MasterControl	Standard Operating Procedure PDP Phase 3 Design Verification	
	SOP-XXX	Revision X
	Effective:	Approved by:

This document is intended to be used for informational purposes. The content, format, and application of this document must be appropriately modified to meet unique company and product development requirements. This document should be carefully reviewed against specific company requirements.

PURPOSE

The purpose of this procedure is to establish requirements for Phase 3 of the Product Development Program: Design Verification. Phase 3 includes documenting and building verification prototypes, writing verification protocols, testing and documenting the results in verification reports. Design Verification is intended to demonstrate that the device design meets physical, functional, and performance requirements.

SCOPE

This procedure applies to a new product or a change to an existing product under development by COMPANY XXX.

REFERENCES

SOP-XXX PDP Glossary of Terms
SOP-XXX Development and Maintenance of Protocol and Reports
SOP-XXX Laboratory Notebook Maintenance

TERMS AND DEFINITIONS

Refer to PDP Glossary of Terms, SOP-XXX.

RESPONSIBILITY

R&D/Engineering- R&D is responsible for developing design verification prototypes and testing in accordance with pre-approved protocols.

Production- Production is responsible for working with R&D to assist in the development of verification prototypes.

Project Team- The Project Team is responsible for reviewing the design verification protocols to assure they are sufficient to demonstrate that the design is able to meet physical, functional, and performance requirements established in the Design Requirements.

Project Leader- will coordinate cross-departmental functions related to design verification. The R & D Project Leader is responsible for assuring that the Design

Activities Tracking Form for Device Design Development is completed in accordance with this procedure.

PROCEDURES

1. At the beginning of phase 3, the Project Leader in cooperation with the project team shall update the project plan, specifically the verification phase, to identify the specific verification protocols, testing, and reports to be completed as well as the responsible person(s) for each.

2. Each design requirement identified in the Design Requirements document must have a corresponding verification or validation method to demonstrate that the requirement was met.
Note: Some design requirements, such as those related to intended uses, are not verified within the scope of Phase 3, but will be validated in Phase 5, Design Validation.

3. Design Verification Protocols

3.1. Verification protocols will be documented in accordance with the SOP SOP-XXX, Development and Maintenance of Protocols and Reports. The Verification protocols will be approved, minimally by the Production, QA, and R&D/Engineering Project Team members.

3.2. A single verification protocol may be generated for all verification testing or the testing may described in multiple protocols.

3.3. If a protocol already exists and it is sufficient and accurate for the testing to be performed, it may be referenced and used rather than creating a new protocol.

3.4. All protocols shall be numbered and maintained in Document Control.

3.5. Design verification protocols must specify acceptance criteria consistent with approved design requirements in the Design Requirements.

3.6. Specific acceptance criteria, expected output, or expected results for a defined test may be specified within the data recording tables or data recording forms where these are specified.

3.7. Design Verification Protocols may include data recording forms for use in documenting results, observation, measurements, or data as the testing occurs. If data recording forms are not included, the protocol must instruct personnel to record test results, observations and data in a laboratory notebook.

3.8. The protocols shall document and justify the number of verification testing prototypes needed for testing.

3.9. Verification protocols must establish methods for statistical analysis of data collected during verification testing.

4. Verification Prototypes

4.1. Design Verification Testing is performed using Verification Prototypes. These are devices that are built using the Pre-Release documentation finalized in Phase 2.

4.2. Verification prototypes may be full assemblies, sub-assemblies and specially constructed assemblies as required for the testing and as documented in the protocol.

4.3. Verification Prototypes shall be built, labeled and documented as delineated in the Prototype Management Procedure, SOP-XXX.

4.4. Verification test prototypes are built by engineering with the assistance of production where necessary.

4.5. Per SOP-XXX for Prototype Management, an Engineering Work Order must be generated to document the build of all verification prototypes. Engineering work orders will be filed in records retention and referenced in the DHF. These records are equivalent to the device history record for manufacture of design verification prototypes.

4.6. Verification prototypes are identified (labeled) and controlled in accordance with the Prototype Management Procedure, SOP-XXX.

5. Design Verification Testing

5.1. Engineering, quality or other qualified individuals within COMPANY XXX may perform verification testing. Certain verification testing may also be contracted out to laboratories or test houses. Responsibility for performing the testing shall be identified in the project plan.

NOTE: Personnel performing tests must have appropriate experience and/or training.

5.2. Prior to the start of verification testing, per the corresponding protocol, the tester shall ensure the following requirements are met:

5.2.1. The device(s) that are to be tested are properly documented and labeled to provide traceability to the specific design version. The Engineering Work Order may be used to provide this traceability. This includes a check of the documentation for each assembly used (traceable to the components) to ensure they are at least at pre-release level (PRE).

5.2.2. Test equipment, fixtures and tooling used for verification testing shall be qualified as required by COMPANY XXX Test Method Validation Procedure, SOP XXX.

5.2.3. All inspection, measure, and test equipment must be within calibration due date, per the Calibration Procedure, SOP XXX.

5.2.4. The tester shall record the ID and calibration status of the equipment used as defined in the test protocol.

5.3. During verification testing the tester shall follow the protocol instructions as written.

5.4. Document the prototype number (or EWO number) on all testing data, lab notebook entries, or data recording forms used during verification testing. All testing documentation, reports, etc., must be traceable to the specific prototype design being testing.

5.5. Changes to approved protocols shall be made in accordance with SOP-XXX, the Protocol and Report Procedure, prior to starting the testing.

5.5.1. If a protocol cannot be changed prior to starting the testing a deviation to the protocol may be made by redlining or correcting the working copy of the protocol. The changes shall be initialed and dated by the tester, R&D/Engineering and Quality Assurance project team members.

5.5.2. All protocol deviations shall be explained in the verification report. If the project team disagrees with the deviation to the point that they would not approve the final report, corrective action and possible re-testing may be necessary.

5.6. In the case that data recording forms or data tables were not provided in the protocol, laboratory notebooks shall be used to record test data and information in real time. All laboratory notebooks used in verification testing must reference protocol numbers, dates of testing, personnel conducting and observing tests, prototype version numbers and serial numbers, test equipment, test fixtures, materials, etc. The test method does not have to be re-written into the laboratory notebook as long as the protocol is referenced.

5.7. At the completion of the testing ensure that the data recording forms or tables used to collect data have been signed and dated both by the tester and by a Quality Assurance Representative.

6. Outside Testing performed as part of Design Verification Testing

6.1. When outside testing laboratories are used, they must be qualified to perform the testing.

6.1.1. All Testing Laboratory audits and vendor approvals shall be kept in the Supplier QA file maintained by the Purchasing Department.

6.2. Reports and data received from outside testing laboratories should be integrated into a COMPANY XXX design verification report. COMPANY XXX shall write a final report to document review and analysis of work performed by outside laboratories. The report shall be reviewed/approved by the project team.

7. Design Verification Failures

7.1. Test articles that fail as a result of verification testing shall be evaluated to identify the failure cause and the results shall be documented in the design verification report.

7.1.1. Design Verification failures will be evaluated, and/or investigated to a degree commensurate with the failure or problem observed during design verification.

7.1.2. Information gained through this evaluation/investigation may be helpful in determining the types of design modification necessary.

7.2. Laboratory notebooks may be used to document evaluation and investigation of the failures. Engineering or QA may conduct the investigation. The results of investigation should be included within the DHF, either as a memo to file, or as part of the design verification report.

7.3. If the failure is determined to be a design failure the project shall return to the design phase as appropriate to correct the design. This may necessitate revision of the Design Requirements, revision of design drawings, and revision of protocols, as appropriate.

7.3.1. Changes to design documentation shall be made in accordance with the change control SOP-XXX.

7.3.2. ECOs for design changes to correct deficiencies discovered during verification testing shall specify the extent of re-verification necessary. All aspects of design that may potentially be affected by the change(s) will be subject to design verification using the pre-approved design verification protocols.

7.3.3. Once the appropriate design changes have been made, new prototypes shall be developed. If the existing prototypes are to be modified or cannibalized to make new prototypes a new Engineering Work Orders shall be generated to document the modification. This EWO can cross reference the previous EWO number. Ultimately the newly revised prototype must have a unique identification number and traceability of components and configuration must be documented within an EWO.

8. Disposition of Verification Prototypes

8.1. Design verification prototypes shall be retained for a minimum of two years after the commercial release of the product.

8.2. Verification prototypes shall be carefully labeled and stored by Engineering.

8.3. Samples that are destroyed in testing need not be retained.

8.4. A verification report is written to document results of each design verification protocol. The Project Team members shall review/approve the verification reports.

9. Completing Phase 3, Design Verification

9.1. The design verification phase is complete when all Design Requirements have been successfully tested or verified and the appropriate Verification Reports have been approved. At this point the design is considered frozen so that design transfer, during which drawings are released under ECO as part of the DMR, can be performed. These released documents shall be used for the manufacture of production devices intended for design validation in Phase 5.

9.2. Once verification testing has been completed, and confirms that all design requirements have been met, Engineering shall update the Design Requirements document to include testing documentation number.

9.3. Engineering shall review the Design FMEA and update it if necessary.

9.4. Once verification is completed successfully, Regulatory Affairs may begin the regulatory approval process, if appropriate.

9.5. A Phase 3 Design Review is conducted and documented per SOP-XXX.

9.6. Regulatory Affairs audits the DHF.

9.7. The Project Plan Checklist is updated by the Project Leader to reflect the completion of Phase 3 tasks and make any revisions necessary for the next phase(s). The revised project plan is reviewed/approved by the Project Team.

10. Elements of the Phase 3 Design Review

10.1. The Project Team shall perform and document a Phase 3 Design Review according to the Design Review Procedure, SOP-XXX.

10.2. The design review shall verify that all design verification has been properly documented and that the tasks specified in the project plan have been completed.

10.3. The Project Leader shall ensure that the outputs from Phase 3 are filed in the project DHF according to the Design History File Procedure, SOP-XXX.

10.4. Regulatory Affairs audits the DHF.

11. PHASE 3 Outputs:

Document	Location
Design Verification Protocols	Originals in Doc. Control; Referenced within the Design Requirements-Traceability Matrix.
Design Verification Reports	Originals in Doc. Control; Referenced

	within the Design Requirements-Traceability Matrix.
Pre-release DMR documentation	Document Control
Updated DESIGN REQUIREMENTS (including X-ref to verification documentation)	DHF, Folder: Design Requirements
Updated FMEA (if update is necessary)	DHF, Folder: DFMEA
Memos, correspondence	DHF: Phase 3/Correspondence
Phase 3 Design Review Form and meeting minutes.	DHF: Phase 3/Design Review