

EPA OW SDWIS/LabToState - CROMERR System Checklist

CROMERR System Checklist	
Item	SDWIS/Lab To State
Registration (e-signature cases only)	
1. Identity-proofing of registrant	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA. Does Not Apply</p>
	<p>System Functions:</p>
	<p>Supporting Documentation (list attachments):</p>
1a. (priority reports only) Identity-proofing <i>before</i> accepting e-signatures	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA. Does Not Apply</p>
	<p>System Functions:</p>
	<p>Supporting Documentation (list attachments):</p>
1b. (priority reports only) Identity-proofing method (See 1bi, 1bii, and 1b-alt)	
1bi. (priority reports only) Verification by attestation of disinterested individuals	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA. Does Not Apply</p>
	<p>System Functions:</p>
	<p>Supporting Documentation (list attachments):</p>

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1bii. (priority reports only) Information or objects of independent origin	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA. Does Not Apply</p>
	<p>Business Practices:</p>
	<p>System Functions:</p>
1b-alt. (priority reports only) Subscriber agreement alternative	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA. Does Not Apply</p>
	<p>System Functions:</p>
	<p>Supporting Documentation (list attachments):</p>
2. Determination of registrant's signing authority	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA. Does Not Apply</p>
	<p>System Functions:</p>
	<p>Supporting Documentation (list attachments):</p>

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3. Issuance (or registration) of a signing credential in a way that protects it from compromise	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA. Does Not Apply</p>
	<p>System Functions:</p>
	<p>Supporting Documentation (list attachments):</p>
4. Electronic signature agreement	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA. Does Not Apply</p>
	<p>System Functions:</p>
	<p>Supporting Documentation (list attachments):</p>
Signature Process (e-signature cases only)	
5. Binding of signatures to document content	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA. Does Not Apply</p>
	<p>System Functions:</p>
	<p>Supporting Documentation (list attachments):</p>

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6. Opportunity to review document content	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA.</p> <p>Does Not Apply</p> <p>System Functions:</p> <p>Supporting Documentation (list attachments):</p>
7. Opportunity to review certification statements and warnings	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA.</p> <p>Does Not Apply</p> <p>System Functions:</p> <p>Supporting Documentation (list attachments):</p>
Submission Process	
8. Transmission error checking and documentation	
	<p>Business Practices: Transmission error checking and documentation will be implemented through SSL and the state selects the version of SSL consistent with their operational environment.</p> <p>If the state elects not to implement SSL, the state must establish its own business practice to support transmission error checking. Note: The state must describe those business practices in the supplemental CROMERR checklist submitted by the state.</p>

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	<p>System Functions: Each primacy agency may elect to implement SSL for transmission error checking.</p>
	<p>Supporting Documentation (list attachments):</p>
9. Opportunity to review copy of record (See 9a through 9c)	
9a. Notification that copy of record is available	
	<p>Business Practices: After the laboratory uploads the sample data file, SDWIS/LabToState validates it against published XML schemas. When the file is uploaded, the laboratory user specifies the one or more e-mail addresses of the people to be notified that the validation is completed. After validation, an e-mail is automatically sent using the e-mail addresses specified during the upload. Additionally, each User Account includes a registered e-mail address. The validation confirmation e-mail is also sent to the e-mail address registered with the User Account of the person uploading the sample data.</p> <p>After validation, the certifier reviews the sample data and approves the sample data by accepting the certification statement. This procedure creates the copy of record. After certification, an automated e-mail is delivered to the e-mail registered with the User Account of the certifier. SDWIS/LabToState provides the ability for a laboratory to upload sample data formatted in an XML document or as comma-separated-values (CSV) in a text file. If the sample data is formatted in CSV files, SDWIS/LabToState generates an XML document containing that data. Regardless of whether SDWIS/LabToState generates the XML document or receives it from the laboratory, it is the XML document that is reviewed and certified. The XML document becomes the principle component of the Copy of Record when it is certified. Note: Please refer to 18c for a more complete description of the COR.</p>
	<p>System Functions: SDWIS/LabToState automatically sends an e-mail indicating the uploaded sample data is validated and ready for review and certification by the laboratory. The automated e-mail is sent to those e-mail addresses specified by the person that uploaded the sample data and to the e-mail address registered with that person's User Account.</p> <p>SDWIS/LabToState also automatically sends an e-mail indicating the sample data has been certified. That e-mail is delivered to the e-mail address registered with the certifier's User Account.</p>
	<p>Supporting Documentation (list attachments):</p>

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9b. Creation of copy of record in a human-readable format	
	<p>Business Practices: None.</p>
	<p>System Functions: SDWIS/LabToState will present the XML document in an HTML format using an XSLT stylesheet. Although the style sheet is not contained in the COR, it is available by the application and may be used to render the COR in human readable format.</p>
	<p>Supporting Documentation (list attachments):</p>
9c. Providing the copy of record	
	<p>Business Practices: The laboratory certifies the uploaded sample data at which time it becomes the principle component of the Copy of Record. The laboratory can download the uploaded sample data before, during, or after the certification process. Only after the uploaded data has been certified can the full, official Copy of Record be downloaded.</p> <p>The primacy agency establishes a retention period, which is the number of days (e.g., 90 days, 180 days) that the copy of record is retained by SDWIS/LabToState after certification. Any time during the retention period, the laboratory may review and download copy of record using functionality offered by SDWIS/LabToState. After the retention period has elapsed, it is the responsibility of the primacy agency to archive the copy of record and develop procedures for the laboratory to request and receive it.</p>
	<p>System Functions: SDWIS/LabToState offers a capability allowing the laboratory to download the copy of record.</p>
	<p>Supporting Documentation (list attachments):</p>
10. Procedures to address submitter/signatory repudiation of a copy of record	
	<p>Business Practices: Note: If a state allows changes to the sample data, the state must describe those procedures in the supplemental CROMERR checklist submitted by the state.</p>

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	<p>System Functions:</p>
	<p>Supporting Documentation (list attachments):</p>
11. Procedures to flag accidental submissions	
	<p>Business Practices: The sole functionality offered by SDWIS/LabToState is the submission of sample data to the primacy agency and that functionality is granted to the user after he/she enters a User ID and password. After obtaining access to the application, the user navigates from the home page to a separate and discrete web page whose only purpose is to upload sample data. Then, the user enters 3 separate data elements. If any of the data elements are not supplied, he/she receives an error. After entering the data, the user makes a discrete request to upload the data by clicking the "Process" button.</p> <p>By implementing the business practices described, it is almost impossible for the user to accidentally upload sample data. However, SDWIS/LabToState automatically sends an e-mail to the address registered with the user's account. Therefore, if he/she does accidentally upload sample data, he/she receives the e-mail and he/she is given ample opportunity to remove the uploaded sample data before it is submitted to and processed by the back-end data system.</p>
	<p>System Functions: SDWIS/LabToState offers the following capabilities: grants application access using a User ID and password; offers a separate web page from which the user uploads sample data; automatically sends an e-mail to the address registered with the user's account; allows users to remove uploaded sample data before it is submitted to and processed by the back-end data system.</p>
	<p>Supporting Documentation (list attachments):</p>
12. (e-signature cases only) Automatic acknowledgment of submission	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA.</p>
	<p>Does Not Apply</p>

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	<p>System Functions:</p> <p>Supporting Documentation (list attachments):</p>
Signature Validation (e-signature cases only)	
13. Credential validation (See 13a through 13c)	
13a. Determination that credential is authentic	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA.</p> <p>Does Not Apply</p> <p>System Functions:</p> <p>Supporting Documentation (list attachments):</p>
13b. Determination of credential ownership	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA.</p> <p>Does Not Apply</p> <p>System Functions:</p> <p>Supporting Documentation (list attachments):</p>

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13c. Determination that credential is not compromised	
	Business Practices: Note: If e-signature is required, please consult with EPA.
	Does Not Apply
	System Functions:
	Supporting Documentation (list attachments):
14. Signatory authorization	
	Business Practices: Note: If e-signature is required, please consult with EPA.
	Does Not Apply
	System Functions:
	Supporting Documentation (list attachments):
15. Procedures to flag spurious credential use	
	Business Practices: Note: If e-signature is required, please consult with EPA.
	Does Not Apply
	System Functions:
	Supporting Documentation (list attachments):

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16. Procedures to revoke/reject compromised credentials	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA.</p> <p>Does Not Apply</p> <p>System Functions:</p> <p>Supporting Documentation (list attachments):</p>
17. Confirmation of signature binding to document content	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA.</p> <p>Does Not Apply</p> <p>System Functions:</p> <p>Supporting Documentation (list attachments):</p>
Copy of Record	
18. Creation of copy of record (See 18a through 18e)	
18a. True and correct copy of document received	
	<p>Business Practices: The laboratory's certifier may review the sample data, which is stored on the application server, any time prior to and after certification. During the certifier's review, he/she can access and download the sample data from SDWIS/LabToState and compare it to what was originally submitted by the laboratory. He/she can compare record counts aggregated by SDWIS/LabToState to the record counts uploaded by the laboratory. All certifiers can access SDWIS/LabToState and review sample data submitted by their facility. This review process, supported by the fact that a laboratory can submit a corrected sample data file any time before certification ensures that a true and correct copy of what was submitted by the laboratory is received by EPA.</p>

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	<p>SDWIS/LabToState provides the ability for a laboratory to upload sample data formatted in an XML document or as comma-separated-values (CSV) in a text file. If the sample data is formatted in CSV files, SDWIS/LabToState generates an XML document containing that data. Regardless of whether SDWIS/LabToState generates the XML document or receives it from the laboratory, the XML document becomes the principle component of the Copy of Record when it is certified. Note: Please refer to 18c for a more complete description of the COR.</p>
	<p>System Functions:</p> <p>During certification, SDWIS/LabToState generates a digital hash of the each submitted file and each XML document generated from the uploaded sample data. The Hash file and the file from which the Hash is generated are compressed (e.g. zipped). The zip file, which contains the COR and its hash, are submitted to the backend data system. Additionally, the Hash is logged and tracked in SDWIS/LabToState's internal database. If the COR is changed in any way, a rehash would produce a completely different digital hash. Although not automatically done so, the rehash may be compared to the hash included in the compressed file that is transferred to the backend data system and it can also be compared to the hash logged and tracked in SDWIS/LabToState's embedded database providing redundancy to the hash check.</p> <p>Additionally, the user may view the COR in human readable format using the application, which renders it in HTML using an XSLT style sheet. Although not automatically done so, the XSLT style sheet remains available to render the COR in an HTML format after the COR is archived.</p> <p>The COR is used to compute the value of the hash using hash algorithm (SHA-256). The hash is encrypted, logged and tracked in a separate table in SDWIS/LabToState's internal database. If the signed file(s) change in any way, a rehash of the file will not result in the same digital hash that is maintained with the file and logged in the tracking database. Although not automatically done so, the hash could be recalculated and compared to the digital hash maintained in the tracking database. The tracking database is embedded with the SDWIS/LabToState software, which is deployed on the application server. Direct access to the database is only available on the machine hosting the application.</p> <p>Any State that proposes to use this tool will need to assure EPA that at least one of the databases to which the COR is committed is read-only. Failing that, the State will need to show that changes to the database are automatically tracked in an audit log (as a system function, not a business practice) or, else, access to the database limited to a single person. This is needed to defeat any defense that the COR was changed and the new hash substituted for the old by Agency personnel.</p>
	<p>Supporting Documentation (list attachments):</p>

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18b. Inclusion of electronic signatures	
	<p>Business Practices: Note: If e-signature is required, please consult with EPA.</p> <p>Does Not Apply</p> <p>System Functions:</p> <p>Supporting Documentation (list attachments):</p>
18c. Inclusion of date and time of receipt	
	<p>Business Practices: The laboratory may list all of the sample data submissions uploaded by its facility using SDWIS/LabToState's Job Listing page. The Job Listing page contains who and when the sample data was uploaded and certified, the physical file name of the uploaded data.</p> <p>System Functions: SDWIS/LabToState assigns a unique number, referred to as a Job ID, to each sample data submission uploaded by the laboratory. That Job ID is logged in its tracking database. All sample data submissions received by SDWIS/LabToState are applied a date/time stamp when the data is uploaded as well as the User ID of the person who uploaded the data. Another date/timestamp is applied when the sample data submission is certified as well as the User ID of the person who certified it. This information is made available to the laboratory using the Job Listing page. SDWIS/LabToState will include in the COR the date, time, and user who submitted the data. It will also include the date, time, and user who certified the XML document. SDWIS/LabToState generates the hash after these elements are included in the COR. The hash is logged and tracked in the database.</p> <p>Supporting Documentation (list attachments):</p>
18d. Inclusion of other information necessary to record meaning of document	
	<p>Business Practices: The laboratory reviews all the metadata about the sample data file before and after it is certified.</p>

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	<p>System Functions: SDWIS/LabToState automatically tracks each submission of sample data by the laboratory. Each submission is assigned a unique tracking number referred to as a Job ID. The Job ID and other metadata about the submission are logged in a tracking database. The metadata includes date and time the sample data is uploaded; the User ID of the person who uploaded the sample data; a flag indicating whether the sample data is certified; the date and time the sample data is certified; the User ID of the person certifying the sample data; the physical name (i.e., the full path and name of the file on the file system) of the uploaded sample data file(s); the physical name of the generated XML document(s); a logical delete flag, the digital hash of each sample data file(s) uploaded and each XML document generated. Metadata about the submission is made available to the laboratory on SDWIS/LabToState's Job Listing page.</p> <p>SDWIS/LabToState also aggregates summary counts for each sample data submission. Those counts include the number of records submitted by record type and the number of records in which validation errors were detected. These summary counts are made available to the laboratory in a Summary report. SDWIS/LabToState also validates the sample data against published XML schemas. The application generates Detail Error reports that clearly identify the record in which the error is detected. The Detail Report also contains a concise text message that describes the error.</p> <p>Both the Summary and Detail Error report are available to the user for review before he/she certifies the sample data. The reports and XML document(s) may also be downloaded to the user's local file system.</p> <p>SDWIS/LabToState will include in the COR the date, time, and user who submitted the data. It will also include the date, time, and user who certified the XML document. SDWIS/LabToState generates the hash after these elements are included in the COR. The hash is logged and tracked in the database.</p>
	<p>Supporting Documentation (list attachments):</p>
18e. Ability to be viewed in human-readable format	
	<p>Business Practices: The laboratory may view and download the XML document both before and after certified.</p>
	<p>System Functions: SDWIS/LabToState generates XML documents containing sample data created and uploaded by the laboratory. Each piece of sample data in the XML document is tagged using a human-readable name that clearly and concisely identifies the tag's content. The XML Schemas used by SDWIS/LabToState are fully documented.</p>

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	<p>Supporting Documentation (list attachments): SDWIS/XML Sampling Mapping Document and Accompanying Schemas (December 30, 2005) SDWIS/XML Sampling Release 1.0 Users Guide (December 30, 2005)</p>
19. Timely availability of copy of record as needed	
	<p>Business Practices: The laboratory receives an e-mail automatically sent by SDWIS/LabToState when the submitted sample data is ready for review and certification. The e-mail contains a hyperlink allowing the laboratory quick access to the reports and generated XML document(s). By certifying the XML document(s), he/she creates the copy of record. During certification process, the copy of record is available for download by the laboratory. The laboratory also receives an automated e-mail indicating that the submission is certified. The sample data is available for download and viewing both before and during the certification process. After certification, it becomes the copy of record, which is also available for viewing and download. Additionally, the state may establish a user account and assign to that user account a role giving the state user access to all of the submissions by all laboratories.</p> <p>System Functions: After the laboratory uploads the sample data file, SDWIS/LabToState generates an XML document containing that sample data and validates it against the published XML schemas. After validation, SDWIS/LabToState automatically sends an e-mail to the laboratory indicating that the XML documents are ready for review and certification. As part of the certification process, SDWIS/LabToState automatically sends an e-mail to the laboratory indicating that the submission is certified. Both before, during and after the certification process, SDWIS/LabToState provides the laboratory with the ability to download the sample data. After the sample data is certified and becomes the COR, it can also be downloaded.</p> <p>SDWIS/LabToState provides a list page with sorting capabilities. The list page can be sorted by the assigned Job ID, the physical name of the submitted file, the date on which it was submitted, whether the file is certified, the user who submitted the file, the date on which it was certified, and the user who certified the file. Since the list page is presented in the standard browser, the user may use the standard "Find" command to search for a specific submission.</p>
	<p>Supporting Documentation (list attachments):</p>
20. Maintenance of copy of record	
	<p>Business Practices: Each primacy agency establishes a retention period, which is the number of days (e.g., 90 days, 180 days) the copy of record will be retained by SDWIS/LabToState after certification. After the retention period, the primacy agency archives the copy of record. Any time during the retention period, the laboratory may review and download copy of record. Note: The state must describe archival procedures in the supplemental CROMERR checklist submitted by the state.</p>

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	<p>System Functions: SDWIS/LabToState logs each submission in a database using a unique tracking number referred to as a Job ID. Along with the Job ID, the tracking database also logs other metadata, which includes the date and time the sample data is uploaded; the User ID of the person who uploaded the sample data; a flag indicating whether the sample data is certified; the date and time the sample data is certified; the User ID of the person certifying the sample data; the physical name of the uploaded sample data file(s); the physical name of the generated XML document(s). The physical files are maintained on the application server's file system.</p> <p>SDWIS/LabToState is an operational system and permanent archiving is outside the scope of its requirements. Each state defines archiving procedures consistent with its all of its operational environment.</p> <p>Supporting Documentation (list attachments):</p>