

alternate system may be used provided that the instrument traceability can be assured.

4. Calibration Records include, and are not limited to, the following:
 - Instrument or equipment identification;
 - Calibration data including initial (as found), and final (as left) results;
 - Comparison of results against specifications;
 - Units of measure;
 - Identification of any standard(s) used;
 - Identification of the procedure used for the calibration;
 - Date calibration performed;
 - Signature of person performing work;
 - Signature of second person reviewing and approving the data and date of approval; and
 - Environmental conditions, if required by the calibration procedure (e.g., temperature, humidity, atmospheric pressure).

Calibration records should be retained in accordance with the Site record retention procedure.

5. Calibration Records should be reviewed by the System Owner to identify potential out-of-tolerance conditions. In addition, calibration records should also be reviewed to support modifying tolerances and to obtain data to support changing calibration frequencies.
6. Calibration Status Labels should be placed on instruments in a conspicuous location, if possible, and should include, but not be limited to, the following information:
 - Date calibrated,
 - Next due date, and
 - Initials of person performing calibration.Instrument Calibration Status may be tracked using other systems besides labels such as validated computerized systems or manual paper-based systems provided the system allows the operator of the instrument to determine the instrument's calibration status.
7. Instrument Calibration Status should be verified prior to use of the instrument.
8. Calibrations should be completed by the due date or the instrument is considered overdue and should be identified as being past due. An investigation should be conducted and documented on the impact of the past due calibration on product or the process, if the instrument was used subsequent to becoming overdue.
9. Instruments [except those that require calibration prior to each use (e.g., pH meters)] should be removed from service or designated out of service (e.g., not used and/or removed from work areas) because of, and not limited to, the following reasons:
 - Inability to calibrate;
 - An out-of-tolerance condition is determined on the initial check, and the adjustments cannot be made; or
 - Past due calibration, if the instrument was subsequently used after becoming past due, unless documented approval to use the instrument is granted by the Site Quality Team.