

## Calibration

16. Transfer Standards should be certified against primary standards either at the Site or by an approved calibration service contractor.
17. The Accuracy of the Calibration Standard should be, at least, equal to the accuracy of the instrument being calibrated.
18. A Calibration Certificate and the Supporting Raw Data should be obtained from the calibration service contractor for each certification of a primary or secondary standard. The System Owner should review the certification for completeness and accuracy and document the results of the review.

For In-House standards, a calibration certificate should be prepared based on supporting raw data. The certificate should include, and should not be limited to:

- Description of the standard;
  - Date the standard was established;
  - Signature of person preparing the standard;
  - Date standard must be recertified or replaced;
  - 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;