Quality Assurance in Measurement

Module 6 - The Guarantee of Quality In Measurement

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Contents

1.0 Introduction

Once the planning for a measurement has been completed, including a comprehensive assessment of uncertainty and capability of the measurement process, and the process has been effectively implemented it is then necessary to maintain and guarantee the quality of measurement. Here we are concerned with issues involved in providing that guarantee. Basically, its fulfillment is vested in the following functions:

- the actions to maintain quality of measurement
- the metrology function, and
- the exercise of audit and review procedures.

By considering each of these issues in turn a framework for guarantee can be identified.

2.0 Actions to Maintain Quality of Measurement

Various actions are necessary to maintain quality of measurement once a measurement process has effectively been installed. Broadly speaking they fall into three categories;

- monitoring the quality of measurement
- maintenance of instrumentation, and
- audit and review.

The latter is considered later in section 4.0. Here we confine our attention to the monitoring and maintenance requirements. However, it should be noted that no one group of actions, alone, is sufficient to guarantee the maintenance of quality, it requires the planned application of each.

2.1 Monitoring the Quality of Measurement

Monitoring of quality can be achieved in various ways:

- through monitoring of the measurement process, using statistical process control techniques,
- through calibration, and
- through instrument verification.

Moreover, as in planning for quality of measurement, it is important to consider the wider issues of people, information, documentation and communication that relate to the realisation of quality measurement.

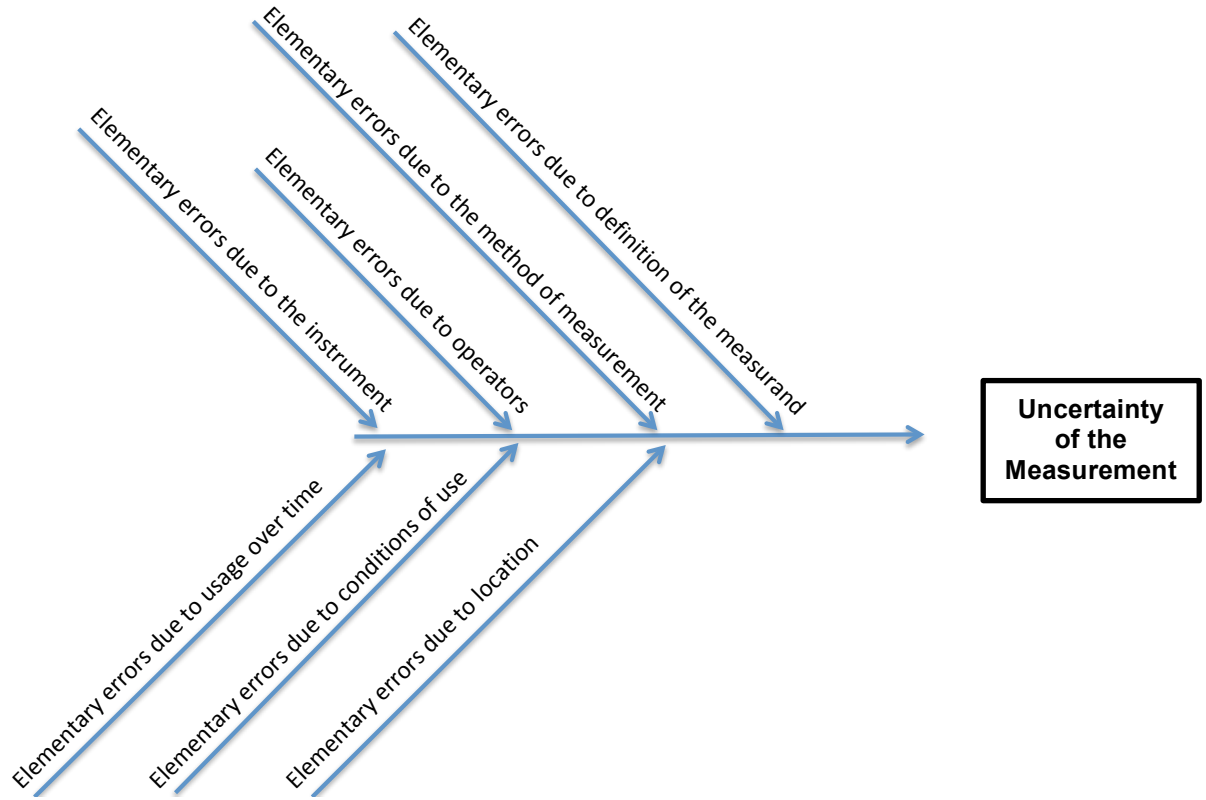
2.1.1 Monitoring the Measurement Process

Following the experimental evaluation of the uncertainty of the measurement process, and confirmation of its capability, it is necessary to monitor its performance when in use. It is therefore necessary to implement a continuing assessment of capability. Now this can be achieved using the same statistically based procedures described in modules 5 and 6 for continually monitoring the measurement process. However, this approach would be both costly and time consuming, and is not generally recommended except on occasions when the measurement process is altered in some way; such as a new operator or substantial change in environmental conditions. Calibration is a more practical and preferable method of monitoring quality of measurement that will be dealt with later. Another practical alternative is the use of control charts to monitor the measurement process.

2.1.2 Calibration

There are many sources of error that contribute to the measurement process, but to all intents and purposes may be conveniently summarised in the form of a cause and effects diagram, as illustrated in figure 2.1 below.

Figure 2.1 *Intrinsic error or errors of the measuring instrument, chain or system (ICS) used in the measurement process.*



The errors of the ICS are monitored by calibration; one of the principal functions of the Metrology Department. It is defined as,

a set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument and the corresponding known values of the quantity subjected to measurement.

Calibration can provide us with information concerning the systematic error (or bias error) of the instrument and the random (or repeatability error) of the instrument. But it can also be used as a means of monitoring the uncertainty of the measurement process. To do this it is necessary to define and control the conditions of utilisation such that all other contributions to the uncertainty of measurement are known and likewise controlled.

In order to monitor the uncertainty it is first of all necessary to define the limits on the systematic and random errors (bias and repeatability), ±e, below which the measurement process is guaranteed to remain capable. The conditions of utilisation must also be specified and documented in the form of a technical information sheet, as part of the documentation for the method of work.

Beyond the limits specified for the measurement process the uncertainty becomes unacceptable. The errors must therefore remain between. ±e, continuously, otherwise the measurement process is judged to be incapable.

Now since we need to ensure that the errors remain within these limits it is also necessary to define another set of limits (±ke), so called limits of alert or action, which if exceeded alert us to take corrective action before the process exceeds the limits of unacceptability (figure 2.2).

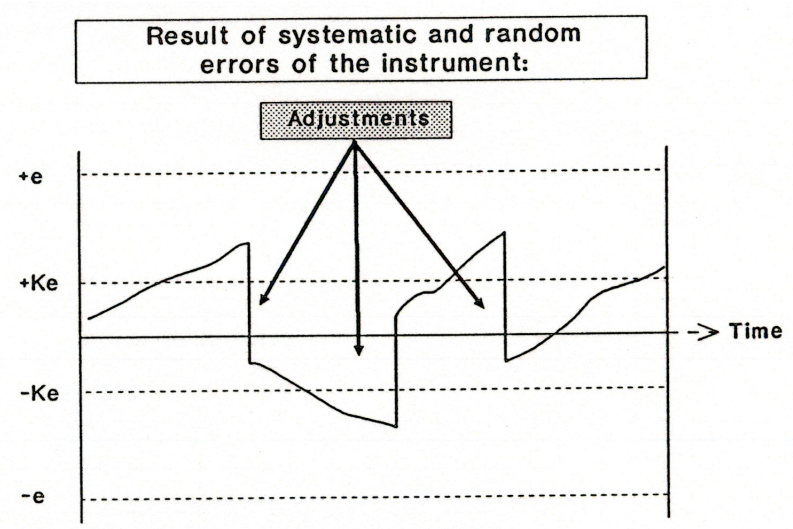


Figure 2.2 Result of systematic and random errors of the instrument:

So if, when calibration is carried out, the bias and repeatability errors remain within ±ke, adjustment is not required. However, if the errors appear to be outside this range an adjustment has to be made and the person responsible for the measuring instrument ('instrument owner') informed.

If, as a result of calibration, the bias and repeatability errors are found to be greater than ±e then the measurement process is judged to be incapable, or non-conforming. Under these circumstances the instrument user must be informed immediately and appropriate action taken to deal with the problem. Figure 2.3 presents a summary of the various actions that may be taken following calibration, including those for non-conformity.,

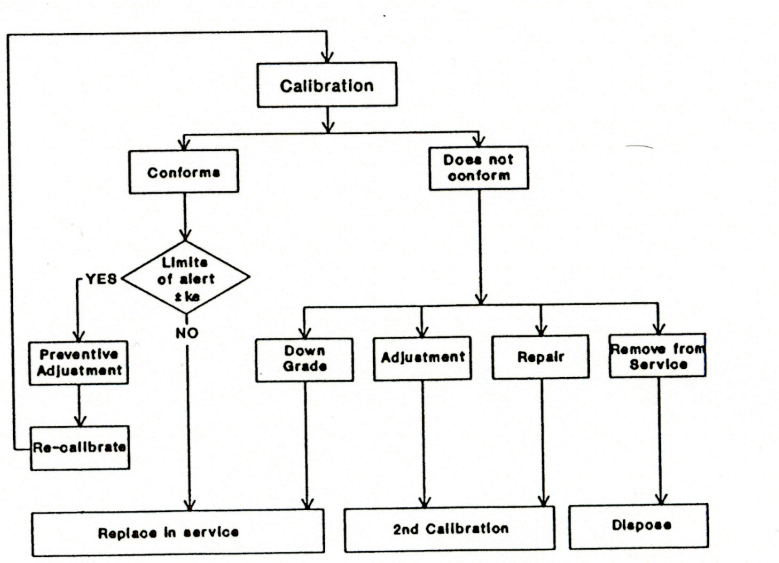


Figure 2.3

To ensure that the estimates for bias and repeatability are reliable it is important to perform the calibration using a standard that is traceable to national standards, through an unbroken chain of comparisons.

2.1.3 Instrument Verification

This source of action for maintaining quality is vested in the user of the measuring instrument and is essentially concerned with checking the performance of the instrument by means of a suitable verification device or devices. For example, verification masses may be used to check the performance weighing machines. The choice of verification device, and the number of devices, depends upon the measurement being undertaken, the range and the verification interval appropriate to the accuracy of the measurement concerned.

In addition to the appropriate selection of verification devices it is also important to specify the frequency of verification and take into account the associated errors. By satisfying these requirements a cost effective check upon the instrument performance and stability with respect to time can be readily achieved.

In some cases the verification of performance of a measuring instrument, system or chain (ICS) may be a regulatory requirement, as with weighing machines used for trade purposes within the UK. Under such circumstances the instruments concerned will generally be classified according to accuracy. The requirement upon the instrument owner/user will be to specify the class of accuracy for the instruments that come within the regulatory requirement and use corresponding verification devices to verify their performance. Verification can of course be used to advantage without there being a regulatory requirement to do so. National and international guidelines for verification strengthen the procedures for guaranteeing quality of measurement and provide the basis for effective comparison.

Taking weighing machines as an example, an EEC directive, "On the approximation of the Laws of Member States relating to Non-automatic Weighing Machines", number 73/360/EEC defines the various classes of accuracy for weighing machines and the maximum permissible errors on initial verification and in service. Machines are grouped into four classes of accuracy:

- **Special accuracy (Class I),**
- **High accuracy (Class II),**
- **Medium accuracy (Class III), and,**
- **Ordinary accuracy (Class 1111).**

Within these classes, sub-division on the basis of non-graduated and graduated machines is identified together with maximum capacity, lower limit on minimum capacity and verification scale interval within these sub-groups. The latter may be generally assumed to be the minimum scale interval or division of the weighing machine (d or d_d)f or digital readouts), but for some machines the verification scale interval will not be equal to the scale interval. For example, the minimum scale interval on a digital readout weighing machine may have a value of d_d = 0.1g but the verification scale interval may be 1g, indicating that the machine is not accurate to the last figure of the displayed readout. However, for the purposes of repeatability the last figure may be used. For such machines the last figure may be identified in a manner that distinguishes it from the other digits, possibly by use of a different colour.

The verification scale interval, "e", provides the basis on which the maximum permissible errors on initial verification and in service are defined and the specification of maximum allowable errors on masses used for verification. Thus, the maximum permissible errors for the various classes of weighing machine are as summarised below (plus or minus the values shown):

Initial Verification	**In service**	
Special accuracy		
0.5 e	1 e	for increasing loads, minimum to 50,000 e capacity inclusive and for decreasing loads, 50,000 e to zero;
1 e	2 e	for loads between 50 000 e exclusive and 200,000 e inclusive;
1.5 e	3 e	for loads > 200,000 e.
High accuracy		
0.5 e	1 e	for increasing loads, to 5 000 e capacity inclusive and for decreasing loads 5 000 e inclusive to zero;
1 e	2 e	for loads between 5 000 e exclusive and 20,000 e inclusive;
1.5 e	3 e	for loads > 20,000 e.
Medium accuracy		
0.5 e	1 e	for increasing loads, minimum to 500 e capacity inclusive and for decreasing loads, 500 e inclusive to zero;
1 e	2 e	for loads between 500 e exclusive and 2000 e Inclusive;
1.5 e	3 e	for loads > 2000 e.
Ordinary accuracy		
0.5 e	1 e	for increasing loads, minimum to 50 e capacity inclusive and for decreasing loads, 50 e inclusive to zero:
1 e	2 e	for loads between 50 e exclusive and 200 e inclusive:
1.5 e	3 e	for loads >200 e.

In selecting the masses for verification the maximum allowable error is taken to be 1/3 the maximum allowable error for the machine. Thus, for a weighing machine with a ±2g maximum allowable error the maximum allowable error on the masses for verification is 0.666g.

2.2 Maintenance of Instruments

Achieving and maintaining quality of measurement naturally depends upon the instrumentation that is used, the care with which it is used and the way in which it is maintained. Appropriate planning will ensure that the right instrumentation is used in the measurement process and appropriate training will assist in ensuring that the instrumentation is well treated. The maintenance requirements depend upon the natural wear in the instrument and the conditions under which it is used. Planning is therefore important in determining the maintenance schedules that need to be applied in performing the maintenance procedure, and the frequency of maintenance.

Maintenance should be viewed as part of a wider set of quality assurance functions concerning instrumentation and equipment, collectively referred to as equipment or instrumentation management. These functions include,

- Equipment selection
- Acceptance testing of equipment
- Traceability of equipment
- Training in the use and maintenance of equipment
- Maintenance of equipment
- Disposal and replacement of equipment

Each of these functions requires attention in planning for quality assurance of measurement and will also have an influence upon the cost of ownership of equipment; which is a further issue of importance in planning a measurement.

The maintenance aspect of equipment management may be partitioned into user, scheduled and unscheduled maintenance activities. Planning will be concerned with the specification of what is required in implementing and controlling these activities and the resources, managerial and physical, that need to be deployed to fulfill them effectively. The extent to which resources are required will depend upon the nature and purpose of the instrument, conditions of use, reliability and susceptibility of variation. A complex co-ordinate measuring system, for example, is likely to demand more resourcing, in terms of operator support and maintenance, than more modest measuring instruments. Planning must consider the relative merits of measuring instruments in a way that includes the cost of ownership.

For an item of instrumentation or ICS to remain serviceable and reliable in operation it is generally expedient to institute a formal system of maintenance to ensure regular inspections, routine servicing and calibration are carried out on a planned and controlled basis. Responsibility for maintenance needs to be clearly defined and where the maintenance activity is separated, on a departmental basis, from other aspects of the equipment management function a vehicle for communication and liaison should established. The division of responsibility, together with the strategy and procedures for maintenance, should also be identified with the organisation's documentary structure.

By distinguishing user, scheduled and unscheduled maintenance activities, a foundation is provided for enhancing the quality of support for equipment in regular use.

The user aspect of maintenance is essentially concerned with the day-to-day care of the equipment whilst in use, including as appropriate the following activities:

- Careful cleaning and general care in the use of equipment
- Formal inspection of equipment, including leads and ancillary devices
- Functional check on equipment
- Verification or calibration check, as appropriate. Note that the latter is likely to involve the metrology department.
- Adjustments, lubrication and permitted replacements, as appropriate repeat functional check
- Safety check, as appropriate

The user maintenance must clearly be restricted to activities that are within the knowledge and capability of the operator concerned. Planning the procedures for user maintenance is likely to be influenced by manufacturer recommendations for the equipment concerned but should also reflect the user demands that are being placed upon the equipment.

The scheduled aspect of maintenance is concerned with the objective of ensuring that the equipment being maintained will continue to function satisfactorily, within prescribed limits, for at least the duration between scheduled maintenance provisions. In practice it is important to ensure a high probability of satisfactory performance for a period significantly longer than the scheduled period between maintenance activities. This should not, however, be used as an excuse for extending the period between maintenance sessions, the margin should be viewed from the point of view of confidence, wherein an extension of the maintenance period would be seen as a lowering of the confidence that the equipment would perform satisfactorily.

The particular activities that can be expected under a scheduled maintenance programme include;

- Comprehensive inspection
- Replacement of particular parts that may be considered to be sufficiently worn or at risk of compromising the performance of the equipment, possibly identified on the basis of reliability data
- Thorough cleaning and lubrication, as appropriate
- Calibration
- Performance tests, as necessary
- Functional check
- Safety check

As with the user defined maintenance the scheduled maintenance should be carefully specified, documented and managed.

Where a scheduled maintenance programme is well planned and operating satisfactorily the incidence of failure and the need for unscheduled maintenance will be small. However, the need to facilitate expeditious handling of repairs and problems relating to the use of equipment should be recognised. In a total quality context the objective should be to obviate the need for such a service, but in planning for quality of measurement a cost effective contingency arrangement should be identified to deal with such problems. Again it is important to identify responsibility for the activity and have appropriately documented procedures for dealing with unscheduled maintenance, indicating clearly what is acceptable on a local basis, a wider company basis and what may require referral to the equipment manufacturer or supplier.

In situations where modifications to equipment may be suggested it is vitally important to consider the justification for the modification, the technical and safety issues involved and only exercise the Implementation of a modification through properly controlled, formal authorisation by a designated competent technical advisor. Bear in mind also that a modification to an item of equipment without sanction from the manufacturer will undoubtedly invalidate any warranty on the equipment.

Once a maintenance activity has been completed the equipment should be formally released to the user or equipment manager with the appropriate documentation to indicate what has been done and that it is fit for use.

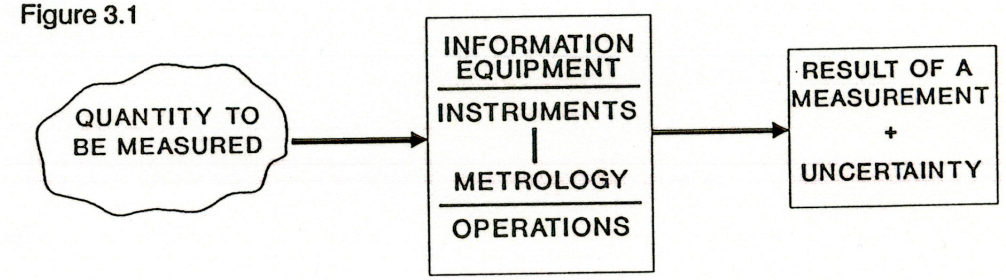
3.0 The Metrology Function

As defined in the International Vocabulary of Basis and General Terms in Metrology (PD 6461 part 1) metrology is the field of knowledge concerned with measurement. Unfortunately, the somewhat embracing definition provides little insight into the function of a metrology department; a function which is essential to the objective of guaranteeing quality of measurement. . In the majority of manufacturing companies the main functions of the metrology department may be considered to be:

- the provision of guarantees for the intrinsic performance of measuring instruments through calibration,
- ensuring traceability to national and international standards, and calibration management, and the supply of conventional true values, and,
- the provision of expert technical advice and guidance on the selection and application of instruments for the purpose of achieving quality of measurement.

On this basis the Metrology Department is primarily concerned with the instrument, which is just one part of the measurement process (figure 3.1). It is, nevertheless a very important part of the process and it is necessary to identify the responsibilities for instruments from acceptance to use.

Figure 3.1



The responsibilities are essentially divided between the Metrology Department and the user

3.1 Responsibilities of the Metrology Department

In providing the services summarised in 3.0, above, the responsibilities of the Metrology Department or function extend to the following activities:

- Reception or acceptance testing of instruments to determine their fitness for purpose within a defined measurement process.
- Identification, labelling and registration of instruments accepted into service.
- Calibration and the determination of uncertainty for measuring instruments.
- The provision of conventional true values, certified reference values and reference values.
- Monitoring of quality of the measurement process, through recall, calibration and audit.
- Initiate of rules for action for dealing with non-conformities.

These responsibilities need to be viewed in relation to those ascribed to the 'owner' (the person or persons responsible for the instrument when in use), in order to avoid misunderstanding on who is responsible for what and ensure that all the requirements concerning the instruments are adequately covered.

3.2 Responsibilities of the Instrument Owner

Wherever an instrument is used in a measurement process it is necessary to identify a person to take responsibility for the instrument while it is in use. Generally speaking a departmental manager will assume responsibility for all the instruments used within his or her department. The responsibilities that attach to this role are those of ensuring:

- the most suitable instrument is used for a particular measurement process
- that the measurement process is capable
- that all instruments used within the department are approximately identified and correctly labelled
- that all instruments used to make measurements that are critical to quality are regularly calibrated, and verified as appropriate, and that no instrument is being used past the date on which it is due for calibration
- that all the instruments assigned to the department are being used correctly and respected
- that all the instruments assigned to the department are regularly maintained, and
- that the Metrology Department is doing its job properly
- application of the Quality of Measurement Manual.

To fulfil these responsibilities certain basic needs have to be satisfied, needs that relate to structure, personnel, training and validation, equipment and environmental facilities.

3.3 Basic Needs for fulfilling the Metrology Function

To fulfil its function effectively the department or group responsible for metrology must be appropriately organised, staffed and otherwise well resourced. Guidance on defining a suitable organisational structure for metrology is presented in BS 5750, part 2 (ISO 9002). It states:

'the responsibility, authority and the interrelation of all personnel who manage, perform and verify work affecting quality shall be defined.'

On this basis it can be seen that the organisational structure must encompass all personnel working in the field of measurement, within the organisation concerned, from the shop-floor to the Metrology Department. Moreover, it is necessary to ensure that the structure is well defined and the responsibilities clearly distinguished.

3.3.1 Personnel, Training and Validation

Within a manufacturing organisation a manager should be identified who takes on the responsibilities for all metrology activities carried out on site, together with the responsibility for all aspects of organisation, management and technical performance of the metrology function. A deputy should also be identified to fulfil the role of the manager in the manager's absence.

The management and the metrology team need to be trained and capable of performing their specific tasks. In addition to training for quality measurement two specific areas of training require attention:

- Management/Systems training and validation, by specialists, for all metrology personnel and based upon the requirements set out in the Quality of Measurement Manual. For example, training in writing calibration procedures.
- Calibration training and validation, by local specialists, for all personnel involved in specific calibrations.

The latter complies with BS 5781, which states that

'all personnel performing calibration functions shall have appropriate experience or training'.

The calibration technician needs to be trained and validated for carrying out specific calibration with specific equipment following a specific calibration procedure that has been duly documented within the Measurement Process Documentary Structure (MPDS) and validated.

3.3.2 Equipment and Traceability

BS 5781 states that

'All measurement standards and measuring equipment shall be calibrated using measurement standards that are traceable to national or international measurement standards'.

In compliance with this requirement the metrology department or group must be appropriately equipped to perform such measures and for calibrations carried out both internally and externally measurement standards must be used that are traceable and of sufficient accuracy. The standards must also be carefully maintained.

3.3.3 Environmental Facilities

A further requirement specified in BS 5781 concerning calibration relates to the need for environmental control in calibration procedures. Specifically, it states that:

'Measurement standards and measuring equipment shall be calibrated and used in an environment controlled to the extent necessary to ensure valid measurement.'

Control of environmental conditions during calibration is a means of minimising the influence of environmental factors upon the uncertainty of the measurement result and estimating the errors of the instrument itself. Consequently, it is advisable and often essential to perform calibrations in environmentally controlled rooms.

Temperature is invariably an important influence quantity in calibration procedures and recommendations are made in international standards for particular ambient conditions. For example, calibrations involving dimensional measurements and mass, the international standard is 20°C (ISO 1). Depending on the tolerance involved the control over this temperature is roughly:

±0.2°C, for NPL or equivalent
±0.5°C, for BCS approved laboratories
±1°C, for normal industrial engineering requirements
±2°C, for less critical cases.

For calibrations involving electrical measurements which, due to the nature of the equipment involved, are concerned with temperature and pressure measurements, the international standard is 23°C (ISO 554). Once again the tolerance on the temperature Is dependent upon the requirements, and for normal industrial purposes is ±1°C or ±2°C is generally considered to be sufficient.

Although temperature is such a commonly encountered influence quantity it is not the only influence quantity and care should be taken to determine those quantities that require monitoring or control. Humidity, local atmospheric pressure and vibrations, In the case of measurements of dimensions and mass, are prime examples other influence quantities that often need to be controlled.

3.4 Important Procedures and Systems

Apart from the basic needs that have to be satisfied in providing the metrology function it Is also important to identify the Important procedures and systems that are required to ensure effective and efficient realisation of metrology services. Since the metrology function, in service terms, is essentially concerned with the instruments it is important to have well installed systems for:

- instrument selection
- identification of instruments and classification
- labelling of instruments, and
- instrument management.

It is also important to have well defined procedures for calibration and verification, including access and use of the external calibration system (NAMAS). And then, of course, there is the Quality of Measurement Manual; the reference document for all aspects of measurement undertaken within the organisation.

3.4.1 Instrument selection system

Selecting an instrument for a particular task generally requires careful consideration and, often as not, considerable insight into the function it has to perform. A system that identifies appropriate sources of advice, contacts and procedures can be of considerable assistance in making such selections and its use can often avoid embarrassing and costly mistakes when it comes to the purchase of instruments. The detailed structure of such a system will, of course, depend upon the company structure and organisation. However, the general features of a system for instrument selection should encompass the stages for selection, summarised in figure 3.2. Here one can see the need for background information, budgetary information, advice and evaluation.

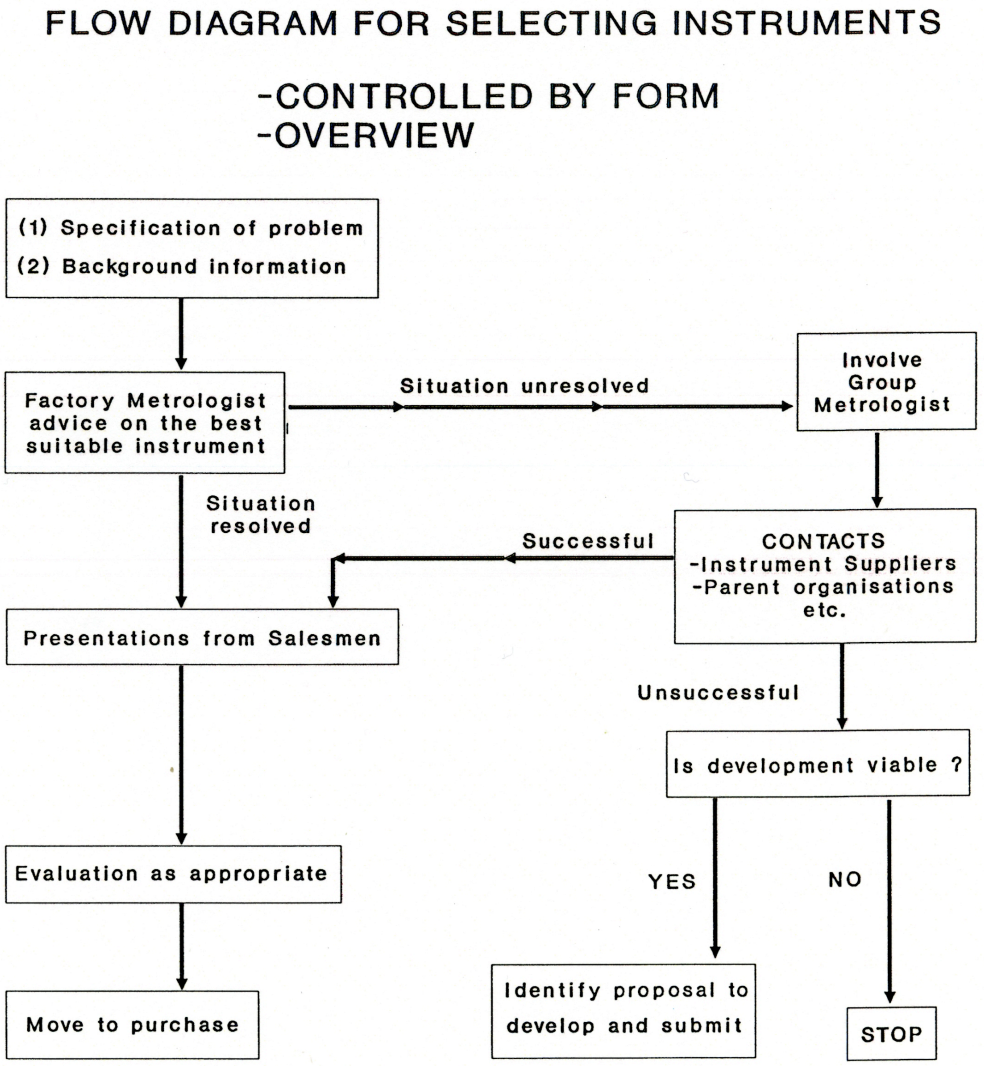

FLOW DIAGRAM FOR SELECTING INSTRUMENTS
-CONTROLLED BY FORM
-OVERVIEW
(1) Specification of problem
(2) Background information
Factory Metrologist advice on the best suitable instrument
Situation unresolved
Involve Group Metrologist
Situation resolved
Successful
CONTACTS
-Instrument Suppliers
-Parent organisations
etc.
Presentations from Salesmen
Unsuccessful
Is development viable ?
Evaluation as appropriate
YES
NO
Identify proposal to develop and submit
STOP
Move to purchase

Figure 3.2

3.4.2 System for identification and classification for instruments

As a basis for appropriate management and traceability of instruments it is necessary to identify each item of equipment by means of a unique number or code. Again, the detail of the coding system used would depend upon the requirements of the organisation or company concerned. A representative system, used within the Michelin organisation, is based upon an 11 character coding system. The basic structure for the code is illustrated in figure 3.3.

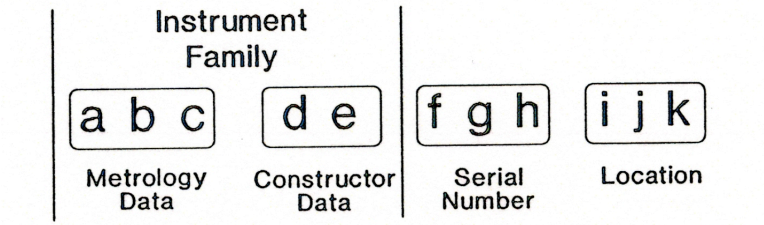


Figure 3.3

Within the 'metrology data' entry 'a' defines the field, 'b', the physical quantity and 'c', the function that the device Is designed to perform. Collectively, the three-character metrology data code defines the type of instrument. Figure 3.4 presents the guidelines for assigning entry numbers within these categories.

FIELD a	PHYSICAL QUANTITY b	FUNCTION c
0 : MULTI-QUANTITY PHYSICAL OR CHEMICAL		1 : SENSOR 2 : TRANSDUCER 3 : INDICATOR 4 : REGULATOR 5 : RECORDER 6 : CONVERTOR 7 : GENERATOR 8 : AMPLIFIER 9 : COUPLING A : TIMER B : PROGRAMMER C : MEASURING CHAIN D : MULTIPLEXER S : MEASURING SYSTEM W : APPARATUS
1 : SPECTRO/RADIO/ PHOTOMETRY		1 : SENSOR 2 : TRANSDUCER 3 : INDICATOR 4 : REGULATOR 5 : RECORDER 6 : CONVERTOR 7 : GENERATOR 8 : AMPLIFIER 9 : COUPLING A : TIMER B : PROGRAMMER C : MEASURING CHAIN D : MULTIPLEXER S : MEASURING SYSTEM W : APPARATUS
2 : MECHANICAL UNITS	1 : DIMENSION 1 : ANGLE 1 : HARDNESS	1 : LENGTH 2 : ANGLE 3 : LENGTH & ASSOCIATED ANGLE 4 : SHAPE/POSITION 5 : SURFACE FINISH/HARDNESS 6 : MECHANICAL MEASURING INST. 7 : ELECTRICAL MEASURING INST. 8 : OPTICAL MEASURING INST. A : CONTROL PROCESSES B : DIVERSE
	2 : MASS	0 : ASSAY BALENCE 1 : ROBERVAL 2 : STEELYARD 3 : MECHANICAL AUTO 4 : MECHANICAL SEMI-AUTO 5 : MECHANICAL HOOK WEIGHER 6 : ELECTRO/OPTICAL AUTO 7 : ELECTRO/OPTICAL SEMI-AUTO 8 : ELECTRO/MECHANICAL 9 : ELECTRONIC A : ELECTRONIC 'DUAL RANGE' B : ELECTRONIC 'MULTI-RANGE' C : ELECTRONIC 'HYBRID' D : ELECTRONIC 'HOOK WEIGHER' E : ELECTRONIC 'PALETTE' M : BOX WEIGHTS P : O.E. WEIGHTS
	3 : FORCE 4 : ACCELERATION 5 : PRESSURE 6 : VISCOSITY 7 : DENSITY - VOLUME FLOW 8 : AIR SPEED 9 : NOISE A : LINEAR VELOCITY	1 : SENSOR 2 : TRANSDUCER 3 : INDICATOR 4 : REGULATOR 5 : RECORDER 6 : CONVERTOR 7 : GENERATOR 8 : AMPLIFIER 9 : COUPLING A : TIMER B : PROGRAMMER C : MEASURING CHAIN D : MULTIPLEXER S : MEASURING SYSTEM W : APPARATUS

3 : ELECTRICITY/ MAGNETISM	1 : DC VOLTAGE 2 : AC VOLTAGE 3 : DC CURRENT 4 : AC CURRENT 5 : RESISTANCE 6 : CAPACITANCE 7 : INDUCTANCE 8 : PHASE 9 : FREQUENCY A : POWER B : ENERGY	1 : SENSOR 2 : TRANSDUCER 3 : INDICATOR 4 : REGULATOR 5 : RECORDER 6 : CONVERTOR 7 : GENERATOR 8 : AMPLIFIER 9 : COUPLING A : TIMER B : PROGRAMMER C : MEASURING CHAIN D : MULTIPLEXER S : MEASURING SYSTEM W : APPARATUS
4 : TIME	1 : TIME INTERVAL (Less/equal to 24 hours). 2 : TIME INTERVAL (Greater than 24 hours).	1 : SENSOR 2 : TRANSDUCER 3 : INDICATOR 4 : REGULATOR 5 : RECORDER 6 : CONVERTOR 7 : GENERATOR 8 : AMPLIFIER 9 : COUPLING A : TIMER B : PROGRAMMER C : MEASURING CHAIN D : MULTIPLEXER S : MEASURING SYSTEM W : APPARATUS
5 : IONIZING RADIATION	1 : RADIOACTIVITY 2 : EXPOSURE 3 : DOSE RATE 4 : DOSE EQUIVALENT	1 : SENSOR 2 : TRANSDUCER 3 : INDICATOR 4 : REGULATOR 5 : RECORDER 6 : CONVERTOR 7 : GENERATOR 8 : AMPLIFIER 9 : COUPLING A : TIMER B : PROGRAMMER C : MEASURING CHAIN D : MULTIPLEXER S : MEASURING SYSTEM W : APPARATUS
6 : TEMPERATURE/ HYGROMETRY	1 : TEMPERATURE 2 : RELATIVE HUMIDITY 3 : THERMOHYGROMETRY	1 : SENSOR 2 : TRANSDUCER 3 : INDICATOR 4 : REGULATOR 5 : RECORDER 6 : CONVERTOR 7 : GENERATOR 8 : AMPLIFIER 9 : COUPLING A : TIMER B : PROGRAMMER C : MEASURING CHAIN D : MULTIPLEXER S : MEASURING SYSTEM W : APPARATUS
F : REFERENCE MATERIALS	1 : REFERENCE MATERIAL	TO BE DEVELOPED

The 'd' and 'e' entries identify the manufacturer of the instrument, with the 'd' being assigned the first letter of the manufacture's name. The second character, 'e' is simply assigned a number within the range 1 to 9 or A to Z depending upon the additive list of manufactures with the same first letter in their name.

The characters assigned to 'f', 'g' and 'h' identify the serial number of the instrument, starting from 001 up to 999, referenced to the appropriate manufacturer. Thus, an instrument with the code, abc de 012 ijk, would refer to instrument number 12 of the manufacturer defined by 'd' and 'e', and of the type defined by 'abc'.

The characters assigned to 'l', 'j' and 'k' are used to identify the location of the instrument within the organisation, according to department, workshop, production unit or other designation considered appropriate.

3.4.3 Labelling of Instruments

A system of identification and classification naturally requires that the instruments be labelled in some way. In applying the 11-character identification code it is necessary to ensure that each instrument is labelled accordingly. But this is only part of the labelling requirement. Other labels are necessary to alert users to particular information, including:

- the classification of instrument, measuring or non-measuring device,
- test information, and
- information on calibration.

Classification, for labelling purposes, may simply be on the basis of whether the instrument is a measuring instrument or non-measuring instrument. The Quality of Measurement Manual should provide an appropriate definition to distinguish between the two. Typically, the following definitions suffice for this purpose:

'A measuring instrument is an instrument whose performance has a direct influence upon the quality of the manufactured product.'

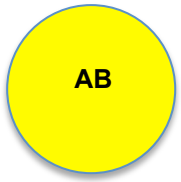
It is calibrated periodically by comparison with standards held by the metrology department.

'A non-measuring instrument is an instrument whose measurement performance has no effect on the quality of the manufactured product.'

Non-measuring instruments are verified by the user or controlled by the maintenance personnel responsible, without any defined periodicity.

In making the distinction between measuring and non-measuring instruments it is only necessary to identify by means of a label those instruments that are considered to be of the non-measuring type (figure 3.5).

Figure 3.5



Color : yellow with black lettering
Size : 38 x 16mm

Examples of other labels needed to convey various items of information are presented in figure 3.6.

Figure 3.6

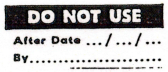
Tested

Colour : Green/White

Size : 38 x 16 mm

Details are written manually using an indelible marker pen.

Do Not Use



Colour : Red/White

Size : 38 x 16 mm

Details are written manually using an indelible marker pen.

NB: Details written on labels can only be entered by authorised personnel.

Calibration Sealed

Colour : Yellow with black lettering.

Size : 24 mm diameter.

Label used on large instruments and measuring systems to highlight identification label.

Colour Red/White

Size : 110 x 45 mm

The durability, legibility and method of attachment are further considerations that need to be applied in respect of labelling. Clearly, all labels should be legible and durable for the purposes intended.

Attachment of labels is a responsibility generally consigned to the metrology department or persons designated by the metrology department. An obvious, but important, consideration in applying labels is where they are put. They need to be prominently displayed and generally attachment to the front of the instrument, or an easily accessible alternative face, Is appropriate. 'DO NOT USE' labels should always be placed over the face of indicating instruments, or over other approved labels for other devices.

In situations where it is difficult to identify a suitable surface for affixing labels it may be considered appropriate to attach suitable labels by means of a tag.

3.5 Instrumentation Management Systems (IMS)

The advent of powerful, low cost, personal computers has provided the basis for developing computer-based instrument management systems. Such systems ease the management task and enable up-date records to be maintained in a cost-effective and flexible manner. Such a system would have the following key features:

- the facility for recording instrument identification data, including, for example, the identification number and location
- the facility for recording calibration status
- the facility for maintaining a complete record of instrument history, and
- the facility to record uncertainty of measurement data.

In use, for the management of calibration, or example, the details for the instrument under consideration may be entered in response to prompts. The following information may be requested in this way:

- Identification number and location (e.g. based upon 11 character code).
- Calibration and verification frequency.
- Details of tolerances and uncertainties of the measurement concerned.
- Manufacturer's specifications.
- Operating conditions.
- Name of the measurement correspondent responsible for the management of calibration.

Using this information an appropriate management system will enable the metrology correspondent to conveniently identify when instruments need to be calibrated, and notification of departments accordingly, maintain a list of instruments due for calibration and maintain a record of calibration results. The system may also assist the correspondent in decision-making, based upon results in relation to pre-determined limits of uncertainty of measurement, issue of calibration certificates where conformance is established and actions for dealing with problems arising in situations of non-conformance.

Developments on system software will undoubtedly lead to the inclusion of more attributes for dealing with calibration and other statistical data. Uncertainty of measurement, for example, may be automatically calculated from data derived during calibration, appropriately linked to specific calibration procedures, and the instrument history updated accordingly. Further developments may include comparisons of uncertainty data for similar instruments from different manufacturers, over a period of time, as a basis for more effective instrument selection.

3.6 External Calibration Services

For the purpose of providing, maintaining and disseminating national standards the UK has established a national body, in the form of the National Physical Laboratory and the National Measurement Accreditation Service (NAMAS).

The National Physical Laboratory (NPL) is charged with the responsibility of maintaining national primary standards in strict accordance with internationally agreed recommendations. It is also concerned with development of standards and investigations into fundamental physical systems that have potential application in establishing standards. As a result of the experience and expertise gained in these activities NPL also participates in, and exercises influence upon, international standards through involvement on national and international organisations charged with the responsibility of developing new standards. This is particularly so in standards where technical issues concerning measurement are prominent.

Secondary standards held by industrial and government organisations throughout the UK are derived from the national standards. Dissemination of these standards is achieved through a hierarchical process of calibration, commencing with the service offered by NPL for direct comparisons and following through to the many external laboratories accredited by the British Calibration Service. The latter is part of the National Measurement Accreditation Service (NAMAS), formed following the amalgamation of the British Calibration Service (BCS) and the National Testing Laboratory Accreditation Scheme (NATLAS) in 1985.

The BCS part of NAMAS is concerned with the accreditation of laboratories in industry and elsewhere for undertaking specified calibrations and measurements, and the issue of BCS certificates. Certification in the form of a BCS certificate not only indicates that the measurements are traceable to national standards, but also provides a high degree of assurance for the correctness of calibration for the instrument Identified on the certificate.

The NATLAS part of NAMAS is concerned with the accreditation of laboratories for general testing, In much the same way as BCS provides accreditation for calibration. Laboratories can apply to NATLAS for accreditation over a wide range of testing services and in the event that a laboratory is judged to be competent, on the basis of comprehensive criteria, such as staff, expertise, equipment, facilities and management, accreditation is granted for defined types of tests. A concise directory of BCS and NATLAS accredited laboratories is issued by NAMAS and includes information on the type of calibration and tests accredited for each of the laboratories listed.

3.7 Calibration and Verification Procedures

Defining a calibration or a verification procedure requires attention to a number of details, appropriately identified under specified divisions. Thus, the contents of a calibration procedure should include the following items:

- Scope of the calibration
- Calibration interval

- Type of calibration
- Method of calibration
- Quantities involved
- Resources required
- Operations details
- Measurement details
- Requirements for reporting results
- Appendices

In detailing resources it is necessary to identify premises, calibrator skill, standards and apparatus and records.

The information presented on operations should include, preliminary operations, connections, standards and apparatus, measured quantities and influence quantities.

In defining the measurement aspect of the procedure it is necessary to specify the number of measurement points to be taken, the method to be applied, any special precautions to be taken, the treatment of results, the calculation of uncertainty and the analysis of results.

Within the section on reporting results the actions for certification and handling of non-conformance should be specified.

BS 5848 provides guidelines on numbering divisions and sub-divisions of the procedures (figure 3.7).

Any reference supporting the procedure should also be included in the documentation.

Contents:

Note: Use BS 5848 Numbering of divisions and sub divisions. You may create your own sub-divisions where they do not exist. Write "not applicable" against division or sub-division which you do not require.

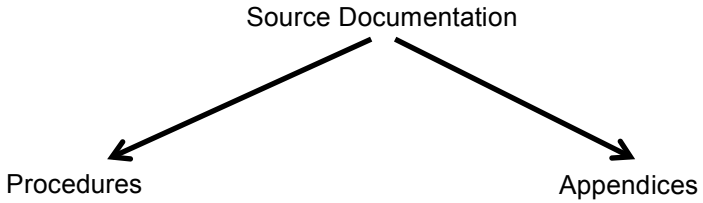
ISSUE:						MODS THIS ISSUE
DATE						
AUTHOR						

Figure 3.7

3.8 The Quality of Measurement Manual

The Quality of Measurement Manual is a primary reference document compiled to meet individual company requirements. Three parts should be distinguishable within this document, source documentation, procedures and appendices (figure 3.8).

Figure 3.8



3.8.1 Source Documentation

The Source Documentation defines, in detail, the policy, mission and responsibilities for achieving and maintaining quality of measurement. It also summarises the various requirements, actions and controls that are necessary for maintaining quality of measurement in an efficient and effective manner.

3.8.2 Procedures

The Procedures part of the manual provides detailed documentation on the procedures, including methodology, resources, reporting directives etc. that are being used within the company to realise quality of measurement. Figure 3.9 presents a representative list of procedures that can be expected in a manufacturing organisation.

The appendices constitutes a collection of documents, important to the objective of realising quality measurement, but consigned to this section for purposes of clarity and ease of reference. Typically, the appendices will include:

- documents defining the requirements for quality of measurement and metrology services, including structure, organisation and responsibilities,
- documents identifying sources of information, such as standards,
- documents defining and explaining in-house systems that are used,
- documents providing general information relevant to the realisation of quality measurement and metrology services.

A representative list of documents that may be expected to be included in the appendices is presented in figure 3.10.

PROCEDURES	
P01	Identification of measurement standards, measuring instruments and chains.
P02	Labelling of measurement standards, measuring and non-measuring instruments.
P03	General rules for drafting Calibration Procedures
P04	Catalogue and Management of Calibration Procedures.
P05	Assessment type, approval and Conformance to type.
P06	Validation, Verification, Inspection (or control).
P07	Measurement Process from the analysis of the requirement to the Exploitation of the results of measurement.
P08	Calibration methods, frequency and recall
P09	Quality of Measurement and Management Indicators.
P10	Monitoring of results - distribution and storage of information.
P11	Rules for handling, transport , and storage of an instrument.
P12	Rules for action following a malfunction of an instrument.
P13	Sealing for integrity of measurement standards measuring instruments, chains and systems.
P14	Rules for updating the Source Document appendices and procedures.
P15	Monitoring of orders (calibration requests).
P16	Expert Opinion to resolve disagrement.
P17	Sub-contracting of calibration and repair work.
P18	Audit procedures.

APPENDICES

A01a	Metrology Glossary
A01b	List of Symbols
A02	Supplementary information to the Quality of Measurement Manual Source Document.
A03	International Metrology Organisation.
A04	UK Metrology Organisation
A05	UK reference and transfer standards
A06	Standard Metrology Document
A07	Result of Measurement
A08	Facilities, Metrology Laboratories and Section premises
A09	Procedure for Analysis of Instrument requirements
A10	Standards and Bibliograpy
A11	Classification of variable ambient conditions
A12	Training modules for explanation of source document
A13	Technical Training and Certification in Metrology
A14	List of Measuring Instruments, chains and systems to be given priority in Quality of Measurement
A15	Instrument Management System - Operating Instruction and User Guide

4.0 Quality Audits

Periodic and systematic audits and reviews are an essential feature of any quality assurance strategy The review is essentially an examination of organisation, methods and procedures, conducted in-house by company employees, with a view to revealing defects or irregularities, the effectiveness of management and the effectiveness of management objectives and methods in achieving desired results. An audit, on the other hand, is an independent examination of the actions that influence quality. The audit provides objective, independent sources of feedback to assist in monitoring and developing quality systems.

Whilst the subject of quality audits can be considered in terms of the requirements for total quality within a company we shall confine our attention here to those aspects of audit that encompass the activities for realising quality measurements. In doing this it is not suggested that the quality of measurement issues are mutually exclusive to the total quality objective. Indeed, the audit initiatives for quality of measurement are seen as an integral part of a total quality strategy.

4.1 Type of Audit

Audits for quality are generally distinguished as being internal, external or extrinsic, with the particular distinction being made on the basis of the relationship between the auditor and the auditee.

4.1.1Internal Audits

Internal audits are used by companies to evaluate their own quality performance, but require the agency of an external auditor if a truly independent assessment is to be made. However, the important feature of an internal audit is its focus upon identifying strengths and weaknesses and the needs for improving the quality system of the company.

4.1.2 External Audits

External audits are generally associated with a need to monitor the quality performance of suppliers. However, for measurement purposes it is also a means of demonstrating to an approving authority the achievement of claimed standard of ability in performing measurement or calibration procedures.

4.1.3 Extrinsic Audits

Extrinsic audits are essentially audits performed by regulatory authorities, but is sometimes used as a term for audits performed by the customer on a company's supplier. The latter use of the term is generally reserved for customers of an official nature, such as government departments.

4.2 Depth and Scope of Quality Audits

In terms of scope a distinction can be made between systems audits and compliance audits. The systems audit is used to determine if an appropriate system is in place for providing assurance that a particular activity is being carried out as required. A compliance audit, on the other hand, is used to determine if an identified assurance system is being used and whether it is effective or not.

Considered on the basis of scope, an audit may be full, partial or a follow-up. Full audits are concerned with all the activities and departments involved in a particular product or process, whereas a partial audit is confined to a particular section of activities and departments. Measurement

audits are generally within this category. The follow-up audits are used to verify that corrective actions have been implemented in response to directives arising from previous audits.

4.3 Audit Checklists and Criteria

In seeking to institute an effective audit it is necessary to adopt a systematic approach that will ensure that appropriate answers are obtained for a series of well-defined questions. But, in addition to the need to ask the right questions and extract accurate and meaningful answers it is also necessary to have a thorough understanding of the processes and relationships to be encountered in the audit and the faculty for correctly interpreting responses obtained during the audit. A checklist is a useful tool for helping to achieve these objectives. For some of the international standards for quality assurance the checklist is mandatory.

For general quality audit purposes criteria and departmental checklists are distinguished. The criteria list is essentially constructed on the basis of the criteria stated within the quality standard on which the particular quality system being audited is based. The departmental checklist sets out, as suggested in the name, the functions and activities that have to be considered. The corresponding checklists for auditing quality of measurement would encompass all aspects of the measurement process; instrumentation, information and operations.

4.4 Regularity of Audits

The regularity with which audits are performed depends upon a number of factors largely determined by the nature and structure of the particular organisation or company. It is generally appropriate to institute quality of measurement audits on a periodic basis, according to need. Their use should also be considered when major changes are made within the organisation that can clearly affect the quality of measurement, such as a factory reorganisation or the introduction of new production processes.

4.5 External Audit of Uncertainty

An external audit activity of considerable importance in monitoring the effectiveness of a company's calibration capability, and those of external calibration services, concerns the assessment of uncertainty. The BCS offer a well-managed and thorough audit service for this purpose.

A sample unit for measurement, generally termed a package, is circulated through a number of calibration laboratories, starting and ending with the National Physical Laboratory. Each laboratory receives and calibrates the sample as a routing assignment, under specified conditions, and issues a calibration certificate, which is then returned to the BCS.

On receipt of the data the BCS plot on an audit result chart the actual measurement values obtained from each of the calibration laboratories, together with the associated assignment of uncertainty. The national determinations are also included on the plot. Each measurement value is identified by a cross and the uncertainty value by a bar intersecting the cross (figure 4.1).

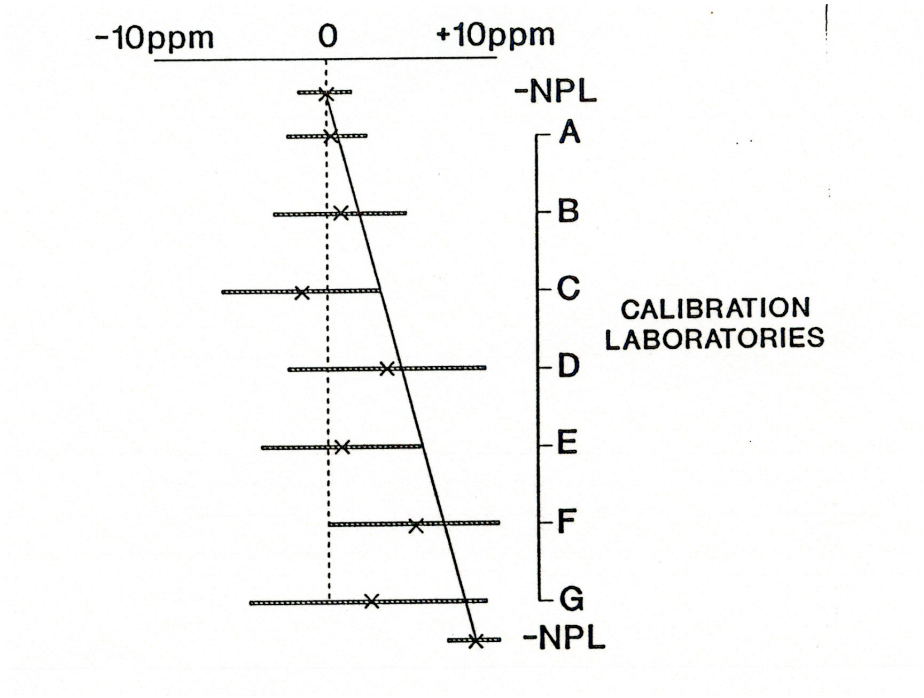


Figure 4.1

If the uncertainty bars on the audit result plot do not intersect with the line projected between the first and last national determinations the calibration laboratory responsible for measurement would be considered to have a problem, requiring further investigation.