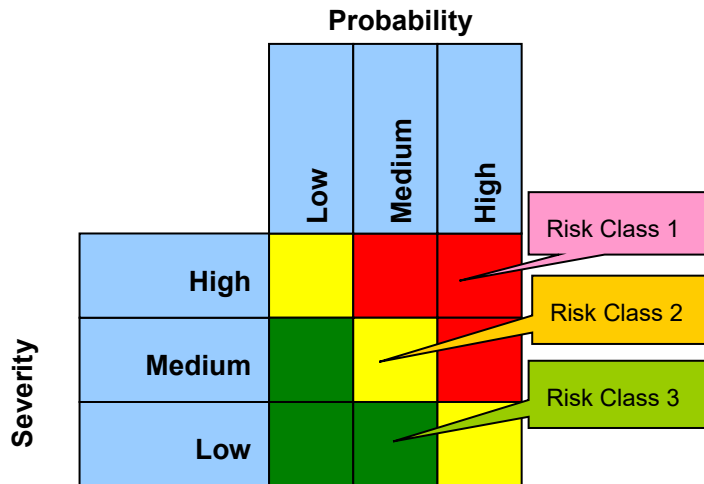


# Standard Operating Procedure VAL 185

**Title:** Guidance for the use of Risk Assessment in Validation

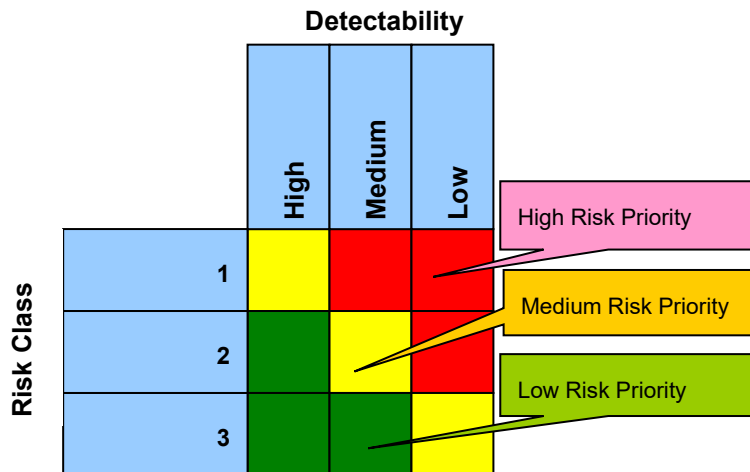
**Figure 1: Risk Classification**



**Severity** = Impact on Patient Safety and Product Quality.

**Probability** = Likelihood of Hazard occurrence

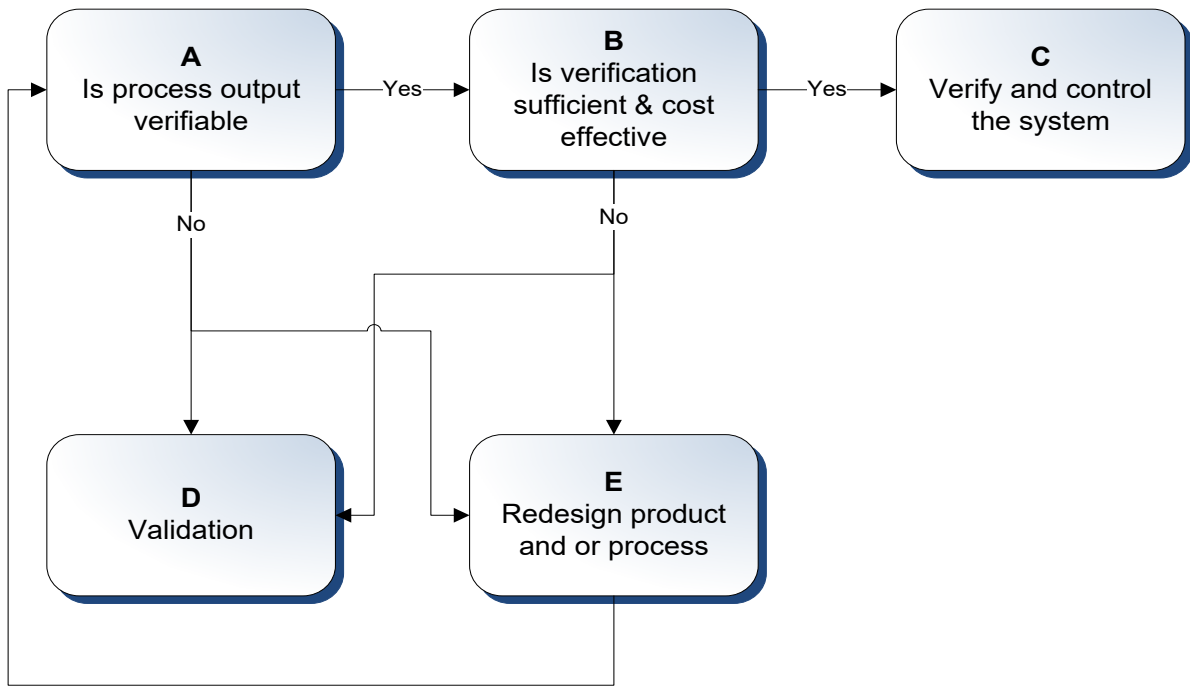
**Figure 2: Risk Priority**



**Detectability** = Likelihood that the fault will be noted before harm occurs.

**Risk Priority** = Risk Class X Detectability

**Figure 3: Validation and Verification Decision Tree**



**Figure 4: Validation - Critical Control Point Decision Tree**

