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WAM Change Management Process

Purpose This process describes the workflow for evaluation, approval, and implementation of proposed changes to the Sysmex WAM rules for the KP Southern California (SCAL) laboratories.

- Policy**
- When there is a proposal for a change to the WAM middleware autoverification system, an evaluation will be done by the stakeholders.
 - The evaluation shall consist of testing the change, and communicating the assessment to the Hematology UA Working Group (HUWG) prior to putting it in production.
 - New rules implemented will be included in the annual validation of rules.

Process for WAM Change The process for any WAM change will involve proposal, evaluation, testing, assessment, and implementation. Refer to the steps below on the entire process.

Stage	Description	
1	The representative shall present the proposal utilizing the SBAR tool.	
2	If ...seventy percent majority of HUWG approved the proposal,	then The decision is captured. A Sysmex Change Request Form (CRF) will be submitted to the Sysmex Technical Assistance Center (TAC). Co-chair/s of HUWG will submit on behalf of the group.
	...proposal didn't obtain approval from the majority,	The decision is captured. No CRF will be submitted by the WG at the current time. The proposal can be revisited.

WAM Change Management Process, Continued

**Process for
 WAM Change**

Continuation

Stage	Description						
3	Once the proposed change is in the Test environment, the change will be tested by at least two members of the WG. The testers shall include at least one medical center representative and a representative of the regional lab.						
4	<p>Testers will assess the results of the testing.</p> <table border="1" data-bbox="548 646 1393 1052"> <thead> <tr> <th data-bbox="548 646 938 682">If</th> <th data-bbox="938 646 1393 682">then</th> </tr> </thead> <tbody> <tr> <td data-bbox="548 682 938 867">...the testing passed by achieving the desired result of the proposal,</td> <td data-bbox="938 682 1393 867">The change will be scheduled to move to Production. The scheduled date will be announced and shall be agreed upon by the WG.</td> </tr> <tr> <td data-bbox="548 867 938 1052">...the testing failed to achieve the desired result of the proposal,</td> <td data-bbox="938 867 1393 1052">The outcome will be shared with the WG to reconsider a new proposal or abandon by seeking an alternate workflow.</td> </tr> </tbody> </table>	If	then	...the testing passed by achieving the desired result of the proposal,	The change will be scheduled to move to Production. The scheduled date will be announced and shall be agreed upon by the WG.	...the testing failed to achieve the desired result of the proposal,	The outcome will be shared with the WG to reconsider a new proposal or abandon by seeking an alternate workflow.
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...the testing failed to achieve the desired result of the proposal,	The outcome will be shared with the WG to reconsider a new proposal or abandon by seeking an alternate workflow.						
5	Upon implementing the proposed change in Production, the laboratories shall document and validate the change with the proper approvals.						

WAM Change Management Process, Continued

Controlled Documents

The following controlled documents support this policy.
Locally approved versions will have different document numbers.

Document Number	Title
SCPMG-QMS-0025	Autoverification Policy

Non-Controlled Documents

The following non-controlled documents support this policy.

Sysmex WAM v5.x User Manual, Document Number 1036-MKT, Rev.3
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Signature Manifest

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WAM Change Management Process

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
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Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	08 Nov 2023, 10:12:08 PM	Approved