# Purpose

This procedure defines the software configuration management process at Terumo Heart, Inc. (THI). This document describes how to control access to and managing changes to software configuration items (CIs).

# Scope

This procedure applies to the development and maintenance of medical device product software at THI or for THI. This process also includes the development of firmware for implementation in FPGAs and CPLDs used in medical devices.

# Abbreviations And Terms

## Software CI (Configuration Item)

Entity that can be uniquely identified at a given reference point. Any item such as unit of code, document, report, etc. that falls under configuration management.

## Software Baseline

A software baseline represents a snapshot of a collection of software CIs.

## Software Build

A software build combines a collection of software source code into executable code that can be loaded onto a system and used for testing or as a released product.

## CPLD

Complex Programmable Logic Device

## FPGA

Field Programmable Gate Array

## DHF

Design History File

## SOUP (Software Of Unknown Provenance)

Software item that is already developed and generally available and that has not been developed for the purpose of being incorporated into the medical device (also known as “off-the-shelf software”) or software previously developed for which adequate records of the development processes are not available.

## Configuration Management System / Software Configuration Management System

A software tool to be used for configuration management. Examples are Surround SCM as used for software CIs, or ETQ Reliance as used for product CIs (see 90180-00 Reliance Document Control Procedure).

# Responsibilities

## Software Quality Engineer (SQE)

SQE fulfills the role of software quality engineer in this procedure and is responsible for ensuring that software configuration management is maintained.

## Software Development Engineer (SDE)

SDE fulfills the role of software development engineer in this procedure and is responsible for:

### Delivering software work product such as source code and documentation.

### Along with the SPM, identifying Software Configuration items for baselines.

## Software Test Engineer (STE)

STE fulfills the role of software test engineer in this procedure and is responsible for delivering software test cases and test harnesses.

## Software Configuration Management Specialist (SCM)

Software Configuration Management Specialist fulfills the role of managing software configuration in this procedure and is responsible for:

### Along with the SPM, establishing and documenting the Software Configuration Management plans.

### Ensuring that the Software Configuration Items are maintained in the Software Configuration Management System.

### Acquiring the appropriate set of configuration items from Software Configuration Management System, creating baselines, and building the formal software image.

### Administering and maintaining the Software Configuration Management System.

## Software Project Manager (SPM)

Software Project Manager fulfills the role of software project manager in this procedure and is responsible for:

### Along with the SCM, establishing and documenting the Software Configuration Management plans.

### Approving the Software Configuration Management plans.

### Along with the SDE, identifying Software Configuration items for baselines.

# Procedure

Software Configuration Management planning activities may be included in a Software Configuration Management Plan or included in the Software Development Plan. This section identifies the Software Configuration Management content.

## Tools, Techniques, Methodologies

### The SCM and SPM identify tools, techniques and methods used for configuration management that are appropriate to the software project and shall be included in Software Configuration Management plan.

## Configuration Scheme

### SPM or SCM shall establish a scheme for the unique identification of configuration items and their versions to be controlled for the project and shall be included in Software Configuration Management plan.

## Identification and Change Control Activities

### Documentation

#### Software documents and their revisions shall be maintained or released in the project file or the DHF as specified in 90408-00 Project File Documentation Retention Procedure or 90180-00 Reliance Document Control Procedure.

#### The software configuration and its versions at release will be captured in a document and stored in project file as specified in 90408-00 Project File Documentation Retention Procedure.

#### Software documents can be controlled in Software Configuration Management System during development. SCM or SDE will configure the document repositories in Software Configuration Management System if necessary. All documents are released to the project file or the DHF when the software is ready to be released.

### Source Code

#### All source code files, and their versions will be stored in a repository as defined in the Software Configuration Management Plan. The SCM or SDE will configure the source code repositories. The SCM will administer access to files and repositories.

#### The Software Configuration Management System (example: Perforce Surround SCM) maintains the revision number of the source code and it is incremented upwards as new revisions of the source code are saved during development.

### SOUP

#### All SOUP items to be contained in the medical device software will be stored in a repository in Software Configuration Management System.

#### All SOUP configuration items, including standard libraries, shall contain

##### The title of SOUP,

##### The manufacturer’s name, and

##### The unique SOUP designator

##### Note: The unique SOUP designator could be, for example, a version, a release date, a patch number or an upgrade designation.

### Software developed outside THI for THI

#### All executable files will be stored in a repository in Software Configuration Management System.

#### The Software Configuration Management System maintains the version number of the files and their version is incremented upwards as new versions of the executable files are saved by the SDE or SCM during development.

### Test Harnesses

#### All unit and integration test harness files will be stored in a repository in Software Configuration Management System. The SCM and STE will configure the test harness repositories. The SCM will administer access to files and repositories.

#### The Software Configuration Management System maintains the revision number of the test harness and it is incremented upwards as new revisions of the test harness code are saved by the STE during test development.

### Build and Baseline Identification

#### A software build produces executable file(s) that represents functionality of the software. A build is created by the SDE or SCM any time during the software development when a snapshot needs to be created.

#### Informal builds are created as needed by the SDE, STE or SCM to do debugging and “dry run testing” in preparation for the Technical Review.

#### A formal build is created by the SCM to freeze the software for test only after technical review approval. Formal builds are created using a baselined version of software source. The build information is documented and used for formal testing or is released for production.

#### Each build shall have a unique identifier and/or label. The format of the build identifier will be defined in the Configuration Management Plan for each project.

#### Each baseline shall have a unique identifier or label. The format of the baseline identifier will be defined in the Configuration Management Plan for each project.

### Software Release Identification

#### An identifier for the software release is defined for each build that is released to production. The format of the software release identifier will be defined in the Configuration Management Plan for each project.

# Records

## Build history for the software shall be maintained in the Configuration Management System.

# PROCESS FLOW CHART

## N/A