Agilent OpenLAB CDS ChemStation Edition with Central Data Storage

Concepts Guide

Agilent Technologies

Notices

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Software Revision

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In This Guide ...

This guide contains reference information on the interface between Agilent OpenLAB CDS ChemStation Edition and the central data storage provided by OpenLAB ECM or OpenLAB Data Store. It also describes the settings required by 21 CFR Part 11, and provides information on the workflows for ChemStation using a central data storage.

1 Introduction

This chapter introduces the integration of a central data storage (OpenLAB ECM or OpenLAB Data Store) with OpenLAB CDS ChemStation Edition. It also describes the requirements of 21 CFR Part 11. In the following, the term ChemStation refers to Agilent OpenLAB CDS ChemStation Edition.

2 Basic Concepts

This chapter describes how to log in to the central data storage system in ChemStation, explains the user interface items and toolbars related to the central data storage, and describes the main preference settings.

3 Working with ChemStation and Central Data Storage

This chapter describes the basic workflows for ChemStation with a central data storage system. There are four data-related workflows and two workflows for methods, sequence templates, or report templates.

4 Administration Regarding 21 CFR Part 11 Compliance

This chapter explains the purpose of 21 CFR Part 11 and how the integration of ChemStation with a central data storage system addresses the requirements of 21 CFR Part 11.

5 Filter and Search Options

This chapter provides an overview of the filter and search options for ChemStation data in the central data storage system.

6 Troubleshooting

The chapter gives some elementary troubleshooting hints.

7 Appendix

Contents

1 Introduction

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Terms and Abbreviations

Table 1 Terms and Abbreviations used in this document

Term	Description
ChemStation	OpenLAB CDS ChemStation Edition
EZChrom	OpenLAB CDS EZChrom Edition
Data Store	OpenLAB Data Store
ECM	OpenLAB Enterprise Content Manager
RC .Net	RapidControl .Net Interface

What is a Central Data Storage?

Agilent provides two systems for central data storage:

- *OpenLAB Data Store*, which is available as an all-in-one server installation as an option with OpenLAB CDS. It is designed for small laboratories with up to 15 instruments.
- *OpenLAB ECM*, which is available as a standalone product. It is designed for laboratories with more than 15 instruments.

Both systems are web-based electronic libraries that allow you to safely archive and catalog any electronic file. You can store and index analytical raw data, reports, and all other types of documents. The stored files can be shared with other users.

You can store any electronic file type, such as Microsoft Office documents, Adobe PDF documents, images, and molecular drawings, as well as raw data and reports generated by ChemStation.

Either of these central data storage systems allow you to easily collect, organize, search, and review all of your data. They automatically extract searchable metadata from files, and provide powerful search capabilities. ECM additionally provides embedded viewers for many file types.

The interface to the central data storage system is opened via Microsoft Internet Explorer, also referred to as the web client.

In this document, the terms *central data storage* or *central repository* refer to instances of either OpenLAB ECM or OpenLAB Data Store. As the interface and workflows for both systems are very similar, the specific product names are only used in places where there is a difference in associated concepts or procedures.

Using ChemStation with Central Data Storage

OpenLAB CDS ChemStation Edition provides an interface to the central data storage, which enable you to store analytical data and reports in a secure location. From ChemStation, you can log in to the central data storage and store all kinds of ChemStation files in the central data repository:

- Methods (*.m)
- Sequence templates (*.s)
- Data files (*.d)
- Report templates for Intelligent Reporting (*.rdl)
- Reports (*.pdf, *.xls, *.doc, or *.txt)
- Library files (*.uvl)
- Column databases (*.mdb)
- Easy Sequence templates (*.est)
- Classic report templates (*.frp)

The storage of ChemStation data can be either automatic (that is, at the end of a single run or sequence) or manual. The data can later be downloaded to ChemStation for review or reprocessing at any time.

Furthermore, OpenLAB CDS ChemStation Edition in combination with central data storage offers features that enable users to comply with 21 CFR Part 11 and similar regulations for electronic records and electronic signatures:

- Mandatory login/connection to the central data storage system
- Configurable session locking
- Configurable ChemStation user roles and privileges
- Full data traceability through audit trails for methods and results
- Full data versioning

You can use *OpenLAB ECM* in the following installation scenarios:

- Workstation
- Networked Workstation
- Distributed System

You can use *OpenLAB Data Store* in the following installation scenarios:

- Networked Workstation
- Distributed System

The main workflows for the transfer of raw data and methods/sequence templates/report templates are listed below. These workflows indicate the system activities in relation to the work processes.

Overview of data-related workflows

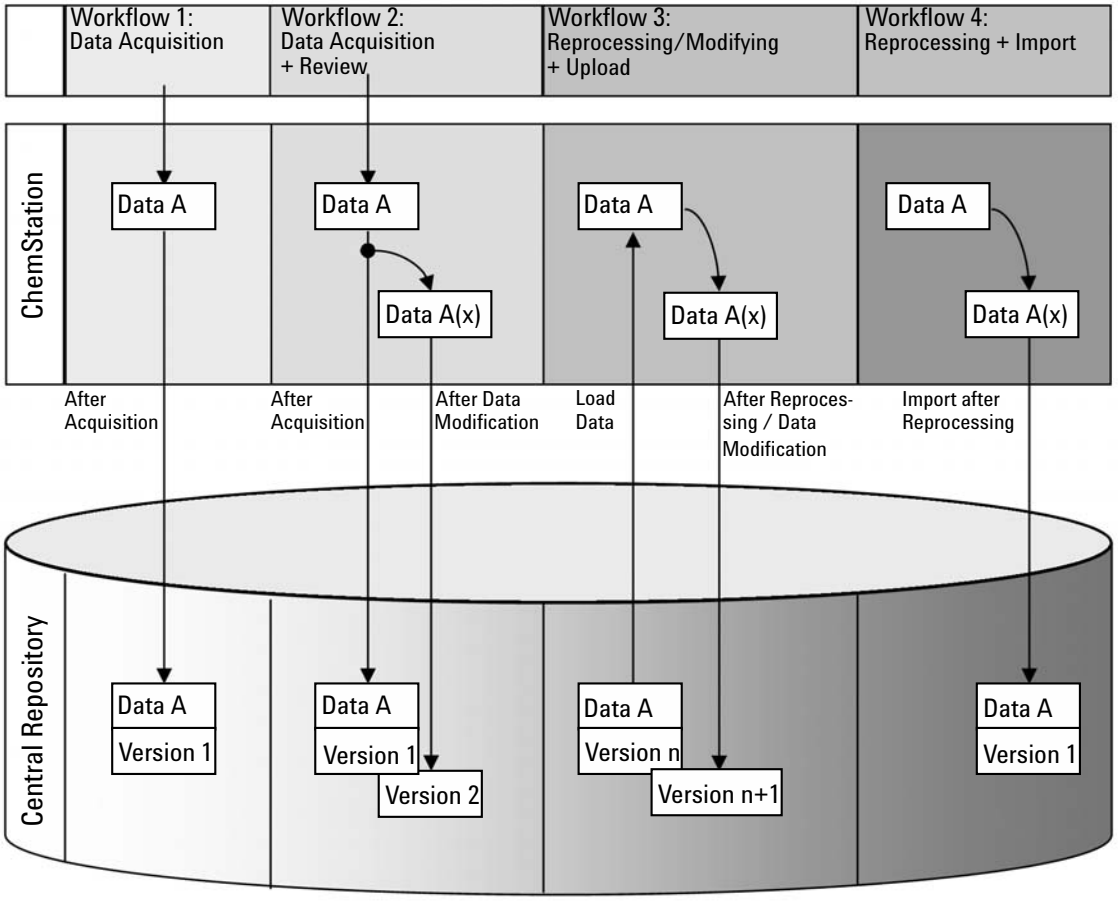


Figure 1 Overview of data-related workflows

Workflow 1: Raw data acquisition and automatic transfer to the central repository

1 Analytical raw data is acquired using ChemStation.

2 The raw data is automatically uploaded to the central repository using the configured path definitions immediately after the single run/sequence is finished.

3 The data is added to the defined storage location.

Workflow 2: Offline revision during acquisition

1 Analytical raw data is acquired using ChemStation.

2 While the acquisition is still running, part of the data is changed using an offline ChemStation.

3 The raw data is automatically uploaded to the central repository using the configured path definitions immediately after the single run/sequence is finished.

The initial version of the data is added to the defined storage location.

4 After work in the offline ChemStation is finished, the changed data is also automatically uploaded to the central repository.

The second version of the data is added to the central repository.

Workflow 3: Reprocessing data and automatic upload to the central repository

1 Existing analytical data is loaded from the central repository into ChemStation.

2 The data is reprocessed in ChemStation.

3 The data is automatically uploaded to the central repository. The storage location in the repository is defined by the original path definitions of the downloaded data.

4 A new version of the data is added to the central repository.

Workflow 4: Import after reprocessing

1. Existing analytical data is opened locally.
2. The data is reprocessed in ChemStation.
3. After reprocessing, the data is automatically uploaded to the central repository. The storage location in the repository is defined by the current preferences in ChemStation.
4. The initial version of the data is added to the central repository.

Overview of workflows for methods/sequence templates/report templates

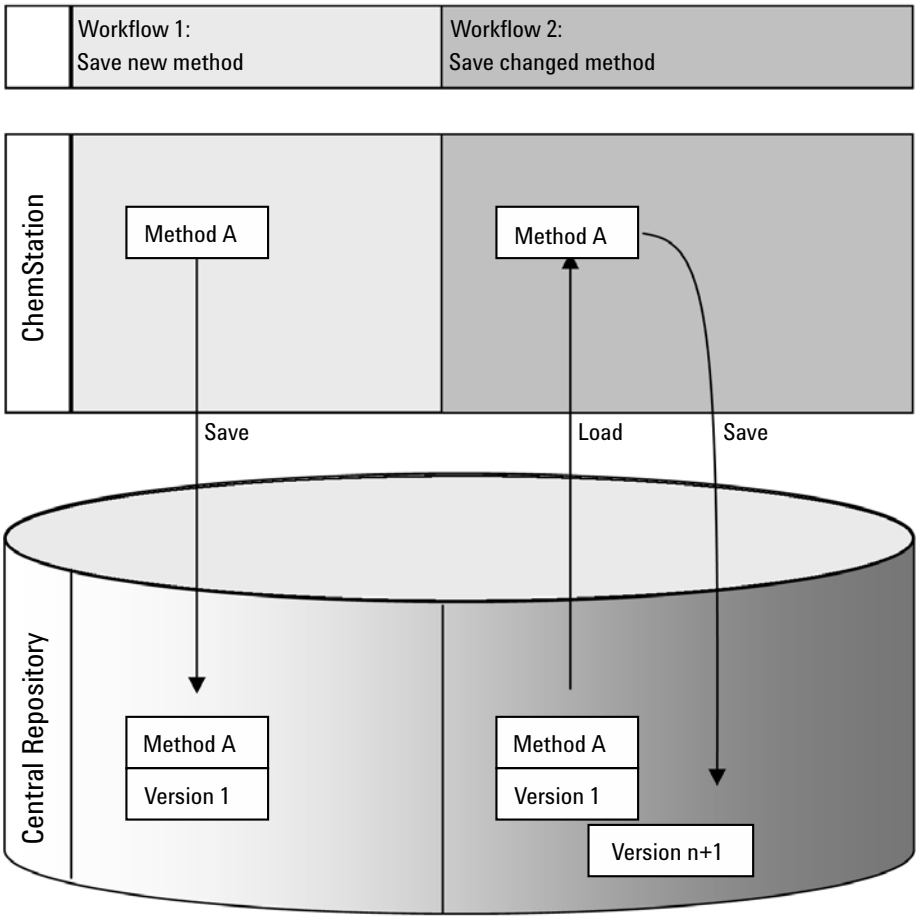


Figure 2 Overview of workflows for methods, sequence templates, or report templates

Workflow 1: Uploading a new method, sequence template or report template

1 A new method, sequence template, or report template is created.

2 The method, sequence template, or report template is uploaded to the central repository using the path selected by the user.

3 The version 1 of the method, sequence template, or report template is automatically created in the central repository.

Workflow 2: Saving a changed method, sequence template or report template

1 An existing method, sequence template, or report template is loaded from the central repository.

2 The method, sequence template, or report template is modified in ChemStation.

3 The changed method, sequence template, or report template is saved to the central repository.

4 A new version of the method, sequence template, or report template is automatically created in the central repository.

Storage Model in OpenLAB ECM and OpenLAB Data Store

File Management in ECM

ECM provides a four-level data storage model with the structure of Location, Cabinet, Drawer, Folder. The Location, Cabinet, Drawer and Folder names comprise the path name (called either LCDF path or Remote Data Path) of the storage location. Data is stored at Folder level only.

The ECM program's content structure is similar to rooms filled with file cabinets. Each cabinet has multiple drawers, which contain hanging folders. Finally, paper files are stored in the folders. The LCDF structure can be created using the ECM Web Client. In addition, it is possible to create additional Locations, Cabinets, Drawers, and Folders using the ChemStation Remote Data Path. In ChemStation, it is also possible to set predefined tokens for the Drawers and Folders.

In the ECM tree view, locations are denoted by a house icon. Inside each Location, Cabinets are denoted by the file cabinet icon. Inside each Cabinet, Drawers are denoted by the drawer icon. Finally, inside each Drawer, Folders are denoted by the folder icon. The entire content structure appears in the Content book.

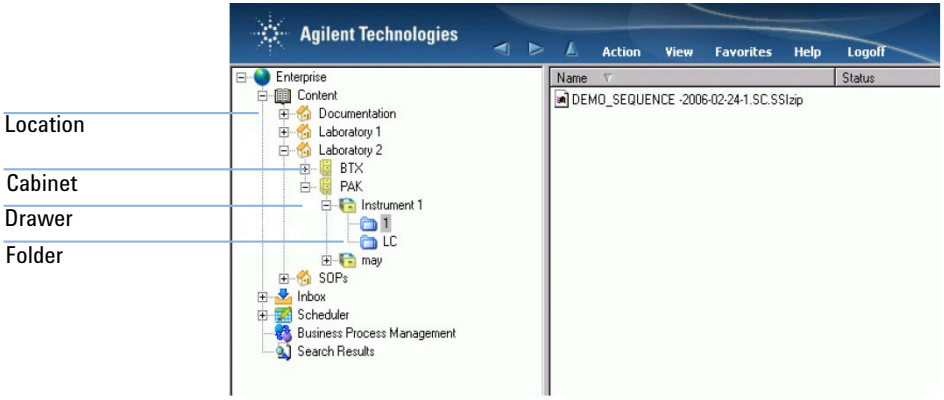


Figure 3 LCDF structure in ECM

Uploaded objects can be stored in the lowest (i.e. Folder) level only. It is not possible to upload data to other levels of the hierarchy.

For convenience, you can use tokens for the Location, Cabinet, Drawer, and Folder. The system then automatically creates the corresponding path elements. The following tokens are available: instrument name, operator name, instrument number, or computer name.

File Management in Data Store

OpenLAB Data Store provides a multi-level storage model. The number of levels is not limited, and you can store your data at any folder level.

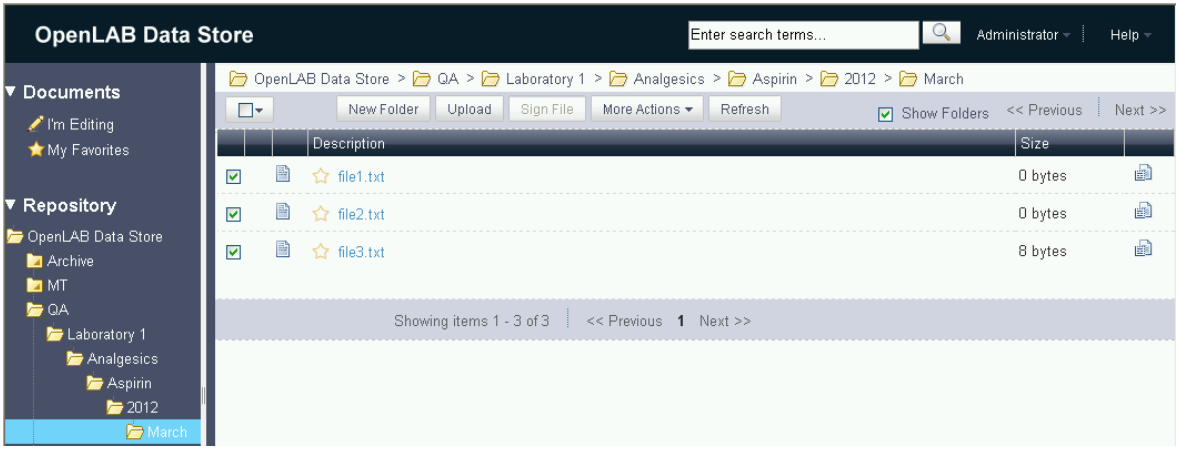


Figure 4 Folder structure in Data Store

For convenience, you can use tokens for all elements of the Remote Data Path. The system then automatically creates the corresponding path elements. The following tokens are available: instrument name, operator name, instrument number, or computer name.

21 CFR Part 11 Compliance

Effective August 20, 1997, the U.S. Food and Drug Administration (FDA) released and published a new rule to enable pharmaceutical companies to approve their results with electronic signatures and to transfer paper-based documentation into electronic records. This rule is known as 21 Code of Federal Regulations Part 11 (referred to as 21 CFR Part 11) and applies to all industry segments regulated by the FDA.

21 CFR Part 11 includes the US Federal guidelines for storing and protecting electronic records and applying electronic signatures. The intent of these guidelines is to ensure that electronic records subject to these guidelines are reliable, authentic, and maintained with high integrity.

OpenLAB CDS ChemStation Edition in combination with OpenLAB ECM or OpenLAB Data Store provides the necessary controls for managing system access, audit trail functions, versioning of ChemStation data, and electronic signature functions. These systems ensure secure record keeping and data archival.

2
Basic Concepts

This chapter describes how to log in to the central data storage system in ChemStation, explains the user interface items and toolbars related to the central data storage, and describes the main preference settings.

Login and Lock Options

User Permissions

You start ChemStation from the OpenLAB Control Panel. To prevent unauthorized access, OpenLAB CDS ChemStation Edition with central data storage requires authentication with a user name and password. With ECM, OpenLAB Shared Services use ECM as an external authentication provider. With Data Store, OpenLAB Shared Services act as the authentication provider. Users can be set up in OpenLAB Shared Services or can be imported from local Windows user management, from Windows Active Directory domain, or from Windows NT 4.0 Domain. You log in with your user credentials of the corresponding system.

You need specific user privileges for working with OpenLAB CDS as well as for working with the central data storage system. You specify the user privileges as follows:

- OpenLAB CDS privileges are set in the OpenLAB Control Panel.
- ECM privileges are set directly in OpenLAB ECM.
- Data Store privileges are set in the OpenLAB Control Panel.

For more information on user privileges, see "Users, Roles, and Privileges Concept with ECM" on page 93 and "Users, Roles, and Privileges Concept with Data Store" on page 95.

User Credentials

The **Login** dialog requires you to enter a set of valid authorization credentials in order to log in to OpenLAB Control Panel.

You need to enter the following login details:

- **Login:** the user name defined in OpenLAB Shared Services.

  With ECM, this is the ECM user, which can be a Windows domain user or an ECM built-in user. With Data Store, this is the OpenLAB Shared Services users, which can be OpenLAB Shared Services internal users, Windows domain users or Windows local users.
- **Password**: the password provided by your administrator, which can be changed on request (for 'built-in' users), or the password of your NT domain account, if you are logging in using your NT domain user name.
- **Domain**: the domain administrating the users

ChemStation Operator Name

ChemStation stores the operator name in the sample info (when running single samples) or in the sequence parameters (when running a sequence). With ECM or Data Store as an authentication provider, this ChemStation operator name is your user name in the data management system. The operator name cannot be overwritten.

Session lock

If you leave the ChemStation computer for a period of time, you can lock ChemStation so that no other user can access the program. This is a safety feature to ensure that there is no unauthorized access to ChemStation. When you activate the session lock, you or another user must first provide a valid login before continuing to work with ChemStation.

In ChemStation, there are the following options to activate the session lock:

- *Privately* (**User > Lock Session > privately**): Only the user who activated the session lock, or a user with the **Break Session Lock** privilege, can log in.
- *Non-privately* (**User > Lock Session > non privately**): Any valid user can log in. This is useful, for example, if there is a shift change, and the leaving personnel secure ChemStation until the personnel of the new shift start work.
- *Toolbar lock button*: The toolbar lock button can be configured to lock the ChemStation session privately or non-privately.
- *Time-based*: Depending on the configuration in OpenLAB Control Panel, ChemStation is automatically locked after a given period of time without any user interaction (**Inactivity Timeout** setting in the Security Policy area of OpenLAB Control Panel).

  The time-based session lock can be configured to lock the ChemStation session either privately or non-privately (see "ChemStation Administration Tool" on page 96).

User Interface in ChemStation Related to the Central Data Repository

Overview of the interface elements

When connected to a central data storage system, additional menus, menu items, and interface elements are available in ChemStation. Depending on the external system, they are automatically labelled either with **ECM** or with **Data Store**.

Menu	Element type	Description
Method	**Enable Audit Trail** Command	See "Method Audit Trail" on page 74. The Method Audit Trail can also be enabled on a system without central data storage.
Sequence > Sequence Parameters	**Sequence Parameters** Tab	See "Remote Data Path as Sequence Parameter" on page 41
Report	**Report History** Command	See "Report History" on page 76
View > Preferences 	Tabs In the **Preferences** dialog: • **Transfer Settings** • **Audit Trail**	See "Preferences" on page 30 and "Audit Trails and Logbooks" on page 74. The Method Audit Trail and Results Audit Trail can also be enabled on a system without central data storage. Therefore the **Audit Trail** tab is visible in the Preferences also in a system without central data storage.
ECM or **Data Store**	**ECM** or **Data Store** Menu	See "The ECM or Data Store menu" on page 27
User	**User** Menu	See "The User menu" on page 29. If authentication has been set up, the **User** menu is also visible on a system without central data storage.

Menu	Element type	Description
Toolbar (depending on the current view)  	• Shortcuts to several commands of the **ECM** or **Data Store** and **User** menus • **LCDF** info	• Path info in the **Data Analysis** view: shows the remote path of a file that has been stored to the central repository. • Path info in the **Method and Run Control** view: shows the remote path for automatic upload after acquisition. • With ECM, the path is shown with backslashes; with Data Store, it uses forward slashes (for example, Location/test/test/test).
Several details related to the central repository in the **System Diagram** in **Method and Run Control** view (classic ChemStation only).	Details view	The following details are available: • **Path** • **Operator** • **Automatic transfer after acquisition** • **Automatic transfer after reprocessing** • **Automatic transfer after any data modification** • **Automatic import after reprocessing**

The ECM or Data Store menu

All commands related to the central repository are available in a separate menu. Depending on the central data storage system, the menu is named either **ECM** or **Data Store**. The menu and its commands depend on the view that is currently active. See the following table for details.

NOTE There is no **ECM** or **Data Store** menu in the **Verification (OQ/PV)** or **Diagnosis** view.

Command	Description	Available in ChemStation views
Update Methods ... **Update Sequences Templates ...**	Update all methods/sequence templates that are stored in the local file system with the current version from the central repository (if it exists there). Local changes are overwritten.	• **Method and Run Control**
Update Report Templates ...	Update all report templates that are stored in the local file system with the current version from the central repository (if it exists there). Local changes are overwritten.	• **Report Layout** (Intelligent Reporting)
Cleanup Data	The **Cleanup Data** command deletes all data or result sets from the local file system that exist in the central repository as well. Make sure you uploaded the latest version to the central repository before you confirm this command. See "Cleanup Data on Shutdown" on page 35.	• **Data Analysis**
Manage Queue	With the **Manage Queue** command you can continue any interrupted data upload to the central repository. See "Manage Queue on Connect" on page 35.	• **Method and Run Control** • **Data Analysis**
 **Preferences**	See "Preferences" on page 30 for more details on the **Preferences** dialog.	• **Method and Run Control** • **Data Analysis** • **Report Layout** (Intelligent Reporting)
Method-related commands:  **Load Method ...**  **Save Method**	See "Workflows for Methods and Templates" on page 59	• **Method and Run Control** • **Data Analysis**

Command	Description	Available in ChemStation views
Data-related commands:  **Load Data ...**  **Save Data** **Save Data As ...**	See "Data-related workflows" on page 48	• **Data Analysis**
Commands related to the sequence template:  **Load Sequence Template ...**  **Save Sequence Template**	See "Workflows for Methods and Templates" on page 59	• **Method and Run Control**
Commands related to report templates:  **Load Report Template**  **Save Report Template**	See "Workflows for Methods and Templates" on page 59	• **Report Layout** (Intelligent Reporting)
Commands related to reports:  **Load Report Template**  **Save as PDF**  **Save as XLS**  **Save as DOC**  **Save as TXT**	• You can load a specific report template from the central repository. • You save the report generated with this template as a PDF, XLS, DOC, or TXT file to the central repository. TXT files do not contain any graphical information.	• **Review** (only available with Intelligent Reporting)
Download Files ...	Download library files (*.uvl), column databases (*.mdb), Easy Sequence templates (*.est), and classic report templates (*.frp) from the central repository.	• **Method and Run Control** • **Data Analysis**
Upload Files ...	Upload library files (*.uvl), column databases (*.mdb), Easy Sequence templates (*.est), and classic report templates (*.frp) to the central repository.	• **Method and Run Control** • **Data Analysis**

The User menu

Command	Description	Available in ChemStation views
Change User ...	Log in as a different user (only affects the ChemStation login, not the OpenLAB Control Panel login).	• **Method and Run Control** • **Data Analysis** • **Review** • **Report Layout**
Lock Session	• **privately** • **non privately** See "Session lock" on page 24.	• **Method and Run Control** • **Data Analysis** • **Review** • **Report Layout**

Preferences

The **Preferences** dialog contains two tabs that are relevant to the central data storage system: the **Transfer Settings** tab and the **Audit Trail** tab.

NOTE

You can change these settings for all ChemStation instances on the client PC in one single step by using the ChemStation Administration Tool (see "ChemStation Administration Tool" on page 96). If settings have been specified for *all* ChemStation instances on the computer, you cannot change the settings in the **Preferences** dialog.

On the **Transfer Settings** tab, you must specify the following preferences in order to automatically store ChemStation data to a central repository:

- Path
- Automatic Data Transfer Settings
- Transfer Management Settings

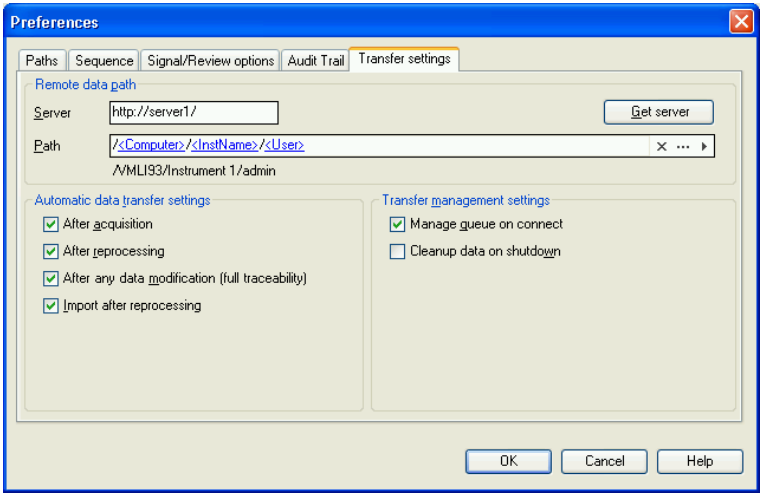


Figure 5 **Transfer Settings** tab in the **Preferences** dialog

Each of these items can be specified independently for each instrument. Offline and online sessions are automatically synchronized.

On the **Audit Trail** tab, you can enable the Method Audit Trail and Results Audit Trail. For details on audit trails see "Audit Trails and Logbooks" on page 74.

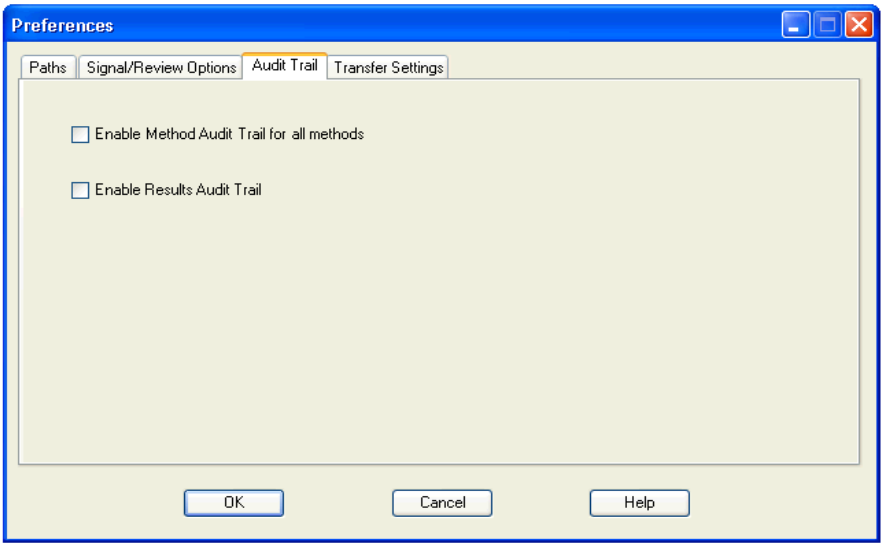


Figure 6 **Audit Trail** tab in the **Preferences** dialog

Remote Data Path

The remote data path needs to be specified in order to save the data to the correct location in central repository.

In the **Preferences** dialog, the **Transfer Settings** tab (see Figure 5 on page 30) allows you to define the **Path** setting. This path reflects the LCDF structure in ECM, shown with backslashes, or the folder path in Data Store, shown with forward slashes.

ChemStation Rev. B and OpenLAB CDS ChemStation Edition Data in one ECM

In ECM, you may have stored data from different ChemStation revisions, for example, from rev. B and OpenLAB CDS ChemStation Edition (rev. C). If you work with ChemStation rev. C, you can load and process data from ChemStation rev. B. However, if you work with ChemStation rev. B, you can only process data from this revision (or older), you cannot process data from rev. C.

CAUTION

Wrong results or incompatible data

If you reprocess ChemStation rev. C data in ChemStation rev. B, you may obtain wrong or incomplete results.

If you reprocess ChemStation rev. B data in ChemStation rev. C, it may no longer be possible to reprocess these data in ChemStation rev. B.

➔ Clearly separate the files from ChemStation rev. B and ChemStation rev. C in ECM.

➔ With OpenLAB ECM Enterprise, we recommend using different ECM Accounts for ChemStation rev. B data and ChemStation rev. C data.

➔ With OpenLAB ECM Workgroup, use clearly separated LCDF locations.

Server/Account

Here, you specify the server on which the central data storage system is installed. For ECM, you must also specify the ECM Account.

ChemStation obtains this information automatically from OpenLAB Control Panel. If the fields are empty or do not match the current configuration, you can click **Get Server** to reset the fields. ChemStation then keeps the information for future sessions.

NOTE

If you manually enter the server name or ECM Account name, and the information does not match the configuration used in OpenLAB Control Panel, data upload will fail.

Path

To specify the storage location in the central repository, you can either browse to a an existing storage location in the central repository using the button with the three dots [···], or click the arrow [▸] to select predefined tokens for automatic path creation. With these tokens, the system automatically creates the required items if they do not already exist in the central repository. Tokens are available for the instrument name, the user name, the instrument number, or the computer name.

Alternatively, the path can be specified as **Sequence Parameter** (see "Remote Data Path as Sequence Parameter" on page 41).

With ECM, uploaded files can be stored only at the Folder level. With Data Store, uploaded files can be stored at any level.

NOTE If no path is specified, a warning message will be shown at ChemStation startup.

NOTE In ECM, there are separate privileges to create content and create folders. If you use tokens, make sure you have the required privileges in ECM to create folders! Alternatively, another user who has the required privileges can create the necessary folders in advance.

Automatic Data Transfer Settings

In the **Preferences** dialog (**View > Preferences**), the **Transfer Settings** tab allows you to specify the automatic settings for the transfer of raw data. The transfer settings, as well as the Remote Data Path, are used to automatically upload data to the central data storage.

NOTE If the connection to the central data storage is lost for any reason, the data cannot be automatically uploaded as specified in the transfer settings. The data is then queued in the Queue Management (see "Queue Management" on page 37).

NOTE If you perform data acquisition from the **Diagnosis** view or **OQ/PV** view, the transfer settings are ignored. The analytical raw data is written to the local ChemStation data file system as predefined in the diagnosis or verification methods.

After Acquisition

If you select this check box the data is automatically uploaded to the central repository after an acquisition. The raw data files are written to the local ChemStation file system while the sequence is still running. When the complete sequence is finished, the raw data files are packed in an SSIZip file which is then uploaded to the central repository.

For more information, please refer to "Workflow 1: Acquisition and automatic upload" on page 48.

After Any Data Modification

If you select this check box, the result set is automatically uploaded to the central repository after you changed the data analysis parameters for a sample. The data is uploaded even if you do not reprocess the sequence.

For more information, please refer to "Workflow 2: Offline review during acquisition" on page 51.

After Reprocessing

If you select this check box, the result set is automatically uploaded to the central repository each time after you reprocessed the sequence.

For more information, please refer to "Workflow 3: Reprocessing data and automatic upload" on page 54.

Import after Reprocessing

If you select this check box, a sequence that is only stored locally is automatically uploaded to the central repository after reprocessing. This setting is useful, for example, if you reprocess data from an older version of ChemStation.

For more information, please refer to "Workflow 4: Import after reprocessing" on page 57.

Transfer Management Settings

Manage Queue on Connect

If the connection to the central data storage is lost for any reason, a running data upload might be interrupted. In this case, the remaining data is written to an internal queue.

If you select the check box **Manage Queue on Connect**, ChemStation tries to upload the remaining data once the connection the central data storage is re-established.

Alternatively, you can open the **Queue Management** dialog (see "Queue Management" on page 37) at any time with the **ECM > Manage Queue** or **Data Store > Manage Queue** command in the **Data Analysis** view. **The Queue Management** dialog box allows you to manage the export of residual ChemStation data to central data storage after, for example, a network failure. You can process the queue, save selected items to the local computer, or delete items from the queue. If you delete an item from the queue, it will not be transferred to central data storage, but an entry will be made in the audit trail in the central data storage system.

Cleanup Data on Shutdown

If you select this check box, upon shutdown ChemStation checks the local file system for files that have already been stored in the central repository. It deletes all local data and sequence files that are stored in the central repository as well. Methods and sequence templates remain on the local file system.

CAUTION

Inadequate check box selection

Loss of data

➔ If you select the **Cleanup Data on Shutdown** check box, you should also select the Automatic Data Transfer Settings **After Acquisition**, **After Reprocessing**, and **After Any Data Modification**. Otherwise, if the users forget to upload the data to the central data storage before closing ChemStation, data might be lost.

NOTE Consider selecting the **Cleanup Data on Shutdown** check box when the system shall be compliant to 21 CFR Part 11. Using this function prevents unauthorized access to the local data files.

Alternatively, you can open the **Data Cleanup** dialog at any time with the **Cleanup Data** command in the **ECM** or **Data Store** menu. This dialog box lists all data sets that are also kept in the central data storage system apart from the currently loaded data. The following columns are available:

- **Directory**: Location of the local file
- **ECM Information** or **Data Store Information**: Server of the central data storage system and path for the file in the central repository. For ECM, also the ECM Account is shown.
- **Last Modified**: Date/Time when the file in the central repository was last changed
- **Locally Modified**: Information whether the local copy has been modified
- **Local Version**: ECM or Data Store version that was downloaded to the local directory

You can now manually select the data sets to be deleted from the local disk.

Alternatively, via a drop down list you can deselect all data sets, select all data sets, select only single runs, select only result sets, select items older than one day, or items older than a week.

After pressing **OK**, the local copies of the selected data sets are deleted.

Both automatic cleanup on shutdown and manual cleanup are only possible if the following conditions are fulfilled:

- the ChemStation user is logged on to the central data storage system
- no other instance of the ChemStation instrument is open
- the queue in the Queue Management is empty

If one of these conditions is not fulfilled, automatic cleanup will not be performed and it is not possible to open the **Data Cleanup** dialog.

Queue Management

The **Queue Management** dialog is opened via **ECM > Manage Queue ...** or **Data Store > Manage Queue ...** respectively. If you selected the check box **Manage Queue on Connect**, and there are interrupted transfers, the dialog is also opened when you start ChemStation.

With this dialog, you can manage the data transfers from ChemStation to the central data storage that were interrupted or could not be started for any reason. Each failed transfer job is listed in a separate line.

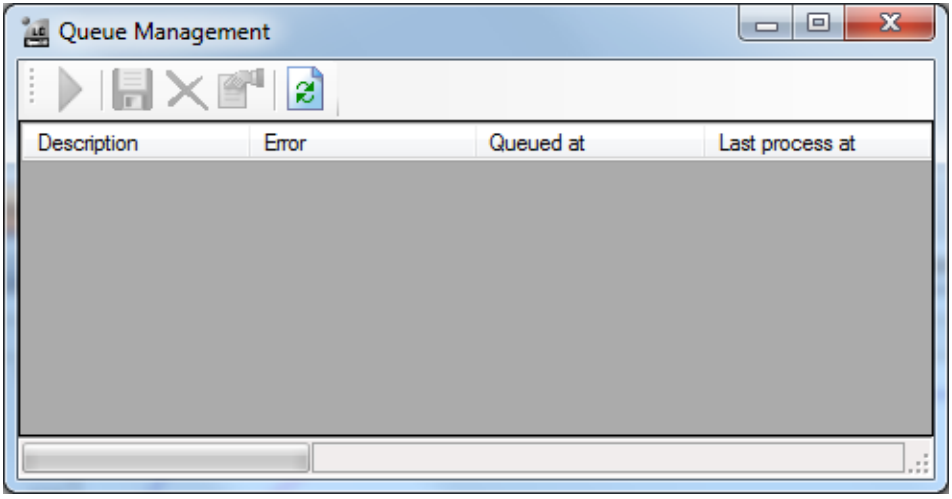


Figure 7 Queue Management

The following information is provided for each line:

- **Description**: Information on the version of the data that will be transferred. Two values are possible:
  - **Import**: No older version of the data exists in the central data storage system at this time. The data has been newly created and will be uploaded as Version 1.
  - **Commit**: There is already at least one version of the data in the central data storage system. The version number of the uploaded data will be increased by one.

- **Error**: Error that disrupted the data transfer. For details on the possible errors, see "Error Messages in the Queue Management" on page 115.
- **Queued at**: Date when the unsuccessful transfer was queued.
- **Last process at**: Date when the transfer was last attempted.

The toolbar offers you the following commands to manage the queue:

Table 2 Queue management toolbar

Icon	Tooltip	Description
	Process queue	Continue processing the transfer jobs. As long as there is no error, all pending transfer jobs will be processed in the order as they are shown in the list. This function is only active if you select the first line in the list.
	Stop processing	Stop processing the transfer jobs.
	Save selected item locally	Save the data of the corresponding item to the file system.
	Delete selected item	Delete the selected transfer job from the queue. The concerned data will not be transferred.
	Properties	Display the **Queue Management** dialog box, which shows details of the items in the queue in either summary or detailed form.
	Refresh view	Update the display of the items in the list.

When items are selected from the queue or saved to the local disk, an audit trail entry will be added to the Audit Trail of the central data storage system.

NOTE When items are deleted from the queue or information on a failed transfer is saved to the local disk, the items have not yet been uploaded to the central data storage system.

Queue Management Details Dialog Box

The **Queue Management Details** dialog box is displayed when you click the  tool in the toolbar of the **Queue Management** dialog box. It shows the command-specific details of the commands in the **Queue Management** dialog box. The **Queue Management Details** tabs offer two views of the command details:

- Summary tab
- Details tab

In either tab, the tools in the toolbar allow you to navigate through the command details:

 Displays the details of the first command in the list.

 Displays the details of previous command in the list.

 Displays the details of next command in the list.

 Displays the details of last command in the list.

Summary tab

The **Summary** tab gives the following summary information about the selected item:

Command Description	The description of the item.
Created	The date and time when the item was added to the queue.
Changed	The date and time when the item was last processed.
Last Error	A description of the error that caused the item to be added to the queue.

Details tab

The **Details** tab gives detailed information about the selected item. You cannot edit the information in this list. The toolbar provides the following tools:

Sorts the properties by category.

Sorts the properties alphanumerically.

Remote Data Path as Sequence Parameter

Instead of specifying the remote data path in the **Preferences** for all acquisition sequences to be run (see "Remote Data Path" on page 31), the remote data path can also be set directly in the sequence template. This allows to set up different remote paths for each sequence without having to modify the Preferences. The **Path** for a sequence template is set up in the **Sequence Parameters** tab.

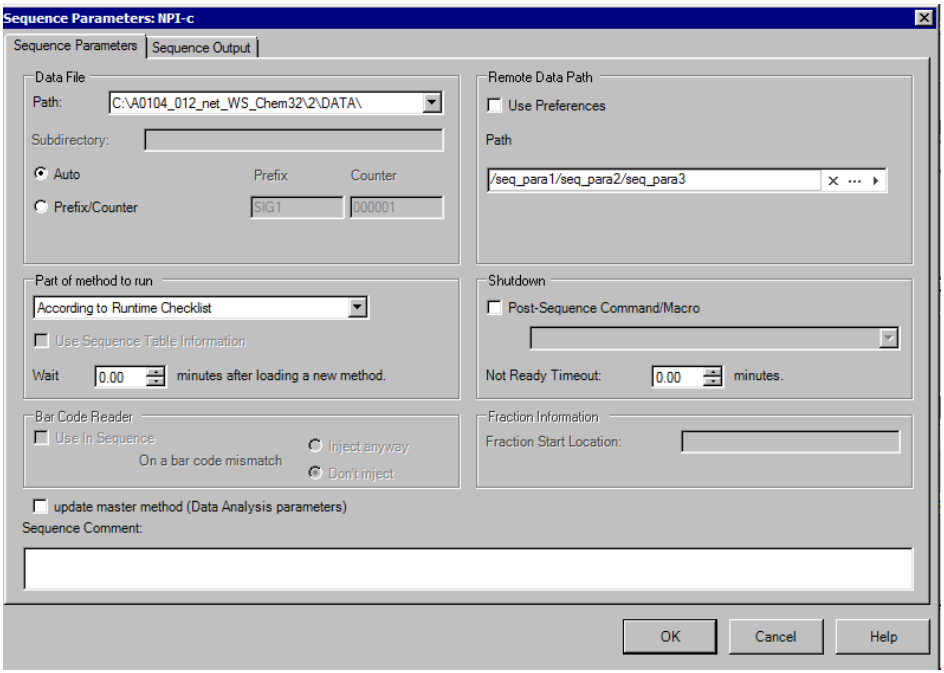


Figure 8 **Sequence Parameters** tab of the **Sequence Parameters** dialog

Use Preferences: When this check box is selected, the remote data path as specified in the **Preferences** will be used. Any path specified in the **Sequence Parameters** will be ignored for this sequence. When this check box is cleared, the remote data path will be used as specified when the sequence template is used for data acquisition.

Path: To specify the remote data path, you need to select a folder path available in the central data storage system. Click the button with the three dots [···] to select the required path. Alternatively, you can click the arrow [▸] to select one of the predefined tokens for an automatic path creation. With these tokens, the system automatically creates the items if they do not already exist in the central data storage system.

NOTE

In ECM, there are separate privileges to create content and create folders. If you use tokens, make sure you have the required privileges in ECM to create folders! Alternatively, another user who has the required privileges can create the necessary folders in advance.

Compressed ChemStation File Formats

When ChemStation data is uploaded to the central repository, the data is automatically packaged into an SSIzip file. Depending on the type of data, different packaging formats are used.

ChemStation data	Packaging format	Icon in ChemStation
Single Runs (containing *.d file, *.rdl files, and DA.M)	*.D.SSIZIP	
Result set The result set contains recursively the whole sequence data stored in the sequence subdirectory: • all *.d files along with DA.M • all methods *.m used during acquisition • batch file *.b • sequence logbook file *.log • all *.rdl files used for sequence summary reports and single injection reports	*.SC.SSIZIP	
Methods	*.M.SSIZIP	
Sequence templates	*.S	

The packaging of ChemStation data is part of OpenLAB CDS ChemStation Edition and cannot be changed manually.

The packaging is automatically carried out when the data is uploaded to the central repository. When the SSIZIP files are downloaded from the central repository to ChemStation, they are automatically unpacked into the corresponding directory in the ChemStation Explorer.

3 Working with ChemStation and Central Data Storage

This chapter describes the basic workflows for ChemStation with a central data storage system. There are four data-related workflows and two workflows for methods, sequence templates, or report templates.

Transferring Data to or from the Central Repository

You can open and save different ChemStation items into their ChemStation contexts:

- Methods
- Sequence templates and Easy Sequence templates
- Report templates for Classic or Intelligent Reporting
- Single run data
- Sequence data
- Library files
- Column databases

Methods, single run data and sequence data are stored in the central repository as SSIZIP file (see "Compressed ChemStation File Formats" on page 43).

When the data is uploaded to the central data storage, local copies of the files still remain in the ChemStation file system. If an item is loaded from the central data storage back into ChemStation, it is automatically loaded into its original location.

Different options are available regarding the automatic upload of single run/sequence data. This is in contrast to downloading stored data from the central repository to ChemStation, which always requires a manual load action. Methods, sequence templates and report templates always require a manual upload to the central data storage as well as a manual download to ChemStation.

For downloading data from the central data storage, several **load** commands are available in the **ECM** or **Data Store** menu. Depending on the current view, you can load different files. In the **Data Analysis** view, you can load single run data or sequence data. These data are automatically set to the status **checked out** in the central data storage system. The checked out status of a data file is visible to another user and prevents him from inadvertently altering a data file that has been downloaded to another ChemStation. In the **Method and Run Control** view, you can load methods and sequence templates. These items are only retrieved from the central repository, but they are not checked out. If you use Intelligent Reporting, you can also download report templates from the central data storage in the **Report Layout** view.

The following workflows are examples that represent typical tasks done with ChemStation and central data storage.

Data-related workflows

Workflow 1: Acquisition and automatic upload

The workflow *Acquisition and automatic upload* illustrates how raw data is uploaded to the central repository directly after the acquisition is finished. The raw data is initially stored locally. After completing the acquisition, the data is automatically uploaded to the central repository.

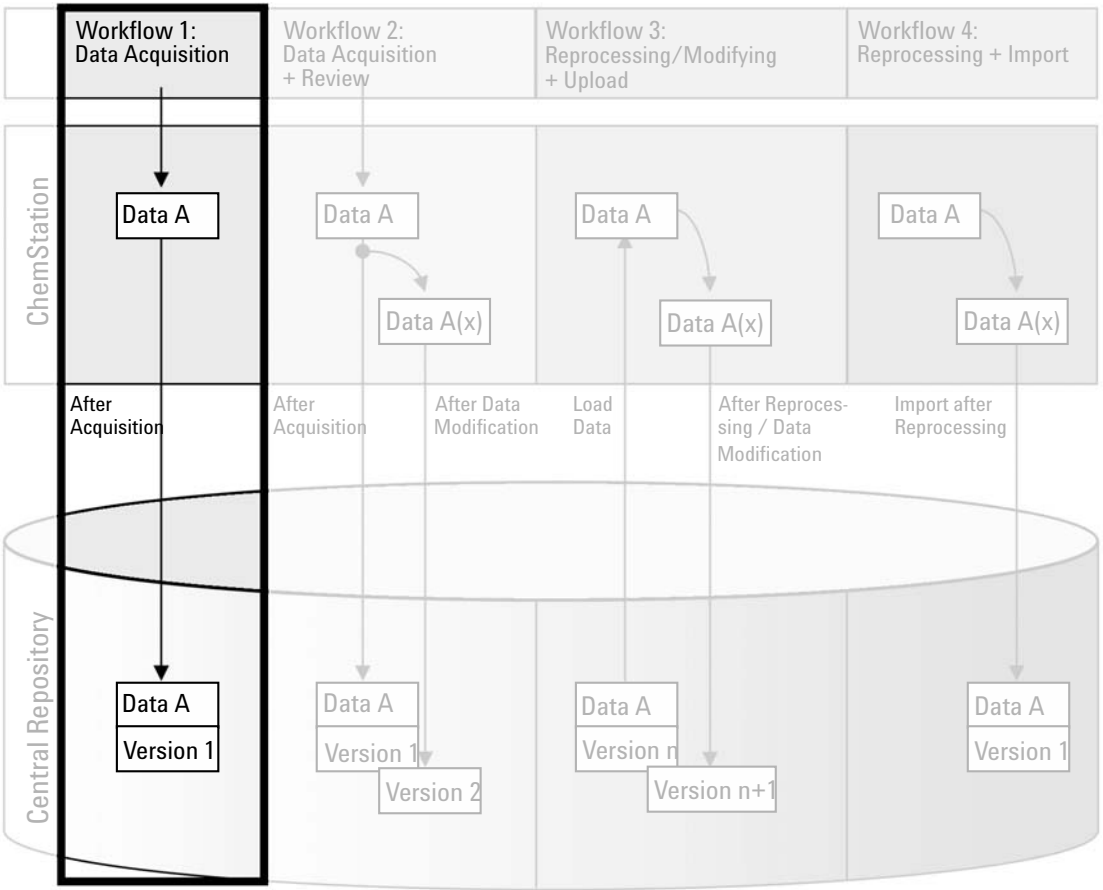


Figure 9 Acquisition and automatic upload

To save data to the central repository automatically after completion of a single run or sequence:

1 Log in to the OpenLAB Control Panel and launch an online ChemStation.

2 Load a sequence template.

Your user name for the central data storage system is automatically inserted as operator name into the sequence template.

3 Click **View > Preferences**.

4 On the **Transfer Settings** tab, configure the following settings:

- **Path**: Select the location in the central repository that you want to use for the sequence data upload.
- Select the **After Acquisition** check box.

5 Configure the sequence parameters and the sequence table.

6 Start the acquisition.

While the acquisition is running, the raw data, method definition, and a copy of the sequence template are locally stored on the ChemStation computer.

After the sequence is finished, all data is automatically uploaded as an *.SC.SSIZIP* file to the central repository to the previously defined remote path. The local copy of the data remains on the ChemStation computer. The file name of the result set is determined by the settings in the sequence template (for more details on the sequence template settings, refer to the manual *Agilent OpenLAB CDS ChemStation Edition Concepts and Workflows*). After uploading the result set the sequence icon in the ChemStation Navigation Pane changes from  to  . The remote path of the result set is shown in the ChemStation toolbar.

NOTE

The color of the **Sequence Data** icon in the Navigation Pane allows to track the modification status of the data:

 : The result set is stored in the central repository and has not been modified locally

 : The result set is stored in the central repository and has been modified locally

NOTE

The upload process may take some time when large amounts of data are uploaded. During this time ChemStation is busy and the user cannot perform tasks in ChemStation. Please wait until the upload is completed.

Workflow 2: Offline review during acquisition

The workflow *Offline revision during acquisition* illustrates how raw data is reviewed while the acquisition is still running. Directly after the acquisition is finished, the original raw data is automatically uploaded to the central repository. After the review, the changed data is again uploaded to the central repository. When the data is uploaded the second time, a new version is created.

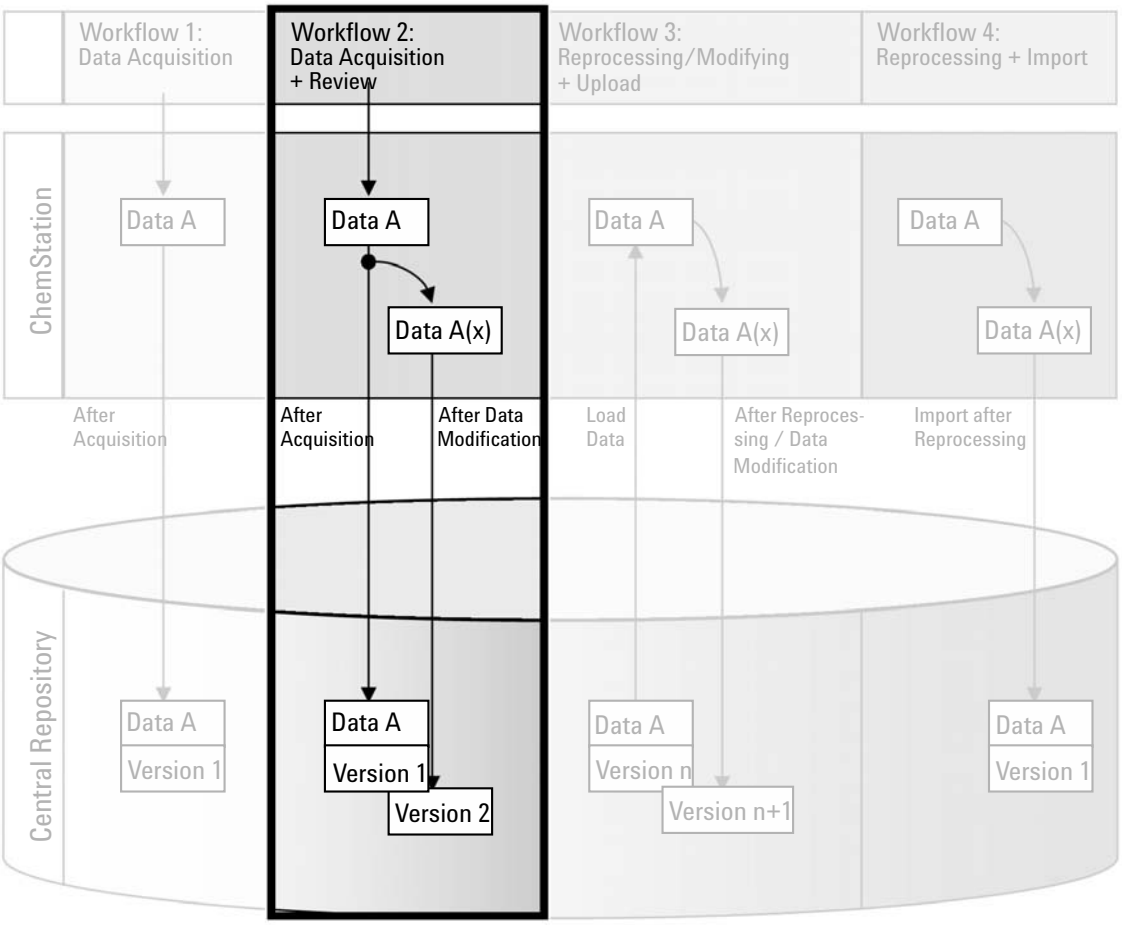


Figure 10 Offline review during acquisition

To save data to the central repository automatically after modification:

1 Log in to the OpenLAB Control Panel and launch an online ChemStation.

2 Load a sequence template.

Your user name for the central data storage system is automatically inserted as operator name into the sequence template.

3 Click **View > Preferences**.

4 On the **Transfer Settings** tab, configure the following settings:

- **Path**: Select the storage location that you want to use for the sequence data upload.
- Select the **After Acquisition** check box.
- Select the **After Any Data Modification** check box.

5 Start the acquisition.

While the acquisition is running, the raw data, method definition, and a copy of the sequence template are stored locally on the ChemStation computer.

6 Open an offline ChemStation and change some data analysis parameters for one of the already finished samples. Save your changes locally.

7 After the acquisition has finished, two things will happen:

- The original raw data is automatically uploaded as an *.SC.SSIZIP* file, *Version 1*, to the central repository using the previously defined remote data path. The path of the new sequence is shown in the toolbar in the online ChemStation.

  The file name of the result set is determined by the settings in the sequence template (for more details on the sequence template settings refer to the manual *Agilent OpenLAB CDS ChemStation Edition Concepts and Workflows*).

  The sequence icon in the ChemStation Navigation Pane changes from  to  .

- An Upload dialog opens in the online ChemStation. Click **OK** to confirm that you finished all work in the offline instance. As soon as you confirm this dialog, the changed data is uploaded as *Version 2* to the central repository.

  A local copy of the changed data remains on the ChemStation computer.

NOTE For both versions (the one after acquisition and the one from the parallel offline review) the ChemStation operator is the user who has run the acquisition, even if another user has performed the review in the Offline ChemStation.

Workflow 3: Reprocessing data and automatic upload

The workflow *Reprocessing data and automatic upload* illustrates how data is reprocessed and then automatically uploaded. This workflow applies to data that has been previously stored in the central repository. A new version of the data is created in the central repository for the reprocessed or changed data.

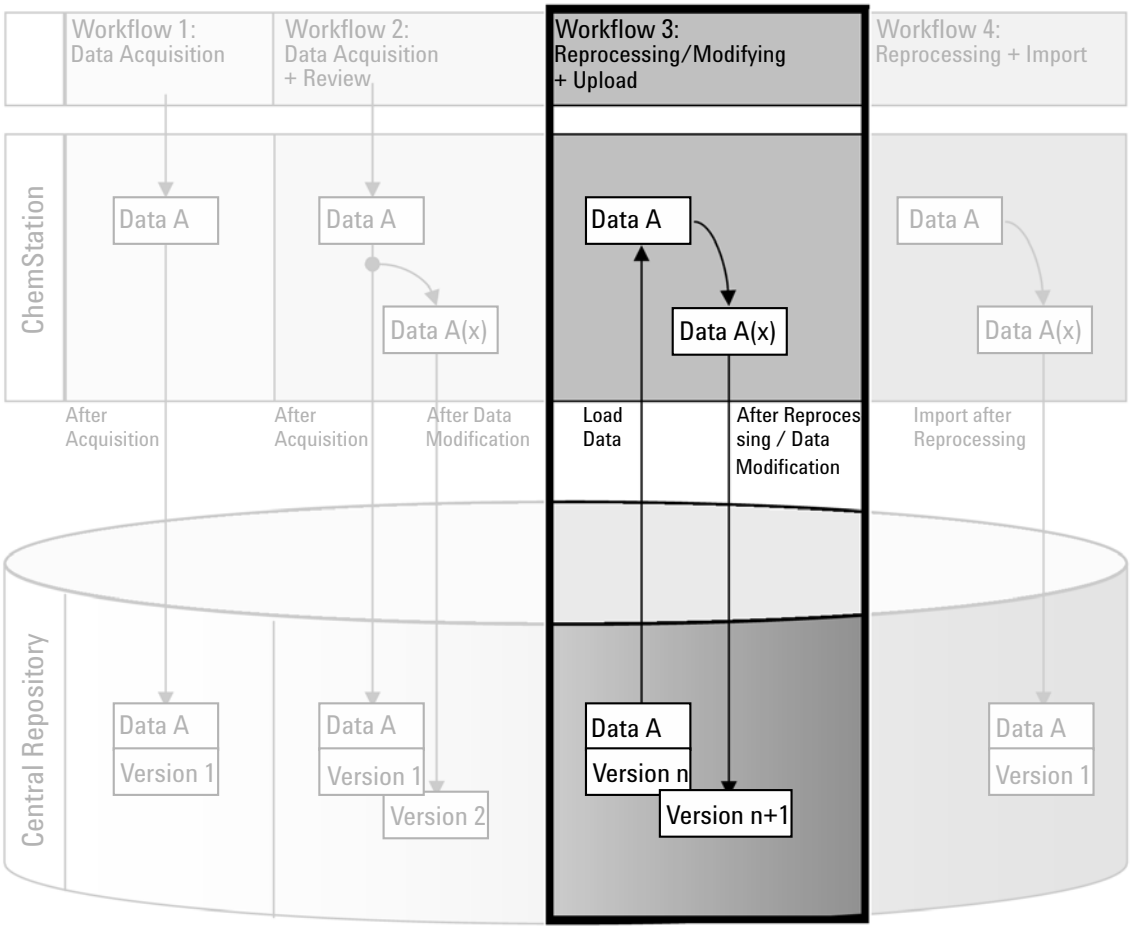


Figure 11 Reprocessing data and automatic upload

To save data to the central repository automatically after reprocessing:

1 Log in to OpenLAB Control Panel and launch an online or offline ChemStation.

2 Select **ECM > Load Data** or **Data Store > Load Data** to download a sequence from the central repository.

A dialog opens where you can select the required data. Navigate to the folder that contains your data and select one of the following packaged files:

- Single run data: **.D.SSIZIP* files
- sequence data: **.SC.SSIZIP* files

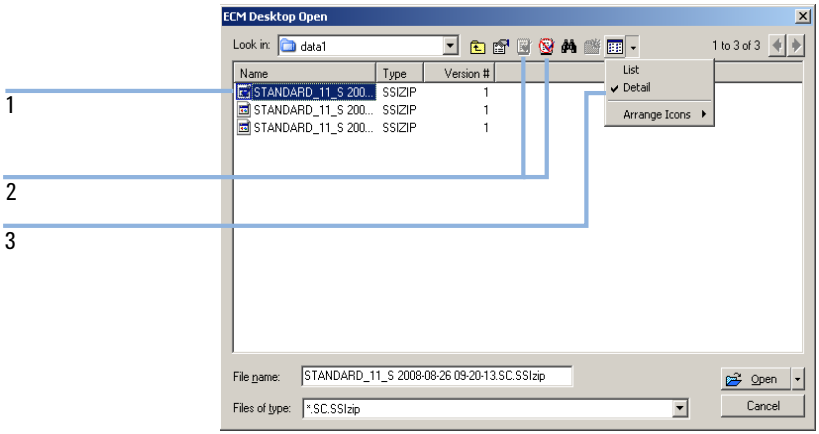


Figure 12 ECM Desktop Open dialog

If the item is checked out, it is marked with a blue or red icon (see marker 1):

(blue icon): the item has been checked out by you (current user)

(red icon): the item has been checked out by another user

You can load any checked out item. However, if an item has been checked out by another user, the other user must check in the item before you can save it back to the central repository.

To check out or check in an item, you can use the respective icons available in the dialog (see Figure 12 on page 55, marker 2). You can only check out the latest version of an item.

In order to see more details regarding the type and version of the available items, select the **Detail** view (see Figure 12 on page 55, marker 3). To open an older version of an item, select the **Open Revisions** command from the **Open** menu (see Figure 13 on page 56). This opens the **File Versions** dialog, where all available versions of the item are listed (see Figure 14 on page 56).

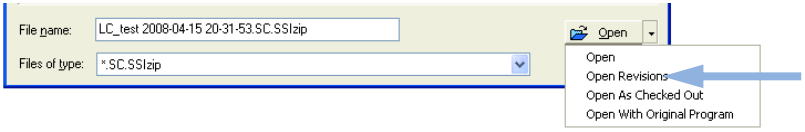


Figure 13 Open Revisions command

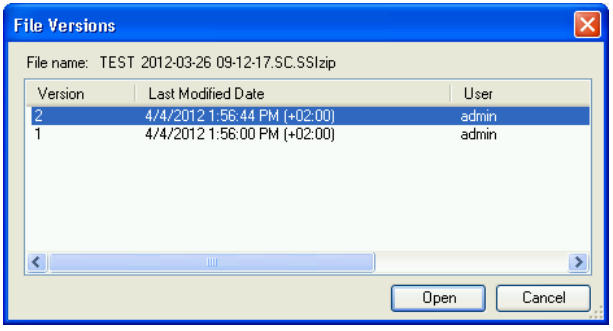


Figure 14 File versions dialog

3 Select **Open** in either dialog to download the item to ChemStation.

   If the item was not already checked out, it is automatically checked out of the central repository when you load it to ChemStation.

   The remote data path is shown in the ChemStation toolbar.

4 In the **Data Analysis** view, click **View > Preferences**.

5 On the **Transfer Settings** tab, configure the following settings:

   - Select the **After Reprocessing** check box.
   - Select the **After Any Data Modification** check box.

6 Modify or reprocess the sequence data.

   After the reprocessing is finished, the sequence data is uploaded with its original name to its original remote data path. The version number is increased by one.

The local copy of the reprocessed data remains on the local file system of the ChemStation computer.

Workflow 4: Import after reprocessing

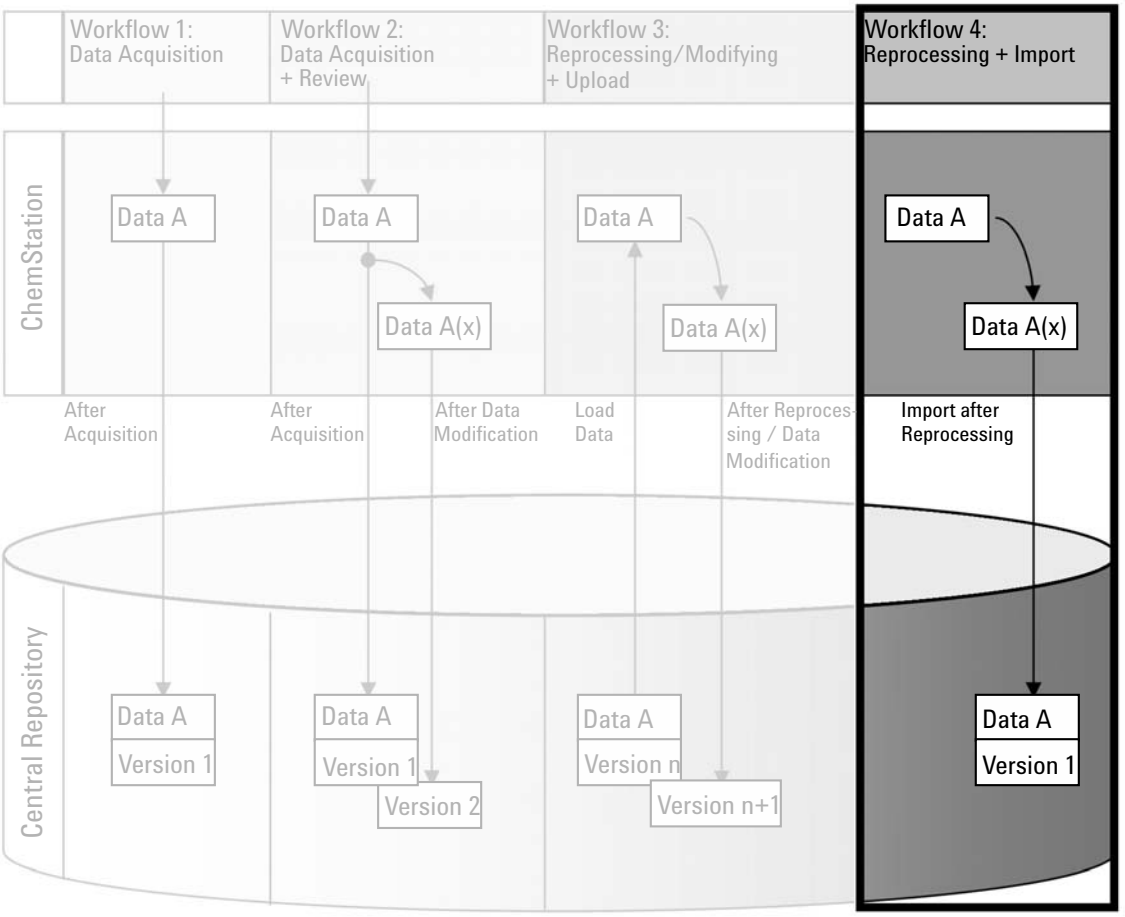


Figure 15 Import after reprocessing

The workflow *Import after reprocessing* illustrates how locally saved data is reprocessed and then automatically imported into the central repository.

To save data to the central repository automatically after reprocessing:

1. Log in to OpenLAB Control Panel and launch an offline ChemStation.
2. From the local file system, open a sequence that has never been saved to the central repository before.
3. In the **Data Analysis** view, click **View > Preferences**.
4. On the **Transfer Settings** tab, configure the following settings:
   - **Path**: Select the storage location that you want to use for the sequence data upload.
   - Select the **Import after Reprocessing** check box.
5. Reprocess the sequence data.

NOTE The data will not be uploaded if you only modify it. You need to reprocess the sequence data.

The sequence data is uploaded as a new *.SC.SSIZIP* file, version 1, to the previously defined remote data path in the central repository. The file name of the result set is determined by the settings in the sequence template (for more details about the sequence template settings refer to the manual *Agilent OpenLAB CDS ChemStation Edition Concepts and Workflows*).

The sequence icon in the ChemStation Navigation Pane changes from  to  .

The local copy of the reprocessed data remains on the local file system of the ChemStation computer.

Workflows for Methods and Templates

The following workflows are applicable to methods and sequence templates. If you enabled Intelligent Reporting in Instrument Configuration in the OpenLAB Control Panel, these workflows also apply to report templates. The diagrams show the workflows using methods as an example.

Workflow 1: Save new method

The workflow *Save new method* illustrates how newly created or locally stored methods or sequence template can be manually uploaded to the central repository.

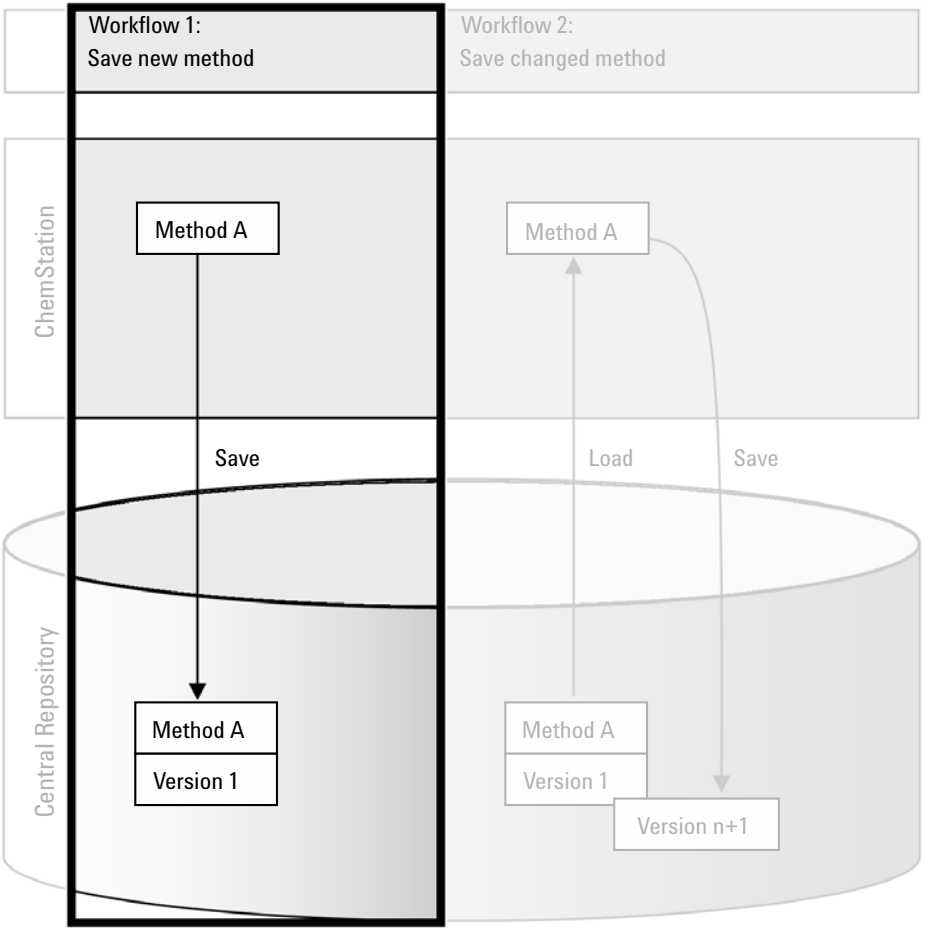


Figure 16 Save new method, sequence template, or report template

To upload a new method, sequence template, or report template:

1 Log in to OpenLAB Control Panel and launch an offline ChemStation.

2 In ChemStation, load the method/sequence template/report template or create a new one.

3 Select the appropriate Save command from the **ECM** or **Data Store** menu.

In the **Method and Run Control** view:

- **Save Method**
- **Save Sequence Template**

In the **Report Layout** view (only with Intelligent Reporting):

- **Save Report Template**

4 In the Save dialog, navigate to the remote data path of your choice to upload the method/sequence template/report template.

In ECM, you can only upload items into a Folder, not into a Location, Cabinet, or Drawer. In Data Store, you can select any path.

5 If necessary, save the item using a different name. The original name is used by default, but you can modify the name.

6 Click **Save**.

The **Add File** dialog opens.

7 Enter a reason for the upload and click **OK**. The reason is then shown in the Audit Trail of the central data storage system (see "Audit Trail of the Central Data Storage" on page 77).

The progress of the upload is displayed in a window until the item is uploaded to Data Store.

After finishing the upload, the SSIZIP file is available in the central repository as version 1. The file is saved to the remote data path defined in the Preferences (see "Remote Data Path" on page 31).

The method icon in the ChemStation Navigation Pane changes from  to  .

The icon for a sequence template changes from  to  .

The icon for report templates changes from  to 

Workflow 2: Save changed method

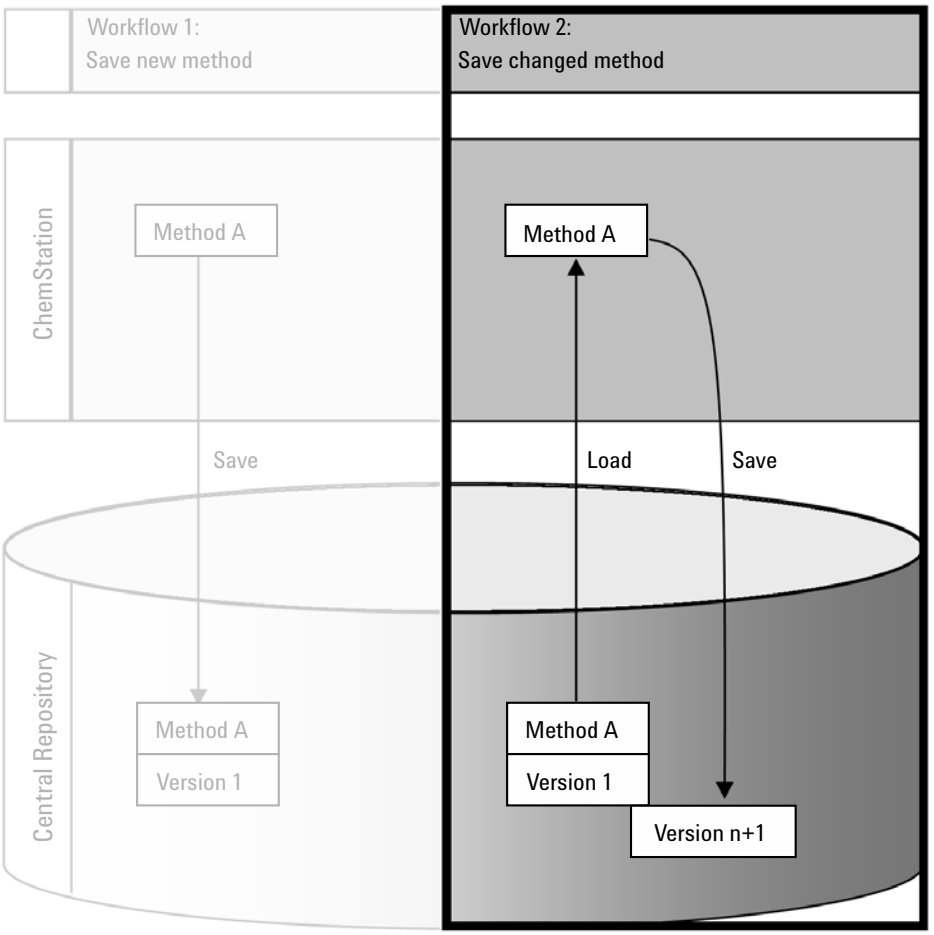


Figure 17 Save changed method

The workflow *Save changed method* illustrates how methods, sequence templates, or report templates that are already stored in the central repository are edited and saved under the same name as a new version.

1 Log in to OpenLAB Control Panel and launch an online or offline ChemStation.

2 Load a method, sequence template, or report template.

- Open a method/sequence template/report template from your local PC. Choose an item that has been uploaded to the central repository before. Methods are indicated by , sequence templates by , and report templates by in the ChemStation Navigation Pane.

– or –

- Select the **Load Method**, **Load Sequence Template**, or **Load Report Template** commands in the **ECM** or **Data Store** menu to download an item from the central repository.

If you use one of the Load commands, a dialog will open where you can select the required data. Navigate to the folder to load the method (**.M.SSIZIP*), sequence template (**.S* or **.S.SSIZIP*), or report template (**.RDL*) of your choice.

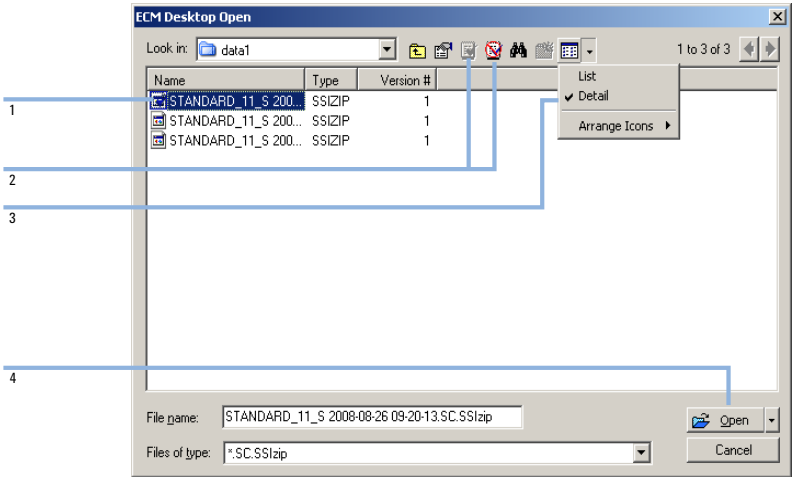


Figure 18 ECM Desktop Open dialog

If the item is checked out, it is marked with a blue or red icon (see Figure 18 on page 63, marker 1):

- (blue icon): the item has been checked out by you (current user)
- (red icon): the item has been checked out by another user

You can load any checked out item. However, if an item has been checked out by another user, the other user must check in the item before you can save it back to the central repository.

To check out or check in an item, you can use the respective icons available in the Open dialog (see Figure 18 on page 63, marker 2). Using these icons, you can only check out the latest version of an item.

In order to see more details regarding the type and version of the available items, select the **Detail** view (see Figure 18 on page 63, marker 3). To open an older version of an item, select the **Open Revisions** command from the **Open** menu (see Figure 19 on page 64, marker 1). This opens the **File Versions** dialog, where all available versions of the item are listed (see Figure 20 on page 64).

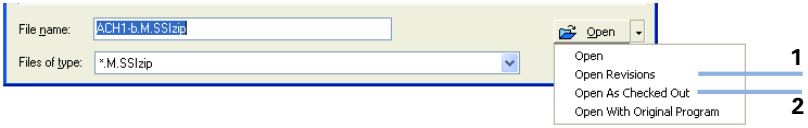


Figure 19 Open Revisions command

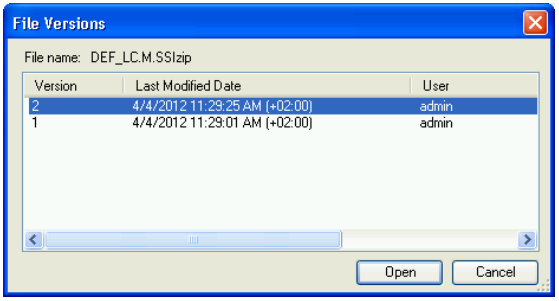


Figure 20 File versions dialog

3 Select **Open** in either dialog to download the item to ChemStation. In order to prevent other users from modifying the item, it is possible to select the **Open As Checked Out** command to mark the item as checked out in the central data storage system (see Figure 19 on page 64, marker 2).

NOTE Unlike data files, the methods, sequence templates, and report templates are not automatically checked out of the central data storage system! In order to modify those items in ChemStation, you should check them out manually. Otherwise, there is no guarantee that you are working on the latest version.

If the file already exists on the ChemStation computer in the specified location, you must choose a different download location.

The remote path of methods and templates is shown in the ChemStation toolbar.

4 Make the required changes to the loaded item.

A modified method is indicated by  in the navigation pane.

A modified sequence template is indicated by  .

A modified report template is indicated by  .

5 Select the appropriate Save command in the **ECM** or **Data Store** menu to save the changed item.:

- **Save Method**
- **Save Sequence Template**
- **Save Report Template**

NOTE If you have not checked out the item before loading it from the central data storage, and another user has checked out the item in the meantime, you cannot proceed with the upload back to the central data storage. A warning message is displayed, and it is not possible to save the item until the other user has released the checked out item.

6 When the **Add File** dialog opens, enter a reason for the upload and click **OK**. The reason is then shown in the Audit Trail of the central data storage system (see "Audit Trail of the Central Data Storage" on page 77).

The progress of the upload is displayed in a window until the item is uploaded to the central repository.

The *.M.SSIZIP/.S/.RDL* file is uploaded with its original name to its original remote data path (the path is shown as a tooltip of the method/sequence template/report template in ChemStation). The version number is automatically increased by one.

Updating the Local Master Method, Sequence Template, or Report Template

If a master method, sequence template, or report template is updated in the central data storage system (i.e. a new version is created), it is possible to update the local copy with the following update procedure.

1 Make sure the master method, sequence template, or report template to be updated is currently not loaded. A currently loaded item is not available for update.

2 Select the appropriate Update command from the **ECM** or **Data Store** menu:

- **Update Methods ...**
- **Update Sequence Templates ...**
- **Update Report Templates ...**

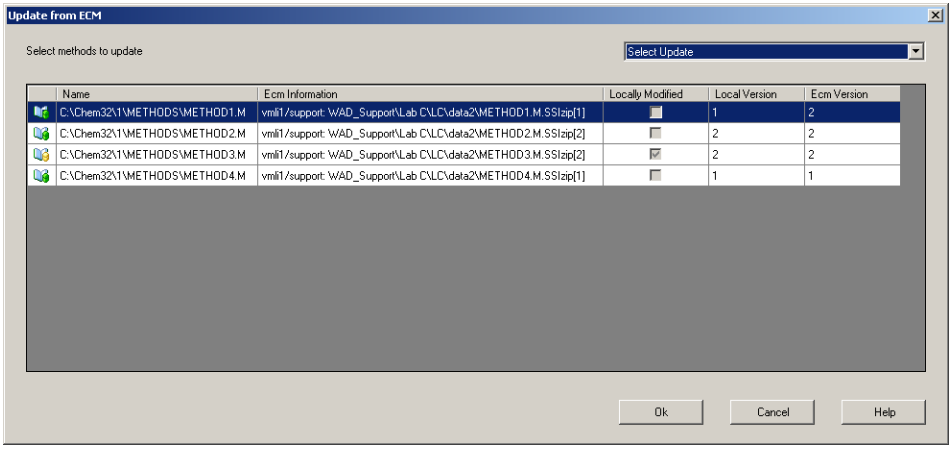


Figure 21 **Update Methods** dialog box

A dialog box is displayed where you can select the items to be updated.

The dialog box lists all items that have previously been uploaded to the central data storage. The following columns are available:

- **Name**: Path and Name of the local copy of the method, sequence template, or report template.
- **ECM Information**/**Data Store Information**: Server of the central data storage system and path of the file in the central repository; for ECM, also the ECM Account is shown.

- **Locally Modified**: A check box indicating whether the local copy was modified.
- **Local Version**: Version number of the local copy of the method, sequence template, or report template.
- **ECM Version**/**Data Store Version**: Version number of the file in the central repository.

3 You can now manually select the items that are to be updated. Alternatively you can use the drop down list to deselect all items, select those items with a higher version number in the central repository, or select all items that have been modified locally.

After clicking **OK**, the selected local items are updated with the version from the central data storage.

4
Administration Regarding 21 CFR Part 11 Compliance

This chapter explains the purpose of 21 CFR Part 11 and how the integration of ChemStation with a central data storage system addresses the requirements of 21 CFR Part 11.

Introduction to 21 CFR Part 11

Effective August 20, 1997, the U.S. Food and Drug Administration (FDA) released and published a new rule to enable pharmaceutical companies to approve their results with electronic signatures and to transfer paper-trail documentation into electronic records. This rule is known as 21 Code of Federal Regulations Part 11 (referred to as 21 CFR Part 11) and applies to all industry segments regulated by the FDA.

The impact of this rule on current work practices and data handling in the pharmaceutical industry has been much higher than expected. *"The industry wanted to have a rule on electronic signatures, but what they got was a rule on electronic records."* (Martin Browning, former FDA inspector, during a validation seminar in Washington D.C.)

21 CFR Part 11 places high emphasis on the implementation of all measures to protect and secure electronic records. Notwithstanding the uncertainties and the changes that 21 CFR Part 11 requires in the behavior of both the pharmaceutical industry and the vendors of chemical analysis equipment, it is well worth implementing in today's laboratories because it can help the industry with one of the most important issues in pharmaceutical research-bringing new drugs on the market faster.

The major benefits of this shift towards electronic data management are in the potential productivity increase for the industry. The industry can decrease its data output on paper, speed up the data review and approval process, and benefit from new automation technology based on computerized system control, for example, in manufacturing or dissolution drug release testing.

In addition to this rule on electronic records, other general requirements for computerized systems are brought to the auditor's attention. These rules cover the basic requirements of validation which are limiting data access and ensuring data integrity and data traceability.

It is, of course, the industry that must ensure that its work practices support the FDA rules, but most of the requirements also affect the chemical analysis systems and suppliers of these systems.

21 CFR Part 11 Requirements

To fulfill the FDA rules and guidelines for compliant electronic records and computerized systems, it is important to understand the basic aspects of secure data handling.

- *Data security:* physical protection of data by limiting access to the system and preventing unauthorized access.
- *Data integrity:* protecting raw data and metadata and preventing these from unauthorized modification, and linking raw data and results to reproduce the original results at any time, for example, in an audit situation, and document each new result copy.
- *Audit traceability:* documenting who did what to the results and when, and tracing the user adding new reanalyzed versions to the original raw data.

General Aspects of Data Security in Computerized Networks - Open Versus Closed Systems

Before discussing details of data security in a chromatographic system, some general aspects of data security in a computerized network need to be considered.

It is generally known that data transfer over a public network can be accessed by unauthorized external persons, "hackers", who gain access either for personal amusement or intentional fraud.

If an electronic identification comprising user ID and a password is used to approve confidential or important data, users must be sure that their signatures are unbreakably linked to the data and that nobody can copy this signature or get access to the passwords. In a public system, this would require additional encryption technology, for example, a private/public key combination of data encryption. In contrast, if a computerized system is protected from unauthorized access, users can be sure that their signatures are private and are not accessible to unauthorized individuals.

The FDA also distinguishes between these two scenarios and defines them as *open* and *closed* systems. A *public* network system can therefore only be viewed as an open system and a protected network as a closed system, if it fulfills additional requirements.

In FDA terms, *"closed system means an environment in which access is controlled by persons who are responsible for the content of electronic records on the system"* (11.3.5). The evidence of a system being a closed system is not a one-time check but an ongoing process of executing and documenting the system controls that make sure that the system is closed. In contrast, in an open system, *"those persons being responsible for the content of electronic records do not control the system access."*

As a result, open systems require additional encryption technology for all data transfer over the network.

Agilent OpenLAB CDS is designed for and supported in closed systems.

Overview of Configuration Steps Required for Part 11

If you want to configure OpenLAB CDS ChemStation Edition with a central data storage system to be compliant with 21 CFR Part 11, you need to go through the following checklist:

- Directory structure in the central data storage system prepared according to your needs

  See "Storage Model in OpenLAB ECM and OpenLAB Data Store" on page 17.

- Roles/Users/Groups configured in the central data storage system and in OpenLAB Control Panel

  See "Users, Roles, and Privileges Concept with ECM" on page 93.

- Configuration of the central data storage system with active audit trail and mandatory reason

  See "To Enable the Data Store Audit Trail" on page 77.

  See "To configure Data Store" on page 84.

- Password policy realized in OpenLAB Control Panel (including E-mail Notification)

  See "To configure password settings in Data Store" on page 86.

- E-Signatures prepared (messages and privileges)

  See "Using electronic signatures" on page 103.

- Automatic Data Transfer Settings and Transfer Management Settings activated

  See "Automatic Data Transfer Settings" on page 33.

- Audit trail active for methods and results

  See "Method Audit Trail" on page 74 and "Results Audit Trail" on page 76.

- Emergency Plan available, based on options of the Administration Tool

  See "ChemStation Administration Tool" on page 96.

Audit Trails and Logbooks

In order to comply to 21 CRF Part 11, ChemStation Edition offers various audit trails and logbooks to document all activities associated with methods, results, reports, or any files stored in the central repository. These audit trails and logbooks track all changes that are made to any file, including data acquisition, re-analysis, and long-term archiving.

The audit trails are stored in separate files, which are stored together with the sample or method data. The audit trail files are archived together with the other data in the respective SSIZIP files. The logbooks are available only in the central data storage system.

Method Audit Trail

Each method has a Method Audit Trail. By default, this Method Audit Trail contains only the comments that you must provide each time when you save a method. As there is no control on the provided text, there is no guarantee that the method changes are reproducible.

With regards to 21 CFR Part 11, OpenLAB CDS ChemStation Edition makes it possible to generate a more detailed Method Audit Trail. If the function is activated, the Method Audit Trail contains not only the user comments, but also each individual changed parameter with its old and new value. All changeable data analysis parameters are tracked. This means that you can reproduce exactly which value has been changed to what, when, and by whom.

Depending on the instrument driver, the Method Audit Trail may also contain an entry for each changed instrument setting. This feature is supported, for example, by Agilent LC System RC.Net drivers and Agilent GC 7890 System drivers.

To enable the Method Audit Trail for all methods

This is required if you want to comply to 21 CFR Part 11.

1 Select **View > Preferences**

2 In the **Audit Trail Status** dialog, select **Enable Audit Trail for all methods**, and click **OK**.

Once enabled, the Method Audit Trail cannot be disabled.

NOTE You can also use the ChemStation Administration Tool to enable the Method Audit Trail for all methods (see "ChemStation Administration Tool" on page 96).

To enable the Method Audit Trail only for the currently open method

You can also activate the Method Audit Trail only for one method. This might be useful, for example, when you finished the development of new method and want to track all further changes.

1 Select **Method > Enable Audit Trail**

2 On the **Audit Trail** tab, select **Enable Method Audit Trail for this method**.

To view the Method Audit Trail for the currently open method in ChemStation

1 Select **Method > Method Audit Trail**.

To create a new method without a detailed Method Audit Trail

Once a method is enabled for the detailed audit trail, you cannot disable it again. You can only save the method under a different method name. The new Audit Trail of the new method will then contain a comment about the method being based on the existing method.

Results Audit Trail

Manual integration events are not saved in the method. Therefore, the Method Audit Trail contains no information on manual integration events. These events are only saved in the data file. Nevertheless, they have an influence on the results. Manual integration events are therefore saved as part of the Results Audit Trail.

If activated, this Results Audit Trail is added to the existing Data File Logbook (file name RUN.LOG). By default, the Data File Logbook only contains the acquisition parameters and reprocessing information for each sample. The Results Audit Trail additionally tracks the changes of all data analysis parameters for a sample.

To enable the Results Audit Trail

If you enable the Results Audit Trail, the relevant changes are tracked for *all* samples, independent of the sequence they belong to and independent of the user who carries out the change.

1 Select **View > Preferences**

2 On the **Audit Trail** tab, select **Enable Results Audit Trail**.

To view the Results Audit Trail for the loaded sample in ChemStation

1 In the **Data Analysis** view, select **View > Current Data File Logbook**.

Report History

If you create a ChemStation report, you can display the report on the screen, send it to a printer, or save the report as a specific file (*report.pdf*). These report outputs may easily be lost or overwritten, especially when you create several reports one after another.

ChemStation automatically tracks all reports that have been generated. In order to reproduce an old or overwritten report, select **Report > Report History**. Here, you can see all reports created for the current data file. You can also export or print this history.

Audit Trail of the Central Data Storage

The Audit Trail of the central data storage system is a record showing who accessed the system and what operations he or she performed during a given period of time.

You can view file-related, system administration, folder administration, and (for ECM) scheduler-related entries. For example, you can see when a file was added and who added it.

For each operation, the central data storage system asks the user for a reason. This reason is also shown in the Audit Trail. For automatic uploads there are default reasons given by the system.

NOTE

In ECM, you must manually enable the Audit Trail. The entry of a reason for the audit trail can be set to be optional or mandatory. If the system shall be compliant to 21 CFR Part 11, the ECM Audit Trail must be enabled, and providing a reason must be mandatory (see "To configure the ECM Account" on page 82). With Data Store, this Audit Trail is always enabled. Using a reason must be regulated by a Standard Operating Procedure (SOP).

To enable the ECM Audit Trail

You can enable the ECM Audit Trail only for a complete ECM Account. To activate the ECM Audit Trail, you must select the check box **Enable audit trail for this account** when creating a new account.

There is no possibility to activate the ECM Audit Trail afterwards for an existing account, or to deactivate the ECM Audit Trail again.

To Enable the Data Store Audit Trail

In Data Store, you do not need to manually enable the Audit Trail. It is always enabled.

To view the Audit Trail for a specific file in ChemStation

For both ECM and Data Store, you can view the Audit Trail for a specific file directly in ChemStation.

1 In the ChemStation Explorer, right-click the respective file.

2 Select **ECM Properties...** or **Data Store Properties...** from the context menu.

This command is only available if the file has been uploaded to central data storage.

3 In the **File Properties** dialog, select the **Audit Trail** tab.

This tab contains all Audit Trail entries associated with the file.

To view the Audit Trail for a specific file in ECM

1 In ECM, right-click the respective file and select **Properties** from the context menu.

2 In the **File Properties** dialog, select the **Audit Trail** tab.

All actions related to this specific file are listed here, together with the date, ECM user name who performed the action, and a reason provided by the according user.

To view the Audit Trail for a specific file in Data Store

1 In Data Store, navigate to the respective file and click the **Properties** icon  of this file.

A file preview is shown, together with several document properties and a list of document actions.

2 Under **Document Actions**, click **Audit trail**.

To view the Audit Trail for all files in ECM

1 In ECM, select the **Administration** page.

2 In the Navigation Pane, select the **Activity Log > Audit Trail** node.

All actions related to any ECM file are listed here, together with the file name, date, ECM user name who performed the action, and a reason provided by the respective user.

You can search the entries, for example, for a specific date or date range, or for entries related to specific categories (Files, Folders, System, Scheduler, or Instrument). Also you can print the entries or export them to a file.

To view the Audit Trail for all files in Data Store

1 In Data Store, select **Tools > View Audit Trail** in the left pane.

You can filter the list by date range and user name.

NOTE The user name is case sensitive and needs to be an exact match.

System Log of the Central Data Storage

The System Log of the central data storage is a record that shows changes to the system, including configuration changes, e-mail notifications, and additions or changes to the directory structure.

You can view file-related, system administration, folder administration, or (for ECM) Scheduler-related entries. For example, you can see when a directory was added and by whom.

The System Log is always active; you do not need to enable it.

To view the ECM System Log

1 In ECM, select the **Administration** page.

2 In the navigation pane, select the **Activity Log > System Log** node.

All general actions related to ECM are listed here, together with the date, ECM user name who performed the action, and a reason provided by the respective user. Depending on the ECM Account administration, the reason may be optional or mandatory (see "To configure the ECM Account" on page 82).

You can search the entries, for example, for a specific date or date range, or for entries related to specific categories (Files, Folders, System, Scheduler, or Instrument). Also you can print the entries or export them to a file.

To view the Data Store System Log

In Data Store, there is only one single activity log for the entire system. System activities are stored at the same place as file activities.

1 In Data Store, select **Tools > View Audit Trail** in the left pane.

You can filter the list by date range and user name.

NOTE The user name is case sensitive and needs to be an exact match.

System Activity Log in OpenLAB Control Panel

The System Activity Log allows you to centrally access all system activities. It contains information on the various events associated with OpenLAB Shared Services or with specific instruments. You can filter the list in order to view only events of a specific type, in a specific time range, created by a specific user, or containing a specific description.

The following types of events are recorded:

- System
- Instrument Management
- Instrument
- Project Management (only applicable to EZChrom)
- Instrument Controller
- User
- Group
- Security
- Printer
- License

The messages can come from other components, such as the user management, or from an instrument module. Instrument messages include error messages, system messages or event messages. ChemStation records these events in its own environment but also sends the events to the System Activity Log. The System Activity Log records these events irrespective of whether you have been alerted to them or not. To get more information on an event, expand the line of interest in the activity logbook viewer.

NOTE By default, activity logging is disabled. To enable it in OpenLAB Control Panel, you must have the **Edit activity log properties** privilege. Once enabled, activity logging cannot be disabled again.

Security Policy

21 CFR Part 11 requires that the company or laboratory have a security policy in place to ensure that only authorized users access the data.

Configuration of the Central Data Storage System

To configure the ECM Account

1 In ECM, select the **Administration** page.

2 In the Navigation Pane, select the **Account Administration** node.

3 Double-click the **Configuration** item.

The **Account Administration** dialog opens.

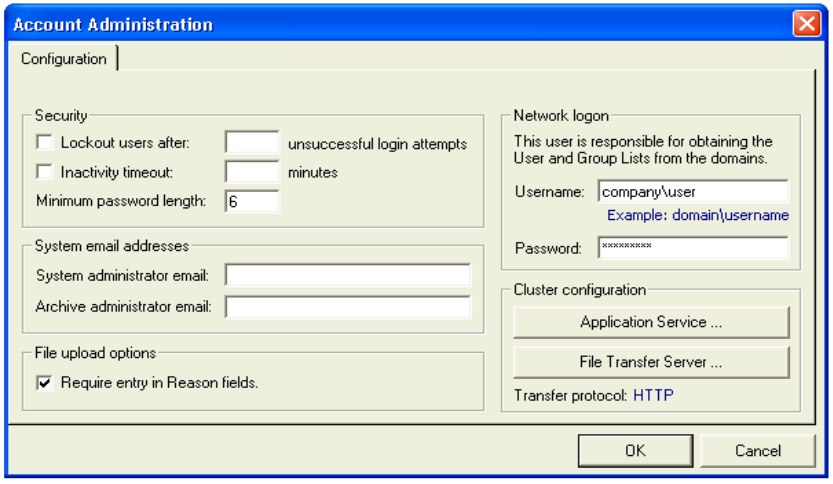


Table 3 Settings in ECM Account Administration

Setting	Description	21 CFR Part 11 Requirements
Lockout	If a user tries too often to log in with invalid user credentials, he is locked out of the system and cannot log in any more – not even with valid user credentials. You can define the number of allowed login attempts. This setting only applies to ECM built-in users, not to Windows domain users.	You should limit the number of allowed login attempts to three.
Inactivity Timeout	If a user does not perform any action for the given period of time, he is automatically logged out of the ECM Web Client. *Note*: The inactivity timeout of ChemStation is set in the Security Policy area of the OpenLAB Control Panel.	You should specify a timeout.
System administrator email	The e-mail address you provide here will automatically be notified when a user was locked out after too many unsuccessful login attempts.	You should provide an e-mail address.
Minimum Password Length	If users change their passwords, they must choose a password with at least the given number of characters. The default setting is *5*. This setting only applies to ECM built-in users, not to Windows domain users.	You should require a minimum password length of at least 5 characters.
Require entry in Reason fields	In each ECM Audit Trail or System Log entry the users can enter a specific reason for the action. If this check box is selected, the entry is mandatory.	The ECM Audit Trail and System Log reasons must be mandatory.

To configure Data Store

1 In the OpenLAB Control Panel, select **Administration > Security Policy** from the navigation pane.

Table 4 Security Policy settings

Setting	Description	21 CFR Part 11 Requirements
Minimum password length	If users change their passwords, they must choose a password with at least the given number of characters. The default setting is *5*. Only available for authentication provider **Internal**.	You should require a minimum password length of at least 5 characters.
Password expiration period (days)	The default value is 30 days. When the user tries to log in after this period of time, the system will ask him to change the password. The expiration period starts with the last password change or with the creation of a user with a new default password. Only available for authentication provider **Internal**.	You should use an expiration period of 180 days or less.
Maximum unsuccessful login attempts before locking account	If a user tries to log in with invalid user credentials a number of times, the user is locked out of the system for a certain period of time (**Account lock time**, see below). Login is impossible, even with valid user credentials. You can define the number of allowed login attempts. The default setting is *3*. Only available for authentication provider **Internal**.	You should limit the number of allowed login attempts to three.

Table 4 Security Policy settings

Setting	Description	21 CFR Part 11 Requirements
Account lock time (minutes)	Once a user has exceeded the maximum number of allowed unsuccessful login attempts, this is the amount of time that must pass before he can try again. The default setting is *5 min*. Only available for authentication provider **Internal**.	
Inactivity time before locking the application	If the OpenLAB Control Panel is inactive for this amount of time, the user interface will be locked. This setting is also used to set the time-based session lock in ChemStation. The default setting is *10 min*. Set the value to zero to never lock.	
Single Sign-On	With Single Sign-On enabled, the user will not see the OpenLAB Control Panel login screen. Only available for authentication provider **Windows Domain**.	

User-Specific Settings

21 CFR Part 11 does not define any specific rules for the password settings. However, your company must have defined a password policy.

To configure password settings in ECM

1 In ECM, select the **Administration** page.

2 In the navigation pane, select the **Account Administration** node.

3 Double-click the **Users/Groups/Roles** item.

You may consider the following settings for ECM built-in users:

- User cannot change password
- User must change password after next login

NOTE The minimum password length for ECM built-in users is defined in the ECM Account configuration (see "To configure the ECM Account" on page 82).

To configure password settings in Data Store

1 In the OpenLAB Control Panel, select **Administration > Users** from the navigation pane.

2 Select a user, and click **Edit** in the ribbon.

If the authentication provider is set to **Internal**, you can configure the following settings on the **General** tab:

Table 5 User Credentials

Value	Description	Mandatory
Name	Username to login in to the system.	Yes
Description	Additional information about the user (e.g. department, function etc.)	No
Password	Password for the user; minimum password length is defined in the Security Policy.	Yes
Email address	Email address of the user.	No
Full name	The full (long) name of the user.	No
Contact Information	General contact information (e.g. telephone number, pager etc.)	No
User disabled	Select the check box to disable a user. Disabled users cannot log in any more. Users may be automatically disabled after too many failed login attempts. If a user is disabled, a corresponding message is displayed instead of the check box. After a given time (see **Account lock time** in the **Security Policy** settings), the user is automatically enabled again.	No
User cannot change password	Flag that indicates whether the user can change his own password. The flag is false by default (that is, users CAN change their passwords).	No
User must change password at next login	If set to true, the user has to change his password at the next login. The flag is automatically set to false after the user has changed the password successfully. The flag is true by default for new users.	No
Group Membership	Assign the user to the relevant groups.	
Role Membership	Assign roles directly to the user.	

Users/Groups/Roles Configuration

Users with specific roles and privileges are needed in both the central data storage system and in ChemStation. First, you need to authenticate with a user name and password when you start ChemStation from the OpenLAB Control Panel. Then, additional privileges are required for specific functions in ChemStation as well as in the central data storage system.

In OpenLAB CDS, user management is part of OpenLAB Shared Services, which you access via the OpenLAB Control Panel. Each user can be member of specific groups. To each group, you can assign predefined roles that comprise specific privileges. If you use an external authentication provider, you can import users and groups from the external system.

Settings in OpenLAB Control Panel

Users in OpenLAB Control Panel

If you use an external authentication provider such as ECM, you cannot create new users, but must import users that exist in the authentication systems. A search function helps you find specific users in the authentication system. In the OpenLAB Control Panel, you can manage the roles for those external users, but not the actual user credentials such as user name and password. If you want to remove an external user, you unmap the user in the OpenLAB Control Panel. The user continues to exist in the external authentication system.

Groups

If you use an external authentication provider, you can either import the names of groups that exist in the external system or create new internal groups. There is no limit on the number of groups that can be mapped or created.

You can assign users to groups in the external system or in OpenLAB Control Panel. If you need additional user assignments that are relevant only for OpenLAB CDS, you create them in OpenLAB Control Panel. Otherwise it is sufficient to only import the groups and assign the required roles to the groups.

If you delete or unmap a group, the users who where members in this group remain unchanged.

Roles and Privileges in OpenLAB Control Panel

Roles are used to assign privileges to a user or a user group globally or for a specific instrument or location. The system contains a list of predefined roles which are installed as part of the system installation (for example, **Instrument Administrator**, **Instrument User**, or **Everything**). Each role has certain privileges assigned.

Privileges are grouped according to the three main role types (Project role, Instrument role, and Administrative role). When you assign privileges to a role, you first select the required role type and then select the privileges related to this role type. Each role can only have privileges of one specific role type; the only exception is the predefined role **Everything**, which has all privileges of all role types. Users or groups may require multiple roles to perform system functions. For example, a user with the role *ChemStation Operator* will always need another role such as *Instrument User* with the privilege to run an instrument.

You can create a tree of different locations in the OpenLAB Control Panel, and add instruments to the relevant locations. For each instrument or instrument group, you can assign different Instrument roles (see also "Specific Privileges for Individual Locations or Instruments" on page 92). For example, a user can have the role **Instrument Administrator** for one instrument, and **Instrument User** for another instrument.

You can also create a tree of different projects or project groups in the OpenLAB Control Panel. With EZChrom, you can assign different Project roles

for different projects (see also "Specific Privileges for Individual Locations or Instruments" on page 92). For example, a user can have the role **Project Administrator** in one project, so that he can manage the settings in the OpenLAB Control Panel. In a second project, he may have a role that allows him to edit the content of a project, but not to change the project settings. As ChemStation does not yet support projects, you can assign the project roles only globally for ChemStation, not at a project level.

Table 6 Description of role types

Role Type	Description
Administrative privileges	These privileges are globally assigned to a user or group and cannot be changed on the instrument/location level. They are the typical administration privileges such as **Backup and restore**, **Manage security**, **Manage printers** etc.
Instrument privileges	These privileges can be assigned globally or on the instrument/location level. Privileges for instruments are, for example, **View instrument or location** and **Run instrument**. Users need the **View instrument or location** on the global level to see the locations and instruments tree in the OpenLAB Control Panel.
Project privileges	Privileges for accessing or modifying different levels of data. • With EZChrom, you can assign these privileges on project level. • As ChemStation does not yet support projects, these privileges are globally assigned to the users with ChemStation.

For a detailed list of privileges, see Appendix.

Privileges Related to Central Data Storage

The following tables describe the privileges that are relevant for OpenLAB Data Store.

Table 7 Administrative privileges

Privilege Name	Description
Archive content	The role **Archivist** includes this privilege by default. The user can archive the content of the Data Store repository.

Table 8 Project privileges

Privilege Name	Description
View project or project group	By default, this privilege is included in the **Project Administrator** role and in all **ChemStation** roles. The user can see a project and project details in OpenLAB Control Panel, but cannot edit. Also, he can view the content of the Data Store repository.
Manage project or project group	By default, this privilege is included in the **Project Administrator** role. User can create or edit project properties and can move the project but cannot access settings (only relevant for EZChrom, as Projects are not supported in ChemStation).
Edit content of project	By default, this privilege is included in the **Project Administrator** role . The user can create new versions of documents in Data Store.

Table 8 Project privileges

Privilege Name	Description
Save data to storage	By default, this privilege is included in all **ChemStation** roles. The user can interactively save data to the central data storage system.
E-Signature Sign Data Files	By default, this privilege is included in the **Project Administrator** role. The user can sign data files, view and edit project properties and create new versions of documents in Data Store.

NOTE As projects are not yet supported by ChemStation, Project roles are applied globally for ChemStation.

Specific Privileges for Individual Locations or Instruments

By default, the roles of users or groups are globally set for all locations, instruments, project groups, or projects. The role settings are inherited from the root node **Instruments** or **Projects** respectively. In order to assign a different role to a user or group for one specific node, you can deselect the **Inherit privileges from parent** check box in the **Edit Privileges** dialog for the required node. Afterwards, you can assign a different role that will be valid only for the specific node.

You can assign **Instrument** roles to individual locations or instruments.

You can assign **Project** roles to individual project groups or projects. As ChemStation does not yet support projects, these settings only have an effect for EZChrom.

Administrative roles are always set globally.

Users, Roles, and Privileges Concept with ECM

With ECM, you must select ECM as an external authentication provider in the OpenLAB Control Panel. In ECM itself, you can either set up internal users or operate with the Windows users (see ECM documentation). Each user can be member of specific groups in ECM and in the OpenLAB Control Panel. The groups available in ECM depend on the ECM configuration. The groups available in the OpenLAB Control Panel can be imported from ECM and supplemented by new internal groups.

There are several default roles in both ECM and OpenLAB CDS. In both systems, you must assign a specific role to each group. Roles and privileges must be configured separately for ECM and ChemStation:

- The privileges set in ECM define the accessible content and functions in ECM.
- The privileges set in the OpenLAB Control Panel define which functions are available in ChemStation, and also which administrative tasks can be carried out in the OpenLAB Control Panel.

NOTE Once you have created a new ECM user, group, or role, you cannot delete it again. You can only deactivate the unused item.

Default ECM Roles and ECM Privileges

There are a number of default roles and privileges in ECM. The following tables show an overview of these roles and privileges.

Name	Description
Roles starting with ":"	Default ECM roles; can be restored by the Reset Roles function.
Privileges starting with **"Content:"**	Privilege related to creating, modifying or deleting content in ECM.
Privileges starting with **"System:"**	Privilege related to administrative tasks in ECM.

In addition, you can create your own roles in ECM, or grant further privileges to the default roles. For detailed information, refer to the ECM Administrator's Guide.

Assigning roles in ECM

Users do not need any specific role in order to log in to ECM. However, in order for users to see a particular Location, Cabinet, Drawer, or Folder in the user interface, they must have the **:Reader** role as a minimum requirement. As a result, domain users with no global roles might not be able to view anything in the content unless they were granted the appropriate privileges.

You should grant the ChemStation users the **:Contributor** role. This can be done at the global level for the entire ECM Account, or individually for specific folders (see "Roles and Folders in ECM" on page 95). The **:Contributor** role allows the ChemStation user to view and add content to ECM. The **:Contributor** role should be enhanced with the **Content: Add Folder** privilege. This allows ChemStation ECM users to add folders to the LCDF hierarchy.

NOTE If the role does not include the **Add Folder** privilege, the users cannot add a new Remote Data Path (LCDF) in ChemStation.

In addition to the configuration of ECM roles, you must also configure ChemStation roles and privileges for ChemStation users. The configuration of ChemStation roles and privileges is done in the OpenLAB Control Panel.

You find a complete list of all ECM and ChemStation privileges in the Appendix.

Roles and Folders in ECM

ECM allows you to assign specific roles to users or user groups. This can be done at the global level for the entire ECM Account, or individually for specific folders. For example, a specific user group may have the **Contributor** role for folder A, but at the same time have only the **Reader** role for folder B. The roles you assign in ECM are only related to content storage in ECM; all roles related to ChemStation and instrument settings are assigned in OpenLAB Control Panel.

Preparations If you want to assign roles at the folder level, you must first enable this feature in ECM. The setting is valid for the complete ECM Account.

To enable roles for folders:

1. In ECM, select the **Administration** page.
2. In the navigation pane, select the **Account Administration** node.
3. Double-click the **Users/Groups/Roles** item.

   The **Account Administration** dialog opens.
4. On the **Roles** tab, select the required role and click **Edit**.
5. Select the **Available in folder access tab** check box.

Users, Roles, and Privileges Concept with Data Store

With Data Store, all users, groups, roles, and privileges are configured in the OpenLAB Control Panel. You can use Windows as an external authentication provider, but you set up all roles and privileges related to OpenLAB in the OpenLAB Control Panel. ChemStation and Data Store refer to these settings.

ChemStation Administration Tool

The ChemStation Administration Tool offers a number of functions related to the ChemStation configuration. As one of these functions is to break the session lock, access to the ChemStation Administration Tool is strictly limited:

- The ChemStation Administration Tool can only be opened directly on the ChemStation PC. In Distributed System installations, you must open the tool on the relevant AIC.
- The ChemStation Administration Tool can only be started by users who are a member of the local user group **CSAdministrators** (see "Enabling users to start the ChemStation Administration Tool" on page 97).

To start the ChemStation Administration Tool:

1 From the Start menu in the Task Bar, select **Start > All Programs > Agilent Technologies > OpenLAB CDS ChemStation Edition > ChemStation Administration Tool**.

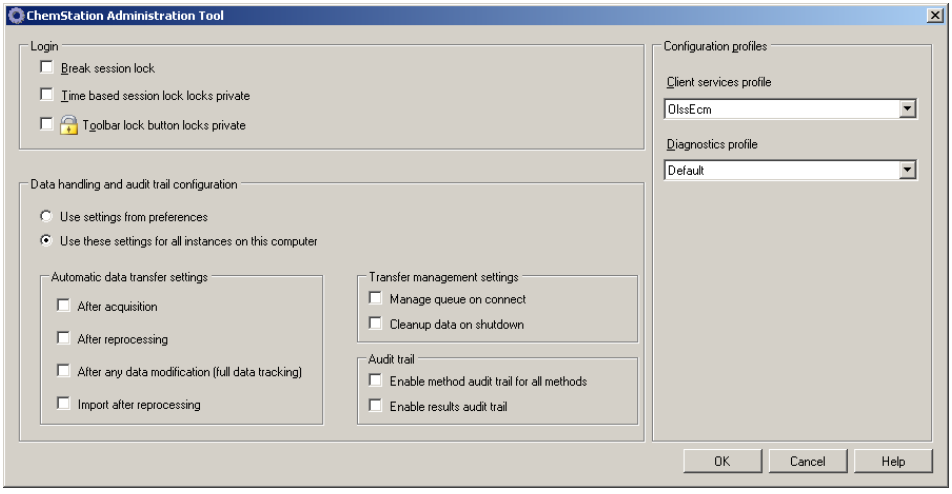


Figure 22 ChemStation Administration Tool

Enabling users to start the ChemStation Administration Tool

During the Installation of OpenLAB CDS ChemStation Edition, the local user group **CSAdministrators** is automatically created. Only members of this group are allowed to run the ChemStation Administration Tool. The user who installs ChemStation, is automatically added to the **CSAdministrators** group. Additionally, the Windows group **Administrators** and the user who installs ChemStation are granted Full Control privileges on the Administration Tool program executable (Agilent.ChemStation.ECM.ECMAdmin.exe) itself, thus they are able to run the tool.

To add a Windows user to the CSAdministrators group:

1 From the Start menu in the Task Bar, select **Start > Settings > Control Panel > Administrative Tools > Computer Management**.

The **Computer Management** window opens.

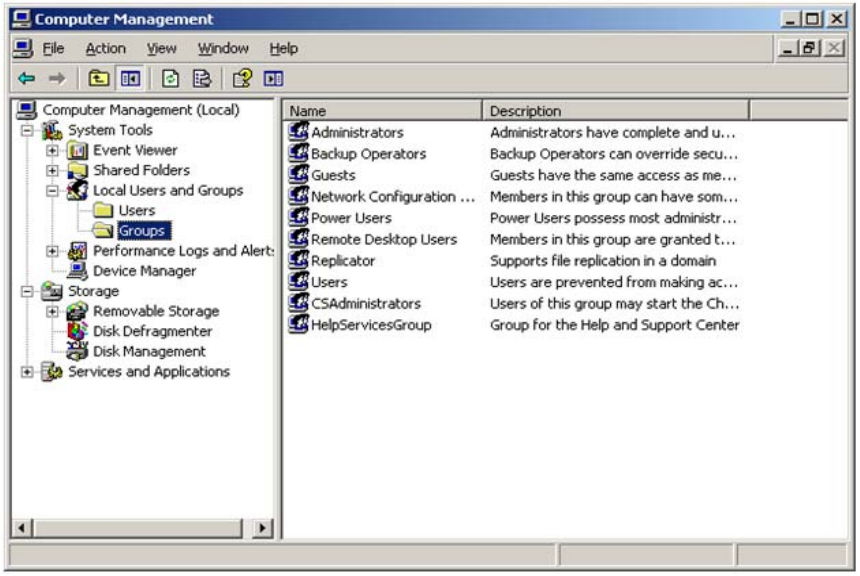
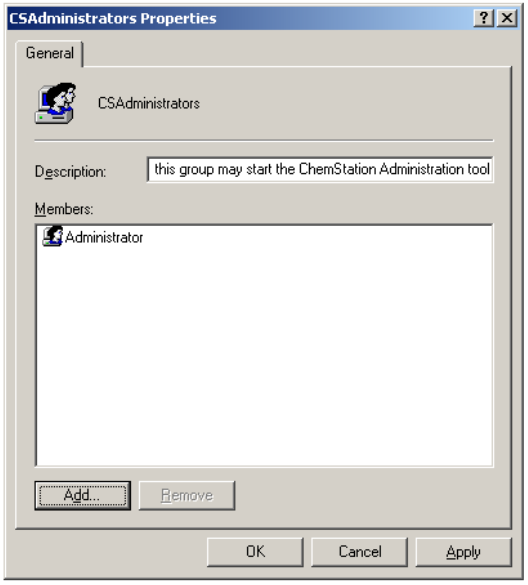


Figure 23 Computer Management window

2 Right-click the group **CSAdministrator** and select **Add to Group...** from the context menu.

The **Properties** dialog shows the users who are currently member of the group.



3 Use the **Add** button to add the required users.

After confirming with **OK**, the **Properties** dialog also contains the newly added users.

Session Lock Settings

Figure 24 ChemStation Administration Tool

In the ChemStation Administration Tool, you can set the following options for creating and breaking session locks:

- **Break session lock**: If you select this check box, a locked ChemStation can be accessed by any user just by clicking **Cancel** in the **Login** dialog. If a ChemStation is currently locked and the authentication provider is unavailable, selecting this check box is the only way to regain access to the current ChemStation session.

NOTE Be aware that, as a consequence, the user who regained access to ChemStation now has unlimited access to all ChemStation functions.

- **Time based session lock locks private**: If ChemStation has been locked by a session time out, only the current user or a user with the required privileges can unlock this session.
- **Toolbar lock button locks private**: If ChemStation has been locked using the Lock button on the ChemStation toolbar, only the current user or a user with the required privileges can unlock this session.

Data Handling and Audit Trail Configuration

The ChemStation Administration Tool offers to conveniently configure all ChemStation instances on a client at the same time with the same settings. By default, the option **Use instance specific settings** is selected, so that the settings are not overwritten.

To change the settings for all ChemStation instances

1. Click **OK**.
2. Select the required check boxes. The settings are the same as in the **Preferences** dialog (see "Preferences" on page 30).
3. Select the option **Use these settings for all instances on this computer**.
4. Select the required check boxes. The settings are the same as in the **Preferences** dialog (see "Preferences" on page 30).
5. Click **OK**.

Configuration Profiles

By providing specific client services profiles, you activate specific functions and behaviors in ChemStation. The following profiles are relevant if you use OpenLAB Shared Services:

- **OIss**

  ChemStation communicates with OpenLAB Shared Services; it sends status information to OpenLAB Shared Services, and uses the settings defined in OpenLAB Shared Services (for example, user authentication, roles and privileges, configuration settings, audit trail settings). Use this profile for ChemStation instances that are connected to OpenLAB Shared Services, but have no connection to a central data storage system.

- **OIssEcm**

  In addition to communication with OpenLAB Shared Services, ChemStation allows transferring data files to and from OpenLAB ECM. Use this profile for ChemStation instances that are connected to both OpenLAB Shared Services and OpenLAB ECM.

  In an emergency scenario, where the connection between the workstation and OpenLAB ECM is interrupted, you can set the authentication provider in OpenLAB Shared Service to **None**. This allows you to log on to ChemStation in the absence of OpenLAB ECM.

  In this case, using the **OIssEcm** profile allows ChemStation to send the data files to the queue. Once the authentication provider in OpenLAB Shared Services is set back to ECM, the upload can be resumed.

- **OIssDataStore**

  In addition to communication with OpenLAB Shared Services, ChemStation allows transferring data files to and from OpenLAB Data Store. Use this profile for ChemStation instances that are connected to both OpenLAB Shared Services and OpenLAB Data Store.

Electronic Signature

Electronic signatures provide a means to sign documents as equally binding as a handwritten signature. In addition, electronic signatures are reproducible, because they are recorded in a secure, time stamped audit trail. Manipulation is prevented by enabling only users with specific privileges to sign electronically.

An electronic signature contains the user name (full name), date, and time when the signature was applied, the location where the signing occurred, and a user-configurable definition associated with the signature. The signature is always related to the complete result set, not to a single file inside the SSIZIP file.

CFR 21 Part 11 requires that companies, especially ones that employ any type of approval process, use electronic signatures.

With OpenLAB ECM, you can use the Agilent OpenLAB Business Process Manager (BPM) module as an Add-on to create highly automated review or approval processes including e-mail notification.

Preparation

Privileges

Users must have a specific privilege in order to be able to sign electronically.

With ECM, a user must have the privilege **Content: File Signatures**. This privilege is, for example, assigned to the default role **:Approver** in ECM.

With Data Store, a user must have the privilege **E-Signature Sign Files**.

Reasons for the signature

With each signature, the users must either select a given reason or, if they are allowed to, provide their own reason.

With ECM, you can either restrict the users to the given reasons or allow them to provide their own reason. Also, you can configure the list of given default reasons.

With Data Store, the list of given default reasons cannot be configured, and users are always allowed to provide their own reason.

To allow specific signature reasons in ECM:

1 In ECM, select the **Administration** page.

2 In the navigation pane, select the **Account Administration** node.

3 Double-click the **Electronic Signature** item.

The **Account Administration** dialog opens.

4 To provide a new reason, enter the required text into the **Reasons** field and click  .

5 To delete an existing reason, select the reason in the **Default reasons** list and click  .

6 If you want to allow users to provide their own reason with a signature, select the **User can specify reason** check box.

NOTE If you clear this check box, the users can only select one of the given default reasons.

7 If necessary, adjust the timeout settings:

- The **Signature screen timeout** defines, how long an e-signature dialog will stay open if no signature is submitted. The default setting is 5 minutes.
- The **Consecutive signature timeout** is relevant if an ECM user carries out several successive e-signatures. If the next e-signature takes place within the given timeout interval, the **location** and the **reason** provided in the first e-signature will be pre-filled in the next dialog. The default setting for the consecutive signature timeout is 5 minutes.

Using electronic signatures

To apply an electronic signature in ECM

1 Right-click the required SSIZIP file and select **Electronically Sign > Electronic Signature** from the context menu.

The **Electronic Signature** dialog opens.

NOTE The other command in the context menu, **Electronically Sign > Acrobat Plug-In Signature**, works only for PDF documents and only if you purchased the respective plugin. It enables you to add signatures directly inside PDF documents.

2 Enter your ECM user credentials (username, password, and domain).

3 Enter your current location. With this information, the location from where you provide the signature is reproducible.

4 Select a reason for the signature from the **Default reason** drop-down list.

- Or -

Select the **User specified** check box and enter a different reason into the text field. Note that this option is only available if the ECM Account is configured accordingly.

5 Click **Sign**.

The file is now signed electronically. The e-signature is shown in the file properties in the **eSig** tab. The e-signature is also included in the ECM Audit Trail.

To apply an electronic signature in Data Store

1 In Data Store, navigate to the respective file and click the **Properties** icon  of this file.

A file preview is shown, together with several document properties and a list of document actions.

2 Under **Document Actions**, click **Sign File**.

The **Sign File** dialog opens.

3 Enter your login credentials for OpenLAB CDS.

4 Select a reason for the signature from the **Reason** drop-down list.

OR

Select the reason **Other**, and enter a different reason into the text field.

5 Click **OK**.

The file is now signed electronically. The e-signature is shown in the list of signatures under **Version History**.

To view electronic signatures in ChemStation

1 In the ChemStation Explorer, right-click the respective file.

2 Select **ECM Properties...** or **Data Store Properties...** from the context menu.

This command is only available if the file has been uploaded to central data storage.

3 In the **File Properties** dialog, select the **eSig** tab.

The electronic signature history for the file, including the date, signer's full name, and reason for each signature are listed.

To view electronic signatures in ECM

The electronic signature itself is shown in the file properties in the **eSig** tab, and it is also part of the ECM Audit Trail.

The user preferences in ECM can be configured in such a way that the number of e-signatures applied to a file is shown by default in the ECM content display, together with the file name and status.

1 In ECM, select the **Administration** page.

2 In the navigation pane, select the **Account Administration** node.

3 Double-click the **User Preferences** item.

4 Click **Modify...** to modify the column settings.

5 Select **# of signatures** and click  to add this property to the selected columns.

6 Click **OK**.

The number of e-signatures is then shown on every content page in ECM.

To view electronic signatures in Data Store

All e-signatures applied to a file are listed under **Version History** in the Properties page of the file.

5
Filter and Search Options

This chapter provides an overview of the filter and search options for ChemStation data in the central data storage system.

Attribute Extraction Services in ECM

ECM Attribute Extraction Services (AES) provides the following AES for the extraction of metadata from ChemStation data files:

- The *ACAML* filter extracts all information contained in the .acaml files, which are part of the SSIZIP files uploaded by ChemStation revision B.03.02 and later.
- The *ChemStation XML* filter extracts peak, compound and result data from the result.xml file generated by the XML export routine in ChemStation revision A.10.02 and later.
- The *ChemStation* filter extracts basic sample and run data from the header of the channel files (*.ch), *.uv and *.txt files generated by all ChemStation revisions.

AES need to be installed by an ECM Administrator on the ECM Server; in addition, the filters need to be enabled for the system. The keys of an AES that are to be applied to a ChemStation file need to be selected for the respective LCDF structure. These are ECM administration tasks, and are described in the Enterprise Content Manager Administrator's Guide and the ECM online help.

The metadata can be queried using various search types in ECM. The ECM Search functionality is also available within ChemStation. When opening a file from ECM, the **ECM Open** dialog allows you to search for files of interest using the 'magnifying glass' icon, see Figure 25 on page 107.

Using the Quick Search, you can search through various alphanumeric fields by entering a search key, such as an operator name. On the upcoming search page, you select the **Advanced** tab where, depending on the enabled filter packages, various keys are enabled, see Figure 26 on page 107.

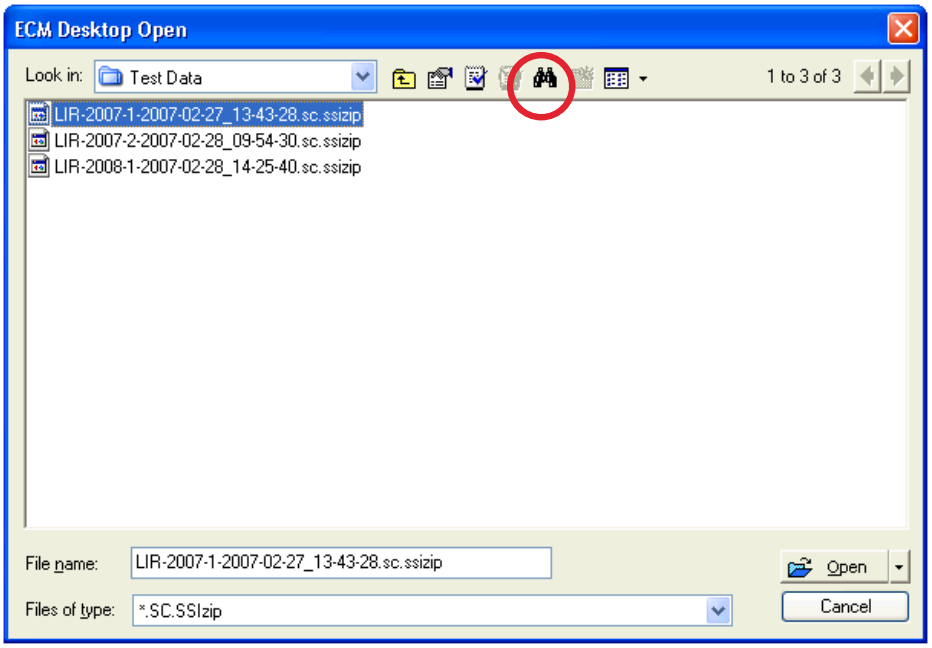


Figure 25 Search options

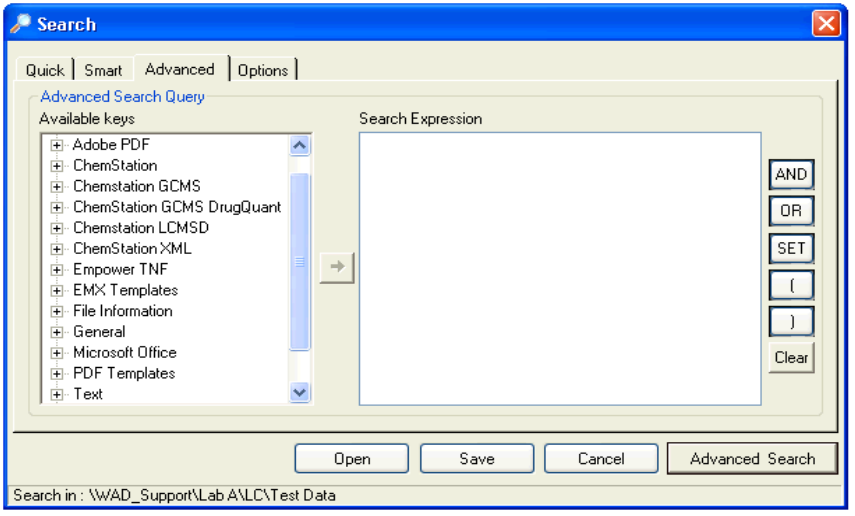


Figure 26 Filters available in search options

In the **Search** dialog, you can specify the available keys, and it is possible to define a search expression by combining two or more of the available keys using boolean operators. For detailed information regarding the use of the various search algorithms, refer to the online help of your ECM system or the Enterprise Content Manager Administrator's Guide, as well as the AES-related manuals.

ACAML Filter

ChemStation stores all data in the ACAML format (ACAML = Agilent Common Analytical Markup Language), which results in .acaml files. There is one .acaml file for each sequence or single run. The .acaml files are always created when acquiring or reprocessing data.

When the data is uploaded to ECM, the .acaml file is part of the SSIZIP file. The ACAML filter extracts information from these files.

Please note that the ACAML filter is only available as of ECM 3.3.2 SP1.

ChemStation XML Attribute Extraction Service

The AES for ChemStation XML extracts key information from the following categories of the result.xml generated by ChemStation per data file. Note that ChemStation must be configured to generate the result.xml file, see the ChemStation XML Connectivity Guide.

- Acquisition (for example, instrument name, method information)
- Chromatogram (for example, derivative order, detector name)
- Custom
- Module
- Peaks (for example, peak name, amount, retention time, compound name)
- Sample (for example, calibration method, LIMS ID)
- Signal/noise

ChemStation Filter

The AES for ChemStation extracts attributes from *.ch, *.uv, and *.txt files created by the 16-Bit ChemStation (Rev A.x.x) or 32-Bit ChemStation (Rev B.x.x or later). It extracts key information from the header of ChemStation *.ch and *.uv data files (for example, sample name, method file, instrument model). From the report.txt file, it extracts key information (for example, sample name, acquisition method, analysis method). In addition, the service extracts information on support files from the category Content.

An ECM Scheduler Add-in for Agilent ChemStation enables the ECM Scheduler to automatically upload data generated by ChemStation to ECM.

Search Options in Data Store

Using the Advanced Search

ChemStation stores all data in the ACAML format (ACAML = Agilent Common Analytical Markup Language), which results in .acaml files. There is one .acaml file for each sequence or single run. The .acaml files are always created when acquiring or reprocessing data. When the data is uploaded to the central data storage, the .acaml file is part of the SSIZIP file.

When using the advanced search in Data Store, you can limit your search to specific metadata based on the values given in the .acaml file

1. In the top pane, click the search icon  .
2. From the **Select field** drop-down list, select the field which you would like to use. You can use, for example, the following fields:
   - Acquisition Operator
   - Compound
   - File name
   - Method Name
   - Sample Name
   - Sequence Name

   The corresponding search expression is entered in the search field.
3. In the search field, click **Type here**, and type your search criteria.
4. Click **Search**.

For more information, refer to the Data Store documentation.

6 Troubleshooting

The chapter gives some elementary troubleshooting hints.

Error messages at OpenLAB Control Panel Startup

Connection to Shared Services failed

When the ECM server or the OpenLAB Shared Services server is not available, the user cannot start the OpenLAB Control Panel. As ChemStation is launched from OpenLAB Control Panel, working with ChemStation is not possible.

When only the Data Store service is not available, the user can start OpenLAB Control Panel and work with ChemStation, but he cannot transfer data to OpenLAB Data Store.

Probable cause	Suggested actions
1 The Data Store service is not available.	Start OpenLAB Control Panel and work only with local data in ChemStation.
2 The ECM server or Shared Services server is not available.	• **Reconnect**: Try again to start the OpenLAB Control Panel. • **Ping**: Ping the Shared Services server. • **Switch to Failover mode**: If the connection to the Shared Services server cannot be re-established in a short period of time, switch to Failover mode. For more information, refer to the technical note *OpenLAB CDS ChemStation Edition – Emergency Procedures*.

Alerts and Error Messages at ChemStation Startup

Your Transfer Settings (Remote Data Path) differ from the current connection. Change Transfer Settings now?

At every startup, Agilent ChemStation checks whether all necessary information is provided for transferring data to the central data storage. This message is shown if the information on the Server provided in the Transfer Settings differs from the server configured in OpenLAB Control Panel.

Probable cause	Suggested actions
1 The Transfer Settings in ChemStation differ from the configuration in OpenLAB Control Panel.	Make sure that the correct information on Server, Account, and Path is provided in the Transfer Settings (**ECM > Preferences > Transfer Settings** or **Data Store > Preferences > Transfer Settings**).

ECM or Data Store Server is not available after login

If the connection to the ECM or Data Store Server is interrupted after login to the OpenLAB Control Panel, the user has already been authenticated by the external system. In this case, ChemStation knows the current logged-in user.

When the ECM or Data Store Server becomes unavailable, ChemStation automatically tries to reestablish the user login.

The Load and Save functions are accessible, but an alert informs the user about the interrupted connection to the central data storage system.

While acquiring data, the automatic transfer of data to the central data storage cannot be completed. The user is notified by an error message. and must manually upload the data as soon as the connection is reestablished (**ECM > Manage Queue** or **Data Store > Manage Queue**).

As soon as the ECM or Data Store Server is available again, all tasks are available without restarting the application. A new login is not required.

For further troubleshooting, please contact the administrator for the central data storage system.

Error Messages in the Queue Management

Independent of Storage Type

`The queue already contains items`

Probable cause	Suggested actions
1 There are items in the queue that have been queued before the current item.	Process queue in the correct order. If necessary, export items that can't be resolved.

`Invalid URI: The format of the URI could not be determined`

Probable cause	Suggested actions
1 In the preferences, the ECM or Data Store server is missing or has been entered by name only, not as URI (http:\\servername\ ).	Correct the server in the preferences, e.g. by using **Get Server**. Save existing items in the queue to the local file system. After correcting the server setting, reprocess the data.

ECM-Specific Messages

`Current connection to '<account1>', expected connection to '<account2>'`

Probable cause	Suggested actions
1 ECM Account setting in Preferences differs from current connection.	Correct the Transfer Settings.

Currently no connection, expected connection to '<server>'

Probable cause	Suggested actions
1 The ECM Server is not available.	Contact your ECM administrator.
2 In the OpenLAB Control Panel, the storage is not set to ECM.	Select ECM as the storage type in OpenLAB Control Panel, or ask your system administrator to do so.

You do not have permission to create a new Drawer/Folder.

Probable cause	Suggested actions
1 You do not have appropriate privileges to create the Drawer or Folder in ECM.	Ask an administrator to give you the corresponding privileges or to create the needed directories.

You do not have permission to add files.

Probable cause	Suggested actions
1 You do not have appropriate privileges to save files to the specified location in ECM.	Ask an administrator to give you the corresponding privileges.

Unable to upload (filename). This file is currently checked out to another user and may not be updated. (error -1).

Probable cause	Suggested actions
1 Another user has checked out the file from ECM.	The other user has to check in the file before you can upload the file.

Data Store-Specific Messages

No connection to remote storage established

Probable cause	Suggested actions
1 The Data Store service is not available.	Contact your Data Store administrator.

Connection to remote storage is broken.

Probable cause	Suggested actions
1 The connection to Data Store has become unavailable during the current session.	• Wait for the connection to be reestablished. • Contact your Data Store administrator.

You cannot upload a file that is checked out by another user

Probable cause	Suggested actions
1 The file you want to upload is currently checked out by another user.	Ask the other user to check in the file, then upload again.

You do not have appropriate permissions to create a folder

Probable cause	Suggested actions
1 You do not have the privilege to create content in Data Store.	Ask an administrator to give you the **Save data to storage** privilege.

7
Appendix

Privileges in OpenLAB Control Panel

Project Privileges

Table 9 Project Management

Name	Description
View project or project group	User can see a project and project details but cannot edit. With Data Store: User can view the content of the Data Store repository. *Note:*This privilege is required for all users, even if ChemStation does not support projects yet.
Manage project or project group	User can create or edit project properties and can move the project but cannot access settings (EZChrom only; Projects are not supported in ChemStation).
Edit content of project	Only relevant for Data Store: User can create new versions of documents in Data Store.
Manage project or project group access	User can view and edit the project access settings (EZChrom only; Projects are not supported in ChemStation).

Table 10 E-Signature

Name	Description
E-Signature Sign Data Files	User can sign data files (with ChemStation, this privilege is only relevant if you use OpenLAB Data Store).

Table 11 Intelligent Reporter templates

Privilege	Description
Edit Intelligent Reporter report template	Only relevant for OpenLAB ECM Intelligent Reporter: This privilege is required to edit report templates in the Reporter Client

Table 12 ChemStation: Control

Privilege	Description
Run Acquisition	Start acquisition (single sample or sequence).

Table 13 ChemStation: Data

Privilege	Description
Delete Data	User can delete data files in ChemStation Explorer.
Manual Integration	User can perform manual integration.
Save data to storage	Interactive saving of data to the central data storage system.

Table 14 ChemStation: Instrument

Privilege	Description
Modify instrument configuration	User can modify the instrument configuration parameters.

Table 15 ChemStation: Logbook

Privilege	Description
Clear Logbook	Clear the current logbook.
Save Logbook	Save the current logbook.

Table 16 ChemStation: Method

Privilege	Description
Edit calibration table	Create and modify the calibration table; change calibration settings.
Delete method	Delete a method in ChemStation Explorer.
Edit integration events	Modify integration events and perform Auto Integration.
Edit ion labels	Edit options for ion labels (LC/MS only).
Edit system suitability	Edit noise ranges and performance limits.
Enable audit trail	Enable the audit trail for a specific method.
Modify instrument method	Modify instrument method parameters.
Modify method properties	Modify Run Time Checklist and Method Information.
Perform method recalibration	Perform interactive recalibration.
Save method changes	Save method changes (includes Update Sequence/Master Method in Data Analysis view).

Table 17 ChemStation: Report

Privilege	Description
Preview/print report	User can preview/print a report.
Modify report	User can modify report calculation/print style and can edit Instrument Curves dialog.
Lock/unlock report template items	Only relevant with Intelligent Reporting: User can lock or unlock report items and composite groups in a report template.

Table 18 ChemStation: Security

Privilege	Description
Break session lock	Unlock a ChemStation session locked by other users.
Command line	Turn on / off the command line
Manage transfer queue	Access to the Transfer Queue and the Queue Management.
Modify storage transfer preferences	Enable / disable the automatic upload to the central data storage system.
Take over ChemStation Remote Session	Only relevant for ChemStation in a Distributed System: User can take over a running remote session.

Table 19 ChemStation: Sequence

Name	Description
Delete sequence	User can delete sequences in ChemStation Explorer.
Edit sequence summary	User can modify sequence summary report and extended statistics settings.
Reprocess	User can reprocess a sequence.
Save sequence template	User can save sequence templates locally (on workstation or AIC).

Table 20 ChemStation: View Access

Privilege	Description
Access Data Analysis view	User has access to Data Analysis view.
Access Diagnostic view	User has access to Diagnostic view.
Access Method & Run Control view	User has access to Method and Run Control view.
Access retention time lock	User has access to the Retention Time Lock menu (GC only).
Access retention time search	User has access to Retention Time Search menu (GC only).
Access Review view	User has access to Review view
Access Tune view	User has access to Tune view (LC-MSD ChemStation only).
Access Verification view	User has access to Verification (OQ/PV) view.
Access Report Layout view	User has access to Report Layout View, ability to create/edit/save report templates.
Enable Batch view	Enables all operations in Batch view.

Instrument Privileges

Table 21 Instrument Management

Name	Description
View instrument or location	User can view and access a location in the tree, but not edit access security, can view properties.
Manage Instrument or location	User can create and move locations and edit properties (name, description etc).
Manage instrument or location access	User can view and edit the location access settings.
Run instrument	User can start an instrument session.
Service instrument	User can lock or unlock an instrument (to service it).

Administrative Privileges

Table 22 System Administration

Name	Description
Manage printers	Can add/remove printers and print server.
Edit activity log properties	Can change the Activity log Settings in OpenLAB Control Panel (that is, can turn logging on for the System Activity Log).
Create administrative reports	Can create any of the system admin reports.
Manage system components	Can install/remove components (applications).
Manage Security	Can change security settings. Can edit (add, change etc) users, groups and roles. *Note:* A user with this privilege can grant himself access to all settings in OpenLAB Shared Services. Be careful who you grant the Manage Security privilege.
Manage instrument controllers	Can edit AIC configuration, manage the AICs in configuration UI.
Unlock any locked UI	Can login into any locked portal or instrument session (will be a re-login), even if privately locked.
Manage Data Store admin settings	User can access the **Admin** sub folder of the **Applications** root note in Data Store.

Table 23 Data Store

Name	Description
Archive content	User can archive the content of the Data Store repository.

Table 24 Lab Applications privileges

Name	Description
Access Lab Applications	User can see the **Sample Submission** dashlet and can access the Lab Journal and Lab Apps Editor toolbar items.
Create/edit sample submission forms	User access the **Create Sample Submission** commands in the **Sample Submission** dashlet and in the Lab Applicatons Editor.
Review/validate	User can be assigned as a reviewer or validator of a lab event or service form.
Manage Lab Journal instruments	User can create, edit, delete, or deactivate a Lab Journal instrument.
Manage lab events	User can create, edit, delete, or deactivate a lab event.
Manage service forms	User can create, edit, delete, or deactivate a service forms.
Manage columns	User can create, edit, delete, or deactivate a column.
Manage samples	User can create, edit, or delete samples.

ECM Privileges related to ChemStation

The privileges described in the following table must be assigned to at least one of your roles in order to become active.

Table 25 List of ECM related privileges

Privilege	View	Edit	Delete	Add	Run	Description
Content: File	X			X		• Minimum privilege for ChemStation to access ECM • Privileges to view ECM Properties in ChemStation
Content: File Filtering		X				• Minimum privilege for ChemStation to access ECM • Privilege to add files manually to an ECM folder
Content: File Revisions	X					• Privilege to view revisions in ChemStation
Content: File Type [XLS]		X		X		• Privilege to add and check in files with an .xls extension
Content: Folder	X	X		X		• Minimum privilege for ChemStation to access ECM • Privilege to view ECM Properties in ChemStation
Content: Folder Access Properties		X				• Privilege to view and change any folder property tab
Content: Rekey File					X	• Privilege to rekey files in ECM e.g. with XML Filters
System: Advanced Search					X	• Privilege to use the Advanced Search in ChemStation
System: Audit Trail	X					• Privilege to view ECM Properties in ChemStation

Table 25 List of ECM related privileges

Privilege	View	Edit	Delete	Add	Run	Description
System: Filtering Configuration	X					• Privilege to view or change the filtering configuration • Privilege to use attribute extraction services and to manage user-defined attributes
System: indexing Configuration	X					• Minimum privilege for ChemStation to access ECM • Privilege to view ECM Properties in ChemStation
System: Quick Search					X	• Privilege to use Quick Search in ChemStation
System: Super Object	X					• Privilege is mandatory for OLIR
System: Project	X					• Privilege to view projects in OLIR
System: Project Access	X					• Privilege to access projects in OLIR

Index

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In This Book

This guide contains reference information on the interface between Agilent OpenLAB CDS ChemStation Edition and the central data storage provided by OpenLAB ECM or OpenLAB Data Store. It also describes the settings required by 21 CFR Part 11, and provides information on the workflows for ChemStation using a central data storage.

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7 Appendix

In This Book

7 Appendix

In This Book

7 Appendix

In This Book