CONTROLLED COPY
RELEASED
DOC-0155 R- 01

MasterControl
6350 South 3000 East
Salt Lake City, UT 84121

Document Number:

Document Title:

Document Notes:

reason1001

Document Information

Revision:	Vault:
Doc Type:	Status:

Date Information

Effective Date:	Next Review Date:
Release Date:	Expiration Date:

Control Information

Author:	Previous Number:
Owner:	Change Number:

All dates and times are in

Print Copy No.: IP-DOC-0155-01-0040R1 Issued to : ADHARSH SREEDHARAN

CONTROLLED COPY
RELEASED
DOC-0155 R- 01
reason1001

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.

Draft

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

CONTROLLED COPY
RELEASED
DOC-0155 R- 01
reason1001

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.

Draft

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.

CONTROLLED COPY
RELEASED
DOC-0155 R- 01
reason1001

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.

CONTROLLED COPY
RELEASED
DOC-0155 R- 01

	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

reason1001
Draft

CONTROLLED COPY
DOC-0155 R- 01 RELEASED

Signature Manifest

Document Number: DOC-0155 **Revision:** 01
Title: Watermark
Effective Date: 06 Jan 2023

All dates and times are in Mountain Time Zone.

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Sonali Shelar (SSHELAR)		06 Jan 2023, 01:12:22 AM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Sonali Shelar (SSHELAR)		13 Jan 2023, 09:12:10 AM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Sonali Shelar (SSHELAR)		13 Jan 2023, 09:22:35 AM	Approved

reason1001