IHE Change Proposal

Tracking information:

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| IHE Domain | Laboratory |
| Change Proposal ID: | CP-LAB-222 (assigned by Domain Technical Committee) |
| Change Proposal Status: | completed |
| Date of last update: | 11-06-2014 |
| Person assigned: | François Macary |

Change Proposal Summary information:

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| Result Progression in the LAW profile |
| Submitter’s Name(s) and e-mail address(es): | François Macary |
| Submission Date: | 26-05-2014 |
| Integration Profile(s) affected: | LAW |
| Actor(s) affected: | Analyzer, AM |
| IHE Technical Framework or Supplement modified: | LAW Supplement  |
| Volume(s) and Section(s) affected: | Vol 2 |
| Rationale for Change:* Correction of the representation of the structure of an AWOS fulfillment in section W.2.5: For an AWOS the Analyzer performs one or more runs. Each run produces one or more observations. Each observation is accompanied by zero or more supplemental results.
* Clarification of the observation result statuses (OBX-11) in correlation with the AWOS statuses (ORC-5) and the transitions thereof.
* In particular the vocabulary result "technically valid", which makes sense in the LTW profile is inappropriate in the LAW profile.
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Correct the content of section W.2.5as follows:

When fulfilling an AWOS, for each observable entity (test performed or computed) of the AWOS, an Analyzer may:

Produce a single observation (referred to as an **Observation Result**)

Produce multiple **Observation Results** with distinct Observation Identifiers (e.g., results associated with a hematology complete blood count AWOS)

Produce multiple **Observation Results** with the same Observation Identifier (e.g., multiple organisms identified in a microbiology “organism identification” AWOS)

Capture supplemental information as images, graphs, and raw values (referred to as a **Supplemental Result**)

Perform multiple runs of the same test (reruns) resulting in groups of results, where each group contains related **Observation Results** and **Supplemental Results**

It is important that the Analyzer provide sufficient details in the messaging so that the Analyzer Manager can correctly distinguish results for the same observation (e.g., multiple organisms), group results from the same run, and distinguish between **Observation Results** and **Supplemental Results**. The **AWOS Fulfillment** structure looks as follows, using the HL7 message elements of braces ([…]) to represent optional items and brackets ({…}) to identify repeatable items:

~~--~~ **~~AWOS Fulfillment~~** ~~begin~~

~~{--~~ **~~Observation Run~~** ~~begin~~

**~~{Observation Result}~~**

~~[{~~**~~Supplemental Result~~**~~}]~~

 ~~--~~ **~~Observation Run~~** ~~end}~~

~~--~~ **~~AWOS Fulfillment~~** ~~end~~

-- **AWOS Fulfillment** begin

 {-- **Observable Entity (test)** begin

{-- **Observation Run** begin

**{**-- **Observation** begin

**Observation Result**

[{**Supplemental Result**}]

-- **Observation** end **}**

 -- **Observation Run** end}

 -- **Observable Entity (test)** end}

-- **AWOS Fulfillment** end

Section W.2.5.1: Correct the explanation of field ORC-5 "Order Status"

* ~~ORC-5 Order Status is the status of the AWOS. If the Analyzer has completed all the runs/observations for the AWOS, then ORC-5 is set to “CM”. Otherwise, if additional runs/observations are expected ORC is set to “IP”.~~
* ORC-5 "Order Status" is the status of the AWOS. Its possible values are:
	+ "**SC**": the AWOS is **scheduled** on the Analyzer. The work for the AWOS has not yet started.
	+ "**IP**": The first run of the AWOS is **in process** by the Analyzer with the specimen. No result has been produced yet for this AWOS.
	+ "**A**": Some of the results for the AWOS have been produced. More results may come later, from the current run, or from an additional run scheduled or in process.
	+ "**CM**": Completed - the Analyzer has finished its work for the AWOS. The results may have been produced or not. No additional result is expected for this AWOS. Nonetheless, a correction of some of the reportable results produced for this AWOS, may still be sent by the Analyzer, in which case the AWOS status will remain "CM".
	+ "**CA**": The AWOS has been cancelled per request of the Analyzer Manager. Cancellation can happen only before the process of the AWOS has started, when the AWOS is created or scheduled.

The possible transitions of the status of an AWOS are represented on figure W.3.7-1, in section W.3.7.

Section W.2.5.1: Correct the explanation of field OBX-11 "Observation Result Status"

* ~~OBX-11 Result Status is used in the following manner. The value ‘P’ is used to identify that a result is a preliminary observation in a progression of results leading to the reportable observation (such as the status of cultures in Microbiology). The value ‘R’ is used when the Analyzer is reporting results from multiple runs, and does not consider this run to be technically valid. In this scenario, the Analyzer will only select one of the runs as technically valid. The value ‘F’ is used to identify a technically valid observation. The value “C” is used to correct the observation of a previous run that was reportable as ‘F’. The value “X” is used when the Analyzer could not compute a value for the observation.~~
* OBX-11 "Observation Result Status" is the status of an observation produced by a run of the AWOS. It is interpreted as follows:
	+ "**P**" represents a **preliminary** **result** in a progression of results leading to the reportable result (such as the status of cultures in Microbiology).
	+ "**R**" (**entered, not verified**) is associated with an Observation Run, which the Analyzer does not claim to be the one reportable to the ordering provider. In case the results of all Observation Runs for an Observable Entity are marked "R", the choice of the reportable one is left up to the Analyzer Manager.
	+ "**F**" (**final**) is associated with the Observation Run, which the Analyzer claims to be the one reportable to the ordering provider, among one or more Observation Runs for this Observable Entity (test). Zero or one Observation Run can be sent as "F" by the Analyzer. In case the run produced multiple results with the same Observation Identifier (e.g.; multiple microorganism identified in a culture), each of the OBX has the status F.
	+ "**C**" represents a **correction** of a result previously sent as part of a reportable Observation Run. The correction stays in the same Observation Run.
	+ "**X**" means that the Analyzer was **not able to produce any result** for this observation in this Observation Run. There will be no results for the observation in this run. If this is the only run, this observation will have no result.

The possible transitions of the status of an observation, no matter how many runs are performed for the AWOS, are represented on figure W.3.6-1, in section W.3.6.

Section W.2.5.1: Split and correct table W.2.5.1-1 as follows:

The two following tables summarize~~s~~ these important fields that are used to identify an observation.

Table W.2.5.1-1: ~~Import~~ Fields Used to Identify Observation Instances

| OBR-2Placer Order Number | OBR-4 Universal Service Identifier | OBX-3Observation Identifier | OBX-4Observation Sub-ID  |
| --- | --- | --- | --- |
| AWOS ID | ~~Unique ID for each request~~The identifier for the requested battery or test | Unique ID for each observation result. In some cases will be the same as OBR-4 | Positive integer 🡪 Run Number‘M’ + integer 🡪 Result identifier for microbiology results |

Table W.2.5.1-2: Possible statuses of an observation result in a run of an AWOS

| Status of the AWOS (ORC-5) | Possible observation result statuses (OBX-11) |
| --- | --- |
| SC: Scheduled | No observation available for this AWOS, in any run. No OBX provided by the Analyzer. |
| IP: In progress |
| CA: Cancelled |
| A: Some (but not all) results available | P – Preliminary result.R – The analyzer does not claim this run to be the one reportable to the ordering provider.F – Final: The analyzer claims this run to be the one reportable to the ordering provider.C – Correction of a result in the same reportable run.X – Result could not be obtained for this run of the observation |
| CM: Completed | R – The analyzer does not claim the result of this run to be the one reportable to the ordering provider.F – Final: The analyzer claims the result of this run to be the one reportable to the ordering provider.C – Correction of a result in the same reportable run.X – Result could not be obtained for this run of the observation |

Notes:

* There cannot be any preliminary result in a completed (CM) AWOS.
* A correction of a final observation (OBX-11 = "C") can still be sent by the Analyzer for an AWOS that was previously declared as completed (ORC-5 = "CM"). This correction is on the same Observation Run.

Section W.2.5.3: Correct table W.2.5.3-1 as follows:

Table W.2.5.3-1: Examples of Order and Result Status values

| Situation | ORC-5Order Status  | OBX-4 Observation Sub-ID | OBX-11Result status  |
| --- | --- | --- | --- |
| The Analyzer reports the result of a single run. A value could not be ~~computed~~ obtained for the observation. The Analyzer considers the AWOS to be complete. | CM | 1 | X |
| The Analyzer reports the result of a single run. There is no intent to perform additional runs. The Analyzer considers the AWOS to be complete. | CM | 1 | F |
| The Analyzer is sending the observations in multiple messages. Observations ‘1’ to ‘n-1’ are ~~reported~~ sent as not ~~validated~~ reportable because the Analyzer intends to perform additional runs. The AWOS is still in process on the Analyzer until run ‘n’ is sent. The Analyzer marks the result in the last run as ~~technically valid~~ the reportable result. | ~~IP~~ACM | 1..(n-1)n | RF |
| The current observation is part of a set of multiple runs and the analyzer considers all of them as equally valid and leaves the choice of the reportable one up to the Analyzer Manager. ~~to be~~ ~~technically valid~~. All runs are reported in the same message. The AWOS is completed on the Analyzer. | CM | 1..n | ~~F~~R |
| The current observation is part of a set of multiple runs for which the Analyzer selects one of the runs as ~~technically~~ reportable. Results of a~~A~~ll runs are sent ~~reported~~ in the same message. The AWOS is completed on the Analyzer. | CM | m1..n – {m} | F for the results of the reportable run R for the results of the other runs |
| ~~The Analyzer has reported results ‘1..n’ and indicated the AWOS is complete. The Analyzer/biotechnologist later detects a defect in the initial run(s) and sends a correction to run ‘m’. The AWOS is complete.~~ | ~~CM~~ | ~~m, where1 <= m <= n~~ | ~~C~~ |
| ~~The Analyzer is sending multiple final results fulfilling the same observation. There are as many OBX segments sharing the same OBX-3 value as results produced.~~  | ~~CM~~ | ~~A distinct result identifier for each OBX~~ | ~~F for all the OBX~~ |
| The Analyzer is correcting one of the results of a run previously sent as the reportable one for this test. ~~set of multiple final results produced for the same observation.~~ | CM | The distinct result identifier ~~for each~~ of the OBX | C ~~for the OBX with the corrected result~~~~If sent, F for the unchanged results~~  |
| The Analyzer has performed a new distinct test (e.g., genotyping) related to a former observation result (e.g., a microorganism identified) for an AWOS. | CM | equal to the OBX-4 of the former observation result | F |

In section W.3.6, description of field OBX-11, replace the table W.3.6-7and add the state transition diagram as follows:

**OBX-11 Observation Result Status (ID)**, mandatory.

Table W.3.6-7: Subset of HL7 Table 0085 – Observation Result Status (ID)

|  |  |  |
| --- | --- | --- |
| Value | HL7 Description | Meaning in the LAW profile |
| X | Results cannot be obtained | Test Exception. The reason for failure is being reported. This test will not produce any result in this run. |
| P | Preliminary results | The result is preliminary in a progression of results leading to the reportable result (such as the status of cultures in Microbiology) |
| R | Result entered – not verified | The Analyzer does not claim the Observation Run to be the one reportable to the ordering provider. In case the results of all Observation Runs for an Observable Entity are marked "R", the choice of the reportable one is left up to the Analyzer Manager. |
| F | Final results; Can only be changed with a corrected result. | The Analyzer claims the Observation Run to be the one reportable to the ordering provider for this observable entity (test). In case the Observation Run produced multiple results with the same Observation Identifier (e.g. multiple microorganism identified in a culture), each of the OBX has the status F. |
| C | Correction replacing a final result | Correction of a result previously sent as part of a reportable Observation Run. The correction stays in the same Observation Run. |

Figure W.3.6-1 represents the possible state transitions for an observation result within an Observation Run.



Figure W.3.6-1 – Observation Result Status transition diagram for an Observation Run

Note: The recurring loops on statuses "P", "R" and "C" reflect the fact that a result can be revised or corrected in one of those statuses, without changing status.

Note: Each Observation Run has its own life cycle for the results it produces. However, there can be no more than one Observation Run of the same Observable Entity (test) of an AWOS, producing results in status "F" or "C".

In section W.3.7, description of field ORC-5, correct the description and table W.3.7-5, and add the state transition diagram as follows:

The allowed values for this field within ~~IHE Laboratory Technical Framework~~ the LAW profile are a subset of HL7 table 0038 - Order Statusas shown below:

Table W.3.7-5: Subset of HL7 Table 0038 – Order Status

|  |  |  |
| --- | --- | --- |
| Value | HL7 Description (Order status) | Meaning in the LAW profile (AWOS status) |
| SC  | In process, scheduled  | The AWOS is scheduled on the Analyzer, but the Analyzer has not started the work for the AWOS.This status can be seen only in message ORL^O34 from transaction LAB-28, for an Analyzer in broadcast mode. |
| IP  | In process, unspecified  | The process of the first run of the AWOS has started on the Analyzer with the specimen. No result has been produced yet for this AWOS. |
| A  | Some, but not all, results available  | Some of the results for the AWOS have been produced. More results may come later, from the current run, or from an additional run. |
| CM  | Order is completed  | Completed - the Analyzer has finished its work for the AWOS. The results may have been produced or not. No additional result is expected for this AWOS. Nonetheless, a correction of some of the reportable results produced for this AWOS may still be sent by the Analyzer, in which case the AWOS status will remain "CM". |
| CA  | Order was canceled  | The AWOS has been cancelled per request of the Analyzer Manager. Cancellation can happen only before the process of the AWOS has started, when the AWOS is created or scheduled. |



Figure W.3.7-1 – AWOS Status transition diagram

Note: The recurring loops on statuses "A" and "CM" reflect the fact that new or corrected results can be sent for the AWOS, without changing its status.

Note: A child AWOS (e.g.; a reflex test) has its own life cycle, independent of the life cycle of the parent AWOS.

*In section 3.Y.5.2 "Message Semantics" of OUL^R22 message of transaction LAB-29, make the RESULT segment group conditional:*

Table 3.Y.5.2-1: OUL^R22

| Segment | Meaning | Usage | Card. | HL7 chapter |
| --- | --- | --- | --- | --- |
|  MSH | Message header | M | [1..1] | 2 |
| [ | -- PATIENT begin | O | [0..1] |  |
|  [PID] | Patient Identification | R | [1..1] | 3 |
| ] | -- PATIENT end |  |  |  |
| [ | -- VISIT begin | O | [0..1] |  |
|  [PV1] | Patient Visit | R | [1..1] | 3 |
| ] | -- VISIT end |  |  |  |
|  { | --- SPECIMEN begin | M | [1..\*] |  |
|  SPM | Specimen information | M | [1..1] | 7 |
|  [{ OBX }] | Observation Result (for Specimen) | O | [0..\*] | 7 |
|  [{ | --- CONTAINER begin | M | [1..1] |  |
|  SAC | Container information | M | [1..1] | 13 |
|  [INV] | Detailed Substance information (e.g., id, lot, manufacturer, … of QC specimen) | C (O/X)1 | [0..1] | 13 |
|  }] | --- CONTAINER end |  |  |  |
|  { | --- ORDER begin | M | [1..\*] |  |
|  OBR | Observation Order | M | [1..1] | 7 |
|  [ORC] | Common Order | M | [1..1] | 4 |
|  [{ | TIMING\_QTY begin | O | [0..1] |  |
|  TQ1 | Timing Quantity | R | [1..1] | 4 |
|  }] | TIMING\_QTY end |  |  |  |
|  [{ | --- RESULT begin | ~~M~~C(M/X) | [~~1~~0..\*] |  |
|  OBX | Observation Result | M | [1..1] | 7 |
|  [TCD] | Test Code Detail | O | [0..1] | 13 |
|  [{INV}]2 | Detailed Substance information (e.g., reagents used for testing) | O | [0..\*] | 13 |
|  [{NTE}] | Notes and comments | O | [0..\*] | 2 |
|  }] | --- RESULT end |  |  |  |
|  } | --- ORDER end |  |  |  |
|  } | --- SPECIMEN end |  |  |  |

(…)

~~The RESULT segment group is mandatory. It shall be used to report the observation results for the AWOS.~~

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

Predicate for the RESULT segment group: Usage is Mandatory if field ORC-5 "Order Status" of the above ORC segment is valued with "A" or CM". Otherwise usage is Not Supported.