



SOP: LFA 00078

SOP for Allocating Document Protocol Number for Instrument Qualification

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1 Objective

To provide a guideline for the allocation of document protocol number for qualified instruments to improve reference and traceability

2 Scope

Applicable to all instrument qualification protocol such as the following:

- User Requirement Qualification
- Functional Requirement Qualification
- Design Qualification
- Installation Qualification
- Operational Qualification
- Performance Qualification

- Re-qualification

3 Responsibility

By Quality Control Department

Check Quality Assurance Department

4 Accountability

Head of the Department

5 Procedure

- 5.1. Allot the following system for the documentation protocol number for the instrument qualification:

Document Protocol Number	Applicable To
XXX/Q.C./000	User Requirement Specification Functional Requirement Specification
XX/Q.C/—	Design Qualification Installation Qualification Operational Qualification Performance Qualification Re-qualifications

Whereas:

xxx= corresponds to the 3 alphabets denoting the document protocol type

xx = relates to the 2 letters denoting the document protocol type

000 = relates to the 3 numerical figure starting from 001

- 5.2. Allot the following code for the protocol in respect to the instrument qualification

- 5.3.

Instrument Qualification Protocol	Code
USER REQUIREMENT SPECIFICATION	URS
FUNCTIONAL REQUIREMENT SPECIFICATION	FRS
DESIGN QUALIFICATION	DQ
INSTALLATION QUALIFICATION	IQ
OPERATIONAL QUALIFICATION	OQ
PERFORMANCE QUALIFICATION	PQ
RE-QUALIFICATION	RQ

6 Abbreviations

SOP Standard Operating Procedure