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.

- Handling or storage conditions for the standard;
- Reference to a method or SOP used to establish the standard; and
- Accuracy (or purity for chemical substance) and precision of the standard.

19. Calibration Service Contractor Quality System SOPs should be reviewed and documented evidence should be available to indicate that the Site Quality Team approved the SOPs for use at the Site. Specific instrument calibration SOPs should be reviewed when possible. If specific instrument calibration SOPs are proprietary and unavailable for review, an alternative method for ensuring acceptability of the SOPs should be established by the Site Quality Team.

20. Initial "As Found" Data should be recorded prior to removing an instrument from the calibration schedule, performing an upgrade, or before an instrument is moved. If the instrument is not calibrated prior to a move, the justification should be documented and approved by the Site Quality Team.

21. The Calibration Range Selected should include the normal process parameter values and expected variability. The instrument calibration should demonstrate that the instrument can reproducibly measure across the selected range.

22. Loop Calibration, in lieu of calibrating individual instruments in the loop, is justified under the following circumstances:

- A documented evaluation of the Instrument Loop is conducted by the Site Calibration Principals. The instrument loop evaluation should include, but is not limited to:
  (a) The instrument loop design;
  (b) Operating characteristics of the individual loop elements; and
  (c) Reliability or experience with the technologies incorporated into the instrument loop; or
  (d) An assessment of the historical data from the specific instrument loop;

- Individual instruments to be incorporated into an instrument loop have been calibrated as required by and demonstrated to be functioning properly, prior to the placement into the instrument loop;

- The instrument loop is periodically calibrated and documented using a loop calibration. If an instrument loop is found to be outside the expected variability, then the individual component instruments should be examined and calibrated individually to return the loop to specification; and

- All other aspects of the loop calibration methodology and system (e.g., systems, documentation, schedules, tolerances, labeling, change control) meet the site requirements.

23. Calibration should be conducted at a minimum of three points (e.g., upper operational range, lower operational range, and NOR), if possible. For instruments that cannot be calibrated at three points, the points to be included in the calibration should be defined and justified.

