# Purpose

This procedure defines the Surround Change Management and Document Control process at Terumo Heart, Inc. (THI). The intent of the process is to ensure that software source code, test harnesses and executables are appropriately controlled. The process is directly responsible for the following:

* Managing changes to controlled software source code
* Managing changes to controlled software test harnesses
* Managing changes to controlled software executables
* Establishing a process for software changes
* Releasing software

# Scope

This procedure applies to source code, test harnesses and executables controlled within Surround software. The process begins with “No State” state and ends with the “Released” state for source code and test harnesses or “Reliance Release” for executables.

# ABBREVIATIONS AND TERMS

## Source code

The file that is created/modified by the developer

## Executable

The file that is generated from the source code and will be run on the target device

## Test Harness

The file that is created/modified by the test engineer

## Software Development Engineer (SDE)

## Software Quality Engineer (SQE)

## Software Test Engineer (STE)

## Software Configuration Management Specialist (SCM)

# ResponsibilitIES

## Software Quality is the owner of this process and is responsible for:

### Maintaining this process

### Ensuring all items addressed in a code review have been addressed

### Releasing the software executable to manufacturing in Surround

### Releasing the software print in Reliance

### Moving the source code, test harness or executable through the states of the workflow

## Software Configuration Management Specialist is responsible for:

### Checking the software build

### Performing smoke test

### Releasing the software in Surround

### Responsible for creating the executable

### Creating Software Print

### Moving the source code, test harnesses or executable through the states of the workflow

## Software Engineering (Development / Test) is responsible for:

### Creating and updating the source code

### Creating Software Print

### Performing smoke test

### Moving the source code or executable through the states of the workflow

### Creating and updating the test harnesses

### Moving the test harness through the states of the workflow

## Reviewers

Responsible for reviewing new or revised source code, test harnesses or executable.

# source code and test harness release Procedure

## Sections 5.2 to 5.3 will describe the workflow for new source code and test harnesses as well as revising and reviewing them. In this section the reference to source code applies to test harnesses as well.

## New Source Code and Test Harnesses

### All source code files reside in development repositories under the main project repository.

### All test harness files reside in test repositories under the main project repository.

### Any new files begin in the “No State” state. Software Engineering can download the files to their respective working directories.

### Software Engineering can move files from “No State” to “Dev Queued” and between the “Dev Queued”, and “In Development” states as needed with no required deliverables. Files can be checked out by the SDE or STE for revision. There can be intermediate check ins and check outs until the work is complete.

#### If Software Engineering determines that the files are no longer needed, then Software Engineering will advance the state to “Obsoleted” and the files will be removed from the project. When files are obsoleted an electronic signature is recorded in Surround.

#### If any files residing in the “Obsoleted” state need to be restored, Software Engineering will go to the Properties menu of the folder where the file was removed from the project and restore the file. Software Engineering will transition the file to the “In Development” state.

### The file is advanced by Software Engineering to the “Ready to Review” state when it is debugged and ready for review. Refer to 90418-00, Software Review Work Instruction for conducting reviews.

#### If the review did not have any action items, Software Engineering will finish the software review meeting minutes and advance to the “Reviewed” state. If the file is for a class A software item which doesn’t require review per 90415-00, then Software Quality will advance through the “Reviewed” state.

#### If the file review result was “Reject”, Software Quality will demote the file to “In Development”.

#### If the file review had any action items, Software Quality advances it to the “Fix after Review” state. Software Engineering shall update the file to address any action items.

### Once action items are completed, Software Engineering advances the state to “QA Check after Review Fixes”. Software Quality will verify that all action items were addressed.

#### If Software Quality determines that minor updating is still needed to address the actions items, then Software Quality will demote the state to “Fix after Review”.

#### If Software Quality determines that major updating is needed to address the actions items, then Software Quality will demote the state to “In Development”. This removes it from the review cycle and returns it to development.

#### If Software Quality determines all the action were addressed, then Software Quality will advance the state to “Reviewed” and publish the software review meeting minutes. The review meeting minutes are stored along with supporting documents and reside in the “Software Reviews” repository under the main project repository.

### Once the software meeting minutes contain the signatures from the approvers, Software Quality will advance the state to “Released”. In this state an electronic signature is recorded in Surround. The reviewed file is complete and ready for build or test.

## Revising Source Code and Test Harnesses

### When files are residing in the “Released” state and need to be modified, as per 90457-00, Software Anomaly Resolution Procedure, SQE will transition the file to the “Dev Queued” state. In this state transition an electronic signature is recorded in Surround.

### Refer to sections 5.2.4 through 5.2.7 for the continuation of the process.

# executable release procedure

## The Software Configuration Management Specialist will upload the executable(s) into Surround, and it will be at “No State”.

## For development releases the executable shall remain in “No State”.

## For Formal Release the Software Configuration Management Specialist will advance to the “Review and Build Check” state. SCM or STE will perform a limited smoke test to check the function of the executable..

### If Software Engineering made changes to the source code after the build was complete, then the Software Configuration Management Specialist will advance the state to “Obsoleted”. In this state an electronic signature is recorded.

### In the “Review and Build Check” state either Software Engineering or the Software Configuration Management Specialist will create the software print(s) according to 90594-00, Software Print Work Instruction. Once the Software Print is completed, then the Software Configuration Management Specialist or Software Engineering will advance the state to “QA Check”.

## In the “QA Check” state, Software Quality will calculate the checksum of the executable and compare the result to the Software Print according to 90596-00, Software Checksum Work Instruction.

### If the checksum does not match the Software Print, then Software Quality will advance the state to “Obsoleted”. In this state an electronic signature is recorded.

### If the checksum matches the Software Print, then formal testing of the software can begin.

#### If formal testing passed, then Software Quality will advance the state to “Reviewed Approved”. In this state an electronic signature is recorded. Software Quality will enter the software print(s) into Reliance and begin the approval process.

#### If formal testing fails, then Software Quality will advance the state to “Obsoleted”. In this state an electronic signature is recorded.

## The executable(s) will reside in the “Reviewed Approved” state until the software print(s) are released in Reliance. Once they are released, then Software Quality will advance the state to “Reliance Release”.

### In “Reliance Release”, Software Quality will copy the executable(s) to the Manufacturing folder in Surround to the appropriate project. Refer to 90597-00, Software Release to Manufacturing Work Instruction for releasing executable.

## If the version of the executable is replacing an existing version, then Software Quality will advance the state of the previous version of the executable to “Obsoleted”.

# Access Control

## Access to code and test harness files is as follows

### During Development the source code files can be edited by the Software Development Team.

### During Development the test harness files can be edited by the Software Test Team

### Once approved, the approved file will be checked out to software quality and no changes can be made until it is released by software quality for further edits.

## Access to Executables files is as follows

### Only Software Configuration Management Specialist can add released executable to the Production Executables folder under the Project repository.

### Only Software Quality Engineer can add verified software executables to the Manufacturing repository after the software print is released.

### Software Engineering Team and Manufacturing Team can copy files from the Manufacturing folder.

# Records

## Electronic copies are retained in Surround.

## The final executable(s) for production are stored under the Manufacturing folder in Surround.

## Final software print is released in Reliance.

# Source code and Test harness Release FLOW CHART

# C:\Users\nayan.chopra\AppData\Local\Microsoft\Windows\INetCache\Content.MSO\CA048926.tmp executable release flow chart

