

	Standard Operating Procedure	SOP Number G-102	Revision 4
	Equipment Profiles	Effective Date 07/26/22	Page Page 1 of 5
Written by/ Date K. Bunnings 04/06/22	Reviewed by/ Date Maurice M. ... 04/06/22	Approved by/ Date [Signature] 06-24-22	
Title: Quality Systems Manager	Title: Maintenance Manager	Title: QA Manager VP Quality [Signature] 06-24-22	

1.0 Purpose

This procedure defines the process of creating and maintaining records on each piece of process equipment or testing equipment used at Ion Labs, Inc.

2.0 Scope

This procedure applies to all process equipment and testing equipment in use at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of Maintenance and/or Engineering Management or designee to complete equipment profiles for equipment within their department and to submit it to DC.
- 3.2 It is the responsibility of DC to assign asset numbers and to maintain the current master equipment list and all equipment profiles.
- 3.3 It is the responsibility of Maintenance and/or R&D to initiate form G-103-F1 Installation and Operational Qualification (IOQ) Checklist (if applicable) after the equipment profile has been approved.

4.0 Definitions

- 4.1 **PM** – Preventative Maintenance
- 4.2 **DC** – Document Control
- 4.3 **QC** – Quality Control

5.0 References

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- 5.1 G-103, SOP, Qualification of Equipment
- 5.2 G-201, SOP, Calibration Program
- 5.3 G-102-F1, Form, Equipment Profile
- 5.4 G-103-F1, Form, Installation and Operational Qualification (IOQ) Checklist
- 5.5 C-502, SOP, Document Storage, Retention, and Destruction

6.0 Procedure

- 6.1 Equipment profiles will be completed for each piece of equipment on the master equipment list.
 - 6.1.1 Form G-102-F1 Equipment Profile lists the primary identifying information about the equipment:
 - 6.1.1.1 Ion Asset Number – each piece of equipment will be assigned a unique sequential asset number consisting of the letters ION, followed by a four digit sequential number (e.g. ION-0001)
 - 6.1.1.2 Equipment Description
 - 6.1.1.3 Manufacturer
 - 6.1.1.4 Model Number (if available)
 - 6.1.1.5 Serial Number (if available)
 - 6.1.1.6 Purchase Order Number
 - 6.1.1.7 Date of Receipt of Equipment
 - 6.1.1.8 Equipment Location

Note: Legacy equipment may not have all of the purchasing information. Document “Legacy Equipment” if not available.

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- 6.1.1.9 Calibration Requirements and Recommended Frequency
- 6.1.1.10 Maintenance Requirements and Recommended Frequency
- 6.1.1.11 Name and Date of Employee Completing the Profile
- 6.1.2 Quality will review for completion and approve the completed profile.
- 6.1.3 A copy of any literature or software, including manuals or bulletins that accompany the equipment, will be filed with the equipment profile if possible.
- 6.1.4 Original machine manuals will be filed in maintenance for ease of use.
- 6.1.5 Once approved, all information will be entered by DC into the Master Equipment List.
- 6.2 Upon approval of the equipment profile:
 - 6.2.1 DC will submit a copy of the profile to QC Laboratory/Analytical Development Management for inclusion in the Calibration Program (refer to SOP G-201 Calibration Program).
 - 6.2.2 SD will submit a copy of the profile to the initiator to that Form G-103-F1 Installation and Operational Qualification (IOQ) Checklist can be completed. (refer to SOP G-103 Qualification of Equipment.
 - 6.2.3 Once G-103-F1 Installation and Operational Qualification (IOQ) Checklist has been finalized, it will be scanned and filed with the associated equipment profile.
- 6.3 When a piece of equipment that has an asset number assigned to it is removed from service, DC must be alerted so that the item may be marked as “Out of Service” on the master equipment list.

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6.4 Equipment Types that require an Asset Number

6.4.1 The following types of equipment require an asset number before they can be used. There may be other equipment types not listed below that must also comply with this procedure.

6.4.1.1 Manufacturing Equipment

6.4.1.2 Packaging Equipment

6.4.1.3 Mobile Fans

6.4.1.4 Hygrometers and Thermometers

6.4.1.5 Scales

6.4.1.6 Test and Calibration Pieces

6.4.1.7 Blender Magnets

6.4.1.8 QC Laboratory Equipment

6.4.1.9 Shop Vacuums

6.4.1.10 Dehumidifiers

6.4.1.11 Humidifiers

6.4.1.12 Sensors

6.5 Documentation Requirements

6.5.1 Documents will be maintained following SOP C-502 Document Storage, Retention, and Destruction.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	04/27/10	New	-	-
1	03/25/13	Changed SOP format and number. Updated SOP.	13-197	I. Ilchev
2	09/15/14	Obsoleted G-102-F2, C-102-F3. Included G-101 in G-102. Clarified SOP to accurately reflect the current process.	14-0740	D. Popp
3	02/05/19	Scheduled review: updated calibration program responsibility. Added additional reference.	19-0124	K. Burris
4	04/06/22	Scheduled review: Updated responsibilities. Changed logo. Added list of equipment that requires asset numbers.	CC-22-0161	K. Burris



Equipment Profile

Form: G-102-F1

CCR No. CC-22-0161

Revision: 4

Ion Number	
Equipment Description	
Manufacturer	
Model Number	
Serial Number	
Location Installed	
Purchase Order Number	Date Received

Calibration Requirements	Frequency
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Maintenance Requirements	Frequency
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IOQ Checklist required	<input type="checkbox"/> Yes / <input type="checkbox"/> No
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Calibration Log Required	<input type="checkbox"/> Yes / <input type="checkbox"/> No
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Cleaning Log Required	<input type="checkbox"/> Yes / <input type="checkbox"/> No
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Comments:

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Completed By: _____ Date: _____

Approved By (Quality): _____ Date: _____