NANODROP EIGHT SciVault

OQ For SciVault Software with NanoDrop Eight Software v1.6

Operational Qualification

☐ N/A

Approved by: _____ Date: _____

Department name: _____

☐ N/A

Reviewed by:_____ Date: _____

Department name: _____

Comments:

Tested Software Version Numbers

NanoDrop Eight Software:_____

SciVault Software:_____

ThermoFisher SCIENTIFIC

Contents

Introduction

This Operational Qualification (OQ) verifies that the Thermo Scientific™ NanoDrop Eight™ SciVault software has been installed correctly and will operate smoothly with preinstalled NanoDrop Eight spectrophotometer software. By performing OQ, you can confirm that Privileges settings are enforced and that logged events are shown in Audit Logs feature.

This OQ procedure was written for NanoDrop Eight software version **v1.6**.

How to Use This Document

Each major section of this document lists all the relevant Privileges settings needed for that section and does not rely on any other settings or prerequisites from the preceding sections.

OQ procedures include instructions for testing using desktop interfaces for NanoDrop Eight software.

What to Expect

In general, each procedure contains two major sections:

- **Setup.** You will edit and review settings in User Privileges feature.
- **Test.** You will verify that the settings are correctly enforced.

We recommend that the OQ procedures are carried out by a user who is familiar with User Privileges feature and NanoDrop Eight software. User Manuals for SciVault software and for NanoDrop Eight software can be found online at **thermofisher.com/nanodrop**.

Local Server and Remote Server Installations of SciVault software

This OQ procedure works equally well for single computer and for different computer installations of SciVault software.

- If you are using a single-computer installation, you will switch between a security administrator account and a test user account.
- If you are using different-computers installation, you will switch between the following:
    - A security administrator account used on the SciVault software server
    - A test user account used on each client machine

Before You Begin

Before you start, run Thermo Software IQ to verify the software installation. Run instrument diagnostics to ensure it is operational.

To run the instrument diagnostics:

1. Open **NanoDrop Eight** software.
2. Navigate to the **Intensity** icon and **Run** the Intensity Check.
3. Navigate to the **Performance** and **Run** the Performance Verification.

NOTE: See the NanoDrop Eight spectrophotometer user guide for detailed instructions on running the instrument diagnostics.

Required Tools and Materials

Completing software OQ requires the following:

- A connection to a NanoDrop Eight instrument. You will measure a sample spectrum during OQ.
- To test the desktop interface of NanoDrop Eight software, you will need a keyboard and mouse.

Required Roles

It requires two people to carry out the OQ procedures:

- A tester to complete the OQ procedure. This is typically a Thermo Scientific representative.
- An approver to confirm that the tests were carried out and that the recorded results are accurate. This is typically an authorized administrator or other representative from the customer's organization.

Required Windows Accounts

You will need access to two user accounts. These accounts should be set up before a Thermo Fisher Scientific representative arrives to perform OQ.

- **A Security Administrator account.** This is a Windows Administrator account with permission to edit settings in SciVault software and to view the audit trail in Audit Logs feature.
- **A Test User account.** This is a test account used to demonstrate restricted security settings for software OQ. This can be either a standard Windows user account or an account created specifically for software OQ. If you create an account to be used specifically for OQ, this OQ Test User account must be a member of the Users group (not an Administrator). The account must have a password. If the account does not have a password, you will not be able to open Thermo Scientific applications during software OQ.

For future reference, list the account information below:

Security Administrator account username: _____

Test User account username: _____

Save Your Settings

During OQ, you will edit and save new settings in User Privileges feature. If you are not starting OQ with the default security settings (for example, if you are repeating the OQ after using the software for some time), record your current settings so that you can restore them after testing more easily.

Conventions Used in this Document

Procedures in this document refer to two type of users:

- **Administrators:** This refers to the Security Administrator account with permission to view the audit trail in the Audit Log feature and to open and edit settings in SciVault software.
- **Test User:** This is the **OQ Test User** account that will be used to verify security settings.

OQ for Access Control

This section tests security settings for the following:

- The ability to open applications
- The ability to access specific features and tools within applications

Together, these tests demonstrate the ability to set unique permissions for each user or user group.

OQ for the Ability to Open Applications

This procedure tests whether you can limit the ability to open the following applications:

- User Privileges feature
- Audit Logs feature
- NanoDrop Eight software

During the procedure, you will carry out two major steps:

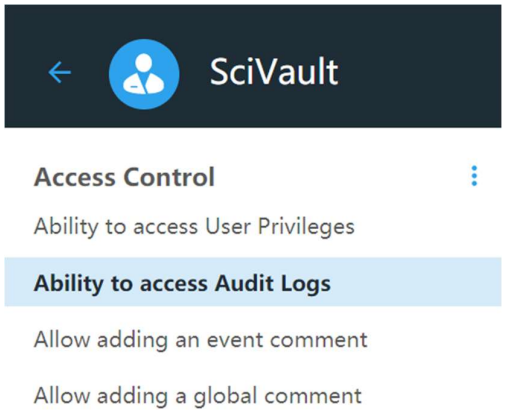
- Edit Access Control settings in User Privileges feature.
- Verify that the Access Control settings are enforced.

Procedure

Setup

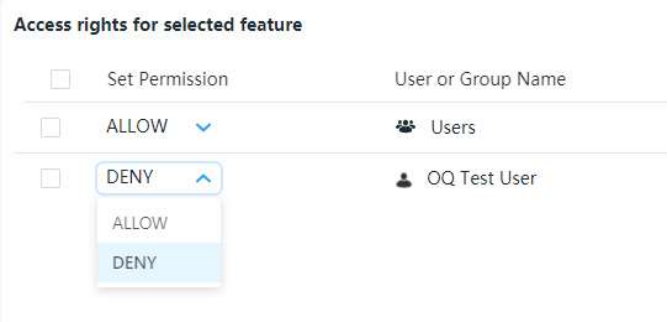
As the Administrator

1. Sign into Windows using the **Security Administrator** account.
2. Open **SciVault** software.
3. In the main interface, navigate to **User Privileges > SciVault > Access Control > Ability to access Audit Logs**.

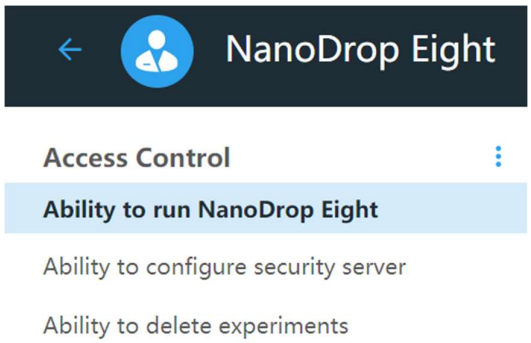


4. Under Access rights for selected feature, add the **OQ Test User** account.

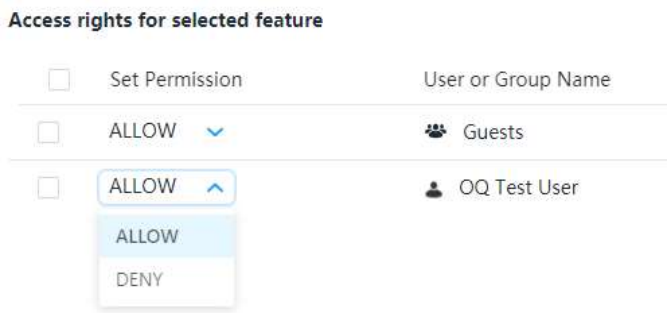
5. Set the permission for OQ Test User to **DENY**.



6. In the main interface, navigate to **User Privileges > NanoDrop Eight > Access Control > Ability to run NanoDrop Eight**.



7. Under Access rights for selected feature, add **OQ Test User**.
8. Set the permission for OQ Test User to **ALLOW**.



9. Close SciVault software.

Test

As the Administrator

1. Test access to Audit Logs feature.

    - Open **SciVault** software. When prompted for a password, enter the correct password. The software may take a moment to open.

Is Audit Logs feature enabled?

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

    - Close SciVault software.

2. Test access to NanoDrop Eight software

    - Open **NanoDrop Eight** software. When prompted for a password, enter the correct password. The software may take a moment to open.

Is NanoDrop Eight software opened?

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

    - Close NanoDrop Eight software.

3. Sign out of the Security Administrator Windows account.

As the Test User

With the Test User account, repeat the process of attempting to open each software. Because this account has limited access to applications, the expected results will be different from those of the Security Administrator account.

1. Sign into Windows using the **OQ Test User** account.

2. Test access to SciVault software.

    - From the desktop, double-click the icon for **SciVault** software.

    - When prompted for a password, enter the correct password. The software may take a moment to open.

Is SciVault software opened?

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

3. Test access to **Audit Logs** feature.

Is Audit Logs feature disabled?

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

- Close SciVault software.

4. Test access to NanoDrop Eight software.

- Open **NanoDrop Eight** software.
- When prompted to enter a password, enter the correct password and click **Login**.

Is NanoDrop Eight software opened?

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

- Close **NanoDrop Eight** software.

Overall Result

Sign below to signify that OQ for the ability to access SciVault- Audit Logs feature and NanoDrop Eight software was completed:

☐ N/A

Comments:

Result: ☐ Pass ☐ Fail

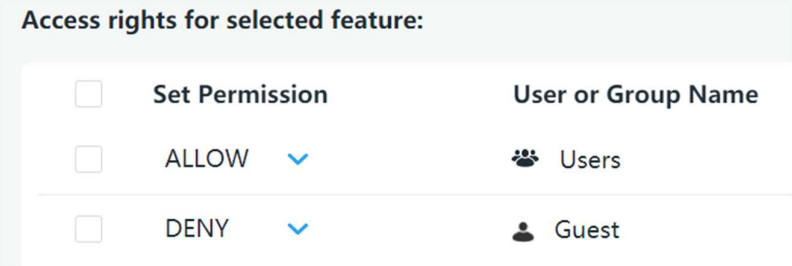
Tested by: _____ Signature:_____ Date:_____

Approved by: _____ Signature: _____ Date: _____

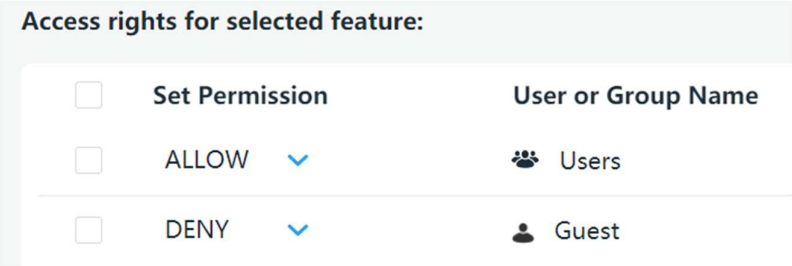
Reset SciVault Settings

Before continuing, restore your security settings to the previous state. These instructions help you restore the default settings.

1. Sign into Windows using the **Security Administrator** account.
2. Open **SciVault** software and login.
3. In the main interface, navigate to **User Privileges > SciVault > Access Control > Ability to access Audit Logs**.
4. Remove the OQ Test User from the list of access rights.



5. Navigate to NanoDrop Eight > Access Control > Ability to run NanoDrop Eight.
6. Remove the OQ Test User from the list of access rights.



7. Close SciVault software.

OQ for Ability to configure security server

This procedure tests the ability to configure SciVault server in NanoDrop Eight software.

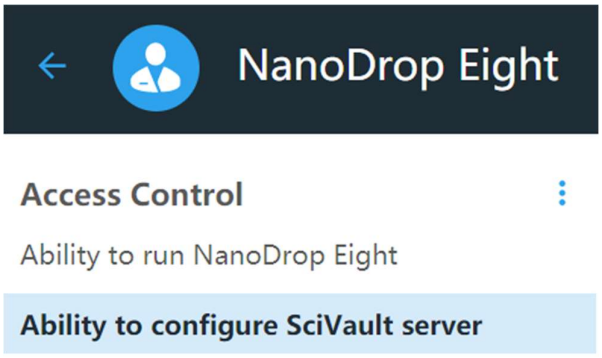
To perform this test, you will restrict access to enter SciVault Server Address of System tab in NanoDrop Eight software for the Test User account. You will then use the Test User account to verify that the settings are enforced.

Procedure

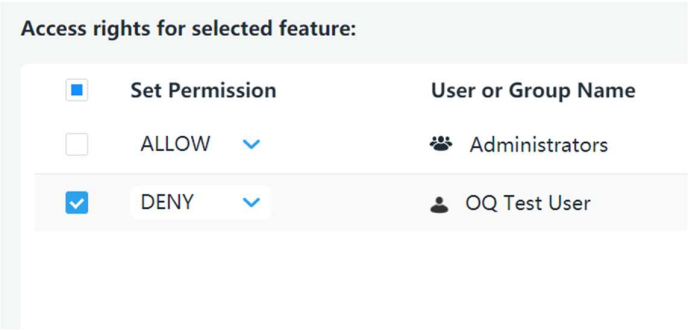
Setup

As the Administrator

1. Sign into Windows using the **Security Administrator** account.
2. Open **SciVault** software.
3. Navigate to **User Privileges > NanoDrop Eight > Access Control > Ability to configure SciVault server**.



4. Add the OQ Test User account to the **Access rights for selected feature** list.
5. Set the permission for OQ Test User to **DENY**.

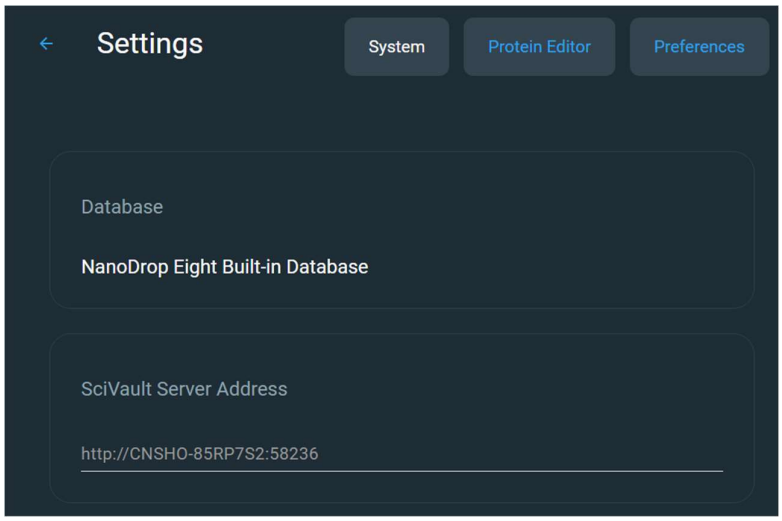


6. Close the **SciVault** software.
7. Sign out of the Security Administrator account.

Test

As the Test User

1. Sign into Windows using the **OQ Test User** account.
2. Open **NanoDrop Eight** software.
3. If the software starts, select **Settings** and go to **System** tab.



4. At this point, SciVault Server Address should be disabled

Is the SciVault Server Address disabled from the Settings?

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

5. Exit to close NanoDrop Eight software.
6. Sign out of the **OQ Test User** windows account.

Overall Result

Sign below to signify that OQ for the ability to access specific features and tools in NanoDrop Eight software was completed:

☐ N/A

Comments:

Result: ☐ Pass ☐ Fail

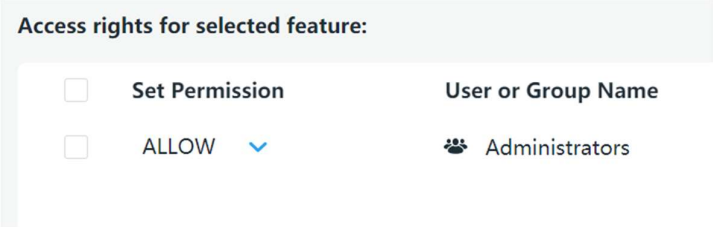
Tested by: _____ Signature:_____ Date:_____

Approved by: _____ Signature: _____ Date: _____

Reset SciVault Settings

Before continuing, restore your security settings to the previous state. These instructions help you restore the default settings.

1. Sign into Windows using the **Security Administrator** account.
2. Open **SciVault** software using the correct password.
3. In the main interface, navigate to **User Privileges > NanoDrop Eight > Access Control > Ability to configure SciVault server**.
4. Remove the OQ Test User from the list of access rights.



5. Close SciVault software.

OQ for System Policies

This section tests settings related to system policies. System Policies are settings in User Privileges feature that are used to enforce digital signatures and to restrict certain application features.

OQ for Digital Signature Policies

This procedure demonstrates that User Privileges feature can be used to enforce digital signatures when creating or modifying a record.

In this procedure, you will create a new policy group for OQ in User Privileges feature, and you will use the OQ Test User account to verify that the settings are enforced.

Procedure

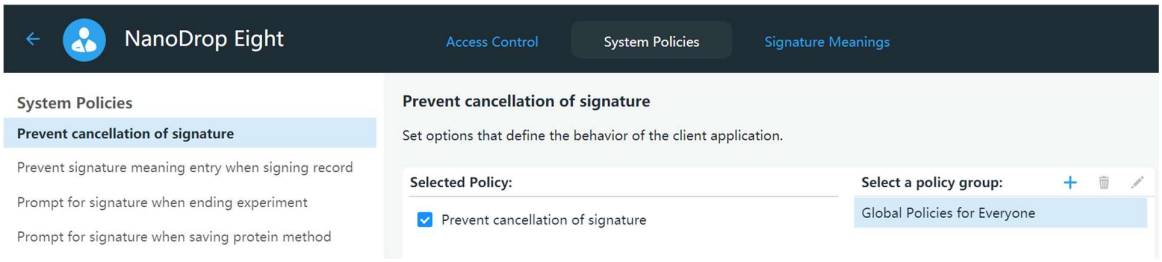
Setup

As the Administrator

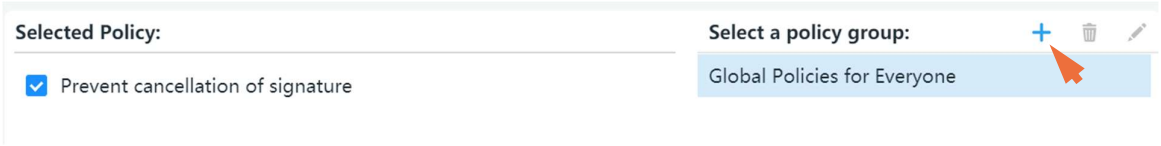
1. Sign into Windows using the **Security Administrator** account.
2. Open **SciVault** software.

Step 1: Create a new policy group for OQ

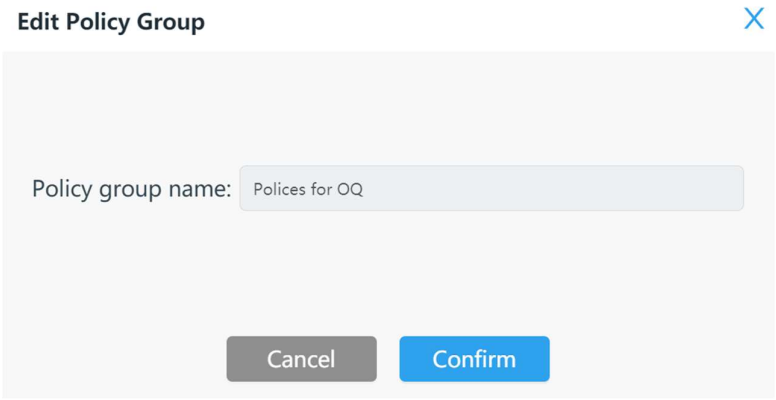
1. In the main interface, navigate to **User Privileges > NanoDrop Eight > System Policies**.
2. Select **Prevent cancellation of signature**.



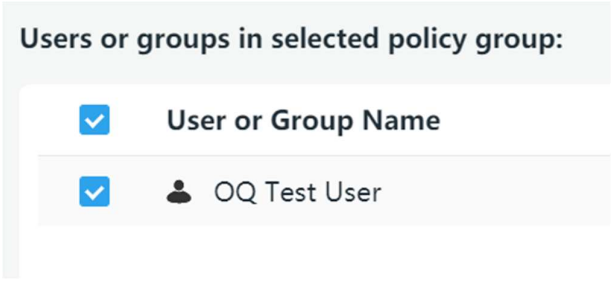
3. Select **Add** near Select a Policy Group.



4. Name the group as "**Polices for OQ**" and click **Confirm**.

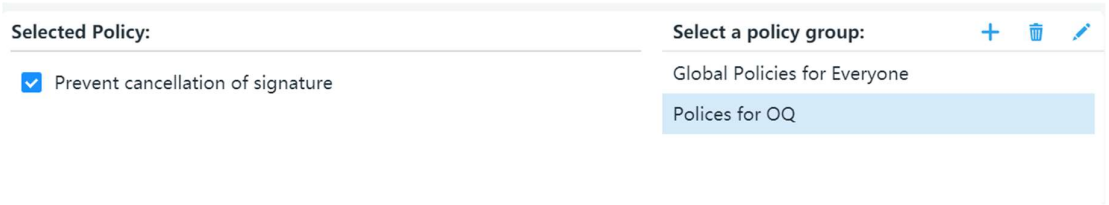


5. Select the new OQ policy group.
6. Add the Test User account to the list of Users in Selected Policy Group.



Step 2: Enforce selected policies

1. In the main interface, select **User Privileges> NanoDrop Eight > System Policies > Prevent cancellation of signature**
2. In the main panel, select **Polices for OQ**.
3. Ensure that the check box is selected to enforce the policy.



4. Repeat these for the following system policy so that they are enabled for the OQ policy group:
    - Prevent signature meaning entry when signing record
    - Prompt for signature when ending experiment
    - Prompt for signature when importing experiment
    - Prompt for signature when saving custom method
    - Prompt for signature when exporting custom method
    - Prompt for signature when saving protein method
    - Prompt for signature when saving history data
    - Prompt for signature when exporting experiment
    - Prompt for signature when importing custom method
    - Prompt for signature when saving dye method
    - Prevent export of .n8db (experiment files) from the PC control software
    - Prevent import of .n8db (experiment files) into the PC control software
5. Close **SciVault** software.
6. Sign out of the Security Administrator Windows account.

Test

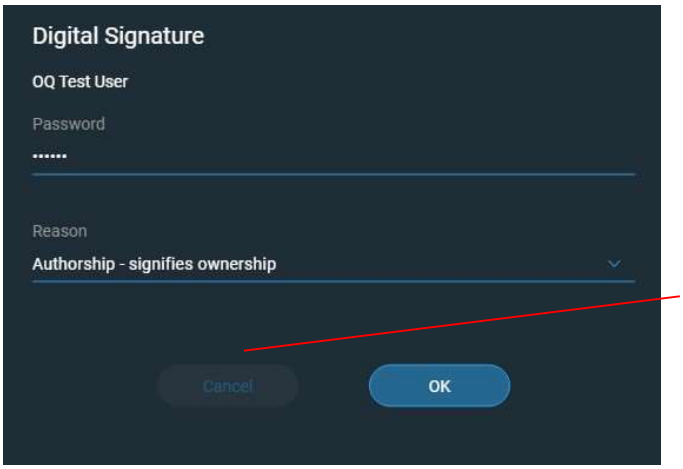
During the test, you will measure a sample. The quality of the sample data is not relevant to this test.

As the Test User

1. Remove any sampling accessory from the instrument and ensure that the pedestal is clean and dry.
2. Sign into the **OQ Test User** Windows account.
3. Open **NanoDrop Eight** software.
4. **OQ Test User** account is displayed in the right top corner of the software.

Step 1: Measure a sample and end experiment

1. Stay on Nucleic Acids tab and select dsDNA application, Select **Blank** icon
2. When the Blank is completed, select **Continue to measurements** option and active first channel, select **Measure** icon.
3. When the measurement is completed, select **End experiment** icon.
4. End experiment dialog opens and select **Save** so that the Digital Signature dialog opens.



Is the user prompted to enter a password and reason?
This tests the Require Signature when End experiment policy.

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

Is the Cancel button disabled?
This tests the Prevent Cancellation of Signature policy.

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

5. Click the **Reason** field and enter custom text in the Reason field.

Does the Reason field limit input to only the listed options?
This tests the Prevent Signature Meaning Entry when Signing Record policy.

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

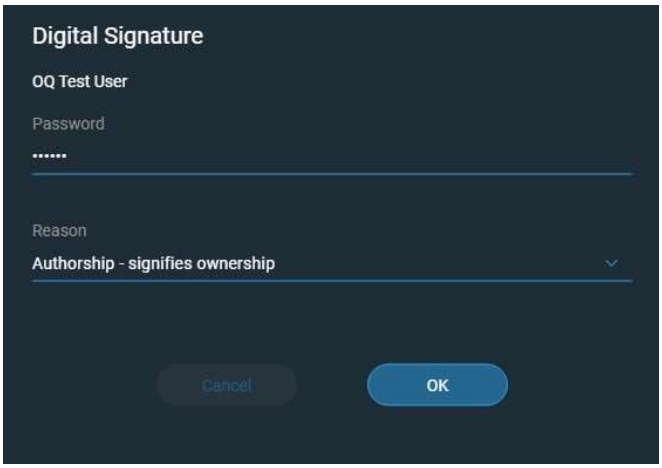
Initials: _____

Comments:

6. Select a reason from the list, enter the correct password, and select **OK**.
7. Select **Continue** to print and export the dialog.
8. Select **Exit** to close the Print and Export dialog.
9. Select **Done** to close the indicating message dialog.

Step 2: Modify the measurement information of history page

1. Select **History** at the left bottom of the Home screen, select the most recent experiment, rename the experiment name to "**OQ"** and click Enter.



Is the user prompted to enter a password and reason?
This tests the Require Signature when saving history data policy.

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

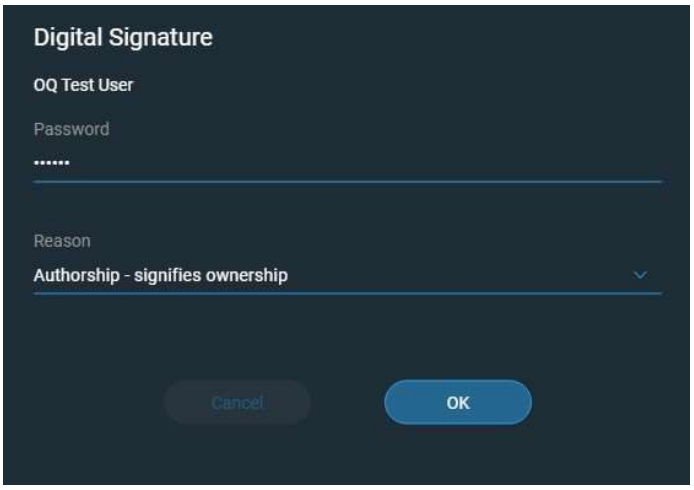
Initials: _____

Comments:

2. Select a reason for the operation.
3. Use the correct password and click **OK** to complete the digital signature.
4. Click **Continue** to dismiss the verification message

Step 3: Create Protein Editor

1. Go to Home page and navigate to **Settings** menu
2. Select **Protein Editor** and select **+Protein** icon
3. Enter the new protein type name as **'OQ2'**
4. Select **Save** so that the Digital Signature dialog opens



Is the user prompted to enter a password and reason?
This tests the Require Signature when saving protein method policy.

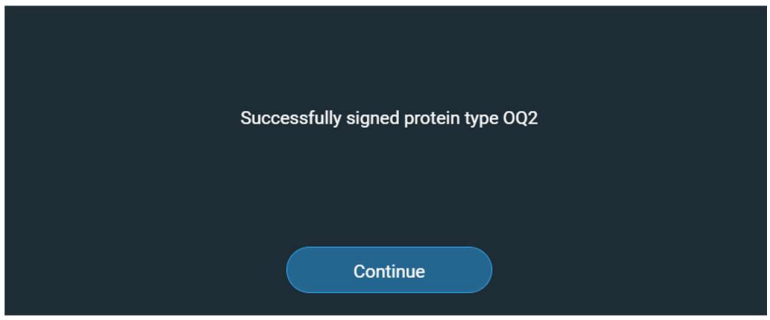
☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

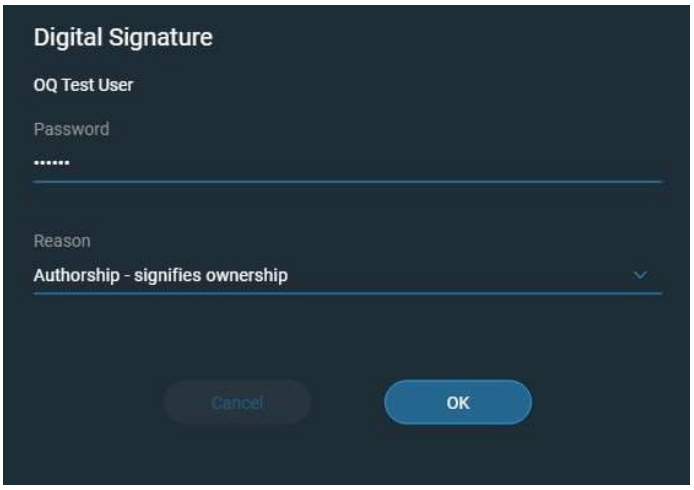
5. Use the correct password and click **OK** to complete the digital signature



6. Click **Continue** to close the dialog

Step 4: Create Dye Editor

1. Go to Home page and navigate to **Settings** menu
2. Select **Dye Editor** and select **+Dye** icon
3. Enter the new dye type name as **'OQ Test'**
4. Enter the wavelength is **350**
4. Select **Save** so that the Digital Signature dialog opens



Is the user prompted to enter a password and reason?
This tests the Require Signature when saving dye method policy.

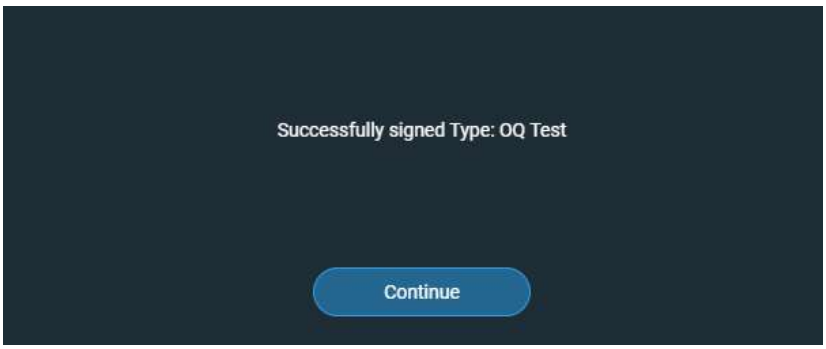
☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

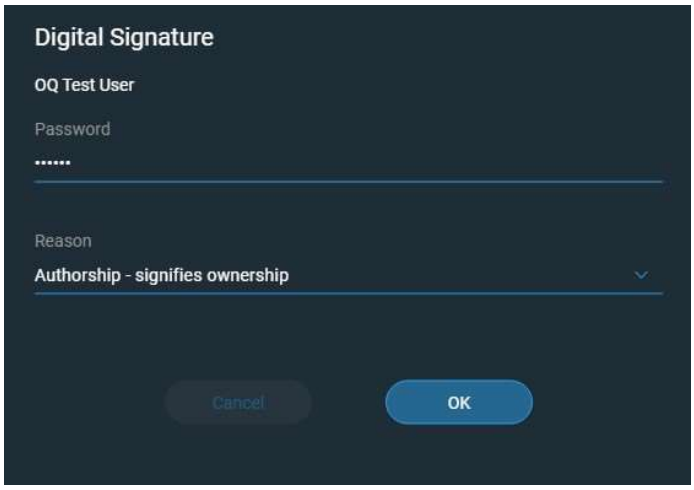
5. Use the correct password and click **OK** to complete the digital signature



6. Click **Continue** to close the dialog

Step 5: Create Custom Method

1. Go to Home page and navigate to **Custom** tab
2. Select **Custom Method application** and select **+New Method** icon
3. Select **Formula** method and enter the method name is **'OQ1'**
4. Select **Save**



Is the user prompted to enter a password and reason?
This tests the Require Signature when saving custom method policy.

☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

5. Use the correct password and click **OK** to complete the digital signature

Overall Result

Sign below to signify that OQ for the ability to set Digital Signature policies for NanoDrop Eight software was completed:

☐ N/A

Comments:

Result: ☐ Pass ☐ Fail

Tested by: _____ Signature:_____ Date:_____

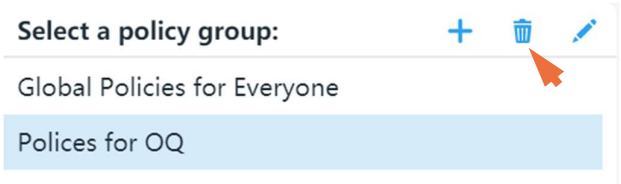
Approved by: _____ Signature: _____ Date: _____

Reset SciVault Settings

Restore your security settings to the previous state. These instructions help you restore the default settings.

1. Sign into Windows using the **Security Administrator** account.
2. Open **SciVault** software.

3. In the main interface, navigate to **User Privileges > NanoDrop Eight > System Policies > Prevent cancellation of signature.**
4. Select the **Policies for OQ** group.
5. Click **Delete**.



6. Repeat to restore security settings of other system policies
7. After completion, close **SciVault** software.

OQ for Signature Meanings

The section tests the ability to add, edit, delete, and assign signature meanings.

OQ for Signature Meanings

This test demonstrates that you can use SciVault software to add, edit, delete, and assign signature meanings. This procedure also demonstrates applying multiple signatures to a single record.

During this procedure, you will collect a sample spectrum. The quality of the sample data does not matter.

The procedure contains four main parts:

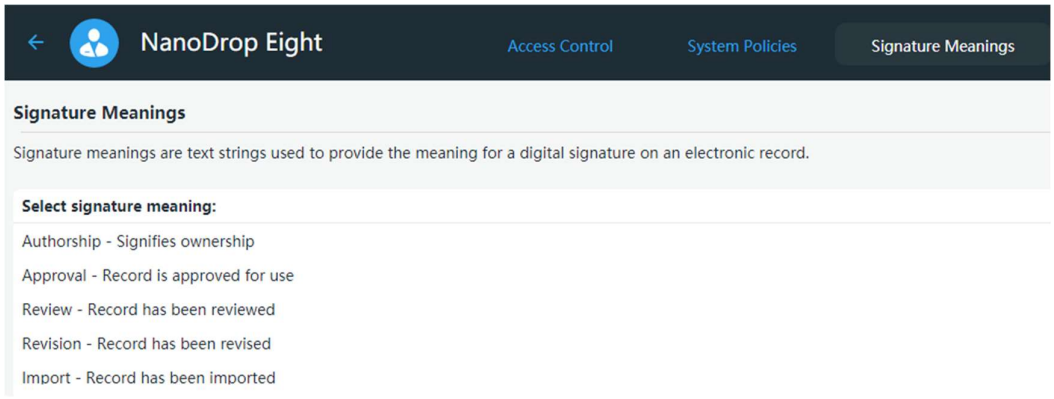
- The security administrator creates a new signature meaning and assigns it to the OQ Test User account
- The Test User signs a record
- The security administrator signs the same record
- The security administrator verifies the signature in Audit Logs

Procedure

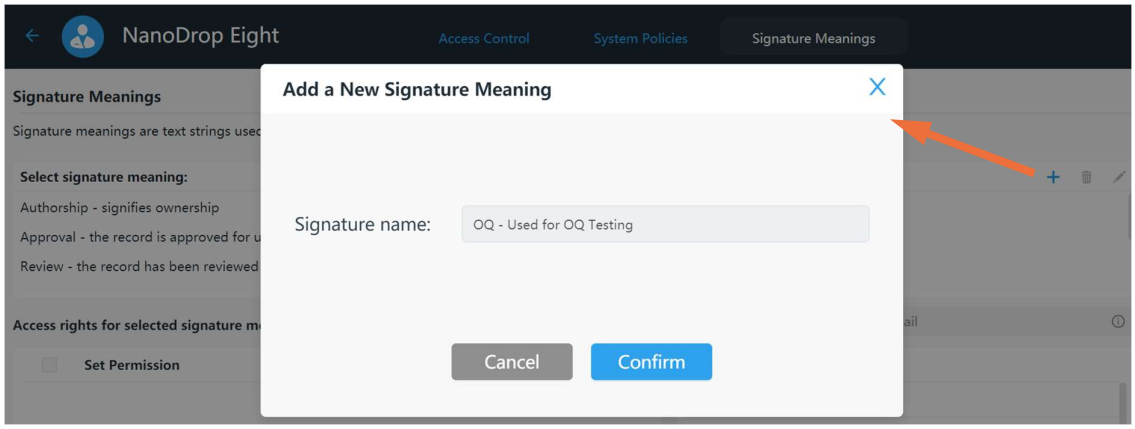
Setup

As the Administrator

1. Sign into Windows as the **Security Administrator.**
2. Open **SciVault** software.
3. Navigate to **User Privileges > NanoDrop Eight > Signature Meanings**.



4. In the Select Signature Meaning group, click **Add**.
5. Enter "**OQ - Used for OQ Testing**" as the description for the signature meaning and click **Confirm**.



6. Select the **OQ - Used for OQ Testing** signature meaning.
7. Select the **OQ Test User** from the list of Names and click **Add**.
8. In the access rights list, set the permission for OQ Test User to **Allow**.
9. Remove **Users** from Access right for selected signature group
10. Close **SciVault** software.
11. Sign out of the Security Administrator account.

Test

As the Test User

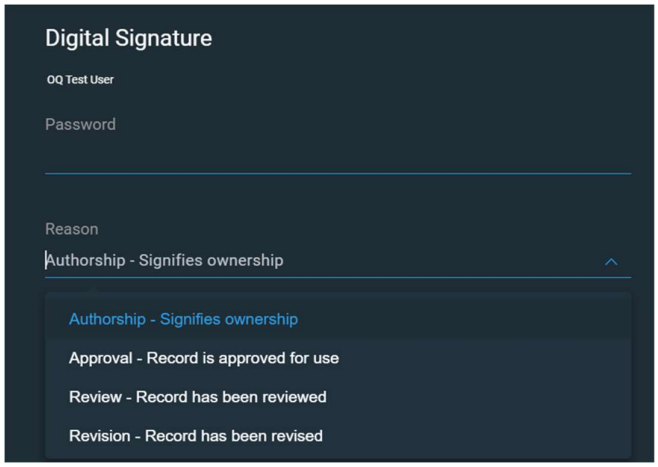
1. Sign into Windows using the **OQ Test User** account.
2. With the Test User account, open **NanoDrop Eight** software using the correct password.

   If the software starts, **OQ Test User** account is displayed in the right top corner of the software.
3. Stay on **Nucleic Acids** tab and select **dsDNA** application, Select **Blank** icon
4. When the Blank is completed, select **Continue to measurements** option and active first channel, select **Measure** icon.
5. When the sample measurement is completed, select **End Experiment** icon and select **Save** so that the Digital Signature dialog opens

6. Select **OQ – Used for OQ Testing** from the list of reasons, enter the password, and click **OK**.
7. Select **Continue** to close the successfully signed dialog.
8. Select **Exit** to close the print and export dialog and select **Done** to end experiment
9. Close **NanoDrop Eight** software
10. Sign out of the OQ Test User account

As the Administrator

1. Sign into Windows using the **Security Administrator** account.
2. Open **NanoDrop Eight** software. Security Administrator account is displayed in the right top corner of the software.
3. Select **History** at the left bottom of the Home screen, double click the most current experiment which is created by OQ Test User
4. Click the **Experiment Name** and rename to “**OQ - Signature Meanings**” and save experiment name. The digital signature dialog opens.



Is the Security Administration able to select Authorship, Approval, Review and Revision?
This test confirms that the Administrator and Test User have different options.

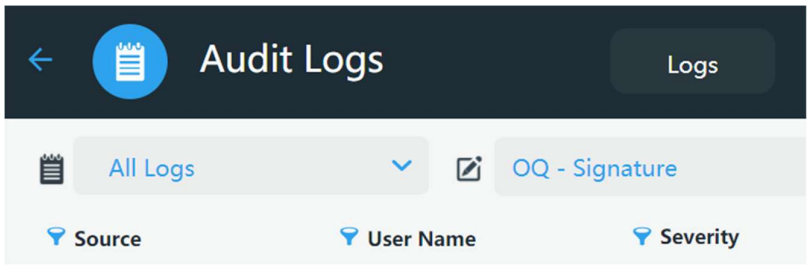
☐ N/A

Expected result: Yes
Actual result: ☐ Yes ☐ No

Initials: _____

Comments:

5. Select a reason, enter a password, and click **OK**.
6. Click **Continue** to dismiss the verification message.
7. Return to the **Home** screen and close **NanoDrop Eight** software.
8. Use the correct password to open **SciVault** software and click **Audit Logs** feature.
9. In the Search By group, enter "**OQ - Signature**."



10. Under the Category column, locate the most recent Signature event.
11. Confirm that the Description states "OQ – Signature Meanings" was signed.
12. Close **SciVault** software.

Overall Result

Sign below to signify that OQ for the ability to add, edit, delete, and assign signature meanings for NanoDrop Eight software was completed.

☐ N/A

Comments:

Result: ☐ Pass ☐ Fail

Tested by: _____ Signature:_____ Date:_____

Approved by: _____ Signature: _____ Date: _____

Reset SciVault Settings

To return the SciVault settings to the previous state, delete the signature meaning used for OQ.

1. Open **SciVault** software.
2. In the main interface, navigate to **User Privileges > NanoDrop Eight > Signature Meanings**.
3. Select **OQ - Used for OQ Testing**.
4. Click **Delete**.
5. Close **SciVault** software.
6. Sign out of the Security Administrator account.

OQ for Event Logging

This section tests if events are logged to the audit trail and if complete records can be viewed in Audit Logs feature.

OQ for Event Logging

In this procedure, you will perform a series of actions in NanoDrop Eight software using the Test User account, and then you will review the audit trail for those actions in the Audit Logs feature.

During this procedure, you will perform the following steps:

- Open NanoDrop Eight software
- Collect, modify and delete a sample measurement

Setup

As the Test User

1. Sign into Windows using the **OQ Test User** account.

   When you open NanoDrop Eight software, you will use an **incorrect password** first. This will verify that a failed login attempt is logged.

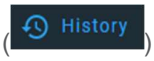
Step 1: Open NanoDrop Eight Software

1. Open **NanoDrop Eight** software.

2. When prompted for a password, enter an **incorrect password** and click **Login**.
3. After receiving an Authentication failed message, enter the **correct password** and click **Login**.
4. When the software starts, **OQ Test User** account is displayed in the right top corner of the software.

Step 2: Measure a sample, modify the measurement information, and delete the measurement.

The quality of your sample data is not important for the purposes of this procedure.

1. Remove any sampling accessory from the instrument and ensure that the pedestal is clean and dry.
2. Stay on **Nucleic Acids** tab and select **dsDNA** application, Select Blank icon.
3. When the Blank is completed, select **Load Sample ID File** option
4. Select **Load** Default 96 well plate.txt and select **Continue**
5. Select **Measure** icon.
6. When the background measurement is completed, click  to advance to next channel, click **Measure** again
7. When the two measurements are complete, select **End experiment** icon.
8. End experiment dialog opens, and select **Save** so that the Digital Signature dialog opens, enter an **incorrect password**, select a reason and click **OK**.
9. After seeing the Authentication Failed message, enter the correct password, select a reason, and click **OK**.
10. Select **Continue** to dismiss successfully signed dialog and select **Exit** icon to close the End experiment successfully saved dialog and Select **Done**.
11. Select **History** (

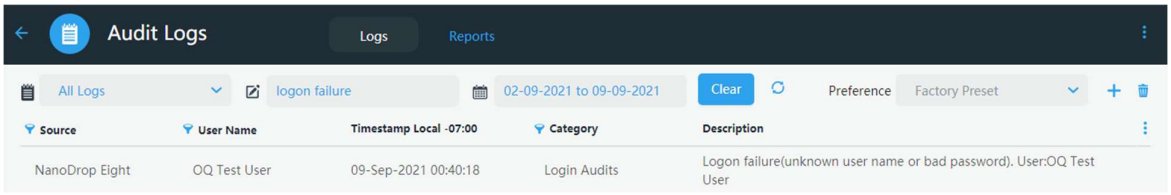
) from the toolbar on the dashboard.
12. Double click into the most recent Measurement page, select sample “1” measurement row.
13. Enter “**OQ**” for the new name and press **Enter** on keyboard to save changes.
14. Digital Signature dialog opens, enter a **correct password**, select a reason and click **OK**.
15. Select **Continue** and dismiss the successfully signed experiment message dialog.
16. Delete the sample “2” measurement by right clicking **Delete Selected Sample** option. Click **Delete** to confirm this action.
17. Digital Signature dialog opens, enter a **correct password**, select a reason and click **OK** to complete the digital signature.
18. Select **Continue** and dismiss the successfully signed experiment message dialog.
19. Return to the Home screen and select **Exit** to close NanoDrop Eight software
20. Sign out of the **OQ Test User** account.

Test

As the Administrator

1. Sign into Windows using the **Security Administrator** account.
2. As the Security Administrator, use the correct password to open **SciVault** software and click **Audit Logs** feature.
3. Click through the list to ensure that each of the following events are listed at least once:

   Use the Search By tools to find the specific events. Type the description below into the description field to limit the results to only those that have a matching description.



Source	Description
NanoDrop Eight	The user successfully exited or logged off the application
NanoDrop Eight	The record “dsDNA timestamp” was signed
NanoDrop Eight	The Experiment “dsDNA timestamp” was modified The data “2” were deleted
NanoDrop Eight	The record “dsDNA timestamp” was signed
NanoDrop Eight	The experiment “dsDNA timestamp” was modified The data “1” changed to “OQ”
NanoDrop Eight	The record “dsDNA timestamp” was signed
NanoDrop Eight	The experiment “dsDNA timestamp” was saved
NanoDrop Eight	Data collect completed Samples: “9”, “10”, “11”, “12”, “13”, “14”, “15”, “16”
NanoDrop Eight	Data collect started
NanoDrop Eight	Data collect completed Samples: “1”, “2”, “3”, “4”, “5”, “6”, “7”, “8”
NanoDrop Eight	Data collect started
NanoDrop Eight	Blank Data collect completed
NanoDrop Eight	Blank collect started
NanoDrop Eight	Successful logon
NanoDrop Eight	Logon failure (unknown user name or bad password)

Overall Result

Sign below to signify that all of the listed events were logged in Audit Logs feature:

☐ N/A

Comments:

Result: ☐ Pass ☐ Fail

Tested by: _____ Signature:_____ Date:_____

Approved by: _____ Signature: _____ Date: _____

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