

	Standard Operating Procedure	SOP Number G-103	Revision 3
	Qualification of Equipment	Effective Date <i>11/03/22</i>	Page Page 1 of 5
Written by/ Date <i>H. Bunn 08/25/22</i>	Reviewed by/ Date <i>Ami Mueller 08/25/22</i>	Approved by/ Date <i>S.A. Pike 08-25-22</i>	
Title: Quality Systems Manager	Title: Maintenance Manager	Title: QA Manager	

1.0 Purpose

The purpose of this procedure is to describe the process for qualifying equipment for use in manufacturing of dietary supplements and pet products to ensure that the equipment functions properly, in accordance with its intended use, and will consistently provide expected results per 21 CFR Part 111.

2.0 Scope

This procedure applies to all equipment used in the manufacturing of dietary supplements and pet products at Ion Labs. This does not apply to the qualification of QC laboratory analytical equipment.

3.0 Responsibility

- 3.1 Operations, Maintenance, Quality, R&D, Safety, and AD personnel are responsible for following this procedure, executing qualification checklists, and for assessing any changes to qualified equipment for requalification.
- 3.2 Quality Management is responsible for maintaining this procedure and reviewing and approving qualification checklists.

4.0 Definitions

- 4.1 **IQ** – Installation Qualification; the process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.
- 4.2 **OQ** – Operational Qualification; the process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

- 4.3 **PQ** – Performance Qualification; the process of establishing by objective evidence that the equipment consistently produces a product which meets all predetermined requirements.
- 4.4 **PPE** – Personal Protective Equipment
- 4.5 **QC** – Quality Control
- 4.6 **R&D** – Research and Development
- 4.7 **DC** – Document Control
- 4.8 **AD** – Analytical Development
- 4.9 **PM** – Preventative Maintenance

5.0 References

- 5.1 C-502, SOP, Record Storage, Retention, and Destruction
- 5.2 G-102, SOP, Equipment Profiles
- 5.3 G-201, SOP, Calibration Program
- 5.4 G-103-F1, Form, Installation and Operation Qualification Checklist

6.0 Rationale

- 6.1 The overall goal of qualification is to ensure all items used in the production and analysis of product is appropriate for its designated use, is in satisfactory working condition and will perform as specified.

7.0 Procedure for New Equipment

Note: IQOQ checklists are not required for all pieces of equipment. They are intended for large pieces of manufacturing equipment, such as tablet presses, blenders, etc.

7.1 DC will assign an equipment number per SOP G-102 Equipment Profiles. Maintenance or Production personnel will complete Form G-102-F1 Equipment Profile. QC Laboratory personnel will enter the equipment into the calibration program per SOP G-201 Calibration Program.

7.2 For new equipment that requires IQOQ to be performed, the following minimum requirements must be assessed:

7.2.1 Operational Requirements

7.2.1.1 Are copies of the manufacturer's operating and maintenance instructions available?

7.2.1.2 Are all operating controls properly labeled?

7.2.1.3 Is a procedure required for use? If so, is one available and current?

7.2.1.4 How often does a PM need to be performed on this item? What does the PM consist of?

7.2.1.5 Are there temperature or humidity requirements for the installation location?

7.2.1.6 Is a sink/water required in the vicinity of use?

7.2.2 Electrical Requirements

7.2.2.1 What are the electrical requirements of this item?

7.2.2.2 Is the requirement met with current capacity?

7.2.2.3 Are all wiring rated for power draw?

7.2.2.4 Is item properly grounded?

7.2.3 Safety

7.2.3.1 Is the item properly installed per manufacturer recommendations?

7.2.3.2 Are employees protected from any exposure to moving parts?

7.2.3.3 Are there any necessary warnings required? If so, are they in conspicuous locations and clearly marked

7.2.3.4 Does the operation, maintenance, or cleaning of the item require hazardous chemicals?

7.2.3.5 Does the operation, maintenance, or cleaning of the item require PPE? If so, what is the PPE needed?

7.2.4 Access

7.2.4.1 Does layout prevent workers from awkward positions during operation?

7.2.4.2 Does layout prevent workers from applying appropriate force during adjustments, changeovers, etc.?

7.2.4.3 Does layout provide a safe operational zone for all operation and maintenance personnel?

7.2.5 Control

7.2.5.1 Can all disconnects and power controls be locked out?

7.2.5.2 Are these controls/ emergency stops/ cords/ cables in easily accessible locations?

7.2.5.3 Have all energy control devices, switches, interlocks, sensors, e-stops, been tested while machine is in operations?

7.2.5.4 Do these items perform their intended function?

7.2.6 Others

7.2.6.1 If other requirements are necessary, they should be listed on the form as well.

7.3 If new equipment or initial qualification, the responsible group, with assistance from R&D or AD groups and Safety, will complete Form G-103-F1 Installation and Operational Qualification (IOQ) Checklist for the equipment and forward to appropriate Operations or R&D/AD personnel.

7.3.1 Operations or Maintenance personnel will refer to the manufacturer's recommendations (e.g. temperature and humidity, utilities, etc.), any equipment literature available (i.e. User manual, product bulletin, manufacturer photos, etc.) and view actual equipment to populate Sections I and II. Ensure items listed are adequate to verify that the equipment functions properly, and in accordance with its intended use, per 21 CFR Part 111. Forward to Quality once complete.

8.0 Documentation Maintenance

8.1 Installation and Operational Qualification checklists will be filed and maintained with the Equipment Profile associated with its piece of equipment.

8.2 Documentation will be maintained per SOP C-502 Record Storage, Retention, and Destruction.

9.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/22/14	New	14-0442	D. Popp
1	03/24/15	Revise for clarification	15-0056	D. Popp
2	12/23/19	Scheduled review: revised for completeness.	19-0967	J. Maignan
3	08/08/22	Scheduled review: updated logo and formatting. Added documentation maintenance requirements. Added definitions.	CC-22-0346	K. Burris



Installation and Operational Qualification (IOQ) Checklist

Form: G-103-F1

CCR No. CC-22-0346

Revision: 4

Confirmation of Equipment Received as Purchased

Ion PO number:	Order date:
Vendor order number:	Shipping date:

Equipment order and shipping paperwork match: Verified No Match

Physical receipt confirmation

Equipment received is as ordered: Verified No Match

Comments:

Performed by: _____

Date: _____

Confirmation of receipt of packing list items

Confirm receipt of all items listed on the packing slip.

All items are received: Yes No

Confirmed packing slip is attached: Yes No

Comments:

Performed by: _____

Date: _____



Installation and Operational Qualification (IOQ) Checklist

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CCR No. CC-22-0346

Revision: 4

Equipment Identification

Equipment Name:	
Model:	Serial number:
Ion #:	Firmware revision:

Component Identification			
Component Name	Model #	Serial #	Ion #
Component Identification			
Component Name	Model #	Serial #	Ion #
Component Identification			
Component Name	Model #	Serial #	Ion #
Component Identification			
Component Name	Model #	Serial #	Ion #

Comments:

Performed by: _____

Date: _____



Installation and Operational Qualification (IOQ) Checklist

Form: G-103-F1

CCR No. CC-22-0346

Revision: 4

Installation Requirements Verification

Equipment Location

Building:

Room:

Comments:

Performed by: _____

Date: _____

Installation location conditions

Is a copy of the manufacturer's operating manual available?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Room temperature and humidity meet specifications in operating manual?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is water source needed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
If so, is it available?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Area free of potential vibration problems	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is area properly ventilated?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
What are the electrical requirements of this item?			
Is the requirement from above met?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is item properly grounded or double insulated per NEC?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is there an SOP required for use?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is the SOP available?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is the SOP current?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is wiring rated for power draw?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Does the operation, maintenance and cleaning require PPE?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
If so, what is the PPE needed?			

Comments:

Performed by: _____

Date: _____



Installation and Operational Qualification (IOQ) Checklist

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Other Considerations

If other considerations are required, please notate them on this page.

Empty box for other considerations.



Installation and Operational Qualification (IOQ) Checklist

Form: G-103-F1

CCR No. CC-22-0346

Revision: 4

Installation Qualification Certification

Installation of this item (Ion #: _____) has been performed according to the guidelines established by the manufacturer and set down in this section describing instrument installation.

Comments:

Performed by: _____

Date: _____

Installation Qualification has been performed, reviewed, and approved according to the guidelines established by the manufacturer and set down in this section describing instrument installation. All results, having met the specified parameters, hereby certify the above item as having been properly installed.

Comments:

Approved by: _____

Date: _____



Installation and Operational Qualification (IOQ) Checklist

Form: G-103-F1

CCR No. CC-22-0346

Revision: 4

OQ Defined

Operation qualification (OQ) is defined as documented verification that all key aspects of equipment operation meet the manufacturer’s established specifications throughout a representative or anticipated operating range.

Equipment, Component, and Location Identification

Equipment Identification	
Model:	Serial Number:
Ion #	Number of Components.:

Component Identification			
Component Name	Model #	Serial #	Ion #
Component Identification			
Component Name	Model #	Serial #	Ion #
Component Identification			
Component Name	Model #	Serial #	Ion #
Component Identification			
Component Name	Model #	Serial #	Ion #

Comments:

Performed by: _____

Date: _____



Installation and Operational Qualification (IOQ) Checklist

Form: G-103-F1

CCR No. CC-22-0346

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Certificates

In the table below, list all certificates/manuals/paperwork associated with this item.

Certificate Name/Description	Certificate Attached

Comments:

Performed by: _____

Date: _____

**Installation and Operational Qualification (IOQ) Checklist**

Form: G-103-F1

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Operational Qualification

Are all operating controls properly labeled?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
How often does PM need to be performed on this item?			
What are the requirements of the PM			
Is item installed per manufacturer recommendations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Are employees protected from exposure to moving parts?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Are there any necessary warnings required?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Are they posted in conspicuous locations and clearly marked?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Does the operation, maintenance or cleaning of the item require hazardous chemicals	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is the electrical draw while being used under normal conditions sufficient?			
If item is product contact, are all components that could contact product stainless steel or food grade materials?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is the item as installed, provide conditions for safe use, cleaning and maintenance?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is operating, cleaning or maintenance going to require or produce hazardous waste or hazardous environmental conditions? :	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Can all disconnects and power controls be locked out? :	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
What are the emergency control items?			
Are all control/emergency stops/ cords/ cables easily accessible? :	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Do each of the items listed above perform their intended function (if possible check each while in operation)? :	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
What is the purpose of this item?			
Does the item after installation perform the function listed above? :	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
Is training required for this item?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Performed by: _____

Date: _____