

## **Metrological Confirmation Process – ISO 10012:2003 – Key to TQM**

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### **Abstract**

“Quality” is at the “Center” of Total Quality Management (TQM), the modern management concept. Quality of products and services in turn depends on the quality of processes deployed in the industries and service organizations. One of the major requirements for establishing, maintaining and thereafter improving the quality of processes, is the establishment of appropriate measurement system in the organization. Hitherto, the standards were laying emphasis on periodic calibration of measuring and test equipment (M&TE). The revised international standard, ISO 10012:2003 has called for establishment of an effective “measurement management system” of which the M&TE is one of the important ingredients. Thus, the revised standard is a tool for leapfrogging in the journey towards TQM especially since the standard stipulates synergy between the measurement process and the measuring equipment seamlessly through the proposed “measurement management system”. The scope of Metrological confirmation as per the pre-revised standard did not cover the metrological requirements of the process explicitly. The same has now been revised to encompass not only the periodic calibration of the measuring equipment, but also ensuring that the measuring equipment complies with customer metrological requirements (CMR) for the process. The standard requires that M&TE should comply with the ultimate metrological requirements of the process, in addition to its meeting the stated accuracies. Therefore, it is possible that a measuring equipment under valid calibration may meet the CMR of one process, but not of the other. Hence, the metrological confirmation is end-to-end verification of the capability of the M&TE to comply with CMR. Thus, the standard has gone one step further from the pre-revised standard towards TQM and highlights that CMR of the process should be estimated correctly and accuracy of the measuring equipment (as confirmed by calibration) should match with the CMR so that the quality of the product or service could be verified and thereafter improved continuously. The standard rightly emphasizes measurement process design and realization. The right implementation of the requirements of this standard in every organization will lead to improved quality of the processes and thereby the products and services, which will all lead to TQM.

## 1. Preamble

The Total Quality Management (TQM) Philosophy was initiated by the Quality Gurus such as Juran, Deming, Feigenbaum and others. These concepts were initiated on a pilot basis in Japan in the mid 1950s. The release of ISO 9000 standards in the year 1987 gave a thrust to practicing TQM in the organizations. These standards have also evolved over the years with the ultimate goal of enabling TQM in every organization. TQM leads to improved quality of products and services delivered. TQM necessitates establishment of appropriate measurement system in the organization. Measurement plays a vital role in assessing and improving the quality of products and services. In this paper, we will highlight the importance of Metrological Confirmation System in ensuring the quality of products and services consistently and meeting the customer needs.

## 2. ISO 9000

One of the most popular standards released by International Organization for Standardization (ISO) is the ISO 9000 family of standards. These standards released in the year 1987 and revised during the years 1994 and 2000, have been well accepted. Table 1 below gives the total number of ISO 9000 certificates issued worldwide and the number of countries where issued.

**ISO 9000 Certificates issued worldwide**

Year	Total Number	Number of countries
December 2004	670,399	157
December 2002	561,747	157
December 1997	223,299	126
January 1993	27,816	48

**Table 1**

More than half-a-million certificates have been issued worldwide, which indicates the quantum of work carried out towards establishing, maintaining and improving the quality of processes and products in the organizations. It is worth noting that nearly 133,000 certificates were issued in China (highest number), followed by 84, 485 certificates in Italy [1].

## 3. ISO 10012:2003

The technical committee ISO/TC 176 which formulated the ISO 9000 family of standards also prepared the standard ISO 10012:2003 dedicated to measurements [2]. Initially, ISO 10012 standard consisted of two parts. However, the same has been revised now and a single standard entitled “Measurement Management System – Requirements for Measurement Processes and Measuring Equipment” was released in the year 2003. The scope of the standard is to provide generic requirements as well as guidance for the management of measurement processes and metrological confirmation of Measuring and Test Equipment (M&TE). Hitherto, Metrological Confirmation referred only to the calibration of measuring equipment. Subburaj [3] asserts that the equipment selection should have a relevance to the process requirement. He also adds “an

organization should identify the monitoring and measuring activities which should be carried out, select the equipment which will meet the monitoring and measuring needs of the organization” [3].

### **3.1 Identification of measurement needs**

The first and foremost task before selecting equipment is to identify the process or product requirements for testing or inspection or measurements in the organization [4]. The organization has to compile the following data while identifying the measurement needs:

- Parameter
- Range
- Minimum accuracy required or Maximum error or uncertainty that can be tolerated in measurement of each parameter

Subburaj also stresses, “What is more demanding in formulating specifications is to specify the performance limit taking into consideration the actual measurement requirements”.

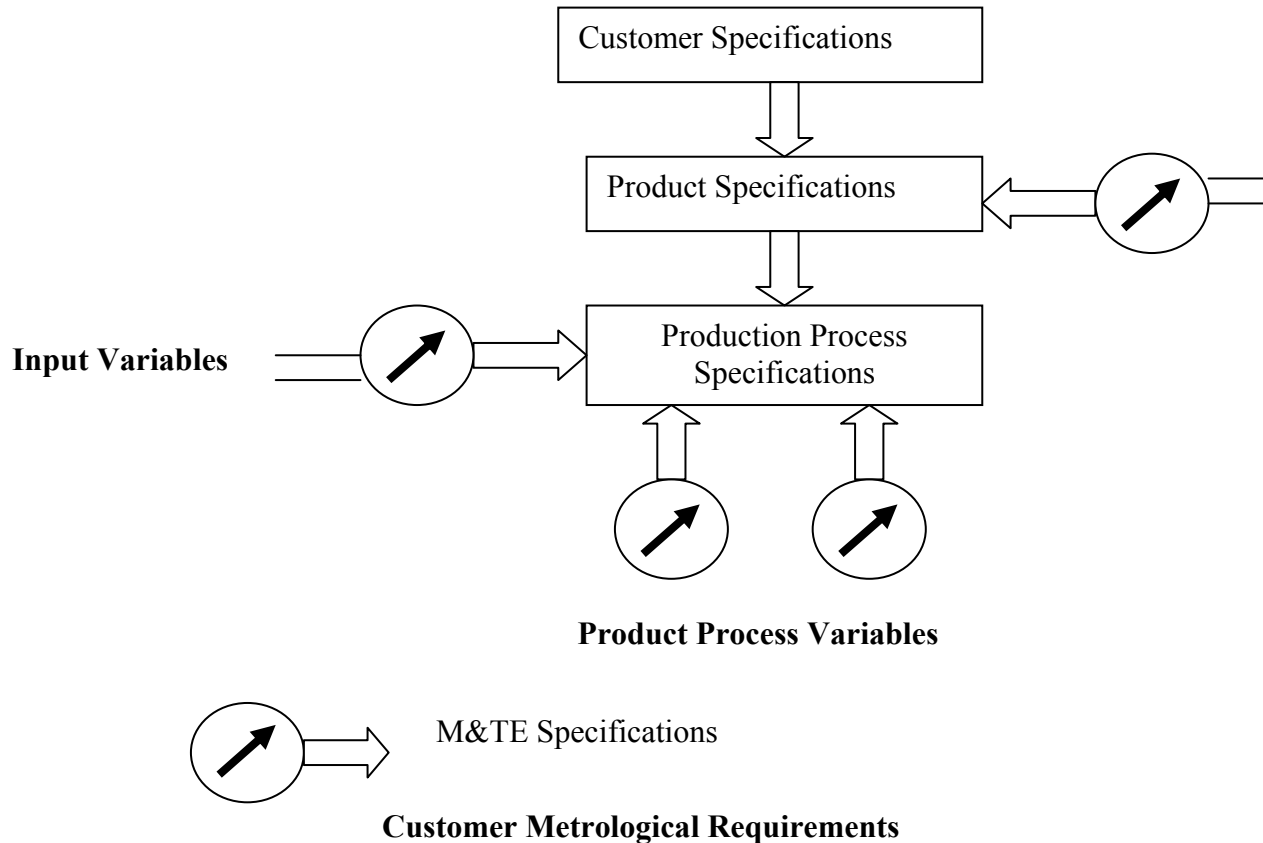
### **3.2 Customer Metrological Requirements**

To quote the Annex A of the standard, “the customer metrological requirements are those requirements specified by the customer as relevant for the customer’s production processes”. The intent is that the product or service delivered should meet customer’s requirements. Therefore, the production process should be capable of producing the same. The capability of the process has to be confirmed by the process performance. The process parameters should therefore have to be measured correctly.

The customer specifications signify the expectation of performance of the product or service. This in turn has to be converted into measurable product specifications. Since the organization will be interested in satisfying the customer all the time, the product specifications may be slightly better than the customer specifications. The product is generated in a production process. Therefore, the production process specifications should be evolved taking into account the following:

- Product process variables
- Input variables

Figure 1 below indicates, input requirements in finalizing Customer Metrological Requirements (CMR).

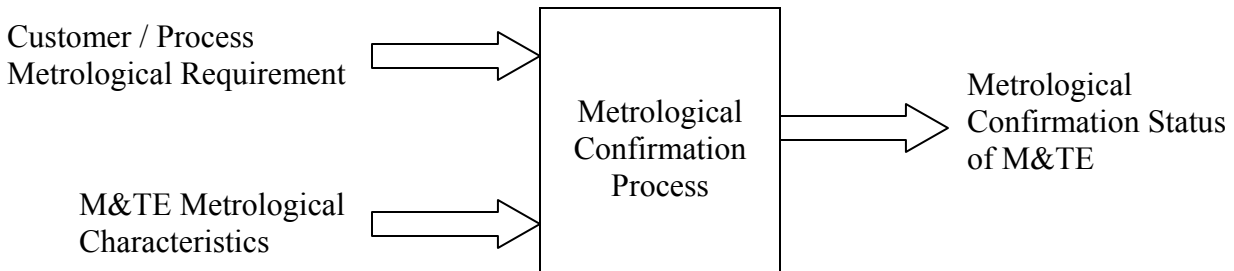


**Figure 1**

The input variables are nothing but parameters that are input to the production processes such as the power supply, (which will contain the variations in terms of voltage and frequency), the ambient environmental conditions such as temperature, humidity etc. The production process specifications are also dictated by the production process variables. For instance, the quality of wave soldering process depends on the purity of metals used, quality of some other process may depend on the purity of water used and quality of oxidation process depends on the accuracy of temperature of furnace. Thus, the production process specifications are dictated by product specifications. However, they in turn depend on the specifications for the production process variables and input variables. Therefore, one has to take a holistic view to match the ultimate customer satisfaction with that of the specifications for input variables and production process variables, which will in turn determine the product process specifications. Therefore, one of the important steps in measurement management system is to determine the customer metrological requirements. While the customer specifications and in turn the product specifications are fixed, the specification for input variables and product process variables should be determined to achieve the product process specification. The points at which measurements are to be carried out are indicated in Figure 1. The specifications for the M&TE to be deployed at these locations are to be determined in such a way to reduce the risk of accepting a poor quality product and rejecting a good quality product [4].

### 3.3 Metrological Confirmation Process

The contribution of 10012 in its 2003 version is to bring out clearly the inter-relationship between the customer metrological requirements and M&TE metrological characteristics. While the previous version of the standard highlighted calibration of M&TE with reference to the specifications stated by its original manufacturer, the need to relate this with customer metrological requirement was missing. Figure 2 below brings out the essence of metrological confirmation process as per the revised standard.



**Metrological Confirmation Process**

**Figure 2**

The metrological confirmation process should be such that M&TE metrological characteristics should be able to match the customer / process metrological requirements. It should be the goal of the organization to match these two or select the M&TE that will meet the customer metrological requirements. Once the M&TE after calibration is confirmed to meet the CMR, metrological confirmation is achieved and metrological confirmation status issued to the M&TE.

The standard brings out clearly, while a calibrated instrument may meet the CMR of one process, it cannot be assumed that it will meet the CMR of every process in the organization. This is the highlight of the standard ISO 10012:2003. Therefore, metrological confirmation of equipment is specific to a process in the organization.

## 4. Summary

Measurement provides quantitative information on the quality of the products delivered. Measurements are carried out using calibrated measuring and test equipment. M&TE should be selected based on the customer metrological requirements. It is important that every organization identifies the measurement needs and the required accuracies. The measuring equipment chosen for a process should be having better accuracy than the requirements of the process in order to control the risk of measurement errors. The release of ISO 10012 standard in the year 2003 has brought out the relationship between customer metrological requirements and measuring equipment metrological characteristics clearly and unambiguously. Each measuring equipment should be confirmed with reference not only to its stated specifications, but also the customer metrological requirements. This is a significant improvement over the previous

standard and will definitely help in improving the quality of the processes, products, thereby facilitating Total Quality Management.

## **References**

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