

## Appendix 1 – Record of Software Validation

Objectives and scope of application	
General description	
Risk analysis	
Environment	
Functional requirements	
Validation plan and scope	
Validation purpose	
Validation scope	
Validation methodology	
Validation results analysis and reporting	

**Commented [AES1]:** A short description of a high-level

**Commented [AES2]:** What is the risk of using this software?

**Commented [AES3]:** How does the software fit into the lab

**Commented [AES4]:** Requirements should be written in user terms. Do not confuse requirements with design or configuration. Keep to what you need the software to do.

Types of requirements include:

- Layout
- Input validation (edit checks)
- Fault tolerance
- Logic
- Math

**Commented [AES5]:** What you are NOT testing

**Commented [AES6]:** How are you going to

**Commented [AES7]:** What are you going to do with the

**Commented [AES8]:** Include all test data here or point to

**Commented [AES9]:** Summarize the testing here.

[job title]  
[name]

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[signature]

**Commented [AES10]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.