

	Standard Operating Procedure		SOP Number G-201	Revision 6
	Calibration Program		Effective Date 05/09/23	Page Page 1 of 11
Written by/ Date SS 01/09/23		Reviewed by/ Date BE 01/09/23		Approved by/ Date KB 01/10/23
Title: Quality Control Director		Title: Metrologist		Title: Quality Assurance Director

1.0 Purpose

The purpose of this procedure is to describe the process for the identification, scheduling, and logging of equipment to be calibrated.

2.0 Scope

This procedure applies to all equipment maintained by Ion Labs, Inc. requiring calibration. This procedure describes general calibration requirements and is superseded by instrument/machine calibration requirements described in its specific procedure. Furthermore, analytical instrument calibrations are governed by SOP G-208 Analytical Calibration and Equipment Control and any calibration requirements described in that procedure supersede these instructions.

3.0 Responsibility

- 3.1 It is the responsibility of Analytical Development Management to align this procedure with current practices and to delegate and oversee management of the program.
- 3.2 It is the responsibility of Maintenance to submit operational equipment profiles to document control, and the Metrologist, or designee, for new analytical equipment as outlined in SOP G-208, Analytical Calibration and Equipment Control.
- 3.3 It is the responsibility of Quality to oversee and ensure compliance to this procedure for all Quality Personnel.
- 3.4 It is the responsibility of Production to oversee and ensure compliance to this procedure for all Production Personnel.
- 3.5 It is the responsibility of the QC Laboratory and Metrologist to oversee and ensure compliance to this procedure for all QC Laboratory Personnel.

- 3.6 Any qualified individual may arrange or execute calibrations, place calibration stickers on equipment, however, logging and maintaining equipment calibration schedules is performed by the Metrologist or designee.

4.0 Definitions

- 4.1 **Calibration** – Comparison of equipment performance against a traceable standard or certified instrument to detect, correlate, report or eliminate by adjustment, any variation in the accuracy of the item being compared
- 4.2 **Certification** – Written verification that the device operates within applicable specifications
- 4.3 **Verification** – An equipment check against a standard to confirm that the equipment is in a state of calibration (or operating as designed where applicable). The equipment can remain in operation if the calibration is verified as within specification for a period not to exceed the recommended verification interval.
- 4.4 **Due Date** – The month the piece of equipment needs to be calibrated or verified. Equipment due in a specific month needs to be calibrated or verified by the last day of the month of the next calibration due date. The instrument may be used within that month. The equipment is not to be used on or after the first day of the next month without a certificate of calibration in effect. In extreme circumstances, an item is used outside its calibration date. In that case, the results gained from the equipment may be deemed valid if the item upon next calibration has its “as found” results within specifications.
- 4.5 **QC** – Quality Control
- 4.6 **QA** – Quality Assurance
- 4.7 **AD** – Analytical Development
- 4.8 **PM** – Preventative Maintenance

4.9 **OQ** – Operational Qualification

4.10 **PQ** – Performance Qualification

4.11 **Asset Essentials** – a cloud-based software that enables you to assign and track the progress of all maintenance activities, manage equipment uptime and reliability. For calibration purposes, Asset Essentials is utilized for scheduling only.

5.0 References

5.1 G-102-F1, Form, Equipment Profile

5.2 G-201-F1, Form, Calibration Certificate

5.3 G-201-F2, Form, Completed Calibration Log

5.4 QS-114, SOP, Risk Management and Risk Analysis

5.5 G-208, SOP, Analytical Calibration and Equipment Control

5.6 C-502, SOP, Record Storage, Retention, and Destruction

5.7 ANSI/NCSL Z540.3-2006; ISO 10012-1, ISO/IEC Guide 25

6.0 Procedure

6.1 Asset Essentials:

6.1.1 New assets that require calibration are logged into Asset Essentials, typically initiated by form G-102-F1 Equipment Profile.

6.1.2 Information entered into Asset Essentials:

6.1.2.1 Description of Equipment

6.1.2.2 Ion Asset Number

- 6.1.2.3 Location of equipment (if needed)
- 6.1.2.4 Calibration Due Date
- 6.1.3 Current Assets already cataloged in Asset Essentials are amended as calibrations are completed and new calibration due dates are assigned.
- 6.1.4 Assets are typically cataloged/ grouped by calibration due date month in Asset Essentials.
- 6.1.5 Monthly, Asset Essentials will generate a work order for all required calibrations due in that month. This work order is emailed to the metrologist or designee for completion.
- 6.1.6 Upon successful completion of calibrations, the work order can either be closed or amended with a new due date in Asset Essentials.
- 6.1.7 Form G-201-F2 Equipment Calibration Log will be completed as needed to log calibration information for equipment. This form will be cataloged by month/year and maintained in a binder or equivalent storage format. The form will include the following information:
 - 6.1.7.1 Month
 - 6.1.7.2 Year
 - 6.1.7.3 Ion Asset #
 - 6.1.7.4 Description
 - 6.1.7.5 Calibration type - Temperature, Humidity, Weight, RPM, etc.
 - 6.1.7.6 Frequency - Weekly, Monthly, Biannual, Annual, etc.
 - 6.1.7.7 Internal or External calibration

6.1.7.8 Date of calibration

6.1.7.9 Logged by/Date

6.1.7.10 Page

6.1.8 Each sheet of form G-201-F2 Equipment Calibration Log can correspond only to one month and one year. At the end of each month, the unused part of the form will be lined out, initialed and dated.

6.1.9 Stored within each monthly section is a calibration certificate for every piece of equipment tested during that specific month.

6.1.9.1 External calibration certificates will be labeled with the Ion# and/ or equipment serial number at the top of each page for tracking purposes, if not already present on certificate.

6.1.9.2 The calibration due date on the external calibration certificate should reflect at least the minimum frequency specified by the Ion Labs calibration/verification program otherwise the Ion Labs frequency supersedes the vendor frequency. Any changes made to the calibration due date on the certificate must be signed or initialed.

6.1.10 Equipment that either does not pass or has an expired calibration can either be removed from service and obsoleted or sent for repair. If repaired, a new calibration must be completed prior to placing back into service.

6.1.11 For new equipment accompanied by a calibration certificate and calibrated by the manufacturer, the manufacturer due date will supersede Ion Labs Frequency specifications. For subsequent calibration verifications, the Ion Labs frequency will be used.

6.1.12 Certificates for scales, weights, thermometers, and calipers are retained by metrology and are also referenced in all equipment profiles in Asset Essentials.

6.2 Execution of the Calibration Program

- 6.2.1 The program will be overseen by the Metrologist or designee.
- 6.2.2 Form G-201-F2 Equipment Calibration Log will be filled out and closed monthly.
- 6.2.3 PM work orders for analytical equipment in production will be generated by Asset Essentials and performed by the metrologist or designee. Analytical equipment in production includes: Friabilator and hardness instruments used for in-process product evaluation.
- 6.2.4 Purchase orders will be prepared from quotes for equipment to be tested by an external calibration service.
- 6.2.5 All calibration vendors must be approved by QA or Metrology before use.
- 6.2.6 For equipment calibrated by external sources, a copy of the calibration certificate will be provided by the service provider and forwarded the metrologist or designee for filing.
- 6.2.7 If applicable, Calibration/PM performed by external vendors must meet any requirements for calibration stated in the equipment's profile and/or SOP.
- 6.2.8 A qualified individual, preferable the metrologist, will review all external calibration certificates and write Ion# and/ or serial number at the top of the certificate, if not already present.
- 6.2.9 All certificates received externally will contain a decision as to the condition "as left", completed by provider. This decision may include a "Pass/ Fail" statement or an "In Tolerance" statement.
 - 6.2.9.1 External service providers used for calibration activities must provide this decision statement.

6.2.10 For in-house calibrations, Form G-201-F1 Calibration Certificate with the Ion# and description listed will be issued to the person who completes the calibration.

6.2.11 The designated person will record all appropriate information about the calibration on Form G-201-F1 Calibration Certificate and the form along with any corresponding paperwork will be returned to the metrologist or designee.

6.2.12 Completed internal forms will be reviewed by qualified personnel for final approval.

6.3 Establishing the Frequency of Calibration

6.3.1 The calibration frequencies listed in Attachment 1 Equipment Calibration Frequency Table, are minimum Ion Labs frequency recommendations. Deviations from the table for specific pieces of equipment may be justified by review of manufacturer's documentation and/or previous certifications.

6.3.2 Early calibrations are permissible. The calibration schedule will reset beginning from the latest calibration date.

6.3.3 Certain equipment (Dickson One Temperature/ Humidity Sensors, Digital Temperature and Humidity Monitor, Conductivity meter, Jumbo Timer etc.) will be replaced after factory certification is expired. The integrity of the metal detector testing balls, rods and sticks will be checked every year to ensure no rusting and chipping of the metal wrapped inside. If they are without defect, they may be used indefinitely.

6.4 Calibration Stickers

6.4.1 Each piece of calibrated equipment will be marked with a sticker indicating its calibration status.

6.4.2 Internally placed stickers will indicate at minimum:

6.4.2.1 ION ID#

6.4.2.2 The initials of the person conducting the calibration, or applying the sticker.

6.4.2.3 The date of the calibration (MM-DD-YY)

6.4.2.4 The due date for the next calibration (MM-YY)

6.4.3 Externally completed calibrations will still be tagged using internal Ion calibration stickers for consistency.

6.4.3.1 External company stickers may also be present on calibrated equipment in conjunction with Ion stickers.

6.5 Failed Calibration

6.5.1 A piece of equipment that does not meet its calibration requirements will be removed from service and logged as per Section 6.1.8.

6.5.2 If the equipment is serviceable an external calibration/repair service will repair and recertify the piece of equipment before returning to service.

6.5.3 A "Do Not Use" placard will be affixed to all pieces of equipment that cannot be internally verified and the sticker will only be removed after it has been repaired and recertified by an approved vendor.

6.6 Failed as Found Calibration

6.6.1 If equipment does not meet its as found specification an investigation/risk assessment should be performed as per QS-114 Risk Management and Risk Analysis to determine its effect.

6.6.2 Any instrument specific procedure instructions supersede this guidance.

6.6.3 Any existing processes can be used for the investigation/risk assessment as well.

6.6.4 If the effect is minimal, the calibration certificate may be used to document any risks.

6.7 Calibration Standards

6.7.1 Reference standards used for internal calibrations must be calibrated or verified in compliance with ANSI/NCSL Z540.3-2006; ISO 10012-1 and/or ISO/IEC Guide 25 using NIST traceable standards or standards derived from accepted values of naturally occurring physical constants by an external service or source. The calibration period of these items are set by the service and may not be extended beyond the period indicated on their certificate.

6.7.2 Standards used for any equipment calibration will be captured as part of the calibration paperwork.

6.7.2.1 Applicable C of A's or certificates of calibration for standards will be maintained with each piece of equipment for each calibration.

6.8 Document Retention

6.8.1 All documents will be maintained following C-502 Record Storage, Retention, and Destruction.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/17/10	New	-	-
1	04/01/13	Changed the SOP format & number, changed forms number	-	-
2	11/05/13	Restructured Calibration Program. Realigned responsibilities. Improved clarity of the process. Added a Master Equipment List (electronic). Reorganized forms G-201-F1-F2-F3.	13-1013	B. Johns
3	01/05/16	Updated SOP format. Realigned responsibilities. Consolidated forms G-201-F1, G-201-F3. Added electronic spreadsheet, Calibration Schedule/Equipment List. Added document retention time. Adjusted calibration frequencies for scales and weights.	16-0022	N. Zhang
4	04/04/17	Add metal detector test kits and thermal and humidity monitor to program	16-1120	N. Zhang
5	11/10/21	Updated to reflect current processes. As found out of specification report requires actions. Changed form numbers.	CC-21-0088	J. Maignan
6	12/08/22	Update to add Asset Essentials as a scheduling program. Updated to reflect a metrologist. Updated to reflect current process and practices.	CC-22-0466	J. Sassman

8.0 Attachments

8.1 Attachment 1 – Equipment Calibration Frequency Table

ATTACHMENT 1 – EQUIPMENT CALIBRATION FREQUENCY TABLE

Equipment Type	Frequency	Internal/ External
Scale / Balance	1 Year	External
Hardness Tester	6 Months	Internal / External
Digital Viscometer	1 Year	Internal / External
Friability Tester	1 Year	Internal / External
Melting Point Tester	6 Months	Internal / External
Temperature / Humidity Device / Chamber / Bath	1 Year	Internal / External
Weight Standard	2 Years / 5 Years	External
Weight Standard – Daily Use	1 Year	External
Torque Tester	1 Year	External
Vacuum	1 Year	Internal / External
Caliper	1 Year	Internal / External
Metal Detector	1 Year	Internal / External
Tachometer	3 Years	External
Gauge Block	5 Years	External
Laboratory and Production Equipment	Variable	Internal / External
Timer	1 Year	Internal / External
Pipette	6 Months	External
Disintegration Tester	1 Year	Internal / External
Miscellaneous	Variable	Internal / External

ATTACHMENT 1 – EQUIPMENT CALIBRATION FREQUENCY TABLE

Equipment Type	Frequency	Internal/ External
Scale / Balance	1 Year	External
Hardness Tester	6 Months	Internal / External
Digital Viscometer	1 Year	Internal / External
Friability Tester	1 Year	Internal / External
Melting Point Tester	6 Months	Internal / External
Temperature / Humidity Device / Chamber / Bath	1 Year	Internal / External
Weight Standard	2 Years / 5 Years	External
Weight Standard – Daily Use	1 Year	External
Torque Tester	1 Year	External
Vacuum	1 Year	Internal / External
Caliper	1 Year	Internal / External
Metal Detector	1 Year	Internal / External
Tachometer	3 Years	External
Gauge Block	5 Years	External
Laboratory and Production Equipment	Variable	Internal / External
Timer	1 Year	Internal / External
Pipette	6 Months	External
Disintegration Tester	1 Year	Internal / External
Miscellaneous	Variable	Internal / External



Calibration Certificate

Form: G-201-F1

CCR No. CC-22-0466

Revision: 1

Calibration of Ion Asset Number:	
Description:	

Ion Asset Number of Standard 1:		Calibration Due Date:	
Ion Asset Number of Standard 2:		Calibration Due Date:	
Ion Asset Number of Standard 3:		Calibration Due Date:	

Calibration Data	Standard 1	Standard 2	Standard 3
Standard Specification			
Unit of Measure			
Test Reading			
Tolerance Allowed (Range)			
Minimum Allowed Reading			
Maximum Allowed Reading			
*In Tolerance As Found (Y/N)			
In Tolerance As Left (Y/N)			

* If "As Found" tolerance is N, an explanation and risk assessment is required. Assessment may be documented below or a reference to another document may be listed below.

To be completed if "As Found" is out of tolerance

Determination (check one): Pass Fail

Performed By:		Date:	
Reviewed By:		Date:	

