

Traceability Documentation Requirements for Chemicals, Reagents, Standards and Consumables Policy (NC WW/GW LC Branch 03/27/2020)

15A NCAC 02H .0805 (a)(7)(K) and (g)(7) requires laboratories to have a documented system of traceability for the purchase, preparation, and use of all chemicals, reagents, standards, and consumables. That system must include documentation of the following information: Date received, Date Opened (in use), Vendor, Lot Number, and Expiration Date (where specified). A system (e.g., traceable identifiers) must be in place that links standard/reagent preparation information to analytical batches in which the solutions are used. Documentation of solution preparation must include the analyst's initials, date of preparation, the volume or weight of standard(s) used, the solvent and final volume of the solution. This information as well as the vendor and/or manufacturer, lot number, and expiration date must be retained for primary standards, chemicals, reagents, and materials used for a period of five years. Consumable materials such as pH buffers, lots of pre-made standards and/or media, solids and bacteria filters, etc. are included in this requirement.