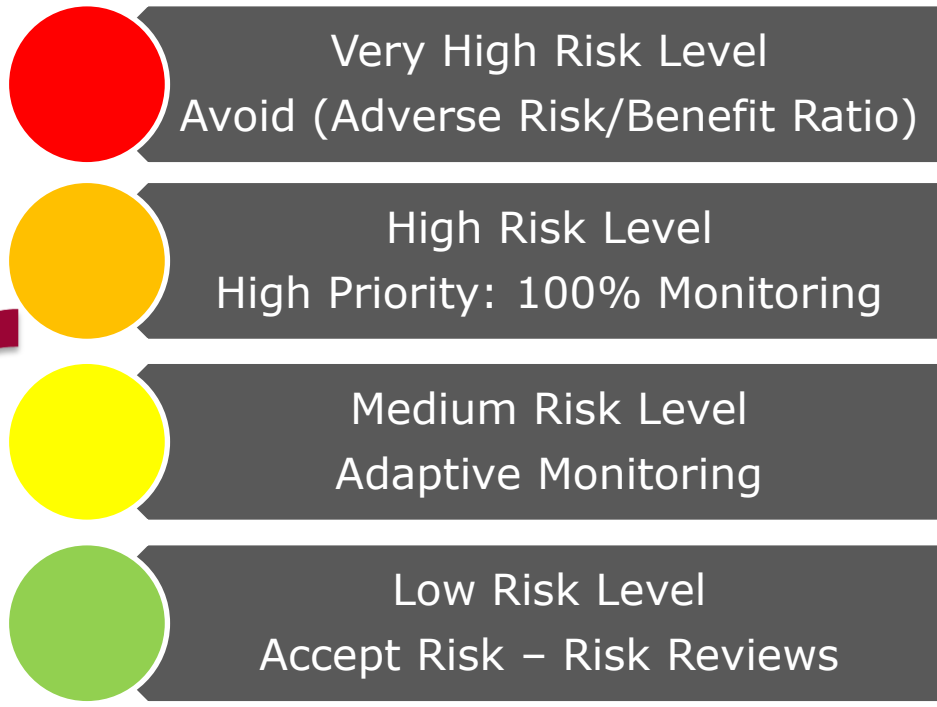


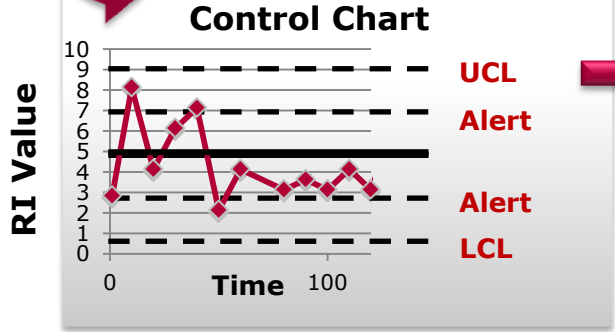
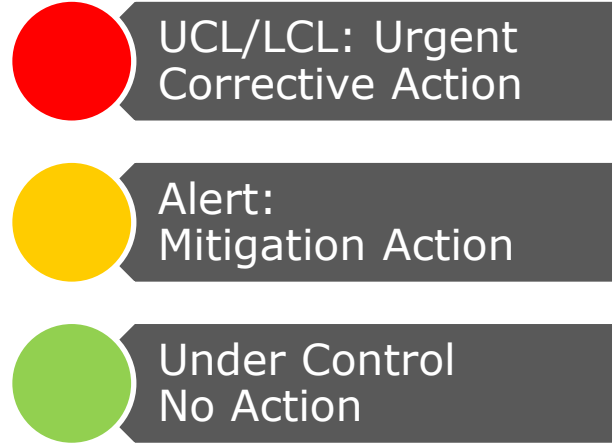
# Risk-based Quality Management – Continuous Improvement

## 1) Plan



- Risk Assessment
- Plan Risk Priorities & Management
  - Select Risk Indicators (RI)

## 2) Control



Risk Monitoring  
(Study Conduct)

UCL: Upper Control Limit Alert  
Alert: Trigger of Preventive/  
Corrective Actions  
LCL: Lower Control Limit Alert