APPROVAL

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PURPOSE

The purpose of this procedure is to describe and define responsibilities, methods, and phases in the software problem-resolution process.

SCOPE

This procedure applies to problem resolution of ASPIVIX SA medical software.

RESPONSIBILITIES

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

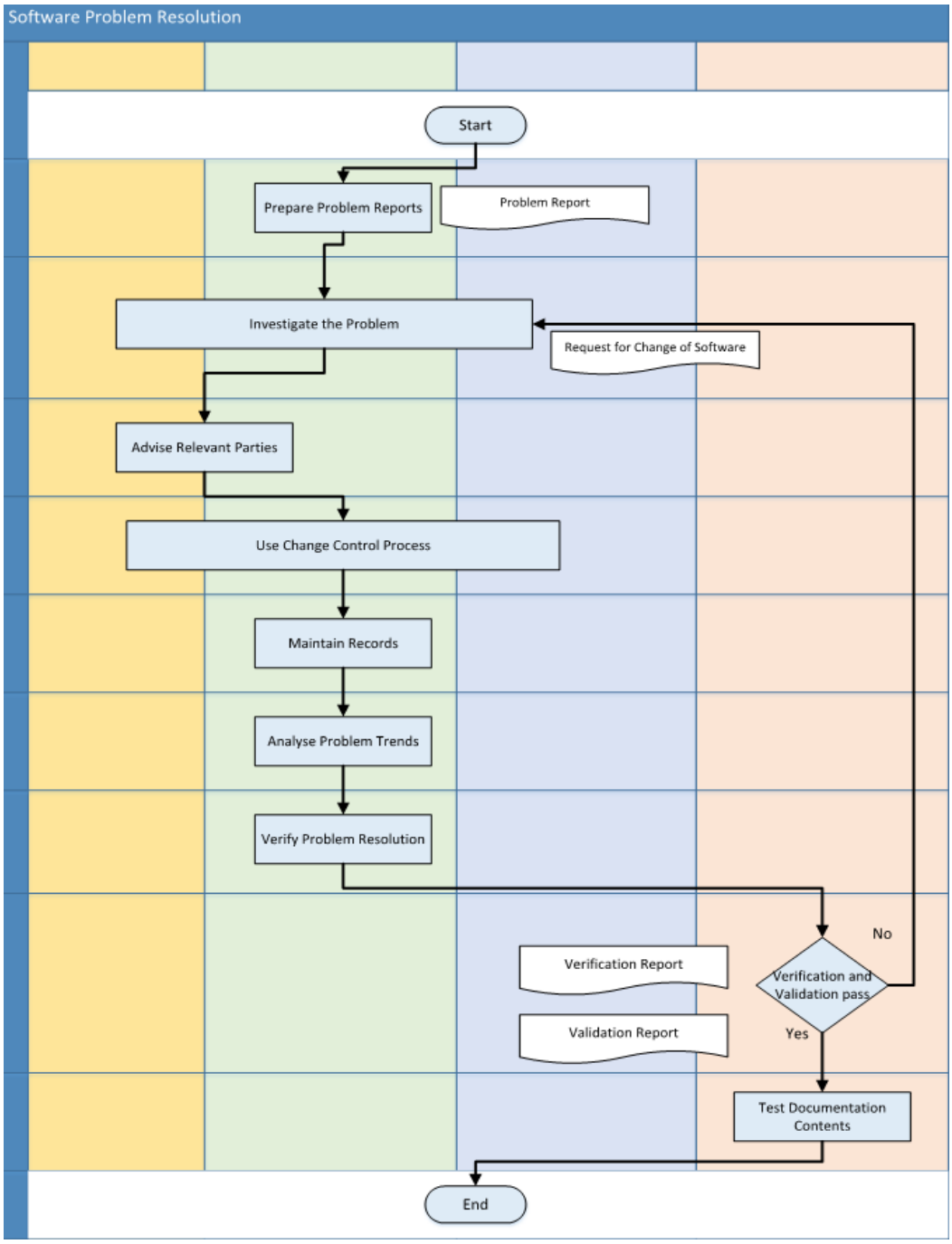
DOCUMENT HISTORY

Description of Changes	Version
Initial version	A

TABLE OF CONTENT

1. PROCEDURE

The procedure defines rules for software problem resolution in the company ASPIVIX SA. The figure below describes the activities of the software problem-resolution process:



1.1. Prepare Problem Reports

At any time during the software life cycle if a problem is found a software problem resolution should be initiated. The initiative may be started:

1. By the Project manager during the development phase and verification procedures (before release) in the case of a negative impact on safety,
2. By QA as an output from testing and validation activities (before release) in the case of negative impact on safety,
3. By customer (after release) (managed through SOP-103 Complaint Handling).

Software problems are reported via direct contact (oral, mail, meetings) with corporate contacts or via the complaint process (SOP-103 Complaint Handling) by customers.

Problem reports (9.1)[1] are classified as follows:

a) Type (e.g., corrective, preventive, or adaptive to new environment)
b) Scope (e.g., size of change, resources involved, time to change)
c) Criticality (effect on performance, safety, or security)

Complaint Management Personnel is obliged to monitor problem reports and track the problem resolution process.

1.2. Investigate the Problem

The investigation phase of software problem resolution (9.2) must provide answers to the following questions:

1. What is the cause of the problem?
2. Problem's relevance to safety?
3. Changes needed?

The investigation is done by complaint management personnel and the project manager. If needed, the software development team or other team members are consulted as well. The outcome of the investigation must be documented. For actions needed to correct the problem, the change request form T-303-1 Change Request Control Sheet has to be filled in. If no action is needed, a rationale for taking no action will be provided.

Note: A problem does not have to be corrected for the manufacturer to comply with the software problem resolution process, provided that the problem is not relevant to safety.

1.3. Advise Relevant Parties

Problems can be discovered before or after release, inside the ASPIVIX SA or outside it. Depending on that complaint management personnel and Project manager should decide if and, where appropriate, which relevant parties will be advised of an existing problem (9.3).

1.4. Use Change Control Process

Change requests are managed according to the SOP-303 Change Management. All change requests approved by the Project manager have to be implemented by the software development team taking into account the change control (9.4) process described in SOP-208 Software Development and INS-208-1

[1] This procedure contains references in brackets (i.e. (9.1)) which are a direct reference to the requirements of EN 62304:2005/A1:2016

Software Maintenance. Approved change requests are delegated as tasks to the software development team.

1.5.Maintain Records

ASPIVIX SA must maintain records of problem reports (9.5) and their resolution including their verification. Complaint management personnel are responsible for keeping problem reports up to date. Complaint management personnel can ask the project manager or software development team for assistance where appropriate.

Also, the risk management file should be updated, as appropriate.

1.6.Analyze problem trends

Complaint management personnel perform problem trend analysis (9.6) upon each new problem report. Analysis should provide an answer to whether adverse trends have been reversed or not. These results are considered when change requests approval shall be made.

1.7.Verify software problem resolution

If a reported problem requires change in software, the record T-303-1 Change Request Control Sheet is created. If an approved change request requires verification, the manufacturer must verify problem resolutions (9.7) to determine whether:

a) The problem has been resolved, and the problem report has been closed.
b) Adverse trends have been reversed.
c) Change requests have been implemented in the appropriate software product and activities; and
d) Additional problems have been introduced.

The problem is considered resolved only upon successful verification of all affected components of the software product. Verification should follow the standard software verification process described in the software development procedure, SOP-208 Software Development.

After positive testing results, the Verification Report is updated. If verification is not successful or new problems are created, the process is repeated from the problem initiation stage.

It does not require that every problem report results in a change to the software product. A problem report can be rejected as a misunderstanding, error, or insignificant event.

1.8.Test documentation contents

If an approved change request (following the resolution of the reported problem) requires validation, the Validation Report is updated after testing and validation of changes. When testing, retesting, or regression testing software items and systems following a change, the manufacturer shall include in the test documentation (9.8):

a) test results,
b) anomalies found,
c) the version of software tested,
d) relevant hardware and software test configurations,
e) relevant test tools,
f) date tested,
g) identification of the tester.

The software can be released under the same condition as in the development process described in the software development process procedure, SOP-208 Software Development.

2. REFERENCE

2.1. Procedures, instructions, and guidelines

- SOP-208 Software Development
- SOP-208-1 Software Maintenance
- SOP-103 Complaints Handling
- SOP-303 Change Management

2.2. Templates and forms

- T-303-1 Change Request Control Sheet

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
- IEC 82304-1 Ed. 1.0 - Health Software - Part 1: General requirements for product safety
- 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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