

Image Studio™ Software 21 CFR Part 11 Compliance Guide



This document describes how Image Studio 21 CFR Part 11 can help your organization comply with the Food and Drug Administration's (FDA) 21 CFR Part 11 regulations.

Note: Image Studio 21 CFR Part 11 is intended to address the technical controls needed for Part 11 compliance. It is the user's responsibility to ensure that the software is appropriately validated within the context of the user's particular environment, and to ensure that the other elements necessary for Part 11 compliance (including procedural and administrative controls) are implemented appropriately.

The regulations listed in this document were copied from the FDA's website.

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11>

Accessed March 17, 2023

21 CFR Part 11 FDA Requirement

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Subpart B--Electronic Records

Sec. 11.10 Controls for closed systems

- 11.10 (a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.
- LI-COR follows a documented software development life cycle process, which includes testing and documentation of Image Studio 21 CFR Part 11 according to LI-COR's ISO 9001 process. Documentation can be obtained at www.licor.com/bio/support. Users are responsible to validate the software in their environment to ensure it performs for their intended use.
- 11.10 (b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.
- All data and records are stored on a user's server. Image Studio 21 CFR Part 11 enables a user to generate the following types of records, which can be viewed using the Image Studio client or System Management Tool.
- **Analysis Data** - Images, analysis data, metadata
 - **Image Log** - Time and date stamped record of what actions were performed to get the image in its current state and produce the current analysis data
 - **User Log** - Time and date stamped record of what actions a particular user performed (e.g. logging in)
- In addition, the **User Log** and **Image Log** can be exported to a .pdf for inspection, review, and copying.
- 11.10 (c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.
- Records are saved to a database on the user's server.
- The Image Studio client and System Management Tool restrict access to the records to users with valid credentials.
- The customer organization is responsible for restricting physical access to the server where data are stored, assigning which personnel have access to the server's file system, and maintaining the master password to the database system.

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11.10 (d) Limiting system access to authorized individuals.

The Image Studio 21 CFR Part 11 client and System Management Tool restrict software access to users with a valid user name and password. The customer organization must designate which users are allowed access to Image Studio 21 CFR Part 11.

The customer organization is responsible for ensuring the security of the hardware and operating systems used for the server and clients.

11.10 (e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

Records can never be altered or deleted using Image Studio 21 CFR Part 11 software.

Image Studio allows the user to generate the following secure, time-stamped audit trail documentation:

- **Image Log:** Record of all actions performed by an operator that affect data. The **Image Log** is available in the Image Studio 21 CFR Part 11 client in the Table section.

The **Image Log** can be exported to a .pdf.

- **User Log:** Record of user activity (logins, incorrect login attempts, system configuration changes, etc.) available on the Logs page of the System Management Tool.

The **User Log** can be exported as a .pdf.

11.10 (f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

Image Studio 21 CFR Part 11 "enforce[s] permitted sequencing of steps and events" by allowing only defined changes per Image Status and users' **Role(s)**.

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<p>11.10 (g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.</p>	<p>The Image Studio 21 CFR Part 11 client and System Management Tool restrict access to users with valid credentials.</p> <p>Image Studio 21 CFR Part 11 uses Roles to perform authority checks. The customer organization is responsible for defining Roles in the system and deciding which Actions each Role is allowed to perform. Image Studio 21 CFR Part 11 prevents users from performing Actions that have not been allowed for that user's Role(s).</p> <p>The customer organization is responsible for ensuring the security of the hardware and operating systems used for the server and clients.</p>
<p>11.10 (h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.</p>	<p>The Image Studio 21 CFR Part 11 client connects directly to the instrument and controls data being transferred to the server <i>via</i> a password-authenticated connection.</p>
<p>11.10 (i) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.</p>	<p>Each customer organization must ensure there are policies in place to determine that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.</p>
<p>11.10 (j) 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.</p>	<p>Each customer organization must ensure this procedural requirement is met.</p>

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- 11.10 (k) Use of appropriate controls over systems documentation including:
- (1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.
 - (2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

Access to modify and distribute LI-COR documentation for Image Studio 21 CFR Part 11 is restricted to authorized users. Documentation is revision controlled, and change control procedures are in place according to LI-COR's ISO 9001 policy. All documentation contains a unique part number and the version of the documentation is identified by the date when the documentation was revised.

Documentation is provided in electronic format within each software release, so each software release contains version appropriate documentation. Updated Image Studio 21 CFR Part 11 documentation will be provided online with the appropriate part number, date, and release notes.

Section 11.30 Controls for open systems

Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in §11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.

Not Applicable - Image Studio 21 CFR Part 11 is a closed system.

Section 11.50 Signature manifestations

11.50 (a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

The full printed name of the user, as specified by the **System Managers** in the System Management Tool, will appear with records signed by the user.

(1) The printed name of the signer;

(2) The date and time when the signature was executed; and

Date and time of the signature are included with the log record.

(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

For each allowed **Action** that is configured to require a signature, the **Action** and a description of the **Action** are recorded with the signature.

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<p>(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).</p>	<p>Signatures are recorded in the Image Log, as described above.</p>
<p>Sec. 11.70 Signature/record linking</p>	
<p>Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.</p>	<p>Handwritten signatures are not part of Image Studio 21 CFR Part 11.</p> <p>Password authentication is required for an electronic signature. Electronic signatures are linked to the electronic record using the Image Log, which cannot be altered or deleted using Image Studio 21 CFR Part 11 software.</p>
<p>Sec. 11.100 General requirements</p>	
<p>(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.</p>	<p>Image Studio 21 CFR Part 11 ensures that each electronic signature and password is unique to one individual.</p>
<p>(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.</p>	<p>This is the customer organization's responsibility.</p>
<p>(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.</p> <p>(1) The certification shall be signed with a traditional handwritten signature and submitted in electronic or paper form. Information on where to submit the certification can be found on FDA's web page on Letters of Non-Repudiation Agreement.</p> <p>(2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.</p>	<p>This is the customer organization's responsibility.</p>
<p>Sec. 11.200 Electronic signature components and controls</p>	
<p>(a) Electronic signatures that are not based upon biometrics shall:</p>	<p>See each requirement below.</p>

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(1) Employ at least two distinct identification components such as an identification code and password.

An electronic signature is composed of two distinct identification components, a user name and password.

(i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.

The first signing is executed at login to the Image Studio 21 CFR Part 11 software, using both electronic signature components (user name and password). Subsequent signings for records will require a password. It is the customer organization's responsibility to determine which Actions in Image Studio 21 CFR Part 11 constitute records.

(ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.

Each part of the electronic signature, the user name and password, is required to access the system.

A continuous session will automatically be ended when a user is inactive for a period of time defined in the System Management Tool. The user name and password are required to re-initiate the session.

(2) Be used only by their genuine owners; and

Image Studio 21 CFR Part 11 prevents the creation of duplicate user names.

Each customer organization is responsible for policies controlling the security of user names and passwords.

(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.

The customer organization must assign trusted users (called **System Managers**) access to the System Management Tool (SMT). **System Managers** use the SMT to assign user names and temporary passwords. **System Managers** are responsible for distributing credentials according to organizational policy.

Once a user logs in with a temporary password, the password must be changed immediately.

(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.

Image Studio 21 CFR Part 11 does not support the use of biometric signatures.

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Sec. 11.300 Controls for identification codes/passwords

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

Image Studio 21 CFR Part 11 ensures uniqueness of user names and passwords.

(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

Image Studio 21 CFR Part 11 can be configured so that passwords expire and must be reset within a time frame that matches the customer organization's policies.

A user account can be deactivated (removed from active use). Each customer organization must ensure that their procedure for communicating changes to user accounts is controlled.

(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.

The customer organization must assign trusted users (called **System Managers**) access to the System Management Tool (SMT). **System Managers** are responsible for using the SMT to deactivate user accounts and reset passwords according to organizational policy.

The System Manager Account may be reset by following the LI-COR *Process for Resetting a Customer Organization System Manager Account*. Email regulatory@licor.com for details.

(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

The number of login attempts for Image Studio 21 CFR Part 11 software is limited according to the customer organization's policies. Invalid login attempts are recorded in the **User Log**. Notifications are displayed in the System Management Tool.

(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.

Image Studio 21 CFR Part 11 does not use cards or physical devices for authentication.



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