

Audit Plan

Audit Team	
Leader:	
Members:	
Audit Date(s)	
Principal Contacts	
Design Manager	
Objectives	Audit Criteria
Evaluate process effectiveness, investigate warranty concerns, investigate customer XYZ complaint.	ISO 9001, Design manual, supporting SOPs.
Process overview	
Introducing new products to market. Management of design projects.	
Risk Issues :	This process has been identified as Medium to High Risk – RPN 240 – 8 x 6 x 5

S - Although few customers specifically ask us to design products, all of our products are our own design. Products are covered by safety regulations.

S - Our manufacturing department relies on the design process so that products can be manufactured efficiently.

O – The R & D department has recently added a new AI software development team (6 people) for next generation products.

O – Current warranty return levels are increasing.

O – Customer XYZ has raised a complaint about the recently introduced Cygnet product failing to consistently perform in elevated temperatures.

O – Latest internal audits have raised only minor nonconformities.

D – Design teams have recently received training in FMEA

D – Recently introduced software to manage design validation has been signed off by the Design Manager and the project team.

Plan prepared:

Plan approved: