LogiLAB SDMS Web Operational Qualification



	• 7.1.	4	
	▲ 7.2		
	• 7.2.	1	
	• 7.2.	2	
	• 7.2.	3	
	• 7.2.	4	
	• 7.2.	5	
	• 7.2.	5.1.	
	• 7.2.	5.2.	
	• 7.2.	5.3.	
	• 7.2.	6	
	4 7.3		
	• 7.3.	1	
	• 7.3.	1.1.	
	• 7.3.	1.2.	
	• 7.3.	1.3.	
	• 7.3.	1.4.	
	4 7.4		
	• 7.4.	1	
	• 7.4.	2	
	• 7.4.	3	
4			
	▲ 8.1 Rec	ord the environment, which this protocol is being executed on:	
4	9.0 Logs	ging into SDMS	
	4 9.1		
	• 9.1.	1	
	• 9.1.	2	
	• 9.1.	.3 Enter in your user name and password in the log in screen. Click the Login button.	

4 9.2
• 9.2.1
10.0 Security Validation – Login User
▲ 10.1 Actions:
• 10.1.1 Login using an invalid User ID and Password.
• 10.1.2
• 10.1.3
• 10.1.4
• 10.1.5
• 10.1.6
▲ 10.2 Expected Results:
• 10.2.1
• 10.2.2
• 10.2.3
• 10.2.4
• 10.2.5
• 10.2.6
4 11.1
• 11.1.1 Try Login using a Domain account with no access to the system.
11.1.2 Login to available Domain with a domain account which does have access to the system and review the available data.
4 11.2
• 11.2.1
• 11.2.2
12.0 Application Lock

▲ 12.1 Actions:

	• 12.1.1	Log into SDMS.			
	• 12.1.2	In the application, Click the "Application Lock" button in the top right corner of the application.			
	• 12.1.3	Log back into SDMS using the same account.			
4	12.2 Expected	Results:			
	• 12.2.1	(Action			
	• 12.2.2	(Action			
1 3	.0 Domain M	aster			
A	13.1				
	• 13.1.1				
	• 13.1.2				
	• 13.1.3	Click on the Submit button without entering any value.			
	• 13.1.4	Enter a invalid Domain Name and click Submit.			
	• 13.1.5	Enter valid information in all fields			
A	13.2				
	• 13.2.1				
	• 13.2.2				
	• 13.2.3				
A	13.3				
	• 13.3.1				
	• 13.3.2	Click on the Edit button to edit the record.			
	• 13.3.3				
A	13.4				
	• 13.4.1				
	• 13.4.2				
A					
4	14.1 Server Co	onfiguration			
	• 14.1.1				

• 14.1.	2
• 14.1.	3
• 14.1	.4 Click on Save button
14.2	
• 14.2.	1
▲ 14.3 Se	rver Drive Configuration
• 14.3.	1
• 14.3	.2 Select Server Name from the dropdown list and click S
• 14.3	.3 Copy and paste the Server Drive path and click Submit.
• 14.3	.4 Enter the appropriate port number and click Submit.
14.4	
• 14.4.	1
• 14.4.	2
▲ 14.5 FT	P Configuration
• 14.5.	1
• 14.5.	2
14.5 Subi	.3 Select the Server Drive path created during FTP site configuration and click the mit button.
14.5 Read	.4 Type in the FTP Alias Name, FTP Virtual Directory Name, and select checkboxes for d/Write/Active. Click S
14. 6	
• 14.6.	1
• 14.6.	2
15.1	
• 15.1.	1
• 15.1.	2
• 15.1	.3 Click on the submit button without entering any value.
• 15.1	.4 Close the error prompt, enter valid data and click the Submit button.

	4	15.2	
		• 15.2.1	
		1 5.2.2	
4			
	A	16.1	
		• 16.1.1	
		• 16.1.2	
		• 16.1.3	Click on the Submit button without entering any value.
		• 16.1.4	
		• 16.1.5	
		• 16.1.6	Select the instruments associated with this client and click Submit.
	A	16.2	
		• 16.2.1	
		• 16.2.2	
A			
	4	17.1	
		• 17.1.1	
		• 17.1.2	Click on New User Group.
		• 17.1.3	Type a group name in the User Group Name textbox and click on the Save button.
		• 17.1.4	Select the created group, edit the User Group Name and click on Save button.
		• 17.1.5	Select the edited User Group and click on Activate / Deactivate User Group.
		•	
	A	17.2	
		• 17.2.1	
		• 17.2.2	
		• 17.2.3	
		• 17.2.3	

4			
	4	18.1	
		• 18.1.1	Create an Administrator group with all rights, if one does not already exist.
		• 18.1.2	Create a user group with limited privileges, if one does not already exist.
		• 18.1.3	Log into SDMS as a user with limited privileges
		• 18.1.4	Click on an option with no access to the logged in user (e.g., Instrument configuration)
	A	18.2	
		• 18.2.1	
		• 18.2.2	
		• 18.2.3	
A			
	4	19.1	
		• 19.1.1	
		• 19.1.2	
		• 19.1.3	
	A	19.2	
		• 19.2.1	
		• 19.2.2	
	A	19.3	
		• 19.3.1	Log into SDMS as an administrator and select User Management
		• 19.3.2	
		• 19.3.3	Select a user and click on Edit User button.
		• 19.3.4	Select a user and click on Retire User button.
		• 19.3.5	Select a user and click on Reset Password button.
		• 19.3.6	Select a user whose state is locked and click on Unlock button.
		• 19.3.7	Select a user and click on the Activate / De-activate button.

• 19.3.8 Select a user whose state is Unapproved and click on the Approve User button. • 19.3.9 Click on Import from ADS and import a user, selecting the relevant group to add it to. • 19.3.10 Click on Export button. Click on Import button and import the file previously exported. • 19.3.11 19.4 • 19.4.1 • 19.4.2 • 19.4.3 • 19.4.4 • 19.4.5 • 19.4.6 • 19.4.7 • 19.4.8 • 19.4.9 • 19.4.10 19.5 Actions - User Id uniqueness validation and Access validation • 19.5.1 Login to SDMS as administrator; go to the user management screen. • 19.5.2 Try to create a user with the same ID as an existing user. Locate a user, which does not have access to user management or the ability to create a client 19.5.3 master. • 19.5.4 Login to SDMS with the user recorded in the previous step ▲ 19.6 Expected Results: • 19.6.1 (Action • 19.6.2 (Action • 19.6.3 (Action

▲ 20.0 Password Policy

	A	20.1	
		• 20.1.1	
		• 20.1.2	Click on DB Based Login.
		• 20.1.3	Click on Complex Password Policy.
	A	20.2	
		• 20.2.1	
		• 20.2.2	
4			
	4	21.1	
		• 21.1.1	
		• 21.1.2	Select an ftp row and click on the Mapping button.
		• 21.1.3	Deselect mapping for one of the users for the selected FTP Alias.
		• 21.1.4	
	4	21.2	
		• 21.2.1	
		• 21.2.2	
4			
	4	22.1 Actions:	
		22.1.1 and map a u	Log into SDMS as an administrator, navigate to the Workflow tab. Select a workflow setup name user group to the workflow.
		• 22.1.2	Log out of SDMS and log back in as a user belonging to the group.
		• 22.1.3	Right click on any file and select Work Complete.
		22.1.4 and a comm	Select the workflow mapped in the above step from the Decision dropdown, enter the user password nent, and then click OK.
	A	22.2 Expected	Results:
		• 22.2.1	(Action
		• 22.2.2	(Action
		• 22.2.3	(Action
4	23.	0 Help	

```
23.1
   • 23.1.1
                 Log into SDMS as any user and select Help
23.2
   • 23.2.1
4 24.1
   • 24.1.1
                 Log into SDMS as an administrator, navigate to Scheduler tab.
                 Click on Data Scheduler.
   • 24.1.2
   • 24.1.3
                 Check for Client Name.
   • 24.1.4
                 Check for Instrument Code.
                 Select Local Path.
   • 24.1.5
   • 24.1.6
                 Select UNC Path.
   • 24.1.7
                 Select Destination FTP.
                 Check – Apply delete policy for server files.
   • 24.1.9
   • 24.1.10
                 Fill in remaining credentials as required and submit by clicking on save button
4 24.2
   • 24.2.1
   • 24.2.2
   • 24.2.3
   • 24.2.4
   • 24.2.5
   • 24.2.6
   • 24.2.7
   • 24.2.8
   • 24.2.9
```

		• 25.1.1	
		• 25.1.2	Enter text into the Tag Name field and click Save.
	A	25.2	
		• 25.2.1	
1	26.	.0 Template S	Settings – Hierarchy Structure
	4	26.1	
		• 26.1.1	From Template Settings, navigate to the Hierarchy Structure tab.
		26.1.2 button to 6	Click the Mapped radio button to display mapped tags. Click on the Unmapped radio display unmapped tags.
		• 26.1.3	
	4	26.2	
		• 26.2.1	
		• 26.2.2	
		• 26.2.3	
		• 26.2.4	
1	27.	.0 Template M	Master
	A	27.1	
		• 27.1.1	Select any tag and add enter text into the Tag Value field in the Add Value pane.
	A	27.2	
		• 27.2.1	
í			
	A	28.1 Actions:	
		• 28.1.1	Log on to SDMS as administrator and click data explorer tab.
		• 28.1.2	Click the template view, which is in the data explorer screen next to the server data tab.
		• 28.1.3	Click the folder in the left tree view of the template view screen.
	4	28.2 16.2 Expe	ected Results:
		• 28.2.1	(Action
		• 28 2 2	(Action

Click on Deactivate hutton

• 32.1.3

▲ 36.1 Actions:

- 36.1.1 Log into SDMS and click the Search Server Data tab in the FTP Data view.
- 36.1.2 Select the option to search like by File and click the filter button.
- 36.1.3 Select the client used in section
- 36.1.4 Click on the Filter button, select the current date in the From and To fields, select File Modified On in the date category, and select the client from section
- 36.1.5 Filter the files by instrument name, client name, FTP Group Name.
- 36.1.6 Click on the Search server data tab to sort the files in the data explorer according to the File Name, then Size, and then Uploaded On.

▲ 36.2 Expected Results:

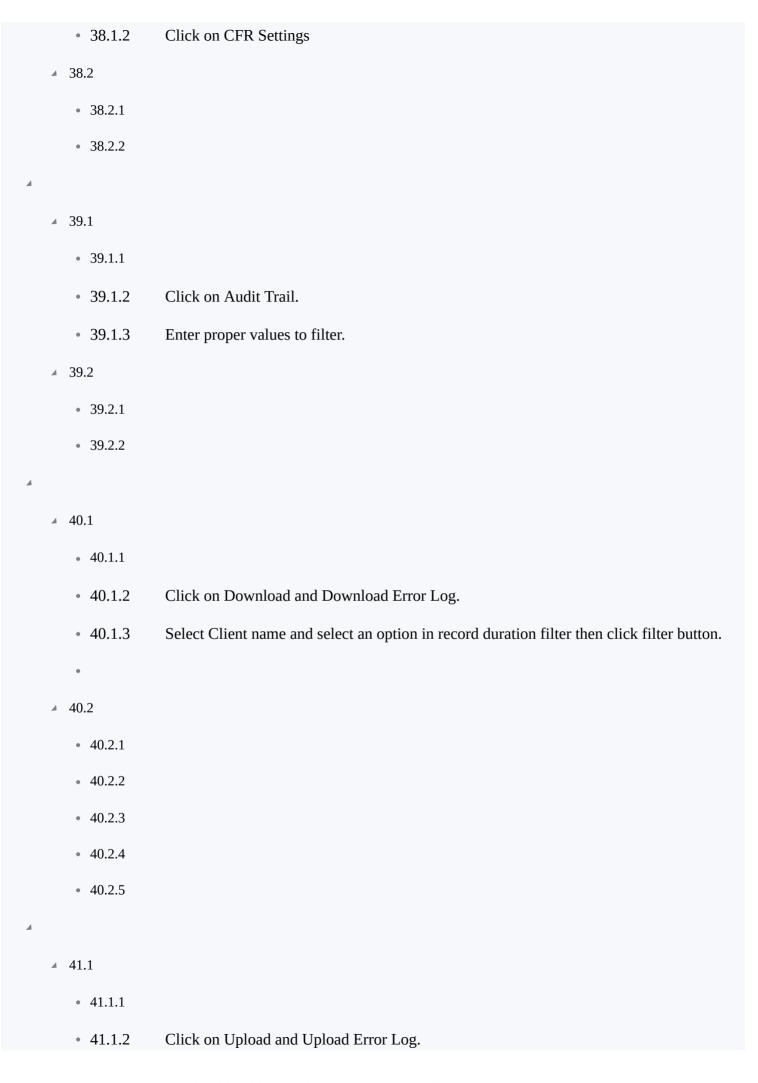
- 36.2.1 (Action
- 36.2.2 (Action
- 36.2.3 (Action
- 36.2.4 (Action
- 36.2.5 (Action
- 36.2.6 (Action

▲ 37.0 Local File Delete Scheduler

- **▲** 37.1
 - 37.1.1
 - 37.1.2 Click on Local File Delete Scheduler.
 - 37.1.3 Select a option in Records duration and click on the Filter button.
 - 37.1.4 Select the required files and click on Authorize button.
- **▲** 37.2
 - 37.2.1
 - 37.2.2
 - 37.2.3

▲ 38.1

• 38.1.1



	• 41.1.3	Select Client name and select a option in record duration filter then click filter button.
	• 41.1.4	Enter required filter values.
4	41.2	
	• 41.2.1	
	• 41.2.2	
	• 41.2.3	
	• 41.2.4	
	• 41.2.5	
A		
4	42.1	
	• 42.1.1	
	• 42.1.2	Click on FTP Server and Local File Deletion Log.
	• 42.1.3	Select Client name and select a option in record duration filter then click filter button.
	• 42.1.4	Enter required filter values.
4	42.2	
	• 42.2.1	
	• 42.2.2	
	• 42.2.3	
	• 42.2.4	
	• 42.2.5	
A		
A	43.1	
	• 43.1.1	
	• 43.1.2	Click on Scheduler Configuration Log.
	• 43.1.3	Select Client name and select a option in record duration filter then click filter button.
	• 43.1.4	Enter required filter values.
4	43.2	

```
• 43.2.1
        • 43.2.2
       • 43.2.3
    44.1
       • 44.1.1
       • 44.1.2
                     Click on Scheduler Configuration and SDMS Log.
                     Select Client name and select a option in record duration filter then click filter button.
       • 44.1.3
       • 44.1.4
                    Enter required filter values.
    44.2
       • 44.2.1
       • 44.2.2

<sup>▲</sup> 45.0 Client Service Monitor
    45.1
       • 45.1.1
                     Log into SDMS as an administrator, navigate to the
    45.2
       • 45.2.1
    46.1
    46.2
▲ 47.0 Attachments
```

1.0 Objective

The objective of this operational qualification protocol is to verify that the LogiLAB SDMS is fit for its intended use.

Each section provides a result area to document the outcome of the procedural elements.

Screenshots will be taken as evidence of all actual results, annotated appropriately, and attached to the executed protocol. The attachments will be referenced in each section.

The Discrepancy Log is to be completed for any discrepancies recorded in the outcome of the procedure execution.

The Attachment Log is to be completed to list any attachments/records used during the procedure execution or generated as protocol execution output.

2.0 Company Details

Company Name:	
Location:	
Department:	
Contact:	

3.0 Purpose

This procedure is intended to verify that the software is functional and fit for use.

4.0 Scope

Validation of the functionality of the LogiLAB SDMS modules for their intended use.

5.0 Acronyms

Acronym/Initials	Meaning
CFR	Code of Federal Regulations
FDA	Food & Drug Administration.
CGMP	Current Good Manufacturing Practice
HTML	Hypertext Markup Language
LAN	Local Area Network
IQ	Installation qualification
IIS	Internet Information Server
N/A	Not applicable
N/AV	Not available
N/S	Not specified
OQ	Operational qualification
PC	Personal Computer
PDF	Portable Data File
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
UPS	Uninterruptible Power Supply
LIMS	Laboratory Information Management System
BLOB	Binary Large Objects
DSN	Domain Source Name
TCP/IP	Transmission control Protocol / Internet Protocol
ASCII	American Standard Code for Information Interchange
SDMS	Scientific Data Management System
FTP	File Transfer Protocol
DB	Database

6.0 Responsibility

6.1 Agaram Technologies has the following responsibilities:

- 6.1.1 Execution of this qualification protocol unless execution is performed by the customer.
- 6.1.2 Collection of all test data.
- 6.1.3 Document all discrepancies, review with the customer project leaders and address as required.

6.2 The LogiLAB SDMS Customer has the following responsibilities:

- 6.2.1 Execution of the qualification protocol unless Agaram performs execution.
- 6.2.2 Overall supervision for execution of this qualification protocol.
- 6.2.3 All regulatory matters within its facilities.
- 6.2.4 Reviewing and approving all qualification documentation (protocol, executed protocol, and final report).
 - 6.2.5 Providing trained users, specialists, and technical support, as required for the preparation, review, and execution of this qualification protocol.
- 6.2.6 Review and sign-off of verification/test data sheets.
- 6.2.7 Preparing a final report that summarizes the protocol execution.

7.0 Test Methodology

7.1 Testing Instructions

- 7.1.1 For each test, perform the instructions indicated in the "Action(s)" section.
- 7.1.2 Execute each test step in sequential order, unless otherwise directed in the test.

- 7.1.3 Each test requires recording a "Pass" or "Fail" entry.
- 7.1.4 Take screen captures, which display the actual result of the action steps, for comparison to the expected result(s).

7.2 Recording Test Results

- 7.2.1 Record handwritten entries and test results using a ballpoint pen using Good Documentation Practices.
- 7.2.2 Initial and date all entries and test results.
- 7.2.3 Screen captures, printed documents, and reports that provide supporting evidence will be printed and attached to the test results.
- 7.2.4 The test compares the actual results to expected results. If the actual result matches the expected result, record a "Pass" result.
- 7.2.5 Discrepancies include the following scenarios:
- 7.2.5.1. Actual results for a test do not match expected results
- 7.2.5.2. A test was incorrectly executed
- 7.2.5.3. An observed test result was incorrectly recorded
- 7.2.6 If a discrepancy occurs after the tester completes the test, record a "Fail" result.

7.3 Reviewing Test Results

- 7.3.1 After the tester selects the test conclusion, a second person must review the protocol for the following:
- 7.3.1.1. A Pass / Fail result was recorded and any required attachment numbers were recorded for each step.

7.3.1.3. The tester initials and date have been recorded.							
7.3.1.4.	If the actual res	ult does not m	natch the expected result, a discrepancy has been initia	ted.			
7.4 A	7.4 Addressing Discrepancies						
7.4.1 results	Each discre	_	be recorded, investigated, and resolved before val page.	the test			
7.4.2 47.0	Record disc	crepancies in	n section 46.0 and document each discrepancy	per section			
7.4.3 end of t	Supporting this protocol.	evidence, if	necessary (e.g. rewritten test), must be attache	ed to the			
8.0	Environ	ment					
8.1 Re	ecord the en	vironmen	nt, which this protocol is being execu	ted on:			
0.11	cord the ch		it, which this protocor is being execu	teu on.			
				7			
			APPSVR				
L				_			
Date: 27-	07-2019	Reviewed By:	Vijay Dhamanaskar				
Pass o / I							
Comment	t: Pass						
Attachme	Attachment / Screenshot: Refer Annexure- B						
	_ •	•					

7.3.1.2. Any referenced attachments for the test are present.

9.0 Logging into SDMS

9.1 Actions:

- 9.1.1 To log into SDMS, Open the Chrome web browser and enter to open the SDMS web link (http://appsvr:8080/SDMS_Web/Login.html).
- 9.1.2 If the site details have not yet been entered, a Site Master Screen will be displayed. Enter the site details if prompted.
- 9.1.3 Enter in your user name and password in the log in screen. Click the Login button.

9.2 Expected Result:

9.2.1 (Action 9.1.3)Once you have successfully logged in, the SDMS home page will be displayed which consists of Navigation, Data Explorer and Search Data tabs.

Date:	Reviewed By:			
Pass o / Fail o				
Comment: Pass				
Attachment / Screenshot: Refer Annexure- B				

10.0 Security Validation – Login User

10.1 Actions:

10.1.1 Login using an invalid User ID and Password.

- **10.1.2** Log into SDMS as an administrator.
- 10.1.3 Open the password policy screen and set "Account Lock Policy" as 3.
- 10.1.4 Log out of SDMS and try to login (using any account other than the administrator account) with an incorrect password for 4 attempts.
- 10.1.5 Login as administrator and go to the preferences screen, set the "Idle Time Out" as 2 minutes. Allow the computer to remain idle for 2 minutes.
- 10.1.6 Login again after the idle lock time.

10.2 Expected Results:

- 10.2.1 (Action 10.1.1) Invalid User message is displayed when attempting to log in using invalid user information.
- 10.2.2 (Action 10.1.3) The account lock policy is set to 3 attempts.
- 10.2.3 (Action 10.1.4) On the fourth attempt a message indicating the account is locked will be displayed. The system audit trail shows the failed logon attempts.
- 10.2.4 (Action 10.1.5) The idle lock time is set to 2 minutes and after 2 minutes of the computer remaining idle, SDMS will lock and display the screen lock with "Session will expire in 180 second" and if not login before 180 second, session will expired.
- 10.2.5 (Action 10.1.5) System will allow login again with a valid username and password.
- 10.2.6 (Action 10.1.6) The idle lock time will be reset when the mouse or any keyboard actions are done in App.

	i			
Date:	Reviewed By:			
24101	rectience by:			
D / E-11 -				
Pass o / Fail o				
Comment: Pass				
Gorment Las				
Attachment / Screenshot: Refer Annexure- B				

11.0 Security Validation – Site Security

4	4	4	•	. •			
1	Ι.	1	А	cti	on	S	•

- 11.1.1 Try Login using a Domain account with no access to the system.
- 11.1.2 Login to available Domain with a domain account which does have access to the system and review the available data.

11.2 Expected Result:

- 11.2.1 (Action 11.1.1) The domain login with no access to the system resulted in the login being refused.
- 11.2.2 (Action 11.1.2) Data available after login to a selected domain is specific to that domain. No data from other domains is accessible.

Date:	Reviewed By:			
Pass o / Fail o				
	-			
Comment: Pass				
Attachment / Screenshot: Refer Annexure- B				

12.0 Application Lock

12.1 Actions:

12.1.1 Log into SDMS.

- 12.1.2 In the application, Click the "Application Lock" button in the top right corner of the application.
- 12.1.3 Log back into SDMS using the same account.

12.2 Expected Results:

- 12.2.1 (Action 12.1.2) The SDMS application will be locked and a login screen is displayed.
- 12.2.2 (Action 12.1.3) The Data explorer screen is displayed.

Date:	Reviewed By:	
Pass o / Fail o		
Comment: Pass		
Attachment / Screenshot: Refer Annexure- B		

13.0 Domain Master

13.1 Create Domain – Actions:

- 13.1.1 Log into SDMS as an administrator and Select Domain Master
- 13.1.2 Click on Add Domain button. The Domain Master Entry screen will be displayed.
- 13.1.3 Click on the Submit button without entering any value.
- 13.1.4 Enter a invalid Domain Name and click Submit.
- 13.1.5 Enter valid information in all fields and select active checkbox then click Submit .

13.2 Create Domain - Expected Result:

•	n 13.1.3) Upon submitting screen with no data, blank textbox displayed as and asking to enter Domain Name.
13.2.2 (Action password.	113.1.4) Upon submitting screen will alert as "invalid username and
•	13.1.5) Upon Submitting screen with valid information and completing een, a new record is displayed in grid rows.
Date:	Reviewed By:
Pass o / Fail o	
Comment: Pass	
Attachment / Screenshot	:: Refer Annexure- B
13.3 Edit Don	nain – Actions:
13.3.1 Select a	any existing domain from the grid rows.
13.3.2 Click o	n the Edit button to edit the record.
13.3.3 Unselec	ct the active checkbox and click submit .
13.4 Edit Don	nain - Expected Result:
•	13.3.2)The Domain Name will not be editable; Domain User Name and
	13.3.3) The Domain status will be change into Deactive and changes
Data	Reviewed By:
Date: Pass o / Fail o	Reviewed by.
Comment: Pass	
	DC A

14.0 FTP Configuration

14.1 Server Configuration – Actions:

NOTE: All the fields in this page are mandatory.

- 14.1.1 Select the Server Name from the available list
- **14.1.2** Select or type Server Type
- 14.1.3 Type in server username and password
- 14.1.4 Click on Save button

14.2 Server Configuration - Expected Result:

14.2.1 (Action 14.1.4) The grid will be populated with the details entered into the system.

Date:	Reviewed By:			
Pass o / Fail o				
Comment: Pass				
Attachment / Screenshot: Refer Annexure- B				

14.3 Server Drive Configuration – Actions

NOTE: Drive Path is created during FTP site configuration

14.3.1 Log into SDMS as an administrator and Select FTP Configuration; go to the Server Drive Configuration tab.

1422 Salast Sarvar Nama from the drander in list and click Submit

- 14.5.2 Select Server Ivalile Irolli tile uropuowii list anu chek Suoliit.
- 14.3.3 Copy and paste the Server Drive path and click Submit.
- 14.3.4 Enter the appropriate port number and click Submit.

14.4 Server Drive Configuration - Expected Result:

- 14.4.1 (Action 14.3.3)Upon submitting a screen with a server name and server drive path, an error is displayed.
- 14.4.2 (Action14.3.4) Upon submitting a screen with valid information, the entry screen is closed and the new record is displayed in grid rows.

Date:	Reviewed By:	
Pass o / Fail o		
	•	
Comment: Pass		
Attachment / Screenshot: Refe	er Annexure- B	

14.5 FTP Configuration – Actions

NOTE: Make sure the FTP Configuration Service is configured and running.

- 14.5.1 Log into SDMS as an administrator and Select FTP Configuration; go to the FTP Configuration tab.
- 14.5.2 Select Server from the dropdown list.
- 14.5.3 Select the Server Drive path created during FTP site configuration and click the Submit button.
- 14.5.4 Type in the FTP Alias Name, FTP Virtual Directory Name, and select checkboxes for Read/Write/Active. Click Submit.

14.6 FTP Configuration - Expected Result:

14.6.1 displayed	·	J pon subn	itting a screen with n	o data, an error scre	en is
14.6.2		-	tting a screen with va	lid information, the	entry screen
Date:	Review	ved By:			
Pass o / Fai	•				
Comment: I	Pass / Screenshot: Refer Annex	cure- B			
15.0	Instrument	t Conf	iguration		
15.1.1	Log into SDMS a	as an adm	nistrator, Click on Ba	se Master and Selec	t Instrument.
15.1.2	Click on the Add	l button. T	he Instrument Maste	r Entry screen will b	e displayed.
15.1.3	Click on the sub	mit buttoı	without entering any	value.	
15.1.4	Close the error p	orompt, er	ter valid data and clic	k the Submit button	l .
15.2 Ex	xpected Result	:			
15.2.1 displayed		J pon subn	itting a screen with n	o data, an error scre	en is
15.2.2	(Action 15.1.4) U	-	itting a screen with va	alid information, the	entry screen

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16.0 Client Configuration

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16.1 Action:

- 16.1.1 Log into SDMS as an administrator and Select Client Configuration.
- 16.1.2 Click on the Add button. The Client Master Entry screen will be displayed.
- 16.1.3 Click on the Submit button without entering any value.
- 16.1.4 Close the error prompt and enter Client Alias Name.
- **16.1.5** Select Client Type as Instrument Client.
- 16.1.6 Select the instruments associated with this client and click Submit.

16.2 Expected Result:

- 16.2.1 (Action 16.1.3) Upon submitting screen with no data, an error is displayed.
- 16.2.2 (Action 16.1.6) Upon submitting a screen with valid information, the entry screen is closed and a new record is displayed in grid rows.

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17.0 User Management

17.1 Action:

- 17.1.1 Log into SDMS as an administrator and select User Management
- 17.1.2 Click on New User Group.
- 17.1.3 Type a group name in the User Group Name textbox and click on the Save button.
- 17.1.4 Select the created group, edit the User Group Name and click on Save button.
- 17.1.5 Select the edited User Group and click on Activate / Deactivate User Group.

17.2 Expected Result:

- 17.2.1 (Action 17.1.2) Add new User Group popup will appear.
- 17.2.2 (Action 17.1.3) User Group Grid will be cleared with no rows and the new Record will be added
- 17.2.3 (Action 17.1.4) Group name will be edited and displayed in the grid.
 - 17.2.3 (Action 17.1.5) The Status Column in the grid says Active; it will change to

Deactive with red color.

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18.0 User Rights

NOTE: Create an Administrator group with all rights and other user groups with required privileges prior to executing the action steps.

18.1 Action:

- 18.1.1 Create an Administrator group with all rights, if one does not already exist.
- 18.1.2 Create a user group with limited privileges, if one does not already exist.
- 18.1.3 Log into SDMS as a user with limited privileges
- 18.1.4 Click on an option with no access to the logged in user (e.g., Instrument configuration)

18.2 Expected Result:

- 18.2.1 (Action 18.1.1) Administrator group with all rights exists.
- 18.2.2 (Action 18.1.2) A user group with limited privileges exists.
- 18.2.3 (Action18.1.3) The Insufficient Rights prompt is displayed.

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19.0 User Master

19.1 Action - Add User

- 19.1.1 Log into SDMS as an administrator and select User Management
- 19.1.2 Click on Add button to create new user.
- 19.1.3 Type in the Login ID and User name, select Group Name and Check the Check box for Approve.

19.2 Expected Result:

- 19.2.1 (Action 19.1.2) New user creation screen is opened.
- 19.2.2 (Action 19.1.3) New user is created and is available for respective User Group

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19.3 Action - Modify User:

- 19.3.1 Log into SDMS as an administrator and select User Management then navigate to the User Master tab.
- 19.3.2 Select the User Group from the User Group name dropdown.
- 19.3.3 Select a user and click on Edit User button.
- 19.3.4 Select a user and click on Retire User button.
- 19.3.5 Select a user and click on Reset Password button.
- 19.3.6 Select a user whose state is locked and click on Unlock button.

- 19.3.7 Select a user and click on the Activate / De-activate button.
- 19.3.8 Select a user whose state is Unapproved and click on the Approve User button.
- 19.3.9 Click on Import from ADS and import a user, selecting the relevant group to add it to.
- 19.3.10 Click on Export button. If any Password Expired On fields are empty, add a value which is in the future.
- 19.3.11 Click on Import button and import the file previously exported.

19.4 Expected Result:

- 19.4.1 (Action 19.3.1) User Master Tab will be open up with all active Users and the User Group Name dropdown.
- 19.4.2 (Action 19.3.3) Other than Login ID, other details will be editable.
- 19.4.3 (Action 19.3.4) The selected user status will change to Retired.
- 19.4.4 (Action 19.3.5) Reset Password will reset the user password. On login the user will be prompted to enter a new password.
- 19.4.5 (Action 19.3.6) The selected user, which is in the Locked status, will change to Active.
- 19.4.6 (Action 19.3.7) Change the status of the user based on the present status.
- 19.4.7 (Action 19.3.8) The user state will change to Active.
- 19.4.8 (Action 19.3.9) A domain user is imported and belongs to the relevant group.
- 19.4.9 (Action 19.3.10) Export will export the grid values to the local system in Excel format.
- 19.4.10 (Action 19.3.11) Import will allow importing the user information from the Excel file.

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19.5 Actions - User Id uniqueness validation and Access validation:

- 19.5.1 Login to SDMS as administrator; go to the user management screen.
- 19.5.2 Try to create a user with the same ID as an existing user.
- 19.5.3 Locate a user, which does not have access to user management or the ability to create a client master.
- 19.5.4 Login to SDMS with the user recorded in the previous step. Try to access/make a change in user management.

19.6 Expected Results:

- 19.6.1 (Action 19.5.2) The system will not allow an account to be created with the same ID as an existing account.
- 19.6.2 (Action 19.5.3) A user exists which does not have permissions to edit users or create clients within SDMS. (Note: evidence should display all permissions assigned/not assigned to this user.)
- 19.6.3 (Action 19.5.4) The system will not allow the user to access user management.

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20.0 Password Policy

20.1 Action:

- 20.1.1 Log into SDMS as an administrator and select Password Policy
- 20.1.2 Click on DB Based Login.
- 20.1.3 Click on Complex Password Policy.

20.2 Expected Result:

- 20.2.1 (Action 20.1.2) Basic credential validation details will be enabled; Saving will save the alterations.
- 20.2.2 (Action 20.1.3) Upon clicking Complex Password Policy, the corresponding credentials will be enabled to set a complex password.

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21.0 FTP Rights

- 21.1.1 Log into SDMS as an administrator and select FTP Rights.
- 21.1.2 Select an ftp row and click on the Mapping button.
- 21.1.3 Decelect manning for one of the users for the selected ETD Alias

41.1.0 Descreet mapping for one or the users for the selected P11 Amas.

21.1.4 Log into SDMS as the unmapped user.

21.2 Expected Result:

- 21.2.1 (Action 21.1.2) A new window with the list of available users will be shown.
- 21.2.2 (Action 21.1.3) FTP access will be missing for the unmapped user.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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22.0 Workflow Setup

22.1 Actions:

- 22.1.1 Log into SDMS as an administrator, navigate to the Workflow tab. Select a workflow setup name and map a user group to the workflow.
- 22.1.2 Log out of SDMS and log back in as a user belonging to the group.
- 22.1.3 Right click on any file and select Work Complete.
- 22.1.4 Select the workflow mapped in the above step from the Decision dropdown, enter the user password and a comment, and then click OK.

- 22.2.1 (Action 22.1.1) A workflow is mapped to a user group.
- 22.2.2 (Action 22.1.2) An electronic signature window is displayed.

22.2.3 (Action 22.1.3) The file has been e-signed.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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23.0 Help

23.1 Action:

23.1.1 Log into SDMS as any user and select Help

23.2 Expected Result:

23.2.1 (Action23.1.1) Help file will open.

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24.0 Data Scheduler

- 24.1.1 Log into SDMS as an administrator, navigate to Scheduler tab.
- 24.1.2 Click on Data Scheduler.
- 24.1.3 Check for Client Name.
- 24.1.4 Check for Instrument Code.
- 24.1.5 Select Local Path.
- 24.1.6 Select UNC Path.
- 24.1.7 Select Destination FTP.
- 24.1.8 Check Delete Local Copy Check box and select the files older than days or date radio button.
- 24.1.9 Check Apply delete policy for server files.
- 24.1.10 Fill in remaining credentials as required and submit by clicking on save button

- 24.2.1 (Action24.1.2) Data Scheduler tab will open
- 24.2.2 (Action24.1.3) Select the client name from dropdown list with the PC name.
- 24.2.3 (Action 24.1.4) The instruments connected to the selected client will be displayed in dropdown list.
- 24.2.4 (Action 24.1.5) The Local Path text box and check button will be enabled, The UNC Path text box, check button and UNC Credential area will be disabled.
- 24.2.5 (Action 24.1.6) The UNC Path text box, check button and UNC Credential area will be enabled. The Local Path text box and check button will be disabled.

- 24.2.6 (Action 24.1.7) The Destination dropdown will change based on action.
- 24.2.7 (Action 24.1.8) The files older than the mentioned days or date range will be appearing in the "Local File Delete Scheduler" screen.
- 24.2.8 (Action 24.1.9) The file delete policy is applied based on the number of version mentioned in the preferences screen. File versions older than the preference version will be appearing in the "Server File Delete Scheduler" screen.
- 24.2.9 (Action24.1.10) Schedule is saved.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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25.0 Template Settings - Tag

25.1 Action:

- 25.1.1 From Template Settings, navigate to the Tag Master tab.
- 25.1.2 Enter text into the Tag Name field and click Save.

25.2 Expected Result:

25.2.1 (Action 25.1.2) A tag is created with the text entered into the Tag Name field.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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26.0 Template Settings – Hierarchy Structure

26.1 Action:

- **26.1.1** From Template Settings, navigate to the Hierarchy Structure tab.
- 26.1.2 Click the Mapped radio button to display mapped tags. Click on the Unmapped radio button to display unmapped tags.
- 26.1.3 Try to create a mapped template without selecting any tag names.
 - 26.1.4 Select a tag in the Master Tag List and add it to the Tag hierarchy list.

- 26.2.1 (Action 26.1.1) Mapped tags are displayed in the hierarchy list.
- 26.2.2 (Action 26.1.2) Unmapped tags are displayed in the hierarchy list.
- 26.2.3 (Action 26.1.3) Error will be prompt to select any tag from Master tag list
- 26.2.4 (Action 26.1.4) The system will allow addition of tags to a template.

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27.0 Template Master

27.1 Action:

27.1.1 Select any tag and add enter text into the Tag Value field in the Add Value pane.

27.2 Expected Result:

27.2.1 (Action 27.1.1) A value is added to the selected tag.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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28.0 Template Data

28.1 Actions:

- 28.1.1 Log on to SDMS as administrator and click data explorer tab.
- 28.1.2 Click the template view, which is in the data explorer screen next to the server data tab.
- 28.1.3 Click the folder in the left tree view of the template view screen.

28.2 16.2 Expected Results:

28.2.1 (Action 28.	(Action 28.1.2) Template View screen appears with created template structure.			
28.2.2 (Action 28.1 structure is clicked.	.3) Files will be displayed in the right side when the specific tag			
Date: 28-07-2019	Reviewed By: Vijay Dhamanaskar			
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29.0 Lock Sec. 29.1 Action:	ettings			
29.1.1 On the Loc selected and click the	ck Settings screen, make sure the "Unlock after Capture" option is Lock button.			
29.2 Expected Re	esult:			
29.2.1 (Action 29.	1.1) The next set of data will be saved under the same tag.			
29.2.2 (Action 29.	1.1) The application will automatically Unlock the Tag after the			
process.				
Date: 28-07-2019	Reviewed By: Vijay Dhamanaskar			
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30.0 View / Edit Scheduler

30.1 Action:

- 30.1.1 Log into SDMS as an administrator, navigate to the Scheduler tab
- 30.1.2 Click on View / Edit Scheduler.

30.2 Expected Result:

30.2.1 (Action30.1.2) The View Scheduler window will open; it will have four tabs with individual grids in each tab.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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Attachment / Screenshot: Refer Annexure- B		

31.0 Activate Scheduler

31.1 Action:

- 31.1.1 Log into SDMS as an administrator, navigate to the Scheduler tab
- 31.1.2 Click on View / Edit Scheduler. Go to Deactivate tab.
- 31.1.3 Select a scheduler which is in Deactivate state
- 31.1.4 Click on the Activate button

31.2.1 (Action31.1.4) The scheduler status will change. The status change can be seen in the grid and the scheduler will move to the activate tab.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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32.0 De-Activate Scheduler

32.1 Action:

- 32.1.1 Log into SDMS as an administrator, navigate to the Scheduler tab
- 32.1.2 Click on View Scheduler, Go to Activate tab
- 32.1.3 Select a scheduler which is in Active state
- 32.1.4 Click on Deactivate button

32.2 Expected Result:

32.2.1 (Action 32.1.4) The scheduler status will change. The status change can be seen in the grid and the scheduler will move to deactivate tab.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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33.0 Retire Task

33.1 Action:

- 33.1.1 Log into SDMS as an administrator, navigate to the Scheduler tab
- 33.1.2 Click on View Scheduler. Go to Retired Task tab.
- 33.1.3 The retired schedulers will be listed in the grid.

33.2 Expected Result:

33.2.1 (Action 33.1.3) The retired schedulers can only viewed by the user.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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34.0 Edit Task

- 34.1.1 Log into SDMS as an administrator, navigate to the Scheduler tab
- 34.1.2 Click on View Scheduler. Go to the Edit Task tab.
- 34.1.3 Select a scheduler which is in the Deactivate state.
- 34.1.4 Click on the Edit button.

34.2 Expected Result:

34.2.1 (Action 34.1.4) Upon clicking the Edit button the scheduler details will open and the user will be able to edit

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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35.0 Monitor Schedule

35.1 Action:

- 35.1.1 Log into SDMS as an administrator, navigate to the Scheduler tab
- 35.1.2 Click on Monitor Scheduler.
- 35.1.3 Select a task which is not "Live" and click on "Update Schedule Mode"
- 35.1.4 Select the same tasks and click on "Update Schedule Mode" to restore the original status of the schedule.

35.2 Expected Result:

25.2.1 (Action 35.1.2) asignature window none unifor naceword and comments and the

schedule is change to "Live" schedule.

35.2.2 (Action 35.1.3) The schedule is reverted to not "Live".

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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36.0 Data Search

36.1 Actions:

- 36.1.1 Log into SDMS and click the Search Server Data tab in the FTP Data view.
- 36.1.2 Select the option to search like by File and click the filter button.
- 36.1.3 Select the client used in section 9.1, leaving all other fields as default, and click ok.
- 36.1.4 Click on the Filter button, select the current date in the From and To fields, select File Modified On in the date category, and select the client from section 9.1. Leave all other fields as default.
- 36.1.5 Filter the files by instrument name, client name, FTP Group Name.
- 36.1.6 Click on the Search server data tab to sort the files in the data explorer according to the File Name, then Size, and then Uploaded On.

36.2 Expected Results:

36.2.1 (Action 36.1.1) The search options By File, By Tag, and By Content will be

displayed.

- 36.2.2 (Action 36.1.2) The filter window is displayed.
- 36.2.3 (Action 36.1.3) The files from section 9.1 will be displayed.
- 36.2.4 (Action 36.1.4) The text file with a modified date of the current date will be displayed. The PDF/image file with modified date prior to the current date will not be displayed.
- 36.2.5 (Action 36.1.5) The files will be filtered by instrument name, client name, and FTP Group Name
- 36.2.6 (Action 36.1.6) Files will be sorted in the data explorer according to the File Name, Size, and Uploaded On date. (Note: evidence should show filtering for each column.)

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37.0 Local File Delete Scheduler

37.1 Action:

- 37.1.1 Log into SDMS as an administrator, navigate to the Scheduler tab
- 37.1.2 Click on Local File Delete Scheduler.
- 37.1.3 Select a option in Records duration and click on the Filter button.
- 37.1.4 Select the required files and click on Authorize button.

- 3/.2.1 (Action 3/.1.2) The Local File Delete Scheduler Window Will Open.
- 37.2.2 (Action 37.1.3) The grid will be populated with the list of files present on the local machine.
- 37.2.3 (Action 37.1.4) After stipulated time the files will be deleted and will no longer be on the list.

Date: 28-07-2019	Reviewed By:	Vijay Dhamanaskar
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38.0 CFR Settings

38.1 Action:

- 38.1.1 Log into SDMS as an administrator, navigate to the Audit Trail tab.
- 38.1.2 Click on CFR Settings tab and enter the Pre-Defined Reasons, click Add button.

- 38.2.1 (Action 38.1.2) The CFR Settings tab will open.
- 38.2.2 (Action 38.1.2) This screen will have the option to enable Audit Trail selected by default, and the option to enter and remove Pre-Defined Reasons.

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39.0 Audit Trail

39.1 Action:

- 39.1.1 Log into SDMS as an administrator, navigate to Audit Trail tab.
- 39.1.2 Click on Audit Trail.
- 39.1.3 Enter proper values to filter.

39.2 Expected Result:

- 39.2.1 (Action 39.1.2) The Audit Trail tab will open.
- 39.2.2 (Action 39.1.3) The grid will be populated with data based on the data filter.

Date: 30-07-2019	Reviewed By:	Vijay Dhamanaskar
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40.0 Download and Download Error Log

- 40.1.1 Log into SDMS as an administrator, navigate to Audit Trail tab
- 40.1.2 Click on Download and Download Error Log.
- 40.1.3 Select Client name and select an option in record duration filter then click filter button.

40.2 Expected Result:

- 40.2.1 (Action 40.1.2) The Download and Download Error Log window will open.
- 40.2.2 (Action 40.1.2) There will be two tabs: Download Log and Download Error Log,
- 40.2.3 (Action 40.1.3) Client Name will have the list of all connected clients.
- 40.2.4 (Action 40.1.3) All fields will be editable.
- 40.2.5 (Action 40.1.3) The grid rows will be populated based on filter values.

Date: 30-07-2019	Reviewed By:	Vijay Dhamanaskar
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41.0 Upload and Upload Error Log

41.1 Action:

- 41.1.1 Log into SDMS as an administrator, navigate to the Audit Trail tab.
- 41.1.2 Click on Upload and Upload Error Log.
- 41.1.3 Select Client name and select a option in record duration filter then click filter button.
- 41.1.4 Enter required filter values.

- 41.2.1 (Action 41.1.2) Upload and Upload Error Log tab will open.
- 41.2.2 (Action 41.1.2) There will be three tabs: Upload Log, Upload Error Log, and Manual Upload Log with individual grids.
- 41.2.3 (Action 41.1.3) Client Name will have the list of all connected clients.
- 41.2.4 (Action 41.1.3) All fields will be editable.
- 41.2.5 (Action 41.1.4) The grid rows will be populated based on filter values.

Date: 30-07-2019	Reviewed By:	Vijay Dhamanaskar	
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42.0 Server and Local File Deletion Log

42.1 Action:

- 42.1.1 Log into SDMS as an administrator, navigate to Audit Trail tab
- 42.1.2 Click on FTP Server and Local File Deletion Log.
- 42.1.3 Select Client name and select a option in record duration filter then click filter button.
- 42.1.4 Enter required filter values.

- 42.2.1 (Action 42.1.2) The FTP Server and Local File Deletion Log window will open.
- 42.2.2 (Action 42.1.2) There will be two tabs: FTP Server File Deletion and Local File Deletion with individual grids.
- 42.2.3 (Action 42.1.3) Client Name will have the list of all connected clients.

- 42.2.4 (Action 42.1.3) All fields will be editable.
- 42.2.5 (Action 42.1.4) The grid rows will be populated based on filter values.

Date: 30-07-2019	Reviewed By:	Vijay Dhamanaskar	
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43.0 Scheduler Configuration Log

43.1 Action:

- 43.1.1 Log into SDMS as an administrator, navigate to the Audit Trail tab
- 43.1.2 Click on Scheduler Configuration Log.
- 43.1.3 Select Client name and select a option in record duration filter then click filter button.
- 43.1.4 Enter required filter values.

- 43.2.1 (Action 43.1.2) The Scheduler Configuration Log tab will open.
- 43.2.2 (Action 43.1.3) Client Name will have the list of all connected clients. All fields will be editable except File Name.
- 43.2.3 (Action 43.1.4) The grid rows will be populated based on filter values.

Date: 30-07-2019	Reviewed By:	Vijay Dhamanaskar	
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44.0 SDMS Application Log

44.1 Action:

- 44.1.1 Log into SDMS as an administrator, navigate to the Audit Trail tab
- 44.1.2 Click on Scheduler Configuration and SDMS Log.
- 44.1.3 Select Client name and select a option in record duration filter then click filter button.
- 44.1.4 Enter required filter values.

44.2 Expected Result:

- 44.2.1 (Action 44.1.2) Client Name will have the list of all connected clients. All fields will be editable except File Name.
- 44.2.2 (Action 44.1.3) The grid rows will be populated based on filter values.

Date: 30-07-2019	Reviewed By:	Vijay Dhamanaskar			
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45.0 Client Service Monitor

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45.1.1 Log into SDMS as an administrator, navigate to the Client Service monitor 45.2 Expected Result:							
45.2.1 (Action 45.1.1) The list of services will be seen in the Service drop down list.							
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Pass o / Fail o							
Comment: Pass							
Attachment / Screenshot: Ref	er Annexure- B						
46.0 Summary of Test Results							
46.1 Have all tests been successfully executed and do actual results match expected results for all tests? Yes □ No□							
46.2 If no, record each discrepancy in the table below and attach the							
completed discrepancy form. (Note: Mark a line through any remaining							
blank lines in the table, initial and date.)							
Discrepancy No.	Test ID		Discrepancy Tile				
Discrepancy 110.	Test ID		Discrepancy The	1			
				7			
				1			

ī.	

47.0 Attachments

Att. No.	Description	No. Of Pages	Document
1	LogiLAB SDMS Operational Qualification Supporting Document.	74	Annexure-B