**[lab name]**

**Policy and Procedures for the Use of Electronic Signatures**

 **[#]**

**In Compliance with V1M2 4.2.8.4**

**VERSION #1.0 Effective date: January 1, 2024**

**APPROVED BY**

**Signature**

 **[name] Technical Manager**

**Signature**

 **[name] Quality Manager**

**New SOP**

**Revision History**

|  |  |
| --- | --- |
| Version number and effective date | Revisions made |
| V 1.0 January 1, 2024 | Conforms to TNI 2016 standards. |
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# Policy and Procedure for Electronic Signatures

Electronic signatures and initials are allowed. At all times the creation and use of electronic signatures must comply with 27 CFR Part 23 and CCR Title 2 section 22000 requirements. The following additional requirements must be met.

* There must be a list or database with the individual’s name and electronic signature and initials.
* There is to be an image file of the signature and one of the initials.
* The image files are under the personal control of the named individual.
* The authorization to use the signature or initials in documents and records.

Electronic signatures for reporting purposes are controlled by the recipient. In cases where the submission is to a governmental database or report portal, only those authorized by the applicable agency are allowed to submit reports using their signature or passkey.

# Electronic Signatures on Laboratory Created Controlled Documents

Electronic signatures may be used in place of signatures in ink if the signer is in the electronic signature database.

# Use of Electronic Signatures and Initials in Records

Electronic signatures or initials may be used under the following conditions.

* There is a copy of the signature or initials on file.
* The record is an electronic file. NO electronic signatures or initials are to be added to paper forms including those generated by software.

# References

* *Management and Technical Requirements for Laboratories Performing Environmental Analyses*, The NELAC Institute (TNI), Rev 2.1, September 1, 2016

# Definitions and Acronyms

Words specific to this document or used outside of their dictionary definition are defined here. Acronyms can be defined in the text above on their first appearance.

## Definitions

## Acronyms

# Appendices