APPROVAL

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PURPOSE

The purpose of this procedure is to describe and define responsibilities, requirements, methods, and phases in the maintenance of software that is in compliance with appropriate national and international requirements, regulations, and standards.

This procedure applies to all product development, product modifications, line extensions, and product change projects.

SCOPE

This procedure applies to the maintenance of ASPIVIX SA medical software.

RESPONSIBILITIES

Responsible for implementing and maintaining this SOP is the is the Regulatory Affairs and Quality Assurance Manager (RAQM). All parties participating must respect the defined procedure.

DOCUMENT HISTORY

Description of Changes	Version
Initial version	A

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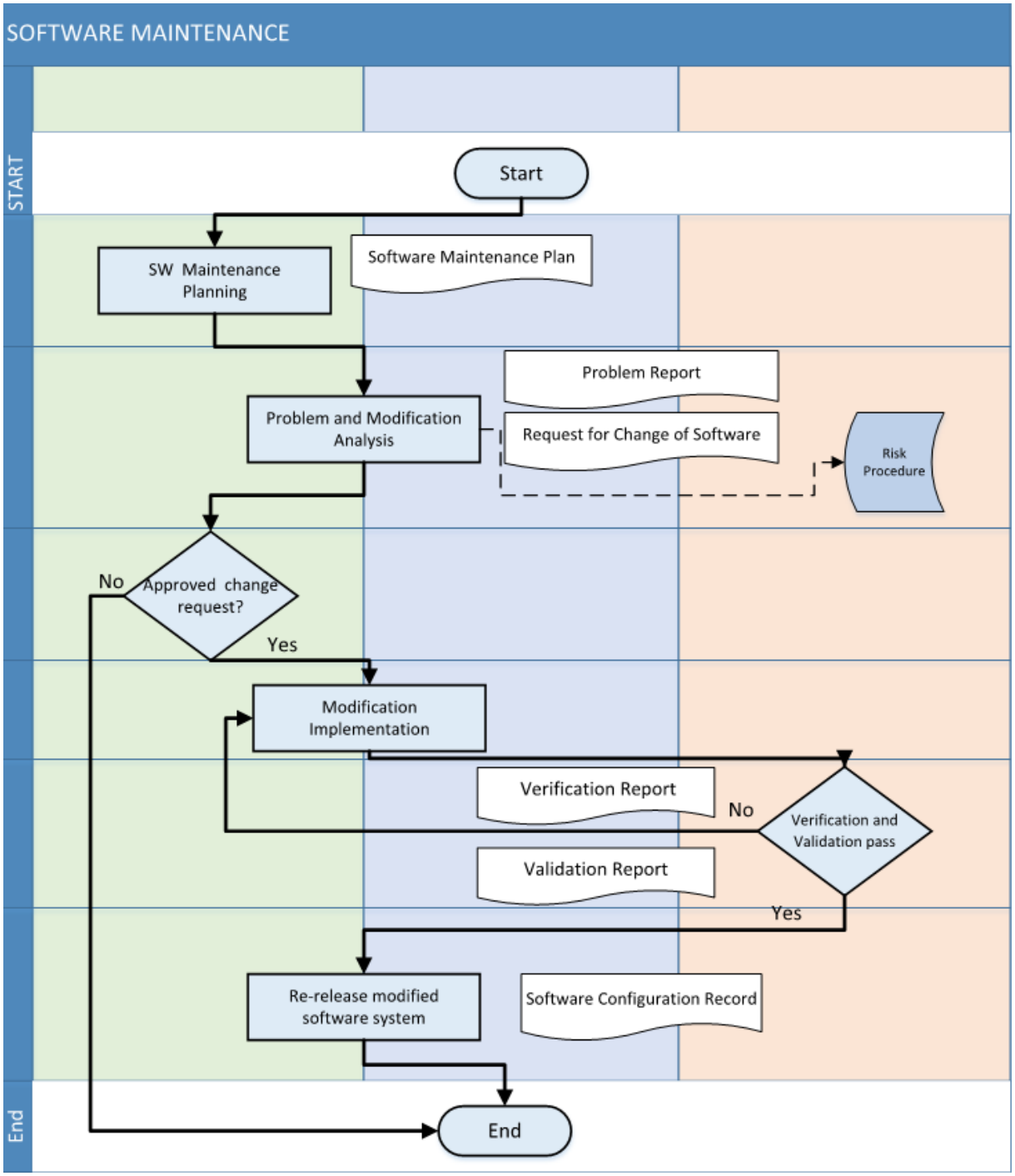
1. PROCEDURE

1.1.Process overview



1.2. Software Maintenance Plan

Software Maintenance Plan (6.1)[1] shall be created in accordance with T-208-2 Software Maintenance Plan and established for conducting the activities and tasks of the maintenance process.

The Software Maintenance Plan addresses the following:

- Procedures for receiving, documenting, evaluating, resolving, and tracking feedback arising after the release of the medical software,
- Criteria for determining whether feedback is considered to be a problem,
- Use of the software risk management process,
- Use of the software problem resolution process for analyzing and resolving problems arising after the release of the medical software,
- Use of the software configuration management process for managing modifications to the existing system,
- Procedure to evaluate and implement upgrades/patches, bug fixes or obsolescence of Software Of Unknown Provence (SOUPs).
- A Software Maintenance Plan needs to be defined in the preparation phase for putting software on the market.

1.3. Problem and Modification Analysis

1.3.1. Monitor feedback

Feedback(s) on released software shall be monitored (6.2.1.1), and they might be from different instances, from company departments, or from user sides directly.

Complaints are reported and handled according to the procedure SOP-103 Complaint Handling.

1.3.2. Document and evaluate feedback

Provided feedback shall be documented by the customer service and evaluated (6.2.1.2) by the development team to determine whether a problem exists in a released medical software.

T-208-4 Problem Report is a record of the actual or potential behavior of a software product that a user or other interested party believes to be unsafe, inappropriate for the intended use, or contrary to specification. Problem reports shall include actual or potential adverse events, and deviations from specifications (6.2.1.2). Not every reported issue is treated as a problem. Additionally, every report doesn't result in a change to the medical software. ASPIVIX SA can reject a problem report as a misunderstanding, error, or insignificant event. In the cases when actions are needed, the Project Manager is responsible for assigning tasks to the software development team based on reported issues.

1.3.3. Evaluate the problem report's effects on safety

Each Problem report shall be evaluated to determine how it affects the safety of medical software released for the intended use and whether a change to the released software product is needed to address the problem (6.2.1.3). The Project Manager shall inform the CEO about every confirmed problem in the released software.

According to the nature of change, and its relevance to safety, the management will decide about notification of customers that are affected by the change. In cases where national regulation in the

[1] The following procedure contains references in brackets i.e. (6.1) which are a direct reference to the requirements of EN 62304:2005/A1:2016

customer country requires so, the customer should be informed of each change.

The customer should be informed about the consequences of continued use of unchanged software, the nature of changes, and the way how to make changes in the software product already released.

1.3.4. Use software problem-resolution process

Software problem resolution activities are performed according to INS-208-3 Software Problem Resolution Process (6.2.2).

1.3.5. Change request approval

Besides reporting problems, customers can request a change in a released software. A change is identified because of an issue or of some change to the project environment (for example, regulatory and/or competitive changes). Each change request shall be analyzed (6.2.3)

Change requests are managed according to the SOP-303 Change Management. In the case of an internal request for change (requested by an interested stakeholder from ASPIVIX SA), the person who is requesting the change completes the T-303-1_ Change Request Control template Request and sends it to the Project Manager. Customers can request a change of software either via the website or other communication channels (e.g., phone, email). Customer Support is responsible for reviewing and updating the T-303-1_Change Request Control when the change is requested by the customer.

Change requests which modify released software products must be evaluated and approved (6.2.4). The project Manager will review these change requests with the software development team to determine the project tasks that will be either created or impacted by the change request and estimate the impacts of the change.

After assessing the cost and schedule impact of the requested change on the project, the request will be either approved or denied.

If a request is approved, the Project Manager is responsible for assigning tasks to the software development team based on the approved change request.

The Customer Support (for customers) and Project Manager (for interested stakeholders from ASPIVIX SA) are responsible for informing change requesters via email if the request is accepted or denied. If the change request is denied, the record will also include a reason for denial.

1.3.6. Communicate to users and regulators

Approved change requests that affect released software products must be identified (6.2.5).

As required by local regulation, users and regulators must be informed about:

a) any problem in released software products and the consequences of continued unchanged use,

b) the nature of any available changes to released software products and how to obtain and install the changes.

1.4. Modification Implementation

1.4.1. Use the established process to implement modification

Modifications are implemented according to SOP-208 Software Development (6.3.1).

The original software development plan is addressed, and a new version is introduced. All relevant elements of the plan that are affected by modification are changed (requirement list, risk analysis and risk reduction measures, verification plan, and possibly validation).

Approved modifications in software are assigned as tasks to the developers.

1.4.2. Verification

If verification of changes is needed, it is included in the T-303-1_Change Request Control. Verification of the modified software release is done in the environment of a fully integrated software system and full application of this software system. Verification is done by QA. After software verification, the Project Manager must approve a new software version before delivery.

1.4.3. Validation

If validation of changes is needed, it is included in the T-303-1_Change Request Control. If the Project Manager considers that a particular modification of software cannot be satisfactorily evaluated only by verification, he/she will recommend validation of changes to be done in the company or externally in a reference medical institution.

In this case, the Project Manager also organizes validation according to procedure SOP-208 Software Development.

1.4.4. Re-release modified software system

The modified software system shall be released according to the SOP-208 Software Development (6.3.2). Modifications may be released as part of a full re-release of a software system or as a modification kit comprising changed software items. Project Manager is responsible for keeping project documentation up to date with changes.

2. REFERENCE

2.1.Procedures, instructions, and guidelines

- SOP-208 Software Development
- SOP-103 Complaint Handling
- INS-208-3 Software Problem Resolution Process
- SOP-303 Change Management

2.2. Templates and forms

- T-208-2 Software Maintenance Plan
- T-208-4 Problem Report
- T-303-1 Change Request Control

2.3.External

- IEC 62304:2006/A1:2015 - Medical device software – Software life cycle processes
- ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
- EN ISO 13485:2016/A11:2021 - Medical devices - Quality management systems - Requirements for regulatory purposes
- FDA QSR 21 CFR Part 820, Medical Devices - Quality System Regulation

- Medical Device Regulation - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
- EN ISO 14971:2019/A11:2021 - Medical devices - Application of risk management to medical devices

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Certificate of Completion

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