# Purpose

This policy describes the software development life cycle (SDLC) process for software products produced for Terumo Heart, Inc. (THI). The intent of SDLC is to provide structure for the software development and maintenance of products. This structure indicates required controls and deliverables expected during software development and maintenance of products. The SDLC is responsible for Planning, Designing, Developing, Testing and Maintenance for software created at THI.

# Scope

This policy applies to the development and maintenance of medical device product software at THI. This process also includes the development of firmware that will be implemented in FPGA in medical devices. The SDLC begins with a Software Development Plan and continues throughout the Software lifecycle.

The procedure to develop and maintain the software tools is defined in 90489-00 Non-Product Software Lifecycle Procedure and is outside the scope of this policy.

CPLDs are not covered by the SDLC as they are considered to be a hardware component and are outside the scope of this policy.

# ABBREVIATIONS AND TERMS

## Anomaly

Any condition that deviates from the expected based on requirement specifications, design documents, standards, etc. or from someone’s perceptions or experiences. Software Anomalies may be found during, but not limited to, the review, test, analysis, compilation or use of software products or applicable documentation.

## CIs

Configuration Items

## CPLD

Complex Programmable Logic Device

## DHF

Design History File

## DIR

Design Inputs Requirements

## FPGA

Field Programmable Gate Array

## SAD

Software Architecture Design

## SCM

Software Configuration Management Specialist

## SDD

Software Design Description

## SDE

Software Development Engineer

## SDLC

Software Development Life Cycle

## SDP

Software Development Plan

## SOUP

Software of Unknown Provenance

## SPD

Software Program Director

## SPM

Software Project Manager

## SQE

Software Quality Engineer

## SRS

Software Requirement Specification

## STE

Software Test Engineer

## STE/TD

Software Lead Test Engineer / Test Director

## SVT

Software Verification Testing

## SWRAR

Software Risk Analysis Report

## THI

Terumo Heart, Inc.

## TRR

Test Readiness Review

# RESPONSIBILITIES

## Software Program Director (SPD)

### Is responsible for this policy

### Participate in review for software production release

## Software Project Manager (SPM)

### Assigned to the program by the Program Manager with overall responsibility for the software development life cycle including responsibility to develop the Software Development Plan (SDP).

### The Program Manager can also serve as the Software Project Manager (SPM).

## Software Project Team

### Associates involved in the software development.

## Software Development Engineer (SDE)

### Writes the software code and prepares design documentation (examples: SRS, SAD, SDD). Builds the software executable and prepares it for test.

### Implements the tested software and investigates/fixes anomalies.

### Supports the Project Team as needed.

## Software Quality Engineer (SQE)

### Ensures documented development processes have been followed.

### Reviews and approves test plans and test case(s) for traceability. Participates in reviews.

### Approves Software documents.

### Reviews all software traceability matrix.

### Supports the Project Team as needed.

## Software Test Engineer (STE)

### Develops test cases and test harnesses. Participates in reviews as needed. Provides updates to traceability. Creates and verifies anomaly fixes. Executes software tests.

### Supports the Project Team as needed.

## Software Lead Test Engineer / Test Director (STE/TD)

### Assigned to the program by the Software Program Director with overall responsibility for the software test cycle. Participates in reviews. Manages test activity by STEs.

### Writes test plans and test manifests. Approves preliminary test reports. Writes final test reports. May perform any activity performed by STEs. Conducts the TRR. Participates in final test report review and approval. Supports the Project Team as needed.

### Approves the use of substitute test equipment during testing.

### Determines action to be taken when issues are found during execution of the test case(s).

### The Software Project Manager (SPM) can also serve as the Software Lead Test Engineer / Test Director (STE/TD).

## Software Configuration Management Specialist (SCM)

### Acquires appropriate set of configuration items from configuration management system and build the formal software image.

### Administers and maintains the configuration management system.

### Supports the Project Team as needed.

# Procedure

## Introduction

### Safety Classification

#### This policy describes activities required to develop a software. Each software system shall be assigned a safety classification as follows. Safety classification will dictate which SDLC activities are required for each system.

##### Class A: No injury or damage to health is possible

##### Class B: Non-serious injury is possible

##### Class C: Death or serious injury is possible

#### Refer to the Software Risk Analysis Procedure, 90048-00 to see how the Safety Classification is identified and how it affects the risk management approach for the software.

| Activity | Required for Safety Classification |
| --- | --- |
| 1. Software Development Controls | See activities below |
| Software Development Planning | A, B, C |
| Software Requirements Analysis | A, B, C |
| Software Architectural Design | B, C |
| Software Design Description | B, C |
| Software Unit Implementation | A, B, C |
| Software Integration | A, B, C |
| Software Release | A, B, C |
| Software Maintenance | A, B, C |
| 2. Software Verification and Validation | See activities below |
| Software Unit Testing | B, C |
| Software Integration Testing | B, C |
| Software System Testing | A, B, C |
| 3. Software Risk Management | A, B, C |
| 4. Software Configuration Management | A, B, C |
| 5. Software Anomaly Management | A, B, C |

Table 1

## Software Development Controls

### Software Development Controls are a list of activities that control and standardize the software development process. See Software Development Controls Procedure, 90415-00 for further information.

## Software Development Planning

### The Software Development Plan (SDP) shall be created per 90415-00 Software Development Controls Procedure.

### The SDP shall be reviewed and routinely updated, by the project team, during the development lifecycle.

### The results of planning (i.e. the SDP) shall be included in the Design History File (DHF).

### Changes to the scope of the project shall be managed per 90529-00, Project Scope Change Procedure.

## Software Requirements Analysis

### Software requirements shall be generated from Design Inputs Requirements (DIR), system level risk mitigations, and software level risk mitigations. The traceability of software requirements to higher level requirements and risk mitigations are recorded in a traceability matrix per the Requirements Management and Traceability Procedure (ref.: 90414-00).

### Each of the Software requirements shall be verifiable by an objective method of testing, inspection, or analysis.

### Software requirements should be created with methods of verification in mind. Whenever possible standard and/or previously validated and accepted test methods should be identified to fulfill verification and validation requirements.

### Software requirements should be approved prior to design development (Design Output) activities.

### All incomplete, ambiguous, not able to be verified or validated, and/or conflicting requirements will be resolved during technical reviews.

### Software requirements inputs shall be included in the DHF.

## Software Design and Implementation

### Software Design outputs includes the Software architecture, Software design description, software documentations and code implementation, Software Design outputs shall be generated per Software Development Controls Procedure, 90415-00.

### Software Design outputs shall be approved prior to Software Verification Testing (SVT).

### Software Design outputs shall be included in the DHF.

## Software Verification and Validation

### Software Design Verification consists of establishing that the Software Design conforms to Software Requirements and the intended use through examination of objective evidence.

### Software Validation may be done in conjunction with System Validation and is not a separate activity.

### Software test preparation and execution occur in Helix ALM per Helix Test Case and Test Run Procedure, 90593-00.

### Software Design Verification is documented and conducted as per the Software Verification and Validation Procedure, 90417-00.

### Software Design Verification may include multiple levels of verification activity as indicated in the Software Verification and Validation Plan. Each level utilizes different methods for verification, for example;

#### Code analysis or inspections.

#### Software Unit level testing: Verifies requirements and/or design specifications at the unit level.

#### Software Integration level testing: Verifies combined software units or combined software and hardware.

#### Software System level testing: verifies the entire software system as a complete software package.

### A final software test report closes Software Design Verification.

### The results and conclusions of Software design verification testing shall be included in the DHF.

## Review of Software Activities

### Software review shall be conducted for software plans, requirements, software code components, design documents and testing activities. Refer Software Review Work Instruction, 90418 for further information.

### Evidence shall be presented during the review and shall be captured in Software Review Meeting Minutes.

### All review records shall be included in the DHF.

## Software Release

### To Release software to production all software related system and risk requirements shall be traced to software documentation through a traceability matrix. See Software Development Controls Procedure, 90415-00 for further information.

### A review shall be conducted of documents and trace matrices necessary to determine if software is ready for production release. See Software Review Work Instruction, 90418-00 for further information.

### Software executable release occurs in Surround per 90592-00 Surround Change Management and Document Control Procedure and a Software Print release occurs in Reliance.

## Software Maintenance

### Software maintenance is the modification of a software product (documentation, design and/or code) after the software has been formally released. Maintenance is intended to correct faults (anomalies) or to enhance software attributes such as performance, features, ongoing cybersecurity issues, etc.

### Software Maintenance is conducted by following the Software Development Controls Procedure 90415-00.

## Software Risk Management

### Software code / documentation that could contribute to a hazardous situation shall be identified and mitigated through the Software Risk Analysis Procedure, 90048-00. The Software Risk Analysis Report (SWRAR) is developed to identify potential failures in the software. The SWRAR is a living document and is addressed under Software Development Controls Procedure 90415-00.

## Device Security Procedure

### Device Security procedure defines the process to apply device security (including cybersecurity) measures to new or revised product designs at Terumo Heart, Inc. (THI). The intent of the device security process is to support the development of devices that are resistant to threats against the Confidentiality, Integrity or Availability of the device, its functions or the information it handles. For more information see Pre-market Device Security Procedure 90578-00.

## Software Configuration Management

### A Software Configuration Management Plan shall be established for each software developed by THI. The Software Configuration Management Procedure 90416-00 shall uniquely identify the CIs and their versions shall be controlled.

## Software Anomaly Management

### Software anomaly management process: The intent is to record and track to completion the addressing of all product software-related anomalies and is defined in 90457-00 Software Anomaly Resolution Procedure.

### A report of open software anomalies shall be generated for all released software and will be stored in DHF.

## Legacy Software

### For Legacy software, THI shall perform a gap analysis of available Deliverables against the document mentioned in Software Development Controls Procedure, 90415-00.

### THI shall determine the deliverables to be created and associated activities to be performed. The minimum deliverable shall be software system test records. THI shall establish and execute a plan to generate the identified deliverables. Where available, objective evidence may be used to generate required deliverables without performing activities.

# Records

## Records and deliverables generated from this policy shall be released as prescribed in the individual project’s Software Development Plan (SDP).

## Software source codes and executables are retained in Surround.

## Software prints are retained in Reliance.

# PROCESS FLOW CHART

## The diagram below illustrates the “life cycle” activities required to develop and maintain software developed at THI.

