

GMSIH, HL7 France H', HL7 Germany, IHE-J, JAHIS, SFIL, IHE Italy
Integrating the Healthcare Enterprise

IHE Laboratory Technical Framework
Supplement 2004-2005

10

Laboratory Code Set Distribution
(LCSD)

Public Comment Version

June 15, 2005

Comments due July 15, 2005

Foreword

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

The approach employed in the IHE initiative is not to define new integration standards, but rather
30 to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. IHE maintain formal relationships with several standards bodies including HL7, DICOM and refers recommendations to them when clarifications or extensions to existing standards are necessary.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the
40 European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Française de Radiologie (SFR), Società Italiana di Radiologia Medica (SIRM), the European Institute for health Records (EuroRec), and the European Society of Cardiology (ESC). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan
50 Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained regularly

through the identification and correction of errata. The current version for these Technical Frameworks may be found at www.rsna.org/IHE or <http://www.gmsih.fr/IHE>.

60 The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

This supplement to the IHE Laboratory Technical Framework V1.2.1 is submitted for Public Comment between **June 15, 2005 and **July 15, 2005**, per the schedule announced in **February 2005**.**

70 **Comments shall be submitted before **July 15, 2005** on the “Public Comment Lab Supplement” sheet, addressed by email to:**

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The IHE Laboratory Technical Committee will address these comments and publish the Trial Implementation version in November 2005.

Document production

80 **Date: June 15, 2005**

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Introduction

This is a new integration profile which will be added to Volume I of the IHE Laboratory Technical Framework. Associated with this profile is one new transaction that will be added to Volume II of the IHE Laboratory Technical Framework.

Open Issues and Questions

Profile Abstract

90 A set of common codes is generally used by multiple application systems in a laboratory workflow environment. These common codes need to be synchronized across the various applications at a given site. In many implementations, one application system will be the author (the "owner") of the code set. The responsibility for managing a code set may also be distributed among different systems.

This profile provides a way for the owner of a code set (battery, test and observation codes) to distribute the code set amongst other applications within the enterprise. This profile involves all dedicated actors currently defined in the Laboratory Scheduled Workflow Integration Profile: Order Placer, Order Filler, Automation Manager and Order Result Tracker.

GLOSSARY

100 **Battery** – A set of one or more observations identified as by a single name and code, treated as a shorthand unit for ordering or retrieving results of the constituent observations. A battery can be a single observation, but also a superset of batteries.

Code set - a code set is any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnosis codes, or medical procedure codes. An example of international code set is LOINC™ (Logical Observation Identifier Names and Codes).

Master File – a common reference file used by one or more application systems. A code set can be considered as a master file.

Observation – a measurement of a single variable or a single value derived logically and/or algebraically from other measured or derived values. A test result is an observation.

Test - a medical procedure that involves testing a sample of blood, urine, or other substance from the body.

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Volume I – Integration Profiles

Changes to Sections 1 – 1.X

Renumber section 1.6 to 1.7

Renumber section 1.7 to 1.8

Renumber section 1.8 to 1.9

1.6 History of Annual Changes

Add the following bullet to the end or the beginning of the bullet list in section 1.6

- Added the Laboratory Code Set Distribution Profile which provides a way for the owner of a code set (battery, test and observation codes) to distribute it to other applications in the enterprise.

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Remove section 2.3 Integration Profiles overview

Renumber 2.4 to 2.3

2.4 Actors in Laboratory Technical Framework

Add the following actors at the end of the list defined in section 2.4

Code Set Master: A system which owns (is responsible for the maintenance of) one or several code sets. This system may also be an Order Filler or an Enterprise Common Repository. Code sets can be sent on a routine basis (e.g. every week) or every time the code set changes. A code set may contain battery, test and observation codes.

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Code Set Consumer: A system which receives code sets from Code Set Master(s) and updates its internal tables to reflect the code set as maintained by the Code Set Master. This system may also be an Order Placer, an Order Result Tracker, an Automation Manager, or an Order Filler.

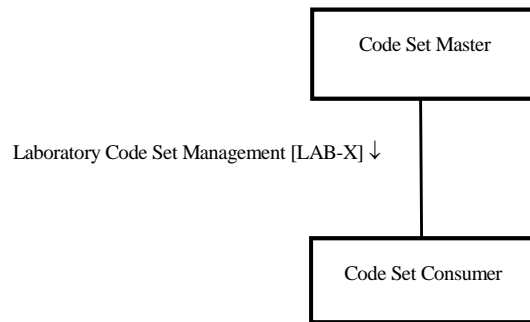
X Laboratory Code Set Distribution Integration Profile

A set of common codes is generally used by multiple application systems in a laboratory workflow environment. These common codes need to be synchronized across the various applications at a given site. In many implementations, one application system will be the author (the "owner") of the code set. The responsibility for managing a code set may also be distributed among different systems.

140 This profile provides a way for the owner of a code set (battery, test and observation codes) to send the code set to other applications. This profile involves all dedicated actors currently defined in the Laboratory Scheduled Workflow Integration Profile: Order Placer, Order Filler, Automation Manager and Order Result Tracker.

X.1 Actors/ Transactions

Figure X.1-1 shows the actors directly involved in the Laboratory Code Set Distribution Integration Profile and the transaction between them. Other actors that may be indirectly involved due to their participation in other profiles are not shown.



150 **Figure X.1-1. Laboratory Code Set Distribution Actor Diagram**

Table X.1-1 lists the transactions for each actor directly involved in the Laboratory Code Set Distribution Profile. In order to claim support of this Integration Profile, an implementation must perform the required transaction (labeled “R”).

Table X.1-1. Laboratory Code Set Distribution Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Code Set Master	Laboratory Code Set Management	R	X.Y
Code Set Consumer	Laboratory Code Set Management	R	X.Y

X.2 Laboratory Code Set Distribution Integration Profile Options

The LCSD profile does not define any optional transactions.

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X.3 Laboratory Code Set Distribution Process Flow

The Code Set Master manages a set of laboratory codes (battery, test and observation). Three use cases are identified:

Use case 1: the entire code set is sent to subscribing systems. These systems must replace the current code set by the new one. Codes which have been removed from the code set are not to be used by the receiving system any more. Codes which have been removed should not be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added codes may be used from the effective date/time given in the transaction.

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Use case 2: a single battery, a single test or a single observation is added, removed or changed by the Code Set Master. The full code set is not sent to the subscribers but only those parts which describe the changes.

Use case 3: upon receipt of an unknown code, the receiver queries the Code Set Master for the full details associated with the code.

Use case 1 will be described in this version of the IHE Laboratory Technical Framework. The other use cases may be added to later versions of this profile.

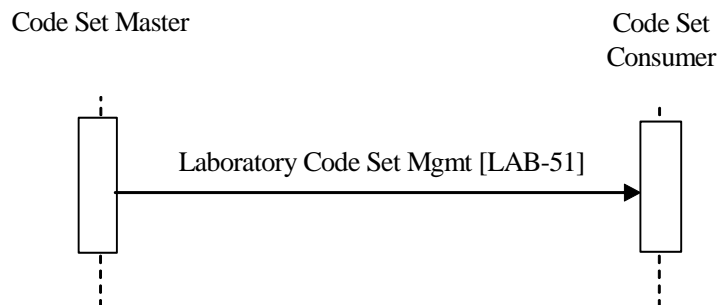


Figure X.3-1. Basic Process Flow in the Laboratory Code Set Distribution Profile

<Appendix A> Actor Summary Definitions

180 **Code Set Master:** A system which owns (is responsible for the maintenance of) one or several code sets. This system may also be an Order Filler or an Enterprise Common Repository. Code sets can be distributed on a routine basis (e.g. every week) or every time the code set changes. A code set may contain battery, test and observation codes.

Code Set Consumer: A system which receives code sets from Code Set Master(s) and updates its internal tables to reflect the code set as maintained by the Code Set Master. This system may also be an Order Placer, an Order Result Tracker, an Automation Manager, or an Order Filler.

<Appendix B> Transaction Summary Definitions

LAB-51. Laboratory Code Set Management: Code set distribution (battery, test, observation).

Volume 2 - Transactions

190 IHE Transactions

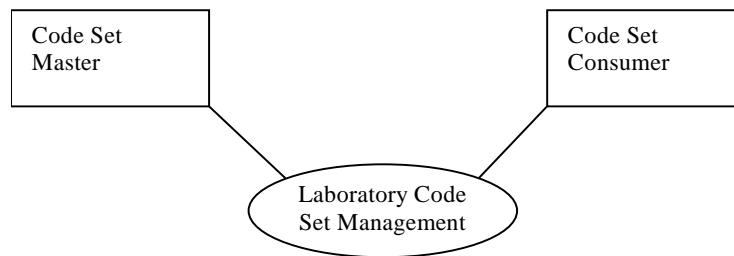
X.Y Laboratory Code Set Management

This section corresponds to Transaction LAB-51 of the IHE Laboratory Technical Framework. Transaction LAB-51 is used by the Code Set Master and Code Set Consumer actors.

X.Y.1 Scope

This transaction is used by the Code Set Master actor to distribute entire code sets to Code Set Consumer actors. A code set may contain battery, test and observation codes. This transaction is initiated on a scheduled based (e.g. weekly) or whenever the organization of the laboratory changes (e.g. because of the addition/removing of an instrument, specialties).

X.Y.2 Use Case Roles



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Figure X.Y.2-1. Use Case Roles for the Laboratory Code Set Management transaction

Actor: Code Set Master

Role: Sends a full code set.

Actor: Code Set Consumer

Role: Receives a code set, and notifies the Code Set Master of its acceptance or refusal.

X.Y.3 Referenced Standard

HL7 2.5 Chapter 8 (Master Files)

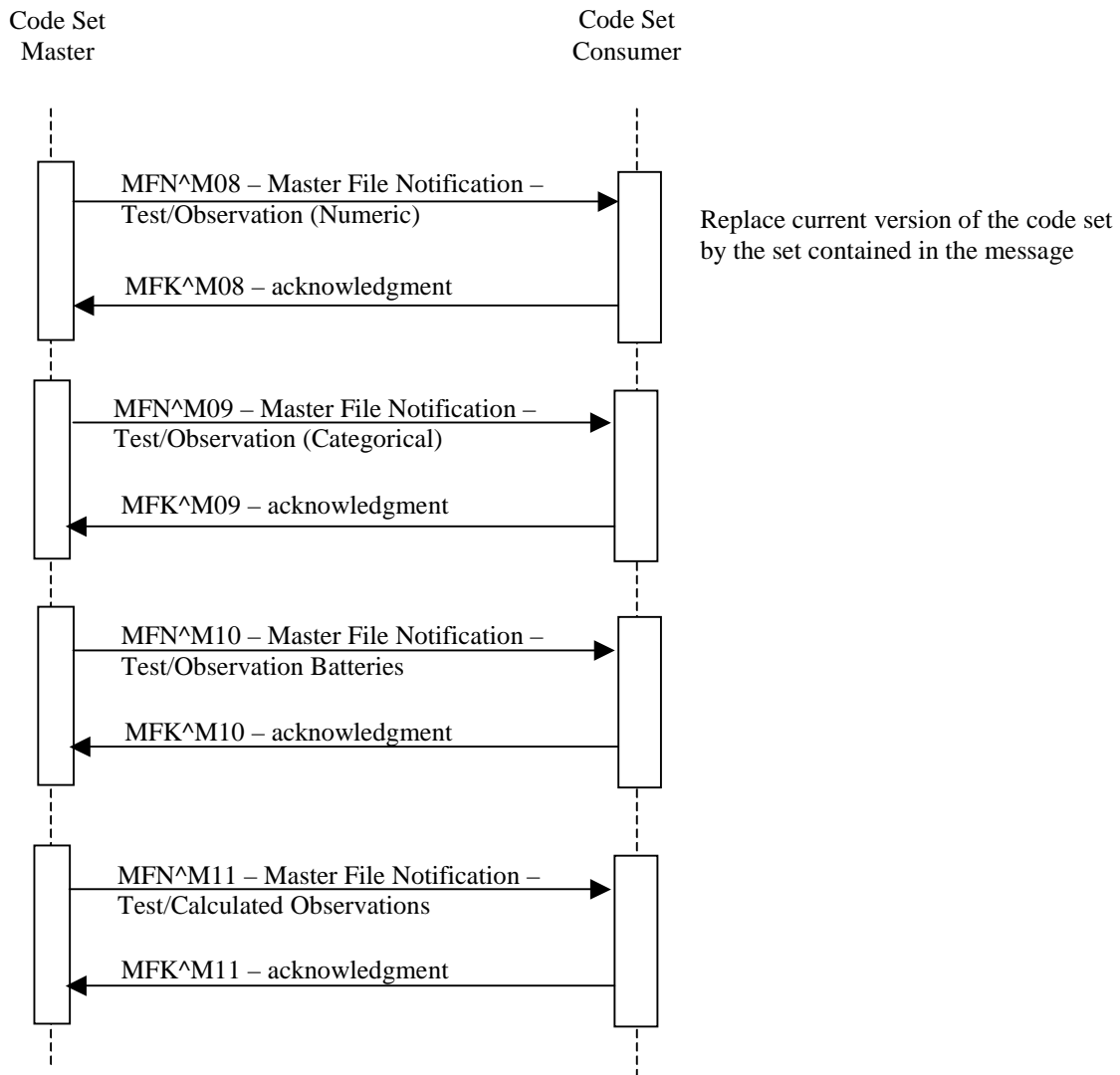
X.Y.4 Interaction Diagram

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The interaction diagram shows the flow of message between a Code Set Master and a Code Set Consumer. Four messages are defined for this transaction:

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- MFN^M08 – Master File Notification – Test/Observation (Numeric). This message is used for codes related to individual tests with numeric results. This message should not be used for battery or profile definitions. If the result of the test is a formulaic expression (a calculation) of other tests, MFN^M11 should be used instead of this message.
- MFN^M09 – Master File Notification – Test/Observation (Categorical). This message is used for codes related to individual tests with results that are NOT numeric. This message should not be used for battery or profile definitions. If the result of the test is a formulaic expression of other tests, MFN^M11 should be used instead of this message
- MFN^M10 – Master File Notification – Test/Observation Batteries. This message is used for codes that identify batteries or profiles. This message should not be used to for individual tests.
- MFN^M11 – Master File Notification – Test/Calculated Observations. This message is used for codes related to individual tests with calculated results. This message should not be used for battery or profile definitions.



In order to simplify the management of observation codes (OBX-3) and battery codes (OBR-4), the MFN^M08, MFN^M09 and MFN^M11 messages will be used to distribute observation codes only (OBX-3), and MFN^M10 will be used to distribute battery codes (OBR-4).

- 230 In order to fully synchronize the code sets between the Code Set Master and the Code Set Consumer 4 messages will have to be sent, each of which conveys the definition of part of the overall laboratory code set. The definitions of atomic tests shall be sent (M08, M09) before the definitions of calculated tests or batteries (M10, M11).

X.Y.4.1 Master File Notification – Test/Observation (Numeric)

This message is used to transmit observation codes, i.e. codes sent in the OBX-3 field (Observation Identifier). Observations must have continuous values (data of type numeric, date, or time stamp).

X.Y.4.1.1 Trigger Events

MFN^M08 – the Code Set Master sends a full set of observation codes.

240 X.Y.4.1.2 Message Semantics

HL7 2.5 Chapter 8 MFN^M08 message. Refer to HL7 Standard for general message semantics. The OM2 segment can be used to transport the Units of Measure if necessary.

Table X.Y.4.1-1. MFN^M08 static definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[OM2]	Numeric Observation Segment	O	[0..1]	8
[OM4]	Observations that Require Specimens	O	[0..1]	8
}	--- MASTER FILE ENTRY end			

A description of the usage of the MSH is contained in section 3.1 of the IHE Laboratory Technical Framework, Volume II.

X.Y.4.1.2.1 MFI – Master File Identification

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Table X.Y.4.1-2. MFI – Master File Identification

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	250	CE	R	[1..1]	0175	00658	Master File Identifier
2	180	HD	R	[1..1]		00659	Master File Application Identifier
3	3	ID	R	[1..1]	0178	00660	File-Level Event Code
4	26	TS	O	[0..1]		00661	Entered Date/Time
5	26	TS	R	[1..1]		00662	Effective Date/Time
6	2	ID	R	[1..1]	0179	00663	Response Level Code

MFI-1 Master File Identifier (CE), required, shall contain the value OMA (Numerical Observation Master File).

MFI-2 Master File Application Identifier (HD), required, contains a code of up to 180 characters which uniquely identifies the application responsible for maintaining this file at a particular site.

The value of this field shall be formatted by concatenating the values below using the “_” (underscore) character as a separator:

- 260 • the name of the application that owns the code set. This shall be equal to the value of the field *MSH-3 Sending Application*.
- the type of master file. This shall be equal to the value of the field *MFI-1 Master File Identifier*.
- the language of the (textual descriptions of the) code set. This shall be equal to the value contained in the field *MSH-19 Principal Language of the Message*.
- (optional, if applicable) the version/revision of the code set. The character string used to identify a new version or revision should sort to be alphabetically “later” when compared to any previous versions or revisions.

270 The resulting identifier will have the form “SENDINGAPP_MFTYPE_LANGUAGE” or “SENDINGAPP_MFTYPE_LANGUAGE_VERSION”. The receiver should not attempt to deconstruct this string into its constituent elements; it should use the identifying string in its entirety. With the exception of version/revision all elements are available elsewhere in the message.

Examples include “Lab1_OMA_EN_1.2” or “X-PAS_OMB_FR”.

MFI-3 File-Level Event Code (ID), required, shall contain the value REP (replace current version of this master file with the version contained in this message).

280 **MFI-5 Effective Date/Time (TS)**, required, contains the date/time the Code Set Master expects that the event is to have been completed on the receiving system. The sending system should use the current date/time as a default. The Code Set Consumer shall process the event as soon as possible if the value of this field is in the past. If the value of this field is at some point in the future, then the Code Set Consumer shall process the event *before* that time.

MFI-6 Response Level Code (ID), required, shall contain the value ER. The acceptance status of the individual master file entries is only to be reported in case of an error. Since the IHE Laboratory Technical Framework uses the HL7 original acknowledgment mode, all MFA segments must be returned via the application-level acknowledgment message.

X.Y.4.1.2.2 MFE – Master File Entry Segment

Table X.Y.4.1-3. MFE – Master File Entry Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	3	ID	R	[1..1]	0180	00664	Record-Level Event Code
2	20	ST	R	[1..1]		00665	MFN Control ID
3	26	TS	O	[0..1]		00662	Effective Date/Time
4	200	Varies	R	[1..1]		00667	Primary Key Value – MFE
5	3	ID	R	[1..1]	0355	01319	Primary Key Value Type

290 **MFE-1 Record-Level Event Code (ID)**, required, shall contain the value MAD (add record to master file). Given that the file-level event code is REP, each MFE segment must have a record-level event code of MAD.

MFE-2 MFN Control ID (ST) is required since the response level code is ER. It contains an identifier that uniquely identifies the change to the record.

MFE-4 Primary Key Value – MFE, required, uniquely identifies a record of the code set. The data type of this field is CE (coded element). One unique identifier shall be provided; the last 3 components of the CE data type shall not be valued.

MFE-5 Primary Key Value Type (ID), required, contains the value CE (coded element).

X.Y.4.1.2.3 OM1 – General Segment

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Table X.Y.4.1-4. OM1 – General Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	4	NM	R	[1..1]		00586	Sequence Number - Test/Observation Master File
2	250	CE	R	[1..1]		00587	Producer's Service/Test/Observation ID
3	12	ID	O	[0..*]	0125	00588	Permitted Data Types
4	1	ID	R	[1..1]	0136	00589	Specimen Required
5	250	CE	R	[1..1]		00590	Producer ID
7	250	CE	O	[0..*]		00592	Other Service/Test/Observation IDs for the Observation
8	200	ST	R	[1..*]		00593	Other Names
18	1	IS	R	[1..1]	0174	00603	Nature of Service/Test/Observation
19	250	CE	RE	[0..1]	99999	00604	Report Subheader
20	20	ST	RE	[0..1]		00605	Report Display order

OM1-1 Sequence Number – Test/Observation Master File (NM), required, shall contain a sequence number from 1 to n (number of records).

OM1-2 MFN Producer's Service/Test/Observation ID (CE) is required. Only the first three sub-fields (Identifier, Text and Name of Coding System) are required. The last 3 components of the CE data type shall not be valued.

OM1-3 Permitted Data Types (ID), optional, should contain numerical, date or time stamp data types.

310 **OM1-4 Specimen Required (ID)**, required, contain the value Y if one or more specimen are required to obtain this observation, and N if a specimen is not required.

OM1-5 Producer ID (CE), required, uniquely identifies the service producing the observation. Only the first three sub-fields (Identifier, Text and Name of Coding System) are required.

OM1-7 Other Service/Test/Observation IDs for the Observation (CE) is optional and repeating. It can be used to send mapped/translated codes to the destination system. This field can be used to convey the mapping of local codes to reference code sets such as LOINC or SNOMED CT.

OM1-8 Other Names (CE), required, contains aliases or synonyms for the name in the context of the Order Placer. By default, this field can contain the same value as OM1-2 (2nd sub-field).

320 **OM1-18 Nature of Service/Test/Observation (IS)**, required, contains the value A (atomic observation).

OM1-19 Report Subheader (CE), required if known, contains an optional string that defines the preferred header under which this observation should be listed on a standard display.

OM1-20 Report Display Order (ST), required if known, contains an optional string that defines the absolute sort order in which this observation is presented in a standard report or display that contains the many observations.

X.Y.4.1.2.4 OM2 – Numeric Observation Segment

Table X.Y.4.1-5. OM2 – Numeric Observation Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
2	250	CE	R	[1..1]		00627	Units of Measure
3	10	NM	RE	[0..*]		00628	Range of Decimal Precision
6	250	RFR	O	[0..*]		00631	Reference (Normal) Range For Ordinal And Continuous Observations

330 **OM2-2 Units of Measure (CE)**, required. Used only if the test contained in OM1 has numeric results. Contains the customary units of measure for the test.

OM2-3 Range of Decimal Precision (NM), required if known. Used only if the test contained in OM1 has numeric results. Specifies the total length in characters of the field needed to display the observation, and the number of digits displayed to the right of the decimal point. This is coded as a single number in the format <length>.<decimal-digits>. For example, a value of 6.2 implies 6 characters total (including the sign and decimal point) with 2 digits after the decimal point. For integer values, the period and <decimal-digits> portion may be omitted (that is, 5.0 and 5 are equivalent). More than one such mask may be transmitted (separated by repeat delimiters) when it is necessary to define possible multiple display formats.

340 **OM2-6 Reference (Normal) Range for Ordinal and Continuous Observations**, Optional. This field contains the reference (normal) ranges for "numeric" observations/tests with a nature code of A or C (see OM1-18 - Nature of Service/Test/Observation). The use of this field is discouraged (but not forbidden) by IHE. This field can identify different reference (normal)

ranges for different categories of patients according to age, sex, race, and other patient conditions. Reference (normal) ranges however also depend on the Analyzer being used, a factor which isn't included in this field. Without having knowledge of the Analyzer generic statements about reference ranges may be clinically misleading and dangerous.

X.Y.4.1.2.5 OM4 – Observations that Require Specimens

350 The OM4 segment is used to convey information related to the (collection of) specimen required for the test/battery. This information can be used by Order Placers (e.g. at the ward) to collect the specimen.

Table X.Y.4.1-6. OM4 – Observations that Require Specimens

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
3	60	TX	R	[1..1]		00643	Container Description
6	250	CE	O	[0..1]		00646	Specimen

OM4-3 Container Description (TX), required. Used only if OM1-4 contains “Y”; contains a textual description of the type of container used for collection of the sample, e.g. “Red capped tube #2”.

OM4-6 Specimen (CE), optional. See SPM-4 for additional information. The actor shall use one and the same vocabulary table for OM4-6 and SPM-4 if the Code Set Master is also an Order Filler actor.

X.Y.4.1.3 Expected Actions

360 The Code Set Consumer must replace its corresponding code set by the received code set.

Codes which have been removed from the code set are not to be used by the receiving system any more, from the effective date/time given in the message. Codes which have been removed should not be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added codes are usable from the effective date/time given in the message.

X.Y.4.2 Master File Notification – Test/Observation (Categorical)

This message is used to transmit the code of observations where the value is free text and other non-numeric data types.

X.Y.4.2.1 Trigger Events

MFN^M09 – the Code Set Master sends a full set of non-numeric observation codes.

370 **X.Y.4.2.2 Message Semantics**

HL7 2.5 Chapter 8 MFN^M09 message. Refer to HL7 Standard for general message semantics. The construction of the message is roughly the same as MFN^M08. The OM3 segment can be

used to transmit categorical results for a test (such a “high”/“low”, or “reactive”/”unreactive”/”transactive”) or to indicate a vocabulary for the results (e.g. SNOMED).

Table X.Y.4.2-1. MFN^M09 static definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[--- MF_TEST_CAT_DETAIL begin	O	[0..1]	8
OM3	Categorical Service/Test/Observation Segment	R	[1..1]	8
[[OM4]]	Observations that Require Specimens	O	[0..*]	8
]	--- MF_TEST_CAT_DETAIL end			
}	--- MASTER FILE ENTRY end			

X.Y.4.2.2.1 MFI – Master File Identification

380 Refer to X.Y.4.1.2.1 for the construction of this segment. The difference with the MFI segment of a MFN^M08 message is:

MFI-1 Master File Identifier (CE), required, shall contain the value OMB (Categorical Observation Master File).

X.Y.4.2.2.2 MFE – Master File Entry Segment

Refer to X.Y.4.1.2.2 for the construction of this segment. There is no difference with the MFE segment of a MFN^M08 message.

X.Y.4.2.2.3 OM1 – General Segment

Refer to X.Y.4.1.2.3 for the construction of this segment. The difference with the OM1 segment of a MFN^M08 message is:

390 **OM1-3 Permitted Data Types (ID)**, optional, should contain data types other than numerical, date or time stamp.

X.Y.4.2.2.4 OM4 – Observations that Require Specimens

Refer to X.Y.4.1.2.5 for the construction of this segment. There is no difference with the OM4 segment of a MFN^M08 message.

X.Y.4.2.3 Expected Actions

400 The Code Set Consumer must replace its corresponding code set by the received code set. . Codes which have been removed from the code set are not to be used by the receiving system any more from the effective date/time given in the message. Codes which have been removed should not be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added codes are usable from the effective date/time given in the message.

X.Y.4.3 Master File Notification – Test/Observation Batteries

This message is used to transmit battery codes, i.e. codes sent in the OBR-4 field (Universal Service Identifier).

X.Y.4.3.1 Trigger Events

MFN^M10 – the Code Set Master sends a full set of battery codes.

X.Y.4.3.2 Message Semantics

HL7 2.5 Chapter 8 MFN^M10 message. Refer to HL7 Standard for general message semantics. The construction of the message is roughly the same as MFN^M08.

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Table X.Y.4.3-1. MFN^M10 static definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[--- MF_TEST_BATT_DETAIL begin	RE	[0..1]	8
OM5	Observation Batteries	R	[1..1]	8
[[OM4]]	Observations that Require Specimens	O	[0..*]	8
]	--- MF_TEST_BATT_DETAIL end			
}	--- MASTER FILE ENTRY end			

X.Y.4.3.2.1 MFI – Master File Identification

Refer to X.Y.4.1.2.1 for the construction of this segment. The difference with the MFI segment of a MFN^M08 message is:

MFI-1 Master File Identifier (CE), required, shall contain the value OMC (Observation Batteries Master File).

X.Y.4.3.2.2 MFE – Master File Entry Segment

Refer to X.Y.4.1.2.2 for the construction of this segment. There is no difference with the MFE segment of a MFN^M08 message.

420 **X.Y.4.3.2.3 OM1 – General Segment**

Refer to X.Y.4.1.2.3 for the construction of this segment. The difference with the OM1 segment of a MFN^M08 message is:

OM1-18 Nature of Service/Test/Observation (IS), required, contains the value P (battery consisting of one or many independent atomic observations), F (functional procedure) and S (superset of batteries or procedure ordered under a single code unit).

X.Y.4.3.2.4 OM5 – Observation Batteries

Table X.Y.4.3.2-1. OM5 – Observation Batteries

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
2	250	CE	R	[1..*]		00655	Test/Observations Included within an Ordered Test Battery

OM5-2 Test/Observations Included within an Ordered Test Battery, required, contains the codes and names of all tests/observations included within a single battery.

430 If the OM1 segment defined serum electrolytes, this field might look like the following:
84132^potassium^AS4~84295^sodium^AS4~82435^chloride^AS4~82374^HCO3^^AS4

X.Y.4.3.2.5 OM4 – Observations that Require Specimens

Refer to X.Y.4.1.2.5 for the construction of this segment. There is no difference with the OM4 segment of a MFN^M08 message.

X.Y.4.3.3 Expected Actions

440 The Code Set Consumer must replace its corresponding code set by the received code set. . Codes which have been removed from the code set are not to be used by the receiving system any more from the effective date/time given in the message. Codes which have been removed should not be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added codes are usable from the effective date/time given in the message.

X.Y.4.4 Master File Notification – Test/Calculated Observation

This message is used to transmit the code of observations where the value is derived from one or more quantities or direct observations.

X.Y.4.4.1 Trigger Events

MFN^M11 – the Code Set Master sends a full set of calculated observation codes.

X.Y.4.4.2 Message Semantics

450 HL7 2.5 Chapter 8 MFN^M11 message. Refer to HL7 Standard for general message semantics. The construction of the message is roughly the same as MFN^M08. The OM6 segment can be used to detail the rule or formula used to determine the value of the test. The OM2 segment can be used to specify the units of measure if the formula results in a numeric value.

Table X.Y.4.4-1. MFN^M11 static definition

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	R	[1..*]	8
MFE	Master File Entry	R	[1..1]	8
OM1	General Segment	R	[1..1]	8
[
OM6	Observation calculated from other observations	O	[0..1]	8
OM2	Numeric Observation Segment	O	[0..1]	8
]				
}	--- MASTER FILE ENTRY end			

X.Y.4.4.2.1 MFI – Master File Identification

Refer to X.Y.4.1.2.1 for the construction of this segment. The difference with the MFI segment of a MFN^M08 message is:

MFI-1 Master File Identifier (CE), required, shall contain the value OMD (Calculated Observations Master File).

460 X.Y.4.4.2.2 MFE – Master File Entry Segment

Refer to X.Y.4.1.2.2 for the construction of this segment. There is no difference with the MFE segment of a MFN^M08 message.

X.Y.4.4.2.3 OM1 – General Segment

Refer to X.Y.4.1.2.3 for the construction of this segment. The difference with the OM1 segment of a MFN^M08 message is:

OM1-18 Nature of Service/Test/Observation (IS), required, contains the value C (single observation calculated via a rule or formula from other independent observations).

X.Y.4.4.3 Expected Actions

470 The Code Set Consumer must replace its corresponding code set by the received code set. .
 Codes which have been removed from the code set are not to be used by the receiving system any more from the effective date/time given in the message. Codes which have been removed should not be deleted but be flagged as disabled/invalid for backward compatibility reasons. New added codes are usable from the effective date/time given in the message.

X.Y.4.5 Acknowledge Mode

Applications that receive HL7 messages defined in the IHE Laboratory Technical Framework shall send acknowledgements using the HL7 original acknowledgement mode. The Master File Application Acknowledgment message is defined in HL7 2.5 Chapter 8. The structure of the acknowledgement messages is the same for all acknowledgements:

480 **Table X.Y.4-5. MFK^M08, MFK^M09, MFK^M10, MFK^M11 static definition**

Segment	Meaning	Usage	Card.	HL7
MSH	Message Header	R	[1..1]	2
MSA	Acknowledgment	R	[1..1]	2
[[ERR]]	Error	C	[1..1]	2
MFI	Master File Identification	R	[1..1]	8
{	--- MASTER FILE ENTRY begin	C	[0..*]	8
MFA	Master File ACK Segment	R	[1..1]	8
}	--- MASTER FILE ENTRY end			

The construction of MSH, MSA and ERR segments is defined in section 3.1 of the IHE Laboratory Technical Framework, Volume II. The ERR segment shall be used in case of negative acknowledgement, i.e. when the receiving application sends an error on one Master File entry.

The MASTER FILE ENTRY segment group is conditional upon the presence of errors (see the description of field MFI-6). The segment group shall only be populated with MFA Segment for those master file entries that could NOT be accepted. If the entire batch can be accepted by the receiver then the acknowledgement message shall not contain any MFA segments.

490 X.Y.4.5.1 MFA - Master File Acknowledgment Segment

The MFA – Master File Acknowledgment segment is defined in the following table.

Table X.Y.4.5-1. MFA – Master File Acknowledgment Segment

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
1	3	ID	R	[1..1]	0180	00664	Record-Level Event Code

SEQ	LEN	DT	Usage	Card.	TBL#	ITEM#	Element name
2	20	ST	R	[1..1]		00665	MFN Control ID
3	26	TS	O	[0..1]		00668	Event Completion Date/Time
4	250	CE	R	[1..1]	0181	00669	MFN Record Level Error Return
5	250	CE	R	[1..1]		01308	Primary Key Value - MFA
6	3	ID	R	[1..1]	0355	01320	Primary Key Value Type - MFA

MFA-1 Record-Level Event Code (ID), required, shall contain the value MAD (add record to master file).

MFA-2 MFN Control ID (ST) is required and contains an identifier that uniquely identifies the change to the record.

MFA-4 MFN Record Level Error Return (CE), required, contains the status of the requested update. The actors of IHE Laboratory Technical Framework should support the following values:

Table X.Y.4-3. MFN record-level error return

Value	Description
S	Successful posting of the record defined by the MFE segment
U	Unsuccessful posting of the record defined by the MFE segment

MFA-5 Primary Key Value – MFA, required, uniquely identifies a record of the code set. It contains the same value as MFE-4.

MFA-6 Primary Key Value Type - MFA (ID), required, contains the value CE (coded element).

X.Y.5 Examples

This section contains a number of examples for the messages defined in the LCSD profile.

510

X.Y.5.1 Example 1: Numeric Observations

The message below is a Dutch (NLD) language example containing a master file definition for numeric tests. The master file has the version ID "1.2". The (optional) OM4 segment defines the type of container (e.g. "*stolbuis rode dop4*" = red capped blood tube #4) and specimen type (e.g. "*BLDV^volbloed*" = venous blood) which is associated with a test. This information is used by the OP in those cases where the OP is responsible for collecting the sample.

520

```
MSH|^~\&|OF|LabSystem|OP||20050205094510||MFN^M08^MFN_M08|2106|2.5|||NLD|8859/1|NL|
MFI|OMA|OF_OMA_NL_1.2|REP|||ER|
MFE|MAD|1846||1846^CREABL/Creatinine^L|CE|
OM1|1|1846^CREABL/Creatinine^L|NM|Y|K231^Klinisch Chemisch
Laboratorium^L||Creatinine|||||||A|
OM2|1|umol/l|6.0||
OM4|1||stolbuis rode dop4|ml|BLDV^volbloed^HL70487|
MFE|MAD|1848||1848^CREAUV/Creatinine^L|CE|
OM1|2|1848^CREAUV/Creatinine^L|NM|Y|K231^Klinisch Chemisch
Laboratorium^L||Creatinine|||||||A|
OM2|2|mmol/l|6.0||
OM4|2||24-uurs bokaal||UR^urine^HL70487|
MFE|... (other master file entries not shown)
```

530

Response message:

Note that those additions that are successful are not explicitly acknowledged. Each OM1 segments that is problematic to the receiver causes a MFA segment to be present in the acknowledgement message. In this example, all updates are accepted except for 1848.

540

```
MSH|^~\&|OP||OF|LabSystem|20050205094520||MFK^M08^MFK_M01|234443|2.5|||NLD|8859/1|NL|
MSA|AA|2106|
MFI|OMA|OF_OMA_NL_1.2|REP|||ER|
MFA|MAD|1848||U^Duplicate ID|1848^CREAUV/Creatinine^L|CE
```

X.Y.5.2 Example 2: Calculated Observation

The message below is a Dutch (NLD) language example containing a master file definition for calculated numeric tests. The calculation algorithm is shown (in textual form) in the OM6 segment.

```
MSH|^~\&|OF|LabSystem|OP||20050205094520||MFN^M11^MFN_M11|2107|2.5|||NLD|8859/1|NL|
MFI|OMD|OF_OMD_NL_1.1|REP|||ER|
MFE|MAD|1849||1849^CLEA/Creatinine clearance^L|CE
550 OM1|1|1849^CLEA/Creatinine clearance^L|NM|Y|K231^Klinisch Chemisch
Laboratorium^L||Creatinine clearance|||||||C|
OM6|1|(CREAUV * HOEV) / (CREASE * 1440)
OM2|1|ml/min|4.0||
MFE|... (other master file entries not shown)
```

Response message:

The entire contents of the message are accepted.

```
MSH|^~\&|OP||OF|LabSystem|20050205094530||MFK^M11^MFK_M01|234450|2.5|||NLD|8859/1|NL|
560 MSA|AA|2107|
MFI|OMD|OF_OMD_NL_1.1|REP|||ER|
```