

M2S
APPROVED
Electronic Signatures

1. PURPOSE:

- 1.1. The purpose for this procedure is to document the M2S policy for the use of electronic signatures.
 - 1.1.1. This document supports 21 CFR Part 11, section 11.10 (j), which requires the establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.
 - 1.1.2. This document supports HIPAA rules, including § 164.312 Technical safeguards; (a)(2)(i) Unique User Identification, and § 164.308 Administrative safeguards; (a)(3)(ii)(A) Authorization and/or supervision

2. SCOPE:

- 2.1. This procedure applies to all employees who use electronic signatures.

3. DEFINITIONS:

- 3.1. Reference DOC-GEN-1-01 for definitions of Digital Signature, Electronic Signature, Electronic Record, and Handwritten Signature

4. RESPONSIBILITY AND AUTHORITY:

- 4.1. QA is responsible for ensuring all applicable employees are trained to this document.
- 4.2. HR is responsible for ensuring the identity of any M2S employee prior to the use of the employee's electronic signature.
- 4.3. All employees who use electronic signatures are responsible for training to this document.

5. RELATED DOCUMENTS:

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| 5.1. DOC-SOP-1-00: | Control of Documents |
| 5.2. DOC-GEN-1-01: | Glossary of Terms |
| 5.3. REC-SOP-1-00: | Control and Retention of Quality Records |
| 5.4. ITS-POL-0-01: | Computer and Network Systems Policy |
| 5.5. ITS-WRK-1-11: | Passwords |
| 5.6. QMS-POL-0-02: | Quality Manual |
| 5.7. SEC-POL-0-01: | General Security Policy |

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5. POLICY:

- 5.1. Electronic signatures at M2S are initiated through the use of usernames and passwords.
- 5.2. Username and password combinations shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.
- 5.3. Usernames and passwords entered into any electronic system within M2S shall be treated as legally binding signatures.
 - 5.3.1. While under a username and password within any electronic system at M2S which is held to 21 CFR Part 11 requirements, the following entries are considered electronically signed:
 - 5.3.1.1. Any additions, deletions or modifications to data or documentation,
 - 5.3.1.2. Any approvals, or comments associated with data or documentation,
 - 5.3.1.3. Any other tasks or job functions affecting any quality record while performed under the electronic signature.
- 5.4. If it is suspected that the username and password combination has been compromised, IT shall be notified immediately and shall change the username or password. IT has the authority to perform an investigation into the breach as they see fit.
- 5.5. All M2S employees are responsible and accountable for any actions initiated under the assigned username and password combination. Misuse of electronic signatures may be subject to M2S and regulatory disciplinary action.