White Paper

Management of Equipment in an ISO/IEC 17025:2017 Accredited Laboratory. Part 1: Classifications of Laboratory Equipment

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1 Introduction

The International Standard ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories, published by the International Organisation for Standardisation and the International Electrotechnical Commission, is the principal international quality assurance scheme for testing and calibration laboratories. This International Standard and the associated policies and guidelines are general documents intended to apply to the entire spectrum of testing and calibration activities. Therefore, they leave significant room for customisation by the individual laboratory to meet its specific requirements.

Clauses 6.4.4 and 6.4.5 of this International Standard require the laboratory to verify that measuring equipment or instrumentation conforms to specified requirements before being placed or returned into service, and can achieve the measurement accuracy and/or uncertainty required to provide valid results throughout the lifetime of the instrument. For a small calibration laboratory that is accredited to carry out just one or two calibrations, such as the temperature calibration of freezers and refrigerators used to store food, the investment necessary to ensure conformance with these Clauses is not great, only consisting of servicing and calibrating the primary thermometers together with a periodic check with a water triple point cell[2].

The situation is quite different for a laboratory performing a larger number of tests using complex measuring instrumentation. In these situations, the concept of risk associated with a failure of a measuring instrument is frequently applied. Indeed Clause 8.5 of the ISO/IEC 17025 International Standards mandates laboratories assess the risks associated with their operations

The risks associated with an equipment failure need to be managed and controlled. First, this is done by identifying the risks of a failure and the consequences for the customer and the laboratory if the failure were not detected and corrected. Once the risks and their associated consequences have been identified, controls need to be identified and implemented. These controls ensure that the instrument constantly performs to established specifications throughout its entire operating life, including routine preventive maintenance and calibration. For a laboratory with many complicated measuring instruments, this can become expensive in terms of the costs to perform the routine maintenance and calibrations and the downtime required to perform such activities when the instrument cannot be used to generate revenue. It is obvious the more preventative maintenance and calibrations carried out, the greater the cost.

The challenge is to optimise the level of assurance, which lies somewhere between doing nothing and total assurance that the instrument is performing to established specifications and capable of providing valid results at an acceptable cost; this is illustrated graphically in **Figure 1**.

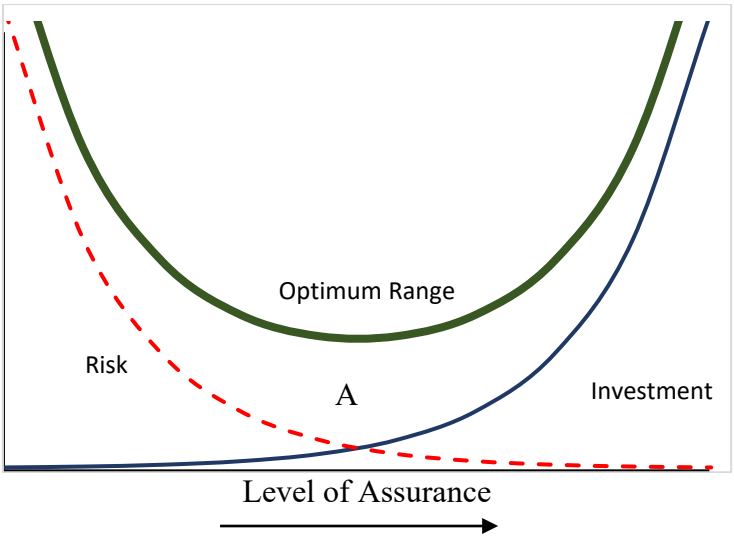

Figure 1: Optimisation of Quality Assurance, Increase in Value and Costs

When done at the start of the process, the risk level associated with a measuring instrument failure, represented by the red line with no investment, is high. The level of risk is reduced as investment, represented by the blue line, is increased. However, after a certain point, represented by A where the red and blue lines cross, in **Figure 1**, progressively higher investment is required to achieve a minimal reduction in the level of risk.

The red line in **Figure 1** can also be considered the potential cost of a failure of the measuring instrument. The thick green line in **Figure 1** represents the combination of the cost associated with a failure of the instrument and the level of investment; This shows there is an optimum range where the combined cost of risk and investment is at a minimum. The challenge is the find this optimum range of investment and level of risk.

For a laboratory with even a moderate amount of equipment management, determining the appropriate amount of maintenance and calibration for each instrument, together with managing, scheduling, and recording all calibration and maintenance activities, can become a significant logistic activity. Which, unless carefully managed, can lead to incorrect maintenance or calibration decisions being made. To help efficiently manage the logistic workload, classifying equipment into different categories is discussed in this paper. This classification, which can be based on different criteria, will enable different equipment with similar uses or complexity to be managed in a similar manner.

2 Schemes for Classifying Laboratory Equipment

The wide range of activities in testing and calibration laboratories means that no single classification scheme can address the requirements of all laboratories. It is for individual laboratories to develop optimised schemes to meet their specific requirements. This section discusses several potential schemes for classifying laboratory equipment. These are suggested options that can be optimised to meet the specific needs of the laboratory.

Whichever classification scheme(s) are selected, the laboratory must adequately define them within its quality management system. In addition, it is also necessary to provide clear and detailed instructions to enable the schemes to be applied consistently by multiple people over an extended period.

2.1 Equipment Quality Criticality Classification

The equipment in modern testing and calibration laboratories can be used for a wide range of activities. These typically include

1. Making measurements that are, or incorporated into results that are, reported to the customer. An example of this would be a laboratory balance used to weigh a sample.
2. Making measurements to assure the quality of the results that are reported to the customer. An example of this would be a set of standard weights used to calibrate the laboratory balance.
3. Other purposes that do not include making measurements that are either reported to or used to quality assure the results reported to the customer.

The consequences, and therefore the risks, of a quality failure associated with each of these activities, is different. For example, a quality failure associated with a measurement incorporated into a reported result will directly affect the quality of that result. Conversely, a quality failure associated with a measurement that is neither reported to a customer nor incorporated into a result reported to a customer will or used to support the quality of such results can be expected to have no consequences for the customer.

Classifying laboratory equipment according to its capability to impact the quality of the results delivered by the laboratory provides a mechanism to manage the quality assurance effort efficiently. In addition, class equipment based on its potential quality impact will ensure that all equipment is managed in a consistent manner.

The recommended categories are:

1. **Quality Critical Equipment** is all equipment used to make measurements that are either reported or incorporated into reported results to the customer; this should include computers that control or collect and process data from equipment that make measurements that are either reported or incorporated into results reported to the customer.
2. **Quality Non – Critical Equipment** is all equipment that, although not used to make measurements that are either reported or incorporated into results reported, to the customer, but is used to assure the quality of such measurements or results.
3. **Non – Quality Equipment** is all equipment not used to make measurements or produce results reported to the client, nor used to assure the quality of the results reported to the customer.

This classification is particularly useful for routine maintenance and calibration intervals when making decisions regarding the frequency of calibration and maintenance.

When defining this scheme within a quality management system or writing instructions for its use, it is important to clearly define the boundaries of each category. Quality critical equipment should include *all* equipment used to make measurements that are either directly or incorporated into results reported to customers. Quality non–critical equipment should include all equipment used to assure the quality of reported measurements and results. As an example, the room temperature of the laboratory is often a significant contributor to the overall quality of measurements and results. The temperature of the laboratory is often specified to be within prescribed limits. Therefore, the laboratory temperature is often measured, monitored and recorded. If the value of the laboratory temperature is not reported to the customer, the thermometer used to measure it should be categorised as quality non–critical, as would the equipment used to calibrate this thermometer. The question of whether the thermometer used to measure the laboratory temperature is either quality critical or non–critical arises in a scenario

of the laboratory temperature being reported to the customer to support the quality of measurements or results reported to the customer. The fact that the laboratory temperature is being reported to the customer would place the respective thermometer in the quality critical category. However, the fact it is only being used to support the quality of the reported measurements or results would place it in the quality non–critical category. Either option is correct, and it is up to the individual laboratory to make that choice. However, the decision must be made consistently and, therefore, the criteria to be considered for making the decision must be included in the laboratory's quality management system.

2.2 Measuring Instrumentation Categories

The risks associated with laboratory instrumentation usually increase significantly as the complexity of the instrumentation increases. Thus, the effort required to provide the required level of confidence that the instrument can provide valid results is often dependent on the complexity of the respective equipment. Therefore, classifying instrumentation according to its complexity will ensure that instrumentation of similar complexity is calibrated and maintained to a level that is constantly consummate with risks associated with the instrument.

The scheme presented here is particularly useful in laboratories carrying out physical testing or calibrations.

1. **Category 1** includes standard equipment with no measurement capability but are used to establish a reference standard. Examples of equipment in this category are standard weights used to calibrate balances and fixed-point temperature cells, such as the water triple point cell, used to calibrate thermometers.

2. **Category 2** includes standard equipment and instruments that are capable of measurement but have no capacity for adjustment. Examples of equipment in this capacity include platinum resistance thermometers and float densitometers.

3. **Category 3** includes commercial off the shelf equipment that is either:
   i. Firmware controlled
   ii. Controlled by software with limited functionality and internal to the equipment
   iii. Capable of independent adjustment in order to conform to specifications
   iv. Does not have a computer with a full operating system controlling the system

   Examples of equipment in this category include: a precision thermometry bridge, pH meter, laboratory balance.

4. **Category 4** includes commercial off-the-shelf equipment with a computer with a full operating system driving the equipment. But which have no capacity for configuration, apart from that required to enable users to operate the equipment and to assign user privileges. This category includes UV and FTIR spectrophotometers and gas and high-performance liquid chromatographs (HPLC).

5. **Category 5** includes commercial off-the-shelf computer-driven equipment connected to a computer network, with single or multiple terminals capable of controlling, and/or monitoring, and/or processing data from multiple sensors or instruments. Examples include a networked environment monitoring system or a networked instrument control, data capture and processing system.

When a new instrument is added to an existing network, such as adding a new HPLC to an existing data collection network, a question that can arise is should this be treated as a category 5 instrument or some other category that is determined by the characteristics of the instrument, as if it was not connected to the network, for example, an unnetworked HPLC is a category 4 instrument, but should it be treated as a category 5 instrument if it is added to an existing network of instruments? This needs to be clarified in the respective standard operating procedure. There are several potential solutions to this type of scenario. Probably the easiest is to apply change control procedures and/or establish a process addressing the addition of new instruments and sensors to the respective network when it is first installed.

6. **Category 6** includes all bespoke equipment.

2.3 Analytical Instrumentation Categories

This system applies to laboratories that carry out chemical testing.

1. **Category 1** includes standard equipment with no measurement capability or usual requirement for calibration. Examples of equipment in this group are nitrogen evaporators, magnetic stirrers, vortex mixers, and centrifuges.

2. **Category 2** includes standard equipment and instruments providing measured values and equipment controlling physical parameters (such as temperature, pressure, or flow) that need calibration. Examples are balances, melting point apparatus, light microscopes, pH meters, variable pipets, refractometers, thermometers, titrators, viscometers, muffle furnaces, ovens, refrigerator-freezers, water baths, pumps, and dilutors.

3. **Category 3** includes instruments and computerised analytical systems, where user requirements for functionality, operational, and performance limits are specific for the analytical application.

4. **Category 4** includes all networked or customised instruments and customised analytical systems. The comment discussed category 5 equipment in **Section 2.2** also apply here.

5. **Category 5** includes all bespoke equipment

2.4 Software Categories

All equipment with associated software shall be allocated a software category according to the following criteria:

1. **Category 1 Infrastructure Software.** This includes:

- Operating systems
- databases
- programming languages
- middleware
- office software
- statistical programming tools and spreadsheet packages.
- network monitoring software

- anti-virus
- backup
- help desk
- IT configuration management tools and other network software

2. **Category 2 Firmware;** This is software embedded into a piece of laboratory equipment, such as laboratory balances, pH meters or digital thermometers, to make it work.

3. **Category 3 Non – Configured Software:** This software can be installed and can operate without modification. Included in this is the software that controls much of the analytical equipment used in the laboratory, such as spectrophotometers and chromatographs.

4. **Category 4 Configured Software:** This software can be configured by the user to optimise its performance to meet the user's requirements. Included in this is software that controls networked equipment and data collection and monitoring systems. Also included in this category are configured Excel spreadsheets not containing macros.

5. **Category 5 Custom Software:** This is software that has been developed and written for a specific organisation and purpose, including applications containing a configuration or scripting language that allows the user to modify a program's functions and includes macros for Microsoft Office applications.

3 References

1. ISO/IEC 17025:2017 General Requirements for the Competence of Testing and Calibration Laboratories. International Organisation for Standardisation, Geneva, 2017
2. UKAS Guidance LAB 11 Traceability of Temperature Measurement: Platinum Resistance Thermometers, Liquid-in-glass Thermometers and Radiation Thermometers, Ed 4, United Kingdom Accreditation Service, Staines-upon-Thames, 2012