

# Quality System: Design Control Procedure CVS / SCR Tools

## CORP Medical Products

Various details have been removed, indicated by "[...]"

### 1. Introduction to CVS / SCR area, tools, and usage

The notation `[ file = path ]` and `[ dir = path ]` indicate the actual locations of the information being discussed, and is followed by the initial file contents.

`[ file = scr/tools/README ]`

How to create and add SCR areas:

#### 1.1 Get the tools first.

```
cd your_cvs_area/scr
cvs update -d tools
```

If you don't have the scr directory, DO NOT just checkout the whole thing. It is huge (and getting bigger). You should grab only the pieces you need.

```
cd your_cvs_area
cvs checkout scr/tools
```

#### 1.2 Then, to create a new SCR directory in which to work, do:

```
cd your_cvs_area/scr
tools/scrnew scr_number (e.g., tools/scrnew 010203-04)
```

This creates the scr\_number directory with all the skeleton directories and files for our design control procedure.

**\*\* IMPORTANT: DO NOT just 'cp -pR tools/SKEL' to make a new directory. This will also grab the SKEL CVS subdirectories, and any changes you make will modify the SKEL area!**

#### 1.3 To add/commit such an SCR directory, do:

```
cd your_cvs_area/scr
tools/scradd scr_number
```

This will add and commit the standard files and directories in scr\_number directory.

If you added your own files or directories, you have to add and commit them, like with any other CVS area.

To verify that it worked, do:

```
cvs release scr_number
(then answer 'no' to the question)
```

If you see any lines with ? in front, like this

```
233 mz> cvs release 020506-04
? Concept/this
? InitialReview
```

It means those files or directories did not get into the repository correctly. If you don't want them, that's fine. Otherwise, go add and commit them.

**\*\* IMPORTANT: If any of your files are BINARY (e.g., images or word docs), you need to set them as such. Do this when you initially add them, via**

```
cd your_cvs_area/scr
cvs add -kb file
```

If you accidentally add them incorrectly, see rtp/tools/README.CVS for how to fix it up.

#### 1.4 If you already have an SCR directory in which you have been working and want to put it into the new format, do the following:

```
cd your_cvs_area/scr
mv 010203-04 010203-04.orig (don't use .tmp, scrnew uses that)
tools/scrnew 010203-04
```

Now, get the info from 010203-04.orig into 010203-04

When all done, do:

```
cd your_cvs_area/scr
tools/scradd 010203-04
rm -rf 01020304.orig
```

#### 1.5 NOTES:

##### Sections that follow

1. Introduction to CVS / SCR area, tools, and usage .....	1
1.1 Get the tools first. ....	1
1.2 Then, to create a new SCR directory in which to work, do: .....	1
1.3 To add/commit such an SCR directory, do:.....	1
1.4 If you already have an SCR directory in which you have been working .....	2
1.5 NOTES:.....	2
2. Checklists: Information on use .....	3
3. Checklist for each State follows .....	4
3.1 Concept Checklist .....	4
3.2 InitialDesign Checklist .....	4
3.3 Input Checklist.....	4
3.4 Output Checklist.....	5
3.5 Verification Checklist.....	5
3.6 Validation Checklist.....	5
4. Output skeleton files for each state.....	6
4.1 InitialReview.Output .....	6
4.2 InputReview.Output.....	6
4.3 OutputReview.Output.....	6
4.4 Verification.Output.....	7
4.5 VerificationReview.Output .....	7
4.6 Validation.Output.....	7
4.7 ValidationReview.Output .....	7
4.8 Final.Output.....	8

---

## 2. Checklists: Information on use

[ file = scr/tools/checklist/README ]

Each file here contains the checklist for each stable state in our design control document. These items describe what must happen to get to that state, and what must be recorded in that state.

We expect these to change frequently at first, as we learn more about what we want and need to do. So update them frequently, and refer back to them, not to old stashed copies.

How to use these:

During a transition to a state, the developer should [...].

At Review time, the reviewer should copy/paste them into the review output document. As items are addressed, the \*REQUIRED\* text is replaced with [...]

---

### 3. Checklist for each State follows

[ dir = scr/tools/checklist/ ]

#### 3.1 Concept Checklist

[ file = scr/tools/checklist/Concept ]

\$Id: Concept,v 1.1 2002/08/01 22:28:53 zeleznik Exp \$

---

Checklist: Concept Document

Title.

\*REQUIRED\*

Description.

\*REQUIRED\*

Name of primary person/institution, entering this.

\*REQUIRED\*

Names of persons/institutions with interest or which should be involved.

\*REQUIRED\*

---

#### 3.2 InitialDesign Checklist

[ file = scr/tools/checklist/InitialDesign ]

\$Id: InitialDesign,v 1.1 2002/08/01 22:28:53 zeleznik Exp \$

---

Checklist: Initial Design Review

Requirements specification.

\*REQUIRED\*

Requirements specification captures general goals comprehensively.

\*REQUIRED\*

[...]

Objectives are in line with user, company, and safety needs.

\*REQUIRED\*

---

#### 3.3 Input Checklist

[ file = scr/tools/checklist/Input ]

\$Id: Input,v 1.1 2002/08/01 22:28:53 zeleznik Exp \$

---

Checklist: Design Input Review

Requirements specification.

\*REQUIRED\*

Master Plan.

\*REQUIRED\*

Risk Assessment.

\*REQUIRED\*

[...]

Record of who was involved with each aspect of this activity.  
\*REQUIRED\*

---

### 3.4 Output Checklist

[ file = scr/tools/checklist/Output ]

\$Id: Output,v 1.1 2002/08/01 22:28:53 zeleznik Exp \$

---

Checklist: Design Output Review

Record of who was involved with each aspect of this activity.  
\*REQUIRED\*

Meet each requirement stated in the Design Input for this cycle.  
\*REQUIRED\*

[...]

Follow guidelines for coding.  
\*REQUIRED\*

---

### 3.5 Verification Checklist

[ file = scr/tools/checklist/Verification ]

\$Id: Verification,v 1.1 2002/08/01 22:28:53 zeleznik Exp \$

---

Checklist: Verification Review

Record of who was involved with each aspect of this activity.  
\*REQUIRED\*

Address each item in the Design Input Verification Criteria  
\*REQUIRED\*

---

### 3.6 Validation Checklist

[ file = scr/tools/checklist/Validation ]

\$Id: Validation,v 1.1 2002/08/01 22:28:53 zeleznik Exp \$

---

Checklist: Validation Review

Record of who was involved with each aspect of this activity.  
\*REQUIRED\*

[...]

Address each applicable item in general system validation criteria (this would include fundamental safety issues).  
\*REQUIRED\*

---

---

## 4. Output skeleton files for each state

[ dir = scr/tools/SKEL/ ]

### 4.1 InitialReview.Output

[ file = scr/tools/SKEL/InitialReview.Output ]

\$Id: InitialReview.Output,v 1.2 2002/08/15 19:11:52 zeleznik Exp \$

---

Initial Design Review: OUTPUT

---

Who:

\*REQUIRED\*

---

Checklist Items:

\*REQUIRED\*

At time of review, just copy the scr/tools/CHECKLIST file into here. Do not do this ahead of time since [...]

---

Required Changes:

\*REQUIRED\* (enter list of changes, or NONE)

---

Notes:

---

### 4.2 InputReview.Output

[ file = scr/tools/SKEL/InputReview.Output ]

\$Id: InputReview.Output,v 1.2 2002/08/15 19:11:52 zeleznik Exp \$

---

Design Input Review: OUTPUT

---

Who:

\*REQUIRED\*

---

Checklist Items:

\*REQUIRED\*

At time of review, just copy the scr/tools/CHECKLIST file into here. Do not do this ahead of time since [...]

---

Required Changes:

\*REQUIRED\* (enter list of changes, or NONE)

---

Notes:

---

### 4.3 OutputReview.Output

[ file = scr/tools/SKEL/OutputReview.Output ]

\$Id: OutputReview.Output,v 1.2 2002/08/15 19:11:52 zeleznik Exp \$

---

Design Output Review: OUTPUT

---

Who:

\*REQUIRED\*

---

Checklist Items:

\*REQUIRED\*

At time of review, just copy the scr/tools/CHECKLIST file into here. [...]

---

Required Changes:

\*REQUIRED\* (enter list of changes, or NONE)

---

Notes:

---

#### 4.4 Verification.Output

[ file = scr/tools/SKEL/Verification.Output ]

\$Id: Verification.Output,v 1.1 2002/07/26 00:16:09 zeleznik Exp \$

---

Verification: OUTPUT

---

Results for each Input.Verification criteria:

---

#### 4.5 VerificationReview.Output

[ file = scr/tools/SKEL/VerificationReview.Output ]

\$Id: VerificationReview.Output,v 1.2 2002/08/15 19:11:52 zeleznik Exp \$

---

Verification Review: OUTPUT

---

Who:

---

Checklist Items:

\*REQUIRED\*

At time of review, just copy the scr/tools/CHECKLIST file into here. [...]

---

Required Changes:

\*REQUIRED\* (enter list of changes, or NONE)

---

Notes:

---

#### 4.6 Validation.Output

[ file = scr/tools/SKEL/Validation.Output ]

\$Id: Validation.Output,v 1.1 2002/07/26 00:16:09 zeleznik Exp \$

---

Validation: OUTPUT

#### 4.7 ValidationReview.Output

[ file = scr/tools/SKEL/ValidationReview.Output ]

\$Id: ValidationReview.Output,v 1.2 2002/08/15 19:11:52 zeleznik Exp \$

---

Validation Review: OUTPUT

---

Who:

---

Checklist Items:

\*REQUIRED\*

At time of review, just copy the scr/tools/CHECKLIST file into here. Do not do this ahead of time since you want to get the latest checklist [...]

---

Required Changes:

\*REQUIRED\* (enter list of changes, or NONE)

---

Notes:

---

## 4.8 Final.Output

[ file = scr/tools/SKEL/Final.Output ]

\$Id: Final.Output,v 1.1 2002/08/15 19:16:52 zeleznik Exp \$

---

Final: OUTPUT

The design transfer occurs on the production side of operations, and is documented there.

Record of who was involved with [...].

Ensure that released software is identical to [...].

Ensure that hardware and system configurations are identical, or [...].

---