

An overview of the supported 21 CFR Part 11 requirements fulfilled by the naica[®] system Pro software.

To ensure fulfillment of all 21 CFR Part 11 sections user's organization responsibilities to establish respective Standard Operation Procedures (SOPs) are indicated in the table with "X".

Section	Subject	User's organization	naica [®] system Pro software	Compliance management
11.10 (a)	Validation	X	X.	System validation as well as experiment result validation is supported by naica [®] system Pro software. SOPs of the user's organization for validation is required.
11.10 (b)	Human readable records	n.a.	X	Electronic records in human readable form supported throughout naica [®] system Pro software
11.10 (c)	Protection of records	X	X	All electronic records are kept within the naica [®] system Pro software environment until the user transfers them to external electronic archives in line with user's organization policies.
11.10 (d)	Limited system access	X	X	Control of access to naica [®] system Pro software through individual user authentication.
11.10 (e)	Audit trails	X	X	naica [®] system Pro software tracks changes in an audit trail which does not expire. The creation of backups is under the responsibility and control of the user's organization.
11.10 (f)	Operating system checks	X	X	naica [®] system Pro software provides guidance and checks for setting up an experiment. naica [®] system Pro software provides default experiment template that can be customized. Customized assays can be released for routine workflows following validation by the user.
11.10 (g)	Authority checks	X	X	Control of access to naica [®] system Pro software by individual authentication and User Role assignments. User cannot modify electronic records. Protocol modification require specified permissions and requires validation prior to release for routine workflow.
11.10 (h)	Device checks	X	X	Experiment configuration and parameters are checked by naica [®] system Pro software. The sample ID input and template file validation is under the responsibility and control of the user's organization.
11.10 (i)	Determination of education	X	X	User Manuals and training documentation are provided by Stilla Technologies. Establishing and maintaining the appropriate training level is the responsibility of the user's organization.
11.10 (j)	Written policies	X	n.a.	Establishing and maintaining SOP to comply with the regulation is the responsibility of the user's organization.

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Section	Subject	User's organization	naica® system Pro software	Compliance management
11.10 (k)	System documentation	X	X	naica® system Pro software documentation cannot be changed by the user. The distribution of documentation to the users and version control of the documentation is the responsibility of the user's organization.
11.100 (a)	Electronic Signature general requirements	X	X	Unique to individual users.
11.100 (b)		n.a.	X	Verification of identity
11.100 (c)		n.a.	X	Certification of equivalence.
11.200 (a/b)	Electronic Signature components and control	n.a.	X	Signature with username and password ensure genuine owner.
11.300 (a)	Controls for identification username and passwords	X	X	Uniqueness of username and password.
11.300 (b)		X	X	Periodical check of issuance.
11.300 (c)		X	X	Loss management.
11.300 (d)		X	X	Safeguards and detection of unauthorized attempts.

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