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.