

Electronic Signature and Data Storage Policy
(NC WW/GW LC Branch 04/03/2020)

Electronic records must be complete and in a form that does not allow alteration without detection. The system must use secure, computer-generated, time-stamped audit trails to automatically record the date and time of operator entries and actions that create, modify, or delete electronic records throughout the entire records retention period required by 15A NCAC 02H .0800 (i.e., 5 years). Audit trails must track the old and new values when a change is made, and these changes shall not obscure previously recorded information.

Electronic records must be searchable and retrievable in readable formats throughout the retention period. The laboratory must ensure that the complete records, including related support data, can be maintained in secure and accessible forms on the preexisting system or migrated to a new system without modification; as needed, throughout the required retention period.

The system must ensure that any record bearing an electronic signature contains the name of the signatory, the date and time of the signature, and information that explains the meaning affixed to the signature (e.g., review, approval, responsibility, authorship, etc.). Electronic signatures must be protected so that any signature that has been affixed to a record cannot be detached, copied or otherwise compromised so as to falsify an electronic record. Electronic signatures must be included in readable format on the electronic record and subsequent printouts, where applicable.

Elements of a comprehensive electronic signature policy involve employees attesting that:

- They agree to protect the signature from use by anyone except themselves and to confirm system security with third parties where necessary.
- They assert that the contents of the documents or records are both truthful and accurate.
- They understand and agree they will be held legally bound, obligated or responsible by their use of their electronic signature as they would with any handwritten signature.
- They agree never to delegate the use of their electronic signature or make it available to anyone else.
- They agree to immediately report any compromise to the security of their electronic signature.