**Personnel responsible:**

All Employees

**Purpose or Objective:**

* To define the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records
* Electronic document control systems
* Referencing 21 CFR – Part 11; Electronic Records

**Definitions:**

* Electronic Records

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 will be controlled

* Closed system

An environment in which system access is controlled by persons who are responsible for the content of any electronic record that is on the system.

* Open system

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

* Electronic Signature

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

* Digital signature

An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified

Digital signatures are required for open systems and as such need higher security levels. Therefore, in addition to electronic signatures, cryptographic methods have to be applied for authentication of the user and integrity of the record.

**Procedure:**

1. One Control / Access point
2. Org chart / control chart -
   * Who has authority and access and ability…
3. All machines time out with password log in
4. Dates on everything that prints out
5. Signatures or pertinent docs – list of pertinent docs…

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| Revision  Number | Revision  Date | Effective  Date | Revision  Author | Quality  Approval | Production Approval | Revision Description |
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