Agilent OpenLAB CDS ChemStation Edition with ECM

Concepts Guide

Agilent Technologies

Notices

Manual Part Number

M8301-90080

Edition

03/2011

Printed in Germany

Agilent Technologies
Hewlett-Packard-Strasse 8
76337 Waldbronn

This product may be used as a component of an in vitro diagnostic system if the system is registered with the appropriate authorities and complies with the relevant regulations. Otherwise, it is intended only for general laboratory use.

Software Revision

This guide is valid for revision C.01.xx of Agilent OpenLAB CDS ChemStation Edition.

Microsoft ® is a U.S. registered trademark of Microsoft Corporation.

Warranty

Technology Licenses

Restricted Rights Legend

Safety Notices

CAUTION

A **CAUTION** notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in damage to the product or loss of important data. Do not proceed beyond a **CAUTION** notice until the indicated conditions are fully understood and met.

WARNING

A WARNING notice denotes a hazard. It calls attention to an operating procedure, practice, or the like that, if not correctly performed or adhered to, could result in personal injury or death. Do not proceed beyond a WARNING notice until the indicated conditions are fully understood and met.

In This Guide ...

This guide contains reference information on the interface between ChemStation and OpenLAB ECM, on the settings required by 21 CFR Part 11, and on the workflows for ChemStation with ECM.

1 Introduction

This chapter introduces the ECM implementation in OpenLAB CDS ChemStation Edition and the requirements of 21 CFR Part 11.

2 Basic Concepts of ChemStation with OpenLAB ECM

This chapter describes how to log in to ECM in ChemStation, and explains the ECM-related user interface items and toolbars, as well as the main preference settings.

3 Working With ChemStation and ECM

This chapter describes the basic workflows for ChemStation with ECM. 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 its implementation in ChemStation with OpenLAB ECM

5 Attribute Extraction Services for ChemStation Data

This chapter provides an overview of the available ECM Attribute Extraction Services (AES) for ChemStation data. The AES extract metadata information from the ChemStation data files. These metadata make the ChemStation data searchable. For detailed information, refer to the ECM documentation.

6 Troubleshooting

The chapter gives some elementary troubleshooting hints.

7 Appendix

Contents

Contents

1
Introduction

This chapter introduces the ECM implementation in OpenLAB CDS ChemStation Edition and the requirements of 21 CFR Part 11.

Agilent Technologies

What is ECM?

The Agilent Enterprise Content Manager (ECM) is a web-based electronic library that allows you to safely archive and catalog any electronic file. ECM allows you to 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.

ECM allows you to easily collect, organize, search, and review all of your data. It automatically extracts searchable metadata from files, and provides powerful search capabilities. In addition, ECM provides embedded viewers for many file types.

The ECM interface is opened via Microsoft Internet Explorer, also referred to as the ECM Web Client.

Using ChemStation with ECM

OpenLAB CDS ChemStation Edition provides an interface to the Agilent Enterprise Content Manager (ECM), which enables you to store analytical data and reports in a secure location. From ChemStation, you can log in to ECM and store methods, sequence templates, data files, report templates, and generated reports in ECM. Data storage can be either automatic (that is, at the end of a single run or sequence) or manual. ChemStation data stored in ECM can later be downloaded to ChemStation for review or reprocessing at any time.

Furthermore, OpenLAB CDS ChemStation Edition in combination with ECM 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 ECM
- 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 ECM in any of the installation scenarios for OpenLAB CDS ChemStation Edition:

- Workstation
- 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

	Workflow 1: Data Acquisition	Workflow 2: Data Acquisition + Review	Workflow 3: Reprocessing/Modifying + Upload	Workflow 4: Reprocessing + Import

ChemStation

Data A → (Workflow 1)
Data A → Data A(x) (Workflow 2)
Data A → Data A(x) (Workflow 3)
Data A → Data A(x) (Workflow 4)

After Acquisition | After Acquisition | After Data Modification | Load Data | After Reprocessing / Data Modification | Import after Reprocessing

ECM

Data A Version 1 | Data A Version 1 / Version 2 | Data A Version n / Version n+1 | Data A Version 1

Workflow 1: Raw data acquisition and automatic transfer to ECM

1 Analytical raw data is acquired using ChemStation.

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

3 A new ECM data set is created in the defined ECM 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 ECM using the configured path definitions immediately after the single run/sequence is finished.

A new ECM data set is created in the defined ECM location.

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

Another new version of the ECM data set is created.

Workflow 3: Reprocessing data and automatic upload to ECM

1 Existing analytical data is loaded from ECM into ChemStation.

2 The data is reprocessed in ChemStation.

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

4 A new version of the data is created in ECM.

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 ECM. The location in ECM is defined by the current preferences in ChemStation.

4 A new version of the data is created in ECM.

Overview of workflows for methods/sequence templates/report templates

	Workflow 1: Local Files – Save new method	Workflow 2: ECM – Save changed method
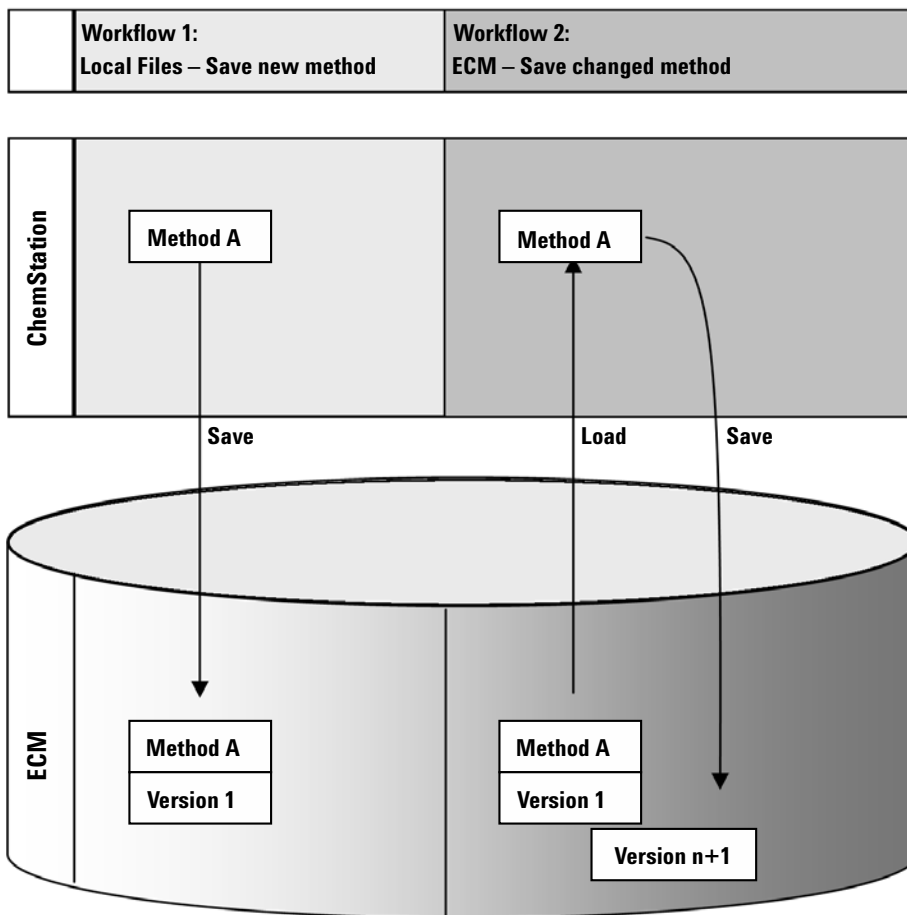
Workflow 1: Uploading a new method, sequence template or report template

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

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

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

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

1 An existing method, sequence template, or report template is loaded from ECM.

2 The changed method, sequence template, or report template is saved to ECM.

3 A new version of the method, sequence template, or report template is automatically created in ECM.

Data Storage 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 then 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.
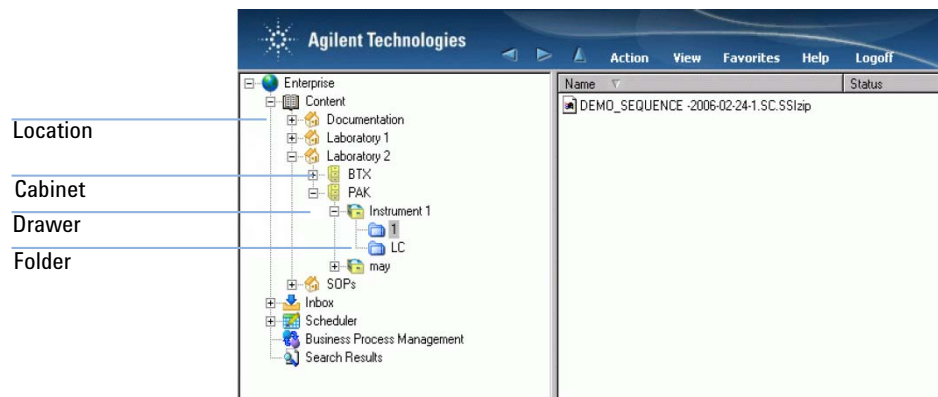

Figure 1 LCDF structure in ECM

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.

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-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.

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 Agilent OpenLAB ECM provides the necessary controls for managing system access, audit trail functions, versioning of ChemStation data, and electronic signature functions. Agilent OpenLAB ECM ensures secure record keeping and data archival. Agilent OpenLAB ECM is proven and has been deployed at many leading life sciences companies to satisfy compliance mandates for 21 CFR Part 11.

1 Introduction

21 CFR Part 11 Compliance

2

Basic Concepts of ChemStation with OpenLAB ECM

This chapter describes how to log in to ECM in ChemStation, and explains the ECM-related user interface items and toolbars, as well as the main preference settings.

Agilent Technologies

Login and Lock Options

User Permissions

You start ChemStation from the OpenLAB Control Panel. To prevent unauthorized access, the OpenLAB Control Panel requires authentication with a user name and password. As the OpenLAB Control Panel uses ECM as an external authentication provider, you log in with your ECM user credentials.

You need specific user privileges for working with OpenLAB CDS as well as for working with OpenLAB ECM. The privileges set in the OpenLAB Control Panel define which functions you can use in ChemStation, and also which administrative tasks you can carry out in the OpenLAB Control Panel. The privileges set in ECM define the accessible content and functions in ECM. For more information on user privileges, see "Users/Groups/Roles Configuration" on page 73.

User Credentials

User credentials

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

You need to enter the following login details:

- **Login:** the user name defined in the Shared Services, or your NT domain user name (depending on the user configuration in the Shared Services)
- **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 and ECM User

With ECM as an authentication provider, the ChemStation operator name in the sample info (when running single samples) or the sequence parameters (when running a sequence) is overwritten by your ECM user name. The operator name cannot be overwritten. Therefore, you cannot change the user with the **Change User ...** command while acquiring data. This prevents the operator name from being changed during data acquisition.

Session lock

If you leave the ChemStation computer for a certain 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 secures ChemStation until the personnel of the new shift starts 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 Shared Services configuration, ChemStation is automatically locked after a given period of time without any user interaction (**Inactivity Timeout** setting in the Security Policy area of the 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 78).

OpenLAB ECM User Interface in ChemStation

Overview of the interface elements

When connected to ECM, the following new menus, menu items, and interface elements are available in ChemStation:

Menu	Element type	Description
Method	**Enable Audit Trail** Command	See "Method Audit Trail" on page 64
Sequence > Sequence Parameters	**Sequence Parameters** Tab	See "Remote Data Path as Sequence Parameter" on page 33
Report	**Report History** Command	See "Report History" on page 66
View > Preferences	Tabs In the Preferences dialog: • **Transfer Settings** • **Audit Trail**	See "ECM Preferences" on page 23 and "Audit Trails and Logbooks" on page 64
ECM	**ECM** Menu	See "The ECM menu" on page 21
User	**User** Menu	See "The User menu" on page 22
Toolbar (depending on the current view)	• Shortcuts to several commands of the **ECM** and **User** menus • **LCDF** info	• LCDF info in the **Data Analysis** view: shows the LCDF path of a file that has been stored to ECM. • LCDF info in the **Method and Run Control** view: shows the LDCF path for automatic upload after acquisition.
ECM related details in the **System Diagram** in **Method and Run Control** view (classic UI only).	Details view	The following details are available: • **LCDF** • **Operator** • **Automatic transfer after acquisition** • **Automatic transfer after reprocessing** • **Automatic transfer after any data modification** • **Automatic import after reprocessing**

The ECM menu

The **ECM** menu and its commands depend on the view that is currently active. See the following table for details.

| NOTE | There is no **ECM** 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 ECM (if existing in ECM). 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 ECM (if existing in ECM). Local changes are overwritten.	• **Report Layout**
Cleanup Data	The **Cleanup Data** command deletes all data or result sets from the local file system that exist in ECM as well. Make sure you uploaded the latest version to ECM before you confirm this command. See "Cleanup Data on Shutdown" on page 28.	• **Data Analysis**
Manage Queue	With the **Manage Queue** command you can continue any interrupted data upload to ECM. See "Manage Queue on Connect" on page 27.	• **Method and Run Control** • **Data Analysis**
Preferences	See "ECM Preferences" on page 23 for more details on the **Preferences** dialog.	• **Method and Run Control** • **Data Analysis** • **Report Layout**
Method-related commands: **Load Method ...** **Save Method**	See "Workflows for Methods and Templates" on page 50	• **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 39	• **Data Analysis**
Commands related to the sequence template: 📂 **Load Sequence Template ...** 💾 **Save Sequence Template**	See "Workflows for Methods and Templates" on page 50	• **Method and Run Control**
Commands related to report templates: 📂 **Load Report Template** 💾 **Save Report Template**	See "Workflows for Methods and Templates" on page 50	• **Report Layout**
Commands related to reports: 📂 **Load Report Template** 📄 **Save as PDF** 📊 **Save as XLS**	• You can load a specific report template from ECM. • You save the report generated with this template as a PDF or XLS file to ECM.	• **Review**

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 19.	• **Method and Run Control** • **Data Analysis** • **Review** • **Report Layout**

ECM Preferences

The **Preferences** dialog contains two tabs that are relevant to OpenLAB ECM: 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 78). 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 ECM:

• Remote Data Path

• Automatic Data Transfer Settings

• Transfer Management Settings
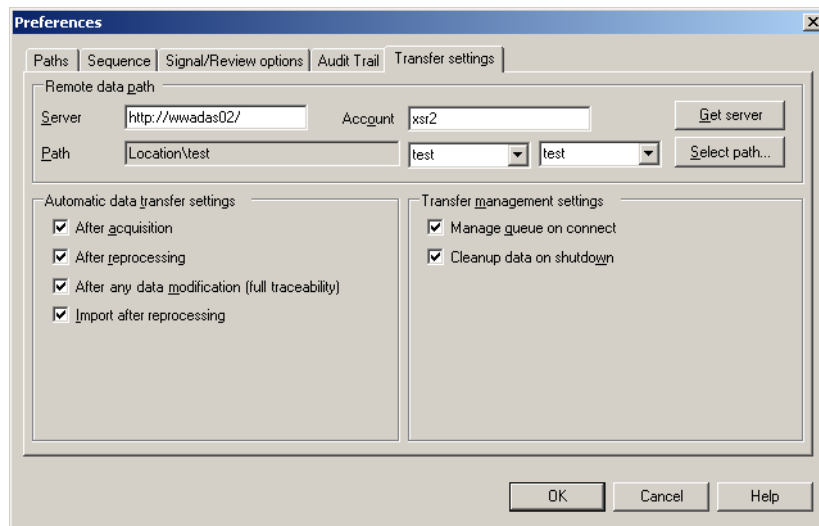
Figure 2   Transfer Settings tab in the Preferences dialog

All 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 64.
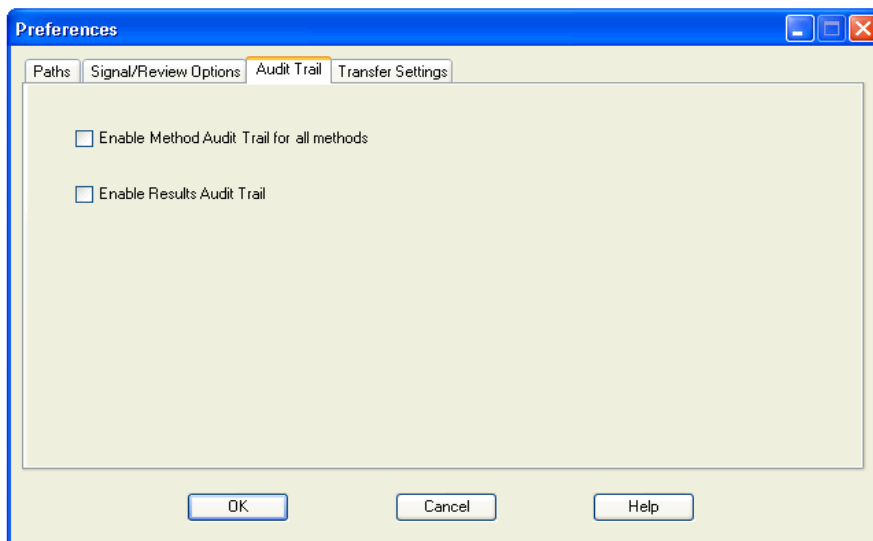
Figure 3   Audit Trail tab in the Preferences dialog

Remote Data Path

The **Remote Data Path** needs to be specified in order to save the data to the correct location in ECM.

In the **Preferences** dialog, the **Transfer Settings** tab (see Figure 3 on page 24) allows you to define the **Remote Data Path**. The **Remote Data Path** reflects the LCDF structure in ECM.

Server/Account

In the text fields **Server** and **Account**, you can specify the ECM Server and ECM Account that you want to use to store the ChemStation data.

At your first login from ChemStation to ECM, you must specify the server and account information. You can either enter the information manually, or you can click **Get Server** to fill the fields with the Server and Account where you are

currently logged in. ChemStation then keeps the Server and Account information for future sessions.

If you log in to a different ECM Server later, you have to update the Server and Account information. You can click **Get Server** again to fill the fields with the current ECM Server name and the current ECM Account.

Path

To specify the Remote Data Path, you need to select a Location and Cabinet available in the ECM Browser. Click **Select Path** to select the required path in an ECM Explorer dialog.

NOTE	If no **Remote Data Path** is specified, a warning message will be shown at ChemStation startup.

For the Drawer and Folder, you can either keep the selected items, or you can select predefined tokens for an automatic path creation. When you use the predefined tokens in the Remote Data Path, the system automatically creates the items if they do not already exist in ECM.

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

Alternatively, the **Remote Data Path** can be specified as **Sequence Parameter** (see). Uploaded objects can be stored only at the Folder level.

Table 1   Remote Data Path items

ECM Data Path Item	Convention
Location	Fixed location to be selected in ECM
Cabinet	Fixed cabinet to be selected in ECM
Drawer	Drawer available in ECM Tokens: Instrument Name, Instrument Number, Operator
Folder	Folder available in ECM Tokens: Instrument Name, Instrument Number, Operator

Automatic Data Transfer Settings

In the **Preferences** dialog (**View > Preferences**), the **ECM** 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 ECM.

NOTE   If you are not logged in to ECM in ChemStation, the data cannot be automatically uploaded to ECM as specified in the transfer settings. The data is then queued in the Spooler Queue Manager (see "Spooler Queue Manager" on page 29).

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 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 ECM 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 compressed to an SSIZip file which is then uploaded to ECM.

For more information, please refer to "Workflow 1: Acquisition and automatic upload" on page 39.

After Any Data Modification

If you select this check box, the result set is automatically uploaded to ECM 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 42.

After Reprocessing

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

For more information, please refer to "Workflow 3: Reprocessing data and automatic upload" on page 44.

Import after Reprocessing

If you select this check box, a sequence that is only stored locally is automatically uploaded to ECM after reprocessing.

For more information, please refer to "Workflow 4: Import after reprocessing" on page 48.

Transfer Management Settings

Manage Queue on Connect

If the connection to ECM breaks down 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 to ECM each time a connection to ECM is established (that is, each time a user logs on to ECM from ChemStation).

Alternatively, you can open the **Spooler Queue Manager** dialog (see "Spooler Queue Manager" on page 29) at any time with the **ECM > Manage Queue** command in the **Data Analysis** view.

Cleanup Data on Shutdown

If you select this check box, ChemStation checks the local file system at each shutdown. It deletes all local data and sequence files that are known to be stored in ECM as well. Methods and sequence templates remain on the local file system.

NOTE	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 ECM 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 **ECM > Cleanup Data** command in the **Data Analysis** view.

This dialog box lists all data sets related to ECM apart from the currently loaded data. The following columns are available:

- **Directory**: Location of the local file
- **ECM Information**: ECM server, account information, and LCDF path of the file in ECM
- **Last Modified**: Date/Time when the copy in ECM was last changed
- **Locally Modified**: Information whether the local copy has been modified
- **Local Version**: 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 deselect all data sets, select all, select only single runs, select only result sets, select items older than today, 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:
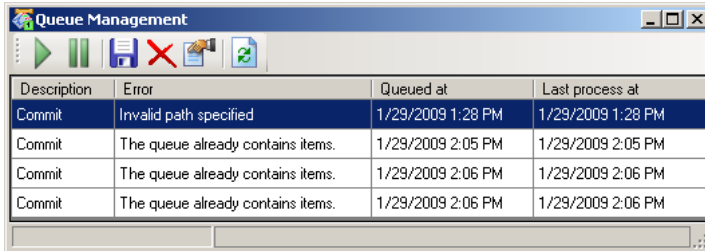
- the ChemStation user is logged on to ECM
- no other instance of the ChemStation instrument is open
- the spooler queue is empty

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.

Spooler Queue Manager

The **Spooler Queue Manager** dialog is opened via **ECM > Manage Queue**. 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 ECM that were interrupted or could not be started for any reason. Each failed transfer job is listed in a separate line.

Figure 4   Spooler Queue Manager

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 ECM 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 ECM. 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 Spooler Queue Manager" on page 99.

- **Queued at**: Date when the unsuccessful transfer was queued in the Spooler Queue Manager.

- **Processed last 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 selected lines to a file. Only the displayed error, description, and dates are saved to the file. The respective data is not included!
	Delete selected item	Delete the selected transfer job from the queue. The concerned data will not be transferred to ECM.
	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 Audit Trail of ECM.

NOTE	When items are deleted from the queue or saved to the local disk, they have not yet been uploaded to ECM.

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.

This tool is disabled under all circumstances in the ChemStation.

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 24), 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 **Remote Data Path** for a sequence template is set up in the **Sequence Parameters** tab.
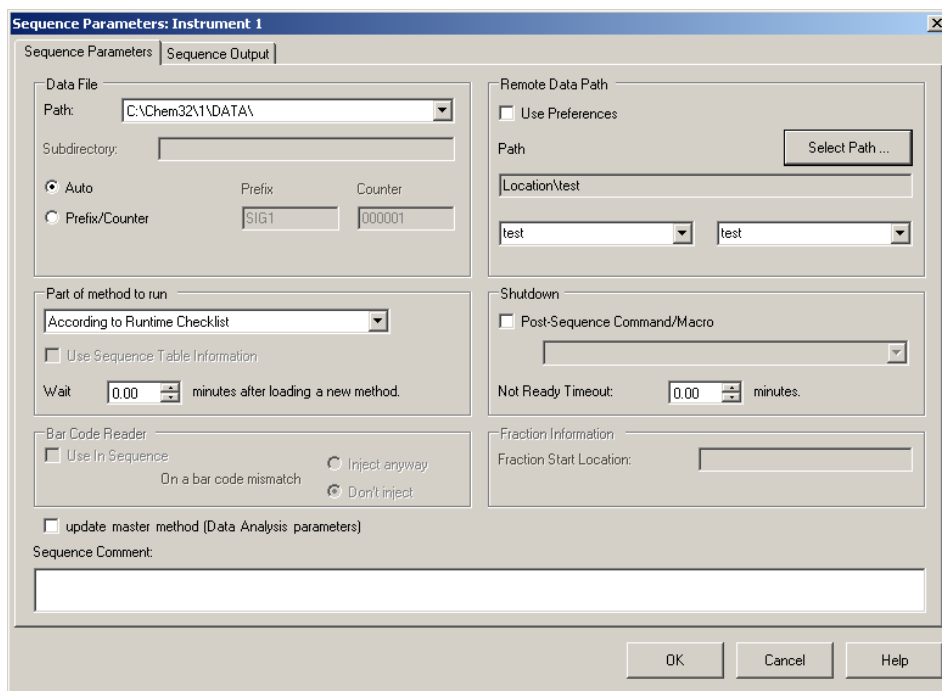
Figure 5   Sequence Parameters tab of the **Sequence Parameters** dialog

Use Preferences: When this checkbox is enabled, the **Remote Data Path** as specified in the **Preferences** will be used. Any LCDF path specified in the **Sequence Parameters** will be ignored for this sequence. When this checkbox is disabled, 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 Location and Cabinet available in the ECM Browser. Click **Select Path** to select the required path in an ECM Explorer dialog. For the Drawer and Folder, you can either keep the selected items, or you can select predefined tokens for an automatic path creation. When you use the predefined tokens in the **Remote Data Path**, the system automatically creates the items if they do not already exist in ECM.

NOTE	If you use tokens, make sure you have the required ECM privileges 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 ECM, 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 (*.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 or *.S.SSIZIP	

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

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

3
Working With ChemStation and ECM

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

Agilent Technologies
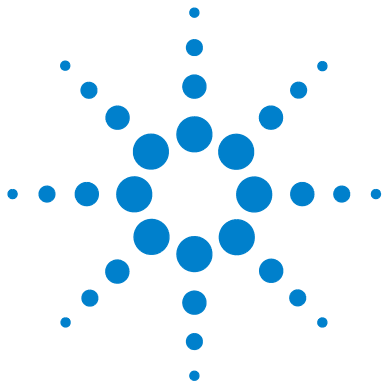
Transferring Data to or from ECM

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

- Methods
- Sequence templates
- Report templates
- Single run data
- Sequence data

All of this data is stored in ECM as SSIZIP result sets (see "Compressed ChemStation File Formats" on page 35).

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

Different options are available regarding the automatic upload of single run/sequence data to ECM. Loading back stored data from ECM to ChemStation, however, always requires a manual load action. Methods, sequence templates and report templates require always a manual upload to ECM as well as a manual load or update into ChemStation.

For downloading data from ECM, several **load** commands are available in the **ECM** menu. Depending on the current view, you can load different files from ECM. 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 ECM. In the **Method and Run Control** view, you can load methods and sequence templates. These items are only retrieved and not checked out. If you use Intelligent Reporting, you can also load report templates from ECM in the **Report Layout** view.

The following workflows are examples that represent typical tasks done with ChemStation and OpenLAB ECM.

Data-related workflows

Workflow 1: Acquisition and automatic upload
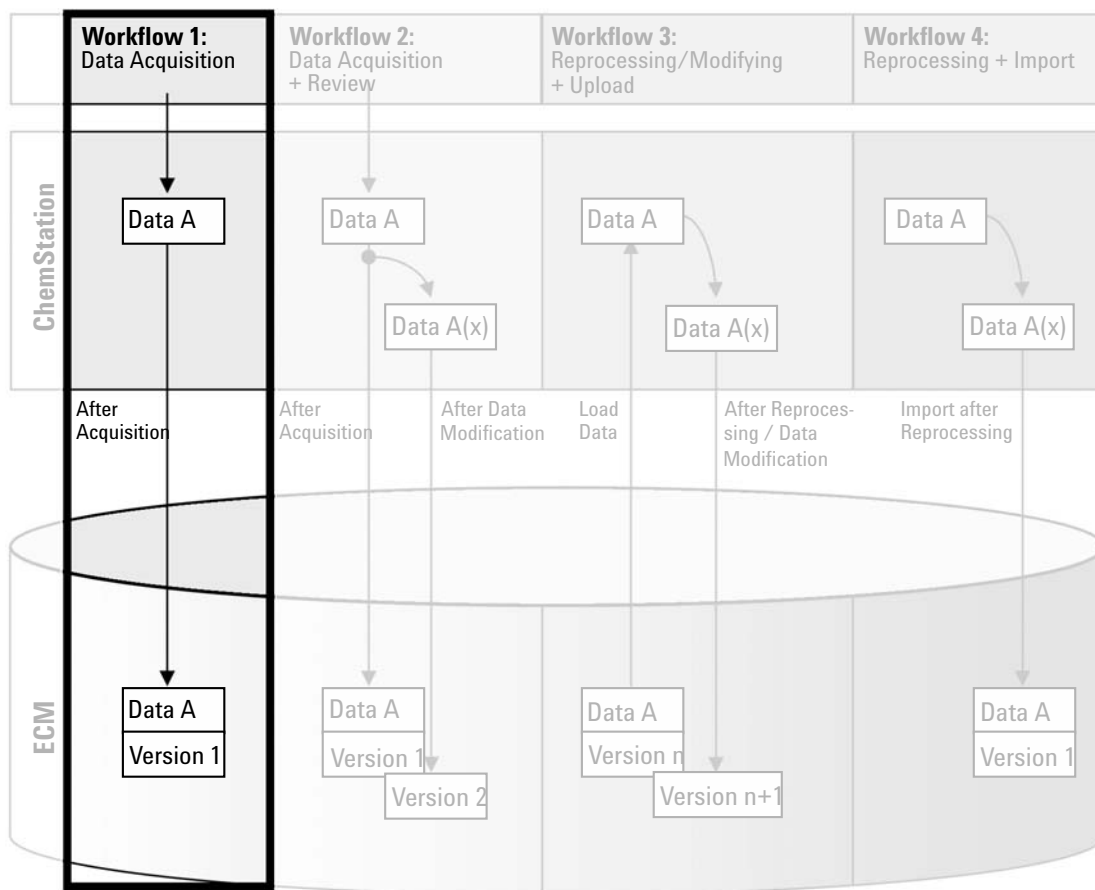
Figure 6   Acquisition and automatic upload

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

To save data to ECM 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 ECM user name is automatically inserted as operator name into the sequence template.

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

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

   • **Remote Data Path**: Select the ECM location 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 ECM to the previously defined LCDF 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 *Understanding Your ChemStation*). After uploading the result set the sequence icon in the ChemStation Navigation Pane changes from ![icon] to ![icon]. The LCDF 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:

![icon]: The result set is stored in ECM and has not been modified locally

![icon]: The result set is stored in ECM 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
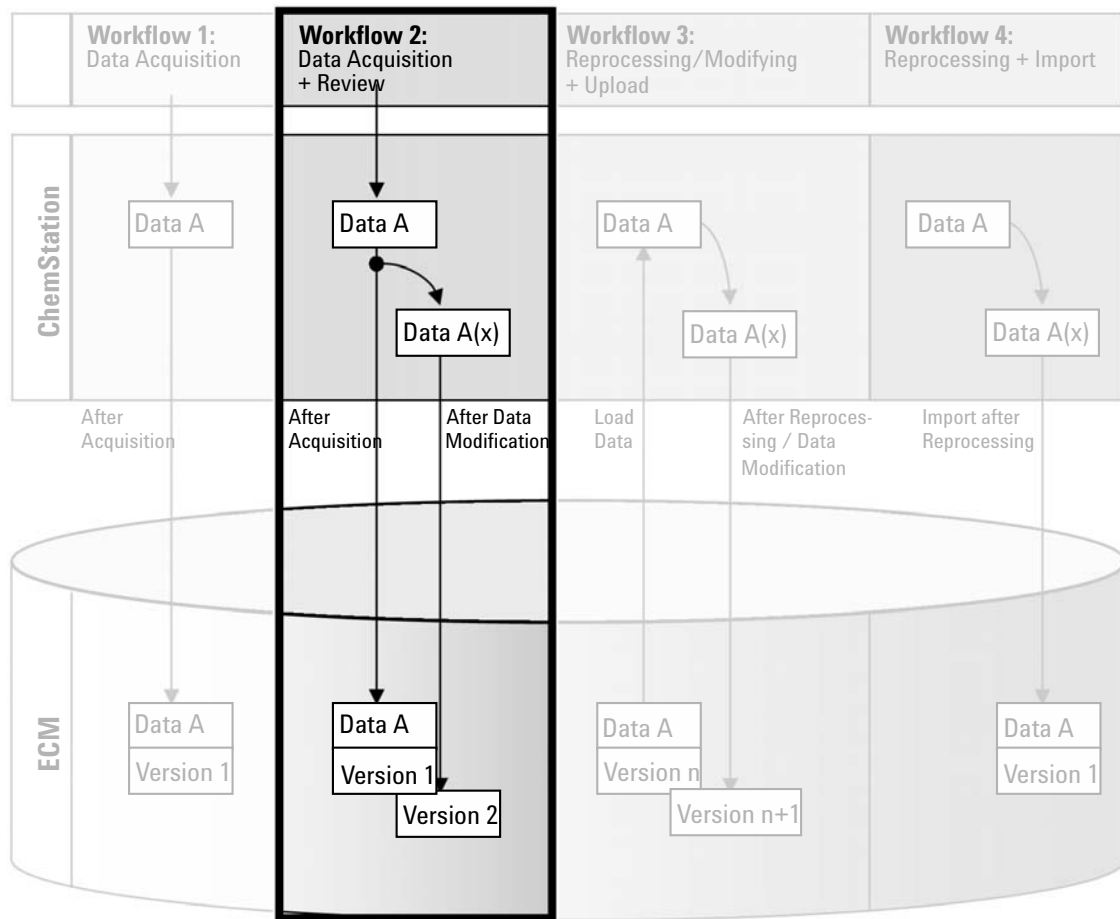
Figure 7   Offline review during acquisition

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 ECM. After the review, the changed data is again uploaded to ECM. When the data is uploaded the second time, a new version is created.

To save data to ECM automatically after changing the data:

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

2 Load a sequence template.

   Your ECM user name is automatically inserted as operator name into the sequence template.

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

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

   • **Remote Data Path**: Select the ECM 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 been finished, two things will happen:

   • The original raw data is automatically uploaded as an *.SC.SSIZIP* file, *Version 1*, to ECM to the previously defined LCDF location. The LCDF 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 *Understanding Your ChemStation*).

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

   • The **ECM forced 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 ECM.

      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 ECM 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
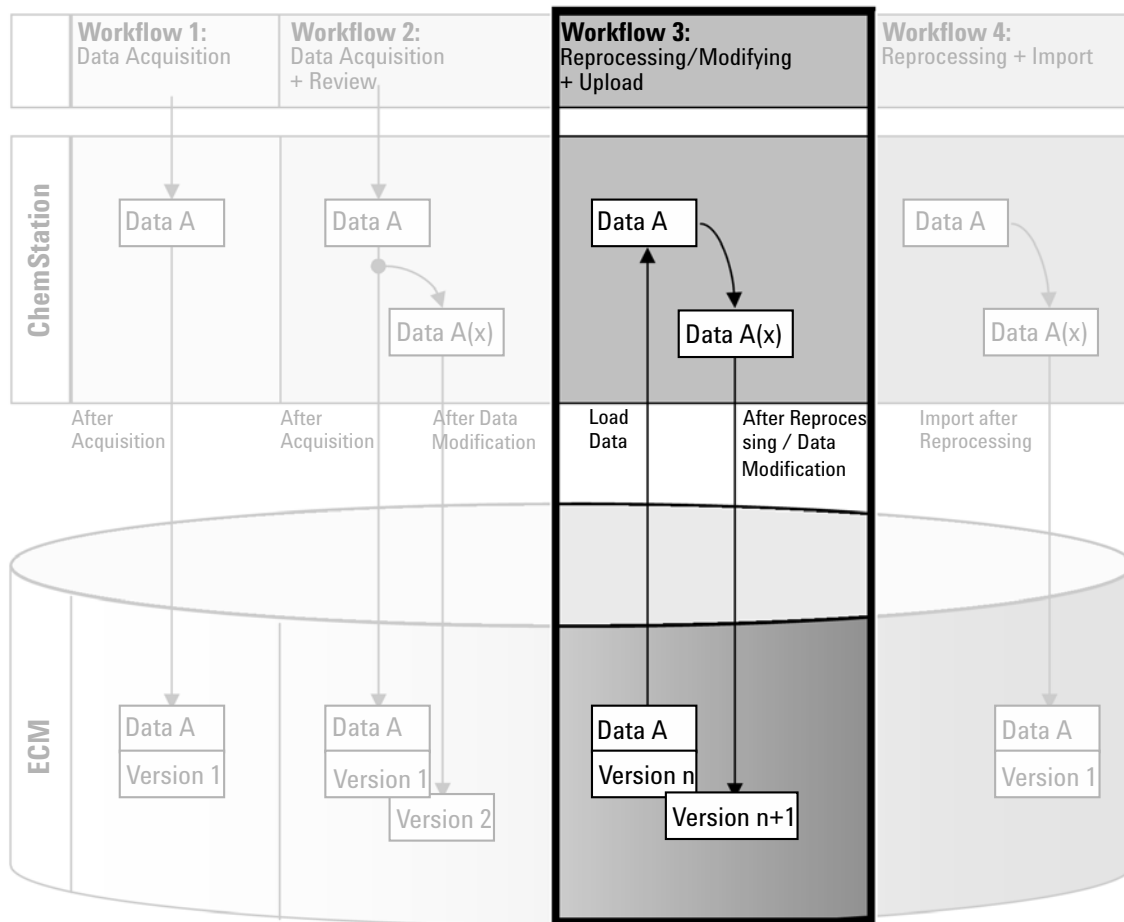
Figure 8 Reprocessing data and automatic upload

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 ECM. A new version of the data is created in ECM for the reprocessed or changed data.

To save data to ECM automatically after reprocessing:

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

2 Select **ECM > Load Data** to download a sequence from ECM.

The **ECM Desktop Open** dialog opens. Navigate to the ECM folder to load the data of your choice and select one of the following packaged files:

• Single run data: **.D.SSIZIP* files

• sequence data: **.SC.SSIZIP* files
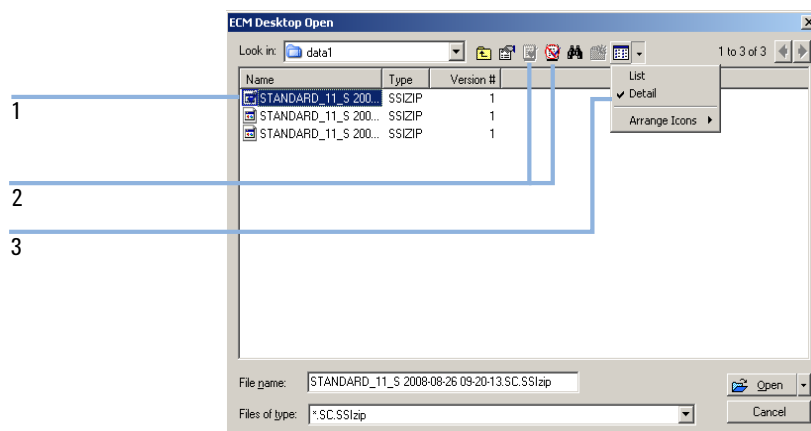
Figure 9   ECM Desktop Open dialog

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 ECM user

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

To check out or check in an item, you can use the respective icons available in the **ECM Desktop Open** dialog (see 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 9 on page 45, marker 3). To open an

older version of an item, select the **Open Revisions** command from the **Open** menu (see Figure 10 on page 46). This opens the **File Versions** dialog, where all available versions of the item are listed (see Figure 11 on page 46).
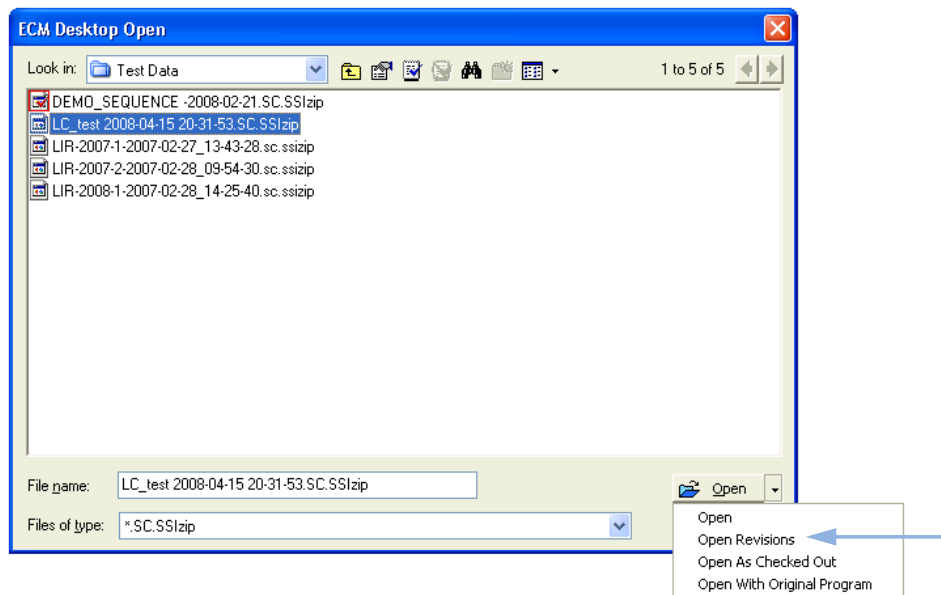
Figure 10   Open Revisions command
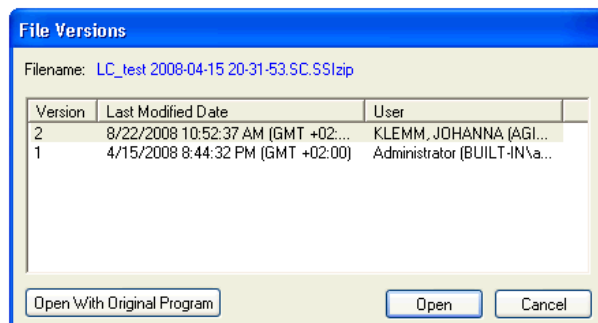
Figure 11   File versions dialog

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 ECM when you load it to ChemStation.

The LCDF path of the data 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 LCDF 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
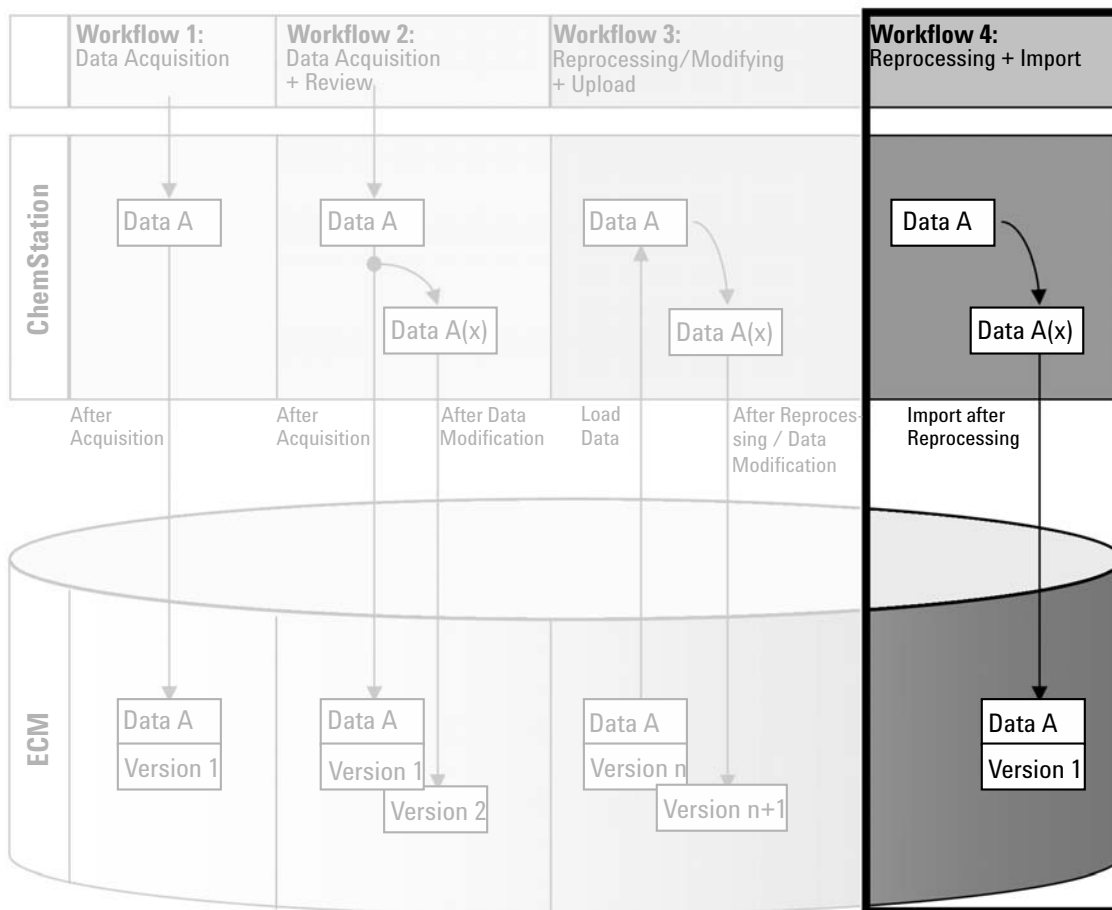
Figure 12 Import after reprocessing

The workflow *Import after reprocessing* illustrates how locally saved data is reprocessed and then automatically imported in ECM.

To save data to ECM 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 ECM before.

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

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

    • **Remote Data Path**: Select the ECM 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 LCDF path in ECM. 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 *Understanding Your ChemStation*).

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: Local files – Save new method
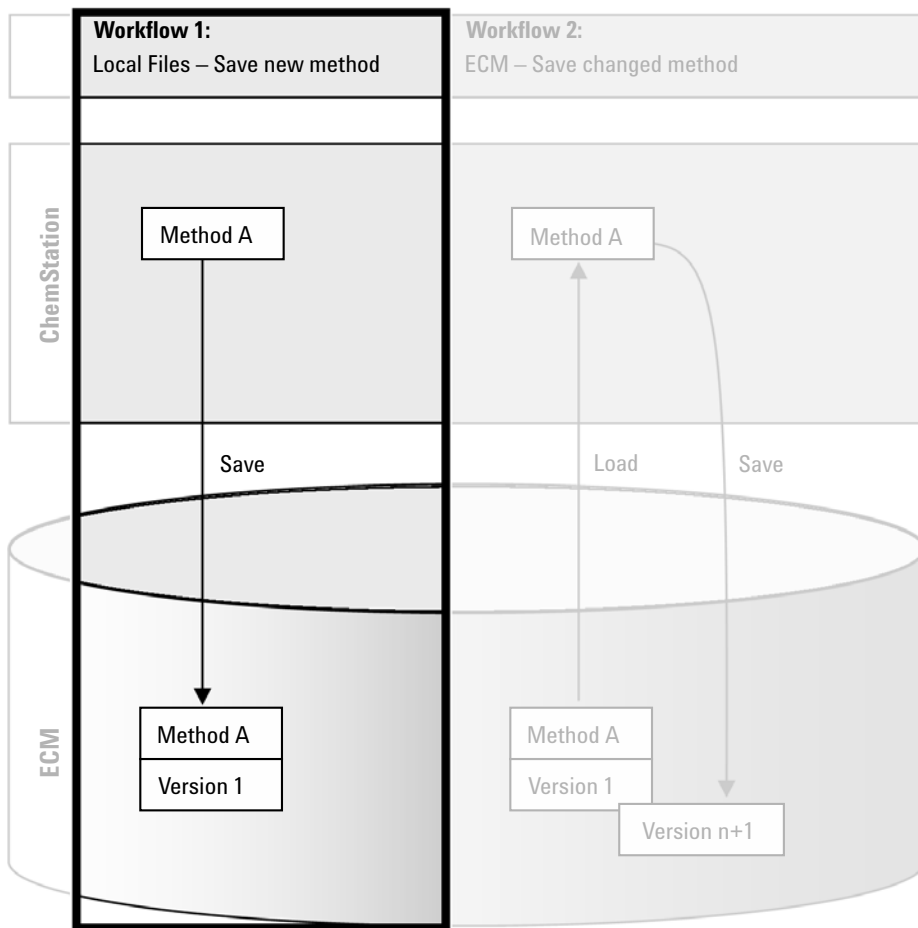
Figure 13   Local files - Save new method

The workflow *Local files - Save new method* illustrates how newly created or locally stored methods or sequence template can be manually uploaded to ECM.

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.

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

- **ECM > Save Method**
- **ECM > Save Sequence Template**

In the **Report Layout** view:

- **ECM > Save Report Template**

The **ECM Save** dialog opens.

4 Navigate to the Remote Data Path of your choice to upload the method/sequence template/report template.

You can only upload items into a Folder, not into a Location, Cabinet, or Drawer.

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 ECM Audit Trail (see "ECM Audit Trail" on page 67).

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

After finishing the upload, the SSIZIP file is available in ECM as version 1. The file is saved to the Remote Data Path defined in the Preferences (see "Remote Data Path" on page 24).

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: ECM – Save changed method
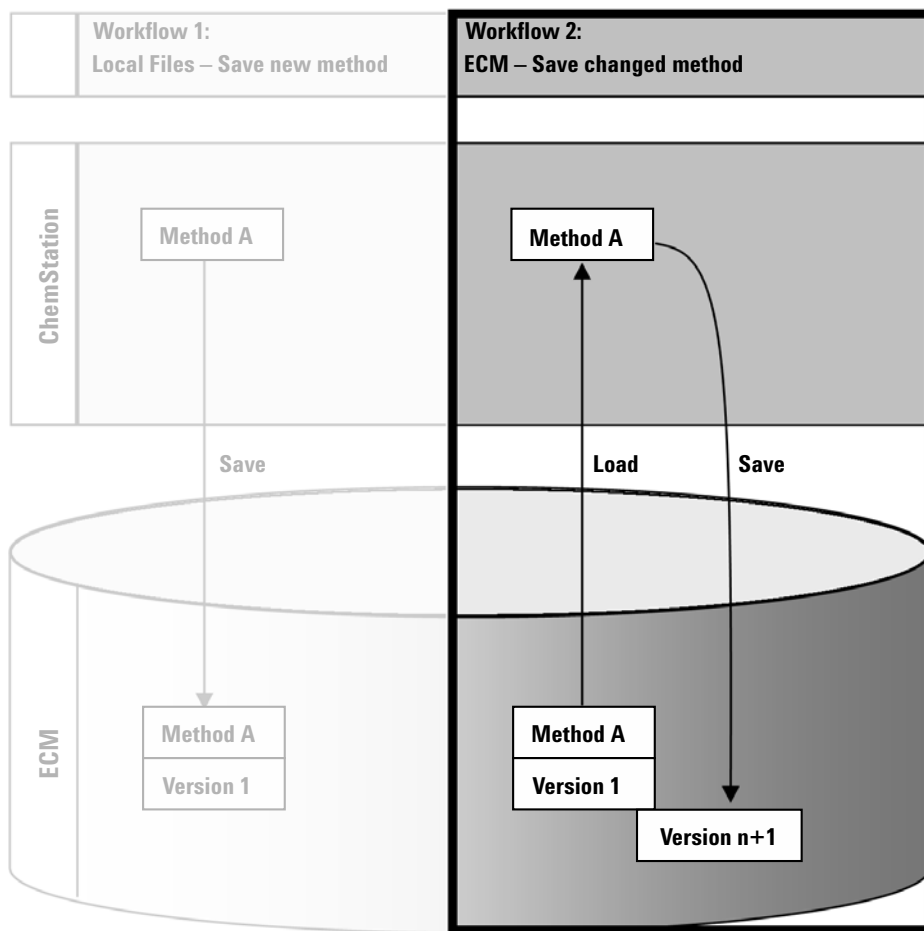
Figure 14   ECM - Save changed method

The workflow *ECM - Save changed method* illustrates how methods, sequence templates, or report templates that are already stored in ECM 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 ECM before. ECM Methods are indicated by 🔧, ECM sequence templates by 🔧, and ECM report templates by 🔧 in the ChemStation Navigation Pane.

   – or –

   • Select **ECM > Load Method**, **ECM > Load Sequence Template**, or **ECM > Load Report Template** respectively to download an item from ECM.

   If you use one of the **Load** commands, the **ECM Desktop Open** dialog will open. Navigate to the ECM folder to load the method (**.M.SSIZIP*) or sequence template (**.S* or **.S.SSIZIP*) of your choice.
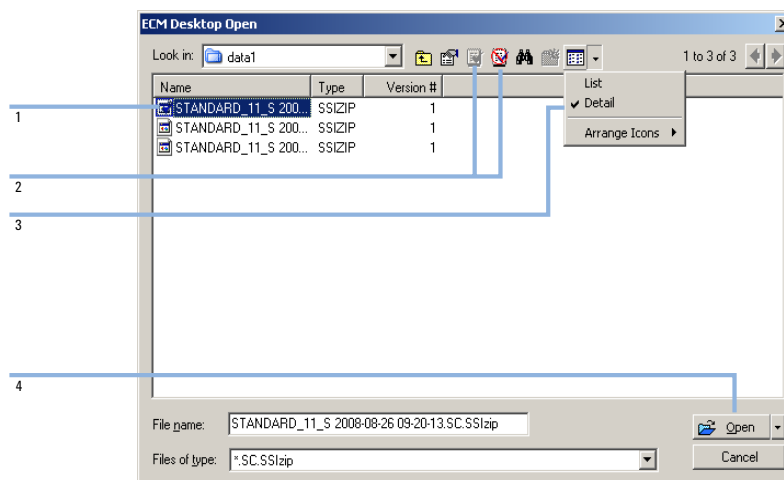
Figure 15   ECM Desktop Open dialog

If the item is checked out, it is marked with a blue or red icon (see Figure 15 on page 54, marker 1):

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

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

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

To check out or check in an item, you can use the according icons available in the **ECM Desktop Open** dialog (see Figure 15 on page 54, marker 2).With 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 15 on page 54, marker 3). To open an older version of an item, select the **Open Revisions** command from the **Open** menu (see Figure 16 on page 55, marker 1). This opens the **File Versions** dialog, where all available versions of the item are listed (see Figure 17 on page 56).
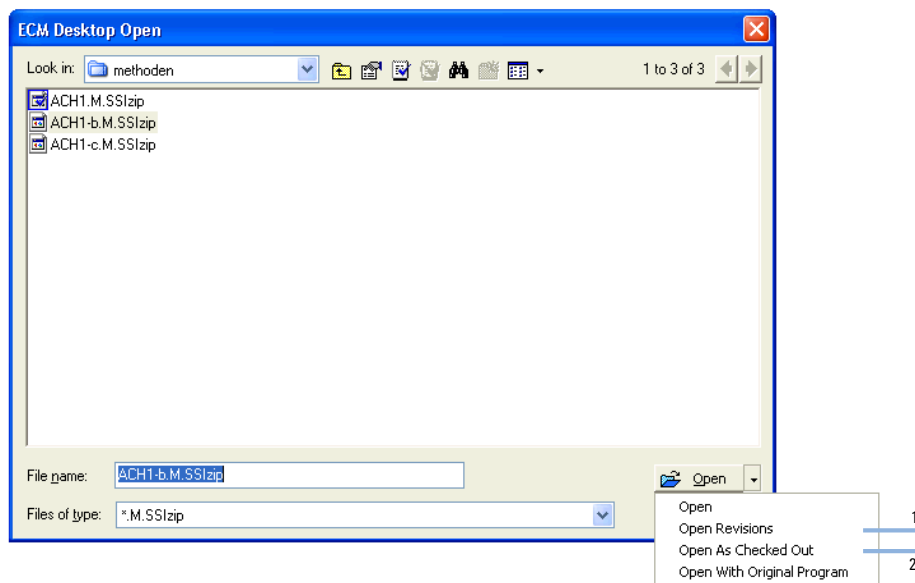
Figure 16   Open Revisions command
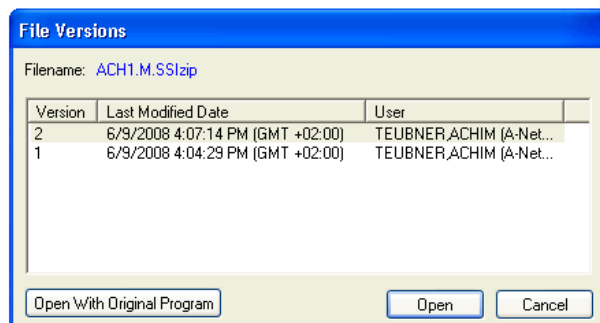
Figure 17   File versions dialog

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 from ECM (see Figure 16 on page 55, marker 2).

> **NOTE**   Unlike data files, the methods, sequence templates, and report templates are not automatically checked out of ECM! In order to modify those items in ChemStation, you should check them out from ECM 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 LCDF path of methods and sequence templates is shown in the ChemStation toolbar in ChemStation.

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 to save the changed item.:

- **ECM > Save Method**
- **ECM > Save Sequence Template**
- **ECM > Save Report Template**

If you have not checked out the item before loading it from ECM, and another ECM user has checked out the item in the meantime, you cannot proceed with the upload back to ECM. A warning message is displayed, and it is not possible to save the item back to ECM 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 ECM Audit Trail (see "ECM Audit Trail" on page 67).

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

The *.M.SSIZIP/.S* file is uploaded with its original name to its original LCDF 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 ECM (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:

- **ECM > Update Methods ...**
- **ECM > Update Sequence Templates ...**
- **ECM > Update Report Templates ....**
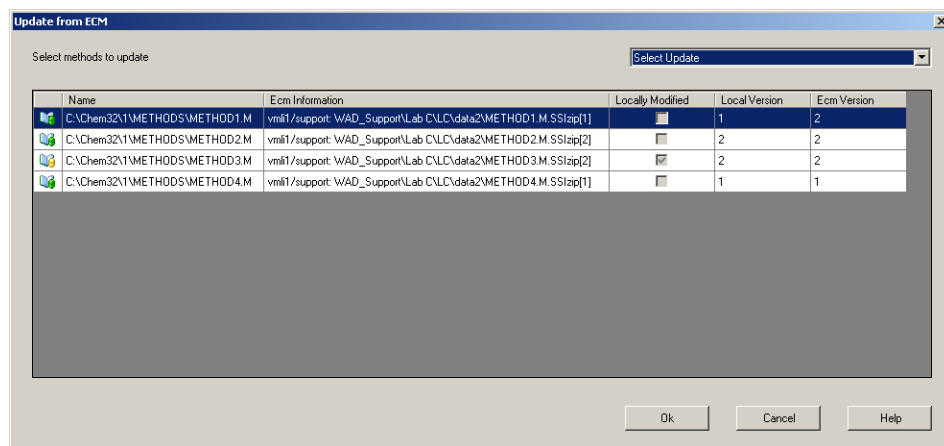
Figure 18 Update Methods dialog box

The **Update from ECM** dialog box is displayed.

The dialog box lists all items that are connected to ECM. The following columns are available:

- **Name**: Path and Name of the local copy of the method, sequence template, or report template.
- **ECM Information**: ECM server, account information, and LCDF path of the file in ECM.
- **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**: Version number of the file in ECM.

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

After pressing OK, the selected items are updated with the version in ECM.

4

Administration Regarding 21 CFR Part 11 Compliance

This chapter explains the purpose of 21 CFR Part 11 and its implementation in ChemStation with OpenLAB ECM

Agilent Technologies

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 ECM to be compliant with 21 CFR Part 11, you need to go through the following checklist:

- LCDF structure on the ECM Server prepared according to your needs

  See "Data Storage in ECM" on page 14.

- Roles/Users/Groups configured in ECM and in OpenLAB Control Panel

  See "Users/Groups/Roles Configuration" on page 73.

- ECM Account configuration with active audit trail and mandatory reason

  See "To enable the ECM Audit Trail" on page 67.

  See "Account Configuration" on page 70.

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

  See "User-Specific Settings" on page 72.

- E-Signatures prepared (messages and privileges)

  See "Using electronic signatures" on page 84.

- Automatic Data Transfer Settings and Transfer Management Settings activated

  See "Automatic Data Transfer Settings" on page 26.

- Audit trail active for methods and results

  See "Method Audit Trail" on page 64 and "Results Audit Trail" on page 66.

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

  See "ChemStation Administration Tool" on page 78.

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 with ECM files generally. 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 according SSIZIP files. The ECM logbooks are available only directly in ECM.

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.

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 this method** 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 78).

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 all methods**.

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

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

To remove the detailed Method Audit Trail

Once a method is enabled for the detailed audit trail, you cannot disable it again. The only way to get rid of an existing Method Audit Trail is to save the method under a different method name. In this case, the only hint in the new method's audit trail is a comment about the method being based on another 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 after each other.

With OpenLAB CDS, ChemStation automatically tracks any report that was 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.

ECM Audit Trail

Audit Trail 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 scheduler-related entries. For example, you can see when a file was added and who added it.

For each operation, ECM asks the user for a reason. This reason is also shown in the ECM Audit Trail. For automatic uploads there are default reasons given by the system. The reason entry may be optional or mandatory, depending on the ECM configuration (see "Account Configuration" on page 70). If the system is configured to be compliant to 21 CFR Part 11, providing a reason is mandatory.

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.

NOTE	If the system shall be compliant to 21 CFR Part 11, the ECM Audit Trail must be enabled.

To view the ECM Audit Trail for a specific file

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 ECM Audit Trail for all files

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 according 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.

ECM System Log

The System Log is a record that shows changes to the system, including configuration changes, e-mail notifications, and additions or changes of Locations, Cabinets, Drawers, or Folders.

You can view file-related, system administration, folder administration, or Scheduler-related entries. For example, you can see when a Location 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 "Account Configuration" on page 70).

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.

System Activity Log in OpenLAB Control Panel

The System Activity Log contains information on the various events associated with the Shared Services or with specific instruments. You can filter the list in order to view only the 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
- Instrument Controller
- User
- Group
- Security
- Printer
- License

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.

Account Configuration

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.

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.	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*.	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.

User-Specific Settings

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.

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

• User cannot change password

• User must change password after next login

Note that the minimum password length is defined in the ECM Account configuration (see "Account Configuration" on page 70).

Users/Groups/Roles Configuration

Concept of users, roles, and privileges

Users with specific roles and privileges are needed in both ECM and OpenLAB CDS. In ECM you can either set up internal users or operate with the Windows users. In OpenLAB CDS, user management is part of the Shared Services, which you access via the OpenLAB Control Panel. There you use ECM as an external authentication provider and import the ECM users.

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. You can also assign roles to single users. However, for the sake of clarity, it is strongly recommended to assign roles only on the group level.

The roles are equipped with numerous specific privileges, which define what the users are allowed to view or do. 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.

Settings in ECM

ECM Default roles and 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 75). 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.

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. In OpenLAB Control Panel, you assign the required users and roles to the groups. The assignment of users to a group is independent of the settings in the external system.

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

Roles and Privileges in OpenLAB Control Panel

You can create a tree of different locations in the OpenLAB Control Panel, and add instruments to the relevant locations. With these locations you can organize your instruments for example by department, by room, or by table.

Roles are used to assign privileges to a user or a user group, either 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**, **ChemStation Lab Manager**, or **ChemStation Operator**). Each role has certain privileges assigned.

For more information on changing the roles and privileges, refer to the OpenLAB Control Panel online help.

Specific Privileges for Individual Locations or Instruments

By default, the roles of users or groups are globally set; that is, a user or group has the same role for all locations and for all instruments. The role settings are inherited from the root node **Instruments**. In order to assign a different role to a user or group for one specific location or instrument, you can deselect the **Inherit access control 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 location or instrument.

For example, a user is a member of the group **ChemStation Operator** in all locations, but in one specific location he is a member of the group **Instrument Administrator**.

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 79).

To start the ChemStation Administration Tool:

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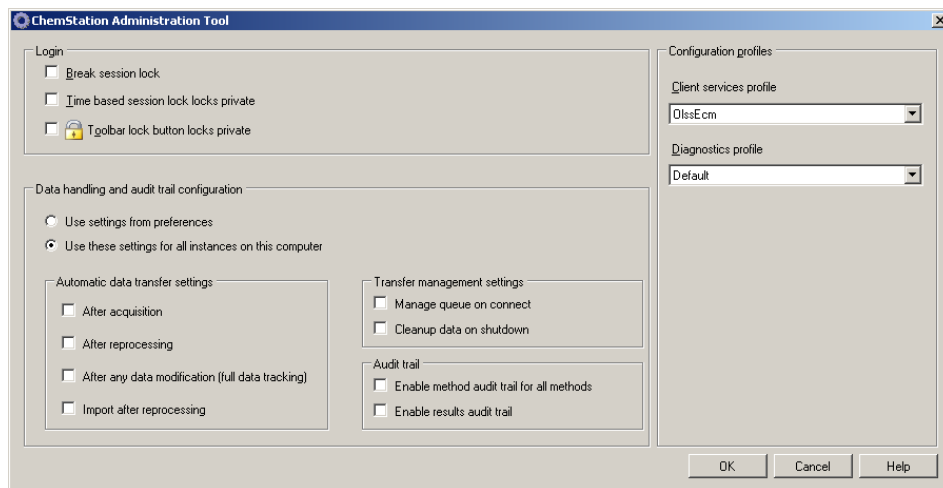

Figure 19 ChemStation Administration Tool

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.
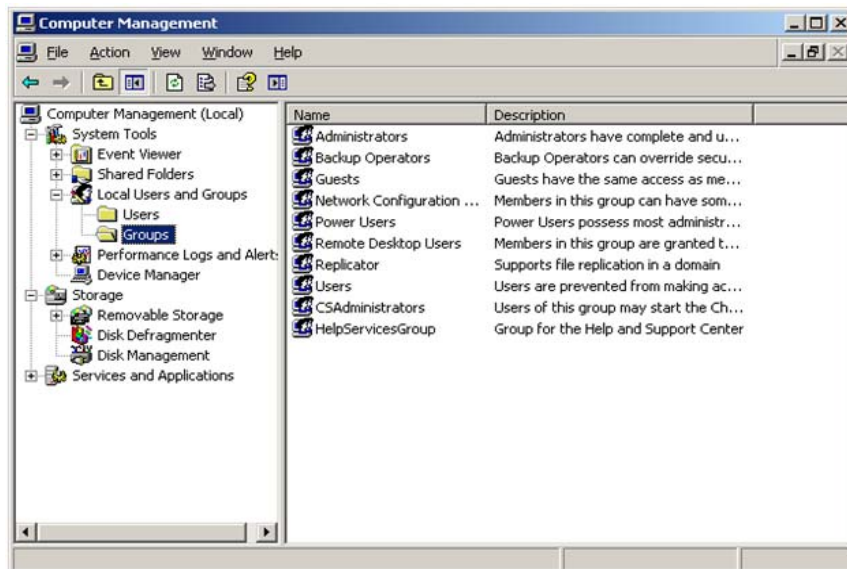
Figure 20   Computer Management window

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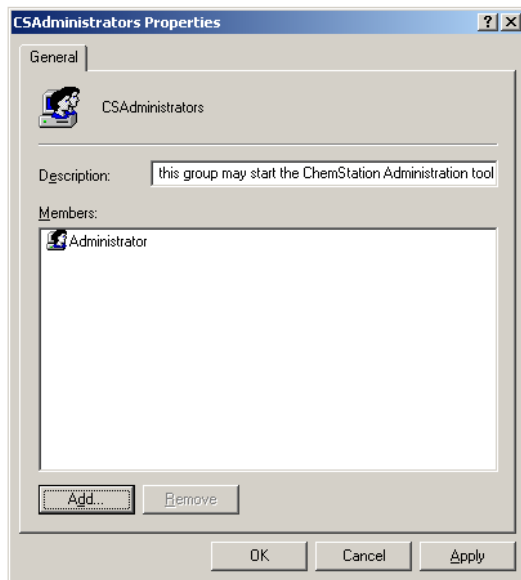
3 Use the **Add** button to add the required users.

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

Session Lock Settings
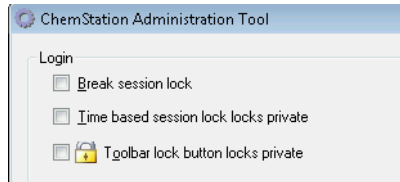
Figure 21   ChemStation Administration Tool

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 Select the option **Use these settings for all instances on this computer**.

2 Select the required check boxes. The settings are the same as in the **Preferences** dialog (see "ECM Preferences" on page 23).

3 Click **OK**.

Configuration Profiles

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

- **Olss**

  ChemStation communicates with OpenLAB Shared Services; it sends status information to the 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 ECM.

- **OlssEcm**

  In addition to communication with OpenLAB Shared Services, ChemStation allows data storage in ECM (upload and download of data files). Use this profile for ChemStation instances that are connected to both OpenLAB Shared Services and ECM.

  You can also use the **OlssEcm** profile in emergency scenarios, when the authentication provider in OpenLAB Shared Services is set to **None**. In this case, ChemStation cannot upload data to ECM, but it still sends the data files to the queue. Therefore, when the authentication provider in OpenLAB Shared Services is set back to ECM, the upload can be resumed.

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 the help of the Agilent OpenLAB Business Process Manager (BPM) module, you can create highly automated review or approval processes including e-mail notification.

Preparation

Privileges

An ECM user needs to have the privilege **Content: File Signatures** in order to be able to sign electronically. This privilege is, for example, assigned to the ECM default role: **:Approver**.

Reasons for the signature

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

To configure the reasons for signatures:

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

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 according 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 view electronic signatures

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.

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

To adjust the user preferences:

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.

5

Attribute Extraction Services for ChemStation Data

This chapter provides an overview of the available ECM Attribute Extraction Services (AES) for ChemStation data. The AES extract metadata information from the ChemStation data files. These metadata make the ChemStation data searchable. For detailed information, refer to the ECM documentation.

Attribute Extraction Services for ChemStation Data

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

• 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 22 on page 89.

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 23 on page 89.
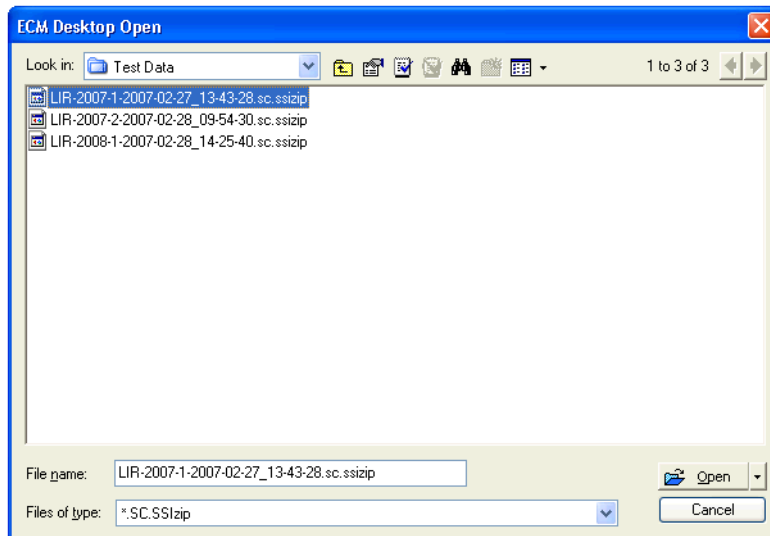
Figure 22 Search options
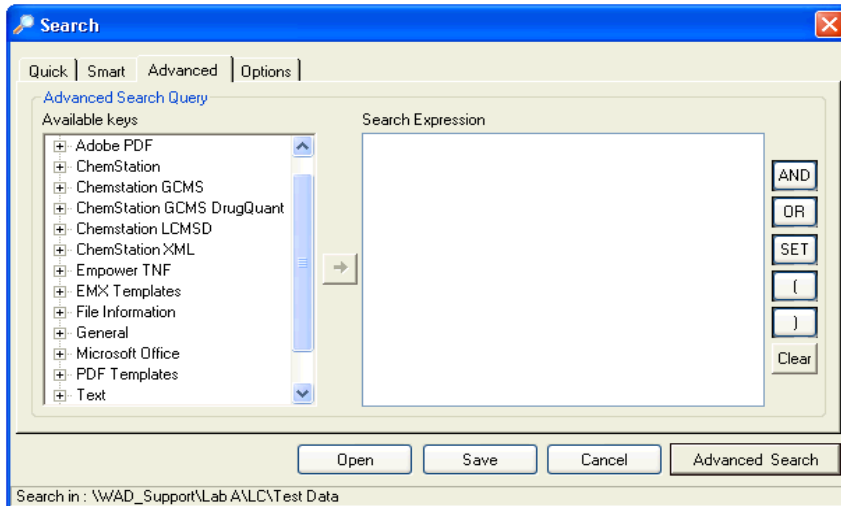
Figure 23 Filters available in search options

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.

6
Troubleshooting

The chapter gives some elementary troubleshooting hints.

Agilent Technologies

Error messages at OpenLAB Control Panel Startup

`Connection to Shared Services failed`

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

Probable cause	Suggested actions
1 The ECM server or the 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 application note *Emergency Procedures for OpenLAB CDS ChemStation Edition*.

Alerts and Error Messages at ChemStation Startup

Your Transfer Settings/Remote Data Path seems to be set to default

At every startup, Agilent ChemStation checks whether all necessary information is provided for transferring data to ECM. This message is shown if the Remote Data Path is not set or is incomplete.

Probable cause

1 The Remote Data Path is not set or is incomplete.

Suggested actions

Make sure that the information on ECM Server, ECM Account, and a complete LCDF path is provided in the Transfer Settings (**ECM > Preferences > Transfer Settings**).

ECM Server is not available after login

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

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

The ECM Load and Save functions are accessible, but an alert informs the user about the interrupted connection to the ECM.

While acquiring data, the automatic transfer of data to ECM 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**).

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

For further troubleshooting, please contact your ECM administrator.

Error Messages in the Spooler Queue Manager

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

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

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

Probable cause	Suggested actions
1 ECM Server in Preferences differs from current connection.	Correct the Transfer Settings in the Preferences, e.g. use **Get Server** to get the current ECM server, and add the server and the correct ECM account to the Transfer Settings.

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 license ID or license has expired.

Probable cause	Suggested actions
1 Server license timeout.	Log out and log in again.

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.	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.	The other user has to check in the file before you can upload the file.

Invalid path specified

Probable cause	Suggested actions
1 Occurs for a Commit action (that is, the item in the queue is not the first version of the data to be uploaded). The previous version cannot be found in ECM. It has been moved to another LCDF or deleted from the queue before upload.	Export the item to local disk and upload it manually to the desired location in ECM.

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

Probable cause	**Suggested actions**
1 The ECM server has been entered in the preferences by name only, not as URI (http:\\servername\).	Correct the server in the preferences, e.g. by using **Get Server**.

7
Appendix

Agilent Technologies

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 3 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 3   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

ChemStation Privileges in OpenLAB Control Panel

Project Privileges

Table 4   Project Management

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

Table 5   E-Signature

Name	Description
E-Signature Sign Data Files	User can sign data files (EZChrom only; E-signature functionality is not supported in ChemStation).
E-Signature Revoke	User can revoke signatures (EZChrom only; E-signature functionality is not supported in ChemStation).

Table 6   ChemStation: Control

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

Table 7 ChemStation: Data

Privilege	Description
Delete Data	User can delete data files in ChemStation Explorer
Manual Integration	User can perform manual integration
Save Data to ECM	Interactive saving of data to ECM

Table 8 ChemStation: Instrument

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

Table 9 ChemStation: Logbook

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

Table 10 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

Table 10 ChemStation: Method

Privilege	Description
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 11 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

Table 12 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 Spooler Queue Manager
Modify ECM transfer preferences	Enable / disable the automatic upload to ECM

Table 13 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

Table 13   ChemStation: Sequence

Name	Description
Reprocess	User can reprocess a sequence
Save sequence	User can save sequences to ECM

Table 14   ChemStation: View Access

Privilege	Description
Access Companion view	User has access to Companion view (GC ChemStation only)
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 (OQ/PV) 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
Enable full menu	Enables the ChemStation full menu

Instrument Privileges

Table 15 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 lock or unlock an instrument.

Administrative Privileges

Table 16 System Administration

Name	Description
Manage printers	Can add/remove printers and print server
Edit activity log properties	
Archive system activity log	Can archive (archive/delete) the system activity log and define archive automation settings
Purge activity logbook	Can purge a logbook after it has been archived
Create administrative reports	Can create any of the system admin reports
Manage system components	Can install/remove components (applications)
Backup and restore	Can create a system (DB) backup and restore the backup

Table 16   System Administration

Name	Description
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.

Index

www.agilent.com

In This Book

This guide contains reference information on the interface between ChemStation and OpenLAB ECM, on the settings required by 21 CFR Part 11, and on the workflows for ChemStation with ECM.

M8301-90080

Agilent Technologies