Development of the management system for metrological assurance of measurements

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Abstract. Issues relating with solving the problems of setting up and managing the system for metrological assurance of measurements at machinery manufacturing plants have been discussed. In order to improve the quality of metrological assurance and mitigate risks relating with unreliable and inaccurate measurement results, it has been proposed to develop a system for management of metrological assurance of measurements. Standards which may be used for building such a system have been analyzed. Metrological assurance has been reviewed from the standpoint of PDCA cycle. Processes that are part of the system of metrological assurance of an enterprise have been reviewed. In accordance with the structure and requirements of ISO 9001 standard a register of processes has been developed and a functional model for the management system for metrological assurance of measurements at a machinery manufacturing plant has been developed.

1. Introduction

The quality of products of machinery manufacturing plants largely depends on metrological assurance of measurements [1]. Over the past several years, many machinery builders for various sectors of the national economy have encountered issues regarding setting up and managing metrological assurance of their manufacturing processes [2, 3]. Among the key factors inducing the occurrence of these problems is reorganization of the engineering industry and introduction of new technologies for product quality assurance [3].

The main challenge of metrological assurance of production at machinery manufacturing plants is to create conditions ensuring reliable and accurate measurement data. Development of the management system for metrological assurance of measurements (MSMAM) is able to assure such reliability in accordance with ISO 9001[4] standards. Quality management systems based on ISO 9001 standard requirements are being actively implemented at various machinery manufacturing plants, the application of quality management methods allows for significant improvement of sustainability of scientific and technological development at the level of an entire country [5, 6], not just certain enterprises.

Of course, in the development of such a system one should take into account not only the relevant international quality standards, but also the provisions of current legislation in the area of assurance of traceability of measurements [7,8]. In this case, MSMAM can be considered as part of the entire system of quality measurement at a machinery manufacturing plant.
In accordance with ISO 9001 the metrological assurance process can be attributed to Item 7.1.5 – resources for monitoring and measurement. In order to comply with this Item a recommendation has been given to apply ISO 10012. Application of this standard for purposes of designing MSMAM results in a number of challenges:

First, this is because at the time of implementation of ISO 10012 standard its structure completely coincided with the structure of ISO 9001 structure. The new version of ISO 9001 standard which was adopted in 2015 is significantly different in terms of structure and in terms of requirements to risk management, as well as process documentation;

Second, ISO 10012 standard failed to cover all the processes relating with metrological assurance at machinery manufacturing plants, and it sets requirements only to measurement processes and measuring instrumentation.

Despite the fact that the aforesaid challenges in the application of ISO 10012, the provisions of this standard may be used for interpretation of the universal requirements of ISO 9001 to specific processes of MSMAM.

Thus, in order to solve the problems relating with setting up and managing MSMAM at machinery manufacturing plants a number of tasks must be tackled:

- Review the process of metrological assurance from the standpoint of Deming Cycle (PDCA);
- Identify and classify processes relating with MSMAM;
- Form a string of metrological processes (register of processes) as part of the operating structure and taking into account ISO 9001 requirements;
- Develop a standard functional model for MSMAM.

2. Implementation of the process approach

One of the fundamental principles of the development of management system within ISO 9001 is process approach. Measurement processes should be viewed as specific processes aimed at assuring product quality and ensuring consumer satisfaction. In case of machinery manufacturing plants engaged in research and development activity, in addition to core manufacturing activity, it is expedient to develop the process of metrological assurance as a system. The system of metrological assurance of measurements is a totality of processes, organizational and methodological forms and techniques, as well as material objects ensuring implementation of metrological assurance at all stages of a lifecycle of machine-building products. Operation of the system of metrological assurance based on the application of process approach and PDCA cycle can be generally illustrated as follows:

Stage 1 (PLAN) – design and development of measurement processes of the system of metrological assurance of measurements: planning of requirements to measurement processes, including modeling of measurement processes (taking into account the conditions, in which the measurement processes will be implemented); risk assessment and analysis of risks relating with unreliable measurement data, as well as errors of the first kind and second kind.

Stage 2 (DO) – Metrological confirmation of fitness of elements of the system of metrological assurance of measurements: standardization of standard samples and calibration of measurement tools; metrological examination of technical documentation; evaluation of qualification of operators engaged in measurement operations; oversight of measurement conditions.

Stage 3 (CHECK) – Analysis of the system of metrological assurance of measurements includes the analysis of the condition of metrological assurance of an object; identification of nonconformities; evaluation of consumer satisfaction and indicators of the level of metrological assurance.

Stage 4 (ACT) – Improvement of the system of metrological assurance of measurements including elimination of nonconformities and development of corrective actions aimed at improvement of the system.

3. Identification and description of processes

In order to generate MSMAM processes for a system of metrological assurance of measurements must be enhanced by management processes. As a result we end up with MSMAM register of processes. One
should take into consideration that formation of the register of processes must be performed with the application of PDCA Deming Cycle and take into account the structure of ISO 9001. In the standard register of processes developed five high level processes are identified. Process tree (register) for the management system for metrological assurance of measurements are presented in figure 1 below.

Figure 1. Process tree (register) for the management system for metrological assurance of measurements.

Higher level processes, depending on their contents, are divided into sub-processes or procedures. Let’s review the contents of higher level processes for the higher level system of metrological assurance of measurements.

1. Planning the system of metrological assurance of measurements includes the following procedures:
   - Determination and establishment of measurable targets and policies in the area of quality for the management system of metrological assurance of measurements which are harmonized with the environment for their setup and strategic direction(s);
   - Determination of objective criteria and procedures for achieving goals and objectives for metrological assurance processes – identification of MSMAM processes;
   - Identification of risks which may affect the quality of metrological assurance of measurements;
   - Development of documented information for MSMAM.

2. Management of MSMAM resources. MSMAM resources include human resources; material resources; infrastructure; and information resources.
   - The process of human resources management as part of MSMAM must be harmonized with human resource management at the enterprise level. Managing human resources as part of MSMAM includes:
     - Putting together a list of personnel responsible for quality of measurements;
     - Development of requirements to professional training, experience, qualification, and skills of the personnel engaged in works influencing quality of measurements;
     - Determination and documentation of roles and responsibilities of all employees engaged in the management of system of metrological assurance of measurements;
     - Development of annual timeline (or if necessary in the course of a year) for professional improvement of the personnel engaged in works that have an impact on measurement quality;
     - Staff attestation – personnel engaged in works that have an impact on measurement quality.
Material resources of MSMAM include measurement (testing) equipment; operating environment. The standard process of management and measurement (testing) equipment consists of the following stages:

- Registration of measurement (testing) equipment;
- Identification of measurement (testing) equipment in the system of metrological assurance of measurements;
- Commissioning;
- Maintenance of measurement (testing) equipment in the process of operation;
- (Long) storage of measurement (testing) equipment;
- Retirement and write-off of measurement (testing) equipment from the system of metrological assurance of measurements.

One of the most crucial factors influencing the quality of resulting measurement data, measurement process conditions (testing, standardization, calibration, etc.). Therefore in order to perform efficient measurements (testing, standardization, calibration, etc.) in MSMAM a process for management of the operational environment of metrological processes must be defined. Implementation of this process includes:

- Establishment of (documentation) requirements to environmental conditions in the process of testing (testing, standardization, calibration, etc.);
- Monitoring and registration of environmental conditions that impact measurements;
- Introduction of adjustment for external conditions into the measurement results.

Management of processes, products, and services by external vendors must be performed in MSMAM in accordance with the purchasing policy adopted at the plant level, and it includes:

- Development of criteria for assessment and selection of external vendors for purchases of measurement (testing) equipment;
- Analysis of engineering and economic terms of supply (delivery time, price, delivery terms, etc.): Its registration in the National Register of Measuring Equipment: for approved types – possibility of standardization and calibration, requirement for the development of calibration techniques, measurement methods (techniques);
- Inwards inspection of products and services as supplied by external vendors for MSMAM.

3. Processes of metrological assurance of measurements include:

- MAM planning and management at stages of product lifecycles;
- Metrological confirmation of MAM elements.

MAM planning at stages of product lifecycles is performed based on the relevant regulatory requirements, technical documentation, and consumer-side documentation. As a result of analysis of requirements the indicators of accuracy, reliability, and relevancy of measurement data must be established. Taking into account the established indicators MAM elements must be then selected:

- Measurement methodology;
- Measurement instrumentation and ancillary equipment;
- Operators (specialists engaged in measurements).

Generally, metrological confirmation of MAM elements versus established requirements includes:

- Calibration of standard samples and calibration of measurement tools and devices;
- Calibration of measurement equipment;
- Metrological examination of technical documentation;
- Attestation of qualification of operators who perform measurements;
- Oversight of measurement operating conditions.

4. Performance measurement.

To determine fitness and efficiency of the management system for metrological assurance of measurement the metrology unit (department) can employ audits, monitoring, and measurements.

Audit of the management system for metrological assurance of measurement is performed in order to ensure its continuous and efficient operation and conformity to the relevant established requirements.
Audits are performed over certain time intervals taking into account requirements of ISO 19011 [10] standard.

Monitoring of the management system for metrological assurance of measurement allows to prevent deviations from the established requirements by way of their timely identification and the relevant corrective actions. Monitoring and measurement is performed in relation to processes of the management system for metrological assurance of measurement.

Analysis of condition of metrological assurance of an object includes:

- Identification of the level of customer satisfaction, including meeting the consumer’s metrological requirements;
- Identification of all existing causes of deterioration of the level of metrological assurance and adequate methods of managing these causes;
- Periodic evaluation of the indicators of metrological assurance levels.

5. Analysis and improvement of the management system for metrological assurance of measurement on the part of senior management.

This analysis must be performed over planned time intervals. The analysis is conducted for purposes of ensuring continuous fitness, relevancy, and efficiency of the metrological assurance system.

Senior management must strive to improve fitness, relevancy, and efficiency of MSMAM. To achieve this, results of analysis and evaluation are used, as well as analysis output data on the part of the senior management. The metrology unit (department) must analyze and identify opportunities for improvement of the measurement management system and, if necessary, modify the same.

4. Functional model of the system

After identification of the processes, for each process input flows and output flows must be determined, as well as management action and resources required. Then they move to the next stage, namely, building of sequencing and interprocess communication. Taking into account results of the work at the previous stage, sequential charts and interprocess communication charts are developed at all levels of detail.

![Functional model of the management system for metrological assurance of measurements](image)

**Figure 2.** Functional model of the management system for metrological assurance of measurements.
The functional model is a conceptual basis for particularization of works on the implementation of process approach to managing the system of metrological assurance of measurements.

For visual demonstration of communication of higher level processes, a functional model of the system of metrological assurance management has been developed. The functional model has been developed taking into account ISO 10012 standard and ISO 9001 standard in notation of the business process modeling IDEF0. Functional model of the management system for metrological assurance of measurements is presented in figure 2 below.

5. Conclusion
The system for managing metrological assurance of measurements allows solving a number of problems at once: First, it ensures better controllability of processes; second, it mitigates the risk of probability that measurement instrumentation and measurement processes yield incorrect results which may, in turn, affect product quality.

Implementation of the system of management of metrological assurance of measurements allows to:

- Improve the quality of metrological assurance of measurements by way of improving resources, methods, techniques, and materials;
- Establish clear responsibilities for core activities in terms of metrological assurance of measurements;
- Analyze and measure capabilities of key types of activities in terms of metrological assurance of measurements;
- Determine interaction of the core activity in terms of metrological assurance of measurements as part of the metrology unit (department) and with other business units and departments of a business entity;
- Assess risks, consequences, and impact of various levels of metrological assurance of measurements on consumers, vendors, and other stakeholders.

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