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MEASURING INSTRUMENT MANAGEMENT IN ISO QUALITY MANAGEMENT SYSTEM ENVIRONMENT

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ABSTRACT

Measuring instrument accuracy and consistently meeting measurement accuracy are the two main issues of argument especially when product conformity is based on the measured results ultimately affect organisation profit. ISO quality management systems required measuring instrument to meet requirements; however there is no specific instruction on how to determine measuring instrument is fit for purpose and continuously to do so. The practices become individualistic and apparently lack of monitoring mechanism to prove that these methods could statistically and or logically justified.

This study researches into process of instrument management from early stage of recording the identity to activities to ensure fitness for use at all time of usage. This study proposes some mathematical models and charting techniques to tackle the research problem. Experiments were conducted with the help of a SAMM accredited calibration laboratory to collect information to investigate implementation feasibility. The contributions can be grouped into two parts they are the formulation of equations involve in measuring instrument capacity, capability and compensation for correction. Whereas second part is using control charts techniques to prove long term continuous meeting fitness for purpose.

Control charts are introduced as intermediate check procedures to qualify the instrument at any time. The technique is completely different from traditional statistical process control chart. There are five different charting techniques meant for various instrument accuracies. The novel part of the study is researching into performing intermediate check for reference standards using ABC chart. There is no doubt that these procedures are more complicated than the traditional methods; however they are convincing due to the use of statistics couple with the current concept of metrological traceability. The application for patent is in progress.

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LIST OF ABRAVIATION

C	Correction
GMP	Good manufacturing practice
GR&R	Gauge repeatability and reproducibility
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organisation for Standardization
LC_L	Lower control limit
M	Measurand
MR	Metrological requirement
MRA	Mutual recognition arrangement
MSA	Measurement system analysis
MU	Measurement uncertainty
QMR	Quality management system
R_{High}	High range
R_{Low}	Low range
U	Expanded uncertainty
UC_L	Upper control limit

LIST OF EQUATION

1	$(R_{low} + U) \leq M \leq (R_{high} - U)$	21
2	$U \leq MR$	25
3	$\|C\| \leq MR - U$	28
4	$\mathrm{c} = -\mathrm{e}$	35
5	$x = p + c$	35
6	Upper control limit, $UC_L = x + MR$	35
7	Lower control limit, $LC_L = x - MR$	35
8	$y = (d + c) \pm U$	36
9	$y \rightarrow d$	38
10	$y = d \pm U_{art}$	38
11	$y = d + U_{art}$	38
12	$y = d - U_{art}$	38
13	$UC_L = x + MR - U_{art}$	38
14	$LC_L = x - MR + U_{art}$	38
15	$\|c\| \geq MR_{art} - U$	39
18	$\overline{x} = \frac{\sum_1^n x}{n}$	44
19	$\sigma = \sqrt{\frac{\sum(x - \overline{x})^2}{n}}$	44
22	$x = x_0 + \delta A + \delta B$	44
23	$xy = y_0 + \delta A + \delta C$	44
24	$z = z_0 + \delta B + \delta C$	44
25	$y = y_0 + \delta A$	44
26	$z = z_0 + \delta B$	44
27	$x = x_0 + \delta A$	44
28	$y = y_0 + \delta A$	44
29	$z = z_0$	47
30	$x = x_0 + \delta A + \delta B + \delta I$	49

31 $$y = y_0 + \delta A + \delta C + \delta I$$ 49

32 $$z = z_0 + \delta B + \delta C + \delta I$$ 49

33 $$confidence \equiv \frac{1}{t} f\left\{\left(\frac{1}{usage}\right), \left(\frac{1}{storage}\right), \left(\frac{1}{handling}\right)\right\}$$ 51

LIST OF PUBLICATION

A) Presented a research paper

a. Title :An Alternative Method To Determine Measuring Instrument Fitness For Use

b. Conference :2012 International Conference on Manufacturing and Optimization (ICMO 2012) 2012

c. Organized by : International Association of Computer Science and Information Technology (IACSIT)

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B) Presented a research paper

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CHAPTER 1

1. Introduction

ISO Quality Management System (QMS) is a family of management systems being practice worldwide. Its acceptance has become a default requirement by manufacturing and marketing sectors. Implementing the systems require commitment, knowledge and will power from all levels of people within an organisation. It is common to encounter problems related to management of the requirements generated internally, external factors or the combination of both for example measurement activities have to meet criteria for its role in determining acceptance or reject of products or services. There is no denying that measuring system management plays an important role in determining quality measurement result. There are few questions as to the validity of measurement result

a) Is the measuring instrument capable of achieving the minimum accuracy required?
b) Is the measuring instrument too accurate to meet the requirement that demands higher budget to acquire?
c) Is the measuring instrument continually meeting the requirements at all times?

In both cases, the user landed in quality cost constrain situation. ISO QMS demand this issue to be addressed for example ISO/IEC 17025 [72] clause 5.5.2 states *Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the test and /or calibrations concerned.*

A similar sentence appear in the latest edition of ISO 9001 [45] clause 7.1.5 states *The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.*

The other ISO QMS [22][24][28][31] capitalise on ISO 9001 requirements as fundamental requirements thus identical statement appear in these QMS too.

1.1. Research problem

Trust worthiness of test report or calibration certificate reflects the integrity of the laboratory performing the test or calibration. It is a practice today that ISO/IEC 17025 accreditation scheme being treated as the default management system for laboratory who wish the report to be accepted, recognised and trusted. There are many issues the laboratory has to comply with and one of them is the management of measuring instrument. Similarly the other ISO QMS too, have such requirement to meet where measurement is a tool to qualify product or process acceptance. Unfortunately this area is also the favourite of auditors as one of the most disputable in terms of implementation. Variation in practices by itself becomes problems encounter by system practitioners. The issues concerned are

a) Non validated, statistical and logically unjustified methods
b) Effectiveness and acceptance of methods by all stakeholders

The latest edition of ISO 9001:2015 includes requirements from ISO/IEC 17025 to ensure that the measuring instrument is fit for purpose and continuously doing so have added to the urgency to address the problems because other ISO QMS shall follow the footsteps soon.

1.2. Objectives of research

This study takes the initiative to research into managing measuring instruments holistic picture as well as providing

a) statistically validated procedures to determine measuring instrument fit for purpose and continuously to so that can be accepted by ISO/IEC 17025 accredited laboratories.
b) The procedures can be adopted by other ISO base and non ISO base QMS without any modification or adjustment made and eventually could become the standard practice.

1.3. Boundary of the research

False signal from measurement may induce negative impact and inflates quality cost. Such signal could have caused by multiple factors. They are

a) Human resource involves in taking the measurement
b) Environmental, accommodation conditions and Measurement method
c) Measuring instrument

This study does not take into account of the holistic picture of measurement system instead only emphasis on the measuring instrument fitness for use, or commonly known as accuracy of measuring instrument determination. Thus factors concern human resource, environment, and methods of measurement are not the interest. This study sub sectionalise into three sections they are

a) measuring instrument list
b) capacity and capability determination of measuring instrument and
c) intermediate check.

The initial section is how to determine which instrument need calibration and which one does not because not every piece of instrument has to be calibrated to determine information to be listed in the list of measuring instrument and the second section is to determine the capability and capacity of measuring instrument meeting requirements for intended use. The third section is to determine measuring instrument continue to be fit for purpose. As such the study provides complete measuring instrument management system readily to be implemented.

The research paper *An Alternative Method to Determine Measuring Instrument Fitness For Use* [1] was an initial research into determining measuring instrument fitness for use in line with ISO/IEC 17025 clause 5.5.2 requirement. This study is the further research to fine tune the subject of study meeting variations in its application. There are limitations encounter during implementation especially in the area of measurement capacity and correction compensation.

1.4. Methodology

The methodology to test the hypothesis is through

a) Fit for purpose study using mathematical models

b) Intermediate check using control chart technique is implemented by pilot laboratory.

The objectives are to understand the feasibility to implement the hypothesis.

1.5. Patent application

Application for the patent is in progress.

1.6. Summary of research intention

Measuring instrument fitness for use and continuously to do so are the problems encounter by people practicing ISO QMS because these management systems do not provide clear procedures. This study researches into providing solutions to the research problems; however with limitation to measuring instrument management of these systems only not as holistic study of the system.

Proposed mathematical models to be tested through empirical data analysis.

CHAPTER 2

2. Literature review

The review divides into two main sections to facilitate the understanding of the subject. Section 2.1 concerns measuring instrument accuracy and Section 2.2 is dealing with continuously meeting the accuracy requirements.

2.1. Fitness for use

This section of literature review is regarding measuring instrument accuracy. Measurement accuracy is defined by VIM [47] as *closeness of agreement between a measured quantity value and a true quantity value of a measurand.* Thus a low accuracy measurement means the result is far away from the agreed value and high accuracy is near zero error of the agreed value. This definition supplemented with a note to provide better understanding.

NOTE 1 states: *The concept 'measurement accuracy' is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.*

Conventionally accuracy relates to measurement error which is defined by VIM 2.16 as *measured quantity value minus a reference quantity value.*

2.1.1. Requirements from ISO QMS

ISO 9001:2008 [44], a very popular ISO QMs and being adopted widely in terms of geographical region and the nature of organisation operations. The system does not specify criteria for accuracy of measuring instrument but does mention the requirement to meet for metrological traceability in clause 7.6

Where necessary to ensure valid results, measuring equipment shall:

be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.

This document emphasis on calibration and traceability seems to be the deficiency of this system; however the latest version ISO 9001:2015 [45] edition has taken this issue by inclusion of clause 7.1.5.1a states

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.
The organization shall ensure that the resources provided:
a) are suitable for the specific type of monitoring and measurement activities being undertaken;
b) are maintained to ensure their continuing fitness for their purpose.
The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.
The sub clause "a" States clearly users of measuring instrument use in the process have to determine its fitness for use and the last sentence of the clause needs to provide evidence of such activity. Unfortunately the system does not provide any solution or procedure.
ISO/IEC 17025 [28][72] the current version of accreditation for testing and calibration laboratory specifies the needs to have measuring instrument meeting requirement in clause 5.5.2. It reads
Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the test, and or calibrations concerned.
At least these two systems recognise the importance of measuring instrument meeting accuracy requirement and provide quality data.
An interesting part of ISO/IEC 17025 is clause 5.5.11 where it mentioned compensation for correction factor. All literatures reviewed do not take this factor into consideration as part of measuring instrument accuracy except OIML R111 [82] the error of standard weight has to be at least three times better than the class below. Clause 5.5.11 reads as
Where calibration gives rise to a set of correction factor, the laboratory shall have procedure to ensure copies are correctly updated.

The other popular ISO QMSs designed for specific business operations are also adopting ISO 9001 document. As such their requirements are similar. ISO/TS 16949 [27] has additional requirement in clause 7.6

2.1.2. QMS certification bodies documents supporting conventional method

Traditional methods of determining accuracy of measuring instrument needed according to multiples of the resolution. Refresh the literatures supporting such procedures as follow:

Literatures from SAC-SINGLAS Singapore issued documents and directives for SINGLAS accredited laboratories. Technical Notes MET 001 [96] clause *3.1 states all measurement standards and equipment shall meet the requirements of the calibration method and/or shall be capable of meeting the measurement uncertainties nominated by the laboratory for the purposes of accreditation.*

Clause 3.2 The laboratory shall ensure that its equipment is suitable for the purpose for which it is used and that its suitability for that purpose is maintained throughout its working life. The two specific requirements clearly state the need to have measuring instrument meeting measurement uncertainties and consistently meeting it.

There is a quantitative statement states in clause 3.4

Accuracy ratio is the ratio of the accuracy of the measurement standards to the accuracy of the equipment under test. Generally, the accuracy ratio is targeted between 4:1 and 10:1 but with a minimum of 2:1, wherever possible.

However SINGLAS Technical Note C&B and ENV 002 [92] the latest additional technical notes issued on 30th June 2016 has discarded the ratio of accuracy instead either not mention at all or refer to accuracy of equipment manufacturer specifications. Thus far this is the document provides quantitative statement. It is interesting to note the ratio of accuracy is between 4:1 and 10.1. Note that there is no reference to these ratios. As well as no mention of under what circumstance need to use the specific ratio.

NATA, The National Association of Testing Authorities Australia too, issued documents relating to measurement system, Biological Testing and Chemical Testing [75] [76], Mechanical testing [77][78] ,these documents mentioned the need to meet

accuracy but miss out concrete procedure to achieve it. NATA Technical notes 23 [81] in Equipment and Instrumentation section states

All equipment and instrumentation should be of a specification consistent with its intended purpose and suitably maintained in good working condition to ensure its continued satisfactory performance.

This statement is no difference from the other statements quoted earlier, they emphasis on the importance of suitability for intended use in other words is the accuracy or fit for purpose.

UKAS, The United Kingdom Accreditation Service, also produces documents relating to the use of measuring instrument and calibration like other national accreditation agency. LAB24 [98] section 4.3

As a guide, any instrument or reference standard used should have accuracy 10 times better than that of the device being calibrated. The actual accuracy required will be determined by calculating uncertainty budgets for particular calibration regimes using defined calibration apparatus.

This statement is for reference equipment use in calibration of routine testing instrument but no mention of the accuracy for this routing testing instrument requirement when use in testing. Again it addresses partially the accuracy requirement for instrument use in upstream measurement not otherwise. This statement also appears in other UKAS documents for example LAB21 [99]. Whereas clause 4.2.4 of LAB 14 [100] indicates calibration of the weights used in calibration of weighing machine will be ⅓ of its specified maximum permissible error. This is different from other documents even though they are from the same organisation. This indicates that there is no specific rule that accreditation bodies adopt and most often is influenced by the practice or other organisations. This ⅓ maximum permissible error is also found in the requirement of OIML R111 part 1 [82] clause 5.2 states the expanded uncertainty U has to be less than ⅓ of maximum permissible error of conventional weights.

The latest edition of ISO 9001:2015 [45] clause 7.1.5 does not mention any thing about the ratio requirement but sub-clause 7.1.5.1(a) states *are suitable for the specific type of monitoring and measurement activities being undertaken*. It does require user to determine measuring instrument need to meet the measurement requirement i.e. it has to be fit for purpose but without providing any guideline.

2.1.3. Documents other than certification bodies

Jain in his book Engineering Metrology [16] clause 1.4.12 mentioned accuracy of measurement is the most important aspect of mechanical inspection. There are many factors affect measurement process include human and measuring instrument. A further statement in the same clause reads

The equipment chosen for a particular measurement which must bear some relation to the desired accuracy in the result, and as a general rule, an instrument which can be read to the next decimal place beyond that required in the measurement should be used, i.e. if a measurement is desired to an accuracy of 0.01mm, then instrument with accuracy of 0.001mm should be used for this purpose.

This is similar to SAC SingLAS ratio of 10:1 and assumed to be suitable for mechanical measurement rather than other fields.

Jain pointed out another important issue of inspection is the accuracy verses cost in clause 1.4.13.

The basic objective of metrology should be to provide the accuracy capability required at the most economical cost. The accuracy of measuring system includes elements of SWIPE. (S = standard, W = work piece, I=instrument, P=person, E=environment).

He pointed out that the cost rises exponentially with accuracy thus in practice the desired ratio of accuracy to tolerance is decided by considering the factors such as the cost of measurement versus quality and reliability criterion of the product. The accuracy formula put forward by Jain contains additional variable of cost on the argument a ratio of 10:1 would be very costly compare to 4:1 or even 2:1.

Six sigma improvement project looks at measuring instrument from different angle. Measurement system analysis or in short MSA, Measurement System Analysis is the recommended procedure. Forrest in his book Implementing Six Sigma [18] stressed that data integrity assessment is part of the activities of MSA. Accuracy of measuring instrument is determined based on at least ten times better than the range of the response that is of interest as stated in section 3.13. However the emphasis is on measurement variability which includes all random and systematic errors of the measuring system.

AIAG MSA-4 [56] is well known and often quoted as reference by ISO/TS 16949 [27] clause 7.6.2 for implementation. There is no difference in concept of MSA with Forrest and this manual state the Rule of 10 or 10-to-1 rule, the instrument discrimination

should divide the tolerance into ten parts or more in Chapter 1 Section B statistical properties of measurement systems. There is an interesting part of this requirement is the word discrimination rather than accuracy of measuring instrument. Discrimination is defined by this manual chapter 1 section E as the smallest scale unit of measure or output for an instrument. VIM [47] does not use this word instead uses resolution as *the smallest change in a quantity being measured that causes a perceptible change in the corresponding indication*.

Both definitions are very close and seem to be interchangeable to certain extent. MSA-4 adopts a fraction of resolution as key factor to determine accuracy of measuring instrument. SAC Technical Notes MET 001 does not relate resolution nor discrimination to accuracy even though it uses the ratio of accuracy to measurement of 4:1.

There is an element of near similar idea in MSA-4 is Gauge Repeatability and Reproducibility, in short is referred to GRnR. Measuring instrument capability to meet requirement is through a series of data collection and analyse the and the component of repeatability represents the capability of measuring instrument to requirements.

Fundamental Good Practice in Dimensional Metrology [15] Chapter 3 page 46 mentioned guideline for decision making rule based on ISO 14253 includes the requirement for measurement uncertainty. Thus the conventional concept of 10:1 ratio is not applicable.

Standard test and calibration methods described by ISO [22] [24] [25] [26] [29] [30] [31] [32] [33] [34] [35] [36] [37] [38] [39] [40] [41] [42] [43], ASTM [4] [5] [6] [7] and BS [8] [9] [10] [11] [12] [13] [14] are some examples quoted, usually stipulate stringent equipment accuracy requirements but there is no standard guidelines established apply cross the board for all standards test methods thus different test methods may adopt different approach for measuring instrument used.

2.2. Continuously fit for purpose

This section is regarding continuously meeting accuracy requirement at time of using the instrument. VIM does not define intermediate check. Similarly there is no document provides any explanation except documents issued by certification bodies for use by accredited or potential accredited laboratories. Neither SAMM SC 1.5 [86] nor SAC-

SingLAS documents mention about this issue. In fact none of Standards Malaysia's Specific Policies and other technical documents (SP 1 to SP 10, SC1.1 to SC 2, STR 1.1 to STR 2.8) suggest any method to carry out intermediate check.

2.2.1. ILAC-G24 [19]

A guideline document for determining calibration interval and intermediate check issued by ILAC touches on this requirement in clause 1. It suggests brief guidelines but not mandatory for implementation due to variations in business operation of accredited laboratories. This document suggests five methods

Method 1: Automatic adjustment or "staircase" (calendar-time)

Method 2: Control chart (calendar-time)

Method 3: "In-use" time

Method 4: In service checking, or "black-box" testing

Method 5: Other statistical approaches

No detail just idea and suggestions are the key issues of this document. The objective is to determine when to perform next calibration in order to improve the biasness and measurement uncertainty that can be achieved with the measuring instrument.

2.2.2. MS ISO/IEC 17025 [72]

This QMS is well known for its suitability in calibration and testing laboratories for the purpose of accepting the test report or calibration certificate, i.e. for laboratory accreditation schemes. It is adopted worldwide as the fundamental document of accreditation schemes. Standards Malaysia too, adopts it in the scheme call SAMM. There is a requirement by ISO/IEC 17025 clause 5.5.10 where measuring instrument needs to perform intermediate check periodically but does not provide specify the terms and conditions nor techniques to perform such checking.

It state *when intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure*.

This statement induces the need for such activities to ensure the performance of measuring instrument continuously meeting the metrological requirements.

2.2.3. ISO 9001:2008 [44]

This is a very popular ISO QMs and being adopted widely in terms of geographical region and the nature of organisation operations. Conducting periodic checking on measuring instrument performance is briefly described in clause 7.6

Where necessary to ensure valid results, measuring equipment shall:

be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.

The other popular ISO QMSs designed for specific business operations are also adopting this document. As such their requirements are similar. ISO/TS 16949 [27] has additional requirement in clause 7.6

Clause 7.6.1 Measurement system analysis, MSA

Statistical studies shall be conducted to analyse variation present in the result of each type of measuring and test equipment system. This requirement shall apply to measurement systems reference in the control plan. The analytical methods and acceptance criteria used shall conform to those in customer reference manuals on measurement system analysis.

Clause 7.6.2 Calibration / verification Records

Records of calibration / verification activities for all gauges, measuring and test equipment need to provide evidence of conformity of product to determined requirements shall include…..

2.2.4. ISO 9001:2015 [45]

This is the latest edition of ISO 9001, not in full implementation yet because the existing certified organisations are given transition time of two to three years to migrate to this new edition. There are two new requirements appeared in this edition, they are clause 7.1.5.1 (a) and (b). The interesting issue is the insertion (b) where it requires the measuring instrument at all time of usage is fit for purpose. This requirement most probably copied from ISO/IEC 17025 clause 5.5.10.

2.2.5. New trend

The latest edition of ISO 9001:2015 shows that this ISO QMS puts heavy weighting on measuring instrument continuously meeting accuracy requirement. One can foresee other QMS shall follow this trend for the coming editions because this QMS forms the skeleton structure of all ISO QMS.

2.2.6. No specific techniques provided except ISO/TS 16949 state MSA

All these management systems emphasis on both the calibration and periodic performance check procedures in order to obtain quality measurement data. Calibration is to ensure measuring instrument meeting metrological requirements whereas conducting periodic performance check is to make sure the instrument continuously meeting the requirements. One of the techniques in MSA-4 is stability, is to check the performance of measuring instrument over period of time. The technique is arguable because it uses process unit as reference or it uses the term Master, which by nature may have drifted in value during production. Mathematical formula is used to identify changes cause by instrument also known as repeatability and changes cause by the operator also known as reproducibility. It is not the formula arguable instead is the procedure to carry out the experiment. It is not easy to differentiate whether the variation s caused by the instrument or the reference.

2.2.7. Current practice by SAMM accredited laboratories

Even though there is no reference document on current practice by SAMM accredited laboratories, it is understood that SAMM allows them to perform any method of verification with no justification to the argument and accuracy of methods. In other words there is no control over the methods adopted.

2.3. Findings of literature review

There are two sections of literature review; one is for fitness for purpose whereas the other one is for continuous fitness for use.

Accuracy of measuring instrument affects the reliability of test result. Literatures from ISO QMS state the need to have proper management of measuring instrument but no mention of techniques or methods. Whereas some documents from QMS certification

organisation suggest certain minimum ratios of measuring instrument accuracy from one in two to one in ten. Various techniques are adopted and the most common technique is based on multiples of resolution. This study shows that there is no one common understanding on the accuracy of measuring instrument use in the testing process not to mention having common practice thus different test methods may adopt different approaches for measuring instrument used.

These conventional methods have been adopted for a long period and yet problems still persist indicates that they are not effective. An effective procedure is urgently needed to address the issue. Documents from other organisations do suggest certain ratio of accuracy. Empirical information from GRnR as suggested by MSA-4 utilises empirical information to justify changes cause by measuring instrument over a period of time.

There is no mention of continuing meeting the accuracy in most literature except ISO/IEC 17025 and the latest edition of ISO 9001. ILAC G24 provides guidelines to perform continuing meeting requirement as well as calibration interval but no detail procedure.

ILAC-G24 provides five principles to carry out intermediate check or measuring instrument verification but without detail. On the other hand one of the techniques in MSA can be treated as intermediate procedure. The other documents from related organisations do mention the need to have control of measuring instrument over period of usage again no specific procedure stated. The element of Stability in MSA-4 is a good method but the procedure is arguable whether the indication of change is due to measuring instrument or the reference.

The situation is again similar to determine fit for purpose. All these documents emphasis on the need to have procedures, to address the issue but limited guidelines are provided.

CHAPTER 3

3. Introduction to measuring instrument information management

This chapter proposes information management regarding documentation and records of measuring instrument control system. Properly managed information reflects trust worthiness of an organisation, effectiveness of the management also to meet QMS requirements. Measuring instrument user is responsible for the control and monitoring of instrument available in the facilities.

Guidelines on the control procedure that can meet all ISO QMS requirements with emphasis on ISO/IEC 17025 are listed in this chapter.

3.1. Measuring instrument list

Measuring instrument is asset of an organisation, there is no excuse not to maintain a list of measuring instrument registration. The function of this registration is to maintain a complete list of measuring instrument available irrespective of status of functionality another function is to meet financial audit purpose.

Minimum common fields to include are description, manufacturer, model number, serial number, control number, location, calibration required, range, unit, calibrated by, calibration date, due date, in service. The critical fields are calibration interval, MR, MU, fitness for use.

3.1.1. Calibration interval

This field is regarding recalibration date. The user has to determine this period not the calibration organisation or department. This field can be in date or time period for example twenty four months or two years. The purpose is to remind the user not just the status of calibration but also as the promise to customer on regular recalibration. Traditionally it is called due date.

3.1.2. Metrological Requirement, MR

MR is metrological requirement which can be the process tolerance, allowable error, process specification or permissible error. The term MR is used to standardize the

terminology use and reduces confusion. Usually this field would not change unless there is new project or new customer or change in process requirement. This field is to monitor the instrument capability.

3.1.3. Measurement Uncertainty, MU

Measurement uncertainty obtain from the calibration certificate is suggested as an important field in the list is to monitor the performance of the instrument every time send for calibration. This can be used as long term monitoring of the instrument.

3.1.4. Fitness for use or fit for purpose

This is field is to monitor the status of fit for purpose of the instrument. The criteria is according to Equation (1). Note that the instrument may not be used even it is fit for purpose. There is another field in the list is the “in service” field which indicates the current status.

3.2. Determine calibration list

User is reminded that not every measuring instrument has to be calibrated because ISO QMS demands those affect the validity of result only need calibration. Thus user has to determine which one need calibration and which does not. Budget for calibration can be reduced through reduced the number of measuring instrument send for calibration; however it is the decision of the organisation whether to calibrate every single piece. The guideline is as follow:

3.2.1. Process measuring instrument

Criteria to determine process instrument calibration is the metrological requirements MR. Measuring instrument use at the process and making decision to check whether the process or product meeting requirements have to meet the MR. Any instrument not to be used for such purpose shall not be calibrated. Refer to Appendix 1 as an example of a process flow chart with measuring instrument indicated with metrological requirement and the identification. Only these instrument need to be calibrated. Any instrument not listed here need not be calibrated.

At times management uses verification instrument to check the validity of process instrument for example supervisor carries an identical instrument taking second measurement. Should this instrument be calibrated? The question is which one determines acceptance of the quality, process instrument or supervisor validation?
If the process instrument is the one being used for acceptance than the supervisor's instrument need not calibrate. Then it has to be listed in the process chart too. In fact is this step of measurement verification necessary?
If on the reverse supervisor's instrument shall be calibrated. Normally the supervisor verification is an additional procedure carries no weighting in quality management. The management has to understand the implication of process requirements.

3.2.2. Laboratory measuring instrument

There is a different method for laboratory instrument. Work instruction or quality instruction shall state the instrument use in the testing or calibration. Instrument not listed need not be calibrated. Note that indirect measurement instrument for example instrument provides environmental condition for example oven still needs to be calibrated because it has to prove that the environmental condition meets the requirement. Measuring instrument providing consistency involve in environment as factor in measurement uncertainty evaluation the laboratory has to ensure no instrument miss out while writing the work instruction.

3.2.3. Instrument needs no calibration

Measuring instrument not listed for calibration may not require calibration; however they may be listed in the master list as organisation assets. No calibration sticker or label preferably shall display on the instrument to differentiate status of metrological traceability. Another function of this sticker is to avoid unnecessary argument with auditor. Refer to Appendix 2 for no calibration sticker. This sticker is an example for illustration purpose. User may change the design to suite organisation culture.
Similarly instrument keep in storage or spare unit need not be calibrated until it is needed.

3.3. Calibration authority

The next step is to determine who can perform calibration. There are specific requirements for some ISO QMS whereas some not specify. Calibration authority can be categorised into

a) ISO/IEC 17025 accredited laboratory

   This laboratory is the reliable third party calibration house. The certificate issued by this laboratory is endorsed by the accreditation body and usually only one accreditation body for a specific scope of work for a country. Cross border recognition through ILAC MRA enables the calibration certificate to be recognised by other countries. Note that accreditation scope is only within the scope listed by the accreditation body thus it is not a blanket type of accreditation.

b) Non accredited laboratory

   This is where a laboratory performing calibration without the endorsement by accreditation body. The reliability is in question. Measuring instrument manufacturer's laboratory and or supplier's laboratory without accreditation status is categorised under this category.

c) Internal calibration facility

   Organisation set up a calibration laboratory for internal consumption. Usually for cost saving purpose due to large quantity of measuring instrument and need to assign budget for external third parties. Accreditation status is not an important issue; however accreditation status would be an advantage for recognition purpose.

The categorisation is to facilitate acceptance of calibration authority.

3.3.1. No specific requirements QMS

ISO 9001, ISO 13485, ISO 14001 are typical QMS do not implement stringent requirements in this area. Calibration can be conducted by anyone of the calibration laboratory in all the categories. ISO/IEC 17025 accreditation is not the primary concern whereas the important issue is calibration need to have metrological traceability. The current edition of ISO 9001and the stated QMS above require

a) personnel performing calibration needs to be competent thus as long as the laboratory can produce information regarding competence of the personnel performing calibration is sufficient to meet the requirement.
b) Metrological traceability to national standards is sufficient to meet the requirement.
c) There is no mention of internal calibration thus organisation with cost sensitive tends to perform internal calibration for cost saving. There is worry whether the calibration and facilities to conduct proper calibration are in place.
d) Records of calibration activities need to be kept according to the organisation stated period. Such records may include the original observation, calculation, reference instrument information for example calibration certificates, documents enable audit trial, calibration certificate.

3.3.2. Special requirements QMS

ISO/TS 16949 requires calibration to be performed by ISO/IEC 17025 accredited laboratory unless no such service available then non-accredited laboratory calibration may be acceptable; however the auditors usually demand cross border calibration service under such situation.

Internal calibration facility is acceptable provided

a) Personnel conducting calibration is competent
b) Proper environmental condition applied
c) Document the calibration procedure in full detail
d) Reference standards calibrated by accredited laboratory
e) Evaluate measurement uncertainty and report it in the calibration certificate
f) Records related to the calibration activity shall be kept and available.

ISO/IEC 17025 accredited laboratory has no option but to accept accredited calibration services includes internal calibration facility. Cross border accreditation calibration service is acceptable as long as the accreditation body signed MRA with ILAC. Similarly a national laboratory without accreditation status can be accepted provided the national laboratory conduct inter-laboratory comparison with other national laboratory.

3.4. Summary of measuring instrument information management

Not all measuring instrument need to be calibrated, the laboratory has to determine the list of measuring instrument through either from the process equipment list or laboratory test method. The list shall include some information such as MU, and fit for purpose. For equipment do not require calibration may not need to be calibrated and a no calibration sticker is a suggested stick to it to avoid confusion and mixing.

ISO/IEC 17025 made it compulsory for the accredited laboratory to have calibration perform by accredited laboratory whereas the other ISO QMS do not mention such requirement except ISO/TS 16949.

CHAPTER 4

4. Introduction to measuring instrument fit for purpose

This chapter is regarding measuring instrument fit for purpose determination. Measurement data quality contributes by many factors but can be categorised into the instrument, personnel and environmental conditions; however this study does not take into the account of all factors affecting the measurand except the measuring instrumentation. Measuring instrument fit for purpose is the main topic of discussion when negative issue made impact on the quality of measured data. This study provides a solution to the arguments through a series of formulae that provides convincing statistical information and follow with judgement to be made upon. The procedure divides into three main parts (a) the range capacity of the instrument to take the load of measurement, (b) capability to provide accuracy and, (c) the correction.

4.1. Determine Measurement Capacity adopt Equation (1)

The range of measurement of the measuring instrument determines its useful measuring range capacity. As a matter of logic the physical measurable range should cover the load to be measured. At no instant the measuring instrument to be used outside of this limits. Use this formula to determine the capacity limits.

$$(R_{low} + U) \leq M \leq (R_{high} - U) \quad \text{.....(1)}$$

R_{low} can be positive, zero or even negative value; however $R_{low} = 0$ is normally the case but not always. Example external micrometer measuring range of 50mm to 75mm range where $R_{low} = 50$ is not at zero instead is at 50mm. Another example is thermometer to measure sub-zero temperature, then$R_{low} < 0$.

U is the expanded uncertainty given in the calibration certificate of measuring instrument. Similarly R_{high} is the maximum load it could take and again it could be either positive or negative.

R_{low} is the lowest measurable point

R_{high} is the maximum measurable point

M is the measurand, the measured value

Literature review indicates that there has not been any concrete proposal in this area and the traditional methods and MSA, too do not address this issue most probably it has been taken for granted. This study taking capacity into consideration is because of the argument of limited calibration and the minimum capacity of measuring instrument to measure. There have been cases where auditors demand calibration to be performed at minimum usage range; however it may be impossible to do so for example smallest single piece standard weights with OIML R111 specification is 1mg and nothing lighter than this. User may weigh less than 1mg in actual weighing process when using analytical or micro balances. Refer to section 3.1.2 below for calibration requirement. This it is not practical to calibrate anything less than 1mg. Another example is linear measurement with less than 1mm where the thinnest standard gauge block is 1mm so a micrometer capable of measuring less than 1mm with accuracy in the region of micron meter i.e. 10^{-6}m may not be able to be calibrated at less than 1mm thick with gauge block. Some auditors consider the calibration range is insufficient for a micrometer to be used at any thickness less than 1mm when it is calibrated with minimum thickness of 1mm. The logic behind this formula as follow:

4.1.1. Metrological traceability

The measuring instrument should be calibrated to demonstrate that it has proper metrological traceability to SI units. There are many system of measurements exists but majority of the world has accepted this unit of measurement as their legal measurement unit. In fact ISO/IEC 17025 requires such requirement to be fulfilled.

Equation (1) fulfils this requirement through the use of expanded uncertainty adopted from calibration certificate.

4.1.2. Calibration

Calibration should cover the measurable range of the instrument as default requirement. Refer to equation (1). Full calibration is recommended in order to maintain wide useful measurable range. It shall cover from R_{low} to R_{high} .

Measurement uncertainty is another factor to consider since it is usually reported at 95% confidence level as norm. Other confidence level may be requested for special quality measurand.

There is shift in the definition of the term calibration. The latest definition according to VIM [48]

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

"No measurement uncertainty no calibration" means all calibration report or certificate must report measurement uncertainty otherwise it cannot be accepted as calibration. The definition clearly states that measurement uncertainty is the key factor in calibration activity.

Usual calibrated range starts with zero setting or no load. Interpolation of range may begin at zero to next setting even though the instrument needs to use at lower than the first setting but higher than zero value. It is not practical at times to use reference standards lower than the existing standards. For example a measurand needed is at 0.5mg and the balance is calibrated at first setting at zero then the next setting is 1mg. There is no such standards exist for standard weights of 0.5mg or 0.1 mg. similarly micrometer is used to measure thickness in micro, there is no reference standard gauge block with thickness of less than 1mm. The minimum length can be calibrated is 1mm. This study proposes calibration should start with no load as minimum range not minimum reference standards load as minimum range R_{low}.

4.1.3. Limited calibration

Limited calibration is where the measuring range is not calibrated at full capacity range instead calibrated at application range only or short range. Such calibration shall not affect measurement uncertainty evaluation. It is common for process instrument to perform this limited calibration for its limited application in manufacturing process, cost of calibration and shorter down time are the main concern; however the user has to understand that due to limited range it should not be used out of the calibrated range.

Extrapolation of the calibrated range is not allowed for its deficiency in metrological traceability. Equation (1) still applicable under such situation.

4.1.4. Interpolation and extrapolation of calibration curve

Interpolation within the calibrated measuring range is acceptable due to “known” values sandwich the unknown. It is common practice to calibrate at steps in between the range usually minimum 5 to maximum 10. Limited calibration may calibrate at particular reading. This unknown value can be estimated easily through several methods and the common ones as follow:

a) Take the nearest value if the difference between the two known value has very small difference, or
b) Estimated through graph plotting method of the whole range, the range values usually act as X-axis and the correction is plotted as Y-axis. Interpolated value of correction is read against the load on the graph. This method is recommended for manual compensation, or
c) Linear ratio is recommended if the difference of the nearest setting is large and near linear because this method is assuming the range is linear. It can be adopted for both manual and computer generated interpolated value of correction, or
d) Least square method through computer generated linear equation. It is good practice to check the validity of the predicted value using standard error of regression. Since the measurement uncertainty is estimated at 95% thus it would be convenience to take two times this error to check whether the predicted value falls within two standard deviations. This best line fit formula may not be practical method because there is no way to obtain the actual value otherwise through polynomial equation. Thus R^2 is recommended to check the quality of projected value and is nothing less than 0.98. One need to remember that 0.98 is not definite it is a guideline only. Any other means may be deployed to proof that it falls within 95% confidence level is acceptable.

   If the trend appears to be logarithmic, then convert the correction Y-axis to logarithm. Then plot the logarithmic least square. The rest is mathematics, or

e) Polynomial equation is good for the variation throughout the full range is not large otherwise calculated value may completely fall out of empirical trend. This method is the best recommended procedure due to its high accuracy of prediction provided the equation maintains high power usually higher than quadratic. It is suitable for computer generated correction and is not suitable for manual calculation.

There is no perfect answer to the solution, the issue matter the most is the accuracy of measurement needed. Calibration at very short range is unnecessary since interpolation is allowed, and not practical to do so.

Measurand through extrapolation in either direction; lower range or higher range cannot be accepted due to its estimated nature and cannot demonstrate proper metrological traceability.

4.2. Determine Metrological characteristics adopt Equation (2)

The next step is to determine capability of the instrument or conventionally is called accuracy. Literature review shows that there is no specific formula or method to determine accuracy. The traditional method of three to ten times ratio may proof too costly. This study proposes capability base on measurement uncertainty obtained from calibration certificate. This figure is compared to the user requirement for example allowable errors or even tolerance, a formula is formulated according to this minimum requirement. The advantage is it varies according to user requirements unlike traditional accuracy ratio disregard user requirement, user with less stringent requirement is penalised for cost of measurement. The formula uses measurement uncertainty to compare with user requirement, along as the logic is true it is capable of meeting the requirement otherwise it should not be used for not meeting user requirement. The equation

$$U \leq MR \qquad \text{.....(2)}$$

Where U is the expanded uncertainty reported in the calibration certificate

MR is the metrological requirement.

Metrological Requirement (MR) is not defined in VIM however this term is used in MS ISO 10012:2003 clause 6.3.1. states

Measuring equipment can be confirmed for use for particular measurement processes, and not confirmed for use for other measurement processes because of differing metrological requirements. Metrological requirements for the measuring equipment are derived from specified requirements for the product or the equipment to be calibrated, verified and confirmed. The maximum permissible error may be designated by reference to the published specification of the measuring equipment manufacturer, or by the metrological function

This statement clearly states metrological requirement can be permissible error, allowable error, tolerance, specification or limits set for measurement.
This fitness formula provides the most economical measuring instrument capability cost unlike the traditional method adopting accuracy or resolution ratio. There is no direct linkage between measurement uncertainty and resolution in fact it is one of the components of measurement uncertainty. Both do not change concurrently in magnitude and phase since measurement uncertainty involves other factors whereas resolution is the smallest indication by design. The argument is the probability of measured value falls within the requirement assuming there is no correction as shown in Appendix 3.
Assuming a measured value is 5mm and requirement is ±0.05mm. Assuming “A” is the measurement requirement or in this case is the metrological requirement, “B” the measurement uncertainty of the measuring instrument reported in the calibration certificate at 95% confidence level just manages to fit into the requirement. This is assuming correction equals to zero where the measured value falls on the mean of the uncertainty. This is the most economical situation and is said to be fit for purpose. “C” is the situation where the measurement uncertainty is less than the metrological requirement. Somehow the probability of measured value falls outside the requirement is less than 5%.This is the condition where measuring instrument has better accuracy than required. On the other hand the cost of measurement may be higher due to smaller uncertainty which usually associates with higher cost of measuring instrument. Nevertheless it is still fit for purpose.

"D" illustrates the situation where the measuring instrument does not meet the requirement due to measurement uncertainty larger than the requirement. There is a probability of measured value falls out of the requirement. Thus it is not suitable for use.

The argument above is extracted from previous research and still applies where the expanded uncertainty may be reported at any confidence level, as norm 95% is acceptable. Higher confidence level shall enlarge the expanded uncertainty. Is it necessary?

As long as this equation is true, the measuring instrument is said to have met the requirement thus it is fit for purpose. On the other hand if the equation is false, then it is not suitable to be used.

4.3. Determine the Need to Compensate for Correction adopt Equation (3)

VIM defines correction as *compensation for an estimated systematic effect*. ISO/IEC 17025 requires this factor be compensated for every reading taken otherwise this systematic error may cause drift in the measurement thus producing poor quality datum.

The probability density diagram shows in Appendix 4, when $C = 0$ black curve, when bias exist it may shift to either left or right of the mean. The amount shifted is indicated as "C"

This bias error exists in all measuring instrument with differences in magnitude. In the past the main calibration activity was to remove it through adjustment to zero or near zero but today adjustment is not a part of calibration activity. Instead measurement uncertainty is part of calibration activity and the calibration certificate usually provides this correction values over the range in the calibration certificate. Any adjustment done today is considered as additional service to reduce its magnitude so that it enables user to use the equipment without compensation.

The argument is how significant is considered significant otherwise as insignificant. If the magnitude is too small to affect the measurement quality or in other words the correction is insignificantly affect the quality of measurement then whether the compensation is necessary?

If the correction magnitude is significantly large to affect the quality of data then it should not be neglected otherwise it shall affect the metrological traceability. How small is the magnitude to consider insignificant?

The early research formula number 2, measurement uncertainty was not considered in the equation,$|C| \leq \frac{2}{3}MR$, the principle may hold when $U = 0$; however when $U \neq 0$ then this equation may encounter problem. Modification to this formula is needed to include *U* irrespective of its magnitude.

This study proposes new formula replacing the old one as follow:

$$|C| \leq MR - U \qquad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots \qquad (3)$$

Equation (3) above taking measurement uncertainty as a factor. Note that when $C = 0$ this equation becomes equation (2).

If equation (3) is true, the correction is insignificantly small to affect the datum; on the other hand the magnitude of correction is significantly large to affect the datum, it is possible to fall out of the requirement. As such there are actions necessary to follow.

4.3.1. Actions to follow

When the logic is true, it is not necessary to compensate for the correction for every datum taken because the effect is too small to affect the quality of measurand with respect to metrological requirement. Thus correction can be assumed $C = 0$ because it is now insignificantly affecting the quality of measurand. On the other hand when the logic relation is false, the user has to consider whether to compensate this correction because it is now significantly affecting the quality of measurand. The correction *C* combine with measurement uncertainty *U* may cause the measured value to fall out of the *MR.* As such it is not suitable to be used.

There are two options to choose, first option is not to compensate then this measuring instrument is not fit for purpose and should be discarded. The second option is to compensate for every datum measured.

Compensation is troublesome especially user at process operation level, could due to

a) inability to conduct arithmetic calculation
b) not practical, when there are multiple units with different correction values.

c) Definition of reference standards. For example standard weights have been defined in OIML R111 for various classes and this value is one of the data taken into account. User is encouraged to understand the impact of classification.
d) Safety issue. Measuring instrument use for safety purpose should have met the design specification. Compensation of correction should not be compromised. Process measuring instrument use in this area for example pressure gauge, safety switches and sensors react to over setting value to avoid unwanted incident to occur.

4.3.2. Treatment for correction as measurement uncertainty component

Correction is one of the factors of deviation in measurement, if assuming $C = 0$ then it should be treated as a component in evaluation of measurement uncertainty of the measurand.

When correction is compensated then it should be removed from the evaluation.

4.4. Sequence of determine measuring instrument fit for purpose

The procedure is according to the sequence below. It serves no purpose when the sequence is not in order.

4.4.1. Equation (1)

This equation is to determine measuring instrument capacity, $(R_{low} + U) \leq M \leq (R_{high} - U)$, if the logic is false then it is not suitable to be used for this measurement; however it may be suitable for other measurement. If the logic is true then go to the next step.

4.4.2. Equation (2)

This logic is to determine metrological characteristics fitness for use, $U \leq MR$, when this logic is false, the action taken is similar to Equation (1) not to be used. If the logic is true then the metrological characteristic is suitable, go to the next step.

Where U is the expanded uncertainty stated in the calibration certificate
MR is the metrological requirement.

4.4.3. Equation (3)

This logic relation is about correction, $|C| \leq MR - U$.

a) If the logic is true then use it assuming correction, $C = 0$, otherwise the management has to decide whether to compensate for the correction.
b) If the decision is not to compensate then it is not suitable to be used,
c) otherwise every measurement has to compensate for the correction.

4.5. Summary for measuring instrument fit for purpose

The measuring instrument is said to be fit for purpose when it has gone through this process. The next step is to perform intermediate check which is not the interest of this study. Appendix 5 shows the flow sequence to determine measuring instrument fitness for use. It is important that the sequence should not be mess up. The initial step is to determine equation (1), If the logic is true then go to the next step other not fit for purpose. One has to make not that the termination of fitness for use is for this particular process only; however it may be suitable for other processes.

Equation (2) shall be followed when the logic is true from equation (1). If this is false then it should be discarded as not fit for purpose. If true then go for next equation (3). The instrument is deem fit for purpose when it goes through this equation test; however if the result is false then the user has to make decision whether to compensate for the correction. If the decision is “yes” then use the instrument with compensation for correction for every datum collected. If not the instrument is said unfit for purpose.

CHAPTER 5

5. Introduction to measuring instrument intermediate check

This chapter is the continuation of chapter 4 and it should be read in sequential order of the chapter. This section is regarding measuring instrument continual meeting the requirements at the time it is in used and prompt action to be taken when it is found to deviate from the agreed norm. Quality data come from quality tool management. It is the responsibility of user to ensure appropriate management is in place. This study is based on the requirements of ISO/IEC 17025 because it has the most stringent terms to meet and thus no problem to cover other ISO QMSs.

This issue of continuing fit for purpose has long been eye catching as measuring instrument tend to drift in its performance over a period of time. Traditionally multiple readings at a measuring position or positions along the entire range are taken or compared to the so called master piece and use some mathematical models to explain the drift and justify for the usage. Such activity is called measuring instrument verification. Due to no agreed procedures and mathematical models to analyse data, interpret and follow up activities, therefore the practice differs very much from one organisation to others.

5.1. Performance properties variation, the significance of change

Handling, storage and usage affect the performance properties of measuring instrument. The variations mainly cause by design, material use and principle of operation and they exhibit systematic and random errors patterns. The concerned is the magnitude of change rather than the change itself since performance properties variation is unavoidable. If the magnitude of change is insignificant with respect to the last calibration, then it means no problem to meet the requirements of fitness for use after some period of usage. On the other hand the instrument may not able to meet accuracy required because the change has significantly affected data quality. The concern is how could the user realise variation has significantly affected the data, or is it too late to realise. Usually visual inspection could not detect such variation.

The weakness of the traditional model is its unknown effectiveness from technical point of view. This paper researches into understanding measuring instrument performance drift and quantify on time base models. The term intermediate check is adopted as in ISO/IEC 17025 to streamline and bridge the gap between users and system requirements. Not only that ILAC-G24 and ISO/IEC 17025 are also adopted as the main references.

5.2. Principles of technique deploy

In view of the commercial nature, cost is the main concerned and next comes user friendliness. Complicated procedures or have to involve heavy financial investment may not be viable. The education background and capability of the users to understand and apply the techniques vary widely may have negative impact on the implementation. Fundamental statistical principles and arithmetic are unavoidable thus simplification of the technique prevails.

A chart is preferred because human visual ability to extrapolate a trend is better than interprets pattern from numerical numbers. Time base charts are plotted instead of mathematical functions relate to acceptance criteria are designed to be user friendly. Run chart provides good visual effect on current and historical pattern of drift or variation. Control limits are added to the chart on both upper and lower sides improve the effect whether the drift still laying within the limits or otherwise. Appropriate actions can be installed according to observed position of the last point plotted.

Fundamental requirement on implementation is the user just need to know how to collect quality data and may not have full understanding of the principle. Later transfer the datum and plotting points on pre-prepared graphical charts follow by appropriate action taken to be taken. Of cause an organisation needs to have at least a champion in order to have effective implementation. The principles, calculations and prepare chart at initial stage may be performed by the champion but may not be their routine function. The distribution of duty depends largely on the organisation size and management philosophy.

There are five charts proposed with variations in theoretical concept as well as practice procedures.

5.3. Control chart base on MR as control limits (MR chart)

This first proposal is a run chart with control limits set base on Metrological requirement, MR. Refer to Appendix 26 Case study on implementation of control chart clause 3.4 as reference.

5.3.1. Principle for MR chart

The fundamental concept is that as long as the value obtained falls within the control limits, it is a good value irrespective of whether it is caused by the measuring instrument, environmental condition or the operator because this is the tolerance where the product or service can tolerate. Any datum collected falls beyond these limits is considered unacceptable. The control limits are the compound effect of

- measuring instrument drift,
- ambient conditions
- user error include the capability of the user's ability to use the instrument in the most appropriate manner
- process variation includes repeatability and reproducibility of the process

5.3.2. Artefact for MR chart

An artefact can be a reference or working standards use as master piece to conduct intermediate check. It is the consistency of physical property of the artefact being measured over period of time. For example artefact for balance is standard weight or gauge block for calliper or micrometer. The balance indicates the weight of artefact this datum is then transferred to the chart for appropriate action to be taken. Thus the choice of artefact is critical as action taken depend largely on this value obtained. There are 3 issues to consider

- Physical properties of the measuring instrument.
- Cost to acquire
- Long period of usage and Replacement

a. Properties of the measuring instrument

Balance is to weigh an object, thus the artefact for balance intermediate check should be weight that can provide consistent weight over some period of time. This is the

basic requirement to maintain its physical property consistency. If the object to be measured remains consistent then the possibility of drift is caused by either human or the measuring instrument. Well trained personnel could eliminate this factor then left the only one that is the measuring instrument. A suggested list of artefact is listed in Appendix 6.

The list is by no means complete but provides a guideline for the choice of artefact. Ice point is preferred for its low cost and easily reproduced at 0°C. Standard weight class F2 and below is recommended for its resistant to corrosion and oxidation as well as low cost. Standard weights class F1, E2 and E1 are not recommended for their high cost to acquire. Similarly gauge block of grade 1 and 2 are recommended not Grade 0, K nor 00 suggested for dimensional instrumentation for its metrological characteristics. It is costly to machine a block of metal with measuring surfaces smooth to mirror shine and parallel.

b. Cost to acquire

The other issue is the cost of acquiring the artefact. Intermediate check is to ensure measuring instrument at the time of usage still fit for purpose otherwise the user may need to perform recalibration more often at much shorter period. This is not a practical solution for cost, down time and availability of the service to be justified. The cost to acquire artefact should be justified otherwise high cost of artefact may be substituted by much shorter period to recalibrate the instrument.

c. Long period of usage

The artefact shall be used for long period of time ideally until the end of intermediate check; however it may be replaced anytime with similar known value artefact. The technique proposed is based on absolute value not relative value. Calibration is important to ensure consistently similar property of artefact is available. How often should it be calibrated? There is no hard and fast rule, generally well maintained artefact may need about 2 to 3 years per calibration and the measurement uncertainty (MU) has to be smaller than MR otherwise annually is no harm. Recalibration at any time may be required when the artefact shows sign of instability or damage.

d. Measurement uncertainty and correction factor of artefact

An artefact with larger measurement uncertainty than the MR is not suitable since the value obtain any one time may fall out of control limit. The small the MU the better it is. The limit is the cost to acquire it.

Recall formula (1) $\mathrm{U} \leq \mathrm{MR}$, this U is the uncertainty for measuring instrument, that means

- $\mathrm{U_{art}} < \mathrm{U_{MI}} \leq \mathrm{MR}$. …….. (3)

Where $\mathrm{U_{art}}$ is the uncertainty of artefact

$\mathrm{U_{MI}}$ is the uncertainty of measuring instrument

This value of certainty has to be included in the chart at stage two.

Correction factor can be obtained from calibration certificate. Some accredited laboratories use the term correction and others use error. There is no specific guideline from Standards Malaysia which term to use. Normally they are interchangeable $\mathrm{c} = -\mathrm{e}$ …….(4)

Where c is the correction and e is the error.

Correction can be very small but do not expect it to be zero. This figure has to be considered or compensated during stage two plotting process.

5.3.3. Stage one charting MR chart

There are two stages during implementation process, stage one is the initial process where the basic structure of chart is formed. There is no base data to be collected since the limits are based on the MR.

Take the value of artefact stated in the calibration certificate p, compensates for the correction, c, as centre tendency value x.

Therefore $x = p + c$ ……..(5)

At time $c \to 0, x = p$

Both upper control limit (UC_L) and lower control limit (LC_L) are calculated using the formulae below

- Upper control limit, $UC_L = x + MR$ ----------(6)
- Lower control limit, $LC_L = x - MR$ ----------(7)

The value x is taken as the centre line and plot it on the centre of a graph paper with X-axis as the time base line. The value of artefact is plotted as Y-axis. UC_L and LC_L

are plotted along the x line. Refer to Appendix 7, illustrates this basic structure of control chart.

5.3.4. Stage Two charting MR chart

Stage two is the application stage where it begins at the completion of stage one. Basically the same piece of artefact is being used to take a reading and only one reading is taken, d which is not the value to be plotted instead has to be compensated for correction. Thus the actual value is y with measurement uncertainty included is

$$y = (d + c) \pm U \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (8)$$

This reading is then transferred to the chart and plotted as the position with respect to t_1 (stock point y_1). This point is plotted as stock point. Refer to diagram 3.3.4. A stock point, due to $\pm U$ is a point plotted with higher and lower values vertically across the y value. Equation (8) indicates y is expressed as range due to measurement uncertainty of artefact is included in the calculation.

This technique is not interested in the repeatability of the measuring instrument thus no average of few readings is required. The first reading should indicate the bias of the instrument.

The process of taking this reading can be performed by anyone trained to do so. In principle the user is the best person but should not be traded for organisation culture. The important issue is not the person to collect data instead it is the follow up action to be taken. Refer to Appendix 8 for the illustration of stock points plotted on MR chart.

5.3.5. Follow up action to be taken

There are 2 options for action to be taken by the user.

- Do not disturb, continue to use
- The equipment shows unhealthy condition, Stop using it

a. Do not disturb, continue to use

Take this action when y and its high and low values transferred to the chart is plotted within the control limits. Note that it is not just the point y within the control limits, should cover the extreme of both high and low stock point. The position can be either upper or lower part of the X value to the worst condition the higher value is below UC_L and

the lower value is above the LC_L. Bias does present but it is insignificantly affecting the quality of datum d collected. It provides confidence that the measuring instrument is in good condition meeting the MR thus the user may continue to use without disturbance to the instrument until next plotting.

New point y_2 is plotted at the next interval. Points are encouraged to joint together so that drifting pattern is easily visible. Refer to diagram 3.3.4

b. The equipment shows unhealthy condition, Stop using it

When either higher or lower value of a stock point is plotted out of these control limits as shown point B in diagram 3.3.5, it indicates the instrument is in unhealthy condition. Bias presence could have affected the quality of the datum collected in other words it is now significantly affecting the measuring instrument. The instrument performance may not be able to meet the MR. User should stop using it while waiting for next action. Note that it is the higher or lower value falls out of control limit not the value y treated as the minimum condition to take this action. There is no difference if the whole stock point falls beyond the control limit.

Ideally another datum point B is taken half an hour later to observe for temporary systematic error being removed. Systematic error can have multiple causes at times they are temporary and others permanent in nature. The causes could be environmental, operator, design, material use, operating procedure, maintenance are just some examples quoted. If the second plot falls within the control limits, it indicates the systematic error could be temporally in nature. A confirmation plot, point C is necessary half an hour later after this second plot. If it falls within the control limits it proves that the instrument may exhibit temporary systematic error and at this moment the systematic error has varnished. The user should take the first action to continue to use.

If the confirmation point C falls out of control limit then the instrument is still in unstable condition and not suitable for use. Plot the next point by double the time, i.e. one hour later. Continue to do so by doubling the time taken until the confirmation point falls within the control limits.

If there is no confirmation point appears after about 5 plotting, then the instrument could have exhibited significant permanent systematic error. Thus it is not suitable for use. The follow up action most probably is to repair, service and recalibrate the

instrument. A new chart may not be necessary since the MR remains, thus current chart still serves the purpose.

5.3.6. Simplified version of MR chart

The charting technique above seems complicated with inclusion of correction and measurement uncertainty of artefact. Equation (8) adds difficulties to whoever plotting the chart. Recall equation (8) $y = (d + c) \pm U$ It is not an easy task to calculate and plotting stock point. If both correction and uncertainty are relatively small then, then equation (8) becomes

When $c_{art} \rightarrow 0, U_{art} \rightarrow 0$

Then $y \rightarrow d$. ……..(9)

It is easy to plot a point under such condition not stock point. Value *d* obtain from the instrument directly transfer onto the chart without calculation as shown in Diagram 3.3.6.

There is a problem with equation (9) when $U_{art} \neq 0$

Therefore $y = d \pm U_{art}$…….(10)

Thus this simplified MR chart has to plot with equation (11) for $y > X$, and use equation (12) when $y < X$

$y = d + U_{art}$ …….(11)

$y = d - U_{art}$ …….(12)

5.3.7. An alternative to simplified MR chart

The simplified MR chart above needs some arithmetic calculation and the instruction for equations (11) and (12) may seem complicated for some. An alternative to this is to plot the value of y direct without making any calculation.

The control limits have to include measurement uncertainty of artefact. Thus equations (6) and (7) are modified to become

$UC_L = x + MR - U_{art}$ ……..(13)

$LC_L = x - MR + U_{art}$ ……..(14)

Where U_{art} is the measurement uncertainty of artefact

These control limits have included uncertainty of artefact so that the user need not worry about equations (11) and (12). The control limits are narrower than the other MR

chart. The advantage of this chart over the other MR charts is that no calculation is required with $y = d$, and transfer the value *d* obtained direct onto the chart.

However this chart could not be used under condition when correction of the artefact is relatively large $|c| \geq MR_{art} - U$ .....(15)

where MR_{art} is the metrological requirement for the artefact not the MR of the measurement. Note that Equation (15) is the reverse of equation (3) that satisfies the condition where the instrument needs compensation of correction otherwise not fit for purpose. Refer to Appendix 10 note that the chart does not have stock points thus the plotting becomes simpler.

5.4. Control chart base on MU as control limits (MU chart)

This second proposal utilises measuring instrument measurement uncertainty as control limits. This figure can be obtained from calibration certificate. Metrological confirmation requires measurement uncertainty, *U* to meet this mathematical relation $\leq MR$. It enables one to adopt uncertainty as limits of control replace MR. The formula indicates these limits are narrower than the MR chart.

Refer to Appendix 26, 3.4 MU chart example.

5.4.1. Principle of MU chart

The concept is similar to MR chart as long as the value obtained falls within the control limits, it is a good value. ISO QMS recommend measurement uncertainty to derive from GUM [20] method which is expressed as probability distribution. The reported uncertainty is an expanded value and usually at 95% confidence level [20] clause 6.3.3. The uncertainty components involve many factors for example measuring instrument resolution, repeatability, environment, metrological characteristics and traceability [48]. There are certain factors could have no influence on the measurement uncertainty after calibration; however there are many factors do have influences and may change according to usage, handling and even storage. It is difficult to identify individual component but not so as composite effect of overall changes which can be translated relative to the position plotted on the chart. The further away from the mean line, the greater the change is. This relative position enables one to determine whether the change is significant or otherwise.

Note that this chart considers very much on the measuring instrument performance unlike MR chart emphasis on measurement. This precondition $U \leq MR$ is required before anyone can use this chart.

5.4.2. Artefact for MU chart

The requirement for artefact use is similar to MR chart. There is an argument for the uncertainty of artefact which must be smaller than the measuring instrument otherwise the probability of variation cause by artefact is much greater than instrument itself.

5.4.3. Stage one charting MU chart

This stage too is similar to MR chart except the limits are drawn based on expanded uncertainty instead of MR. Take the value of artefact as centre tendency value x, both upper control limit (UC_L) and lower control limit (LC_L) are calculated using the formulae below

- Upper control limit, $UC_L = x + U_{MI}$ ----------(16)
- Lower control limit, $LC_L = x - U_{MI}$ ----------(17)

Where U_{MI} is the expanded uncertainty given in the calibration certificate

5.4.4. Stage two charting MU chart

The process of stage two is similar to MR chart where the points are plotted as stock points.

5.4.5. Follow up action to be taken

The actions to be taken also similar to MR chart

5.4.6. Simplified version of MU chart

Similar procedure with the MR chart where equations (10), (11) and (12) are applied.

5.4.7. An alternative to simplified MR chart

Similar procedure as simplified MR chart above where equations (13), (14) and (15) apply.

5.5. Control chart base on standard deviation as control limits (SD chart)

SD chart is basically a control chart plotted with control limits calculated from multiple standard deviations of a pool of base data collected. Refer to Appendix 26 3.1 SD chart examples. There are three examples in the experiment.

5.5.1. Principle of SD chart

A set of base data is needed to form the platform for future comparison. This set of base data is obtained at initial stage one, through multiple measurements using an artefact. Reproducibility base on standard deviation is calculated as the spread of distribution and is being used to determine the control limits. Future determination of the stability of the measuring instrument is basically compared to this set of base data. Drift of measuring instrument performance usually cause by

- User
- Environmental condition
- Measuring instrument components / parts

This SD chart eliminates the problems cause by user and environmental condition through this data collection procedure and proper training of staffs to use the instrument. Eventually the drift of performance is caused by the instrument.

A time base chart is plotted with the mean value at the centre and the control limits plot at both upper and lower sides of this mean line similar to the other two charts proposed above. The positions of these control limits are determined by the multiple of standard deviation. 2σ is taken for 95% and 99% use 3σ. The measuring instrument is considered stable and accepted when points are plotted within the control limits. 2σ is recommended to be in line with measurement uncertainty usually reported at 95% confidence level because it covers the probability of about 96%. Whereas 3σ covers 99.7% is unmatched.

There are similarities to Statistical Process Control chart (SPC); however there are dissimilarities too. The obvious dissimilarities are 2σ control limits, fixed average centre line, no averaging of multiple data collected instead just a single reading then transfer to the chart. This chart is preferred to name as SD chart instead of SPC chart to prevent confusion. The two charts i.e. MR and MU charts have completely different philosophy in terms of construction and theory.

5.5.2. Artefact for SD chart

There are similarities and differences in the choice of artefact from the other charts.

a. This is relative chart

This chart is based on relative variation not absolute value thus the actual value of artefact is not important. The crucial point is the measuring instrument shows value after some period of usage and if there is insignificant change compare to the base data than it should show variation less than 2σ in line with measurement uncertainty confidence level. Thus the value recorded after some period of usage is relative to the base data. The choice of artefact may refer to Diagram 3.3.3 but is not critical.

b. No replacement of artefact,

It must be the same piece throughout the exercise. Change of artefact shall change the mean value because there is no two pieces with similar physical value. Maintenance of artefact is critical to avoid unnecessary change to the physical property. New chart has to be plotted when the artefact shows sign of drift.

c. No calibration is required

The artefact is not required to calibrate because measurement uncertainty and correction factor are not considered in the calculation.

5.5.3. Stage One for SD chart

This stage is the data collection stage where the data is going to be used as reference for future comparison. Measuring instrument calibration is conducted under controlled environment however the usage may not be under similar condition. Data collected have to consider influences of operating conditions. Deviations may occur due to different ambient conditions. Thus it needs to include the environmental factors so that the drift caused by environment can be eliminated.

In principle the number of data collected should be as large as possible to have a representative set of data. However this is not possible due to limitation of time and cost of measurement. Minimum n=40 is the suggested number to compromise for the cost, time and the population standard deviation calculation requirement.

four data is collected daily representing the working hours as illustrated in Appendix 11.

These data contain ambient effect for the whole working time frame. The number, n can be increased for shift duties and is usually the multiple of shift. For 5 days working week, a total of n=20. This process is repeated for the second week to obtain n=40. There is no constrains to the person collecting these data, as long as they are the users of the measuring instrument or assign a person responsible for it. All users are involve is preferred because the effect of personnel systematic error could be taken care. In this case the base data not only contains environmental factors, it too includes users' effect.

Calculate the mean, standard deviation and control limits as follow

- Mean, $\overline{x} = \frac{\sum_1^n x}{n}$ ----------(18)
- Standard deviation, $\sigma = \sqrt{\frac{\sum(x-\overline{x})^2}{n}}$ ----------(19)
- Upper control limit, $UC_L = \overline{x} + 2\sigma$ ----------(20)
- Lower control limit, $LC_L = \overline{x} - 2\sigma$ ----------(21)

Note that the centre line is not the value of the artefact anymore instead is the mean of the set of data collected $\overline{x}$. The control limits are calculated based on 2 standard deviations which is at about 95% probability. This derived information is then transferred into a time series chart. A sample chart is shown in Appendix 12.

Stage one completes at this blank time series chart. No more taking 4 readings per day. This control limits form the basis of comparison in future.

5.5.4. Stage two for SD chart

Stage two is similar to the other two charts except that the artefact should not be replaced. A point is plotted rather than stock point. It resembles simplified MR chart (Diagram 3.3.6).

5.5.5. Follow up action to be taken

The actions to be taken also similar to MR and MU charts.

5.6. Control chart base on difference of artefacts as control limits (DA chart)

DA chart is similar to SD chart which is based on deviation of base data collected. Refer to Appendix 26, 3.2 there is an example of DA charting for µ-checker.

5.6.1. Principle of DA chart

The fundamental principle is identical to SD chart which is based on the standard deviation as control limits except two pieces of artefact are required instead of one. The standard deviation is calculated from the differences of the 2 pieces of artefacts. Usually the difference is very small and is not possible to have an artefact stand alone with that physical value for example gap of 10µm. There is no single piece of artefact with thickness of 10µm. The other procedures are identical to SD chart. In fact this is a diversion of SD chart.

5.6.2. Artefact for DA chart

There are similarities and differences in the use of artefact with the other charts. Everything is the same except a pair of artefact is required. This pair should have small difference and the difference is the interested magnitude. Usually there is no single piece of artefact possible available for example 10µm; however a distance of 10µm is easily obtained from difference of 1mm and 1.01mm gauge blocks. The rest is identical to SD chart.

5.6.3. Stage one of DA chart

The standard deviation is calculated from the differences of the pair of artefacts. The rest of the procedure is identical to SD chart.

5.6.4. Stage two of DA chart

Stage two is identical to SD charts.

5.6.5. Follow up action to be taken

The actions to be taken also similar to SD charts.

5.7. Control chart base on same level artefact as control limits (ABC chart)

Again ABC chart is similar to SD chart which is based on deviation of base data collected. The difference is a triangular relation of three artefacts which have similar physical properties as the measuring instrument. Refer to Appendix 26, 3.3 there are two examples of ABC charts. One chart for 1mm gauge block and the other is 1kg standard weight.

5.7.1. Principle of ABC chart

The four charts proposed above are suitable under the condition where the measuring instrument can be checked by artefacts with higher order of physical properties. Calibration, testing laboratories and manufacturing working standards are in this category; whereas calibration laboratories reference standards usually have no higher order of physical properties available due to very high cost and at time beyond the financial capability of the laboratory. Reference standards may include gauge block set, standard weights, standard resistors, standard volts, dead weight balance sound level meter, piston phone. Not all calibration laboratories maintain similar classes, grades or accuracy of these reference standards but they have a common issue where these standards are the highest order available and maintained in the laboratory.

Intermediate check procedure is not avoidable for SAMM accredited laboratories because ISO/IEC 17025 clause 5.6.3.3 states these reference standards need to conduct intermediate check; however the four charts propose above are not suitable because these four charts need artefacts of higher physical property order than the measuring instrument. Modification to the charting techniques is in the artefact. This modification utilises two artefacts with similar physical property order that means all the artefacts and the measuring instrument have similar physical property. The triangular relation is the principle to determine drift. Refer to Appendix 13.

Let A be the measuring instrument, B and C are artefacts with same order of accuracy. The difference of physical proper A f AB is x, AC is y and BC is z. Diagram 3.7.1 illustrates the triangular relation of artefacts and measuring instrument. The values of $x \neq y \neq z$, also do not necessarily behave according to Pythagoras Theorem neither to form a triangle mathematically.

a. All A, B and C drift,

When all the three items drifted the values of x, y and z shall drift with no specific pattern.

$x = x_0 + \delta A + \delta B$ ..... (22)

$y = y_0 + \delta A + \delta C$ ..... (23)

$z = z_0 + \delta B + \delta C$ ..... (24)

Where $x_0, y_0, and\ z_0$ are the initial values before drift.

Equations 22, 23, and 24 indicate when drift cause by all the items then x, y, and z drifting with multiple causes. Further more $\neq \delta B \neq \delta C$, it is difficult to induce the drift pattern of A.

b. Two drifted

Assuming C remains constant with $\delta C \rightarrow 0$, the other artefact B and the measuring instrument A drift, then equation 22 remains, equations 23 and 24 become

$y = y_0 + \delta A$ ..... (25)

$z = z_0 + \delta B$.....(26)

Equations 22, 25 and 26 remain no difference from the case (3.7.1.1) where all three drifted. It is difficult to conclude drift by A.

c. Only one drifted

When there is only one item drifted, assuming A, $\delta B \rightarrow 0$, $\delta C \rightarrow 0$, then equation 22, 23 and 24 become

$x = x_0 + \delta A$ ..... (27)

$y = y_0 + \delta A$ ..... (28)

$z = z_0$ ..... (29)

Two sides (x and y) shall drift but not z. This drift pattern indicates there is one piece drifted and the other two pieces remain unchanged. One may adopt this characteristic to conduct intermediate check on reference standards. The drift δA indicates in values of x and y.

The principle of SD or DA charts can be adopted for this purpose with modifications where drift patterns of x, y and z are plotted on charts with same time line as shown in Appendix 14. These charts are staggered instead of individual piece of chart for convenience to compare the drift among the three charts at the same time line. The decision to use SD chart or DA chart depends on the method obtain value of x, y, and z. Refer to Proposals 3 and 4 for detail procedures.

5.7.2. Artefact of ABC chart

a. BC artefacts

There is limitation to the accuracy of the pattern of drift, equation 29 shows that both artefacts need to remain very stable otherwise no pattern of drift can be concluded. Handling of these artefacts is critical usually they should be assigned for this specific task and no other task.

SD and DA charts emphasis on the consistency of the physical property not the grade neither class, based on this argument artefacts B and C may not have the same class or grade of specification with A and their physical value to measure, too not necessarily identical ; however they should be as close as possible. Example A is standard weight class E_2 then B and C may not be class E_2, class F_1 is sufficient. However class M is not suitable because it could not maintain consistent over long time due to the nature of material use.

When A is gauge block grade 00 then B and C may use grade 0 or 1. The measurement should only be the centre point and should not ignore to reduce deviation cause by parallelism and flatness of the measuring faces.

b. Supporting device

Equation 29 is an ideal condition where the drift causes by supporting device approaching zero. Measuring instrument supporting device for example gauge block comparator, mass comparator provides indication of the physical property value. In actual situation equations 22, 23, 24 should include deviation cause by drift of supporting device δI

$x = x_0 + \delta A + \delta B + \delta I$ ..... (30)

$y = y_0 + \delta A + \delta C + \delta I$ ..... (31)

$z = z_0 + \delta B + \delta C + \delta I$ ..... (32)

When $\delta I \rightarrow 0$ then equations 30, 31 and 32 revert back to equations 27, 28 and 29 respectively. In order to understand the drift pattern of δI this supporting device too, need to perform intermediate check. In fact this intermediate check should be the prerequisite before ABC chart can be proceeded otherwise x, y, and z would be compounded with δI similar to the conditions where all three items or two items drifted result in no specific pattern can be drawn.

5.7.3. Stage one of ABC chart

Stage two is identical to SD and DA charts.

5.7.4. Stage two of ABC chart

Stage two is identical to SD and DA charts.

5.7.5. How many charts needed

Reference standards usually stand alone or use as sets. For example gauge block, standard resistors, capacitor and standard weights are by set of multiple pieces with different values. Dead weight balance generates range of pressure and is used as stands alone measuring instrument. Single ABC chart is sufficient for stands alone reference standards; however single chart is not sufficient for sets standards. Gauge block is sold usually as set of 114 or 76 pieces. Other combinations are available depends on market demand. Standard weights usually come as combination of 1-2-2-5 configuration.

a. ABC charts for all pieces in the set?

Performing intermediate check for stands alone reference standards is not a problem; on the other hand conduct intermediate check for all pieces in the sets will definitely cause uneasiness among the laboratory managements. Cost incurred to purchase the artefacts, time and labour involve are the other factors need to compromise. Gauge

block set 114 pieces is an example of this problem. It is not practical to perform intermediate check for all pieces in the set. MS ISO 2859 [64] provides solution to this problem. This acceptance sampling standards provides statistical valid sampling technique to reduce the number of intermediate check for the set of gauge block. Table 3.7.5.1 provides an example using this technique to determine the number of charts to construct instead of all.

The propose program is as follow

a) Attribute program is used even though the values are measured value because the count is the number of charts plotting not the measured value. Thus acceptance sampling for variables MS ISO 3951:2007 [66] is not adopted.
b) Special inspection level S1 is chosen instead of General level 2 because the historical performance characteristics of A, B and C are known.
c) Table 2-A is adopted because the plot on chart is only 1 time not average.
d) Table 2-C may be used for well track records of ABC charts.
e) AQL 4.0 correspond to the control limits of 2σ

Appendix 15 summarises information gather from the standard. Inspection code B corresponds to 3 intermediate check charts to be constructed. The charting has to stop when one of the charts is found out of control limits. That means the whole set has to be recalibrated. This sampling technique offers economic practice where only 3 charts to be constructed instead of 114 charts.

If Table 2-C is used then 2 intermediate check charts are needed instead of 3. Care has to exercise when using Table 2-C because it is a reducing inspection level.

b. Which piece to conduct intermediate check

Which piece out of the set to be chosen for intermediate check is not important but factors to consider below are the minimum.

a) Frequency of usage
b) Availability of artefacts B and C
c) Randomness

5.8. Chart plotting interval

How often should intermediate check be carried out? There is no standard answer to the question. This paper provides some guidelines as reference and may vary according to the management requirement. Before any time frame suggested, one has to ask how much risk the management is willing to accept due to unreliable measuring instrument.

5.8.1. Suggested interval for charting

Measuring instrument changes performance properties with usage, storage and handling and all these factors are related to time, t. The confidence on using the measuring instrument can be expressed as inverse relation of these factors

$$confidence \equiv \frac{1}{t} f\left\{\left(\frac{1}{usage}\right), \left(\frac{1}{storage}\right), \left(\frac{1}{handling}\right)\right\} \ldots\ldots\ldots\ldots (33)$$

Working standards usually needs more regular checking than reference standards because the probability of drift is greater for working standards due to higher usage and handling. As a thumb of rule, working standards for commercial calibration laboratory may need to conduct intermediate check weekly at initial period. This time frame may be doubled after consistently fall within the control limits over a quarter of a year. On the reverse may need to maintain this time interval when the pattern of drift indicates instability. Two months one check may prove to be the longest duration for heavily used instrument.

From quality point of view once the chart falls out of control limits, the user or quality department has to trace back product or testing affected by this particular instrument. An average monthly interval check is acceptable. One has to remember the longer the interval, the higher risk has to bear. On the other hand intermediate check should not be conducted more often than usage. It goes back to how much risk can the management accept. How far should be traced? As guideline, traced back to the previous check point. If the plotting is weekly then should trace back one week because the instrument still functional properly during that period.

5.8.2. Pre usage check

This procedure is suggested for measuring instrument with low usage. It is unreasonable to conduct intermediate checking while is in storage. SD, DA and ABC charts need to perform stage one even it is in storage. Stage two would be depending on the usage time. Check the instrument performance every time before it is put into service. The rest of the procedure is identical. Not to surprise, such checking usually needs confirmation point because the instrument may not fully warm up, it is still in cold state while taking the first reading because warming up time varies with instrument.

This procedure can be adopted for super heavy usage instrument or shifting from one location to next where the movement may affect the performance. Pre usage check reduces risk of unreliable data collected.

5.8.3. Post usage check

This intermediate check procedure can be adopted for instrument performance confirmation after data collection process. Could the instrument drifted while using? This procedure is suitable for such investigation purpose. There is a pre requirement where stage one has completed and is ready or is already in stage two process.

5.9. Implementation of intermediate check procedure

The implementation procedure determines success or failure of a project. The procedure could be divided into 2 main sectors and which one to adopt largely depend on the organisation culture and management preferences.

5.9.1. Manual plotting

Usually a chart is plotted on graph paper. The control limits are plotted manually on it. It is then displayed on the wall adopting one of TPS [97] concept i.e. Kanban. This quality tool is to display the chart so that everyone can have a good look at the chart drift pattern. The display enables the user knowing the performance of measuring instrument at a glance. Refer to the picture in Appendix 16. illustrates Kanban concept of display control chart. Another advantage of Kanban system is constant reminder to conduct the checking regularly.

5.9.2. Software plotting

Management may choose to conduct this intermediate check paperless. There is no hard and fast rule that it has to be plotting on graph paper manually. However one has to take note that tapping the advantage of computer plotting can provide good accuracy and nice presentation, the price is no Kanban system can be installed unless it is done as real time information. People tend to forget to perform checking when the subject is out of sight.

5.10. End of charting

End of charting occurs when these conditions appear:-

5.10.1. MR chart

There is no end to charting for MR chart as long as the MR remains and the instrument still in service unless the plotting persistently fall out of control limit. Extend the graph paper into new sheet when current sheet has filled up completely.

Five to seven consecutive points out of control limits can be considered as permanent bias occur thus charting can be stopped at this time. The follow up action is repair, or service and recalibrate the measuring instrument. A new chart with similar control limits to be proceeded.

5.10.2. MU, SD, DA and ABC charts

This intermediate check has to end when the chart shows permanent systematic error or the chart persistently fall out of control limits. Five to seven consecutive points out of control limits can be considered as permanent bias occur. The instrument needs to service, repair and calibrate. New control limits and charts are needed since the performance characteristics have changed.

5.11. Challenges to intermediate check implementation

In view of the weaknesses and challenges, Implementing these procedures have to follow some procedures:

5.11.1. Disseminate the knowledge through series of training

Training at the early stage is important where the key personnel must understand the concepts and principles. There are two groups of staffs need to be trained as follow:

(a) Senior management staffs involve directly in the system management. This group of personnel are the decision makers thus they have to understand the subject matters before others.

(b) Executives, process owners and the system management key personnel are the next group. This is the working group thus they determine success of the project.

(c) Training should be provided to these two groups especially the key personnel and process owner. They are the group to implement this study proposal.

5.11.2. Prepare standard operating procedure and policy of organisation.

The working group has to write the operating procedure and policy of the organisation in relation to this subject. The function of this operating procedure is to ensure implementation is systematic and accordingly. This procedure should be incorporated into the existing QMS and able to be cross reference.

5.11.3. Planned initial stage

This is a learning stage to test the understanding and measurement requirements by the users. Select a station or a process with measurement requirements to begin with. Assign personnel involve for example the users to determine metrological requirements and system executives to evaluate according to the three equations. Any problem arise should be solved as team work otherwise it is frustrating without the support of other team members especially support from higher authority. Expected problem is the availability of metrological requirement of the process.

5.11.4. Total implementation programme

The team may expand to other processes and eventually organisation wide upon satisfactory implementation. The experience gained during the initial stage implementation should provide good guideline to solve problems.

5.11.5. Intermediate check procedure should be implemented concurrently

This study is a part of the total solution to measuring instrument management. The front portion is the technique to determine whether instrument need to calibrate because not every instrument is required to be calibrated at specified period. Proper implementation of the procedure could have cost saving through reduce number of instrument for calibration. Whereas the real portion is the intermediate check. This activity enables the user to determine instrument fitness for use at any of usage. If implemented properly, the calibration interval could be extended through the specific pattern of drift indicated by the control chart. Again cost saving is enhanced. The whole cycle of measuring instrument completes when the instrument is ready for next calibration and is in line with ISO/IEC 17025 requirements states it in clause 5.5.11.

5.12. Application and differences among the various types of charts

Five techniques proposed possess individuality in their characteristics and fields of application.

5.12.1. Technical similarities among the five charts

The technical similarity among them is the stage two procedures on transferring datum collected and plot onto the chart and actions taken. This similarity enables the user to apply the knowledge organisation wide without much variation and is an advantage to reduce mistake and miss understanding among the users who are at the operators' level.

Another area of similarity is the choice and handling of artefact for MR and MU charts. Both techniques do not require maintaining physical property of artefact consistency throughout the exercise, when the artefact is found drifted it can be replaced with similar value piece but routine calibration of artefact is necessary.

DA chart is a deviation from SD chart thus majority of the procedures do not show any difference except base data is collected from single piece for SD chart and the differences of a pair of artefacts for DA chart. ABC chart share common stage one and

two with DA and SD charts except the points plotted are the relative differences of A, B and C.

5.12.2. Technical differences among the five charts

There is a major difference in stage one of SD, DA and ABC charts from MR and MU charts. A set of base data is needed to set the foundation for future comparison. Whereas MR and MU charts do not require such information because the performance of measuring instrument at any one time is compared directly with the known value of artefact. SD, DA and ABC charts compare the performance of the instrument at time t_n with respect to the set of base data collected during stage one call it t_0. It is actually comparing the performance at time t_n to t_0. Any drift observe indicates variation in the performance. This variation is unavoidable according to Shewhart and GUM due to random error characteristics. The interest is the magnitude of systematic error which is shown by the point falls outside the control limits. Under such condition the systematic error has affected the performance and if it is used for measurement, bias may present may affect the quality of the measurand. Thus there is time reference for SD, DA and ABC charts but not MR and MU charts.

This time reference t_0 provides relative differences of value induces a problem to the artefact. Is the drift caused by the artefact or the performance of the instrument? In order to avoid complication cause by drift due to artefact,

a. SD, DA and ABC charts demand constant use of same artefacts during the whole exercise. The same piece of artefacts should be used throughout and not interchangeable with other pieces because the mean value of two different pieces is different.
b. Handling and maintenance of artefact is critical. The exercise has to stop when the artefact shows sign of drift. Whereas MU and MR charts are not affected by this problem thus need to change the artefact and the chart continue to use.
c. Artefacts B and C of ABC chart are very sensitive to variation may cause the exercise fail. Care for supporting device differentiates this chart from others for its role in total variation.

5.12.3. Single or multiple charts

MR and MU charts are based on absolute value, the drift compose of both systematic and random errors. The position on the plot could not differentiate them. Measuring instrument linearity does not exhibit linear relation so drift at low range may not necessary have the same magnitude at high. Furthermore the value obtained contains effect of environment factor therefore a single chart plotted may not indicate overall performance of the instrument linearity drift. In principle multiple charts are needed for both MR and MU charts; how it is recommended to plot at usage range for single chart otherwise multiple charts are needed for wide range application.

There is an argument for using single chart if MR has no difference at different range of application after all MR is for the measurand. The second argument is meeting the most stringent requirement. Single chart with the most stringent MR control limits should have no problem for measurand with less stringent control limits. Similarly MU chart may need single chart when there is only single MU figure from the measuring instrument irrespective of range of measurement.

On the other hand SD and DA charts are relative charts. The point plotted indicates the presence of systematic error minus the effect of environment. Thus the position shows purely on the systematic error. Systematic error usually demonstrates consistency over full range of the linearity. The drift at low range should have the same magnitude at high range. In fact the linearity curve moves along the y-axis irrespective of range. A single chart is sufficient for both SD and DA charts irrespective of usage range.

ABC chart as discussed in 3.7.5 suitable for reference standards needs only limited chart for a set according to principle of acceptance standards.

5.12.4. Uses of the control charts

The objectives of control chart are

- maintain high confidence with the measuring instrument
- meet the requirements of ISO QMS.

There are many possible areas of usage

a) Maintain high confidence on the measuring instrument at all times

ISO/IEC 17025 states *when intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure*. These charts are designed to perform intermediate check of measuring instrument to meet this ISO requirement. The issue is confidence is an inverse function of usage, storage and handling. All these functions are related to time then. Refer to equation (33)

$$\text{confidence} \equiv \frac{1}{\text{t}} f\left\{\left(\frac{1}{\text{usage}}\right), \left(\frac{1}{\text{storage}}\right), \left(\frac{1}{\text{handling}}\right)\right\}$$

Maintaining high confidence means shorter interval. (Refer to 3.8.1 suggested interval). Annual or fixed periodic longer than calendar year recalibration post doubts on measuring instrument capability confidence. Time t has to be much shorter in order to maintain high confidence level; however recalibrate at short interval may inflate cost of maintaining the instrument. This intermediate check procedures are designed to reduce maintaining cost at the same time maintaining high confidence level.

b) Determine calibration interval

Calibration is part of metrological traceability activities of ISO QMS requirement. When measuring instrument continuously showing insignificant drift indicates the performance is well within the requirement. If the drift pattern is proven to be insignificantly affect the measurement by the end of calibration interval the instrument need not be recalibrated until further time in future. In other words calibration interval may be extended and it is then translated into cost saving. How far should it extend? One year? 2 years?

A suggested maximum interval is to refer to either NATA or UKAS recommendation otherwise is extended by 2 folds as standard practice.

What happen when the chart plots out of control limits persistently before the calibration interval indeed, then it shows the presence of special cause which is permanent in nature and the magnitude is significantly affecting the measurement uncertainty. The measuring instrument may have lost the confidence causing it not fit for purpose. It needs to undergo repair, service and recalibrate at earlier date than the schedule. This reduction of interval is irrespective of usage time lapse.

5.13. Uses of various types of charts

The charts proposed are suitable for specific measuring instrument. The applications suggested are as follow:

5.13.1. MR chart

MR chart utilises the Metrological Requirement as control limits which represents the largest gap among all the 5 types of charts. It is suitable for process measuring instrument because the MR is usually fixed thus not for calibration laboratory's working standards nor reference standards. Table in Appendix 17 shows summary of suitability of MR chart.

5.13.2. MU chart

This chart is simple to use but the control limits gap is larger than SD chart but smaller than MR chart. This chat is suitable for calibration, testing laboratories low end working standards where metrological requirements may change from job to job. Conditions suitable for MR chart also adoptable by this procedure. Table in Appendix 18 shows summary of suitability of MU chart.

5.13.3. SD chart

This chart has the small control limits gap. It can be adopted for working standards of calibration function, laboratory or high precision process measurement. Reference standards may adopt when artefact with higher order of physical property is available. Table in Appendix 19 shows summary of suitability of MR chart.

5.13.4. DA chart

Measuring instrument similar to SD chart except for very small measurand where it is difficult to have artefact with such small measurement. Table in Appendix 20 shows summary of suitability of MR chart.

5.13.5. ABC chart

This chart is only suitable for reference standards use in calibration laboratory. Table in Appendix 21 shows summary of suitability of ABC chart.

5.14. Summary for measuring instrument intermediate check

Handling, storage and usage affect the performance properties of measuring instrument, the concerned is the magnitude of change rather than the change itself since performance properties variation is unavoidable.

This study suggested control charting techniques to observe time base variations whether at the time of usage the measuring instrument still maintain fitness for use. There are five types of control charts being suggested. These charts are name after the critical properties of the charting techniques MA, MU, SD, DA and ABC charts to suite various conditions of use of the measuring instrument. Appropriate actions to be taken are also suggested according to the pattern of the variations.

The advantages of such techniques not just enable the user to understand the variations but also determine calibration interval and thus cost savings.

CHAPTER 6

6. Discussion

Quality data is the uncompromised factor in quality control process. There are three main factors concern the making of decision in quality control process; they are (a) measuring instrument, (b) person taking measurement and (c) object of measurement. This research proposes a method to determine measuring instrument fit for purpose in an unconventional way. Statistical information and measurement uncertainty are the key approach to this study compare to conventional methods normally adopting ratios and accuracy.

6.1. Measurement capacity

The initial step to determine measuring instrument fitness for use is to determine its capacity. If the capacity could not meet the measurement load then it is not necessary to continue to the next process, it is then not fit for purpose. Capacity ability is represented by Equation (1), $(R_{low} + U) \leq M \leq (R_{high} - U)$. This equation determines the capacity at both low and high ranges. Measurand to be has to fall within these limits otherwise it is not fit for purpose.

6.1.1. Equation includes measurement uncertainty

This equation includes measurement uncertainty for its probability to fall within the value at specific confidence level that answers the question of minimum capacity it can measure. The other side of the equation determines the maximum load capacity. The instrument is said to be meeting this requirement as long as the measurand falls within these limits. This equation also applies to limited calibration.

6.1.2. Missing link at extreme ends of measured values

Review of literature shows that there is no mention of capacity as part of determining fitness for use. It has been taken for granted that measuring instrument should be able to cover the range of measurement needed without fail.

The argument for this missing link in the study happens at both extreme ends of measuring instrument where the challenge is the presence of measurement uncertainty. In the past when measurement uncertainty was not in the picture of measurement, this capacity verification seems redundant because it is believed that as long as the measurement is at or within either extreme ends of the measuring instrument, then the measurement is acceptable. The interesting part is MSA-4 also does not consider this capacity check as part of the MSA components.

The problem now is that when the measuring instrument is used at the extreme ends of the capacity it has the probability to fall out of the uncertainty limits. Such situation is not justified where it is impossible to have measured value out of the capacity range. For example calliper is used at zero M_0, thus the measured value M becomes $M = M_0 \pm U$, but there is no way to have *M* less than zero. In order to have true measurable value the minimum capacity has to include the positive value of uncertainty so the measured value becomes $M = M_0 + U$, it is not at zero now but something larger than zero and the magnitude is the measurement uncertainty. Similarly the upper capacity needs to consider such effect $M = M_{max} - U$. In such cases measured value to fall out of the limits is then not possible.

This missing link Equation (1) bridging the capacity with fitness for use completes the answer to fit for purpose.

6.1.3. One set point calibration challenge

There is a challenge to this formula when one step setting calibration procedure is adopted which at times user prefers to calibrate at specified step, i.e. one particular setting or at commonly usage setting. An example is heat enclosure calibration according to Euramet cg20 [17] encouraged to calibrate at usage temperature. When $(R_{low} = R_{high})$ one step temperature without any range is possible but when U is included then the equation becomes $M \pm U$. That means the measured value has to fall within the uncertainty limits, any shift in the value shall deem unfit for purpose. Thus Equation (1) is still applicable under such situation. It is still possible to have calibration set at a one setting; however correction has to be compensated which is in line with equation (3) when using the instrument.

6.2. Metrological characteristics

Performance characteristics of an instrument determine its ability to perform consistently with the requirements. The criteria depend on the nature of measurand, different instrument has different criteria there is no common criteria for all. Accreditation body like Standards Malaysia does not provide any guideline for the type of information to be reported in the calibration certificate except measurement uncertainty. No instruction from the authority causes variations in the information reported among the calibration houses. On top of that there is no proper guideline to set the criteria for performance of instrument; however TLAS, Thailand Laboratory Accreditation Scheme, do provide some guidelines example Publication G20 [86] for its accredited laboratories to follow in evaluating and reporting the uncertainty and its components to be included in the calibration certificate. Accreditation body like TLAS facilitates standardisation of metrological characteristics reduces arguments among the stack holders. Traditionally users judge measuring instrument performance through several methods, these traditional criteria as discuss in literature review developed various methods

a) adopt the accuracy which usually derives from the specification of the measuring instrument. Manufacturer usually attaches specification as proof of quality.
b) error of readings from calibration certificate or
c) multiples of resolution and some even consider calibration renders fitness for use.

6.2.1. Accuracy ratio

Literatures have common stand for the right measuring instrument for the right job. The problem is that there is no common definition of terminology and concept of right instrument. OIML publishes definitions of terms in metrology, VIM [48] and is being adopted by ISO/IEC 17025 as normative reference, it is not being referred to by general public

a) ISO QMS uses the term accuracy of measurement whereas literatures from books and metrologies especially dealing with MSA use discrimination of instrument.

b) Definition of accuracy does not equal to discrimination. Accuracy contains element of measuring instrument errors deviate from true value. On the other hand discrimination refers to resolution.
c) No specific agreement on capability of measuring instrument to requirement ratio.
d) No consistency as a result of the absence of specific instructions on the use of accuracy ratio.

The issue is the conceptual differences on accuracy and discrimination. Jain's [16] definition of accuracy contains the elements of resolution, readability, sensitivity and consistency of measurement. Discrimination only consists of resolution of measuring instrument. VIM defines accuracy [47] as closeness of agreement between a measured
quantity value and a true quantity value of a measurand. Thus the value of accuracy in ISO QMS may be larger than discrimination.

Metrologists are more specific in determining the capability of measuring instrument. Instrument fit for purpose ratios of 10:1 and 4:1 are common. The problem is no instruction on when and under what conditions to use which ratio. Pharmaceutical manufacturing industry implementing GMP Good Manufacturing Practice and GLP Good Laboratory Practice, have to meet similar stringent requirement on this aspect. On the other hand ISO QMS usually do not specify the ratio or provide any formula or figures other than specific requirement lay down by SAC-SINGLAS accreditation but the ratio is based on accuracy not discrimination. It allows practitioners to interpret and implement at will causing variations in implementation.

6.2.2. Measurement uncertainty

In the olden days people were talking about accuracy of measurement with exact measured value without any error; however the understanding of measurement theory today is that even measurement at SI level which is the most accurate human manages to measure can never be repeated to the exact value. There is always small deviation and this deviation is referred as measurement uncertainty. This value expanded as it propagates to the industrial level. Thus according to this definition there

is no such thing as exact measured value. People taking measurement shall be required to qualify the accuracy of measurement through presenting this information. Measurement uncertainty is not new it has been an important subject in high accuracy measurement and scientific research in primary and secondary standards measurement. It is not a popular subject among industrial users in the past before ISO introduced this subject through published *ISO Guide to the expression of Uncertainty in Measurement* [20] [46] in the year 1995 or generally known as GUM. Measurement uncertainty is expressed as distribution and indicated in equation number 10, clause 5.1.2 of page 19.

$$u_c{}^2 = \sum_1^n \left(\frac{dy}{dx}\right)^2 . u_n{}^2$$

The formula indicates measurement uncertainty is expressed as weighted distribution of measured result deviation. The deviation elements consist of multiple sources and metrological traceability is just a component, other components could be contributed by the process of measurement, reference standards, person conducting the measurement, environmental conditions. On the other hand accuracy according to MSA-4 refers to the precision of instrument and is calculated based on bias. Thus there is no equivalent of accuracy to measurement uncertainty. They do not demonstrate similarity in concept.

Measurement uncertainty defines the probability of a measured value to fall within. A properly evaluated series of measurement uncertainty demonstrates the metrological traceability [50] until SI Units of Measurement, *Système international d'unités*. Thus there are stringent requirements by accreditation bodies to ensure such linkage is properly done as such it is required to be presented in the calibration certificate by Standards Malaysia in SP5 [87] and usually it is expressed as expanded uncertainty (*U*) represented by semi-range at 95% confidence level [87]. Coverage factor *k* may obtain from *student–t* table for combined standard uncertainty (u_c) which is at one sigma level to cover wider area of the distribution. According to GUM para 6.3.3 states taking *k =2*, the u_c is expanded at 95% and *k=3* for 99% respectively. Whether to accept at 95% depends on the user's requirements for example six sigma practitioner may not accept 95% which is not in line with the practice, instead 99% is more suitable.

The conventional methods of determining fitness for use do not take into consideration of measurement uncertainty and disregard ISO/IEC 17025 clause 5.6 metrological traceability requirements is due to historical reason. Users of instrument are not interested in the reported uncertainty figure. They are only interested to know that calibration is endorsed by accreditation organisation. Whereas the main problem for calibration laboratories to report measurement uncertainty is the components to be included in the evaluation. GUM does not suggest any specific components and refer to the person who evaluates it. GUM special note in clause 3.4.8 [20] states clearly

it cannot substitute for critical thinking, intellectual honesty and professional skill. The evaluation of uncertainty is neither a routine task nor a purely mathematical one; it depends on detailed knowledge of the nature of the measurand and of the measurement process. The quality and utility of the uncertainty quoted for the result of a measurement therefore ultimately depend on the understanding, critical analysis and integrity of those who contribute to the assignment of its value.

GUM provides for creativity on the other hand it leaves arguments for every uncertainty figure reported, unlike TLAS provides rigid framework but leaves argument for the freedom to choose the methods and reference instrument use. This study appreciates the effort of management of TLAS to streamline uncertainty components so that Equations (1) (2) and (3) shall be meaning full to implement. The worry is calibration house or personnel involve intentionally reduce measurement uncertainty through reduce the magnitude of some components. The equations could not differentiate whether the uncertainty figure given represents the true value of the performance. A case study in Appendix A1 shows clearly an unfit oven turned out to be fit for purpose with some components of uncertainty excluded.

6.2.3. Measurement uncertainty and metrological requirement MR relation

For any measurement process it always come with limits of accuracy, the larger these limits, the lesser accuracy is demanded. In fact there is no common term adopted, normally they are referred to accuracy, allowable error, maximum permissible error or tolerance of a process or measurement. This study adopted the term Metrological Requirement MR to collectively refer to them. It is usually expressed as semi range

$\pm MR$. Any measurement made within the limits of MR is considered good value and vice versa. That means the result is within the limits of accuracy. In a manufacturing or servicing process decision is made according to the measured value, the product shall be accepted as long as it is a good value irrespective of the positive or negative side.

MR can be obtained from

a) External Customer. It is the duty of external customer to provide this figure as a quality control parameter. Thus similar products may have different MR from different customers.
b) Specification of product or service. Usually this is from internal customer. Product specification usually comes with such demand for quality control purpose.
c) Standards. Laboratory testing procedures are usually referred to specific test methods adopted from international or national methods are the common practice among ISO/IEC 17025 accredited laboratories. Taking the example of case study in Appendix (1) oven temperature for soil drying process stated in BS 1377 part 2 required to be set at 105ºC to 110ºC, translate into mathematical format drying temperature T, $T = 107.5 \pm 2.5℃$ where $M = 107.5℃$ and $MR = \pm 2.5℃$.
d) Self declared. This is the last option when none of the above is available. In the situation in the absence of MR, people involve cannot make appropriate decision due to no criteria. This is common to old standards habitually no MR given to test methods. Self- declared MR through experience and knowledge would be the option.
    i. Taking MR equals to three times the measurement uncertainty reported in the calibration certificate. This is an empirical conclusion where MU normally falls within two to three times the resolution when it is in perfect condition.
    ii. Never use the resolution as MR because the performance of instrument degrades as the usage and age increases. In no time the uncertainty reported shall get larger, Equation (2) may turn false soon.

Since MR plays such an important role in the controlling of process variables and is being used as controlling factor varies with stack holders thus it is wise to take it into consideration of the fitness for use of instrument. Equation (2) factors them in the equation. The other key issues are

a) it considers user's requirements unlike the traditional method disregard this through fixed ratio.
b) Same model of a measuring instrument may be used by users from various fields and applications, their requirements vary widely. Ignoring this issue may contribute to budget and quality problems.

The traditional methods never consider measurement uncertainty, metrological traceability and users' requirements. It rigidly taking the resolution into consideration, it is easily interpreted and convenience to make decision on fitness for use. On the other hand the flexibility and simplicity of Equation (2) facilitates the learning and adopting process. Flexibility in the sense of obtain specific information from calibration certificate rather than do not know where to hunt for information and user's requirements. Simplicity refers to the logic relation of two variables and the follow up actions to be taken.

The weakness of traditional method is the resolution retains but the performance degrades according to usage, handling and aging. When the degradation is not taking into consideration, it increases the probability of false measurement results, whereas Equation (2) considers the performance through measurement uncertainty. It reflects consideration to use the instrument is irrespective of cost, technology, size, age and brand, as long as Equation (2) is true it is fit for purpose.

6.3. Correction

What is correction? Appendix 22 illustrates the black colour distribution is the condition where no correction is observed. Green distribution illustrates the shift of distribution to a new position and the amount of shift is the value of correction, c. Note that the shift can be either positive or negative. It is the modulus of this figure conventionally being adopted to judge accuracy of measuring instrument as well as accuracy of measurement.

Equation (2) $U \leq MR$ is valid when correction reported in the calibration certificate equals to zero. This perfect condition does not always happen in reality. In the past when adjustment was part of calibration procedure was used to reduce the offset. It is to bring the green distribution to coincide with the original black distribution. However the new definition of calibration by VIM 2.39 [48] has changed the overall picture where adjustment is not part of calibration procedure any more. It is reported as an independent information as part of performance characteristics of the instrument together with measurement uncertainty.

ISO/IEC 17025 clause 5.5.11 states the requirement to include this figure in the measurement. It states

where calibration give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies are correctly updated.

The user has to compensate for this correction figure into the measured value so that the measured value is corrected for this error. This compensation shall ensure proper metrological traceability to SI units.
However in practice it is difficult to perform this arithmetic due to

a) Additional procedure means troublesome procedure for people in the process.
b) Human resource capability in mathematics where mistake is unavoidable.
c) Different correction values along the full range due to non-linear in nature.

The problem is correction error must be compensated otherwise the measured value may not have proper metrological traceability. To overcome this difficulty, this study proposes Equation (3) to determine whether the correction value is insignificantly affecting the measured result.
The interpretation is

a) If this statement is true then the effect of correction is insignificantly affecting the measured value. The user may not need to compensate this correction or may assume it to be equal to zero. That means the measuring instrument is still fit for purpose without compensation for correction.

b) If this statement is false then the user has no option but to compensate for it for every measured value obtained. Otherwise there is systematic error in the measurement. This is due to significant effect on the measured value. The error is now considered significant.
c) When the error is significantly affecting the measurand, and the management decision is not to compensate then the instrument is said to be unfit for use.

The argument for $|C| \leq MR - U$ is based on the "significant" effect of the compensation and at the least stringent term. Metrological requirement allows for certain deviation of measured value as long as the value obtained is within this spectrum, it is acceptable because it is unnecessary to have the value falls on the expected value exactly.

Correction is a systematic error it has to be considered as a component of measurement uncertainty. This figure equals to zero when compensated otherwise its magnitude shall affect the combined standard uncertainty.

Correction shall not be compensated for instrument fixed at single value or for safety purpose. When the relation is false then the user should consider it to be unfit for use rather than compensation. For example OIML R111 lists the maximum permissible error of a classification of standard weights, no compensation of the error is allowed for a particular class of weight to upgrade it. Another example is pressure gauge use in pressure line where the gauge is supposed to indicate actual pressure not for the user to compensate for the correction.

Correction in the past has been taken for granted that calibration process should be adjusted to zero or near zero and is because of this reason that traditional method to determine fitness for use did not consider this factor. This study considers it in the equation because if it is not compensated and the value is significantly large then metrological traceability is in doubt. When this situation happens for example measured result of 1mm using an instrument may not equal to 1mm measured using different instrument, defy the principle of metrological traceability.

6.4. Compare with MSA

Measurement system analysis, MSA is a common practice in GMP and ISO/TS 16949. It is a statistical procedure to determine variation of measurement process to induce

decision for appropriateness of measuring instrument and the personnel involve. There are similarities and dissimilarities between MSA and this study. One thing for certain is MSA does not involve measurement uncertainty even though MSA-4 does mention. It is treated isolated from the other components. There are five components in MSA:

6.4.1. Bias

This tool is similar to the correction; however the method to derive this datum is complete different. AIAG MSA-4 suggested use process unit as master piece whereas this study suggests use reference standards. The problem with production unit is its metrological property is inconsistent and metrological traceability cannot be assured. The arguable point of this exercise is the measurand contains the compound effect of the inconsistency of the artefact, the people, environmental condition and the measuring instrument. There are two methods of analysis, one is disregard the user's requirements and the other adopted user's requirement as part of criteria.

a) The analysis disregards user's requirements are calculated from the experimental standard deviation of means at 95% confidence level. The criteria is to test whether the error from average value falls within this limit. The positive test value obtained has to be positive and the negative test has to be negative value. Both tests have to meet these criteria otherwise not fit for purpose.
b) Another method is to calculate the average bias at a particular reading. The percentage of bias from the user's specification is calculated. If the error percentage is greater than 30%, it shall not be accepted because not fit for purpose. When the percentage is within 10% to 30% the instrument may be used at caution. It is perfectly fit for purpose when the percentage error is less than 10%.
c) Both methods may not result in same conclusion but it is the decision of user to make the judgement which method to adopt.
d) Another difference is bias is treated as error and this study treats correction as deviation. The difference of these two terms is the treatment of "good value and "bad value". A measured value shall not

fall naturally on the average nor intended value but within limited small distance away. Why good? Because it is obtained empirically. On the other hand error is treated as mistake, negative impression, should be removed otherwise it causes inaccuracy in measurement.

6.4.2. Linearity

This tool is the extension of bias taken along the measurable range of the measuring instrument. Minimum five biases have to be calculated at different loads along the range of measuring instrument.

a) Least square is calculated from these data assuming linearity is linear. The criteria of acceptance are the 95% probability deviates from least square error. The arguments are similar to bias where user's requirements are not considered and the bias is assumed to be linear. On the other hand this study does not assume linearity to be linear, correction has to be calculated at usage load and the criteria always consider user's requirements.
b) This study does not need to consider the deviation of linearity because correction is needed at usage load not the overall linearity. The principle of interpolation is adopted to calculate correction at usage value.

6.4.3. Stability

Measuring instrument unavoidably exhibits long term drift in its performance characteristics. The technique adopted is using statistical process control (SPC chart) $\bar{x}\ range\ chart$ to observe the trend of drift. The control limits are plotted at three sigma level which is close to 99.7%. The artefacts are five pieces of production units with running average charting.

This study does involve long term drift where ISO/IEC17025 clause 5.5.10 and the latest ISO9001 clause 7.1.6 (b) stipulate the user has to determine the instrument continuous to be fit for purpose. Intermediate check of measuring instrument is the tool for this purpose. Both adopted control chart technique but the mathematical models are completely different and the charting techniques are different, too. The

only common issue is to determine performance meeting requirements continuously on time base.

a) SPC adopts moving average whereas this study suggested fixed average which is obtained from the base data according to SD, DA and ABC charts. MU and MR charts adopt the value of artefact as centre line.
b) SPC uses five pieces of master pieces and the average is then transferred to the chart. On the other hand this study suggests only one and is the first reading taken is transferred to the chart, adopting the concept of first time right. The principle is to compare with initial sets of data.
c) Environmental condition were taken into consideration when collecting base data thus any drift in the chart indicates effect purely from the measuring instrument for SD, DA and ABC charts. On the other hand SPC chart could not separate environmental effect from the instrument performance.

6.5. Intermediate check and MSA

6.5.1. Brief comparison with GRR

ISO/TS 16949 demands the system to include measurement system analysis (MSA) as part of exercise to determine measurement system meeting requirements. MSA-4 [2] states the components to be included in the study a) stability, b) bias, c) linearity, d) Repeatability and Reproducibility. The objective of the study is to have knowledge about the quality of data collected so that manufacturing process can be adjusted. There is no direct comparison of these control charts with Gauge Repeatability and Reproducibility (GRR). In fact the approach to data collection also different. This research briefly compares control charts with GRR but not as a whole of MSA. Appendix 23 summarises the differences based on MSA-4 procedure

6.5.2. Compare with stability test

Stability test is one of the four parameters to conduct in MSA-4. This test is basically to investigate the performance stability of measuring instrument over time. The

philosophy is similar to intermediate check; however the procedures show some differences in implementation.

The comparison in Appendix 24 indicates no direct comparison especially GRR, on the other hand stability has common objective but difference in implementation. The comparison would be more meaning full between MSA and measuring instrument management as a whole adopting ISO/IEC 17025 requirements.

6.6. Control charts compare with traditional instrument verification technique

There is no specific document to address traditional verification technique, generally majority collect multiple readings over full range or interest range and an average is calculated to determine its fitness. The data obtained is then compared direct with the requirement. This simple procedure induce some questions

- what is the requirement?
- Is the comparison meeting target?
- Can the procedure solve the measuring instrument stability problem?
- Can the user have confidence with the measuring instrument where the calibration status still valid?

6.6.1. Instrument specification or accuracy

Measuring Instrument specification is the manufacturer requirement to produce serviceable instrument. The specifications are usually very tight it has no problem when the unit is brand new. There is high chance for used or aged instrument not to meet the requirement due to wear and tear. The probability gets larger as the usage and age increase.

If the Metrological Requirement is larger than this specification, then the unit is still possible to meet even though it has aged and changed in performance properties beyond it specification, as long as it still meets the requirement stated in equation (1). MR chart serves better than this traditional technique.

6.6.2. Trend

Human has better visual observation and interpretation on trend than figures. Trend by itself includes historical information and its inter-relation whereas datum is individual and shows no relation with past data. The charts proposed in this paper taking this factor into consideration. Trend interpretation encourages preventive actions as well as planning for the measuring instrument management. Traditional method without plotting trend cannot tap the advantage

a) Pattern of the drift
b) Historical information at a glance

Traditional method to conduct checking for reference standards is by comparing the values of A, B and C or x, y and z direct could not tap these advantages.

6.6.3. Practicality

One point plot comparatively takes less resource than collecting multiple readings and then calculates the average. The procedure also very simple to practise enables every user irrespective of levels to follow. Control charts provide practical procedure reduce resource consumption.

6.6.4. Gauge repeatability and reproducibility (GR&R)

One of the most common activities of MSA is to determine GR&R. This tool is to study the error cause by personnel and the measuring instrument through statistical techniques evaluation. Repeatability is the study of error cause by instrument and reproducibility is the error cause by the personnel. Percentage of error against the overall error is compared with the criteria for example if the percentage of error of repeatability is less than 10% then it is said the measuring instrument have met the criteria no specific action is needed other than continue to use because it is fit for purpose, when the percentage is within 10% to 30% then instrument needs to be used with care since it performs near the boundary, most probably the exercise need to be repeated in near future. On the other hand when the percentage of error is greater than 30% it deems fail to comply with the requirements. The management need to consider the suitability of the instrument for use at this location.

Similarly reproducibility is to evaluate the skill of personnel using the instrument to collect data. The evaluation process has no difference from evaluate repeatability, of cause there is an important litmus test to meet before all these percentages of errors can be analysed; i.e. the number of distinct category (ndc) where it should be greater than five otherwise the exercise need to be repeated. This value represents the number of groups instrument can distinguish from the data itself. The higher this number, the better chance the tool has in discerning one part from another. This is the weakness of using production unit as master pieces instead of reference standards.

This tool requires two to three staffs involve in the actual measurement at the particular location to collect the data. The artefacts, again similar to the other tools, production units are used instead of reference standards. The process of evaluation needs some cares otherwise the mathematical models could not distinguish repeatability from reproducibility.

This study only deal with measuring instrument makes it differentiated from this MSA tool. MSA utilises all five tools to evaluate suitability of instrument and personnel whereas this study concentrates on capability of instrument according to the three equations.

6.7. Compare with traditional methods

Traditional methods have been discussed in the literature review section. Most of them are based on the multiples of resolution. The key differences from this research are:

6.7.1. Users requirement

The consideration of user's requirements not included in the measurement process that is similar to MSA.

6.7.2. Static information

Statistical information of measuring instrument is adopted and treated as the performance characteristics irrespective of the actual performance. Usually calibration information is not taking into consideration. The user considers adjustment is part of calibration process if necessary and accepts the instrument to perform with the specification.

6.7.3. Degradation

Measuring instrument deteriorates during usage, handling and even storage, when the instrument is new there is no problem to meet the requirements; however when it has aged there is no guarantee it shall perform within its specification.

6.8. Strength of this study

The comparison with MSA and the traditional methods above list arguments for differences and similarities with the study. There are certain issues emerged as the strength of this study over the other methods:

6.8.1. Consider user's requirements

Consider user's requirement. Equation (1) considers the usable range, Equation (2) involves directly the user's requirements and Equation (3) taking correction into consideration. On top of these actions taken, Equation (3) also considers the capability of the users to perform arithmetic and provide optional actions for the compensation.

6.8.2. Quality cost

Measurement cost overrun occurs when the measuring instrument use is unjustifiably possess much higher performance capability than required; on the other hand instrument unfit for purpose may result in higher quality cost as product not meeting specification may not be detected. The balance of quality cost needs to consider process requirements where this study provides the solution.

6.8.3. Metrological traceability

Demonstrates metrological traceability where the measuring instrument needs to be properly calibrated and the measurement uncertainty and correction data are the key information to determine fitness for use. Meeting ISO QMS requirement of traceability is important as part of business activities as well as for accreditation purposes. This is the weakness of MSA and traditional methods where no such consideration is allowed.

6.8.4. Holistic consideration

Holistic consideration of measuring ins4drtrument not merely on accuracy or resolution. The capability for fitness for use includes (a) capacity, (b) metrological characteristics, (c) correction compensation, (d) intermediate check

6.8.5. Adopt mathematical models

Adopt mathematical models to determine fitness for use is much more convincing than base on instrument resolution and accuracy because it is objective and consistent.

6.8.6. Universal

The equations are universal, can be adopted by any measuring instrument as long as it is calibrated with proper metrological traceability.

6.8.7. Simple and easy methods

Intermediate check procedures are simple and straight forward. Only stage one needs some calculation whereas stage two takes the least effort to complete.

6.8.8. Guideline for calibration interval

Intermediate check can be adopted as guideline for calibration interval. If the charting remains within control limits, it shows that the instrument still performing well within accepted target then there is no reason to recalibrate at predetermined time frame after all calibration is to provide performance characteristics information. Calibration interval may be extended to further date in future.

6.9. Weakness of this study

These proposals do exhibit some weaknesses. They are:

6.9.1. Calculations

Mathematical calculations to some users may find it difficult to understand not to mention adopt them. The alternative methods do not involve as much calculation.

6.9.2. Difficult to understand measurement uncertainty

The concept of measurement uncertainty is still relatively new to users at large and perform calibration is to meet QMS requirement not to mention understanding of metrological traceability. Whereas the traditional methods adopting the multiples of resolution is easily understood and implemented.

6.9.3. Source of criteria

User needs to determine metrological requirement for every measurement is not an easy task. Normally customers do not provide it is the user has to determine.

6.9.4. Relatively lengthy procedure

Lengthy procedure with three steps and actions to follow may confuse the user especially Equation (3) provides option to compensate for correction. This action may

cause misunderstanding and messing up the whole process. The procedure to compensate for correction may cause uneasiness to users with difficulty in arithmetic.

6.9.5. Excludes some factors

The study does not include effect cause by

a. User. MSA GR&R involve error due to user.
b. Environment. Under normal condition measuring instrument has to be calibrated at standard ambient temperature but may not use at this temperature. User may have to determine the effect of such differences in environmental condition. Other environmental conditions to consider include lighting, vibration, atmospheric pressure, gravitational force, air humidity, electrical signal interference comparability and many to list.

6.10. Opportunity

This study proposes systematic and consistent method to evaluate measuring instrument fitness for use as well as continuous meeting the requirements of ISO/IEC 17025 clauses 5.5.1, 5.5.2, 5.5.11 and 5.6.2.1.1, 5.5.11. The key issues are systematic and consistency. If the practice becomes norm,

6.10.1. Improve consistency in implementation

It could reduce the problems associated with different methods for example reduce assessment inconsistency and harmonise international practice.

6.10.2. Harmonise practice

Harmonise inter-laboratory comparison of test results. Different methods to determine measuring instrument fitness for use may result in differences in the test results.

6.10.3. Minimise arguments among people in practice

Reduce arguments among intra and inter ISO QMS on the subject of measuring instrument management.

6.10.4. Commercialisation

There is ample of opportunity to commercialise the study via package offer for intermediate checks. Refer to comments in Appendix 25

6.11. Challenges to the proposals

This proposal may not be accepted for reason other than the weaknesses stated above, other factors are the challenges:

6.11.1. Inconsistency in uncertainty evaluation

Measurement uncertainty components, expanded uncertainty reported in the calibration certificate is the result of the combination of components. The question arises where two accredited calibration laboratories with similar technical capacities perform calibration may not produce identical uncertainties. This is due to differences in the components considered in the evaluation. As mentioned earlier there is no standard list of components to be evaluated for a particular instrument calibration. Commercial laboratories tend to reduce this figure through intentional and unintentional ignorance of some important components in order to satisfy customer requirements. Refer o Appendix 25 Case study 1. Thus inconsistency of uncertainty may have negative impact on this study.

6.11.2. Selective implementation of the proposals

Selective implementation, of this study proposes three formulae plus intermediate check procedures to be adopted according to their sequence: however user may be selective example adopt only Equation (2) and ignore the other two either for advantage or lack of knowledge. Partially adopting the proposal may not bring in the benefits of systematic statistical examination of measuring instrument.

6.11.3. Resistance to accept proposals

MSA acceptance, MSA is widely accepted in GMP as well as ISO/TS 16949 factories since it is stipulated in the requirements by these standards. Resistance to changes in the system which have been in place for decades is evidence in all new concepts. One can foresee resistance to implement this proposal replacing the existing methods, it is an over haul of the measuring instrument system , the existing method has to be up rooted before this new proposal can be put in place. A good example of resistant to change is the measurement units. UK accepted SI units in the seventies, the general public still used to imperial system after more than half a century.

A study conducted on behave of a solder paste company review that intermediate check adopting the study proposal provide more conducive result than MSA GR&R. Refer to Appendix C 4 for detail of the study.

6.12. Impact of the research

This study emphasises on instrument fitness for use in relation to the users' requirements, practicality and cost effectiveness thus its impact on the industry can be expected to bring harmonisation and consistency in the management of measuring instrument. These solutions could become the common practice in future.

CHAPTER 7

7. Conclusion

Measurement is an important activity for its role in determining acceptance or rejects products or services. It needs measuring instrument to complete the activity, thus the accuracy is of vital importance to this process. This study provides full procedures from determine registration until perform intermediate check procedures to determine measuring instrument fitness for use that capitalises on statistical analysis couple with control charts technique.

7.1. Contribution of this work

This study contributes towards efficient measuring instrument management in the ISO QMS environment. The solutions put forwards are statistically based, consider the users' requirements and finally cost effectiveness.

7.1.1. The first solution

The first solution is regarding measuring instrument fit for purpose. The initial formula is to examine capacity of the instrument. The study provides a solution in the form of a logic format to determine the minimum and maximum capacity. The measured value has to be within this limit otherwise not for purpose. The second formula suggested is regarding metrological characteristics of the measuring instrument where measurement uncertainty is the key factor. Again it is in logic format follow with suggested action to be taken. When the formula is true, the instrument is regarded as acceptable to be used and the next step should be followed. When is false it cannot be accepted because measured value has very high probability to fall out of the requirements. The third formula provides method to deal with correction reported in the calibration certificate. Equation (3) provides a solution to determine the correction magnitude significantly might affect the measured result. When the correction is insignificant then no compensation is needed since the effect is insignificantly small. On the other hand there is an option for measurement result whether to be compensated for every measurement taken otherwise not fit for purpose.

7.1.2. The second solution

The second solution contributes is regarding time base continuous fitness for use. There are five types of chart proposed utilises the concept of time base run chart. These charts are to determine measuring instrument maintain fitness for use over certain time frame. They are differentiated according to method of deriving control limits. MR chart is where the control limits are according to the metrological requirements of the process. MU chart is according to the measurement uncertainty of the measuring instrument as control limits. SD and DA charts utilise the standard deviation of a set of data collected during stage one. SD chart using only 1 piece of artefact whereas DA chart takes the difference of a pair of artefact with small difference. These charts are suitable for working standards where artefacts can be found easily. Reference standards are recommended to adopt ABC chart. This control chart utilises two pieces of artefacts with similar physical property and the differences among them are translated into control chart similar to SD and DA charts.

Actions are taken according to the location of point plotted with respect to the control limits. User continues to use the instrument when the point falls within the control limits otherwise stop using it.

The suggestions made by this study through three formulae when compare with traditional methods and MSA, there are advantages over them in systematic, consistency and statistically determined evaluation for fit for purpose; however implementation may encounter problems due to calculations and complicated procedures. Users may find that it is not easy to perform calculation relates to compensation of correction.

These proposed techniques for intermediate check proved more efficient than traditional measuring instrument verification technique. They are user friendly and easy to follow at the same time meeting ISO QMS requirement especially ISO/IEC 17025. An important issue is that intermediate check procedure can be commercialised as package deal with hard ware, software and training.

7.1.3. Impact of the study

This study provides solutions to long term inconsistency in measuring instrument management. It could become the common knowledge and practice throughout the ISO QMS environment.

7.2. Suggestion for further research

Further research into differences between control chart techniques and MSA is needed to encourage understanding of the subject and improve the procedure to be more efficient and user friendly.

REFERENCE

[1] Advance Material Research Vols.622-623 (2013) pp 1401 - 1404

[2] AIAG Measurement systems analysis reference manual, 4th edition, 2010, Pg 15

[3] ASTM D2166/D2166M - 16. Standard Test Method for Unconfined Compressive Strength of Cohesive Soil, 2016

[4] ASTM D3441 - 16. Standard Test Method for Mechanical Cone Penetration Testing of Soils, 2016

[5] ASTM E126 - 13a. Standard Test Method for Inspection, Calibration, and Verification of ASTM Hydrometers, 2013

[6] ASTM E1502 - 10. Standard Guide for Use of Freezing-Point Cells for Reference Temperatures, 2010 .

[7] ASTM E2730 - 10(2015)E2. Standard Practice for Calibration and Use of Thermocouple Reference Junction Probes in Evaluation of Electronic Reference Junction Compensation Circuits, 2015

[8] BS 1647-2:1984. pH measurement. Specification for reference value standard solutions and operational reference standard solutions, 1984

[9] BS 1881-124:2015. Testing concrete. Methods for analysis of hardened concrete

[10] BS EN 12390-4:2000 Testing Harden concrete, Part 4: Compressive strength – specification for testing machine, 2000

[11] BS ISO 15790:2004. Graphic technology and photography. Certified reference materials for reflection and transmission metrology. Documentation and procedures for use, including determination of combined standard uncertainty, 2004

[12] BS EN 480-13:2015. Admixtures for concrete, mortar and grout. Test methods. Reference masonry mortar for testing mortar admixtures, 2015

[13] BS EN ISO 6926:2001. Acoustics. Requirements for the performance and calibration of reference sound sources for the determination of sound power levels, 2001.

[14] B.W. Mangum, Reproducibility of the temperature of the ice point in routine measurement. NIST Technical Note 1411, June 1995

[15] D. Flank, J Hannaford, Measurement Good Practice Guide No. 80, Fundamental Good Practice in Dimensional Metrology, 2005, NPL, Pg 46

[16] Er. R.K. Jain, Engineering Metrology, 7th edition, 2000, Khanna Publishers, Pg 9

[17 Euramet cg20 Calibration of Climatic Chambers Guidance for Calibration Laboratories, 20, Version 3.0 (03/2011)

[18] Forrest W. Breyfogle III, Implementing Six Sigma smarter solutions using statistical methods, second edition, 2003, John Wiley, Pg 306-341

[19] International Laboratory Accreditation Cooperation ILAC-G24:2007, Guidelines for the determination of calibration intervals of measuring instruments, 2007, Pg 5 – 10

[20] ISO, ISO Guide to the expression of uncertainty in measurement , 1995

[21] ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes, 2016

[22] ISO 13820 Paper, board and corrugated fibreboard -- Description and calibration of compression-testing equipment, 2014

[23] ISO 14001 Environmental management systems -- Requirements with guidance for use, 2015

[24] ISO 14556 Metallic materials -- Charpy V-notch pendulum impact test -- Instrumented test method, 2015

[25] ISO 14577-2 Metallic materials -- Instrumented indentation test for hardness and materials parameters -- Part 2: Verification and calibration of testing machines, clause 6 Apparatus, 2015

[26] ISO 14577-3 Metallic materials -- Instrumented indentation test for hardness and materials parameters -- Part 3: Calibration of reference bloc, 2015

[27] IS/ISO/TS 16949 Quality Management Systems - Particular Requirements for the Application of ISO 9001:2008 for Automotive Production and Relevant Service Part Organizations [MSD 2: Quality Management], 2016

[28] ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories, Pg 17

[29] ISO 17662:2016 Welding -- Calibration, verification and validation of equipment used for welding, including ancillary activities, 2016

[30] ISO 1920-7:2004 Testing of concrete -- Part 7: Non-destructive tests on hardened concrete, 2004

[31] ISO 22000 (2005): Food Safety Management Systems -Requirements for any organization if the food chain [FAD 15: Food Hygiene, Safety Management and Other Systems]

[32] ISO 376:2011, Metallic materials – calibration of force proving instrument use for verification of uniaxial testing machine, 2011

[33] ISO 377:2013, Steel and steel products -- Location and preparation of samples and test pieces for mechanical testing, 2013

[34] ISO 3951-1:2013 Sampling procedures for inspection by variables -- Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL, 2013

[35] ISO 4113:2010 Road vehicles -- Calibration fluids for diesel injection equipment, 2010

[36] ISO 4965-1:2012, Metallic materials -- Dynamic force calibration for uniaxial fatigue testing -- Part 1: Testing systems, 2012

[37] ISO 4965-2:2012, Metallic materials -- Dynamic force calibration for uniaxial fatigue testing -- Part 2: Dynamic calibration device (DCD) instrumentation, 2012

[38] ISO 6506-2:2014, Metallic materials – Brinell hardness test – Part 2: Verification and calibration of testing machines, 2014

[39] ISO 6506-3:2014 Metallic materials -- Brinell hardness test -- Part 3: Calibration of reference blocks, 2014

[40] ISO 6508-2:2015, Metallic materials -- Rockwell hardness test -- Part 2: Verification and calibration of testing machines and indenters, 2015

[41] ISO 6508-3:2015 Metallic materials -- Rockwell hardness test -- Part 3: Calibration of reference blocks, 2015

[42] ISO 7500-1:2015, Metallic materials -- Calibration and verification of static uniaxial testing machines -- Part 1: Tension/compression testing machines -- Calibration and verification of the force-measuring system, 2015

[43] ISO 7500-2:2006 Metallic materials -- Verification of static uniaxial testing machines -- Part 2: Tension creep testing machines -- Verification of the applied force, 2006

[44] ISO 9001:2008, Quality management systems- Requirements, clause 7.6

[45] ISO 9001:2015, Quality management systems- Requirements, clause 7.1.5

[46] JCGM 101, Evaluation of measurement data — Supplement 1 to the "Guide to the expression of uncertainty in measurement" — Propagation of distributions using a Monte Carlo method, 2008.

[47] JCGM 200:2008, International vocabulary of metrology – basic and general concepts and associated terms, VIM 2.13 Measurement accuracy

[48] JCGM 200:2008, International vocabulary of metrology – basic and general concepts and associated terms, VIM 2.39 Calibration

[49] JCGM 200:2008, International vocabulary of metrology – basic and general concepts and associated terms, 2008

[50] JCGM 200:2008, International vocabulary of metrology – basic and general concepts and associated terms, VIM 2.47 Metrological Traceability

[51] J K Liker, The Toyota Way, 2004, McGraw-Hill

[52] James L. Thomas, Reproducibility of the ice point, Research paper RP658, Part of Bureau of Standards Journal of Research Vol 12 March 1934,

[53] JV Nicholas， DR White - Traceable Temperatures: An Introduction to Temperature Measurement and Calibration, Second Edition, John Wiley & Sons, Ltd, 2002:95-124

[54] Kl Lua, An Alternative Method To Determine Measuring Instrument Fitness 2012

[55] Measuring instrument intermediate check, ICDQM-2013, pg 61 – 69, ISBN 978-86-86355-15-7

[56] Measurement System Analysis, 4th Edition, 2010, ISBN 978-1-60-534211-5

[57] Measuring instrument intermediate check, ICDQM-2013, pg 61 – 69, ISBN 978-86-86355-15-7

[58] MS 1514, STANDARDS MALAYSIA, REQUIREMENTS FOR THE ACCREDITATION OF BODIES OPERATING CERTIFICATION OF GOOD MANUFACTURING PRACTICE FOR FOOD TO MS 1514, Issue 1 18 June 2013

[59] METALLIC MATERIALS - KNOOP HARDNESS TEST - PART 2: VERIFICATION AND CALIBRATION OF TESTING MACHINES (FIRST REVISION) (ISO 4545-2:2005, IDT), 2009

[60] MS EN 932-5: 2011, TESTS FOR GENERAL PROPERTIES OF AGGREGATES - PART 5: COMMON EQUIPMENT AND CALIBRATION (SECOND REVISION), 2011

[61] MS ISO 10012:2003 Measurement management systems -- Requirements for measurement processes and measuring equipment.

[62] MS ISO 13820: 2004, Paper, Board and Corrugated Fibreboard – Description and Calibration of Compression – Testing Equipment (ISO 13820:1996, IDT), 2004

[63] MS ISO 15189, Requirements for Quality and Competence, 2014

[64] MS ISO 18899: 2008, Rubber – Guide to the Calibration of Test Equipment (ISO 18899:2004, IDT), 2008

[65] MS ISO 2859:2001, Sampling procedures for inspection by attributes, 2001

[66] MS ISO 376:2015, Metallic Materials – Calibration of Force--Proving Instruments Used For The Verification of Uniaxial Testing Machines (First Revision) (ISO 376:2011, IDT), 2015

[67] MS ISO 3951:2007, Sampling procedures for inspection by variables, 2007

[68] MS ISO 5725-3: 2002, Accuracy (Trueness and Precision) of Measurement Methods and results - Part 3 : Intermediate Measures of The Precision of A Standard Measurement Method (ISO 5725-3:1994, IDT) , 2002

[69] MS ISO 6506-2: 2009, Metallic Materials - Brinell Hardness Test - Part 2: Verification And Calibration Of Testing Machines (ISO 6506-2:2005, IDT), 2009

[70] MS ISO 7500-1: 2003, Metallic Materials – Verification Of Static Uniaxial Testing Machines – Part 1: Tension/Compression Testing Machines – Verification and Calibration of The Force-Measuring System, 2003

[71] MS ISO 9513: 2015, Metallic Materials - Calibration of Extensometer Systems Used In Uniaxial Testing (First Revision) (ISO 9513:2012, IDT), 2015

[72] MS ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories, clause 5.5.2

[73] NATA, Biological Testing Field Application Document – Supplementary requirements for accreditation, 2009, Pg 23-25

[74] NATA, Calibration ISO/IEC 17025 Application Document, August 2015

[75] NATA, Chemical Testing Field Application Document – Supplementary requirements for accreditation, 2007, Pg 11-12

[76] NATA, Chemical Testing ISO/IEC 17025 Application Document, November 2014

[77] NATA, Mechanical Testing ISO/IEC 17025 Application Document Annex B: Metals, June 2015

[78] NATA, Mechanical Testing ISO/IEC 17025 Application Document Annex H: Microstructural tests, June 2015

[79] NATA , Policy Circular 11, Policy on Metrological Traceability, October 2015

[80] NATA, Policy Circular 12, Policy on equipment assurance in house calibration and equipment verification , October 2015

[81] NATA, Technical Notes 23 Quality assurance in chemical testing laboratories, 2008, Pg 4

[82] OIML R111-1 Weights of class E1, E2, F1, F2, M1, M1-2, M2, M2-3, M3, Part 1 Metrological and technical requirements, 2004, Pg 11

[83] Oakland, J. (2002). Statistical Process Control. ISBN 0-7506-5766-9.

[84] PD 6532-5:1997. Reference materials. Guide to the contents of certificates of reference materials. Quality system guidelines for the production of reference materials, 1997

[85] SAE AS9100C, Quality Management Systems - Requirements for Aviation, Space and Defense Organizations, 2009

[86] SC 1.5 – Specific criteria for accreditation of mechanical testing and non-destructive testing (NDT) Issue 1, 28 December 2010, JABATAN STANDARD

[87] SAMM POLICY 5 (SP5) – Policy on Measurement Uncertainty Requirements For SAMM Testing Laboratories, Issue 2, 28 February 2007

[88] Standards Malaysia, MS 1514:2012 (BM), Amalan Pengilangan yang Baik (GMP) bagi makanan (Semakan Pertama), 2012

[89] SPRING Technical Guide 1, The SAC Accreditation Programme, Singapore, Second Edition, March 2001

[90] SPRING Technical Guide 2, A Guide on Measurement Uncertainty in Chemical & Microbiological Analysis, Second Edition, March 2008

[91] SPRING Technical Guide 3, Guidance on Measurement Uncertainty for Civil Engineering and Mechanical Testing Laboratories, First Edition, Jun 07

[92] SPRING Technical Note C&B and ENV 002, Chemical lab requirement for equipment management, 30 June 2016

[93] SPRING Guidance Notes EL 001, Guidelines on the Evaluation and Expression of Measurement Uncertainty for Electrical Testing Field, May 2002

[94] SPRING Technical Notes EL 002, Specific Policy for Uncertainty Measurement for Electrical Testing Laboratory, Nov 2006

[95] SPRING Technical Note, ENV 001, Specific Requirements for Environmental
Testing Laboratories, 30 June 2016

[96] SPRING, Technical Notes MET 001, Specific requirements for calibration and measurement laboratory, SAC, 2010, Pg 5 – 7

[87] TLAS, Publication G20, Guidelines for Calibration and Checks of Temperature Controlled Enclosures, G-20-1/02-08

[98] UKAS, LAB24, Calibration and Traceability in mechanical testing of matellic materials, 2000, Pg 4-7, 11-20

[99] UKAS, LAB 21, Calibration and traceability for construction materials, 2000, Pg 5-6, 9-27

[100] UKAS, LAB 14 Calibration of weighing machine, Edition 4, 2006, Pg 2-4, 8

[101] UKAS, LAB 5, Reporting Calibration Results, Edition 2, November 2012

[102] UKAS, LAB 12, The Expression of Uncertainty in Testing, Edition 2, August 2016

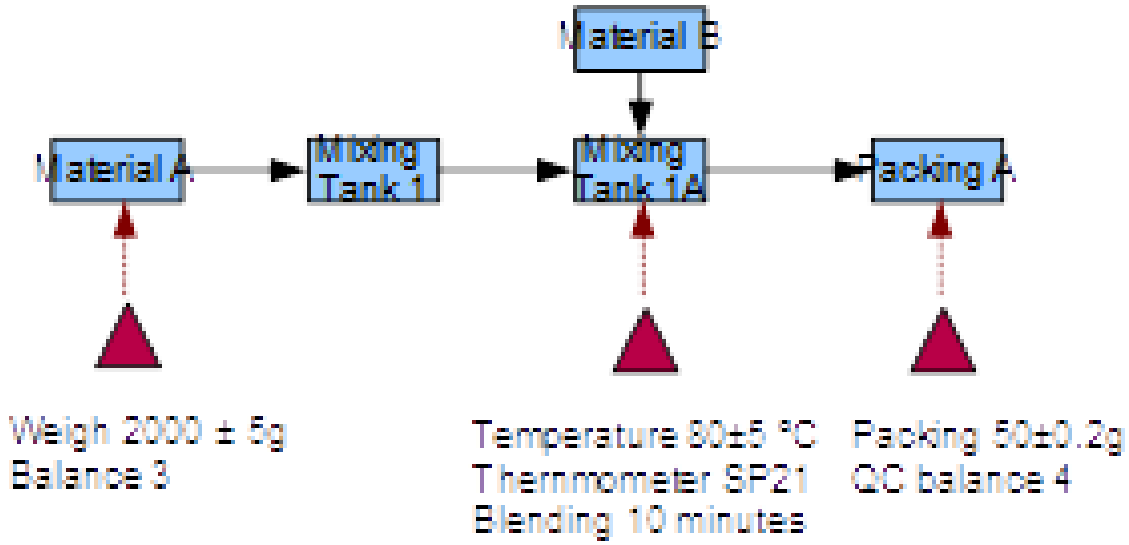
[103] UKAS, LAB 14, In - House Calibration and Use of Weighing Machines, Edition 5, July 2015

[104] UKAS, TPS 25, Measurement of Surface Regularity of Road Pavement Surfaces using the Rolling Straight Edge – Requirements for Calibration and Performance Checks, Edition 5, March 2008

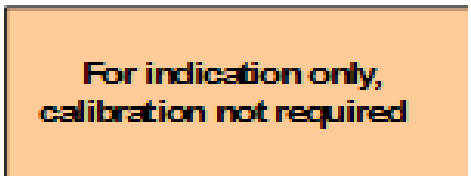
[105] UKAS, TPS 41,P olicy on Metrological Traceability, Edition 4, June 2014

APPENDICES

Appendix 1 Process flow chart indicates the measuring instrument need to be calibrated

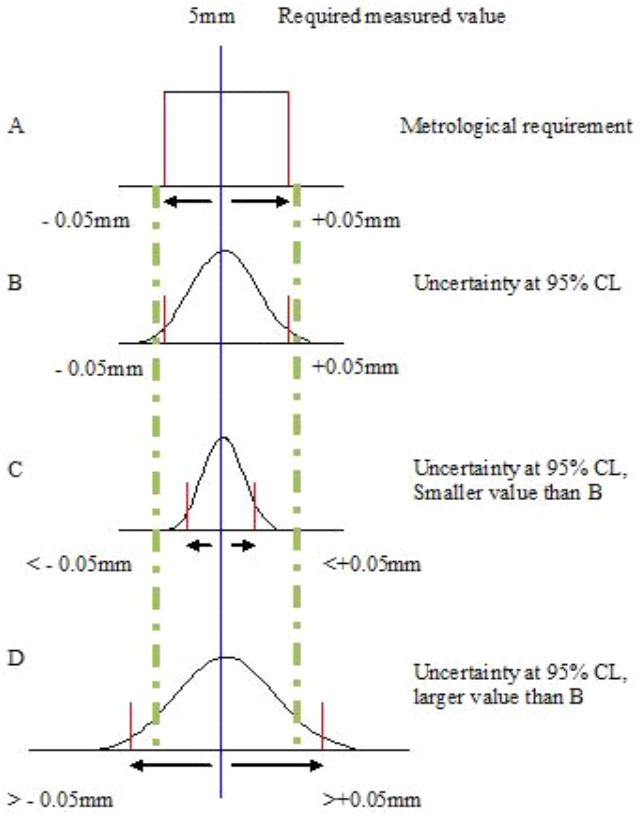


Appendix 2 No calibration sticker



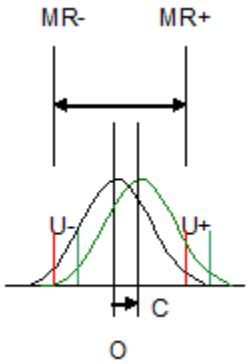
The colour, wordings and size of the sticker may change to suite organisation culture

Appendix 3 Illustrates the logic behind equation (2)

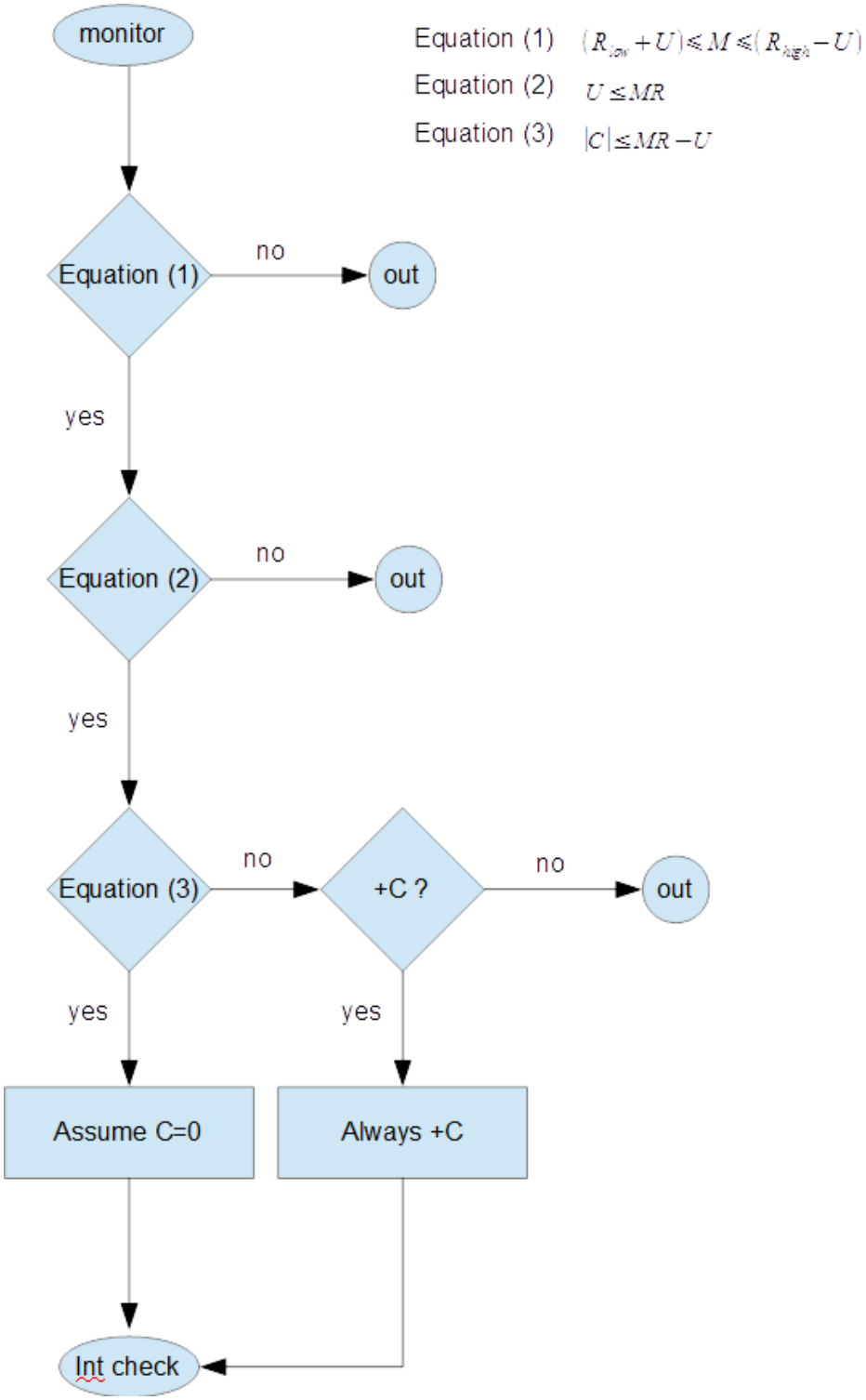


Fundamental concept of measurement uncertainty and metrological requirement

Appendix 4 Illustrates the drift of mean



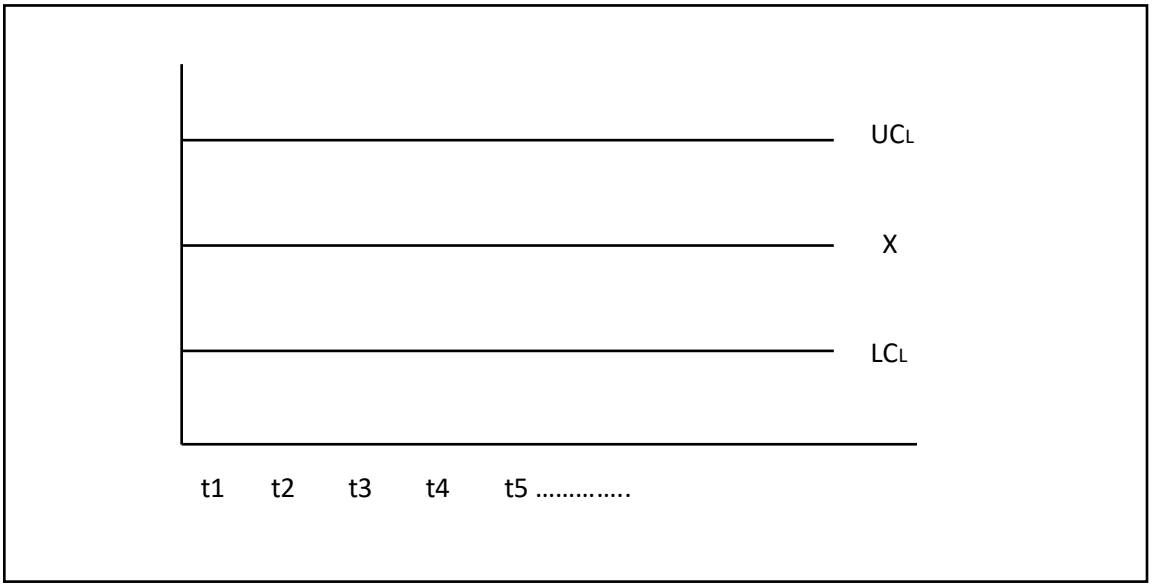
Appendix 5 Flow chart showing process to determine measuring instrument fitness for use



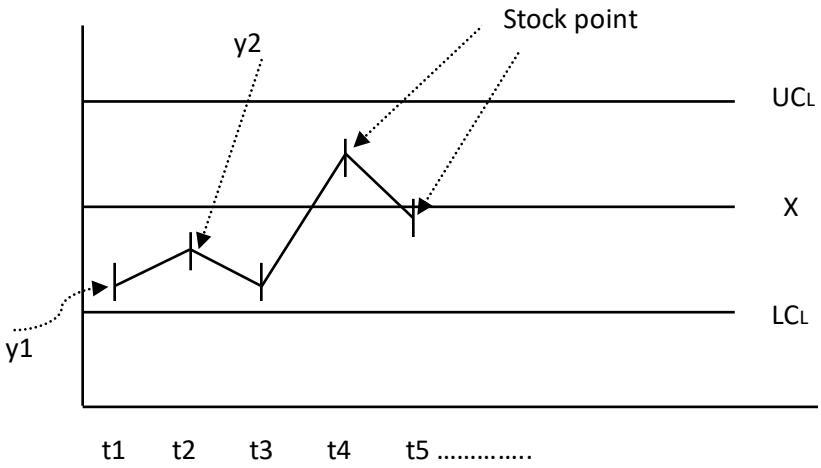
Appendix 6 Suggested artefacts list

Field of measurement	Measuring instrument	Artefact
Dimension	Calliper	Gauge block or stainless steel block with mid-point measurement
	Micrometer	
Temperature	Thermometer (RTD, TC, mechanical)	Ice point
	Instrumentation (RTD input	Fixed resistor about 100Ω or any other resistance suitable for the input about 0°C
	Heat enclosure (oven, incubator, furnace)	Thermocouple wire or RTD probe fixed permanent in the chamber or removable probe but able to repeat the location
Force	Balance	Standard weight or stainless steel block with mid-point measurement
	Tensile testing machine	Dead weight or stainless steel block with mid-point measurement suspension

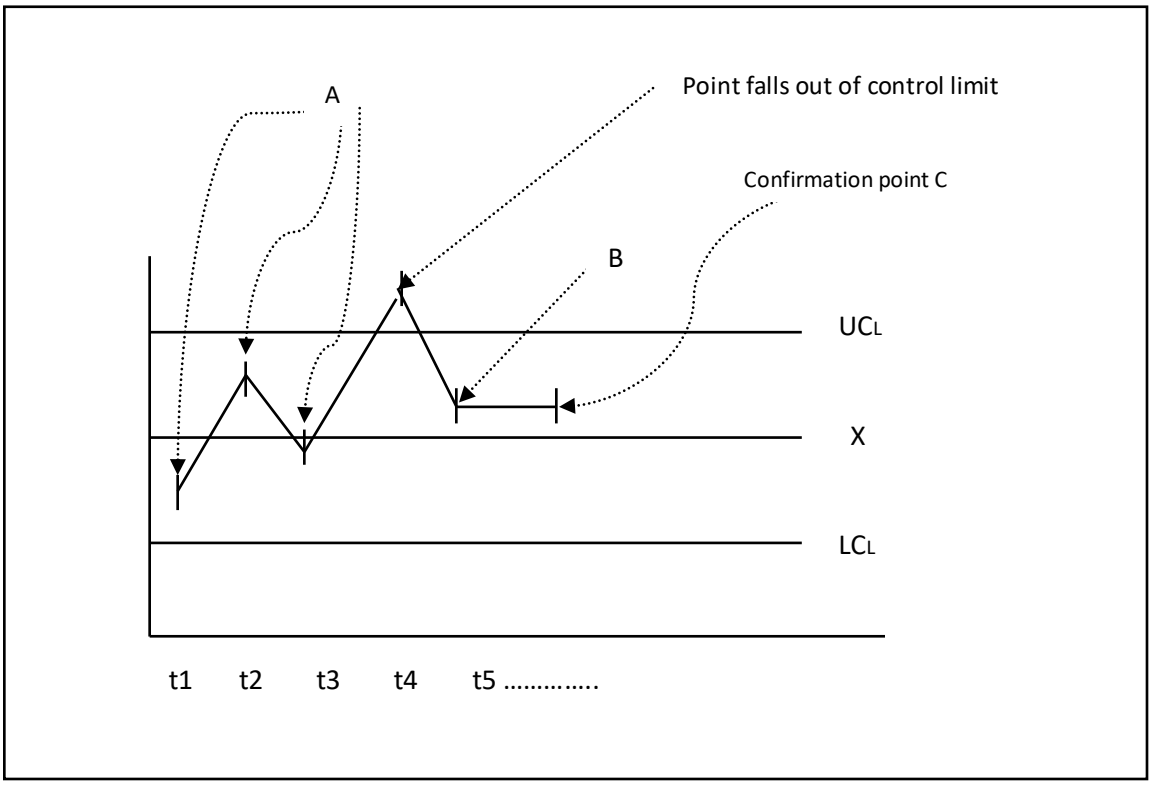
Appendix 7 The basic control chart with MR as control limits. UCL and LCL are calculated based on MR ±X



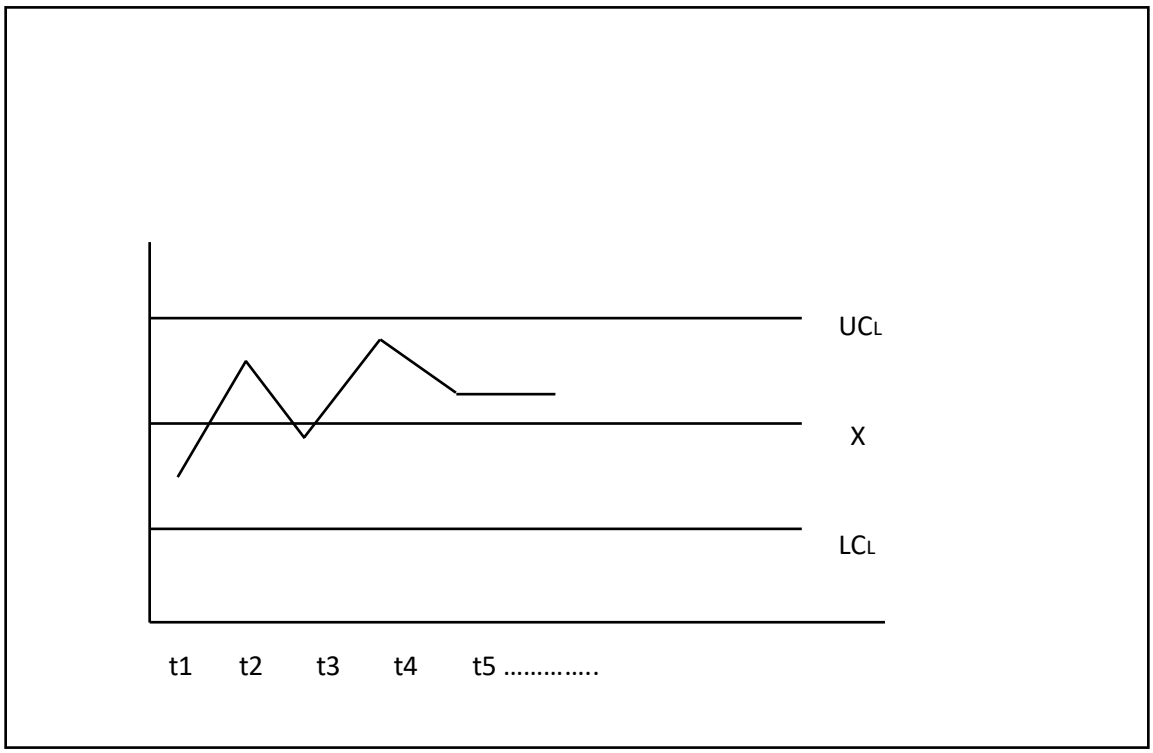
Appendix 8 Illustrates stock point plotted on the MR chart



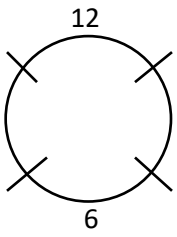
Appendix 9 Illustrates the confirmation point



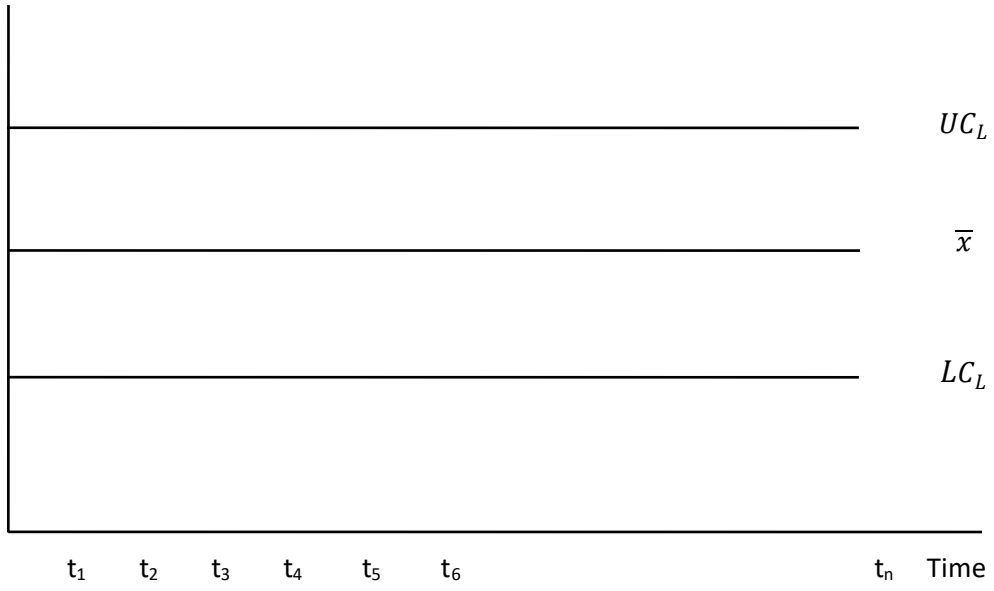
Appendix 10 simplified MR chart



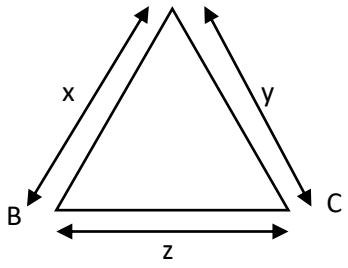
Appendix 11 Illustrates the time to collect n

		Count, n	
A	Early morning	1	
B	Late morning	1	
C	Early afternoon	1	
D	Late afternoon	1	
Total per day		4	
Total per 5 day week		20	
Total for 2 weeks		40	

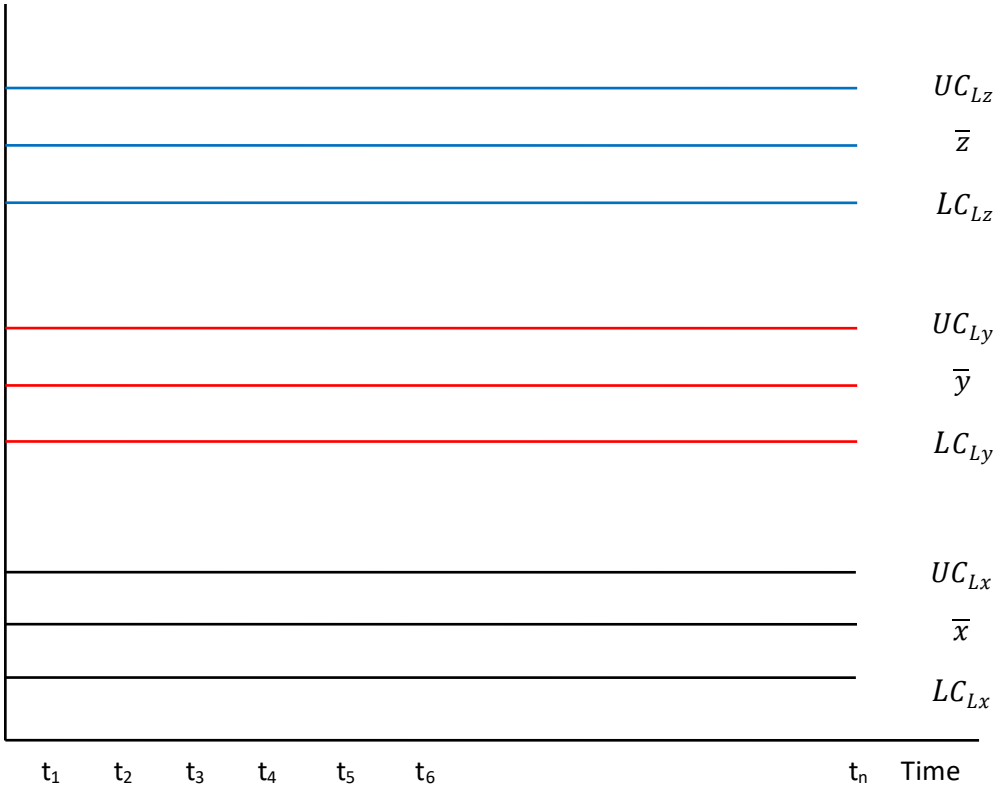
Appendix 12 The basic SD chart with control limits drawn from deviation of base data



Appendix 13 Triangular relation of artefacts and measuring instrument



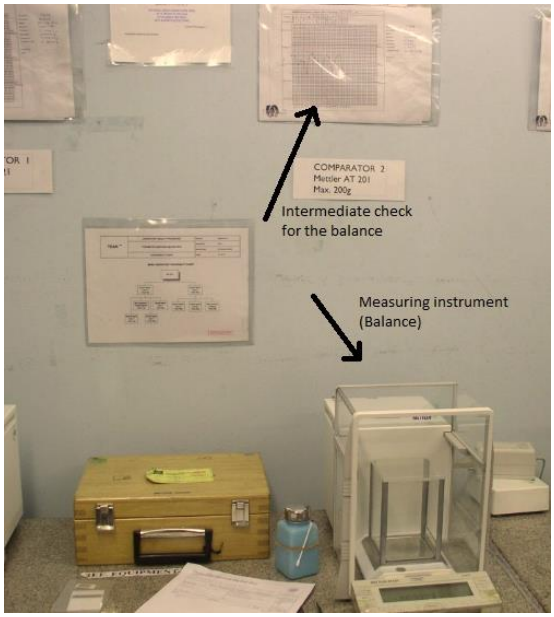
Appendix 14 staggered charts of x, y and



Appendix 15 Demonstrates the use of MS ISO 2859 acceptance sampling theory

Item	No of piece for a set	Inspection level S1 Code	Table 2C	AQL
Gauge block	114	B/3	0/1	4.0

Appendix 16 Illustrates Kanban concept in implementation



Appendix 17 Table shows summary of suitability of MR chart.

Suitable for measuring instrument use in		Unsuitable for measuring instrument use in	
1	Low precision	1	Medium and high precision measurement
2	Cannot calculate standard deviation due to low accuracy	2	High precision measurement system with narrow MR
3	Large MR	3	Variation is insignificantly to the process
		4	Need to take difference value of the artefacts

Appendix 18 Table shows summary of suitability of MU chart.

Suitable for measuring instrument use in		Unsuitable for measuring instrument use in	
1	Medium precision measurement	1	Low precision and very large MR
2	Medium precision measurement system with narrow MR	2	Stability of measuring instrument is high and the variation is insignificant
3	Variation is significant to the process	3	Small measurement uncertainty with large MR ratio
4	Low sensitivity where σ cannot be detected from the pool of data at stage one	4	Need to take difference value of the artefacts
		5	Wide measuring range

Appendix 19 Table shows summary of suitability of SD chart.

Suitable for measuring instrument use in		Unsuitable for measuring instrument use in	
1	Medium and high precision measurement	1	Low precision and very large MR
2	High precision measurement system with narrow MR	2	Stability of measuring instrument is high and the variation is insignificant
3	Variation is significantly to the process	3	Small measurement uncertainty with large MR ratio
		4	Sensitivity of measuring instrument is low where σ from stage one is not able to be detected.

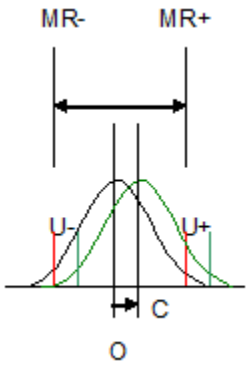
Appendix 20 Table shows summary of suitability of DA chart.

Suitable for measuring instrument use in		Unsuitable for measuring instrument use in	
1	High precision measurement. Not practical to have single piece of artefact for the measured value.	1	Low precision and very large MR
2	High precision measurement system with narrow MR	2	Stability of measuring instrument is high with insignificant variation
3	Cannot use single piece of artefact	3	Small measurement uncertainty with large MR ratio
4	Need to take difference value of the artefacts		

Appendix 21 Table shows summary of suitability of ABC chart.

Suitable for measuring instrument use in		Unsuitable for measuring instrument use in	
1	Reference standards	1	Working standards and Low precision and very large MR
2	Artefacts has same physical property as the measuring instrument		

Appendix 22 Illustrates correction is the shift of centre tendency line either to positive or negative side of the population density chart.



Appendix 23 Summarised the differences between control chart base on MR as control limits and R&R

	Control chart base on MR as limit	R&R study
Input resources	Minimum 1 user involve	Many users involve
	Short time consume to take measurement and transfer onto the chart	Lengthy process of data collection and many readings required for calculation
	No calculation	Need to use some formulae to determine the value of repeatability, reproducibility and number of distinct categories (ndc)
Interpretation	Base on position and trend of points plotted on the chart	Base on preset value compare with the calculated value
Action taken	Either continue to use the instrument or stop using it	Need to retrain the user or evaluate the environmental condition to meet the requirement.
Characteristic	Evaluate measuring instrument only	Evaluate user and measurement system.
	Capitalise on MR	Parts of expected variations are used. There is no mention of process specification, thus assuming the expected variation equals to process specification

Appendix 24 Intermediate check Vs Stability test

	Intermediate check	Stability test
1	Single reading is taken	Multiple readings taken and the average is transferred to the control chart.
2	utilises 2σ coincide with probability of confidence level of 95% measurement uncertainty	Control limits are drawn at 3σ equivalent to 99.7% probability
3	Single chart	Multiple charts
4	Base data include environmental condition	Collect within short time to exclude environmental condition

Appendix 25 Case study 1

Case study 1

Calibration certificate from a SAMM accredited laboratory conducting oven calibration for a soil testing laboratory. Soil moisture content testing according to BS 1377 part 2 requires the oven to be set at $107.5 \pm 2.5℃$ for drying purpose.

This laboratory calibrated the oven according to AS 2862. Multiple thermocouples were inserted into the oven cavity at specific locations to measure the temperature distribution. Data were recorded by data logger and the performance characteristics were derived and reported in the calibration certificate. The expanded uncertainty quoted in the calibration certificate is $U = \pm 1.0℃$ at 95% confidence level. This AS 2862 provides guideline to install temperature sensors and evaluate the performance but no guideline to evaluate uncertainty. The laboratory has the freedom to evaluate the uncertainty within their knowledge and integrity. An investigation into the uncertainty evaluation shows that the quoted figure is not representative of the performance of the oven, it is too small. There are two important components the spatial and temporal variations are extremely large to result in very small uncertainty quoted. Spatial variation is the temperature variation from one location to another within the working space, some refer it to temperature profile is reported $9.6℃$ at $105.0℃$ setting. The temporal variation on the other hand refers to temperature stability at equilibrium state is reported $13.6℃$ at the same temperature setting. On further investigation from the calibration house, shows that these two components were not included in the evaluation of measurement uncertainty. There were only four components involve in the evaluation, i.e. reference thermocouple wires with data logger, long term drift of the reference, resolution of oven and repeatability. These components were combined using Equation (4)

$$u_c{}^2 = \sum_1^n \left(\frac{dy}{dx}\right)^2 . u_n{}^2 \qquad \text{----------(4)}$$

Then expanded using this equation

$U = u_c \; x \; k$

where k is the coverage factor and it was assumed to be equal to 2 for 95% confidence level.

Cross reference to other reference methods

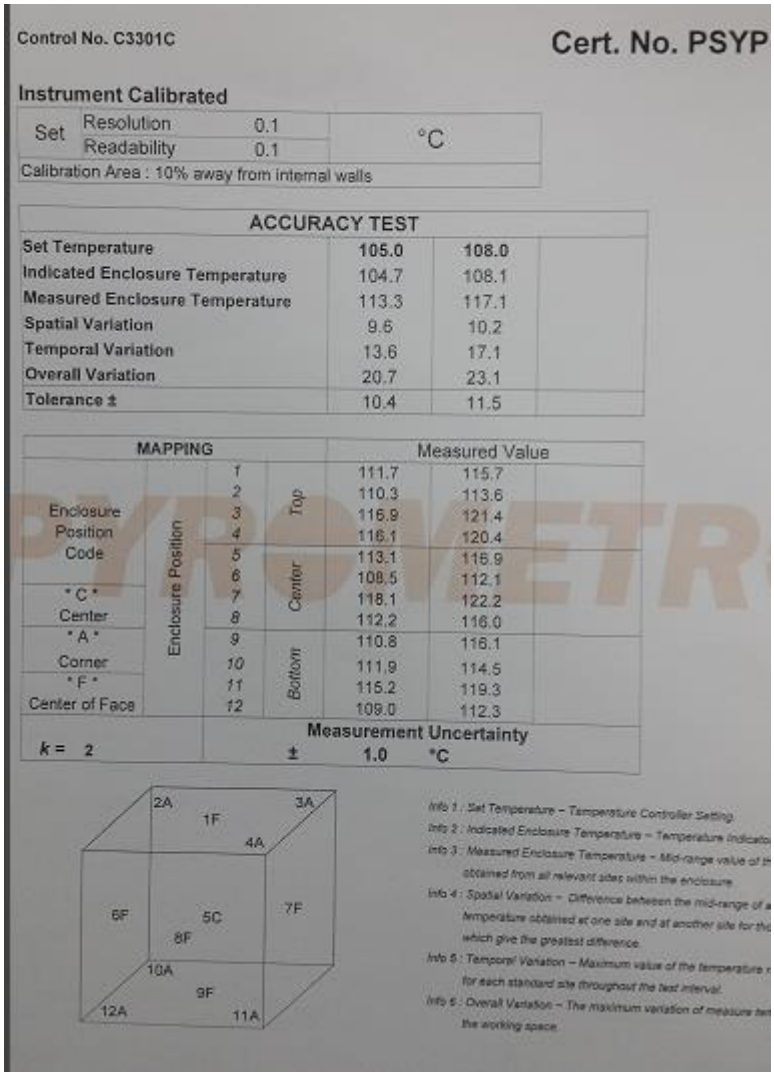
a) TLAS management issued test method for heat enclosure calibration *Guidelines for Calibration and Checks of Temperature Controlled EnclosuresG-20-1/02-08* provides a guideline to evaluate uncertainty.
    a. δ T Stab is the stability of measurement or repeatability of standard;
b) EURAMET cg-20 Version 3.0 (03/2011) CALIBRATION OF CLIMATIC CHAMBERS Guidance for Calibration Laboratories
    a. Air temperature/humidity spatial distribution in the specified calibration volume
    b. Air temperature/humidity temporal stability over a representative period of time

There is no common stand in determining the components, TLAS emphasis on the stability that is the temporal variation whereas EURAMET cg-20 requires both spatial and temporal variations to be included. The table below shows recalculation adopting the fundamental data from the calibration certificate according to these references.

Organisation	Common u	$u_{spatial}$	$u_{temporal}$	u_c	U	MR	Meet Equation 2
Calibration laboratory	1.0÷2	-	-	0.5	1.0	2.5	Yes
TLAS	1.0÷2	-	13.6÷(2*√3)	3.9	7.9		No
EURAMET cg-20	1.0÷2	9.6÷(2*√3)	13.6÷(2*√3)	4.8	9.6		No

The recalculated table above shows that both TLAS and EURAMET cg-20 methods have much higher uncertainties and they both could not meet the requirement of Equation (2) $U \leq MR$. Whereas the laboratory reported uncertainty definitely has no problem to meet Equation (2) requirement.

GUM does not provide the uncertainty components for specific instrument may lead to variations in the uncertainty reported from different organisations.



Control No. C3301C

Cert. No. PSYP

Instrument Calibrated

Set	Resolution	0.1	°C
	Readability	0.1	

Calibration Area : 10% away from internal walls

ACCURACY TEST		
Set Temperature	105.0	108.0
Indicated Enclosure Temperature	104.7	108.1
Measured Enclosure Temperature	113.3	117.1
Spatial Variation	9.6	10.2
Temporal Variation	13.6	17.1
Overall Variation	20.7	23.1
Tolerance ±	10.4	11.5

MAPPING				Measured Value	
Enclosure Position Code	Enclosure Position	1	Top	111.7	115.7
		2		110.3	113.6
		3		116.9	121.4
		4		116.1	120.4
		5	Center	113.1	116.9
		6		108.5	112.1
" C " Center		7		118.1	122.2
		8		112.2	116.0
" A " Corner		9	Bottom	110.8	116.1
		10		111.9	114.5
" F " Center of Face		11		115.2	119.3
		12		109.0	112.3

Measurement Uncertainty

$k = 2$ ± 1.0 °C

Info 1 : Set Temperature – Temperature Controller Setting
Info 2 : Indicated Enclosure Temperature – Temperature Indicato
Info 3 : Measured Enclosure Temperature – Mid-range value of th obtained from all relevant sites within the enclosure.
Info 4 : Spatial Variation – Difference between the mid-range of a temperature obtained at one site and at another site for th which give the greatest difference.
Info 5 : Temporal Variation – Maximum value of the temperature v for each standard site throughout the test interval.
Info 6 : Overall Variation – The maximum variation of measure te the working space.

Appendix 26 Case study 2

1. INTRODUCTION

The experiment was conducted in Pyrometro Services Sdn Bhd from February 2013 to October 2013. This company is a SAMM ISO/IEC 17025 accredited calibration laboratory. The objectives of the experiment are to test

a) the hypothesis and
b) implementation by accredited laboratory

Due to limitation of measuring instrument and knowledge at the company, measuring instrument in the field of a) dimension, b) temperature, c) electrical and d) force and pressure are involved. SD, DA and ABC charts are tested because MR chart has no difference from MU chart except the limits and the implementation process is similar to the other three charts.

1.1. Back ground of the company

Pyrometro Services (M) Sdn. Bhd. Is a private own calibration laboratory set up in the year 1993 with head quarter
located in Glenmarie Industrial Part outskirt of Kuala Lumpur. It attained SAMM accreditation in 1993 in the field of temperature calibration as initial scope. Later the scope extends to

a) Temperature, main reference is SPRT25 thermometer
b) Mass, force and pressure, main references are class 1 standard weights for mass and 0.005% dead weight tester
c) Dimension, main reference is grade 00 gauge blocks
d) Electrical, main reference is Flute 5500

There are three branches located at Penang, Ipoh and Johore Bahru and all are also accredited. The total strength is about a hundred staffs comprises 60% technical staffs. The study was conducted at the head quarter laboratory. The management agreed to participate in the study for their benefit to meet accreditation requirement.

2. PROCEDURE

The personnel involved in the programme were senior technical staffs performing calibration of measuring instrument as routine function. Each one only performed one instrument to reduce confusion among them. Training on intermediate check procedure was given to during a half day session. The content of training not limited to the procedure, it also involve the use of prewritten spread sheet base on Open Office Cal. This particular application software was chosen to be in line with the company policy of using Open Office application software in routine operation to reduce problems associated with software familiarity.

There were four fields of measurement involve,

a) Temperature
b) Electrical
c) Mass, for and pressure
d) Dimension

3. DATA AND CHARTING

There are four charts being tested, SD, DA, ABC and MU charts. MR chart was not included due to its

a) nature of stage 1 closely resemble MU chart and stage 2 has no difference from others.
b) The control limits are usually wider than MU chart. If the plot is out of control limit for MU chart may not have the same effect on MR chart.

The study categorised the findings according to the type of charts.

3.1. SD chart

An SD chart is designed to have control limits by deviation of a pool of data obtain at early stage i.e. stage 1. The characteristics of this data is then utilise to compare the datum obtain at later stage. Any variation shall reflect the performance characteristic of the measuring instrument.

3.1.1. SD chart 1.

This chart is the intermediate check for a high precision thermometer. The reading is in resistance Ohm (Ω) of the sensing elements. This resistance value is inserted into

a polynomial equation with specific coefficients for this particular thermometer to obtain reading in temperature scale. According to ITS 90 triple point of water is one of the reference points for calibration of such thermometer; however it is inconvenience to setup this point for most laboratories. A suggested alternative is to use ice point which is very close to triple point of water with accuracy of 0.01K is sufficient for most commercial accredited calibration laboratories. Another advantage of using ice point is its readiness to reproduce and at low cost.

Stage 1

Resistance is read and recorded without converted to temperature scale since both reading in resistance and temperature are parallel. Readings were taken according to the time scale of

a) Early morning
b) Late morning
c) Early afternoon, and
d) Late afternoon

The exercise continued for two weeks with forty readings taken as base data. Refer to the work sheet below. The average, sample standard deviation, two standard deviation, upper control limit and lower control limit were calculated according to the formulae below

Average	$\bar{x} = \frac{\sum_1^{40} n}{n}$
Standard deviation	$\sigma = \sqrt{\frac{\sum(x - \bar{x})^2}{n - 1}}$
Upper control limit	$UC_L = \bar{x} + 2\sigma$
Lower control limit	$LC_L = \bar{x} - 2\sigma$

Measuring instrument: high precision thermometer SPRT25

Serial No: C3838

Artefact: Ice Point

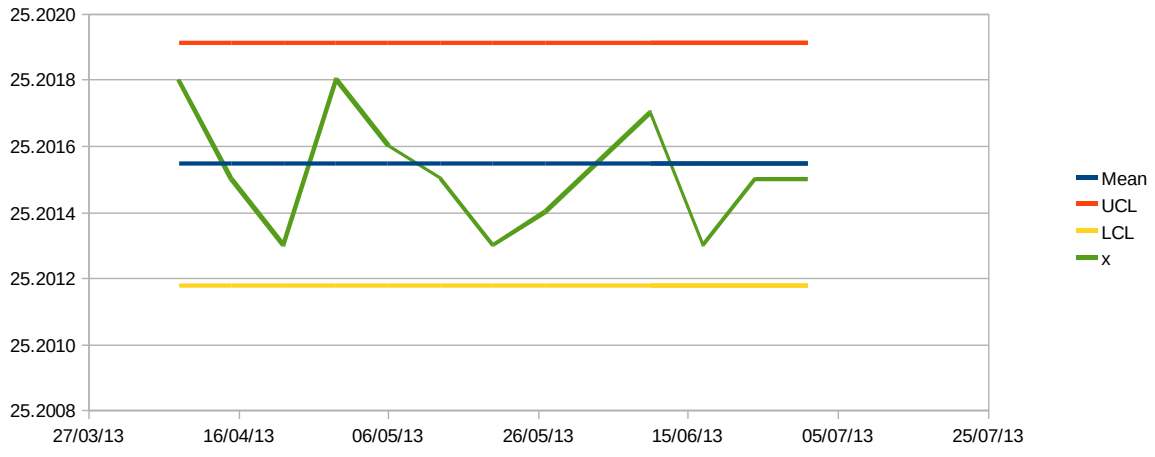
Date	Time			
	9.00am	12.00pm	3.00pm	5.00pm
13th march 13	25.2014	25.2020	25.2016	25.2015

14th	25.2016	25.2020	25.2016	25.2015	
15th	25.2013	25.2020	25.2016	25.2015	
18th	25.2014	25.2018	25.2014	25.2015	Average = 25.2015
19th	25.2013	25.2015	25.2016	25.2016	σ = 0.0002
20th	25.2014	25.2015	25.2016	25.2015	2σ = 0.0004
21st	25.2015	25.2015	25.2016	25.2015	UCL = 25.2019
22nd	25.2014	25.2013	25.2014	25.2015	LCL = 25.2012
25th	25.2014	25.2015	25.2016	25.2015	
26th	25.2013	25.2020	25.2016	25.2015	

Stage 2

Weekly one datum was collected and transferred to the chart.

Date	X	Date	x
08/04/13	25.2018	20/05/13	25.2013
15/04/13	25.2015	27/05/13	25.2014
22/04/13	25.2013	10/06/13	25.2017
29/04/13	25.2018	17/06/13	25.2013
06/05/13	25.2016	24/06/13	25.2015
13/05/13	25.2015	01/07/13	25.2015



Analysis

The chart was done weekly according to the procedure. It shows the value changes from over time; however the fluctuation was well within two standard deviations limit. This chart indicates that the instrument does fluctuate but the fluctuation has insignificant impact on the measurand. Thus it is proven that the measuring instrument is still fit for purpose until the last date of plotting.

3.1.2. SD chart 2

This SD chart is to check the dimension instrument which has complete different field and method of measurement from SD chart 1. A digimatic head is basically a digital micrometer without the fixed anvil. It is used as reference for the calibration dial gauge.

Stage 1

A 50mm gauge block was used as artefact. The process of collecting base data is identical to SD chart 1 above.

UUT:	DIGIMATIC HEAD INTERMEDIATE CHECK
Serial No.	
Artefact	5mm gauge block

Date	Time	Range (mm)	9.00am	12.00pm	3.00pm	5.00pm
13th march		50	50.001	50.001	50.001	50.001
14th			50.001	50.000	50.001	50.001
15th			50.001	50.001	50.001	50.001
18th			50.000	50.001	50.001	50.001
19th			50.001	50.001	50.000	50.001
20th			50.000	50.000	50.000	50.000
21th			50.000	49.999	49.999	50.000
22nd			49.999	49.999	50.000	50.000
25th			50.000	50.000	50.000	50.001
26th			50.000	50.000	50.000	50.000

Average	50.0004
σ	0.0007
2σ	0.0013
UCL	50.0017
LCL	49.9990

Stage 2, one datum collected on the date with the same piece of artefact and it was then transferred to the chart.

08/04/13	50.000
15/04/13	50.001
22/04/13	50.001
29/04/13	50.001
06/05/13	50.001
14/05/13	50.001
22/05/13	50.001
29/05/13	50.001
04/06/13	50.001
11/06/13	50.001
17/06/13	50.001
24/06/13	50.001
01/07/13	50.001
08/07/13	50.001
15/07/13	50.001
22/07/13	50.000
29/07/13	50.001
05/08/13	50.001
12/08/13	50.001
19/08/13	50.001
26/08/13	50.001
02/09/13	50.001
09/09/13	50.001
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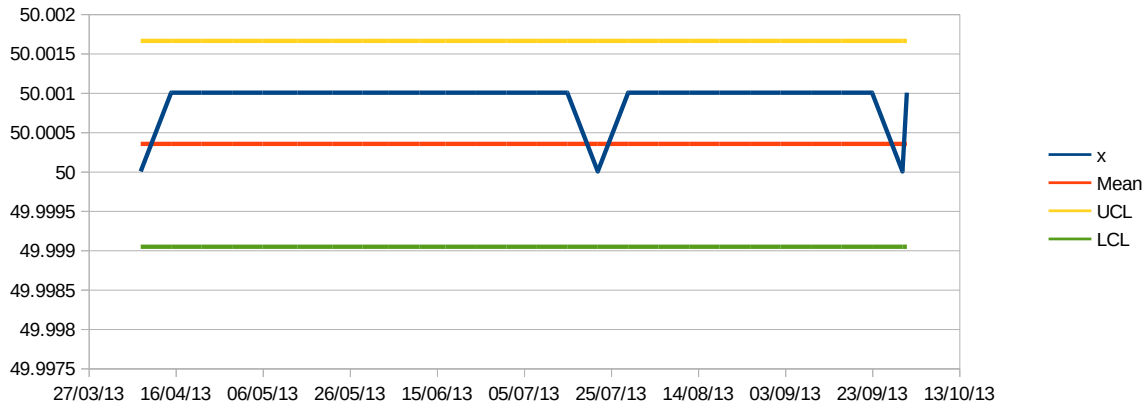
23/09/13	50.001
30/09/13	50.000
01/10/13	50.001



Analysis

This digimatic micrometer head is very stable, the deviation is within the last significant digit. The long term pattern can be projected to be quite stable. The user need not worry much about the stability.

3.1.3. SD chart 3

Another test for SD chart is in the field of Electrical measurement. The artefact was a self designed and made 1V, 10V and 100V DC power supply to check on Agelant Multimeter 5531 .

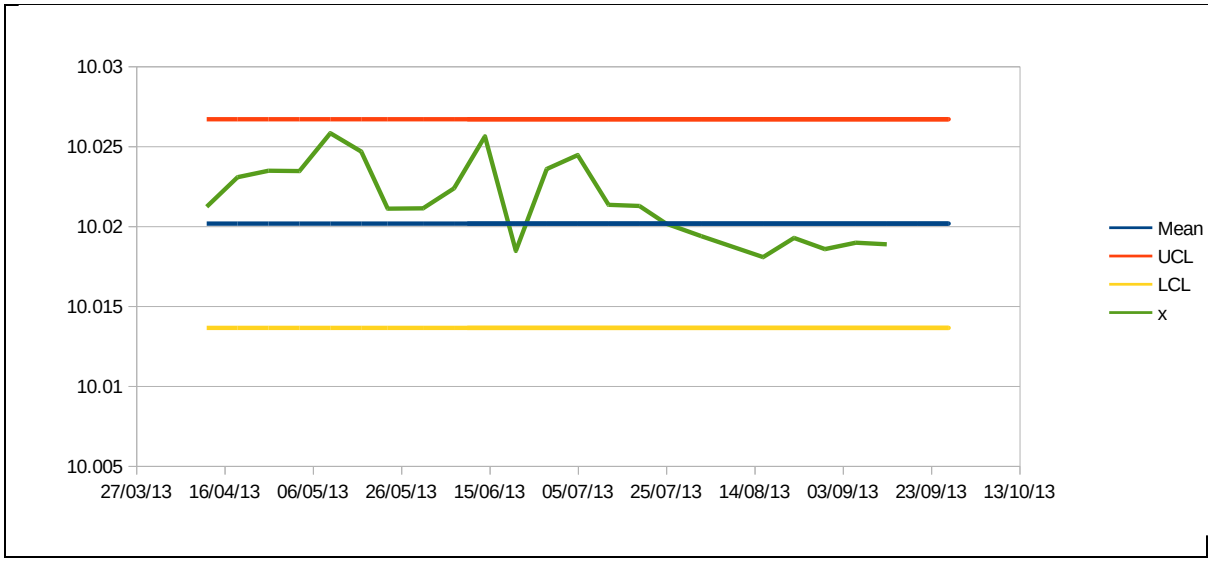
UUT:	DC 1
Serial No.	
Artefact	10V

Date	Time				
	10V	9.00am	12.00pm	3.00pm	5.00pm
13th march		10.01615	10.01785	10.01750	10.01665
14th		10.01662	10.01715	10.01598	10.01815
15th		10.01724	10.01732	10.01723	10.01818
18th		10.01625	10.01730	10.01725	10.01816
19th		10.01750	10.01745	10.01835	10.01851
20th		10.01775	10.01735	10.02445	10.02440
21st		10.02265	10.02325	10.02372	10.02315
22nd		10.02226	10.02345	10.02365	10.02325
25th		10.02015	10.02320	10.02465	10.02580
26th		10.02225	10.02265	10.02445	10.02665

Average	10.0201
Σ	0.0033
2σ	0.0065
UCL	10.0267
LCL	10.0136

Date	x
12/04/13	10.02120
19/04/13	10.02305
26/04/13	10.02345

03/05/13	10.02343
10/05/13	10.02580
17/05/13	10.02465
23/05/13	10.02108
31/05/13	10.02110
07/06/13	10.02235
14/06/13	10.02560
21/06/13	10.01844
28/06/13	10.02356
05/07/13	10.02443
12/07/13	10.02132
19/07/13	10.02125
25/07/13	10.02015
02/08/13	10.01936
16/08/13	10.01805
23/08/13	10.01925
30/08/13	10.01855
06/09/13	10.01895
13/09/13	10.01885



Analysis

The chart shows well behaved pattern of fluctuation indicating the measuring instrument is in healthy condition. There is no specific pattern of fluctuation except within the control limit.

3.2. DA chart

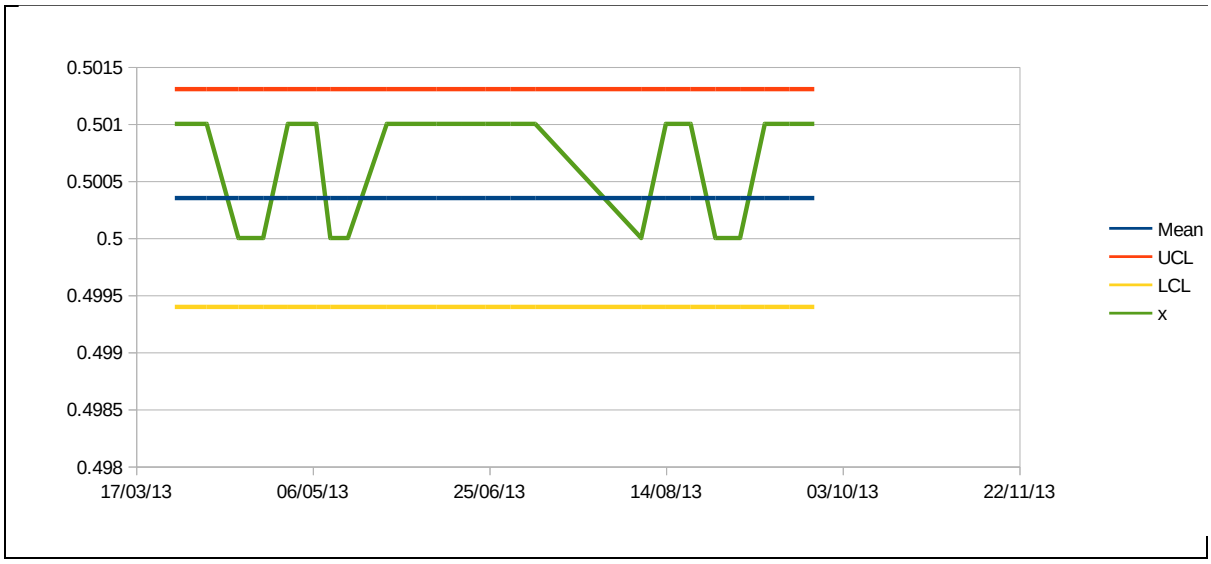
A DA chart is a deviated chart from SD chart. This chart is suitable for very small measurement range where it is not practical to find a suitable single piece artefact.
The technique is to take the difference of two pieces of artefact and this difference is then treated as SD chart.
MU checker is a very sensitive small displacement measurement instrument. The range of measurement is in the region of hundredth of nanometre (0.1µm). The experiment used one micrometer (1µm) difference of two pieces of gauge blocks.

UUT:	MU CHECKER INTERMEDIATE CHECK using DA chart					
Serial No.	PH D47					
Artefact	gauge block	1.000mm				
		1.500mm				
Date	Time					
	Range (mm)		9.00am	12.00pm	3.00pm	5.00pm
13th march		0.5	0.500	0.501	0.501	0.500
14th			0.500	0.501	0.500	0.501
15th			0.500	0.501	0.501	0.501
18th			0.500	0.501	0.501	0.501
19th			0.500	0.501	0.500	0.501
20th			0.500	0.500	0.501	0.500
21st			0.500	0.500	0.500	0.500
22nd			0.500	0.500	0.500	0.501
25th			0.500	0.500	0.500	0.500
26th			0.500	0.500	0.500	0.500

Average	0.5004
Σ	0.0005
2σ	0.0010
UCL	0.5013
LCL	0.4994

Date	x
28/03/13	0.501

06/04/13	0.501
15/04/13	0.500
22/04/13	0.500
29/04/13	0.501
07/05/13	0.501
11/05/13	0.500
16/05/13	0.500
27/05/13	0.501
03/06/13	0.501
10/06/13	0.501
17/06/13	0.501
24/06/13	0.501
01/07/13	0.501
08/07/13	0.501
07/08/13	0.500
14/08/13	0.501
21/08/13	0.501
28/08/13	0.500
04/09/13	0.500
11/09/13	0.501
18/09/13	0.501
25/09/13	0.501



Analysis

The chart shows similar pattern with other SD charts. In fact one cannot detect whether the chart an SD chart of DA chart. The arguments for SD chart can be adopted here. Looking at the pattern the instrument performed well within the range.

3.3. ABC chart

An ABC chart is designed for measuring instrument use as reference standards of the laboratory. Usually it has the highest order of accuracy the laboratory could afford. SD and DA charts are not suitable because the artefact is usually has higher order of accuracy than the instrument. Another factor could be the cost to acquire artefact is beyond the financial and technical capability of the laboratory.

An ABC chart utilises the difference of three pieces of artefact, in fact it is the additional artefact to confirm the drift is caused by the instrument not the artefact. Stage 1 is taking the differences of artefact between reference instrument and the two artefacts and the process is similar to DA chart and SD char, .whereas stage 2 has no difference from these charts. It solves== the problem of cost to implement intermediate check refer to proposal of the study for detail.

3.3.1. ABC chart 1

Measuring instrument: 1 mm gauge block
Serial No: A: 1.000
Artefact: B: 1.002
Artefact: C: 1.003

Description

Gauge block is a very high precision length measurement instrument with accuracy of 10nm. Handling and usage becomes high operational risk to damage. ABC chart is introduced to check the variation of length cause by such damage. MU and MR charts are not suitable because there is no suitable artefact available to detect changes in tenth or hundredth of Nano meter or maintain stability at this magnitude. SD is not suitable which needs an artefact and a reader. The laser indicator can measure length

at tenth Nano meter but it is not suitable to be used as artefact due to its nature of short distance measurement. It is used as differential length measurement than direct measurement.

DA chart may not suite this application because only one piece of artefact being used, any difference may not cause by the gauge block, it could possibly due to change in artefact for this accuracy. Whereas ABC chart provides an improvement to DA chart by additional artefact to detect the changes due to gauge block by eliminating the relative change between these two artefacts.

Stage 1

This stage is similar to the SD chart above with additional two near equivalent artefacts. High resolution laser measurement system usually use in calibration of gauge block that read to 0.01µm (tenth Nano meter) was used.

All three pieces of gauge blocks length were measured sequentially according to the time schedule. Forty readings were taken for each piece over two weeks period. Similar to SD chart, UCL and LCL are calculated. Three base charts are plotted

Date	18 mar				
Marking		9.00am	12.00pm	3.00pm	5.00pm
A	1.0000	0.00000	0.00001	-0.00001	-0.00001
B	1.0020	0.00140	0.00145	0.00145	0.00143
C	1.0030	0.00239	0.00241	0.00241	0.00241

Date	19 mar			
Marking	9.00am	12.00pm	3.00pm	5.00pm
A	-0.00001	0.00002	-0.00001	-0.00001
B*	0.00140	0.00141	0.00143	0.00140
C	0.00238	0.00238	0.00240	0.00245

Date	20 mar			
Marking	9.00am	12.00pm	3.00pm	5.00pm
A	-0.00001	-0.00001	0.00000	0.00000
B*	0.00147	0.00148	0.00150	0.00151
C	0.00243	0.00251	0.00245	0.00243

Date	21 mar			
Marking	9.00am	12.00pm	3.00pm	5.00pm
A	0.00001	-0.00001	0.00000	-0.00001
B*	0.00148	0.00143	0.00145	0.00143
C	0.00244	0.00245	0.00240	0.00240

Date	22 mar			
Marking	9.00am	12.00pm	3.00pm	5.00pm
A	-0.00001	-0.00002	-0.00001	-0.00001
B*	0.00149	0.00143	0.00143	0.00141
C	0.00245	0.00241	0.00240	0.00240

Date	25 mar			
Marking	9.00am	12.00pm	3.00pm	5.00pm
A	-0.00001	0.00001	0.00001	-0.00001
B*	0.00145	0.00148	0.00146	0.00146
C	0.00235	0.00239	0.00241	0.00240

Date	26 mar			
Marking	9.00am	12.00pm	3.00pm	5.00pm
A	-0.00001	-0.00002	-0.00001	0.00000
B*	0.00148	0.00146	0.00147	0.00151
C	0.00241	0.00243	0.00242	0.00243

Date	27 mar			
Marking	9.00am	12.00pm	3.00pm	5.00pm
A	0.00000	0.00001	-0.00001	0.00001
B*	0.00149	0.00145	0.00143	0.00144
C	0.00242	0.00243	0.00239	0.00240

Date	28 mar			
Marking	9.00am	12.00pm	3.00pm	5.00pm
A	0.00000	0.00000	-0.00001	0.00001
B*	0.00148	0.00145	0.00143	0.00145
C	0.00241	0.00245	0.00244	0.00242

Date	29 mar			
Marking	9.00am	12.00pm	3.00pm	5.00pm
A	0.00000	-0.00001	-0.00002	0.00000
B*	0.00149	0.00146	0.00143	0.00145
C	0.00244	0.00243	0.00243	0.00245

x=A- B	9.00am	12.00pm	3.00pm	5.00pm
18 mar	-0.00140	-0.00144	-0.00146	-0.00144
19 mar	-0.00141	-0.00139	-0.00144	-0.00141
20 mar	-0.00148	-0.00149	-0.00150	-0.00151
21 mar	-0.00147	-0.00144	-0.00145	-0.00144
22 mar	-0.0015	-0.00145	-0.00144	-0.00142
25 mar	-0.00146	-0.00147	-0.00145	-0.00147

26 mar	-0.00149	-0.00148	-0.00148	-0.00151
27 mar	-0.00149	-0.00144	-0.00144	-0.00143
28 mar	-0.00148	-0.00145	-0.00144	-0.00144
29 mar	-0.00149	-0.00147	-0.00145	-0.00145

y=A-C	9.00am	12.00pm	3.00pm	5.00pm
18 mar	-0.00239	-0.00240	-0.00242	-0.00242
19 mar	-0.00239	-0.00236	-0.00241	-0.00246
20 mar	-0.00244	-0.00252	-0.00245	-0.00243
21 mar	-0.00243	-0.00246	-0.0024	-0.00241
22 mar	-0.00246	-0.00243	-0.00241	-0.00241
25 mar	-0.00234	-0.0024	-0.00242	-0.00239
26 mar	-0.00240	-0.00241	-0.00241	-0.00243
27 mar	-0.00242	-0.00244	-0.00238	-0.00241
28 mar	-0.00241	-0.00245	-0.00243	-0.00243
29 mar	-0.00244	-0.00244	-0.00245	-0.00245

z=B-C	9.00am	12.00pm	3.00pm	5.00pm
18 mar	-0.00099	-0.00096	-0.00096	-0.00098
19 mar	-0.00098	-0.00097	-0.00097	-0.00105
20 mar	-0.00096	-0.00103	-0.00095	-0.00092
21 mar	-0.00096	-0.00102	-0.00095	-0.00097
22 mar	-0.00096	-0.00098	-0.00097	-0.00099
25 mar	-0.0009	-0.00091	-0.00095	-0.00094
26 mar	-0.00093	-0.00097	-0.00095	-0.00092
27 mar	-0.00093	-0.00098	-0.00096	-0.00096
28 mar	-0.00093	-0.00100	-0.00101	-0.00097
29 mar	-0.00095	-0.00097	-0.001	-0.001

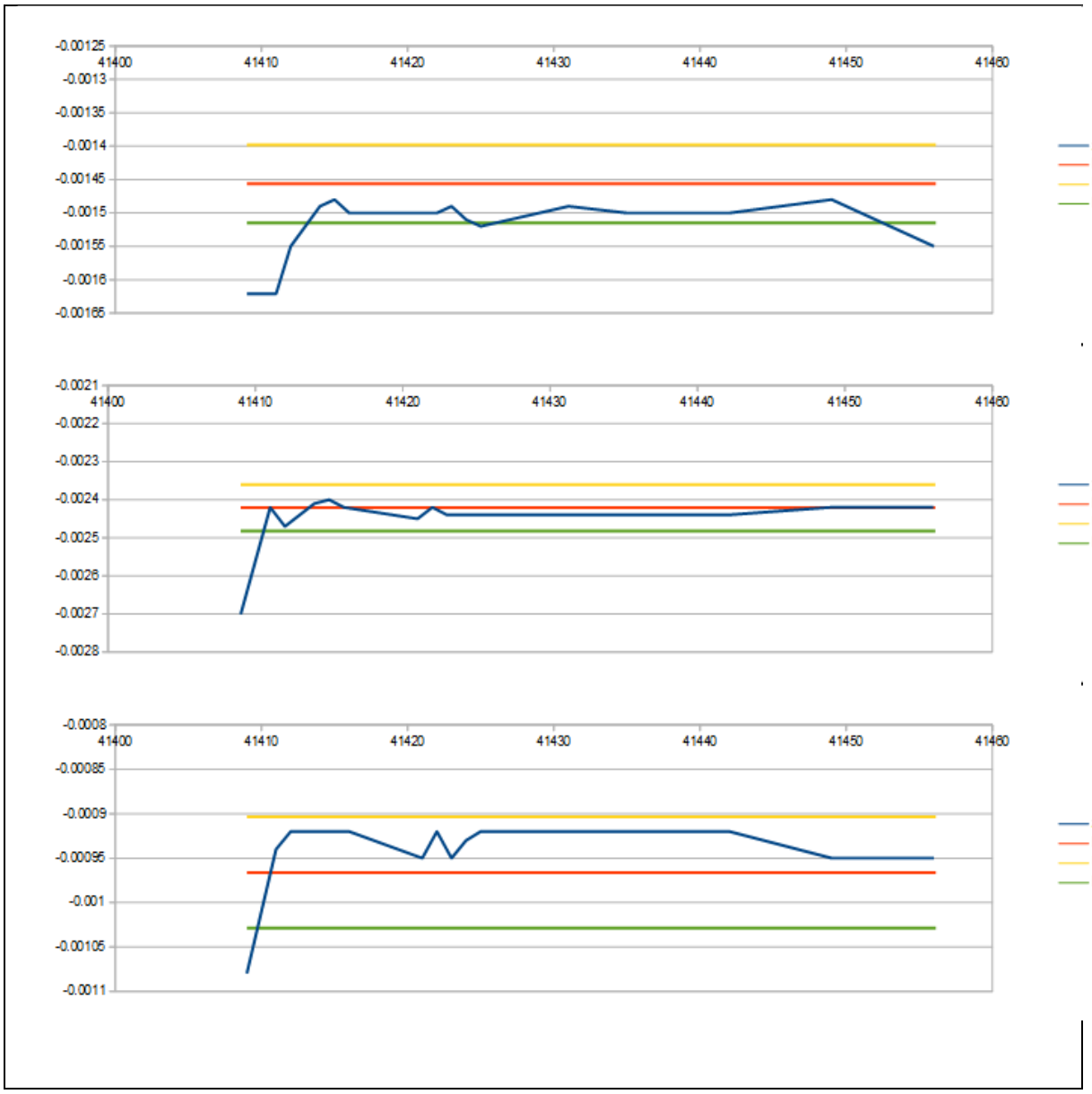
Chart	x	y	z
Average	-0.0015	-0.0024	-0.0010
Σ	0.0000	0.0000	0.0000
2σ	0.0001	0.0001	0.0001
UCL	-0.0014	-0.0024	-0.0009
LCL	-0.0015	-0.0025	-0.0010

Stage 2

The process of stage is similar to stage one except only one reading for each artefact and the gauge block were taken then calculate the values for x, y and z. They are then

plotted onto individual X chat, Y chart and Z chart. These three charts are then aligned base on same time scale.

Date	X	y	z
15/05/13	-0.00162	-0.002701	-0.001080
17/05/13	-0.00162	-0.002420	-0.000940
18/05/13	-0.00155	-0.002470	-0.000920
20/05/13	-0.00149	-0.002410	-0.000920
21/05/13	-0.00148	-0.002400	-0.000920
22/05/13	-0.00150	-0.002420	-0.000920
27/05/13	-0.00150	-0.002450	-0.000950
28/05/13	-0.00150	-0.002420	-0.000920
29/05/13	-0.00149	-0.002440	-0.000950
30/05/13	-0.00151	-0.002440	-0.000930
31/05/13	-0.00152	-0.002440	-0.000920
06/06/13	-0.00149	-0.002440	-0.000920
10/06/13	-0.00150	-0.002440	-0.000920
17/06/13	-0.00150	-0.002440	-0.000920
24/06/13	-0.00148	-0.002420	-0.000950
01/07/13	-0.00155	-0.002420	-0.000950



Interpretation

The chart showed early stage out of range for all the three charts (x, y and z) with similar pattern. Investigation showed that it was due to operator mistake setting the laser measurement system zero reading while taking the artifact reading. Thus all the three charts showed consistency in pattern.

The charts showed consistent pattern for long period of time until towards the end of charting where x-chart, there were points plotted out of control limit whereas the other

two charts did show variation but within the control limits. Information can extract from these charts are:

a) z chart showed insignificant drift , indicates B and C remains
b) y chart showed insignificant drift, indicates A and C remains
c) x chart drifted significantly, indicates A has drifted because B remains
d) A has significantly changed. The artefacts showed no significant change.
e) A is unhealthy thus needs to take action according to the proposal.

3.3.2. ABC chart 2

This second chart is testing on the utility of ABC chart for different field of measurement. Standard weight is defined according to OIML R111 as Classes E, F and M. Each main class the sub classified as E1, E1 and F1 F2 and F3, then M1, M2 and M3. Most calibration laboratories would acquire class E as reference weights.

UUT:	Standard weight 1kg
Serial No.	A
Artefact	Two pieces of 1kg

18 mar				
	9.00am	12.00pm	3.00pm	5.00pm
	1000	1000.001	1000	1000.001
	1025.348	1025.35	1025.348	1025.348
	1024.665	1024.665	1024.665	1024.665
19 mar				
	9.00am	12.00pm	3.00pm	5.00pm
	1000	1000	1000.001	1000.001
	1025.348	1025.349	1025.349	1025.349
	1024.665	1024.664	1024.665	1024.665
20 mar				
	9.00am	12.00pm	3.00pm	5.00pm
	1000.001	1000.001	1000.001	1000.001
	1025.349	1025.349	1025.349	1025.349
	1024.666	1024.665	1024.665	1024.665
21 mar				
	9.00am	12.00pm	3.00pm	5.00pm

	1000.001	1000.001	1000.001	1000.001
	1025.349	1025.349	1025.349	1025.349
	1024.666	1024.666	1024.665	1024.665

22 mar

	9.00am	12.00pm	3.00pm	5.00pm
	1000.001	1000	1000	999.998
	1025.349	1025.348	1025.348	1025.347
	1024.665	1024.665	1024.664	1024.664

25 mar

	9.00am	12.00pm	3.00pm	5.00pm
	1000.001	1000.001	1000.001	1000.001
	1025.349	1025.349	1025.349	1025.349
	1024.665	1024.665	1024.665	1024.664

26 mar

	9.00am	12.00pm	3.00pm	5.00pm
	1000.001	1000.001	1000.001	1000.001
	1025.348	1025.348	1025.348	1025.347
	1024.665	1024.665	1024.665	1024.664

27 mar

	9.00am	12.00pm	3.00pm	5.00pm
	1000.001	1000.001	1000.001	1000
	1025.349	1025.349	1025.348	1025.348
	1024.665	1024.665	1024.666	1024.666

28 mar

	9.00am	12.00pm	3.00pm	5.00pm
	1000.001	1000.001	1000.001	1000
	1025.349	1025.349	1025.348	1025.348
	1024.665	1024.665	1024.665	1024.665

29 mar

	9.00am	12.00pm	3.00pm	5.00pm
	1000.001	1000.001	1000.001	1000
	1025.349	1025.349	1025.349	1025.349
	1024.665	1024.665	1024.665	1024.665

x=A- B	9.00am	12.00pm	3.00pm	5.00pm
18 mar	-25.34800	-25.34900	-25.34800	-25.34700
19 mar	-25.34800	-25.34900	-25.34800	-25.34800
20 mar	-25.34800	-25.34800	-25.34800	-25.34800

21 mar	-25.348	-25.348	-25.348	-25.348
22 mar	-25.348	-25.348	-25.348	-25.349
25 mar	-25.348	-25.348	-25.348	-25.348
26 mar	-25.34700	-25.34700	-25.34700	-25.34600
27 mar	-25.34800	-25.34800	-25.34700	-25.34800
28 mar	-25.34800	-25.34800	-25.34700	-25.34800
29 mar	-25.348	-25.348	-25.348	-25.349

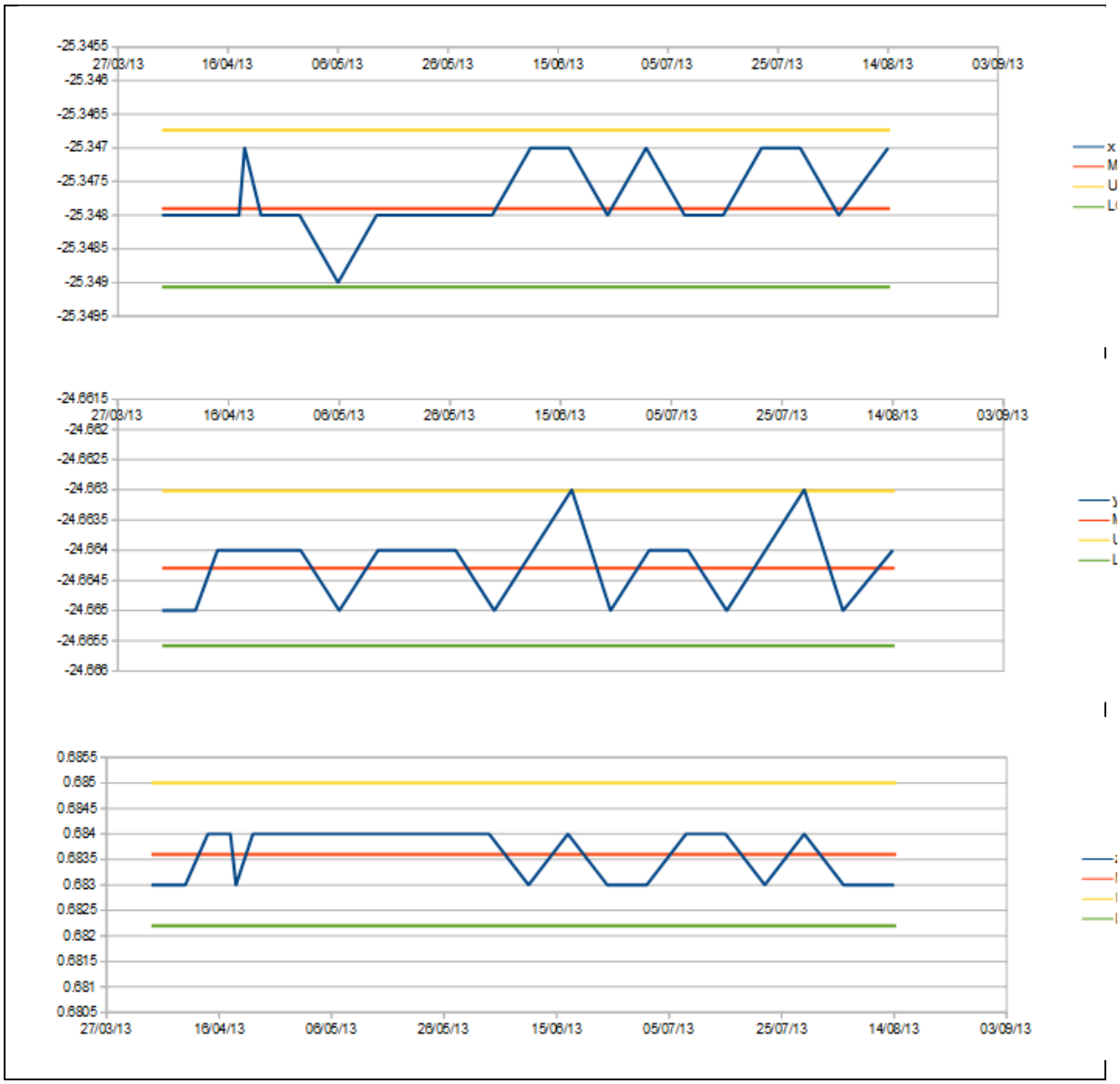
y=A-C	9.00am	12.00pm	3.00pm	5.00pm
18 mar	-24.66500	-24.66400	-24.66500	-24.66400
19 mar	-24.66500	-24.66400	-24.66400	-24.66400
20 mar	-24.66500	-24.66400	-24.66400	-24.66400
21 mar	-24.665	-24.665	-24.664	-24.664
22 mar	-24.664	-24.665	-24.664	-24.666
25 mar	-24.664	-24.664	-24.664	-24.663
26 mar	-24.66400	-24.66400	-24.66400	-24.66300
27 mar	-24.66400	-24.66400	-24.66500	-24.66600
28 mar	-24.66400	-24.66400	-24.66400	-24.66500
29 mar	-24.664	-24.664	-24.664	-24.665

z=B-C	9.00am	12.00pm	3.00pm	5.00pm
18 mar	0.68300	0.68500	0.68300	0.68300
19 mar	0.68300	0.68500	0.68400	0.68400
20 mar	0.68300	0.68400	0.68400	0.68400
21 mar	0.683	0.683	0.684	0.684
22 mar	0.684	0.683	0.684	0.683
25 mar	0.684	0.684	0.684	0.685
26 mar	0.68300	0.68300	0.68300	0.68300
27 mar	0.68400	0.68400	0.68200	0.68200
28 mar	0.68400	0.68400	0.68300	0.68300
29 mar	0.684	0.684	0.684	0.684

Chart	x	Y	z
average	-25.3479	-24.6643	0.6836
Σ	0.0006	0.0006	0.0007
2σ	0.0012	0.0013	0.0014
UCL	-25.3467	-24.6630	0.6850
LCL	-25.3491	-24.6656	0.6822

Date	A	B	C	x=A- B	y=A-C	z=B-C
04/04/13	1000.000	1025.348	1024.665	-25.348	-24.665	0.683
06/04/13	1000.000	1025.348	1024.665	-25.348	-24.665	0.683
08/04/13	1000.001	1025.349	1024.666	-25.348	-24.665	0.683

10/04/13	1000.001	1025.349	1024.666	-25.348	-24.665	0.683
14/04/13	1000.001	1025.349	1024.665	-25.348	-24.664	0.684
18/04/13	1000.001	1025.349	1024.665	-25.348	-24.664	0.684
19/04/13	1000.001	1025.348	1024.665	-25.347	-24.664	0.683
22/04/13	1000.001	1025.349	1024.665	-25.348	-24.664	0.684
29/04/13	1000.001	1025.349	1024.665	-25.348	-24.664	0.684
06/05/13	1000.000	1025.349	1024.665	-25.349	-24.665	0.684
13/05/13	1000.001	1025.349	1024.665	-25.348	-24.664	0.684
20/05/13	1000.001	1025.349	1024.665	-25.348	-24.664	0.684
27/05/13	1000.001	1025.349	1024.665	-25.348	-24.664	0.684
03/06/13	1000.000	1025.348	1024.664	-25.348	-24.664	0.684
10/06/13	1000.000	1025.347	1024.664	-25.347	-24.664	0.683
17/06/13	1000.001	1025.348	1024.664	-25.347	-24.663	0.684
24/06/13	1000.000	1025.348	1024.665	-25.348	-24.665	0.683
01/07/13	1000.000	1025.347	1024.664	-25.347	-24.664	0.683
08/07/13	1000.001	1025.349	1024.665	-25.348	-24.664	0.684
15/07/13	1000.000	1025.348	1024.664	-25.348	-24.664	0.684
22/07/13	1000.000	1025.347	1024.664	-25.347	-24.664	0.683
29/07/13	1000.001	1025.348	1024.664	-25.347	-24.663	0.684
05/08/13	1000.000	1025.348	1024.665	-25.348	-24.665	0.683
14/08/13	1000.000	1025.347	1024.664	-25.347	-24.664	0.683



Analysis

x and y charts showed similar trend whereas z chart does not follow instead its fluctuation is much smaller the other two. Z chart is in fact shows very stable difference between artefacts B and C. Since both x and y charts are relatively fluctuating with greater amplitude, it indicates that A, the reference standard weight has drifted more than the artefacts B and C.

3.4. MU chart

This chart is an absolute chart and uses the measurement uncertainty of the instrument as control limits. Artefact can be any reference and is calibrated to provide accuracy within tolerance. This charting technique is versatile can be adopted for most measuring instrument at working standards level, not to the very high accuracy instrument. No base data is required, the control limits are drawn according to the measurement uncertainty obtain from calibration certificate.

This force gauge is a 30kg but charting at 5kg for convenience of handling a piece of weight of 5kg.

Force gauge	30kg	
Identification	CC8000	
Artefact	5kg dead weight	
Identification	C14411	
MU of force gauge		0.020 kg
correction at 5kg		0.000 kg
MU of dead weight		0.0003 kg

Stage 1

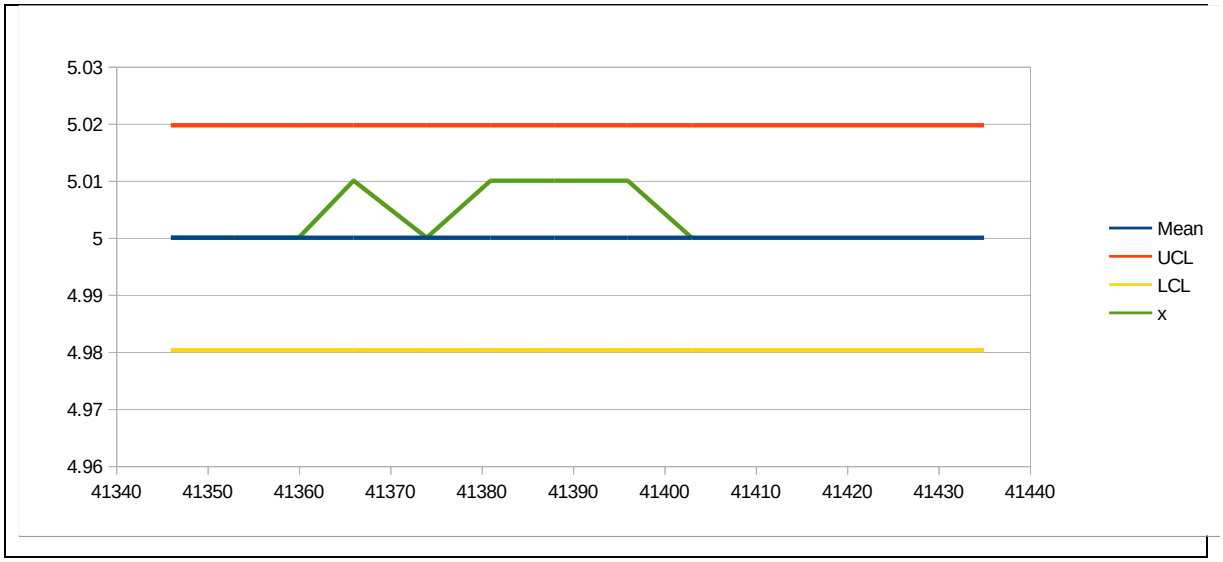
There was no datum collected except obtain measurement uncertainty of the gauge and calculate the upper control limit and lower control limit

X	5.0000
MU	0.019
UCL	5.019
LCL	4.981

Stage 2

This chart was charting at an interval of once a week and it was the first reading and only one reading was taken, then transfer to the chart.

Date	X
13/03/13	5.000
20/03/13	5.000
27/03/13	5.000
02/04/13	5.010
10/04/13	5.000
17/04/13	5.010
24/04/13	5.010
02/05/13	5.010
09/05/13	5.000



Interpretation

This chart is straight forward and very simple with no calculation required. It shows the actual value fluctuation well within the limits of uncertainty. It indicates that it is still fit for purpose.

4. INTERMEDIATE CHECK USING CONTROL CHART DISCUSSION

These experiments show that control chart technique as proposed is suitable to be used as intermediate check procedure and is implementable. Various charting techniques were tried and they show consistency over the period of testing.

4.1. Positive indication

Three charts were plotted for SD chart two for ABC chart one each for Da and MU chart. They showed that the proposal to use as intermediate check has no barrier technically and well as financially. The breakthroughs are

a) High accuracy of time base instrument performance pattern
b) ABC chart is suitable for high accuracy measuring instrument
c) SD chart where technique of charting is simple
d) Cost effectiveness where cost of artefacts and time taken to complete the chart is at minimal.

4.2. Difficulty

There were some problems facing during the course of implementation

4.2.1. Availability of artifacts

Some artefacts are easily available whereas some are difficult. For example standard weights and gauge blocks are easily available but not for electrical items.
I have to design stable DC voltage in order to conduct SD chart for multimeter. Stable DC power supply with the parallel accuracy is available in the market but not for the price to conduct intermediate check as artefact. Similarly same issue for resistance and current mode.

4.2.2. No knowledge to choose the most suitable artifact

This is another anticipated problem by the user as to the choice of artefact. This was one of the issues brought up by the participants where some of them did suggest inferior artefacts for example use 9V battery or 1.5VDC button cell battery to replace the self designed DC power supply. It was later proven that these dry cells degrade in performance and no one cell produces similar value.
Similar problem also probed up for concrete cube compressive strength compression testing machine. The force required for grade 40 cube size 150mm x 150 mm is about 1000kN and grade 60 require machine can reach 1800kN. Whereas cement bricks requires minimum 20kN and clay bricks need about 40kN force. \Currently the only available load column or load cell that comes with price tag is about a third of the price of the machine. Tensile testing or universal testing machine as some manufacturers refer to also in similar situation. The cost of load indicating system available in the market has two types, one with low accuracy and the other with high accuracy. Low accuracy may not provide necessary accuracy and stability for the job but come with affordable price tag; whereas high accuracy load indicating system could come with price tag ten folds of low accuracy unit.
Sieves use in soil and material testing laboratories have similar problem where there is no suitable equipment to be used as artefact. Profile projector use in calibrating sieves is not financially feasible to be used as artefact.

4.2.3. One chart for SD, DA and ABC charts sufficient?

The personnel involved in the project always ask repeated question as to a single charting whether sufficient for the instrument. It was difficult to convince them at early stage of implementation using mathematical model. They could not visualize the difference between absolute value and relative values and hence implementing with doubt. It took few months later after a series of points plotted then began to notice the value of these relative charts.

4.2.4. Small portion of the staff involve miss understood this new technique, they assume similar to SPC

Mistakes were made at early stage 1, common mistakes were 5 readings were taken and record the average as single datum. Another common mistake was at stage 2 where five readings were taken, average then transfer to the chart. These mistakes were brought in by the knowledge of statistical process control chart technique (SPC). The perceived concept of this proposal was identical to SPC chart. Such mistake may be expected from new comer to adopt this technique.

4.3. Deficiency of the experiment

4.3.1. Time

Time factor is the deficiency of the experiment where most charts show fluctuation within the control limits except ABC chart 1 where the final plot was out of control limit. Most probably the drift for most instrument well within control within short time. Perhaps it may take at least one to two years to be able to see larger amplitude of drift.

4.3.2. Only one accredited laboratory involved

The experiments were carried out only one accredited calibration laboratory off cause they meet the objective of application for ISO/IEC 17025 accredited laboratory; however there is no verification from other calibration accredited laboratories. There is no information regarding variation in technical knowhow, skill of staffs, environment, management attitude and measuring instrument.

This acid test of the proposal not conducted in manufacturing environment where the usage could be higher as well as handling by production people. The most common question manufacturing facility shall ask are

a) who shall conduct the periodic charting, production? Or facility? Or QA/QC?
b) Who has the authority to take the appropriate action as recommended in the proposal especially at the process bottle neck.
c) how long is the period

The lack of information from manufacturing facilities unable this proposal to be introduced to them.

4.4. Commercial opportunity

There is great deal of commercialise the proposal since it is a basic requirement for accredited laboratories and ISO 9001 QMS facilities to meet. Packages of intermediate check may include artefacts, software and training especially relative charts.

Example of artefact for compression machine. Design an elasto-mechanism when compress to specific load shall activate an electronic circuit to indicate the pre-calibrated force. This mechanism should justify for the cost otherwise it shall fail to capture the market.

Another example is the calibrated sand to be used as artefact.

5. CONCLUSION

All the four types of charts experimented show consistency with the proposal, implementable. Thus it is in the right direction for use as intermediate check technique. There are rooms for improvement in the area of selection of artefacts and software to facilitate understanding of the theoretical background and ease of use.

Commercialisation of the study is possible to deal as package for intermediate check includes artefact, software and training.

Appendix 27 Research on consistency of measuring instrument

Research on consistency of measuring instrument in Selayang Solder

1. INTRODUCTION

Selayang solder received a non-conformance report regarding the use of measuring instrument from a second party audit recently. A suggestion was given by the auditor to conduct GR&R as evidence on equipment capability to meet process requirements.

The quality control department conducted GR&R studies on some equipment; however the results were not satisfactorily where the variations were beyond the criteria set for 30% limits. The repeated studies conducted showed no positive improvement. The manager then seeks advice from external sources for solutions to the non-conformance of the audit.

A study on suitability of GR&R for this company environment is the prime concern of the study and eventually proposes solution.

2. LITERATURE REVIEW

Measurement system analysis (MSA) is an important procedure in ISO/TS 16949 quality management system. MSA-4 is the common reference adopts by ISO/TS 16949 certified organizations. There are many elements in the analysis includes bias, stability, linearity, and GR&R. The objective of MSA study is to understand the performance of the equipment and operator in a process to provide accurate measurement. It studies the interaction between operator and measuring instrument and their variations. Statistical principles are the common tools adopted to analyses and understand the variations.

On the other hand an intermediate check procedure is introduced as an alternative. This method is according to Measuring Instrument Intermediate Check where control chart is the basic technique adopted.

3. EXPERIMENT PROCEDURE AND DATA COLLECTION

There are few measuring instrument involved in this study and they represent major types of measuring tools use in the quality control process. The list of tools include

a. Spectrophotometer model Spectro M10
b. Micrometer Mitutoyo 293-521-30

c. Caliper Mitutoyo 500-196-20

The initial stability study is to adopt Gauge Repeatability and Reproducibility (GRR) instead of other elements in MSA since the request is to conduct GRR not the others.

3.1. The procedure adopts recommendation by MSA-4 range method.

3.1.1. Spectrophotometer

- Artifact – QC sample (bar)
- Tune the instrument before taking analysis sample result.
- Parameter – tin, copper, silver percentage composition
- GRR - 3 appraisals
- Mark these samples in sequence
- Take 10 reading each in sequence

3.1.2. Micrometer mitutoyo 293-521-30

- Artifact – wire 1.0mm (spec 0.95-1.05mm)
- GRR - 3 appraisal
- Cut 10 sample
- Mark these samples in sequence
- Take 10 reading each in sequence

3.1.3. Calliper mitutoyo 500-196-20

- Artifact – ball 20mm (19-21mm)
- GRR - 3 appraisal
- Cut 10 sample
- Mark these samples in sequence
- Take 10 reading each in sequence

3.2. The results are summarized as follow

GR&R study range method					
Description	%EV	%AV	%GRR	%PV	Ndc
Silver %	70	62	94	35	0.5
Cupper %	65	69	95	33	0.5
Tin %	66	72	98	21	0.3
Micrometer	67	64	93	37	0.6
Calliper	70	27	75	67	1.3

Table 1 GR&R study range method

The data from the experiment above is reconfirmed using ANOVA method. This ANOVA method is summarized below in Table 2

GR&R study ANOVA method					
Description	%EV	%AV	%GRR	%PV	Ndc
Silver %	0	36	36	93	3.7
Cupper %	63	24	68	74	1.5
Tin %	72	29	77	64	1.2
Micrometer	0	80	80	61	1.1
Calliper	78	19	80	60	1

Table 2 GR&R study ANOVA method

3.3. The results of Table 1 show unfavorable outcome where majority of them are far beyond 30% limit for all elements and equipment under study. The same data is recalculated using ANOVA method is as Table 2. The purpose is to confirm the results in Table 1 and the outcome suggested similar trend.

3.4. The results were recalculated using R&R short and long methods to verify the calculation according AGAG MSA-4. These methods were recommended by AGAG MSA-2. The results as shown in Table 3 GR&R short and long methods.

		Micrometer 1mm	Calliper 20mm	Cu	Ag	Sn
Repeatability	EV	0%	8%	49%	53%	66%
Appraiser	AV	65%	65%	28%	26%	72%
AppraiserxPart	INT					
R&R	R&R	93%	93%	57%	59%	98%

Part	PV	38%	38%	83%	81%	21%

Table 3

3.5. The results reflect consistency in the value obtained even though there are differences.

3.6. An alternative to GRR is to adopted. This procedure is measuring instrument intermediate check proposed by Dr. CK Lim and K L Lua. The results is as shown in the Table 4.

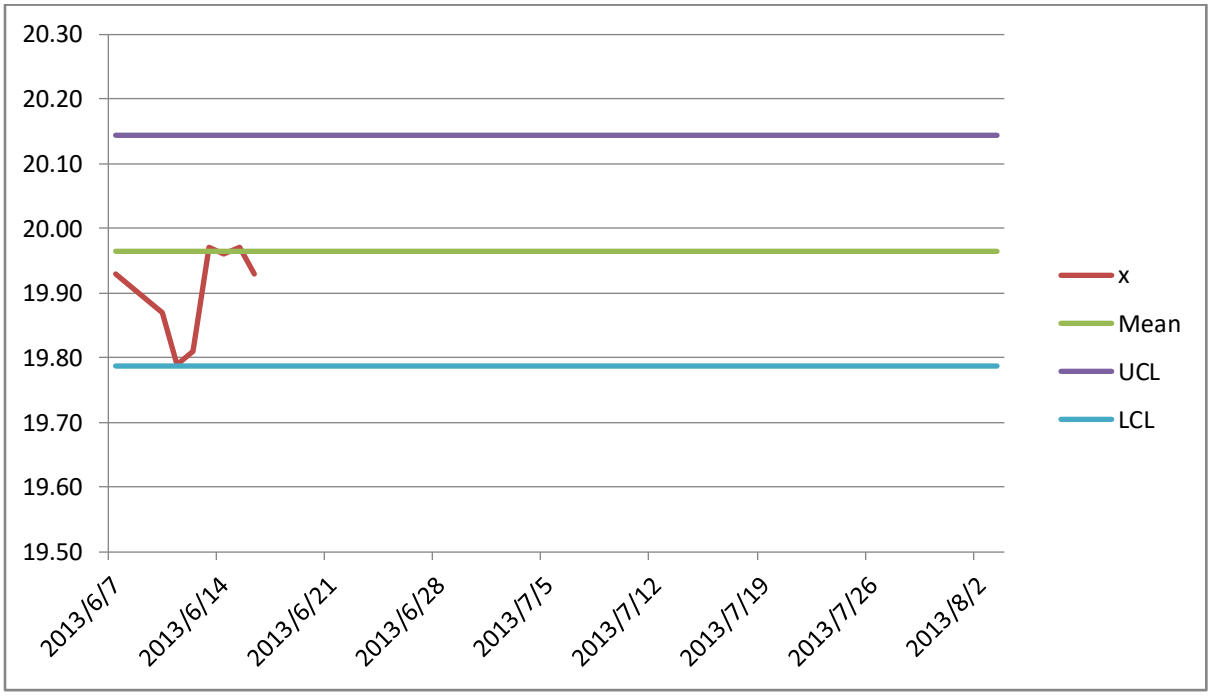


Table 4.1 Calliper

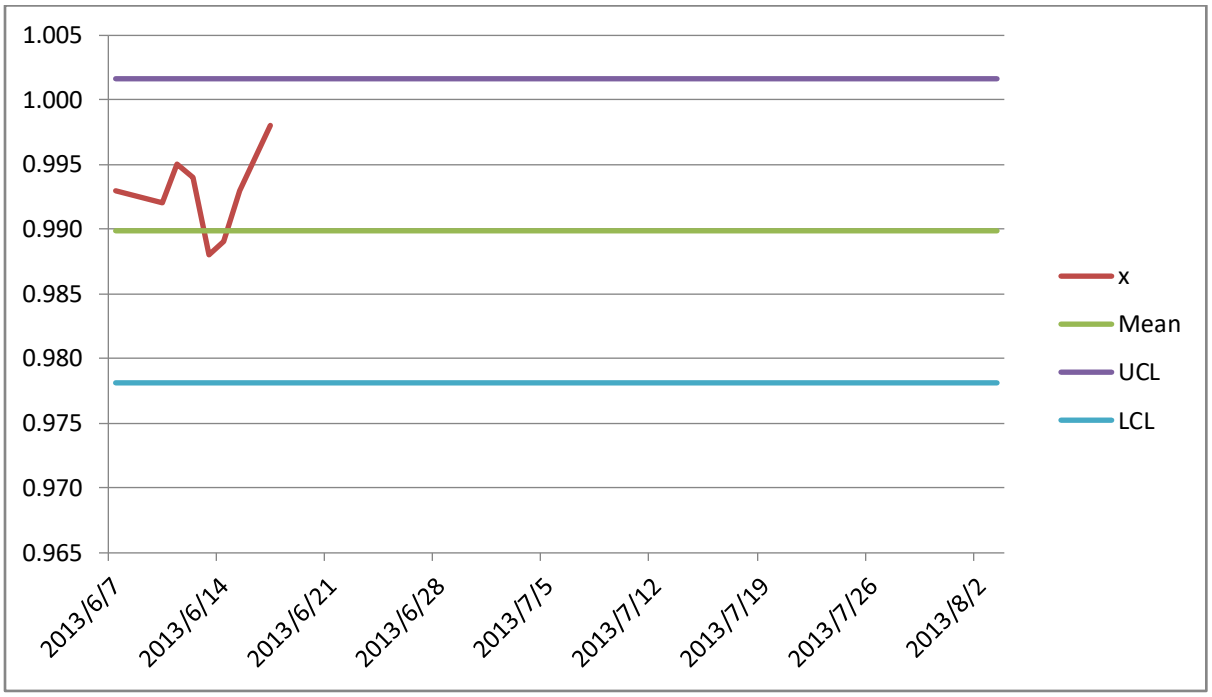


Table 4.2 Micrometer

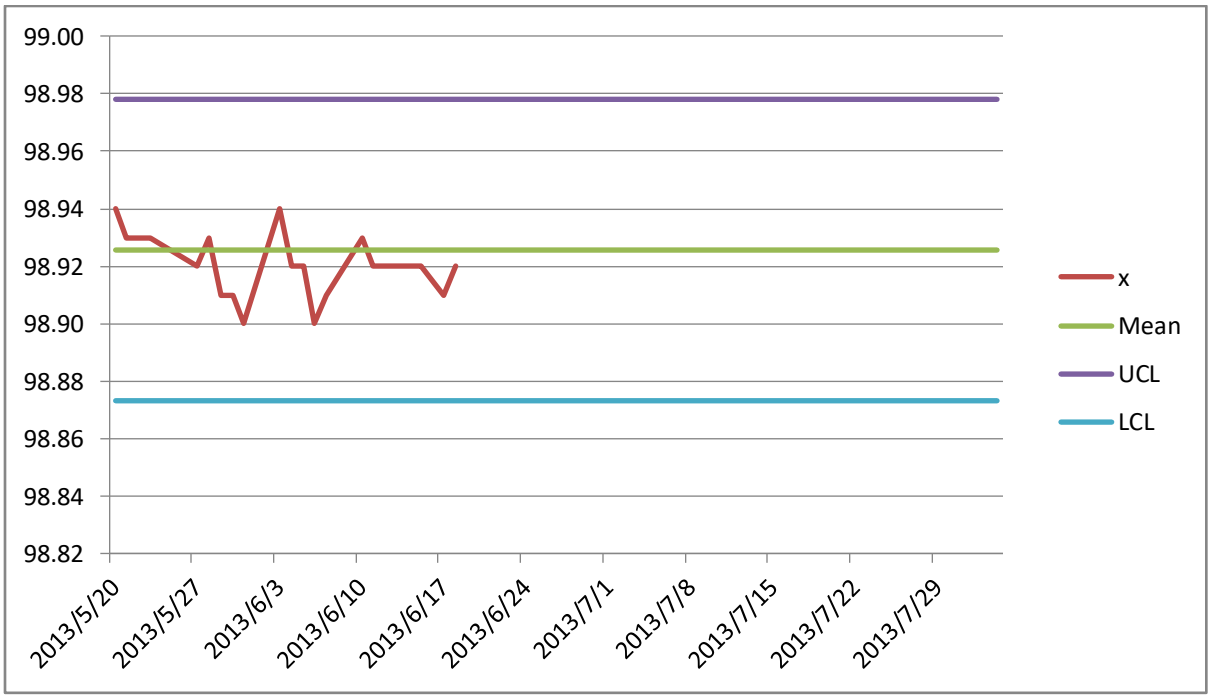


Table 4.3 Sn

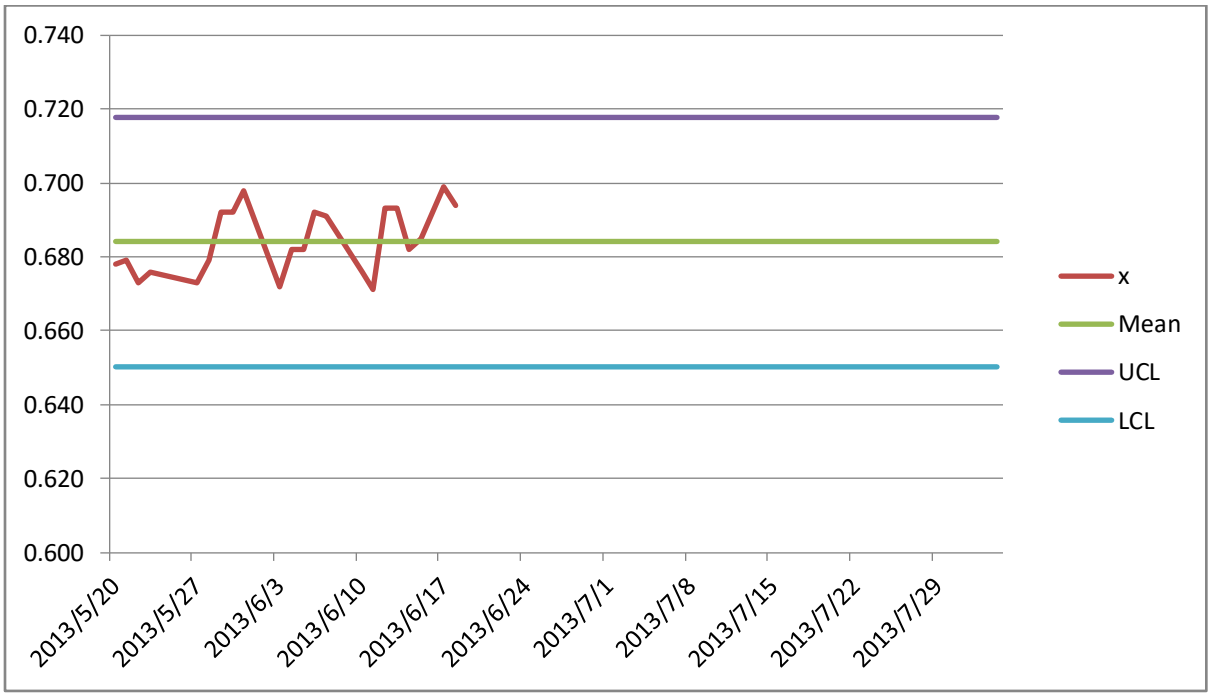


Table 4.4 Cu

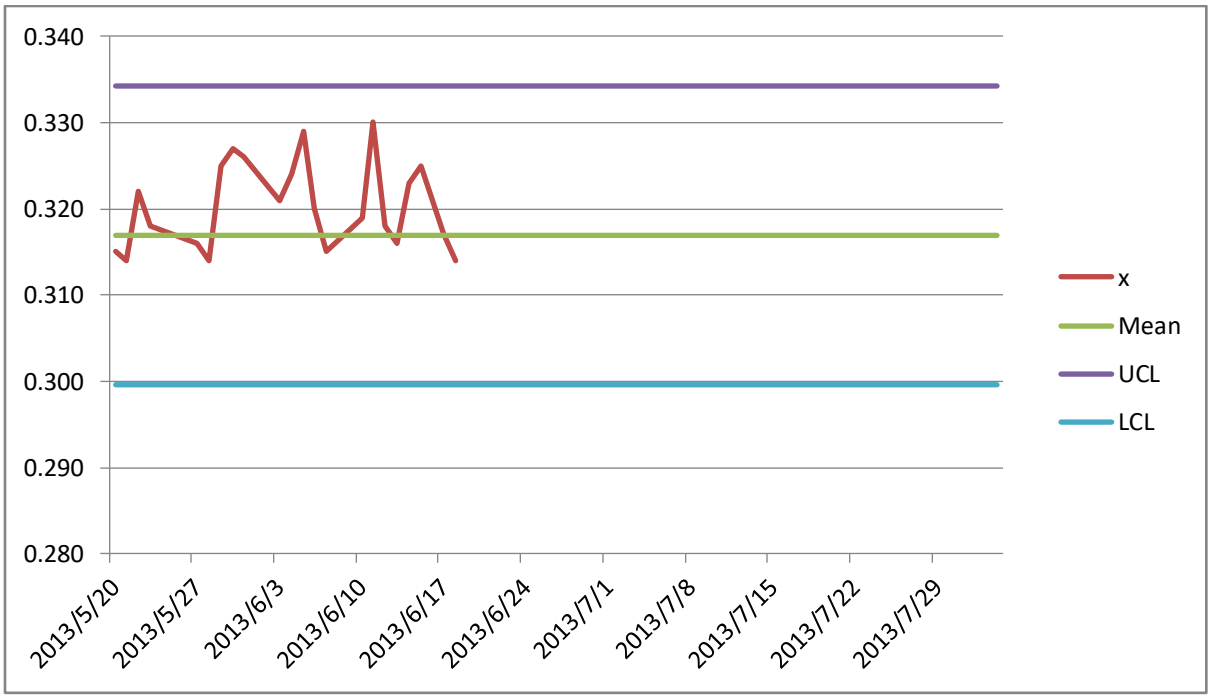


Table 4.5 Ag

4. ANALYSIS AND INTERPRETATION

4.1. GR&R tables show instability of the instrument and the people involves in taking reading.

4.2. Parts variation for GR& micrometer and caliper are unexpectedly high and beyond acceptance criterium of 30%; however they constitute only single piece for each instrument meeting specification of gauge blocks calibration to grade 1. These specifications as shown in Table 5 below. The deviation of length of gauge blocks from the specification is more than hundred times smaller than the variation among the readings recorded.

	Specification	
Length	Deviation from length ± µm	
1mm	0.2	
20mm	0.3	

Table 5

However the calculations from GR&R for both caliper and micrometer indicate very large variation. Parts variation PV% calculation inherit other errors or the calculation could not isolate errors due to human, environment and measuring instrument from parts variation. Table 3 shows identical pattern in Sn, Cu and Ag PV% calculation.

These figures indicate there is no instrument or reference material suitable for the application. On the other hand could it be GR&R is not a suitable for such study.

4.3. The alternative method adopted is control chart technique. This technique was developed to meet ISO/IEC 17025 clause 5.5.10 requirement. The result of drift pattern as shown in Table 4.1 to 4.5.

4.4. They indicate continuing meeting the requirement compare to GR&R calculation. The drift patterns for all show randomness within 2σ limits coincide with the argument for measurement uncertainty confidence level not less than 95%.

4.5. These control charts demonstrate that the measuring instrument still function al within the metrological requirements. This technique does not differentiate variation caused by operator and parts variation. The trend plotted is the composite effect of variation due to wear and tare and degradation of measuring instrument. The trend is plotted week thus the variation is observed at weekly basis. Notice that there is no part variation calculated in fact no calculation was done after initial stage of plotting the control limits which is obtained from the variation of the base data collected 2 weeks in advance.

4.6. GR&R show very large parts variation even though caliper and micrometer only used single piece. The formula to calculate the repeatability and reproducibility may not be appropriate for this condition.

5. CONCLUSION

The prime objective for measuring instrument to be serviceable is to ensure consistently meeting measurement requirements. Nonconformance record received indicates the customer has doubt over the use of measuring instrument capability to meet the requirement consistently.

GR&R was adopted to address the problem; however the result obtained was unsatisfactory and unable to solve the problem because all indicators showed negative influence.