Electronic Records and Signatures

Electronic records and signatures are considered the legal equivalents of paper records and handwritten signatures executed on paper.

A predicate rule is any regulation or law that includes a requirement to keep a record. Look to predicate rule for:

- what records to keep
- how long to maintain records
- what signatures are required

An electronic record is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

An electronic signature is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

System Requirements:

- Validation
- Qualification:
  - Installation qualification
  - Operational qualification
  - Performance qualification—test

Electronic signature mechanisms may be based on:

- biometrics such as scan of retina (eye), face, fingerprint, or voice recognition
- two distinct components such as identification code or card and password

Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

Open system means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.