SOP 1

Recommended Standard Operating Procedure for Calibration Certificate Preparation

1. Introduction

1.1. Calibration certificates are the visible outputs of the calibration laboratory that must be prepared with utmost care to ensure that they accurately convey all information pertaining to a calibration so that data may be used with maximum benefit by all concerned. Carefully prepared calibration certificates must contain or refer to all information necessary to justify the measurement results and must be thoroughly reviewed and authorized prior to release.

1.2. A detailed reporting of results is preferred and often required by customers in accredited and recognized laboratory systems, which includes a complete narrative describing and documenting the calibration, including those for special calibrations or tests. According to the ISO/IEC 17025 standard, calibration results may be reported in a simplified way when agreed to by the customer. For weights and measures (legal metrology applications) reporting of elements of metrological traceability for reference to the International System of Units (SI), measurement results, and uncertainty results continue to be required with few exceptions[1]. All information not provided to the customer must be maintained by the laboratory and readily available.

1.3. The laboratory is responsible for all information provided within the calibration certificate, except for information that was provided by the customer. When information is provided by the customer, it shall be clearly identified. The calibration certificate will include a disclaimer notifying users that information supplied by the customer can affect the validity of results. When sampling is provided by the customer (e.g., the method sampling stage), the calibration certificate shall state that the results apply to the sample as received from the customer.

2. Content of calibration certificates.

Regardless of the final form, the calibration certificate must contain the basic information described in this procedure (see also Section 7.8 of ISO/IEC 17025[2] and the attached template Calibration Certificate Review Checklist, Appendix B).

[1] See GMP 13, Ensuring Traceability, ISO/IEC 17025, Annex A, and International Laboratory Accreditation Cooperation (ILAC) and accreditation body policies.

[2] ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories.

Each calibration certificate, supplied in hard copy or electronic format, shall contain the following information to minimize the possibility of misunderstanding or misuse:

2.1. Title (e.g., “Calibration Certificate”).

2.2. Name and address of the laboratory where the calibration is performed (e.g., permanent facility), including any alternative location where a calibration is performed (e.g., temporary, mobile, or alternative facility).

2.3. Unique identification that all calibration certificate components are recognized, and an identification on each page to ensure that the page is recognized as part of the complete document, and a clear identification of the end of the certificate. A unique calibration number and page X of Y formatting are frequently used to uniquely identify the components of a calibration certificate.

2.4. Customer name and contact information.

2.5. Method used –Cite the Standard Operating Procedure (SOP), including the full title or description and the version date. In the absence of a nationally or internationally published SOP, a brief but informative description of the methodology shall be included. When a customer approves of an addition, deviation, or exclusion from the published method, these departures shall also be included

2.6. Unambiguous identification and description of the calibration artifact, and when necessary, the condition of the item. Serial numbers are assigned to items by the customer, laboratory, or manufacturer to facilitate the internal control of the item during the calibration process and subsequent use by the customer. Unique identification is verified when an item is submitted to the laboratory for calibration.

2.7. Date(s) of:

- Calibration item receipt;
- Sampling, where critical to the validity and application of the results;
- Calibration or laboratory activity performance; and
- Certificate issuance.

2.8. Cite the sampling plan and methods used. Uniquely identify the items sampled. Include the:

- The date and location of sampling;
- Environmental conditions during sampling that affect the interpretation of results; and
- Information related to the measurement uncertainty, where relevant.

2.9. Calibration results and corresponding units of measurement are clearly organized in a tabular or other convenient format. When a calibration item has been repaired or adjusted, the calibration results *before* and *after* repair or adjustment shall be reported. The

measurement units reported are typically related to the nominal value of the calibration item. Measurement units may be selected to reflect an industry practice or a customer request.

2.10. A statement of the measurement uncertainty, and corresponding measurement unit, coverage factor, and estimated confidence interval shall accompany the measurement result. The measurement uncertainty is reported in the same measurement units as the measurement result (e.g., multiple or submultiple). Special care shall be used when the coverage factor is not consistent for all calibrated items. The results table should be formatted to clearly identify individual coverage factors when variations exist (e.g., an additional column containing the corresponding coverage factors). When appropriate, significant uncertainty components and the rationale for their inclusion are included. Note: the use of standard industry practices or reporting units based on customer requests is permitted.

2.11. Environmental or other conditions under which the calibrations were made that influence the measurement results.

2.12. Clearly identify the person(s) performing the calibration and authorizing calibration certificate by stating their corresponding name, title, and signature. Each authorized signatory accepts responsibility for the technical accuracy and validity of the reported results.

2.13. A statement to the effect that the results relate only to the items calibrated or sampled.

2.14. A statement identifying how the measurements are metrologically traceable (e.g., the laboratory establishes metrological traceability to the International System of Units (SI) and is recognized by NIST OWM). The inclusion of supplemental supporting information may be requested by the customer.

2.15. When statement of compliance or non-compliance with requirements and/or specifications (e.g., a conformity assessment), where relevant. Compliance refers to an assessment of *all* criteria of a referenced documentary standard and not a limited assessment of a portion or specific clauses (e.g., compliance to all specifications versus only the tolerance specification). When a statement of conformity is made, the laboratory must clearly identify to which results the statement of conformity applies (e.g., all results or a specific portion of the results), which specifications, standards or parts thereof are *met* or *not met*, and the decision rule applied (unless the decision rule is inherent in the specification or documentary standard). When a statement of conformity to a specification or documentary standard is made, the laboratory shall document the decision rule applied, take into account the level of risk associated with the decision rule employed (such as false accept, false reject, and statistical assumptions), and apply the decision rule. Where decision rules regarding uncertainties and tolerances are not part of the documentary standard, decision rules will be agreed to by the customer and reported on the calibration certificate.

2.16. Opinions and interpretations, where appropriate and needed, shall be based on the measurement results, clearly stated, and identified as such. Only technically competent laboratory personnel are permitted to express opinions and interpretations (e.g., an authorized signatory). When opinions and interpretations are directly communicated and discussed with the customer, a record of the conversation shall be documented and retained.

2.17. Results from external providers shall be clearly identified.

2.18. Additional information which may be required by specifications, specific methods, customers, or groups of customers.

2.19. To ensure parts of the calibration certificate results are not taken out of context, a statement specifying that the calibration certificate shall not be reproduced except in full, without written approval of the laboratory may be included.

2.20. A calibration certificate or calibration label shall not include any recommended calibration interval, except when required for legal applications or where requested and agreed to by the customer.

3. Review and Issue to Customer.

3.1. A thorough technical and quality review of each calibration certificate should be conducted according to laboratory Quality Management System before issuance to prevent errors, recall, and certificate amendment.

3.2. Review measurement units and symbols according to the current edition of NIST Special Publication (SP 811), *The NIST Guide for the Use of the International System of Units* (https://www.nist.gov/physical-measurement-laboratory/special-publication-811).

3.3. The template Calibration Certificate Review Checklist may be used by the laboratory to aid in multiple evaluation functions (Appendix B).

3.3.1 Review each calibration certificates before issue to the customer to ensure it meets the requirements of this procedure.
3.3.2 Review external calibration certificates during the supplier evaluation process.
3.3.3 Review issued and/or template calibration certificates during a technical or quality audit.

4. Calibration Certificate Amendment.

4.1. When a calibration certificate issued to a customer must be changed, amended, or re-issued, the changed information shall be clearly identified. The reason for the change shall be included in the report, when appropriate.

4.2. Amendments made after issue to the customer shall be made only in the form of a further

document or data transfer, which includes the statement “Amendment to Calibration Certificate” or an equivalent form of wording.

4.3. When it is necessary to issue a completely new calibration certificate, it shall be uniquely identified and contain a reference to the original calibration certificate that it replaces.

4.4. Amended calibration certificates shall meet all the requirements of this procedure.

5. Records

5.1. The laboratory shall file, organize, and retain all calibration certificates in a systematic manner for ease of retrieval.

5.2. Retain legible copies of all issued and amended calibration certificates according to the laboratory Quality Management System.

Appendix A – Example Certificate

COMPLIANT CALIBRATION LABORATORY

123 Some Ave.

City, State Mail code

XYZ Accreditation Body: 1234567890

CALIBRATION CERTIFICATE

FOR

1 kg to 10 mg kit

(Twenty-one weights)

Manufacturer: DENTROM LAKE

Serial No.: 27269

SUBMITTED BY:

YOUR CUSTOMER, INC.

Customer's Address

City, State Zip code

Phone/Email

Nominal (g)	Conventional Mass (g)	Conventional Mass[3] Correction (mg)	Expanded Uncertainty (mg)
1000	1000.000 82	0.82	0.92
500	500.000 71	0.71	0.53
300	299.999 87	- 0.13	0.27
200	200.000 67	0.67	0.18
100	100.000 411	0.411	0.091
50	50.000 318	0.318	0.051
30	30.000 117	0.117	0.028
20	19.999 987	- 0.013	0.023
10	10.000 011	0.011	0.018
5	5.000 022	0.022	0.015
3	3.000 112	0.112	0.013
2	1.999 965	- 0.035	0.012
1	1.000 117	0.117	0.010
0.500	0.500 013 2	0.013 2	0.005 1
0.300	0.300 022 3	0.022 3	0.004 8
0.200	0.200 001 7	0.001 7	0.004 3
0.100	0.100 001 3	0.001 3	0.004 2
0.050	0.050 001 8	0.001 8	0.004 0
0.030	0.030 001 1	0.001 1	0.003 7
0.020	0.020 000 9	0.000 9	0.003 3
0.010	0.009 999 7	- 0.000 3	0.003 1

The data in the above table applies only to those items specifically listed on this calibration certificate.

[3] Conventional Mass: The conventional value of the result of weighing a body in air is equal to the mass of a standard, at reference density 8.0 g/cm³, at a reference temperature 20 °C, which balances this body at this reference temperature in normal air density 0.0012 g/cm³. See OIML D28 (2004), "Conventional value of the result of weighing in air."

Uncertainty Statement:

The combined standard uncertainty includes the standard uncertainty reported for the standard, the standard uncertainty for the measurement process, the standard uncertainty for any uncorrected errors associated with buoyancy corrections, and a component of uncertainty to account for any observed deviations from NIST values that are less than surveillance limits. The combined standard uncertainty is multiplied by a coverage factor (*k*) of 2 to provide an expanded uncertainty, which defines a level of confidence of approximately 95 percent. The expanded uncertainty presented in this report is consistent with the ISO/IEC Guide to the Expression of Uncertainty in Measurement (2008). The expanded uncertainty is not to be confused with a tolerance limit for the user during application.

Traceability Statement:

The Standards of the Compliant Calibration Laboratory are traceable to the International System of Units (SI) through the National Institute of Standards and Technology, and are part of a comprehensive measurement assurance program for ensuring continued accuracy and measurement traceability within the level of uncertainty reported by this laboratory. The unique laboratory calibration number identified above shall be used in referencing metrological traceability for artifacts identified only in this certificate.

Supplemental Information:

Description of Artifacts Submitted for Calibration:
Twenty one weights from 1 kg to 10 mg, marked ASTM E617 (2013), Standard Specification for Laboratory Weights and Precision Mass Standards, Class 4. Weights from 1 kg to 1 g: two-piece weights, with assumed density of 8.0 g/cm^3. Weights from 500 mg to 50 mg: sheet weights, with assumed density of 16.6 g/cm^3. Weights from 30 mg to 10 mg: sheet weights, with assumed density of 2.7 g/cm^3.

Conditions of Artifacts Submitted for Calibration:
Artifacts showed evidence of improper handling. Fingerprints and dents were visible on the surface of the weights.

Treatment of Artifacts Prior to Calibration:
Artifacts were cleaned with cheesecloth and ethyl alcohol. Thermal equilibrium time/conditions: seven days next to balances in mass laboratory.

Procedure Used:
Double Substitution (NISTIR 6969, SOP 4, 2018)

Environmental Conditions at Time of Calibration:
Temperature: 20.1 °C to 20.2 °C Barometric Pressure: 752.7 mmHg Relative Humidity: 43.35 % to 43.40 %

Date Artifacts Received: January 5, 2018 Date Certificate Issued: January 13, 2018

Date of Calibration: January 12, 2018

Due Date (Requested by Customer): January 15, 2018

Josh Balani II

Calibration Performed by: Josh Balani II, Metrologist

Appendix B - Calibration Certificate Review Checklist

ISO/IEC 17025:2017, Section 7.8 - Reporting of Results

This evaluation form may be used as an assessment tool for calibration certificates. Its use needs to include objective evidence of the assessment (e.g., a marked-up certificate).

Criteria Guide		Compliance
7.8.1.2	Reported accurately, clearly, unambiguously and objectively; in accordance with method instructions; include all info requested by customer, necessary for interpretation of the results, & required by the method	
Calibration Certificate Core Requirements (Include at least the following information, unless valid reasons for not)		
7.8.2.1 a)	Title	
7.8.2.1 b, c)	Laboratory name & address and location where tests/calibrations performed	
7.8.2.1 d)	Unique identification that allows the user recognize all the portions of the certificate. Clearly identify document end (a way to recognize a complete report) For Example: page number and total number of pages	
7.8.2.1 e)	Customer name and contact information	
7.8.2.1 f, n)	Identify method used; additions, deviations, exclusions from the method	
7.8.2.1 g)	Description and unambiguous identification of the item(s) calibrated and when necessary condition	
7.8.2.1 h-j)	Dates: receipt, sampling if applicable, date(s) of performance of lab activity, certificate issue	
7.8.2.1 k)	Reference to sampling plan and procedures used where relevant to validity or application of results	
7.8.2.1 l)	Statement to the effect that the results relate only to the calibrated items Note: Recommend statement shall not be reproduced except in full, without written lab approval	
7.8.2.1 m)	Calibration results with appropriate units of measurement, where appropriate	
7.8.2.1 o)	Name(s), function(s) & signature(s) or equivalent ID of person(s) authorizing the certificate	
Calibration Certificates (In addition to 7.8.2.1)		
7.8.4.1 a)	Uncertainty of the measurement result in the same unit as that of the measured item, or unit relative to item	
7.8.4.1 b)	Calibration conditions (e.g., environmental) that influence the measurement results	
7.8.4.1 c)	Statement on how the measurements are metrologically traceable	
7.8.4.1 d)	Before and after measurement results when adjustment or repair is made	
7.8.4.1 e), 7.8.6	If compliance statement is made: Identify to which results they apply, clauses met/not met, and account for the decision rule (e.g., uncertainty)	
7.8.4.3	No calibration interval on certificate/label except if customer agrees (superseded by legal regulations)	
Sampling (7.8.5) Specific requirements noted in 7.8.3.2, 7.8.4.2		
7.8.5 a-f)	Sampling date, unique identify, material or product, location, diagrams, sketches, photographs; reference plan & procedures; environmental conditions; information for uncertainty evaluation	
Opinions and Interpretations		
7.8.4.1. f) 7.8.7	Document basis of opinions and interpretations when included with reference to basis, performed by authorized personnel only; clearly identify	
Amendments		
7.8.8	Amendments after issue made as further document/data transfer with statement, meet all requirements. New certificate is uniquely identified, and reference to the original that it replaces	

Appendix C - Calibration Certificate Review Checklist
ISO/IEC 17025:2017, Section 7.8 - Reporting of Results

This evaluation form may be used as an assessment tool for evaluating multiple calibration certificates; for example, during an internal audit or during review of proficiency testing certificates. Its use needs to include objective evidence of the assessment (marked-up certificates).

X = Nonconformity C = Comment										
Lab Names or Parameters:										
7.8.1.2										
Calibration Certificate Core Requirements (Include at least the following information, unless valid reasons for not)										
7.8.2.1 a)										
7.8.2.1 b, c)										
7.8.2.1 d)										
7.8.2.1 e)										
7.8.2.1 f, n)										
7.8.2.1 g)										
7.8.2.1 h-j)										
7.8.2.1 k)										
7.8.2.1 l)										
7.8.2.1 m)										
7.8.2.1 o)										
Calibration Certificates (In addition to 7.8.2.1)										
7.8.4.1 a)										
7.8.4.1 b)										
7.8.4.1 c)										
7.8.4.1 d)										
7.8.4.1 e), 7.8.6										
7.8.4.3										
Sampling (7.8.5) Specific requirements noted in 7.8.3.2, 7.8.4.2										
7.8.5 a-f)										
Opinions and Interpretations										
7.8.4.1. f), 7.8.7										
Amendments to Test Reports and Calibration Certificates										
7.8.8										
***** Participants that apply tolerances										