

GOOD MEASUREMENT PRACTICE - CALIBRATION CONTROL

BY

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INTRODUCTION

Since the 1960s when one of the first formal documents for calibration system requirements - the NATO Allied Quality Assurance Publication AQAP 6 - was introduced, there has been a growing demand for companies to have calibration control of instrumentation within their quality/management systems. Further calibration system requirements documents Def-Stan 05-26, BSI 5781 and ISO 100012 part 1, have given new impetus to the need for intelligent calibration control of instrumentation. In 1999 the ISO/IEC Standard 17025 was introduced and calibration control of instrumentation is fundamental in its requirements. This paper has been written to show how one accredited calibration laboratory has tackled the problem and to give guidance and ideas on meeting the requirements for calibration control of instrumentation set by the various standards including ISO/IEC Standard 17025.

1. Categorisation of instruments

The first step is to categorise all instrumentation into classes. Each instrument used for inspection, measurement or test is identified and classified. It is also assigned a current calibration status¹.

There are, effectively, 6 classes of calibration - defined as follows:

Class 1: Instruments reserved for use as reference standards only

Class 2: Instruments used for recorded inspection, measurement or test

Class 3: Instruments which are for general purpose use to give an indication only and thereby not requiring calibration but being subject to periodic functional checks

Class 4: Instruments used for experimental work, which may require adjustment or modification immediately prior to use .

Class 5: Instruments not maintained in accordance with any of these classes of calibration are labelled Uncalibrated.

Class 6: Instruments quarantined or otherwise withdrawn from service

2. Equipment List

All instruments are recorded in a central database along with details of the calibration class, current status and the next scheduled calibration/cross-check. A file is generated for each instrument which is used for inspection, measurement or test, and requires controlled calibration. This file contains a header or summary sheet, locally referred to as an "instrument history card". This card contains a summary of critical information; eg purchase details, when it was placed in service, calibration dates/certificate references and any anomalous behaviour. The file contains copies of all calibration data and evidence of performance acceptance by the relevant designated authority.

For equipment, which requires no calibration but controlled maintenance, a similar file and instrument history card is raised although the type of card is clearly differentiated. .

Depending on the instrument's calibration class an appropriate label is raised and attached to the instrument or its normal container - if the label could affect performance. These labels clearly indicate the company name and the status, i.e.

“Calibrated”
“Calibrated” (with limitations of use)
“For indication only”
“Check before use”
“Uncalibrated”
“Out of Service”

3. New Instruments

New instruments are checked for the following details: -

Manufacturer/supplier of the instrument
model number (including associated components)
serial number(s)
permanent/normal location.

The instrument class is determined in conjunction with the relevant designated authority.

If the new instrument has a certificate of calibration, the calibration results must be examined by the relevant designated authority to check that the results are satisfactory for the intended purpose. The designated authority must determine the calibration interval.

The new instruments are added to the equipment list.

4. Call-in and Calibration

The responsibility for ensuring that the calibration schedule is maintained lies with the Quality Manager.

At the beginning of each month or other specified period the Quality Manager will identify which instruments are due for re-calibration by printing out the relevant month's "due for calibration" list.

Calibration is normally arranged at an approved supplier by the relevant Laboratory Manager. He/she will raise a purchase order and raise a despatch note. If supplying the instrument with mains/test leads or manuals this information is recorded on the despatch note. Consideration is given to the most suitable shipping arrangements – reference standards usually being carried in company vehicles only. To despatch other general-purpose instruments, the appropriate company is contacted and arrangements are made for them to collect.

On return of the calibrated instrument, the Laboratory Manager or designated authority will arrange for the instrument and the calibration data to be checked/accepted before placing the unit back in service. . The Quality Manager is informed that the instrument has arrived back on site and is passed any calibration certificate.

The calibration results must be examined by the relevant designated authority, together with the results of prior calibrations. A decision must be made as to whether the instrument has a calibration satisfactory for its intended purpose, ie: whether the quoted measurement uncertainty and any errors are within the limits set in the relevant uncertainty budgets. The designated authority must also check if the calibration interval needs to be extended or reduced, whether any interim calibration checks are needed, whether a calibration label has been raised and attached to the instrument and whether any relevant software has been updated and verified.

The Quality Manager will ensure that:

- The equipment list on the database is amended to include the latest calibration change
- The appropriate instrument history card is updated and correctly filed

- The new calibration data has been reviewed and accepted and the re-calibration data has been justified
- For calibrations, where relevant and practical, a check will be made that the instrument has been sealed to prevent from tampering

If any instruments are not re-calibrated and the period of calibration expires, an uncalibrated label will be attached to the instrument

The Quality Manager will also ensure that an “uncalibrated” label is generated for instruments, which cannot be found or are still being calibrated by a sub-contractor. The label is then filed in a pending file so that it can be attached to the instrument when it is located - except if the instrument has returned from the sub-contractor and the results are satisfactory. In this case the uncalibrated label can be destroyed and the normal acceptance/labelling procedure can be followed

All other paperwork is passed to the Quality Manager and filed as appropriate.

5. Calibration Intervals

Calibration intervals are to be reviewed for each item of measurement equipment after every routine calibration. This review is the responsibility of the appropriate Laboratory Manager. Although each Laboratory will have particular requirements, the following general principles are applied:

5.1 Nature/design of equipment

The instrument under consideration will be susceptible to change in performance over time to greater or lesser extent, based partly on the construction, materials and operating principle. A high quality stainless steel standard mass, for example, is inherently stable by design. Similarly, most mechanical dimensional measurement equipment if used carefully in a clean environment will remain stable. In all these cases contamination and handling are the main factors affecting stability.

In the case of electronic equipment the likelihood of change is greater and relates to circuit design and stress experienced by the components. Assuming that the design is good (e.g. well-established instrument amplifiers etc) and the components are adequately rated, then performance after initial burn-in is likely to be stable. Probably, the most likely source of change is due to temperature cycling and for this reason critical laboratory equipment should be left powered (unless Health and Safety requirements dictate otherwise). Most electrical reference standards (e.g. dc/ac calibrators) incorporate an oven to keep Zener references at a constant temperature. These standards must be left powered if low drift characteristics are expected.

If the instrument’s operating mode entails certain forces (mechanical or electromagnetic) then wear potential will need to be considered. For example pressure balances are essentially piston/cylinder assemblies and in normal operation the surfaces are subject to relative motion and hence friction. It is therefore likely that drift due to wear (change in area and hence pressure) will occur with use.

5.2 Requirements of specific measurement procedures

Although different laboratories may use similar pieces of equipment, the actual allowable performance of the equipment may well be very different. Clearly, the effect and requirements of the measurement procedures associated with low-uncertainty primary standard work will be very different from simple high-uncertainty routine calibration. When evaluating the appropriate calibration interval for reference equipment the Laboratory Manager must consider the actual use of the equipment and the relative magnitude of drift-related change compared with other factors such as repeatability of measurement, temperature or noise. For example, a well protected and infrequently used FI class mass will exhibit virtually no drift – the principle uncertainties in use coming from balance performance (off-centre loading etc). In such cases any apparent drift in the mass is more likely to be associated with measurement uncertainty of the reference laboratory. Therefore, intervals will be long as drift is a far less dominant contribution to the overall measurement uncertainty.

5.3 Recommendations of the equipment – manufacturer

Once the history of a particular reference equipment has been obtained, the manufacturer's claims for the instrument's performance become far less important. Although the original manufacturer's information may be useful, it is only the performance of the instrument over time which will dictate how best to decide on the calibration interval. It should be noted that manufacturer's claimed performance should be regarded with caution as they are often found to be optimistic.

The most important use of the manufacturer information will be when an item has first been purchased and there is no other available information. In this case the Laboratory Manager should consider either reducing the manufacturer's quoted calibration period as a precaution or take clear steps to provide an internal crosscheck of the item with another reference standard (or stable artefact e.g. a check-weight) to be sure the performance of the equipment remains acceptable.

5.4 Precedence of model/type

If similar or duplicate equipment is purchased to expand a Laboratory's throughput capability, it is generally acceptable to consider the calibration history of the current equipment in deciding on the appropriate calibration interval (obviously the decision to purchase such equipment may well have been based on this information).

5.5 Extent and severity of use

All reference equipment should be fit for purpose based not only on the amount of use, but also the severity. E.g. if a reference item is continually being used at the limit of its range, consideration must be made for any long-term deterioration and whether it is appropriate for continued use. In some cases it may be necessary to recalibrate (or at least crosscheck) a reference item immediately after extreme use to be sure that the performance is satisfactory.

In the case of mechanical devices e.g. weights, if they are unused for long periods it would be expected that their long-term stability should be good and therefore an extended calibration interval could well be justified.

5.6 Influence of the environmental conditions

In all cases the environmental conditions should be suitable for obtaining acceptable measurements. This includes influences such as vibration, power supply levels and cleanliness as well as temperature and humidity. In most laboratory situations the impact of such factors will be moderated and therefore unlikely to adversely affect stability. However, in the case of on-site calibration the normal laboratory conditions may well not exist. It may therefore be necessary to consider a reduction of the calibration interval accordingly.

5.7 Uncertainty of the measurement claimed

The most important consideration for stating a calibration interval is to ensure that the claimed measurement uncertainty, when using a particular reference standard, can be met and maintained. In the case of UKAS accredited calibration laboratories there will be an agreed best measurement capability based on a particular procedure and reference standard. To ensure that this capability can be sustained the performance of the reference standard must be reviewed and if necessary the calibration period altered. It is essential that this remains a purely technical decision and not a commercial decision, unless the best measurement capability is to be increased (degraded).

As new and improved reference standard equipment is purchased it may release lower uncertainty (better) equipment for higher uncertainty (less precise) calibration. As the performance of the reference standard may be sufficiently over-specified, it could enable the laboratory manager to increase the calibration interval (for that specific application), but still maintain the required level of uncertainty (for the service offered).

5.8 History of previous calibrations

The calibration history of the reference standard is critical in providing a justifiable technical basis for the calibration interval. In most circumstances three consecutive calibrations are required to provide a history. With less than three calibrations the manufacturer or similar equipment information will also be required.

The calibration history is used to provide the reference standard drift information that can justify the proposed calibration interval. It is suggested that simple spreadsheets be used to analyse the calibration history in a statistical or graphical form. From this analysis the laboratory manager can determine the level of reference standard drift which forms an important part of any uncertainty budget. If the determined drift is sufficiently low and there is no requirement to reduce the best measurement capability there could be justification for extending the calibration interval.

5.9 Evidence from service and maintenance records

If an item of reference equipment is found to drift outside acceptable limits and requires adjustment or component replacement then the interval will need to be reconsidered and usually reduced until confidence is regained. The same is true of any item that receives a shock or unexpected overload. The performance must be monitored more closely either by increasing the frequency of crosschecks or reducing the re-calibration interval.

5.10 Results of in-house checks detailed in individual procedures manuals

An essential process of maintaining confidence in reference standards is through the use of in-house checks. These are stated in the individual laboratory procedures manual, but for example it could be a check at a point which is included in the upper range limit of one particular standard and the lower range limit of the next stated standard. Both points will have proven traceability and should agree within the acceptable uncertainty limits. This type of check provides vital stability information and can also be used to justify or extend the calibration interval.

5.11 Changes to calibration intervals

Having considered all of the general principles it is the responsibility of the appropriate Laboratory Manager to review the calibration interval of each reference item. If there is a sound technical basis for changing the calibration intervals e.g. from calibration history, this must be submitted and authorised by the appropriate Technical Manager or relevant Laboratory Manager.

6. Extension for the use of uncalibrated equipment

If an instrument requires to be used for a short period after the calibration period has lapsed, for example due to instrument being booked "in" to a subcontractor or awaiting return of an instrument to replace equipment with an expired calibration period, the Laboratory Manager/ Laboratory staff must: -

Produce written justification and reasons to extend the calibration period together with any data as appropriate.

The written justification must be agreed by, signed and dated by the relevant area Laboratory Manager and also agreed by, signed and dated by the relevant Technical Manager.

The written justification will be sent to the Quality Manager for final acceptance.

On acceptance, the Laboratory Manager/Laboratory Staff will raise a new calibration label with new date and attach it to the instrument, removing the old label.

The Quality Manager will amend the database and all relevant paperwork.

When the instrument has been properly re-calibrated the calibration results must be examined by the relevant designated authority, together with the results of prior calibrations.

If the designated authority discovers a problem with the calibration data, which could have an affect on the calibration of customer equipment. The relevant customer equipment must be recalled and re-calibrated.

7. Repair and maintenance

Any member of staff finding an instrument which has suffered damage, or possible damage due to impact, vibration, overload etc, or is evidently not functioning correctly, is responsible for promptly taking the equipment out of service and informing the relevant Laboratory Manager.

Laboratory Managers will inform the Quality Manager by raising a report and the Quality Manager will arrange for the instrument to be taken out of service, amend the equipment list on the database and amend the instrument history record card.

The relevant designated authority will decide whether to repair or scrap the instrument. If a decision is made to repair, the relevant Laboratory Manager is responsible for sending the equipment away.

If the instrument is normally calibrated, the Laboratory Manager will arrange for re-calibration to be carried out at the same time.

On receipt of the instrument, the Laboratory Manager will arrange for the instrument to be checked and placed back in service in the appropriate laboratory, using the same procedure as detailed previously described.

The Laboratory Manager/Laboratory staff will raise a calibration label or other appropriate label and attach it to the instrument.

If a decision is made to scrap the instrument, the Quality Manager must be informed. The Quality Manager will amend the equipment list and archive the history card and calibration certificates.

8. Equipment on short term lease or loan

Laboratory Managers are responsible for informing the Quality Manager of test and measuring equipment, which has been hired or borrowed for use in the laboratories.

The Quality Manager will record the details of the loan.

The Laboratory Manager must file all instrument records in the relevant project file.

Long term loan or hire instruments will be subject to the same calibration controls, as equipment owned by the company/laboratory.

9. Personally owned instruments

Personally owned instruments are not permitted.

10. Conclusions

It is hoped by the authors of this paper, that their contribution to this conference will assist and help other organisation in planning their own calibration control of instrumentation system, especially the section on calibration intervals.

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Ref: 1. Sira Instrument Test and Calibration Work Instruction WI 05, Issue 12, 23.06.2004

Further reading;_

1. ISO 10012-1 and ISO 10012-2
2. Papers from 2005 NCSL International Workshop and Symposium 7th to 11th August 2005, Washington DC as follows:-
 - a) Dr Howard Castrup – Calibration Intervals from Variables Data.
 - b) Suzanne Castrup – Obtaining and Using Equipment Specifications.
 - c) Alex Lepex – Status Report on the WG on Standards for Instrument Specifications.
 - d) Timothy Mason and James Smith – Essential Elements and Benefits of a Successful Test Equipment Management Program.
 - e) Edward Snell – Equipment Management Description and Analysis of Methods to achieve and maintain All Active Assess in Calibration Status.