The Content Creator that supports the Diagnostic Option should support the following Procedures listed below:

Procedure
Diagnostic Cardiac Catheterizations
Temporary LV Mechanical Support
Endomyocardial Biopsy
Right Heart Catheterization
Pericardiocentesis

12.2.3 PCI Option

The Content Creator that supports the PCI Option shall also support the Diagnostic Option and the following procedures listed below:

1. PCI

12.2.4 Structural Heart Intervention Option

The Content Creator that supports the Structural Heart Intervention Option shall be capable of supporting both the Diagnostic and PCI Options and at least one of the following procedures listed below:

1. Percutaneous replacement of aortic valve using fluoroscopic guidance
2. Percutaneous replacement of mitral valve using fluoroscopic guidance
3. Repair of mitral valve using fluoroscopic guidance (mitral valve clip)

12.3 CRC Actor Required Groupings

The Content Creator shall be grouped with Time Client of the IHE IT Infrastructure Consistent Time Profile, as specified in ITI TF-1:7. This allows the Legal Authentication timestamp to be accurate.

Content modules describe the content of a payload found in an IHE transaction. Content profiles are transaction neutral. They do not have dependencies upon the transaction that they appear in.

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12.4 CRC Document Content Module

There is often a very clear distinction between the transactions in a messaging framework used to package and transmit information, and the information content actually transmitted in those messages. This is especially true when the messaging framework begins to move towards mainstream computing infrastructures being adopted by the healthcare industry.

In these cases, the same transactions may be used to support a wide variety of use cases in healthcare, and so more and more the content and use of the message also needs to be profiled, sometimes separately from the transaction itself. Towards this end IHE has developed the concept of a Content Profile.

Content Profiles specify how the payload of a transaction fits into a specific use of that transaction. A content profile has three main parts. The first part describes the use case (this is found in Volume 1 in the definition of each Profile). The second part is a Content Module (found in this Volume 3), which describes the payload of the transaction; a content module is specified so as to be independent of the transaction in which it appears. The third part is binding to a specific IHE transaction, which describes how the content affects the transaction. The binding of CDA-based medical documents to workflow transactions is described in the profile definition in Volume 1 (e.g., see IHE CARD TF-1:12.7).

12.5 CRC Overview

The Cath Report Content (CRC) Profile specifies the content structure for a clinical cath procedure report. Such procedures include those in Table 12-1: CRC Profile Supported Procedures.

The CRC Profile specifies the use of an HL7 Clinical Document Architecture (CDA) format for the cath procedure report. This format supports both the human readable narrative historically used for clinical reports, as well as a substantial set of discrete data elements that may be used for longitudinal or population analysis or other computer processing.

There may be a DICOM Study associated with the exam. In addition to reference images, the DICOM Study data may include discrete data elements encoded in DICOM Structured Report information objects that may be transcoded into the discrete data elements specified in this Profile. (See the Evidence Documents Profile and its cardiology options in Section 7.)

The CRC Profile does not presume to describe the complete content of an imaging study report. It does provide the framework of high level section titles and a set of discrete data elements. Within that framework reports can be created with the clinical content desired by their authors, including additional discrete data elements. In general, there are no constraints on the narrative text and figures that the cardiologist could include in the report document, although there are requirements on minimum data elements reflecting expert consensus (ACC-NCDR Cath PCI data elements)

This profile also does not provide all of the details necessary to construct a CDA compliant document. Please refer to the HL7 CDA Release 2 Standard.

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12.5.1 Concepts

Not applicable

12.5.2 Use Case #1: Compile and Transfer Cath Procedure Report with Use of ACC-NCDR Cath/PCI Data Elements

12.5.2.1 Compile and Transfer Cath Procedure Report with Use of ACC-NCDR Cath/PCI Data Elements Use Case Description

This use case addresses the generation and transfer of a cath procedure report based on either or both of the: A.) NCDR CathPCI Registry v4.4 Coder's Data Dictionary data elements and B.) STS/ACC TVT Registry™ v2.0 Coder's Data Dictionary. The initial content, structure and coding of the report to support this use case are detailed as part of this profile (see IHE CARD TF-3: 6 Content Modules). However various reporting system implementations, institute reporting guidelines and individual Reporting Physician usage may result in some variability in the specific report content provided.

12.5.2.2 Compile and Transfer Cath Procedure Report with Use of ACC-NCDR Cath/PCI Data Elements Process Flow

Pre conditions

The systems underlying the data collection and management for the various elements of the cath procedure report have all the *mandatory* data elements identified using codes, and are expected to be the source for the information used in creating the *majority* of the cath procedure report document.

Main Flow

- Cardiologist reviews and/or records the codified
  - procedures and protocols used in the procedure
  - Data generated from the various modalities and monitoring equipment used during the procedure so that the key physiological measures, acquired and derived (pre, during and post intervention) are present in line with the ACC-NCDR Cath/PCI guidelines.
  - Other relevant patient characteristics
  - Medications documented for the patient both pre and during procedure.
  - Equipment used and implanted in the patient
  - Indications and observations/complications noticed during the procedure.
  - Findings, assessment and plan
- Cardiologist approves the procedure report and this marks it ready for distribution

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- The Content Creator system will format the report appropriately (this profile) and send it via one of the IHE mechanisms to a content consumer system (an appropriate workflow profile).

Post conditions

The subsequent clinical stakeholder (system) receives the Document for import, processing and optionally viewing of the data.

12.5.3 Use Case #2: Perform Discrete Data-analysis on Procedure Report Content

12.5.3.1 Perform Discrete Data-analysis on Procedure Report Content Use Case Description

The goal of this use case is to assist data collection for comparative and research purposes. Based on a report generated in the previous use cases an advanced medical data analysis system collects discrete data from multiple patients and their procedure, e.g., for cardiac Clinical Decision Support or for advanced lifetime patient records.

12.5.3.2 Perform Discrete Data-analysis on Procedure Report Content Process Flow

Pre conditions

The Content Consumer (e.g., an advanced medical data analysis system) received a cath procedure report with coded/structured content as defined in IHE CARD TF-3: 6 CDA Release 2 Content Modules.

Main Flow

The consuming system collects and processes the data from the various reports it receives and extracts those relevant data for either:

- A specific clinical concern for a population e.g., pre-populating a procedure-specific registry; extracting a data subset for a specific research question.
- A more comprehensive longitudinal patient record (e.g., an EMR) which can provide trending over time on an individual patient's key cardiac measures.

Post conditions

The Content Consumer generated new (derived) data for use by others. The type of data generated is out of the scope of this profile.

12.5.4 Use Case #3: Review Procedure Report

12.5.4.1 Review Procedure Report Use Case Description

A secondary use-case addressed by this profile involves the direct human use of the procedure report. In most practical cases this will be:

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- The referring physician who instigated/ordered the procedure, and other healthcare providers who manage subsequent patient care activities
- Another person involved in downstream clinical or administrative data processing e.g., someone validating/source-checking for QA the original report as part of JCAHO audits, or pre-submission checking on the original reporting data against the case-data imported in the ACC-NCDR Cath/PCI registry-submission application

12.5.4.2 Review Procedure Report Process Flow

Pre conditions

- The Reviewing Physician consumer has a system (EMR or other) capable of importing and displaying the received report in a clinically useful format
- The cath procedure report has been received at this system

Note: This profile does not assume any explicitly specified relationship between the creator and consumer.

Main Flow

- The reviewing physician selects the report of his patient and opens it for review
- The system displays the human readable content for the reviewing physician to review

Post conditions

The Reviewer has extracted (visually) the necessary information from the report.

12.6 CRC Security Considerations

Security considerations are dealt with by the transport mechanism (e.g., XDS, DRPT) and are outside the scope of this content profile. See PCC TF-1: 3.8

12.7 CRC Cross Profile Considerations

A Content Creator or Content Consumer should be grouped with appropriate actors from workflow profiles that manage interchange of clinical data. Such groupings are described in this section.

Content profiles may impose additional requirements on the transactions used when grouped with actors from other IHE Profiles. The metadata sent in the document sharing or interchange messages has specific relationships to the content of the clinical document described in the content profile. These mappings between the workflow metadata and the content attributes are described in IHE PCC TF-2:4.

12.7.1 Content Bindings for Displayable Reports (DRPT) Profiles

CDA documents using the CRC content may be exchanged between a Report Creator and a Report Manager, as defined in the Displayable Reports (DRPT) Profile using the Encapsulated Report Submission [CARD-7] transaction. In this case, the CRC Content Creator is grouped with

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the DRPT Report Creator, and the CRC Content Consumer is grouped with the DRPT Report Manager.

12.7.2 Content Bindings for XDS, XDM, XDR, XDS-I, and XDR-I

It is expected that the transfers of care will occur in an environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ) and notification of availability of documents (NAV). An extension for imaging study exchange is Cross Enterprise Document Sharing for Imaging (XDS-I).
- A media-based infrastructure is defined by the IHE Cross Enterprise Document Media Interchange (XDM) Profile.
- A reliable messaging-based infrastructure is defined by the IHE Cross Enterprise Document Reliable Interchange (XDR) Profile. An extension for imaging study exchange is Cross Enterprise Document Reliable Interchange for Imaging (XDR-I).
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) Profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, and the IHE Radiology Technical Framework for XDS-I and XDR-I.

Document Source and Document Consumer Actors from the ITI XDS, XDM and XDR Profiles are logically grouped with the CRC Content Creator and Content Consumer Actors, respectively.

12.7.3 Binding for Portable Data for Imaging (PDI)

CDA documents using the CRC content may be exchanged on interchange media in accordance with the Portable Data for Imaging (PDI) Profile. Such documents may be encapsulated within DICOM SOP Instances, or may be native CDA documents, as described in the IHE Radiology Technical Framework. In this case, the CRC Content Creator is grouped with the PDI Portable Media Creator, and the CRC Content Consumer is grouped with the PDI Display or Portable Media Importer Actors.

12.7.4 Content Binding for Retrieve Form for Data Capture (RFD)

A CDA document may be used for pre-population of a data entry form managed by actors of the Retrieve Form for Data Capture (RFD) Profile. In particular, the CRC content, as a carrier of discrete encoded data, may be used to pre-populate data entry forms for cardiovascular data registries. The CRC Profile has been developed with key data elements that support common research related data fields. This profile, however, does not provide mapping between CRC field content and any specific registry field content. In this case, the CRC Content Consumer is

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grouped with the RFD Form Manager for the purpose of extracting discrete data from the report to pre-populate the data capture form.

12.7.5 Relationship to Document Digital Signature (DSG)

When a Content Creator needs to digitally sign a document in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source. When a Content Consumer needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

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Appendices

Actor Summary Definitions

Add the following terms to the IHE TF General Introduction Namespace list of Actors:

None

Transaction Summary Definitions

Add the following terms to the IHE TF General Introduction Namespace list of Transactions:

None

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Glossary

Add the following terms to the IHE Technical Frameworks General Introduction Glossary:

None

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Volume 3 – Content Modules

Add Section 6.3

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6 Content Modules

6.3 Cath Report Content Modules

6.3.1 Cath Report Content Specification 1.3.6.1.4.1.19376.1.4.1.1.2

This is the template for Cardiac Catheterization Diagnostic and Interventional Reports (hereafter, cath procedure reports) with support for discrete data elements as described in the following NCDR data dictionaries that are collected just prior to and during the procedure:

1. CathPCI Registry version 4.4 Coder's Data Dictionary.
2. STS/ACC TVT Registry 2.0 Coder's Data Dictionary for Transcatheter Aortic Valve Replacement procedures, Transcatheter Mitral Valve-in-Valve or Valve-in-Ring procedures, and Transcatheter Mitral Leaflet Clip Valve Procedures

The Template ID for conformance to this template is OID = 1.3.6.1.4.1.19376.1.4.1.1.2.

This CDA document is not a direct specialization of any existing CDA document template ID. However, some parts were based on the IHE Card CIRC document specification and the HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, Release 1.1 DSTU - July 2012 (C-CDA) Procedure Note document specification.

6.3.1.1 Format Code

The XDSDocumentEntry format code for this content is **urn:ihe:card:CRC:2012**

The mapping of CDA header attributes to XDS metadata shall be identical to the XDS-MS mapping specified in PCC TF-2: 4.1.1.

6.3.1.2 Relationship to the IHE Cardiology CIRC Profile

This CRC document is inconsistent with the existing Cardiac Imaging Report Content (CIRC) content profile that was published for Trial Implementation in 2011.

These inconsistencies include:

- Overall document structure
- This is not based on the IHE PCC section and entry templates but is based on the C-CDA section and entry templates.

6.3.1.3 Relationship to C-CDA

Some CDA section and entries used within this CRC document were based on the HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, Release 1.1 DSTU (C-CDA) section and entry definitions.

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a. Where constraints defined in C-CDA were not modified, the constraint remains as the C-CDA constraint identifier (e.g., CONF:5361). If only the value set was modified, then the constraint is considered unchanged.

b. Where constraints defined in C-CDA were modified, the original constraint ID is also modified by appending "-CRC" (e.g., CONF:5253-CRC). Modifications could include changes in the cardinality.

c. Where new constraints were introduced, a new constraint identifier was defined (e.g., CONF:CRC-xxx)

If there are no new or modified constraints for a section or entry or if only the value sets are constrained, then the definition of the section or entry is considered unchanged from the C-CDA definition and the C-CDA template Id will be used. These unchanged sections/entries are referenced directly from the C-CDA specification and are not included in this specification.

If there are new or modified constraints for a section or entry, then that section or entry is assigned a new IHE Card specific template Id.

The description of the type of modification to affected section or entry content modules are outlined with boxes.

6.3.1.4 Conventions

6.3.1.4.1 Conformance Terms

The definitions of the conformance verbs, the terms *optional* and *required* and the cardinality indicator are as defined in C-CDA Section 1.8 – Conformance Conventions.

6.3.1.4.2 Narrative requirements

There is no general requirement for the section text narrative to completely contain the full coded content of all the elements of the section and its contained entries. However, for this profile, it is recommended that all coded content in the section and its contained entries SHOULD be included in the narrative for each section. In any case, there SHALL be no conflicts between the narrative and the coded content.

In the case where the section ACT relationship is specified to be "DRIV" (derived), then the section narrative SHALL be based solely on the coded content. This narrative content SHOULD include as much of the coded content as possible.

The coded content may not be an equivalent of the narrative.

6.3.1.5 Standards

The following table identifies the standards upon which this specification is based.

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Table 6.3.1.5-1: Reference Standards

Standard Name (short)	Standard Name (full)	Reference to Published Standard
CathPCI Registry	NCDR CathPCI Registry v4.4 Coder's Data Dictionary	https://www.ncdr.com/WebNCDR/docs/public-data-collection-documents/cathpci_v4_codersdictionary_4-4.pdf?sfvrsn=2
STS/ACC TVT Registry	STS/ACC TVT Registry™ v2.0 Coder's Data Dictionary	https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry-2_0_coderdatadictionary.pdf?sfvrsn=2
CDAR2	HL7 CDA Release 2.0	http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition2010.zip
C-CDA	HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
DICOM	NEMA PS3.16 – DICOM Part 16: Content Mapping Resource	http://dicom.nema.org/standard.html

6.3.2 Cath Report Content Header Element Constraints

The header for the Cardiac Report Content document shall support the following header constraints as noted in this section. Note that this content profile is realm agnostic. These header constraints are based on the C-CDA header constraints but all references to US Realm specific types have been removed.

1. **SHALL** contain exactly one [1..1] **`typeId`** (CONF:5361).
    a. This typeId **SHALL** contain exactly one [1..1] **`@root`**="`2.16.840.1.113883.1.3`" (CONF:5250).
    b. This typeId **SHALL** contain exactly one [1..1] **`@extension`**="`POCD_HD000040`" (CONF:5251).
2. **SHALL** contain exactly one [1..1] **`templateId`** (CONF:5252) such that it
    a. **SHALL** contain exactly one [1..1] **`@root`**="`1.3.6.1.4.1.19376.1.4.1.1.2`" for the Cath Report Content document template (CONF:CRC-xxx).
3. **SHALL** contain exactly one [1..1] **`id`** (CONF:5363).
    a. This id **SHALL** be a globally unique identifier for the document (CONF:9991).
4. **SHALL** contain exactly one [1..1] **`code`** (CONF:5253).
    a. This code **SHALL** contain exactly one [1..1] **`@code`**, which **SHALL** be selected from ValueSet `ProcedureNoteDocumentTypeCodes` `2.16.840.1.113883.11.20.6.1` **DYNAMIC** (CONF:17183). Either of the following codes should be included:

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Value Set: ProcedureNoteDocumentTypeCodes 2.16.840.1.113883.11.20.6.1 DYNAMIC Code System: LOINC 2.16.840.1.113883.6.1			
LOINC Code	**Type of Service 'Component'**	**Setting 'System'**	**Specialty/Training/Professional Level 'Method_Type'**
18745-0	Study report	Heart	Cardiac catheterization
34896-1	Interventional procedure note	{Setting}	Cardiology

5. **SHALL** contain exactly one [1..1] **`title`** (CONF:5254).
    a. Can either be a locally defined name or the display name corresponding to clinicalDocument/code (CONF:5255).
6. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF:5256).
    a. Signifies the document creation time, when the document first came into being. Where the CDA document is a transform from an original document in some other format, the ClinicalDocument.effectiveTime is the time the original document was created. The time when the transform occurred is not currently represented in CDA (CONF:9995).
7. **SHALL** contain exactly one [1..1] **`confidentialityCode`**, which **SHOULD** be selected from ValueSet `HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926` **STATIC** 2010-04-21 (CONF:5259).

```
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<!—CRC Template -->
<templateId root="1.3.6.1.4.1.19376.1.4.1.1.2"/>
<id extension="999021" root="2.16.840.1.113883.19"/>
<code codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" code="18745-0"
      displayName="Cardiac catheterization study report"/>
<title>Cardiac catheterization study report</title>
<effectiveTime value="20050329171504+0500"/>
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
```

Figure 6.3.2-1: header example

8. **SHALL** contain exactly one [1..1] **`recordTarget`** (CONF:5266-CRC). The recordTarget records the patient whose health information is described by the clinical document.
    a. This recordTarget **SHALL** contain exactly one [1..1] **`patientRole`** (CONF:5267).
        i. This patientRole **SHALL** contain at least one [1..*] **`id`** (CONF:5268)
        ii. This patientRole **SHALL** contain at least one [1..*] **`addr`** (CONF:5271).
            1. This addr **SHALL** contain at least one [1..*] **`postalCode`** (CONF:CRC-xxx).

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iii. This patientRole **SHALL** contain at least one [1..*] **telecom** (CONF:5280).

iv. This patientRole **SHALL** contain exactly one [1..1] **patient** (CONF:5283).

1. This patient **SHALL** contain exactly one [1..1] **name** (CONF:5284).
    a. This name **SHALL** contain exactly one [1..1] **family** (CONF:7159).
    b. This name **SHALL** contain at least one [1..*] **given** (CONF:7157).
        i. The second occurrence of given (given[2]) if provided, **SHALL** include middle name or middle initial (CONF:7163).
2. This patient **SHALL** contain exactly one [1..1] **administrativeGenderCode**, which **SHALL** be selected from ValueSet `Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1` **DYNAMIC** (CONF:6394).
3. This patient **SHALL** contain exactly one [1..1] **birthTime** (CONF:5298).
    a. **SHALL** be precise to year (CONF:5299).
    b. **SHOULD** be precise to day (CONF:5300).

```
<recordTarget>
  <patientRole>
    <id extension="12345" root="2.16.840.1.113883.19"/>
    <addr use="HP">
       <streetAddressLine>17 Daws Rd.</streetAddressLine>
       <city>Blue Bell</city>
       <state>MA</state>
       <postalCode>02368</postalCode>
       <country>US</country>
    </addr>
    <telecom value="tel:(781)555-1212" use="HP"/>
    <patient>
       <name>
          <prefix>Mr.</prefix>
          <given>Adam</given>
          <given>Frankie</given>
          <family>Everyman</family>
       </name>
       <administrativeGenderCode code="M"
              codeSystem="2.16.840.1.113883.5.1" displayName="Male"/>
       <birthTime value="19541125"/>
    </patient>
  </patientRole>
</recordTarget>
```

Figure 6.3.2-2: recordTarget example

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9. **SHALL** contain at least one [1..*] **author** (CONF:5444). The author element represents the person who created the clinical document. If there are multiple procedures performed, there may be multiple authors for the content of this document.
    a. Such authors **SHALL** contain exactly one [1..1] **time** (CONF:5445). This is the time the author started to contribute to this document.
    b. Such authors **SHALL** contain exactly one [1..1] **assignedAuthor** (CONF:5448).
        i. This assignedAuthor **SHALL** contain exactly one [1..1] **id** (CONF:5449).
        i. This assignedAuthor **SHALL** contain at least one [1..*] **addr** (CONF:5452).
        ii. This assignedAuthor **SHALL** contain at least one [1..*] **telecom** (CONF:5428).
        iii. This assignedAuthor **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5430-CRC).
            1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:16789).

```
<author>
  <time value="20120329224411+0500"/>
  <assignedAuthor>
     <id extension="KP00017" root="2.16.840.1.113883.19.5"/>
     <addr>
        <streetAddressLine>21 North Ave.</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>US</country>
     </addr>
     <telecom use="WP" value="tel:(555)555-1003"/>
     <assignedPerson>
        <name>
           <given>Henry</given>
           <family>Seven</family>
        </name>
     </assignedPerson>
  </assignedAuthor>
</author>
```

Figure 6.3.2-3: Person author example

10. **SHALL** contain exactly one [1..1] **custodian** (CONF:5519).
    a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:5520).
        i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** (CONF:5521).

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1. This representedCustodianOrganization **SHALL** contain at least one [1..*] **id** (CONF:5522).
2. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name** (CONF:5524).
3. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **telecom** (CONF:5525).
4. This representedCustodianOrganization **SHALL** contain at least one [1..*] **addr** (CONF:5559).

```
<custodian>
  <assignedCustodian>
     <representedCustodianOrganization>
        <id root="2.16.840.1.113883.19.5"/>
        <name>Good Health Clinic</name>
        <telecom value="tel:(555)555-1212" use="WP"/>
        <addr use="WP">
           <streetAddressLine>17 Daws Rd.</streetAddressLine>
           <city>Blue Bell</city>
           <state>MA</state>
           <postalCode>02368</postalCode>
           <country>US</country>
        </addr>
     </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

Figure 6.3.2-4: custodian example

11. **SHALL** contain exactly one [1..1] **legalAuthenticator** (CONF:5579-CRC).
    a. This legalAuthenticator **SHALL** contain exactly one [1..1] **time** (CONF:5580).
    b. This legalAuthenticator **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5583).
        i. This signatureCode **SHALL** contain exactly one [1..1] **@code**="S" (CodeSystem: `Participationsignature 2.16.840.1.113883.5.89`) (CONF:5584).
    c. This legalAuthenticator **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5585).
        i. This **assignedEntity** **SHALL** contain at least one [1..*] **id** (CONF:5586).
        ii. This assignedEntity **MAY** contain zero or one [0..1] **code** (CONF:17000-CRC).
        ii. This assignedEntity **SHALL** contain at least one [1..*] **addr** (CONF:5589).
        iii. This assignedEntity **SHALL** contain at least one [1..*] **telecom** (CONF:5595).
            1. Such telecoms **SHOULD** contain **@use** (CONF:7999-CRC).

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iv. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5597).

1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:5598).

The **legalAuthenticator** identifies the single person legally responsible for the document and must be present if the document has been legally authenticated.

```
<legalAuthenticator>
  <time value="20050329224411+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
     <id extension="KP00017A" root="2.16.840.1.113883.19"/>
     <addr>
        <streetAddressLine>21 North Ave.</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>US</country>
     </addr>
     <telecom use="WP" value="tel:(555)555-1003"/>
     <assignedPerson>
        <name>
           <given>Henry</given>
           <family>Seven</family>
        </name>
     </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
```

Figure 6.3.2-5: legalAuthenticator example

12. **MAY** contain zero or more [0..*] **authenticator** (CONF:5607).
    a. Such authenticators, if present, **SHALL** contain exactly one [1..1] **time** (CONF:5608).
    b. Such authenticators, if present, **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5610).
        i. This signatureCode **SHALL** contain exactly one [1..1] **@code**="S" (CodeSystem: `Participationsignature 2.16.840.1.113883.5.89`) (CONF:5611).
    c. Such authenticators, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5612).
        i. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:5613).
        iii. This assignedEntity **SHALL** contain at least one [1..*] **addr** (CONF:5616).
        ii. This assignedEntity **SHALL** contain at least one [1..*] **telecom** (CONF:5622).

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iii. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5624).

1. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:5625).

The **authenticator** identifies a participant or participants who attested to the accuracy of the information in the document. There may be one authenticator for the content for each of the Cath procedures – e.g., diagnostic and PCI.

```
<authenticator>
  <time value="20050329224411+0500"/>
  <signatureCode code="S"/>
  <assignedEntity>
     <id extension="KP00017" root="2.16.840.1.113883.19"/>
     <addr>
        <streetAddressLine>21 North Ave.</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>02368</postalCode>
        <country>US</country>
     </addr>
     <telecom use="WP" value="tel:(555)555-1003"/>
     <assignedPerson>
        <name>
           <given>Henry</given>
           <family>Seven</family>
        </name>
     </assignedPerson>
  </assignedEntity>
</authenticator>
```

Figure 6.3.2-6: Authenticator example

13. **MAY** contain zero or one [0..1] **inFulfillmentOf** (CONF:9952-CRC).
    a. Such inFulfillmentOf elements, if present, **SHALL** contain exactly one [1..1] **order** (CONF:9953-CRC).
        i. This order **SHALL** contain at least one [1..*] **id** (CONF:9954).
            1. One id **SHALL** be the Accession Number with the root representing the Assigning Authority (Issuer of Accession Number) (CONF:CRC-xxx).
        ii. This order **SHALL** contain at least one [1..*] **priorityCode** which **SHALL** be selected from ValueSet `ActPriority Value Set 2.16.840.1.113883.1.11.16866` **DYNAMIC** (CONF:8300-CRC).

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```
<inFulfillmentOf>
  <order>
    <id root="1.2.3.4.5.6" extension="acc#1" />
    <priorityCode code="R" codeSystem=" 2.16.840.1.113883.5.7"
     codeSystemName="ActPriority" displayName="Routine">
  </order>
</inFulfillmentOf>
```

Figure 6.3.2-7: inFulfillmentOf example

14. **MAY** contain zero or more [0..*] **authorization** (CONF:16792).
    a. **SHALL** contain exactly one [1..1] **consent**. (CONF:16793).
        i. This consent **MAY** contain zero or more [0..*] **id** (CONF:16794).
        ii. This consent **MAY** contain zero or one [0..1] **code** (CONF:16795).
            1. The type of consent (e.g., a consent to perform the related serviceEvent) is conveyed in consent/code (CONF:16796).
            2. The following LOINC codes **SHOULD** be used (CONF:CRC-xxx):
                a. 64293-4 – procedure consent
                b. 61359-6 – anesthesia consent
        iii. This consent **SHALL** contain exactly one [1..1] **statusCode** (CONF:16797).
            1. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC)** (CONF:16798)

An authorization consent **MAY** be provided for the procedure and an authorization consent **MAY** be provided for the anesthesia.

```
<authorization typeCode="AUTH">
    <consent classCode="CONS" moodCode="EVN">
       <id root="629deb70-5306-11df-9879-0800200c9a66" />
       <code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC"
             code="64293-4" displayName="Procedure Consent"/>
       <statusCode code="completed"/>
    </consent>
</authorization>
<authorization typeCode="AUTH">
    <consent classCode="CONS" moodCode="EVN">
       <id root="629deb70-5306-11df-9879-0800200c9a66" />
       <code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC"
             code="61359-6" displayName="Anesthesia Consent"/>
       <statusCode code="completed"/>
    </consent>
</authorization>
```

Figure 6.3.2-8: consent example

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15. **SHALL** contain exactly one [1..1] **componentOf** (CONF:9955-CRC).
    a. This componentOf element **SHALL** contain exactly one [1..1] **encompassingEncounter** (CONF:9956).
        i. This encompassingEncounter **SHALL** contain at least one [1..*] **id** (CONF:9959).
        ii. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:9958).
            1. This effectiveTime **SHALL** be accurate to the day and **MAY** be accurate to the second (CONF:CRC-xxx).
        iii. This encompassingEncounter **SHALL** contain exactly one [1..1] **code** (CONF:8501).
        iv. This encompassingEncounter **SHALL** contain at least one [1..*] **location/healthCareFacility** (CONF:8500).
            1. This healthCareFacility **SHALL** contain at least one [1..*] **code** representing the type of location (CONF:CRC).
            2. This healthCareFacility **SHALL** contain at least one [1..*] **id** (CONF:8500).
            3. This healthCareFacility **SHOULD** contain at least one [1..*] **serviceProviderOrganization** (CONF:CRC-xxx).
                a. This serviceProviderOrganization **SHALL** contain at least one [1..*]**name** (CONF:CRC-xxx).
                b. This serviceProviderOrganization **SHALL** contain at least one [1..*]**addr** (CONF:CRC-xxx).
                c. This serviceProviderOrganization **SHALL** contain at least one [1..*] **telecom** (CONF:CRC-xxx).
            4. This healthCareFacility **MAY** contain zero or more [0..*] **location** (CONF:CRC-xxx).
                a. If present, this location **SHALL** contain at least one [1..*]**name** and/or **addr** to identify the place of the encounter (CONF:CRC-xxx).
        v. This componentOf/encompassingEncounter **MAY** contain zero to four [0..4] **encounterParticipant** (CONF:8502-CRC) such that it
            1. **MAY** contain at most two [0..2] **@typeCode**="REF" Referrer (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) for the referring cardiologist and referring physician (CONF:8503-CRC).
            2. **MAY** contain zero or one [0..1] **@typeCode**="ATND" Physician of Record (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) (CONF:8503-CRC).
            3. **MAY** contain zero or one [0..1] **@typeCode**="RESP" Responsible Party (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) (CONF:8503-CRC).

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```
<componentOf>
  <encompassingEncounter>
     <id extension="KP00017" root="2.16.840.1.113883.19"/>
     <effectiveTime value=”20110407”/>
     <code code="1234097013" codeSystem="2.16.840.1.113883.6.96"
           codeSystemName="SNOMED CT"
           displayName="Diagnostic Coronary Angiography ">
     <location>
      <healthCareFacility>
        <id root=”1.2.3.4.5.6.7” extension=”facility ID”/>
        <code code=”CARD” codeSystem=”2.16.840.1.113883.5.111”
          codeSystemName=”roleCode” displayName=”Cardiology Clinic”>
        <serviceProviderOrganization>
           <name>My Favorite Cardiac Care Organization</name>
           <addr>
               <streetAddressLine>Healthcare Lane</streetAddressLine>
               <city>East Town</city>
               <state>OH</state>
               <country>US</country>
           </addr>
           <telecom value=”1-800-555-1212” use=”WP”/>
        </serviceProviderOrganization>
        <location>
           <name>My Cardiac Hospital</name>
           <addr>
               <streetAddressLine>Healthcare Lane</streetAddressLine>
               <city>East Town</city>
               <state>OH</state>
               <country>US</country>
           </addr>
        </location>
      </healthCareFacility>
    </location>
    <encounterParticipant typeCode=”REF”>
      <assignedEntity>
        <id root=”2.16.840.1.113883.4.6” extension=”12345”/>
        <code code=”xyz” codeSystem=”2.16.840.1.113883.6.101”
              codeSystemName=”nuccProviderCodes”
              displayName=”Referring cardiologist”/>
        <addr>Referring Physician Lane, USA</addr>
        <telecom value=”1-800-555-1212” use=”WP”/>
        <assignedPerson>
          <name>Dr. Referring Physician</name>
        </assignedPerson>
      </assignedEntity>
    </encounterParticipant>
  </encompassingEncounter >
</componentOf>
```

Figure 6.3.2-9: componentOf/encompassingEncounter example

16. **SHALL** contain exactly one [1..1] **documentationOf** (CONF:8510-CRC).

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a. This documentationOf **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:10061).
    i. The value of serviceEvent/code **SHOULD** be selected from SNOMED CT (codeSystem 2.16.840.1.113883.6.96) and **MAY** be selected from a localized procedure coding system for a given country such as ICD9 CM Procedures (codeSystem 2.16.840.1.113883.6.104), ICD10 CM Procedures (codeSystem: 2.16.840.1.113883.6.4) or CPT-4 (codeSystem 2.16.840.1.113883.6.12) in the U.S. (CONF:CRC-xxx).
    ii. This serviceEvent **SHOULD** contain zero or more [0..*] id. If there is an associated DICOM study, the Study instance UID of the DICOM study should be included in the root attribute of one id.
    iii. This serviceEvent **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:10062).
        1. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:26449).
        2. If a width is not present, the serviceEvent/effectiveTime **SHALL** include effectiveTime/high. (CONF:8514)
        3. When only the date and the length of the procedure are known a width element **SHALL** be present and the effectiveTime/high **SHALL** not be present. (CONF:8515).
        4. The effectiveTime **SHALL** be accurate to the day and **MAY** be accurate to the second (CONF:CRC-xxx).
    iv. This serviceEvent **SHALL** contain at least one [1..*] **performer** (CONF:8520-CRC) such that it
        1. **SHALL** contain one or two [1..2] **@typeCode**="PPRF" Primary Performer (CodeSystem: `HL7ParticipationType 2.16.840.1.113883.5.90`). This is for the case where both a cath and PCI are performed in the same procedure. (CONF:8521-CRC).
        2. **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:14911).
            a. This assignedEntity **SHOULD** contain zero or one [0..1] **code** (CONF:14912).
                i. The code, if present, **SHOULD** contain zero or one [0..1] **@code**. (CONF:14913-CRC).
        3. Any assistants **SHALL** be identified and **SHALL** be identified as secondary performers (SPRF). (CONF:8524).

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```
<documentationOf>
  <serviceEvent classCode="PROC">
    <code code="70051019" codeSystem="2.16.840.1.113883.6.96"
         codeSystemName="SNOMED CT"
         displayName="Diagnostic catheterization"/>
    <id root="DICOM study instance UID" extension=”acc1”/>
    <effectiveTime>
      <low value="201003292240" />
      <width value="15" unit="min"/>
    </effectiveTime>
    <performer typeCode="PPRF">
      <assignedEntity>
        <id extension="IO00017" root="2.16.840.1.113883.19.5" />
        <code code="17561000"
            codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"
            displayName="Cardiologist" />
        <addr>
          <streetAddressLine>1001 Hospital Lane</streetAddressLine>
          <city>Ann Arbor</city>
          <state>MI</state>
          <postalCode>99999</postalCode>
          <country>US</country>
        </addr>
        <telecom value="tel:(999)555-1212" />
        <assignedPerson>
          <name>
            <prefix>Dr.</prefix>
            <given>Tony</given>
            <family>Tum</family>
          </name>
        </assignedPerson>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>
```

Figure 6.3.2-10: documentationOf/serviceEvent example

6.3.3 Cath Report Content Body Containment

The body for the Cardiac Report Content document shall include section content modules. The section content modules will be specified by a set of constraints.

1. **SHALL** contain exactly one [1..1] **component** (CONF:9588).
    a. A Cath Report Content **SHALL** have a **structuredBody** (CONF:9589-CRC).
        i. A Cath Report Content document **SHALL** conform to CDA Level 3 (structuredBody containing sections that contain a narrative block and coded entries). In this template (templateId

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1.3.6.1.4.1.19376.1.4.1.1.2), some coded entries are used. (CONF:9590-CRC).

b. The component/structuredBody **SHALL** conform to the section constraints below (CONF:9595-CRC).

i. Each section **SHALL** have a **`title`** and the **`title`** **SHALL NOT** be empty (CONF:9937).

Table 6.3.3-1 identifies the set of specific *section content modules* that may be required, recommended, or allowed to be included in the CRC document. This table also identifies the most important *entry content modules* contained within those section content modules. The containment relationship among the section and entry content modules in the body of a Cath Report Content document is represented in the "Template Title" column as noted by the indentation relative to the other content modules.

1. Section content modules
    a. Any section content module that is used exactly as specified in C-CDA shall not have the C-CDA constraints replicated in this specification.
    b. If the section content module is used in this profile but with different vocabulary constraints, then the vocabulary constraints shall be listed in the "Constraints" columns of the table and shall be included in this specification.
    c. Sample XML shall be included for each section content module and should include XML for each entry contained within the section.
2. Entry content modules
    a. Any entry content module that is used exactly as specified in C-CDA shall not have the specific constraints replicated in this specification.
    b. If the entry content module is relevant to this CRC Profile, it shall be included in Table 6.3.3-1 following the section content module it is contained within.
    c. If the entry content module has CRC specific vocabulary constraints, the constraints shall be identified in the "Constraints" columns of the table and shall be documented in this specification.
    d. Sample XML should be included for the entries within the section content module where it is used.

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Table 6.3.3-1: Template Containment for a Cath Report Content document

Template Title	Cardinality	Template Type	templateId	Specification Document	Constraints
Cath Report Content	R[1..1]	document	1.3.6.1.4.1.19376.1.4.1.1.2	CARD TF-3: 6.3	
Document Summary Section	O[0..1]	section	1.3.6.1.4.1.19376.1.4.1.2.16	CARD TF-3 6.3.4.1	CARD TF-3 6.3.4.1
Medical History - Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.17	CARD TF-3: 6.3.4.2 (C-CDA 4.31 - parent)	CARD TF-3: 6.3.4.2
Procedure Activity Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.13	C-CDA 5.62	CARD TF-3: 6.3.4.2.2
Procedure Activity Procedure	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.14	C-CDA 5.63	CARD TF-3: 6.3.4.2.3
Problem Observation - Cardiac	O[0..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.9	CARD TF-3: 6.3.5.1 (C-CDA 5.59 – parent)	CARD TF-3: 6.3.4.2.1
Age Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.31	C-CDA 5.3	
Health Status Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.5	C-CDA 5.30	
Problem Status	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.6	C-CDA 5.60	
Severity Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.8	C-CDA 5.74	
Allergies Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.6	C-CDA 4.2	CARD TF-3: 6.3.4.3
Allergy Problem Act	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.30	C-CDA 5.5	
Allergy – Intolerance Observation	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.7	C-CDA 5.4	CARD TF-3: 6.3.4.3.1
Allergy Status Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.28	C-CDA 5.6	
Reaction Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.9	C-CDA 5.68	
Severity Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.8	C-CDA 5.74	
Family History Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.15	C-CDA 4.12	CARD TF-3: 6.3.4.4
Family History Organizer	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.45	C-CDA 5.26	
Family History Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.46	C-CDA 5.25	CARD TF-3: 6.3.4.4.1
Social History Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.17	C-CDA 4.57	CARD TF-3: 6.3.4.5
Social History Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.38	C-CDA 5.76	CARD TF-3: 6.3.4.5.1

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Template Title	Cardinality	Template Type	templateId	Specification Document	Constraints
Smoking Status Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.78	C-CDA 5.75	
Physical Exam Section	R[1..1]	section	2.16.840.1.113883.10.20.2.10	C-CDA 4.38	CARD TF-3: 6.3.4.6
Vital Signs Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.4	C-CDA 4.60	CARD TF-3: 6.3.4.7
Vital Signs Organizer	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.26	C-CDA 5.82	
Vital Sign Observation	R[2..*]	entry	2.16.840.1.113883.10.20.22.4.27	C-CDA 5.81	CARD TF-3: 6.3.4.7.1
Pre-Procedure Results – Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.23	CARD TF-3 6.3.4.8 (C-CDA 4.55 – parent)	CARD TF-3: 6.3.4.8
Result Organizer - Cardiac	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.11	CARD TF-3 6.3.4.8.1 (C-CDA 5.71 – parent)	CARD TF-3 6.3.4.8.1
Result Observation	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.2	C-CDA 5.70	CARD TF-3 6.3.4.8.2
Planned Procedure Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.30	C-CDA 4.40	CARD TF-3 6.3.4.9
Plan of Care Activity Procedure	R[1..2]	entry	2.16.840.1.113883.10.20.22.4.41	C-CDA 5.49	
Procedure Indications Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.29	C-CDA 4.50	CARD TF-3 6.3.4.10
Indication	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.19	C-CDA 5.37	CARD TF-3 6.3.4.10.1
Severity Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.8	C-CDA 5.74	
Anesthesia Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.25	C-CDA 4.3	CARD TF-3 6.3.4.11
Procedure Activity Procedure	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.14	C-CDA 5.49	CARD TF-3 6.3.4.11.1
Medication Activity	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.16	C-CDA 5.39	

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Template Title	Cardinality	Template Type	templateId	Specification Document	Constraints
Medications Administered Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.38	C-CDA 4.32	CARD TF-3 6.3.4.12
Medication Activity	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.16	C-CDA 5.39	
Medication Information	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.23	C-CDA 5.41	CARD TF-3 6.3.4.12.1
Procedure Description - Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.19	CARD TF-3 6.3.4.13 (C-CDA 4.45 – parent)	CARD TF-3 6.3.4.13
Lesion Observation	O[0..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.10	CARD TF-3 6.3.5.2	
Procedure Device Organizer - Cardiac	O[0..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.12	CARD TF-3 6.3.4.13.2	CARD TF-3 6.3.4.13.2
Device Observation	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.13	CARD TF-3 6.3.4.13.3	CARD TF-3 6.3.4.13.3
Procedure Activity Procedure - Cardiac	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.14	CARD TF-3 6.3.4.13.1 (C-CDA 5.63 – parent)	CARD TF-3 6.3.4.13.1
Lesion Observation	O[0..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.10	CARD TF-3 6.3.5.2	
Product Instance	O[1..*]	entry	2.16.840.1.113883.10.20.22.4.37	C-CDA 5.65	
Procedure Device Organizer - Cardiac	O[0..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.12	CARD TF-3 6.3.4.13.2	CARD TF-3 6.3.4.13.2
Device Observation	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.13	CARD TF-3 6.3.4.13.3	CARD TF-3 6.3.4.13.3
Procedure Specimens Taken Section	O[0..1]	section	2.16.840.1.113883.10.20.22.2.31	C-CDA 4.51	CARD TF-3 6.3.4.14
Procedure Disposition Section	R[1..1]	section	2.16.840.1.113883.10.20.18.2.12	C-CDA 4.46	CARD TF-3 6.3.4.15
Procedure Results - Cardiac Section	R[1..1]	section	1.3.6.1.4.1.19376.1.4.1.2.20	CARD TF-3 6.3.4.16 (C-CDA 4.48 – parent)	CARD TF-3 6.3.4.16
Procedure Results Organizer - Cardiac	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.15	CARD TF-3 6.3.4.16.1 (C-CDA 5.71 – parent)	
Result Observation - Cardiac	R[1..*]	entry	1.3.6.1.4.1.19376.1.4.1.4.16	CARD TF-3 6.3.4.16.2 (C-CDA 5.70 – parent)	
Severity Observation	O[0..1]	entry	2.16.840.1.113883.10.20.22.4.8	C-CDA 5.74	

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Template Title	Cardinality	Template Type	templateId	Specification Document	Constraints
Complications Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.37	C-CDA 4.8	CARD TF-3 6.3.4.17
Problem Observation	O[0..*]	entry	2.16.840.1.113883.10.20.22.4.4	C-CDA 5.59	CARD TF-3 6.3.4.17.1
Postprocedure Diagnosis Section	R[1..1]	section	2.16.840.1.113883.10.20.22.2.36	C-CDA 4.42	CARD TF-3 6.3.4.18
Postprocedure Diagnosis	R[1..1]	entry	2.16.840.1.113883.10.20.22.4.51	C-CDA 5.53	
Problem Observation	R[1..*]	entry	2.16.840.1.113883.10.20.22.4.4	C-CDA 5.59	CARD TF-3 6.3.4.18.1
Plan of Care – Cardiac Section	O[0..1]	section	1.3.6.1.4.1.19376.1.4.1.2.22	CARD TF-3 6.3.4.19 (C-CDA 4.39 - parent)	CARD TF-3 6.3.4.19
Plan of Care Activity Act - Cardiac	R[1..1]	entry	1.3.6.1.4.1.19376.1.4.1.4.17	CARD TF-3 6.3.4.19.1 (C-CDA 5.46 – parent)	CARD TF-3 6.3.4.19.1
Key Images – Cardiac Section	O[0..1]	section	1.3.6.1.4.1.19376.1.4.1.2.21	CARD TF-3 6.3.4.20	CARD TF-3 6.3.4.20
Sop Instance Observation	R[1..*]	entry	2.16.840.1.113883.10.20.6.2.8	C-CDA 5.77	
DICOM Object Catalog Section	O[0..1]	section	2.16.840.1.113883.10.20.6.1.1	C-CDA 4.9	
Study Act	R[1..*]	entry	2.16.840.1.113883.10.20.6.2.6	C-CDA 5.78	
Series Act	R[1..*]	entry	2.16.840.1.113883.10.20.6.4.63	C-CDA 5.72	
Sop Instance Observation	R[1..*]	entry	2.16.840.1.113883.10.20.6.2.8	C-CDA 5.77	

6.3.4 Cath Report Content Document Section/Entry Constraints

6.3.4.1 Document Summary Section 55112-7

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.16 (open)]

The Document Summary section content module includes a summary of most significant aspects of the procedures in a narrative form. It is a condensed form of the full narrative report whose structure has no constraint.

This Document Summary section content module is a new content module that has no equivalent in C-CDA. The complete set of constraints for the Document Summary section content module are listed below.

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1. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.16" (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **code** (CONF:CRC-xxx).
    a. This code **SHALL** contain exactly one **@code**="55112-7" Document Summary (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:CRC-xxx).
3. **SHALL** contain exactly one [1..1] **title** (CONF:CRC-xxx).
4. **SHALL** contain exactly one [1..1] **text** (CONF:CRC-xxx).
    a. The text element **MAY** contain one or more **renderMultiMedia** element representing an in-line graphic. The related observationMedia entry may be within the summary section structured entries or may be referenced from another section.
5. **MAY** contain zero or more [0..*] **entry** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **ObservationMedia** element (CONF:CRC-xxx) such that it
        i. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CONF:CRC-xxx).
        ii. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:CRC-xxx).
        iii. **SHALL** contain at least one [1..*] **id** (CONF:CRC-xxx).
        iv. **SHALL** contain at least one [1..*] **value** with @xsi:type=”ED” (CONF:CRC-xxx)
            1. This value **SHALL** contain exactly one [1..1] **@mediaType** drawn from the ValueSet SupportedFileFormats 1.3.6.1.4.1.19376.1.4.1.5.45 **STATIC** (CONF:CRC-xxx).
            2. This value **MAY** contain zero or one [0..1] **reference** (CONF:CRC-xxx).
                a. The URL of a referenced graphic element **MAY** be present (CONF:CRC-xxx).
            3. An encapsulated data value may have both inline data and a reference. The reference must point to the same data as provided inline as per HL7 v3 Data Types – Abstract Specification, Release 1, Section 2.4.5 (CONF:CRC-xxx).

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```
<!-- example with external content referenced by file name -->
<section>
    <templateId root="1.3.6.1.4.1.19376.1.4.1.2.16"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="55112-7" displayName="DOCUMENT SUMMARY"/>
    <title>CATH PROCEDURE SUMMARY</title>
    <text>
      <paragraph>A cath procedure was performed. The following image shows the
region of interest.</paragraph>
       <renderMultiMedia referencedObject="CRC-image1"/>
      <paragraph>The patient needed no further interventions.</paragraph>
    </text>
    <entry>
      <observationMedia classCode="OBS" moodCode="EVN" ID="CRC-image1">
         <id root="2.16.840.1.113883.19.2.1"/>
         <value xsi:type="ED" mediaType="image/jpeg">
            <reference value="sample cath image.jpeg"/>
         </value>
      </observationMedia>
    </entry>
</section>

<!-- alternative example - embed the content within the reference element value
attribute -->
<section>
    …
    <text mediaType="image/jpeg" representation="B64">e1xydGY...</text>
    <entry>
      <observationMedia classCode="OBS" moodCode="EVN" ID="CRC-embedded">
         <id root="2.16.840.1.113883.19.2.1"/>
         <value xsi:type="ED" mediaType="image/jpeg" reference=”B64”>
            <reference value="e1xydGY..."/>
         </value>
      </observationMedia>
    </entry>
</section>
```

Figure 6.3.4.1-1: Document Summary – Cardiac section example

6.3.4.2 Medical History - Cardiac Section 11329-0

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.17(open)]

([section: templateId 2.16.840.1.113883.10.20.22.2.39(open)] - parent)

The Medical History – Cardiac section content module describes all aspects of the medical history of the patient even if not pertinent to the current procedure, and may include chief complaint, past medical history, social history, family history, surgical or procedure history, medication history, and other history information. The history may be limited to information pertinent to the current procedure or may be more comprehensive. The history may be reported as a collection of random clinical statements or it may be reported categorically. Entries for History of Past Illness and History of Present Illness have been consolidated into this section.

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Social and Family History are discussed in their own sections. For this Cath Report Content profile, this Medical History – Cardiac section content module may also contain history about specific relevant problems as problem observations.

In the event that the patient was transferred from another facility where there was a problem indication that the patient was determined to need a cath procedure, this will be noted as a problem observation in this medical history section as text in the narrative for now until there is a code representing this.

This Medical History – Cardiac section content module extends the Medical (General History Section (C-CDA 4.31). The additional constraints are listed below.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:8160) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.17" (CONF:10403-CRC).
2. **MAY** contain zero or more [0..*] **entry** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **Problem Observation - Cardiac** (templateId:1.3.6.1.4.1.19376.1.4.1.4.9) (CONF:CRC-xxx).
3. **MAY** contain zero or more [0..*] **entry** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **Procedure Activity Observation** (templateId:2.16.840.1.113883.10.20.22.4.13) (CONF:CRC-xxx).
4. **MAY** contain zero or more [0..*] **entry** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **Procedure Activity Procedure** (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:CRC-xxx).

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```
<section>
  <templateId root="1.3.6.1.4.1.19376.1.4.1.2.17"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.39"/>
  <code code="11329-0" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        displayName="MEDICAL (GENERAL) HISTORY"/>
  <title>MEDICAL (GENERAL) HISTORY</title>
  <text>
    <list listType="ordered">
      <item>Patient has had a recent issue with chest pain that does
           not seem to be related to any particular cause.</item>
      <item>Previous concerns of heart disease were actually
related to other causes.</item>
      <item>Patient had recent weight gain due to sedentary lifestyle and
           new job.</item>
    </list>
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.4.1.4.9"/>
      <!-- Problem Observation - Cardiac template -->
      <id root="d11275e7-67ae-11db-bd13-0800200c9a66"/>
      <code code="55607006" codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"
            displayName="Problem"/>
      <text>There was history of hypertension.</text>
      <statusCode code="completed"/>
      <effectiveTime>
      </effectiveTime>
      <value xsi:type="CD" code="38341003"
            codeSystem="1.2.840.10008.6.1.253" codeSystemName="SNOMED CT"
            displayName="Hypertension"/>
      <entryRelationship typeCode="SUBJ" inversionInd="true">
        <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.31"/>
         <!-- Age observation template -->
         <code code="445518008" codeSystem="2.16.840.1.113883.6.96"
               displayName="Age At Onset"/>
         <statusCode code="completed"/>
         <value xsi:type="PQ" value="57" unit="a"/>
        </observation>
      </entryRelationship>
      <entryRelationship typeCode="SUBJ" inversionInd="true">
        <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.6"/>
         <!—Problem status template -->
         <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
               displayName="Status"/>
         <statusCode code="completed"/>
         <value xsi:type="CD" code="55561003"
                     codeSystem="2.16.840.1.113883.6.96"
                     codeSystemName="SNOMED CT" displayName="Active"/>
        </observation>
      </entryRelationship>
```

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```
      <entryRelationship typeCode="REFR" inversionInd="true">
        <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.5"/>
         <!-- Health status observation template -->
         <code code="11323-3"
               codeSystem="2.16.840.1.113883.6.1"
               codeSystemName="LOINC"
               displayName="Health status"/>
         <statusCode code="completed"/>
         <value xsi:type="CE" code="413322009"
               codeSystem="2.16.840.1.113883.6.96"
               codeSystemName="SNOMED CT"
               displayName="Resolved"/>
        </observation>
      </entryRelationship>
      <entryRelationship typeCode="REFR" inversionInd="true">
        <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.8"/>
         <!-- Severity observation template -->
         <code code="SEV" displayName="Severity Observation"
               codeSystem="2.16.840.1.113883.5.4"
               codeSystemName="ActCode"/>
         <text>
            <reference value="#severity"/>
         </text>
         <statusCode code="completed"/>
         <value xsi:type="CD" code="371924009" displayName="Moderate to severe"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT"/>
        </observation>
      </entryRelationship>
    </observation>
  </entry>
  </entry>
    <procedure classCode="PROC" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.14"/>
      <!-- Procedure Activity Procedure template -->
      <id root="e401f340-7be2-11db-9fe1-0800200c9a66"/>
      <code code="500786010" codeSystem="1.3.6.1.4.1.19376.1.4.1.5.40"
            displayName="Left Heart Cath Procedure">
        <originalText>Left Heart Cath Procedure
            <reference value="procedure1"/></originalText>
      </code>
      <text>
        <reference value="procedure1"/>
      </text>
      <statusCode code="completed"/>
      <effectiveTime value="1998"/>
      <targetSiteCode code="41879009" codeSystem="2.16.840.1.113883.6.96"
             displayName="Distal RCA"/>
```

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```
    </procedure>
  </entry>
  </entry>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.13"/>
      <!-- Procedure Activity Observation template -->
      <id extension="proc1" root="2.16.840.1.113883.19"/>
      <code code="500786010" codeSystem="2.16.840.1.113883.6.96"
            displayName="Left Heart Cath Procedure" codeSystemName="SNOMED CT">
        <originalText>
           <reference value="#procedure1"/>
        </originalText>
      </code>
      <statusCode code="aborted"
                  codeSystem="2.16.840.1.113883.5.14"
                  codeSystemName="ActStatus"/>
      <effectiveTime value="20110203"/>
      <priorityCode code="CR" codeSystem="2.16.840.1.113883.5.7"
                    codeSystemName="ActPriority"
                    displayName="Callback results"/>
      <value xsi:type="CD" code="" codeSystem="2.16.840.1.113883.6.96"/>
      <methodCode nullFlavor="UNK"/>
      <targetSiteCode code="91083009" codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED CT"
                  displayName=" Proximal Right Coronary Artery" />
      <performer>
        <assignedEntity>
          <id root="1.2.3.4" extension="1234"/>
          <addr>
            <streetAddressLine>17 Daws Rd.</streetAddressLine>
            <city>Blue Bell</city>
            <state>MA</state>
            <postalCode>02368</postalCode>
            <country>US</country>
          </addr>
          <telecom use="WP" value="1(555)555-1234"/>
          <representedOrganization>
            <id root="2.16.840.1.113883.19.5"/>
            <name>Good Health Clinic</name>
            <telecom nullFlavor="UNK"/>
            <addr nullFlavor="UNK"/>
          </representedOrganization>
        </assignedEntity>
      </performer>
    </observation>
  </entry>
</section>
```

Figure 6.3.4.2-1: Medical History – Cardiac section example

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6.3.4.2.1 Problem Observation – Cardiac Constraints

[Observation: templateId 1.3.6.1.4.1.19376.1.4.1.9(open)]

This Problem Observation – Cardiac entry is used exactly as specified in the CRC Common Entry Content Modules - section 6.3.5.1, except for vocabulary constraints.

A Content Creator SHALL be able to include a Problem Observation – Cardiac Entry for each of the conditions identified in Value Set 1.3.6.1.4.1.19376.1.4.1.5.31 Cardiac Problems/Concerns. The value set for CONF:9058 (**value**) **SHOULD** be selected from ValueSet Cardiac Problems/Concerns Value Set 1.3.6.1.4.1.19376.1.4.1.5.31 **STATIC**.

A Content Creator SHALL be able to indicate the absence of the condition for the patient using the negation indicator.

A Content Creator SHALL be able to include a Problem Observation – Cardiac Entry with code {160245001, SNOMED CT, "No current problems or disability"}.

6.3.4.2.2 Procedure Activity Observation - Constraints

[observation: templateId 2.16.840.1.113883.10.20.22.4.13(open)]

This entry is used exactly as specified in C-CDA - section 5.62, except for vocabulary constraints for targetSiteCode.

This entry is used to document the prior procedures for this patient that may be relevant to this cath procedure.

The value set for CONF:10121 (**targetSiteCode**) **SHOULD** be selected from ValueSet Body Site Value Set 1.3.6.1.4.1.19376.1.4.1.5.32 **STATIC**.

6.3.4.2.3 Procedure Activity Procedure - Constraints

[procedure: templateId 2.16.840.1.113883.10.20.22.4.14(open)]

This entry is used exactly as specified in C-CDA - section 5.63, except for vocabulary constraints for code and targetSiteCode.

This entry is used to document the prior procedures for this patient that may be relevant to this cath procedure. Prior procedures can include but are not limited to Cath, PCI and CABG.

The value set for CONF:7657 (**code**) **SHOULD** be selected from ValueSet Cardiac Activity Procedures Value Set 1.3.6.1.4.1.19376.1.4.1.5.40 **STATIC**.

The value set for CONF:7683 (**targetSiteCode**) **SHOULD** be selected from ValueSet Body Site Value Set 1.3.6.1.4.1.19376.1.4.1.5.32 **STATIC**.

6.3.4.3 Allergies Section 48765-2

[section: templateId 2.16.840.1.113883.10.20.22.2.6(open)]

This Allergies section content module lists and describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape

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adhesives) used to assure the safety of health care delivery. At a minimum, it should list currently active and any relevant historical allergies and adverse reactions.

This Allergies section content module is used exactly as specified in C-CDA - section 4.2.

Within this Allergies section content module, the Content Creator SHALL be able to create an Allergy – Intolerance Observation entry for each of the cardiac imaging agent classes identified in ValueSet Contrast Agents Classes for Adverse Reactions Value Set `1.3.6.1.4.1.19376.1.4.1.5.34`.

```
<section>
    <templateId root="2.16.840.1.113883.10.20.22.2.6"/>
    <code code="48765-2"
          displayName="Allergies, adverse reactions, alerts"
          codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <title>Allergies</title>
    <text>
      The patient has allergies to penicillin based products
    </text>
    <entry typeCode="DRIV">
      <act classCode="ACT" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.30"/>
        <!--   Allergy Problem Act template   -->
        ...
      </act>
    </entry>
</section>
```

Figure 6.3.4.3-1: Allergies section example

6.3.4.3.1 Allergy – Intolerance Observation - Constraints

[`observation`: `templateId` `2.16.840.1.113883.10.20.22.4.7(open)`]

This Allergy – Intolerance Observation entry content module is used exactly as specified in C-CDA - section 5.4, except for vocabulary constraints on CONF:10083.

If the allergy is to Contrast Agents, the value set for CONF:10083 (**`code`**) **SHALL** be selected from ValueSet Contrast Agents Classes for Adverse Reactions Value Set `1.3.6.1.4.1.19376.1.4.1.5.34` **STATIC**.

6.3.4.4 Family History Section 10157-6

[`section`: `templateId` `2.16.840.1.113883.10.20.22.2.15 (open)`]

This Family History section content module contains data defining the patient's genetic relatives in terms of possible or relevant health risk factors that have a potential impact on the patient's healthcare risk profile.

This Family History section content module is used exactly as specified in C-CDA - section 4.12.

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If the relatedSubject of the Family History Organizer is a family member but the specific family member role is not known, the value “FAMMEMB” can be used to represent that the relatedSubject is a family member.

```
<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.15"/>
  <!--  Family history section template  -->
  <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Family history</title>
  <text> No Family History of Cardiovascular Disease</text>
  <entry typeCode=”DRIV”>
    <organizer classCode=”CLUSTER” moodCode=”EVN”>
      <templateId root=”2.16.840.1.113883.10.20.22.4.45”/>
      <statusCode code=”completed”/>
      <subject>
        <relatedSubject classCode=”PRS”>
          <code code=”FAMMEMB” codeSystem=”2.16.840.1.113883.5.111”>
            <translation code=”303071001” codeSystem=”2.16.840.1.113883.6.96”/>
          </code>
        </relatedSubject>
      </subject>
      <component>
        <observation classCode=”OBS” moodCode=”EVN”>
          <templateId root=”2.16.840.1.113883.10.20.22.4.46”/>
          <id root=”d11275e7-67ae-11db-bd13-0800200c9a66”/>
          <code code=”404684003” codeSystem=”2.16.840.1.113883.6.96”
                codeSystemName=”SNOMED CT” displayName=”Finding”/>
          <text>There was no family history of cardiovascular disease.</text>
          <statusCode code=”completed”/>
          <effectiveTime>
          </effectiveTime>
          <value xsi:type=”CD” code=”160270001”
              codeSystem=”2.16.840.1.113883.6.96” codeSystemName=”SNOMED CT”
              displayName=” No family history of cardiovascular disease”/>
        </observation>
      </component>
    </organizer>
  </entry>
</section>
```

Figure 6.3.4.4-1: Family History section example

6.3.4.4.1 Family History Observation - Constraints

`[Observation: templateId 2.16.840.1.113883.10.20.22.4.46(open)]`

The Family History Observation entry content module is used exactly as specified in C-CDA - section 5.25, except for vocabulary constraints on CONF:8591.

The value set for CONF:8591 (**code**) **SHOULD** be selected from ValueSet Cardiovascular Family History Value Set `1.3.6.1.4.1.19376.1.4.1.5.33` **STATIC**.

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6.3.4.5 Social History Section 29762-2

[section: templateId 2.16.840.1.113883.10.20.22.2.17(open)]

The Social History section content module is used exactly as specified in C-CDA - section 4.57.

This Social History section content module contains data defining the patient's occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. Social history can have significant influence on a patient's physical, psychological and emotional health and wellbeing so should be considered in the development of a complete record.

Smoking status shall be documented using the Smoking Status Observation entry content module as specified in C-CDA section 5.75.

```
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.17"/>
   <!--  **  Social history section template   ** -->
   <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
      displayName="Social History"/>
   <title>Social History</title>
   <text>
      The patient was a former smoker.
   </text>
   <entry typeCode="DRIV">
      <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.22.4.78"/>
         <!--  **  Smoking status observation template   ** -->
         <id root="45efb604-7049-4a2e-ad33-d38556c9636c"/>
         <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
         <statusCode code="completed"/>
         <effectiveTime>
            <low value="1973"/>
            <high value="2001"/>
         </effectiveTime>
         <value xsi:type="CD" code=”8517006”
                codeSystem=”2.16.840.1.113883.6.96”
                displayName=”Former Smoker”/>
      </observation>
   </entry>
</section>
```

Figure 6.3.4.5-1: Social History section example

6.3.4.5.1 Social History Observation - Constraints

[observation: templateId 2.16.840.1.113883.10.20.22.4.38(open)]

The Social History Observation entry content module is used exactly as specified in C-CDA - section 5.76.

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To include cocaine misuse behavior, the value allowed for CONF:8559 (**value**) **SHOULD** be "78267003" from SNOMED CT "Cocaine abuse".

6.3.4.6 Physical Exam Section 29545-1

[section: templateId 2.16.840.1.113883.10.20.2.10(open)]

The Physical Exam section content module is used exactly as specified in C-CDA - section 4.38.

The Physical Exam section content module includes direct observations made by the clinician. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient's body. This Physical Exam section includes only observations made by the examining clinician using inspection, palpation, auscultation, and percussion; it does not include laboratory or imaging findings. The exam may be limited to pertinent body systems based on the patient's chief complaint or it may include a comprehensive examination. The examination may be reported as a collection of random clinical statements or it may be reported categorically.

```
<section>
    <templateId root="2.16.840.1.113883.10.20.2.10"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="29545-1" displayName="PHYSICAL FINDINGS"/>
    <title>PHYSICAL EXAMINATION</title>
    <text>
      <paragraph>All normal to examination.</paragraph>
    </text>
</section>
```

Figure 6.3.4.6-1: Physical Exam section example

6.3.4.7 Vital Signs Section 8716-3

[section: templateId 2.16.840.1.113883.10.20.22.2.4(open)]

The Vital Signs Section content module is used exactly as specified in C-CDA - section 4.60.

The Vital Signs section content module is intended to include vital sign measurements taken at admission and at the time of procedure, if feasible.

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```
<section>
  <templateId root="2.16.840.1.113883.10.20.22.2.4"/>
  <code code="8716-3"
        codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        displayName="VITAL SIGNS" />
  <title>Vital Signs</title>
  <text>These are the vital signs related to the procedure </text>
  <entry typeCode="DRIV">
    <organizer classCode="CLUSTER" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.26"/>
      <!-- Vital signs organizer template -->
      <id root="c6f88320-67ad-11db-bd13-0800200c9a66"/>
      <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT" displayName="Vital signs"/>
      <statusCode code="completed"/>
      <effectiveTime value="19991114"/>
      <component>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
          <!-- Vital sign observation for height -->
          <id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>
          <code code="8302-2"
                codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC"
                displayName="Height"/>
          <text><reference value="#height1"/></text>
          <statusCode code="completed"/>
          <effectiveTime value="19991114"/>
          <value xsi:type="PQ" value="177" unit="cm"/>
          <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
        </observation>
      </component>
    </organizer>
  </entry>
</section>
```

Figure 6.3.4.7-1: Vital Signs section example

6.3.4.7.1 Vital Sign Observation - Constraints

[observation: templateId 2.16.840.1.113883.10.20.22.4.27(open)]

The Vital Sign Observation entry content module is used exactly as specified in C-CDA - section 5.81, except for vocabulary constraints.

The value set for CONF:7301 (**code**) **SHOULD** be selected from ValueSet Vital Sign Result Value Set 1.3.6.1.4.1.19376.1.4.1.5.36 **STATIC**.

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6.3.4.8 Pre-Procedure Results – Cardiac Section 30954-2

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.23 (open)]

([section: templateId 2.16.840.1.113883.10.20.22.2.3(open)] – parent)

This Pre-Procedure Results – Cardiac Section content module is based on the C-CDA Results Section content module as specified in C-CDA - section 4.55.

The Pre-Procedure Results – Cardiac section content module contains the results of pre-procedure tests that are required to prepare for the cath procedure. Results from prior diagnostic cath procedures are included here if they provide indications for the current interventional procedure. There may also be a reference to an optional external document in the result organizer.

This Pre-Procedure Results – Cardiac section content module contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes observations such as hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. The section often includes notable results such as abnormal values or relevant trends, and could contain all results for the period of time being documented.

Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echocardiogram.

This Pre-Procedure Results – Cardiac section content module modifies the Results Section (C-CDA 4.55). The complete set of constraints for the Pre-Procedure Results – Cardiac section content module are defined below. The substitutions are highlighted in yellow. This Pre-Procedure Results – Cardiac section content module is also conformant to the C-CDA Results Section content module.

1. **SHALL** contain two or more [2..*] **templateId** (CONF:7116-CRC) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.3" (CONF:9136).
   b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.23" (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15431).
   a. This code **SHALL** contain exactly one [1..1] **@code**="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15432).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8891).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7118).
5. **SHALL** contain at least one [1..*] **entry** (CONF:7119) such that it
   a. **SHALL** contain exactly one [1..1] **Result Organizer - Cardiac** (templateId:1.3.6.1.4.1.19376.1.4.1.4.11) (CONF:15515-CRC).

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```
<section>
    <templateId root="1.3.6.1.4.1.19376.1.4.1.2.23"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.3"/>
    <code code="30954-2"
          codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          displayName="RESULTS" />
    <title>Results</title>
    <text>
       ...
    </text>
    <entry typeCode="DRIV">
      <organizer classCode="CLUSTER" moodCode="EVN">
        <templateId root="1.3.6.1.4.1.19376.1.4.1.4.11"/>
        <id root="7d5a02b0-67a4-11db-bd13-0800200c9a66"/>
        <code code="57021-8" displayName="CBC W Auto Differential panel"
              codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
        <statusCode code="completed"/>
        <component>
          <observation classCode="OBS" moodCode="EVN">
            <!-- Result observation template -->
            <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
            <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
            <code code="30313-1" displayName="HGB"
                  codeSystem="2.16.840.1.113883.6.1"
                  codeSystemName="LOINC"/>
            <statusCode code="completed"/>
            <effectiveTime value="200003231430"/>
            <value xsi:type="PQ" value="13.2" unit="g/dl"/>
            <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
            <methodCode/>
            <targetSiteCode/>
            <referenceRange>
              <observationRange>
                <text>M 13-18 g/dl; F 12-16 g/dl</text>
              </observationRange>
            </referenceRange>
          </observation>
        </component>
        <reference typeCode="REFR">
          <externalDocument>
             <id root="b50b7910-7ffb-4f4c-bbe4-177ed68cbbf3"/>
             <text mediaType="application/pdf">
                <reference
                    value="PreProcedureResults.pdf"/>
             </text>
          </externalDocument>
        </reference>
      </organizer>
    </entry>
</section>
```

Figure 6.3.4.8-1: Pre-Procedure Results section example

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6.3.4.8.1 Result Organizer - Cardiac

[organizer: templateId 1.3.6.1.4.1.19376.1.4.1.4.11 (open)]

([organizer: templateId 2.16.840.1.113883.10.20.22.4.1(open)] – parent)

This clinical statement identifies a set of result observations. It contains information applicable to all of the contained result observations. Result type codes categorize a result into one of several commonly accepted values (e.g., "Diagnostic Cath", "PCI", "Structural Heart", "Diagnostic Cath and PCI"). These values are often implicit in the Result Organizer code (e.g., an Organizer/code of "complete blood count" implies a Result Observation code of "Hematology").

An appropriate nullFlavor can be used when a single result observation is contained in the organizer, and organizer/code or organizer/id is unknown.

There may also be a reference to an optional external document in the result organizer.

This Result Organizer – Cardiac entry content module extends the C-CDA Result Organizer entry definition (C-CDA 5.71) by adding the constraints listed below.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.11" (CONF:CRC-xxx).
2. **MAY** contain zero or more [0..*] **reference** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:CRC-xxx).
    b. **SHALL** contain exactly one [1..1] **externalDocument** (CONF:CRC-xxx).
        i. This externalDocument **SHALL** contain at least one [1..*] **id** (CONF:CRC-xxx).
        ii. This externalDocument **MAY** contain zero or one [0..1] **text** (CONF:CRC-xxx).
            1. The text, if present, **MAY** contain zero or one [0..1] **@mediaType** (CONF:CRC-xxx).
            2. The text, if present, **MAY** contain zero or one [0..1] **reference** (CONF:CRC-xxx).
                a. The URL of a referenced pre-procedure results document **MAY** be present, and **SHALL** be represented in organizer/reference/ExternalDocument/text/reference (CONF:CRC-xxx).
                b. If a URL is referenced, then it **SHOULD** have a corresponding linkHTML element in narrative block (CONF:CRC-xxx).

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6.3.4.8.2 Result Observation - Constraints

[observation: templateId 2.16.840.1.113883.10.20.22.4.2(open)]

This clinical statement represents details of a lab, radiology, or other study performed on a patient.

This Result Observation entry is used exactly as specified in C-CDA - section 5.70 except for vocabulary constraints for the code and value elements. The constraints on the code and value elements are defined in the Results Observations Constraints Set 1.3.6.1.4.1.19376.1.4.1.5.38 **STATIC**.

The value set for CONF:19211 (**code**) **SHOULD** be selected from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT using the codes specified in the Result Observations Constraints Set 1.3.6.1.4.1.19376.1.4.1.5.38 **STATIC**.

The value set for CONF:19212 (**code**) **SHOULD** be selected from ValueSet Cardiac Lab Results Value Set 1.3.6.1.4.1.19376.1.4.1.5.35 **STATIC**.

The value set for CONF:7153 (**targetSiteCode**) **SHOULD** be selected from ValueSet Body Site Value Set 1.3.6.1.4.1.19376.1.4.1.5.32 **STATIC**.

6.3.4.9 Planned Procedure Section 59772-4

[section: templateId 2.16.840.1.113883.10.20.22.2.30(open)]

The Planned Procedure section content module is used exactly as specified in C-CDA - section 4.40.

The Planned Procedure section content module records the procedure(s) that a physician or clinician thought would need to be done based on the preoperative assessment. Procedures include but are not limited to Diagnostic Cath, Angiography, PCI, and structural heart interventions, including TAVR. It may be important to record the procedure(s) that were originally planned for, consented to, and perhaps pre-approved by the payor, particularly if different from the actual procedure(s) and procedure details, to provide evidence to various stakeholders that the providers are aware of the discrepancy and the justification can be found in the procedure details.

The specific procedures in the Plan of Care Activity Procedure entry content module **SHOULD** be selected from ValueSet Cardiac Activity Procedures Value Set 1.3.6.1.4.1.19376.1.4.1.5.40 **STATIC**.

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```
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.30"/>
   <!--  ******** Planned Procedure Section template  ******** -->
   <code code="59772-4" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="Planned Procedure"/>
   <title>Planned Procedure</title>
   <text>
      A diagnostic catheterization is planned.
   </text>
   <entry>
      <procedure moodCode="RQO" classCode="PROC">
         <templateId root="2.16.840.1.113883.10.20.22.4.41"/>
         <!-- ** Plan of Care Activity Procedure Template ** -->
         <id root="9a6d1bac-17d3-4195-89c4-1121bc809b5a"/>
         <code code="41976001" codeSystem="2.16.840.1.113883.6.96"
               displayName="Diagnostic Catheterization"/>
         <statusCode code="new"/>
         <effectiveTime>
             <center value="20000421"/>
         </effectiveTime>
      </procedure>
   </entry>
</section>
```

Figure 6.3.4.9-1: Planned Procedure section example

6.3.4.10 Procedure Indications Section 59768-2

[section: templateId 2.16.840.1.113883.10.20.22.2.29(open)]

The Procedure Indications section content module is used exactly as specified in C-CDA - section 4.50.

The Procedure Indications section content module records details about the reason for this Diagnostic, PCI or Structural Heart Intervention (StHrt-Int) procedure. This Procedure Indications section content module may include the pre-procedure diagnosis or diagnoses as well as one or more symptoms that contribute to the reason the procedure is being performed.

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```
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.29"/>
   <code code="59768-2" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="PROCEDURE INDICATIONS"/>
   <title>Procedure Indications</title>
   <text>The procedure is performed for screening in a low risk individual.
   </text>
   <entry>
      <observation classCode="OBS" moodCode="EVN">
         <!-- Indication Entry -->
         <templateId root="2.16.840.1.113883.10.20.22.4.19"/>
         <code code="409586006"
               codeSystem="2.16.840.1.113883.6.96"
               codeSystemName="SNOMED CT" displayName="Complaint"/>
         <statusCode code="completed"/>
         <value xsi:type="CD"
                code="29857009" codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED CT" displayName="Chest pain"/>
          <entryRelationship typeCode="SUBJ" inversionInd="true">
             <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.22.4.8"/>
                 <!-- ** Severity observation template ** -->
                 <code code="SEV" displayName="Severity Observation"
                     codeSystem="2.16.840.1.113883.5.4"
                     codeSystemName="ActCode"/>
                 <text>
                    <reference value="#severity1"/>
                 </text>
                 <statusCode code="completed"/>
                 <value xsi:type="CD" code="371924009"
                      displayName="Moderate to severe"
                      codeSystem="2.16.840.1.113883.6.96"
                      codeSystemName="SNOMED CT"/>
             </observation>
         </entryRelationship>
      </observation>
   </entry>
</section>
```

Figure 6.3.4.10-1: Procedure Indications section example

6.3.4.10.1 Indication - Constraints

[observation: templateId 2.16.840.1.113883.10.20.22.4.19(open)]

This Indication entry content module is used exactly as specified in C-CDA - section 5.37 except for vocabulary constraints. If an indication requires a severity, then the Indication entry can be extended to include an entryRelationship to a Severity Observation. The Severity Observation would be used exactly as specified in C-CDA – section 5.74.

The Indication entry content module documents the rationale for an activity. It can do this with the id element to reference a problem recorded elsewhere in the document or with a code and

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value to record the problem type and problem within the Indication. For example, the indication for Diagnostic Catheterization might be chest pain.

The value set for CONF:15985 (**value**) **SHOULD** be selected from ValueSet Procedure Indications Value Set `1.3.6.1.4.1.19376.1.4.1.5.37` **STATIC**.

6.3.4.11 Anesthesia Section 59774-0

`[section: templateId 2.16.840.1.113883.10.20.22.2.25(open)]`

The Anesthesia section content module is used exactly as specified in C-CDA - section 4.3.

The Anesthesia section content module briefly describes the general anesthesia used and may state the actual agent used. The Procedure Activity Procedure entry content module describes the anesthesia procedure. The Medication Activity entry content module may describe the general anesthesia medication used during this cath procedure.

```
<section>
    <templateId root="2.16.840.1.113883.10.20.22.2.25"/>
    <code code="59774-0"
          codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          displayName="PROCEDURE ANESTHESIA"/>
    <title>Procedure Anesthesia</title>
    <text> Conscious sedation with propofol 200 mg IV </text>
    <entry>
      <procedure classCode="PROC" moodCode="EVN">
        <!-- Procedure activity procedure template -->
        <templateId root="2.16.840.1.113883.10.20.22.4.14"/>
        <id root="e401f340-7be2-11db-9fe1-0800200c9a66"/>
        <code code="415070008" codeSystem="2.16.840.1.113883.6.96"
              displayName="PCI">
           <originalText> PCI <reference value="procedure1"/></originalText>
        </code>
        <text>
          <reference value="procedure1"/>
        </text>
        <statusCode code="completed"/>
        <effectiveTime value="201109261015"/>
        <targetSiteCode code="41879009"
                  codeSystem="2.16.840.1.113883.6.96"
                  displayName="Distal RCA"/>
        <participant typeCode="DEV">
          <participantRole classCode="MANU">
            <!-- Product instance template -->
            <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
             ...
          </participantRole>
        </participant>
        <entryRelationship typeCode="COMP" inversionInd="true">
```

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```
          <substanceAdministration classCode="SBADM" moodCode="INT">
            <!-- Medication activity template -->
            <templateId root=" 2.16.840.1.113883.10.20.22.4.16"/>
            ...
          </substanceAdministration>
        </entryRelationship>
      </procedure>
    </entry>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <!-- Medication activity template -->
        <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
        ...
      </subtanceAdministration>
    </entry>
</section>
```

Figure 6.3.4.11-1: Anesthesia section example

6.3.4.11.1 Procedure Activity Procedure - Constraints

[procedure: templateId 2.16.840.1.113883.10.20.22.4.14(open)]

The Procedure Activity Procedure entry content module is used exactly as specified in C-CDA - section 5.63, except for vocabulary constraints.

The Procedure Activity Procedure entry content module describes the anesthesia procedure.

The value set for CONF:19207 (**code**) **SHOULD** be selected from ValueSet Cardiac Activity Procedures Value Set 1.3.6.1.4.1.19376.1.4.1.5.40 **STATIC**.

The value set for CONF:16082 (**targetSiteCode**) **SHOULD** be selected from ValueSet Body Site Value Set 1.3.6.1.4.1.19376.1.4.1.5.32 **STATIC**.

6.3.4.12 Medications Administered Section 29549-3

[section: templateId 2.16.840.1.113883.10.20.22.2.38(open)]

This Medications Administered section content module is used exactly as specified in C-CDA - section 4.32 except for vocabulary constraints.

The Medications Administered section content module defines medications and fluids administered during the procedure, encounter, or other activity excluding general anesthetic medications.

A Content Creator **SHALL** be able to create a Medications Activity entry with a Medication Information Entry for each of the cardiac medication classes identified in ValueSet Drug Classes and Specific Cardiac Drugs Used in Cardiac Procedures Value Set 1.3.6.1.4.1.19376.1.4.1.5.41 **STATIC**.

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A Content Creator **SHALL** be able to create a Medications Activity entry with a Medication Information entry for the relevant cardiac contrast agents identified in ValueSet Contrast Agents Value Set `1.3.6.1.4.1.19376.1.4.1.5.39` **STATIC**.

The set of contrast agents implemented may be limited to a subset of the Value Set, based on the types of procedures for which the Content Creator creates reports, hence the term "*relevant* cardiac contrast agents".

```
<section>
    <templateId root="2.16.840.1.113883.10.20.22.2.38" />
    <code code="29549-3"
          codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          displayName="MEDICATIONS ADMINISTERED" />
    <title>Medications Administered</title>
    <text>Aspirin, other antiplatelet agents</text>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
        <!-- Medication Activity template -->
        <id root="cdbd33f0-6cde-11db-9fe1-0800200c9a66"/>
        <text>
          <reference value="#med1”/>
          Aspirin, other antiplatelet agents
        </text>
        <statusCode code="completed"/>
        <effectiveTime xsi:type="IVL_TS">
          <low value="20110926"/>
          <high value="20111014"/>
        </effectiveTime>
        <effectiveTime xsi:type="PIVL_TS" institutionSpecified="true"
            operator="A">
          <period value="6" unit="h"/>
        </effectiveTime>
        <doseQuantity value="1"/>
        <consumable>
          <manufacturedProduct classCode="MANU">>
            <templateId root="2.16.840.1.113883.10.20.22.4.23"/>
            <!-- Medication Information template -->
            <id/>
            <manufacturedMaterial>
              <code code="7947003"
                    codeSystem="2.16.840.1.113883.6.96"
                    displayName="Aspirin"/>
            </manufacturedMaterial>
            <manufacturerOrganization>...</manufacturerOrganization>
          </manufacturedProduct>
        </consumable>
```

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```
        <performer>
        </performer>
      </substanceAdministration>
    </entry>
</section>
```

Figure 6.3.4.12-1: Medications administered section example

6.3.4.12.1 Medication Information - Constraints

[manufacturedProduct: templateId 2.16.840.1.113883.10.20.22.4.23(open)]

This Medication Information entry is used exactly as specified in C-CDA - section 5.41 except for vocabulary constraints.

The value set for CONF:7412 (**manufacturedMaterial/code@code**) **SHOULD** be selected from ValueSet Medication Clinical Drug Value Set 1.3.6.1.4.1.19376.1.4.1.5.41 **STATIC** or **SHOULD** be selected from ValueSet Contrast Agents Value Set 1.3.6.1.4.1.19376.1.4.1.5.39 **STATIC**.

6.3.4.13 Procedure Description – Cardiac Section 29554-3

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.19(open)]

([section: templateId 2.16.840.1.113883.10.20.22.2.27(open)] – parent)

The Procedure Description – Cardiac section content module records the details of the cardiac procedures and may include procedure site preparation, surgical site preparation, pertinent details related to sedation/anesthesia, pertinent details related to measurements and markings, procedure times, medications administered, estimated blood loss, specimens removed, instrumentation, sponge counts, tissue manipulation, wound closure, sutures used, vital signs and other monitoring data. Local practice often identifies the level and type of detail required based on the procedure or specialty.

This Procedure Description – Cardiac section content module may include a device organizer to record information about each device used during the procedures. All devices should be defined at this section level within a Procedure Device Organizer – Cardiac entry.

Additional characteristics inherent to these devices, like length and diameter, should be defined using an additional Procedure Device Organizer – Cardiac entry within this section. In addition, dynamic attributes of these devices, like balloon inflation atmospheres, should be recorded in the Procedure Activity Procedure – Cardiac entry within this section content module.

For PCI procedures, individual lesions will be defined in this section as separate lesion observations identified by a unique “lesion ID”. Only the location of the lesion will be identified here. Procedures, procedure findings, and results can then reference to the lesion to which it is related by creating an entryRelationship of type=”REFR” to the lesion observation based on the “lesion ID” within the Procedure Activity Procedure – Cardiac entry.

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This Procedure Description – Cardiac section content module extends the C-CDA Procedure Description section (C-CDA 4.45) by adding the constraints listed below.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.19" (CONF:CRC-xxx).
2. **MAY** contain zero or more [0..*] **entry** (CONF:CRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **Procedure Device Organizer - Cardiac**(templateId:1.3.6.1.4.1.19376.1.4.1.4.12) (CONF:CRC-xxx).
3. **MAY** contain zero or more [0..*] **entry** (CONF:CRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **Lesion Observation** (templateId:1.3.6.1.4.1.19376.1.4.1.4.10) (CONF:CRC-xxx). These identify the lesions including where they are located.
4. **SHALL** contain at least one [1..*] **entry** (CONF:CRC-xxx) such that it
   a. **SHALL** contain exactly one [1..1] **Procedure Activity Procedure - Cardiac** (templateId:1.3.6.1.4.1.19376.1.4.1.4.14) (CONF:CRC-xxx).

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```
<section>
    <templateId root="1.3.6.1.4.1.19376.1.4.1.2.19"/>
    <templateId root="2.16.840.1.113883.10.20.22.2.27"/>
    <!-- Procedure Description – Cardiac section template -->
    <code code="29554-3"
          codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          displayName="PROCEDURE DESCRIPTION" />
    <title>Procedures</title>
    <text>
      This is the narrative for this section...
    </text>
    <entry>
    <!-- Procedure Device Organizer for device inventory – this could include
the guide wire, the balloon and the stent… -->
       <organizer classCode="CLUSTER" moodCode="EVN">
          <templateId root=”1.3.6.1.4.1.19376.1.4.1.4.12”/>
          <participant typecode=”SUBJ”>
             <participantRole classCode=”MANU”>
                  <id root=” eb936010-7b17-11db-9fe1-0800200c9b66”>
                  <playingDevice>    <!-- guidewire -->
                     <code code=”272224001” codeSystem="2.16.840.1.113883.6.96"
                           displayName="guide wire”/>
                  </playingDevice>
                  <scopingEntity>
                     <id root="eb936010-7b17-11db-9fe1-0800200c9b65"/>
                  </scopingEntity>
             </paricipantRole>
          </participant>
       </organizer>
    </entry>
    <entry>
    <!-- Organizer for specific device with observations (e.g.,
size/dimensions) -->
       <organizer classCode="CLUSTER" moodCode="EVN">
       <!-- Procedure Device Organizer template -->
          <templateId root=”1.3.6.1.4.1.19376.1.4.1.4.12”/>
          <participant typecode=”SUBJ”>
             <participantRole classCode=”MANU”>
                  <id root=” eb936010-7b17-11db-9fe1-0800200c9b68”>
                  <playingDevice>    <!-- stent -->
                     <code code=”3831886012”
                           codeSystem="2.16.840.1.113883.6.96"
                           displayName="JJ-stent”/>
                  </playingDevice>
                  <scopingEntity>
                     <id root="eb936010-7b17-11db-9fe1-0800200c9b65"/>
                  </scopingEntity>
             </paricipantRole>
          </participant>
          <component>
             <observation classCode="SUBJ" moodCode="EVN">
             <!-- Device Observation template -->
                <templateId root=”1.3.6.1.4.1.19376.1.4.1.4.13”/>
```

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```
                <id root=" eb936010-7b17-11db-9fe1-0800200c9b6a">
                <code code="408706001" displayName="vascular stent diameter"
                      codeSystem="2.16.840.1.113883.6.96"
                      codeSystemName="SNOMED CT"/>
                <statusCode code="completed"/>
                <effectiveTime value="201109261015"/>
                <value xsi:type="PQ" value="13.2" unit="mm"/>
             </observation>
          </component>
          <component>
             <observation classCode="SUBJ" moodCode="EVN">>
             <!-- Device Observation template -->
                <templateId root="1.3.6.1.4.1.19376.1.4.1.4.13"/>
                <id root=" eb936010-7b17-11db-9fe1-0800200c9b6a">
                <code code="408703009" displayName="vascular stent length"
                      codeSystem="2.16.840.1.113883.6.96"
                      codeSystemName="SNOMED CT"/>
                <statusCode code="completed"/>
                <effectiveTime value="201109261015"/>
                <value xsi:type="PQ" value="11.8" unit="mm"/>
             </observation>
          </component>
       </organizer>
    </entry>

<!-- define lesions by indicating the targetSiteCodes where located -->
    <entry>
      <observation classCode="OBS" moodCode="EVN">
      <!-- Lesion Observation template -->
        <templateID root="1.3.6.1.4.1.19376.1.4.1.4.10" />
        <id root="2.840.110893.98120.74.8" ext="lesion #1" />
        <code code="404684003"
          codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
          displayName="Finding" />
        <targetSiteCode code="56322004"
          codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
          displayName="Left PDA">
          <qualifier>
            <value code="40415009"
                   codeSystem="2.16.840.1.113883.6.96"
                   codeSystemName="SNOMED CT" displayName="proximal" />
          </qualifier>
        </targetSiteCode>
        <targetSiteCode code="56322004"
          codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
          displayName="Left PDA">
          <qualifier>
            <value code="255562008"
                  codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED CT" displayName="mid" />
          </qualifier>
        </targetSiteCode>
      </observation>
    </entry>
```

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```
    <entry typeCode="DRIV">
      <procedure classCode="PROC" moodCode="EVN">
        <!-- Procedure Activity Procedure – Cardiac template -->
        <templateId root="1.3.6.1.4.1.19376.1.4.1.4.14"/>
        <templateId root="2.16.840.1.113883.10.20.22.4.14"/>
        <id root="CPAC1"/>
        <code code="415070008" codeSystem="2.16.840.1.113883.6.96"
              displayName="PCI>
          <originalText>PCI<reference value="procedure1"/></originalText>
        </code>
        <text>
          <reference value="procedure1"/>
        </text>
        <statusCode code="completed"/>
        <effectiveTime value="201109261015"/>
        <targetSiteCode code="41879009" codeSystem="2.16.840.1.113883.6.96"
                        displayName="Left PDA”/>
        <participant typeCode="PRD">
          <participantRole classCode="MANU">
            <!-- Product instance template -->
            <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
            <playingDevice>
               <id root="P123">
               <code code="102319006" codeSystem="2.16.840.1.113883.6.96"
                     displayName=”Percutaneous transluminal angioplasty
                                  balloon, device (physical object)"/>
            </playingDevice>
            <scopingEntity>
               <id root="eb936010-7b17-11db-9fe1-0800200c9b65"/>
            </scopingEntity>
          </participantRole>
        </participant>
        <participant typeCode="PRD">
          <participantRole classCode="MANU">
            <!-- Product instance template -->
            <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
            <id root="G456">
            <playingDevice>
               <code code="272224001" codeSystem="2.16.840.1.113883.6.96"
                     displayName=”guide wire"/>
            </playingDevice>
            <scopingEntity>
               <id root="eb936010-7b17-11db-9fe1-0800200c9b65"/>
            </scopingEntity>
          </participantRole>
        </participant>
        <entryRelationship typeCode=”REFR”>
           <organizer classCode="CLUSTER" moodCode="EVN">
             <participant typeCode="PRD">
               <participantRole classCode="MANU">
                 <id root="p123">
                 <playingDevice>
                    <code code="102319006"
                          codeSystem="2.16.840.1.113883.6.96"
```

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```
                            displayName=" Percutaneous transluminal angioplasty
                                    balloon, device (physical object)"/>
                  </playingDevice>
                  <scopingEntity>
                    <id root="eb936010-7b17-11db-9fe1-0800200c9b65"/>
                  </scopingEntity>
                </participantRole>
              </participant>
              <component>
                <observation classCode="OBS" moodCode="EVN">
                  <!-- Device observation template -->
                  <templateId root="1.3.6.1.4.1.19376.1.4.1.4.13"/>
                  <id root=" eb936010-7b17-11db-9fe1-0800200c9b6b"/>
                  <code code=”371851006” displayName="angioplasty inflation
pressure"
                    codeSystem="2.16.840.1.113883.6.96"
                    codeSystemName="SNOMED CT"/>
                  <statusCode code="completed"/>
                  <effectiveTime value="201109261015"/>
                  <value xsi:type="PQ" value="13.2" unit="[ATM]"/>
                </observation>
              </component>
              <component>
                <observation classCode="OBS" moodCode="EVN">
                  <!-- Device observation template -->
                  <templateId root="1.3.6.1.4.1.19376.1.4.1.4.13"/>
                  <id root=" eb936010-7b17-11db-9fe1-0800200c9b6c"/>
                  <code code=”371852004”
                        displayName="angioplasty inflation duration"
                        codeSystem="2.16.840.1.113883.6.96"
                        codeSystemName="SNOMED CT"/>
                  <statusCode code="completed"/>
                  <effectiveTime value="201109261015"/>
                  <value xsi:type="PQ" value="11.6" unit="s"/>
                </observation>
              </component>
            </organizer>
          </entryRelationship>

<!-- link to the lesion for this procedure which was defined previously in this
section -->
          <entryRelationship typeCode=”REFR”>
             <observation classCode=”OBS” moodCode=”EVN”>
               <templateID root="1.3.6.1.4.1.19376.1.4.1.10" />
               <id root="2.840.110893.98120.74.8" ext=”lesion #1” />
               <code code="404684003"
                     codeSystem="2.16.840.1.113883.6.96"
                     codeSystemName="SNOMED CT" displayName="Finding" />
             </observation>
          </entryRelationship>
        </procedure>
      </entry>
</section>
```

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Figure 6.3.4.13-1: Procedure Description - Cardiac section example

6.3.4.13.1 Procedure Activity Procedure - Cardiac

[procedure: templateId 1.3.6.1.4.1.19376.1.4.1.4.14 (open)]

([procedure: templateId 2.16.840.1.113883.10.20.22.4.14(open)] – parent)

This clinical statement represents procedures whose immediate and primary outcome (post-condition) is the alteration of the physical condition of the patient. Examples of these procedures are a diagnostic cardiac catheterization and PCI.

This Procedure Activity Procedure – Cardiac entry content module may also include a device organizer to record specific properties of the devices as observed during the procedure. Dynamic attributes of these devices, like balloon inflation atmospheres, should be recorded in this Procedure Activity Procedure – Cardiac entry.

Within this Procedure Activity Procedure – Cardiac entry content module, Product Instances are used to document the devices used. Record as many devices as needed unless the cath lab procedure is aborted. In this case, there may be no devices used.

Developers using this CRC Content Profile will map specific equipment using appropriate inventory numbering and product descriptions provided by the hemodynamic monitoring system or equivalents. If this CRC Content Profile is to be consumed and used in a CVIS, it is up to the developer to map the actual codes to the appropriate ACC NCDR-Cath/PCI codes.

This Procedure Activity Procedure – Cardiac entry content module is used exactly as specified in C-CDA - section 5.63 except for the modifications to the constraints highlighted in yellow below. This Procedure Activity Procedure – Cardiac entry content module is also conformant to the C-CDA Procedure Activity Procedure entry content module.

1. **SHALL** contain exactly one [1..1] **@classCode**="PROC" Procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:7652).
2. **SHALL** contain exactly one [1..1] **@moodCode**, which **SHALL** be selected from ValueSet MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 **STATIC** 2011-04-03 (CONF:7653).
3. **SHALL** contain two or more [2..*] **templateId** (CONF:7654-CRC) such that
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.14" (CONF:10521).
   b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.14" (CONF:CRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:7655).
5. **SHALL** contain exactly one [1..1] **code** (CONF:7656).
   a. This code **SHOULD** be selected from ValueSet Cardiac Activity Procedures Value Set 1.3.6.1.4.1.19376.1.4.1.5.40. If the code is not found in the value set it **MAY** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96), or CPT-4

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(CodeSystem: 2.16.840.1.113883.6.12), or ICD9 Procedures (CodeSystem: 2.16.840.1.113883.6.104), or ICD10 Procedure Coding System (CodeSystem: 2.16.840.1.113883.6.4). (CONF:19207-CRC)

b. This code **SHOULD** contain zero or one [0..1] **originalText** (CONF:19203).
    i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:7659).
        1. The originalText, if present, **SHOULD** contain zero or one [0..1] **@value** (CONF:19205).
            a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:19206).

6. **SHALL** contain exactly one [1..1] **statusCode**, where the @code **SHALL** be selected from ValueSet `ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22` **DYNAMIC** (CONF:7661).
7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:7662).
8. **MAY** contain zero or one [0..1] **priorityCode**, where the @code **SHALL** be selected from ValueSet `ActPriority 2.16.840.1.113883.1.11.16866` **DYNAMIC** (CONF:7668).
9. **MAY** contain zero or one [0..1] **methodCode** (CONF:7670).
    a. methodCode **SHALL NOT** conflict with the method inherent in Procedure / code (CONF:7890).
10. **SHALL** contain at least one [1..*] **targetSiteCode** (CONF:7683-CRC).
    a. The targetSiteCode **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet `Body Site Value Set 1.3.6.1.4.1.19376.1.4.1.5.32` **STATIC** (CONF:16082-CRC).
    b. This code **SHOULD** contain zero or one [0..1] **originalText** (CONF:CRC-xxx).
        i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:CRC-xxx).
            1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:CRC-xxx).
            2. This text is used to describe the native or graft structures in the patient's coronary anatomy.
11. **MAY** contain zero or more [0..*] **specimen** (CONF:7697).
    a. This specimen is for representing specimens obtained from a procedure (CONF:16842).
    b. The specimen, if present, **SHALL** contain exactly one [1..1] **specimenRole** (CONF:7704).
        i. This specimenRole **SHOULD** contain zero or more [0..*] **id** (CONF:7716).

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1. If you want to indicate that the Procedure and the Results are referring to the same specimen, the Procedure/specimen/specimenRole/id **SHOULD** be set to equal an Organizer/specimen/ specimenRole/id (CONF:7717).

12. **SHOULD** contain zero or more [0..*] **performer** (CONF:7718) such that it
    a. **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:7720).
        i. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:7722).
        ii. This assignedEntity **SHALL** contain exactly one [1..1] **addr** (CONF:7731).
        iii. This assignedEntity **SHALL** contain exactly one [1..1] **telecom** (CONF:7732).
        iv. This assignedEntity **SHOULD** contain zero or one [0..1] **representedOrganization** (CONF:7733).
            1. The representedOrganization, if present, **SHOULD** contain zero or more [0..*] **id** (CONF:7734).
            2. The representedOrganization, if present, **MAY** contain zero or more [0..*] **name** (CONF:7735).
            3. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **addr** (CONF:7736).
            4. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **telecom** (CONF:7737).
13. **MAY** contain zero or more [0..*] **participant** (CONF:7751) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="DEV" Device (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:7752).
    b. **SHALL** contain exactly one [1..1] **Product Instance** (templateId:2.16.840.1.113883.10.20.22.4.37) (CONF:15911).
14. **MAY** contain zero or more [0..*] **participant** (CONF:7765) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="LOC" Location (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) (CONF:7766).
    b. **SHALL** contain exactly one [1..1] **Service Delivery Location** (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:15912).
15. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:7768) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:7769).
    b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" true (CONF:8009).
    c. **SHALL** contain exactly one [1..1] **encounter** (CONF:7770).
        i. This encounter **SHALL** contain exactly one [1..1] **@classCode**="ENC" Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:7771).
        ii. This encounter **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:7772).

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iii. This encounter **SHALL** contain exactly one [1..1] **id** (CONF:7773).
1. Set the encounter ID to the ID of an encounter in another section to signify they are the same encounter (CONF:16843).

16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7775) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:7776).
    b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" true (CONF:7777).
    c. **SHALL** contain exactly one [1..1] **Instructions** (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:15913).
17. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:7779) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:7780).
    b. **SHALL** contain exactly one [1..1] **Indication** (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:15914).
18. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:7886) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:7887).
    b. **SHALL** contain exactly one [1..1] **Medication Activity** (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15915).
19. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" References (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:CRC-xxx).
    b. **SHALL** contain exactly one [1..1] **Procedure Device Organizer - Cardiac** (templateId:1.3.6.1.4.1.19376.1.4.1.4.12) (CONF:CRC-xxx).
20. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" References (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:CRC-xxx).
    b. **SHALL** contain exactly one [1..1] **Lesion Observation** (templateId:1.3.6.1.4.1.19376.1.4.1.10) (CONF:CRC-xxx). This refers to the lesion that this procedure is related to.

6.3.4.13.2 Procedure Device Organizer - Cardiac

[organizer: templateId 1.3.6.1.4.1.19376.1.4.1.4.12 (open)]

This Procedure Device Organizer – Cardiac entry content module identifies a set of observations related to a device used during procedures. It is intended to be used to further describe the devices used during these procedures.

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1. **SHALL** contain exactly one [1..1] **@classCode**="CLUSTER" Cluster (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:CRC-xxx).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.12" (CONF:CRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:CRC-xxx).
5. **SHALL** contain exactly one [1..1] **statusCode** (CONF:CRC-xxx)..
    a. This statusCode **SHALL** contain exactly one [1..1] **@code** which **SHALL** be selected from CodeSystem: ActStatus 2.16.840.1.113883.5.14 (CONF:CRC-xxx).
6. **SHOULD** contain zero or one [0..1] **participant** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SBJ" (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) (CONF:CRC-xxx).
    b. **SHALL** contain exactly one [1..1] **participantRole** (CONF:CRC-xxx).
        i. This participantRole **SHALL** contain exactly one [1..1] **@classCode**="MANU" Manufactured Product (CodeSystem: RoleClass 2.16.840.1.113883.5.110) (CONF:CRC-xxx).
        ii. This participantRole **SHALL** contain exactly one [1..1] **playingDevice** (CONF:CRC-xxx).
            1. This playingDevice **SHALL** contain exactly one [1..1] **@classCode**="MMAT" Manufactured Material (CodeSystem: EntityClass 2.16.840.1.113883.5.41) (CONF:CRC-xxx).
            2. This playingDevice **SHALL** contain exactly one [1..1] **code** (CONF:CRC-xxx).
        iii. This participantRole **SHALL** contain at least one [1..*] **id** (CONF:CRC-xxx).
7. **MAY** contain zero or more [0..*] **component** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **Device Observation** (templateId:1.3.6.1.4.1.19376.1.4.1.4.13) (CONF:CRC-xxx).

6.3.4.13.3 Device Observation

[observation: templateId 1.3.6.1.4.1.19376.1.4.1.4.13(open)]

This Device Observation entry represents observations made of devices used during a procedure, such as a cardiac procedure. An example of a device observation would be balloon inflation time.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:CRC-xxx).

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3. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.13" (CONF:CRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:CRC-xxx).
5. **SHALL** contain exactly one [1..1] **code** (CONF:CRC-xxx).
    a. **SHOULD** be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:CRC-xxx).
6. **SHOULD** contain zero or one [0..1] **text** (CONF:CRC-xxx).
    a. The text, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:CRC-xxx).
        i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:CRC-xxx).
7. **SHALL** contain exactly one [1..1] **statusCode**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:CRC-xxx).
8. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:CRC-xxx).
    a. This represents the clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when the sample was taken (and measured some time afterwards) (CONF:CRC-xxx).
9. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ANY" (CONF:CRC-xxx).

6.3.4.14 Procedure Specimens Taken Section 59773-2

[section: templateId 2.16.840.1.113883.10.20.22.2.31(open)]

This Procedure Specimens Taken section is used exactly as specified in C-CDA - section 4.51.

The Procedure Specimens Taken section records the tissues, objects, or samples taken from the patient during the procedure including biopsies, aspiration fluid, or other samples sent for pathological analysis. The narrative may include a description of the specimens.

```
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.31"/>
   <code code="59773-2"
         codeSystem="2.16.840.1.113883.6.1"
         codeSystemName="LOINC"
         displayName="PROCEDURE SPECIMENS TAKEN"/>
   <title>Procedure Specimens Taken</title>
   <text>Ascending colon polyp</text>
</section>
```

Figure 6.3.4.14-1: Procedure specimens taken section example

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6.3.4.15 Procedure Disposition Section 59775-7

[section: templateId 2.16.840.1.113883.10.20.18.2.12(open)]

This Procedure Disposition section is used exactly as specified in C-CDA - section 4.46.

```
<section>
  <templateId root="2.16.840.1.113883.10.20.18.2.12"/>
  <code code="59775-7" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"
        displayName="PROCEDURE DISPOSITION"/>
  <title>PROCEDURE DISPOSITION</title>
  <text>The patient was taken to the ICU Recovery Unit in stable
        condition.</text>
</section>
```

Figure 6.3.4.15-1: Procedure disposition section example

6.3.4.16 Procedure Results - Cardiac Section 30954-2

[section: templateId 1.3.6.1.4.1.19376.1.4.1.2.20 (open)]

([section: templateId 2.16.840.1.113883.10.20.22.2.3.1(open)] – parent)

This Procedure Results – Cardiac section content module records clinically significant results confirmed or discovered during the procedure. Results include findings, measurements, calculations, and observations.

For this CRC Profile, this Procedure Results – Cardiac section content module should be organized using Procedure Results Organizer – Cardiac entry content modules for specific categories (e.g., right heart cath findings, coronary anatomy findings, left heart cath findings, PCI findings, and structural heart interventional procedure findings). There shall be a Procedure Result Organizer – Cardiac entry content module for one or more of these categories of findings. The allowed categories are defined in ValueSet CRC Procedure Findings Types Value Set 1.3.6.1.4.1.19376.1.4.1.5.43 which can be expanded to include other procedures.

Result Observation – Cardiac entries are used to record specific findings (e.g., stenosis, timi flow, lesion characteristics, or wall motion characteristics) in each category. The specific findings should be selected from the Result Observations Constraints Set 1.3.6.1.4.1.19376.1.4.1.5.38. Note that these findings may apply to lesions and coronary anatomy.

This Procedure Results – Cardiac section content module is a modification of the C-CDA Results Section with Coded Entries Required (C-CDA 4.48). The modifications are highlighted in yellow below. This Procedure Results – Cardiac section content module is also conformant to the C-CDA Results Section content module.

1. **SHALL** contain three or more [3..*] **templateId** (CONF:7108-CRC) such that it

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a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.3" (CONF:9136).
b. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.3.1" (CONF:9137).
c. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.2.20" (CONF:CRC-xxx).

2. **SHALL** contain exactly one [1..1] **code** (CONF:15433).
    a. This code **SHALL** contain exactly one [1..1] **@code**="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15434).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8892).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7111).
5. **SHALL** contain at least one [1..*] **entry** (CONF:7112-CRC) such that it
    a. **SHALL** contain exactly one [1..1] **Procedure Results Organizer - Cardiac** (templateId:1.3.6.1.4.1.19376.1.5.3.1.4.15) (CONF:7113-CRC).

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```
<section>
    <templateId root="21.3.6.1.4.1.19376.1.4.1.2.20" />
    <templateId root="2.16.840.1.113883.10.20.22.2.3.1" />
    <templateId root="2.16.840.1.113883.10.20.22.2.3" />
    <code code="30954-2"
          codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC"
          displayName="RESULTS" />
    <title>Procedure results</title>
       <text>
       Left Main:  No significant narrowing noted. Proximal LAD:  No significant
       narrowing Noted. Mid/Distal LAD, Diag Branches:  No significant
       narrowing noted. RCA, RPDA, RPL, AM Branches:  The distal RCA has a
       stenosis of 90 percent. Circ., OMs, LPDA, LPL Branches:  The proximal
       Left Circumflex has a stenosis of 80 percent. Ramus:  No Significant
       narrowing noted.
        <content ID="observation1">Post procedure stenosis of the Distal RCA is
0%.</content>
       <content ID="severity3">Moderate to severe</content>
       </text>
    <entry>
      <organizer classCode="CLUSTER" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
        <!-- Procedure Results Organizer - Cardiac -->
        <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.15"/>
        <id root="7d5a02b0-67a4-11db-bd13-0800200c9a66"/>
        <code code="500786010" displayName="Left Heart Cath Procedure"
              codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
        <statusCode code="completed"/>
        <component>
          <observation classCode="OBS" moodCode="EVN">
            <!-- Result observation – cardiac template -->
            <templateId root="1.3.6.1.4.1.19376.1.4.1.4.16"/>
            <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
            <id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>
            <code code="233970002" codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED CT"
                  displayName="Post procedure stenosis"/>
            <text><reference value="observation1"/></text>
            <statusCode code="completed"/>
            <effectiveTime value="19991114"/>
            <targetSiteCode code="41879009"
                            codeSystem="2.16.840.1.113883.6.96"
                            displayName="Distal RCA"/>
```

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```
            <value xsi:type="PQ" value="0" unit="%"/>
            <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
            <entryRelationship typeCode=”SUBJ” inversionInd=”TRUE”>
              <observation classCode="OBS" moodCode="EVN">
                <!-- Severity observation template -->
                <templateId root=" 2.16.840.1.113883.10.20.22.4.8"/>
                <id root="c6f88321-67ad-11db-bd13-0800200c9a66" ext=”Lesion1”/>
                <code code="SEV" displayName="Severity Observation"
                      codeSystem="2.16.840.1.113883.5.4"
                      codeSystemName="ActCode"/>
                <text><reference value="#severity3"/></text>
                <statusCode code="completed"/>
                <value xsi:type="CD" code="371924009"
                       displayName="Moderate to severe"
                       codeSystem="2.16.840.1.113883.6.96"
                       codeSystemName="SNOMED CT"/>
              </observation>
            </entryRelationship>
          </observation>
        </component>
        <component>
          <observation classCode="OBS" moodCode="EVN">
            <!-- Result observation – cardiac template -->
            <templateId root="1.3.6.1.4.1.19376.1.4.1.4.16"/>
            ...
          </observation>
        </component>
        <entryRelationship typeCode=”REFR”>
          <observation classCode="OBS" moodCode="EVN">
            <!-- Lesion observation template -->
            <templateId root="1.3.6.1.4.1.19376.1.4.1.4.10"/>
            <id root="2.840.110893.98120.74.8" ext=”lesion #1” />
            <code code="404684003" displayName="Finding"
                  codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED CT"/>
          </observation>
        </entryRelationship>
      </organizer>
    </entry>
</section>
```

Figure 6.3.4.16-1: Results section example

6.3.4.16.1 Procedure Results Organizer - Cardiac

[`organizer`: `templateId` `1.3.6.1.4.1.19376.1.5.3.1.4.15 (open)`]

([`observation`: `templateId` `2.16.840.1.113883.10.20.22.4.1(open)`] – `parent`)

This Procedure Results Organizer – Cardiac entry content module identifies a set of related procedure results, findings and observations. It contains information applicable to all of the contained procedure findings, including the lesion for PCI procedures. Related

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procedure findings type codes categorize a finding into one of several commonly accepted values (e.g., “Right heart cath”, “Left heart cath”, “PCI”, “TAVR”).

This Procedure Results Organizer – Cardiac entry content module is a modification of the C-CDA Result Organizer Section (C-CDA 5.71). The modifications are highlighted in yellow below. This Procedure Results Organizer – Cardiac entry content module is also conformant to the C-CDA Results Organizer entry content module.

1. **SHALL** contain exactly one [1..1] **@classCode** (CONF:7121).
    a. **SHALL** contain exactly one [1..1] @classCode="CLUSTER" Cluster (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF: 7165-xxx).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:7122).
3. **SHALL** contain two or more [2..*] **templateId** (CONF:7126-CRC) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.1" (CONF:9134).
    b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.15" (CONF:CRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:7127).
5. **SHALL** contain exactly one [1..1] **code** (CONF:7128).
    a. **SHOULD** be selected from Cardiac Procedure Results Organizers Value Set 1.3.6.1.4.1.19376.1.4.1.5.64 or **MAY** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), or CPT-4 (codeSystem 2.16.840.1.113883.6.12) (CONF:19219-CRC).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7123).
    a. This statusCode **SHALL** contain exactly one [1..1] **@code** which **SHALL** be selected from ValueSet ResultStatus 2.16.840.1.113883.11.20.9.39 **STATIC** (CONF:14848).
7. **SHALL** contain at least one [1..*] **component** (CONF:7124) such that it
    a. **SHALL** contain exactly one [1..1] **Result Observation - Cardiac** (templateId:1.3.6.1.4.1.19376.1.4.1.4.16) (CONF:14850-CRC).
8. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" References (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:CRC-xxx).
    b. **SHALL** contain exactly one [1..1] **Lesion Observation** (templateId:1.3.6.1.4.1.19376.1.4.1.10) (CONF:CRC-xxx). This refers to the lesion that these results are related to.

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6.3.4.16.2 Result Observation - Cardiac

`[observation: templateId 1.3.6.1.4.1.19376.1.4.1.4.16 (open)]`

(`[observation: templateId 2.16.840.1.113883.10.20.22.4.2(open)]` – `parent`)

A result observation is a clinical statement that a clinician has noted during the Cath Lab procedure. This Result Observation – Cardiac entry content module is used to describe the specific procedure findings that were observed during the specific Cath Lab procedure.

The specific result observations are defined in the Result Observations Constraints Set `1.3.6.1.4.1.19376.1.4.1.5.38`.

The targetSiteCode may be used for diagnostic cath procedures.

This Result Observation – Cardiac entry content module is a modification of the C-CDA Result Observation (C-CDA 5.70). The modifications are highlighted in yellow below. This Result Observation – Cardiac entry content module is also conformant to the C-CDA Result Observation entry content module.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:7130).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:7131).
3. **SHALL** contain two or more [2..*] **templateId** (CONF:7136-CRC) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.2" (CONF:9138).
    b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.16" (CONF:CRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:7137).
5. **SHALL** contain exactly one [1..1] **code** (CONF:7133).
    a. **SHOULD** be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) or Result Observations Constraints Set (1.3.6.1.4.1.19376.1.4.1.5.38) (CONF:19211-CRC).
6. **SHOULD** contain zero or one [0..1] **text** (CONF:7138).
    a. The text, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:15924).
        i. The reference, if present, **SHOULD** contain zero or one [0..1] **@value** (CONF:15925).
            1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15926).
7. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7134).
    a. This statusCode **SHALL** contain exactly one [1..1] **@code** which **SHALL** be selected from ValueSet Result Status 2.16.840.1.113883.11.20.9.39) **STATIC** (CONF:14849).

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8. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7140).
    a. Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards) (CONF:16838).
9. **SHALL** contain exactly one [1..1] **value** (CONF:7143).
10. **SHOULD** contain zero or more [0..*] **interpretationCode** (CONF:7147).
11. **MAY** contain zero or one [0..1] **methodCode** (CONF:7148).
12. **MAY** contain zero or one [0..1] **targetSiteCode** (CONF:7153).
    a. The targetSiteCode, if present, **SHALL** contain exactly one [1..1] **code** where the @code **SHALL** be selected from ValueSet `Body Site Value Set 1.3.6.1.4.1.19376.1.4.1.5.32` **STATIC** (CONF:CRC-xxx).
13. **MAY** contain zero or one [0..1] **author** (CONF:7149).
14. **SHOULD** contain zero or more [0..*] **referenceRange** (CONF:7150).
    a. The referenceRange, if present, **SHALL** contain exactly one [1..1] **observationRange** (CONF:7151).
        i. This observationRange **SHALL NOT** contain [0..0] **code** (CONF:7152).
15. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: `HL7ActRelationshipType 2.16.840.1.113883.5.1002`) (CONF:CRC-xxx).
    b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" TRUE (CONF:CRC-xxx).
    c. **SHALL** contain exactly one [1..1] **Severity Observation** (`templateId:2.16.840.1.113883.10.20.22.4.8`) (CONF:CRC-xxx).

6.3.4.17 Complications Section 55109-3

[`section: templateId 2.16.840.1.113883.10.20.22.2.37(open)`]

This Complications section content module records problems that occurred during the cath lab procedure. The complications may have been known risks or unanticipated problems.

This Complications section content module is used exactly as specified in C-CDA - Section 4.8, except for vocabulary constraints for Problem Observation entries.

There is a CRC specific value set defined for complications recorded as Problem Observation entries in this Complications section content module.

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```
<section>
  <templateId root=”2.16.840.1.113883.10.20.22.2.37”/>
  <code code=”55109-3” codeSystem=”2.16.840.1.113883.6.1”
        codeSystemName=”LOINC”
        displayName=”Complications”/>
  <title>Complications</title>
  <text>Complications for the cath procedure for patient included:
        x, y, z…
  </text>
  <entry>
    <observation classCode=”OBS” moodCode=”EVN”>
      <templateId root=”2.16.840.1.113883.10.20.22.4.4”/>
      <id root=”d11275e7-67ae-11db-bd13-0800200c9a66”/>
      <code code=”404684003” codeSystem=”2.16.840.1.113883.6.96”
            displayName=”Finding”/>
      <text>The patient has had a myocardial infarction..</text>
      <statusCode code=”completed”/>
      <effectiveTime>
         <low value=”201201251000”/>
      </effectiveTime>
      <value xsi:type=”CD” code=”22298006”
            codeSystem=”2.16.840.1.113883.6.96” codeSystemName=”SNOMED CT”
            displayName=”Myocardial Infarction (Biomarker Positive)”/>
      <entryRelationship typeCode="REFR">
         <observation classCode="OBS" moodCode="EVN">
           <templateId root="2.16.840.1.113883.10.20.22.4.6"/>
           <!-- Problem Status template -->
           <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
                 codeSystemName="LOINC" displayName="Status"/>
           <statusCode code="completed"/>
           <value xsi:type="CD" code="55561003"
                  codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED CT" displayName="Active"/>
         </observation>
      </entryRelationship>
    </observation>
  </entry>
  <entry>
    <observation classCode=”OBS” moodCode=”EVN”>
      <templateId root=”1.3.6.1.4.1.19376.1.4.1.4.9”/>
      <id root=”xyz”/>
      …
    </observation>
  </entry>
</section>
```

Figure 6.3.4.17-1: Complications section example

6.3.4.17.1 Problem Observation – Constraints

`[observation: templateId 2.16.840.1.113883.10.20.22.4.4 (open)]`

A problem is a clinical statement that a clinician has noted during the Cath procedure. This entry is used to describe the presence or absence of specific “complications” as defined by ACC.

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This Problem Observation entry content module is used exactly as specified in C-CDA - section 5.59, except for vocabulary constraints.

The value set for CONF:9058 (**`value@code`**) **SHOULD** be selected from ValueSet Complications Value Set `1.3.6.1.4.1.19376.1.4.1.5.46` **STATIC.**

6.3.4.18 Postprocedure Diagnosis Section 59769-0

[`section`: `templateId` `2.16.840.1.113883.10.20.22.2.36(open)`]

The Postprocedure Diagnosis section content module records the diagnosis or diagnoses discovered or confirmed during the procedure. Often it is the same as the pre-procedure diagnosis or indication.

This Postprocedure Diagnosis section content module is used exactly as specified in C-CDA - section 4.42, except for vocabulary constraints.

There is a CRC specific value set defined for problem observations recorded as part of postprocedure diagnosis which is included in the Problem Observation entry.

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```
<section>
   <templateId root="2.16.840.1.113883.10.20.22.2.36"/>
   <code code="59769-0" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="POSTPROCEDURE DIAGNOSIS"/>
   <title>Postprocedure Diagnosis</title>
   <text>It was observed that there was complication of myocardial
         infarction during the cath procedure.</text>
   <entry>
      <act moodCode="EVN" classCode="ACT">
         <templateId root="2.16.840.1.113883.10.20.22.4.51"/>
         <!-- ** Postprocedure Diagnosis Entry ** -->
         <code code="59769-0" codeSystem="2.16.840.1.113883.6.1"
               codeSystemName="LOINC"
               displayName="Postprocedure Diagnosis"/>
         <entryRelationship typeCode="SUBJ">
            <observation classCode="OBS" moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
               <!-- Problem Observation template -->
               <id root=”d11275e7-67ae-11db-bd13-0800200c9a66”/>
               <code code=”404684003” codeSystem=”2.16.840.1.113883.6.96”
                     codeSystemName=”SNOMED CT”
                     displayName=”Finding”/>
               <text>It was observed that there was complication of myocardial
                     infarction during the cath procedure.</text>
               <statusCode code=”completed”/>
               <effectiveTime>
                  <low value=”201201251000”/>
               </effectiveTime>
               <value xsi:type=”CD” code=”22298006”
                      codeSystem=”2.16.840.1.113883.6.96”
                      codeSystemName=”SNOMED CT”
                      displayName=”Myocardial Infarction (Biomarker
Positive)”/>
               <entryRelationship typeCode="REFR">
                 <observation classCode="OBS" moodCode="EVN">
                    <templateId root="2.16.840.1.113883.10.20.22.4.6"/>
                    <!-- Problem Status template -->
                    <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
                          codeSystemName="LOINC" displayName="Status"/>
                    <statusCode code="completed"/>
                    <value xsi:type="CD" code="55561003"
                           codeSystem="2.16.840.1.113883.6.96"
                           codeSystemName="SNOMED CT" displayName="Active"/>
                 </observation>
               </entryRelationship>
            </observation>
         </entryRelationship>
         ...
      </act>
   </entry>
</section>
```

Figure 6.3.4.18-1: Postprocedure diagnosis section example

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6.3.4.18.1 Problem Observation – Constraints

`[observation: templateId 2.16.840.1.113883.10.20.22.4.4 (open)]`

The Problem Observation entry is used to describe a final diagnosis.

This Problem Observation entry is used exactly as specified in C-CDA - section 5.59, except for vocabulary constraints.

The value set for CONF:9058 (**`value`**) **SHOULD** be selected from ValueSet CRC Postprocedure Diagnosis Value Set `1.3.6.1.4.1.19376.1.4.1.5.44` **STATIC**.

6.3.4.19 Plan of Care - Cardiac Section 18776-5

[`section: templateId 1.3.6.1.4.1.19376.1.4.1.2.22 (open)`]

([`section: templateId 2.16.840.1.113883.10.20.22.2.10(open)`] – `parent`)

This Plan of Care - Cardiac section content module is intended to be used to describe the post-procedure plan.

The Plan of Care - Cardiac section content module contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only, which are indicated by the `@moodCode` of the entries within this section. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education was given or will be provided.

This Plan of Care – Cardiac section content module is a modification of the C-CDA Plan of Care section (C-CDA 4.39). The modifications are highlighted in yellow below. This Plan of Care – Cardiac section content module is also conformant to the C-CDA Plan of Care section content module.

1. **SHALL** contain two or more [2..*] **`templateId`** (CONF:7723-CRC) such that it
   a. **SHALL** contain exactly one [1..1] **`@root`**`="2.16.840.1.113883.10.20.22.2.10"` (CONF:10435).
   b. **SHALL** contain exactly one [1..1] **`@root`**`="1.3.6.1.4.1.19376.1.4.1.2.22"` (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **`code`** (CONF:14749).
   a. This code **SHALL** contain exactly one [1..1] **`/@code`**`="18776-5"` Plan of Care (CodeSystem: `LOINC 2.16.840.1.113883.6.1`) (CONF:14750).
3. **SHALL** contain exactly one [1..1] **`title`** (CONF:16986).
4. **SHALL** contain exactly one [1..1] **`text`** (CONF:7725).
5. **MAY** contain zero or more [0..*] **`entry`** (CONF:7726) such that it

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a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Act - Cardiac** (templateId:1.3.6.1.4.1.19376.1.4.1.4.17) (CONF:14751-CRC).

6. **MAY** contain zero or more [0..*] **entry** (CONF:8805) such that it
   a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Encounter** (templateId:2.16.840.1.113883.10.20.22.4.40) (CONF:14752).
7. **MAY** contain zero or more [0..*] **entry** (CONF:8807) such that it
   a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Observation** (templateId:2.16.840.1.113883.10.20.22.4.44) (CONF:14753).
8. **MAY** contain zero or more [0..*] **entry** (CONF:8809) such that it
   a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Procedure** (templateId:2.16.840.1.113883.10.20.22.4.41) (CONF:14754).
9. **MAY** contain zero or more [0..*] **entry** (CONF:8811) such that it
   a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Substance Administration** (templateId:2.16.840.1.113883.10.20.22.4.42) (CONF:14755).
10. **MAY** contain zero or more [0..*] **entry** (CONF:8813) such that it
    a. **SHALL** contain exactly one [1..1] **Plan of Care Activity Supply** (templateId:2.16.840.1.113883.10.20.22.4.43) (CONF:14756).
11. **MAY** contain zero or more [0..*] **entry** (CONF:14695) such that it
    a. **SHALL** contain exactly one [1..1] **Instructions** (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:16751).

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```
<section>
   <templateId root="1.3.6.1.4.1.19376.1.4.1.2.22" />
   <templateId root="2.16.840.1.113883.10.20.22.2.10" />
   <!--  **** Plan of Care – Cardiac section template  **** -->
   <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="Treatment plan"/>
   <title>Plan of Care</title>
   <text>
      ...
   </text>
   <entry>
      <act moodCode="RQO" classCode="ACT">
         <!--  ****  Plan of Care Activity Act - Cardiac template   **** -->
         <templateId root="1.3.6.1.4.1.19376.1.4.1.4.17"/>
         <templateId root="2.16.840.1.113883.10.20.22.4.39"/>
         <id root="9a6d1bac-17d3-4195-89a4-1121bc809a5c"/>
         <code code="415070008" codeSystem="2.16.840.1.113883.6.96"
               displayName="PCI without planned CABG"/>
         <statusCode code="new"/>
         <effectiveTime>
            <center value="20000421"/>
         </effectiveTime>
      </act>
   </entry>
</section>
```

Figure 6.3.4.19-1: Plan of care section example

6.3.4.19.1 Plan of Care Activity Act - Cardiac

[act: templateId 1.3.6.1.4.1.19376.1.4.1.4.17 (open)]

([act: templateId 2.16.840.1.113883.10.20.22.4.39(open)] – parent)

This Plan of Care Activity Act – Cardiac entry content module is a modification of the C-CDA Plan of Care Activity Act (C-CDA 5.46). The modifications are highlighted in yellow below. This Plan of Care Activity Act – Cardiac entry content module is also conformant to the C-CDA Plan of Care Activity Act entry content module.

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:8538).
2. **SHALL** contain exactly one [1..1] **@moodCode**, which **SHALL** be selected from ValueSet Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 **STATIC** 2011-09-30 (CONF:8539).
3. **SHALL** contain two or more [2..*] **templateId** (CONF:8544-CRC) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.39" (CONF:10510).
   b. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.4.17" (CONF:CRC-xxx).

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4. **SHALL** contain at least one [1..*] **id** (CONF:8546).
5. **SHALL** contain exactly one [1..1] **code** (CONF:CRC-xxx)
    a. This code **SHALL** contain exactly one [1..1] **/@code** which **SHOULD** be selected from ValueSet Rx Recommendation `1.3.6.1.4.1.19376.1.4.1.5.42` **STATIC** (CONF:CRC-XXX).
6. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:CRC-xxx).

6.3.4.20 Key Images – Cardiac Section – DCM 121180

[section: `templateId 1.3.6.1.4.1.19376.1.4.1.2.21(open)`]

The Key Images section content module contains narrative description of and references to DICOM Image Information Objects that illustrate the findings of the procedure reported.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="`1.3.6.1.4.1.19376.1.4.1.2.21`" (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **code** (CONF:CRC-xxx).
    a. This code **SHALL** contain exactly one [1..1] **@code**="`121180`" Key Images (CodeSystem: `1.2.840.10008.2.16.4 DCM`) (CONF:CRC-xxx).
3. **SHALL** contain exactly one [1..1] **text** (CONF:CRC-xxx).
4. **SHALL** contain at least one [1..*] **entry** (CONF:CRC-xxx)
    a. **SHALL** contain exactly one [1..1] **Sop Instance Observation** (`templateId:2.16.840.1.113883.10.20.6.2.8`) (CONF:CRC-xxx).

6.3.5 Common Entry Content Modules

6.3.5.1 Problem Observation – Cardiac

`[Observation: templateId 1.3.6.1.4.1.19376.1.4.1.9(open)]`

`([Observation: templateId 2.16.840.1.113883.10.20.22.4.4(open)] – parent)`

A problem is a clinical statement that a clinician has noted. In health care it is a condition that requires monitoring or diagnostic, therapeutic, or educational action. It also refers to any unmet or partially met basic human need. In cardiology, problems include hypertension, diabetes, and dyslipidemia.

This Problem Observation – Cardiac entry content module extends the C-CDA Problem Observation entry definition (C-CDA 5.59) by adding the following constraints:

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:CRC-xxx) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="`1.3.6.1.4.1.19376.1.4.1.9`" (CONF:CRC-xxx).
2. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:CRC-xxx) such that it

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a. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:CRC-xxx).
b. **SHALL** contain exactly one [1..1] **@inversionInd**="true" TRUE (CONF:CRC-xxx).
c. **SHALL** contain exactly one [1..1] **Severity Observation** (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:CRC-xxx).

6.3.5.2 Lesion Observation

[Observation: templateId 1.3.6.1.4.1.19376.1.4.1.10(open)]

This Lesion Observation entry content module identifies a lesion of interest for a PCI procedure. The lesion is identified by a global ID in the **id** element and one or more target sites.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:CRC-xxx).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:CRC-xxx).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:7299) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.4.1.10" (CONF:CRC-xxx).
4. **SHALL** contain at least one [1..*] **id** (CONF:CRC-xxx)
   a. where the **@root SHALL** be a globally unique root and the **@ext SHALL** be a text string representing the lesion ID (CONF:CRC-xxx).
5. **SHALL** contain exactly one [1..1] **code**, where the @code **SHOULD** be “404684003” selected from SNOMED CT and has @displayName=”Finding” (CONF:CRC-xxx).
6. **SHOULD** contain zero or one [0..1] **text** (CONF:CRC-xxx).
   a. The text, if present, **SHOULD** contain zero or one [0..1] **reference/@value** (CONF:CRC-xxx).
      i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:CRC-xxx).
7. **MAY** contain zero or more [0..*] **targetSiteCode**, where the @code **SHOULD** be selected from ValueSet Body Site 1.3.6.1.4.1.19376.1.4.1.5.32 **STATIC** (CONF:CRC-xxx).
   a. The targetSiteCode, if present **MAY** contain zero or more [0..*] **qualifier** to further identify the exact location of the lesion (CONF:CRC-xxx).

6.3.6 Cath Report Content Vocabulary Constraints

6.3.6.1 Cardiac problems/concerns - Vocabulary Constraints

The Content Creator shall be capable of creating a problem/concern selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.31, listed below.

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3155 **Table 6.3.6.1-1: Cardiac problems/concerns 1.3.6.1.4.1.19376.1.4.1.5.31 STATIC**

Coding Scheme / Concept	SNOMED CT CODE	NCDR CathPCI Sequence No.	ACC-STS TVT Sequence No.
Hypertension (disorder)	38341003	4000	4155
Dyslipidemia (disorder)	370992007	4010	4105
Diabetes (disorder)	73211009	4085	4165
Diabetic on insulin (finding)	170747006		4170
Diabetic on oral treatment (finding)	170746002		4170
Diabetic on diet only (finding)	170745003		4170
Acute renal failure (disorder)	14669001		
Chronic kidney disease	236425005		
Dependence on renal dialysis (finding)	105502003		4175
Peripheral arterial disease	399957001		4145
Cerebrovascular disease	62914000	4070	
Erectile dysfunction	398175007		
Cardiac arrhythmia	44808001		
Asthma	195967001		
Bronchospasm	4386001		
Implanted pacemaker	371821000		4010
Heart failure	84114007	5040	5020
H/O Heart failure	416683003		
Myocardial infarction	22298006	5000	
Angina	194828000		
Currently on Dialysis (dependence on renal dialysis)	105502003	4065	4175
Chronic Lung Disease	413839001	4080	4180
Chronic Left Ventricular Systolic	430396006	5050	

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Coding Scheme / Concept	SNOMED CT CODE	NCDR CathPCI Sequence No.	ACC-STS TVT Sequence No.
Dysfunction			
Ischemic Cardiomyopathy	194849004		5012
Non-ischemic (congestive) Cardiomyopathy	111000119104		
Cardiogenic Shock	89138009	5060	
Cardiac Arrest	410429000	5065	
Prior MI	22298006	4020	5005
Prior Valve Surgery/Procedure	73544002		
Prior PCI	415070008	4035	4020
Prior CABG	232717009	4045	4030
Angina Type	Pick one from Value Set 1.3.6.1.4.1.19376.1.4.1.5.49	5020	
Endocarditis	56819008		4000
Infective Endocarditis (disorder)	233850007		4005
Permanent Pacemaker (finding)	119551000119102		4010
ICD in situ (finding)	443325000		4015
History of removal of ICD (situation)	11007231000119107		4015
aortic stenosis (disorder)	60573004		
History of aortic valve repair	119481000119105		4060
History of aortic valve replacement	1231000119100		4060
Percutaneous balloon valvuloplasty of aortic valve (procedure)	77166000		4085
Repair of implanted aortic paravalvular leak (procedure)	232841002		4091
AV Replacement Surgical (situation)	1231000119100		4070
AV Repair – Surgical (situation)	119481000119105		4080
Transapical	443887000		4090

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Coding Scheme / Concept	SNOMED CT CODE	NCDR CathPCI Sequence No.	ACC-STS TVT Sequence No.
implantation of aortic valve (procedure)			
Percutaneous replacement of aortic valve using fluoroscopic guidance (procedure)	441873006		4090
MV Repair Surgical	429219001		4110
H/O Prior Tricuspid Valve Repair	119541000119104		4118
H/O Prior Tricuspid Valve Replacement	36791000119109		4119
H/O pulmonic valve replacement	94461000119106		
History of cerebrovascular accident (situation) - Stroke	275526006		4120
Transient Ischemic Attack	275526006		4130
Carotid atherosclerosis (condition)	300920004		4135
H/O Carotid endarterectomy (situation)	428534000		4140
H/O Carotid Angioplasty (situation)	429259003		4140
Percutaneous transluminal insertion of stent into carotid artery (procedure)	4225611003		4140
Patient on oxygen (finding)	371825009		4181
Immunocompromise Present (finding)	370388006		4185
Atherosclerosis of aorta (disorder)	81817003		5045
Conduction disorder of the heart (disorder)	44808001		5055
Right Ventricle	473365008		

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Coding Scheme / Concept	SNOMED CT CODE	NCDR CathPCI Sequence No.	ACC-STS TVT Sequence No.
Dysfunction			
Chemotherapy for Malignancy	161653008		5908
Major Bleeding Diathesis	64779088		5909
Immobility	203041005		5910
AIDS (Disorder)	62479008		5911
Severe Dementia	52448006		5912
High Risk of Aspiration	371736008		5913
IMA at High Risk of Injury			5914

6.3.6.2 Body Site Value Set - Vocabulary Constraint

The Content Creator shall be capable of creating a body site selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.32, listed below. This structure is used to represent the native coronary structure of the heart.

Table 6.3.6.2-1: Body Site Value Set 1.3.6.1.4.1.19376.1.4.1.5.32 STATIC

Coding Scheme / Concept	SNOMED CT
Left Main Coronary Artery	3227004
Left Main Coronary Artery Ostium	76862008
Left Anterior Descending Coronary Artery	59438005
Proximal Left Anterior Descending Coronary Artery	68787002
Mid Left Anterior Descending Coronary Artery	91748002
Distal Left Anterior Descending Coronary Artery	36672000
Left Posterior Descending Artery	56322004
Left Posterior Descending Circumflex Coronary Artery	91760001
Left Posterolateral Circumflex Coronary Artery	57823005
Right Coronary Artery	13647002
Right Coronary Artery Ostium	56789007
Proximal Right Coronary Artery	91083009
Mid Right Coronary Artery	450960006
Distal Right Coronary Artery	41879009
Circumflex Coronary Artery	57396003
Proximal Circumflex Coronary Artery	52433000

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Concept \ Coding Scheme	SNOMED CT
Mid Circumflex Coronary Artery	91753007
Distal Circumflex Coronary Artery	6511003
Posterior Descending Right Coronary Artery	53655008
Intermediate Artery (Ramus)	244252004
Right posterior AV Coronary Artery	12800002
1st Diagonal Coronary Artery	91750005
1st Left Posterolateral Coronary Artery	91757008
1st Marginal Coronary Artery	91754001
1st Right posterolateral Coronary Artery	91761002
1st Septal Coronary Artery	244251006
2nd Diagonal Coronary Artery	91751009
2nd Left Posterolateral Coronary Artery	91758003
2nd Marginal Coronary Artery	91755000
2nd Right Posterolateral Coronary Artery	91762009
3rd Diagonal Coronary Artery	91752002
3rd Left Posterolateral Coronary Artery	91759006
3rd Marginal Coronary Artery	91756004
3rd Right posterolateral Coronary Artery	91763004
Marginal Right Coronary Artery	22765000
AV groove continuation of Circumflex Artery	75902001

6.3.6.3 Cardiovascular Family History - Vocabulary Constraint

The Content Creator shall be capable of creating a family history selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.33, listed below.

Table 6.3.6.3-1: Cardiovascular Family History 1.3.6.1.4.1.19376.1.4.1.5.33 STATIC

Concept \ Coding Scheme	SNOMED CT
Family history of coronary artery disease	430091005
Family history: Diabetes mellitus	160303001
Family history of myocardial infarction	266897007

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Concept \ Coding Scheme	SNOMED CT
No Family history of Diabetes	160274005
No Family history of Cardiovascular disease	160270001
Family History Unknown	407559004

Adapted from DICOM PS3.16-2009

6.3.6.4 Contrast Agents Classes for Adverse Reactions

The Content Creator shall be capable of creating a Contrast Agents Classes for Adverse Reactions selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.34, listed below.

Table 6.3.6.4-1: Contrast Agents Classes for Adverse Reactions 1.3.6.1.4.1.19376.1.4.1.5.34 STATIC

Concept \ Coding Scheme	SNOMED CT
Iodinated contrast agent	426722004
Gadolinium compound	105879004
Echocardiography agent	409290009
Radiopharmaceutical	349358000

6.3.6.5 Cardiac Lab Results - Vocabulary Constraints

The Content Creator shall be capable of creating cardiac lab results selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.35, listed below.

Table 6.3.6.5-1: Cardiac Lab Results 1.3.6.1.4.1.19376.1.4.1.5.35 DYNAMIC

Concept \ Coding Scheme	LOINC	SNOMED
Cholesterol.in HDL	2085-9	
Cholesterol.in LDL	2089-1	
Cholesterol	2093-3	
Triglyceride	2571-8	
High sensitivity C reactive protein	30522-7	
Creatine kinase.MB	13969-1	1224421017
Natriuretic peptide.B	30934-4	
Natriuretic peptide.B prohormone	33762-6	
Troponin T.cardiac	6598-7	186259011
Troponin I.cardiac	10839-9	
Creatinine	2160-0	489161011
Hemoglobin A1c	41995-2	373201015

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Concept \ Coding Scheme	LOINC	SNOMED
Urea nitrogen	3094-0	
Fasting glucose	1557-8	
Platelets	11126-0	488930013
Potassium	11148-4	489169013
Urea Nitrogen	11065-0	489160012
Prothrombin Time		2534465010

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6.3.6.6 Vital Sign Result - Value Set

The Content Creator shall be capable of creating vital signs organizers selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.36, listed below.

3190 **Table 6.3.6.6-1: Vital Sign Result 1.3.6.1.4.1.19376.1.4.1.5.36 STATIC**

Concept \ Coding Scheme	Coding System	Code
Respiratory Rate	LOINC	9279-1
Heart Rate	LOINC	8867-4
O2 % BldC Oximetry	LOINC	2710-2
BP Systolic	LOINC	8480-6
BP Diastolic	LOINC	8462-4
Body Temperature	LOINC	8310-5
Height	LOINC	8302-2
Height (Lying)	LOINC	8306-3
Head Circumference	LOINC	8287-5
Weight Measured	LOINC	3141-9
BMI (Body Mass Index)	LOINC	39156-5
BSA (Body Surface Area)	LOINC	3140-1

6.3.6.7 Procedure Indications - Vocabulary Constraints

The Content Creator shall be capable of creating procedure indications selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.37, listed below.

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3195 **Table 6.3.6.7-1: Procedure Indications 1.3.6.1.4.1.19376.1.4.1.5.37 STATIC**

Procedure Type Applicability	Concept	SNOMED Code	Value	NCDR CathP CI v4.4 Seq. No.	STS-ACC TVT v2.0 Seq. No.
ALL	Angina pectoris	194828000		5000	
Diagnostic PCI	Canadian Cardiovascular Society classification of angina (assessment scale)	134438001	Anginal Class 1.3.6.1.4.1.19376.1.4.1.5.47		
Diagnostic	Preoperative cardiovascular examination	444733009			
Diagnostic PCI	Coronary Artery Disease	53741008			
ALL	Heart failure	84114007		5040	5020
ALL	New York Heart Association Classification (for Heart Failure)	420816009	New York Heart Class 1.3.6.1.4.1.19376.1.4.1.5.48		
ALL	Dyspnea	267036007			
Diagnostic PCI	Abnormal exercise tolerance test	165084003			
Diagnostic PCI	Abnormal ECG	102594003			
Diagnostic PCI	Myocardial Infarction (Biomarker Positive)	22298006			
Diagnostic PCI	ST Segment Elevation Myocardiac Infarction (STEMI)	401303003			
Diagnostic	Pulmonary hypertension	70995007			
StHrt-Int	Syncope	271594007			
Diagnostic StHrt-Int	Valvular heart disease	368009			
Diagnostic	cardiogenic shock	89138009		5060	
Diagnostic PCI	ischemic heart disease	414545008			
Diagnostic PCI	cardiac function test abnormal	165076002			
Diagnostic	heart transplant	32413006			
Diagnostic StHrt-Int	heart disease - congenital	13213009			
Diagnostic	Cardiomyopathy	85898001		5050	
Diagnostic	Pericardial effusion (disorder)	373945007			
Diagnostic	Pericardial Tamponade	35304003			
Diagnostic	Aoritc Stenois	60573004			6060

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Procedure Type Applicability	Concept	SNOMED Code	Value	NCDR CathPCI v4.4 Seq. No.	STS-ACC TVT v2.0 Seq. No.
StHrt-Int					
Diagnostic StHrt-Int	Aortic Insufficiency	60234000			6060
Diagnostic StHrt-Int	Mixed AS and AI	194987006			6060
Diagnostic StHrt-Int	Failed Bioprosthetic Valve	703171005			6060
Diagnostic StHrt-Int	Tricuspid valve regurgitation (disorder)	111287006			5907

6.3.6.8 Result Observations Constraints

The Content Creator shall be capable of creating result observations selected from the Result Observations Constraints Set `1.3.6.1.4.1.19376.1.4.1.5.38` listed below. These results will apply to procedure findings for lesions and the coronary anatomy.

The Procedure Results – Cardiac section content module records clinically significant observations confirmed or discovered during the procedure or surgery.

For this CRC Profile, the findings should be organized using Procedure Results Organizer – Cardiac entry content modules for specific categories (e.g., findings for right heart cath, coronary anatomy, left heart cath, PCI and structural heart interventions). There shall be a Procedure Results Organizer-Cardiac entry content module for one or more of these categories of findings. The allowed categories are defined in CRC Procedure Findings Types Value Set `1.3.6.1.4.1.19376.1.4.1.5.43`.

Result Observations – Cardiac entry content modules are used to record specific findings (e.g., stenosis, timi flow, lesion characteristics, or wall motion characteristics) in each category. The specific findings should be selected from the Result Observations Constraints Set `1.3.6.1.4.1.19376.1.4.1.5.38`.

The “Procedure Type” column in the table below indicates which procedure type the observation is applicable: “Diagnostic”, “PCI” or “Structural Heart Intervention (Str-Hrt).” If “All” is specified, then the value set member applies to all procedure types.

The “Cardinality” column in the table below indicates the minimum and maximum instances of the results observations allowed for each procedure instance. In the case of coronary lesion assessment the cardinality applies to each lesion.

For Data Type BL in the table below the value is either “true” or “false”.

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3220 **Table 6.3.6.8-1: Result Observation Constraints 1.3.6.1.4.1.19376.1.4.1.5.38 STATIC**

Procedure Type	Cardi-nality	observation/code	Data Type	Unit of Measure	Value Set
PCI	[0..1]	"Previously Treated Lesion"	BL		
PCI	[0..1]	449389000, SNOMED CT, "Previously Treated Lesion with Stent"	BL		
PCI	[0..1]	251030009, SNOMED CT, "In-stent Restenosis"	BL		
PCI	[0..1]	421327009, SNOMED CT, "In-stent Thrombosis"	BL		
PCI	[0..1]	408716009, SNOMED CT, "Stenotic lesion length"	PQ	cm	Value
PCI	[0..1]	421327009, SNOMED CT, "Thrombus Present"	BL		
PCI	[0..1]	371894001, SNOMED CT, "Bifurcation Lesion"	BL		
PCI Diagnostic	[0..1] [0..1]	233970002, SNOMED CT, “Stenosis”	PQ	%	
PCI Diagnostic	[0..1] [0..1]	"TIMI Flow"	CD		371867000, SNOMED CT, (TIMI-0) 371866009, SNOMED CT, (TIMI-1) 371864007, SNOMED CT, (TIMI-2) 371865008, SNOMED CT, (TIMI-3)
PCI Diagnostic	[0..1] [0..1]	371842003, SNOMED CT, “Fractiol flow reserve”	PQ	Ratio	
PCI	[0..1]	70390005, SNOMED CT, "Significant Dissection"	CD		True or False
PCI	[0..1]	234010000, SNOMED CT, "Corory artery perforation"	CD		True or False
Diagnostic	[0..1]	"Corory Dominance"	CD	DIAGNOSTIC	253729004, SNOMED CT, (Left) 253728007, SNOMED CT, (Right) 253730009, SNOMED CT, (Balanced)

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Procedure Type	Cardi-nality	observation/code	Data Type	Unit of Measure	Value Set
Diagnostic	[0..*]	8583-7, LOINC, "Right atrial A wave amplitude"	PQ	mm[Hg]	
Diagnostic	[0..*]	8582-9, LOINC, " Left atrial A wave amplitude"	PQ	mm[Hg]	
Diagnostic	[0..*]	8593-6, LOINC, "Right atrial V wave amplitude"	PQ	mm[Hg]	
Diagnostic	[0..*]	8592-8, LOINC, "Left atrial V wave amplitude"	PQ	mm[Hg]	
Diagnostic	[0..*]	8400-4, LOINC, "Right atrial Intrachamber mean pressure"	PQ	mm[Hg]	
Diagnostic	[0..*]	8399-8, LOINC, "Left atrial Intrachamber mean pressure"	PQ	mm[Hg]	
Diagnostic	[0..*]	8432-7, LOINC, "Right ventricular Intrachamber systolic pressure"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8430-1, LOINC," Left ventricular Intrachamber systolic pressure"	PQ	mm[Hg]	
Diagnostic	[0..*]	8377-4, LOINC," Right ventricular Intrachamber diastolic pressure"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8375-8, LOINC," Left ventricular Intrachamber diastolic pressure"	PQ	mm[Hg]	
Diagnostic	[0..*]	8392-3, LOINC," Right ventricular End diastolic blood pressure"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8391-5, LOINC, "Left ventricular End diastolic blood pressure"	PQ	mm[Hg]	
Diagnostic	[0..*]	8440-0, LOINC, "Pulmonary Artery Systolic Blood Pressure"	PQ	mm[Hg]	
Diagnostic	[0..1]	8414-5, LOINC, “Pulmonary Artery Mean Blood Pressure”	PQ	mm[Hg]	
Diagnostic	[0..1]	8393-1, LOINC, “Pulmonary Artery Diastolic Blood Pressure”	PQ	mm[Hg]	
Diagnostic	[0..*]	8441-8, LOINC," Pulmonary artery - left Systolic blood pressure"	PQ	mm[Hg]	
Diagnostic	[0..*]	8387-3, LOINC, "Pulmonary artery - right Diastolic blood pressure"	PQ	mm[Hg]	
Diagnostic	[0..*]	8386-5, LOINC," Pulmonary artery - left Diastolic blood pressure "	PQ	mm[Hg]	
Diagnostic	[0..*]	8416-0, LOINC, "Pulmonary artery - right Mean blood pressure"	PQ	mm[Hg]	
Diagnostic	[0..*]	8415-2, LOINC, "Pulmonary artery - left Mean blood pressure"	PQ	mm[Hg]	

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Procedure Type	Cardi-nality	observation/code	Data Type	Unit of Measure	Value Set
Diagnostic	[0..*]	8584-5, LOINC, “Pulmonary artery wedge A wave amplitude”	PQ	mm[Hg]	
Diagnostic	[0..*]	8596-9, LOINC, "Pulmonary artery wedge V wave amplitude"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8587-8, LOINC, "Pulmonary artery wedge Mean blood pressure"	PQ	mm[Hg]	
Diagnostic StHrt-In	[0..*] [0..*]	8368-3, LOINC, "Aorta thoracic ascending Diastolic blood pressure"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8367-5, LOINC, "Aorta thoracic proximal ascending Diastolic blood pressure"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8396-4, LOINC, "Aorta thoracic ascending Mean blood pressure"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8397-2, LOINC, "Aorta thoracic proximal ascending Mean blood pressure"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8423-6, LOINC, "Ascending thoracic aorta Systolic blood pressure"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8422-8, LOINC, "Aorta thoracic proximal ascending Systolic blood pressure"	PQ	mm[Hg]	
Diagnostic StHrt-Int	[0..*] [0..*]	8840-1, LOINC, " Left atrium Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8841-9, LOINC, "Right atrium Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8842-7, LOINC, " High right atrium Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8843-5, LOINC, " Low right atrium Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8844-3, LOINC, " Mid right atrium Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8845-0, LOINC, " Left ventricular Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8847-6, LOINC, " Right ventricular Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8846-8, LOINC, " Right ventricular outflow tract Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8851-8, LOINC, " Pulmonary artery - left Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8852-6, LOINC, " Main pulmonary artery Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8853-4, LOINC, " Pulmonary artery - right Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8854-2, LOINC, " Pulmonary wedge Oxygen saturation"	PQ	%	

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Procedure Type	Cardi-nality	observation/code	Data Type	Unit of Measure	Value Set
Diagnostic	[0..*]	8850-0, LOINC, " Inferior vena cava Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	8855-9, LOINC, " Superior vena cava Oxygen saturation"	PQ	%	
Diagnostic	[0..*]	14775-1, LOINC, " Hemoglobin [Mass/volume] in Arterial blood by Oximetry"	PQ	g/dL	
Diagnostic	[0..*]	50188-2, LOINC, " Arterial-venous oxygen saturation difference"	PQ	vol%	
Diagnostic	[0..*]	8741-1, LOINC, "Left ventricular Cardiac output"	PQ	L/min	
Diagnostic	[0..*]	8736-1, LOINC, "Left ventricular Cardiac output by Fick method"	PQ	L/min	
Diagnostic	[0..*]	8733-8, LOINC, " Left ventricular Cardiac output by Angiography single plane"	PQ	L/min	
Diagnostic	[0..*]	8732-0, LOINC, "Left ventricular Cardiac output by Angiography biplane"	PQ	L/min	
Diagnostic	[0..*]	8750-2, LOINC, " Left ventricular Cardiac index by Fick method"	PQ	L/min/m2	
Diagnostic	[0..*]	8747-8, LOINC, "Left ventricular Cardiac index by Angiography single plane"	PQ	L/min/m2	
Diagnostic	[0..*]	8746-0, LOINC, "Left ventricular Cardiac index by Angiography biplane"	PQ	L/min/m2	
Diagnostic	[0..*]	8743-7, LOINC, "Pulmonary blood flow/Systemic blood flow by Imaging"	PQ	Qp/Qs	
Diagnostic	[0..*]	8828-6, LOINC, "Pulmonary vascular Resistance"	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8826-0, LOINC, " Pulmonary vascular Resistance by Fick method"	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8827-8, LOINC, "Pulmonary vascular Resistance by Indicator dilution"	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8831-0, LOINC, ”Systemic vascular Resistance"	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8829-4, LOINC, "Systemic vascular Resistance by Fick method"	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8830-2, LOINC, "Systemic vascular Resistance by Indicator dilution”	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8834-4, LOINC, "Pulmonary vascular Resistance index"	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8832-8, LOINC, "Pulmonary vascular Resistance index by Fick method"	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8833-6, LOINC, "Pulmonary vascular Resistance index by Indicator dilution"	PQ	dyn.s/cm5	

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Procedure Type	Cardi-nality	observation/code	Data Type	Unit of Measure	Value Set
Diagnostic	[0..*]	8837-7, LOINC, "Systemic vascular Resistance index"	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8835-1, LOINC, "Systemic vascular Resistance index by Fick method"	PQ	dyn.s/cm5	
Diagnostic	[0..*]	8836-9, LOINC, "PV Systemic vascular Resistance index by Indicator dilution"	PQ	dyn.s/cm5	
Diagnostic	[1..1]	10230-1, LOINC, "Left ventricular Ejection fraction" methodCode= ● 258083009, SNOMED CT, "Visual estimation" ● 258090004, SNOMED CT, "Calculated"	PQ	%	
Diagnostic	[0..1]	250929008, SNOMED CT, left ventricular cavity size	CD	DIAGNOSTIC	1.3.6.1.4.1.19376.1.4.1.5.22 Cardiac Chamber Size Assessments
Diagnostic	[0..1]	8823-7, LOINC, left ventricle systolic volume	PQ	ml	
Diagnostic	[0..1]	8821-1, LOINC, Left ventricle diastolic volume	PQ	ml	
Diagnostic	[0..1]	250964004, SNOMED CT, right ventricular cavity size	CD	DIAGNOSTIC	1.3.6.1.4.1.19376.1.4.1.5.22 Cardiac Chamber Size Assessments
Diagnostic	[0..1]	399121005, SNOMED CT, Left atrium cavity size	CD		1.3.6.1.4.1.19376.1.4.1.5.22 Cardiac Chamber Size Assessments
Diagnostic	[0..1]	439749006:363698007=73829009, SNOMED CT, Right atrium volume by imaging	CD		1.3.6.1.4.1.19376.1.4.1.5.22 Cardiac Chamber Size Assessments
Diagnostic	[0..1]	18087-7, LOINC, Left Ventricle Mass	CD		260395002, SNOMED CT, "normal" 35105006, SNOMED CT, "Increased"
Diagnostic	[0..1]	304522008, SNOMED CT, Pulmonary vein finding	CD		1.3.6.1.4.1.19376.1.4.1.5.23 Pulmonary Veins Assessments

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Procedure Type	Cardi-nality	observation/code	Data Type	Unit of Measure	Value Set
Diagnostic	[0..*]	404684003, SNOMED CT, "Finding"	ED (text/ plain) or CD		indicate the type of intracardiac mass if present. ● Vegetation ● Thrombus ● Neoplasm ● Mass of Unknown Etiology May use CD with value ● 387842002, SNOMED CT, "neoplasm of heart" ● 309519009, SNOMED CT, "LV Thrombus"
Diagnostic	[0..*]	442119001, SNOMED CT, "Cardiac shunt finding"	CD		1.3.6.1.4.1.19376.1 .4.1.5.29 Cardiac Shunt Types
Diagnostic	[0..1]	301123005, SNOMED CT, "Pericardial finding"	CD		373945007, SNOMED CT, "Pericardial effusion" + size [CARD TF-2: 6.2.2.7.5.1]
Diagnostic	[0..1]	301123005, SNOMED CT, "Pericardial finding"	CD		35304003, SNOMED CT, "Tamponade"
Diagnostic	[0..1]	301123005, SNOMED CT, "Pericardial finding"	ED text/p lain or CD		Indicate the thickness of the pericardium. ● Normal ● Thickened ● Calcified May use CD with value 42653000, SNOMED CT, "Calcified pericardium"

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Procedure Type	Cardi-nality	observation/code	Data Type	Unit of Measure	Value Set
Diagnostic	[0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		301100007, SNOMED CT, "Aortic valve normal" 84683006, SNOMED CT, "Aortic valve prosthesis" 8722008, SNOMED CT, "Aortic valve disorder"
Diagnostic StHrt-Int	[0..*]	301099004, SNOMED CT, "Aortic valve finding"	CD		253612007, SNOMED CT, aortic valve cusp prolapse 301184001, SNOMED CT, aortic valve vegetations 13689005, SNOMED CT, congenital anomaly of aortic valve
Diagnostic StHrt-Int	[0..1] [0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		60573004, SNOMED CT, aortic valve stenosis + severity [CARD TF-2: 6.2.2.7.5.2]
Diagnostic StHrt-Int	[0..1] [0..1]	301099004, SNOMED CT, "Aortic valve finding"	CD		60234000, SNOMED CT, Aortic regurgitation + severity [CARD TF-2: 6.2.2.7.5.2]

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Procedure Type	Cardi-nality	observation/code	Data Type	Unit of Measure	Value Set
Diagnostic StHrt-Int	[0..1] [0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		301103009, SNOMED CT, "Mitral valve normal" 11851006, SNOMED CT, "Mitral valve disorder" 17107009, SNOMED CT, "Mitral valve prosthesis" 360063009, SNOMED CT, "Annuloplasty ring"
Diagnostic StHrt-Int	[0..1] [0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		409712001, SNOMED CT, Mitral valve prolapse 270906004, SNOMED CT, mitral chordae rupture 301185000, SNOMED CT, Mitral valve vegetations 75372006, SNOMED CT, congenital anomaly of Mitral valve
Diagnostic StHrt-Int	[0..1] [0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		251002009, SNOMED CT, mitral valve annular calcification
Diagnostic StHrt-Int	[0..1] [0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		79619009, SNOMED CT, Mitral valve stenosis + severity [CARD TF-2: 6.2.2.7.5.2]
Diagnostic StHrt-Int	[0..1] [0..1]	301101006, SNOMED CT, "Mitral valve finding"	CD		48724000, SNOMED CT, Mitral regurgitation + severity [CARD TF-2: 6.2.2.7.5.2]

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Procedure Type	Cardi-nality	observation/code	Data Type	Unit of Measure	Value Set
Diagnostic StHrt-Int	[0..1] [0..1]	301104003, SNOMED CT, "Pulmonic valve finding"	CD		91434003, SNOMED CT, Pulmonic regurgitation + severity [CARD TF-2: 6.2.2.7.5.2]
Diagnostic StHrt-Int	[0..1] [0..1]	404684003, SNOMED CT, "Finding" + targetSiteCode [CARD TF-2: 6.2.2.7.5.3]	CD		308546005, SNOMED CT, "Dissection of aorta"
Diagnostic StHrt-Int	[0..1] [0..1]	404684003, SNOMED CT, "Finding"	CD		251036003, SNOMED CT, "Aortic root dilation"
Diagnostic PCI StHrt-Int	[0..1] [0..1] [0..1]	113730, DCM, "Total Fluoro Time"	PQ	s	
Diagnostic	[0..*]	2576595010, SNOMED CT, "Finding" + targetSiteCode [CARD TF-2: 6.2.2.7.5.3]	CD		2576595010, SNOMED CT, "Bruits – femoral" 2576593015, SNOMED CT, "Bruits – carotid"
Diagnostic StHrt-Int	[0..1] [0..1]	251088005, SNOMED, "Mean aortic value gradient"	PQ	mm[Hg]	Value
Diagnostic StHrt-Int	[0..1]	24526-6, LOINC, "Left ventricular cardiac output by US"	PQ	mm[Hg]	Value
Diagnostic StHrt-Int	[0..1]	18089-3, LOINC, "Aortic Valve Orifice Area by US"	PQ	cm^2	Value
StHrt-Int	[0..1]	18590009, SNOMED "Cardiac pacing"	PQ	seconds	Value

6.3.6.9 Contrast Agents - Vocabulary Constraints

The Content Creator shall be capable of creating Contrast Agents selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.39, listed below.

3225

Table 6.3.6.9-1: Contrast Agents 1.3.6.1.4.1.19376.1.4.1.5.39 STATIC

Coding Scheme / Concept	SNOMED CT	NDC
Radionuclide: F-18 FDG for viability	422975006	
Radionuclide: Rubidium-82 perfusion	79197006	
Radionuclide: Nitrogen-13 ammonia perfusion	21576001	

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Concept \ Coding Scheme	SNOMED CT	NDC
Radionuclide: Tc-99m tetrofosmin (Myoview)	404707004	
Radionuclide: Tc-99m sestamibi (Cardiolite)	404706008	
Radionuclide: Tl-201	353842007	
Echo Contrast: Optison (Perflutren)	409291008	00019-2707-03
Echo Contrast: Definity (Perflutren Lipid Microsphere)		11994-*011-04
Echo Contrast: Agitated saline	373757009	
Echo Contrast: Iodinated contrast	426722004	
High Osmolar Ionic Contrast: Diatrizoate meglumine and diatrizoate sodium (Renografin, etc.)	416688007	
High Osmolar Ionic Contrast: Iothalamate dimeglumine (Conray)	109221002	
Low osmolar non-ionic contrast: Iopamidol (Isovue)	109219007	
Low osmolar non-ionic contrast: Iohexol (Omnipaque)	109218004	
Low osmolar non-ionic contrast: Ioversol (Optiray)	109222009	
Low osmolar non-ionic contrast: Ioxaglate (Hexabrix)	353924001	
Low osmolar non-ionic contrast: Iomeprol (Iomeron)	356671000	
Low osmolar non-ionic contrast: Iopromide (Ultravist)	353903006	
Iso-osmolar nonionic contrast: Iodixanol (VisiPaque)	353962003	
Paramagnetic agent: Gadopentetate dimeglumine (Magnevist)	404846007	
Paramagnetic agent: Gadodiamide (Omniscan)	354088005	
Paramagnetic agent: Gadoversetamide (Optimark)	409477004	
Paramagnetic agent: Gadobenate dimeglumine (MultiHance)	414307008	

6.3.6.10 Cardiac Activity Procedures - Vocabulary Constraints

The Content Creator shall be capable of creating Cardiac Activity Procedures selected from
3230 Value Set 1.3.6.1.4.1.19376.1.4.1.5.40, listed below.

Table 6.3.6.10-1: Cardiac Activity Procedures 1.3.6.1.4.1.19376.1.4.1.5.40 STATIC

Concept \ Coding Scheme	SNOMED CT
PCI	415070008
IABP	28718015
Endomyocardial Biopsy	1481899014
Right Heart Cath	67358018
Fick Cardiac Output	53921011
Cardiac output measurement by thermal dye dilution method (procedure)	373104003
Other Mechanical Ventricular Support: LVAD	349042010

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Concept \ Coding Scheme	SNOMED CT
Other Mechanical Ventricular Support: CPB	105872012
Other Mechanical Ventricular Support: ECMO	349972019
Diagnostic Coronary Angiography	1234097013
Left Heart Cath Procedure	500786010
Intravascular Ultrasound	241466007
Fractional Flow Reserve (observable entity)	371842003
Percutaneous replacement of aortic valve using fluoroscopic guidance	441873006
Mitral valve replacement + fluoroscopic guidance	53059001+282721001
Mitral Valvuloplasty: Percutaneous balloon valvuloplasty of mitral valve (procedure)	384642005
Aortic Valvuloplasty: Percutaneous balloon valvuloplasty of aortic valve (procedure)	77166000
Repair of mitral valve using fluoroscopic guidance (procedure). Mitral valve clip	432394003
VSD Closure: Closure of ventricular septal defect using fluoroscopic guidance (procedure)	442087005
ASD Closure: Closure of atrial septal defect using fluoroscopic guidance (procedure)	432114008
PFO Closure: Closure of patent foramen ovale using fluoroscopic guidance (procedure)	43267006
Pericardiocentesis using fluoroscopic guidance (procedure)	431822000

6.3.6.11 Drug Classes and Specific Cardiac Drugs - Vocabulary Constraints

3235 The Content Creator shall be capable of creating cardiac procedure Drug Classes and Specific Cardiac Drugs selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.41, listed below.

Table 6.3.6.11-1: Drug Classes and Specific Cardiac Drugs 1.3.6.1.4.1.19376.1.4.1.5.41 STATIC

Concept \ Coding Scheme	SNOMED CT	NDF-RT (DRUG CLASSES)	RxNorm
ACE inhibitor	69306018	N0000029130	836
Angiotensin receptor blocker	96308008	N0000175561	133049
Thyroid replacement		N0000029627	691804
Aspirin, other antiplatelet agents	7947003	N0000145918	1191
Calcium channel blockers	48698004	N0000029119	1899
Beta-blockers	33252009	N0000029118	691779
Erectile dysfunction medication: sildenafil		N0000022115	136411

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Coding Scheme / Concept	SNOMED CT	NDF-RT (DRUG CLASSES)	RxNorm
Erectile dysfunction medication: tadalafil		N0000148829	358263
Nitrates	31970009	N0000007647	7439
Antiarrhythmics	67507000	N0000029121	883
Antiarrhythmics: Potassium Channel Antagonist	415151000		
Antiarrhythmics: Amiodarone		N0000005761	703
Antiarrhythmics: Propafenone		N0000006692	8754
Antiarrhythmics: Flecainide		N0000147848	4441
Antiarrhythmics: Dofetilide		N0000148648	49247
Antiarrhythmics: Sotalol		N0000148334	9947
Antiarrhythmics: Disopyramide		N0000005784	3541
Antiarrhythmics: Dronedarone		N0000179804	233698
Antiarrhythmics: Quinidine		N0000148010	9068
Antiarrhythmics: Procainamide		N0000147989	8700
Digitalis	65774009	N0000147198	91235
Digitalis: Digoxin		N0000146388	3407
Metformin	109081006	N0000021984	6809
Lipid-lowering medication	57952007	N0000029122	969
Other antihypertensives		N0000029427	714568
Xanthines		N0000008118	11357
Xanthines: Aminophylline	55867006	N0000146397	689
Xanthines: Theophylline	66493003	N0000146467	10438
Dipyridamole	66859009	N0000146237	3521
Inhaler		N0000177906	992544
Diabetic medications	384953001		
Lidocaine		N0000006071	6387
Diphenhydramine		N0000006794	3498
Hydromorphone		N0000005957	3423
Midazolam		N0000006704	6960
Normal Saline			125464
Isovue			Isovue 370 155031 Isovue-M-200 217822 Isovue-M-300 262238
Anticoagulants: Fondaparinux		N0000148733	321208
Anticoagulants: Low Molecular Weight Heparin		N0000007961	5227
Anticoagulants: Unfractionated Heparin		N0000175474	1036221
Anticoagulants: Warfarin	48603004	N0000148057	11289

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Concept \ Coding Scheme	SNOMED CT	NDF-RT (DRUG CLASSES)	RxNorm
Direct Thrombin Inhibitors: Bivalirudin		N0000010076	60819
Glycoprotein IIb/IIIa Inhibitors		N0000009962	986894
Thienopyridines		N0000182125	1031667
Thienopyridines: Clopidogrel		N0000022101	32968
Thienopyridines: Ticlopidine		N0000006471	10594
Thienopyridines: Prasugrel		N0000179815	613391
Thienopyridines: Ticagrelor			1116632

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6.3.6.12 Rx Recommendation - Vocabulary Constraints

The Content Creator shall be capable of creating an Rx recommendation selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.42, listed below.

3245 **Table 6.3.6.12-1: Rx Recommendation 1.3.6.1.4.1.19376.1.4.1.5.42 STATIC**

Concept \ Coding Scheme	SNOMED CT
Medical therapy	243121000
Counseling about disease	445142003
percutaneous coronary intervention (implicitly without planned CABG, unless there is a separate plan of care item for CABG)	415070008
coronary artery bypass graft	232717009
cardiac rehabilitation	313395003
Percutaneous replacement of aortic valve using fluoroscopic guidance	441873006
Mitral valve replacement + fluoroscopic guidance	53059001+282721001
Repair of mitral valve using fluoroscopic guidance (procedure). Mitral valve clip	432394003

6.3.6.13 CRC Procedure Findings Types - Vocabulary Constraints

The Content Creator shall be capable of creating CRC Procedure Findings Types selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.43, listed below.

3250 **Table 6.3.6.13-1: CRC Procedure Findings Types 1.3.6.1.4.1.19376.1.4.1.5.43 STATIC**

Concept \ Coding Scheme	SNOMED CT
PCI	415070008
IABP	28718015

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Concept \ Coding Scheme	SNOMED CT
Endomyocardial Biopsy	1481899014
Right Heart Cath	67358018
Fick Cardiac Output	53921011
Other Mechanical Ventricular Support: LVAD	349042010
Other Mechanical Ventricular Support: CPB	105872012
Other Mechanical Ventricular Support: ECMO	349972019
Diagnostic Coronary Angiography	1234097013
Left Heart Cath Procedure	500786010
Intravascular Ultrasound	241466007
Percutaneous replacement of aortic valve using fluoroscopic guidance (procedure)	441873006
Mitral valve replacement + fluoroscopic guidance	53059001+282721001
Repair of mitral valve using fluoroscopic guidance (procedure) - mitral valve clip	432394003

6.3.6.14 CRC Postprocedure Diagnoses - Vocabulary Constraints

The Content Creator shall be capable of creating CRC Postprocedure Diagnoses selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.44, listed below.

3255

Table 6.3.6.14-1: CRC Postprocedure Diagnoses 1.3.6.1.4.1.19376.1.4.1.5.44 STATIC

Concept \ Coding Scheme	SNOMED CT
Chest Pain	29857009
Pre-operative	262068006
Coronary Artery Disease	53741008
Heart failure	84114007
Heart disease risk factors	171224000
Dyspnea	267036007
Post PTCA	373108000
History of CABG	399261000
Abnormal exercise tolerance test	165084003
Abnormal ECG	102594003
Arrhythmia	44808001
Angina pectoris	194828000
Hypertension	38341003
Palpitations	80313002
Supraventricular tachycardia	6456007

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Concept \ Coding Scheme	SNOMED CT
Syncope	271594007
History of Myocardial Infarction	399211009
Left bundle branch block	63467002
Valvular heart disease	368009
Occupational requirement	429060002
cardiogenic shock	89138009
ischemic heart disease	414545008
cardiac function test abnormal	165076002
heart transplant	32413006
heart disease - congenital	13213009
Cardiomyopathy	85898001
heart disease	56265001
Perioperative Evaluation	430091005
structural disorder of heart	128599005
Pericardial disease	55855009

6.3.6.15 Supported File Formats - Vocabulary Constraints

The Content Creator shall be capable of creating Supported File Formats selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.45, listed below.

Table 6.3.6.15-1: Supported File Formats 1.3.6.1.4.1.19376.1.4.1.5.45 STATIC

Value Set: SupportedFileFormats 1.3.6.1.4.1.19376.1.4.1.5.45 STATIC	
Graphic Formats	**Code**
GIF Image	image/gif
TIF Image	image/tiff
JPEG Image	image/jpeg
PNG Image	image/png

6.3.6.16 Complications - Vocabulary Constraints

The Content Creator shall be capable of creating a complication selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.46, listed below.

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Table 6.3.6.16-1: Complications 1.3.6.1.4.1.19376.1.4.1.5.46 STATIC

Coding Scheme / Concept	NCDR CathPCI Seq #	NCDR TVT Complication Code	SNOMED CT
Myocardial Infarction (Biomarker Positive)	8000		22298006
Cardiogenic Shock	8005		89138009
Heart Failure	8101		84114007
CVA/Stroke	8015	E013	230690007
Hemorrhagic Stroke	8021	E012	230706003
Cardiac Tamponade	8025		35304003
Renal Failure	8030		42399005
Other vascular complications requiring treatment	8035		213217008
Anemia due to blood loss	8040		413532003
Bleeding event	8050		131148009
Bleeding at access site	8055	E017	110265006
Hematoma at access site	8060	E018	213262007
Retroperitoneal bleeding	8070	E019	308898001
Gastrointestinal bleeding	8080	E020	74474003
Genital-urinary bleeding	8090	E021	417941003
Other bleeding	8100	E022	131148009
Death in lab	9055		419099009
Acute myocardial infarction during procedure		E059	703212004
Conduction disorder of the heart		E039	44808001
Cardiac arrest as a complication of care		E005	213213007
Atrial fibrillation (disorder)		E006	49436004
Dehiscence of aortic valve annulus as complication of procedure (disorder)		E007	457697002
Dissection of Aorta		E008	308546005
Accidental cut, puncture, perforation or hemorrhage during heart catheterization (navigation concept)		E009	216893009
Transient ischemic attack (disorder)		E010	266257000
Ischemic stroke (disorder)		E011	422504002
Peripheral vascular complication of procedure		E042	363261001
Postoperative hemorrhage		E017	110265006

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Coding Scheme / Concept	NCDR CathPCI Seq #	NCDR TVT Complication Code	SNOMED CT
(disorder)			
Migration of implant or internal device		E023	370512004
Device Embolization Left Ventricle		E024	370512004|123037004 = 8787800
Device Embolization Aorta		E025	370512004|123037004 = 15825003
Removal of device from cardiovascular system (procedure)		E026	128409001

6.3.6.17 Anginal Class - Vocabulary Constraints

The Content Creator shall be capable of picking one angina class selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.47, listed below.

Table 6.3.6.17-1: Anginal Class 1.3.6.1.4.1.19376.1.4.1.5.47 STATIC

Coding Scheme / Concept	SNOMED CT
Anginal Class: 1	61490001
Anginal Class: 2	41334000
Anginal Class: 3	85284003
Anginal Class: 4	89323001

6.3.6.18 New York Heart Class - Vocabulary Constraints

The Content Creator shall be capable of picking one New York Heart class selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.48, listed below.

Table 6.3.6.18-1: New York Heart Class 1.3.6.1.4.1.19376.1.4.1.5.48 STATIC

Coding Scheme / Concept	SNOMED CT
NYHA Class 1	420300004
NYHA Class 2	421704003
NYHA Class 3	420913000
NYHA Class 4	422293003

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6.3.6.19 DICOM CID 3718 - Myocardial Wall Segments in Projection - Vocabulary Constraints

The Content Creator shall be capable of picking Myocardial Wall Segments in Projection selected from Value Set 1.2.840.10008.6.1.219, listed below.

Table 6.3.6.19-1: Myocardial Wall Segments in Projection 1.2.840.10008.6.1.219 STATIC

Coding Scheme / Concept	SNOMED CT
left ventricle basal anterior segment	264850008
myocardium of anterolateral region	73050001
myocardium of apex of heart	47962008
myocardium of diaphragmatic region	72542009
left ventricle basal inferior segment	264846001
left ventricle basal lateral segment	277631004
myocardium of posterolateral region	33272004
myocardium of inferolateral region	16239001
left ventricle apical septal segment	264845002
left ventricular basal septal segment	277630003
left ventricular posterobasal segment	408720008

Copied from DICOM PS3.16

6.3.6.20 Cardiac Chamber Size Assessments -1.3.6.1.4.1.19376.1.4.1.5.22 DICOM - Vocabulary Constraints

The Content Creator shall be capable of picking Cardiac Chamber Size Assessments in Projection selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.22, listed below.

Table 6.3.6.20-1: Cardiac Chamber Size Assessments 1.3.6.1.4.1.19376.1.4.1.5.22 STATIC

Coding Scheme / Concept	SNOMED CT
normal size cardiac chamber	373124004
abnormally small cardiac chamber	373125003
mildly enlarged cardiac chamber	373126002
moderately enlarged cardiac chamber	373127006
markedly enlarged cardiac chamber	373128001

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6.3.6.21 Pulmonary Veins Assessments - 1.3.6.1.4.1.19376.1.4.1.5.23 DICOM - Vocabulary Constraints

The Content Creator shall be capable of picking Pulmonary Veins Assessments selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.23, listed below.

Table 6.3.6.21-1: Pulmonary Veins Assessments 1.3.6.1.4.1.19376.1.4.1.5.23 STATIC

Coding Scheme / Concept	SNOMED CT
pulmonary venous connections normal	446158009
variant number of pulmonary veins (usually 3 or 5), but with normal pulmonary venous drainage into left atrium	
anomalous pulmonary venous drainage	59631007

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6.3.6.22 Cardiac Shunt Types -1.3.6.1.4.1.19376.1.4.1.5.29 DICOM - Vocabulary Constraints

The Content Creator shall be capable of picking Cardiac Shunt Types selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.29, listed below.

Table 6.3.6.22-1: Cardiac Shunt Types 1.3.6.1.4.1.19376.1.4.1.5.29 STATIC

Coding Scheme / Concept	SNOMED CT
patent foramen ovale	204317008
atrial septal defect	70142008
ventricular septal defect	30288003
patent ductus arteriosus	83330001

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6.3.6.23 Angina Type -1.3.6.1.4.1.19376.1.4.1.5.7 DICOM - Vocabulary Constraints

The Content Creator shall be capable of picking AnginaType selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.7, listed below.

Table 6.3.6.23-1: Angina Type 1.3.6.1.4.1.19376.1.4.1.5.7

STATICCoding Scheme / Concept	SNOMED CT
Stable angina	233819005
Unstable angina	4557003

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Concept \ Coding Scheme STATIC	SNOMED CT
Atypical chest pain	371807002
Myocardial infarction	22298006

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6.3.6.24 Cardiac Procedure Results Organizers - Vocabulary Constraints

The Content Creator shall be capable of creating Cardiac Procedure Results Organizers selected from Value Set 1.3.6.1.4.1.19376.1.4.1.5.64, listed below.

Table 6.3.6.24-1: Cardiac Procedure Results Organizers 1.3.6.1.4.1.19376.1.4.1.5.64 STATIC

Concept \ Coding Scheme	SNOMED CT
PCI	415070008
IABP	28718015
Endomyocardial Biopsy	1481899014
Right Heart Cath	67358018
Fick Cardiac Output	53921011
Cardiac output measurement by thermal dye dilution method (procedure)	373104003
Other Mechanical Ventricular Support: LVAD	349042010
Other Mechanical Ventricular Support: CPB	105872012
Other Mechanical Ventricular Support: ECMO	349972019
Diagnostic Coronary Angiography	1234097013
Left Heart Cath Procedure	500786010
Intravascular Ultrasound	241466007
TAVR Procedure (Percutaneous replacement of aortic valve using fluoroscopic guidance)	441873006
Mitral valve replacement + fluoroscopic guidance	53059001+282721001
Mitral Valvuloplasty: Percutaneous balloon valvuloplasty of mitral valve (procedure)	384642005
Aortic Valvuloplasty: Percutaneous balloon valvuloplasty of aortic valve (procedure)	77166000
Repair of mitral valve using fluoroscopic guidance (procedure). Mitral valve clip	432394003
VSD Closure: Closure of ventricular septal defect using fluoroscopic guidance (procedure)	442087005
ASD Closure: Closure of atrial septal defect using fluoroscopic guidance (procedure)	432114008

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Coding Scheme / Concept	SNOMED CT
PFO Closure: Closure of patent foramen ovale using fluoroscopic guidance (procedure)	43267006
Pericardiocentesis using fluoroscopic guidance (procedure)	431822000
Baseline state (finding)	128974000

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Namespace Additions

Add the following terms to the IHE Namespace:

Level (e.g., Section/Document/Entry)	Template id	Name
Document template id	1.3.6.1.4.1.19376.1.4.1.1.2	Cath Report Content (CRC)
Section template id	1.3.6.1.4.1.19376.1.4.1.2.16	Document Summary
Section template id	1.3.6.1.4.1.19376.1.4.1.2.17	Medical History - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.19	Procedure Description - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.20	Procedure Results - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.21	Key Images - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.22	Plan of Care - Cardiac
Section template id	1.3.6.1.4.1.19376.1.4.1.2.23	Pre-Procedure Results – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.9	Problem Observation – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.10	Lesion Observation
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.11	Result Organizer – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.12	Procedure Device Organizer – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.13	Device Observation
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.14	Procedure Activity Procedure - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.15	Procedure Results Organizer - Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.16	Result Observation – Cardiac
Entry template id	1.3.6.1.4.1.19376.1.4.1.4.17	Plan of Care Activity Act – Cardiac
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.31	Cardiac Problems / Concerns
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.32	Body Site
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.33	Cardiovascular Family History
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.34	Contrast Agent Classes for Adverse Reactions
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.35	Cardiac Lab Results
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.36	Vital Sign Result
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.37	Procedure Indications
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.38	Result Observations

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Level (e.g., Section/Document/Entry)	Template id	Name
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.39	Contrast Agents
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.40	Cardiac Activity Procedures
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.41	Drug Classes and Specific Cardiac Drugs
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.42	Rx Recommendations
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.43	CRC Procedure Finding Types
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.44	CRC Postprocedure Diagnoses
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.45	Supported File Types
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.46	Complications
Vocabulary/value set id	1.3.6.1.4.1.19376.1.4.1.5.64	Cardiac Procedure Results Organizers

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Volume 4 – National Extensions

Add appropriate Country section

NA

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