

## Guidance Number: 032

### Appendix 1: Equipment Classification

Table 1 – Equipment Classification

	SYSTEM		
	Simple	Moderate	Complex
Equipment/Instrument	Yes	Yes	Yes
Firmware	Yes	Yes	Yes
Software		Yes	Yes
Local or Network Data Storage		Yes	Yes
Data Processing		Yes	Yes
Data Reprocessing with Human Intervention			Yes
E-Record E-Signatures			Yes
Minimum Qualification Activities	User Requirements Specifications (URS) <sup>1</sup> , IQ, Calibration <sup>2</sup>	URS <sup>1</sup> , IQ Equipment/ Software, OQ and PQ may be supported by initial calibration. For OQ, vendor defined. For PQ, defined by the range of intended use at the Site. Supplemental Qualification <sup>3</sup> may be required.	URS, Validation/ Qualification plan, IQ equipment/software, OQ System <sup>2</sup> , PQ System, Supplemental Qualification <sup>3</sup> required. Initial calibration, and Report to release system.
Vendor Evaluation	None or Vendor Assessment	None or Vendor Assessment	Vendor Assessment or Vendor Audit

Table 1 Footnotes:

1. User Requirement Specifications for simple and moderate equipment- user manuals and purchase requisition documentation.
2. OQ may be supported by the initial calibration.
3. Supplemental Qualification- this may include equipment configuration, security, access control, data integrity checks.