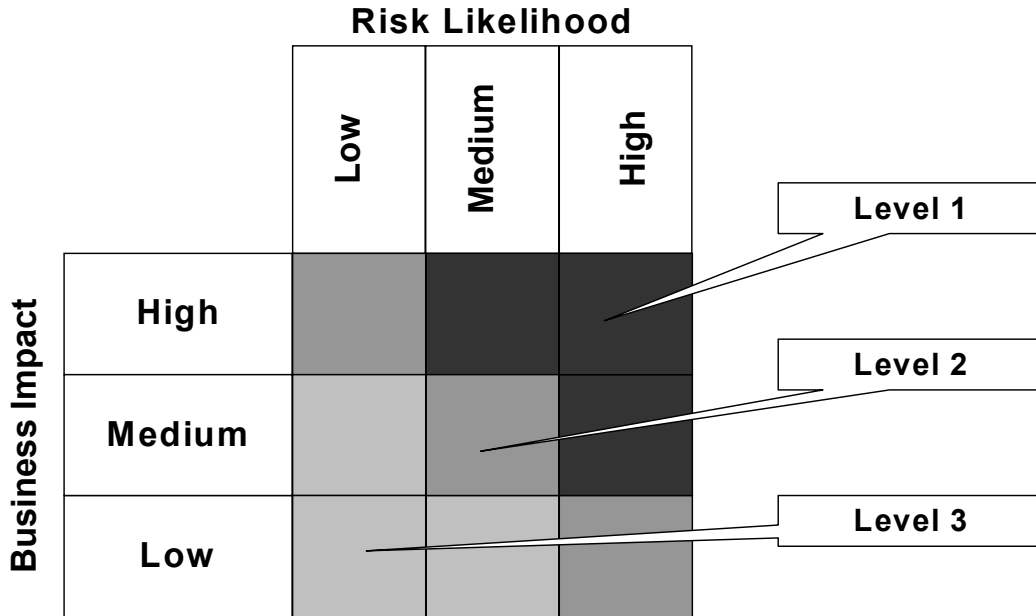


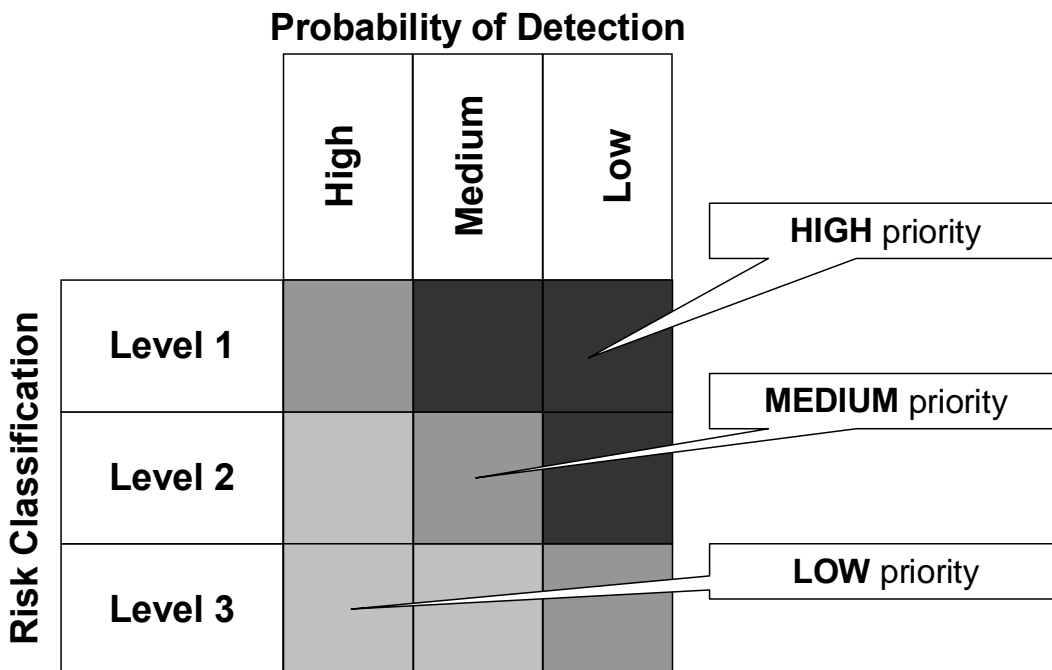
Standard Operating Procedure VAL 135

Title: Risk Assessment for Computer Validation Systems

Appendix 1 – Risk Classification



Appendix 2 – Probability of Detection



Appendix 3 – Risk Assessment Form

Project Title / Risk Assessment Overview:									
Assessment Scope:									
Function	Sub-Function	Assessment of Risk							Mitigation Measures
		Relevance (GxP/Business) (L, M, H)	Risk Scenario (Events) (L, M, H)	Likelihood of Occurrence (L, M, H)	Severity of Impact (L, M, H)	Risk Classification (L, M, H)	Probability of Detection (L, M, H)	Priority (L, M, H)	
Function Risk Assessed By (Initial & Date)						Function Risk Assessment Reviewed By (Initial & Date):			