Integrating the Healthcare Enterprise

IHE

IHE Pathology and Laboratory Medicine Technical Framework Supplement

Digital Pathology Workflow – Image Acquisition (DPIA)

Revision 1.0 – Draft for Public Comment

Date: December 12, 2019
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Foreword

This is a supplement to the IHE PaLM Technical Framework 10.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on December 12, 2019 for Public Comment. Comments are invited and can be submitted at https://www.ihe.net/PaLM_Public_Comments. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by January 11, 2020.

This supplement describes changes to the existing technical framework documents.

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

> *Amend Section X.X by the following:*

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

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

Information about the IHE Pathology and Laboratory Medicine domain can be found at ihe.net/IHE_Domains.

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

The current version of the IHE Pathology and Laboratory Medicine Technical Framework can be found at http://ihe.net/Technical_Frameworks.

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Introduction to this Supplement

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The primary function of the Digital Pathology Image Acquisition workflow is to acquire a digital image from a physical asset, usually a glass slide, but possibly also a gross specimen. Recent advancements in whole slide digital imaging technologies serve to significantly alter traditional workflows within pathology laboratories. Digital imaging in pathology typically spans two

160 primary aspects of the conventional workflow, notably the gross / macroscopic examination and the histologic / microscopic examination.

The Digital Pathology Workflow – Image Acquisition (DPIA) Profile defines workflows and messaging transactions which focus on acquisition of a digital asset from a physical asset. These additions update the Technical Framework Volumes 1 and 2.

165 The full clinical Digital Pathology workflow will include other profiles to cover the full spectrum of use cases involved in tissue-based diagnostics.

Open Issues and Questions

Issue 2: We have to check the availability on the market of imaging modalities, PACS, and image reviewing and annotating software solutions, supporting the DICOM®[1] standard with the

170 DICOM 122 supplement "Specimen Module and Revised Pathology SOP Classes" and the DICOM 145 supplement "Whole Slide Microscopic Image IOD and SOP Classes" available on the market?

Vendors that have incorporated functionality from latest DICOM connectathons include:

175
- *Support for acquisition modality (hardware/software) that can generate a DICOM compliant object for archival purposes.*

- *Implemented an image manager/archive, image display functionality that is DICOM compliant.*

- *Support for DICOM compliant objects and standard Radiology transactions for storage in their VNA. Specific IOD support would need to be confirmed.*

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- *Plans to add DICOM support within the next year (slide uploading, slide viewer)*

- *Support for acquisition modality that can output DICOM compliant image objects for archival purposes.*

- *Acquisition manager and image display functionality that is being planned for interoperable support to be DICOM compliant.*

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

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185   •   *Support for acquisition modality that supports output of DICOM compliant image objects for archival purposes.*

Issue 11: Modeling and guidance for Quality Control (QC) processes needs to be addressed.

There are no known industry standards to normalize digital images in a way that minimizes preanalytic variation (i.e., cutting thickness, staining variations, scanner variations, etc.). Once
190 *there is a proposed solution then the profile can be evolved to accommodate it. QA/QC processes exist as best practices in histology laboratories today and should be followed to create consistent digital images at least within a single laboratory. These types of activities are outside the scope of the current profile but should be considered by vendors and laboratories. This issue will be left as an open issue for implementers to consider.*

195 **Issue 14A**: A pathology accession equates to one study. Every DICOM data file per the current specification represents exactly one image. However, the data model supports redundant metadata inclusion in those files so that images that are part of multiple series of images but all associated with a single study (accession) can be appropriately collated and displayed for users. Does this data model need to be modified, for example to accommodate image sort order, which
200 by definition spans multiple slides?
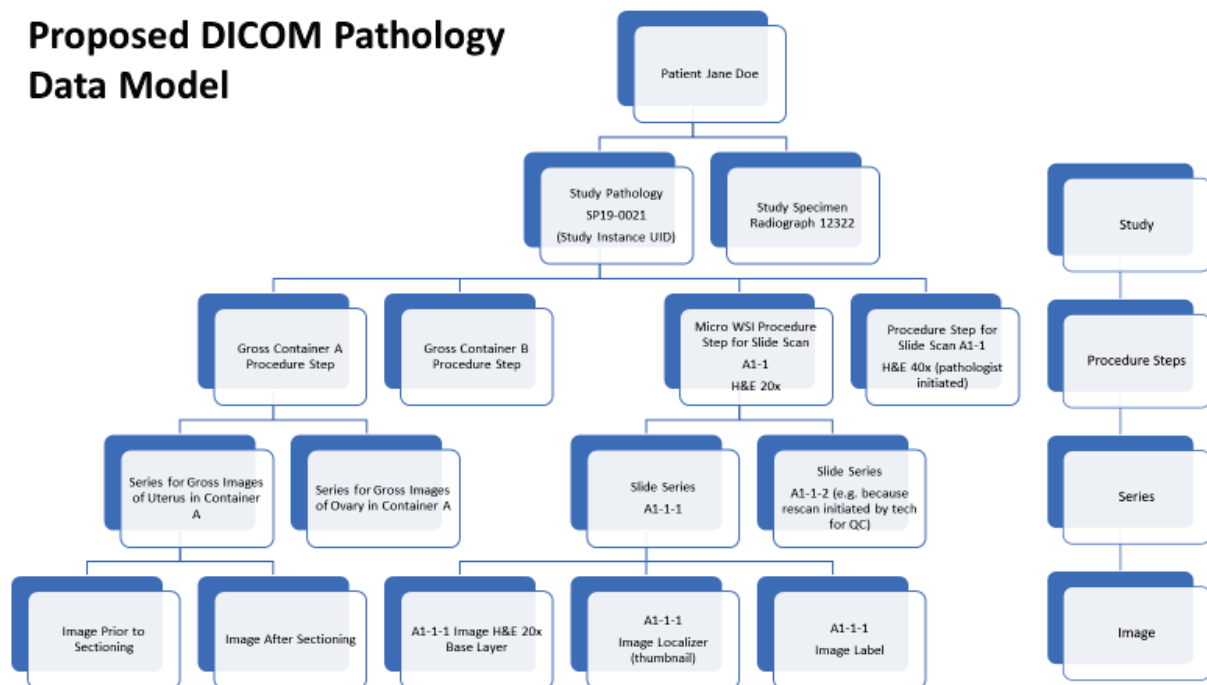
Issue 19: We need a mechanism / guidance to extend this core set of requisite data elements to accommodate additional supplement 122 data elements.

We will provide the DICOM to Specimen DAM mapping in an appendix with examples via OBX segments of how to augment the core set of data in a transaction. To maintain conformance with the profile, language in the profile will provide guidance that standard IHE change request processes should be employed where the profile or underlying standards are insufficient or ambiguous in their implementation. OBX-3 / OBX-5 pairs will be used to support the optional supplement 122 data elements.

Issue 23: Quality Control Image (yes/no) is a DICOM data element that we have not considered. Many glass slides may have on slide or off slide (unlabeled) controls as part of the scanning process. Downstream algorithms might benefit from having color calibration or other QC data available as part of the DICOM object. This might be a process completely outside the scope of this image acquisition profile but this doesn't take advantage of the DICOM object model to store data that might be critical for downstream processing and analysis by machine learning algorithms.

It may be advantageous to return not only the thumbnail of the entire slide, but include separate thumbnails for the label and for an optional on slide positive control tissue. The DICOM object created by the acquisition modality can specify regions of interest that indicate different tissue sections and label image information. Please reference rows 61-68 in the message spreadsheet (https://docs.google.com/spreadsheets/d/12i6hoEjX-h0k11vbg2VE0-jTSI_m42NcfFTlTQMhSH8/edit?usp=sharing).

Issue 25: Should the OBX segments required for the [LAB-80] message fall under the SPM group or under the ORDER group. Falling under the ORDER group matches the paradigm within DPIA.

Issue 27: The observation identifier data field OBX-3 / OBX-5 combination is used to represent name/value pairs of string data to pass over the interface. OBX-4 is a sub-identifier that may be used to pass an additional ordinal to group additional name/value pairs together in an enumerated sequence. This may be the mechanism to support multiple "parts" on the same glass slide, such as a tissue microarray (currently deemed out of scope) or on slide control tissue.

Issue 29: The Barcode field for [LAB-80] will be represented as an OBX-3/5 for trial implementation with request for feedback.

Issue 30: The sort order (display asset sequencing) requirements for digital assets in a digital pathology workflow have currently not been addressed. Requirements likely need to convey the ability to sort order digital assets in different ways, some of which cannot be predicted in advance. Please suggest guidance and what we as an interoperability group should identify as workflow requirements in a digital pathology workflow. The following draft requirements will help to support common workflows:

1. The default sort order is configurable

2. The sort order can be changed to reflect common needs (e.g., show me all the cytokeratin IHC images first, show me the slides flagged for tumor board first, etc.)

3. There is an ability to reset the sort order back to default

4. There is an ability to preserve the sort order across sessions and across users who view the slides (e.g., Pathologist A might rearrange the slides to reflect their area of focus or expertise while another Pathologist B, who might be consulted to review the case, might rearrange some slides. Pathologist C should be able to see either sequence of slides when viewing the case at some later point in time.

5. New digital assets should "fall into" the correct place based on the currently selected sort order "template" but should be readily distinguishable as having been created at some later point to draw attention to the viewer as the sort order may obfuscate this (indeed a required sort order template might be to "show assets in reverse chronological order based on scan date")

6. The sort order mechanism needs to be standardized so that different viewers have the ability to sort in a sequence set by a prior viewer

Issue 31: Only new transactions are to be declared in this IHE overall transaction list. In case we reuse the RAD DICOM transactions as they are, we have only 3 new transactions ([LAB-80], [LAB-81, [LAB-82]). In case we need to define PaLM-specific DICOM transactions to correlate to RAD-8, 10, 107, 129), the numbers will be 83, 84, 85, 86. DICOM WG26 leadership to clarify this need.

Issue 32: Barcode data supplied on the glass slide should uniquely identify that physical asset across all actors in this profile. The barcode ID usually is derived from a unique slide ID with additional delimiter characters (such as a backslash) optionally added as a prefix and suffix. The slide ID is usually created from the case accession number but need not be. The critical requirement is that the slide ID is unique for the physical asset and is somehow linked to a single case accession number. It is assumed that scanner vendors will want to use the slide barcode to programmatically link slide image to case data received from Acquisition Manager. Are there any situations that exist today that present challenges to this paradigm?

Issue 33: DICOM experts are requested to review need / use of ORC-38 (filler order group number) and relationship to study instance UID. Do we need a series instance UID?

Issue 34: We need to include a table listing all supported codes for ORC-5 (HL70038) to convey information such as scanned or deleted (due to technical malfunction or QC failure).

Issue 35: The NTE segments described in this profile are retained for trial implementation but will be discarded if they serve no useful purpose.

Issue 36: The order status ID (ORC-5) needs to be harmonized with HL7[®2] table 0038.

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

Issue 38: For the SPM segment, confirm if the specimen received date/time is helpful as an optional element or should be required (SPM-18).

Issue 39: For the SPM segment, SPM-17 is used to indicate the date/time of collection of the specimen (date of service) on the [LAB-80] message but it is used to indicate the date/time of the scan on the return [LAB-82] message. Other date fields exist within the SPM segment that may be leveraged to prevent confusion.

Closed Issues

Issue 1: Is there an industrial offer to the market, to cover archiving and communication of whole slide images, independent of slide scanner manufacturers?

Yes, vendors do offer such products.

Issue 3: Gross / macroscopic imaging use cases are deferred until greater participation from vendors in this space is achieved. *Confirmed on DICOM call, 5/21/2019.*

Issue 4: Does an acquisition modality report any observations back, other than notifying the status change of its IWOS? An imaging process (DPIA) does not sound like a testing process (DPIA) to me.

An acquisition process is not a "test", but it may be very beneficial to have detail around failed scans (e.g., not able to focus, label not detected) and successful scans (thumbnail, ROI scanned or other data beneficial for the acquisition manager). This may be leveraged as the primary error reporting mechanism specific to the vendor of the acquisition modality. OBX segments shall be used to convey these observations.

Issue 5: Are we sure that some modalities work in Broadcast mode while others work only in query mode? We do not want options.

We must support [LAB-81] to account for physical assets that appear unannounced in the acquisition modality.

Issue 6: The version of HL7 required for the digital pathology profiles.

The required base version is 2.5.1 with pre-adopted features from 2.9 (will be specified in the profiles, for example, unique observation identifiers to carry the thumbnails).

Issue 7: What are the assumptions for this profile regarding the DICOM capability to model tissue from multiple patients on a single slide?

We assume for the sake of this profile that there is only one patient's sample for diagnostic interpretation placed on a given glass slide and this sample is associated with a single tissue block, which itself is derived from a single specimen container. Positive control tissue may optionally be present.

Issue 8: Scanner vendors may need to support a model where images are stored locally for a period of time (potentially hours) before being committed to the Image Archive / Manager. Or

recognize there may be multiple Image Manager / Archive actors as part of a single workflow (e.g., the Pathology Image Archive vs the Enterprise or Radiology Image Archive).

Instrument vendors can temporarily store images however it is necessary. One possible architecture may have a scanner that represents roles of Acquisition Modality, Image Display, Image Manager, and Image Archive. The current IHE profile allows an acquisition modality to optionally leverage DICOM RAD transactions for image storage and commitment.

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Issue 9: Multiple IWOS in queue for the same glass slide at different points of its life cycle (unstained vs stained) will be challenging to solve because there will be no way to match up a static glass slide ID with the correct order ID. For example, an unstained glass ID will have the same ID as that same asset later stained for cytokeratin based on current labeling practices.

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- *Considered but discarded: combining the glass asset ID with the stain / task name to ensure a unique ID for the IWOS. This should require minimal change to the LIS information model given that the slide ID and stain name are already usually printed on the glass slide label. The acquisition modality would not have any way of knowing that the appropriately stained slide is loaded unless the ID + stain name is encoded in the barcode.*

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- *Considered but discarded: consider a "version number" appended to the end of the current slide labeling schema (e.g., unstained may be appended with -1, H&E may be appended with -2, destained might be -3, restain with cytokeratin might be -4).*

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- *Recommendation: should not try to augment identifiers but capture metadata within the order (when the glass slide is re-labeled, the system that relabels will be aware of the new metadata (e.g., new stain name). If multiple sequential scan order step/task are broadcast, the temporal span across which these are submitted should not usually be a problem in discriminating which order in the modality worklist should be executed for a given glass slide.*

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  - *Option 1: All acquisition modalities must monitor all update messages so worklists are up to date (completed tasks do not remain on the acquisition modality to preclude confusion with subsequent orders on the same glass slide ID). If an acquisition modality receives a new order for the same glass slide ID, it should replace the original acquisition order. This presumes that a 2nd scan is never intentionally requested simultaneously or serially (currently there are no known use cases that require this).*

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  - *Option 2: Query at the time of barcode scan of the physical asset to ensure latest order available has been obtained by the acquisition modality.*

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Issue 10: How to manage fluorescent images with more than 3 channels (DICOM ICC profiles currently limited to 3 channels). Is fluorescent imaging in our out of scope? More than 3 channels not supported currently in the same DICOM image file but multiple files could be created as a temporary workaround.

It may be possible to calibrate fluorescent color channels leveraging only 3 color ICC profiles. Calibration of colors for clinical FISH testing is not prevalent today regardless. A subgroup of DICOM WG26 will be exploring this further but the current standard is deemed sufficient for supporting the image acquisition profile.

Issue 12: DisplayIdentifiers ([LAB-80]: an identifier that is sortable and conveys an explicit display sequence requested by the user) are currently recommended to be sent in SPM-31, we find challenges with the HL7 data type of that field (CX) and how the Assigning Authority & ID Type (CX.4 & CX.5) must be valued. In particular:

7. CX.5 (ID Type) is constrained to be a value from the HL7 defined list of values in Ch. 2C's table 0203. However, there are no clearly appropriate values which are indicated.

Would these concepts be better represented by assigning individual fields in the SPM segment?

The Assigning Authority may be the system creating the image or the one resequencing the image sort order at some later point. The ID Type will be called "Image Display Sort Order (IDSO)". A harmonization proposal will be submitted to HL7 (estimated June 2019). SPM-31 will be used for this.

Issue 13: It is possible for multiple scans to be generated for a single order in the case where QC intervention upon the first scan results in the need for additional scans. This will result in a new SOP ID and additional outbound messages.

There must be an identification schema that uniquely identifies every new digital scan. This should leverage an Assigning Authority. SPM-2.2 will hold the unique scan identifier in [LAB-82].

Issue 14B: The Study Instance UID may need to be generated by the acquisition manager or may need to be generated by the acquisition modality in order to provide the most flexible environments of managers and modalities. Should we use the IPC segment for the Study Instance UID and if so, how do we go about it? For now we recommend the acquisition manager pass along the Study Instance UID.

Use of the IPC segment will require discussion with Image Integration of HL7. This is pending. We have currently selected a message structure that does not leverage the IPC segment. We leverage an OBX segment whose result field will carry the Study Instance UID (OBX-5). The Study Instance UID will map 1:1 with the case accession number. The case accession number was originally mapped to SPM-30 but ORC-38 may be used consistently across all profiles for the case level identifier. Therefore ORC-38 (filler order group number) is chosen for all digital pathology profiles to convey the case accession number.

Issue 15: Are clinical trial use cases supported in this profile?

Clinical trial associated use cases and data elements that might be packaged into a DICOM object are out of scope for the initial profile. A separate profile will specifically cover use cases, actors, transactions, and data elements to support clinical trials.

Issue 16: Should we incorporate a checksum or CRC to provide a digital signature of the scan data at the time the scan is created. This has largely not been addressed in production systems today and will be deferred for a future effort, but mechanisms to support this are part of the DICOM standard.

390   *Optional data elements supported by DICOM could be leveraged as part of the HL7 message to provide data integrity and security features. Guidance on proper, standardized use of this DICOM functionality will be provided in the future by WG26. It is deemed out of the scope of the current IHE profile.*

Issue 17: Is there metadata associated with HL7 identifiers?

395   *Metadata associated with identifiers are inherently part of the HL7 concept of an ID (e.g., assigning authority for the block ID or accession ID).*

Issue 18: A version control number should be part of the core data set to reflect the firmware used by the scanner or the software capturing and creating the DICOM object. The firmware version and manufacturer of the scanner may be part of the DICOM header and may need to be

400   part of the HL7 transactions going back to the Image Acquisition Manager.

OBX-18 will be used to carry the equipment information in [LAB-82]. First repeat is for the model #, second repeat for the serial #, and the third repeat is for the firmware version. The manufacturer is the assigning authority for all of these.

Issue 20: There is a request for a free form text field (to accommodate vendor proprietary data).

405   This should be well documented and follow DICOM/HL7 guidelines.

Vendor specific (proprietary) comments may be carried in an NTE segment associated with another OBX segment it speaks to. The NTE segment should not contain any results. We do not recommend use of vendor-specific OBX segments as this does not promote use of the HL7 specimen DAM and DICOM, decreasing interoperability.

410   **Issue 21:** For an IWOS query [LAB-81], we need to be able to send back error codes so that the scanner can be informed that, for example, this slide needs to be removed from the scanner. We should clarify the sequence of messages received (the QAK must be received before the [LAB-80])? What does DPIA permit for payload on the ACK message?

DPIA does not permit overloading the ACK message with application level content. If a glass
415   *slide identifier is sent via an IWOS query [LAB-81] from the modality to the acquisition manager and it should not be scanned by that modality, a subsequent [LAB-80] message will be sent with ORC-1 = DC (discontinue). See Section 3.Z.4.1.3 in volume 2 of the current supplement 2B.*

Issue 22: How will acquisition modality performance issues be managed?

If the acquisition modality cannot perform the request sent to it via [LAB-80] (e.g., scan at 40x
420   *when only 20x is available), the modality shall send a [LAB-80] acknowledgement message where ORC-1=UA (unable to accept). The reason for not being able to send could leverage ORC-16.*

Issue 24: Does [LAB-82] status change report scan completed or storage commitment/failure as well?

425 *Since there is no established communication between the image manager/archive and the acquisition manager, the [LAB-82] status change message must accommodate both the completion of the scan and storage commitment / failure.*

Issue 26: The Universal Service Identifier is an OBR-4 data field in the [LAB-80] message that indicates an unambiguous code to represent the order for the acquisition modality to process
430 (e.g., SCAN20x, SCAN40x). The enumerated list of possible values (answer set) need not be arrived upon by consensus amongst the scanner vendors for the trial implementation. IHE private codes will be used for the short term. These may be used to designate a "scan profile", which may configure a number of settings such as magnification, Z-stacking, region of interest to scan (e.g., "skin biopsy protocol", "breast needle core protocol", "Thinprep protocol", etc.).

435 **Issue 28:** LOINC® appears to be more widely referenced in existing profiles but SCT is the better vocabulary to support this profile. How does this relate, if at all, with the alternate coding fields of OBX-3? This profile allows vendors to use whichever coding system they feel is appropriate (SNOMED CT®, LOINC , etc.) or as needed.

Issue 37: For the SPM segment, Specimen Role element (SPM-11), we will be using code H
440 (Historical specimen) which has been added to table 0369, indicating that the SPM segment conveys details about the preceding parent specimen(s) of the submitted sample. IHE convention as follows: RE/X = conditional (if profile DPIA_SPECIMEN supported, then RE, else is X) = required if not empty (RE) or X (not supported). M = mandatory. R = required.

IHE Technical Frameworks General Introduction

The [IHE Technical Framework General Introduction](#) is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

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9.1.3 LOINC (Logical Observation Identifiers Names and Codes)

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9.1.4 SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms)

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490 # IHE Technical Frameworks General Introduction Appendices

The IHE Technical Framework General Introduction Appendices are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

495 | *Update the following appendices to the General Introduction as indicated below. Note that these are **not** appendices to this domain's Technical Framework (TF-1, TF-2, TF-3 or TF-4) but rather, they are appendices the IHE Technical Frameworks General Introduction located here.* |

Appendix A – Actor Summary Definitions

500 | *Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:* |

New (or modified) Actor Name	Definition
Acquisition Manager	Generic definition (For the Appendix): System that controls use of acquisition modality instances for all orders received in the same workflow. In this profile this actor receives request from the order filler which identifies those physical assets for which digital asset acquisition is desired. Identifies the most appropriate acquisition modality available to fulfill this request and submits the work order steps that comprise the acquisition request to the acquisition modality.
Acquisition Modality	Generic Definition (for the Appendix): System that acquires and creates medical images. In this profile this is an image acquisition device (e.g., digital camera or whole slide imaging scanner) that receives instructions from an acquisition manager indicating a forthcoming physical asset that requires digital capture. The captured image is stored in the image manager/archive and the acquisition manager is notified of the completion of the acquisition process.
Image Manager / Image Archive	General Definition (from Appendix): A system that provides functions related to safe data storage and image data handling. It supplies image availability information to the Department System Scheduler. It is always grouped with an Image Archive to provide long term storage of images, presentation states, Key Image Notes, and Evidence Documents. For this profile this manages the storage of recently captured digital images in a manner that facilitates ready retrieval upon request by all other actors for display or analysis. An image manager may be queried for the presence of digital assets associated with a pathology case and if present, return the count of or the actual digital assets available to the requestor with various configuration options, such as resolution, with or without annotations, with or without the label, with or without the thumbnail etc.

New (or modified) Actor Name	Definition
Image Display	General Definition (From Appendix): A part of a system that can access imaging evidence objects (images, Presentation States, Key Image Notes, Evidence Documents) through network query/retrieve or reading interchange media and allow the user to view these objects.

Appendix B – Transaction Summary Definitions

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Add the following new or modified transactions to the IHE Technical Frameworks General Introduction Appendix B:

New (or modified) Transaction Name and Number	Definition
Imaging Work Order Step (IWOS) Broadcast [LAB-80]	An Acquisition Manager orders the execution of an imaging work order step (IWOS) to an Acquisition Modality
Imaging Work Order Step (IWOS) Query [LAB-81]	An Acquisition Modality requests an imaging work order step (IWOS) from an Acquisition Manager
Imaging Work Order Step (IWOS) Status Change [LAB-82]	An Acquisition Modality notifies the change of status (initiated, completed, aborted, …) of an imaging work order step (IWOS) to the ordering Acquisition Manager

Appendix D – Glossary

510

Add the following new or updated glossary terms to the IHE Technical Frameworks General Introduction Appendix D.

New (or modified) Glossary Term	Definition
Physical asset	A tissue specimen or part thereof, which is identified by a unique accession number and representing a distinct entity having diagnostic value.
Digital image asset	The digital representation of a physical asset, of which there may exist multiple versions for the same physical asset (e.g., a 20x image, a 40x image, and a 40x z-stacked image of a glass slide physical asset)
Image Acquisition	The process of creating a digital image asset from a physical asset
IWOS	Imaging Work Order Step A service request that defines the detail for image acquisition.
VNA	Vendor neutral archive
Barcode	An array or matrix of rectangular bars and spaces that creates a symbology representing a number or alphanumeric identifier. A key assumption of this profile is that the data encoded by the barcode on the glass slide ID uniquely identifies that physical asset and can be used to link case data to slide data across all actors.

New (or modified) Glossary Term	Definition
Block	Tissue slice, fixed in formalin, placed in a plastic cassette, and embedded in paraffin
Slide	Specimen shaved from a block, usually only a few microns thick, placed on glass, and stained.
Tissue	Clinical material that is used to divide into part(s), block(s) and slides for pathological evaluation.
WSI	Whole Slide Image General definition (From Appendix D): A digitized histopathology glass slide that has been created on a slide scanner. The digitized glass slide represents a high-resolution replica of the original glass that can then be manipulated through software to mimic microscope review and diagnosis. Also referred to as a virtual slide.

Volume 1 – Profiles

515 ***<Domain-specific additions>***

NA

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520 ## X Digital Pathology - Image Acquisition (DPIA) Profile

The Digital Pathology - Image Acquisition (DPIA) Profile provides specifications for clearly communicating the status and outcomes of workflows pertaining to Image Acquisition of prepared tissue specimens obtained from a patient.

525 The DPIA Profile represents the first and initial portion of the full clinical Digital Pathology workflow. The subsequent portions include evidence creation and display of acquired digital assets. These additional workflow elements will be described in other profiles and together these three profiles will specify the full integration needs of Digital Pathology.

X.1 <Profile Acronym> Actors, Transactions, and Content Modules

530 This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

535 Figure X.1-1 shows the actors directly involved in the DPIA Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a required grouping are shown in conjoined boxes (see Section X.3).
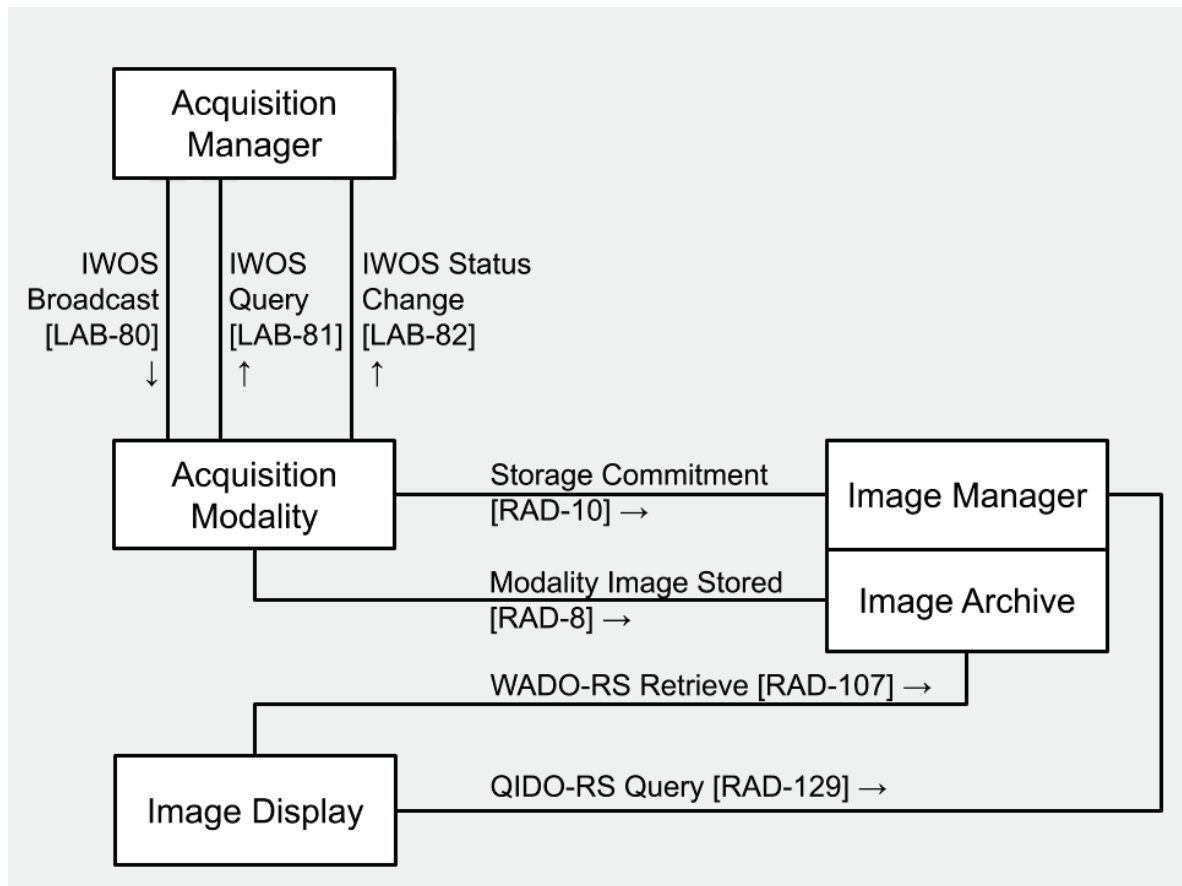
Figure X.1-1: DPIA Actor Diagram

540   Table X.1-1 lists the transactions for each actor directly involved in the DPIA Profile. To claim
        compliance with this profile, an actor shall support all required transactions (labeled "R") and
        may support the optional transactions (labeled "O").

Table X.1-1: DPIA Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Acquisition Manager	IWOS Broadcast [LAB-80]	R	Volume 2 of this supplement
	IWOS Query [LAB-81]	R	Volume 2 of this supplement
	IWOS Status Change [LAB-82]	R	Volume 2 of this supplement
Acquisition Modality	IWOS Broadcast [LAB-80]	R	Volume 2 of this supplement
	IWOS Query [LAB-81]	R	Volume 2 of this supplement
	IWOS Status Change	R	Volume 2 of this supplement

Actors	Transactions	Optionality	Reference
	Modality Image Stored [RAD-8]	O	RAD TF-2:4.8
	Storage Commitment [RAD-10]	O	RAD TF-2:4.10
Image Manager / Image Archive	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF
	Modality Image Stored [RAD-8]	R	RAD TF-2:4.8
	Storage Commitment [RAD-10]	R	RAD TF-2:4.10
Image Display	QIDO-RS Query [RAD-129]	R	Web-based Image Access (WIA) supplement to RAD TF
	WADO-RS Retrieve [RAD-107]	R	Web-based Image Access (WIA) supplement to RAD TF

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements for actors with the same name are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

X.1.1.1 Acquisition Manager

This actor assumes these interoperability responsibilities in the context of the digital pathology workflow:

- Identifies those physical assets for which digital asset acquisition are desired.

- Identifies the acquisition modalities capable of producing those digital assets.

- Creates a number of imaging work order steps (IWOS) to accomplish this process, and directs each IWOS to the appropriate Acquisition Modality.

- Follows up on this process, by capturing the status changes of the IWOS sent by acquisition modalities, and by querying the Image Manager for the created digital assets.

X.1.1.2 Acquisition Modality

An image acquisition device (e.g., digital camera or whole slide imaging scanner) that receives instructions (image work order steps, IWOS) from an acquisition manager about a physical asset to capture into one or more digital assets. The captured image is stored in the image

manager/archive and the acquisition manager is notified of the completion of the acquisition and storage.

X.1.1.3 Image Manager / Image Archive

565 These may represent two separate but coupled components that manage the storage of captured digital images in a manner that facilitates ready retrieval upon request by all other actors for display or analysis. An image manager may be queried for the presence of digital assets associated with a pathology case and, if present, returns the count of or the actual digital assets available to the requestor with various configuration options, such as resolution, with or without 570 annotations, with or without the label, with or without the thumbnail etc.

X.1.1.4 Image Display

Queries and retrieves digital assets from the Image Manager/Image Archive, in order to display them to its user.

X.2 DPIA Actor Options

575 Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: DPIA - Actors and Options

Actor	Option Name	Reference
Acquisition Manager	No options defined	
Acquisition Modality	External image storage and commitment	
Image Manager / Image Archive	No options defined	
Image Display	No options defined	

X.2.1 External Image Storage and Commitment Option

580 This option represents the capability of the Acquisition Modality to store and commit images to an external image manager/archive (RAD-8/RAD-10).

X.3 DPIA Required Actor Groupings

Image Manager and Image Archive SHALL be grouped.

X.4 DPIA Overview

585 In the image acquisition workflow the actors represent a subset of a larger, more holistic digital pathology workflow as presented in the IHE PALM Digital Pathology White Paper. This profile focuses on the steps involved up to the acquisition of an image, its permanent storage into an

590 archive, and its access for visualization. Please refer to the white paper for other aspects of the overall workflow. The data elements declared in scope for the core set of required data elements for this initial set of transaction to support image acquisition is generally based on the need to have that data available to aid in acquisition and interpretation of the digital image.

X.4.1 Concepts

This profile relies on context and use cases presented in the IHE PALM White Paper on Digital Pathology. The primary foundational "use case" for this profile focuses on acquisition of an image.

595

X.4.2 Use Cases

X.4.2.1 Use Case #1: Whole Slide Image Acquisition

In this use case microscopic image acquisition of a tissue specimen is performed for the patient. One or multiple barcoded glass slides are placed into a scanner.

600 **X.4.2.1.1 Whole Slide Image Acquisition Use Case Description**

Steps upstream of this profile are covered in more detail in the digital pathology whitepaper. In summary, the pathology laboratory receives an electronic order indicating collection of a gross specimen for evaluation will soon be received. Reception into the laboratory is documented, the case is accessioned, and gross examination is performed. Tissue cassettes are generated as part of
605 the prosection process and submitted to histology for processing. Processed blocks are embedded in wax and cut into thin (generally 5 micron) slices to generate barcoded glass slides.

Steps covered by this profile begin when some or all barcoded glass slides for a case are placed into a whole slide scanner for digitization. The scanner scans each slide, notifying the Acquisition Manager of status changes (such as completion) of the imaging work order steps as
610 they occur. The scanner stores images in the Image Archive, which provides notification of availability of these stored images back to the Acquisition Manager.

Steps downstream of this profile are also covered in the digital pathology white paper. Generally once all physical assets requested for digitization have been completed, the order filler (e.g., LIS) receives notification and in conjunction with the Acquisition Manager facilitates diagnostic
615 interpretation by a pathologist. Once the pathologist interpretation is complete, a report is generated by the order filler and sent to the order placer actor (usually to his EHR system).

620

X.4.2.1.2 DPIA Whole Slide Image Process Flow
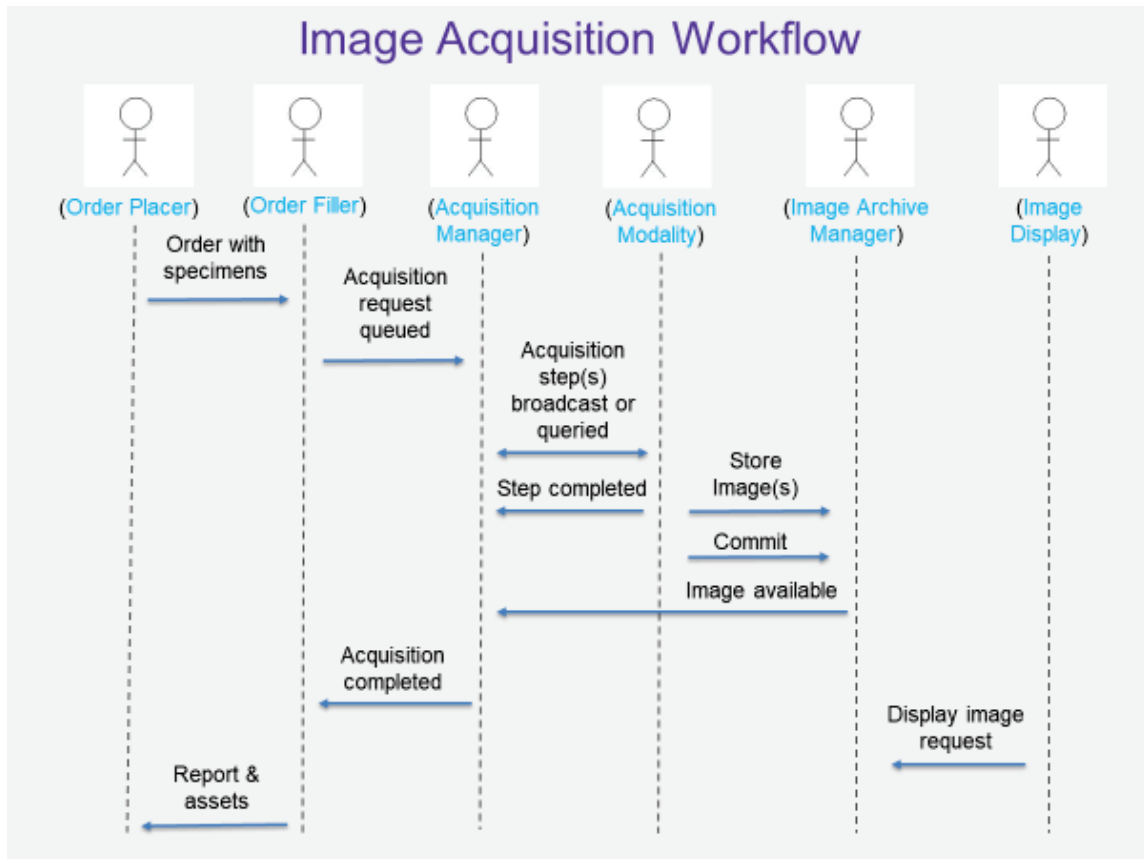
Figure X.4.2.1.2-1: Basic Process Flow in DPIA Profile

X.5 DPIA Security Considerations

X.5.1 Consistent Time (CT)

In order to address identified security risks, all actors in DPIA SHOULD be grouped with Consistent Time (CT) Profile - Time Client Actor. This grouping will assure that all systems have a consistent time clock to assure a consistent timestamp for audit logging and form accuracy.

X.5.2 Audit Trail and Node Authentication (ATNA)

DPIA will likely include clinical content related to the information subject. When it does, it is anticipated that transfers of Personal Health Information (PHI) will be protected. The IHE ITI Audit Trail and Node Authentication (ATNA) Profile SHOULD be implemented by all of the actors involved in the IHE transactions specified in this profile to protect node-to-node

communication and to produce an audit trail of the PHI related actions when they exchange messages. Other private security mechanisms MAY be used to secure content within enterprise managed systems.

X.5.3 Cross-Enterprise User Assertion (XUA)

640 For security and auditing purposes, when sending information between clinical documentation and laboratory systems it may be necessary to firmly establish the identity of the users performing each action. In this case the Cross-Enterprise User Assertion (XUA) Profile MAY be utilized to support this implementation.

Note that XUA is recommended over Internet User Authorization (IUA) as XUA is more
645 applicable to known trusted partners and IUA is generally more applicable to Internet-facing applications in which users are less likely to be known to each other and OAuth-style authentication is necessary. DPIA is expected to be used between systems owned by the same organization and on the same internal network, hence IUA in unnecessary.

X.6 DPIA Cross Profile Considerations

650 ### X.6.1 Invoke Image Display (IID)

The Invoke Image Display (IID) simplifies the task of integrating non-image-aware systems like EHRs, EMRs, PHRs, LIS and other information systems with image-aware systems like PACS, VNA and Image Sharing solutions, by providing a standard mechanism to request that imaging studies be displayed.

655 By implanting this profile it will be possible to provide interactive viewing, and both review or diagnostic quality, and key images, under the control of the user.

Appendices to Volume 1

None

660 # Volume 2 – Transactions

Add Section 3.Z

3.Z IWOS Broadcast [LAB-80]

3.Z.1 Scope

This transaction is used between an Acquisition Manager and an Acquisition Modality. It enables
665 the Acquisition Manager to send to the Acquisition Modality a new IWOS, unsolicited if the
Acquisition Modality operates in "Broadcast Mode" or in response to a query initiated via
transaction [LAB-81] by the Acquisition Modality operating in "Query Mode".

It also enables the Acquisition Manager to cancel an existing IWOS previously sent to the
Acquisition Modality. Modification of an existing IWOS is achieved by combining cancellation
670 and sending of a new IWOS.

3.Z.2 Actor Roles
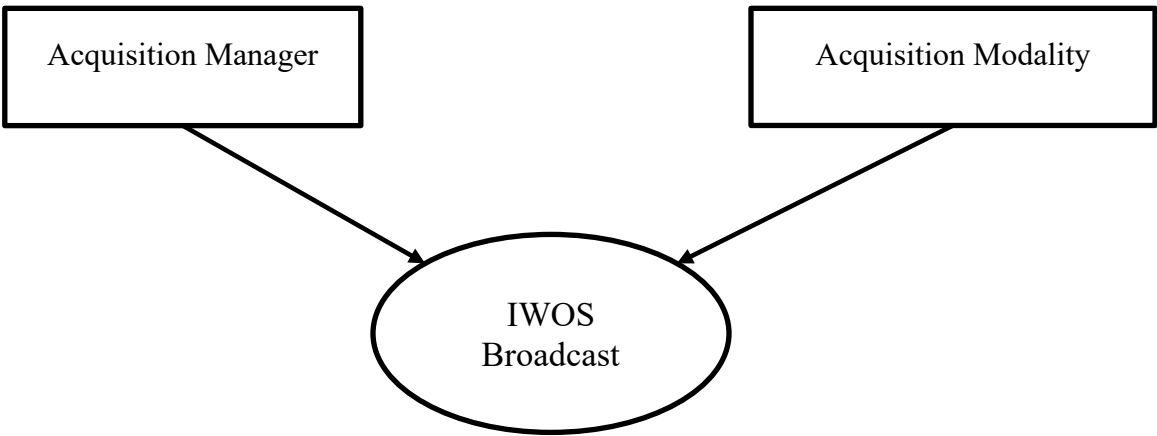
Figure 3.Z.2.1: Use Case Diagram

Table 3.Z.2-1: Actor Roles

Actor:	Acquisition Manager
Role:	Translates a Work Order into a series of IWOS assigned to the Acquisition Modality.
	Broadcasts an IWOS related to a specimen to the appropriate Acquisition Modality, either unsolicited (broadcast mode) or in response to a query (query mode).

Actor:	Acquisition Modality
Role:	Receives the IWOS from the Acquisition Manager.
	Acknowledges it, sending back its intent regarding this IWOS.
	If the IWOS was accepted, performs it on the related specimen.

675

3.Z.3 Referenced Standards

HL7 v2.5.1, plus some pre-adopted features from v2.8.2, where explicitly indicated:

- chapter 2 "Control": generic segments and data types,
- chapter 3 "ADT": PID & PV1 segments,

680
- chapter 4 "Order": OML^O33 and ORL^O34 message structures, with the OMI message having an IPC segment, OBR, ORC and TQ1 segments.
- chapter 7 "Observation": SPM segment

3.Z.4 Messages
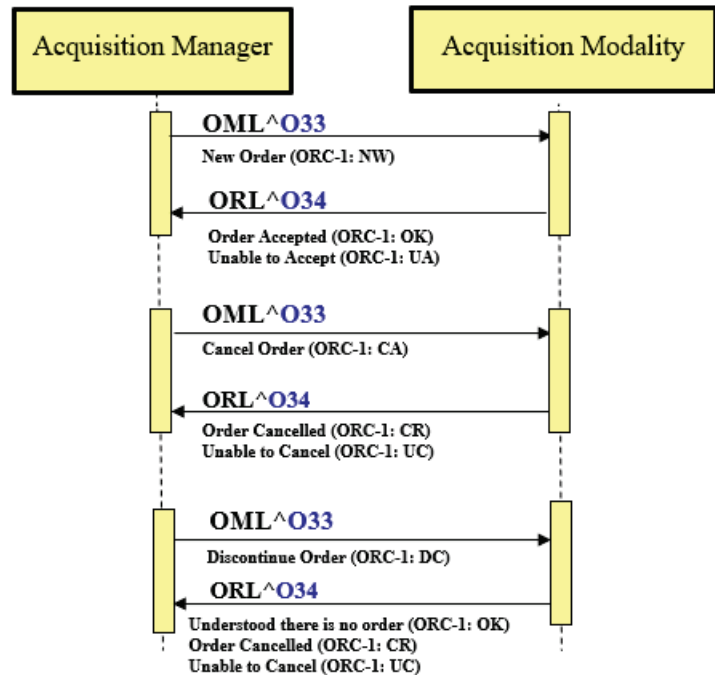
685
Figure 3.Z.4-1: LAB-80 Interactions

3.Z.4.1 Message OML^O33 and its acknowledgement ORL^O34

3.Z.4.1.1 Trigger Events

- The Acquisition Manager has converted a new Work Order into a series of IWOSs assigned to Acquisition Modalities. It wants to send to each Acquisition Modality operating in "broadcast mode" its assigned IWOS.

690

- The Acquisition Manager wants to cancel an IWOS previously sent to an Acquisition Modality, either because this IWOS is actually to be canceled or because it must be modified, in which case the modified IWOS will be sent as a new IWOS.

- The Acquisition Modality has initiated a query via transaction [LAB-81] and the Acquisition Manager wants to send the actual response consisting of zero or more IWOS.

695

3.Z.4.1.2 Message Semantics

The message OML^O33 contains zero or more IWOSs for one or more specimens. The IWOSs are grouped by specimen.

3.Z.4.1.2.1 OML^O33 Message Static Definition

700

Table 3.Z.4.1.2.1-1: OML^O33

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message Header	M	[1..1]	2
[	--- PATIENT begin	RE	[0..1]	
PID	Patient Identification	R	[1..1]	3
]	--- PATIENT end			
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	M	[1..1]	7
[{ OBX }]	Observation/Result	R	[1..*]	7
{	--- ORDER begin	M	[1..1]	
ORC	Common Order (for one battery)	M	[1..1]	4
[	--- OBSERVATION REQUEST begin	Negative Query Response [See Note 1.] (X/RE)	[0..1]	
OBR	Observation Request	M	[1..1]	4
[{	--- OBSERVATION begin	RE	[0..*]	
OBX	Observation/Result	R	[1..1]	7
}]	--- OBSERVATION end			
]	--- OBSERVATION REQUEST end			
}	--- ORDER end			
}	--- SPECIMEN end			

Note 1: Sent in response to [LAB-81] Query only (e.g., manager asks modality, "please look for a particular slide" but is unable to find it).

MSH-9 Message Type (MSG) SHALL have its three components respectively valued to "OML", "O33" and "OML_O33".

MSH-21 Message Profile Identifier SHALL be populated with at minimum one occurrence of "LAB-80^IHE".

The ORDER segment group carries the Acquisition Manager request for execution of new IWOS, request to cancel an IWOS, or Negative Query Response.

To request that the Acquisition Modality perform an IWOS, ORC-1 Order Control is set to "NW". The TQ1 segment can be used to carry additional information about the request. The OBR segment of the OBSERVATION REQUEST group contains the request details (OBR-2 IWOS ID, OBR-4 Universal Service Identifier, etc.).

When requesting an IWOS, the Acquisition Manager may use the OBSERVATION segment group to provide the Acquisition Modality with results or a variety of clinically relevant information that is obtained during the ordering or specimen collection process. The OBX segments of the OBSERVATION segment group are used for information specifically observed/measured as part of the ordering process (including specimen collection).

OBX-3 and OBX-5 of the OBX segment contained in the OBSERVATION segment group can be used to provide name/value paired information that is not otherwise captured in the SPM segment. At the moment only a single use is defined where OBX-3 = "Stain Name" and OBX-5 = "H&E", "GMS", "IHC" etc. This may assist the acquisition modality to properly configure and/or calibrate itself for the glass slide to be scanned.

Please note that the message structure proposed for this profile includes OBX segments associated with the order (ORC segment) and OBX segments associated with the specimen (SPM segment). The Study Instance UID represents an OBX segment to be associated with the order whereas the Stain Name represents an OBX segment to be associated with the specimen. Both of these represent required data elements in the message.

Please also note that the PaLM LAW Profile supports more than one order per specimen but this has been deemed unnecessary for the current profile. Exactly one specimen and one order is specified in the [LAB-80] message sent to the acquisition modality.

To request that an Acquisition Modality cancel an IWOS, ORC-1 Order Control is set to "CA". The OBR segment of the OBSERVATION REQUEST group contains details (OBR-2 IWOS ID and OBR-4 Universal Service Identifier).

To indicate there is no work to perform (Negative Query Response) for a [LAB-81] Query for IWOS, only the SPM and ORC segments will be sent. For the SPM segment, the SPM-4 Specimen Type will be set to NULL ("") and SPM-11 Specimen Role will be set to "U" (Unknown).

3.Z.4.1.2.2 ORL^O34 Message Static Definition

740

Table 3.Z.4.1.2.2-1: ORL^O34[1]

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
MSA	Message Acknowledgement	M	[1..1]	2
[{ERR}]	Error	C (R/X)[1]	[0..*]	2
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	M	[1..1]	7
{	--- ORDER begin	M	[1..*]	
ORC	Common Order (for one battery)	M	[1..1]	4
}	--- ORDER end			
}	--- SPECIMEN end			

Note 1:Usage is Required when MSA-2 is not equal to "AA". There may be multiple repetitions when multiple errors have
been discovered. Otherwise usage is Not Supported.

745 MSH-9 Message Type (MSG) SHALL have its Message Code (MSH-9.1) and Trigger Event
(MSH-9.2) components respectively valued to "ORL" and "O34". The Message Structure
component (MSH-9.3) SHALL be valued to "ORL_O42".

MSH-21 Message Profile Identifier SHALL be populated with "LAB-80^IHE".

ORC-2 Placer Order Number SHALL be used to uniquely identify the IWOS to the Acquisition
Manager when the RESPONSE segment group is included.

750 The RESPONSE segment group SHALL be used by the Acquisition Modality to inform the
Acquisition Manager about its intent to perform an individual IWOS contained in the OML
message:

- For accepted IWOS
  - the ORC-1 Order Control should have value OK and
755 - the ORC-5 Order Status should have value SC, IP, or CM.
- For rejected IWOS
  - the ORC-1 Order Control should have value UA and
  - the ORC-5 Order Status should have value CA.

The RESPONSE segment group SHALL be used by the Acquisition Modality to respond to a
760 cancellation request from the Acquisition Manager for each IWOS contained in the OML
message:

- In case of successful cancellation

o the ORC-1 Order Control should have value CR and

o the ORC-5 Order Status should have value CA.

765 • In case of not being able to cancel

o the ORC-1 Order Control should have value UC and

o the ORC-5 Order Status should have value IP or CM .

The ERR (error) segment only indicates a problem with the message structure (standard HL7 usage).

770 **3.Z.4.1.3 Expected Actions**

The Acquisition Manager may send multiple IWOSs for multiple specimens in the same OML^O33, in which case the response message SHALL convey an acknowledgement for each of these IWOSs, in field ORC-1 of the ORC segment representing this IWOS.

For an individual new IWOS (ORC-1 = "NW"), the Acquisition Modality will register the new
775 IWOS information. This IWOS in the ORL^O34 response will be acknowledged as either "request accepted" (ORC-1 = "OK") or "unable to accept order/service" (ORC-1 = "UA"). This will happen immediately if the glass slide is available in the acquisition modality (and represents an expectation to perform the scan in the future). It is possible that an error occurs and the scan cannot be performed. The [LAB-82] message must be used to convey this situation. A slide scan
780 request that is canceled or deleted by the acquisition modality either by direct user input or based on internal logic should also leverage the [LAB-82] message to notify the acquisition manager (ORC-1 = OC, ORC-5 = CA, OBR-25 = X).

For an individual IWOS to be cancelled (ORC-1 = "CA"), the Acquisition Modality will evaluate the cancel request. This IWOS in the ORL^O34 response will be acknowledged as
785 either "cancelled as requested" (ORC-1 = "CR") or "unable to accept order/service" (ORC-1 = "UC").

If the Acquisition Manager retransmits an IWOS or reuses an IWOS ID, the Acquisition Modality will reject the IWOS request by responding with "Unable to accept order/service". The rejection is for this specific request only, and has no influence on the original request. For
790 example, if an IWOS is retransmitted, the Acquisition Modality is rejecting the duplicate request but not the original request. See the ORC-1/ORC-5 discussion above for further details.

When the Acquisition Manager sends the OML^O33 in response to a [LAB-81] Query for IWOS, the Acquisition Modality will require that the OML^O33 be received in a specific period of time. If the time period elapses, the Acquisition Modality will assume that the query has failed
795 and may notify the user that no response was received.

When the OML^O33 is sent in response to a [LAB-81] Query for IWOS for a single specimen, it will only contain the IWOSs or Negative Query Response related to that specimen. If the OML message contains the Order Control Code "DC", the Acquisition Modality will evaluate the

Negative Query Response. The Acquisition Modality will respond only with the MSH and MSA segments in the ORL^O34 to acknowledge receipt of the Negative Query Response.

A Negative Query Response for an unrecognized specimen is considered an unexpected situation. An unrecognized Negative Query Response might be received because:

- the response was received after the query time-out period elapsed

- the Acquisition Manager erroneously retransmitted the response and the Acquisition Modality is no longer tracking a query for that specimen

- the Acquisition Manager erroneously sent the response to the Acquisition Modality

In this situation, the Acquisition Modality will respond with an **Application Acknowledgement: Reject** in the ORL^O34 by setting MSA-1 to "AR" and reporting the appropriate specimen container values in the ERR segment.

3.Z.5 Protocol Requirements

NA

3.Z.6 Security Considerations

None.

3.Z.6.1 Security Audit Considerations

NA

Add Section 3.Y

3.Y IWOS Query [LAB-81]

This transaction is used between an Acquisition Manager and an Acquisition Modality working in query mode. It enables the Acquisition Modality to query the Acquisition Manager for imaging work order steps (IWOSs) to be performed on specimens. Transaction [LAB-81] conveys the query, and is combined with IWOS Broadcast [LAB-80] transaction, which carries the actual response to the query, as zero or more IWOS.

The Acquisition Modality uses this transaction to query for the IWOS related to one recognized specimen, or to query for all pending IWOSs prior to the arrival of the specimens.

The transaction provides an initial message exchange of a query for one specimen or all IWOS, and the reply that carries the acknowledgement status of the query. For a query for a single specimen, the Acquisition Manager will follow the query exchange with a second message

---

exchange consisting of a IWOS Broadcast [LAB-80] that provides the IWOS to perform or an indication that there is no IWOS (Negative Query Response) for that specimen. For a query for all work, the Acquisition Manager will follow with one or more IWOS Broadcast [LAB-80] interactions containing the IWOSs to perform, or carrying the Negative Query Response.

835 The Acquisition Modality can send multiple queries prior to receiving the IWOS Broadcast from the Acquisition Manager. This allows the Acquisition Modality to send a batch of queries, or asynchronous queries, without waiting for the IWOS Broadcast of the two-part message exchange.

3.Y.1 Scope

840 This transaction is used by an Acquisition Modality to request from an Acquisition Manager imaging work order steps that need to be performed in order to produce digital assets out of a physical asset (specimen). The actual response to the query will come back to the modality through a [LAB-80] transaction.

3.Y.2 Actor Roles
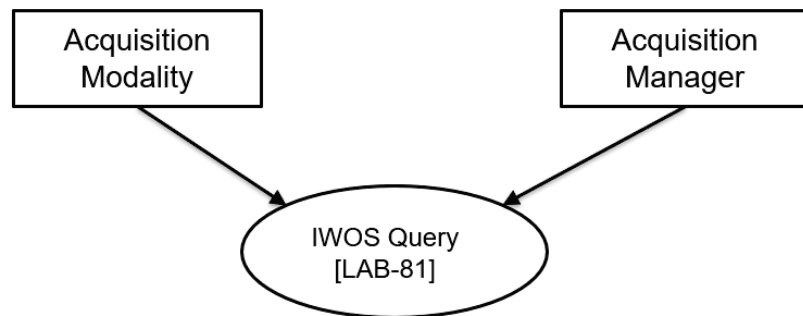
845

Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

Actor:	Acquisition Modality
Role:	Queries the Acquisition Manager in order to obtain one or more imaging work order steps (IWOS) for processing. The query may be related to a particular physical asset (tissue specimen) or may be a query for all pending work.
Actor:	Acquisition Manager
Role:	Distributes imaging work order steps (IWOS) to the Acquisition Modality in response to a query.

3.Y.3 Referenced Standards

850 HL7 v2.5.1, plus some pre-adopted features from v2.8.2, where explicitly indicated:

Chapter5: "Query" ❼ QBP and RSP messages.

Chapter5: "Query" ❼ QPD, RCP and QAK segments.

3.Y.4 Interaction Diagram
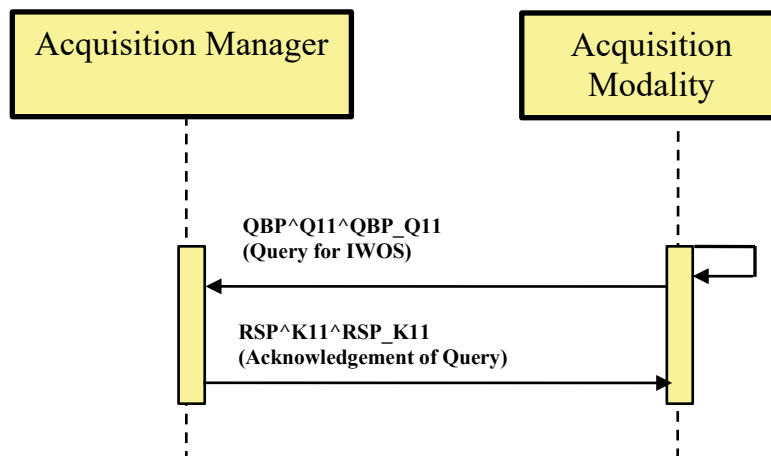
855

Figure 3.Y.4-1: Query for IWOS related to a specimen or for all pending IWOS

3.Y.4.1 Message QBP^Q11 and its acknowledgement RSP^K11

3.Y.4.1.1 Trigger Events

860 • The only supported query occurs when the Acquisition Modality wants to obtain the IWOS related to an identified container (i.e., barcoded glass slide that appears unexpectedly, that is without a prior broadcast message indicating work steps to be performed on that glass slide).

3.Y.4.1.2 Message Semantics

3.Y.4.1.2.1 QBP^Q11 Message Static Definition

865 **Table 3.Y.4.1.2.1-1: QBP^Q11^QBP_Q11**

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
QPD	Query Parameter Definition	M	[1..1]	5
RCP	Response Control Parameter	M	[1..1]	5

MSH-9 – Message Type (MSG) SHALL have its components respectively valued to "QBP", "Q11", and "QBP_Q11".

MSH-21 – Message Profile Identifier SHALL be "LAB-81^IHE".

870 ### 3.Y.4.1.2.2 RSP^K11 Message Static Definition

Table 3.Y.4.1.2.2-1: RSP^K11^RSP_K11

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
MSA	Message Acknowledgement	M	[1..1]	2
[ERR]	Error	C (R/X)[1]	[0..*]	2
QAK	Query Acknowledgement	M	[1..1]	5
QPD	Query Parameter Definition	M	[1..1]	5

Note 1: Predicate: Usage is Required when MSA-2 is not equal to "AA". There may be multiple repetitions when multiple errors have been discovered. Otherwise usage is Not Supported.

875 MSH-9 – Message Type (MSG) SHALL have its components respectively valued to "RSP", "K11", and "RSP_K11".

MSH-21 – Message Profile Identifier SHALL be "LAB-81^IHE".

QPD SHALL be the same as the QPD sent in QBP^Q11^QBP_Q11. If the segments are not the same, the Acquisition Modality may report an error to the user.

880 ### 3.Y.4.1.2.3 QPD Segment Static Definition

HL7 v2.8.2: chapter 5 (5.5.4 QPD – Query Parameter Definition).

This segment provides the specimen information for the query.

Table 3.Y.4.1.2.3-1: QPD segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	60	CE	M	[1..1]		01375	Message Query Name
2	32	ST	M	[1..1]		00696	Query Tag
3	80	EI	C (M/X)	[0..1]		01331	Container Identifier

885   **QPD-1 Message Query Name (CE)**, mandatory.

This field contains the value of the query for either a single specimen or for all specimens. HL7 User-defined Table 0471 – Query Name defines the identifier and description values to use for each query type. The contents for each query type are described below.

Table 3.Y.4.1.2.3-2: HL7 User-defined Table 0471 – Query Name

Value	Description	Comment
WOS	Work Order Step	Use to query for a single specimen

890   Query for a Single Specimen

Table 3.Y.4.1.2.3-3: Element QPD-1 Message Query Name (CE) for single specimen

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	4	Fixed "IWOS"
Text (ST)	R	11	Fixed "Imaging WOS"
Name of Coding System (ID)	R	6	Fixed "IHEDIA"

QPD-2 Query Tag (ST), mandatory.

A unique identifier assigned to each query message instance.

895   **QPD-3 Container Identifier (EI)**, mandatory.

Used when the query is based upon the Container Identifier. It is expected that the Identifier is the value encoded on the barcode of the glass slide.

Predicate: QPD-3 is Mandatory when QPD-1 is equal to IWOS. Otherwise usage is Not Supported.

900   **Table 3.Y.4.1.2.3-4: Element QPD-3 Container Identifier (EI)**

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	Container ID

3.Y.4.1.2.4 RCP Segment Static Definition

HL7 v2.8.2: chapter 5 (5.5.6 RCP – Response Control Parameter).

This segment provides additional information about the expected query response.

905

Table 3.Y.4.1.2.4-1: RCP segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	1	ID	M	[0..1]	0091	00027	Query Priority
3	60	CE	M	[0..1]	0394	01440	Response Modality

RCP-1 Query Priority (ID), mandatory.

This field is always set to the value of "I" (Immediate).

RCP-3 Response Modality (CE), mandatory.

910

Table 3.Y.4.1.2.4-2: Element RCP-3 Response Modality (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	1	Fixed "R"
Text (ST)	O	9	Fixed "Real Time"
Name of Coding System (ID)	R	7	Fixed "HL70394"

3.Y.4.1.2.5 QAK Segment Static Definition

HL7 v2.8.2: chapter 5 (5.5.2 QAK – Query Acknowledgment).

This segment contains information about the query response.

915

Table 3.Y.4.1.2.5-1: QAK segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	32	ST	M	[1..1]		00696	Query Tag
2	2	ID	M	[1..1]	0208	00708	Quantity Response Status
3	60	CE	M	[1..1]	0471	01375	Message Query Name

QAK-1 Query Tag (ST), mandatory.

This field contains "QPD-2 Query Tag" from the query message.

QAK-2 Query Response Status (ID), mandatory.

920 This field contains one of the following codes from the HL7 Table 0208.

Table 3.Y.4.1.2.5-2: HL7 Table 0208 – Query Response Status

Value	Description	Comment
OK	Query accepted	The query has been accepted for processing

Value	Description	Comment
AE	Application Error	An application error occurred when processing the query request
AR	Application Reject	The application has rejected the query request

QAK-3 Message Query Name (CE), mandatory.

This field contains "QPD-1 Message Query Name" from the query message.

925

Table 3.Y.4.1.2.5-3: Element QAK-3 Message Query name (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	4	Contains value from QPD-1-1
Text (ST)	R	11	Contains value from QPD-1-2
Name of Coding System (ID)	R	6	Contains value from QPD-1-3

3.Y.4.1.3 Expected Actions

The following scenarios describe the expected actions for a query transaction.

Query for a Single Specimen

930 When a specimen arrives on the Acquisition Modality it sends a QBP message to the Acquisition Manager to get the IWOS. The Acquisition Modality identifies the query by using the query name (see description for QPD-1).

The Acquisition Modality can identify the specimen by providing the following:

- QPD-3 Glass Slide Identifier

935 The following example table shows how to correctly populate the QPD fields for proper specimen identification:

Table 3.Y.4.1.3-1: Specimen Identification Examples

QPD Fields	Glass slide with barcode
QPD-1.1 Message Query Name. Identifier	WOS
QPD-3 Glass Slide Identifier	SP19-001234

The Acquisition Manager receives the QBP message and returns the RSP message with the query
940 acknowledgment status. The Acquisition Manager prepares the IWOS(s) by checking the specimen identification information in the QBP message with a query, and initiates the IWOS

Broadcast [LAB-80]. The Acquisition Modality receives the IWOS(s) and processes the specimen.

945   If the Acquisition Manager has no work for that specimen, it sends a Negative Query Response by setting ORC-1 to "DC" in a [LAB-80] IWOS Broadcast message.

3.Y.5 Protocol Requirements

NA

3.Y.6 Security Considerations

None.

950   ### 3.Y.6.1 Security Audit Considerations

NA

Add Section 3.T

955

3.T IWOS Status Changes [LAB-82]

3.T.1 Scope

This transaction is used by the Acquisition Modality to send test results and IWOS status changes to the Acquisition Manager.

960   ### 3.T.2 Actor Roles
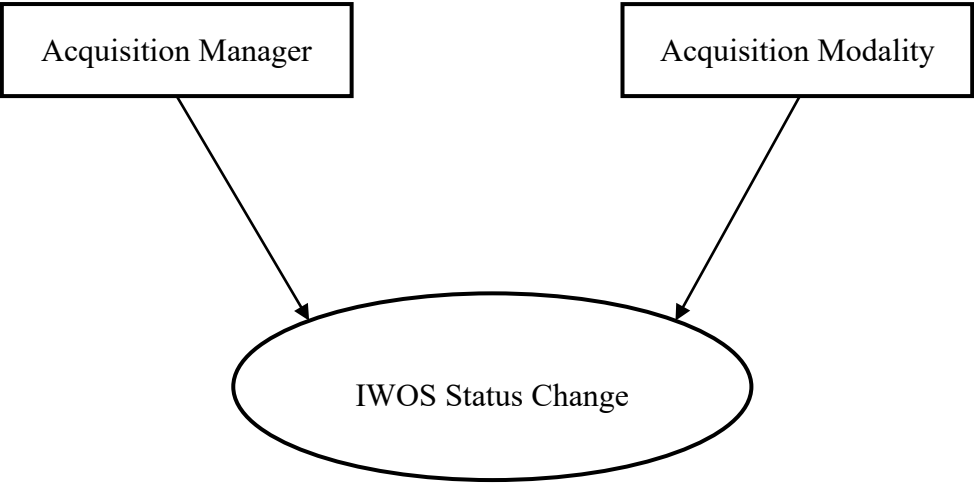
Figure 3.T.2-1: Use Case Diagram

965

Table 3.T.2-1: Actor Roles

Actor:	Acquisition Manager
Role:	Receives IWOS status changes and the corresponding test results from the Acquisition Modality. Manages the status of the IWOS and of its parent Work Order.
Actor:	Acquisition Modality
Role:	Notifies the Acquisition Manager of the status change of an IWOS, sending test results fulfilling this IWOS.

3.T.3 Referenced Standards

HL7 v2.5.1, plus some pre-adopted features from v2.8.2, where explicitly indicated:

- chapter 2 "Control": generic segments and data types,

970
- chapter 3 "ADT": PID & PV1 segments,

- chapter 7: OUL^R22 message, OBR, OBX and SPM segments,

- chapter 13 "Clinical Laboratory Automation": SAC, INV & TCD segments.

3.T.4 Interaction Diagram

975
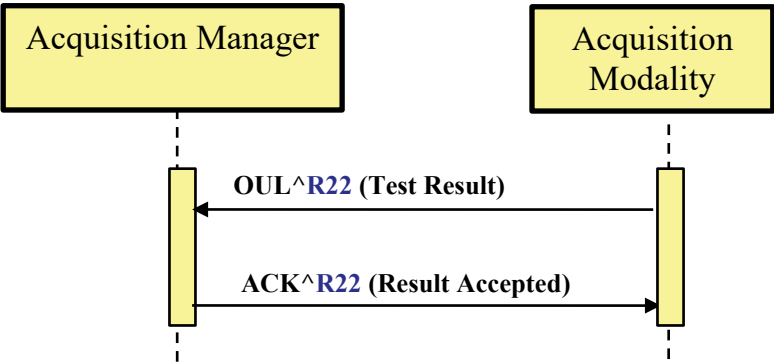
Figure 3.T.4-1: IWOS Status Change

3.T.4.1 Message OUL^R22 and its acknowledgement ACK^R22

3.T.4.1.1 Trigger Events

980
- The Acquisition Modality sends test results corresponding to one or more IWOSs.

3.T.4.2 Message Semantics

The message OUL^R22 contains zero or more observations for one or more IWOS for one or more specimens, containing such information as a thumbnail of the recently scanned image. Each specimen is in one container. It is assumed that by the time [LAB-82] is sent back to the
985 acquisition manager, the storage commitment has occurred and the image has been stored to the image manager/archive (RAD-10 followed by RAD-8). The location of the stored image is not explicitly stated in the result message.

If the patient is known, then all results/specimens in the message must be for the same patient.

3.T.4.2.1 OUL^R22 Message Static Definition

990
Table 3.T.4.2.1-1: OUL^R22

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
[	-- PATIENT begin	RE	[0..1]	
[PID]	Patient Identification	R	[1..1]	3
]	-- PATIENT end			
{	--- SPECIMEN begin	M	[1..*]	

Segment	Meaning	Usage	Card.	HL7 chapter
SPM	Specimen information	M	[1..1]	7
[{ OBX }]	Observation Result (for Specimen)	RE	[1..*]	7
{	--- ORDER begin	M	[1..*]	
ORC	Common Order	M	[1..1]	4
[	--- Observation Request Begin	Negative Query Response: (X/RE)	[0..1]	
OBR	Observation Order	M	[1..1]	7
[{	--- RESULT begin	C(M/X)[1]	[0..*]	
OBX	Observation Result	M	[1..1]	7
[{NTE}]	Notes and comments	RE	[0..*]	2
}]	--- RESULT end			
]	--- Observation Request End			
}	--- ORDER end			
}	--- SPECIMEN end			

Note 1: Predicate: Usage is Mandatory if field ORC-5 "Order Status" of the above ORC segment is valued with "IP" or "CM". Otherwise usage is Not Supported.

The message conveys the status change of the IWOS related to a specimen. Each specimen is in one container and there may be one or more observation results for each container.

MSH-9 Message Type (MSG) SHALL have its three components respectively valued to "OUL", "R22", and "OUL_R22".

MSH-21 Message Profile Identifier SHALL be populated with at minimum one occurrence of "LAB-82^IHE".

The PATIENT segment group is optional and may be used to convey patient information.

The SPECIMEN group is mandatory and SHALL be used to convey specimen and specimen container information.

Please note that the message structure proposed for this profile includes OBX segments associated with the order (ORC segment) and OBX segments associated with the specimen (SPM segment). For example, the Study Instance UID represents an OBX segment to be associated with the order whereas the Slide Thumbnail ID represents an OBX segment to be associated with the specimen. Some of these represent required data elements in the message while others are optional (please refer to details in Appendix A, SPM Segment).

The ORDER group is mandatory and SHALL be used to provide order information.

The OBR segment is mandatory and SHALL be used to transmit information about the requested IWOS.

- OBR-2 Placer Order Number SHALL contain the IWOS ID for orders transmitted to the Acquisition Modality by the Acquisition Manager. For orders created at the Acquisition Modality, the field SHALL contain the NULL ("") value.

1015
- The optional OBR-3 Filler Order Number may be used by the Acquisition Modality to provide a unique identifier for the observation.

- OBR-4 Universal Service Identifier SHALL contain the identifier for the IWOS that was ordered.

The ORC segment is mandatory and SHALL be used to transmit information about the status of
1020 the IWOS.

- ORC-1 Order Control SHALL be populated with the code "SC".

- ORC-2 Placer Order Number is not populated because OBR-2 Placer Order Number is used to carry the IWOS ID.

- ORC-5 Order Status is populated with the status of the IWOS reported by the Acquisition
1025 Modality.

The RESULT segment group contains the observation results for the IWOS represented by the above (OBR, ORC) pair.

The OBX segment will be used to carry the observation results and supporting clinical information.

1030
- OBX-3 will be used to identify the observation.

- OBX-29 should identify the OBX segment as containing a result. The Acquisition Manager may discard segments that are not identified as results.

- The other OBX fields are used to convey information about the observation result. See A.2 OBX Segment in Appendix A for more details.

1035 The optional NTE segments following the OBX segments may be used to provide human-readable notes and comments about the patient, order, and result respectively. The receiver should be able to ignore the NTE segments. For comments generated at the Acquisition Modality, NTE-2 SHALL be populated with "Z" (for Acquisition Modality) as specified by A.5 in Appendix A. The contents of NTE-3 SHALL not be considered interpretable by a machine.

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3.T.4.2.2 ACK^R22 Message Static Definition

Table 3.T.4.2.2.-1: ACK^R22

Segment	Meaning	Usage	Card.	HL7 chapter
MSH	Message header	M	[1..1]	2
MSA	Message Acknowledgement	M	[1..1]	2
[{ERR}]	Error	C (R/X)[1]	[0..*]	2

Note 1: Predicate: Usage is Required when MSA-2 is not equal to "AA". There may be multiple repetitions when multiple
errors have been discovered. Otherwise usage is Not Supported.

MSH-9 Message Type (MSG) SHALL have its three components respectively valued to "ACK",
"R22" and "ACK".

MSH-21 Message Profile Identifier SHALL be populated at minimum with one occurrence of
"LAB-W^IHE".

3.T.4.1.3 Expected Actions

The Acquisition Modality notifies the Acquisition Manager of the current status of the IWOS in
the OUL^R22 message. The Acquisition Manager accepts and registers information, and
responds to the Acquisition Modality with the ACK^R22 message.

3.T.5 Protocol Requirements

NA

3.T.6 Security Considerations

None.

3.T.6.1 Security Audit Considerations

NA

Appendices to Volume 2

Appendix A – Common HL7 Message Segments for DPIA Transactions

The following segment definitions supersede for DPIA transactions the common segment definitions from PaLM TF-2x: Appendix C.

Cardinalities and usages are defined to clarify differences when segments are sent by the Acquisition Manager versus the Acquisition Modality.

A.1 OBR Segment

HL7 v2.5.1: chapter 4 (4.5.3 OBR – Observation Request Segment).

This segment is used to transmit information specific to an order for a diagnostic study or observation. The primary use of this segment is to identify the test/analysis to be run by the Acquisition Modality on the specimen.

Table A.1-1: OBR Segment

SEQ	LEN	DT	Usage AM	Usage Acquisition Modality	Card	TBL #	ITEM #	Element name
2	50[1]	EI	M	M	[1..1]		00216	Placer Order Number (IWOS ID)
3	50[1]	EI	X	RE	[0..1]		00217	Filler Order Number
4	250	CE	M	M	[1..1]		00238	Universal Service Identifier

Note 1: The maximum field length has been extended to 50 characters from the HL7 defined length of 22, allowing globally unique identifiers (such as GUIDs).

OBR-2 Placer Order Number (EI), mandatory.

Each ordered scan is assigned to a unique Order, identified by a unique IWOS ID. The Placer Order Number is generated by the Acquisition Manager and should be unique across all OBR segments across all messages. For the Acquisition Modality, if the IWOS ID does not exist, then this field is populated with NULL (""). This happens when sending results for:

- IWOS manually entered on the Acquisition Modality;

1085

- Reflex tests scheduled by the Acquisition Modality in a new IWOS distinct from the original IWOS. In this case the original IWOS(s) is (are) referenced as the parent IWOS in field ORC-8 (parent order).

The use of NULL ("") by the Acquisition Modality should not be interpreted as requirement to delete IWOS information from IWOS data records maintained by the Acquisition Manager.

1090

Note on Element Length: The maximum element length for OBR-2 has been established as 50 characters to allow globally unique identifiers (such as GUIDs) for IWOS IDs.

Table A.1-2: Element OBR-2 Placer Order Number (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	Placer order number (unique ID for the digital scan request, aka IWOS ID)

OBR-3 Filler Order Number (EI), required if available from Acquisition Modality (Acquisition Modality).

1095

This field is the order number associated with the Acquisition Modality. This is a permanent identifier for an order and its associated observations. This may be blank on inbound messages to the acquisition modality.

Note on Element Length: The maximum element length for OBR-3 has been established as 50 characters to allow globally unique identifiers (such as GUIDs).

1100

Table A.1-3: Element OBR-3 Filler Order Number (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	A unique order ID generated by the Acquisition Modality

OBR-4 Universal Service Identifier (CE), mandatory.

This field contains one or more scan test requests. A local code or standard vocabulary is required and should be agreed upon by the vendor community. This is important to ensure an

1105 unambiguous, standard order is presented to the acquisition modality.

Table A.1-4: Element OBR-4 Universal Service Identifier (CE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Scan Order Identifier
Text (ST)	R	199	Name for the scan order
Name of Coding System (ID)	R	12	Name of coding system, "SCT" for SNOMED CT

A.2 OBX Segment

HL7 v2.5.1, plus OG datatype for OBX-4 pre-adopted from v2.8.2: chapter 7 (7.4.2 OBX – Observation/Result Segment).

The OBX segment is used to transmit a single observation or observation fragment.

Table A.2-1: OBX Segment

SEQ	LEN	DT	Usage AM	Usage Acquisition Modality	Card.	TBL#	ITEM#	Element name
3	250	CE	M	M	[1..1]		00571	Observation Identifier
4	20	OG	RE	M	[0..1]		00572	Observation Sub-ID
5	99999	Varies	M	M	[1..*]		00573	Observation Value
18	427	EI	M	M	[2..*]		01479	Equipment Instance Identifier

OBX-1 Set ID (SI), mandatory.

This field contains the sequence number of the observations.

Within the DPIA Profile, the sequence number is set to '1' for the first occurrence of the OBX segment in a segment group representing an IWOS. For example, the field is set to one in the first occurrence of the OBX segment in an instance of the ORDER segment group of the [LAB-

___

82] transaction. Subsequent occurrences of the segment within that ORDER segment group are
1120 sequentially numbered.

OBX-2 Value Type (ID), conditional.

This field contains the format of the observation value in OBX-5.

Predicate: Usage is Mandatory if OBX-5 (Observation Value) is not NULL (""). Otherwise, usage is Not Supported.

1125 **OBX-3 Observation Identifier (CE)**, mandatory.

This field contains one observation reported by the Acquisition Modality. A local code or standard vocabulary is required to ensure an unambiguous observation.

Table A.2-3: Element OBX-3 Observation Identifier

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	R	Observation Identifier Code
Text (ST)	199	R	Observation Identifier Description
Name of Coding System (ID)	12	R	"SCT" for SNOMED CT
Alternate Identifier (ST)	7	RE	Supplemental result code from Table 2.3.1-5 DPIA Codes for Supplemental Results
Alternate Text (ST)	199	C (R/X)	Supplemental result name from Table 2.3.1-5 DPIA Codes for Supplemental Results
Name of Alternate Coding System (ID)	6	C (R/X)	Fixed "IHEDPIA"

1130 Alternate components OBX-3-4 to OBX-3-6 SHALL be used only when the given OBX segment carries supplemental result information. OBX-3-4 "Alternate Identifier" is populated with a DPIA supplemental result identifier associated with the vendor supplemental identification provided in OBX-3-1 to OBX-3-3. The condition for both OBX-3-5 "Alternate Text" and OBX-3-6 "Name of Alternate Coding System" is that OBX-3-4 "Alternate Identifier" is
1135 populated.

OBX-3 is used in the current profile for conveying the following information.

Direction	Segment	Card.	Meaning	Example	Notes
Inbound [LAB-80]	OBX-3		Stain Name (like CID 8112)	104210008 | Hematoxylin and eosin stain method (procedure) |	OBX-3 = "Stain Name", OBX-5 = "H&E", "PAS", etc.

OBX-4 Observation Sub-ID (OG), required if available (Acquisition Manager), mandatory (Acquisition Modality).

This field ensures results from multiple regions of interest on the same glass slide scanned by the Acquisition Modality can be distinctly identified. Each region is uniquely identified (see Note 1 below table A.2-4).

Table A.2-4: Element OBX-4 Observation Sub-ID (OG: Observation Grouper)

Component/Sub-component	Usage	LEN	Comment
Original (ST)	R	20	Run identifier starting from "1"
Group (NM)	C(R/O)[1]	5	Group Identifier starting from "1"
Sequence (NM)	C(R/O)[1]	5	Sequence Number starting from "1"

Note 1: Predicate for OBX-4.2 and OBX-4.3: When a result message with multiple OBX segments uses the same observation ID (OBX-3) under the same OBR, OBX-4 is used to uniquely identify each observation. This is the case when multiple regions of interest on the same glass slide scanned by the Acquisition Modality need to be identified. This is accomplished by use of OBX-4.2, which must be populated with an integer starting from "1". It creates a group of related OBXs. OBX-4.3 must be set with an integer starting from "1" for further differentiation. Otherwise, the Acquisition Modality MAY use the fields may to further classify the OBX segments.

OBX-5 Observation Value (varies), mandatory.

This field contains the result value for the test result identified in OBX-3 Observation Identifier. The observation value SHALL be reported based on the value type specified in OBX-2.

The use of NULL ("") by the Acquisition Modality should not be interpreted as a requirement to delete observation information from IWOS data records maintained by the Acquisition Manager.

In DPIA repeating OBX-5 values are not allowed. The minimal set of OBX-5 data fields employed in this interoperability profile include:

Direction	Segment	Card	Meaning	Example	Notes
Inbound [LAB-80]	OBX-5 or IPC	R	Study Instance UID		Study Instance globally UID (1:1 related to accession # generally)
Outbound [LAB-82]	OBX-5 or IPC	R	Study Instance UID		1:1 mapping to the case accession # (unique at the case level, one per case)
Outbound [LAB-82]	OBX-5	RE	Slide Thumbnail ID	T201500038002001001^thumbnailimage^L	6/10/19 changed to type 2 as a scan attempt may fail
Outbound [LAB-82]	OBX-5	RE	Slide Thumbnail Base64	JPG^Base64^/9j/……h QODwwQFx	6/10/19 changed to type 2 as a scan attempt may fail
Outbound [LAB-82]	OBX-5	RE	Label Thumbnail ID		See open issue #23

Direction	Segment	Card	Meaning	Example	Notes
Outbound [LAB-82]	OBX-5	RE	Label Thumbnail Base64		See open issue #23
Outbound [LAB-82]	OBX-5	RE	On Slide Control Thumbnail ID		See open issue #23
Outbound [LAB-82]	OBX-5	RE	On Slide Control Thumbnail Base64		See open issue #23
Outbound [LAB-82]	OBX-5	RE	Tissue Thumbnail ID		See open issue #23
Outbound [LAB-82]	OBX-5	RE	Tissue Thumbnail Base64		See open issue #23

1160

The most common data types are described below.

Coded Entry (CE): The coded entry data type is used to represent coded qualitative results or exceptions. The following table defines the components of the CE data type.

Table A.2-5: Element OBX-5 Observation Value (when CE data type)

Component/Sub-Component	LEN	Usage	Comment
Identifier (ST)	20	R	Coded result
Text (ST)	199	R	The meaning of the code
Name of Coding System (ID)	12	R	Can be an analyzer-specific coding system or a national or international terminology, depending on the observation performed and of the type of result produced.

1165

Encapsulated Data (ED): The encapsulated data type is used for observations that are represented as thumbnail images. The following table defines the components of the ED data type.

Table A.2-6: Element OBX-5 Observation Value (when data type is ED)

Component/Sub-Component	LEN	Usage	Comment
Source Application (HD)	20	RE	Only the Namespace ID component is used. A unique name that identifies the system which was the source of the data.
Type of Data (ID)	9	R	A value from HL7 Table 0191. E.g., the value for image data is "IM"
Data Subtype (ID)	18	RE	A value from HL7 Table 0291. E.g., "JPEG"

Component/Sub-Component	LEN	Usage	Comment
Encoding (ID)	6	R	A value from HL7 Table 0299 Recommended value is "Base64"
Data (TX)	unlimited	R	The data representing the image or other encapsulated data being sent.

1170

String (ST): The string data type is used for observations that are represented as structured or unstructured text data limited to 200 characters. The following table defines the components of the ST data type.

Table A.2-7: Element OBX-5 Observation Value (when data type is ST)

Component/Sub-Component	LEN	Usage	Comment
String Data	200	R	The string that represents the value of the observation.

1175

OBX-18 Equipment Instance Identifier (EI), recommended.

This field specifies the manufacturer, model, serial number/ID, and optional UID of the analyzer that performed the test. It may also contain additional vendor or site specific identifiers. Entity identifier (EI) data type (can repeat to capture model, serial, firmware #s, and manufacturer is the 1180 assigning authority). This information is captured in the DICOM object so it may not need to be part of the message going back to the acquisition manager.

Table A.2-8: Element OBX-18 Equipment Instance Identifier (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R R O	50	First repeat: Model Second repeat: Serial number Subsequent repeats: Vendor/site defined
Namespace ID (IS)	R R O	20	First Repeat: Manufacturer Second Repeat: Manufacturer Subsequent repeats: Vendor/site defined
Universal ID (ST)	O X	199	First Repeat: UID Subsequent repeats: Not supported
Universal ID Type (ID)	O X	6	First Repeat: ISO Subsequent repeats: Not supported

A.3 ORC Segment

1185   HL7 v2.5.1: chapter 4 (4.5.1 ORC – Common Order Segment).

The Common Order segment (ORC) is used to transmit elements that are common to all of the tests ordered.

Table A.3-1: ORC Segment

SEQ	LEN	DT	Usage AM	Usage Acquisition Modality	Card. Acquisition Modality	TBL #	ITEM#	Element name
2	50[1]	EI	X	ORL^O34 (M/X)	[0..1]		00216	Placer Order Number (IWOS ID)
5	2	ID	X	M	[1..1]		00219	Order Status
9	26	TS	M	X	[1..1]	0038	00223	Date/Time of Transaction
16	250	CWE	RE	X	[0..1]		01311	Order Control Code Reason

1190   **ORC-2 Placer Order Number (EI)**, not supported (Acquisition Manager), mandatory (Acquisition Modality with ORL^O34).

The field is used by the Acquisition Modality to uniquely identify an IWOS when used as part of an ORL^O34 response to the Acquisition Manager.

Table A.3-2: Element ORC-2 Placer Order Number (EI)

Component/Sub-Component	Usage	LEN	Comment
Entity Identifier (ST)	R	50	IWOS ID

1195

Note on Element Length: The maximum element length for ORC-2 has been established as 50 characters to allow globally unique identifiers (such as GUIDs) for IWOS IDs.

ORC-5 Order Status (ID), mandatory (Acquisition Modality).

1200   The Acquisition Modality uses this field to provide the status of the IWOS. The allowed values for this field within the DPIA Profile are a subset of HL7 Table 0038 - Order Status as shown below:

Table A.3-3: Subset of HL7 Table 0038 – Order Status

Value	HL7 Description (Order status)	Meaning in the DPIA Profile (IWOS status)
SC	In process, scheduled	The IWOS is scheduled on the Acquisition Modality, but the Acquisition Modality has not started the work for the IWOS. This status can be sent in ORL message of [LAB-80] in response to OML (NW) when the IWOS is accepted.
IP	In process, unspecified	The process of the first run of the IWOS has started on the Acquisition Modality with the specimen. There may be some results or none. This status can be sent in ORL message of [LAB-80] in response to OML (NW) when the IWOS is accepted. This status can be sent in ORL message of [LAB-80] in response to OML (CA) when the IWOS cannot be cancelled because the IWOS work is in process. This status can be sent in OUL message of [LAB-82] to update the IWOS Status.
CM	Order is completed	The Acquisition Modality has finished its work for the IWOS. The results may have been produced or not. No additional result is expected for this IWOS. Nonetheless, a correction of some of the final (candidates for reporting) results produced for this IWOS may still be sent by the Acquisition Modality, in which case the IWOS status will remain "CM". This status can be sent in ORL message of [LAB-80] in response to OML (NW) when the IWOS is accepted. This status can be sent in ORL message of [LAB-80] in response to OML (CA) when the IWOS cannot be cancelled because the IWOS work is complete. This status can be sent in OUL message of [LAB-82] to update the IWOS Status.
CA	Order was canceled	The Acquisition Modality considers the IWOS work cancelled. This status can be sent in ORL message of [LAB-80] in response to OML (NW) when the IWOS request is rejected. An IWOS was not created by the Acquisition Modality. This status can be sent in ORL message of [LAB-80] in response to OML (CA) when the IWOS is cancelled. The Acquisition Modality can cancel the IWOS before the process of the IWOS has started, when the IWOS status is scheduled ("SC").

ORC-9 Date/Time of Transaction (TS), mandatory (Acquisition Manager), not supported (Acquisition Modality).

This field contains the date and time of the event that initiated the current transaction as reflected in ORC-1 Order Control Code. It is used by the Acquisition Manager for new orders and order cancellations in the OML^O33 message.

Time zone indicator is not supported with the acquisition manager and modality assumed to be in the same time zone.

Table A.3-4: Element ORC-9 Date/Time of Transaction (TS)

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDDHHMMSS	R	14	Date/time of initiating event

A.4 PID Segment

1215   This segment is only used with the LAW_PAT_DEM Profile Option (see Section 2.2.4.5).

The PID segment is used by all applications as the primary means of communicating patient identification information. This segment contains permanent patient identifying and demographic information that, for the most part, is not likely to change frequently.

1220   This segment allows an Analyzer to use patient demographic information for additional clinical evaluation of a test result, and to indicate when patient demographic information is applicable for the observations reported. Only a minimal set of identifying data is specified, as it is the responsibility of the Analyzer Manager to maintain patient demographic information. The scope of the PID segment in the context of LAW is the message only. Within LAW, the PID segment is not used to manage patient records, but rather to provide additional context for orders and

1225   observations.

Table A.4-1: PID Segment

SEQ	LEN	DT	Usage	Card.	TBL #	ITEM#	Element name
3	278	CX	R	[1..1]		00106	Patient Identifier List
5	250	XPN	R	[1..1]		00108	Patient Name
7	26	TS	RE	[0..1]		00110	Date/Time of Birth
8	1	IS	RE	[0..1]	0001	00111	Administrative Sex
10	250	CE	RE	[0..1]	0005	00113	Race
35 See Note 1	250	CWE	RE	[0..1]		01539	Taxonomic Classification Code

Note 1: This usage was pre-adopted from HL7 v2.8.1

PID-3 Patient Identifier List (CX), required.

1230   For the LAW Profile, this field contains the identifier used to uniquely identify a patient. The field is constrained to just one identifier, because it is the responsibility of the Analyzer Manager to manage multiple identifiers used by the healthcare facility (medical record number, billing number, birth registry, etc.). The Analyzer should not receive multiple identifiers for the same patient.

1235 If the identifier is not applicable, then the field is set to NULL (""). This may occur when an Analyzer is using the PID segment to identify demographic information applicable to the observation, such as PID-7 Date/Time of Birth, but does not use or maintain the patient identifier. The use of NULL ("") by the Analyzer should not be interpreted as a requirement to delete the patient identifier from patient data records maintained by the Analyzer Manager.

1240 PaLM TF-2x: A.1 specifies the usage for CX.4 "Assigning Authority" as Required. In most cases this information is not needed when exchanging patient identification information in the LAW transactions. It is the responsibility of the Analyzer Manager to manage the list of patient identifiers and not the Analyzer, and the Analyzer is not required to persist information about the Assigning Authority.

1245 **Table A.4-2: Element PID-3 Patient Identifier List (CX)**

Component/Sub-Component	Usage	LEN	Comment
ID (ST)	R	50	Locally defined
Assigning Authority (HD)	RE	227	
Namespace ID (IS)	RE	20	
Universal ID (ST)	RE	199	
Universal ID Type (ID)	C (R/X)	6	Must be populated if PID-3-4-2 is populated; otherwise is not supported

If all three sub-components of PID-3-4 Assigning Authority are populated, they must reference the same entity.

1250 Note on Element Length: The maximum element length for PID-3-1 has been extended to 50 characters from the HL7-prescribed length of 15 characters. This extension allows sending systems to use globally unique identifiers (such as GUIDs) for patient IDs.

PID-5 Patient Name (XPN), required.

This element contains the legal name of the patient.

1255 If the patient name is not applicable, then the field is set to NULL (""). This may occur when an Analyzer is using the PID segment to identify demographic information applicable to the observation, such as PID-7 Date/Time of Birth, but does not use or maintain the patient name. The use of NULL ("") by the Analyzer should not be interpreted as a requirement to delete the patient name from patient data records maintained by the Analyzer Manager.

1260 XPN.7 SHALL be populated with the value "L" from HL7 Table 0200 – Name type, which is the code for "Legal".

Table A.4-3: Element PID-5 Patient Name (XPN)

Component/Sub-Component	Usage	LEN	Comment
Family Name (FN)	RE		
Surname (ST)	RE	20#	Last Name
Given Name (ST)	RE	20#	First name
Second and Further Given Names or initials Thereof (ST)	RE	20#	Multiple middle names may be included by separating them with spaces
Suffix (e.g., JR or III) (ST)	RE	10#	A name suffix
Name Type Code (ID)	R	1	Always "L"

1265

PID-7 Date/Time of Birth (TS), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

This field contains the patient's date and optional time of birth to support neonatal patient specimens where hours/minutes is a significant criteria. Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. Degree of precision component is not supported.

1270

Table A.4-4: Element PID-7 Date/Time of Birth (TS)

Component/Sub-Component	Usage	LEN	Comment
YYYYMMDD[HHMMSS]	R	8/14	Date/time of birth

PID-8 Administrative Sex (IS), required if available (Analyzer Manager), required if available from Analyzer (Analyzer).

This field contains the patient's sex. Can be blank or contain only a value from HL7 User-
1275 defined Table 0001 (see below).

Table A.4-5: HL7 User-defined Table 0001 – Administrative Sex

Value	Description	Comment
F	Female	
M	Male	
U	Unknown	

A.5 SPM Segment

HL7 v2.5.1: chapter 7 (7.4.3 SPM – Specimen Segment).

1280   The SPM segment is used to describe the characteristics of a single specimen. The SPM segment relays information about the type of specimen and the date/time the specimen was received. It differs from the intent of the OBR segment in that the OBR addresses order-specific information. It differs from the SAC segment in that the SAC addresses specimen container attributes and the ID that is normally encoded on the sample container (barcode, RFID tag, etc.).

1285   In the case of an IWOS related to a single patient, the specimen role is "patient" (SPM-11 = P) and the specimen properties type, collection method, collection date, source site, source site modifier, and risk always represent the primary specimen that was collected from the patient, even in the case where the current specimen used by the IWOS is an aliquot or an isolate (a pure colony of a microorganism obtained after culture).

1290   **Table A.5-1: SPM Segment**

SEQ	LEN	DT	Usage Acquisition Manager [LAB-80]	Usage Acquisition Modality [LAB-82]	Card.	TBL#	ITEM#	Element name
2	80	EIP	M	DPIA_SPECIMEN (RE/X)	[1..1]		01755	Specimen ID
3	80	EIP	M	DPIA_SPECIMEN (RE/X)	[1..1]		01756	Specimen Parent IDs
4	250	CWE	DPIA_SPECIMEN (RE/X)	X	[0..1]	0487	01900	Specimen Type
6	250	CWE	DPIA_SPECIMEN (RE/X)	X	[0..1]			Specimen Additive
7	250	CWE	DPIA_SPECIMEN (RE/X)	X	[0..1]	0488	01759	Specimen Collection Method
8	250	CWE	M	X	[1..1]		01901	Specimen Source Site
11	250	CWE	M	X	[1..1]	0369	01762	Specimen Role
14	250	ST	DPIA_SPECIMEN (RE/X)	X	[0..1]		01764	Specimen Description
17	26	DR	DPIA_SPECIMEN (RE/X)	DPIA_SPECIMEN (RE/X)	[0..1]		01765	Specimen Collection Date/Time
18	26	TS	DPIA_SPECIMEN (RE/X)	X	[0..1]		00248	Specimen Received Date/Time
27	250	CWE	DPIA_SPECIMEN (RE/X)	X	[0..1]		01773	Container Type

SEQ	LEN	DT	Usage Acquisition Manager [LAB-80]	Usage Acquisition Modality [LAB-82]	Card.	TBL#	ITEM#	Element name
30	250	CX	M	X	[1..1]		02314	Accession ID

SPM-2 Specimen ID (EIP), required if available (Acquisition Manager with DPIA_SPECIMEN), required if available from Acquisition Modality (Acquisition Modality with DPIA_SPECIMEN).

1295 This field contains the specimen identifier. It may be the enterprise-wide unique specimen identifier.

Table A.5-2: Element SPM-2 Specimen ID (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	20	
Namespace ID (IS)	C (R/RE)[1]	20	
Universal ID (ST)	C (R/RE)[1]	199	
Universal ID Type (ID)	C (R/RE)[1]	6	

Note 1: Predicate: Either Placer Assigned Identifier.2 (Namespace ID) or both sub-components Placer Assigned Identifier.3 (Universal ID) and Placer Assigned Identifier.4 (Universal ID Type) are required. Sub-components 2, 3 and 4 may all
1300 be present.

SPM-3 Specimen Parent ID (EIP), required (Acquisition Modality with DPIA_POOL_NOAN), required if available (Acquisition Manager with DPIA_SPECIMEN), required if available from Acquisition Modality (Acquisition Modality with DPIA_SPECIMEN).

1305 This field contains the identifiers for the specimen or specimens that contributed to the specimen that is described by the segment instance.

When used with the DPIA_POOL_NOAN Profile Option, this required field will contain the specimen identifiers of the specimens that were pooled.

Table A.5-3: Element SPM-3 Specimen Parent IDs (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	20	
Namespace ID (IS)	C (R/RE)1	20	
Universal ID (ST)	C (R/RE)1	199	

Component/Sub-Component	Usage	LEN	Comment
Universal ID Type (ID)	C (R/RE)1	6	

1310   Note 1: Predicate: Either Placer Assigned Identifier.2 (Namespace ID) or both sub-components Placer Assigned Identifier.3 (Universal ID) and Placer Assigned Identifier.4 (Universal ID Type) are required. Sub-components 2, 3 and 4 may all be present.

SPM-4 Specimen Type (CWE), mandatory.

1315   This field describes the precise nature of the entity that will be the source material for the observation. The values defined in HL7 Table 0487 – Specimen Type will be used. The Acquisition Modality may define extensions to the table, and the Acquisition Modality may identify a subset of specimen types that are supported.

This field is populated with a value from HL7 Table 0487 – Specimen Type if the SPM-11

1320   Specimen Role is "P" (Patient specimen). This field is populated with NULL ("") if the SPM-11 Specimen Role is "Q" (Control specimen) or "U" (Unknown specimen as part of a Negative Query Response).

For some Acquisition Modalities, the IWOS performed is not impacted by the Specimen Type. The field must also be set to NULL ("") when sent by an Acquisition Modality if the specimen

1325   type is not applicable for the IWOS(s).

The use of NULL ("") by the Acquisition Modality should not be interpreted as a requirement to delete specimen information from specimen data records maintained by the Acquisition Manager.

Table A.5-4: Element SPM-4 Specimen Type (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Code from HL7 Table 0487, code from a vendor-defined coding system.
Text (ST)	RE	199	Description from HL7 Table 0487, or vendor-defined description
Name of Coding System (ID)	R	12	Fixed "HL70487" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

1330

SPM-7 Specimen Collection Method (CWE), required if available (Acquisition Manager, and Acquisition Modality supports DPIA_SPECIMEN), otherwise not supported.

This field describes the procedure or process by which the specimen was collected.

Table A.5-5: Element SPM-7 Specimen Collection Method (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Code from HL7 Table 0488 or a vendor-defined coding system
Text (ST)	RE	199	Description of the specimen collection method
Name of Coding System (ID)	R	12	Fixed "HL70488" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

1335

SPM-8 Specimen Source Site (CWE), required if available (Acquisition Manager, and Acquisition Modality supports DPIA_SPECIMEN), otherwise not supported.

This field specifies the source from which the specimen was obtained.

Table A.5-6: Element SPM-8 Specimen Source Site (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined value
Text (ST)	RE	199	Vendor description of the specimen source site
Name of Coding System (ID)	R	12	Vendor-defined coding system name "99zzz" (where z is an alphanumeric character)

1340

SPM-11 Specimen Role (CWE), mandatory.

This identifies the role of the specimen to be a Patient sample, QC specimen, or Unknown in support of the DPIA use cases and messaging constructs. However, an Acquisition Modality may extend the set with additional codes for HL7 Table 0369 or codes from a vendor-defined coding system.

1345

Table A.5-7: Subset of HL7 User-defined Table 0369 – Specimen Role

Value	Description	Comment	LAB-28	DPIA_POOL_NOAN
P	Patient specimen		Permitted	Excluded
Q	Control specimen		Permitted	Excluded
U	Unknown specimen role	Unknown specimen role; used for negative query response in [LAB-80]; requires IHEDPIA for the Name of Coding System	Permitted	Excluded

Table A.5-8: Element SPM-11 Specimen Role (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	A code from the "Value" column of Table A.12-8 or HL70369, or a vendor-defined coding system
Text (ST)	RE	199	Text from the "Description" column of Table A.12-8 or HL70369, or a vendor-defined description
Name of Coding System (ID)	R	12	Fixed "HL70369" or "IHEDPIA" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

SPM-17 Specimen Collection Date/Time (DR), required if available (Acquisition Manager, and Acquisition Manager supports DPIA_SPECIMEN), otherwise not supported.

The date and time when the specimen was acquired from the source. Only the start date/time component is supported (i.e., first component).

This element SHALL be reported to a precision of seconds. Time zone indicator is not supported, and is assumed to be the same as the value in MSH-7 Date/Time of Message. The degree of precision component is not supported.

Table A.5-9: Element SPM-17 Specimen Collection Start Date/Time (DR)

Component/Sub-Component	Usage	LEN	Comment
Range Start Date/Time	R		
YYYYMMDDHHMMSS	R	14	When the specimen was collected

SPM-27 Container Type (CWE), required if available (Acquisition Manager, and Acquisition Modality supports DPIA_SPECIMEN), otherwise not supported.

The container type in or on which a specimen is transported.

Table A.5-10: Element SPM-27 Container Type (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Container type code from a vendor-defined coding system
Text (ST)	RE	199	Vendor description of the container type code
Name of Coding System (ID)	R	12	Vendor-defined coding system name "99zzz" (where z is an alphanumeric character)

SPM-30 Accession Number (CX), required (Acquisition Manager, and Acquisition Modality supports DPIA_SPECIMEN).

1365   The accession number of the case under which the glass slide is associated.

Table A.5-11: Element SPM-27 Container Type (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Container type code from a vendor-defined coding system
Text (ST)	RE	199	Vendor description of the container type code
Name of Coding System (ID)	R	12	Vendor-defined coding system name "99zzz" (where z is an alphanumeric character)

Example usage for SPM segment data is described in the table below:

Direction	Segment	Card	Meaning	Example	Notes
Inbound [LAB-80]	SPM-2	R	Glass Slide ID	SP19-000425 B2 L1	Slide Unique ID
Inbound [LAB-80]	SPM-31	R	Display Identifiers	\SP19-000425 B2 L1\^^^Beaker^Barcode~ 00001^^^Beaker^SortForDisplay~SP19-425-B2-L1^^^Beaker^DisplayID	Will be repeated for Glass Slide ID, Block ID, Parent Specimen ID as needed (optional sort order / display order)
Inbound [LAB-80]	SPM-2	R	Block ID	SP19-000425 B2	
Inbound [LAB-80]	SPM-3	R	Parent Specimen ID	SP19-000425-B	Container (Bucket) Unique ID
Inbound [LAB-80]	SPM-31	R	Specimen UID	1.2.3.23.34.23.3	Specimen OID
Inbound [LAB-80]	SPM-30	R	Accession number	SP19-000425	Case Unique ID
Inbound [LAB-80]	SPM-17	RE	Collection DateTime	201902231200	Collection Date/Time (Date of Service)
Inbound [LAB-80]	SPM-6	RE	Specimen Additive	434162003 | Neutral buffered formalin (substance) |	this field repeats paraffin embedded could indicate the fixative used for the block here

Direction	Segment	Card	Meaning	Example	Notes
Inbound [LAB-80]	SPM-27	RE	Specimen Container Type (like CID 8103)	Glass Slide with coverslip	
Inbound [LAB-80]	SPM-4	RE	Specimen Type	119376003 | Tissue specimen (specimen) |	
Inbound [LAB-80]	SPM-7	RE	Specimen Collection (like CID 8109)	86273004 | Biopsy (procedure) |	
Inbound [LAB-80]	SPM-8	R	Specimen Source (like CID 8104)	44714003 | Structure of upper lobe of left lung (body structure) |	
	SPM-14	RE	Specimen description	Bronchial margin	
Inbound [LAB-80]	SPM-11	RE	Specimen Role	H	Would need to request new code for History = describes the parent specimen(s) of the submitted sample
Outbound [LAB-82]	SPM-3	R	Glass Slide ID	SP19-000425 B2 L1	Parent of the new digital image
Outbound [LAB-82]	SPM-2	R	Digital Specimen ID	1.3.46.670589.45.1.1.52 088736.1.6920.1424644 2.3	Unique Image Object ID (unique per each scan; this will be the same as the UID of the base level image in the DICOM object). The base layer metadata provides a link to all other layers.
Outbound [LAB-82]	SPM-17	R	DateTime Of Scan	201902231220	

1370

Appendix B - DICOM Supplement 122 Data Elements

How to Leverage DICOM Data Elements to Extend IHE Transactions

The current set of transactions focus on a minimal data set required to provide a useful interoperability profile supporting image acquisition from a device. Additional data elements are supported as part of the DICOM WG26 supplement 122 and may best be leveraged by submitting a request to DICOM WG26 and IHE PALM (palm@ihe.net). A draft mapping of data elements from DICOM supplement 122 to the HL7 Specimen Domain Analysis Model has been completed but specific use cases are requested to be reviewed as needs arise.

1375

1380 ## Namespace Additions for Volume 2

No new namespace additions.

The Pathology and Laboratory Medicine registry of OIDs is located at
ftp://ftp.ihe.net/PaLM/OIDregistry/PaLM_OIDs.pdf

1385

Volume 3 – Content Modules

There is no Volume 3 content for this profile.

1390

Appendices to Volume 3

Not applicable

Volume 4 – National Extensions

1395

Add appropriate Country section

There is no Volume 4 content (i.e., no National Extensions) for this profile.

Appendices to Volume 4

Not applicable.