

Guideline for Equipment and System Qualification

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Standard Operating Procedure (SOP) and Guideline for preparation of Equipment / System Qualification (URS, IQ, OQ, PQ, FAT, SAT, etc.) documents, execution of Qualification activities, Review and Compilation of data, Assessment and Interpretation of Qualification & validation activity results.

Equipment and System Qualification

1.0 Purpose :

To lay down the procedure for preparation of Qualification documents, execution of Qualification activities, Review and Compilation of Data, Assessment, and Interpretation of Qualification & validation activity results.

2.0 Scope :

The standard operating procedure applicable for the preparation of qualification and re-qualification documents for all equipment & system and execution of qualification activities performed.

3.0 Responsibility :

Officer and above of User, Engineering and QA Department shall be responsible for the preparation and execution of the equipment and system Qualification and Re-qualification activities.

4.0 Accountability

Head- User, Engineering, and Quality Assurance shall be responsible for compliance.

5.0 Procedure – Equipment and System Qualification :

- **Qualification Approach – Equipment and System :**
- The universal “V model” approach shall be followed for all the Qualification and Validation activities.
- The model is as follows:

Equipment System Verification Qualification

S Ashworth



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