Adjusting external calibration intervals for auxiliary devices in testing laboratories according to intermediate checks results

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ABSTRACT

An unfortunate thing which is not desirable to happen in testing laboratories is that after working for weeks on tests, it is discovered that one of the used equipment is not accurate. Therefore, intermediate checking these devices from time to time is a reasonable way to reduce the risk of errors in laboratory work. The Central Laboratory for Environmental Quality Monitoring (CLEQM) performs intermediate check for testing equipment, besides the annual calibration done by an accredited body, to maintain confidence in its accuracy and precision between calibration intervals. This paper discusses the laboratory procedures to perform intermediate checks for electronic balances and micropipettes to comply with ISO/IEC:17025 requirements in the field of water quality testing. Intermediate check for balances was carried out according to OIML R111-2004 (E), while intermediate check for micropipettes was performed according to ISO 8655-6:2002. The results of intermediate checks and control charts were used to monitor equipment needs for recalibration. The results indicated that calibration of laboratory equipment is not necessarily neither to be annually nor at fixed time intervals. However, it should be based on the drift in measurements, which can be detected through regular intermediate check. Where results are tracked through control charts and in case that, it is drifted out of control limits, a nonconformance is reported, and appropriate corrective actions are taken including calibration if required. It is concluded that calibration of supporting equipment according to their intermediate check is more favorable than fixed time intervals due to the high degree of reliability of the generated test results in addition to reduced financial costs, which is expected to be 25% to 40% lower than the cost of calibration with fixed intervals.

INTRODUCTION

The environmental sampling and sample analyses are expensive. The risk of questionable analysis results can trigger severe economic and social consequences because it leads to hazards being undetected or to false detection of unreal hazards (Quevauviller, Coelho & Cortez, 1998).

Despite the awareness of the importance of data quality, however, many inter-laboratory studies including chemical and microbiological constituents show poor comparability (Quevauviller, Maier, & Grieppink, 2011). The solution for the achievement of comparable results is the application of an integrated quality management system (Meriem & Ebrahim, 2021; Uriano & Gravatt, 1977).

Accreditation is the right short way for laboratories to facilitate the development, integration, and maintenance of their management and technical system (Agostini, 2018; Cortez, 1999; Maier, Boenke, & Meériguet, 1997; Middlebrook, 2017; Omar & Rana, 2021).

Metrology-related activities are an essential feature of the laboratory integrated management system, serving to make certain that the laboratory can routinely produce data with a consistent quality that fulfills expectations of customers over time (Thompson & Magnusson, 2013).

The calibration includes an evaluation of measurement uncertainty and provides metrological traceability to SI units (Paul, René, Aleš Fajgelj, & Brynn, 2011). The need to document an unbroken chain of the calibration process for accreditation purposes is often driving-up costs. Both instrument vendors and calibration bodies benefit the most from the ISO systems calibration processes (Karina, María, Teresa, Marcela, & Luis, 2018).

Performing the calibration, annually or whenever determined, will allow us to identify and reveal the possible deviations of the equipment over time. Testing laboratories shall have a plan and tools to establish a validity period during which equipment can be used without worrying about the inaccuracy of measurement outputs. This plan should be dynamic, allowing for calibration intervals to be shortened or extended, according to the data collected from a regular intermediate check between calibration (Paul & Barringer, 1995).

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Calibration overall costs can be reduced if calibration intervals were stretched in a way that can be justified logically. This can be done when daily, weekly, or monthly cross-checks are made against a known standard. The target of intermediate checks is to maintain confidence in the calibration validity of auxiliary equipment in-between calibrations. Intermediate checks can provide reasonable grounds for the extension of calibration intervals or not (Egyptian Accreditation Council, 2018; Southern African Development Community Accreditation Services, 2017; Volodarsky, Kosheva, & Pototskiy, 2020).

Timely and adequate records for intermediate checks shall be documented, including an uncertainty estimate, as evidence for an equipment calibration status continues to satisfy the test requirements. The third edition of ISO/IEC 17025:2017 standard stated in item 7.7.1.e that maintaining confidence in equipment calibration status through intermediate checks is a procedure the laboratory shall use for monitoring the validity of results (Ivana, 2020; Adriana & Adela, 2018; ISO/IEC 17025, 2017).

Mass measurement and volume pipetting are critical in analytic laboratories, particularly in highly sensitive tests where a small mistake in weighing and pipetting may produce an inaccuracy in the reported result. Calibration is required under laboratory conditions to identify and reduce potential errors in balances and micropipettes (Batista, et al., 2007).

In addition to certified calibration, daily or before-use, the intermediate check should be made on balances and micropipettes, while it is still within calibration date, to ensure that it meets the acceptable calibration criteria. The result of the intermediate check is recorded for the purpose of internal quality control (Gonzalez & Herrador, 2007; UKASLAB14, 2001).

The Central Laboratory for Environmental Quality Monitoring (CLEQM) is the analytical laboratory of the National Water Research Center; (NWRC) in Egypt. CLEQM is accredited in conformance with the recognized International Standard ISO/IEC 17025:2017 for selected chemical and microbiological tests in water.

The objective of this paper is to use equipment intermediate checks to establish a rational method for adjustment of recalibration intervals considering financial impacts, consequently, finding a cost-effective period taking risk into consideration instead of using the conventional “one-year” recalibration interval.

Materials and methods

Reference materials, reagents, and equipment

Intermediate check of balances was carried out using calibrated set weight class E2, (1 mg-200 mg) HAFNER, Germany, Micropipettes with manufacturer’s recommended tips for best results, intermediate check of micropipettes was carried out using Deionized water daily prepared, Grade 2 (ISO 3696, 1987), 50 ml glass beaker, temperature sensor (with accuracy±0.2°C) and calibrated sensitive balance.

The environmental conditions for testing rooms including temperature, humidity, and atmospheric pressure were recorded systematically in data loggers of the laboratory central air condition system.

Intermediate check procedure and schedule

According to the CLEQM calibration plan (Table 1), sensitive balances and micropipettes are calibrated annually to maintain their performance. CLEQM performs a routine check to test the performance of this equipment in order to be confident with results.

This procedure requires a reference standard that can be used to compare against the reading of the intermediate check tool. The reference standard and the intermediate check tool should have a valid calibration status from the National Institute of Standards (NIS) or the Egyptian Organization of Standardization (EOS).

Balance intermediate check procedure

Each balance in the laboratory goes through a daily verification (working day) for sensitivity, the measurement is recorded in a spreadsheet, and each set of one-week readings is considered a subgroup. Subgroup averages and ranges are calculated and represented in the form of a control chart to evaluate the balance reproducibility and process performance over time by studying variation.

The precision of balance is monitored using a statistical control technique, according to OIML R111-2004 (E) (OIML, 2004). The test depends on the standard deviations history of the same balance, if there are m standard deviations, the standard deviation of balance is an estimate as pooled standard deviation S_p, in this research intermediate check for balances was done using available historical data from the years 2019 and 2020.

Table 1. Full calibration and intermediate check plan.

| Equipment       | Action                  | Frequency | Procedure                      |
|-----------------|-------------------------|-----------|-------------------------------|
| Balances        | Certified calibration   | Annually  | External provider (NIS, EOS)  |
| Intermediate    | Check                   |           | On site by laboratory senior  |
| Verification    | Check                   | daily     | On site by analyst            |
| Calibration     |                         |           |                               |
| Weights         | Certified               | Annually  | External provider (NIS, EOS)  |
| Intermediate    | Calibration             |           | On site by laboratory senior  |
| Micropipettes   | Certified               | Annually  | External provider (NIS, EOS)  |
| Intermediate    | Calibration             | Monthly   | On site by laboratory senior  |
| Verification    | Check                   | daily     | On site by analyst            |


\[ S_p = \sqrt{1 \sum s_i^2} \]  

(1)

Equation (1) assumes that the single standard deviations have degrees of freedom \( n \), where the pooled standard deviation has degrees of freedom \( mn \). For new series of measurements, the standard deviation, \( S_{\text{new}} \), can be tested against the pooled value, the test statistic is:

\[ F = \frac{S_{\text{new}}^2}{S_p^2} \]  

(2)

The precision of the balance is judged to be in control if:

\[ F \leq \text{critical value from the F-distribution} \]

**Micropipettes intermediate check procedure**

The intermediate check of micropipettes was carried out using a gravimetric method based on ISO 8655-6:2002 standards (ISO 8655-2, 2002; ISO 8655-6, 2002).

Under a constant temperature and atmospheric pressure, the density of distilled water is constant. The volume of water can be determined by weighting dispensed water. The intermediate check of the micropipette is carried out by gravimetric method monthly. When determining the volume of water, the accuracy of measurements is affected by ambient temperature, atmospheric pressure, and relative humidity. These factors are usually combined to give the Z factor (ISO 8655-6, 2002). Standards shall be used in the calculation of the volume of water. Then, the mean volume \( V_m \) of calculated volumes of water from equation (3) is compared with the theoretical volume to determine the accuracy and precision of the micropipette.

Calculation includes the mean volume \( V_m \), systematic error \( e_s \) microliters using equation (4) or in percent using equation (5), random error as the repeatability standard deviation \( S \) equation (6) random error can also be expressed as a percentage by the coefficient of variation \( CV \) equation (7).

\[ V_i = m_i x Z \]  

(3)

\[ e_s = V_m - V_i \]  

(4)

\[ e_s\% = 100 \times \frac{V_m - V_i}{V_i} \]  

(5)

\[ S = \sqrt{\frac{\sum_{i=1}^{n} (V_i - V_m)^2}{n - 1}} \]  

(6)

\[ CV = 100 \times \frac{S}{V_m} \]  

(7)

Where,

- \( m_i \) = mass of each delivered quantity
- \( Z \) = correction factors at the mean temperature and pressure measured
- \( V_i \) = volume to each delivered quantity

\( e_s \) = Systematic error
\( V_i \) = Selected Micropipette volume
\( V_m \) = Mean volume
\( S \) = Standard deviation
\( n \) = the number of measurements
\( CV \) = Coefficient of variation,

The values calculated from equations (3) to (6) were compared directly with the absolute or relative maximum permissible random errors specified in ISO 8655-2:2002. If the calculated results do not exceed these specified values, the micropipette calibration is acceptable. If not, the micropipette has to be fixed or adjusted by the manufacturer’s agent and calibrated again before returning it to service (Blues, Bayliss, & Buckley, 2004).

**Control charts**

Control charts describe process variation with time and differentiate between common cause variation and special cause variation. Common cause variation usually results from essential elements of the process, which is called background noise and is usually predictable in any process. Special cause variation is usually due to some specific or assignable cause, something that is not predictable. Control charts show how the process is doing and, when the process changes, show very quickly that a change has occurred.

The control chart uses the result mean of a large data as the centerline, where the upper and lower control limits (UCL, LCL) are mean plus and minus 3 times the standard deviation (Mean ±3S) respectively. Once the chart is applied to the process, it shows how the mean of the processed samples varies over time (Grimshaw, Blades, & Miles, 2013).

Western Electric Rules (WECO rules) are decision rules for detecting “out-of-control” or nonrandom conditions on control charts. The Western Electric Rules were identified by a specially appointed committee of the manufacturing division of the Western Electric Company and published in the first edition of its Statistical Quality Control Handbook in 1956 (Western Electric Company, 1956).

The four WECO control chart rules are

Rule 1. Any single data point falls outside 3S limits from the centerline above UCL or below LCL.

Rule 2. Two out of three consecutive points fall beyond 2S limits on the same side of the centerline.

Rule 3. Four out of five consecutive points fall beyond 1S limits on the same side of centerline.

Rule 4. Nine consecutive points fall on the same side of the centerline.

**Results**

The precision of balances was checked in July 2020, using intermediate check historical data from
March 2019 to February 2020 and it is judged to be in control because of the calculated $F \leq$ critical value from the F-distribution with $n = 10$ degrees of freedom for $S_{h_{20}}$ and $m.n = 120$ degrees of freedom for $S_p$. Critical values of $F$ for a one-sided test at $\alpha = 0.05$ significance, Table 2.

Table 3 represents the results of intermediate checks carried out for CLEQM micropipettes included in the study in addition to the error limit according to ISO 8655-2:2002 standard for single-channel air displacement micropipettes. The results showed that the calculated random and systematic errors for micropipettes were less than the limit errors specified in parts 2 of ISO 8655 and so, all micropipettes are considered to be under control and achieve the appropriate accuracy for performing CLEQM routine work with the required precision.

The precision and accuracy of micropipettes in CLEQM were checked in March 2020, the test was carried out in a normal laboratory stable environment. The test rooms have a relative humidity (51.3% to 53.6%), the constant temperature ranged from (19.2 to 20.1°C) and atmospheric pressure of 1021.3 ± 0.25 (mbar).

Micropipette error was evaluated according to ISO 8655-2:2002, which gives individual limits for the accuracy or systematic error ($e_i$) and another limit for precision or random error ($S$) or (CV%).

Sensitivity verification of laboratory equipment is done in a continuous way and represented in the form of a control chart to evaluate the equipment with regard to its reproducibility and process performance over time by studying variation. An example of control charts for balance #D449800220 in the inorganic laboratory and micropipette #13587154 in the microbiology laboratory are represented in Figures 1 and 2 respectively.

Applying the four WECO rules on the control chart are represented in Figure 1 All readings included in the chart were within the control limits for 20 months (from Jan. 2019 to Aug. 2020) till it got out of control in Sept.2020, the balance #D449800220 is out-of-control conditions, according to both the 2nd and 3rd rules, and this indicates a shift in the population average and could be due to that the measuring equipment going out of calibration so this balance need certified calibration and till this action takes place it will be out of service.

Control charts for 16 balances were monitored through the same time period (January 2019 to December 2020) and it was found that the stability periods for 10 balances were ranged from 18 to 20 months and there are 3 balances completed the monitoring period (24 months) without getting out of control limits, while 3 balances were out of service.

Regarding micropipette results of the check, applying the same rules (WECO rules) to Figure 2, it was noted that all readings included in the chart were within the control limits for about 11 months (from January to November 2019) and the micropipette #13587154 got out of control in December 2019 according to the 3rd WECO ‘s rule.

Control charts for 23 micropipettes were monitored, and it was found that the period of stability of all micropipettes sensitivity ranged from 8 to 13 months before it needed recalibration.

Regarding the implementation of the CLEQM calibration plan for the last 5 years (2015–2019), as shown in Figure 3, it is noted that CLEQM calibrated 78 equipment in 2015 with a total cost of 33,154 L.E.

### Table 2. The results of intermediate checks (IC) for balances, using a weight of 100 g.

| Laboratory Balances | Balances | Organic | Inorganic | Soil | Soil | Plant |
|---------------------|----------|---------|-----------|------|------|-------|
| Balance serial #    |          |         |           |      |      |       |
| $S_p$ ($\text{March,19 to Feb,20}$) | 0.091 | 0.066 | 0.199 | 0.214 | 0.143 | 0.139 |
| $S$ ($\text{Jul,20}$) | 0.083 | 0.050 | 0.202 | 0.226 | 0.139 | 0.139 |
| $F$ Calc.           | 0.832 | 0.810 | 1.030 | 1.115 | 0.945 | 0.945 |
| $F$ Critical degree of freedom $n = 10$ for $S$, $m = 12$ and $m.n = 120$ for $S_p$ | | | | | | 1.91 |

### Table 3. Intermediate check results of micropipettes in CLEQM for March, 2020 compared with error limits according to ISO 8655-2:2002.

| Micropipette vol. | 1000 µl | 500 µl | 200 µl | 100 µl | 50 µl | 10 µl |
|------------------|--------|-------|-------|-------|------|------|
| Micropipette serial No. | 13587154 | 13563653 | 13556398 | 13854543 | BC0106 | 14616850 |
| Mean volume ($V_m$) | 1004.38 | 502.35 | 200.84 | 100.75 | 50.38 | 9.93 |
| Random error | | | | | | |
| $S$ µl | 2.16 | 1.13 | 0.52 | 0.30 | 0.18 | 0.04 |
| $S$ (% (ISO 8655–2002)/±µl | 3.00 | 1.50 | 0.60 | 0.30 | 0.20 | 0.08 |
| CV% (Coefficient of Variance) | 0.22 | 0.23 | 0.26 | 0.29 | 0.35 | 0.36 |
| Systematic error | | | | | | |
| $e_i$ µl (Accuracy) | 4.38 | 2.35 | 0.84 | 0.75 | 0.38 | −0.07 |
| $e_i$ (% (ISO 8655–2002)/±µl | 8.00 | 4.00 | 1.60 | 0.80 | 0.50 | 0.12 |
| $e_i$ (% (ISO 8655–2002)/±% | 0.44 | 0.47 | 0.42 | 0.75 | 0.76 | −0.68 |
| $e_i$ (% (ISO 8655–2002)/±% | 0.80 | 0.80 | 0.80 | 0.80 | 1.00 | 1.20 |
and there was a normal increase for both the number of the equipment and the cost till reaches 128 equipment in the year 2019 with a total cost of 108,347 L.E. the overall cost of the external calibration was more than 338,000 L.E. during the last five years, and it is expected that the cost of calibration performed externally will be doubled within the forthcoming 4 years.

Through the analysis of results of the external calibration of some electronic balances and micropipettes over the last five years, which were conducted by accredited external calibration bodies, it is clear that the differences between the uncertainty values for the same equipment are almost negligible, and some balances have remained that way for the 5 years as shown in Table 4.

The usual budget for equipment calibration could be reduced if intervals between recalibrations can be stretched legitimately. The objective of intermediate checks is to preserve trust in the calibration status suitability of auxiliary equipment in-between calibrations. Where results are favorable, intermediate checks can justify the extension of calibration intervals, and

![Figure 1](image1.png)

**Figure 1.** Evaluation of balance sensitivity using control chart.

![Figure 2](image2.png)

**Figure 2.** Evaluation of micropipette sensitivity using control chart.

![Figure 3](image3.png)

**Figure 3.** CLEQM annual calibration cost and number of calibrated equipment from 2015 to 2019.
Table 4. Annual calibration uncertainties reported by calibration body for some balances and micropipettes over the last 5 years.

| Equipment                  | Sensitive Balances | Micropipettes |
|----------------------------|--------------------|---------------|
| Laboratory:                | Microbiology13584543 |               |
| Serial no:                 | 28910901           | 15003216      |
| Microbiology2910901        | D44900050220       | Plant 16306746|
| Soil                      | 135556398          | Microbiology 71206480 |
|                           | 13557154           | Microbiology 13587154 |
| Annual calibration uncertainty |                    |               |
| 2015                      | ±0.4 mg ±0.5 mg    | ±0.03 mg ±0.03 g |
| 2016                      | ±0.4 mg ±0.5 mg    | ±0.03 g ±0.03 g |
| 2017                      | ±0.4 mg ±0.5 mg    | ±0.03 mg ±0.03 g |
| 2018                      | ±0.4 mg ±0.5 mg    | ±0.03 g ±0.03 g |
| 2019                      | ±0.4 mg ±0.5 mg    | ±0.03 g ±0.03 g |

Table 5. Comparison between advantages and disadvantages of fixed calibration intervals and calibration according to control chart.

| Calibration Interval | Advantages | Disadvantages |
|----------------------|------------|---------------|
| Fixed Intervals (every 6, 12 months …) | Easy to implement equipment | "Out-of-calibration" equipment may be in use, Test reports may need to be recalled |
|                      | Easy record-keeping | Equipment may be calibrated too often (Extra cost) |
|                      | Requires little expertise for staff | More work, Unbalanced work load |
| Control Charts       | Calibration intervals are flexible | |
|                      | Can help to predict out of control situations | |
|                      | Cost effective | |

consequently, intermediate checks are not a substitute for calibration.

It is expected that the value of the external calibration cost reduction will be from 25% to 40% of the total annual cost when adopting the fixed intervals policy according to the device's intermediate check and control chart. Table 5, represents a comparison between the advantages and disadvantages of calibration using fixed intervals and a control chart.

Conclusion

CLEQM perform a regular intermediate check to maintain confidence in the calibration status of measuring equipment between recalibrations as a part of its integrated quality management system. This paper presents the results of intermediate checks of electronic balances and micropipettes used in CLEQM daily analytical routine work in the field of water quality monitoring. Regular intermediate check allows for shortening calibration intervals if errors larger than allowed are detected. Similarly, calibration periods are lengthened if instruments are fluctuating within close limits of the original calibration.

It is concluded from all the above that laboratory equipment needs for a certified calibration are not necessarily neither to be annually nor at fixed time intervals. But equipment should be tracked through its control charts, and in case that the device goes out of control, calibration is performed immediately.

It is expected that the value of the external calibration cost will be reduced by about 25% to 40% of the total annual cost when recalibration intervals were decided according to regular intermediate checks.

Recommendation

From the results obtained, it can be recommended to advise laboratory managers to replace their calibration plan from fixed time intervals to a more dynamic plan according to getting out of control limits. Consequently, they should provide the required certified reference materials and qualify their analysts to carry out a regular intermediate check for laboratory equipment. Following this procedure will decrease potential risks that can be raised from getting out of calibration limits, in addition, to reduce annual calibration costs by up to 40%.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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