Integrating the Healthcare Enterprise

IHE Anatomic Pathology Technical Framework Supplement

Anatomic Pathology Structured Reports (APSR)

Trial Implementation

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Foreword

This is a supplement to the IHE Anatomic Pathology Technical Framework Trial Implementation V2.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is submitted for Trial Implementation as of March 31, 2011 and will 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 Anatomic Pathology Technical Framework. Comments are invited and may be submitted on the IHE forums at http://forums.rsna.org/forumdisplay.php?f=411 or by email to pat@ihe.net.

This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as addition of large new sections introduced by editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

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

Replace Section X.X by the following:

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

Information about the IHE Anatomic Pathology can be found at: http://www.ihe.net/Domains/index.cfm and wiki.ihe.net/index.php?title=Anatomic_Pathology

Information about the structure of IHE Technical Frameworks and Supplements can be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm

The current version of the IHE Technical Framework can be found at: http://www.ihe.net/Technical_Framework/index.cfm

CONTENTS

INTRODUCTION **7**

Profile Abstract 7
Open Issues and Questions 7
Closed Issues 7

VOLUME 1 – INTEGRATION PROFILES **12**

1.7 History of Annual Changes 12
1.12 Glossary 12
1.15 Scope of the Anatomic Pathology Technical Framework 13
1.16 Anatomic Pathology Integration Profiles 13
1.17 Dependencies among Integration Profiles 14
1.18 Profiles Overview 14
1.18.3 Anatomic Pathology Structured Reports (APSR) *14*
1.19 Actors Description 14

4 ANATOMIC PATHOLOGY STRUCTURED REPORTS (APSR) PROFILE **15**

4.1 APSR Actors/Transactions 17
4.1.1 Actor Descriptions and Requirements *17*
4.1.2 Document Content Modules *18*
4.1.2.1 Anatomic Pathology Structured Report (APSR) 18
4.1.2.2 Organ specific APSR document content modules 19
4.2 APSR Options 20
4.3 APSR Actor Groupings and Profile Interactions 20
4.4 APSR Process Flow 21
4.4.1 Use Cases *21*
4.4.1.1 Use case 1: General case 21
4.4.1.2 Use case 2: Specimen collector is not the ordering physician 21
4.4.1.3 Use case 3: Multi-step reporting 21
4.4.1.4 Use case 4: Opinion request 22
4.5 APSR Security considerations 23
4.5.1 Integrity *23*
4.5.2 Confidentiality *23*
4.5.3 Auditability *23*

VOLUME 3 – CONTENT MODULES **24**

1 INTRODUCTION **24**

1.1 Overview of the Anatomic Pathology Technical Framework 24
1.2 Overview of Volume 3 24
1.3 Audience 24
1.4 Relationship to Standards 25
1.5 Relationship to Real World Architecture 25
1.6 Conventions 25
1.7 Scope Introduced in the Current Year 25
1.8 Copyright Permission 25
1.9 Glossary 25

2 CONTENT MODULES – BASIC PRINCIPLES **26**

3 IHE TRANSACTIONS 27

3.1 CROSS ENTERPRISE DOCUMENT CONTENT TRANSACTIONS 27
3.1.1 View Option 27
3.1.2 Document Import Option 27
3.1.3 Section Import Option 27

4 IHE ANATOMIC PATHOLOGY BINDINGS 28

4.1 ANATOMIC PATHOLOGY DOCUMENT BINDING TO XDS, XDM AND XDR 28
4.1.1 XDSDocumentEntry Metadata 28
4.1.1.1 XDSDocumentEntry.formatCode 29
4.1.1.2 XDSDocumentEntry.eventCodeList 29
4.1.1.3 XDSDocumentEntry.parentDocumentRelationship 29
4.1.2 XDSSubmissionSet Metadata 29
4.1.3 XDSFolder Metadata 29
4.1.4 Configuration 29

5 NAMESPACES AND VOCABULARIES 30

5.1 OID TREE OF PAT TF 30
5.2 TERMINOLOGIES AND CONTROLLED CODED VOCABULARIES 30
5.3 VALUE SETS 31
5.4 NAMESPACES 31
5.5 REFERENCES TO CONTENT MODULES BUILT OUTSIDE OF IHE PAT TF 31
5.6 IHE CODES FOR ANATOMIC PATHOLOGY DOCUMENT TEMPLATES 31

6 ANATOMIC PATHOLOGY CONTENT MODULES 33

6.1 CONVENTIONS 33
6.2 HL7 CDA R2 CONTENT MODULES 34
6.2.1 Organization 34
6.2.1.1 Various Types of Content Modules 34
6.2.1.2 General constraints added by IHE PAT to a CDA R2 document 34
6.2.1.3 Common structure for all CDA APSR 36
6.2.2 Common layout for the specification of a CDA Content Module 36
6.2.2.1 Content Module Name – OID 37
6.2.2.1.1 Definition and purpose 37
6.2.2.1.2 Example 37
6.2.2.1.3 Specification 37
6.2.3 CDA R2 Document Content Modules 38
6.2.3.1 AP Structured Report (APSR) - 1.3.6.1.4.1.19376.1.8.1.1.1 38
6.2.3.1.1 Definition and purpose 38
6.2.3.1.2 Example 38
6.2.3.1.3 Specification 40
6.2.3.2 Organ-Specific APSR Content Modules 45
6.2.3.2.1 Definition and purpose 45
6.2.3.2.2 Example 45
6.2.3.2.3 Specification 45
6.2.4 CDA R2 <section> Content Modules 46
6.2.4.1 Clinical Information <section> - 1.3.6.1.4.1.19376.1.8.1.2.1 46
6.2.4.1.1 Definition and Purpose 46
6.2.4.1.2 Example 46
6.2.4.1.3 Specification 48
6.2.4.2 Intraoperative Observation <section> - 1.3.6.1.4.1.19376.1.8.1.2.2 49
6.2.4.2.1 Definition and Purpose 49

6.2.4.2.2 Example 49
6.2.4.2.3 Specification 49
6.2.4.3 Macroscopic Observation <section> - 1.3.6.1.4.1.19376.1.8.1.2.3 50
6.2.4.3.1 Definition and Purpose 50
6.2.4.3.2 Example 50
6.2.4.3.3 Specification 50
6.2.4.4 Microscopic Observation <section> - 1.3.6.1.4.1.19376.1.8.1.2.4 51
6.2.4.4.1 Definition and Purpose 51
6.2.4.4.2 Example 51
6.2.4.4.3 Specification 51
6.2.4.5 Diagnosis <section> - 1.3.6.1.4.1.19376.1.8.1.2.5 52
6.2.4.5.1 Definition and Purpose 52
6.2.4.5.2 Example 52
6.2.4.5.3 Specification 53
6.2.4.6 Procedure steps <section> - 1.3.6.1.4.1.19376.1.8.1.2.6 53
6.2.4.6.1 Definition and Purpose 53
6.2.4.6.2 Example 53
6.2.4.6.3 Specification 54
6.2.4.7 Report Textual Summary <section> - 1.3.6.1.4.1.19376.1.8.1.2.7 54
6.2.4.7.1 Definition and Purpose 54
6.2.4.7.2 Example 54
6.2.4.7.3 Specification 55
6.2.5 CDA R2 <entry> Content Modules 56
6.2.5.1 Common Specification for all APSR Entry Content Modules 56
6.2.5.2 Specimen Clinical Information <entry> - 1.3.6.1.4.1.19376.1.8.1.3.1 57
6.2.5.2.1 Definition and Purpose 57
6.2.5.2.2 Example 57
6.2.5.2.3 Specification 57
6.2.5.3 Specimen Intraoperative Observation <entry> - 1.3.6.1.4.1.19376.1.8.1.3.2 57
6.2.5.3.1 Definition and Purpose 57
6.2.5.3.2 Example 57
6.2.5.3.3 Specification 57
6.2.5.4 Specimen Macroscopic Observation <entry> - 1.3.6.1.4.1.19376.1.8.1.3.3 57
6.2.5.4.1 Definition and Purpose 57
6.2.5.4.2 Example 58
6.2.5.4.3 Specification 58
6.2.5.5 Specimen Microscopic Observation <entry> - 1.3.6.1.4.1.19376.1.8.1.3.4 58
6.2.5.5.1 Definition and Purpose 58
6.2.5.5.2 Example 58
6.2.5.5.3 Specification 58
6.2.6.5 Specimen Diagnosis <entry> - 1.3.6.1.4.1.19376.1.8.1.3.5 58
6.2.5.6.1 Definition and Purpose 58
6.2.5.6.2 Example 58
6.2.5.6.3 Specification 59
6.2.6 CDA R2 Child Element Content Modules 60
6.2.6.1 Specimen Collector in Header – 1.3.6.1.4.1.19376.1.8.1.4.1 60
6.2.6.1.1 Definition and purpose 60
6.2.6.1.2 Example 60
6.2.6.1.3 Specification 60
6.2.6.2 Author – 1.3.6.1.4.1.19376.1.8.1.4.2 61
6.2.6.2.1 Definition and purpose 61
6.2.6.2.2 Example 61
6.2.6.2.3 Specification 62
6.2.6.3 Content Validator – 1.3.6.1.4.1.19376.1.8.1.4.3 62
6.2.6.3.1 Definition and purpose 62

6.2.6.3.2 Example 63
6.2.6.3.3 Specification 63
6.2.6.4 Specimen Information Organizer – 1.3.6.1.4.1.19376.1.8.1.4.4 64
6.2.6.4.1 Definition and purpose 64
6.2.6.4.2 Example 64
6.2.6.4.3 Specification 65
6.2.6.5 Specimen Collection Procedure generic template – 1.3.6.1.4.1.19376.1.3.1.2 67
6.2.6.5.1 Definition and purpose 67
6.2.6.5.2 Example 68
6.2.6.5.3 Specification 69
6.2.6.6 Informant – 1.3.6.1.4.1.19376.1.8.1.4.6 71
6.2.6.6.1 Definition and purpose 71
6.2.6.6.2 Example 71
6.2.6.6.3 Specification 71
6.2.6.7 Additional participant in an entry - 1.3.6.1.4.1.19376.1.8.1.4.7 72
6.2.6.7.1 Definition and purpose 72
6.2.6.7.2 Example 72
6.2.6.7.3 Specification 73
6.2.6.8 Problem Organizer – 1.3.6.1.4.1.19376.1.8.1.4.8 74
6.2.6.8.1 Definition and purpose 74
6.2.6.8.2 Example 74
6.2.6.8.3 Specification 74
6.2.6.9 AP Observation generic template – 1.3.6.1.4.1.19376.1.8.1.4.9 77
6.2.6.9.1 Definition and purpose 77
6.2.6.9.2 Examples 78
6.2.6.9.3 Specification 79
6.2.6.10 Embedded Image – 1.3.6.1.4.1.19376.1.8.1.4.10 83
6.2.6.10.1 Definition and purpose 83
6.2.6.10.2 Example 83
6.2.6.10.3 Specification 83

VOLUME 4 – VALUE SETS 85

Introduction

This supplement is written for Trial Implementation.

This supplement prepares a new volume, Volume 3, of the IHE Anatomic Pathology (PAT) Technical Framework. The supplement also prepares an update to the existing PAT Technical Framework Volume 1.

This supplement references other documents the reader should be aware of:

1. IHE IT Infrastructure Technical Framework Volume 1, Revision 7.0
2. IHE IT Infrastructure Technical Framework Volume 3, Revision 7.0
3. IHE PCC Technical Framework Volume 2, Revision 7.0
4. IHE LAB Technical Framework Volume 3, Revision 3.0
5. HL7 CDA r2 normative edition 2005
6. Goldsmith, J.D., et al., Reporting guidelines for clinical laboratory reports in surgical pathology. Arch Pathol Lab Med, 2008. 132(10): p. 1608-16
7. CAP Cancer Protocols and Checklists 2010

Profile Abstract

Anatomic pathology reports (APR) document the pathologic findings in specimens removed from patients for diagnostic or therapeutic reasons. This information can be used for patient care, clinical research and epidemiology.

This Content Profile is the result of a joint initiative from IHE and HL7 anatomic pathology workgroups who brought along a methodology and tools to facilitate the development of consensus-based anatomic pathology structured reports (APSR) and to publish an HL7 Clinical Document Architecture (CDA) implementation guide for these APSR.

Open Issues and Questions

APSR-13 – Missing LOINC code for intraoperative section: This code does not seem to be available in LOINC. The creation will be submitted to the Regenstrief Institute.

Closed Issues

APSR-01 – List of potential sections of an AP structured report:

- Clinical information (content supposedly provided by the ordering physician)

- Intraoperative observations (in case of intraoperative consultation, which may be macroscopic only or may include cytology and/or frozen section)
- Macroscopic observations
- Microscopic observations
- Diagnosis
- Procedure steps (this technical section is also useful for tracking the sequence of operations performed on the specimen at the work area), which does not preclude some of this information from appearing in one of the other sections (e.g., the Macroscopic observations section).

APSR-02 – Content of sections:

- Each section SHALL contain a *text* element presenting the content to the human reader. The profile does not constrain the layout of this narrative block.
- The Diagnosis section SHALL contain an *entry* element with the corresponding machine-readable data.
- The other sections SHOULD contain an *entry* element with the corresponding machine-readable data.
- The Clinical information section MAY contain other sections.

APSR-03 – Handling the mix of coded content and free unstructured text:

AP reports are often composed of free text (which can be dictated), assembled with a set of coded information (e.g., some AP observations). The Content Creator application must handle these two kinds of content, and provide a user interface, which avoids any confusion between these two kinds of content, both at creation time and update time (e.g., using forms with dedicated free text areas and distinct areas for coded fields).

The body of the report is a hierarchy of sections. Each section presents its content in its *text* element, as human-readable text, possibly illustrated by some embedded images. This human-readable content of the section, or a part of it, may also be present as machine-readable data coded with the appropriate terminologies (e.g., ICD-O-3, SNOMED CT, LOINC, ADICAP, or any other terminology admitted by this profile or a national extension of it …) in *entry* elements at the bottom of the section.

There are zero or more *entry* elements in a section. Each entry element carries the machine-readable data related to a specimen or to a group of specimens (see APSR-10). The entry is then subdivided per problem investigated on the specimen(s) (see closed issue APSR-06 below).

The *text* element of the section is supposed to reflect the same organization: per specimen or group of specimens, and then, per problem investigated. However, this APSR Content Profile does not explicitly describe the structure of this *text* element, and leaves it up to the Content Creator applications, or to further constraints brought by national extensions of this profile. The *text* element of a section in an APSR instance may be a mix of

paragraphs, tables, diagrams and images, composed by the author of the report with the sole purpose of clarity and comprehensiveness for the reader.

APSR-04 – **Linking AP observations to images/evidence documents**: It is sometimes useful to present to the reader of the report the images related to the observations. The CDA AP report provides the CDA R2 standard means to embed images at the observation level or at the organizer level in an entry, using the *observationMedia* element and potentially the *regionOfInterest* element. These images can only be small illustrations. Big images – like whole slide images or evidence documents – will stay in their own storage infrastructure, accessible via the DICOM standard protocol, and may be associated with the APSR document, via a DICOM KOS list of references (as described in the XDS-I profile from the Radiology domain), issued in the same submission set.

APSR-05 – **Coding of the TNM**: The value sets for the TNM of various tumors will be created into the PathLex terminology built by IHE PAT, based on the reference material of this profile.

APSR-06 – T**wo (or more) distinct problems observed on the same specimen**: In this case, the AP report template should provide a means to group the observations per problem. The solution consists in inserting a battery organizer grouping all observations related to the same problem below the specimen information organizer. See also APSR-03 above.

APSR-07 – **Representing the hierarchy of specimens in an entry**: This APSR supplement does not represent the hierarchy of specimens at the CDA level 3 (within an entry). The operations on specimen and production of child specimens are tracked in the "Procedure Steps" section, which does not have a level 3 entry, in this current release of the profile.

APSR-08 – **Human authors and/or authoring devices**: Do we have use cases for recording authoring devices as "author" in the report or a part of it? Or do we allow only human authors? The answer is "Both": Image modalities may be authoring devices in some situations.

APSR-09 – **Transcriptionist**: A transcriptionist may appear in the CDA report in the header as a *dataEnterer* element, or within an entry (organizer or observation) as a *participant* element. In both cases the element uses a *participationType* "ENT" whose definition in HL7 V3 vocabulary is: "A person entering the data into the originating system. The data entry person is collected optionally for internal quality control purposes. This includes the transcriptionist for dictated text."

APSR-10 – Observation related to multiple specimens: For example tumor staging requiring combining data from multiple specimens (e.g., a breast excision with positive margins followed by a re-excision with clear margins – in this case the tumor size may be a composite of measurements from both specimens. Another example – staging of ovarian carcinomas with multiple biopsies of pelvis, peritoneum, nodes, omentum, etc.). To accommodate these use cases, the specimen organizer is able to represent either a single specimen or a group of specimens investigated together. The specimen collection procedure nested in this organizer is repeatable to give the possibility to describe each of the specimens of the group.

APSR-11 – Derivative **specimens**. Specimens derived from primary specimens for ancillary studies, which may be sent to a reference lab or done in another part of the same institution, are included in the scope of this profile. The results produced on a derived specimen are attached to this specimen in the report. However the hierarchy of specimens is not explicitly represented in the report (see APSR-07), apart from being tracked in the "Procedure steps section" (see APSR-01).

APSR12 – Multipart report. In some cases the pathologist may create report(s) or report contents in a third-party application and embed, link, or refer to that separate report in the report produced by the LIS. This use case is natively taken care of by the underlying document sharing infrastructure: The profiles "Cross Enterprise Document Sharing" (XDS), "Cross Enterprise Document Media Interchange" (XDM) and "Cross Enterprise Document Reliable Interchange" (XDR) enable the sharing of a "submission set" which groups the collection of documents issued from a particular healthcare act. The APSR could be grouped with a DICOM Key Object Selection list (DICOM KOS) referring to the whole slide images representing the specimens investigated. It could also be grouped with a related report produced in some format by a third-party application. In addition to being in the same "submission set" these related documents or references to images can also be explicitly referred from within an *entry* of the CDA APSR, as a reference to an *externalDocument*, *externalObservation*, *externalProcedure* or *externalAct* element.

APSR-14 – Gaps in SNOMED CT: It is not straightforward to encode Anatomic Pathology observations and AP ancillary technique observations and their corresponding value sets described in Volume IV (Value Sets for APSR) using SNOMED CT concepts (missing concepts, issues of postcoordination versus precoordination). Therefore these observations and value sets are encoded using a coding system currently being built by the IHE Anatomic Pathology domain (PathLex - OID: 1.3.6.1.4.1.19376.1.8.2.1). PathLex codes are provided with the "Trial Implementation" version of this profile. The terms and expressions of PathLex are being currently mapped to SNOMED CT concepts in collaboration with IHTSDO. Part of this mapping are available in the "Trial Implementation" version and completed over time. Using SNOMED CT as a reference terminology offers promising perspectives in terms of scalable semantic queries that could be performed over distributed Anatomic Pathology Information Systems (APIS), EHRs or Clinical Data Warehouses storing these structured reports. In national extensions, vocabulary domains may be specifically constrained, for example the possible values for the observation "Histologic type" may be encoded in France using the ADICAP code.

APSR15 – Preadopting codes from upcoming releases of terminologies or value sets. For some AP observations, the value sets are changing regularly, which may bring the need for APSR producers to encode some observations using new codes approved by the source organization in a future version not available yet. This process is enabled by the "*other, specify*" mechanism described in volume 3.

APSR16 – Exportable human-readable summary of an AP report. Need for a "summary version" of the anatomic pathology report intended to be subsequently extracted for use in

other medical documents. Thus when authors of other medical documents feel the need to include a segment such as "...the pathology report states '[...]'", the "summary version" of the report would ideally be included in the square brackets instead of the entire report including all of its sections. In the future it may be possible to generate and populate the summary version using the controlled vocabulary and discrete data elements used in the report. However, in order to allow the pathologist to control how the report is summarized, should we introduce an optional (free text) "summary version" section into the standard? This would encourage those who are interested to control concise versions of their reports, and on the flip side help the natural language processing algorithm developers. This need of a free text summary is addressed by an optional “Report Textual Summary” sub-section nested in the mandatory Diagnosis section. This Report Textual Summary sub-section does not contain any entry.

Volume 1 – Integration Profiles

1.7 History of Annual Changes

Append the following at the end of section 1.7

Scope of changes introduced in the current year:

- The Anatomic pathology Structured Reports (APSR) Content Profile extends the scope of the Anatomic Pathology Technical Framework to the provision of persistent anatomic pathology and Cytopathology structured reports for various purposes such as care provision, care coordination, screening, and health surveillance.

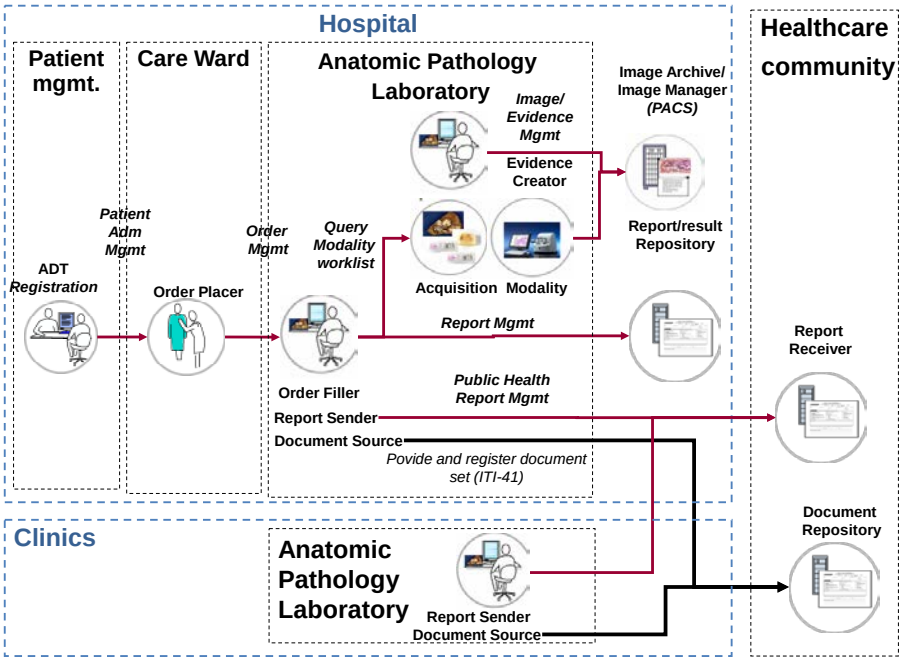
1.12 Glossary

Add the following terms to the Glossary in section 1.12:

APSR Anatomic Pathology Structured Reports Content Profile

1.15 Scope of the Anatomic Pathology Technical Framework

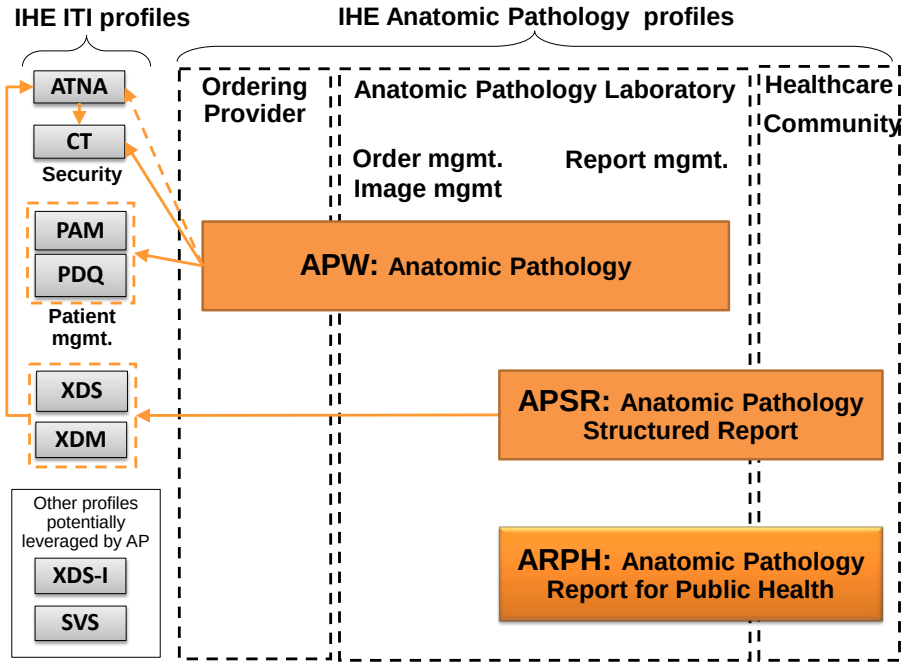
Replace figure 1.15-1 by the one below



410

1.16 Anatomic Pathology Integration Profiles

Replace figure 1.16-1by the new one below, taking the new profile(s) into account.



1.17 Dependencies among Integration Profiles

Add the following lines to Table 1.17-1

Anatomic Pathology Structured Reports to (APSR)	*Cross-Enterprise Document Sharing (XDS) in ITI-TF*	Implementers of APSR Content Profile may implement the XDS Profile to enable sharing of the pathology reports within an XDS Affinity Domain. In this case, the Content Creator actor must be grouped with an XDS Document Source actor, and the Content Consumer actor must be grouped with an XDS Document Consumer actor.	Ensure that the sharing of laboratory reports within an XDS Affinity Domain can co-exist with the sharing of other types of documents
Anatomic Pathology Structured Reports to (APSR)	*Cross-Enterprise Document Media Interchange (XDM) in ITI-TF*	Implementers of APSR Content Profile may implement the XDM Profile to enable sharing of the laboratory reports using media. In this case, the Content Creator must be grouped with an XDM Portable Media Creator and the Content Consumer with an XDM Portable Media Consumer.	Ensure that the sharing of laboratory reports on media can co-exist with the sharing of other types of documents
Anatomic Pathology Structured Reports to (APSR)	*Cross-Enterprise Document Reliable Interchange (XDR) in ITI-TF*	Implementers of APSR Content Profile may implement the XDR Profile to enable sharing of the laboratory reports using reliable point-to-point network messages. In this case, the Content Creator must be grouped with an XDR Document Source, and the Content Consumer must be grouped with an XDR Document Recipient.	Ensure that the sharing of laboratory reports through reliable point-to-point messages can co-exist with the sharing of other types of documents

1.18 Profiles Overview

Append sub-section 1.18.3 (taken from the current profile abstract) at the end of section 1.18.

1.18.3 Anatomic Pathology Structured Reports (APSR)

This content profile describes an anatomic pathology structured report (APSR) as a CDA r2 document to be published towards a document sharing resource such as a shared electronic health record used by a community of care providers, relying on one of the infrastructure document sharing/exchanging profiles defined in IHE ITI TF.

1.19 Actors Description

Add the following actors' descriptions

Content Creator: An application responsible for the creation of content and transmission to a Content Consumer. This actor is involved in the APSR profile to issue anatomic pathology structured reports.

Content Consumer: An application responsible for viewing, importing, or other processing of content created by a Content Creator Actor. This actor is involved in the APSR profile to consume anatomic pathology structured reports.

Add Section 4 below, after the "ARPH integration profile" section.

4 Anatomic Pathology Structured Reports (APSR) Profile

This content profile describes an anatomic pathology structured report (APSR) as a CDA r2 document to be published towards a document sharing resource such as a shared electronic health record used by a community of care providers, relying on one of the infrastructure document sharing/exchanging profiles defined in IHE ITI TF.

Anatomic pathology reports (APR) document the pathologic findings in specimens removed from patients for diagnostic or therapeutic reasons. This information can be used for patient care, clinical research and epidemiology. Standardizing and computerizing APRs is necessary to improve the quality of reporting and the exchange of APR information.

The current scope of this IHE content profile covers APSR for surgical pathology in all fields of anatomic pathology (cancers, benign neoplasms as well as non-neoplastic conditions) as well as for Cytopathology. The profile handles information of "traditional" pathology observation using light microscopy (including immunohistochemistry, FISH, etc.).

Forensic pathology (autopsy, toxicology) will be addressed in further cycles as well as special ancillary techniques (e.g., flow cytometry, cytogenetics, electron microscopy).

Goldsmith provides recent recommendations that delineate the required, preferred, and optional elements which should be included in any APR for surgical pathology, regardless of report types.

Several international initiatives intend to define standard structured templates for specific types of APRs. In the cancer domain, in the United States, the CAP (College of American Pathologists) has published 80 cancer APSR templates (cancer checklists and background information) [www.cap.org]. In France, the SFP (French society of pathology) [http://www.sfpathol.org] and the INCa (French National Cancer Institute) [www.e-cancer.fr] have published 23 APSR templates of minimal set of data required for a primary tumor. In Australasia, the Royal College of Pathologists Australasia (RCPA) and the Cancer Australia developed an initial 6 reporting protocols (lung, melanoma, breast, colorectal, lymphoma and prostate) and a framework to guide development of the protocols, in partnership with national clinician and pathologist organizations. In some countries, the recommendations for generic and specific APSR requirements have become clinical guidelines, the use of which may be required by accrediting bodies.

This profile has also benefited from the guidance on cancer AP reports provided by the North-American Association of Central Cancer Registries; some of the example snippets captured in the profile leverage the NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting.

In addition to standardizing the cancer APR contents, it is necessary to computerize them. Several studies have focused on defining an appropriate IT standard comprising the structured

and encoded clinical documents. Some of the implementation guides of APSRs proposed within these initiatives are not based on international healthcare IT standards (e.g., CAP eCC), other are based on either HL7 CDA r2 or CEN archetypes. HL7 CDA r2 is one of the most reliable standards that can support these needs. CDA allows the clinical data to be both machine and human-readable and provides a framework for incremental growth in the granularity of structured, codes-bound clinical information. This document takes into consideration current very few national CDA implementation guides for the APSR developed in Netherlands (National IT Institute for Healthcare in the Netherlands [www.nictiz.nl] and in Germany.

This content profile describes an anatomic pathology report shared in a human-readable format, which may include images. In addition, this electronic AP report SHALL contain anatomic pathology observations in a machine-readable format, to facilitate the integration of these observations in the database of a consumer system.

The definition of required, preferred and optional elements in this content profile is mainly based on Goldsmith, for generic surgical pathology APSR (regardless of report types) and, in the cancer domain, on standard structured templates provided by United States, the CAP (College of American Pathologists) [www.cap.org.], the SFP (French society of pathology) [www.sfpathol.org] and INCa (French National Cancer Institute) [www.e-cancer.fr] and the Royal College of Pathologists Australasia (RCPA).

Structured reports are composed of a header, which provides the context of care (patient, care providers, pathologists, laboratories, order, act documented …), and a body. The latter provides the clinical information, which accompanied the order and specimens as well as the observations, findings and conclusions delivered by the pathologist after examination.

The anatomic pathology report described in this profile, with its set of anatomic pathology observations in a machine-readable format, MAY also be used to share historical results with appropriate content anonymization and patient identification pseudonymization to create shared distributed repositories of anatomic pathology information.

Both the header and the body provide human-readable information. The body is a hierarchy of sections. Each section presents its content in its *text* element, as human-readable text, possibly illustrated by some embedded images. This human-readable content, or a part of it, may also be present as machine-readable data coded with the appropriate terminologies (e.g., ICD-O-3, SNOMED CT, LOINC, ADICAP, etc.) in *entry* elements at the bottom of the section.

There are zero or more *entry* elements in a *section*. Each *entry* element carries the machine-readable data related to a single specimen or to a group of specimens observed together. The *entry* is then subdivided per problem investigated.

The *text* element of the section is supposed to reflect the same organization: per specimen, and then, per problem investigated on the specimen. The profile leaves the layout of the *text* element up to the Content Creator applications, or to further constraints brought by national extensions. However, given that the *text* element is usually composed of free text (e.g., dictated text), assembled with the text generated from the set of data, machine-encoded in the *entry* elements below, the Content Creator application MUST handle these two kinds of content, and provide a user interface, which precludes any confusion between them, both at creation time and update

time (e.g., using forms with dedicated free text areas and distinct protected areas for coded fields).

4.1 APSR Actors/Transactions

This section references two other IHE Technical Frameworks:

- IT Infrastructure Technical Framework (ITI TF)
- Patient Care Coordination Technical Framework (PCC TF)

There are two actors in this profile, the Content Creator and the Content Consumer.

Content Creator A Content Creator Actor is responsible for the creation of content and transmission to a Content Consumer.

Content Consumer A Content Consumer Actor is responsible for viewing, import, or other processing of content created by a Content Creator Actor

Content (i.e., an anatomic pathology structured report) 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 IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor.

The sharing or transmission of anatomic pathology structured reports from one actor to the other is addressed by the use of appropriate content bindings with XDS, XDM or XDR integration profiles as explained in section 4 of Volume 3 of the Anatomic Pathology Technical Framework.

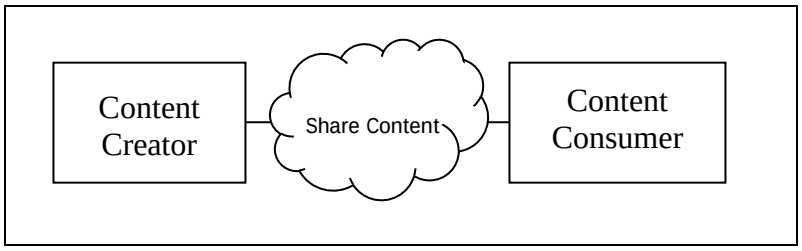


Figure 4.1-1 APSR Actor Diagram

4.1.1 Actor Descriptions and Requirements

This section is intentionally empty.

4.1.2 Document Content Modules

4.1.2.1 Anatomic Pathology Structured Report (APSR)

This document content module represents the generic set of constraints applied to any structured report for surgical pathology in all fields of anatomic pathology (cancers, benign neoplasms as well as non-neoplastic conditions) as well as for Cytopathology.

This document content module is identified by templatecId 1.3.6.1.4.1.19376.1.8.1.1.1

The structure of the header of this document content module is inherited by all its specialized children.

The body of this document content module and of all its specialized children share a common hierarchy of sections and entries depicted by figure 4.1.2.1-1.

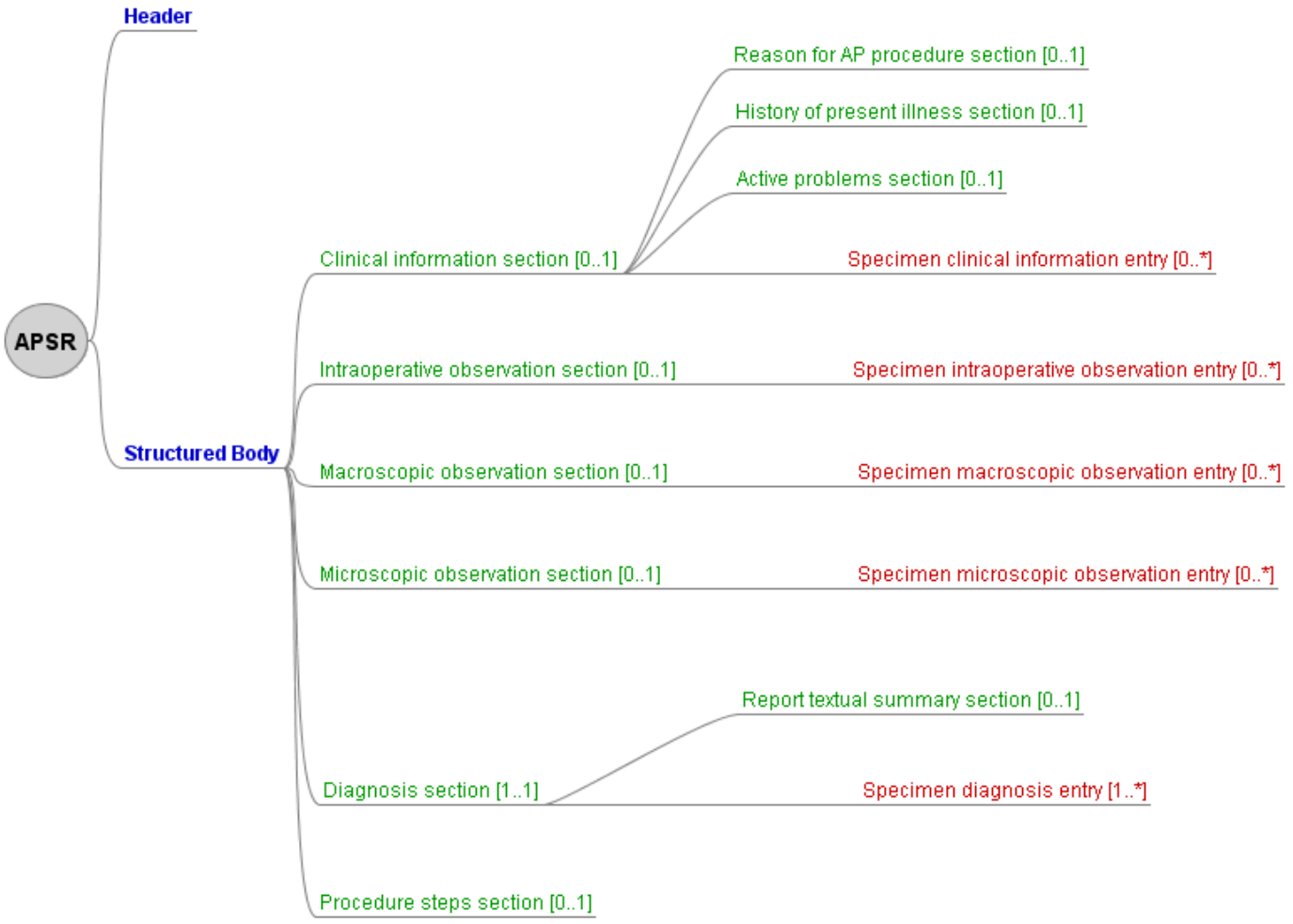


Figure 4.1.2.1-1 Common hierarchy for all APSR document content modules

4.1.2.2 Organ specific APSR document content modules

The organ-specific document content modules are children of the generic APSR document content module. These organ-specific APSR document content modules provide additional organ-specific constraints:

- Organ-specific "specimen Collection Procedure" templates
- Organ-specific "AP observations" templates grouped per "problem" in organizers.

In particular, for each organ, AP observations related to infiltrating malignant neoplasm or in situ neoplasm have been specified according to cancer check lists (CAP, INCa, etc.).

Table 4.1.2.2-1 lists the organ specific document content modules.

Table 4.1.2.2-1 Organ specific APSR document content modules

Organ specific APSR document Content Modules	
templateId	**Name**
1.3.6.1.4.1.19376.1.8.1.1.2.1	breast APSR
1.3.6.1.4.1.19376.1.8.1.1.2.2	colon APSR
1.3.6.1.4.1.19376.1.8.1.1.2.3	prostate APSR
1.3.6.1.4.1.19376.1.8.1.1.2.4	thyroid APSR
1.3.6.1.4.1.19376.1.8.1.1.2.5	lung APSR
1.3.6.1.4.1.19376.1.8.1.1.2.6	skin APSR
1.3.6.1.4.1.19376.1.8.1.1.2.7	kidney APSR
1.3.6.1.4.1.19376.1.8.1.1.2.8	cervix APSR
1.3.6.1.4.1.19376.1.8.1.1.2.9	endometrium APSR
1.3.6.1.4.1.19376.1.8.1.1.2.10	ovary APSR
1.3.6.1.4.1.19376.1.8.1.1.2.11	esophagus APSR
1.3.6.1.4.1.19376.1.8.1.1.2.12	stomach APSR
1.3.6.1.4.1.19376.1.8.1.1.2.13	liver APSR
1.3.6.1.4.1.19376.1.8.1.1.2.14	pancreas APSR
1.3.6.1.4.1.19376.1.8.1.1.2.15	testis APSR
1.3.6.1.4.1.19376.1.8.1.1.2.16	urinary bladder APSR
1.3.6.1.4.1.19376.1.8.1.1.2.17	lip oral cavity APSR
1.3.6.1.4.1.19376.1.8.1.1.2.18	pharynx APSR
1.3.6.1.4.1.19376.1.8.1.1.2.19	salivary gland APSR
1.3.6.1.4.1.19376.1.8.1.1.2.20	larynx APSR

4.2 APSR Options

Table 4.2-1 summarizes the options that actors may take for this content profile. Dependencies between options when applicable are specified in notes. These options are summarized below the table, and further detailed in PCC TF-2, as indicated in the right column of the table.

Table 4.2-1 Actors and Options

Actor	Options	Domain, Vol & Section
Content Consumer	*View Option (1)*	PCC TF-2:3.1.1
	Document Import Option (1)	PCC TF-2:3.1.2
	Section Import Option (1)	PCC TF-2:3.1.3

Note 1: The Actor shall support at least one of these options.

4.3 APSR Actor Groupings and Profile Interactions

It is expected that the sharing of anatomic pathology structured reports 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).
- 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.
- 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

Such an infrastructure is assumed by the use cases described in this Profile.

A content binding describes how the payloads used in IHE transactions are related to and/or constrained by the data elements contained within the content sent or received in those transactions. The APSR Content Profile applies one binding, which is used when grouping the Content Creator with the IHE ITI XDS, XDM or XDR Integration Profiles.

The content and the binding are described in Volume 3 of the IHE Anatomic Pathology Technical Framework.

4.4 APSR Process Flow

4.4.1 Use Cases

4.4.1.1 Use case 1: General case

Barbara Breast visits Sammy Surgeon for removal of a breast tumor. Sammy Surgeon orders the Requested Procedure “Breast surgical specimen - pathological examination” and sends the specimen(s) to the anatomic pathology department.

Specimen(s) is (are) accessioned by the anatomic pathology department. The staff performs a macroscopic examination of the specimen(s); gross imaging is performed if needed. The specimen(s) are processed for microscopic examination and other special ancillary techniques or tissue banking if needed. During the imaging interpretation process, microscopic imaging is performed if needed. At the end of the interpretation process, pathologist queries the **Content Creator application** for the appropriate APSR template, fills the form, binds some relevant images and/or regions of interest to specific observation(s), validates and signs the document.

4.4.1.2 Use case 2: Specimen collector is not the ordering physician

Patricia Pathologist collects bone marrow from Peter Patient in the clinical ward.

Specimen(s) is (are) accessioned by the anatomic pathology department. The staff performs a macroscopic examination of the specimen(s); gross imaging is performed if needed. The specimen(s) are processed for microscopic examination and other special ancillary techniques or tissue banking if needed. During the imaging interpretation process, microscopic imaging is performed if needed. At the end of the interpretation process, pathologist queries the **Content Creator** for the appropriate APSR template, fills the form, binds some relevant images and/or regions of interest to specific observation(s), validates and signs the document.

4.4.1.3 Use case 3: Multi-step reporting

Barbara Breast visits Sammy Surgeon for removal of a breast tumor. Sammy Surgeon orders the Requested Procedure “Breast surgical specimen - Frozen sections & pathological examination” and sends the specimen(s) to the anatomic pathology department.

Specimen(s) is (are) accessioned by the anatomic pathology department. The staff performs a macroscopic examination of the specimen(s), gross imaging is performed if needed. The specimen(s) are processed for intraoperative observation if needed, and tissue banking if needed (e.g., for research purpose). During the imaging interpretation process of frozen sections, microscopic imaging is performed if needed. At the end of the interpretation process, pathologist queries the **Content Creator** for the appropriate APSR template, fills the intraoperative observation section, binds some relevant images and/or regions of interest to specific observation(s) if needed, validates and signs (i.e., legally authenticates) the preliminary APSR.

The day after, the specimen(s) are processed for microscopic examination and other special ancillary techniques if needed. During the imaging interpretation process, microscopic imaging is performed if needed. At the end of the interpretation process, pathologist queries the **Content**

Creator for the preliminary APSR, fills the form, binds some relevant images and/or regions of interest to specific observation(s), validates and signs (i.e., legally authenticates) the final APSR.

4.4.1.4 Use case 4: Opinion request

There are various situations in which an opinion request is issued: External expert consultation (requested by Philip Pathologist, often before a final report is issued). Second opinion request (usually made by a treating physician or patient/family, or lawyer/court in malpractice cases). External slide review (usually routine review of slides required by protocols in an outside treating institution). These may vary in terms or workflow and even the materials accessed by the outside lab.

Requiring pathologist

Philip Pathologist asks for second opinion for the case of Peter Patient diagnosed as lymphoma. He sends block(s) or slide(s) or shares/sends whole slide images to Patricia pathologist, requesting her expertise on this material. He uses the **Content Creator application** to derive the anatomic pathology opinion request document from the preliminary APSR of Peter Patient.

Philip Pathologist later on uses his **Content Consumer** application to view and import the APSR from Patricia Pathologist. He uses this report to finalize and issue his own APSR in his application acting as a Content Creator.

Requested pathologist

Patricia Pathologist accepts to deliver second opinion about the case of Peter Patient diagnosed as lymphoma.

Block(s)

The specimen(s) are processed for microscopic examination and other special ancillary techniques if needed. During the imaging interpretation process, microscopic imaging is performed if needed. At the end of the interpretation process, Patricia Pathologist queries the **Content Creator** for the appropriate APSR template, fills the form, binds some relevant images and/or regions of interest to specific observation(s), validates and signs the document.

Slide(s)

During the imaging interpretation process, microscopic imaging is performed if needed. At the end of the interpretation process, Patricia Pathologist queries the **Content Creator** for the appropriate APSR template, fills the form, binds some relevant images and/or regions of interest to specific observation(s), validates and signs the document.

Whole slide image(s)

At the end of the interpretation process, Patricia Pathologist queries the **Content Creator** for the appropriate APSR template, fills the form, binds some relevant images and/or regions of interest to specific observation(s), validates and signs the document.

4.5 APSR Security considerations

4.5.1 Integrity

The choice on whether the digital signature is performed at the transaction level (XDS, XDM, XDR) or at the content level is left up to national extensions. If the report is digitally signed, the person having signed it SHALL be the person represented in the *legalAuthenticator* element of the CDA header.

4.5.2 Confidentiality

In the context of patient care coordination the anatomic pathology report described in this profile contains patient personal data, and as such must be handled in conformance to the local privacy policies.

In other contexts such as public health, surveillance, research, appropriate content anonymization and patient identification pseudonymization may be required by local policies.

4.5.3 Auditability

Addressed by the CT and ATNA profiles from ITI TF.

Volume 3 – Content Modules

1 Introduction

Insert the text from the same section in volume 1 of the PAT TF

1.1 Overview of the Anatomic Pathology Technical Framework

Insert the text from the same section in volume 1 of the PAT TF

1.2 Overview of Volume 3

The IHE Technical Framework is based on actors that interact through transactions using some form of content.

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

Transactions are interactions between actors that transfer the required information through standards-based messages.

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. The second part is binding to a specific IHE transaction, which describes how the content affects the transaction. The third part is a Content Module, which describes the payload of the transaction. A content module is specified so as to be independent of the transaction in which it appears. This overall content module is itself an assemblage of smaller content modules, which in turn may assemble smaller content modules, conforming to the chosen standard.

In particular, the Anatomic Pathology Technical Framework provides a set of content profiles for the sharing of persistent clinical document produced by the anatomic pathology domain.

This Volume 3 specifies the content modules produced at various granularity levels (from a whole clinical document to a tiny reusable piece of coded data) by the Anatomic Pathology domain of IHE for its own content profiles.

Some of these content modules produced here, may be used by content modules of higher granularity from other domains (e.g., Patient Care Coordination).

Some of these content modules produced here, may leverage content modules of lower granularity from other domains (e.g., PCC, LAB, etc.).

1.3 Audience

Insert the text from the same section in volume 1of the PAT TF

1.4 Relationship to Standards

Insert a simplified version of the text from the same section in volume 1of the PAT TF

1.5 Relationship to Real World Architecture

Insert the text from the same section in volume 1 of the PAT TF

1.6 Conventions

Insert a simplified version of the text from the same section in volume 1 of the PAT TF

1.7 Scope Introduced in the Current Year

Content Modules for the APSR Profile

1.8 Copyright Permission

1.9 Glossary

The glossary of the Anatomic Pathology Technical Framework is centralized in PAT TF-1:1.12.

2 Content Modules – Basic Principles

This Volume 3 of the PAT TF organizes content modules categorically by the base standard. At present, PAT TF-3 uses only one base standard, CDA Release 2.0, but this is expected to change over time. Underneath each standard, the content modules are organized using a very coarse hierarchy inherent to the standard.

Each content module can be viewed as the definition of a "class" in software design terms, and has associated with it a name. Like "class" definitions in software design, a content module is a "contract", and the PAT TF-3 defines that contract in terms of constraints that must be obeyed by instances of that content module. Each content module has a name, also known as its template identifier. The template identifiers are used to identify the contract agreed to by the content module. The Anatomic Pathology Technical Committee is responsible for assigning the template identifiers to each content module.

Like classes, content modules may inherit features of other content modules of the same type (e.g., Document, Section or Entry) by defining the parent content module that they inherit from. They may not inherit features from a different type.

Constraints that apply to any content module will always apply to any content modules that inherit from it. Thus, the "contracts" are always valid down the inheritance hierarchy.

The PAT TF-3 uses the convention that a content module cannot have more than one parent (although it may have several ancestors). This convention is not due to any specific technical limitation of the technical framework, but does make it easier for software developers to implement content modules.

Each content module has a list of data elements that are required (R), required if known (R2), conditional (C) or optional (O).

Other data elements may be included in an instance of a content module over what is defined by the PAT TF-3. Content consumers are not required to process these elements, and if they do not understand them, must ignore them. Thus, it is not an error to include more than is asked for, but it is an error to reject a content module because it contains more than is defined by the framework. This allows value to be added to the content modules delivered internationally in this framework, through national extensions built by the national IHE organizations in various countries. It further allows content modules to be defined later by IHE that are refinements or improvements over previous content modules.

3 IHE Transactions

This section defines each IHE transaction in detail, specifying the standards used, and the information transferred.

3.1 Cross Enterprise Document Content Transactions

At present, all transactions used by the Anatomic Pathology Content Profiles appear in ITI TF-2a and ITI TF-2b.

General Options defined in content profiles for a Content Consumer are listed below.

3.1.1 View Option

A Content Consumer that supports the View Option shall be able to:

1. Use the appropriate XD* transactions to obtain the document along with associated necessary metadata.
2. Render the document for viewing. This rendering shall meet the requirements defined for CDA Release 2 content presentation semantics (See Section 1.2.4 of the CDA Specification: Human readability and rendering CDA Documents). CDA Header information providing context critical information shall also be rendered in a human readable manner. This includes at a minimum the ability to render the document with the stylesheet specifications provided by the document source, if the document source provides a stylesheet. Content Consumers may optionally view the document with their own stylesheet, but must provide a mechanism to view using the source stylesheet.
3. Support traversal of links for documents that contain links to other documents managed within the sharing framework.
4. Print the document to paper.

3.1.2 Document Import Option

This Option requires that the View Option be supported. In addition, the Content Consumer that supports the Document Import Option shall be able to support the storage of the entire APSR document (as provided by the sharing framework, along with sufficient metadata to ensure its later viewing). The machine-readable content (from the entry elements) shall also be imported. This Option requires the proper tracking of the document origin. Once a document has been imported, the Content Consumer shall offer a means to view the document without the need to retrieve it again from the sharing framework. When the document is used after it was imported, a Content Consumer may choose to access the sharing framework to find out if the related Document viewed has been deprecated or replaced.

3.1.3 Section Import Option

This Option requires that the View Option be supported. In addition, the Content Consumer that supports the Section Import Option shall be able to support the import of one or more sections of

the APSR document (along with sufficient metadata to link the data to its source). The machine-readable content (from the entry elements beneath the imported sections) shall also be imported. This Option requires the proper tracking of the document section origin. Once sections have been selected, a Content Consumer shall offer a means to copy the imported section(s) into local data structures. When a section is used after it is imported, a Content Consumer may choose to access the sharing framework to find out if the related information has been updated.

4 IHE Anatomic Pathology Bindings

This section describes how the payload used in a transaction of an IHE profile is related to and/or constrains the data elements sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined.

A content profile can define multiple bindings. Each binding should identify the transactions and content to which it applies.

The source for all required and optional attributes have been defined in the bindings below. Three tables describe the three main XDS object types: XDSDocumentEntry, XDSSubmissionSet, and XDSFolder. XDSSubmissionSet and XDSDocumentEntry are required. Use of XDSFolder is optional. These concepts are universal to XDS, XDR and XDM.

The structure of these three tables is presented in **PCC TF-2:4**

4.1 Anatomic Pathology Document Binding to XDS, XDM and XDR

This binding defines a transformation that generates metadata for the *XDSDocumentEntry* element of appropriate transactions from the XDS, XDM and XDR profiles given a medical document and information from other sources. The medical document refers to the document being stored in a repository that will be referenced in the registry. The other sources of information include the configuration of the Document Source actor, the Affinity Domain, the site or facility, local agreements, other documents in the registry/repository, and this content profile.

In many cases, the CDA document is created for the purposes of sharing within an affinity domain. In these cases the context of the CDA and the context of the affinity domain are the same, in which case the following mappings shall apply.

In other cases, the CDA document may have been created for internal use, and are subsequently being shared. In these cases the context of the CDA document would not necessarily coincide with that of the affinity domain, and the mappings below would not necessarily apply.

4.1.1 XDSDocumentEntry Metadata

The general table describing the *XDSDocumentEntry* Metadata requirements for IHE domains is shown in **PCC TF-2:4.1.1**

The sub-sections below list the only requirements which are specific to the Anatomic Pathology Domain, and which supersede those from the general table mentioned above.

4.1.1.1 XDSDocumentEntry.formatCode

The values of *formatCode* per document template are listed in table 5.6-1.

The associated *codingScheme* Slot SHALL be **1.3.6.1.4.1.19376.1.2.3** in all cases.

4.1.1.2 XDSDocumentEntry.eventCodeList

This metadata provides a means to index anatomic pathology reports by reportable conditions (e.g., certain types of tumors…) so as to facilitate later queries in a registry of shared clinical documents. The conclusions coded in the *entry* element of the diagnosis *section* are good candidates for this metadata.

4.1.1.3 XDSDocumentEntry.parentDocumentRelationship

The Anatomic Pathology document Content Modules only permit the “replace” relationship between instances of APSR documents.

Thus, XDSDocumentEntry.parentDocumentRelationship is constrained to the "**RPLC**" (replace) value. The new document issued replaces completely the parent one, which will be considered as deprecated.

4.1.2 XDSSubmissionSet Metadata

The submission set metadata is as defined for XDS, and is not necessarily affected by the content of the clinical document. Metadata values in an *XDSSubmissionSet* with names identical to those in the *XDSDocumentEntry* may be inherited from *XDSDocumentEntry* metadata, but this is left to affinity domain policy and/or application configuration.

This content format uses the submission set to create a package of information to send from one provider to another. All documents or images referenced by the Anatomic Pathology Structured Report in this Package must be present (at least as references in the case of images) in the submission set.

4.1.3 XDSFolder Metadata

No specific requirements identified.

4.1.4 Configuration

The Anatomic Pathology Content Profiles using this binding require that Content Creators and Content Consumers be configurable with institution and other specific attributes or parameters. Implementers should be aware of these requirements to make such attributes easily configurable.

5 Namespaces and Vocabularies

5.1 OID tree of PAT TF

1.3.6.1.4.1.19376.1.81.3.6.1.4.1.19376.1.8 is the OID of the IHE Anatomic Pathology domain. All exchangeable objects specified by this domain are identified by OIDs built on this root:

Branch 1.3.6.1.4.1.19376.1.8.1 is dedicated to CDA Content Modules created by this domain.

Sub-branch 1.3.6.1.4.1.19376.1.8.1.1 is dedicated to Document Content Modules.

Sub-branch 1.3.6.1.4.1.19376.1.8.1.2 is dedicated to Section Content Modules.

Sub-branch 1.3.6.1.4.1.19376.1.8.1.3 is dedicated to Entry Content Modules.

Sub-branch 1.3.6.1.4.1.19376.1.8.1.4 is dedicated to Element Content Modules.

Branch 1.3.6.1.4.1.19376.1.8.2 is dedicated to Terminologies defined by this domain.

OID 1.3.6.1.4.1.19376.1.8.2.1 is dedicated to PathLex terminology.

Branch 1.3.6.1.4.1.19376.1.8.5 is dedicated to Value Sets defined by this domain.

Branch 1.3.6.1.4.1.19376.1.8.9 is used to identify instances in the examples built by the PAT TF.

5.2 Terminologies and controlled coded vocabularies

This section lists the terminologies and the coded vocabularies referenced by this Volume 3 of the IHE PAT TF.

Table 5.2-1 Anatomic Pathology Terminologies and Coded Vocabularies

codeSystem	codeSystemName	Description	Owner
2.16.840.1.113883.6.1	LOINC	Logical Observation Identifier Names and Codes	Regenstrief Institute
2.16.840.1.113883.6.96	SNOMED-CT	Systematized Nomenclature of Medicine – Clinical Terms	IHTSDO
1.3.6.1.4.1.19376.1.5.3.2	IHEActCode	Vocabulary defined by IHE PCC in PCC TF-2:5.1.2	IHE PCC
2.16.840.1.113883.6.3	ICD-10	International Classification of Diseases revision 10	WHO
2.16.840.1.113883.6.43	ICD-O	International Classification of Diseases for Oncology	WHO
1.2.250.1.213.2.11	ADICAP Thesaurus	French thesaurus of lesions in anatomic pathology	ADICAP
1.2.250.1.213.2.12	SNOMED International (3.5)	Systematized Nomenclature of Medicine	ASIP santé
1.3.6.1.4.1.19376.1.8.2.1	PathLex	Terminology covering the scope of anatomic pathology observations and specimen collection procedures	IHE PAT

5.3 Value Sets

The value sets defined or referenced by this Volume 3 of the IHE PAT TF are listed in the separate appendix spreadsheet “IHE_PAT_Suppl_APSR_AppendixValue_Sets”.

5.4 Namespaces

5.3.1 Namespace protecting extensions to the CDA schema

There is currently one single extension to the CDA.xsd schema used in PAT TF-3. This extension has been created by IHE LAB and is protected by this particular namespace in document instances: *xmlns:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2"*

5.5 References to Content Modules built outside of IHE PAT TF

The Content Modules specified in this Volume 3 of the PAT TF leverage a number of Content Modules (currently CDA templates) produced and maintained by other groups, including other domains of IHE. Table 5.5-1 lists them.

Table 5.5-1 External Content Modules referenced by PAT TF-3

templateId	Standard	Definition	Source of specification
1.3.6.1.4.1.19376.1.5.3.1.3.1	CDA R2	Reason for referral	IHE PCC TF-2:6.3.3.1.2
1.3.6.1.4.1.19376.1.5.3.1.3.4	CDA R2	History of present illness	IHE PCC TF-2:6.3.3.2.1
1.3.6.1.4.1.19376.1.5.3.1.3.6	CDA R2	Active Problems	IHE PCC TF-2:6.3.3.2.3
1.3.6.1.4.1.19376.1.5.3.1.4.2	CDA R2	Annotation Comment	IHE PCC TF-2:6.3.4.6
1.3.6.1.4.1.19376.1.3.3.1.7	CDA R2	Performing laboratory	IHE LAB TF-3:2.3.3.22
1.3.6.1.4.1.19376.1.3.3.1.6	CDA R2	Ordering Provider (ordering physician)	IHE LAB TF-3:2.3.3.19
1.3.6.1.4.1.19376.1.3.3.1.4	CDA R2	Intended Recipient	IHE LAB TF-3:2.3.3.16
1.3.6.1.4.1.19376.1.3.1.6	CDA R2	Laboratory Observation	IHE LAB TF-3:2.3.5.11
1.3.6.1.4.1.19376.1.3.1.2	CDA R2	Specimen Collection Procedure	IHE LAB TF-3:2.3.5.5 (specification captured in this APSR supplement for easier readability)

5.6 IHE Codes for Anatomic Pathology Document Templates

Table 5.6-1 below lists the template identifiers, document type codes, format codes, and media types used by the IHE Profiles specified in this Volume 3 of the Anatomic Pathology Technical Framework.

Note 1: The code system (codingScheme) for all formatCode metadata is **1.3.6.1.4.1.19376.1.2.3** as assigned by the ITI Domain for codes used for the purposes of cross-enterprise document sharing (XDS).

Note 2: The media type associated with all PAT TF CDA document templates is "**text/xml**".

Note 3: The metadata typeCode is always the '**11526-1**' LOINC code, standing for "**Pathology study**".

Table 5.6-1 formatCode and typeCode per document Content Module

PAT TF-3 Document Content Module	Associated Metadata in XDSDocumentEntry	
templateId (default title)	**typeCode**	**formatCode**
1.3.6.1.4.1.19376.1.8.1.1.1 (APSR)	11526-1	urn:ihe:pat:apsr:all:2010
1.3.6.1.4.1.19376.1.8.1.1.2.1 (breast APSR)	11526-1	urn:ihe:pat:apsr:breast:2010
1.3.6.1.4.1.19376.1.8.1.1.2.2 (colon APSR)	11526-1	urn:ihe:pat:apsr:colon:2010
1.3.6.1.4.1.19376.1.8.1.1.2.3 (prostate APSR)	11526-1	urn:ihe:pat:apsr:prostate:2010
1.3.6.1.4.1.19376.1.8.1.1.2.4 (thyroid APSR)	11526-1	urn:ihe:pat:apsr:thyroid:2010
1.3.6.1.4.1.19376.1.8.1.1.2.5 (lung APSR)	11526-1	urn:ihe:pat:apsr:lung:2010
1.3.6.1.4.1.19376.1.8.1.1.2.6 (skin APSR)	11526-1	urn:ihe:pat:apsr:skin:2010
1.3.6.1.4.1.19376.1.8.1.1.2.7 (kidney APSR)	11526-1	urn:ihe:pat:apsr:kidney:2010
1.3.6.1.4.1.19376.1.8.1.1.2.8 (cervix APSR)	11526-1	urn:ihe:pat:apsr:cervix:2010
1.3.6.1.4.1.19376.1.8.1.1.2.9 (endometrium APSR)	11526-1	urn:ihe:pat:apsr:endometrium:2010
1.3.6.1.4.1.19376.1.8.1.1.2.10 (ovary APSR)	11526-1	urn:ihe:pat:apsr:ovary:2010
1.3.6.1.4.1.19376.1.8.1.1.2.11 (esophagus APSR)	11526-1	urn:ihe:pat:apsr:esophagus: 2010
1.3.6.1.4.1.19376.1.8.1.1.2.12 (stomach APSR)	11526-1	urn:ihe:pat:apsr:stomach: 2010
1.3.6.1.4.1.19376.1.8.1.1.2.13 (liver APSR)	11526-1	urn:ihe:pat:apsr:liver:2010
1.3.6.1.4.1.19376.1.8.1.1.2.14 (pancreas APSR)	11526-1	urn:ihe:pat:apsr:pancreas: 2010
1.3.6.1.4.1.19376.1.8.1.1.2.15 (testis APSR)	11526-1	urn:ihe:pat:apsr:testis:2010
1.3.6.1.4.1.19376.1.8.1.1.2.16 (urinary bladder APSR)	11526-1	urn:ihe:pat:apsr:urinary_bladder:2010
1.3.6.1.4.1.19376.1.8.1.1.2.17 (lip oral cavity APSR)	11526-1	urn:ihe:pat:apsr:lip_oral_cavity:2010
1.3.6.1.4.1.19376.1.8.1.1.2.18 (pharynx APSR)	11526-1	urn:ihe:pat:apsr:pharynx:2010
1.3.6.1.4.1.19376.1.8.1.1.2.19 (salivary gland APSR)	11526-1	urn:ihe:pat:apsr:salivary_gland:2010
1.3.6.1.4.1.19376.1.8.1.1.2.20 (larynx APSR)	11526-1	urn:ihe:pat:apsr:larynx:2010

6 Anatomic Pathology Content Modules

6.1 Conventions

In all Content Modules specified in this section, the abbreviation "**AP**" stands for "Anatomic Pathology".

Various tables used in this section will further constrain the content. Within this volume, the following conventions are used:

R

A "**Required**" data element is one that shall always be provided. If there is information available, the data element must be present. If there is no information available, or it cannot be transmitted, the data element must contain a value indicating the reason for omission of the data.

R2

A "**Required if data present**" data element is one that shall be provided when a value exists. If the information cannot be transmitted, the data element shall contain a value indicating the reason for omission of the data. If no such information is available to the content creator or if such information is not available in a well identified manner (e.g., buried in a free form narrative that contains additional information relevant to other sections) or if the content creator requires that information be absent, the R2 section shall be entirely absent. The Content Creator application must be able to demonstrate that it can populate all required if known elements, unless it does not in fact gather that data[1].

O

An "**Optional**" data element is one that may be provided, irrespective of whether the information is available or not. If the implementation elects to support this optional section, then its support shall meet the requirement set forth for the "Required if data present" or R2.

C

A "**Conditional**" data element is one that is required, required if known or optional depending upon other conditions. These will have further notes explaining when the data element is required, et cetera.

[1] This "R2" code is the equivalent of the HL7 standard "RE" usage code. The value "R2" has been chosen in harmonization with the IHE PCC TF, which is the source of a large number of CDA R2 content modules.

6.2 HL7 CDA R2 Content Modules

6.2.1 Organization

6.2.1.1 Various Types of Content Modules

For the CDA Release 2.0 standard, the content modules are organized by:

- **document**: The template for a whole document.
- **section**: The template for a <section> element
- **entry**: The template for a <entry> element
- **child element**: An element of the CDA header or an element of a <section>, or an element nested at various depths below an <entry>, or an element appearing at some combination of these locations.

6.2.1.2 General constraints added by IHE PAT to a CDA R2 document

In the structured body of a CDA R2 document, a section has a narrative block (the *text* element), which presents the human-readable content of the section, and MAY have one entry or more. Sections MAY be nested within one another.

The content modules designed by the PAT TF bring or highlight the following constraints:

- When a section has a *text* element and one or more *entry* element, the content coded for machine-processing in the entries SHALL be completely transcribed into human-readable content in the *text* element.
- Conversely the *text* element MAY contain pieces of information, which are not available in machine-readable format in any *entry* element of the section.
- For a document of the Anatomic Pathology domain, the *entry* elements are instantiated per specimen or per group of specimens observed together. One *entry* contains in machine-readable format observations of the section related to the same specimen or group of specimens. Beneath an *entry*, the observations are organized per problem.
- The *text* element of the section is supposed to be also laid out per specimen or group of specimens and per problem observed.
- The APSR Content Profile leaves the layout of the *text* element up to the Content Creator applications, or to further constraints brought by national extensions of this profile. However, given that the *text* element is usually composed of free text (e.g. dictated text), assembled with the text generated from the set of data, machine-encoded in the *entry* elements below, the Content Creator application MUST handle these two kinds of content, and provide a user interface, which avoids risks of overwriting text automatically derived from the entries with free text typed in by the user (e.g., using forms with dedicated free text areas and distinct protected areas for text generated out of structured data).
- Information that is sent SHALL clearly identify distinctions between:

  None:

It is known with complete confidence that there are none. This indicates that the sender knows that there is no relevant information of this kind that can be sent.

None Known

None known at this time, but it is not known with complete confidence that none exist.

Asked but unknown

The information was requested but could not be obtained. Used mainly in the context where an observation was made but the result could not be determined.

Unknown

The information is not known, or is otherwise unavailable.

Other, not specified

The actual value does not belong to the assigned value set and is not reported at all by the author.

Other, specify

The actual value does not belong to the assigned value set and the author of the report provides this *foreign* value anyway.

Not applicable

No proper value is applicable in this context.

Sections that are required to be present but have no information should use one of the above phrases where appropriate in the *text* element.

Structural elements that are required but have no information shall provide a "nullFlavor" attribute coding the reason why the information is missing.

Situation	nullFlavor	HL7 Definition
Asked but unknown	ASKU	Information was sought but not found
Unknown	UNK	A proper value is applicable, but not known.
Other, not specified	OTH	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).
Not applicable	NA	No proper value is applicable in this context

The two situations "None" and "None known" represent effective values, which are part of the related value sets.

The situation "Other, specify" can be handled in two ways in a coded data element:

- Leaving empty the *code* attribute and providing the non-coded answer in the *originalText* attribute.
- Providing a value coded from a different coding scheme, when the coding strength of the element is "CWE" (coded with extensions). The attributes *code*, *displayName*, *codeSystem* and *codeSystemName* then describe the foreign code.

6.2.1.3 Common structure for all CDA APSR

Figure 6.2.1.3-1 summarizes the common structure of all CDA APSR conforming to the Content Modules specified here. Regarding the machine-readable part, the figure highlights the organization of entries within a section and of observations within an entry. Specific details such as the structure of sub-sections are not shown on this global picture.

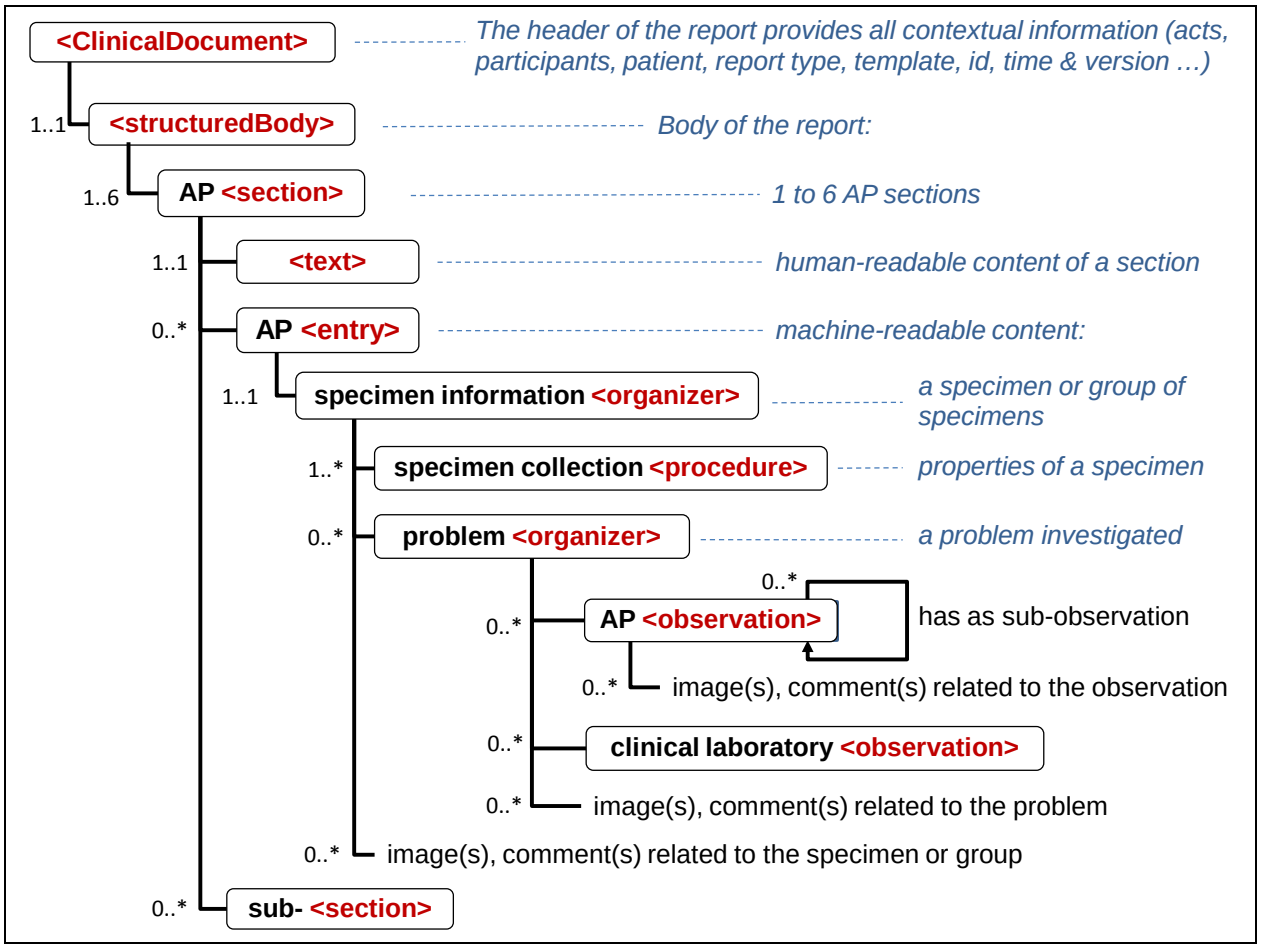


Figure 6.2.1.3-1 CDA APSR: common structure of machine-readable content

Note 1: In order to facilitate a further de-identification process of CDA AP reports for some secondary use (biosurveillance, epidemiology…) the producer of an APSR SHOULD avoid populating any patient identification data (name, sex, birthdate, address …) into the body of the report (neither <entry> elements nor <text> elements). The appropriate location for patient identification data is the CDA header exclusively.

Note 2: The 6 AP sections are those shown on figure 4.1.2.1-1 of Volume 1.

Note 3: The possible sub sections are shown on figure 4.1.2.1-1 of Volume 1.

6.2.2 Common layout for the specification of a CDA Content Module

Each CDA R2 Content Module specified in this Volume is presented with this layout:

6.2.2.1 Content Module Name – OID

Each Content Module is uniquely identified by a unique OID.

6.2.2.1.1 Definition and purpose

This section presents the content module and its purpose.

In case this module is a specialization of a more generic one, the section references its parent template.

6.2.2.1.2 Example

This section delivers a snippet, showing an example of the content module.

6.2.2.1.3 Specification

The form of the specification depends upon the kind of CDA Content Module (document, section, entry, header and/or entry element). It respects the guidelines below:

- The specification provides a table describing the structure of the content module, each element being located through an XPATH expression combined with indentation. The table provides cardinalities, meaning for each elements, references value sets described in section 5 for attributes, and provides the mapping with HL7 V2.5.1 relevant fields. The table also points the content modules nested in the current one, by showing their templateId, and locating their specification in the current PAT TF-3 or in the IHE TF they belong to (PCC, LAB, etc.).
- The table is simplified for section content modules: It only lists the content modules nested in the section template.
- Below the tables appear notes providing additional information and detailing particular constraints on some elements or attributes.

6.2.3 CDA R2 Document Content Modules

6.2.3.1 AP Structured Report (APSR) - 1.3.6.1.4.1.19376.1.8.1.1.1

6.2.3.1.1 Definition and purpose

This Document Content Module defines the base set of constraints that apply to all AP structured report, related to any kind of lesion or diagnostic. In other words, this is the generic template for any AP structured report.

The body of this Document Content Module and of all its specialized children share a common hierarchy of sections and entries depicted by figure 4.1.2.1-1 in Volume 1.

6.2.3.1.2 Example

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='1.3.6.1.4.1.19376.1.8.1.1.1'/>
  <id root='1.3.6.1.4.1.19376.1.8.9' extension='123'/>
  <code code='11526-1' displayName='Pathology study'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>Anatomic pathology structured report</title>
  <effectiveTime value='20100114153000-0700'/>
  <confidentialityCode code='N' displayName='Normal' codeSystem='2.16.840.1.113883.5.25'/>
  <languageCode code='en-US'/>

  <!-- one patient -->
  <recordTarget><patientRole> .. </patientRole></recordTarget>

  <!-- one or more author -->
  <author> .. </author>

  <!-- one or more transcriptionists -->
  <dataEnterer> .. </dataEnterer>

  <!-- one or more person who provided useful information as input to this document -->
  <informant> .. </informant>

  <!-- the organization (laboratory) issuing this report and in charge with its lifecycle -->
  <custodian> .. </custodian>

  <!-- zero or more intended recipient other than the ordering physician (« copy to ») -->
  <informationRecipient> .. </informationRecipient>

  <!-- the person (lab director) legally responsible for this report, who may have signed it -->
  <legalAuthenticator> .. </legalAuthenticator>

  <!-- one or more pathologists who validated and/or corrected the content -->
  <authenticator> .. </authenticator>

  <!-- the ordering physician, and the date-time the order was issued -->
  <participant typeCode='REF'> .. </participant>
  <!-- zero or more distinct specimen collector, and the date-time the specimen was collected -->
  <participant typeCode='DIST'> .. </participant>[2]
```

[2] Specimen related information is normally precisely provided at the entry level. At the header level, this information will only appear in the rare cases where a specimen collector is distinct from the ordering physician or


```
<!-- The order ID -->
<inFulfillmentOf> .. </inFulfillmentOf>

<!-- The service documented and the primary laboratory having performed it -->
<documentationOf> .. </documentationOf>

<!-- zero or one encompassing encounter -->
<component><encompassingEncounter> .. </encompassingEncounter></component>

<!-- The body of the report -->
<component>
    <structuredBody>
     <component>
        <section>
           <templateId root='1.3.6.1.4.1.19376.1.8.1.2.1'/>
           <code code='22636-5' displayName=’Pathology report relevant history'
                    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
           <title>CLINICAL INFORMATION SECTION</title>
           <text>
              Tissue submitted: left breast biopsy and apical axillary tissue
           </text>

           <component>
             <section>
                <templateId root= '1.3.6.1.4.1.19376.1.5.3.1.3.1'/>
                <code code='42349-1' displayName= ‘Reason for referral’
                      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
                <title>Reason for anatomic pathology procedure</title>
                <text>Breast mass - left breast</text>
             </section>
           </component>
           <component>
             <section>
               <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.4'/>
               <code code=’10164-2’ displayName= ‘History of present illness’
                     codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
               <title> History of present illness </title>
               <text>Carcinoma of breast. Post operative diagnosis: same.
                     left UOQ breast mass.
              </text>
             </section>
           </component>
         </section>
       </component>

       <component>
        <section>
          <templateId root='1.3.6.1.4.1.19376.1.8.1.2.3'/>
          <code code='22634-0' displayName='Pathology report gross observation'
                codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <title>MACROSCOPIC OBSERVATION SECTION</title>
          <text>    </text>
          <entry>   <entry/>
          :
        </section>
      </component>

      <component>
        <section>
          <templateId root='1.3.6.1.4.1.19376.1.8.1.2.4'/>
          <code code='22635-7' displayName='Pathology report microscopic observation'
```

surgeon. In that case the period of time of specimen collection is represented by the “time” sub-element of participant[@typeCode=’DIST’]


```
                codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <title>MICROSCOPIC OBSERVATION SECTION</title>
            <text>    </text>
            <entry>   <entry/>
            :
          </section>

        </component>
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.8.1.2.5'/>
            <code code='22637-3' displayName='Pathology report diagnosis'
                  codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <title>DIAGNOSIS SECTION</title>
            <text>    </text>
            <entry>   <entry/>
            :
          </section>
        </component>

        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.8.1.2.6'/>
            <code code='46059-2' displayName=' Special treatments and procedures section'
                  codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <title>PROCEDURE STEPS SECTION</title>
            <text>    </text>
            <entry>   <entry/>
            :
          </section>
        </component>

      </structuredBody>
  </component>

</ClinicalDocument>
```

6.2.3.1.3 Specification

Table 6.2.3.1.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, the value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate.

The nested content modules are the elements having a child templateId in the “Path and Constraints (Xpath + indentation)” column, the column “Vocab. / Source” locating in this case the specification of the nested content module.

The notes below the table provide additional explanations and constraints. They are indexed by column “N.”

Table 6.2.3.1.3-1 APSR Content Module: Structure and Value Sets

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
CDA header	R	[1..1]	ClinicalDocument[@xmlns="urn:hl7-org:v3"]				
CDA conformance	R	[1..1]	typeId[@extension="POCD_HD000040" and @root="2.16.840.1.113883.1.3"]				

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Content Module conformance	R	[1..*]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.1.1"]			II	
Report revision ID	R	[1..1]	id[@root]		(1)	II	
Document type	R	[1..1]	code[@code="11526-1" and @codeSystem="'2.16.840.1.113883.6.1" and @displayName="Pathology Study" and @codeSystemName="LOINC"]	LOINC		CE	
Report title	R	[1..1]	title			ST	
Time of the report	R	[1..1]	effectiveTime@value		(2)	ts	ORC-9
Confidentiality level	R	[1..1]	confidentialityCode[@code and @codeSystem="2.16.840.1.113883.5.25"]	x_BasicConfidentialityKind		CE	
Principal language	R	[1..1]	languageCode[@code]	RFC 1766		CS	MSH-19
Report set ID	R	[1..1]	setId[@root]		(1)	II	
Report version#	O	[0..1]	versionNumber[@value]		(1)	int	
Patient	R	[1..1]	recordTarget/patientRole		(3)		
Patient identifier	R	[1..*]	id			II	PID-3
Patient address	R	[1..*]	address			AD	PID-11
Patient telecom	R	[1..*]	telecom			TEL	PID-13
Patient identity	R	[1..1]	patient				
Patient full name	R	[1..1]	name			PN	PID-5
Patient sex	R	[1..1]	administrativeGenderCode[@code]	AdministrativeGender		CE	PID-8
Patient birth time	R	[1..1]	birthTime@value			ts	PID-7
Author	R	[1..*]	author /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.2"]	PAT TF-3: 6.2.6.2	(8)		
Transcriptionist	O	[0..*]	dataEnterer/assignedEntity				OBR-35
Informant	O	[0..*]	informant / templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.6"]	PAT TF-3: 6.2.6.6	(5)		
Custodian organization	R	[1..1]	custodian/assignedCustodian/ representedCustodianOrganization				
id	R	[1..*]	id			II	
name	R	[1..1]	name			ON	
telecom	R	[1..1]	telecom			TEL	
address	R	[1..1]	address			AD	
Intended recipient	O	[0..*]	informationRecipient /templateId[@root="1.3.6.1.4.1.19376.1.3.3.1.4"]	LAB TF-3: 2.3.3.16	(9)		OBR-28
Legal authenticator	R	[1..1]	legalAuthenticator				OBR-32
D/T endorsement	R	[1..1]	time@value			ts	
Signature status	R	[1..1]	signatureCode@code	ParticipationSignature		CS	
Person	R	[1..1]	assignedEntity				
identifier	R	[1..*]	id			II	
address	R	[1..*]	addr			AD	
telecom	R	[1..*]	telecom			TEL	
Full name	R	[1..*]	assignedPerson/name			PN	
Content validator	O	[0..*]	authenticator /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.3"]	PAT TF-3: 6.2.6.3	10		OBR-33
Ordering physician	R2	[0..1]	participant[@typeCode="REF"] /templateId[@root="1.3.6.1.4.1.19376.1.3.3.1.6"]	LAB TF-3: 2.3.3.19	(6)		ORC-12, OBR-16, ORC-9
Specimen collector	R2	[0..*]	participant[@typeCode="DIST"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.1"]	PAT TF-3: 6.2.6.1	(7)		OBR-10, SPM-17
Order	R2	[0..1]	inFullfillmentOf/order				

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Order id	R	[1..*]	id[@root]			II	OBR-2, ORC-2
Documented act	R	[1..1]	documentationOf/serviceEvent				
Act id	R	[1..*]	id[@root]			II	OBR-3, ORC-3
Act code	O	[0..1]	code			CE	OBR-4
Status of the act	R2	[0..1]	lab:statusCode	LAB TF-3: 2.3.6.3	(4)	CS	OBR-25
Time performed (interval or point)	R2	[0..1]	effectiveTime			IVL_TS	
Performing lab	O	[0..1]	performer[@typeCode="PRF"] /templateId[@root="1.3.6.1.4.1.19376.1.3.3.1.7"]	LAB TF-3: 2.3.3.22	11		OBX-23, OBX-24, OBX-25
Previous release of the report replaced	R2	[0..1]	relatedDocument[@typeCode="RPLC"]		(1)		
Previous rel. id	R	[1..1]	parentDocument/id[@root]		(1)	II	N/A
Previous version#	O	[0..1]	parentDocument/versionNumber[value]		(1)	int	N/A
Patient encounter	R2	[0..1]	componentOf/encompassingEncounter				
Encounter id	R2	[0..1]	id[@root]			II	PID-18 or PV1-19
Encounter period	R	[1..1]	effectiveTime			IVL_TS	
Start	R2	[0..1]	low@value			ts	PV1-44
End	R2	[0..1]	high@value			ts	PV1-45
Report body	R	[1..1]	component/structuredBody				
Clinical information section	R2	[0..1]	component/section [/templateId/@root="1.3.6.1.4.1.19376.1.8.1.2.1"]	PAT TF-3: 6.2.4.1	12		OBR-13
Intraoperative Observation section	R2	[0..1]	component/section [/templateId/@root="1.3.6.1.4.1.19376.1.8.1.2.2"]	PAT TF-3: 6.2.4.2	13		
Macroscopic Observation section	R2	[0..1]	component/section [/templateId/@root="1.3.6.1.4.1.19376.1.8.1.2.3"]	PAT TF-3: 6.2.4.3	14		
Microscopic Observation section	R2	[0..1]	component/section [/templateId/@root="1.3.6.1.4.1.19376.1.8.1.2.4"]	PAT TF-3: 6.2.4.4	15		
Diagnosis section	R	[1..1]	component/section [/templateId/@root="1.3.6.1.4.1.19376.1.8.1.2.5"]	PAT TF-3: 6.2.4.5	16		
Procedure steps section	O	[0..1]	component/section [/templateId/@root="1.3.6.1.4.1.19376.1.8.1.2.6"]	PAT TF-3: 6.2.4.6	17		

Notes:

(1) A report may have several successive revisions over time, in case corrections or complements are provided by the custodian after the initial release of the report.

The unique id of the current revision of the report is carried by the *id* element, and is composed of *id@root*, which SHALL be an OID, and optionally *id@extension*, which can be any string so that the concatenation of the two attributes *root* and *extension* provide a globally unique id, which identifies this release of the report.

The *setId* element provides a globally unique identifier that is common across all successive revisions of the report. This identifier is similarly composed of *setId@root*, which SHALL be an OID, and optionally *setId@extension.*

The version number of the current revision of the report is a positive integer (1, 2 …) provided in the *versionNumber* element.

When the current revision of the report is not the first one, this new revision SHALL replace the previous one, which SHALL be deprecated. Hence the *relatedDocument@typeCode* attribute SHALL be valued “RPLC”, and the *relatedDocument/parentDocument/id* SHALL provide the identifier of the previous revision that is to be deprecated.

Optionally the *relatedDocument/parentDocument/versionNumber* MAY provide the version number of the previous revision.

(2) This is the date and time when the current version of the report was released.

(3) The anatomic pathology report is related to one single patient. A patient SHALL be identified with at least one unique id. The patient address and telecom SHALL be provided (or null flavored). The patient identity SHALL provide at least the patient full name, sex and date/time of birth.

(4) The *lab:statusCode* below *documentationOf/serviceEvent* is an extension to the CDA R2 standard, added by LAB TF-3 to distinguish a preliminary report (*lab:statusCode@code="active"*) from a final report (*lab:statusCode@code="completed"*). This extension to the standard is protected by a dedicated namespace associated in the ClinicalDocument element to the prefix lab:

<Clinical Document xmlns:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2" … >

(5) Zero or more informant may be mentioned in the header of the report. An informant is either an *assignedEntity* (a professional participating to the healthcare process, and who was assigned a defined role in that process) or a *relatedEntity* (a person who knows the patient and has provided relevant information concerning the patient). Hence the condition is either *assignedEntity* is present or *relatedEntity* is present. These two elements are defined in the content module "Informant" in PAT TF-3: 6.2.6.6.

(6) The Ordering Provider Content Module represents the physician who has submitted the specimen examination order to the anatomic pathology laboratory. As specified in LAB TF-3, this physician is represented in the CDA header as a *participant* element with the *typeCode* attribute valued "REF". The sub-element *participant/time* carries the date/time of issuance of the order.

(7) The Specimen Collector Content Module is only used in case a specimen provided as input to the AP act documented in this report, was collected by a different party than the ordering physician. In that case, this specimen collector is represented in the CDA header as a *participant* element with the *typeCode* attribute valued "DIST" and the sub-element *participant/time* carries the time period of the specimen collection.

(8) The Author Content Module represents an author of the report. This element is repeatable. The sub-element *author/time* carries the date/time of the authoring action.

(9) The Intended Recipient Content Module represents a healthcare provider, other than the ordering physician, expecting to receive a copy of the report. This repeatable element *informationRecipient* of the CDA header is used to list the intended recipients who were known at the time the report was created and issued.

(10) The Content Validator Content Module represents a pathologist having verified and interpreted the report, and having contributed to its conclusion. This pathologist is represented in the CDA header as an *authenticator* element. The sub-element *authenticator/time* carries the date/time of the validation/verification. More than one pathologist may verify the content of the report.

(11) The AP report is documenting a service (*documentationOf/serviceEvent*) performed by a pathology laboratory. The Laboratory Performer Content Module represents this laboratory, and is fully described in the sub-element *documentationOf/serviceEvent/performer*. In case more than one laboratory contributed to a service, only the primary laboratory is in the CDA header, attached to the *serviceEvent* element, and the other (secondary) laboratories are described only in the sections of the report that they contributed to, in the body of the report.

(12) The Clinical Information section contains the information provided by the ordering physician: Clinical history, preoperative diagnosis, postoperative diagnosis, clinical laboratory data, specimen(s) description, collection procedure, reason for anatomic pathology procedure

(13) The Intraoperative Observation section contains an intraoperative diagnosis for each specimen examined, the specimen identification and description, intraoperative observation procedure description (frozen section, gross examination, intraoperative cytology) and derived specimen dissected for other ancillary procedures (flow cytometry, cytogenetics, molecular studies, and electron microscopy).

(14) The Macroscopic Observation section contains the description of the specimen received or obtained by the laboratory (specimen type and state), the gross observation, links to gross images, if taken, processing information and tissue disposition (representative sampling and tissue submitted for additional studies or sent to biorepository.

(15) The Microscopic Observation section contains optionally the histopathologic findings of the case and many laboratories use this section to record the results of histochemical and immunohistochemical stains.

(16) The Diagnosis section contains diagnoses on all specimens that are delivered to the pathology department from one operation or patient visit to a single clinician on a particular day. The diagnoses for each specimen (or group of specimens) are reported separately. This section includes additional pathologic finding(s) and the results of ancillary studi(es) and may include diagrams and/or still images or virtual slides, if taken. The Diagnosis section collects the minimal set of relevant information to establish the diagnostic. This may involve clinical information, macroscopy, microscopy and intraoperative observations.

(17) The Procedure steps section contains the description of tissue dissection: representative specimens and derived specimens dissected for other ancillary procedures (flow cytometry, cytogenetics, molecular studies, electron microscopy, etc.) or biorepository.

6.2.3.2 Organ-Specific APSR Content Modules

6.2.3.2.1 Definition and purpose

APSR Content Modules are specialized per organ.

An organ-specific APSR is identified by the templateId of the organ APSR Content Module it conforms to. The parent template is 1.3.6.1.4.1.19376.1.8.1.1.1 (generic APSR Content Module)

6.2.3.2.2 Example

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <!-- conformance to a generic APSR content module -->
  <templateId root='1.3.6.1.4.1.19376.1.8.1.1.1'/>
  <!-- conformance to a breast content module -->
  <templateId root='1.3.6.1.4.1.19376.1.8.1.1.2.1'/>

  <!-- remainder of the header not shown, similar to the header content of a generic APSR -->

  <component>
     <structuredBody>
        <!—Same hierarchy of sections and entries as in generic APSR -->
     </structuredBody>
  </component>
</ClinicalDocument>
```

6.2.3.2.3 Specification

The organ-specific Document Content Modules are listed in table 5.6-1 in section 5.6 (PAT TF-3:5.6-1).

The organ-specific Document Content Modules respect the hierarchy of <section> and <entry> elements shown on Figure 6.2.3.1.1-1 of IHE TF-3:6.2.3.1.1 as well as the constraints of their parent template described in Table 6.2.3.1.3-2 of IHE TF-3: 6.2.3.1.3.

Each organ-specific Document Content Module consists in a set of vocabulary constraints applied to the Content Modules “AP Observation” and “Specimen Collection Procedure” nested within any of the <entry> Content Modules used by this Document Content Module.

6.2.4 CDA R2 <section> Content Modules

6.2.4.1 Clinical Information <section> - 1.3.6.1.4.1.19376.1.8.1.2.1

6.2.4.1.1 Definition and Purpose

The Clinical Information section contains the information provided by the ordering physician: Clinical history, preoperative diagnosis, postoperative diagnosis, reason for anatomic pathology procedure, clinical laboratory data, specimen collection procedure including target site, performer, specimen type, specimen(s) clinical description, and tumor site in case of a cancer.

6.2.4.1.2 Example

```
          <section>
             <templateId root='1.3.6.1.4.1.19376.1.8.1.2.1'/>
             <code code='22636-5' displayName=’Pathology report relevant history'
                       codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
             <title>CLINICAL INFORMATION SECTION</title>
             <text>
                Tissue submitted: left breast biopsy and apical axillary tissue
             </text>

             <entry typeCode="COMP">
               <templateId root="1.3.6.1.4.1.19376.1.8.1.3.1"/>
               <!-- Specimen Information Organizer -->
               <organizer classCode="CLUSTER" moodCode="EVN">
                      <templateId root="1.3.6.1.4.1.19376.1.8.1.4.4"/>
                      <statusCode code="completed"/>
                      <!-- Specimen collection procedure -->
                      <component>
                             <procedure classCode="PROC" moodCode="EVN">
                                    <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>
                                    <code code="310638008"
codeSystem="2.16.840.1.113883.6.96"
displayName="Wire guided excision of breast lump under radiological control (procedure"
codeSystemName="SNOMED-CT"/>
                                    <effectiveTime>
                                           <low value="201012150905"/>
                                           <high value="201012150935"/>
                                    </effectiveTime>
                                    <targetSiteCode code="76752008"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT" displayName="Breast structure">
                                       <qualifier>
                                           <name code="272741003" displayName="laterality"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"/>
                                           <value code="7771000" displayName="left"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"/>
                                       </qualifier>
                                    </targetSiteCode>
                                    <!-- Specimen collector: the surgeon in this case -->
                                    <performer>
                                           <assignedEntity>
                                                  <id />
                                                  <addr nullFlavor="NASK"/>
                                                  <telecom value="tel:0147150000" use="EC"/>
                                                  <assignedPerson>
                                                     <name>
                                                          <prefix>Doctor</prefix>
                                                          <given>Eva</given>
```



```
                                                        <family>Surgeon</family>
                                                    </name>
                                                </assignedPerson>
                                                <representedOrganization>
                                                        <name>Hospital Lullaby</name>
                                                </representedOrganization>
                                        </assignedEntity>
                                </performer>
                                <!-- the specimen collected -->
                                <participant typeCode="PRD">
                                        <participantRole classCode="SPEC">
                                                <!-- specimen ids -->
                                                <id root="1.3.6.1.4.1.19376.1.8.9.7"
extension="0102030405"/>
                                                <playingEntity>
                                                        <!-- Specimen type -->
                                                        <code code="309546004"
codeSystem="2.16.840.1.113883.6.96" displayName="Lumpectomy breast sample (specimen)"/>
                                                </playingEntity>
                                        </participantRole>
                                </participant>
                        </procedure>
                </component>
                <!-- Problem organizer -->

                <component>
                        <organizer classCode="BATTERY" moodCode="EVN">
                                <templateId root="1.3.6.1.4.1.19376.1.8.1.4.8"/>
                                <statusCode code="completed"/>
                                <component>
                                        <observation classCode="OBS" moodCode="EVN">
                                            <code code="7" codeSystemName="PATHLEX"
codeSystem="1.3.6.1.4.1.19376.1.8.2.1" displayName="tumor location in the organ"/>
                                                <statusCode code="completed"/>
                                                <value xsi:type="CD" code="76365002"
codeSystem="2.16.840.1.113883.6.96"
displayName="Structure of upper outer quadrant of breast (body structure)"/>
                                        </observation>
                                </component>
                        </organizer>
                </component>
              </organizer>
             </entry>

            <!-- Sub-sections -->
             <component>
               <section>
                  <templateId root= '1.3.6.1.4.1.19376.1.5.3.1.3.1'/>
                  <code code='42349-1' displayName= 'Reason for referral'
                        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
                  <title>Reason for anatomic pathology procedure</title>
                  <text>Breast mass - left breast</text>
               </section>
             </component>
             <component>
               <section>
                  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.4'/>
                  <code code='10164-2' displayName= 'History of present illness'
                        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
                  <title> History of present illness </title>
                  <text>Carcinoma of breast. Post operative diagnosis: same.
                        left UOQ breast mass.
                   </text>
               </section>
             </component>
             </component>
             :
```



```
        </component>
      </section>
    </component>
```

6.2.4.1.3 Specification

This section SHALL contain a *code* element populated with these attributes:

@code="22636-5"
@codeSystem="'2.16.840.1.113883.6.1"
@displayName=" Pathology report relevant history"

This section SHALL contain a narrative block, represented by a *text* element, which renders the information to the human reader.

The section SHOULD contain as many Specimen Clinical Information *entry* elements as there are specimens (or groups of specimens) to be described. These entries provide the machine-readable data corresponding to the narrative block.

This section MAY contain a number of elements *component/section* introducing sub-sections among the list described below in table 6.2.4.1.3-1, each of these sub-sections providing a particular type of clinical information.

This section SHOULD contain *author* elements in case the authors of this section differ from those declared at a higher level in the document.

Table 6.2.4.1.3-1 lists the Content Modules, which are nested at the first level in the current one, with their type, usage, cardinalities, and source. The last column provides the LOINC code and displayName for the sections.

Table 6.2.4.1.3-1 Content Modules Nested in Clinical Information <section>

Name	Type	Opt.	Car.	Template ID	Source	LOINC section code
Reason for referral (Reason for AP procedure)	Section	R2	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.3.1	PCC TF-2: 6.3.3.1.1	42349-1 "Reason for referral"
History of present illness	Section	R2	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.3.4	PCC TF-2: 6.3.3.2.1	10164-2 "History of present illness"
Active Problems	Section	R2	[0..1]	1.3.6.1.4.1.19376.1.5.3.1.3.6	PCC TF-2: 6.3.3.2.3	11450-4 "Problem List"
Specimen Clinical Information Entry	Entry	R2	[0..*]	1.3.6.1.4.1.19376.1.8.1.3.1	PAT TF-3: 6.2.5.2	
Author of the section	Child	C	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.2	PAT TF-3:6.2.6.2	

6.2.4.2 Intraoperative Observation <section> - 1.3.6.1.4.1.19376.1.8.1.2.2

6.2.4.2.1 Definition and Purpose

The Intraoperative Observation section contains an intraoperative diagnosis for each specimen examined, the specimen identification and description, intraoperative observation procedure description (frozen section, gross examination, intraoperative cytology) and derived specimen dissected for other ancillary procedures (flow cytometry, cytogenetics, molecular studies, and electron microscopy).

6.2.4.2.2 Example

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.8.1.2.2'/>
    <code code='TBD' displayName='intraoperative section in anatomic pathology report'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>INTRAOPERATIVE OBSERVATION</title>
    <text>
        Frozen section diagnosis of infiltrating duct carcinoma, left breast
    </text>
    <entry>
      <--! Detail not shown -->
    </entry>
  </section>
</component>
```

6.2.4.2.3 Specification

This section SHALL contain a *code* element populated with these attributes:

@code="TBD request to Regenstrief Institute for creation of this code"
@codeSystem="2.16.840.1.113883.6.1"
@displayName="intraoperative section in anatomic pathology report"

This section SHALL contain a narrative block, represented by a *text* element, which renders the information to the human reader.

The section SHOULD contain as many Specimen Intraoperative Observation *entry* elements as there are specimens or groups of specimens observed. These entries provide the machine-readable data corresponding to the narrative block.

This section does not contain any subsection.

This section SHOULD contain *author* elements in case the authors of this section differ from those declared at a higher level in the document.

Table 6.2.4.2.3-1 lists the Content Modules, which are nested at the first level in the current one, with their type, usage, cardinalities, and source.

Table 6.2.4.2.3-1 Content Modules Nested in Intraoperative Observation <section>

Name	Type	Opt.	Car.	Template ID	Source
Specimen Intraoperative Observation Entry	Entry	R2	[0..*]	1.3.6.1.4.1.19376.1.8.1.3.2	PAT TF-3: 6.2.5.3
Author of the section	Child	C	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.2	PAT TF-3:6.2.6.2

6.2.4.3 Macroscopic Observation <section> - 1.3.6.1.4.1.19376.1.8.1.2.3

6.2.4.3.1 Definition and Purpose

The Macroscopic Observation section contains the description of the specimen(s) received or obtained by the laboratory (specimen type and state), the gross observation, links to gross images, if taken, processing information and tissue disposition (representative sampling and tissue submitted for additional studies or sent to biorepository.

6.2.4.3.2 Example

```
<component>
 <section>
   <templateId root='1.3.6.1.4.1.19376.1.8.1.2.3'/>
   <code code='22634-0' displayName='Pathology report gross observation'
         codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
   <title>MACROSCOPIC OBSERVATION SECTION</title>
   <text>
     Part #1 is labeled “left breast biopsy” and is received fresh after frozen section
     preparation. It consists of a single firm nodule measuring 3cm in circular diameter
     and 1.5cm in thickness surrounded by adherent fibrofatty tissue. On section a pale
     gray, slightly mottled appearance is revealed. Numerous sections are submitted for
     permanent processing. Part #2 is labeled "apical left axillary tissue" and is
     received fresh. It consists of two amorphous fibrofatty tissue masses without
     grossly discernible lymph nodes therein. Both pieces are rendered into numerous
     sections and submitted in their entirety for history.
   </text>
   <entry> <--! Content not shown -->  </entry>
 </section>
</component>
```

6.2.4.3.3 Specification

This section SHALL contain a *code* element populated with these attributes:

@code="22634-0"
@codeSystem="2.16.840.1.113883.6.1"
@displayName="Pathology report gross observation"

This section does not contain any subsection. The section SHALL contain a narrative block, represented by a *text* element, which renders the information to the human reader.

The section SHOULD contain as many Specimen Macroscopic Observation *entry* elements as there are specimens or groups of specimens to be described. These entries provide the machine-readable data corresponding to the narrative block.

This section SHOULD contain *author* elements in case the authors of this section differ from those declared at a higher level in the document.

Table 6.2.4.3.3-1 Content Modules Nested in Macroscopic Observation <section>

Name	Type	Opt.	Car.	Template ID	Source
Specimen Macroscopic Observation Entry	Entry	R2	[0..*]	1.3.6.1.4.1.19376.1.8.1.3.3	PAT TF-3: 6.2.5.4
Author of the section	Child	C	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.2	PAT TF-3:6.2.6.2

6.2.4.4 Microscopic Observation <section> - 1.3.6.1.4.1.19376.1.8.1.2.4

6.2.4.4.1 Definition and Purpose

The Microscopic Observation section contains optionally the histopathologic findings of the case and many laboratories use this section to record the results of histochemical and immunohistochemical stains.

6.2.4.4.2 Example

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.8.1.2.4'/>
    <code code='22635-7' displayName='Pathology report microscopic observation'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>MICROSCOPIC OBSERVATION SECTION</title>
    <text>
      Sections of part #1 confirm frozen section diagnosis of infiltrating duct
      carcinoma. It is to be noted that the tumor cells show considerable pleomorphism,
      and mitotic figures are frequent (as many as 4 per high power field). Total size of
      primary tumor is estimated to be 3cm in greatest dimension. Many foci of
      calcification are present within the tumor. Part #2 consists of fibrofatty tissue
      and includes 18 lymph nodes. All lymph nodes are free of disease with the exception
      of one lymph node, which contains several micrometastases.
    </text>
    <entry> <--! Content not shown -->  </entry>
  </section>
</component>
```

6.2.4.4.3 Specification

This section SHALL contain a *code* element populated with these attributes:

@code="22635-7"
@codeSystem="2.16.840.1.113883.6.1"
@displayName="Pathology report microscopic observation"

This section SHALL contain a narrative block, represented by a *text* element, which renders the information to the human reader.

The section SHOULD contain as many Specimen Microscopic Observation *entry* elements as there are specimens investigated, or groups of specimens investigated together. These entries provide the machine-readable data corresponding to the narrative block.

This section SHOULD contain *author* elements in case the authors of this section differ from those declared at a higher level in the document.

This section does not contain any subsections.

Table 6.2.4.4.3-1 Content Modules Nested in Microscopic Observation <section>

Name	Type	Opt.	Car.	Template ID	Source
Specimen Microscopic Observation Entry	Entry	R2	[0..*]	1.3.6.1.4.1.19376.1.8.1.3.4	PAT TF-3: 6.2.5.5
Author of the section	Child	C	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.2	PAT TF-3:6.2.6.2

6.2.4.5 Diagnosis <section> - 1.3.6.1.4.1.19376.1.8.1.2.5

6.2.4.5.1 Definition and Purpose

The Diagnosis section contains diagnoses on all specimens that are delivered to the pathology department from one operation or patient visit to a single clinician on a particular day. The diagnoses for each specimen or group of specimens are reported separately. This section includes additional pathologic finding(s) and the results of ancillary study(ies) and may include diagrams and still images or virtual slides, if taken. In case of cancer, this section includes the cancer checklist.

6.2.4.5.2 Example

```
        <component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.8.1.2.5'/>
            <code code='22637-3' displayName='Pathology report diagnosis'
                  codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <title>DIAGNOSIS SECTION</title>
            <text>
               1.Single intact complete excision of invasive ductal carcinoma. Upper outer
               quadrant, left breast. Nottingham Histologic Grade = 2 (Glandular differenciation:
               Score 2, Nuclear pleomorphism: score 3, Mitotic count: score 2). Margin uninvolved
               by invasive ductal carcinoma. No DCIS. pT2.pN1a.cM0.
               2. Micrometastases, left axillary lymph node. Free of disease 17 of 18 lymph nodes
            </text>
            <entry>    <--! Content not shown -->   </entry>
          </section>
        </component>
```


6.2.4.5.3 Specification

This section SHALL contain a *code* element populated with these attributes:

@code="22637-3"
@codeSystem="2.16.840.1.113883.6.1"
@displayName="Pathology report diagnosis"

This section SHALL contain a narrative block, represented by a *text* element, which renders the information to the human reader.

The section SHALL contain as many Specimen Diagnosis *entry* elements as there are specimens or groups thereof investigated. Each *entry* provides machine-readable data.

This section SHOULD contain *author* elements in case the authors of this section differ from those declared at a higher level in the document.

This section MAY contain the “Report Textual Summary” subsection.

Table 6.2.4.5.3-1 Content Modules Nested in Diagnosis <section>

Name	Type	Opt.	Car.	Template ID	Source
Specimen Diagnosis Entry	Entry	R	[1..*]	1.3.6.1.4.1.19376.1.8.1.3.5	PAT TF-3: 6.2.5.6
Report Textual Summary Section	Section	O	[0..1]	1.3.6.1.4.1.19376.1.8.1.2.7	PAT TF-3: 6.2.4.7
Author of the section	Child	C	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.2	PAT TF-3:6.2.6.2

6.2.4.6 Procedure steps <section> - 1.3.6.1.4.1.19376.1.8.1.2.6

6.2.4.6.1 Definition and Purpose

The Procedure steps section contains the description of tissue dissection: representative specimens and derived specimens dissected for other ancillary procedures (flow cytometry, cytogenetics, molecular studies, electron microscopy, etc.) or biorepository.

6.2.4.6.2 Example

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.8.1.2.6'/>
    <code code='46059-2' displayName='Special treatments and procedures section'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>PROCEDURE STEPS</title>
    <text>
       Part #1 is labeled “left breast biopsy” and has been sampled for frozen section
       preparation. Numerous sections are submitted for permanent processing. Part #2
       received in two pieces is labeled "apical left axillary tissue". Both pieces are
       rendered into numerous sections and submitted in their entirety for history.
    </text>
    <entry>   <--! Content not shown --> </entry>
  </section>
</component>
```


6.2.4.6.3 Specification

This section SHALL contain a *code* element populated with these attributes:

@code="46059-2"
@codeSystem="2.16.840.1.113883.6.1"
@displayName="Special treatments and procedures section"

This section SHALL contain a narrative block, represented by a text element, which renders the information to the human reader.

This section SHOULD contain *author* elements in case the authors of this section differ from those declared at a higher level in the document.

This section does not contain any subsections or entries.

Table 6.2.4.6.3-1 Content Modules Nested in Diagnosis <section>

Name	Type	Opt.	Car.	Template ID	Source
Author of the section	Child	C	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.2	PAT TF-3:6.2.6.2

6.2.4.7 Report Textual Summary <section> - 1.3.6.1.4.1.19376.1.8.1.2.7

6.2.4.7.1 Definition and Purpose

The Report Textual Summary section is an optional sub-section of the Diagnosis section. This section contains a textual summary of the AP report, which can be extracted from the document and inserted into other clinical documents. It addresses the use case where authors of other medical documents feel the need to include a segment such as "...the pathology report states '[...]'", the text content of this section filling the brackets.

6.2.4.7.2 Example

```
<section>
    <templateId root='1.3.6.1.4.1.19376.1.8.1.2.5'/>
    <code code='22637-3' displayName='Pathology report diagnosis'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>DIAGNOSIS SECTION</title>
    <text>1. Single intact complete excision of invasive ductal carcinoma. Upper outer quadrant,
left breast. Nottingham Histologic Grade = 2 (Glandular differenciation: Score 2, Nuclear
pleomorphism: score 3, Mitotic count: score 2). Margin uninvolved by invasive ductal carcinoma.
No DCIS. pT2.pN1a.cM0.
2. Micrometastases, left axillary lymph node. Free of disease 17 of 18 lymph nodes</text>
    <entry> <!-- detail not shown --> </entry>
    <component>
       <section>
           <templateId root='1.3.6.1.4.1.19376.1.8.1.2.7'/>
           <code code='35660-0' displayName='Pathology report final diagnosis section - text'
                 codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
           <title>REPORT TEXTUAL SUMMARY</title>
           <text>Left breast invasive carcinoma</text>
       </section>
    <component>
```



```
</section>
```

6.2.4.7.3 Specification

This section SHALL contain a *code* element populated with these attributes:

@code="35660-0"
@codeSystem="2.16.840.1.113883.6.1"
@displayName="Pathology report final diagnosis section - text"

This section SHALL contain a narrative block, represented by a *text* element, which renders the information to the human reader.

This section SHOULD contain *author* elements in case the authors of this section differ from those declared at a higher level in the document.

The section SHALL not contain any *entry* element or any sub-section.

Table 6.2.4.7.3-1 Content Modules Nested in Diagnosis <section>

Name	Type	Opt.	Car.	Template ID	Source
Author of the section	Child	C	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.2	PAT TF-3:6.2.6.2

6.2.5 CDA R2 <entry> Content Modules

6.2.5.1 Common Specification for all APSR Entry Content Modules

The <entry> Content Modules available for all templates of APSR are:

- Specimen Clinical Information Entry
- Specimen Intraoperative Observation Entry
- Specimen Macroscopic Observation Entry
- Specimen Microscopic Observation Entry
- Specimen Diagnosis Entry

Each <entry> Content Module is bound to the corresponding <section> Content Module and carries machine-readable data related to one specimen or to one group of specimens observed for this section.

Each <entry> Content Module is repeatable below its section, so as to support the use cases where a section reports on more than one specimen or more than one group of specimens.

All APSR <entry> Content Modules have a common structure, as shown on Table 6.2.5.1-1:

Table 6.2.5.1-1 Common Structure of <entry> Content Modules

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT
Entry			entry		(1)	
Content Module conformance	R	[1..1]	templateId[@root]		(2)	II
Specimen Information Organizer	R	[1..1]	organizer[@classCode="CLUSTER" and @moodCode="EVN"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.4"]	PAT TF-3: 6.2.6.4		

Notes:

(1): The Specimen Diagnosis entry is required (usage R) and repeatable (cardinalities [1..*]). The other <entry> Content Modules listed above are "required if known" (usage R2) and repeatable (cardinalities [0..*]).

(2): The value of the root attribute is the templateId of the particular <entry> Content Module.

6.2.5.2 Specimen Clinical Information <entry> - 1.3.6.1.4.1.19376.1.8.1.3.1

6.2.5.2.1 Definition and Purpose

The Specimen Clinical Information <entry> Content Module contains in machine-readable format the clinical information provided by the ordering physician, regarding a single specimen or a group of specimens observed together. This Content Module is nested within a Clinical Information <section> Content Module.

6.2.5.2.2 Example

See complete example of CDA APSR in separate file.

6.2.5.2.3 Specification

This <entry>Content Module is required if known (R2) with cardinalities [0..*].

entry/templateId@root SHALL be present and valued "1.3.6.1.4.1.19376.1.8.1.3.1".

6.2.5.3 Specimen Intraoperative Observation <entry> - 1.3.6.1.4.1.19376.1.8.1.3.2

6.2.5.3.1 Definition and Purpose

The Specimen Intraoperative Observation <entry> Content Module contains in machine-readable format the information regarding a single specimen or group of specimens issued from an intraoperative anatomic pathology procedure. This Content Module is nested within an Intraoperative Observation <section> Content Module.

6.2.5.3.2 Example

See complete example of CDA APSR in separate file.

6.2.5.3.3 Specification

This <entry> Content Module is required if known (R2) with cardinalities [0..*].

entry/templateId@root SHALL be present and valued "1.3.6.1.4.1.19376.1.8.1.3.2".

6.2.5.4 Specimen Macroscopic Observation <entry> - 1.3.6.1.4.1.19376.1.8.1.3.3

6.2.5.4.1 Definition and Purpose

The Specimen Macroscopic Observation <entry> Content Module contains in machine-readable format the information regarding a single specimen or group of specimens. This Content Module is nested within a Macroscopic Observation <section> Content Module.

6.2.5.4.2 Example

See complete example of CDA APSR in separate file.

6.2.5.4.3 Specification

This <entry>Content Module is required if known (R2) with cardinalities [0..*].

entry/templateId@root SHALL be present and valued "1.3.6.1.4.1.19376.1.8.1.3.3".

6.2.5.5 Specimen Microscopic Observation <entry> - 1.3.6.1.4.1.19376.1.8.1.3.4

6.2.5.5.1 Definition and Purpose

The Specimen Microscopic Observation <entry>Content Module contains in machine-readable format the information regarding a single specimen or group of specimens. This Content Module is nested within a Microscopic Observation <section> Content Module.

6.2.5.5.2 Example

See complete example of CDA APSR in separate file.

6.2.5.5.3 Specification

This <entry>Content Module is required if known (R2) with cardinalities [0..*].

entry/templateId@root SHALL be present and valued "1.3.6.1.4.1.19376.1.8.1.3.4".

6.2.6.5 Specimen Diagnosis <entry> - 1.3.6.1.4.1.19376.1.8.1.3.5

6.2.5.6.1 Definition and Purpose

The Specimen Diagnosis <entry>Content Module contains in machine-readable format the information regarding a single specimen or group of specimens. It is nested within a Diagnosis <section> Content Module.

6.2.5.6.2 Example

```
<entry>
       <templateId root="1.3.6.1.4.1.19376.1.8.1.3.5"/>
       <!-- Specimen Information Organizer -->
       <organizer classCode="CLUSTER" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.8.1.4.4"/>
              <statusCode code="completed"/>
              <!-- Specimen collection procedure -->
              <component>
                     <procedure classCode="PROC" moodCode="EVN">
                            <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>
                            <code code="277261002" codeSystem="2.16.840.1.113883.6.96"
                                  displayName="Excision Biopsy"/>
                            <targetSiteCode code="76752008" codeSystem="2.16.840.1.113883.6.96"
```



```
                                        displayName="Breast"/>
                        <participant typeCode="PRD">
                                <participantRole classCode="SPEC">
                                        <playingEntity>
                                                <code code="309220004"
                                                      codeSystem="2.16.840.1.113883.6.96"
                                                      codeSystemName="SNOMED-CT"
                                                      displayName="Mastectomy sample"/>
                                        </playingEntity>
                                </participantRole>
                        </participant>
                </procedure>
        </component>
        <!-- Problem organizer -->
        <component>
                <organizer classCode="BATTERY" moodCode="EVN">
                        <templateId root="1.3.6.1.4.1.19376.1.8.1.4.8"/>
                        <statusCode code="completed"/>
                        <component>
                                <observation classCode="OBS" moodCode="EVN">
                                        <templateId root="1.3.6.1.4.1.19376.1.8.1.4.9"/>
                                        <code code="371441004"
                                              codeSystem="2.16.840.1.113883.6.96"
                                              codeSystemName="SNOMED-CT"
                                              displayName="Histologic type"/>
                                        <statusCode code="completed"/>
                                        <effectiveTime value="20100321063000.0000-0500"/>
                                        <value xsi:type="CD" code="408643008"
displayName="Infiltrating duct carcinoma of breast (disorder)"
codeSystem="2.16.840.1.113883.6.96"/>
                                </observation>
                        </component>
                </organizer>
        </component>
    </organizer>
</entry>
```

6.2.5.6.3 Specification

This <entry>Content Module is required (R) with cardinalities [1..*].

entry/templateId@root SHALL be present and valued "1.3.6.1.4.1.19376.1.8.1.3.5".

6.2.6 CDA R2 Child Element Content Modules

This section specifies the Content Modules designed for child elements. A child element is a child of the CDA header or a child of a <section>, or an element nested at various depths below an <entry>, or an element appearing at some combination of these locations.

6.2.6.1 Specimen Collector in Header – 1.3.6.1.4.1.19376.1.8.1.4.1

6.2.6.1.1 Definition and purpose

This Content Module is usable only in the CDA header.

This Content Module is used only in the situation where the specimen was not collected by the ordering physician. (See use cases in volume 1)

6.2.6.1.2 Example

```
<participant typeCode="DIST">
  <time><high>200911140805</high></time> <!-- date&time of specimen collection -->
  <associatedEntity classCode="CAREGIVER">
    <id root="1.3.6.1.4.1.19376.1.8.9.1" extension="801234567897"/>
    <addr nullFlavor=”NASK”/>
    <telecom nullFlavor=”NASK”/>
    <associatedPerson>
      <name>
        <given>Roberta</given>
        <family>Slicer</family>
      </name>
    </associatedPerson>
 </associatedEntity>
</participant>
```

6.2.6.1.3 Specification

This Content Module does not contain any other Content Module.

Table 6.2.6.1.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate. The notes below the table provide additional constraints.

Table 6.2.6.1.3-1 Structure of Specimen Collector Content Module

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Specimen Collector	O	[0..*]	ClinicalDocument/participant[@typeCode="DIST"]				OBR-10,
Conformance	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.1"]				
Specimen collection time	R	[1..1]	time		(1)	IVL_TS	SPM-17
Role	R	[0..1]	associatedEntity				
identifier	R	[1..*]	id			II	
address	R	[1..*]	addr			AD	

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
telecom	R	[1..*]	telecom			TEL	
Person	C	[0..*]	associatedPerson		(2)		
Full name	R	[1..*]	name			PN	
Organization	C	[0..1]	scopingOrganization		(2)		
identifier	R2	[0..*]	id			II	
name	R2	[0..*]	name			ON	
telecom	R2	[0..*]	telecom			TEL	
address	R2	[0..*]	addr			AD	

Notes:

(1) The specimen collection time is an interval, which may be reduced to a point in time (see usage of data type IVL_TS).

(2) At least one of the two elements *associatedPerson* and *scopingOrganization* must be present. Both may be present.

6.2.6.2 Author – 1.3.6.1.4.1.19376.1.8.1.4.2

6.2.6.2.1 Definition and purpose

This Content Module is usable in the CDA header, in a <section> and at various depths of an <entry>.

It describes an author having contributed to the document wholly or to a portion of it (e.g., a section, an observation, a group of observations).

A given document or any delimited portion of it may have more than one author.

An author MAY be a person or a device (manufactured device or software system). In both cases the scoping organization MAY be described.

6.2.6.2.2 Example

```
<author>
      <templateId root="1.3.6.1.4.1.19376.1.8.1.4.2"/>
      <time value="20090529094914.827+0100"/>
      <assignedAuthor>
         <id root="1.3.6.1.4.1.19376.1.8.9.1" extension="801234567897"/>
         <telecom value="tel:+33-602030499"/>
         <assignedPerson>
            <name>
               <given>Charles</given>
               <family>DOCTORANT</family>
            </name>
         </assignedPerson>
         <representedOrganization>
           <id root="1.3.6.1.4.1.19376.1.8.9.2" extension="1120456789"/>
           <name>cabinet du docteur D.</name>
           <telecom nullFlavor="MSK"/>
           <addr nullFlavor="MSK"/>
         </representedOrganization>
      </assignedAuthor>
</author>
```


6.2.6.2.3 Specification

This content module does not contain any other content module.

Table 6.2.6.2.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate. The notes below the table provide additional constraints.

Table 6.2.6.2.3-1 Structure of Author

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Author	O	[0..*]	author				OBR-35
Conformance	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.2"]				
Authoring time	R	[1..1]	time@value		(1)	ts	
Identification	C	[0..1]	assignedAuthor				
Identifier	R	[1..*]	id			II	
Address	R	[1..*]	addr			AD	
Telecom	R	[1..*]	telecom			TEL	
Person	C	[0..1]	assignedPerson		(2)		
Name	R	[1..*]	name			PN	
Authoring device	C	[0..1]	authoringDevice		(2)		
Type	R2	[0..1]	code			CE	
Model name	R2	[0..1]	manufacturerModelName			SC	
Software name	R2	[0..1]	softwareName			SC	
Organization	O	[0..1]	representedOrganization				
Identifier	R2	[0..*]	id			II	
Name	R	[1..1]	name			ON	
Telecom	O	[0..*]	telecom			TEL	
Address	O	[0..*]	addr			AD	

Notes:

(1) The authoring time is the date & time that this author contributed to the document. It SHALL be provided.

(2) The author is either an assigned person or an authoring device.

6.2.6.3 Content Validator – 1.3.6.1.4.1.19376.1.8.1.4.3

6.2.6.3.1 Definition and purpose

This Content Module is usable only in the CDA header.

It describes a pathologist having verified the content of the report, using the element *authenticator*. This element *authenticator* is used when the pathologist having verified the content of the report is distinct from the pathologist assuming the legal responsibility for this report, described in the *legalAuthenticator* element.

The report MAY have zero or more Content Validators.

6.2.6.3.2 Example

```
<authenticator>
      <templateId root="1.3.6.1.4.1.19376.1.8.1.4.3"/>
      <time value="20090529094914.827+0100"/>
      <assignedEntity>
         <id root="1.3.6.1.4.1.19376.1.8.9.1" extension="801234567897"/>
         <telecom value="tel:+33-602030499"/>
         <assignedPerson>
            <name>
               <given>Charlie</given>
               <family>DOCTORANT</family>
            </name>
         </assignedPerson>
         <representedOrganization>
           <id root="1.3.6.1.4.1.19376.1.8.9.2" extension="1120456789"/>
           <name>cabinet du docteur D.</name>
           <telecom nullFlavor="MSK"/>
           <addr nullFlavor="MSK"/>
         </representedOrganization>
      </assignedEntity>
</authenticator>
```

6.2.6.3.3 Specification

This content module does not contain any other content module.

Table 6.2.6.3.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate. The notes below the table provide additional constraints.

Table 6.2.6.3.3-1 Structure of Content Validator in the CDA Header

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Content validator	O	[0..*]	authenticator				
Conformance	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.3"]				
Time of validation	R	[1..1]	time@value			ts	
Identification	C	[0..1]	assignedEntity				
Identifier	R	[1..*]	id			II	
Address	R	[1..*]	addr			AD	
Telecom	R	[1..*]	telecom			TEL	
Person	R	[1..1]	assignedPerson				
Name	R	[1..*]	name			PN	
Organization	O	[0..1]	representedOrganization				
Identifier	R2	[0..*]	id			II	
Name	R	[1..1]	name			ON	
Telecom	O	[0..*]	telecom			TEL	
Address	O	[0..*]	addr			AD	

6.2.6.4 Specimen Information Organizer – 1.3.6.1.4.1.19376.1.8.1.4.4

6.2.6.4.1 Definition and purpose

This Content Module is usable only within an <entry> element.

The specimen information organizer is used by most entries of an APSR. It organizes information related to the various acts (procedures, observations) performed on a single specimen or group of specimens investigated together.

6.2.6.4.2 Example

```
<organizer classCode="CLUSTER" moodCode="EVN">
    <templateId root="1.3.6.1.4.1.19376.1.8.1.4.4"/>

    <!-- specimen collection procedure -->
    <component>
       <procedure classCode="PROC" moodCode="EVN">
          <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>   <!-- generic template -->
          <templateId root=" "/>       <!-- template of organ-specific procedure -->
          :                                          <!-- See detail in 6.2.4.5 -->
       </procedure>
    </component>

    <!-- as many batteries of observations as problems observed on this specimen -->
    <component>
     <organizer classCode="BATTERY">
       <templateId root="1.3.6.1.4.1.19376.1.8.1.4.8"/>
       <id>     </id> <!-- optional problem identifier -->
       <code>     </code> <!-- optional type of problem -->

       <!-- tumor site observation (this specimen, this problem) -->
       <component>
          <observation>

          </observation>
       </component>

       <!-- tumor focality observation (this specimen, this problem) -->
       <component>
          <observation>

          </observation>
       </component>

       <!-- ancillary tests observation (this specimen, this problem) -->
       <component>
          <observation>

          </observation>
       </component>
    </organize>
   </component>

</organizer>
```


6.2.6.4.3 Specification

Table 6.2.6.4.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate. The notes below the table provide additional constraints.

The nested content modules are the elements having a child templateId in the "Path and Constraints (Xpath + indentation)" column, the column "Vocab. / Source" locating in this case the specification of the nested content module.

The notes below the table provide additional explanations and constraints. They are indexed by column "N."

Table 6.2.6.4.3-1 Structure of Specimen Information Organizer in an Entry

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Specimen organizer			organizer[@classCode="CLUSTER" and @moodCode="EVN"]				
Conformance	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.4"]				
Status	R	[1..1]	statusCode[@code ="completed"]			CS	OBR-25
Organizer time (interval or point)	O	[0..1]	effectiveTime		(3)	IVL_TS	OBR-7, OBR-8
Performing lab	C	[0..1]	performer[@typeCode="PRF"] /templateId[@root="1.3.6.1.4.1.19376.1.3.3.1.7"]		(8)		
Laboratory Performer	R	[1..1]	templateId [@root="1.3.6.1.4.1.19376.1.3.3.1.7"]	LAB TF-3: 2.3.3.22			OBX-23, OBX-24, OBX-25
Author	C	[0..*]	author /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.2"]	PAT TF-3: 6.2.6.2	(4)		
Informant	O	[0..*]	informant /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.6"]	PAT TF-3: 6.2.6.6	(5)		
Transcriptionist	O	[0..*]	participant[@participationType="ENT"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.7"]	PAT TF-3: 6.2.6.7			OBR-35
Device	O	[0..*]	participant[@participationType="DEV"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				OBX-18
Responsible	O	[0..1]	participant[@participationType="RESP"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				OBX-25
Validator	O	[0..*]	participant[@participationType="AUTHEN"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				OBR-33
Specimen collection procedure	R	[1..*]	component/procedure[@classCode="PROC " and @moodCode="EVN"] /templateId[@root="1.3.6.1.4.1.19376.1.3.1.2"]	PAT TF-3: 6.2.6.5	(1)		
Problem organizer	R2	[0..*]	component/organizer[@classCode="BATTERY" and @moodCode="EVN"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.8"]	PAT TF-3: 6.2.6.8	(6)		
Embedded Image	O	[0..*]	component/observationMedia /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.10"]	PAT TF-3: 6.2.6.10	(7)		OBX
Region of interest	O	[0..*]	component/regionOfInterest [@classCode="ROIOVL" and moodCode="EVN"]		(7)		
	R	[1..*]	id				
Overlay shape	R	[1..1]	code				
Dimensions	R	[1..*]	value				

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
	R	[1..*]	entryRelationship[@typeCode="SUBJ"]				
Embedded image	R	[1..1]	observationMedia /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.10"]	PAT TF-3: 6.2.6.10			OBX
General comment on this specimen	O	[0..*]	component/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.2'] code[@code='48767-8' and @displayName='Annotation Comment' and @codeSystem=' 2.16.840.1.113883.6.1'] text/reference/@value statusCode[@code='completed']	PCC TF-2: 6.3.4.6	(2)		

Notes:

(1): The specimen collection procedure SHALL be present in all cases. It may be more or less complete depending on the information available to the Content Creator Actor. In cases where a group of specimens have been investigated together to produce the observations of this entry, the specimen collection procedure can be repeated to represent the characteristics of each specimen of the group.

(2): This general comment will appear at the higher level (the specimen level) in the human-readable narrative block of the current section.

(3): The period of time (possibly reduced to a point in time) during which the information was collected and assembled.

(4): The author SHALL be present if it is different from the main author of the report. For instance the author could be the ordering physician contributing to the Clinical Information section, inside a report authored by the pathologist.

(5): The informant is an actor (person and organization) who provided some of the clinical information carried by this organizer.

(6): Observations on this specimen (or group of specimen) are organized per problem. There SHALL be one problem organizer per problem observed.

(7): This organizer may carry an image of the specimen, either directly embedded or encapsulated within a region of interest.

(8): The performing laboratory is present at this level only if the examination of this particular specimen (or group thereof) was performed by a (subcontractor) laboratory distinct from the one issuing the consolidated report

6.2.6.5 Specimen Collection Procedure generic template – 1.3.6.1.4.1.19376.1.3.1.2

6.2.6.5.1 Definition and purpose

This Content Module is usable within an <entry> element.

This Content Module structures the machine-readable data representing the characteristics of the specimen (identifiers and type) and the procedure that collected it: Type of procedure, time interval, performer (person and organization), approach site, target site.

The "Specimen Collection Procedure" generic template is usable in all <entry> elements of all APSR Document Content Modules.

Each organ-specific APSR Document Content Module mandates an organ-specific template, child of the "Specimen Collection Procedure" generic template. This organ-specific child template has exactly the same structure as the generic one, and brings only a number of vocabulary constraints related to this specific organ:

- The value set bound to the *procedure/code* element, consisting in a list of triplets (code, codeSystem, displayName) representing the various specimen collection procedures that can be performed on this specific organ.
- The value set bound to the *procedure/targetSiteCode* element, consisting in a list of triplets (code, codeSystem, displayName) representing the various precise locations for collecting specimens from this specific organ.

Thus, a specimen collection procedure in an <entry> within an organ-specific APSR Document Content Module declares conformance to two templates: The "Specimen Collection Procedure" generic template and the "Specimen Collection Procedure" child template constraining the vocabularies for the contextual organ.

These specimen collection procedure child templates and their attached value sets are provided by the appendix "IHE_PAT_Suppl_APSR_AppendixValue_Sets.xlsx"

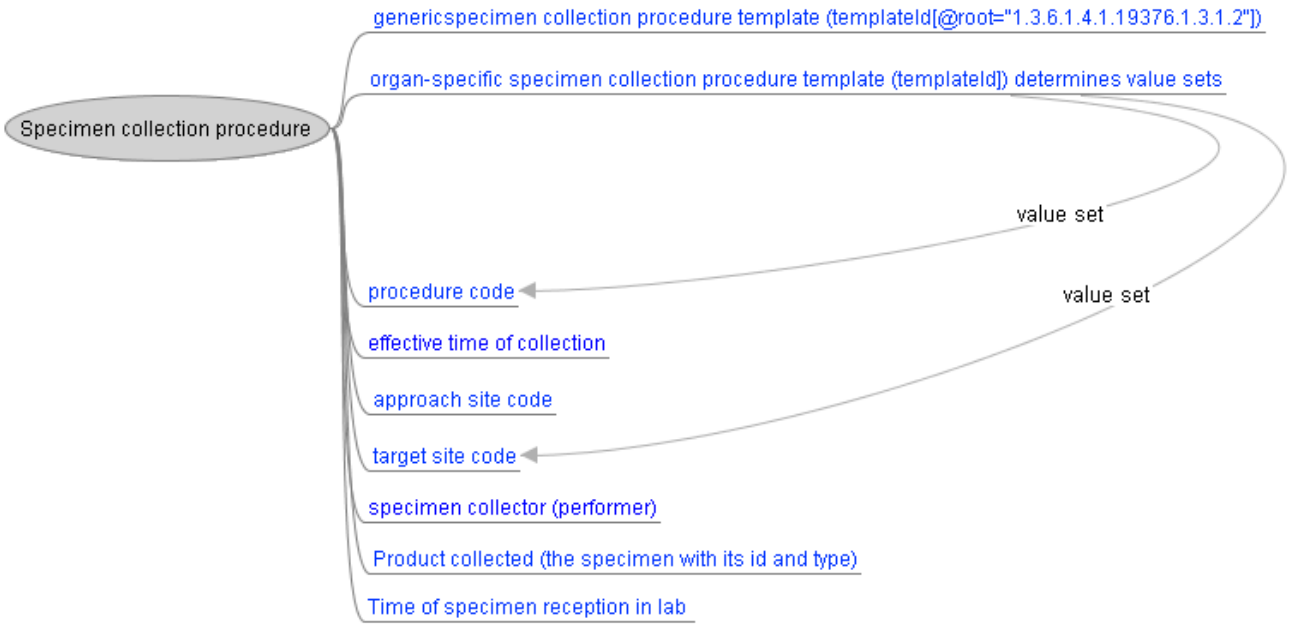


Figure 6.2.6.5.1-1 Conformance of a specimen collection procedure

6.2.6.5.2 Example

```
    <!-- Specimen collection procedure -->
    <procedure classCode="PROC" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.3.1.2"/>    <!-- generic template -->
      <templateId root="1.3.6.1.4.1.19376.1.8.1.4.28"/> <!-- breast template -->
      <!-- specimen collection act -->
      <code code="277261002" codeSystem="2.16.840.1.113883.6.96"
            displayName="Excision Biopsy"/>
      <effectiveTime>            <!-- Specimen collection date& time -->
        <low value="201012150905"/>
        <high value="201012150935"/>
      </effectiveTime>
      <!-- Specimen source -->
      <targetSiteCode code="76752008" codeSystem="2.16.840.1.113883.6.96"
                      displayName="Breast"/>

      <performer>                <!-- Specimen collector -->
        <assignedEntity>
          <id root=" "/>
          <!-- ID of Organization collecting specimen -->
            <representedOrganization>
              <name> </name>     <!-- Name of Organization collecting specimen -->
            </representedOrganization>
        </assignedEntity>
      </performer>

      <participant typeCode="PRD">      <!-- the specimen collected -->
```



```
        <participantRole classCode="SPEC">
          <!-- specimen ids -->
          <id root="d5a9ef50-d05e-11dd-ad8b-0800200c9a66"/>
          <playingEntity>
             <!-- Specimen type -->
             <code code="309220004" codeSystem="2.16.840.1.113883.6.96"
                   displayName="Mastectomy sample">
             </code>
          </playingEntity>
        </participantRole>
      </participant>

    </procedure>
</component>
```

6.2.6.5.3 Specification

The generic template is imported from « *Specimen collection* » template in IHE LAB TF-3:2.3.5.5.

This content module does not contain any other content module.

Table 6.2.6.5.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate. The notes below the table provide additional constraints.

Table 6.2.6.5.3-1 Structure of Specimen Collection Procedure

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Specimen collection			procedure[@classCode='PROC' and @moodCode='EVN']				
Conformance to generic template	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.3.1.2"]				
Conformance to organ-specific template	R	[1..1]	templateId[@root]	(V0)			
Collection procedure	O	[0..1]	code[@code and @displayName and @codeSystem]	(V1)		CD	SPM-7
Collection time (interval or point)	R2	[0..1]	effectiveTime			IVL_TS	SPM-17
Approach site	O	[0..1]	approachSiteCode[@code and @displayName and @codeSystem]			CD	SPM-10
Target site	R2	[0..1]	targetSiteCode[@code and @displayName and @codeSystem]	(V2)		CD	SPM-8 & SPM-9
Collector	R2	[0..1]	performer/assignedEntity				OBR-10
Identifier	R	[1..*]	id				OBR-10.1
Address	R2	[0..*]	addr			AD	missing
Telecom	R2	[0..*]	telecom			TEL	missing
Name	R2	[0..1]	assignedPerson/name				
Family name	R2	[0..1]	family				OBR-10.2
Given name	R2	[0..1]	given				OBR-10.3
Prefix	R2	[0..1]	prefix				OBR-10.5

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Suffix	R2	[0..1]	suffix				OBR-10.4
Organization	R	[1..1]	representedOrganization				
Id	R2	[0..*]	id			II	
Name	R	[1..1]	name			ON	
Type	O	[0..1]	standardIndustryClassCode	(V3)		CE	
Product	R	[1..1]	participant[@typeCode='PRD']				
Is a specimen	R	[1..1]	participantRole[@classCode='SPEC']				
Specimen id	R2	[0..*]	id			II	SPM-2
Characteristics	R	[1..1]	playingEntity				
Specimen type	R	[1..1]	code[@code and @displayName and @codeSystem]	(V4)		CE	SPM-4 & SPM-5
Specimen arrival in lab	R2	[0..1]	entryRelationship[@typeCode='COMP']				
Act of reception	R	[1..1]	act[@classCode='ACT' And @moodCode='EVN']				
Specimen received in lab	R	[1..1]	code[@code="SPRECEIVE" and @codeSystem="1.3.5.1.4.1.19376.1.5.3.2" and @codeSystemName="IHEActCode"]			CD	
Time of specimen reception	R	[1..1]	effectiveTime[@value]			ts	SPM-18

Vocabulary notes:

(V0) The specific template identifier of the organ-specific specimen collection procedure is provided in the value sets appendix (see Volume 4).

(V1) For a generic AP structured report (1.3.6.1.4.1.19376.1.8.1.1.1) the value set for specimen collection act is the *Procedure* axis of SNOMED CT.

For an organ-specific APSR the value set is mandated by the organ-specific specimen collection procedure template. These organ specific value sets are listed in Volume 4.

(V2) For a generic AP structured report (1.3.6.1.4.1.19376.1.8.1.1.1) the value set for target site of the specimen collection is the *Body Structure* axis of SNOMED CT.

For an organ-specific APSR the value set is mandated by the organ-specific specimen collection procedure template. These organ specific value sets are listed in Volume 4.

(V3) The value set for standardIndustryClassCode is constrained neither in the standard nor in this content module at the international level of IHE. It may be constrained by IHE national extensions, according to national classifications of organizations.

(V4) For a generic AP structured report (1.3.6.1.4.1.19376.1.8.1.1.1) or a generic AP structured cancer report (1.3.6.1.4.1.19376.1.8.1.1.2), the value set for specimen type is the Specimen axis of SNOMED CT.

6.2.6.6 Informant – 1.3.6.1.4.1.19376.1.8.1.4.6

6.2.6.6.1 Definition and purpose

This Content Module is usable in the CDA header, in a <section> and within an <entry>.

It describes a person having provided some piece of relevant information for the document.

A <ClinicalDocument> or a <section> or any kind of act below an <entry>, MAY have zero or more informant.

6.2.6.6.2 Example

```
<informant>
      <templateId root="1.3.6.1.4.1.19376.1.8.1.4.6"/>
      <assignedEntity>
         <id root="1.3.6.1.4.1.19376.1.8.9.1" extension="801234567897"/>
         <telecom value="tel:+33-602030499"/>
         <assignedPerson>
            <name>
               <given>Charles</given>
               <family>DOCTORANT</family>
            </name>
         </assignedPerson>
         <representedOrganization>
           <id root="1.3.6.1.4.1.19376.1.8.9.2" extension="1120456789"/>
           <name>Hospital GoodHealth</name>
           <telecom nullFlavor="MSK"/>
           <addr nullFlavor="MSK"/>
         </representedOrganization>
      </assignedEntity>
</informant>
```

6.2.6.6.3 Specification

This content module does not contain any other content module.

Table 6.2.6.6.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate. The notes below the table provide additional constraints.

Table 6.2.6.6.3-1 Informant

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Informant	O	[0..*]	informant				
Conformance	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.6"]				
Assigned person	C	[0..1]	assignedEntity		(1)		
Role identifier	R	[1..*]	id			II	
Address	R	[1..*]	addr			AD	
Telecom	R	[1..*]	telecom			TEL	
Person name	R	[1..1]	assignedPerson/name			PN	
Name	R	[1..*]	name				
Organization	O	[0..1]	representedOrganization				
Identifier	R2	[0..*]	id			II	

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Name	R	[1..1]	name			ON	
Telecom	O	[0..*]	telecom			TEL	
Address	O	[0..*]	addr			AD	
Related person	C	[0..1]	relatedEntity		(1)		
Address	R	[1..*]	addr			AD	
Telecom	R	[1..*]	telecom			TEL	
Person name	R	[1..1]	relatedPerson/name			PN	

Notes:

(1) The *informant* is either an *assignedEntity* (i.e. a person playing an identified role in the process of care) or a *relatedEntity* (a person related to the patient).

6.2.6.7 Additional participant in an entry - 1.3.6.1.4.1.19376.1.8.1.4.7

6.2.6.7.1 Definition and purpose

This Content Module is usable only within an <entry> element.

Additional participants MAY take part in any *organizer* as well as in any *observation* of an APSR. These participants MAY be any of these 4:

- Validator: This is the same participation as Content Validator in the header of the report: a pathologist having verified the content (of this particular subset of results).
- Device: A device used to produce this particular subset of results.
- Responsible: The director of a laboratory (described in a performer element at the same level) who produced this particular subset of results.
- Transcriptionist: This is the same participation as dataEnterer in the header of the report: a staff who entered, possibly from dictation, this particular subset of results.

6.2.6.7.2 Example

```
<!-- a transcriptionist -->
<participant typeCode="ENT">
      <templateId root="1.3.6.1.4.1.19376.1.8.1.4.7"/>
      <time value="20090529094914.827+0100"/>
      <participantRole>
         <id root="1.3.6.1.4.1.19376.1.8.9.1" extension="801234567897"/>
         <telecom value="tel:+33-602030499"/>
         <playingEntity>
            <name>
               <given>Charlie</given>
               <family>TRANSCRIPTIONIST</family>
            </name>
         </playingEntity>
      </participantRole>
</participant>
```


6.2.6.7.3 Specification

This content module does not contain any other content module.

Table 6.2.6.7.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate. The notes below the table provide additional constraints.

Table 6.2.6.7.3-1 Structure of Additional Participant

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Additional participant in an entry	O	[0..*]	participant[@participationType="AUTHEN" or @participationType="DEV" or @participationType="RESP" or @participationType="ENT"]		(1)		OBR-33 OBX-18 OBX-25 OBR-35
Conformance	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				
Time of action	O	[0..1]	time@value			ts	
Role	R	[1..1]	participantRole				
Identifier	O	[0..*]	id			II	
Address	O	[0..*]	addr			AD	
Telecom	O	[0..*]	telecom			TEL	
Person	C	[0..1]	playingEntity		(1)		
Name	R	[1..*]	name			PN	
Device	C	[0..1]	playingDevice		(1)		
Code or name	C	[0..1]	code		(2)	CE	
Model name	C	[0..1]	manufacturerModelName		(2)	SC	
Software name	C	[0..1]	softwareName		(2)	SC	

Notes:

(1) The participationType attribute SHALL be one of:

- AUTHEN if the participant is a validator who verified this set of results.
- DEV if the participant is a device that was used to produce this set of results.
- RESP if the participant is the responsible person of the organization having produced this set of results. The typical situation is the director of a subcontractor laboratory described as a *performer* element at the same level.
- ENT if the participant is a transcriptionist having entered this set of results, possibly from dictation.

If the participationType is DEV, then the playingDevice sub-element SHALL be present and the playingEntity sub-element SHALL NOT be present.

In all other cases the playingDevice sub-element SHALL NOT be present and the playingEntity sub-element SHALL be present.

(2) When the participant is a device at least one of the sub-elements *code*, *softwareName* and *manufacturerModelName* SHALL be present.

6.2.6.8 Problem Organizer – 1.3.6.1.4.1.19376.1.8.1.4.8

6.2.6.8.1 Definition and purpose

This Content Module is usable only within an <entry> element.

The problem organizer is used by most entries of an APSR. It groups the battery of observations performed to investigate on a single problem identified on a specimen or group of specimens.

6.2.6.8.2 Example

```
    <!-- The set of observations related to a single problem on a specimen -->
     <organizer classCode="BATTERY" moodCode="EVN">
       <templateId root="1.3.6.1.4.1.19376.1.8.1.4.8"/>
       <id>     </id> <!-- optional problem identifier -->
       <code>     </code> <!-- optional type of problem -->

       <!-- participants -->
       <author> ... </author>
       <informant> ... </informant>

       <!-- tumor site observation (this specimen, this problem) -->
       <component>
          <observation>

          </observation>
       </component>
       <!-- tumor focality observation (this specimen, this problem) -->
       <component>
          <observation>

          </observation>
       </component>
       <!-- ancillary tests observation (this specimen, this problem) -->
       <component>
          <observation>

          </observation>
       </component>
    </organize>
```

6.2.6.8.3 Specification

Table 6.2.6.8.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate.

The nested content modules are the elements having a child templateId in the “Path and Constraints (Xpath + indentation)” column, the column “Vocab. / Source” locating in this case the specification of the nested content module.

The notes below the table, indexed by column “N”, provide additional explanations and constraints.

Table 6.2.6.8.3-1 Structure of Problem Organizer

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Problem organizer			organizer[@classCode="BATTERY" and @moodCode="EVN"]				
Conformance	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.8"]				
Problem type	O	[0..1]	code	(V1)		CD	OBR-4
Status	R	[1..1]	statusCode[@code in {"completed", "aborted"}]	(V2)		CS	OBR-25
Organizer time (interval or point)	O	[0..1]	effectiveTime		(1)	IVL_TS	OBR-7, OBR-8
Performing lab	C	[0..1]	performer[@typeCode="PRF"] /templateId[@root="1.3.6.1.4.1.19376.1.3.3.1.7"]	LAB TF-3: 2.3.3.22	(8)		OBX-23, OBX-24, OBX-25
Author	C	[0..*]	author /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.2"]	PAT TF-3: 6.2.6.2	(2)		OBR-35
Informant	O	[0..*]	informant /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.6"]	PAT TF-3: 6.2.6.6	(3)		
Transcriptionist	O	[0..*]	participant[@participationType="ENT"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.7"]	PAT TF-3: 6.2.6.7			OBR-35
Device	O	[0..*]	participant[@participationType="DEV"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				OBX-18
Responsible	O	[0..1]	participant[@participationType="RESP"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				OBX-25
Validator	O	[0..*]	participant[@participationType="AUTHEN"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				OBR-33
Anatomic pathology observation	C	[0..*]	component/observation /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.9"]	PAT TF-3: 6.2.6.9	(4)		OBX
Clinical Laboratory observation	C	[0..*]	component/observation /templateId[@root="1.3.6.1.4.1.19376.1.3.1.6"]	LAB TF-3: 2.3.5.11	(6)		OBX
Embedded Image	O	[0..*]	component/observationMedia /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.10"]	PAT TF-3: 6.2.6.10	(7)		OBX
Region of interest	O	[0..*]	component /regionOfInterest [@classCode="ROIOVL" and moodCode="EVN"]		(7)		
	R	[1..*]	id				
Overlay shape	R	[1..1]	code				
dimensions	R	[1..*]	value				
	R	[1..*]	entryRelationship[@typeCode="SUBJ"]				
Embedded image	R	[1..1]	observationMedia /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.10"]	PAT TF-3: 6.2.6.10			OBX
General comment on this particular problem observed on this particular specimen	O	[0..*]	component/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.2'] code[@code='48767-8' and @displayName='Annotation Comment' and @codeSystem='2.16.840.1.113883.6.1'] text/reference/@value statusCode[@code='completed']	PCC TF-2: 6.3.4.6			

Notes:

(1): The period of time (possibly reduced to a point in time) during which the information was collected and assembled.

(2): The author SHALL be present if it is different from the main author of the report. For instance the author could be the ordering physician contributing to the Clinical Information section, inside a report authored by the pathologist.

(3): The informant is an actor (person and organization) who provided some of the clinical information carried by this organizer.

(4): There are as many Anatomic Pathology observations as needed for this specimen/problem investigation.

(5): There are as many AP ancillary technique observations as needed for this specimen/problem investigation.

(6): There are as many Laboratory observations as needed for this specimen/problem investigation. These clinical laboratory observations conform to the Laboratory Observation template specified in LAB TF-3:2.3.5.11

(7): This organizer may carry an image focusing on the problem, either directly embedded or encapsulated within a region of interest.

(8): The performing laboratory is present at this level only if this particular problem on this particular specimen was investigated by a (subcontractor) distinct laboratory from the one issuing the consolidated report

Vocabulary notes:

(V1): The problem type code is unconstrained at this stage.

(V2): The status of the organizer is *completed* if the battery of observations for this problem has been performed. It is *aborted* in case some of the intended observations could not be achieve and have been aborted, and appear as such below the organizer.

6.2.6.9 AP Observation generic template – 1.3.6.1.4.1.19376.1.8.1.4.9

6.2.6.9.1 Definition and purpose

This Content Module is usable only within an <entry> element.

The "AP Observation" generic template is usable for all AP observations, including ancillary techniques.

Each specific AP observation is associated to a specific template, child of the "AP Observation" generic template. This specific child template has exactly the same structure as the generic one, and brings only a number of vocabulary constraints related to the type of observation and to the type of organ source of the specimen observed:

- The code for the specific observation, defined as a value set bound to the *observation/code* element, containing a single triplet (code, codeSystem, displayName) representing this specific observation.
- The cardinalities and default type for the *observation/value* element carrying the results of this observation.
- The domain of values for this observation in case these values are coded. This domain of coded values is defined as a value set bound to the *observation/value* element, containing as many triplets (code, codeSystem, displayName) as there are admissible result values for this specific observation performed on a specimen taken from this specific organ.

Thus, an AP observation in an <entry> within an organ-specific APSR Document Content Module declares conformance to two templates: The "AP Observation" generic template and the AP observation child template representing this specific observation related to this specific organ.

These AP observation child templates and their attached value sets are provided by the appendix "IHE_PAT_Suppl_APSR_AppendixValue_Sets.xlsx"

An AP observation has a status and an effective time, may describe various participants (persons, devices, organizations), may have a number of additional properties (method, interpretation, text), and may contain embedded images, comments, and sub-observations, which are also AP observations.

Figure 6.2.6.9.1-1 Conformance of an AP Observation

6.2.6.9.2 Examples

A histologic type:

```
<observation classCode="OBS" moodCode="EVN">
    <!-- Generic observation template -->
    <templateId root="1.3.6.1.4.1.19376.1.8.1.4.9"/>
    <!-- child observation template -->
    <templateId root="1.3.6.1.4.1.19376.1.8.1.4.443"/>
    <code code="1904"
```

```
          codeSystem="1.3.6.1.4.1.19376.1.8.2.1"
          codeSystemName="PATHLEX"
          displayName="Breast-Infiltrating malignant neoplasm-Histologic type"/>
    <statusCode code="completed"/>
    <effectiveTime value="20100321063000.0000-0500"/>
    <value xsi:type="CD"
           code="408643008"
           displayName="Infiltrating duct carcinoma of breast (disorder)"
           codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED-CT"/>
    <!-- participants -->
    <performer> ... </performer>
    <author> ... </author>
    <informant> ... </informant>
</observation>
```

An ancillary technique:

```
<observation classCode="OBS" moodCode="EVN">
    <!-- Generic observation template -->
    <templateId root="1.3.6.1.4.1.19376.1.8.1.4.9"/>
    <!-- child observation template -->
    <templateId root="1.3.6.1.4.1.19376.1.8.1.4.439"/>
    <code code="432" codeSystem="1.3.6.1.4.1.19376.1.8.2.1"
          codeSystemName="PATHLEX"
          displayName="Breast-Infiltrating malignant neoplasm-Estrogen receptor"/>
    <statusCode code="completed"/>
    <effectiveTime value="20100321063000.0000-0500"/>
    <value xsi:type="CD"
           code="2269"
           codeSystem="1.3.6.1.4.1.19376.1.8.2.1"
           codeSystemName="PATHLEX"
           displayName="Immunoreactive tumor cells present (> = 1%) (Specify
Quantitation)"/>
    <value xsi:type="PQ" value="10" unit="%"/>
    <interpretationCode code=" " codeSystem=" "/>
    <methodCode code="127798001"
                displayName="Immunocytochemical procedure"
                codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMED-CT"/>
    <!-- participants -->
    <performer> ... </performer>
    <author> ... </author>
    <informant> ... </informant>
</ observation >
```

6.2.6.9.3 Specification

Table 6.2.6.9.3-1 lists the Content Modules, which are nested at the first level in the current one, with their type, usage, cardinalities and reference to the specification.

Table 6.2.6.9.3-1 Content Modules Nested in Anatomic Pathology Observation

Name	Type	Opt.	Car.	Template ID	Source
Author	h/e elt	O	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.2	PAT TF-3: 6.2.6.2
Informant	h/e elt	O	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.6	PAT TF-3: 6.2.6.6

Additional participant	e elt	O	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.7	PAT TF-3: 6.2.6.7
Annotation Comment	e elt	O	[0..*]	1.3.6.1.4.1.19376.1.5.3.1.4.2	PCC TF-2: 6.3.4.6
Performing laboratory	h/e elt	C	[0..1]	1.3.6.1.4.1.19376.1.3.3.1.7	LAB TF-3: 2.3.3.22
AP Observation	e elt	O	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.9	PAT TF-3: 6.2.6.9
Embedded image	e elt	O	[0..*]	1.3.6.1.4.1.19376.1.8.1.4.10	PAT TF-3: 6.2.6.10

Table 6.2.6.9.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate. The notes below the table provide additional constraints.

The nested content modules are the elements having a child templateId in the "Path and Constraints (Xpath + indentation)" column, the column "Vocab. / Source" locating in this case the specification of the nested content module.

The notes below the table, indexed by column "N", provide additional explanations and constraints.

Table 6.2.6.9.3-1 Structure of AP Observation

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Anatomic pathology observation			observation[@classCode="OBS" and @moodCode="EVN"]				OBX
Conformance to AP observation generic template	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.9"]				
Conformance to specific AP observation template	R	[1..1]	templateId[@root]	(V0)			
Identifier	O	[0..*]	id			II	
Code	R	[1..1]	code	(V1)		CD	OBX-3
Text	O	[0..1]	text			ED	
Status	R	[1..1]	statusCode[@code in {"completed", "aborted"}]	(V3)		CS	OBX-11
Observation time	R	[1..1]	effectiveTime			IVL_TS	OBX-19
Value	R2	[0..*]	value	(V2)		ANY	OBX-2, OBX-5, OBX-6
Interpretation	R2	[0..1]	interpretationCode			CE	OBX-8
Method	R2	[0..1]	methodCode			CE	OBX-17
Performing lab	C	[0..1]	performer[@typeCode="PRF"] /templateId [@root="1.3.6.1.4.1.19376.1.3.3.1.7"]	LAB TF-3: 2.3.3.22	(1)		OBX-23, OBX-24, OBX-25
Author	C	[0..*]	author /templateId [@root="1.3.6.1.4.1.19376.1.8.1.4.2"]	PAT TF-3: 6.2.6.2			OBX-16
Informant	O	[0..*]	informant /templateId [@root="1.3.6.1.4.1.19376.1.8.1.4.6"]	PAT TF-3: 6.2.6.6			
Transcriptionist	O	[0..*]	participant[@participationType="ENT"] /templateId [@root="1.3.6.1.4.1.19376.1.8.1.4.7"]	PAT TF-3: 6.2.6.7			OBR-35
Device	O	[0..*]	participant[@participationType="DEV"] /templateId [@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				OBX-18

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Responsible	O	[0..1]	participant[@participationType="RESP"] /templateId [@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				OBX-25
Validator	O	[0..*]	participant[@participationType="AUTHEN"] /templateId [@root="1.3.6.1.4.1.19376.1.8.1.4.7"]				OBR-33
Sub-observation	O	[0..*]	entryRelationship[@typeCode="COMP"]		(3)		OBX
AP observation			observation[@classCode="OBS" and @moodCode="EVN"] /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.9"]	PAT TF-3: 6.2.6.9			
Conformance	R	[1..1]					
Embedded Image	O	[0..*]	entryRelationship[@typeCode="COMP"]		(2)		OBX
	R	[1..1]	observationMedia /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.10"]	PAT TF-3: 6.2.6.10			
Region of interest	O	[0..*]	entryRelationship[@typeCode="COMP"]		(2)		
			regionOfInterest[@classCode="ROIOVL" and @moodCode="EVN"]				
	R	[1..*]	id				
Overlay shape	R	[1..1]	code				
Dimensions	R	[1..*]	value				
	R	[1..*]	entryRelationship[@typeCode="SUBJ"]				
Embedded image	R	[1..1]	observationMedia /templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.10"]	PAT TF-3: 6.2.6.10			OBX
Comment on this observation	O	[	entryRelationship[@typeCode='SUBJ' and @inversionInd='TRUE'] /act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.2'] code[@code='48767-8' and @displayName='Annotation Comment' and @codeSystem= '2.16.840.1.113883.6.1'] text/reference/@value statusCode[@code='completed']	PCC TF-			

Notes:

(1): The performing laboratory is present at this level only if this particular observation was performed by a (subcontractor) laboratory distinct from the one issuing the rest of the observations in this organizer.

(2): This observation may carry an illustrative image, either directly embedded or encapsulated within a region of interest.

(3): The result obtained for an observation may lead to an additional AP observation to refine this result. This sub-observation is again an Anatomic Pathology Observation.

Vocabulary notes:

(V0): The specific template identifier of the specific AP observation in conjunction to a specific organ is provided in the value sets appendix (see Volume 4).

(V1): The Anatomic pathology observation code is taken from a value set mandated by the AP observation specific template (see Volume 4).

(V2): The default data type, cardinalities and value set for the <value> element are mandated by the AP observation specific template (see Volume 4).

(V3): The observation statusCode is "*completed*" if the observation was actually performed and has produced a result in the *value* element. In other cases the status of the intended observation is "*aborted*" and the result will never come.

6.2.6.10 Embedded Image – 1.3.6.1.4.1.19376.1.8.1.4.10

6.2.6.10.1 Definition and purpose

This Content Module is usable within an <entry> element, in relationship with a display anchor carried in the *referencedObject* attribute of a <renderMultimedia> element in the <text> element of the <section> holding this <entry>.

The <observationMedia> element carries an image, embedded in B64. This element may be standalone, or encapsulated within a <regionOfInterest> element which defines an overlay shape to focus on a part of the image.

This <observationMedia> element embeds the image binary data, encoded in B64.

6.2.6.10.2 Example

```
<section>
   …
 <text>
   …
   <renderMultimedia referencedObject="PHOTO_SPEC"/>
   …
 </text>
 <entry>
  …
    <observationMedia classCode="OBS" moodCode="EVN" ID="PHOTO_SPEC">
       <value mediaType="image/gif" representation="B64">Here is the inline B64
        multimedia content</value>
    </observationMedia>
  …
 </entry>
</section>
```

6.2.6.10.3 Specification

Table 6.2.6.10.3-1 provides the precise structure of this Content Module, with usage, cardinalities, path and constraints of its data elements, value sets /terminologies bound and mapping to HL7 v2.5.1 ORU^R01 message structure where appropriate. The notes below the table provide additional constraints.

The nested content modules are the elements having a child templateId in the “Path and Constraints (Xpath + indentation)” column, the column “Vocab. / Source” locating in this case the specification of the nested content module.

The notes below the table, indexed by column “N”, provide additional explanations and constraints.

Table 6.2.6.10.3-1 Structure of Embedded Image

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
Embedded Image	O	[0..*]	observationMedia[@classCode="OBS"		(1)		

Data element	Usage	Car.	Path and Constraints (Xpath + indentation)	Vocab. / Source	N.	DT	HL7 v2.5.1
			and @moodCode="EVN" and @ID]				
Conformance	R	[1..1]	templateId[@root="1.3.6.1.4.1.19376.1.8.1.4.10"]				
Image in B64	R	[1..1]	value[@mediaType and @representation="B64"]	(V1)	(2)		
Comment on this image	O	[0..*]	entryRelationship[@typeCode='SUBJ' and @inversionInd='TRUE'] act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.2'] code[@code='48767-8' and @displayName='Annotation Comment' and @codeSystem= '2.16.840.1.113883.6.1'] text/reference/@value statusCode[@code='completed']	PCC TF-2: 6.3.4.6			

Notes:

(1): The ID attribute is pointed to by the anchor in the *referencedObject* attribute of a <renderMultimedia> element in the <text> element of the <section> holding this <entry>.

(2): The <value> element contains the image encoded in Base 64. This is indicated by the value "B64"of attribute *representation*.

Vocabulary notes:

(V1): The *mediaType* attribute specifies the type of media/application to be used to display the image. For instance 'image/gif' or 'image/jpeg'.

Volume 4 – Value Sets

The value sets built for this supplement are externalized in the separate appendix spreadsheet "**IHE_PAT_Suppl_APSR_Appendix_Value_Sets**".