# **Integrating the Healthcare Enterprise**



# IHE Radiology Technical Framework Supplement

Results Distribution (RD)

# **Rev. 1.1 – Trial Implementation**

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Please verify you have the most recent version of this document. See <a href="here">here</a> for Trial Implementation and Final Text versions and <a href="here">here</a> for Public Comment versions.

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#### **Foreword**

This is a supplement to the IHE Radiology Technical Framework V16.0. 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 15, 2017 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Radiology Technical Framework. Comments are invited and may be submitted at <a href="http://ihe.net/Radiology/Public Comments">http://ihe.net/Radiology/Public Comments</a>.

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.

40 *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.

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

Information about the IHE Radiology domain can be found at http://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 <a href="http://ihe.net/IHE\_Process">http://ihe.net/Profiles</a>.

The current version of the IHE Radiology Technical Framework can be found at <a href="http://ihe.net/Technical">http://ihe.net/Technical</a> Frameworks.

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# **Introduction to this Supplement**

The IHE Radiology Results Distribution (RD) Profile sends radiology results, i.e., radiology reports, between systems, such as from a report management system to an electronic healthcare record system. This profile uses an HL7<sup>®1</sup> v2.5.1 Observations Results (ORU) message to maximize compatibility with existing installed systems.

The profile was split from the IHE RAD Follow-up of Non-critical Actionable Findings (FUNC) Profile. As a result, the ORU message has a significant number of structured OBX segments to fulfill FUNC downstream requirements, but the message can be used generally.

## Open Issues and Questions

#	Document section	Open Issue	
13	Many – Vol 1 and Vol 2	When the IHE FUNC Profile is published for TI, references will have to be put back into this profile to refer to FUNC. On hold for now.	
14	Vol 2	In 4.128.4.1.2.13 OBX Segment – Imaging Result Payload: Monitor if a "by reference" option is necessary for the payload. Currently, this OBX segment, which is focused on the current installed base, only provides a "by value" option for the payload. By reference would require an "RP" (reference pointer) for the payload, which, in turn, would probably be a URL reference, but perhaps an OID reference also.	
15	Vol 2	If DICOM <sup>®2</sup> Part 20 "Imaging Reports in HL7 CDA <sup>®3</sup> " is updated (CP'd) to include explicit "Radiologist Requests Consult" and/or "Radiologist Requests Feedback" entries, this profile should be updated to include those direct mappings in the corresponding OBX segments in 4.128.4.1.2.11 and 4.128.4.1.2.12.	
16	Vol 1 Options and Vol 2 OBX mappings	When FHIR <sup>®4</sup> Diagnostic Report Resource becomes widely implemented and deployed, an additional Option should be created in this profile to mirror the DICOM Part 20 option and mappings should be created in a similar manner for each OBX segment to marry the installed base implementations to FHIR.	

<sup>&</sup>lt;sup>1</sup> HL7 is the registered trademark of Health Level Seven International.

<sup>&</sup>lt;sup>2</sup> DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

<sup>&</sup>lt;sup>3</sup> CDA is the registered trademark of Health Level Seven International.

<sup>&</sup>lt;sup>4</sup> FHIR is the registered trademark of Health Level Seven International.

#	Document section	Open Issue	
17	Vol1 Options and Vol 2 OBX mappings	In the U.S., ONC is advocating the use of Consolidated CDA (C-CDA) Diagnostic Imaging Report that is a level 1 CDA without some of the specific radiology requirements such as follow-up requests and non-actionable findings categorizations. However, given the ONC backing, do we want to add an ONC C-CDA optionalso?	
18	Vol 2 Imaging Result OBX	For the real-world scenario provided by Mt Sinai where an ORU is still sent if a result is not created (e.g., the patient moved (image quality) or could not stay in the MR), they would like to send a consistent ORU message to close the loop. So, in other words, this profile allows for an "Imaging Result" with no result, just a message. Reevaluate during Trial Implementation and after we get a few real-world installs.	
19	Vol 2 Imaging Result OBX	Should there be a Priority Value for "unknown" or should the Report Manager always be required to be capable of setting the critical actionable finding flag, even if the report is received from a Report Creator which has not implemented the RD Profile. It is clear that the Report Creator shall always set that flag properly.	

# **Closed Issues**

#	Document section	Open Issue	Resolution to Issue
1	Vol 2	Try to reuse CARD-7 or just create an ORU message?	A: creating new Y1 transaction. Not trying to reuse CARD-7 (MDM).
2	Vol 2	If we use CARD-8 we should use both complete report and by reference, correct? Need to include that somehow.	A: creating new Y1 transaction. Not trying to reuse CARD-7 (MDM) or CARD-8.

#	Document section	Open Issue	Resolution to Issue
3	X.3	Do we need to add another actor -a Report Manager back in and define the HL7 v2.5.1 critical results flag as an option to the follow-up source? This might require a new transaction if we can't find an ORU transaction? (may need to CP that transaction to include HL7 v2 CF element) - see emails from European folks. If we do this, then I also want to include DICOM Part 20 CDA CF flag. (as an option) Is this transaction then required on the Follow-up Source? Separate Use Case B-1 into two use cases then also.	A: Report Manager has been added back into profile based on input from folks in Europe.
1	X.3 AT diagram	Should this profile include a Report Repository and address archiving of reports? Or limit to transmission.	A: this profile will address transmission and format, but not archiving/storage
2	Entire profile	BIG: The original intent of this profile was to focus on pulling the installed base of reporting systems into the world of standardization. However, should this profile focus on the current installed base to drive adoption or focus on fulfilling the strategic vision of ONC including computer process-able report formats? Also see David Clunie's full email on this topic.	A: options have been redefined to include DICOM Part 20 CDA Level 3 as an OPTION
3	X.6	Does RAD-128 meet the needs of the combinations of the profiles/actors listed in X.6 Cross Profile Considerations? As part of public comment period, take into consideration that this RAD-128 transaction was developed initially for FUNC.	A: See X.6 for final decisions.
4	ROL	P: In RAD-128 - In ROLE segment, is the ROL-2 correct as Add?	A: correct, but ROL segment removed since not part of ORU message.
5	OBR	S: In RAD-128, we are putting Accession Number into OBR-18 (Placer Field 1) to mirror RAD-4 (Procedure Scheduled). Is this correct?	A: accept. See OBR-18 definition in Vol 2.

#	Document section	Open Issue	Resolution to Issue
6	OBR	T: In RAD-128, Laterality has been put into Placer Supplemental Service Information OBR-46 to mirror RAD-4. is that correct?	A: accept. See OBR-46 definition in Vol 2.
7	OBR	U: In RAD-128, OBR-25 Result Status and OBX says an amendment must include the complete report content, not just the differential. Verify.	A: accept. See OBR-25 definition in Vol 2.
8	OBX	V: In RAD-128, for the DICOM Instance OBX, what value should OBX-2 Value Type be? OBX for OID sections RP Reference Pointer is used. See HL7 v2.5.1 Ch 2A page 2-207 - please review. In HL7 v2.6 OBX-21 is Observation Instance Identifier - it is reserved in HL7 v2.5.1. Should we use this for OID/UID?	A: decision is to limit OBX to CONTAIN the report. The Reference Pointer (RP) has been removed for now, but see the Open Issue created just to track if it is really a requirement or not.
9		Y: IN RAD-128: we need a full example ORU	A: accept. Will create and add to ftp server.
10		Z: In RAD-128: how do we submit mapping ideas from this ORU to the FHIR organization for their mappings page? We do not currently seem to agree on all mappings.	A: accept, but it is not par to this profile. Contribute to FHIR website, not here.
11		AY1: In RAD-128: In IHE RAD-4/RAD-13 Procedure Scheduled puts the Study Instance UID into a ZDS segment, however, this is an ORM order message from an Order Filler (RIS). Should we stay consistent with that message or stay consistent within the ORU message as currently defined in RAD-128, as it is now? Note that there are not any KNOWN reporting systems using the ZDS segment in ORU (but some may still exist that we do not know about).	A: do not proliferate the use of Z segments per the HL7 O&O recommendation. Move to dedicated and coded OBX segment.

#	Document section	Open Issue	Resolution to Issue
12		BY1: IN RAD-128 alignment with the FHIR DiagnosticReport resource, should we at least propose to FHIR that they accept our mappings, because right now, that FHIR mapping section appears quite hacked/incomplete. See http://build.fhir.org/diagnosticreportmappings.html	A: accept, but it is not par to this profile. Contribute to FHIR website, not here.

#### **General Introduction**

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

# **Appendix A - Actor Summary Definitions**

Add and edit the following actors to the IHE Technical Frameworks General Introduction list of actors:

Actor	Definition	
Report Consumer	A system that receives imaging results (i.e., reports).	
Report Manager	A system that provides management and short-term storage of <b>DICOM</b> Structured Report objects reports during the reporting process then distributes them.text or structured reports to report repositories. It may also manage worklists and status of reporting.	
Report Creator	A system that generates and transmits preliminary, final, or amended diagnostic results (i.e., reports). presenting them as DICOM Structured Reporting Objects. It may also retrieve worklist entries for reporting steps from the Report Manager and provide notification of completion of the step, allowing the enterprise to track the status of an awaited report.	

# **Appendix B - Transaction Summary Definitions**

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

Transaction	Definition
Send Imaging Result [RAD-128]	Transfer imaging results (i.e., radiology reports) using an HL7 v2 ORU message.

# **Glossary**

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

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No new glossary terms

# **Volume 1 – Profiles**

# 45 Results Distribution (RD) Profile

The IHE Radiology Results Distribution (RD) Profile conveys imaging results (i.e., radiology reports) using an HL7 v2.5.1 Observation Results (ORU) message.

This profile specifies the metadata for imaging results and allows for several types of result payload formats.

Archiving, persistence, conversion to other formats, analysis, and display of results are outside the scope of this profile.

#### 45.1 RD Actors, Transactions, and Content Modules

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 at <a href="http://ihe.net/TF">http://ihe.net/TF</a> Intro Appendices.

Figure 45.1-1 shows the actors directly involved in the Results Distribution Profile and the relevant transaction between them.

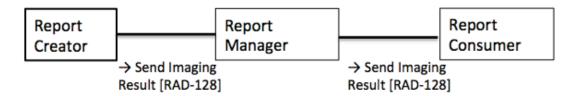


Figure 45.1-1: RD Actor Diagram

Table 45.1-1 lists the transactions for each actor directly involved in the RD 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 45.1-1: RD Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Report Creator	Send Imaging Result [RAD-128]	R	RAD TF-3: 4.128
Report Manager	Send Imaging Result [RAD-128]	R (See Note 1)	RAD TF-3: 4.128
Report Consumer	Send Imaging Result [RAD-128]	R	RAD TF-3: 4.128

Note 1: The Report Manager shall support the Send Imaging Result transaction as both the Sender and Receiver.

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#### 45.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 3). This section documents additional requirements on actors in this profile.

#### 45.1.1.1 Report Creator

The Report Creator shall be capable of sending the [RAD-128] transaction containing the Imaging Result Payload OBX Segment with an OBX-2 *Value Type* of "TX" for text reports. See RAD TF-3: 4.128.4.1.2.13.

#### 200 **45.1.1.2** Report Manager

The Report Manager shall be capable of sending and receiving the [RAD-128] transaction containing the Imaging Result Payload OBX Segment with an OBX-2 *Value Type* of "TX" for text reports, "ED" for Base64 encoded PDFs, and "ED" for HL7 CDA reports. See RAD TF-3: 4.128.4.1.2.13.

The Report Manager is recommended, but not required, to convert between result formats, e.g., to support Report Consumers that require alternate payload formats. At a minimum, the Report Manager shall be capable of sending result payloads using the format in which the result was originally received.

#### 45.1.1.3 Report Consumer

- The Report Consumer shall be capable of receiving the [RAD-128] transaction containing the Imaging Result Payload OBX Segment with an OBX-2 *Value Type* of "TX". See RAD TF-3: 4.128.4.1.2.13.
- If the Report Consumer is an EMR system, it may create an entry in a patient record which, when selected, displays the report in a simple to read manner and automatically display the associated imaging study using the DICOM Study Instance UID by launching an image viewer. The EMR system may also create a request for the ordering physician to consult the radiologist directly.
- If the Report Consumer is a follow-up critical results management system, it may create a request for a primary care physician to order the recommended follow-up study. This system may also create a request for the primary care physician to provide feedback to the radiologist when the order for the follow-up imaging procedure is ordered, perhaps including if the recommendation was followed and if not, the reason for not following the recommendation.
- If the Report Consumer is a clinical trials analysis system, it may analyze the types of findings and provide specific clinical trial recommendations for this patient to be reviewed by a clinical trials specialist. For example, if a liver mass of greater than 10mm is observed, the patient may be eligible for a new clinical trial or clinical care pathway.

# **45.2 RD Actor Options**

Options that may be selected for each actor in this profile are listed in the Table 45.2-1.

Table 45.2-1: Results Distribution - Actors and Options

Actor	Option Name	Reference
Report Creator	PDF Option	Section 45.2.1
	CDA Level 3 Option	Section 45.2.2
Report Manager	No options defined (See Note 1)	
Report Consumer	PDF Option	Section 45.2.1
	CDA Level 3 Option	Section 45.2.2

Note 1: The Report Manager shall support both PDFs and CDA results payloads as described in these options. Also see Section 45.1.1.2.

#### 45.2.1 PDF Option

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This option enables actors to exchange imaging results as a Portable Data Format (PDF) document.

A Report Creator that supports this option shall be able to send the [RAD-128] transaction containing an Imaging Result Payload OBX Segment with an OBX-2 *Value Type* of "ED" and a payload of Base64 encoded PDF as described in RAD TF-3: 4.128.4.1.2.13.

A Report Consumer that supports this option shall be able to receive and consume an Imaging Result Payload OBX Segment with an OBX-2 *Value Type* of "ED" and a payload of Base64 encoded PDF as described in RAD TF-3: 4.128.4.1.2.13. The Report Consumer may use the result content in a variety of manners, including presenting (i.e., displaying) the PDFs.

#### 45.2.2 CDA Level 3 Option

This option enables actors to exchange imaging results that include discrete and coded data and are formatted as xml-wrapped text as defined by HL7 CDA Level 3.

The content and semantics of the CDA document included or referenced in the Imaging Result Payload OBX Segment shall conform to DICOM Part 20 "Imaging Reports using HL7 CDA", with Level 3 specifications.

- A Report Creator that supports this option shall be able to send the [RAD-128] transaction containing an Imaging Result Payload OBX Segment with an OBX-2 *Value Type* of "ED" as described in RAD TF-3: 4.128.4.1.2.13. The Report Creator shall map the information in the HL7 ORU message segments from the HL7 CDA report itself as described in the message segment definitions in RAD TF-3: 4.128.4.1.2 Message Semantics.
- A Report Consumer that supports this option shall be able to receive and consume the [RAD-128] transaction containing an Imaging Result Payload OBX Segment with an OBX-2 *Value Type* of "ED" as described in RAD TF-3: 4.128.4.1.2.13. The Report Consumer may use the result content in a variety of manners, including:
  - presenting the CDA using a style sheet

- processing the data provided in the CDA, with no requirement to display the results
- instantiating additional workflows, such as creating a notification to the ordering physician regarding the follow-up of non-critical actionable findings
- incorporating data to mine for population health studies

# **45.3 RD Required Actor Groupings**

An actor from this profile shall implement all of the required transactions and/or content modules in this profile *in addition to* all of the transactions required for the grouped actor.

Section 45.5 describes some optional groupings that may be of interest for security considerations and Section 45.6 describes some optional groupings in other related profiles.

RD Actor	Actor to be grouped with	Reference	Content Bindings Reference
Report Creator	IHE ITI Consistent Time (CT) Time Client	IHE ITI TF-1: 7	
Report Manager			
Report Consumer			

Table 45.3-1: Results Distribution - Required Actor Groupings

#### 270 **45.4 RD Overview**

Actors in this profile communicate imaging results (i.e., radiology reports) between physicians, medical staff, and various facilities. This profile provides a consistent mechanism, and definition of metadata, to simplify the distribution of imaging results. When a radiologist creates an interpretation, or a "result", of an imaging study, the imaging result is often sent to an EMR for review by the physician who ordered the study. These imaging results are used to determine the on-going care, or "clinical care pathway", for the patient. Additionally, radiologists often use prior (comparison study) imaging results in the interpretation of a new imaging procedure. Imaging results may also be used for data mining for public health studies or clinical trial evaluations.

- 280 The content of an imaging result may include some or all of the following:
  - preliminary, final, or amended result status
  - normal, non-critical, urgent, or emergent results
  - structured, coded findings
  - references to imaging studies
  - overall impression or summary

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- radiologist's recommendations
- radiologist's requests for feedback and follow-up

#### 45.4.1 Concepts

#### 45.4.1.1 Reports versus Results

- The terms "reports" and "results" are often used interchangeably. Additionally, the terms "measurements" and "reports" are sometimes used interchangeably. HL7 v2 refers to "Observation Results". In most healthcare facilities, however, providers will often ask for "the radiology report".
- In this profile, the term "imaging result" specifically refers to a complete set of observations containing all of the findings, impressions and relevant measurements observed in a radiology imaging study. This is intended to cover what is often called "the radiology report".
  - Some measurements included in an imaging result may be obtained by importing DICOM Structured Reports (SR) objects. The DICOM SR information object is often used to convey measurements, for example ultrasound measurements, in a structured and coded object.
- A DICOM SR information object may use a full report template, such as DICOM TID 2000 "Basic Diagnostic Imaging Report", which contains a complete, signed imaging result, but that is not addressed in this profile.

## 45.4.1.2 Semantic Interoperability of Imaging Results

- Semantic interoperability refers to the ability of computer systems to exchange data, such as imaging results, with unambiguous, shared meaning. This is often a pre-requisite for advanced functions such as clinical decision support, automated alerts of critical situations, population health data mining, process automation, etc.
- Many current radiology reporting systems create simple, unstructured text reports. More advanced reporting systems are capable of creating results containing discrete, coded data which are machine readable. For structured and coded results, a more advanced radiology reporting system may send a DICOM Part 20 HL7 CDA document using this profile.
  - The baseline results payload format required in this profile is "text". In the case of free format text and PDF, the content of an imaging result may only be human readable or processed by natural language processing (NLP).
- 315 However, as the need for automation increases, structured and coded is increasingly more critical and required. For example, the U.S. Health and Human Services Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework has a stated goal of facilitating "computer processable" results (<a href="https://www.healthit.gov/policy-researchers-implementers/standards-interoperability-si-framework">https://www.healthit.gov/policy-researchers-implementers/standards-interoperability-si-framework</a>).
- 320 Similarly, Cancer Care Ontario has adopted entirely coded structured reports, also known as "synoptic reports", in radiology, surgery, and pathology which allow for "the standardized collection, transmission, storage, retrieval and sharing of data between clinical information

systems."

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(https://www.cancercare.on.ca/ocs/clinicalprogs/imaging/synoptic radiology reporting/).

- To enable the semantic interoperability, HL7 V3 Clinical Document Architecture (CDA) defines three levels (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC130066/):
  - Level 1 xml-wrapped text
  - Level 2 xml-wrapped text with section headers
  - Level 3 xml-wrapped text with section headers and structured and coded data
- Only "Level 3" data constructs (called "entries") of a CDA document enable individual structured and coded results.

When imaging results are exchanged using DICOM Part 20 "Imaging Reports using HL7 CDA", including Level 3 data constructs, the information is structured and coded such that it may be interpreted by a computer and workflow steps may be automated. As examples, if specific measurements are coded, it may be possible to identify additional clinical trials that may be relevant for a patient, or it may be possible to initiate follow-up of non-critical findings such as a small lung mass that needs to be monitored.

#### **45.4.1.3 Clinical Reporting Guidelines**

- The American College of Radiology (ACR), the European Society of Radiology (ESR), the Radiological Society of North America (RSNA), and several other societies have jointly issued recommendations (<a href="http://pubs.rsna.org/doi/full/10.1148/radiol.2523081992">http://pubs.rsna.org/doi/full/10.1148/radiol.2523081992</a>) regarding the basic content of imaging results. These recommendations include the following imaging result section headings:
  - 1. Clinical Information relevant patient information and medical history
  - 2. Current Imaging Procedure Description –the imaging procedure being reported
    - 3. Comparison Studies patient's prior imaging procedures used for comparisons
    - 4. Findings individual observations and details
    - 5. Impression summary and recommendations

These recommendations also provide guidance on addenda.

The section headings listed above correspond to the CDA section headings defined in DICOM Part 20. Individual structured and coded observations are typically in the "Findings" section.

#### 45.4.1.4 Report Templates and Classification Systems

The content, structure, and consistency of imaging results benefit from the use of report templates and classification systems.

The IHE Radiology Management of Radiology Report Templates (MRRT) Profile (<a href="http://ihe.net/uploadedFiles/Documents/Radiology/IHE\_RAD\_Suppl\_MRRT.pdf">http://ihe.net/uploadedFiles/Documents/Radiology/IHE\_RAD\_Suppl\_MRRT.pdf</a>) provides a format for the content of reports for specific imaging procedures (e.g., Two-view Chest X-ray or

CT lung screening). Examples of the clinical report templates may be found at <a href="https://www.radreport.org">www.radreport.org</a>.

- Additionally, ACR, ESR, and other societies have developed classification systems, or well-defined categories, to consistently describe the stage of particular conditions. One example is the breast imaging radiology screening categories (BI-RADS). These categories range from "Category 1" which is defined as "Negative no significant abnormality" to "Category 5" which is defined as "Highly suggestive of malignancy Appropriate action should be taken".
- Such categories can be combined with report templates. For example, a BI-RADS classification category can be incorporated into an MRRT report template for Mammography screening. This BI-RADS classification can then be exported as a specific coded value in a Level 3 CDA result.
  - Another advantage of using a template to generate a specific radiology result is that the template can specify all of the questions required to complete a DICOM Part 20 result instance. Thus,
- MRRT templates are particularly useful when coupled with the DICOM Part 20 imaging results format for automating follow-up workflow steps and future data mining of results.
  - An RSNA RadioGraphics article describes the integration of MRRT content, classification systems, and DICOM Part 20 in more detail. (http://www.ncbi.nlm.nih.gov/pubmed/28968194)
- For additional information, see "The Radiology Report". Langlotz, Curtis P. *The Radiology*Report: A Guide to Thoughtful Communication for Radiologists and Other Medical
  Professionals. CreateSpace Independent Publishing Platform, 2015.

# 45.4.1.5 Actionable Findings Categories and Results Priority

A finding is an observation made by a radiologist during interpretation of an imaging study. Findings may be quantitative or qualitative and may be normal or abnormal. Additionally, an abnormal finding may be actionable or non-actionable. Actionable findings are further categorized by the time interval within which a response to the finding is required.

An example of a finding is the observation of a lung nodule in a chest CT study. Depending on the size of the nodule, the radiology follow-up recommendation for additional imaging may vary. For example, according the Fleischner Criteria, a solitary lung nodule between 6mm and 8mm in size in a low risk patient is an actionable finding. The follow-up action is that the patient should have the study repeated in 6 to 12 months to detect changes in the size of the nodule. (https://radiopaedia.org/articles/fleischner-society-pulmonary-nodule-recommendations)

Findings may be non-actionable (i.e., no action required) for different reasons:

- Non-Actionable:
  - 1. Normal the observation is as expected or unremarkable. No action is required.
  - 2. Non-actionable the observation may not quite be as expected, or not strictly normal, but no action is required.

Normal findings are often included to communicate positively that something was observed and found to be normal. Another example of a normal finding is a "pertinent negative" such as the absence of abnormal findings related to the clinical question. Examples of non-actionable

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findings are "The spleen is slightly enlarged." or "Mild degenerative changes in the spine." Such findings are not strictly "normal", but are not intended to be actionable.

For actionable findings, the ACR recommends (<a href="http://www.jacr.org/article/S1546-1440(13)00840-5/pdf">http://www.jacr.org/article/S1546-1440(13)00840-5/pdf</a>) that findings be categorized as:

- 400 Actionable:
  - 1. Category 1 Emergent findings requiring immediate medical attention within minutes
  - 2. Category 2 Urgent findings requiring medical attention within hours
  - 3. Category 3 Non-critical findings requiring medical attention within days to months
- Consistency of the definition of actionable categories is very important because, although ACR Category 1 and 2 findings are usually handled person-to-person within the hospital where the imaging study was performed, it is common for the follow-up of non-critical ACR Category 3 findings to be performed at a different institution.
- The RSNA/ESR RadLex coding system (<u>www.radlex.org</u>) provides unique codes for each of the ACR Actionable Finding Categories as well as the non-actionable values.

This profile addresses these categories and codes, both for individual findings and a "summary actionable value" for the "worst case" finding in an imaging result (i.e., the most severe of all the individual findings), in RAD TF-3: 4.128.4.1.2 "Mapping of Finding Abnormality, Category and Priority".

#### 415 **45.4.2 Use Cases**

#### 45.4.2.1 Use Case 1: Send to EMR

After an imaging study is completed at the modality, the images are interpreted and the imaging result(s) is created and signed by a radiologist. The imaging result is then sent to the EMR for permanent archiving and access by providers, such as the ordering or referring physician.

#### 420 45.4.2.1.1 Send to EMR Use Case Description

The imaging result (i.e., a radiology report) is created and signed at the Report Creator and sent to a Report Manager with a status of "final". This imaging result is then forwarded to the Report Consumer, in this case the EMR. In other use cases, the result may be held for some time period, such as when batch sending to a cancer registry. The Report Manager may send the imaging

- result to multiple Report Consumers based on their various roles, such as EMR, cancer registry, administrative business analysis, clinical trials evaluation, etc.
  - If the result is not yet signed, as when created by a resident and awaiting an overread, the result may be sent to the Report Manager with a status of "preliminary" (not shown in this diagram). Once the result is signed, the Report Creator will resend the results, incorporating any changes, to the Report Manager with a status of "final". If the radiologist chooses to amend the report at

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the Report Creator or Report Manager, the complete amended result is sent to the Report Consumer with a status of "amended".

The business logic of the Report Manager may use the status of the imaging result (preliminary, final, amended) to determine when to send or re-send results to a specific type of Report Consumer, but that logic is outside the scope of this profile.

#### 45.4.2.1.2 Send to EMR Process Flow

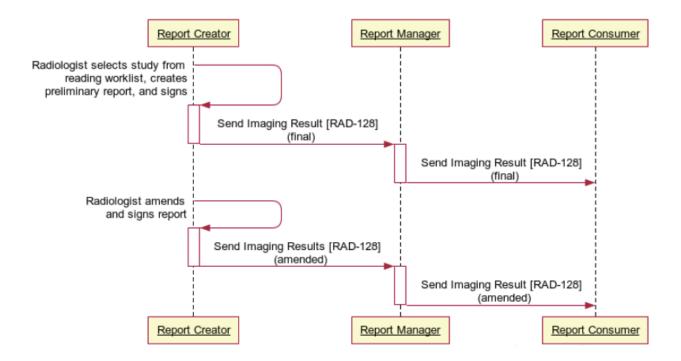


Figure 45.4.2.1.2-1: Send to EMR Process Flow

The text in Figure 45.4.2.1.2-2 was used to generate the diagram in Figure 45.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

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title RD: Send Imaging Result to EMR Process Flow

participant Report Creator participant Report Manager participant Report Consumer

Report Creator->+Report Creator: Radiologist selects study from \n reading worklist, creates\n preliminary

report, and signs

Report Creator->-Report Manager: Send Imaging Result [RAD-128]\n (final)

activate Report Manager

Report Manager->Report Consumer: Send Imaging Result [RAD-128]\n (final)

deactivate Report Manager

Report Creator->+Report Creator: Radiologist amends\n and signs report

Report Creator->-Report Manager: Send Imaging Results [RAD-128]\n (amended)

activate Report Manager

Report Manager->Report Consumer: Send Imaging Result [RAD-128]\n (amended)

deactivate Report Manager

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#### Figure 45.4.2.1.2-2: Diagram Pseudocode for Send to EMR Process Flow

#### 45.4.2.2 Use Case 2: Actionable Finding Trigger

As an imaging study is being interpreted, the radiologist identifies unexpected or incidental findings such a nodule in the lung. Sufficiently rich data should be conveyed to inform the appropriate care provider of the "non-critical actionable finding".

#### 45.4.2.2.1 Actionable Finding Trigger Use Case Description

In this use case, the Report Consumer is grouped with a system that monitors and tracks the follow-up of non-critical actionable findings. The priority and actionable category values of the imaging result act as a trigger for a findings follow-up management system to notify the appropriate provider (e.g., ordering physician) of the lung nodule finding, including the recommendation for follow-up provided by the radiologist.

For this use case, the imaging result payload may be text, PDF, or DICOM Part 20 because the summary actionable findings category and priority information is mapped into the HL7 ORU message.

## 45.4.2.2.2 Actionable Finding Trigger Process Flow

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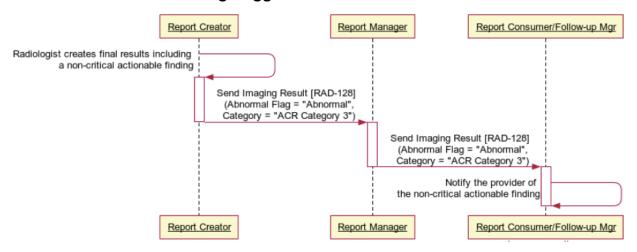


Figure 45.4.2.2.2-1: Actionable Finding Trigger Process Flow

The text in Figure 45.4.2.2.2-2 was used to generate the diagram in Figure 45.4.2.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
participant Report Creator
participant Report Manager
participant Report Consumer/Follow-up Mgr

Report Creator->+Report Creator: Radiologist creates final results including \n a non-critical actionable finding
Report Creator->-Report Manager: Send Imaging Result [RAD-128]\n (Abnormal Flag = "Abnormal", \n Category = "ACR Category 3")
activate Report Manager
Report Manager->+Report Consumer/Follow-up Mgr: Send Imaging Result [RAD-128]\n (Abnormal Flag = "Abnormal", \n Category = "ACR Category 3")
deactivate Report Manager
Report Consumer/Follow-up Mgr: Notify the provider of \n the non-critical actionable finding
```

Figure 45.4.2.2.2-2: Diagram Pseudocode for Actionable Finding Trigger Process Flow

# 45.5 RD Security Considerations

Personal Healthcare Information (PHI) is present in both the transmission metadata as well as the message payload.

#### 45.5.1 Security Considerations for Actors

All actors in the RD Profile should consider grouping with a Secure Application or Secure Node actor in the ITI Audit Trail and Node Authentication (ATNA) Profile.

This profile strongly recommends implementation of the ATNA Record Audit Event [ITI-20] transaction to record when and where imaging results are distributed.

The ATNA Profile also recommends that all RD actors implement the Authenticate Node [ITI-19] transaction to further ensure the integrity of transactions. Implementers are advised to take advantage of the authentication and communication encryption capabilities that Authenticate Node [ITI-19] provides between Secure Nodes and to take advantage of TLS when communicating over the Internet.

The Report Creator will contain PHI from orders and imaging results that may or may not be transiently stored.

The Report Manager might be the target of malicious attacks given the content of the imaging results that are stored.

The Report Consumer may store the imaging results in an EMR or Patient Portal. The Report Consumer will need to implement access control mechanisms consistent with the organization's policies, e.g., when to make reports available to patients, which care team members and non-members are permitted to view reports, etc.

#### 490 **45.5.2 Security Considerations for Imaging Results**

Imaging results contain not only personal demographic information, but also clinical results and diagnosis. A result such as a cancer diagnosis may need to be kept entirely confidential if a patient has not chosen to disclose that information to an employer, for example. For this reason, access to imaging results by unauthorized persons can be a significant concern. Facilities commonly have various forms of control limiting access to authorized personnel.

#### 45.6 RD Cross Profile Considerations

The RD actors would operate in a more integrated manner if grouped with actors in other IHE profiles. Table 45.6-1 contains some recommended groupings.

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RD Actor	Might group with	Potential Purpose				
Report Creator	RAD Radiology Report Templates (MRRT) / Report Creator	To generate the distributed radiology reports using a consistent, coded, complete template; especially useful with the CDA Level 3 Option. See Section 45.4.1.4.				
	RAD Access to Radiology Information (ARI) / Report Reader	To incorporate evidence created as part of the diagnostic study. For example, a radiology department may have a core lab or advanced analysis system when creates additional evidence documents such as DICOM SR for ultrasound measurements or 3D images for CT/MR. These measurements or images could be mapped directly into the radiology report to eliminate the need for data reentry.				

Table 45.6-1: Results Distribution – Optional Actor Groupings

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RD Actor	Might group with	Potential Purpose
	RAD Standardized Operational Log of Events (SOLE) / Event Reporter	To capture events such as the time that imaging results are signed. Such events support measuring business processes.
Report Manager	ITI Consistent Time (CT) / Time Client	To ensure consistent time stamps for log events and workflow analysis. For example, provide consistent time in logs from the time that results were received from a Report Creator until the time that the results were forwarded to a Report Consumer such as a critical follow-up management system.
	RAD Standardized Operational Log of Events (SOLE) / Event Reporter	To capture events such as the time that imaging results are distributed throughout the enterprise.
Report Consumer	ITI Consistent Time (CT) / Time Client	To ensure consistent time stamps for log events. For example, provide consistent time in logs from the time that results were received by a Report Consumer until the time that the end user was notified that results were available to be viewed.
	RAD Standardized Operational Log of Events (SOLE) / Event Reporter	To capture events such as the time that imaging results are reviewed by the ordering physician.
	RAD Invoke Image Display (IID) Image Display Invoker	To easily display images referenced in the distributed results.
	ITI Cross Enterprise Document Sharing (XDS-I.b) / Imaging Document Consumer	To easily display images referenced in the distributed results, similar to the IID Image Display Invoker, but in a different technology infrastructure
	ITI Cross Enterprise Document Sharing (XDS.b) / Document Source (See Note 1)	To further distribute the imaging results throughout the enterprise. Consider also other related Cross Enterprise Sharing Profiles.

Note 1: The mapping of the metadata codes (e.g., Patient ID, Procedure Codes) in the imaging results to corresponding values in the recipient site in the Affinity Domain is not explicitly defined.

# **Volume 3 – Transactions**

Add Section 4.128

# **4.128 Send Imaging Result [RAD-128]**

#### 4.128.1 Scope

This transaction is applicable to the communication of an imaging result (i.e., a radiology report) as an HL7 v2.5.1 Unsolicited Observation (ORU) message. The imaging result payload content may be text, Base64 encoded PDF, or a DICOM Part 20 CDA document.

- This transaction is limited to one imaging result or one amended imaging result per ORU message. The complete result or complete amended result is contained in a specific OBX segment(s), coded with a LOINC code as a "Diagnostic Imaging Report"; see Section 4.128.4.1.2.13 for result content requirements.
- The result may include normal, non-actionable, non-critical actionable, or critical actionable findings, which are represented in the "Priority" element in the OBR and TQ1 segments of the ORU message; see Section 4.128.4.1.2.1 for actionable finding values.
  - This ORU message may contain a series of optional, coded OBX segments as described in Section 4.128.4.1.2 that may be used to enable downstream workflow steps such as the follow-up of non-critical actionable findings; see Section 4.128.4.1.2 for a summary of OBX segments.
- 520 HL7 MDM messages are not used in this transaction. For encapsulated imaging results using HL7 v2.5.1 MDM messages, refer to IHE Cardiology Displayable Reports (DRPT) Trial Implementation Supplement CARD TF-2: 4.7.1.

#### 4.128.2 Actor Roles

The Roles in this transaction are defined in the following table and may be played by the actors shown here:

#### Table 4.128.2-1 Actor Roles

Role:	Sender:			
	Sends an imaging result.			
Actor(s):	The following actors may play the role of Sender:			
	Report Creator- when sending to a Report Manager			
	Report Manager- when sending to a Report Consumer			

Role:	Receiver:			
	Receives an imaging result.			
Actor(s):	The following actors may play the role of Receiver:			
	Report Manager- when receiving from a Report Creator			
	Report Consumer - when receiving from a Report Manager			

#### 4.128.3 Referenced Standards

HL7 Messaging Standard v2.5.1, Observation Reporting (Chapter 7)

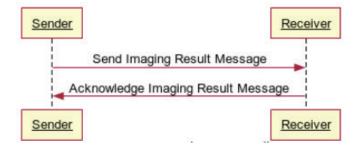
530 HL7 Messaging Standard v2.5.1, Control (Chapter 2)

RAD TF-2: 2.3.1 Conventions for HL7 v2.5.1 messages

DICOM PS3.20 Imaging Reports using HL7 Clinical Document Architecture (CDA)

#### 4.128.4 Interaction Diagram

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Figure 4.128.4-1: Send Imaging Result Interaction Diagram

#### 4.128.4.1 Send Imaging Result Message

The Sender sends an imaging result (e.g., a radiology report) to the Receiver.

The Sender shall be able to send an imaging result to more than one Receiver. The Receiver shall support reception of such messages from more than one Sender.

#### **4.128.4.1.1 Trigger Events**

The Sender determines, or is instructed by an operator, that it is necessary to send an imaging result to the Receiver.

#### 4.128.4.1.2 Message Semantics

The message is an HL7 2.5.1 Observation Reporting (ORU^R01) message. The Sender is the HL7 sender. The Receiver is the HL7 recipient. The content is an imaging result.

The imaging result payload may be encoded as text, as a Base64 encoded PDF, or as a DICOM Part 20 CDA document. The Sender and Receiver shall support "text". Senders and Receivers may also support PDF and CDA (See RAD TF-1: 45.2). Senders are not required, but may be able, to convert an imaging result payload into a format supported by the Receiver. Since HL7 v2.5.1 does not provide "association negotiation" of payload formats, such conversion behaviors on the Sender should be managed through a priori configuration.

This HL7 v2.5.1 ORU message is very similar to an HL7 v2.3 ORU message with the addition of the TQ1 segment.

The Sender shall encode the ORU message and segments as defined in this section.

Table 4.128.4.1.2-1: HL7 v2.5.1 Send Imaging Result (ORU) Message

ORU^R01 Segments	Message Content	HL7 v2.5.1 Chapter	Reference
MSH	Message Header	2	Section 4.128.4.1.2.2 MSH Segment
PID	Patient Identification	3	Section 4.128.4.1.2.3 PID Segment
PV1	Patient Visit	3	Section 4.128.4.1.2.4 PV1 Segment
[ORC]	Order Common	4	Section 4.128.4.1.2.5 ORC Segment
OBR	Order Detail	4	Section 4.128.4.1.2.6 OBR Segment
TQ1	Timing/Quantity	4	Section 4.128.4.1.2.7 TQ1 Segment
[{OBX}]	Observation/Result (See Note 1)	7	Sections 4.128.4.1.2.8 through 4.128.4.1.2.13 OBX Segments

Adapted from the HL7 Standard, version 2.5.1

Note 1: The type of any given OBX segment is identified by a coded value in OBX-3 Observation Identifier.

See RAD TF-2: 2.3.1 "Conventions for HL7 v2.5.1 messages" for a complete definition of the notation used in the sections referenced by Table 4.128.4.1.2-1.

The OBX segments in this transaction are summarized in Table 4.128.4.1.2-2.

Table 4.128.4.1.2-2: Summary of Send Imaging Result OBX Segments

OBX Segment Name	Required	Multiplicity of OBX segment	Reference
DICOM Study Instance UID OBX	Required if DICOM Study Instance UID(s) known	[0n] – one DICOM Study Instance UID OBX segment per DICOM study to which the result applies	Section 4.128.4.1.2.8
Finding OBX	Recommended if any observed finding is actionable	[0n] – one Finding OBX segment per finding being observed (It is common that there may be more than one coded finding.)	Section 4.128.4.1.2.9

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OBX Segment Name	Required	Multiplicity of OBX segment	Reference
Radiologist's Recommendation OBX	Recommended if the radiologist specifies a follow-up imaging procedure	[0n] – one Radiologist's Recommendation OBX segment per recommendation (usually only one recommendation)	Section 4.128.4.1.2.10
Radiologist Requests Consultation OBX	Recommended if the radiologist requests a direct consult with a result recipient	[0n] – one Radiologist Requests Consultation OBX segment per consult request (usually only one consult request)	Section 4.128.4.1.2.11
Radiologist Requests Feedback OBX	Recommended if the radiologist requests feedback on a follow-up recommendation	[0n] – one Radiologist Requests Feedback OBX segment per feedback request (usually only one request for feedback)	Section 4.128.4.1.2.12
Imaging Result Payload OBX	Required if an imaging result is present	[0n] –only one imaging result per ORU; however, multiple Imaging Result Payload OBX segments are permitted if the number of characters exceeds the maximum length of an OBX segment.	Section 4.128.4.1.2.13

#### 4.128.4.1.2.1 Mapping of Finding Abnormality, Category and Priority

A number of the segments in this message (OBR, TQ1 and all the OBX segments) have fields to encode Abnormality, Category, and Priority. This section explains how to consistently populate those fields.

Actionable and non-actionable findings are discussed extensively in RAD TF-1: 45.4.1.5 It is important to understand the concepts of actionable findings prior to reading this section.

The following *Abnormal Flag* values from HL7 v2.5.1 Abnormal Flag (Table 0078) shall be used in this transaction:

- N Normal
- A Abnormal
- AA Critical abnormal

The following *Priority* values from HL7 v2.5.1 Priority (Table 0485) shall be used in this transaction:

- R Routine
- A ASAP
- 585 S STAT

Table 4.128.4.1.2.1-1 explains how to populate fields in OBX, OBR and TQ1 segments for the different types of observations.

An ORU message shall contain only a single OBR segment and a single TQ1 segment, but may contain multiple OBX segments. However, different OBX segments may contain different levels of actionable observations. Therefore, the OBR and TQ1 segments shall reflect the most severe of the observations in the ORU. Table 4.128.4.1.2.1-1 lists the observations in order of severity where a Normal observation is the least severe and an Emergent Actionable Finding observation is the most severe.

Table 4.128.4.1.2.1-1: Abnormal Flag, Category, and Priority Mapping

Table 4.120.4.1.2.1 1. Abhormar rag, Category, and Thorax mapping						
	In Findin (OBX-3 = "59776-5^Pro ar in Imaging (OBX-3 = "18748-4^ Repor	OBR and TQ1				
Field	Abnormal Flag	Category	Priority			
Segment field:	OBX-8 Abnormal Flag	OBX-15 Producer's Reference	OBR-27.6 and TQ1-9.1 Priority			
Value Set:	HL7 v2.5.1 Table 0078	RadLex	HL7 v2.5.1 Table 0485			
Normal observation: (least severe)	N^Normal^HL70078	RID13173^Normal^RadLex	R^Routine^HL70078			
Non- actionable observation:	N^Normal^HL70078	RID50261^Non-actionable^ RadLex	R^Routine^HL70078			
Non-critical Actionable Finding observation:	A^Abnormal^HL70078	RID49482^Category 3 Non- critical Actionable Finding^ RadLex	R^ Routine^HL70078			
Urgent Actionable Finding observation:	AA^Critical Abnormal^HL70078	RID49481^Category 2 Urgent Actionable Finding^ RadLex	A^ASAP^HL70078			
Emergent Actionable Finding observation: (most severe)	AA^Critical Abnormal^ HL70078	RID49480^Category 1 Emergent Actionable Finding^RadLex	S^STAT^HL70078			

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It is possible that a result sent to a Report Manager was created by system that does not comply with the Report Creator in the Results Distribution (RD) Profile and that the *Abnormal*, *Category*, and *Priority* values are not known. If the Report Manager is unable to determine these values from the result content, the result shall set the *OBX-8 Abnormal Flag* as

"N^Normal^HL70078", the *OBX-15 Producer's Reference* as "RID5655^Unknown^RadLex", and the *OBX-27.6* and *TQ1-9.1 Priority* as "R^Routine^HL70078". A Report Creator in the RD Profile shall not send a result with the *OBX-15 Producer's Reference* set to "RID5655^Unknown^RadLex".

#### 4.128.4.1.2.2 MSH Segment

The Message Header (MSH) segment shall be constructed as defined in ITI TF-2b: 3.30.5.1 MSH – Header Segment.

Field MSH-9-Message Type shall have three components. The first component shall have a value of ORU; the second component shall have a value of R01. The third component shall have a value of ORU\_R01.

#### 610 **4.128.4.1.2.3 PID Segment**

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The Patient Identification (PID) segment definition is based on HL7 Version 2.5.1 (Chapter 3, Patient Administration, Section 3.4.2). This definition does not conflict with the PID Segment as defined in ITI TF-2b: 3.30.5.3 PID – Patient Identification Segment.

This PID Segment shall be further constrained as specified in Table 4.128.4.1.2.3-1.

Table 4.128.4.1.2.3-1: HL7 v2.5.1 ORU PID Segment

SEQ	LEN	DT	OPT	TBL#	ITEM#	ELEMENT NAME
2	20	CX	X		00105	Patient ID
3	250	CX	R		00106	Patient Identifier List
4	20	CX	X		00107	Alternate Patient Identifier List
5	250	XPN	R		00108	Patient Name
7	26	TS	R2		00110	Date/Time of Birth
8	1	IS	R2	0001	00111	Administrative Sex
9	250	XPN	X		00112	Patient Alias
11	250	XAD	R2		00114	Patient Address
12	4	IS	X	0289	00115	Country Code
13	250	XTN	R2		00116	Phone Number – Home
14	250	XTN	R2		00117	Phone Number - Business
18	250	CX	R2		00121	Patient Account Number
19	16	ST	X		00122	SSN Number – Patient
20	25	DLN	X		00123	Driver's License Number - Patient
27	250	CE	R2	0172	00130	Veterans Military Status
28	250	CE	X	0212	00739	Nationality

Adapted from the HL7 Standard, version 2.5.1

Field *PID-3 – Patient Identifier List* contains a list of identifiers (one or more) used by the healthcare facility to uniquely identify a patient. Subcomponents *PID-3.1* "ID number", *PID-3.4* "Assigning authority" shall be present, and for each identifier *PID-3.5* "Identifier Type Code" shall be present, if known. ITI TF-2b: 3.30.5.3 and ITI TF-2x: Appendix N.1 contain additional descriptions on *PID-3* and the constrained profile definition of data type CX.

Subcomponent *PID-3.5* "Identifier Type Code" may be populated with values given in HL7 Table 0203 (HL7 Version 2.5, Chapter 2A, Section 2A.17.5). Commonly used values are:

- BC Bank card number. Assigning authority is the bank.
- BR Birth Certificate number. Assigning authority is the state or national government that issues the Birth Certificate.
  - DL Driver's license number. Assigning authority is the state.
  - NH National Health Plan Identifier. Assigning authority is the national organization.
  - PE Living Subject Enterprise Number. Assigning authority is the enterprise.
- PI Patient Internal Identifier. Assigning authority is the healthcare organization.
  - PPN Passport number. Assigning authority is the national government.
  - PRC Permanent Resident Card Number. Assigning authority is the national government.
  - SS Social Security Number. Assigning authority is the national government.

#### 635 **4.128.4.1.2.3.1 CDA Level 3 Option**

In addition to the PID segment mapping described in Table 4.128.4.1.2.3-1, if a Sender supports the CDA Level 3 Option in the RD Profile, it shall map data from the DICOM Part 20 CDA document directly into the PID segment, as described in Table 4.128.4.1.2.3.1-1.

Table 4.128.4.1.2.3.1-1: DICOM Part 20 to ORU PID Segment mapping

DICOM Part 20 Business Name	SEQ	OPT	ITEM#	ELEMENT NAME
ImagingReport:Patient:ID Issuer, ImagingReport:Patient:ID	3	R	00106	Patient Identifier List
ImagingReport:Patient:Name	5	R	00108	Patient Name
ImagingReport:Patient:BirthTime	7	R2	00110	Date/Time of Birth
ImagingReport:Patient:Gender	8	R2	00111	Administrative Sex
ImagingReport:Patient:Addr	11	R2	00114	Patient Address
ImagingReport:Patient:Tele	13	R2	00116	Phone Number - Home
ImagingReport:Patient:Tele	14	R2	00117	Phone Number – Business

Adapted from the HL7 Standard, version 2.5.1

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#### 4.128.4.1.2.4 PV1 Segment

The Patient Visit (PV1) Segment definition is based on HL7 Version 2.5.1 (Chapter 3, Patient Administration, Section 3.4.3). This definition does not conflict with the PV1 Segment as defined in ITI TF-2b: 3.30.5.4 PV1 – Patient Visit Segment.

This PVI Segment shall be further constrained as specified in Table 4.128.4.1.2.4-1.

SEQ	LEN	DT	ОРТ	TBL#	ITEM #	ELEMENT NAME
2	1	IS	R	0004	00132	Patient Class
3	80	PL	R2		00133	Assigned Patient Location
6	80	PL	R2		00136	Prior Patient Location
7	250	XCN	R2	0010	00137	Attending Doctor
8	250	XCN	R2	0010	00138	Referring Doctor
9	250	XCN	X	0010	00139	Consulting Doctor
10	3	IS	С	0069	00140	Hospital Service
17	250	XCN	R2	0010	00147	Admitting Doctor
19	250	CX	R2		00149	Visit Number
40	1	IS	X	0116	00170	Bed Status
51	1	IS	С	0326	01226	Visit Indicator
52	250	XCN	R2	0010	01274	Other Healthcare Provider

Table 4.128.4.1.2.4-1: HL7 v2.5.1 ORU PV1 Segment

Adapted from the HL7 Standard, version 2.5.1

Note that fields *PV1-3-Assigned Patient Location*, *PV1-10-Hospital Service*, and *PV1-17*650 *Admitting Doctor* are primarily applicable to in-hospital patients. If the patient is an outpatient, these fields may be omitted.

Field PV1-7 Attending doctor shall be valued, if known. If this field is sent, the second, Family Name, and third components, Given Name, shall be valued. It is strongly recommended that the first component, ID Number, and the ninth component, Assigning Authority, are valued. The attending doctor may be useful for follow-up notifications.

Field PV1-8 Referring doctor shall be valued, if known. If this field is sent, the second, Family Name, and third components, Given Name, shall be valued. It is strongly recommended that the first component, ID Number, and the ninth component, Assigning Authority, are included. The referring doctor may be useful for follow-up notifications.

Field *PV1-17 Admitting doctor* shall be valued, if known. If this field is sent, the second, *Family Name*, and third components, *Given Name*, shall be valued. It is strongly recommended that the first component, *ID Number*, and the ninth component, *Assigning Authority*, are valued. The admitting doctor may be useful for follow-up notifications.

Field *PV1-51 Visit Indicator* shall be valued with value "V" to indicate a "Visit" (as opposed to account information) if the field *PV1-19 Visit Number* is valued.

Field PV1-52 Other Healthcare Provider, if sent, then the second, Family Name, and third components, Given Name, shall be valued. It is strongly recommended that the first component, ID Number, and the ninth component, Assigning Authority, are valued. Other healthcare providers may be useful for follow-up notifications.

#### 670 **4.128.4.1.2.4.1 CDA Level 3 Option**

In addition to the PV1 segment mapping described in Table 4.128.4.1.2.4-1, if a Sender supports the CDA Level 3 Option in the RD Profile, it shall map data from the DICOM Part 20 CDA document directly into the PV1 segment, as described Table 4.128.4.1.2.4.1-1.

DICOM Part 20 Business Name		ОРТ	ITEM #	ELEMENT NAME
ImagingReport:AttendingPhysicianName	7	R2	00137	Attending Doctor
ImagingReport:Performer[REF]:ReferrerName, ImagingReport:Performer[REF]:ReferrerID	8	R2	00138	Referring Doctor
ImagingReport:EncounterID	19	R2	00149	Visit Number

Table 4.128.4.1.2.4.1-1: DICOM Part 20 to ORU PV1 Segment mapping

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Adapted from the HL7 Standard, version 2.5.1

#### 4.128.4.1.2.5 ORC Segment

The Common Order (ORC) segment conveys common order information. In an HL7 v2.5.1 ORU message, however, the OBR segment is intended to primarily convey the imaging result specific information. Therefore, it is recommended that the ORC segment is not sent in this ORU message. However, the ORC segment may be necessary for backward compatibility for some systems. If the Sender chooses to send information in an ORC segment, it shall ensure that the ORC information is identical to the analogous fields in the OBR segment, including the mandatory mapping fields defined in HL7 v2.5.1.

If the ORC segment is included it shall not conflict with HL7 v2.5.1 Section 4.5.1 (Common Order Segment).

#### 4.128.4.1.2.6 OBR Segment

The Observation Request (OBR) Segment defines attributes ("metadata") for the entirety of the imaging result (i.e., the summary information, not specific to an individual finding or measurement). The imaging result payload itself is contained in an OBX segment.

The OBR segment definition is based on HL7 Version 2.5.1 (Chapter 4, Order Entry, Section 4.5.3).

This OBR Segment shall be further constrained as specified in Table 4.128.4.1.2.6-1.

Table 4.128.4.1.2.6-1: HL7 v2.5.1 ORU OBR Segment

SEQ	LEN	DT	ОРТ	TBL#	ITEM #	ELEMENT NAME
2	22	EI	R2		00216	Placer Order Number
3	22	EI	R2		00217	Filler Order Number
4	250	CE	R		00238	Universal Service ID
5	2	ID	X		00239	Priority (retired)
6	26	TS	X		00240	Requested Date/time
7	26	TS	R2		00241	Observation Date/Time
12	250	CE	R2		00246	Danger Code
13	300	ST	R2		00247	Relevant Clinical Info.
16	250	XCN	R2		00226	Ordering Provider
17	250	XTN	R2		00250	Order Callback Phone Number
18	60	ST	R		00251	Placer Field 1
19	60	ST	R2		00252	Placer Field 2
20	60	ST	R2		00253	Filler Field 1
21	60	ST	R2		00254	Filler Field 2
22	26	TS	R		00255	Results Rpt/Status Chng - Date/Time
24	10	ID	R2	0074	00257	Diagnostic Serv Sect ID
25	1	ID	R	0123	00258	Result Status
27	200	TQ	R		00221	Quantity/Timing
28	250	XCN	R2		00260	Result Copies To
31	250	CE	R2		00263	Reason for Study
32	200	NDL	R		00264	Principal Result Interpreter
33	200	NDL	R2		00265	Assistant Result Interpreter
34	200	NDL	R2		00266	Technician
35	200	NDL	С		00267	Transcriptionist
44	250	CE	R	0088	00393	Procedure Code
46	250	CE	R2	0411	01474	Placer Supplemental Service Information
48	250	CWE	R2	0476	01646	Medically Necessary Duplicate Procedure Reason

Adapted from the HL7 Standard, version 2.5.1

Constraining usage of fields *Placer Order Number (ORC-2, OBR-2)* and *Filler Order Number (ORC-3, OBR-3)* is beyond the scope of this transaction and may be locally defined. In this message, the Placer system is often a HIS or EMR used by a primary care physician or specialist.

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The Filler system is typically a RIS or EMR ordering component. The Sender in this transaction may obtain the information for these fields from a Procedure Scheduled [RAD-4] transaction (see RAD TF-2: 4.4.4.1.2.2.7) or from images that are referenced during the interpretation process. The first three components of field OBR-3 Filler Order Number may also contain the Accession Number if that is the local definition of that field. Also see field *OBR-18 Placer Field 1* for Accession Number.

Field *OBR-4 Universal Service ID* shall contain the Performed Procedure Code in the first three components as:

- identifier
- text code meaning
- coding system

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If the Performed Procedure Code is not known, the Requested Procedure Code shall be used. The source of the Performed Procedure Code is beyond the scope of this transaction, but may be the DICOM image objects. The source of the Requested Procedure Code is beyond the scope of this transaction, but may be an order message (ORM) or DICOM image objects. Use of codes from a standardized coding system for procedures such as RadLex Playbook is recommended.

Field *OBR-7 Observation Date/Time* is the clinically relevant date/time of the observation; i.e., it is the date/time of the imaging procedure, not the date/time of the imaging result. If the date and time of the imaging procedure is not known, this field should not be sent. The source of the imaging procedure date and time is beyond the scope of this transaction, but may be the DICOM image objects. See the *OBR-22 Results Rpt/Status Chng - Date/Time* for the time of the imaging result.

Field *OBR-12-Danger Code* value will most likely be a locally defined value. The second component should hold a text description, if not coded.

Field *OBR-13-Relevant Clinical Info* should be populated if the patient record contains any medical alerts that may be relevant. The value will most likely be a locally defined value.

Fields *OBR-16 Ordering Provider* and *OBR-17 Order Callback Phone Number* shall be valued if known. These fields are critical for proper distribution of the result and for follow-up communication. The information that is populated in these fields is the provider who ordered this imaging study. This may be a primary care provider, a referring provider, a specialist, or may be a provider in the ED department. For *OBR-16*, subcomponents *OBR-16.2 Family Name* and *OBR-16.3 Given Name* shall be valued. It is strongly recommended that *OBR-16.1 ID Number* and *OBR-16.9 Assigning Authority*, at a minimum, are also valued. All other known components should be included.

Field *OBR-18 Placer Field 1* shall contain the imaging study Accession Number. Note that in the original HL7 2.5.1 semantics for the Procedure Scheduled [RAD-4] transaction the Accession Number is provided in IPC Segment IPC-1, but the IPC Segment is not included in an ORU Message, so the HL7 v2.3.1 interpretation of this field is used.

- Field *OBR-20 Filler Field 1* and *OBR-21 Filler Field 2* may be locally defined, but should be sent if valued.
- Field *OBR-22 Results Rpt/Status Chng Date/Time* shall contain the date and time the imaging result was signed or amended.
  - Field *OBR-24 Diagnostic Serv Sect ID* should be set to "CUS" for Cardiac Ultrasound, "CTH" for Cardiac Catheterization, "VUS" for Vascular Ultrasound, or "RAD" for a Radiology procedure.
- Field *OBR-25 Result Status* shall use the values in Table 4.128.4.1.2.6-2. If an amended imaging result is sent with a status of "C", the entire content of the changed imaging result shall be sent. Differential content alone (i.e., only the changed content) shall not be sent. Field *OBR-25* shall be identical to the Imaging Result Content OBX segment field *OBX-11*.
- Field *OBR-27 Quantity/Timing* shall be retained for backwards compatibility only. The 6th component, *Priority*, shall use the values from HL7 v2.5.1 *Table 0485* as defined in Table 4.128.4.1.2.1. The value of *OBR-27.6 Priority* shall match *TQ1-9.1 Priority*, as described in Section 4.128.4.1.2.1. Other components of *OBR-27* shall not be valued.
  - Field *OBR-28 Copy Results To* shall be valued, if known. This field may be useful in identifying the follow-up Recipients.
- 755 Field *OBR-31 Reason for Study* shall be valued, if known.
  - Field *OBR-32 Principal Result Interpreter* shall be the coded name of the interpreting radiologist who is responsible for the content of the imaging result. For *OBR-32.1*, subcomponents of *Name*: *OBR-32.1*^2 *Family Name* and *OBR-32.1*^3 *Given Name* shall be valued. It is strongly recommended that *OBR-32.1*^1 *ID Number*, *OBR-32.1*^8 *Assigning Authority-Namespace*, and
- 760 *OBR-32.1*^9 *Assigning Authority Universal ID* at a minimum, are also valued. All other known components should be valued. *OBR-32.7 Facility* should also be valued if known.
  - Field *OBR-33 Assistant Result Interpreter* shall be valued if known and contributed to generating these imaging results.
  - Field *OBR-34 Technician* should be valued, if known.
- Field *OBR-35 Transcriptionist* shall be valued if dictated imaging results were transcribed, if known.
  - Field *OBR-44 Procedure Code* shall match *OBR-4*.
- Field *OBR-46 Placer Supplemental Service Information* shall contain the laterality (Left/Right) indicator (when used) in the <site modifier (CE)> component. See RAD TF-2: Appendix B for details.
  - Field *OBR-25 Result Status* shall contain values from Table 4.128.4.1.2.6-2.

Table 4.128.4.1.2.6-2: HL7 v2.5.1 ORU OBR-25/OBX-11 Result Status Values

Value	Description					
R	Results stored; not yet verified (see Note)					
F	Final results; results stored and verified. Can only be changed with a corrected result.					
С	Correction to results					

Adapted from the HL7 Standard, version 2.5.1, Table 0123

Note: Table 0123 in HL7 V2.5.1 also contains a value of "P" for "Preliminary". Unverified imaging results, also commonly referred to as "preliminary imaging results", are sent with status value "R" rather than "P". The value "P" is used more often in the case of laboratory results, where a final result may be awaiting development of a culture, but the preliminary results are usable for clinical treatment planning. Therefore, the value of "R" is used for preliminary imaging results.

780 The value "F" is a final, signed imaging result. The value "C" is for an amended/final imaging result. An amended imaging result shall contain the entire imaging result content, not only the differential content (not only the portion of the report which was changed).

The relationship between the status of various imaging result messages (e.g., matching a preliminary result with a subsequent final result) is out of scope of this transaction.

- Not all elements in the OBR segment are applicable to an unsolicited imaging results message. Several of the elements defined in the OBR segment are specific to laboratory specimen results while other elements are used in response to an order placer system, and these are denoted by an "\*" in the attribute name of the HL7 v2.5.1 standard. These elements are optional, but their presence in an imaging result message would be unusual. These elements are listed below for clarity:
  - OBR-9 Collection Volume
  - OBR-10 Collector Identifier
  - OBR-11 Specimen Action Code
  - OBR-14 Specimen Received Date/Time
- *OBR-15 Specimen Source*

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- OBR-37 Number of Sample Containers
- OBR-38 Transport Logistics of Collected Samples
- OBR-39 Collector's Comments

#### 4.128.4.1.2.6.1 CDA Level 3 Option

In addition to the OBR segment mapping described in Table 4.128.4.1.2.6-1, if a Sender supports the CDA Level 3 Option in the RD Profile, it shall map data from the DICOM Part 20 CDA document directly into the OBR segment, as described in Table 4.128.4.1.2.6.1-1.

Table 4.128.4.1.2.6.1-1: DICOM Part 20 to ORU OBR Segment mapping

DICOM Part 20 Business Name	SEQ	ОРТ	ITEM #	ELEMENT NAME
ImagingReport:Order:OrderPlacerNumber, ImagingReport:Order:OrderAssigningAuthority	2	R2	00216	Placer Order Number
May be (locally defined usage): ImagingReport:Order:AccessionNumber, ImagingReport:Order:AccessionAssigningAuthority	3	R2	00217	Filler Order Number
ImagingReport:Order:OrderedProcedureCode	4	R	00238	Universal Service ID
ImagingReport:Study:StudyTime	7	R2	00241	Observation Date/Time
ImagingReport:Order:Performer[REF]:ReferrerID, ImagingReport:Order:Performer[REF]:ReferrerName	16	R2	00226	Ordering Provider
ImagingReport:Order:Performer[REF]:ReferrerTel	17	R2	00250	Order Callback Phone Number
ImagingReport:Order:AccessionNumber, ImagingReport:Order:AccessionAssigningAuthority	18	R	00251	Placer Field 1
ImagingReport:CreationTime	22	R	00255	Results Rpt/Status Chng - Date/Time
If ImagingReport:ParentDocument@typecode = RPLC, then "C" for amended results; else if ImagingReport:ParentDocument@typecode is not present, then "F" for final results	25	R	00258	Result Status
ImagingReport:Order:OrderPriority	27	R	00221	Quantity/Timing
ImagingReport:Recipient:Name, ImagingReport:Recipient:Org, ImagingReport:Recipient:Tel, ImagingReport:Recipient:Addr	28	R2	00260	Result Copies To
ImagingReport:Author:ID, ImagingReport:Author:Name, ImagingReport:Author:Addr, ImagingReport:Author:Tele	32	R	00264	Principal Result Interpreter
ImagingReport:Performer[SPRF]:Name, ImagingReport:Performer[SPRF]:ID	33	R2	00265	Assistant Result Interpreter
ImagingReport:Performer[SPRF]:Name, ImagingReport:Performer[SPRF]:ID	34	R2	00266	Technician
ImagingReport:TranscriptionistID, ImagingReport:TranscriptionistName	35	С	00267	Transcriptionist
ProcedureDescription:ProcedureTechnique:ProcedureCode	44	R	00393	Procedure Code
ProcedureDescription:ProcedureTechnique:Laterality	46	R2	01474	Placer Supplemental Service Information

Adapted from the HL7 Standard, version 2.5.1

### 4.128.4.1.2.7 TQ1 Segment

The HL7 v2.5.1 TQ1 Segment defines the priority of the imaging results. The Timing/Quantity (TQ1) Segment definition is based on HL7 Version 2.5.1 (Chapter 4, Order Entry, Section 4.5.4).

This TQ1 Segment shall be further constrained as specified in Table 4.128.4.1.2.7-1.

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Table 4.128.4.1.2.7-1: HL7 v2.5.1 ORU TQ1 Segment

SEQ	LEN	DT	ОРТ	TBL#	ITEM #	ELEMENT NAME
9	250	CWE	R	0485	01635	Priority

Adapted from the HL7 Standard, version 2.5.1

Field *TQ1-9 Priority* CWE components shall be present to identify normal or actionable findings. Values from HL7 v2.5.1 *Table 0485* shall be used as defined in Table 4.128.4.1.2.1-1. Field *TQ1-9* shall match *OBR-27.6 Priority*.

### 4.128.4.1.2.7.1 CDA Level 3 Option

In addition to the TQ1 segment mapping described in Table 4.128.4.1.2.7-1, if a Sender supports the CDA Level 3 Option in the RD Profile, it shall map data from the DICOM Part 20 CDA document directly into the TQ1 segment, as described in Table 4.128.4.1.2.7.1-1. If the CDA document did not use values from Table 4.128.4.1.2.1-1, the Sender shall map the Priority values from the CDA into those values.

Table 4.128.4.1.2.7.1-1: DICOM Part 20 to ORU TQ1 Segment mapping

DICOM Part 20 Business Name	SEQ	OPT	ITEM #	ELEMENT NAME
ImagingReport:OrderPriority	9	R	01635	Priority

Adapted from the HL7 Standard, version 2.5.1

#### 4.128.4.1.2.8 OBX Segment - DICOM Study Instance UID

This OBX segment identifies the imaging study used to produce this imaging result.

The Observation/Result (OBX) Segment definition is based on HL7 Version 2.5.1 (Chapter 7, Observation Reporting, Section 7.4.2). This definition does not conflict with the OBX Segment as defined in ITI TF-2b: 3.30.5.7 OBX – Observation/Result Segment.

A summary of the OBX segments in this ORU message is provided in Table 4.128.4.1.2-2.

**Optionality:** This OBX segment shall be included if the DICOM Study Instance UID(s) is known.

**Multiplicity:** This OBX segment may repeat if the imaging result applies to multiple imaging studies. However, there shall be only one DICOM Study Instance UID per DICOM Study Instance UID OBX segment. Field *OBX-4 Observation Sub-ID* is used to differentiate multiple Study Instance UIDs as described below.

This OBX Segment shall be further constrained as specified in Table 4.128.4.1.2.8-1.

Table 4.128.4.1.2.8-1: HL7 v2.5.1 ORU OBX Segment - DICOM Study Instance UID

SEQ	LEN	DT	ОРТ	TBL#	ITEM#	ELEMENT NAME
1	4	SI	R		00569	Set ID – OBX
2	2	ID	R	0125	00570	Value Type =ST
3	250	CE	R		00571	Observation Identifier
4	20	ST	С		00572	Observation Sub-ID
5	99999	HD	R		00573	Observation Value
11	1	ID	R	0085	00579	Observation Result Status = O
23	567	XON	С		02283	Performing Organization Name
24	631	XAD	С		02284	Performing Organization Address
25	3002	XCN	С		02285	Performing Organization Medical Director

Adapted from the HL7 Standard, version 2.5.1

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Field OBX-2 Value Type shall have the value "ST" to indicate that OBX-5 is a text string.

Field *OBX-3 Observation Identifier* shall have the value "113014^DICOM Study^DCM" in the first three components.

Field *OBX-4 Observation Sub-ID* is typically a sequential integer which distinguishes between multiple OBX segments with the same field *OBX-3 Observation Identifier*. For example, this imaging result may apply to a CT abdomen and a CT pelvis study which were interpreted together.

Field *OBX-5 Observation Value* shall include the Study Instance UID. The method by which the Sender obtains the Study Instance UID is beyond the scope of this transaction. The Sender may obtain this information from a DICOM object during the interpretation process (preferred) or a Procedure Scheduled [RAD-4] transaction.

Field *OBX-11 Observation Result Status* shall have the value "O" (Order detail description - no result).

Fields *OBX-23 Performing Organization Name, OBX-24 Performing Organization Address*, and *OBX-25 Performing Organization Medical Director* should be populated with information of the organization where the imaging study was acquired.

Examples of multiple Study Instance UID references are shown below:

## 4.128.4.1.2.8.1 CDA Level 3 Option

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In addition to the DICOM Study Instance UID OBX segment mappings described in Table 4.128.4.1.2.8-1, if a Sender supports the CDA Level 3 Option in the RD Profile, it shall map data from the DICOM Part 20 CDA directly into this OBX segment, as described in Table 4.128.4.1.2.8.1-1.

Table 4.128.4.1.2.8.1-1: DICOM Part 20 to DICOM Study Instance UID OBX mapping

DICOM Part 20 Business Name	SEQ	ОРТ	ITEM#	ELEMENT NAME
ImagingReport:Study:StudyUID	5	R	00573	Observation Value
ImagingReport:HealthcareFacilityName	23	С	02283	Performing Organization Name
ImagingReport:HealthcareFacilityAddress	24	С	02284	Performing Organization Address

Adapted from the HL7 Standard, version 2.5.1

# 4.128.4.1.2.9 **OBX Segment - Finding**

This OBX segment is used to convey the specific, discrete findings which are part of these imaging results. These findings may be plain text or coded.

The Observation/Result (OBX) Segment definition is based on HL7 Version 2.5.1 (Chapter 7, Observation Reporting, Section 7.4.2). This definition does not conflict with the OBX Segment as defined in ITI TF-2b: 3.30.5.7 OBX – Observation/Result Segment.

A summary of the OBX segments in this ORU message is provided in Table 4.128.4.1.2-2.

**Optionality:** This OBX segment should be included if the Imaging Result Payload OBX Segment contains findings which are not normal. However, this OBX segment may also be included for normal findings.

Multiplicity: This OBX segment may repeat, one for each finding in the imaging result, since each Finding OBX segment shall only contain a single finding but it is common for an imaging result to have many findings.

See RAD TF-1: 45.4.1.5 for an explanation of non-actionable and actionable findings.

A Finding OBX should be sent for each finding that is not "Normal". It is especially useful to send Finding OBX segments if the result payload is text or a PDF, which do not inherently contain such coded information.

For findings which are text, it is recommended that each discrete finding is included in a separate Finding OBX segment. In other words, for findings which are text, it is not recommended that multiple findings are included in a single text Finding OBX.

This OBX Segment shall be further constrained as specified in Table 4.128.4.1.2.9-1.

Table 4	4.128.4.1.2	.9-1: HL	7 v2.5.1 O	RU OBX Se	gment - Finding

SEQ	LEN	DT	OPT	TBL#	ITEM#	ELEMENT NAME
1	4	SI	R		00569	Set ID – OBX
2	2	ID	R	0125	00570	Value Type = CE or TX
3	250	CE	R		00571	Observation Identifier
4	20	ST	С		00572	Observation Sub-ID
5	483 or 99999	CE or TX	R		00573	Observation Value
8	5	IS	R	0078	00576	Abnormal flag
11	1	ID	R	0085	00579	Observation Result Status = R, F, C
15	250	CE	R		00583	Producer's Reference

Adapted from the HL7 Standard, version 2.5.1

Field *OBX-2 Value Type* identifies the encoding of Field *OBX-5 Observation Value*. *OBX-2* shall have the value "CE" (coded entry) or "TX" (text data for display).

- If Field *OBX-2* has the value "CE" or "TX", Field *OBX-3 Observation Identifier* should have the coded value of the finding itself. For example, "|300332007^Liver Mass^SCTID|" would identify a finding of a mass in the liver using the SNOMED coding system. Universally recognized coding systems, such as LOINC and SNOMED are strongly recommended, although local coding systems may be used.
  - If Field *OBX-2* has the value "TX", then Field *OBX-3 Observation Identifier* may have the value "|59776-5^Procedure Findings^LN|" and then *OBX-5 Observation Value* shall contain the actual finding in uncoded (free format) text.

Field *OBX-4 Observation Sub-ID* is typically a sequential integer number used to distinguish between multiple OBX segments with the same *OBX-3 Observation ID* (i.e., if more than one finding in a single imaging result). Field *OBX-4 Observation Sub-ID* shall be populated with a distinct value in each of these OBX segments. An example of this for coded entries (*OBX-2* = "CE") is that different values of *OBX-4 Observation Sub-ID* would differentiate findings of the same code, for example differentiate multiple liver masses. An example of this for text entries (*OBX-2* = "TX") is that different values of *OBX-4 Observation Sub-ID* would differentiate more than one finding as plain text. Examples are given below.

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Field *OBX-5 Observation Value* shall contain the finding itself as:

- When *OBX-2* = "CE", if *OBX-3* is a coded concept (i.e., a coded question), then *OBX-5 Observation Value* Components 1-3 shall be contain whether the finding is "present", "absent" or value, as a coded value, for example a SNOMED code. If *OBX-3* identifies a quantitative measurement, then *OBX-5 Observation Value* Component 2 shall contain the measurement value.
- When *OBX-2* = "TX", the *OBX-5 Observation Value* shall contain the finding itself as text
- Field *OBX-6 Units* should contain the ISO or ANSI units, as defined in HL7 v2.5.1, if the finding is a quantitative measurement.

Field *OBX-8 Abnormal Flag* shall use the mapped values defined in Table 4.128.4.1.2.1-1 for normal and abnormal findings. For this OBX segment, the *OBX-8 Abnormal Flag* shall contain the abnormal status that is applicable to this specific finding value identified in *OBX-5*. The abnormal flag may differ between OBX Finding segments, based on the abnormality of each individual finding.

Field OBX-11 Observation Result Status shall have the same value as OBR-25 Result Status.

Field *OBX-15.1 - OBX-15.3 Producer's Reference* shall use the mapped coded values defined in Table 4.128.4.1.2.1-1. For this OBX segment, the *OBX-15 Producer's Reference* shall contain the actionable category which is applicable to this specific finding. The actionable category may differ between OBX Finding segments, based on each individual finding.

Examples of multiple Finding OBX segments including both coded entries and text findings are shown below:

OBX|1|TX|859776-5^Procedure Findings^LN|1|The right kidney is slightly enlarged, but otherwise normal.N^Normal^HL70078 |||F||||RID50261^Non-actionable^RadLex|

OBX|2|TX|859776-5^Procedure Findings^LN|2|There is a small mass in the left lung measuring approximately 3mmx2mm.

945 OBX|3|TX|300332007^Liver Mass^SCT|1|4mmx6mm |mm||||A^Abnormal^HL70078|||F||||RID49482^Category 3 Non-critical Actionable Finding^RadLex|

OBX|4|TX|300332007^Liver

Mass^SCT|2|5mmx7mm|mm||||A^Abnormal^HL70078|||F||||RID49482^Category 3
950 Non-critical Actionable Finding^RadLex|

 $\label{local_observable} OBX | 5 | CE | 309088003 ^Renal Mass ^SCT | 1 | C65.2 ^Malignant neoplasm of left renal pelvis ^ICD-10 | | | | | AA ^Critical$ 

Abnormal^HL70078|||F||||RID49481^Category 2 Non-critical Actionable Finding^RadLex|

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955 OBX|6|TX|24646-2^CXR PA+LAT^LN|1|Infiltrate probably representing bronchopneumonia in the right lower lobe. Also pulmonary venous congestion cardiomegaly and cephalization, indicating early congestive heart failure. ||||AA^Critical

 $\label{eq:abnormal} Abnormal^{HL70078} |||F||||RID49481^{Category~2~Non-critical~Actionable~960~Finding^{RadLex}|$ 

OBX|7|CE|24646-2^CXR PA+LAT^LN|2|51.71^Congestive heartfailure^ACR||||AA^Critical Abnormal^HL70078|||F|||RID49481^Category 2 Non-critical Actionable Finding^RadLex|

# 965 **4.128.4.1.2.9.1 CDA Level 3 Option**

In addition to the Finding OBX segment mappings described in Table 4.128.4.1.2.9-1, if a Sender supports the CDA Level 3 Option in the RD Profile, it shall map data from the DICOM Part 20 CDA document directly into this OBX segment, as described in Table 4.128.4.1.2.9.1-1 and Table 4.128.4.1.2.9.1-2.

There are two types of Findings measurements: Quantity Measurement (DICOM PS3.20 Section 10.5) and qualitative observation as a Coded Observation (DICOM PS3.20 Section 10.1).

Each quantity measurement shall be mapped as described in Table 4.128.4.1.2.9.1-1.

Table 4.128.4.1.2.9.1-1: DICOM Part 20 to ORU Finding OBX mapping – Quantity Measurement

DICOM Part 20 Business Name	SEQ	OPT	ITEM#	ELEMENT NAME
QuantityMeasurement[*]:MeasurementName	3	R	00571	Observation Identifier
QuantityMeasurement[*]:MeasurementValue, QuantityMeasurement[*]:MeasurementUnits	5	R	00573	Observation Value
QuantityMeasurement[*]:InterpretationCode	8	R	00576	Abnormal flag
QuantityMeasurement[*]:ActionableFindingCode	15	R	00583	Producer's Reference

Adapted from the HL7 Standard, version 2.5.1

Each qualitative observation shall be mapped as described in Table 4.128.4.1.2.9.1-2.

Table 4.128.4.1.2.9.1-2: DICOM Part 20 to Finding OBX mapping – Qualitative Observation

DICOM Part 20 Business Name	SEQ	ОРТ	ITEM #	ELEMENT NAME
CodedObservation[*]:ObsName	3	R	00571	Observation Identifier
CodedObservation[*]:ObsValue	5	R	00573	Observation Value
CodedObservation[*]:InterpretationCode	8	R	00576	Abnormal flag
CodedObservation [*]:ActionableFindingCode	15	R	00583	Producer's Reference

Adapted from the HL7 Standard, version 2.5.1

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### 980 4.128.4.1.2.10 OBX Segment - Radiologist's Recommendation

This OBX segment is useful to convey the radiology recommendation to the primary care physician if a follow-up imaging study is suggested.

The Observation/Result (OBX) Segment definition is based on HL7 Version 2.5.1 (Chapter 7, Observation Reporting, Section 7.4.2). This definition does not conflict with the OBX Segment as defined in ITI TF-2b: 3.30.5.7 OBX – Observation/Result Segment.

A summary of the OBX segments in this ORU message is provided in Table 4.128.4.1.2-2.

**Optionality:** This OBX segment should be included if the imaging result contains a Radiologists Recommendation.

Multiplicity: This OBX segment may repeat if the imaging result contains multiple radiology recommendations. However, there shall be only one radiology recommendation per Radiologist's Recommendation OBX segment.

This OBX Segment shall be further constrained as specified in Table 4.128.4.1.2.10-1.

**SEQ LEN** DT **OPT** TBL# ITEM# **ELEMENT NAME** 1 4 SI R 00569 Set ID - OBX 2 2 ID R 0125 00570 Value Type = CE or TX3 250 CE R 00571 Observation Identifier 4 C 20 ST 00572 Observation Sub-ID 5 250 or 99999 CE or TX R 00573 Observation Value ID R 11 1 0085 00579 Observation Result Status = R, F, 15 250 CE R2 00583 Producer's Reference

Table 4.128.4.1.2.10-1: HL7 v2.5.1 ORU OBX Segment - Radiologist's Recommendation

Adapted from the HL7 Standard, version 2.5.1

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The OBX-2 Value Type field shall have the value "CE" (coded entry) or "TX" (text).

The *OBX-3 Observation Identifier* field shall have the value "18783-1\Study recommendation\LN".

The *OBX-4 Observation Sub-ID* is typically a sequential integer which is used to distinguish between multiple OBX segments with the same *OBX-3 Observation ID*. When field *OBX-3 Observation Identifier* has an identical value in two or more OBX segments of the message, Field *OBX-4 Observation Sub-ID* shall be populated with a distinct value in each of these OBX segments.

When *OBX-2* = "TX" (text), the *OBX-5 Observation Value* shall contain the recommended follow-up procedure itself as text. An example of *OBX-5* as text could be |Follow-up with CT of the Abdomen without contrast is recommended in 6 months.| Two OBX Radiologist's Recommendation segments might be sent, one with a RadLex Playbook Code, and one as descriptive text which may include timing.

The OBX-11 Observation Result Status shall have the same value as OBR-25 Result Status.

Field *OBX-15 Producer's Reference* shall contain the Guidelines used to generate the recommendation (e.g., Fleischner's Criteria for lung nodule follow-up), if known. The text description shall be contained in the second component.

### 4.128.4.1.2.10.1 CDA Level 3 Option

In addition to the Radiologist's Recommendation OBX segment mappings described in Table 4.128.4.1.2.10-1, if a Sender supports the CDA Level 3 Option in the RD Profile, it shall map data from the DICOM Part 20 CDA document into this OBX segment, as described in Table 4.128.4.1.2.10.1-1 and Table 4.128.4.1.2.10.1-2.

Radiologist's Recommendations as coded recommendations (e.g., RadLex Procedure Code) shall be mapped as shown in Table 4.128.4.1.2.10.1-1.

Table 4.128.4.1.2.10.1-1: DICOM Part 20 to ORU Radiologist's Recommendation OBX mapping - coded recommendations

DICOM Part 20 Business Name	SEQ	OPT	ITEM#	ELEMENT NAME
Recommendation: FollowupProcedure[*]:ProcedureCode	5	R	00573	Observation Value
Recommendation: Content[*]:GuidelineRef, Recommendation: Content[*]:GuidelineURI	15	R2	00583	Producer's Reference

Adapted from the HL7 Standard, version 2.5.1

Radiologist's Recommendations as text recommendations (e.g., "Repeat CT Chest in 6 months.") shall be mapped as shown in Table 4.128.4.1.2.10.1-2.

1030 Table 4.128.4.1.2.10.1-2: DICOM Part 20 to Radiologist's Recommendation OBX mapping - text recommendations

DICOM Part 20 Business Name	SEQ	ОРТ	ITEM #	ELEMENT NAME
Recommendation: Text	5	R	00573	Observation Value
Recommendation: Content[*]:GuidelineRef, Recommendation: Content[*]:GuidelineURI	15	R2	00583	Producer's Reference

Adapted from the HL7 Standard, version 2.5.1

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# 4.128.4.1.2.11 OBX Segment - Radiologist Requests Consultation

This OBX segment is useful to convey that a radiologist requests a direct consultation with the ordering or referring provider. This is especially useful for complex clinical cases.

The Observation/Result (OBX) Segment definition is based on HL7 Version 2.5.1 (Chapter 7, Observation Reporting, Section 7.4.2). This definition does not conflict with the OBX Segment as defined in ITI TF-2b: 3.30.5.7 OBX – Observation/Result Segment.

A summary of the OBX segments in this ORU message is provided in Table 4.128.4.1.2-2.

Optionality: This OBX segment should be included if a consultation to the intended recipient is requested by the interpreting physician for this study.

Multiplicity: This OBX segment may repeat if multiple consultation requests are made, although those circumstances would be unusual.

If this OBX segment is included, it is strongly recommended that *OBR-32 Principal Result*1045

Interpreter is also provided in the ORU.

This OBX Segment shall be further constrained as specified in Table 4.128.4.1.2.11-1.

Table 4.128.4.1.2.11-1: HL7 v2.5.1 ORU OBX Segment - Radiologist Requests Consultation

SEQ	LEN	DT	OPT	TBL#	ITEM #	ELEMENT NAME
1	4	SI	R		00569	Set ID – OBX
2	2	ID	R	0125	00570	Value Type = TX
3	250	CE	R		00571	Observation Identifier
5	99999	TX	R		00573	Observation Value
11	1	ID	R	0085	00579	Observation Result Status = R, F, C

Adapted from the HL7 Standard, version 2.5.1

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Field OBX-2 Value Type shall have the value "TX".

Field OBX-3 Observation Identifier shall have the value "11487-6\"Consultation Request\"LN".

Field *OBX-5 Observation Value* shall contain the consultation request and preferred communication method. For example, *OBX-5* may contain |Patricia R. Smith, MD, requests a consultation to review findings. Contact at 1-732-123-4567 during normal business hours.|

Field OBX-11 Observation Result Status shall have the same value as OBR-25 Result Status.

## 4.128.4.1.2.12 OBX Segment - Radiologist Requests Feedback

This OBX segment is useful to convey that the radiologist requests feedback from the ordering physician, often regarding whether a recommended follow-up imaging study was ordered or regarding outcomes.

The Observation/Result (OBX) Segment definition is based on HL7 Version 2.5.1 (Chapter 7, Observation Reporting, Section 7.4.2). This definition does not conflict with the OBX Segment as defined in ITI TF-2b: 3.30.5.7 OBX – Observation/Result Segment.

A summary of the OBX segments in this ORU message is provided in Table 4.128.4.1.2-2.

Optionality: This OBX segment should be included if the interpreting physician has requested feedback for one more recommendations.

Multiplicity: This OBX segment may repeat, although the circumstances for multiple feedback requests would be unusual.

If this OBX segment is included, it is strongly recommended that *OBR-32 Principal Result Interpreter* is also provided in the ORU.

This OBX Segment shall be further constrained as specified in Table 4.128.4.1.2.12-1.

**SEQ** LEN DT **OPT** TBL# ITEM# **ELEMENT NAME** 4 SI 00569 R Set ID - OBX 2 2 ID R 0125 00570 Value Type = TX3 250 CE R 00571 Observation Identifier 99999 TX R 00573 Observation Value 11 1 ID R 0085 00579 Observation Result Status = R, F,

Table 4.128.4.1.2.12-1: HL7 v2.5.1 ORU OBX Segment - Radiologist Requests Feedback

Adapted from the HL7 Standard, version 2.5.1

Field *OBX-2 Value Type* shall have the value "TX".

Field *OBX-3 Observation Identifier* shall have the value "74466-4^Feedback to user-post question^LN".

Field *OBX-5 Observation Value* shall contain the feedback request and preferred communication method. For example, *OBX-5* may contain "|Patricia R. Smith, MD, requests a feedback regarding whether or not recommended follow-up study was ordered. Contact at 1-414-123-4567 during normal business hours.|"

Field OBX-11 Observation Result Status shall have the same value as OBR-25 Result Status.

## 4.128.4.1.2.13 OBX Segment - Imaging Result Payload

This OBX segment contains the complete imaging result, including any amendments.

This Observation/Result (OBX) Segment definition is based on HL7 Version 2.5.1 (Chapter 7, Observation Reporting, Section 7.4.2). This definition does not conflict with the OBX Segment as defined in ITI TF-2b: 3.30.5.7 OBX – Observation/Result Segment.

A summary of the OBX segments in this ORU message is provided in Table 4.128.4.1.2-2.

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**Optionality:** This OBX segment shall be included if an imaging result is present.

Multiplicity: There may be at most one imaging result per ORU message. However, this

OBX segment may repeat if the length of the imaging result exceeds the allowable length of an OBX segment. HL7 v2.5.1 rules of "continuation" as defined in Chapter 2- Control, shall be followed.

Information from the content of this imaging result may be extracted into other OBX segments (e.g., Findings, Radiology Recommendations, etc.), but that information shall also be included in the full content of the report contained in this OBX segment.

It is possible, in unusual circumstances, to have an Imaging Results (ORU) message without an Imaging Result Payload OBX segment. One example is a study where the patient moved or was unable to complete the imaging procedure such that the study was not interpretable. In this case, the ORU message may be used to ensure that the order is closed properly.

If an imaging result is amended, the complete amended report (not the differential or changed portion) content shall be contained in this message. The imaging result payload shall not be a partial imaging result.

This OBX Segment shall be constrained as specified in Table 4.128.4.1.2.13-1.

SEQ OPT **LEN** DT TBL# ITEM# **ELEMENT NAME** 4 SI R 00569 Set ID - OBX 2 2 ID R 0125 00570 Value Type = TX or EDCE R 250 00571 Observation Identifier 5 99999 TX or ED R 00573 Observation Value 5 IS R 0078 00576 Abnormal flag 1 11 ID R 0085 00579 Observation Result Status = R, F, C 15 250 CE R 00583 Producer's Reference

Table 4.128.4.1.2.13-1: HL7 v2.5.1 ORU OBX Segment - Imaging Result Payload

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Adapted from the HL7 Standard, version 2.5.1

Field *OBX-2 Value Type* shall have the value "TX" for Text, or "ED" for a PDF or CDA (xml).

Field *OBX-3 Observation Identifier* shall have the value "18748-4^Diagnostic Imaging Report^LN". Recall that the specific Procedure Code is conveyed in the OBR segment.

- The format of Field *OBX-5 Observation Value* shall vary based upon the value of *OBX-2*:
  - If Field *OBX-2*= "TX", then *OBX-5* has a single component and it shall be the imaging result text encoded as ASCII text, per HL7 v2.5.1.
  - If Field OBX-2 = "ED", then OBX-5 has multiple components.
    - o For a PDF document:

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- Field *OBX-5.1 Source Application* shall not be valued
- Field *OBX-5.2 Type of Data* shall be "Application"
- Field OBX-5.3 Data Subtype shall be "PDF"
- Field *OBX-5.4 Encoding* shall be "Base64"
- Field OBX-5.5 Data shall contain the imaging result as a Base64 encoded PDF

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- o For a CDA document:
  - Field *OBX-5.1 Source Application* shall not be valued
  - Field *OBX-5.2 Type of Data* shall be "Text"
  - Field *OBX-5.3 Data Subtype* shall be "text/xml"
  - Field *OBX-5.4 Encoding* shall be "A" (ASCII)

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- Field *OBX-5.5 Data* shall contain the imaging result as a CDA XML document. Non-ASCII characters (e.g., CR/LF) in the CDA document shall use proper escape sequences (e.g., "~"). A style sheet to render the CDA document may be referenced within the CDA.
- Field *OBX-8 Abnormal Flag* shall use the mapped values defined in Table 4.128.4.1.2.1-1. The *OBX-8 Abnormal Flag* shall contain the "worst case" (most severe) abnormal finding or abnormal imaging result value as described in Section 4.128.4.1.2.1.
  - Field OBX-11 Observation Result Status shall have the same value as OBR-25 Result Status in this ORU.
- Field *OBX-15.1 OBX-15.3 Producer's Reference* shall use the mapped coded values defined in Table 4.128.4.1.2.1-1. The *OBX-15 Producer's Reference* shall contain the "worst case" (most severe) actionable category as described in Section 4.128.4.1.2.1.

#### 4.128.4.1.2.13.1 CDA Level 3 Option

In addition to the Imaging Result Payload OBX segment mappings described in Table 4.128.4.1.2.13-1, if a Sender supports the CDA Level 3 Option in the RD Profile, it shall map data from the DICOM Part 20 CDA document into this OBX segment, as described in Table 4.128.4.1.2.13.1-1.

Table 4.128.4.1.2.13.1-1: DICOM Part 20 to ORU Imaging Result Payload OBX mapping

DICOM Part 20 Business Name	SEQ	OPT	ITEM #	ELEMENT NAME
ImagingReport	5	R	00573	Observation Value

Adapted from the HL7 Standard, version 2.5.1

Field *OBX-2 Value Type* shall be "ED".

Field *OBX-5 Observation Value* shall follow the CDA document encoding described in Section 4.128.4.1.2.13.

Field *OBX-5.3 Data Subtype* shall contain "text/xml".

### 4.128.4.1.3 Expected Actions

1150 The Receiver shall accept and process the message.

The Receiver shall support receiving multiple imaging result messages for the same order and/or same DICOM Study Instance UID. That is, a single DICOM Study Instance UID may result in multiple Imaging Results. For example, a CT Chest/Abdomen/Pelvis may be interpreted as multiple imaging results by two different radiologists, for example, one interpreting the CT

1155 Chest images and the other interpreting the CT Abdomen/Pelvis.

The Receiver shall support receiving one imaging result message for multiple DICOM Study Instance UIDs. That is, multiple DICOM Study Instance UID may be reported in a single Imaging Result. For example, a CT abdominal study and a CT chest study, each with separate Study Instance UIDs, may be reported together.

- 1160 Receiver actions subsequent to receiving an image result will depend on internal business logic and/or the Profile in which the transaction is being performed. It is recommended that the Receiver be prepared to carefully examine the following data elements:
  - the *OBR-25 Report Status* of "R" (Preliminary), "F" (final) or "C" (amended) to manage the distribution of the imaging results
  - the OBR-27.7/TQ1-9 Priority flag to determine the priority of the imaging result
    - the *OBX-8 Abnormal flags* and *OBX-15 Producer's Reference* of the OBX segments, especially the Imaging Result Payload OBX Segment, to determine normal or actionable findings
    - the content of DICOM Study Instance UID OBX segment(s) to coordinate the display of images
    - the content of Radiologist's Recommendation, Radiologist Requests Consult, or Radiologist Requests Feedback OBX segments to enable subsequent workflows

# 4.128.4.2 Acknowledge Imaging Result Message

The Receiver acknowledges to the Sender the receipt of the Send Imaging Result Message.

The Sender shall support receiving responses from more than one Receiver. The Receiver shall support acknowledging results from more than one Sender.

### 4.128.4.2.1 Trigger Events

The Receiver receives and processes a Send Imaging Result Message.

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## 4.128.4.2.2 Message Semantics

The message is an HL7 2.5.1 MSA-1 Original Mode Acknowledgement message. The Receiver is the HL7 acknowledgment sender. The Sender is the HL7 acknowledgment recipient.

The Receiver is not required to send any attributes within the MSA segment beyond what is specified in the HL7 standard. See ITI TF-2x: C.2.3 for the list of all required and optional fields within the MSA segment.

### 1185 **4.128.4.2.3 Expected Actions**

If the HL7 ORU was invalid, the Receiver shall send an error message indicating that the received ORU message was invalid. Otherwise, the Receiver shall respond with valid acknowledgment message.