5.3.2 Qualification, calibration, validation and maintenance

Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for generation, measurement, or assessment of data shall be adequately tested, calibrated and/or standardized. These activities are frequently called qualification for equipment hardware and single modules and validation for software and complete systems. A schedule shall be established for such operations based on manufacturer's recommendations and laboratory experience.

5.3.3 Time interval for calibration, re-validation and testing

The frequency for calibration, re-validation and testing (performance verification) depends on the instrument itself, the recommendations from manufacturers of the equipment, laboratory experience, and the extent of use. E.g. a pH meter should be calibrated before each use and the wavelength of an HPLC variable wavelength detector should be calibrated about every month or whenever the cell is removed and reinstalled. Typically proof of chromatographic instrument performance should be done every 6 to 12 months.

5.3.4 Equipment records and other documents

Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or qualification / validation operations. These records, containing the date of operation, shall describe whether the maintenance operations followed written SOPs. Written records shall be kept of non-routine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect. Written records may be in log books especially designed for that purpose. A log book should accompany the instrument when it is moved. Remedial action should include a review of effects on data generated before the defect was discovered. Such equipment records should be maintained as long as the data generated by the equipment. Equipment records should include for example:

- name of the equipment
- name of the manufacturer
- model or type for identification
- serial number
- date equipment was received in the laboratory
- condition when received (new, used)
- details of checks made for compliance with relevant calibration or test standard specification