

SigmaCERF - 21 CFR PART 11 COMPLIANCE



Subpart B - Electronic Records

11.1	Controls for Closed Systems		
	Employ controls designed to ensure the authenticity, integrity and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following:	Compliant	<p>SigmaCERF provides security controls, audit trails and an e-signature system to ensure the authenticity, integrity and confidentiality of records. The SigmaCERF system only accepts records and document updates from authorized users who supply suitable credentials in authenticated sessions. Record integrity is achieved by providing a complete audit trail and version history, which can only be accessed by authorized users.</p> <p>SigmaCERF offers robust role-based access controls, ensuring highly granular permissions that can restrict unauthorized users from viewing or accessing documents, providing complete confidentiality of records. The SigmaCERF user authentication controls, digital signature passwords and signature workflows, and the matching audit trail collectively ensure that the signer can not readily repudiate the signing or the signed electronic record.</p>
	11.10(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records	Compliant	Thorough and systematic testing to validate the performance of SigmaCERF is conducted with every release cycle and with each customer installation.
	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.	Compliant	SigmaCERF accomplishes the generation of accurate and complete copies in two ways. The original electronic records are readable, reviewable, and capable of being copied directly within the operating SigmaCERF software system by anyway with suitable credentials. For system-independent and software-independent use, SigmaCERF creates PDF reports of the contents of the electronic notebooks and pages. These PDF records are stored in the system and are readily retrieved, printed, or transferred to other storage systems. PDF is intended to offer a long-term solution for maintaining copies of records in human readable and electronic form suitable for inspection, review and copying. Individual electronic records can also be copied to desktop applications for these purposes. SigmaCERF also supports exports of complete notebooks (with full contents, records, and metadata) in open standard XML format.

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	11.10(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	Compliant	Users cannot directly modify or delete records in SigmaCERF – all actions are mediated by the SigmaCERF Server, a secure middle tier which prevents direct access to data. Records are protected by restricting access to authorized users and preventing any unauthorized changes. SigmaCERF offers a complete document/record control system with system locks when records are checked out for editing, maintenance of all versions of lab records, and the capability to finalize lab records to restrict any further changes. Accurate records are accessible and retrievable throughout their lifecycle in SigmaCERF.
	11.10(d) Limiting system access to authorized individuals.	Compliant	<p>All users must be registered in the system by qualified system administrators and users are given unique user names and user-designated passwords (that must be changed by the user when assigned or reset by the administrator). SIGMACERF has strong name/password controls, and passwords are transmitted only in encrypted form and not stored on the server (only a digital hash code).</p> <p>Users are placed into defined workgroups and have specific, fine-grained role-based access privileges within these workgroups. Users may be in multiple workgroups and have different privileges for each projects/notebooks, template, action, or service.</p> <p>When users successfully log on to SIGMACERF, unique session IDs are created and transmitted with every system communication to prevent inappropriate access. Simultaneous sessions (from multiple workstations) are not permitted for a user, so connecting from a different computer or IP address will close the previous session.</p>
	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.	Compliant	<p>The SigmaCERF system includes a complete audit trail function that captures all actions that create, modify or delete data. Audit trails are secure, computer-generated and time-stamped. Recorded fields include creation date and time, update date and time, user name, object modified (by name and system resource object type), action taken, reason (where appropriate), and the new content and metadata. A complete copy of the previous record and its metadata is retained in the system if the content has been placed under version control.</p> <p>The audit trail can be viewed in the SIGMACERF web client by authorized SIGMACERF administrators, and the database can be queried to generate custom audit trail reports. The audit trail is independent of the database entries for each record, and can be compared to verify that user actions and lab records have been documented correctly.</p>

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	11.10(e) Record changes shall not obscure previously recorded information.	Compliant	Documents, data, and notebook entries must be checked out before any changes can be made. Records are locked when contents are checked out. On checking in, the file is stored as a new version, with previous versions stored in the SigmaCERF system. The previous version of the metadata is also retained with its record. The version history may be inspected and previous record versions viewed by authorized users.
	11.10(e) Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and required for the subject electronic records and shall be available for agency review and copying.	Compliant	SigmaCERF audit trail records are maintained in the database and can be viewed or extracted from the system directly or through queries for the functional life of the software system. The audit trail information cannot be deleted or modified for records in the SigmaCERF system. The audit trail documentation is available for agency review, and reports can be made for inspection or copying.
	11.10(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	Compliant	<p>All actions are operational sequences performed by users authorized to carry out the function and system workflows. These workflows verify the events, data management workflows, and the validity of the data and records. SigmaCERF actions are defined and limited by the SigmaCERF system components and business policies, and are distributed to individuals automatically and securely by the system according to the type of system object, the user's role-based access privileges, and the services available for the selected object.</p> <p>Workflows and actions in SIGMACERF are defined by ontologies which cannot be changed by end-users. SIGMACERF utilizes internal controls at every step of processes that create or manipulate records to ensure that only appropriate actions and steps of action sequences and workflows are permitted.</p>

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11.1	Controls for Closed Systems		
	<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>	Compliant	<p>SigmaCERF provides authority checks throughout user operation of the software, including all actions that add or modify records or signatures. The system requires that an operator has an active SigmaCERF account and has logged in with a valid user name and password before any actions can be taken. Once logged in (and until manual or system initiated logout or timeout), a session identifier is passed with every user action to ensure that the operation is specified by the authenticated user. If available actions or user access rights change during SIGMACERF operation, the effects will be propagated to the user and thereby modify or deny access or other privileges and actions.</p> <p>Allowable SigmaCERF actions are offered to the operator as dynamically created, context-dependent menus and tool bars. Inappropriate actions cannot be specified (such inputs are not made available in the interface) and would be rejected by the SigmaCERF server if somehow delivered (such as if record status changed immediately after selection of an action).</p> <p>Workflows such as digital signatures require that an authorized user with an active SigmaCERF session selects a record that the user has contributed to SigmaCERF, with requirements that the record is in a signable state, and that the record is owned by a workgroup for which the signer has required co-signers available (if needed) and that the user enters a valid signature password.</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>	Compliant	<p>SigmaCERF can be configured to accept data or other instructions from specific devices. SigmaCERF utilizes the same controls as for user operation, such as requiring a device name and password to create an active session, and may add additional checks, such as validation of data or device IP address requirements. The user organization is responsible for ensuring the security of access to external devices and computers when not operated manually by an authorized SigmaCERF user.</p>

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11.1	Controls for Closed Systems		
	<p>11.10(i), (j), and (k)</p> <p>(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>(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>(k) Use of appropriate controls over systems documentation including:</p> <p>(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.</p> <p>(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.</p>	<p>See Details</p> <p>Not Applicable</p> <p>Not Applicable</p> <p>See Details</p> <p>Compliant</p> <p>Not Applicable</p>	<p>The ability of SigmaCERF to meet these requirements is dependent upon the operational controls and procedures established at the client site. Systat Software Inc will assist the user organization in developing and implementing appropriate recordkeeping and electronic signature policies. Systat Software Inc offers training in operation of the SigmaCERF software and can make recommendations on recordkeeping and electronic signature practices. The client organization is responsible for ensuring that users have appropriate training and experience to perform their assigned tasks, including maintaining lab records and signing their lab notebooks. The client organization is responsible for developing and following written policies (SOPs) for electronic signatures, SigmaCERF signature workflows and lab recordkeeping practices.</p> <p>Systat Software Inc provides system administration documentation to the client. The client is responsible for disseminating or controlling access to operational and maintenance documents, and also for managing system passwords for administrators.</p> <p>Systat Software Inc supplies new system operation and administration documents and release notes with its installation and updates of SigmaCERF. The client organization is responsible for maintaining records and audit trails for any SigmaCERF system, SigmaCERF component, or policy changes that are made to its system.</p>

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11.3	Controls for Open Systems		
	<p>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.</p>	Not Applicable	<p>SigmaCERF is considered a closed system. However, SigmaCERF does support all the necessary procedures and controls for managing electronic records in an open system, including encryption of documents and all communications between client and server.</p>

11.3	Signature Manifestations		
	<p>11.50(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:</p> <ul style="list-style-type: none"> (1) The printed name of the signer; (2) The date and time when the signature was executed; and (3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature. 	Compliant	<p>Signed electronic records in SigmaCERF contain the full printed name of signer, date/time when the signature was executed, the meaning of the signature, the role of the signer, and any comments provided by the signer. The system administrator can configure various signature roles, such as Submitter, Peer Reviewer (Witness), Manager/Approve, and Legal/Regulatory acceptance. The SigmaCERF administrator can also configure various signature workflows (for example, a single witness for Project documents, a Manager approval for lab SOPs, and two witnesses and a Manager for lab notebook pages). User authority for signatures can be restricted to specific roles, documents/records and work events.</p>
	<p>11.50(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>	Compliant	<p>Electronic signature records are fully secure from unauthorized access, and can be displayed or printed for any electronic record. Notebook printing can be configured to meet the signature requirements of the client.</p>

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11.7	Signature Record/Linking		
	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	Compliant	Once an E-signature (a PKI digital signature in SigmaCERF) is applied to a lab notebook page/entry, file object, or other SigmaCERF resource, an irrevocable link is established between the signature and the object. The E-signature cannot be deleted, copied or otherwise transferred to falsify the electronic record. A Rescentris PKI digital signature is cryptographically based on the object contents and cannot be falsified or tampered with, nor can the object signed be modified without invalidating the E-signature.

Subpart C- Electronic Signatures

11.1	General Requirements		
	11.100(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else	Compliant	SigmaCERF enforces the uniqueness of each user ID/password combination, and further requires an additional Digital Signature password. The signature cannot be reused or reassigned to anyone else, even after the original user id has been deactivated or is no longer active. The private key used to generate the digital signature is unique and not known or accessible to anyone else.
	<p>11.100(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>11.110(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 submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.</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>	Not Applicable	These are dependent upon the operational controls and procedures established at the client. It is the client organization's responsibility to verify the identity of its SigmaCERF users and to maintain and submit records for each user certifying that their electronic signatures (E-signatures, digital signatures) in SigmaCERF are intended to be the legally binding equivalent of traditional handwritten signatures. Any additional requirements, certifications, or testimonies regarding an organization's use of electronic signatures is the responsibility of the client. Systat Software Inc can assist its clients in planning and implementing E-signature policies and practices.

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11.2	Electronic Signature Components and Controls		
	<p>11.200(a)(1) Electronic signatures that are not based upon biometrics shall: Employ at least two distinct identification components such as an identification code and password.</p>	<p>Compliant</p>	<p>SigmaCERF employs a model that requires a unique user id and password combination for general SigmaCERF system access (for the thick client software or the web interface). Users must be logged into SigmaCERF using this pair of credentials and have an authorized active SigmaCERF session in order to be able to electronically sign a document or record. Then, a third identification component, a digital signature password, is required to complete the signing process.</p>
	<p>11.200(a)(1)(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.</p>	<p>Compliant</p>	<p>To execute a series of signings, a SigmaCERF user must first create an authorized user session by supplying a unique combination of user id and password. During a single, continuous period of controlled system access, the user may then sign numerous or multiple documents, resources, or other lab records by using the third electronic signature component, known only to the signer, which is the digital signature password.</p>
	<p>11.200(a)(1)(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.</p>	<p>Compliant</p>	<p>Each time an individual executes signings not performed during a single, continuous period of controlled system access, the user must first be authenticated by the SigmaCERF server with the two signature components of unique user id and password. Then, once authorized, the user may execute one or more electronic signatures with the third signature component, the digital signature password. Any break in the controlled system access – whether manual or automatic – terminates the user session and requires all signature components in order to execute additional electronic signatures.</p>

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11.2 Electronic Signature Components and Controls		
	<p>11.200(a) Electronic signatures shall: (2) Be used only by their genuine owners; and (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.</p>	<p>Compliant</p> <p>Executing an electronic signature in SigmaCERF requires a unique combination of user id and password plus a third component, the digital signature password. When a system administrator adds a new user or resets a password, the SigmaCERF user must change the password before being able to create a new user session. The login password is therefore known only to the individual user, and not to the administrator or to other users. The individual is also responsible for creating or updating the digital signature password, which is encrypted and not known to the administrator or other users. Furthermore, it is actually the private digital signature key that is used to sign lab records, and this key is not known to anyone (it is calculated from the user credentials).</p> <p>SigmaCERF electronic signatures are administered and executed to ensure that the only way anyone other than the genuine owner of the could sign with the individual's electronic signature is for a system administrator to collaborate with another user and to supply that other user with signature components (user id and password) so that this other user could log in and change the rightful user password and then update the digital signature password, and then finally, while supplying all the credentials of the genuine owner, execute a signature. In SigmaCERF, these activities would be logged.</p> <p>Furthermore, the genuine owner would discover upon next attempted login that the system access password had been changed, then later, upon attempting an electronic signature, that the digital signature password had been changed. This would, presumably result in an investigation which would uncover the series of events and co-conspirators who enabled a fraudulent signature. It is the client's responsibility to protect and not share user passwords</p>
	<p>11.200(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners</p>	<p>Not Applicable</p> <p>Use and maintenance of biometric devices and software is outside the scope of the SigmaCERF system. Systat Software Inc will advise its clients on the use of such methods for signatures, and may offer customized solutions for use of biometrics for electronic signatures.</p>

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11.3	Controls for Identification Codes/Passwords		
	<p>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</p>	Compliant	<p>SigmaCERF provides robust controls for use of identification codes/passwords in electronic signatures. These controls ensure the security and integrity of digital signature identification components in SigmaCERF.</p>
	<p>11.300(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.</p>	Compliant	<p>Uniqueness of each user id and password combination is enforced – no two individuals may have the same user id in SigmaCERF. SigmaCERF business policies also control the required complexity of the password, such as password length and the number of non-alphabetic characters required.</p>
	<p>11.300(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging</p>	Compliant	<p>Password aging is fully supported by SigmaCERF. System business policies specify the frequency of required password renewals (every thirty days is a common setting). The user is first challenged to re-enter the current password before submitting a new password that must be different, meet organizational requirements for password complexity, and be entered twice identically in order for the password to be accepted.</p>
	<p>11.300(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.</p>	Not Applicable	<p>SigmaCERF does not use identification devices. However, the SigmaCERF administrator has authority to disable user accounts and to reset passwords. Users are required to modify their passwords immediately on login following a password reset.</p>

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11.3	Controls for Identification Codes/Passwords	
	<p>11.300(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.</p>	<p>Compliant</p> <p>SigmaCERF offers several transaction safeguards to prevent unauthorized use, or attempted use, of the software. SigmaCERF can be set by the administrator to disable an account after a series of three incorrect logins (for example, three attempts with the wrong password). For security, only the administrator can re-enable the account for the genuine owner. Administrators can also specify a time-out period of inactivity after which a log-out is forced automatically by the system; after this, a user must login again with user id and password to create a new user session. If a user is known to be gone for a long period, the account can be temporarily inactivated by the administrator, thus preventing any system access or electronic signatures associated with the user id of that individual. SigmaCERF prevents any user from having more than one active session at a given time. If a user logs into SigmaCERF successfully, then goes to another computer and attempts to login, the individual is informed that there is already an active session at another IP address. They can choose to log onto a new SigmaCERF session, closing the previous session, or they can return to the other computer. All of these transactions are logged and available for monitoring and reporting by the administrator, who can investigate any unauthorized SigmaCERF use or attempted use, and can present these reports to organizational management.</p>
	<p>11.300(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.</p>	<p>Not Applicable</p> <p>SigmaCERF user authentication does not use devices or tokens for user identification. Systat Software Inc does recommend periodic verification of system security and documentation of testing practices and results. (Systat Software Inc performs these tests with all new updates to the SigmaCERF software system before release.) If clients desire to use identification devices, Systat Software Inc will offer consulting and customization services. Periodic testing after initial SigmaCERF deployment is dependent upon the operational controls and procedures established at the client.</p>