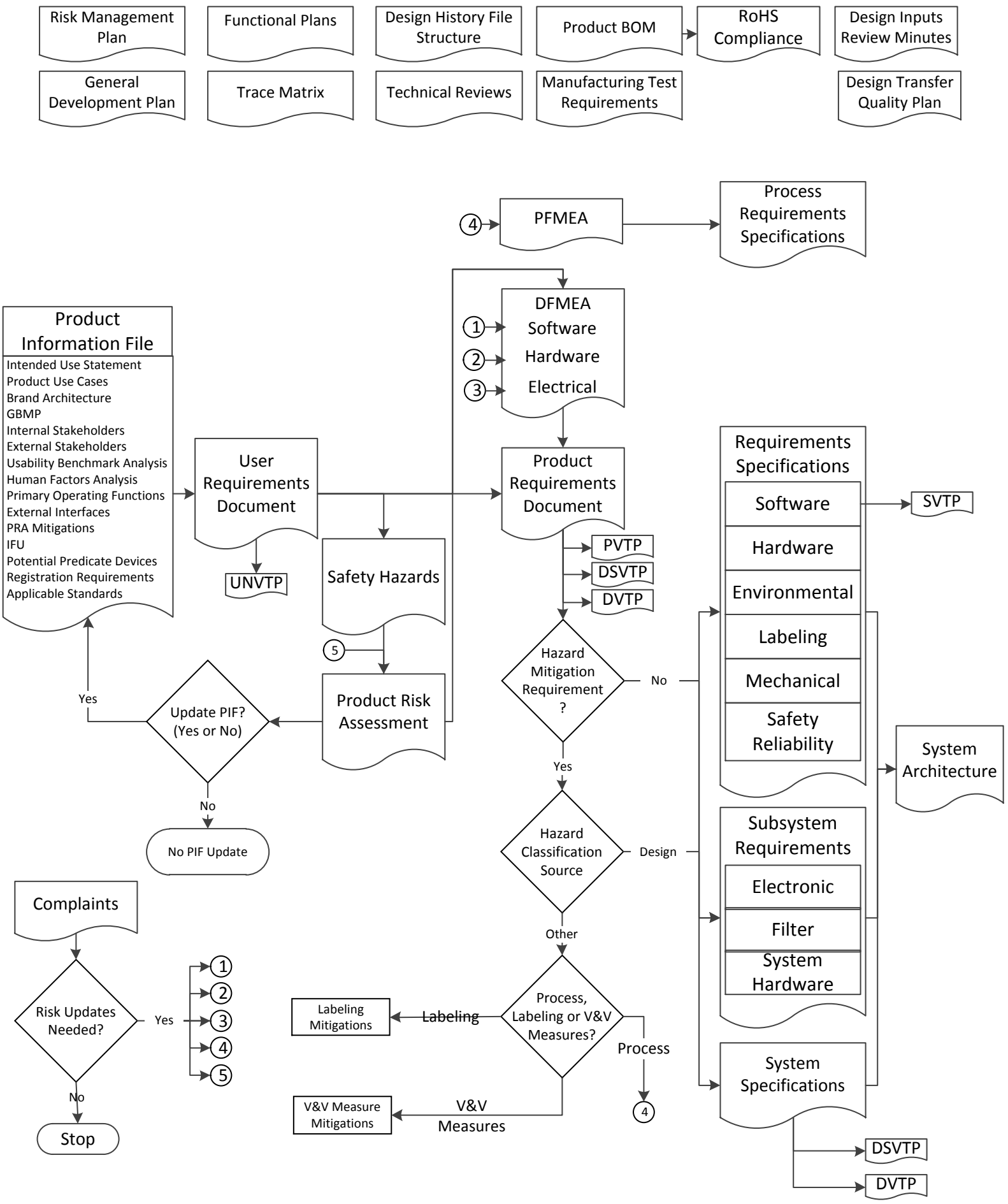
Risk Management Plan
Functional Plans
Design History File Structure
Product BOM
RoHS Compliance
Design Inputs Review Minutes
General Development Plan
Trace Matrix
Technical Reviews
Manufacturing Test Requirements
Design Transfer Quality Plan
4
PFMEA
Process Requirements Specifications
DFMEA
1
Software
2
Hardware
3
Electrical
Product Information File
Intended Use Statement
Product Use Cases
Brand Architecture
GBMP
Internal Stakeholders
External Stakeholders
Usability Benchmark Analysis
Human Factors Analysis
Primary Operating Functions
External Interfaces
PRA Mitigations
IFU
Potential Predicate Devices
Registration Requirements
Applicable Standards
User Requirements Document
UNVTP
Safety Hazards
5
Product Risk Assessment
Update PIF? (Yes or No)
Yes
No
No PIF Update
Product Requirements Document
PVTP
DSVTP
DVTP
Hazard Mitigation Requirement ?
No
Yes
Hazard Classification Source
Design
Other
Process, Labeling or V&V Measures?
Labeling
Labeling Mitigations
Process
4
V&V Measures
V&V Measure Mitigations
Requirements Specifications
Software
SVTP
Hardware
Environmental
Labeling
Mechanical
Safety Reliability
System Architecture
Subsystem Requirements
Electronic
Filter
System Hardware
System Specifications
DSVTP
DVTP
Complaints
Risk Updates Needed?
Yes
1
2
3
4
5
No
Stop