identification. The results are compared to the acceptance criteria as published in the method. If there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits.

(7) **Maintenance logs.** Maintenance logs shall be kept for each instrument, to include dates and description of repairs, preventive maintenance, malfunctions, and other actions or events affecting performance. All instruments not in service must be tagged out of service. Maintenance logs shall also be kept for all devices that are necessary to support laboratory operations. These include, but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf [Registered Trademark] or automatic diluting dispensing devices), if quantitative results are dependent on their accuracy, such as in standard preparation and dispensing or dilution into a specified volume. Each balance shall be annually serviced and calibrated by a recognized accredited metrological service.

(8) **Corrective action procedures.** Procedures for evaluating, documenting and reporting corrective action used for audits, PT failures, out-of-control situations and in response to enforcement actions.

(9) **Quality protocols.** Procedures for monitoring the validity of the environmental testing and the resulting data shall be recorded in such a way that trends are detectable, and statistical techniques shall be applied to the reviewing of the results. All laboratories shall have documentation for positive and negative controls, reproducibility, repeatability, and accuracy of the method.

(10) **Chain of custody and sample acceptance.** Procedural plans for sample login, unique sample identification (all sample containers), date, time, source of sample (including name, location (location code) and sample matrix), preservative used, analysis required, name of collectors and any pertinent field data.

(11) **Spike duplicates and spike-duplicate data.** The laboratory shall document procedures for determining the effect of the sample matrix on method performance. These procedures relate to the analyses of quality system matrix-specific quality control samples, and are designed as data quality indicators for a specific sample using the designated method. Information shall include, but is not limited to: date, analyst, laboratory sample number, amount spiked, percent recovery, percent of difference, and makeup and concentration in the spiking solution.

(12) **Electronic data.** Control electronic data including security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entry shall be preserved.

(13) **Sensitivity, LOD and LOQ.** Procedures used for determining limits of detection and quantitation shall be documented. Documentation shall include the quality system matrix type. All supporting data shall be retained. LOQ shall be verified annually within the established control limits.