

Company Name	Procedure Number:	Page 10 of 20
Title: CFR 21 Part 11 Compliance Plan	Implementation Date:	Version Number 1.0

3.4 Prioritization Process

The purpose of the prioritization process is to identify the systems with the greatest potential to directly impact product quality. Acknowledged Risk Assessment tools will be used to make clear and comprehensible evaluations on the associated product risk for each system. The overall assessment will result into three categories.

- Red: Highest Risk
- Orange: Medium Risk
- Green: Low Risk

Each system will be assessed and assigned to one of these categories.

3.5 Compliance Assessment

3.5.1 Existing (Legacy) Systems

The compliance status of each system will be assessed. Associates performing the compliance assessment must have successfully participated in the basic and the expert training.

3.5.2 New Systems

Part 11 compliance for new systems have to involve the following points:

- Identification of applicable Part 11 requirements. Specific Part 11 requirements for a system or application must be incorporated into appropriate project documentation such as User Requirement specifications (URS).
- Application of agreed technical and/or procedural solutions to the system or application development, development, qualification and validation activities.

Where the system or application in development does not achieve all Part 11 requirements specified in the project documentation, compliance Strategy Documents must be developed at appropriate stage in the development lifecycle.

3.6 Remediation

A gap analysis will be performed on all systems listed in the inventory list in order to determine the adequacy of compliance and any need for remediation. Corrective actions will be identified for each system item listed as a gap in compliance. Both short and long term actions will be included in the plans along with roles, responsibilities and timelines.