
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: IT and Electronic Records	Number: Q12-PR-100-020	
	Owner: Jason Bumgarner	Revision: 0	
	Effective Date: DRAFT	Page: 1 of 2	

1.0 Purpose

- 1.1 To define the criteria at Giles Chemical under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records.

2.0 Scope

- 2.1 This procedure applies to the electronic document system referencing 21 CFR – Part 11; Electronic Records.

3.0 Responsibility

- 3.1 IT Department and Process Engineer are responsible for this procedure.

4.0 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.

5.0 Safety Considerations

- 5.1 Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

6.0 Materials/Equipment

- 6.1 N/A

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7.0 Procedure

- 7.1 One Control / Access point
- 7.2 Org chart / control chart -
- 7.3 Who has authority and access and ability...
- 7.4 All machines time out with password log in
- 7.5 Dates on everything that prints out
- 7.6 Signatures or pertinent docs – list of pertinent docs...

8.0 Reference Documents

8.1 N/A

9.0 Amendment Record

Revision Number	Revision Date	Revision Author	Revision Description
0	DRAFT	JB	New Document