**IHE-International**
**Integrating the Healthcare Enterprise**

# Pathology Technical Framework Volume 1

# (PAT TF-1) Integration Profiles

**Revision 1.15 – Trial Implementation**

**January 25, 2008**

Developed under the sponsorship of GMSIH, ADICAP, SEIS, SEAP, SFP

# CONTENTS

# 1 Introduction

## 1.1 Overview of IHE

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework, organizes educational sessions, exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is to support the use of existing standards, e.g HL7, ASTM, DICOM, ISO, IETF, OASIS, CLSI and others as appropriate, rather than to define new standards. IHE profiles further constrain configuration choices where necessary in these standards to ensure that they can be used in their respective domains in an integrated manner between different actors. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA) and the American College of Cardiology (ACC).IHE Canada has also been formed. IHE Europe (IHE-EU) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electro medical Industries (COCIR), the Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), the Société Francaise de Radiologie (SFR), Deutsche Röntgengesellschaft (DRG), the Euro-PACS Association, Società Italiana di Radiologia Medica (SIRM) and the European Institute for Health Records (EuroRec). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). The list presented here is not closed and other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

## 1.2 Overview of the technical framework

This document, the IHE PAT Technical Framework (ITI TF), defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The current version, rev. 1.14 for Trial Implementation, specifies the

IHE transactions defined and implemented as of January 2008. The latest version of the document is always available via the Internet at www.ihe.net.

The IHE Pathology Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The present volume (PAT TF-1) provides a high-level view of IHE functionality, showing the transactions organized into functional units called integration profiles that highlight their capacity to address specific IT Infrastructure requirements.

Volume 2 of the PAT Infrastructure Technical Framework (PAT TF-2) provides detailed technical descriptions of each IHE transaction used in the IT Infrastructure Integration Profiles. These two volumes are consistent and can be used in conjunction with the Integration Profiles of other IHE domains.

The other domains within the IHE initiative also produce Technical Frameworks within their respective areas that together form the IHE Technical Framework. Currently, the following IHE Technical Framework(s) are available:

- IHE IT Infrastructure Technical Framework
- IHE Cardiology Technical Framework
- IHE Laboratory Technical Framework
- IHE Pathology Technical Framework
- IHE Patient Care Coordination Technical Framework
- IHE Radiology Technical Framework

Where applicable, references are made to other technical frameworks. For the conventions on referencing other frameworks, see Section 1.6.3 within this volume.

## 1.3 Overview of the IT Pathology Volume I

The remainder of Section 1 further describes the general nature, purpose and function of the Technical Framework. Section 2 introduces the concept of IHE Integration Profiles that make up the Technical Framework.

Section 3 and the subsequent sections of this volume provide detailed documentation on each integration profile, including the IT Infrastructure problem it is intended to address and the IHE actors and transactions it comprises.

The appendices following the main body of the document provide a summary list of the actors and transactions, detailed discussion of specific issues related to the integration profiles and a glossary of terms and acronyms used.

The aim is to extend the IHE initiative to pathology laboratories, their information, automation and imaging systems and equipment. This document, the **Pathology Technical Framework** identifies the workflow, the IHE **actors** (i.e. functional components, application roles), and shows the **transactions** between them. This description is organized into functional units called **integration profiles** that highlight their capacity to address specific clinical needs. It also chooses the appropriate messages of established standards to cover this new domain, and defines their implementation.

## 1.4 Audience

The intended audience of this document is:

- Technical staff of vendors participating in the IHE initiative
- IT departments of healthcare institutions
- Experts involved in standards development
- Anyone interested in the technical aspects of integrating healthcare information systems.

## 1.5 Relationship to Standards

The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on ASTM, DICOM, HL7, IETF, ISO, OASIS and W3C standards. As the scope of the IHE initiative expands, transactions based on other standards may be included as required.

In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities in their products may publish IHE Integration Statements to communicate their products' capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different products, a user familiar with the IHE concepts of actors and integration profiles can determine the level of integration between them. See Appendix C for the format of IHE Integration Statements.

In Pathology, SNOMED is a de facto terminology standard. In Europe, Technical Committee CEN/TC 251 is dealing with "Health informatics" and two specific working groups have been recently created within DICOM and HL7.

- ***DICOM WG26***

The group will be responsible for formulating components of the DICOM standard that relate to imaging for Pathology.

Some pathology-related image formats do not as yet have applicable DICOM Information Object Definitions. Examples include whole-slide images (WSI), high-order multispectral images, flow cytometry, electron microscopy.

- ***HL7 Pathology Special Interest Group***

The group will achieve a complementary effort, focusing on the "orders and observations" aspects of the pathology workflow

HL7 Pathology Special Interest Group international mailing list: pathology@lists.hl7.org

- ***SNOMED Standard Board***

This group is integrated with internal staff from SNOMED International and external collaborators. They work in the definition of new terms and relationships between accepted terms. There is a need to define the best way to integrate SNOMED Clinical Terms in Pathology Information Systems (SNOMED Pathology subset), and how to exchange information with other clinical departments and other institutions, using a common terminology.

- ***CEN TC 251***

The document TC 251 Work Item 130.( Health informatics — Service request and report messages), prepared under mandate M/255 given by the European Commission and the European Free Trade Association, has been prepared by Technical Committee CEN/TC 251 "Health informatics", and has replaced the previous standards ENV 1613 (Medical informatics - Messages for exchange of laboratory information)., ENV 12538 (Medical informatics - Referral and discharge messages), and ENV 12539 (Medical informatics - Request and report messages for medical service departments). The scope of the messages specified by this EN comprises healthcare service requests and reports related to investigations carried out by healthcare service providers on subjects of care. They cover electronic information exchange between computer systems used by healthcare parties requesting the services of, healthcare service providers.

Typical use cases are available by CEN TC251 in prEN 14720-1:2003 (Health informatics — Service request and report messages — Part 1: Basic services including referral and discharge, TC 251 WI 130.1.1:2003 – E. See: http://www.centc251.org/):

- Service to be performed on specimens supplied by the requester
- Services that require scheduling prior to the receipt of the sample collected by the requester (frozen sections, renal biopsy)
- Services performed on samples collected by the service provider (fine needle aspiration)
- Services in which the subject of care is examined by the service provider
- Services involving evaluation of an existing sample or study product (second opinion)
- Modification of an existing request following any of the above scenarios (additional investigations or revised clinical information)
- Cancellation of an existing request following any of the above scenarios

**Scheduling**: See section B.2.3 Services that require scheduling prior to the receipt of the sample collected by the requester in CEN TC-251 WI 130 Part 1 (examples: frozen section and renal biopsy).

- ***Harmonization***

It is important the five parallel efforts - IHE-pathology initiative, DICOM WG 26 and Pathology Special Interest Group being formed for HL7, SNOMED Standard Board, and CEN CT 251 - aligned, yet distinct, each with its own purpose and organizational context.

Clearly there will be overlap in defining the information model for specimens, in standardizing reports including quantitative measurements and assessments made with reference to images, etc.

Information model for specimens and templates for structured reports should be established in common across both standards.

HL7-DICOM interoperation in pathology will be addressed in a HL7-DICOM joint working group (HL7 Pathology SIG / DICOM WG26) defining clauses for harmonization of standards.

## 1.6 Relationship to Real-world Architectures

The IHE actors and transactions described in the IHE Technical Framework are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Clinical Data Repository, Radiology Information Systems, Clinical Information Systems or Cardiology Information Systems), the IHE Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

The reason for defining actors and transactions is to provide a basis for defining the interactions among functional components of the healthcare information system environment. In situations where a single physical product implements multiple functions, only the interfaces between the product and external functions in the environment are considered to be significant by the IHE initiative. Therefore, the IHE initiative takes no position as to the relative merits of an integrated environment based on a single, all-encompassing information system versus one based on multiple systems that together achieve the same end. IHE demonstrations emphasize the integration of multiple vendors' systems based on the IHE Technical Framework.

## 1.7 Conventions

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

IHE Pathology Technical Framework adopts without any change, the conventions defined in IHE radiology Technical Framework Rev. 6.0.

### *1.7.1 IHE Actor and Transaction Diagrams and Tables*

Each integration profile is a representation of a real-world capability that is supported by a set of actors that interact through transactions. Actors are information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in the enterprise. Transactions are interactions between actors that communicate the required information through standards-based messages.

The diagrams and tables of actors and transactions in subsequent sections indicate which transactions each actor in a given profile must support.

The transactions shown on the diagrams are identified both by their name and the transaction number as defined in ITI TF-2. The transaction numbers are shown on the diagrams as bracketed numbers.

In some cases, a profile is dependent on a prerequisite profile in order to function properly and be useful. For example, Enterprise User Authentication depends on Consistent Time. These dependencies can be found by locating the desired profile in Table 2-1 to determine which profile(s) are listed as prerequisites. An actor must implement all required transactions in the prerequisite profiles in addition to those in the desired profile.

### *1.7.2 Process Flow Diagrams*

The descriptions of integration profiles that follow include process flow diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

These diagrams are intended to provide an overview so the transactions can be seen in the context of an institution's workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in *italics* to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems.

These diagrams are not intended to present the only possible scenario. Often other actor groupings are possible, and transactions from other profiles may be interspersed.

In some cases the sequence of transactions may be flexible. Where this is the case there will generally be a note pointing out the possibility of variations. Transactions are shown as arrows oriented according to the flow of the primary information handled by the transaction and not necessarily the initiator.

### *1.7.3 Technical Framework Cross-references*

When references are made to another section within a Technical Framework volume, a section number is used by itself. When references are made to other volumes or to a Technical Framework in another domain, the following format is used:
<domain designator> TF-<volume number>: <section number>, where
<domain designator> is a short designator for the IHE domain (ITI = IT Infrastructure, RAD = Radiology, PAT=Pathology)
<volume number> is the applicable volume within the given Technical Framework (e.g., 1, 2, 3), and
<section number> is the applicable section number.
For example: ITI TF-1: 3.1 refers to Section 3.1 in volume 1 of the IHE IT Infrastructure Technical Framework, RAD TF-3: 4.33 refers to Section 4.33 in volume 3 of the IHE Radiology Technical Framework. PATTF-1:2.5 refers to section 2.5 in volume I of the IHE Pathology Technical Framework.

When references are made to Transaction numbers in the Technical Framework, the following format is used:
[<domain designator><transaction number>], where
<transaction number> is the transaction number within the specified domain.
For example [PAT-1] refers to Transaction 1 from the IHE PAT Technical Framework.

## 1.8 Scope introduced in the current year

The IHE Technical Framework is updated annually to reflect new profiles, corrections and new transactions (refer to PAT TF-2) used in those profiles.

This document refers to 2007-2008 cycle of the IHE PAT Infrastructure initiative. It will be the basis for the 2009 Connectathon process and exhibition process associated.

The latest version of the document is available via the Internet at www.gmsih.fr and www.ihe.net. It has been produced with the help of the following organizations:

- **GMSIH (Groupement pour la Modernisation du Système d'Information Hospitalier)**
- **ADICAP (Association pour le Développement de l'Informatique en Cytologie et Anatomie Pathologique)**
- **SEIS (Spanish Health Informatics Society)**
- **SEAP (Spanish Society of Pathology)**
- **SFP (French Society of Pathology)**
- **HL7 and its affiliate organizations (HL7 pathology SIG)**
- **IHE organization in each participating country: IHE-France, IHE-Spain.**
- **IHE-J (IHE Japan)**

The scope of the anatomic pathology includes surgical pathology, biopsies pathology, cytopathology, autopsies, and related techniques (immunohistochemistry, molecular pathology, etc).

Information systems in pathology laboratories gather medical data (text, images, etc) throughout specimen management from specimen reception to report editing.

The diagnostic process in anatomical pathology (figure 1) differs from that in the clinical laboratory since it relies on image interpretation. It also differs from that in radiology since it is specimen-driven and when digital imaging is performed many types of imaging equipments (gross imaging, microscopic still imaging, whole slide imaging, multispectral imaging, etc) may be involved for a single examination. Moreover, images of the same study may be related to different specimen (parts and/or slides) from one or even different patients (e.g. Tissue Micro Array). Finally, slides are always available to acquire more images, if needed. In radiology, the diagnostic process is patient-driven, an examination (study) usually involves a single image acquisition modality and all images of the study are related to one and only one patient.

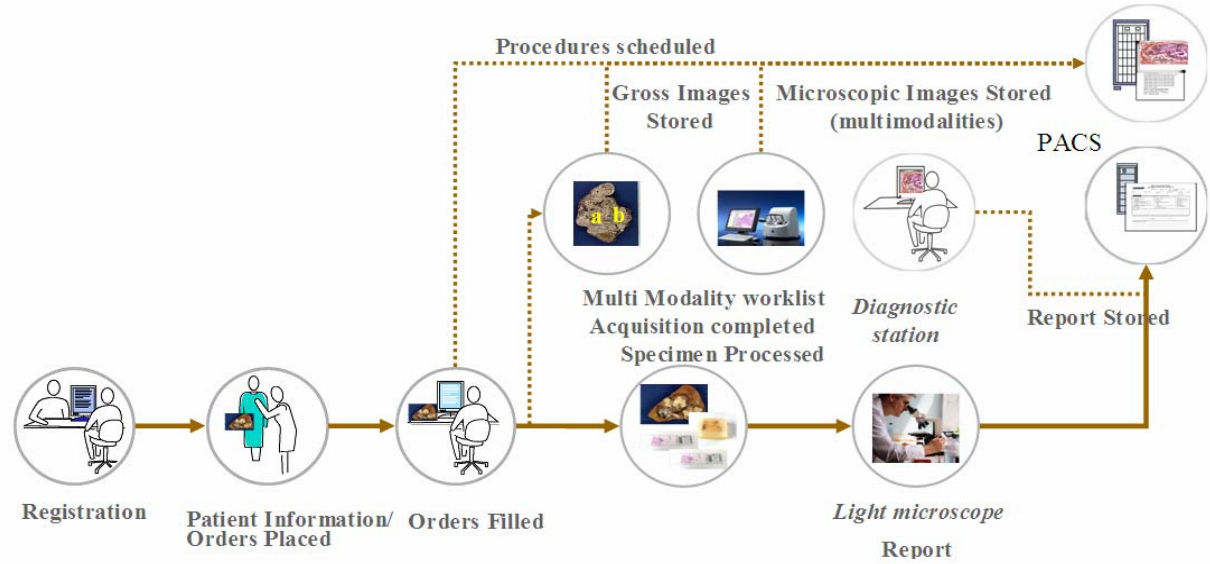

*Figure 1: Anatomic pathology workflow*

## 1.9 Comments

ADICAP, GMSIH, SEIS, SEAP, SFP welcome comments on this document and the IHE initiative. They should be directed to co-chairs:


| | |
|---|---|
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| 15 rue de l'école de médecine | Servicio de Salud de Castilla |
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Comments may also be addressed to the IHE Pathology international mailing list:
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## 1.10 Copyright Permission



## 1.11 IHE Technical Framework Development and Maintenance Process

The IHE PAT Technical Framework is continuously maintained and expanded on an annual basis by the IHE PAT Technical Committee. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users may use it reliably in specifying, developing and acquiring systems with IHE integration capabilities.

The first of these principles is that any extensions, clarifications and corrections to the Technical Framework must maintain backward compatibility with previous versions of the framework in order to maintain interoperability with systems that have implemented IHE Actors and Integration Profiles defined there.

The IHE PAT Technical Framework is developed and re-published annually following a three-step process:

1. The Pathology Technical Committee develops supplements to the current stable version of the Technical Framework to support new functionality identified by the IHE Strategic and Planning Committees and issues them for public comment.
2. The Committee addresses all comments received during the public comment period and publishes an updated version of the Technical Framework for "Trial Implementation." This version contains both the stable body of the Technical Framework from the preceding cycle and the newly developed supplements. It is the version of the Technical Framework used by vendors in developing trial implementation software for the annual Connectathon.

3. The Committee regularly considers change proposals to the Trial Implementation version of the Technical Framework, including those from implementers who participate in the Connectathon. After resolution of all change proposals received within 60 days of the Connectathon, the Technical Framework version is published as “Final Text”.

# OPEN ISSUES

Volume 2:

4. Examples of transactions corresponding to use cases will be further provided.
5. Vocabulary tables for HL7 SPM-Specimen segment (SPM-4 Specimen Type (table 0487), SPM-8 Specimen Source Site, etc) and DICOM Specimen Module ((Coded Specimen Type (context ID ccc5), Specimen (“general”) type (context ID ccc3), “general” specimen collection procedure (context ID cc10)) should be aligned (defined with SNOMED and/or LOINC codes?
6. Instance availability notification
   Add a new transaction from the Image Imager to the Order Filler to notify that a DICOM instance has been stored. It may enable the Order Filler to include such information in the transaction to the Order Result Tracker. Additionally it may be used by the Order Filler to update the Worklist contents for the Modality which produced the instance for the particular specimen, considering the modality no longer needs this entry in the worklist.

# 2 Integration profiles

## 2.1 Scope

**Pathology Technical Framework** describes the integration of the pathology department in the healthcare enterprise. The diagnostic process requires tight consultation between different healthcare providers: pathologists and technicians, surgeons, oncologists, clinicians, radiologists, etc. The ultimate goal is a comprehensive digital pathology record for the patient, of which images are a significant part.

The primary focus will be digital formats for clinical patient management, but digital imaging for research applications may also be addressed as appropriate (dealing with Tissue Micro Arrays (one slide for hundreds of patient) with a link to patient information or dealing with animal experimentation, etc).

Not all sub-specialties will be covered by the current framework. The aim is to progressively include all sub-domains of pathology: surgical pathology, clinical autopsy, cytopathology, etc and all special techniques (gross examination, frozen section, immunohistochemistery (including TMAs), molecular pathology, flow cytometry, special microscopy techniques (confocal laser scanning, multispectral microscopy), etc.

Table 2.1-1: List of specialties

| Value | Description | Addressed by Pathology TF 2007 – 2008 |
|---|---|---|
| SP | Surgical Pathology<br>- Surgical specimen<br>- Biopsies | Yes<br>(Use cases 1.1, 1.2, 1.3, 1.4)<br>(Use cases 2.1, 2.2) |
| CP | Cytopathology (including fine needle aspiration biopsy – FNAB) | Yes (Use cases 3.1, 3.2) |
| CA | Clinical Autopsy | Yes (Use cases 4) |
| RP | Research in Pathology (TMA) | Partially (Use cases 5) |

## 2.2 Integration Profiles overview

Integration profiles describe real-world scenarios or specific sets of capabilities of integrated systems. An Integration Profile applies to a specified set of actors and for each actor specifies the transactions necessary to support those capabilities.

### *2.2.1 Integration Profiles presentation*

Integration profiles (IP) in pathology are specific IP defined in the Pathology Technical Frameworks or existing IP from other Technical Frameworks that are useful in pathology.

Figure 2.2.1 provides a graphical view of the dependencies between Integration Profiles. Table 2.2.1 defines the required dependencies between the Integration Profiles in a tabular form. Integration Profiles that are specific to pathology and that will be addressed by the

488 2007-08 cycle, are highlighted in grey in figure 2.2.1. Existing integration profiles useful in pathology are marked with (*) in figure 2.2.1 and table 2.2.2.

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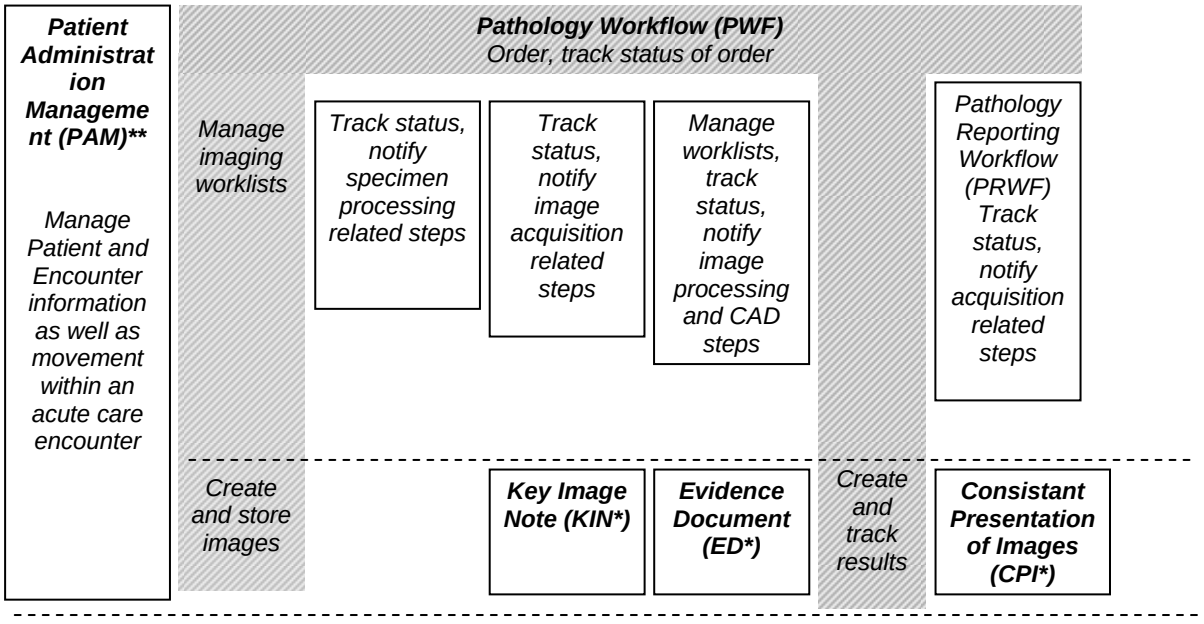


*Figure 2.2.1: IHE Integration Profiles in pathology. Existing integration profiles useful in pathology are with (*). Existing integration profiles mandatory in pathology are with (**). Pathology Workflow (PWF), in grey, is an IP specific of Pathology that will be addressed by the 2007-08 IHE Pathology cycle.*

492 Table 2.2.2: Integration Profiles (IP) Dependencies

| Integration profile | **Tech. FW**[1] | Depends on | Dependency Type | Comments |
|---|---|---|---|---|
| Patient Administration Management (PAM) | ITI | *None* | *None* | |
| Pathology Workflow (PWF) | PAT | PAM | Required for Patient and Encounter management | Cycle 2007-08 |
| Pathology Reporting Workflow (PRWF) | PAT | *PWF* | Required for order and specimen management | Cycle 2008-09 |
| Key Image Note (KIN*) | RAD | *None* | *None* | |
| Presentation of Grouped Procedures (PGP*) | RAD | PWF, CPI | Required for workflow and content output | |
| Consistent Presentation of Images (CPI*) | RAD | *None* | *None* | |
| Evidence Documents (ED*) | RAD, CARD, EYECARE | *None* | *None* | |
| Portable Data for Imaging (PDI*) | RAD | *?* | *?* | |

494 Other IHE profiles like IT Infrastructure (ITI) profiles (Retrieve Information for Display - RID, Enterprise User Authentication – EUA, Patient Identifier Cross-referencing – PIX, 496 Patient Synchronized Applications - PSA, Consistent Time - CT, Patient Demographics Query - PDQ, Audit Trail and Node Authentication - ATNA, Personnel White Pages - PWP, 498 and Cross-Enterprise Document Sharing - XDS) are useful in pathology.

### *2.2.2 Pathology Workflow (PWF)*

500 The Pathology Workflow Integration Profile establishes the continuity and integrity of basic pathology data acquired for examinations being ordered for an identified inpatient or 502 outpatient. It focuses on the main transactions of:

**a) the ordering aspects of the workflow**. The PWF specifies a number of transactions to 504 maintain the consistency of ordering information and specimen management information.

**b) the reporting aspects of the workflow** The PWF specifies a number of transactions to 506 create and store observations and reports outside the Pathology department and to maintain the consistency of these results. For this cycle, the reporting workflow is basic. A complete

and more precise workflow will be defined by the Pathology Reporting Worflow (PRWF) in a next cycle.

**c) the imaging aspects of the workflow**. The PWF specifies a number of transactions to create and store images and to maintain the consistency of these images. Worklists for image acquisition is generated and can be queried. This Integration Profile also describes evidence creation.

Some actors and transactions of the Pathology Workflow Integration Profile are reused from existing profiles described within Radiology Technical Framework and Laboratory Technical Framework.

Table 2.2.2: New Integration Profiles in pathology

| Integration profile (IP) of the Pathology Technical Framework (PAT) | Adapted from other Technical Framework |
|---|---|
| Pathology Workflow (PWF) | Adapted from Laboratory Technical Framework (ordering and reporting aspects)<br>Adapted from Radiology Technical Framework (imaging aspects) |

## 2.3 Actors Description

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise. The following are the actors defined by IHE and referenced throughout the rest of this document (in alphabetic order).

**Acquisition Modality –** A system that acquires and creates medical images while a patient is present, e.g. a Computed Tomography scanner or Nuclear Medicine camera. A modality may also create other evidence objects such as Grayscale Softcopy Presentation States for the consistent viewing of images or Evidence Documents containing measurements.

**Department System Scheduler/Order Filler** – A pathology department-based information system that provides functions related to the management of orders received from external systems or through the department system's user interface. The system receives orders from Order Placer actors, collects or controls the related specimens, accepts or rejects the order, schedules work orders, and sends them to processing room, receives the results of gross study (specimen status and adequacy), controls the status of each specimen, and appropriately manages all state changes of the order. In some cases, the Order Filler will create test orders itself (e.g. a paper order received from a department not connected to an Order Placer, or a paper order was received from a physician external to the organization). In some cases the Order Filler is responsible for collecting and identifying the specimens. An Order Filler may receive orders from various Order Placers.

**Order Result Tracker –** A system that stores pathology observations obtained for the patients of the healthcare institution, registers all state changes in the results notified by Order Fillers. This actor stores observations in the context of their Order or Order Group. This actor also stores reports outside the Pathology department.

**Evidence Creator** – A system that creates additional evidence objects such as images, presentation states, Key Image Notes, and/or Evidence Documents and transmits them to an Image Archive. It also makes requests for storage commitment to the Image Manager for the data previously transmitted.

**Image Archive** – A system that provides long term storage of evidence objects such as images, presentation states, Key Image Notes and Evidence Documents.

**Image Manager –** A system that provides functions related to safe storage and management of evidence objects. It supplies availability information for those objects to the Department System Scheduler.

**Order Filler**: (See **Department System Scheduler - DSS)**

**Order Placer –** A hospital or enterprise-wide system that generates orders for various departments and distributes those orders to the correct department, and appropriately manages all state changes of those orders. In some cases the Order Placer is responsible for collecting and identifying the specimens. Therefore, the transaction between Order Placer and Order Filler may carry specimen related information. There may be several Order placer actors in the same enterprise.

## 2.4 Transaction Descriptions

Transactions are interactions between actors that transfer the required information through standards-based messages. The following are the transactions defined by IHE and referenced throughout the rest of this document.

**PAT-1 (from LAB-1): Placer Order Management –** This transaction contains all the messages required between the Order Placer and the Order Filler for the management of the life cycle of the order. Its main goal is to keep a consistent vision of the order, (content and status), between the two actors.

**PAT-2 (from LAB-2), in option: Filler Order Management –** This transaction contains all the messages required between the Order Filler and the Order Placer for the notification of a new filler order, as well as the creation of the placer order that reflects it. Its main goal is to ensure that each filler order will be represented by a placer order, and will have both a filler order number and a placer order number.

**PAT-3 (from LAB-3): Order Results Management** - This transaction carries the results of an Order, as well as status changes, modifications, cancellations of these results, from the Order Filler to the Order Result Tracker.

**PAT-4 (from RAD-4, RAD-13): Procedure Scheduled and Updated** – The Department System Scheduler/Order Filler sends the Image Manager and Report Manager scheduled procedure information or procedure update.

**PAT-5 (from RAD-5): Query Modality Worklist –** Based on a query entered at the Acquisition Modality, a modality worklist is generated listing all the items that satisfy the query. This list of Scheduled Procedure Steps with selected demographic information **and information about specimen** is returned to the Acquisition Modality.

**RAD-8, RAD-43, RAD-10 (cf Radiology Technical Framework)**

# 3 Pathology Workflow (PWF)

## 3.1 Actors/Transactions

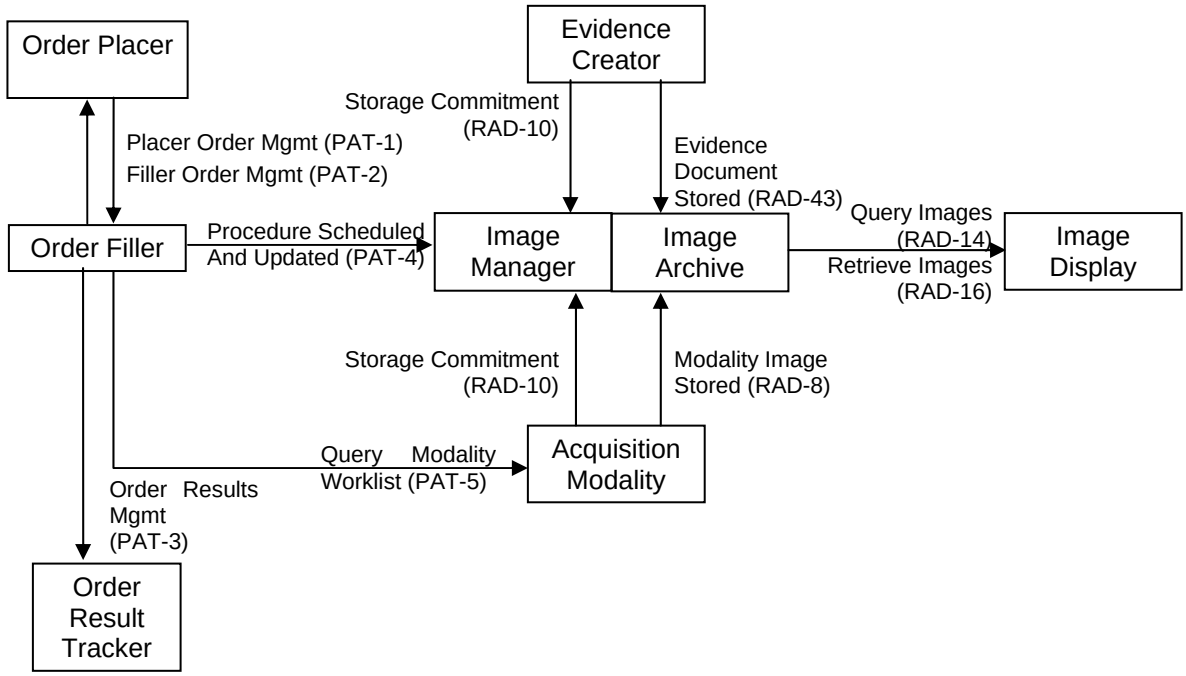


*Figure 3.1-Pathology Workflow (PWF)*

Table 3.1 – Pathology Workflow – Actors and Transactions

| Actors | Transactions | Optionality | Documentary reference |
|---|---|---|---|
| Order Placer | Patient Identity Feed (ITI-030) | R | ITI TF-2 : 3.30 |
| | Patient Encounter Management (ITI-031) | R | ITI TF-2 : 3.31 |
| | Placer Order management (PAT-1) | R | Pathology TF-2 |
| | Filler Order Management (PAT-2) | R | Pathology TF-22 |
| Order Filler | Patient Identity Feed (ITI-030) | R | ITI TF-2 : 3.30 |
| | Patient Encounter Management (ITI-031) | R | ITI TF-2 : 3.31 |
| | Placer Order Management (PAT-1) | R | Pathology TF-2 |
| | Filler Order Management (PAT-2) | R | Pathology TF-2 |
| | Order Results Management (PAT-3) | R | Pathology TF-2 |
| | Procedure Scheduled and Updated (PAT-4) | R | Pathology TF-2 |
| | Modality Worklist Provided (PAT-5) | R | Pathology TF-2 |
| Acquisition Modality | Modality Worklist Provided (PAT-5) | R | Pathology TF-2 |
| | Storage Commitment (RAD-10) | R | Radiology TF-2 : 4.10 |
| | Modality Image Stored (RAD-8) | R | Radiology TF-2 : 4.8 |
| Image Manager/ Image Archive | Procedure Scheduled and Updated (PAT-4) | R | Pathology TF-2 |
| | Storage Commitment (RAD-10) | R | Radiology TF-2 : 4.10 |
| | Modality Image Stored (RAD-8) | R | Radiology TF-2 : 4.8 |

| | | | |
|---|---|---|---|
| | Evidence Document Stored (RAD-43) | R | Radiology TF-2 : 4.43 |
| | Query Images (RAD-14) | R | Radiology TF-2 : 4.14 |
| | Retrieve Images (RAD-16) | R | Radiology TF-2 : 4.16 |
| Image Display | Query Images (RAD-14) | R | Radiology TF-2 : 4.14 |
| | Retrieve Images (RAD-16) | R | Radiology TF-2 : 4.16 |
| Evidence Creator | Storage Commitment (RAD-10) | R | Radiology TF-2 : 4.10 |
| | Evidence Document Stored (RAD-43) | R | Radiology TF-2 : 4.43 |
| Order Result Tracker | Order Results Management (PAT-3) | R | Pathology TF-2 |

## 3.2 Process Flow

Process flow is expressed with the following UML sequence diagrams, with time scale from top to bottom.

These diagrams present a high-level view of the flow: each transaction is represented by a single arrow with the initial triggering event, but without any detail on the various messages that compose the transaction. For instance, transaction [PAT-1] starts with the placing of an order, but the message flow of this transaction keeps going on until the order is completed, cancelled, or nullified. Individual messages aren't shown, the detailed message flow of each transaction can be found in volume 2.

### *3.2.1 Pathology General Workflow without image acquisition*

A physician or a surgeon in a care department orders for macroscopic and microscopic examination of specimen collected from the patient. Each order may contain one or more Requested Procedure possibly reported by different pathologists. It must be possible to add or link rough drawings, photographs (gross imaging) or vocal messages to an order. The **Order Placer** sends the order with Requested Procedure(s) and all pertinent information to the **Order Filler (PAT-1)[2].**

The specimens may arrive in the pathology department without any order. Sometimes pathologists are also responsible for collecting the specimens. In these cases, the **Order Filler** sends the order with Requested Procedure(s) to the **Order Placer (PAT-2)**.

The **Order Filler** automatically accessions the Requested Procedure(s) (Study Accession Number)[3]. The pathology Department staff checks the order and ensures that all required parts are available and conform to the order. Containers are labeled and specimen (parts) are identified.[4] Order and specimen(s) conformance statuses are sent to the **Order Placer**[5] **(PAT-1, PAT-2).**

The pathology department staff performs a macroscopic examination of the specimens and processes specimen for tissue banking and/or microscopic examination[6].

[2] *See appendix A*

3 *The pathology department can modify the breakdown of the order in Requested Procedures.*

4 *This intrinsic pathology department Specimen ID (Specimen Accession Number) is linked to the corresponding (clinical) Specimen ID that is stored by the Order Filler.*

5 *Specimen and Order conformance statuses require a controlled vocabulary (Appendix B)*

[6] *(see appendix B for Specimen identification and description issues).*

After slide examination, the pathologist sends observations and/or reports. The **Order Filler** sends observations and/or reports to the **Order Result Tracker** and provides the **Order Result Tracker** with up-to-date information and statuses of the observations and/or the report (**PAT-7**).

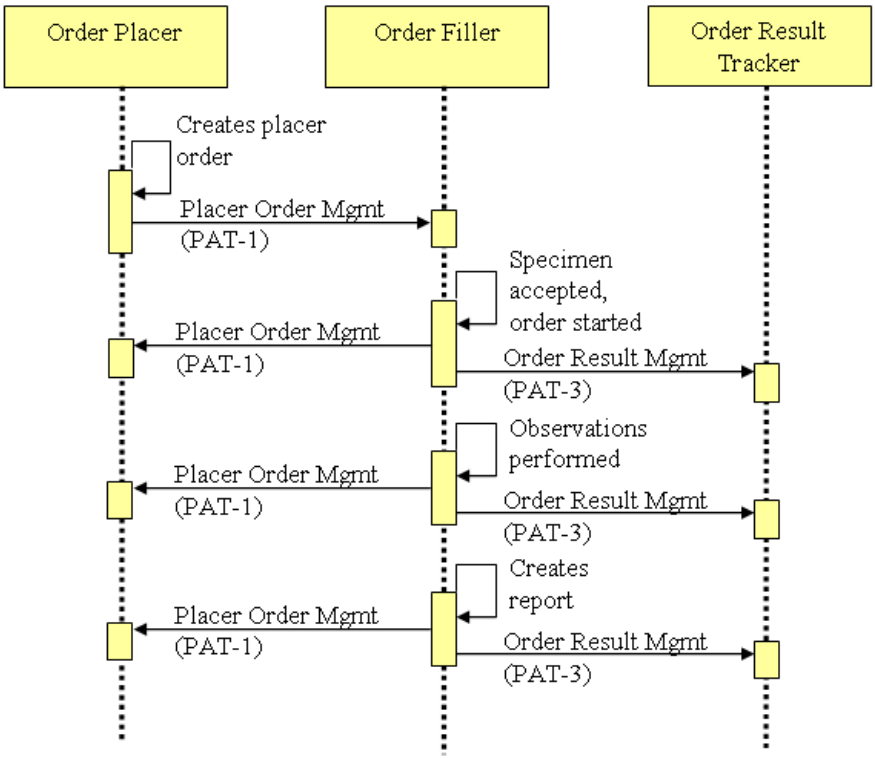


*Figure 3.2.1-Pathology General Workflow without acquisition of images*

### *3.2.2 Pathology General Workflow with acquisition of images*

Gross imaging and/or microscopic imaging is performed using the **Acquisition Modality**. The technician queries the **Order Filler** to retrieve the information about the specimen and the corresponding Requested Procedure **(PAT-5)**. While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** (**RAD-8, RAD-10**) and available for the **Image Display**.

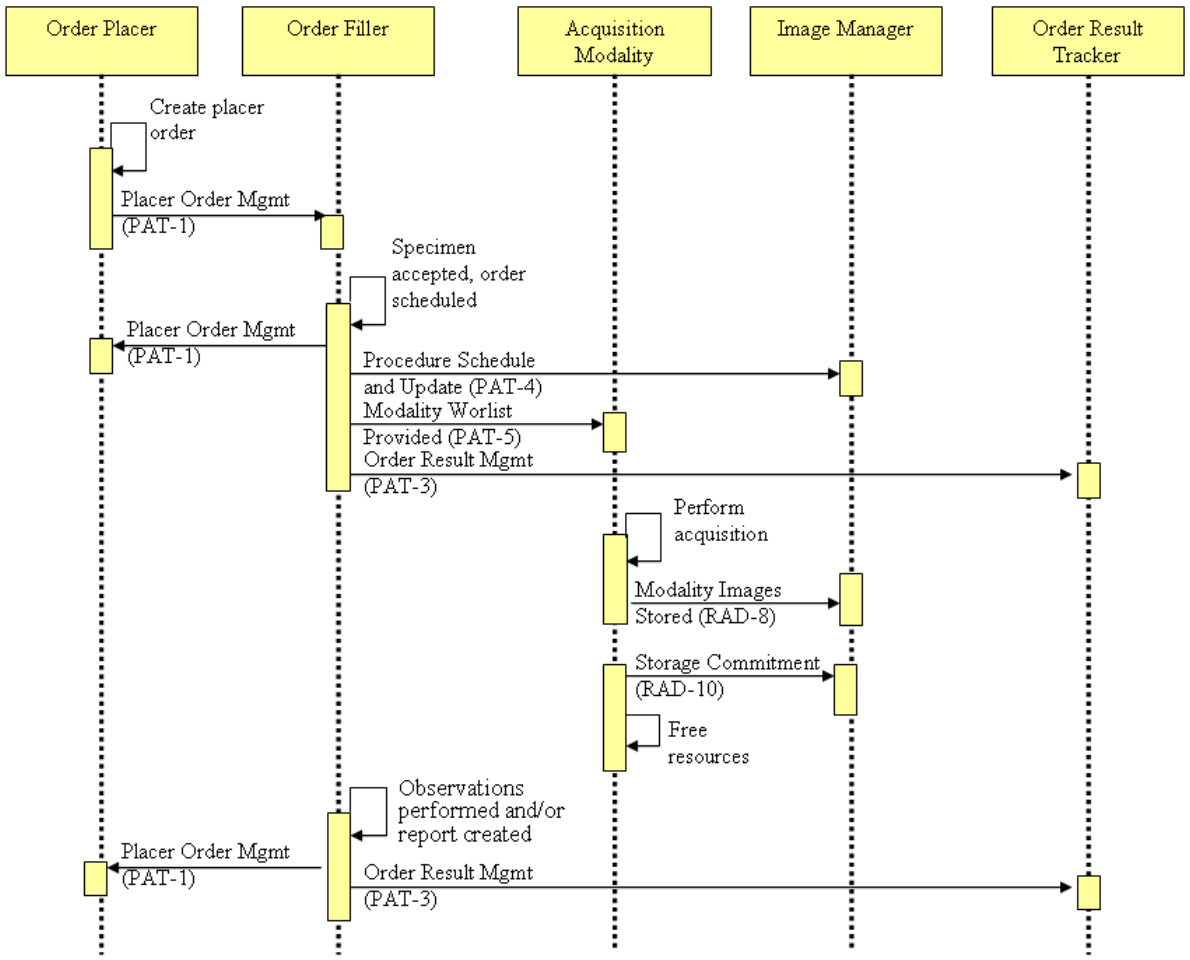


*Figure 3.2.2-Pathology General Workflow with acquisition of images*

### *3.2.3 Pathology General Workflow with post processing*

Post processing imaging is performed using the **Evidence Creator**. The technicians queries the **Image Manager/Image Archive** to retrieve the images (querying thanks to the patient ID, the study ID or the Specimen ID) **(RAD14, RAD-16)**. While performing Evidence Documents, a new STUDY and a new SERIES are created, stored in the **Image Archive** (**RAD-43, RAD-10**) and available for the **Image Display**.

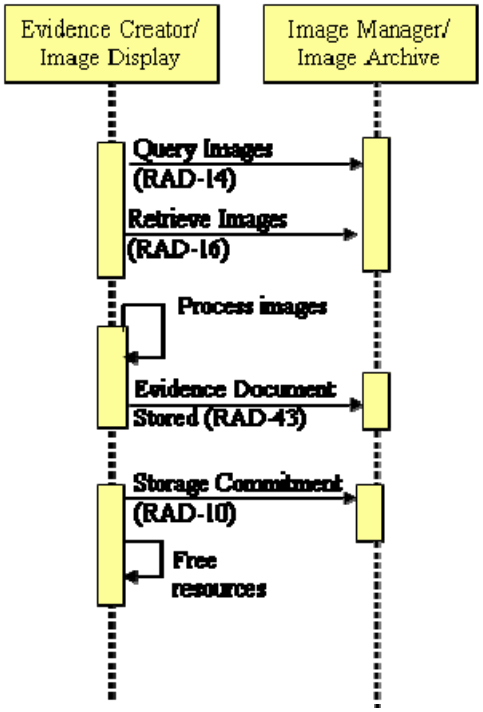


*Figure 3.2.3-Pathology General Workflow with post processing*

# 4 Use cases

## 4.1 Use case 1: Surgical pathology – Operative specimen

### *4.1.1 Use case 1.1: Surgical pathology - one specimen per container*

Luke Lung visits Sammy Surgeon for removal of a lung tumor. Sammy Surgeon orders the Requested Procedure "Lungectomy - Pathological examination" and sends six parts. A rough drawing and a vocal message are attached to the order (see PAT-1 in vol 2).

The **Order Filler** automatically accessions the Requested Procedure DP07110 (Accession Number). Terri Technician prints labels DP07110-A for "Left upper lobe", DP07110-B for "Upper division left upper apical posterior & anterior segments", DP07110-C for "AP Window, posterior lymph node biopsy", DP07110-D for "Anterior AP window, lymph node biopsy", DP07110-E for "12L, lymph node biopsy", DP07110-F for "Lymph node biopsy designated 8". The **Order Filler** sends to the **Order Placer** the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

The pathology department staff performs a macroscopic examination of the specimens and processes part A for frozen section examination. After frozen section examination, the pathologist sends preliminary observations. The **Order Filler** sends the observations and/or a report and the status to the **Order Result Tracker** (see PAT-3 in vol 2).

The day after, the pathologist performs a macroscopic examination of the specimens and processes specimens for tissue banking and/or microscopic examination. Table 4.1.1 depicts the sampling process of the specimens.

Table 4.1.1: Use Case 1.1 - Sampling process (one specimen per container)

| Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID |
|---|
| P072345: LUNG Luke |
| OR123: Lungectomy |
| DP07110 : Lungectomy |
| **DP07110-A: Left upper lobe (gross image)** |
| DP07110-A-1: Frozen section, mass |
| DP07110-A-1-1: FS |
| DP07110-A-1-2: H&E |
| DP07110-A-2: Entire stapled |
| DP07110-A-2-1: H&E |
| DP07110-A-3: Entire stapled |
| DP07110-A-3-1: H&E |
| DP07110-A-4: Entire stapled |
| DP07110-A-4-1: H&E |
| DP07110-A-5: Entire mass |
| **DP07110-A-5-1: H&E (WSI)** |
| DP07110-A-5-2: Elastic |
| DP07110-A-6: Entire mass |
| DP07110-A-6-1: H&E |
| DP07110-A-6-2: Elastic |
| DP07110-A-7: Unvolved lung tissue |
| DP07110-A-7-1: H&E |
| DP07110-A-8: Unvolved lung tissue |
| DP07110-A-8-1: H&E |
| DP07110-B: Upper division left upper apical posterior & anterior segments |
| DP07110-B-1: Vascular margin |
| DP07110-B-1-1: H&E |

DP07110-B-2: Bronchial margin
DP07110-B-2-1: H&E
DP07110-B-3: Stapled line margin
DP07110-B-3-1: H&E
DP07110-B-4 : Stapled line margin
DP07110-B-4-1: H&E
DP07110-B-5: Stapled line margin
DP07110-B-5-1: H&E
DP07110-B-6 : Lung tissue representative
DP07110-B-6-1: H&E
DP07110-B-7 : Lung tissue representative
DP07110-B-7-1: H&E
DP07110-B-8 : Lung tissue representative
DP07110-B-8-1: H&E
DP07110-C: AP Window, posterior lymph node biopsy
DP07110-C-1: Embedded entirely
DP07110-C-1-1: H&E
DP07110-D: Anterior AP window, lymph node biopsy
DP07110-D-1: Embedded entirely
DP07110-D-1-1: H&E
DP07110-E: 12L, lymph node biopsy
DP07110-E-1: Embedded entirely
DP07110-E-1-1: H&E
DP07110-F: Lymph node biopsy designated 8
DP07110-F-1 : Embedded entirely
**DP07110-F-1-1: Level 1, H&E (WSI)**
DP07110-F-1-2: Level 2, H&E

Gross imaging is performed on Part A "Left upper lobe" (***DP07110-A: Left upper lobe***). The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2). While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

Microscopic imaging is performed on two slides (***DP07110-A-5-1: Left upper lobe/Entire mass/H&E*** *and* ***DP07110-F-1-1: Lymph node biopsy 8/Embedded entirely/Level1,H&E***). The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2). While performing images, a new STUDY and a new SERIES are created, stored in the Image **Archive** and available for the **Image Display**.

**IMPORTANT NOTE : In conformance with DICOM supp122, the short textual description of a specimen retrieved from the Order Filler is a concatenation of the short description of the specimen and all the short descriptions of all the ancestries**

Example for the short description of the slide ***DP07110-A-5-1***
DP07110-A: Left upper lobe
DP07110-A-5: Left upper lobe/Entire mass
**DP07110-A-5-1: Left upper lobe/Entire mass/H&E (WSI)**

Example for the the short description of the slide ***DP07110-F-1-1***
DP07110-F: Lymph node biopsy designated 8
DP07110-F-1; Lymph node biopsy designated 8/Embedded entirely
**DP07110-F-1-1: Lymph node biopsy 8/Embedded entirely/Level1,H&E (WSI)**

**In conformance with DICOM supp122, the same concatenation principle is applied to detailed textual specimen description**

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Placer** and the **Order Result Tracker** with up-to-date information and statuses of the order (see PAT-1 and PAT-3 in vol 2).

### *4.1.2 Use case 1.2: Surgical pathology - more than one specimen per container*

Barbara Breast visits Sammy Surgeon for removal of a breast tumor. Sammy Surgeon orders the Requested Procedure "Breast surgical specimen with axillary lymph node - Frozen sections & pathological examination" and sends six parts. A rough drawing and a vocal message are attached to the order (see PAT-1 in vol 2).

The **Order Filler** automatically accessions the Requested Procedure DP07120. Terri Technician prints labels DP07120-A for "Tumorectomy", DP07120-B for "Lymph node 1" and DP07120-C for "Lymph node 2". The **Order Filler** sends to the **Order Placer** the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

The pathology department staff performs a macroscopic examination of the specimens.

Gross imaging is performed on Part A "Tumorectomy" (***DP07120-A: Tumorectomy*****)**. The technician queries the **Order Filler** to retrieve the information about the specimen and the the Requested Procedure (see PAT-5 in vol 2). While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

The day after, the pathologist performs a macroscopic examination of the specimens and processes specimens for tissue banking and/or microscopic examination. Table 4.1.2 depicts the sampling process of the specimen.

Table 4.1.2: Use Case 1.2 - Sampling process (more than one specimen per container)

Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID

P0723456: BREAST Barbara
OR234 : Breast surgical specimen with axillary lymph node - Frozen sections & pathological examination
DP07120 : Tumorectomy and lymphectomy
**DP07120-A: Tumorectomy (gross image)**
DP07120-A-1: Tumor, frozen section
DP07120-A-1-1: Toluidine blue
DP07120-A-1-2: HE
DP07120-A-1-3: Paraffin, HE
DP07120-A-2: Tumor, fresh sample
DP07120-A-3: Tumor, mirror paraffin blocks
DP07120-A-3-1: HE
DP07120-A-3-2: HER2
DP07120-A-4 : Tumor
**DP07120-A-4-1: HE, level1&level2 (WSI)**
DP07120-A-5: Upper margin, red ink
DP07120-A-5-1: HE
DP07120-A-6: Lower margin, blue ink
DP07120-A-6-1: HE
DP07120-A-7: Adjacent breast tissue
DP07120-A-7-1: HE
DP07120-B: Axillary lymph node1
DP07120-C: Axillary lymph node 2
DP07120-BC-1: Axillary lymph nodes 1-Axillary lymph node 2/Entire
DP07120-BC-1*1 Axillary LN1-Axillary LN 2/Entire*Lymph node 1
DP07120-BC-1*2 Axillary LN1-Axillary LN 2/Entire *Lymph node 2
DP07120-BC-1-1: Axillary LN1-Axillary LN 2/Entire/HE
**DP07120-BC-1-1*1: HE*Lymph node 1 (WSI)**
DP07120-BC-1-1*2: LN1-LN2/Entire/HE*Lymph node 2

Microscopic imaging is performed on slide (***DP07120-A-4-1***: ***Tumorectomy/Tumor/HE, level1&level2).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

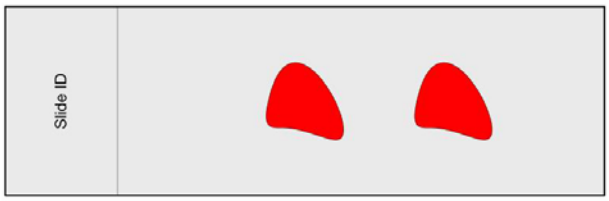


*Figure 4.1.2-1: Two tissue items come from the same tissue in block but different levels. IN this example, specimen ID and Container ID are the same (DP07120-A-4-1).*

Microscopic imaging is performed on slide (***DP07120-BC-1-1*1 Axillary lymph nodes 1-Axillary lymph node 2/Entire/HE*Lymph node 2).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

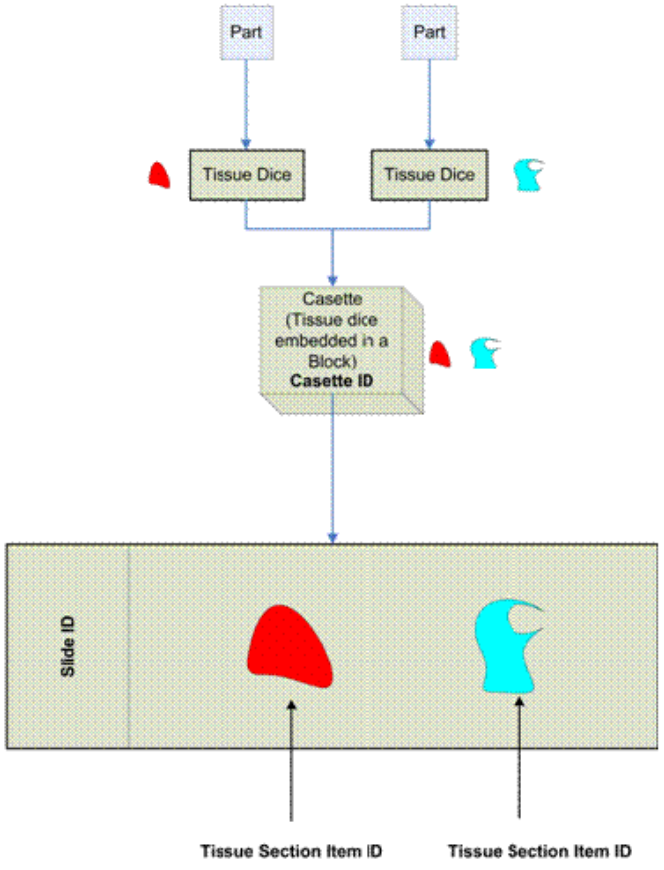


*Figure 4.1.2-2: Two tissue items come from the same tissue in block (DP07120-BC-1) but from two different parts B and C. Specimen ID (DP07120-BC-1-1*1 and DP07120-BC-1-1*2) and Container ID (DP07120-BC-1-1) are different.*

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Placer** and the **Order Result Tracker** with up-to-date information and statuses of the order (see PAT-1 and PAT-3 in vol 2).

### *4.1.3 Use case 1.3: Surgical pathology – two requested procedure per order*

Table 4.1.3 depicts the sampling process of the specimen.

P0734567: NAEVUS Natalia
OR345: Breast tumorectomy and naevus
DP07130 : Tumorectomy and lymphectomy
DP07130-A: Tumorectomy
**DP07130-A-1: Tumor (gross image)**
DP07130-A-1-1: HE
DP07130-A-2: Tumor
DP07130-A-2-1: HE
DP07130-A-3: Tumor
DP07130-A-3-1 DP07130-A-3-1 Tumorectomy/Tumor/HE
DP07130-A-4: Upper margin, red ink
**DP07130-A-4-1: Tumorectomy/Upper margin, red ink/HE (WSI)**
DP07130-A-5: Lower margin, blue ink
DP07130-A-5-1: HE
DP07140 : Naevus excision
DP07140-A: Naevus
DP07140-A-1: Entirely embedded
**DP07140-A-1-1: Naevus/Entirely embedded/HE (WSI)**

### *4.1.4 Use case 1.4: Surgical pathology – creating an order in the Order Filler*

Peter Patient visits Sammy Surgeon for removal of a naevus. Sammy Surgeon sends the naevus to the pathology department without any order.

Terri Technician accessions a new Requested Procedure “Naevus - Pathological examination” DP07140 in the **Order Filler**. The **Order Filler** sends to the **Order Placer** the order, Requested Procedure and specimen(s) conformance statuses (see PAT-2 in vol 2).

## 4.2 Use case 2: Surgical pathology – Biopsies

### *4.2.1 Use case 2.1: Biopsies – one specimen per container*

Pakkun Patient visits Eisaku Endoscopist for endoscopy examination of Stomach and Duodenum. During the observation, Eisaku Endoscopist finds doubtful places of malignancy. Eisaku Endoscopist performs biopsies from the two organs. Eisaku Endoscopist orders the Requested Procedure “Stomach and Duodenum biopsy specimen - Pathological examination” and sends 4 parts: 2 “Endoscopic biopsies of Stomach” and 2 “Endoscopic biopsies of Duodenum”. A rough drawing of collected places of organs is attached to the order (see PAT-1 in vol 2).

The **Order Filler** automatically accessions the Requested Procedure DP07210. Terri Technician prints labels DP07210-A for “Fundus”, DP07210-B “Antrum”, DP07210-C for “D1”, DP07210-D for “D2”.

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

The technician processes the specimens. Table 4.2.1 depicts the sampling process of the specimen.

Table 4.2.1: Use Case 2.1 - Sampling process (one specimen per container)

| Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID |
|---|
| P0745678: PATIENT Pakkun |
| OR456: Endoscopic biopsies of Stomach and Duodenum - Pathological examination |
| DP07210 : Endoscopic biopsies of Stomach and Duodenum |
| DP07210-A: Fundus |
| DP07210-A-1: Entirly embedded |
| **DP07210-A-1-1: HE (WSI)** |
| DP07210-B: Antrum |
| DP07210-B-1: Entirly embedded |
| DP07210-B-1-1: HE |
| DP07210-C: D1 |
| DP07210-C-1: Entirly embedded |
| DP07210-C-1-1: HE |
| DP07210-D: D2 |
| DP07210-D-1: Entirly embedded |
| DP07210-D-1-1: HE |

Microscopic imaging is performed on the slide (***DP07210-A-1-1 Fundus/Entirly embedded/HE).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**. After image interpretation, the pathologist sends structured observations. The **Order Filler** sends the observations to the **Order Result Tracker** and provides the **Order Placer** and **Order Result Tracker** with up-to-date information and statuses of the order (see PAT-1 and PAT-3 in vol 2).

### *4.2.2 Use case 2.2: Biopsies – more than one specimen per container*

Pakkun Patient visits Eisaku Endoscopist for endoscopy examination of Stomach and Duodenum. During the observation, Eisaku Endoscopist finds doubtful places of malignancy. Eisaku Endoscopist performs biopsies from the two organs. Eisaku Endoscopist orders the Requested Procedure “Stomach and Duodenum biopsy specimen - Pathological examination” and sends 6 parts in one 6 partitioned tissue cassette: “Endoscopic biopsies of Stomach” and “Endoscopic biopsies of Duodenum”. A rough drawing of collected places of organs is attached to the order (see PAT-1 in vol 2).

The **Order Filler** automatically accessions the Requested Procedure DP07220. Terri Technician prints labels DP07220-A for “Fundus”, DP07220-B for “Fundus”, DP07220-C “Antrum”, DP07220-D for “Antrum”, DP07220-E for “D1”, DP07220-F for “D2”.

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

The technician processes the specimens. Table 4.1.2 depicts the sampling process of the specimen.

Table 4.1.2: Use Case 1.2 - Sampling process (more than one specimen per container)

| Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID |
|---|
| P0745678: PATIENT Pakkun |
| OR456: Endoscopic biopsies of Stomach and Duodenum - Pathological examination |
| DP07220 : Endoscopic biopsies of Stomach and Duodenum |
| DP07220-A: Fundus |
| DP07220-B: Fundus |
| DP07220-C: Antrum |
| DP07220-D: Antrum |

DP07220-E: D1
DP07220-F: D2
DP07220-ABCDEF-1: Entirely embedded
DP07220-ABCDEF-1-1: HE
**DP07220-ABCDEF-1-1*1: HE*Fundus (WSI)**
**DP07220-ABCDEF-1-1*2: HE*Fundus (WSI)**
DP07220-ABCDEF-1-1*3: HE*Antrum
DP07220-ABCDEF-1-1*4: HE*Antrum
DP07220-ABCDEF-1-1*5: HE*D1
DP07220-ABCDEF-1-1*6: HE*D2

Microscopic imaging is performed on two slides (DP07220-ABCDEF-1-1*1: Fundus-Antrum-D1-D2/Entirly embedded/HE*Fundus and DP07220-ABCDEF-1-1*2: Fundus-Antrum-D1-D2/Entirly embedded/HE*Fundus). The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

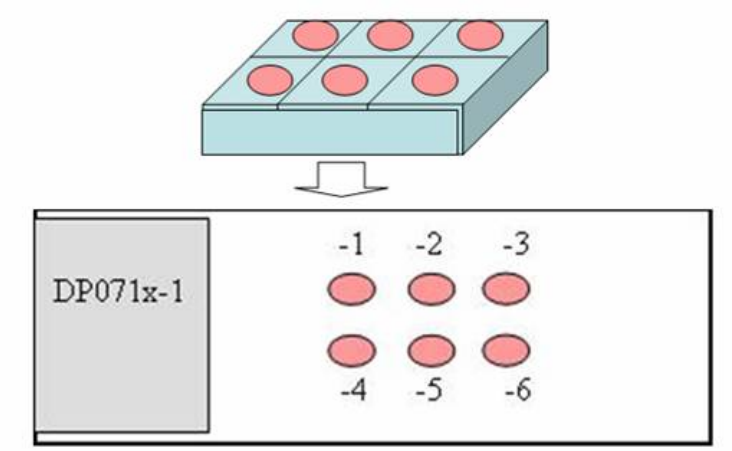


*Figure 4.2.2: Six tissue items come from the same tissue cassette but different organs. Specimen ID (DP07220-ABCDEF-1-1*1, DP07220-ABCDEF-1-1*2, DP07220-ABCDEF-1-1*3, DP07220-ABCDEF-1-1*4,DP07220-ABCDEF-1-1*5,DP07220-ABCDEF-1-1*6) and Container ID (DP07220-ABCDEF-1-1) are different.*

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends structured observations. The **Order Filler** sends the observations to the **Order Result Tracker** and provides the **Order Placer** and **Order Result Tracker** with up-to-date information and statuses of the order (see PAT-1 and PAT-3 in vol 2).

## 4.3 Use case 3: Cytology

### *4.3.1 Use case 3.1: Cytology – one specimen per container*

Bernard Bronchus visits Paul Pneumologist to receive a bronchoscopy with cytological examination. During the bronchoscopy two samples are taken. The material from Bronchus S1 is placed on a glass slide and the material from Bronchus S1 is placed into a test tube. Paul Pneumologist orders the requested procedure – Cytology using the **Order Placer** and sends the glass slide and test tube to the Pathology Department (see PAT-1 in vol 2).

790 The **Order Filler** automatically accessions the Requested Procedure DP07310. Terri Technician prints labels DP07310-A for "Bronchus S1" and DP07310-B for "Bronchus S5".
792 The **Order Filler** sends to **the Order Placer** the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

794 The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

796 *In case of the automated slide scanning, the **Order Filler** sends a message to the **Acquisition Modality**.*

798 The pathologist processes specimens for microscopic examination. Table 4.3.1 depicts the sampling process of the specimen.

800 Table 4.3.1: Use Case 3.1 - Sampling process (one specimen per container)

| Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID |
|---|
| P0756789: BRONCHUS Bernard |
| OR567: Bronchoscopy with cytological examination |
| DP07310 : Cytology |
| DP07310-A: Bronchus S1 |
| **DP07310-A-1: HE (WSI)** |
| DP07310-B: Bronchus S5 |
| DP07310-B-1: HE |
| **DP07310-B-2: HE (WSI)** |
| DP07310-B-3: HE |
| DP07310-B-4: HE |

802 Microscopic imaging is performed on two slides (***DP07310-A-1 Bronchus S1/HE and DP07310-B-2: Bronchus S5/HE***). The technician queries the **Order Filler** to retrieve the
804 information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image**
806 **Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the
808 report to the **Order Result Tracker** and provides the **Order Result Tracker** and the **Order Placer** with up-to-date information and statuses of the order and the report (see PAT-1 and
810 PAT-3 in vol 2).

### *4.3.2 Use case 3.2: Cytology – more than one specimen per container*

812 Catherine Cervix visits Gina Gynecologist for a routine cytological screening test. Gina Gynecologist takes samples from the different regions and distributes the specimen with the
814 brush in different directions. Both samples are on the same glass slide. Gina Gynecologist orders the requested procedure: "gynaecological cytology" using the **Order Placer** and sends
816 the glass slide to the Pathology Department (see PAT1 in vol 2).

The Department of Pathology receives a glass slide and confirms the conformance of
818 specimen. The **Order Filler** sends to the Order Placer the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

820 The **Order Filler** automatically accessions the Requested Procedure DP07320. Terri Technician prints labels DP07320-AB-1 for "Cervix and Vagina".

822 The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

*In case of the automated slide scanning, the **Order Filler** sends a message to the **Acquisition Modality**.*

The pathologist processes the glass slide for microscopic examination. Table 4.3.2 depicts the sampling process of the specimen.

Table 4.3.2: Use Case 3.2 – Sampling process (more than one specimen per container)

| Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID |
|---|
| P0767890: CERVIX Catherine<br>OR678: Gynecological cytology<br>DP07320 : Gynecological cytology<br>DP07320-AB-1: Cervix-Vagina<br>**DP07320-AB-1*1: PAP*1**<br>**DP07320-AB-1*2: PAP*2** |

Microscopic imaging is performed on specimens on slide (***DP07320-AB-1*1: Cervix-Vagina/PAP*1 and DP07320-AB-1*2: Cervix-Vagina/PAP*2)***. The technician queries the **Order Filler** to retrieve the information about the specimens and the Requested Procedure (see PAT-3 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Result Tracker** and the **Order Placer** with up-to-date information and statuses of the order and the report (see PAT-1 and PAT-3 in vol 2).

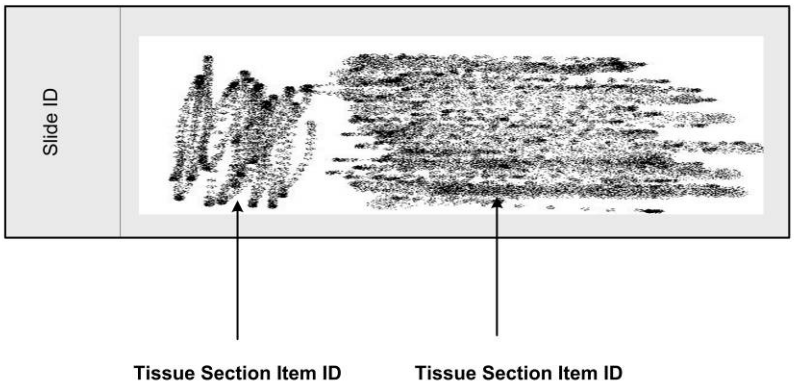


Figure 4.3.2: Two tissue items come from different organs. Specimen ID (DP07320-AB-1*1 (cervix), DP07320-AB-1*2 (vagina)) and Container ID (DP07320-AB-1) are different.

## 4.4 Use case 4: Autopsy

Pauline Patient is died in the hospital. Resident physician want to confirm the diagnosis and the treatment quality by an autopsy and sends a order to the Pathology Department using the **Order Placer**. The order contains the identification data of the patient, the causes of death and the request for an autopsy and is send to the **Department System Scheduler** (**Order Filler**) (see PAT-1 in vol 2).

The **Department System Scheduler** (**Order Filler**) automatically accessions the requested procedure A07400.

The pathologist performs the autopsy, collects some specimen and writes a preliminary report.

Terri Technician prints labels A07400-A for Heart Left Ventricle, A07400-B for Heart Right Ventricle, A07400-C for Liver, and A07400-D for Left kidney. The **Order Filler** sends to the **Order Placer** the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

The day after, the pathologist performs a macroscopic examination of the specimens and processes specimens for tissue banking and/or microscopic examination. Table 4.4 depicts the sampling process of the specimen.

Table 4.4: Use Case 4 - Sampling process

| Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID |
|---|
| P0713579: Pauline Patient |
| OR135: Autopsy |
| A07400: Autopsy |
| **A07400-A: Heart Left Ventricle (gross image)** |
| A07400-A-1: Necrosis |
| **A07400-A-1-1: HE (WSI)** |
| A07400-B: Heart Right Ventricle |
| A07400-B-1: Undefined |
| A07400-B-1-1: HE |
| A07400-C: Liver |
| A07400-C-1: Node: HE |
| A07400-D: Left kidney |
| A07400-D-1: Undefined |
| **A07400-D-1-1: HE (WSI)** |

Gross imaging is performed on Part A "Left upper lobe" (***DP07400-A: Heart Left Ventricle***). The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

Microscopic imaging is performed on slide (***A07400-A-1-1: Heart Left Ventricle/Necrosis/HE*** and ***A07400-D-1-1: Left kidney/Undefined/HE).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Result Tracker** and the **Order Placer** with up-to-date information and statuses of the order and the report (see PAT-1 and PAT-3 in vol 2).

## 4.5 Use case 5: Tissue Micro Array (more than one specimen from more than one patient per container) (under construction)

Slides created from TMA block have small fragments of many different tissues coming from different patients all of which may be processed at the same time, under the same conditions by a desired technique. These are typically utilized in research.

The **Specimen (spot) ID** must be different from the Container (TMA Slide) ID. If the TMA slide is imaged, a single image must be created for each spot. A complete view of the TMA slide is created only as an "index" low resolution image

Table 4.5: Use Case 5 - TMA process (more than one specimen per container)

| Patient ID / Order ID / Case ID (OF) / Part ID / Donor Block ID/(TMA Block ID)-Core ID/(Slide ID)-Spot ID |
|---|
| P072345 : LUNG Luke<br>DP07100 : Lungectomy : Left upper lobe<br>DP07110-A-5 : Left upper lobe/Entire mass<br>DP-TMA510/DP07110-A-5: Left upper lobe/Entire mass<br>**DP-TMA510-1/DP07110-A-5: Left upper lobe/Entire mass/H&E (spot)** |

Microscopic imaging is performed on spot of the TM slide (***DP-TMA510-1/DP07110-A-5: Left upper lobe/Entire mass/H&E).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Result Tracker** and the **Order Placer** with up-to-date information and statuses of the order and the report (see PAT-1 and PAT-3 in vol 2).

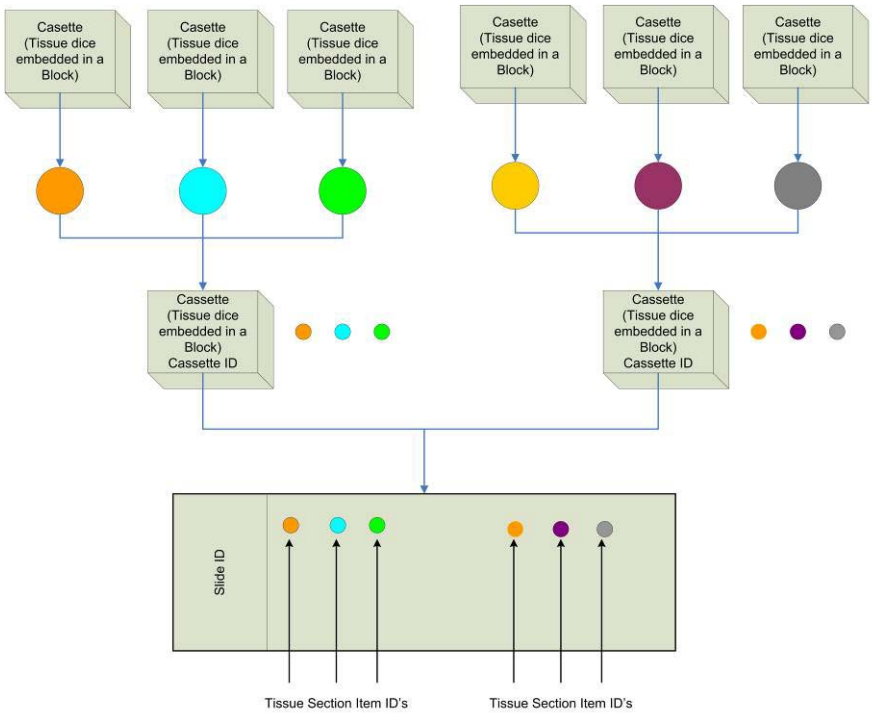


*Figure 4.5: Spots come from the same TMA block (DP-TMA510) but different donor blocks, parts and patients. Specimen ID (DP-TMA510-1/DP07110-A-5) and Container ID (DP-TMA510-1/) are different.*

# 5 Appendix

## 5.1 Appendix A: Orders, requested procedures, Procedure steps

There are multiple information systems involved in the fulfillment of the orders directed to the Department of Pathology (and sent to the Pathology Information System (PIS))

The **order** for the pathological examination is communicated between the Order Placer (of the Order Entry system) and the Order Filler (of the PIS). In the pathology department environment, the Order Filler identifies the set of procedures and sub-procedures (procedure steps) that have to be performed in the process of fulfilling the order.

Each Order is identified by an Order ID. **Required information associated to the order** are: patient and visit identification (PID, name, visit number …), order identification (Order Placer and Order Filler ID), order date & time, identification of the ordering physician and of the ordering care department (including call back telephone number), identification of the collector, identification of the care unit of the patient (if different from the ordering care department), results status, priority of the order, (date & time when the results are expected to be available). Required information related to the specimen is described in Appendix B.

Each order may contain one or more **Requested Procedure** possibly reported by different pathologists. A Requested Procedure is a unit of work resulting in one report with associated codified, billable acts. Each Requested Procedure is identified by a Requested Procedure ID (**Accession Number**).

For each Requested Procedure, the basic or special techniques involved in the processing of the corresponding specimen(s) may require different devices (automatons, image acquisition modality, etc). Each Requested Procedure may contain one or more Procedure Steps. A Procedure Step is the smallest unit of work in the workflow that is scheduled (work to do) and/or performed (work done) by a person or a machine (automaton, image acquisition modality, etc) on an object (specimen, tissue sample, tissue section, etc)

The concept of an "Accession Number" in Pathology has been determined to be sufficiently equivalent to an "Accession Number" in Radiology that the DICOM data element "Accession Number" at the Study level at the DICOM information model may be used for the Pathology Accession Number with essentially the existing definition.

It is understood that the value of the laboratory accession number is often incorporated as part of a Specimen ID. However, there is no presumption that this is always true, and the Specimen ID should not be parsed to determine an accession number. The accession number will always be sent in its own discrete attribute.

## 5.2 Appendix B: Specimen model

This section comes from joint efforts from DICOM WG26, HL7 Pathology SIG and IHE Pathology (see SS2.1 DICOM Supp 122-v.13)

### *5.2.1 Basic concepts and definition*

- Specimen

A physical object (or a collection of objects) is a specimen when the laboratory considers it a single discrete, uniquely identified unit that is the subject of one or more steps in the laboratory (diagnostic) workflow.

To say the same thing in a slightly different way: "Specimen" is defined as a role played by a physical entity (one or more physical objects considered as single unit) when the entity is identified uniquely by the laboratory and is the direct subject of more steps in a laboratory (diagnostic) workflow.

- Container

Specimen containers (or just "containers") play an important role in laboratory (diagnostic) processes. In most, but not all, process steps, specimens are held in containers, and a container

often carries its specimen's ID. Sometimes the container becomes in intimately involved with the specimen (e.g. a paraffin block), and in some situations (such as examining tissue under the microscope) the container (the slide and coverslip) become part of the optical path.

Containers have identifiers that are important in laboratory operations and in some imaging processes (such as whole slide imaging). In many laboratories where there is one specimen per container, the value of the specimen ID and container ID will be same. However, there are use cases in which there are more than one specimen in a container. In those situations, the value of the container ID and the specimen IDs will be different.

### *5.2.2 Laboratory workflow and specimen types*

In typical anatomic pathology practice, and in Laboratory Information Systems, there are conventionally three identified levels of specimen preparation – part, block, and slide. These terms are actually conflations of the concepts of specimen and container. Not all processing can be described by only these three levels.

A part is the uniquely identified tissue or material collected from the patient and delivered to the pathology department for examination. A box is a container for a part, and conveys the part unique identifier. Examples of parts would include a lung resection, colon biopsy at 20 cm, colon biopsy at 30 cm, peripheral blood sample, cervical cells obtained via scraping or brush, etc.

A block is a uniquely identified container, typically a cassette, containing one or more tissue dice. A dice is a sampling of a part. The tissue dice may optionally be separately identified, although most LIS do not presently have this capability.

A slide is a uniquely identified container, typically a glass microscope slide, containing tissue or other material. Common slide preparations include:

- "Tissue sections" created from Tissue Dice embedded in blocks. (1 slide typically corresponds to a tissue section coming from one block)
- "Touch preps" prepared by placing a slide into contact with unprocessed tissue.
- "Dispersions" are a thin layer of cells created from a suspension.

### *5.2.3 Relationship between Specimens and Containers*

Virtually all specimens in a clinical laboratory are associated with a container, and specimens and containers are both important in imaging. In most clinical laboratory situations there is a one to one relationship between specimens and containers. In fact, pathologists and LIS systems routinely consider a specimen and its container as single entity; e.g. the slide (a container) and the tissue sections (the specimen) are considered a single unit.

However, there are legitimate use cases in which a laboratory may place two or more specimens in the same container (see Section 5.2.4 for examples).

Some Laboratory Information System may, in fact, not support multiple specimens in a container, i.e., they manage only a single identifier used for the combination of specimen and container. This is not contrary to the DICOM Standard; images produced under such a system will simply always assert that there is only one specimen in each container. However, a pathology image display application that shows images from a variety of sources must be able to distinguish between container and specimen IDs, and handle the 1:N relationship.

In the DICOM Specimen Module, in allowing for one container to have multiple specimens, the Specimen Module asserts that it is the Container, not the Specimen, that is the unique

target of the image. In other words, one Container ID is required in the Specimen Module, and multiple Specimen IDs are allowed in the Specimen Sequence.

In the HL7 v2.5 SPM-Specimen segment, the SAC segment should be used only if the number of containers differs from the number of specimens (e.g. a specimen is split between several containers or multiple specimens placed in or on the same container). Otherwise, when there is one container for one specimen the SPM segment is sufficient and the SPM-2 Specimen ID provides both the specimen/container identifier. In case of multiple specimens placed in or on the same container, the message will contain as many SPM segment as specimens. All SPM segments will have the same Container ID but different Specimen ID. In case of a specimen split between several containers, the SPM segments will include multiple SAC segments with different Container ID.

### *5.2.4 Specimen identification examples*

- One Specimen Per Container

In normal clinical practice, when there is one specimen per container, the value of the specimen identifier and the value of the container identifier will be the same. In Figure 5.2.4-1, each slide is prepared from a single tissue sample from a single block (cassette).

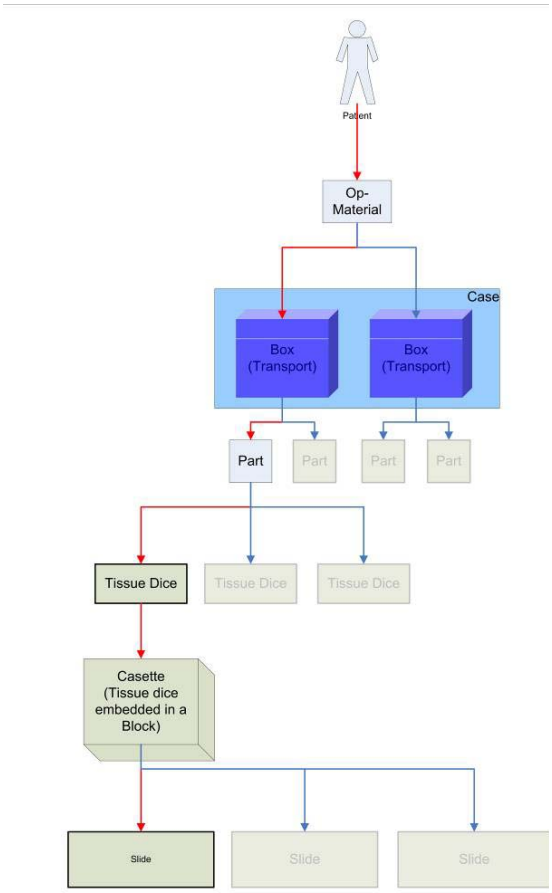


*Figure 5.2.4-1 Sampling for one specimen per container*

- Multiple Items From Same Block

Figure 5.2.4-2 shows more than one tissue item on the same slide coming from the same block (but cut from different levels). The laboratory information system considers two tissue sections (on the same slide) to be separate specimens.

Two Specimen ID's will be assigned, different from the Container (Slide) ID. The specimens may be localized, for example, by descriptive text "Left" and "Right".

If the slide is imaged, a single image with more than one specimen may be created. In this case, both specimens must be identified in the Specimen Sequence of the Specimen Module. If only one specimen is imaged, only its Specimen ID must be included in the Specimen Sequence; however, both IDs may be included (e.g., if the image acquisition system cannot determine which specimens in/on the container are in the field of view).

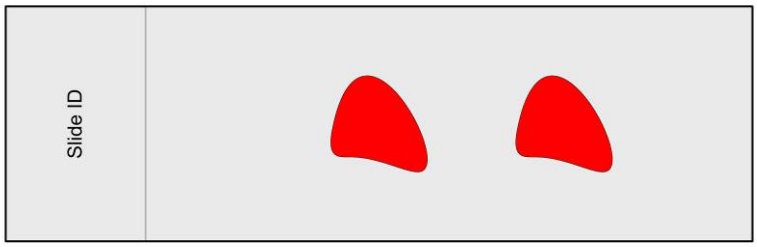


*Figure 5.2.4-2 Container with two specimens from same parent*

- Items From Different Parts in the Same Block

Figure 5.2.4-3 shows processing where more than one tissue item is embedded in the same block within the same Cassette, but coming from different clinical specimens (parts). This may represent different lymph nodes embedded into one cassette, or different tissue dice coming from different parts in a frozen section examination, or tissue from the proximal margin and from the distal margin, and both were placed in the same cassette. Because the laboratory wanted to maintain the sample as separate specimens (to maintain their identity), the LIS gave them different IDs and the tissue from Part A was inked blue and the tissue from Part B was inked red.

The specimen IDs must be different from each other and from the container (cassette) ID. The specimens may be localized, for example, by descriptive text "Red" and "Blue" for Visual Coding of Specimen.

If a section is made from the block, each tissue section will include fragments from two specimens (red and blue). The slide (container) ID will be different from the section id (which will be different form each other).

If the slide is imaged, a single image with more than one specimen may be created but the different specimens must be identified and unambiguously localized within the container.

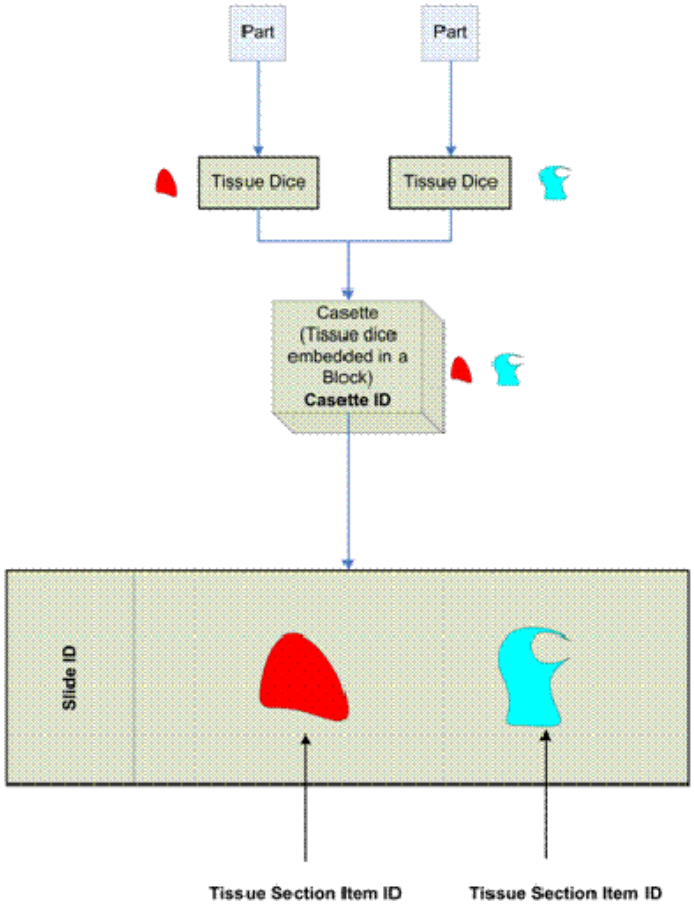


*Figure 5.2.4-3 Sampling for two specimens from different ancestors*

- Items From Different Parts on the Same Slide

Figure 5.2.4-4 shows the result of two tissue collections placed on the same slide by the surgeon (e.g in gynecological smears the different directions of smears represent different parts (portio, cervix).

The specimen IDs must be different from each other and from the container (slide) ID. The specimens may be localized, for example, by descriptive text “Short direction smear” and “Long direction smear”.

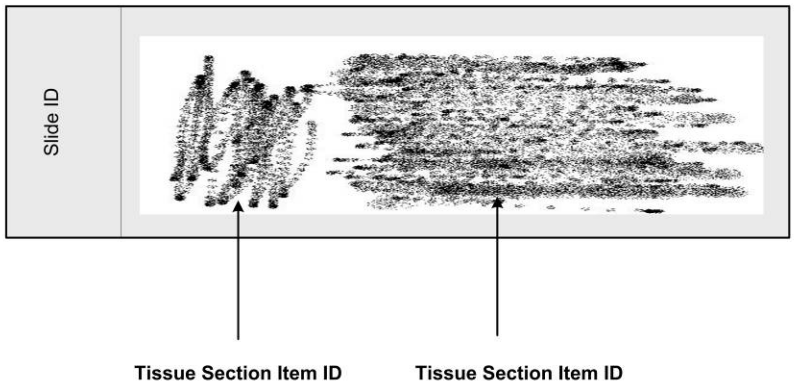


*Figure 5.2.4-4 Two specimens smears on one slide*

### *5.2.5 Tissue Micro Array*

Slides created from TMA block have small fragments of many different tissues coming from different patients, all of which may be processed at the same time, under the same conditions by a desired technique. These are typically utilized in research. See Figure 5.2.5. Tissue items (spots) on the TMA slide come from different tissue items (cores) in TMA blocks (from different donor blocks, different parts and different patients).

Each Specimen (spot) must have its own ID. The specimens may be localized, for example, by X-Y coordinates, or by a textual column-row identifier for the spot (e.g., “E3” for fifth column, third row).

If the TMA slide is imaged as a whole, e.g., at low resolution as an index, it must be given a “pseudo-patient” identifier (since it does not relate to a single patient). Images created for each spot should be assigned to the real patients.

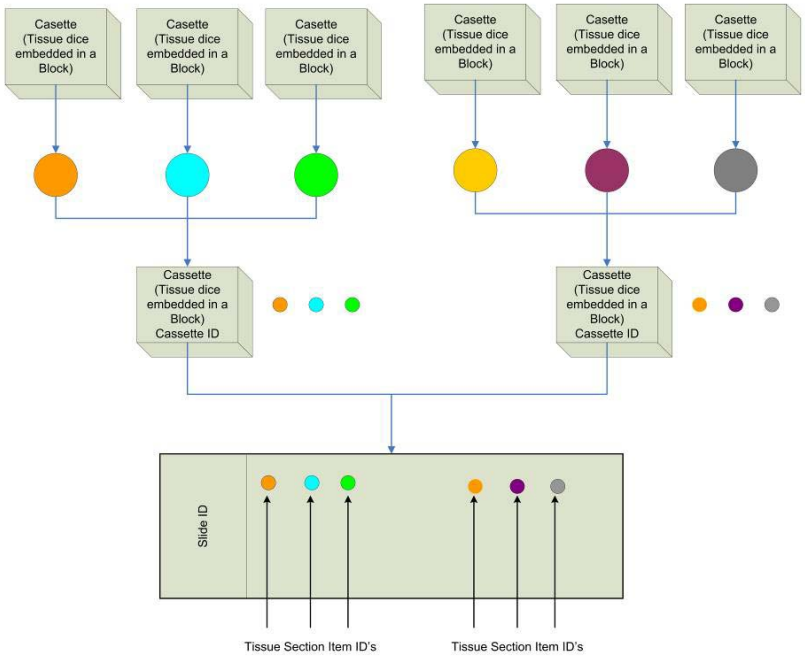


*Figure 5.2.5 Sampling for TMA Slide*

## 5.3 Appendix C: Image

In pathology, the image folder (STUDY) is defined at the level of the Requested Procedure (Study accession number).

For each Requested Procedure, images acquisition may require different modalities (for gross imaging, microscopic images, etc). When an image is acquire from an object (specimen, tissue sample (block), slide, etc) by a new acquisition modality a new SERIES is created.

## 5.4 Appendix D: Report

Observation results progress through different steps of validation:

A **non-validated result** is acquired from some device (flow cytometry, automated image analysis), without any human acceptance.

A **technically validated result** has been accepted by the laboratory technician or cytotechnician who ensures that this result has been obtained through the correct procedures, taking into account quality control results, together with other criteria.

A **pathologist validated result** has been accepted and interpreted by a pathologist. Pathologist validation includes interpretation of the non-validated results or technically-validated results, if available, and morphological and ancillary techniques results. The pathologist considers the consistency of the gross and microscopic findings, with the special techniques, and the available clinical and therapy information.

In pathology, reports are delivered only after pathologist validation.

Since 1993, Association of Directors of Anatomic and Surgical Pathology publishes recommendations for the reporting in many different fields [I]. A generic model of structured report can be derived from these templates. In complement, studies about quality assessment of reports provide lists of mandatory items and stress the positive role of checklists to enhance the reporting process.

The different parts of the pathology report are presented (see CEN TC 251 WI 130.1.1:2003):

A histology report may be divided into sections describing the: macroscopic appearance, microscopic features and the conclusion of the service provider based on these findings. Each of these sections may consist of free-text, measurements (e.g. size, weight etc.) and code values representing the findings.

Different healthcare parties may be responsible for different parts of a report. Furthermore, overall responsibility for reviewing and signing-off the reports may rest with yet another supervisory healthcare party.

According to “evidence-based pathology”, only features that are reproducible and relevant – with a demonstrated diagnostic or prognostic signification – should be reported in description and corresponding evidence available”. A crucial issue is to identify a technical solution to handle templates of structured reports including findings and their evidences.

It must be possible to link each observation or finding to the specimen source (part(s) (Box ID) for macroscopic findings, tissue item (Slide ID) for microscopic findings)). Moreover it must be possible to link each observation or finding to the image(s) or region of interest of image(s) acquired from the specimen source.

Complex diagnostic structured reports include numeric quantitative measurement, images or graphs, image annotation and links between image (and/or evidence) information and textual information. These complex structured reports will be described in future extension of the Technical Framework. The post-processing and evidence creation are described in other integration profiles.