

*XVII IMEKO World Congress  
Metrology in the 3rd Millennium  
June 22–27, 2003, Dubrovnik, Croatia*

## SPECIFIC POINTS AND FEATURES IN DEVELOPMENT OF QUALITY SYSTEM AT ULUSAL METROLOJİ ENSTİTÜSÜ

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**Abstract** – Setting up a quality system at the level of national metrology laboratories became especially important after the signing of the CIPM Mutual Recognition Arrangement (MRA). Each laboratory, signatory of MRA, must demonstrate its technical competence and confidence, where an established and smooth running quality system is a critical milestone. This paper presents details of a rather sophisticated quality system established at the Turkish National Metrology Institute. General recommendations to other institutes and possible ways for further improvements are also discussed in the paper.

**Keywords:** quality system, ISO 17025 standard

### 1. INTRODUCTION

Signing of CIPM MRA in 1999 brought new obligations to the national metrology institutes and laboratories involved in the process of mutual recognition. National metrology institutes must demonstrate their technical competence, which can be monitored through the results of key and supplementary comparisons and CMC entries. But on the other hand, each institute has to be able to convince the metrological community in the quality of the provided services, and an established quality system is a strong indicator for it.

MRA leaves to the institutes the matter of choosing the way for the fulfilment of requirements related to a quality system [1]. This can be done either through an accreditation by a third party or a self-declaration. Ulusal Metroloji Enstitüsü (UME), signatory of the MRA, started its activities on the established of a quality system in 1994 and completed the implementation of ISO 17025 standard in 2000. UME has chosen self-declaration approach to fulfil MRA's requirements. UME developed sophisticated quality system, and a part related to the ISO 17025 standard is only sub-set of the entire system. UME quality system has successfully passed review within EUROMET QS-Forum in 2002. Details of establishment of the UME quality system with its strong and weak points are presented in this paper.

### 2. BRIEF HISTORY OF THE QUALITY SYSTEM DEVELOPMENT AT UME

First work on a quality system at UME has started in 1994 by two laboratories preparing quality manuals

according to EN 45001. As the second step, 20 UME laboratory scientists were trained by NAMAS (currently UKAS) assessors for accreditation and self-assessment. During the course, since there were differences between EN 45001 and ISO Guide 25, at the request of the trainees, ISO Guide 25 was used for main assessment tasks. As a result of this training, Quality Manuals of two UME laboratories were reviewed and the laboratories were “accredited” by the trainees under the supervision of the NAMAS trainers. Based on this experience, both Quality Manuals were improved, and the Quality Manuals for other laboratories were prepared. Another 20 UME staff were trained by DKD in 1995 and after the training all manuals were reviewed.

After these two trainings, it was decided that UME quality system will be based on the total quality philosophy and the documentation will be prepared according to ISO Guide 25 for the laboratories and ISO 9001 for the whole institute. By the end of 1996, all laboratories have completed work on their Quality Manuals according to EN 45001, and by the end of 1997, according to ISO Guide 25.

In the year 2000, UME has decided to use ISO 17025 as the sub-quality system for the laboratories and all the laboratories have prepared their new Quality Manuals using a prototype developed by one of the laboratories. All procedures were rewritten in 2000 and 2001. UME laboratory quality system is currently based on ISO 17025, every laboratory has its own Quality Manual.

At the institute level, UME has developed the quality system in 1998-1999 term using ISO 9001:1994. During this period, based on a gained experience UME decided to establish its quality system on a rather sophisticated self-assessment model that is based on the EFQM model with some elements from Baldrige and Deming systems. UME has decided to seek a professional help for the development of the self-assessment system. Arthur Andersen was contracted to develop a self-assessment model with experienced UME staff.

### 3. SPECIFIC POINTS AND FEATURES OF UME QUALITY SYSTEM

The self-assessment model developed at UME can be considered as one of the specific points of UME quality system. At the initial stage, existing situation was assessed, and then a self assessment model with one third covering UME strong area and two third covering weak areas was

developed. Model uses three modules, namely Organization, Processes, and Individuals. Each module has three schemes for an assessment, as Operating System Mechanism, Output Performance, and Operating System Review Mechanism. So the total model is “3 X 3” matrix. Subsections of the model are given in Table 1. Along with the model, many accompanying documents were prepared for the assessment and instructions to assessors.

TABLE I. Subsections of self-assessment model

ORGANISATION	PROCESS	INDIVIDUAL
O1. Operating System Mechanism	P1. Operating System Mechanism	I1. Operating System Mechanism
O2. Output Performance	P2. Output Performance	I2. Output Performance
O2.1. Vision and Strategy	P2.1. Customer Focus and Satisfaction	
O2.2. Organisational Leadership	P2.2. Employee Focus and Satisfaction	
	P2.3. Administrative Services	
	P2.4. Sharing and Management of Knowledge and Information	
O3. Operating System Review Mechanism	P3. Operating System Review Mechanism	I3. Operating System Review Mechanism

In 1999 and 2001 UME conducted two integrated assessments using this model scoring 646 in 1999 and 750 in 2001 (next one is scheduled to 2003). Once the 850 level is reached, the model will be reviewed in order to cover the strong areas as one third of the model and weak areas to cover remaining two thirds forcing the score somewhere between 500-600. This process will repeat when the score reaches to 850 again. 850 is chosen as a limit, since best organizations in Europe and Turkey reach score 800-850 in the current EFQM Model.

After establishment of the self-assessment system and based on previous experience in the development of the quality system it was decided to split the Quality management into two independent groups: Forward Quality Team (Quality Assurance Team) headed by quality manager responsible for setting up the operating system and preparing the documentation in line with ISO 9001 and ISO 17025, and Feedback Quality Team headed by another quality manager responsible for assessing the implementation of the UME Quality System. Steering mechanism in UME Quality System is shown in Figure 1.

The success in the establishment of the quality system at UME is due to the following reasons:

- Clear, well defined quality policy

- Operating of two quality teams
- Intensive usage of powerful tools in QS such as internal audits and management reviews
- Close relation with customers, careful analysis of customer complaints

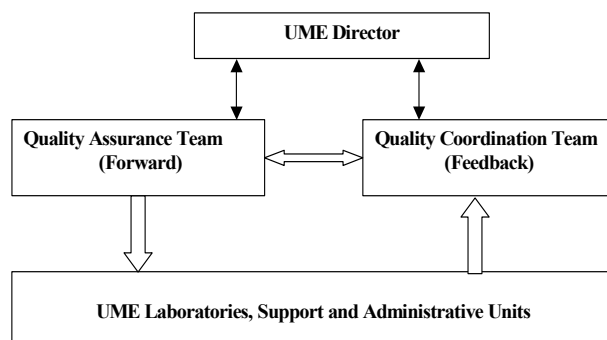


Fig.1. Scheme of UME QS-structure

UME quality policy describes main rules and criteria for the achievement of institutional goals. Taking into account that the most important requirement of the quality is satisfaction of our customers, UME’s first goal is to determine and meet its’ customers needs and expectations at the highest professional level. Quality policy and other regulatory documents promotes active participation of all employees in the process of development and improvement of the quality system, which positively affects the services provided by UME. “Team work” spirit dominates in nearly all tasks.

Considering internal audits and management reviews as an important parts of UME Quality System UME pay great attention to them, carefully evaluating all obtained information. Since performing of internal audits and management reviews are mandatory requirements of ISO 17025 and other relevant standard [2], UME conducting them periodically in order to check efficiency of the quality system implementation. At the beginning stage two internal audits per year have been scheduled for each UME unit. Depending on the results of audits, this number may be changed. However, an annual internal audit for UME units will be mandatory. The main objectives of internal audits are:

- To detect any anomalies or deviations from procedures and regulatory documents during QS-implementation;
- To evaluate the degree of QS-implementation in accordance with requirements of relevant standards;
- To find possible ways for improvement of the existing quality system

All findings and non-compliances registered during internal audits are classified according to their importance, and subjects common to the most of UME laboratories and administrative units are discussed in general UME meetings with participation of all institute staff. During these meetings, alternative solutions for problems encountered are discussed, and decisions based on consensus are made. These meetings are very important, since they enable to

reach “bottom-up” approach in the Quality System implementation.

In order to monitor trend in the implementation of the quality system by each UME unit and institute in general, numeric indicators system is developed. The system is based on the questionnaire distributed within EUROMET countries in order to measure the degree of implementation of ISO 17025 by National Metrology Institutes. Taking this system as a core, a few additions and modifications were made. This questionnaire is filled for laboratories and other units based on observations during internal audits, and then average score for each ISO 17025 criteria is estimated for whole institute.

In addition to the internal audits Quality Coordination team performs survey of general procedures and other related documentation annually. Hierarchical structure of quality documentation at UME is similar to other metrology laboratories with one exception. UME has own Quality Manual, and each laboratory has its Quality Manual, which is following item-by-item criteria of ISO 17025 standard. The aim of documentation survey is to determine how frequent each procedure or other document is used, or to find out how efficient they are. Based on results of survey, decision about revision and updating of documentation is made. Revision and updating of general and administrative procedures is a responsibility of Quality Assurance Team.

Management reviews are performed at different levels in four different ways:

- Periodic reviews organized and conducted twice per year by Quality Assurance Team;
- Reviews performed by means of regular meetings of UME laboratories and administrative units with UME Director;
- Review as a meetings at the end of an internal audits with participation of UME Director, Quality Assurance, Quality Coordination teams and all laboratory staff;
- Output produced by various UME units are monitored and reviewed periodically (from daily to quarterly).

Management reviews provide information about problems and difficulties, encountered by the institute in its operation. All of them are discussed and ways for improvement of the existing system are investigated.

UME considers the customer complaints as a source of feedback for the current situation of the quality of the institute’s services and future improvements. Errors or non-compliances determined during the evaluation of these complaints force to take further steps in the technical and managerial review of our services.

Any oral or written accusation of errors or non-compliances on the services supplied by the institute is regarded as a complaint. Resolution of complaints is performed in accordance with the corporative procedure. Complaints or objections transmitted by printed document, phone, fax, e-mail, or directly are to be recorded on Customer Complaints Form. Then related units or laboratories evaluate the complaints or objections. Necessary actions are taken according to the “Corrective and

preventive actions procedure. The results about any action are transmitted to the customer in written form. The Customer Complaints Form and other correspondence transmitted to the customer are kept in “Customer Complaints” folder in the Director’s office and related laboratories or administrative UME units. In general all complaints registered at UME since 1993 can be classified in five main categories, which are related to customer affairs, calibration and measurements, calibration certificates and measurement reports, prices of the services, training and other services. The average number of complaints does not exceed 5 per year.

Taking into account that quality related activities have a common goal to improve current system, UME is investigating continuously possible ways for further developments of the quality system based on problems faced during an establishment of the existing system. Performing systematic customer and employees satisfaction survey on more professional way is an example for improvement of the system.

### 3. CONCLUSION

Having started activities related to the establishment of the quality system at the very beginning of its operation, UME developed a complex quality system, meeting requirements both ISO 9001 and ISO 17025 standards. UME has now fully operational and smooth running quality system, which was approved by the metrological community within the framework of EUROMET QS-Forum.

### REFERENCES

- [1] ”Mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes”, BIPM, Paris, 14 October 1999
- [2] ISO/IEC 17025:2000 Standard ”General requirements for the competence of testing and calibration laboratories”