Thermo Fisher
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Title: OQ Software Chromeleon

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Qualification #: 50559

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CHANGE SUMMARY

(Only changes within the last 18 months are listed below.)

Revision Number	Effective Date	Description of Changes
009	See Cover Sheet	• Section 4: Added OQ Acceptance Criteria. • Added section 5.1: Configuring RPG Reports. • Section 5.2 and 5.3: Added additional support for RPG Reports 3. • Added Section 7: What to do if a Test Fails. • Updated end sections 8-10 to match latest RPG qualification document template.

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SOFTWARE OQ FOR CHROMELEON-BASED SYSTEMS

1 INTRODUCTION

Documented evidence must be provided to demonstrate the integrity of data collected and validate the results obtained on laboratory instrumentation.

Many laboratories achieve this by formal quality systems, which are generally implemented in accordance with one or more of the following recognized quality standards and other quality guidelines:

- Good Laboratory Practice (GLP)
- Current Good Manufacturing Practice (cGMP)
- ISO guidelines
- USP / EP

These standards are written in broad terms, to make them as widely applicable as possible. All stipulate general requirements specifying instruments must be fit for purpose, properly maintained, and calibrated to national or international standards. The procedure used for the Thermo Fisher Scientific qualification is adapted to these standards.

This procedure is intended to guide a trained and qualified person through the Software Operational Qualification of the Thermo Fisher Scientific Chromeleon software platform.

The instrument hardware control functionality of the software is indirectly tested during the hardware OQ.

2 RECOMMENDED DOCUMENTS

Use this document along with the software user manuals.

3 RECOMMENDED MATERIALS

Use this document along with:

- Chromeleon 6.8
- Chromeleon 7.x or higher version
- RPG Reports UI

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4 OPERATIONAL QUALIFICATION SCOPE

Software Operational Qualification is documented verification that a system operates according to written and preapproved limits throughout all specified operating ranges.

Qualification testing is recommended:

- At initial installation or upon reinstallation of the software
- When a software change has been made to an existing system (e.g., Thermo QuickFix)

OQ documents the following items:

- **System Information**: Record the specific computer system hardware and software information being qualified.
- **Operational Verification**: Record the operational qualification report that indicate that the software meets the qualification acceptance criteria.

OQ acceptance criteria:

- Testing is performed using a Chromeleon Software OQ feature that is built into the Chromeleon application.
- The OQ will pass if the OQ Report indicates a **PASS** status, or if any unexpected results can be satisfactorily resolved.

5 PERFORMING THE OPERATIONAL QUALIFICATION

An automated software operational qualification is run within the Chromeleon software. The software OQ ensures that the software functions properly on certain levels. This is accomplished through:

- Regeneration/re-evaluation of data against reference results
- Establishing a connection between the client and local PC server
- Automatic comparison of:
  - Calibration coefficients/results
  - Newly evaluated parameters with reference values

5.1 Configuring RPG Reports

1. Open the RPG Reports UI and start a new project (a license must be activated for the project).
2. Configure the UI as follows:
   a. Reports 2.x:
      i. Qualification Type: **GCMS Systems**, **IC Systems**, or **LCMS Systems**
      ii. System Type: ***Set as applicable to instrument configuration***
      iii. Qualification Control Software: **Chromeleon**
   b. RPG Reports 3.x:
      i. Group: **Analytical Instrument Group**
      ii. Service: **IQOQ** or **OQ**
      iii. Hardware Configuration: **IC**, **GC**, or **LC**
      iv. Control Software: **Chromeleon**, ***and enter the version***
3. To Create the SW OQ Test Page:

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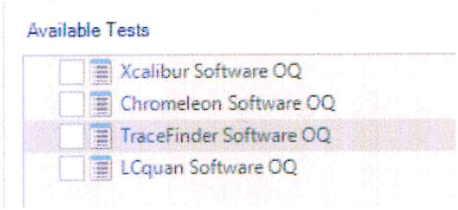
a. Reports 2.x:
   i. Go to **Installed Software** in Section 2.
   ii. Select **Chromeleon** as **Installed Software** (OQ test pages will be created for any supported platform).

b. RPG Reports 3.x:
   i. On the Settings screen, under Available Modules, select **Instrument Controller > Software > Windows**
   ii. Click the **Next** button to advance.
   iii. This will create a Report page section for the Instrument Controller PC (with a numeric identifier in case more than one PC are added).
   iv. The individual PC details can then be entered, and once **Powered On Successfully?** is completed, Available Tests are displayed for the supported software.



   v. Check the Chromeleon Software OQ test and use the arrows to move it to the Selected Tests
   vi. When ready, click Next to create the Software OQ Test Pages.
   vii. Additional Software tests can be added as needed.
   viii. The project should be saved before then proceeding with testing.

5.2 Chromeleon 6.8 OQ Test

1. Open **Chromeleon**.
2. Ensure that the Chromeleon software IQ has already been run.
3. Select the **Qualification** menu item.
4. Select **Chromeleon OQ...**
5. Follow the on-screen instructions.
6. Allow the automated qualification to run until completion.
7. Verify the results of the automated tests upon completion.
8. In the RPG Reports UI, record the results from the OQ report.
9. Print the resulting PDF report and attach it to the Qualification Package.

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5.3 Chromeleon 7.x OQ Test

1. Open the **Chromeleon** console.
2. Ensure that the Chromeleon software IQ has already been run.
3. Select the **Tools** menu item.
4. Select **Station Qualification**.
5. Choose the **Operational Qualification** type.
6. Enable the option to automatically print the report.
7. Follow the on-screen instructions.
8. Allow the automated qualification to run until completion.
9. Verify the results of the automated tests upon completion.
10. In the RPG Reports UI, record the results from the OQ report.
11. Print/Attach the resulting PDF report to the Qualification Package (*with RPG Reports 3.x this may be attached electronically using the Load Documents feature*).

6 EXCEPTIONS AND COMMENTS

If an exception is made during the qualification, the exception must be recorded in the appropriate **Exceptions & Comments** section of the RPG Reports UI.

7 WHAT TO DO IF A TEST FAILS

If at any point the test results do not pass within the specified limits, the cause of the failure must be determined. Some failures are the result of an easily identifiable problem (e.g., operator error). Other failures can require software/computer repair, and thus it is necessary to notify the customer, as they may have internal documentation that must be completed detailing the event.

The appropriate software manuals may need to be referenced to complete the repair or service. Once the corrective action has been completed, all affected OQ tests will need to be performed. The failing and passing data, or result reports, must be kept as part of the Qualification record. All actions for failures and repairs should be recorded on the Comments section of the Qualification Checklist or in the RPG Reports UI.

8 PRINTING AND SAVING DATA

Ensure that all supporting data and reports have been printed from the CDS software.

Ensure that all qualification test reports have been printed. If reporting is electronic, ensure all materials have been generated in a suitable file format (e.g., PDF).

Save to a storage device or other specified media or location all qualification related data and files that may have been created during the qualification process; this is an optional convenience for the customer.

9 BUILDING THE QUALIFICATION PACKAGE

1. Place all documentation (paper and electronic) in the appropriate section of the qualification binder (or eBinder). All certificates must be current and not expired when they include a defined period of validity.

   Note: Alternative / customer-oriented document storage is allowed.

2. Documentation required as follows (as applicable):

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- Software Installation Procedures
- Software Installation Qualification Reports/Checklists
- Software Operational Qualification Procedure
- Software Operational Qualification Reports/Checklists
- Qualification Service Representative's Training Certificates
- Software Validation Certificates
- Any Additional Supplementary Documentation (e.g., Deviation Memo)

10 OQ REVIEW AND COMPLETION

The Service Representative must sign and date the qualification results (electronically or pen and ink). It is important that all qualification attachments have been properly labeled, initialed, and dated (as applicable).

It is critical the final Qualification Package be reviewed with the customer as the final step in completing the Qualification. The customer can perform any reviewer signoffs at this time. This will help educate the customer on the work performed, allow any questions to be answered, and help prevent return visits.

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