REPORT OF PEER ASSESSMENT

Introduction

This report was prepared as an output of peer assessment performed within the activity 3.3 under the project "Technical assistance for capacity building of the Bureau of Metrology Europeaid/129224/C/SER/MK". In addition, this activity is registered as the EURAMET project No 1205 "On site peer review". The report is structured in the simple way providing the evaluation of the currently operating quality management system (QMS) of Bureau of Metrology of the Former Yugoslavian Republic of Macedonia with respect to the requirements of the international standard ISO/IEC 17025.

International standard ISO/IEC 17025 "General requirements for competence of calibration and testing laboratories" describes requirements in two chapters, chapter 4 and chapter 5. Structure of these chapters is followed in the report underlying the current status of the implementation of BoM's QMS. All findings were identified based on the review of the QMS documentation and study visit performed at BoM (Skopje) between 24th and 28th of October 2011.

RESULTS OF ASSESSMENT

1. Organization (clause 4.1, ISO/IEC 17025)

Bureau of Metrology operates under Ministry of Economy according to the Law on Metrology (55/2002). The law was amended three times (84/07, 120/09, 36/11). The structure of organisation is described in general procedure "Organization and Management Structure of Bureau of Metrology" (GP 1-01/ ver.1/July 2011) and Quality Manual (QM-BoM/ver.1/ July 2011). BoM performs calibrations both in laboratory premises and on-site. This fact is described in GP 1-01 (page 2). Organizational structure of the Bureau is presented in GR 1-01-1-1-2011 (version 1). Quality manager's responsibility is taken over under position of State Counsellor for Calibration, Verification, Precision Metals and Homologation. Many positions in the organizational chart are empty, e.g. vice manager of sector of calibration, managers of department for mechanical quantities, physical quantities, etc. In the overall, expected number of staff is 114, while currently just 33 persons are working at BoM.

Role and responsibilities of top management is described in "Organizational Structure – Description of Working Posts" document (GR 1-01-2-1-2011/ver.1/July 2011). In addition, other tasks required by ISO/IEC 17025 are described in the general procedure GP 1-01.

Impartiality, independence and confidentiality is assured through declaration ("Declaration of Confidentiality, Independence and Integrity"/GR 1-01-3-1(14)-2011/ver.1/July 2011) signed by each persons involved in providing calibration services.

By decision of director, Dančo Pendovski was appointed as a Quality Manger, and Beti Vukovojac as a Deputy Quality Manager.

Mechanisms for communication between top management and employees described in the general procedure GP 1-01 under sub-chapter "Communication". Communication is established mainly by means of meetings and e-mail messages. Minutes of meetings took place on 25/07/2011 and 09/05/2011 were analyzed.

Recommendation (R-1): Interviewed staff indicated the fact of regular meetings with top management. However records of such meetings were very limited. It is recommended to keep records of all meetings with planned actions and defined responsibilities and deadlines.

2. Management System (clause 4.2, ISO/IEC 17025)

Quality Management System of BoM covers calibration services in Mass Laboratory, Volume and Flow Laboratory, Temperature Laboratory and Pressure Laboratory.

BoM has structured quality management documentation, which includes Quality Manual, general procedures, technical procedures, etc.

Quality policy is signed by BoM's director and presented in the Quality Manual. Quality objectives are explained in very generic way in connection with strategic plans, while measurable objectives do not exist.

Non-conformity (NC-1): Measurable and clearly stated quality objectives do not exist.

3. Document Control (clause 4.3, ISO/IEC 17025)

BoM has policy and procedure for document control. Process of preparation, review and approval of documents is described in the general procedure "Document Control and Control of Records" (GP 1-03/ver.1/July 2011). The current classification of documents on 3 categories (1st, 2nd and 3rd level); where records placed in the category of 3rd level could lead to misunderstanding.

All general documents are registered in the "List of Document Control of General Documents" (GF 1-03-1) and laboratory documents are registered in the "List of Document Control of Laboratory Documents" (LF 1-03-LAB-01).

Non-conformity (NC-2): "GP XX" code for identification of document codes is not explained correctly in the general procedure "Document Control and Control of Records" (GP 1-03/ver.1/July 2011).

Non-conformity (NC-3): Mechanism and periodicity for checking the status of external documents (standards, guides, etc.) is not described in the general procedure "Document Control and Control of Records" (GP 1-03/ver.1/July 2011).

Non-conformity (NC-4): Template for "Calibration Certificate" does not include information about code and version of the document.

Non-conformity (NC-5): Worksheets (templates) for calculation of measurement results (pressure calibrations) are not included in Quality Management System documentation.

Non-conformity (NC-6): "Catalogue of external documents" of pressure laboratory includes out of date document (Calibration certificate issued by DH Budenberg).

Recommendation (R-2): Reference to the standard ISO/IEC 17025 is presented in the QMS documentation in different ways (ISO 17025 (GP 1-06, GP 2-02), MKC ISO/IEC 17025 (GF 1-11-1), etc.). Reference shall be given in the same way in all QMS documents and to be consistent with "Catalogue of External Documents".

Recommendation (R-3): Reference to the European Association of National Metrology Institutes in general procedure "Calibration Methods/Method Validation" (GP 2-04, ver. 1/July 2011) is given as EUROMET. It should be corrected and written as "EURAMET".

Recommendation (R-4): MRA is written as Mutual Recognition Agreement instead of Arrangement (see GP 2-06/ver.1/July 2011). Wording "Arrangement" has to be used.

Recommendation (R-5): General procedures and chapters of Quality Manual contain wording "quality system". It is recommended to use "quality management system" instead.

Recommendation (R-6): The current classification of documents on 3 categories (1st, 2nd and 3rd level), where records placed in the category of 3rd level could lead to misunderstanding. General and laboratory procedures belong to the same level. It is recommended to separate them.

Recommendation (R-7): Font in the certificates and documents within quality management system should be harmonized. Font "Times New Roman" is used in majority

of cases, while sometime Arial is used. It is recommended to describe it in the "Document Control Procedure".

4. Review of Requests, Tenders and Contracts (clause 4.4, ISO/IEC 17025)

Review of requests, tenders and contracts is performed according to the general procedure "Review of Requests for Services/Service to the Customer" (GP 1-04/ver.1/July 2011). Having reviewed the procedure one can conclude that it is not clear who submit offer for calibration to customer.

Implementation of the procedure was checked during the vertical audit of randomly selected services and issued certificates from Mass, Volume and Flow, Temperature, Pressure Laboratories.

Non-conformity (NC-7): Responsibility for preparation and submission of offer/order to customer is not specified in the general procedure "Review of Requests for Services/Service to the Customer" (GP 1-04/ver.1/July 2011).

Non-conformity (NC-8): Some files for calibration orders/requests are incomplete. As an example filled "Protocol for Acceptance/Delivery of Calibration Services/Calibration" (GF 1-04-2/ver.1/July 2011) is missing in few cases (e.g. Archive No: 0802-1310/1).

Recommendation (R-8): To have written records on all communications with customer related to a calibration service (including date of calibration, price, etc.).

5. Subcontracting of Tests and Calibrations (clause 4.5, ISO/IEC 17025)

BoM does not use subcontracting for calibration services. This fact is clearly reflected in the Quality Manual.

6. Purchasing Services and Supplies (clause 4.6, ISO/IEC 17025)

Purchasing of goods and services is performed according to the general procedure "Purchasing of Goods and Supplies" (GP 1-06/ver.1/July 2011). "Annual plan for public procurement" (GF 1-06-1-1-2011) prepared each year. "List of referenced suppliers" (GF 1-06-3-1-2001/updated on 20 August 2011) used to choose suppliers. Suppliers are evaluated mainly based on the performance during supply of procured goods regularly. It was noticed that "Annual procurement plan" for the year 2011 is not realized at all.

7. Service to the Customer (clause 4.7, ISO/IEC 17025)

Implementation of this requirement of the standard is described in the general procedure "Review of Requests for Services/Service to the Customer" (GP 1-04/ver.1/July 2011). Implementation was checked during the vertical audit of services provided by Mass, Volume and Flow, Temperature, Pressure laboratories.

8. Complaints (clause 4.8, ISO/IEC 17025)

BoM has adequate policy and procedure for handling of customer complaints. General procedure GP 1-07 (ver.1/July 2011) clearly describes steps to be followed in case of customer complaints. "Procedure for Corrective and Preventive Actions" (GF 1-08/ver.1/July 2011) is applied, if necessary. Records related to customer complaints are kept in the "Complaint Form" (GF 1-07-1) and the "Catalogue of Complaints" (GF 1-07-2). No complaints were received orally or by other means in 2010 and 2011. However feedback from three customers in "Customer Satisfaction Questionnaire" was treated as a complaint. Item related to customer complaints were discussed during recent management review meeting hold on 22nd of August 2011.

Recommendation (R-9): For some complaints immediate actions could be planned instead of planning long term objective (e.g. explanatory letter instead of awareness event).

9. Control of Non-conforming Testing and Calibration Work (clause 4.9, ISO/IEC 17025)

BoM has policy and procedure for handling of non-conforming work. Details of the process are written in the general procedure "Handling of non-conforming work" (ver.1/July 2011). Almost all records (53) related to non-conforming work concerns with findings during internal audits performed in the period from July to August 2011.

Non-conformity (NC-9): Responsibility for filling the "Non-conforming Work Form" in case of detection of non-conforming work is not clearly described in the general procedure "Handling of non-conforming work" (ver.1/July 2011).

10. Improvement (clause 4.10, ISO/IEC 17025)

Mechanisms for continuous improvement are described in the general procedure "Improvement" (GP 1-09/ver. 1/July). Various quantitative indicators are used for planning necessary actions.

Quality Manager prepares the "Report from Evaluation of BoM Services" (GR 1-04-1-1-2011) on the annual basis. In the year 2011 evaluation report was prepared based on 17 filled questionnaires. In three cases response from questionnaire led to implementation of the "Customer Complaint" procedure. In addition, general procedure "Improvement" describes the mechanism for performing a risk analysis. However the risk analysis has not been performed yet.

11. Corrective Action (clause 4.11, ISO/IEC 17025)

BoM has adequate policy and procedure for corrective actions. Details of the process are written in the general procedure "Corrective and Preventive Actions" (ver. 1/July 2011). 41

corrective actions out of 53 were completed in 2011. Completed actions are mainly concerned with documents and records.

12. Preventive action (clause 4.12, ISO/IEC 17025)

BoM has adequate policy and procedure for preventive actions. Details of the process are written in the general procedure "Corrective and Preventive Actions" (ver. 1/July 2011). Single preventive action was identified and registered by the time of peer assessment.

13. Control of Records (clause 4.13, ISO/IEC 17025)

BoM does not have separate procedure for control of records. General policy related to records presented in the Chapter 1-03 of the Quality Manual and specific details related to the implementation are described in the general procedure "Document Control and Control of Records" (GP 1-03/ver.1/July 2011). Records kept both as hardcopies and electronically. BoM has Document Management System (DMS) database for keeping electronic records, which is used quite efficiently. Access to records within the database DMS is password protected. 10 years period is tabulated for keeping of all kind of records.

Non-conformity (NC-10): Some records and documents of pressure laboratory stored on individual computers of personnel, but not server or intranet.

14. Internal Audits (clause 4.14, ISO/IEC 17025)

BoM has adequate policy and written procedure for internal audit. General policy is presented in the Chapter 1-11 of the Quality Manual, which refers to general procedure "Internal Audits" (GP 1-11/ver.1/July 2011). The general procedure describes steps to be followed during internal audits. The procedure specifies in the current version performing an internal audit in all laboratories. However this was not a case in the year 2011. Quality Manager of BoM explains the situation as just 4 laboratories and their services are covered by Quality Management System.

Training on "Internal Audit in Accordance with ISO 19011 standard" was performed in June 2011. Training was delivered by international expert from Turkish National Metrology Institute, who is involved in Quality Management activities at his institute for many years.

Following the training, internal audits in Mass, Volume and Flow, Temperature, Pressure laboratories were performed with the assistance of technical experts from other NMIs. This approach enabled to perform audit deeply focused on technical requirements of ISO/IEC 17025 standard. All persons assisting BoM staff in internal audits in the laboratories are well respected persons internationally within specific subject fields. However possibility of performing audit in the same way in forthcoming years is a matter of availability of financial resources. Internal audit of quality management system requirements (Quality Manager and his deputy were audited) was performed by BoM's team. Reports of all audits are available

both in electronic version and as a hardcopy. All reports and status of planned corrective actions were checked during peer assessment. Corrective actions with respect to findings of internal audits are in progress.

Non-conformity (NC-11): Currently implemented process of internal audit is not described correctly in the "Internal Audits Procedure" (GP 1-11/ver. 1/July 2011).

Non-conformity (NC-12): The "Internal Audits Procedure" (GP 1-11/ver. 1/July 2011) does not specify which kind of records has to be kept by laboratories.

Non-conformity (NC-13): Top management (Director of BoM) was not audited during recent internal audit.

Recommendation (R-10): Criteria for internal auditors described in the general procedure "Internal Audits" are very broad. More specific criteria for internal auditors should be developed.

15. Management Reviews (clause 4.15, ISO/IEC 17025)

BoM has adequate policy and written procedure for management review. General policy is presented in the Chapter 1-12 of the Quality Manual, which refers to general procedure "Management Review" (GP 1-11/ver.1/July 2011). The general procedure describes steps to be followed during planning and implementation of management review.

Recent management review was performed on 22nd of August 2011. Meeting was attended by BoM's director, quality manager, his deputy and technical managers of all laboratories. Agenda of the management review meeting contained all items required in the ISO/IEC 17025 standard. However due to the fact of missing quality objectives (see NC-1) they were not discussed specifically. Various actions were planned during the meeting as stated in minutes of the meeting (GR 1-12-2-1-2011).

Recommendation (R-11): Minutes of management review meeting could be supplemented with list of actions with clear identifications of the action, person responsible for implementation and deadline for completion. This list would be used as an input for the next management review to monitoring the status of planned actions.

16. Personnel (clause 5.2, ISO/IEC 17025)

BoM has established necessary mechanisms for hiring and employing of qualified staff as described in the general procedure "Personnel" (GP 2-02/ver.1/July 2011). Implementation of the procedure was checked based on the interview with BoM staff and Quality manager. All necessary records "Personal Data Form" (GF 2-02-2), "Training Record" (GF 2-02-3) kept updated and in the relevant files both as hardcopy and electronic form. Mechanisms for authorization of new staff for calibration services is described in the general procedure.

Implementation of the mechanism was checked based on the records of Biljana Atanasov, who was authorized to perform mass calibrations apart of main responsibilities in the Length Laboratory.

Annual training plan for BoM staff is prepared each year based on the needs identified by Technical Managers of laboratories. Implementation of the Annual Training Plan is monitored periodically. Evaluation of effectiveness of received trainings is performed formally, marking them “satisfactory”, “excellent”, etc.

Recommendation (R-12): Current mechanism for evaluation of training could lead to subjective evaluation based on personal attitude. Clear and measurable objective criteria for evaluation of trainings have to be developed.

17. Accommodation and Environmental Conditions (clause 5.3, ISO/IEC 17025)

General policy for accommodation and environmental conditions of BoM laboratories is presented in Chapter 2-03 of the Quality Manual. Details and steps to be followed in order to establish, control and monitor required conditions for performing calibrations are described in the general procedure “Accommodation and Environmental Conditions” (GP 2-03/ver.1/July 2011). BoM has proper allocation of space for laboratories and appropriate environmental conditions to perform calibrations. The environmental conditions are monitored and recorded on a continuous basis. The laboratories are equipped with data loggers with interval of logging specified by each laboratory. Records from data loggers transferred and stored on server and CDs.

Access to BoM laboratories is limited to authorized persons as described in the general procedure.

Implementation of the procedure was checked during guided tour to BoM laboratories. In addition, records of environmental conditions on server were checked.

18. Test and Calibration Methods and Method Validation (clause 5.4, ISO/IEC 17025)

BoM laboratories use internationally accepted methods as described in ISO standards, OIML recommendations, EURAMET Calibration Guides, etc. General procedure “Calibration Methods/Method Validation” (GP 2-04/ver.1/July 2011) applies for implementation of the requirement of para 5.4 of the ISO/IEC 17025 standard at BoM. Procedure describes broadly steps to be followed for selection, validation and application of calibration methods. Detailed procedures for calibrations exist as LP 04-LAB-01, 02, etc. During vertical audit of calibration certificates issued by Mass, Volume and Flow, Temperature, Pressure laboratories it was detected that all calibrations were performed according to written procedures. General contents of the procedures are satisfactory. However recommended corrections outlined by technical experts in the reports of internal audits have to be taken into consideration.

BoM specifies in the QMS documentation the fact, that all software are recorded in the "List of Validated Software" (LF 2-04-LAB-03). In reality laboratories do not use developed software, but Excel sheets for calculation. It was observed that records related to calculation sheets (titles in the relevant cells) in the lists are different from laboratory to laboratory.

General principles for estimation of measurement uncertainty is given in the general procedure GP 2-04, which refers to internationally accepted documents. Each laboratory has chapter related calculation of measurement uncertainty in laboratory procedures. Calculations are performed by using templates prepared as Excel worksheets, "Laboratory Calculation Table for Uncertainty Calculation" (LC 2-04-LAB-01,02,...).

Non-conformity (NC-14): Some of calculation sheets in Excel are not validated yet and not protected, e.g. sheets for calculation of measurement results and measurement uncertainty in pressure and temperature laboratory.

19. Equipment (clause 5.5, ISO/IEC 17025)

General policy for use of equipment in BoM is presented in Chapter 2-05 of the Quality Manual, while details and specific points for the implementation of necessary mechanisms are described in the general procedure "Equipment" (GP 2-05 /ver.1/ July 2011). Records for equipment are kept in the list LF-2-05-LAB-02 "List of Laboratory Equipment" and individual records for each piece of equipment is available in the LF 2-05-LAB-01 "Equipment Form".

"Annual plan for (re)calibration of equipment" (LF 2-05-01) is prepared during the year. It was observed that realization of the (re)calibration plan for the year 2011 is in progress with a slight delay.

Non-conformity (NC-15): Not updated records for reference equipment were detected (e.g. recalibration date PT 100 PW-E Z100 thermometer).

Recommendation (R-13): To develop labelling mechanism to prevent use of defective equipment.

Recommendation (R-14): To add new column in the "Annual Plan for (Re)calibration of Equipment" in order to monitor the status of realization of the plan.

20. Measurement Traceability (clause 5.6, ISO/IEC 17025)

General policy for measurement traceability is presented in Chapter 2-06 of the Quality Manual and steps to be followed during the implementation are described in general procedure "Measurement Traceability" (GP 2-06/ver.1/July 2011). Traceability of calibrations performed by BoM's laboratories is ensured through use of reference standards calibrated by NMIs of other countries. Information and records reviewed during assessment show traceability mainly to DMDM (Serbia), EIM (Greece) and UME (Turkey). All these

institutes are signatories of CIPM MRA and have published CMCs on the BIPM Key Comparison Database (KCDB) in the related subject fields.

21. Sampling (clause 5.7, ISO/IEC 17025)

Calibration activities, covered by Quality Management System of Bureau of Metrology, do not include sampling process.

22. Handling of Test and Calibration Items (clause 5.8, ISO/IEC 17025)

BoM has a policy and written procedure for handling of calibration items. Details of the process are described in the general procedure "Handling of Calibration Items" (GP 2-08/ver.1/July 2011). Various QMS documents are used within the process, e.g. "Protocol for Acceptance of Calibration Services/Calibration Items" (GF 1-04-2), "Calibration Order Execution Form" (GF 1-04-1). Implementation of the general procedure was assessed through review of records related to calibration services provided by Mass, Volume and Flow, Temperature, Pressure laboratories.

Non-conformity (NC-16): Calibration label used both for internal and external calibrations are described in the QMS documentation in generic way without clear identification of its format.

23. Assuring the Quality of Test and Calibration Results(clause 5.9, ISO/IEC 17025)

Policy and general principles to assure quality of calibration results are presented in the Chapter 2-09 of the Quality Manual. Specific and detailed information is given in the general procedure "Quality Assurance of Calibration Results" (GP 2-09/ver.1/July 2011). BoM uses both internal quality control scheme and external quality control tools.

The main tools used for assurance of quality of calibration results is participation in interlaboratory comparisons. All comparisons are registered in the "Protocol of Intercomparisons" (LF 2-09-LAB-01/ver.1/July 2011). None of the comparisons participated by BoM laboratories during recent two years proves calibration capabilities in full range. Technical managers together with quality manager performed cause analysis and planned corrective actions. Planning and participation in new, mainly bilateral comparisons, is corrective action in majority of cases.

Non-conformity (NC-17): "Protocol of Intercomparisons" for pressure laboratory does not exist.

24. Reporting the Results (clause 5.10, ISO/IEC 17025)

General principles for reporting of calibration results are described in the Chapter 2-10 of Quality Manual and details are presented in general procedure ""Reporting Calibration Results" (GP 2-10/ver.1/July 2011).

Before July 2011 BoM laboratories issued certificates with contents varying from laboratory to laboratory. But currently BoM has standard template for “Calibration Certificate” (GF 2-10-1 / ver. 1/July 2011). Calibration certificates fully meet the requirements of clause 5.10 of the ISO/IEC 17025 standard regarding the format and the content of information.

Implementation of the procedure was checked by vertical audit of certificates issued by Mass (BoM-M-0221/2011), Temperature (BoM-T-0011/2011), Volume and Flow (BoM-VF-0044/2011), Pressure (BoM-P-0005/2011) laboratories.

CONCLUSION

Bureau of Metrology of Former Yugoslavian Republic of Macedonia (FYROM) has implemented Quality Management System meeting requirements of the international standard ISO/IEC 17025. Many processes, mechanisms became operational recently. Majority of written quality management documents were put into operation in July 2011. It demonstrates that for some mechanisms procedures so far exist formally on paper (e.g. risk evaluation). They did not neither proved nor evaluated for efficiency. Based on these it could be concluded, that BoM’s QMS is on immature stage. Monitoring of the efficiency of the QMS shall be performed on the short and mid term scale. Monitoring shall include intensive communication within the organization and collecting feedback from staff involved in the implementation of various processes. Based on the results of monitoring further improvements have to be planned. Simplification of the structure of the quality management documentation could be helpful, since many experts expressed opinion about the comprehensiveness of the documentation and difficulties in following its structure. In addition, some procedures require more detailed and precise description of responsibilities. For completion of corrective actions due to non-conformities mentioned in this report and also registered during internal audit cycle, and for further improvement of the quality management system, an allocation of appropriate time is required. Sustainability of the existing system strongly depends on available financial and human resources.

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