

# Quality System: Design Control Standard Operating Procedure

## CORP Medical Products

Various details have been removed, indicated by “[...]”

### 1. Overview

#### 1.1 Objective

This document describes the standard operating procedures required to carry out the process described in the “CORP Quality System: Design Control Procedure” for Project Change Requests (PCR). Refer to that document for more detail, along with other CORP references cited here.

#### 1.2 Scope

This is required for any PCR.

#### 1.3 Responsibility

This document shall be maintained by CORP Management personnel.

This document shall be followed by all CORP personnel involved with PCRs.

#### 1.4 Procedure and Outputs

Each of the following sections applies to one process in the CORP Cyclic Development State Machine.

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#### 1.5 Definitions

**PCR** Product Change Request

**CDSM** Cyclic Development State Machine

## **1.6 References**

CORP Quality System: Design Control Procedure (CORP.820.30.top.txt)

CORP Quality System: Design Control Procedure Appendix (CORP.820.30.app.txt)

CORP Quality System: Design Control Procedure Tools (CORP.820.30.tools.txt)

CORP Quality System: Introductory presentation (CORP.820.30.intro.ppt)

CORP Quality System WEB SCR Tool

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## 2. Create Concept

### 2.1 Objective

To create an initial high-level description of the Project Change Request (PCR). This shall capture input from all parties with an interest in the PCR goals.

### 2.2 Scope

A PCR shall be created for any proposed change to a CORP product or new product. This can range from simple cosmetic modifications, to bug fixes, to complex functional enhancements, to new programs.

All PCRs shall be subject to the CORP Design Control Standard Operating Procedure, regardless of the complexity or type of change.

A PCR can be created for many reasons, including:

- Hazard analysis results
- [...]
- Suggestions for improvements

### 2.3 Responsibility

Create Concept shall be carried out by:

- Any CORP Trusted Personnel.

Suggestions and input can come from many sources, such as:

- Alpha or beta test sites
- [...]
- Literature reviews

### 2.4 Procedure and Outputs

The following Outputs shall be created:

- [...]
- Unique Identifier

Title: Simple title for PCR.

[...]

Unique Identifier: A unique identifier for this PCR.

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### 3. Create Initial Design

#### 3.1 Objective

Evaluate the Concept and create the Initial Design plan.

#### 3.2 Scope

This is required for any PCR to progress into a development state.

#### 3.3 Responsibility

Create Initial Design shall be carried out by:

- Any CORP Trusted Personnel.

#### 3.4 Procedure and Outputs

The following Outputs shall be created:

- Requirements specification
- Risk Assessment
- [...]
- Review Checklist

Requirements Specification: High-level requirements of PCR, which will generally include one or more of:

- Functional requirements
- [...]
- Interface requirements

Master Plan: Roadmap of anticipated design phase cycles.

Risk Assessment: Evaluation of risks associated with this project, and consequences. This shall be utilized for two purposes:

- [...]

[...]

Review Checklist: List of issues that shall be addressed in a Review of this step, including at least the following:

- Requirements specification captures overall goals comprehensively.
- Requirements specification is written unambiguously.
- Master Plan is appropriate.
- [...]
- Overall objectives are in line with user, company, and safety needs.
- Participants are valid.

.....

#### **4. Standard Review: of Create Initial Design**

REQUIRED for any PCR to progress further.

**Standard Review is defined in Section 14 of this document.**

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## 5. Create Design Input

### 5.1 Objective

Create the design input specifications, which are the starting point for any design phase.

### 5.2 Scope

Required for any PCR to progress further.

The completion of any PCR shall require one or more design phase cycles as determined by the Master Plan, where a design phase consists of:

- Create Design Input
- Optional: Standard Review of Design Input
- [...]
- Optional: Verification

### 5.3 Responsibility

Create Design Input shall be carried out by:

- Any CORP Trusted Personnel with appropriate training/skills.

### 5.4 Procedure and Outputs

The following Outputs shall be created upon completion of all required design phase cycles. Prior to final cycle, one or more may be incomplete:

- Requirements Specification
- High level architecture specification
- Verification Criteria
- [...]
- Review Checklist

Requirements Specification: Upon completion of all required design phase cycles, this shall specify the requirements at an engineering level of detail. Prior to [...]:

- Functional requirements
- [...]
- Interface requirements

High level architecture specification: Specification of the anticipated means of achieving the Requirement Specifications for this design phase.

Verification Criteria: Detailed specification of the means of verifying conformance between Design Output and Design Input [...].

Review Checklist: List of issues that shall be addressed in a Review of this step, [...]:

- Requirements specification captures goals comprehensively.
- Requirements specification is written unambiguously.
- [...]

.....

**6. Standard Review: of Create Design Input**

OPTIONAL: Shall be carried out only if specified in Review Schedule.

**Standard Review is defined in Section 14 of this document.**

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## 7. Design Process

### 7.1 Objective

The process of “realizing” the Design Input requirements for this design phase cycle, thus creating the Design Output.

### 7.2 Scope

Required for any PCR to progress further.

### 7.3 Responsibility

Design Process shall be carried out by:

- Any CORP Trusted Personnel with appropriate training/skills.

### 7.4 Procedure and Outputs

The following Outputs shall be created:

- Means of providing for each Design Input requirement
- Means of demonstrating that each requirement has been met
- [...]

Means of providing for each Design Input requirement: This is everything required [...].

Means of demonstrating that each requirement has been met: This can be included in any of the actions and documents listed below.

The actions that shall occur during this step depend on the phase of development and target of development, and can include:

- Evaluations
- Meetings
- Risk/fault analysis
- [...]

Design Output documentation shall provide for at least:

- Assessment of conformance to design input requirements.
- Identifying characteristics of the design and that are crucial to the safety and proper functioning of the device.

Design Output documentation shall be maintained as appropriate for the complexity or criticality of the problem. Such documentation can include:

- Software pseudo-code
- Software source code
- Risk or Fault analysis
- Verification activities
- Test procedures and results
- [...]
- QA specifications and procedures

CORP Pair Programming shall be employed if specified in risk assessment.

CORP guidelines for documentation and coding shall be employed as required to improve correctness, safety, robustness, and maintainability.

[...]

Review Checklist: List of issues that shall be addressed in a Review of this step, including at least the following:

- Output documentation meets Design Input requirements for this cycle.
- [...]
- Appropriate guidelines for coding were followed.
- Participants are valid.

.....

## **8. Standard Review: of Design Process**

OPTIONAL: Shall be carried out only if specified in Review Schedule.

**Standard Review is defined in Section 14 of this document.**

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## 9. Verification

### 9.1 Objective

To establish conformance of the Design Output with the Design Input as specified in Verification Criteria.

### 9.2 Scope

Required for any PCR to progress further.

### 9.3 Responsibility

Verification shall be carried out by:

- Any CORP Trusted Personnel with appropriate training/skills.

### 9.4 Procedure and Outputs

The following Outputs shall be created:

- Results of Design Input Verification Criteria
- [...]
- Review Checklist

Results of Design Input Verification Criteria: Address each item in the Verification Criteria (which was produced in Create Design Input) and record results.

[...]

Review Checklist: List of issues that shall be addressed in a Review of this step, including at least the following:

- Each item in Design Input Verification Criteria has been addressed.
- Each item in Standard Verification Criteria has been addressed.
- Participants are valid

.....

## **10. Standard Review: of Verification**

OPTIONAL: Shall be carried out only if specified in Review Schedule.

**Standard Review is defined in Section 14 of this document.**

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## 11. Validation

### 11.1 Objective

To establish conformance of the Design Output with the Design Input and comprehensive environment as specified in Validation Criteria.

### 11.2 Scope

Required for any PCR to progress further.

### 11.3 Responsibility

Validation shall be carried out by:

- Any CORP Trusted Personnel with appropriate training/skills.

### 11.4 Procedure and Outputs

The following Outputs shall be created:

- Results of Design Input Validation Criteria
- [...]
- Review Checklist

Results of Design Input Validation Criteria: Address each item in the Validation Criteria (which was produced in Create Design Input) and record results.

[...]

Review Checklist: List of issues that shall be addressed in a Review of this step, including at least the following:

- Each item in Design Input Validation Criteria has been addressed.
- [...]
- Participants are valid.

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## **12. Standard Review: of Validation**

REQUIRED for any PCR to progress further.

**Standard Review is defined in Section 14 of this document.**

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## 13. Transfer

### 13.1 Objective

To get the verified and validated product to the end user.

### 13.2 Scope

Required for any PCR to progress further.

### 13.3 Responsibility

Transfer shall be carried out by:

- Any CORP Management Personnel with appropriate training/skills.

### 13.4 Procedure and Outputs

The following Outputs shall be created:

- Verification of released software
- [...]

Verification of released software: Ensure that released software is identical to that which was verified and validated.

[...].

Review Checklist: List of outputs or processes that shall be reviewed for correctness in a Review of this step, including at least the following:

- Verification of released software has been addressed.
- [...]

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## 14. Standard Review

### 14.1 Objective

Verify that the previous state has met its requirements. If so, allow progression to the next CDSM transition. If not, recommend changes and cycle back to a previous CDSM transition.

### 14.2 Scope

Input is taken from the Outputs of the previous state. Output determines the next CDSM transition, and can add action items to other CDSM states.

### 14.3 Responsibility

Standard Review shall be carried out by:

- Any CORP Design Review Committee personnel.

### 14.4 Procedure and Outputs

The following Outputs shall be created:

- Results of Review
- Next CDSM transition
- [...]

Results of Review: Evaluation of whether the previous state's Review Checklist requirements were met in terms of:

- The transition process that created the state.
- [...]

If they were not met, this shall also provide recommendations for change.

Next CDSM transition: If previous state met the requirements, this shall be set to [...]. Otherwise, this shall be set to [...], causing a "cycle back".

Action items added to other CDSM states: If previous state did not meet the requirements, then, if necessary, [...] as required to correct the problems. [...]