

	Standard Operating Procedure		SOP Number D-815	Revision 5
	QC Laboratory Computer System Access and Backup		Effective Date 05/09/23	Page Page 1 of 3
Written by/ Date H. Bunn 04/15/23		Reviewed by/ Date SAS 04/17/23	Approved by/ Date SS 04/20/23	
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1.0 Purpose

This procedure explains the access and backup of the computers located in the QC laboratory.

2.0 Scope

This procedure is applicable to access and backup of the computers located in the QC laboratory that are designated for cGMP applications.

3.0 Responsibility

- 3.1 It is the responsibility of all personnel to access only the systems they are authorized to access and are currently qualified to operate (except for training purposes).
- 3.2 Users are responsible for performing all duties under their own unique login and password.
- 3.3 It is the responsibility of QC Laboratory Management to implement this procedure and to ensure that the procedure is being followed.
- 3.4 It is the responsibility of QC Laboratory Management to keep this procedure aligned with current practices.

4.0 Definitions

- 4.1 QC – Quality Control
- 4.2 IT – Information Technology

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5.0 References

- 5.1 21CFR Part 11, FDA Regulations on Electronic Records and Electronic Signatures

6.0 Procedure

6.1 QC Laboratory Computer and Software Access

6.1.1 QC Laboratory computers and software accesses are restricted with the use of a unique username and password.

6.1.2 Only QC Laboratory Personnel, IT, and Quality Management are permitted to have accounts or log into QC Laboratory computers and instrument software.

6.1.2.1 Access to all software and laboratory computers must be made through Quality Management and/or IT.

6.1.3 Only IT and QC Management have full access to computer software functions.

6.1.3.1 General users will have limited functional access to equipment software.

6.1.4 Users are responsible for logging into the computer and/or software using their own unique username and password.

6.1.4.1 If two users are required to operate the same computer the second user can use the <switch user> function in the Windows menu to open a separate desktop.

6.1.4.2 Usernames and passwords are not to be shared.

6.2 Backup

6.2.1 The laboratory computers are configured by IT to backup any and all raw data created by the instrument or instrument software onto the company network server in timely intervals.

6.2.2 IT will maintain all backups on the company network server.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/06/10	New	-	-
1	01/24/12	Updated SOP	-	-
2	03/07/13	Updated SOP format, defined responsibilities	13-126	B. Johns
3	02/19/15	Biennial review. Updated SOP format. Changed Title. Updated software lists. Expanded responsibilities.	15-0178	B. Johns
4	09/03/19	Scheduled review: Updated SOP to match current practices and procedures.	19-0618	I. Garrett
5	04/04/23	Scheduled review: updated format, logo, and responsibilities.	CC-23-0188	K. Burris