5.5.4 All testing equipment should be identified in the protocol and calibrated before use.

5.5.5 All critical instruments will be calibrated prior to Operational Qualification.

5.5.6 Where sampling is performed, the specific sampling site must be identified in the protocol.

5.5.7 Commissioning performed following installation is not a substitute for OQ, however if the commissioning is documented and witnessed / reviewed by a Site employee, the results may be used as part of the OQ.

5.5.8 The completion of satisfactory Installation Qualification and Operational Qualification exercises should permit a formal 'release' of the facility / utility for the next stage in the validation exercise. This release should be documented through completion of the validation exercise.

5.6 **Facility / Utility Validation Requirements**

5.6.1 Protocols for each type of qualification will be written as per approved SOP. (See all types of protocol templates from the site http://www.gmpsop.com). Depending on the size of the system or item to be validated IQ and OQ may be combined into one protocol and one report.

5.6.2 For new utilities where possible the manufacturer's validation package will be reviewed and if suitable purchased. The validation team will make additions to the package as necessary to meet Site Quality Standards. Vendor protocols must be pre approved by the validation committee to meet Site requirement as outlines in this document. A validation report will be issued for vendor protocols.

5.6.3 When there is more than one identical building or utility, each has to be qualified however identical protocols can be used.

5.6.4 Where operating manuals exist for a utility, protocols should reference these manuals.

5.6.5 Validation reports will be written for each protocol. Protocols written for specific utilities must adequately describe the intended use.

5.6.6 An EH&S risk assessment will be considered an essential part of any utility protocol.

5.6.7 The acceptance criteria for each item will be described and justified in the specific protocols for that item. Generally the facility / utility must conform to GMP requirements, OHS standards and applicable Australian standards.

5.6.8 Any deviations encountered during the validation study must be documented in the validation protocol/report and must be approved by Quality Operations.

5.7 **Qualification of Existing Facilities and Utilities**

