

SECOND-SOURCE STANDARD POLICY

(NC WW/GW LCB 9/24/2021)

The purpose of this policy is to expand upon and explain the requirements described in 15A NCAC 02H .0805 (a) (7) (H) (ii).

When a calibration curve is manually prepared (as opposed to a factory-set calibration curve), it is required to analyze one known standard in addition to the calibration standards each time the curve is analyzed and in accordance with the reference method requirements thereafter to document accuracy. This standard (often referred to as a second-source standard or external reference standard) must be prepared from materials obtained from a source independent from the one used for preparing the calibration standards and treated in the same manner. A second-source standard may be:

- a certified standard obtained from a vendor,
- a standard prepared from primary standards obtained from a second vendor, or
- a standard made from primary standards from the same vendor but from a different lot number (i.e., an independent lot) as those used to make the calibration standards.

Second-source standards must be evaluated using one of the following: vendor supplied criteria, method-defined acceptance criteria, in-house calculated acceptance limits that are statistically-derived from historical data based on three standard deviations from the mean in the detectable range or other statistically viable evaluation criterion. If the results fall outside of acceptance limits, the analysis must be terminated, and the problem corrected prior to sample analysis.