

Standard Operating Procedure VAL 045

Title: Impact Assessment for Computerised Systems

Figure 1: An illustration of the structure of a Computerized system is the following Finishing Line PLC

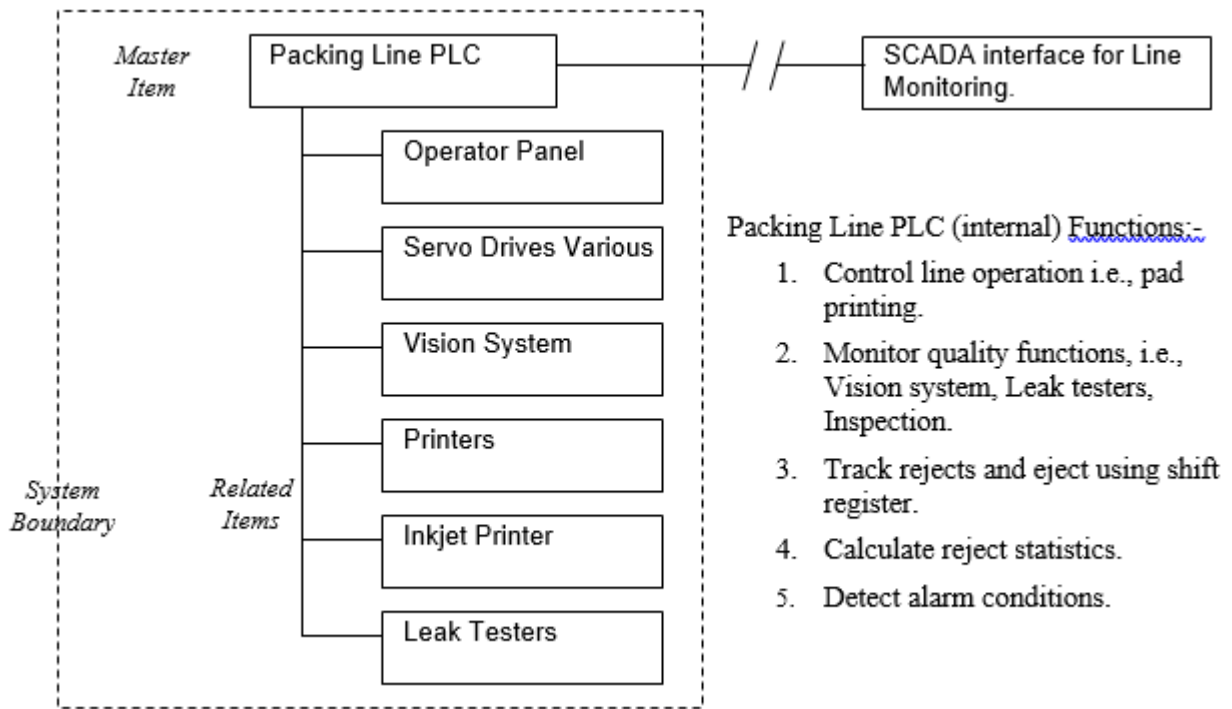


Figure 2: Technology Level Vs GAMP Ratings

Technology Level	GAMP Rating
<i>Data</i>	<i>No GAMP rating but may have GxP Impact</i>
Customised Application	GAMP 5
Base Application	GAMP 3
Operating System	GAMP 1
Firmware	GAMP 2

Figure 3: Flow-chart of the Impact Assessment updating process

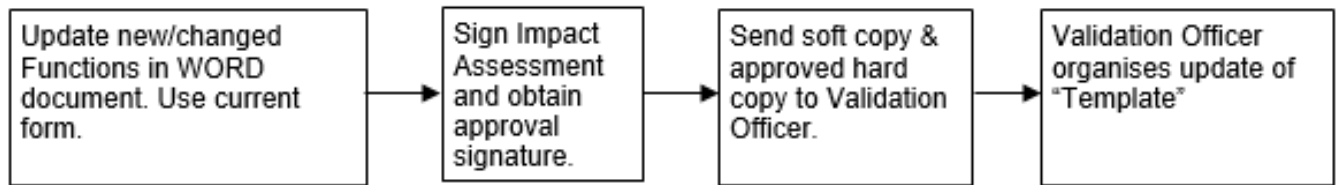


Figure 4: Some Functional Testing

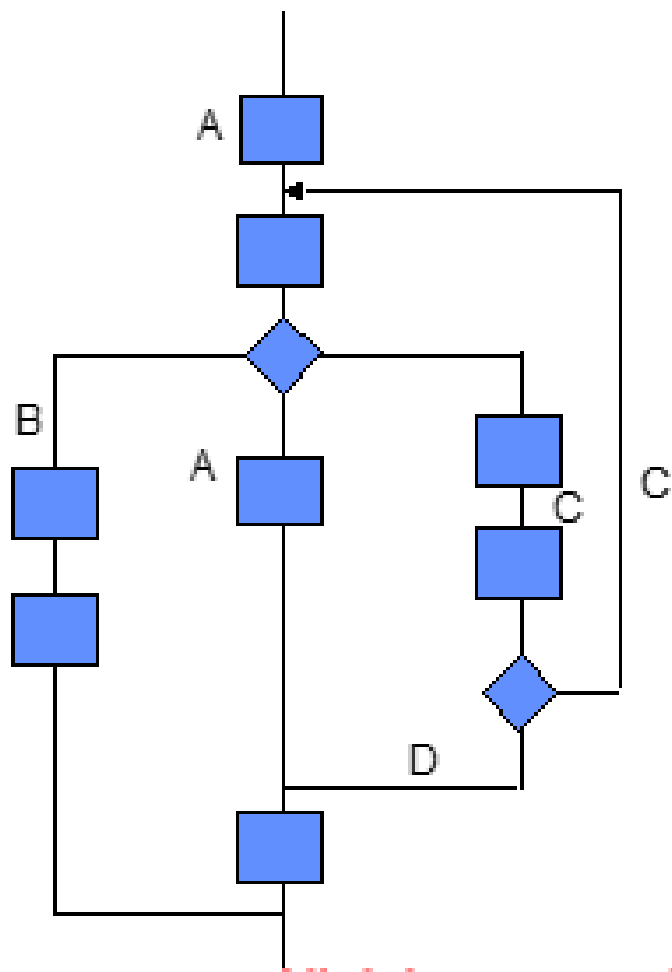


Figure 5: Impact Assessment Process Overview

