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DDK Driver Certification Requirements

Topics:

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Content

1 Scope

This document provides detailed information about the certification process of a DDK driver. It contains a detailed list of test cases for various scenarios Thermo Fisher Scientific will check before a driver gets certified.

The document is mainly intended for external driver developers who want to prepare their driver specifications for certification and is therefore handed out to 3rd party DDK developers as part of the DDK setup package. It is useful to review this document in an early stage of the development process of the driver in order to avoid delays later on due to a driver concept that does not fit the CM regularities.

Thermo Fisher Scientific however, cannot and therefore will not accept responsibility for the correctness of the functionality of drivers that were developed by 3rd parties (such as MFClass 3 drivers, see chapter 5.2). It is entirely the responsibility of the driver manufacturer to apply a thorough test to their driver to ensure it meets the high quality requirements.

Note:

- This document applies to both Chromeleon 6 and 7, however Chromeleon 7 terminology is used throughout this document. See also chapter [5.1].

2 Document History

Version	Date	Author	Description
1.0 Draft 1	08-AUG-2012	Mjochum	Initial document for review
1.0 Draft 2	09-AUG-2012	Mohlhaut	Reviewed
1.0 Draft 3	16-AUG-2012	Dauerbac	Reviewed
1.0 Draft 4	20-AUG-2012	Mjochum	Adaptations after review meeting
1.0 Draft 5	22-AUG-2012	Dauerbac	Final adaptations for 1.0
1.0	22-AUG-2012	Dauerbac	Approved for Release
1.1 Draft	22-AUG-2012	Dauerbac	Changed Date in title to document revision; removed project note template version from heading page.
1.1	22-AUG-2012	Dauerbac	Approved for Release
1.2 Draft 1	10-JUL-2103	MJochum	Adaptations for 7.2 release
1.2	12-Jul-2013	Dauerbach	Approved for Cm 7.2 release.
1.3 Draft 1	09-SEP-2014	Mjochum	Added some new items regarding documentation availability.
1.3 Draft 2	13-11-2014	Mjochum	Added tests for several driver instances on a PC, availability of user documentation for installation and use.
1.3	24-11-2014	Dag Auerbach	Reviewed, approved for 7.2SR2 release.
1.4 Draft	08-AUG-2016	MJochum	Restructure chapters and test suites due to feedback.
1.4 Draft	26-AUG-2016	MJochum	Further changes due to review by TSchoene
1.4	04-JAN-2017	MJochum	Finalize doucment

3 Abbreviations

Abbreviation	Description
CM	Chromeleon
DDK	Chromeleon Device Driver Development Kit
GAC	.NET Global Assembly Cache
IM	Instrument Method (CM7 nomenclature, PGM in CM6)
IME	Instrument Method Editor
IQ	Installation Qualification, a tool to check the driver installation
MFClass	Manufacturer Class
OQ	Chromeleon Operational Qualification Procedure
OS	Operating System
PC	Personal Computer
PGM	CM 6 sample program
RC	Ready Check
SC	Semantic Check
SR	Service Release

4 References

[1] Chromeleon DDK Cookbook and Developer Guidelines.pdf

5 General Notes

5.1 CM6 versus CM7 Terminology

With the introduction of Chromeleon 7 we have adapted some terminology for a better understanding and/or to follow industry conventions. This document is written in CM7 terminology, even though is is used for Chromeleon 6 certification procedures as well and some test cases apply to Chromeleon 6 only. The following table may help to understand the following chapters when writing a Chromeleon 6 driver or setting up a test procedure for it.

CM6	CM7
Batch	Queue
CM Client	Console
CM Client	Studio
Sample	Injection
Timebase	Instrument
Program (PGM)	Instrument Method (IM)
Program Editor / Wizard	Instrument Method Editor / Wizard
Server	Instrument Controller
Timebase Class	Instrument Class
Demo mode	Simulation mode
Panel	ePanel
Report	Report Template
Manual Acquisition	Monitor Baseline

5.2 Manufacturer Classes

CM DDK based drivers are classified according to so-called manufacturer classes (MFClass). With these classes it is specified who is responsible for the driver development and who is responsible to distribute it, to maintain it and to provide support in case of errors or customer questions.

There are three manufacturer classes:

Class	Responsibilities
MFClass 1	Drivers developed by one of the Thermo Fisher Scientific CM software teams. Driver is part of the CM package, support will be provided through Thermo Fisher Scientific.
MFClass 2	Drivers developed by external teams on behalf of Thermo Fisher Scientific. Driver may become part of the CM package, support will be provided through Thermo Fisher Scientific.
MFClass 3	Drivers developed by external software teams; deployment and support cannot be provided by Thermo Fisher Scientific and therefore is entirely the responsibility of the driver manufacturer.

5.3 Licensing

Every DDK driver also gets an 'Instrument Class' as part of the certification process. This class determines the CM license package a customer has to buy to be able to control an instrument with such a driver. Thermo Fisher Scientific defines the instrument class of a driver. It is encrypted in the final driver certification file.

Beside the instrument class, more license options may be required to run a driver, e.g. a 3D license to acquire 3D spectra with diode array detectors. Thermo Fisher Scientific will add these license options automatically during the certification process, if necessary.

There is no correspondence between the MFClass and the instrument class.

6 Certification Scenarios

6.1 Final Certification

This is the standard procedure for a certification process. It is used if a new driver package is to be released of if there are major extensions or design changes with respect to a previous version.

For a full certification the following test suites are mandatory:

- 8.2.1 - 8.2.11
- In case of a major driver update, also suite 8.2.12 is mandatory

6.2 Final Certification of a Driver Update

In some cases it might become necessary to upgrade a driver due to bug fixes or minor changes or extensions, which does not affect the general functionality. In this case, a reduced set of test cases are sufficient. The decision, whether a full certification test or a reduced test is required, is made by Thermo Fisher Scientific.

In case of a driver update certification the following test suites must be executed:

- 8.2.1
- 8.2.3
- 8.2.12

6.3 Preliminary Certification

Note: This section is only relevant for MFClass 3 drivers; i.e. when driver tests are not performed by Thermo Fisher Scientific.

In some cases Thermo Fisher Scientific can provide a preliminary certification, e.g. to support:

- An external beta test of the driver at a customer site
- Tests on several instrument controllers (but not enough CM licenses with the DDK license bit available)

In that case, the certification is given an expiration date. It is not possible to load the driver after the testing period has elapsed (usually 3 month).

Thermo Fisher Scientific does not guarantee that a preliminary certification will be granted in every case. Please clarify with Thermo Fisher Scientific as early as possible if you need such a certification. Thermo Fisher Scientific will not provide more than 2 preliminary certifications per driver release.

For a preliminary certification, the driver must pass the following test suites:

- 8.2.1
- 8.2.13

7 Preconditions for the Certification Test

The following components must be provided by the development team before a certification process is officially started by Thermo Fisher Scientific:

- A deployment package, which installs all necessary files and other components of the driver (if the driver is distributed as a separate package).

- A help document, which contains at least the details of the installation procedure.

- In case the driver or even the driver setup is locked with a separate license key we need at least a simulation license so that we can install the driver and run it in simulation mode with all available features.

- Documentation about known
  - OS related restrictions (minimum OS / SR version;
  - OS server version compatibility,
  - Required .NET/VC runtime version (should be the same as for the corresponding Chromeleon version – see the DDK release notes or ask DDK support).
  - SQL versions and so on.

- Documentation about the development environment: e.g. Visual Studio version, used source code language, DDK version, CM version used to build the binaries.

- A list of additional files, external components or 3rd party components that are required to run the driver / configuration / method editor components and/or are installed by the driver setup (This can be OCX components, other DLL's like special low level hardware drivers or components that are installed in the GAC).

- Release Notes for the driver version that is to be certified. In case of a driver upgrade, these Release Notes must also include the changes with respect to the previous version.

  Note: In case of a preliminary certification (6.3) this does not have to be an official document.

- If the driver does not provide a simulation mode or cannot be loaded without a real device attached, the developer must provide a testing device in a common configuration.

  Note: If the device to be controlled requires extended safety precautions and may not be operated in a standard laboratory (e.g. because of radioactive parts, poisonous or rare gases, liquids or other components are used) a simulation mode is mandatory. This must be clarified with Thermo Fisher Scientific as early as possible.

- A copy of the driver test protocols

8 Test

The requirements described in the test cases in the following chapters must be fulfilled according to the information given in the "Relevance" column to get a final certification. Thermo Fisher Scientific however, recommends fulfilling all of these conditions to ensure that a CM customer has a common look-and-feel with the new driver. The column 'Relevance' specifies whether this test case is absolutely mandatory to receive a certification by Thermo Fisher Scientific or if it's only mandatory for certain manufacturer classes. 'All' means that it is mandatory for all drivers, regardless of the manufacturer class and therefore must be fulfilled in order to get a certification by Thermo Fisher Scientific.

8.1 Test Summary

To be filled in by the tester:

Tester:	Date:	Signature:
	4-Jan-17	
Certification Test Type [ ] Full Driver Certification [ ] Driver Update Certification [ ] Preliminary Certification		
Result: [ ] Passed [ ] Failed		
Comments[1]:		

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[1] Use for general summary comments only. Please place detailed comments about the result of a special test case in the 'Comments' column of the respective test case table.

8.2 Test Suites

8.2.1 Driver Structure / Setup / Distribution

	Title	Description Requirement	Relevance	Result
1	External setup[2] package	If an external setup package is provided for the driver: The external setup must: • Detect whether CM is installed and whether it's new enough to support the driver. • Detect the CM installation folder properly • Install all relevant driver and other related files and components to the correct location (see also test case 8.2.1). • Copy ePanel files and selectors to the appropriate location – see also 8.2.8[3] • Leave the CM installation intact (Chromeleon IQ should show no new warnings or errors after installation)	All	
2	Use of Thermo Fisher icons	The external setup does not use, display or install any bitmaps, logos or icons that are copied or adapted from original Chromeleon or other Thermo Fisher icons (unless there is an explicit agreement between Thermo Fisher and the company that develops the driver). This applies to: • UI components in the setup (e.g. installation dialogs) • Icon used for the driver package in the Windows list of installed programs .	3	
3	External setup package: Uninstall routine[2]	The setup must provide an uninstall routine, which allows the removal of all files and registrations from the CM installation. CM IQ and Station OQ must still pass after unistallation.	All	
4	External Setup: Unattended Mode[2]	The setup must provide an unattended mode. The corresponding command line options must be specified in the installation procedure help document The unattended mode must install the driver package without errors and without any user interactions. There must also be an unattended mode for removing the driver again.	All	

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[2] Only relevant if the driver is distributed in a separate package, which is mostly relevant with MFClass 3 only. Test case can be omitted when driver is distributed with CM setup.
[3] If present

| 5 | Driver directory structure | DDK driver code is only placed in a common folder structure, which resides in a sub folder of:

`<Chromeldir>\bin\DDK\V1 Drivers\<DeviceManufacturer>`,
where
- `<Chromeldir>` is the CM installation path
- `<DeviceManufacturer>` is the name of the company that builds the hardware.

Ensure that the name of your sub folder clearly indicates for which product the driver is intended.

The same applies to the instrument method plug-in (CM7 only) in
`<Chromeldir>\bin\DDK\V2\Drivers\<DeviceManufacturer>` | All | |
| 6 | <Chromelfolder>\bin , bin\DDK\V1 and <Chromelfolder>\bin\DDK\V2 folders | No files may be copied into any of these folders directly. Use the dedicated Driver subfolders instead. | All | |

8.2.2 Setup / Distribution (Extended)

	Title	Description Requirement	Relevance	Result
1	Installation Documentation	Installation documentation must be made available to the end user. MFClass 3: It is not necessary to incorporate the help into the configuration dialog (e.g. by adding 'Help' buttons that open up a context help). However, the setup package (or the setup DVD) should at least contain an installation guide for the driver in a common documentation format (e.g. PDF, RTF, WORD)	All	
2	List of files / IQ Tool	The deployment package must contain an IQ tool or at least documentation with a list of all distributed files and OS related changes like registry settings, firewall exemptions, changes of security settings and so on … If the IQ tool is not started automatically by the setup, the installation documentation (see previous test case) must document how to run an IQ for this driver package manually.	All	
3	ePanels / Reports	Any related ePanels and reports must be available for review at certification time.	All	

8.2.3 Driver Configuration

	Title	Description Requirement	Relevance	Result

	Title	Description Requirement	Relevance	Result
1	Driver List	Driver(s) must be present in driver list in the correct manufacturer section. Correct capitalization, unique name.	All	
2	Initial configuration	It must be possible to load and configure a driver instance. The initial installation should open a dialog or wizard and contain an 'Ok' button (or 'Finish' in case of a wizard) to confirm the initial configuration as well as a 'Cancel' button so that the user can cancel the loading of a new driver instance.	All	
3	Initial configuration: Simulation mode	It must be possible to load and configure a driver instance without a real device. It must be possible to create an IM with this driver later on and to run a sequence.	MFClass 3	
4	Driver reconfiguration	It must be possible to reconfigure a driver instance, including a change of the connection specification.	All	
5	Abort Driver reconfiguration	If one aborts a reconfiguration of the driver with 'Cancel' the old configuration is preserved. No actions done during reconfiguration will have altered the driver behavior (e.g. ISendReceive actions).	All	
6	Configuration checks	The configuration plug-in should contain checks for a valid configuration so that the driver cannot be loaded with an invalid configuration. Examples: Empty connection information, invalid characters in device names.	All	
7	Several driver instances[5]	It's possible to run several driver instances on the same instrument and/or server PC. They must not interfere with each other.	All	
8	Reject several driver instances[6]	If the driver does not allow more than one driver instance per server PC or instrument, the configuration plug-in must reject the addition of a second driver instance to the server configuration.	All	
9	Support of client/server architecture	Ensure that it is possible to configure an instrument controller on PC 1 with an instrument configuration that runs on PC 2.	All	
10	Configuration report	The configuration report provides full information about all configuration options.	All	
11	Configuration report format	The configuration report is formatted according to the Chromeleon standards – see reference [1] for details.	MF class 1,2	

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[5] If supported
[6] If only one instance per server PC supported

8.2.4 Symbol Tree

	Title	Description Requirement	Relevance	Result
1	Help Text	Every property and command provides a useful help text (except service level symbols).	MFClass 1,2	
2	Standard Properties	Standard property and command names are only used for their original purpose in CM.	All	
3	ITypeDouble Property range	Range of so-called ITypeDouble properties may not exceed the floating point range for backward compatibility reasons (1.175494351 E – 38 - 3.402823466 E + 38)	All	

8.2.5 Instrument Method Editor

This section is only relevant if an explicit IME plug-in is provided. For CM7 this is mandatory.

	Title	Description Requirement	Relevance	Result
1	Wizard: Correct driver detection	Corresponding property pages appear in the wizard when the driver instance is present on the instrument	All	
2	Wizard: Multiple driver instances[5]	IME plug-in can handle several driver instances on an instrument	All	
3	Wizard: Method validation	If one click through the wizard pages, the resulting method does not trigger any errors in SC. Property pages must prevent users leaving a page with an incorrect setting.	All	
4	Editor	It is possible to re-open a method saved with the wizard. The corresponding page re-opens and it's possible to edit the script once more.	All	
5	Leave method unmodified if nothing has changed	Open an existing method. Open and close all editor pages and corresponding tab sub pages but don't change anything. Close the method: The method should not be marked as 'modified' and can be closed without being asked by Chromeleon if the modified method is to be saved first.		
6	Support of client/server architecture	IME works fine even if CM console is running on PC 1 while CM instrument controller is running on PC 2	MFClass 1,2	

8.2.6 Manual Injection

This section is only relevant for sampler drivers.

'Manual Injection' means that one executes the sampler's 'Inject' command outside the context of a sequence run; e.g. from an ePanel or directly from the command list (F8) dialog on the 'Instruments' pane.

	Title	Description Requirement	Relevance	Result
1	Ready Check	If the driver does not support manual injection, the RC must reject a manual injection	All	
2	Manual Injection	Manual Injection is performed with the specified Position and Volume values and the current sampling parameters	All	

8.2.7 Monitor Baseline

	Title	Description Requirement	Relevance	Result
1	Ready Check	If the driver does not support monitor baseline (i.e. data acquisition without an injection run) the driver must reject this during the RC	All	
2	Data Acquisition	If the driver does support monitor baseline, it sends the correct data according to the actual method parameter set.	All	

8.2.8 Installation of ePanel / Report Templates

This test suite is only relevant if ePanels (Chromeleon 6 : panel templates) are provided.

	Title	Description Requirement	Relevance	Result

1A	Correct Installation Location (CM6)	This applies for Chromeleon 6 drivers only:
		
		The external setup is able to detect the default data source and it copies the panels to a location
		
		`'Other Templates'\Panels\<ManufacturerName>\<Driver Name>'`
		
		and the reports to
		
		`'Other Templates'\Reports\<ManufacturerName>\<Driver Name>'`.
		
		If no default datasource can be determined, the files are copied to
		
		`'<ChromeleonDir>\Data\Other Templates …'`
			All	

1B	Correct Installation Location (CM7)	This applies for Chromeleon 7 drivers only:
		
		The ePanel templates are copied to
		
		`<Chromeldir>\bin\ePanelTemplates`
		
		The corresponding selector files are copied to
		
		`<Chromeldir>\bin\ePanelSelectors`
		
		Panels and selector files are named is a way that makes clear that they belong to this driver package so that it's unlikely that other driver packages will install files with the same name here.
			All	

2	Panel Timebase information	This applies for Chromeleon 6 drivers only: The panels do not contain a default timebase connection information.	All	
3	Panel layout	Panel does not pop up error messages if one connects it with a corresponding configuration of the driver. All user controls are correctly connected (visual check: all controls linked to properties should display current values or should be disabled if not available with current driver configuration).	All	

8.2.9 Injection Runs and Data Acquisition

	Title	Description Requirement	Relevance	Result
1	Ready Check	Using a common configuration, create an IM with default values and all channels activated. The RC should return reasonable results (we don't expect any errors here, especially not in simulation mode)	All	
2	Ready Check Performance	Use an appropriate sampler with a configuration that gives the highest possible number of vials. Create a queue with at least two sequences and total number of injections = 2 x max number of vials. Check that the RC lasts less than a minute	MFClass 1,2	
3	Run Queue	Queue is running without errors	All	
4	Hold/Continue during analysis	If the hardware supports Hold / Continue broadcasts during an analysis (i.e. after the injection and during data acquisition) it must put the device in a 'Hold'/'Continue' state. If that's not supported, the RC must issue an error that the device does not support this feature See reference [1] for more details about this feature.	All	
5	Data Acquisition	Run this test with the highest and lowest possible data acquisition rate: - Incoming data can be displayed on an online panel. A small delay between retention and signal time is acceptable because of internal buffering. But shift between signal time and retentions time may not increase continuously with increasing acquisition time. - The retention time range of the resulting data matches the [AcqOn - AcqOff] period.	All	
6	Abort queue / restart	The driver has no problems with restarting a queue after an abort (if real device is available: let the device trigger an error; otherwise abort the queue explicitly with the CM console).	All	

8.2.10 Blank Run Support

	Title	Description Requirement	Relevance	Result
1	Ready Check	If the driver does not support blank run injections in sequences the driver must reject this in RC.	All	
2	Blank Run	Blank run works as expected, i.e. sampler omits injection, pump runs the pump program and detectors acquire data as if an injection has taken place.	All	

8.2.11 Reporting

This section is only relevant if the driver does not use the original CM concept of Properties/Commands but uses a method blob concept to transport method related information from the IME to the driver.

	Title	Description Requirement	Relevance	Result
1	Provide report information	The driver must be able to write the full method information to the injection audit trail so that it can be read and stored with the CM report mechanism.	MFClass 1,2	

8.2.12 Driver Backward Compatibility

Note: This section is only relevant if one intends to upgrade an existing version of a driver that is already released.

	Title	Description Requirement	Relevance	Result
1	External Setup[2]	An external setup package must be able to • Install a driver on a system where no driver was installed so far. • Upgrade a present installation of an older driver version; or force uninstall of the old driver first.	All	
2	Instrument Controller Start	It is possible to start an instrument controller whose configuration contains an instance of the driver that was added with an earlier version of the driver/configuration plug-in. Driver behavior must be compatible with old version.	All	
3	Instrument Controller Configuration	It is possible to edit a driver configuration, that was originally added with an earlier version of the driver/configuration plug-in.	All	
4	Queue run	It is possible to run a sequence with IMs written with an older version of the driver / IME plug-in. i.e., the property and symbol list must be compatible with old driver version.	All	
5	IME	It is possible to edit and save an IM that was written with an older version of the driver / IME plug-in.	All	

8.2.13 Preliminary Certification Test

Note: This section is only relevant for a preliminary certification of a driver.

	Title	Description Requirement	Relevance	Result
1	IMW	It is possible to open the IMW to set up a default method. The corresponding SC does not issue any errors or	All	
2	IME	It is possible to re-open the stored default method with the IME. All method specifications of the default method are correctly displayed.	All	
3	Queue run	It is possible to run a sequence with the default method in simulation mode.	All	