ION Nutritional Labs	Standard Operating Procedure **Calibration Verification and Operation of Scales and Load Cells**	**SOP Number** **G-207**	**Revision** **5**
		Effective Date 09/09/24	**Page** **Page 1 of 12**
Written by/ Date 07/23/24	**Reviewed by/ Date** 07/26/24	**Approved by/ Date** 08/01/24	
Title: Metrologist	**Title: Quality Control Director**	**Title: Quality Assurance Director**	

1.0 Purpose

The purpose of this procedure is to establish the process for the calibration verification and operation of scales and load cells used in Manufacturing and QC Inspection areas.

2.0 Scope

This procedure applies to all scales used in Manufacturing and QC Inspection areas at Ion Nutritional Labs.

3.0 Responsibility

3.1 DC is responsible for issuing, maintaining, and archiving logbooks for each as outlined in SOP C-501 Document Control Procedure and SOP C-502 Record Storage, Retention, and Destruction.

3.2 All personnel operating scales are responsible for following this procedure and ensuring that calibration is verified daily if in use, or after being moved.

3.3 All personnel operating scales are responsible for verifying that an ION Equipment ID# is present and calibration is current prior to use.

3.4 It is the responsibility of the Metrologist or designee to maintain calibration verification, calibration due dates, and scheduling of verified vendors to perform calibrations on all scales in use at Ion Nutritional Labs as per SOP G-201 Calibration Program.

3.5 It is the responsibility of the Metrologist or designee to maintain all documentation pertaining to calibration certificates, installation, and repair of all scales in use at Ion

Nutritional Labs as per SOP G-201 Calibration Program.

4.0 Definitions

4.1 **Calibration** – The process of adjusting an instrument or device to ensure that it produces accurate and consistent results

4.2 **Calibration Verification** – The process of checking that an instrument is still producing accurate results after it has been calibrated

4.3 **Check Weight** – Calibrated weight standard used to perform accuracy checks on scales

4.4 **DC** – Document Control

4.5 **QC** – Quality Control

4.6 **Asset Number** – Unique identification number assigned to each piece of equipment

4.7 **IPA** – 70% Isopropyl Alcohol

4.8 **BPR** – Batch Production Record

4.9 **Sensitivity** – the smallest weight that produces a stable reading

4.10 **Minimum Weight** – the smallest weight that can be placed on the scale and produce a reading within the scale's specified accuracy limits

4.11 **Linearity** – The ability of a balance to follow the linear relationship between a load and the indicated weighing value. Nonlinearity is expressed as the largest magnitude of any linearity deviation within the test interval.

4.12 **Eccentricity** – Deviation in measurement of a load that is measured in the center of the balance against the same load being measured off the center of the balance. This is expressed as the largest magnitude of any of the deviation between an off-center reading and the center reading for a given test load.

4.13 **Repeatability** – The ability of a scale to display identical measurement values for repeated weighings of the same load under the same circumstances

4.14 **Tolerance** – Maximum permissible error. A value fixing the limit of allowable error or departure from the true performance or value

4.15 **Simple Green** – A precision concentrated cleaning detergent

4.16 **Red Zone** – Manufacturing software pertaining to this SOP in regards to daily scale verifications.

5.0 References

5.1 G-201, SOP, Calibration Program

5.2 G-207-F1, Form, Scale Calibration Verification Log

5.3 A-101, SOP, Numeric Data Entry and Rounding

5.4 USP-NF <41>

5.5 USP-NF <1251>

5.6 B-911, SOP, Continuous Gummy Manufacturing Process

5.7 B-911-F1, Form, Gummy Inline Equipment Verification

5.8 C-501, SOP, Document Control Procedure

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

5.10 A-106, SOP, Documentation Guidelines for cGMP Records

6.0 General

6.1 Redzone will be used to record scale verification data, on the rare occurance that Redzone is unavailable data will be recorded using form G-207-F1 Scale Calibration Verification Log, DC will issue a logbook for any scale that may need to be verified without Redzone. The asset number and other relevant data will be recorded on this form.

6.2 An annual calibration verification is required for each scale as per SOP G-201 Calibration Program. Analytical balance calibrations and calibration verifications will be performed by a verified vendor. Floor scales that measure over 40 kg (100 lbs) will also be calibrated/verified by a verified vendor.

6.3 Load cells equipped with tanks on the continuous gummy manufacturing lines are unable to have a NIST traceable weight to check calibration due to the nature of the configuration. As such, the load cells will be checked to ensure that they are operational and able to detect weight change. Document the verification on form B-911-F1 Gummy Inline Equipment Verification Log.

6.3.1 Load Cells on the continuous gummy manufacturing lines will be verified and calibrated externally at least once per year by Mettler Toledo or a qualified vendor as per SOP G-201 Calibration Program.

6.4 Before using any new scales at Ion Nutritional Labs:

6.4.1 All scales must have an asset number and be entered into the appropriate option list in Red Zone software..

6.4.2 Any scale that is an analytical balance or floor scale must be installed, calibrated, and verified by the scale vendor or a verified vendor.

6.5 For scales and balances that are already in use at Ion Nutritional Labs:

6.5.1 Wear powder-free gloves or use plastic forceps when handling bench scale Check Weights.

6.5.2 Ensure unit is free of any material or product, unit has been cleaned and calibration sticker is visible and current.

6.5.3 Bench and floor scales must sit on a firm, flat surface, free from air currents and vibrations.

6.5.3.1 If unit has a built-in leveling device (e.g. bubble), ensure it is level prior to use (minor adjustments may be necessary). The unit is level when the bubble is inside the circle without touching any point on the circle.

6.5.4 For analytical scales to be used at full accuracy, the unit must be placed on a firm, flat surface composed of granite or marble and the slab isolated using vibration dampening system.

6.5.4.1 If the analytical scale is not fully isolated from vibration the accuracy of the reading is reduced to that of a bench scale +/- 0.1g to +/- 0.02g and readings will be rounded as per SOP A-101 Numeric Data Entry and Rounding.

6.5.5 Before use, ensure unit is plugged into power source or ensure appropriate quantity and sized batteries are properly installed into the unit.

6.5.6 Ensure scales are isolated from electromagnetic sources.

6.6 Cleaning Scales

6.6.1 Remove all containers and utensils from the previous batch.

6.6.2 Vacuum any material from the scale and surrounding area.

6.6.3 Wipe down the scale using a damp cloth with water and Simple Green solution, or 70% IPA as needed. Take care when cleaning around any decals with calibration information. If any become unreadable, contact the metrologist to create a new one.

6.6.4 After cleaning of the bench and floor scales, the scales are to be turned off.

6.6.5 Ensure that scales are kept free of any items on the load cell when not in use. Scales and balances should not be used to hold or store items until use under any circumstances.

7.0 Daily Calibration Verification

7.1 The scale calibration will be verified by users once daily when in use, or after being moved using a verified NIST traceable Check Weight.

7.2 For bench scales with ranges from 1g to 1000g, the accuracy of each weight will be measured to within +/- 0.1g or +/- 0.02g depending on the resolution of the instrument.

7.2.1 A single check weight of either 100g or 200g can be used for the daily verification.

7.3 For analytical scales with ranges from 1mg to 250g the accuracy of each weight will be measured to within +/- 0.2mg. See SOP D-707 Use of Balances in the QC Laboratory and D-708 Use of a Top Loading Balance for full instructions on analytical balances in the QC Laboratory.

7.3.1 Three check weights are required for daily calibration verification. The weights required include 100g, 1g and 100mg. Other weight ranges can be used to meet the needs of an application.

7.3.2 If the analytical scale is not fully isolated from vibration then the procedure for bench scale verification can be used with the adjusted accuracy.

7.4 For floor scales with ranges up to 1000kg, the accuracy of each weight will be measured to within 0.2kg.

7.4.1 A single 20kg check weight can be used for the daily verification.

7.5 Check weight are calibrated once per year as per SOP G-201 Calibration Program. The weights are certified to an exact weight. The measurement tolerance is applied to the certified weight. Example: 100g → certified to 100.0021. Tolerance: 100.0021 +/- 0.0002. 20kg → certified to 20.1kg. Tolerance 20.1kg +/- 0.2kg.

7.6 The certified weight should be listed with the calibration tag otherwise it can be obtained from the metrologist, who maintains the calibration log as per SOP G-201 Calibration Program.

7.7 Scales will be color coded based on their readability. The current color codes are as follows:

7.7.1 Green – 0.02g

7.7.2 Yellow - 0.1g

7.7.3 Red - 0.2kg

7.8 Perform the following steps on the appropriate scale form.

7.8.1 Initiate Verification Process:

7.8.1.1 Log into Redzone software.

7.8.1.2 Navigate to the production checks section.

7.8.1.3 Select the appropriate scale grouping.

7.8.1.4 Start the data sheet for scale verification.

7.8.2 Select Room ID:

7.8.2.1 Choose the Room ID, where the verification is being performed, from the option list.

7.8.3 Select Scale ID:

7.8.3.1 Choose the Scale ID from the option list that matches the identification tag of the scale being verified.

7.8.4 Enter Check Weight ID:

7.8.4.1 Input the Check Weight ID in the designated formatted text field, ensuring it matches the physical check weight used.

7.8.5 Enter Check Weight Expiry Date:

7.8.5.1 Input the expiration date of the check weight in the date field, verifying it is within its valid calibration period.

7.8.6 Enter Calibrated Weight of Check Weight:

7.8.6.1 Input the calibrated weight of the check weight in grams, as specified in its calibration certificate, into the numeric field.

7.8.7 Is Scale Level?

7.8.7.1 Select "Yes" or "No" from the option list to indicate if the scale is level, confirming by checking the scale's level indicator.

7.8.8 Enter Scale Reading:

7.8.8.1 Input the current reading from the scale into the numeric field after placing the check weight on the scale and recording the reading accurately.

7.8.9 Automatic Limit Check:

7.8.9.1 The system will automatically perform the calculation to determine if the scale reading falls within the established tolerance range by setting a negative lower limit and positive upper limit of the tolerances. It will subtract the scale reading from the calibrated check weight weight.

7.8.10 Report Any Damages or Non-Conformances:

7.8.10.1 Immediately report any damages to the scale or non-conformances in the readings to the Metrologist for further investigation and action.

7.8.11 Save and Submit:

7.8.11.1 Save the recorded data and submit the verification log, ensuring all fields are correctly filled before submission for quality review.

7.8.12 Acceptance Criteria

7.8.12.1 The scale reading must fall within the specified tolerance range established by the upper and lower limits.

7.8.12.2 Any deviations must be documented and investigated as per SOP C-201 Deviation and Investigation Procedure.

8.0 General Scale Operation

8.1 Turn scale on by pressing or holding down the “ON” button.

8.2 If necessary, press the “TARE/CLEAR/ZERO” button (depending on model) to obtain a zero “0.0” reading.

8.3 Ensure the correct unit of measurement is displayed (e.g. kg or g). Change as necessary.

8.4 Center an empty container or empty plastic bag with all attachments (cap, label, as applicable) on the load receiver.

8.5 Press the "TARE/ZERO" key to store the container weight in memory and the display will automatically return to zero "0.0".

8.6 Dispense the material into the container until the desired weight is achieved.

8.7 Record the result in the BPR, protocol, etc. and initial and date or sign entry as appropriate.

9.0 Annual Calibration Verification of Bench Scales

9.1 Calibration verification may be performed on bench scales in-house with NIST traceable calibration weights by the Metrologist or outsourced to a verified vendor.

9.2 If the scale does not meet the criteria below, the scale must be removed and a valid alternate may be used. Additionally, the Metrologist will notify Quality Management and arrange for an approved vendor to repair the scale or (if needed) order a new one.

9.3 Calibration Verification Performance Test Procedures

9.3.1 Prior to starting, ensure the scale is clean, level, and powered on

9.3.2 These procedures can be followed in any order, but all must completed.

9.3.3 All results must be passing and documented on an NIST traceable certificate for the calibration verification to be valid.

9.3.4 Accuracy – Using NIST traceable calibration weights that have a mass between 5% and 100% of the balance's capacity, place each weight on the balance and record the value. Acceptance Criteria: Nominal weight ± 0.10%

9.3.5 Linearity - Start by placing the lowest value NIST traceable calibration weight

on the scale and record the reading. Then, add the next calibration weight and record the reading. At least 3 measurements must be taken. Using Excel, plot the readings on a graph with the weight on the x-axis and the reading on the y-axis. Acceptance Criteria: r^2 = NLT 0.9999 and NMT 1.0001

9.3.6 Eccentricity- Place a NIST traceable weight at the four corners and at the center. Record the weight readings for each location and calculate the difference between the highest and lowest readings. Divide the difference in weight readings by the known weight to obtain the eccentricity measurement. Acceptance Criteria: NMT 0.05%

9.3.7 Repeatability- Place a NIST traceable calibration weight on the weigh plate 10 times. Each time the weight is recorded, remove the weight, allow the balance to return to 0, and place the weight again. After 10 data points have been recorded, calculate the standard deviation of the data population. Record the scale interval (this is shown as how many decimal places the scale shows). Multiply the scale interval by 0.41. Determine which is greater: the SD or the product of the scale interval and 0.4, then multiply that value by 2000. This value is the scale's minimum net weight, adjust decimal to reflect appropriate denomination. Acceptance Criteria: Calculated Minimum weight ≥ Minimum Weight as set by manufacturer

10.0 Revision History

Revision	Date		CCR #	By
0	02/09/15	New	14-0772	D. Popp
1	11/12/15	Description of Changes	15-0730	B. Johns
2	02/15/16	Aligned SOP with requirements outlined in SOP G-201.	16-0148	B. Johns
3	04/08/19	Scheduled review: Added cautions to scale use.	19-0246	J. Maignan
4	10/20/23	Updated Logo, added information about load cells in gummy production, added USP instructions	CC-23-0519	B. Echevarria
5	07/23/24	Updated daily verification information to be performed on Red Zone.	CC-24-0325	J. Nicholson

ION Nutritional Labs	Scale Calibration Verification Log		
	Form: G-207-F1	CCR No. CC-24-0325	Revision: 4

Logbook Number: _____

Calibration Verification Date	Asset #	Scale Tolerance (+/-)	Check Weight Asset Number	Calibrated Weight of Check Weight	Calibration Result	Pass/Fail (Y/N)*	Performed By / Date
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	
						Y / N	

* If the check weight fails to conform to calibrated weight, inspect for cleanliness and clean with a wipe as necessary. If weight fails multiple times, notify Quality Management and obtain a replacement check weight.

PQV: _____