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Instrument Manager (IM-Abbott) and Laboratory Information System (LIS) Change Process

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

Laboratory Information System (LIS) and Middleware systems often require necessary changes and adjustments to be compliant and to optimize patient care and results. The purpose of this document is to define laboratory process for the change documentation and processes between Instrument Manager (IM-Abbott) and SOFT (LIS).

II. CLINICAL SIGNIFICANCE

Changes and optimizations made in LIS and Middleware applications are necessary for patient care and growth. Connections between these applications aids in the flow of laboratory information, including test orders, and results, specimen information, and patient information.

III. DEFINITIONS:

A. **South sites:** Dearborn, Taylor, Trenton, Wayne

B. **North sites:** Farmington Hills, Grosse Pointe, Royal Oak, Troy

IV. PROCEDURE:

A. **Consensus of Change Items for Beaumont Laboratory LIS/ IM**

1. A change or modification to the LIS system or IM must be presented to the Chemistry Best Practices team for consensus.
    a. The change/modification/addition request will be presented to the team members with appropriate background, information, studies, etc.
    b. If additional information is requested, the initial requestor will provide this, unless otherwise noted.

B. **Entering a Request for Change/Modification for LIS/IM**

1. The designated IM team member for both North and South sites will enter a Remedy request ticket to the respective LIS systems, including the name of the change/modification requestor for validation

purposes.

a. The request ticket will include all necessary information needed for the change/modification including, but not limited to, units, decimals, test code, etc. This will generate a service request number.

b. The designee will create a new log entry on the Share Point Validation Log under Chemistry Line Implementation.

2. The designee will then make appropriate changes to IM, in the TEST mode

3. A designated team member from LIS will make the appropriate changes/modifications as necessary in the TEST system and notify the IM designee and the requestor when task is ready for validation.

C. **Validating Changes in TEST Systems**

1. Once changes/modifications have been made in both IM TEST and LIS TEST, validation can proceed.

a. The LIS team member will notify the requestor and the IM designee when a change/modification is ready for validation.

2. One designated team member from a North site and one designate team member from a South site will validate changes.

a. If the change is individual instrument interface specific, and not IM specific, then each Beaumont Laboratory site must validate.

3. Documentation of all validation, including screen shots and instant reports, are to be posted on the Validation Log entry.

4. Once all team members have validated that the change/modification is working as specified or requested, a move to LIVE production will be determined.

D. **Moving Changes to LIVE Production**

1. Determining the date of going live with change/modification

a. A change that is only made in TEST IM will go into production on an agreed time and date by the Beaumont Laboratory.

b. Changes that are made in TEST LIS and TEST IM will go into production on the first Tuesday of the month, unless otherwise determined by the team members.

2. An open Skype conference call will be created before the determined LIVE production change time. All involved team members will join the conference call.

a. Changes will be applied to LIVE production by the LIS team member and the designated IM team member.

b. All communications will be made through the Skype conference call.

3. LIVE production validation will follow the same guidelines as validation in TEST systems. (Refer to item C. Validating Changes in TEST Systems)

4. All documentation of LIVE production validation, including screen shots and instant reports, will be saved on the Validation Log.

a. Once all documentation has been filed and the LIVE production validation has been signed off or agreed on, the Validation Log item will be marked as “Complete”.

E. **Vendor Changes and Maintenance**

1. Any changes made by the vendor including, but not limited to, server back-up and copies of testing and live environments must be communicated to the LIS and Chemistry Best Practices team members prior to making the changes.
2. Details will be provided to the Beaumont Laboratory team members including the action that will be taking place, the impact of production and test environments, and any downtime that may be necessary.
3. These items will be documented in the Validation Log on Share Point.
4. A weekly change report will be sent by the Systems Integration Coordinator to the vendor of changes that are in progress and changes that have been completed.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	11/15/2021
CLIA Medical Directors	Muhammad Arshad: Chief, Pathology	11/10/2021
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	11/3/2021
CLIA Medical Directors	John Pui: Chief, Pathology	11/2/2021
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr Laboratory	11/2/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	11/2/2021
	Ann Marie Blenc: System Med Dir, Hematopath	11/2/2021
	Elizabeth Sykes: System Med Dir, Chemistry	11/1/2021
	Qian Sun: Tech Dir, Clin Chemistry, Path	11/1/2021
	Colette Kessler: Mgr Laboratory	11/1/2021
	Colette Kessler: Mgr Laboratory	11/1/2021

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne