The role of laboratory managerial personnel in improvement of the management system

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Abstract
Examples of tasks, authorities and responsibilities of the laboratory managerial personnel, consistent with provisions of PN-EN ISO/IEC 17025:2005, were given. The methods as well as basic areas for improvement of the management system efficiency in conformity with this standard were indicated. Actions recommended for improvements introduced to individual fields of activity were outlined.

Keywords: laboratory managerial and technical personnel, authorities, tasks and responsibilities, improvements of the management system efficiency - tools, means, areas and methods

1. Introduction
The provisions of PN-EN ISO/IEC 17025:2005 „General requirements for the competence of testing and calibration laboratories” as stated under Clause 4.10 clearly indicate the necessity of applying in the activities of a laboratory the principle of continual improvement of the efficiency of a management system, enumerating at the same time tools that can possibly serve this purpose. The above mentioned requirements are addressed to all members of the laboratory staff, but no doubt that the leading role in continual improvement is played by the management who, as follows from other provisions of this standard, have relevant authorities and resources to, on one hand, supervise the carried out processes and, on the other, initiate and enforce their improvement.

2. The laboratory managerial personnel – the authorities, tasks and responsibilities
According to Clause 4.1.5 of PN-EN ISO/IEC 17025:2005, the responsibilities of the managerial and technical personnel (having at their disposal adequate authorities and resources) are focussed on:
- system management,
- supervision of all substantial issues covered by the scope of the carried out activities,
- initiation of actions to prevent or minimise the cases of departure from the management system or from the procedures for performing tests and/or calibrations.

Further under this Clause of the Standard, the duties of the technical management have been formulated as including:
- full responsibility for the technical operations (performing tests and/or calibrations),
- provision of resources (personnel, accommodation and environmental conditions, methods of tests and/or calibrations, equipment).

Additionally, the duties of the quality management in a laboratory have been defined. The Quality Manager is responsible for the management system, i.e. for the correct functioning of its individual elements, and also for the provision of necessary resources.

Summing up, according to the provisions of the standard, the managerial personnel of a laboratory has strictly defined duties and responsibilities, which can be delegated further to individual functionals nominated according to the specific needs of each laboratory and operating within its organisation structure, for example, according to the following schemes:
- the responsibility for correct functioning of a management system implemented in laboratory – assigned to Quality Manager,
- the substantial responsibility for the carried out activities, i.e. for the performed tests and calibrations, including supervision of the personnel and of the methods of tests and calibrations - assigned to Laboratory Manager, and finally
- the responsibility for technical resources, i.e. conditions at work place, work environment, and equipment - assigned to Technical Manager.

So diversified personal constitution of a laboratory management may not be practical sometimes and, as mentioned above, according to the current needs, the three above mentioned different functions can be performed by one single person.

For example, in a laboratory with well-established management system, the Quality Manager may have the following tasks and duties related with correct functioning of this system and its continuous improvements:
- supervising the entire management system documentation, following the previously adopted guidelines (evidencing, distribution and updating),
- supervising the assigned processes and collecting reliable proofs of their conformity,
- cooperation with accreditation body at the time of the accreditation process and throughout the entire period of the accreditation validity,
- collecting, analysing and applying in practice the information from both „internal” and „external” sources to serve an improvement of the management system,
- making laboratory personnel aware of the relevance and importance of a management system and ensuring proper training in this system for the newly employed staff.

The responsibilities of Quality Manager resulting from the above mentioned tasks and duties can be described in the following way.

The Quality Manager is responsible for the correct functioning of a quality management system in laboratory, and within this scope of activities his authorities and duties shall specifically include:
- implementation of a management system and supervision of its correct functioning, as well as solution of problems related with the operation and improvement of this system in laboratory, cooperating in this respect with Laboratory Manager and Technical Manager,
- close cooperation with the aforementioned personnel in establishment of a quality policy and measures taken to ensure full impartiality of the laboratory,
- direct contacts with the customers of laboratory,
- running, updating, emission and storing of a complete documentation set of the quality management system, permanent control and updating of these documents,
- keeping archive records of the quality management system documentation,
- systematic control of practical application of the provisions of a quality manual,
- planning, organisation, supervision and participation in the programme of audits, and preparation as well as documentation of the management reviews in a laboratory,
- proposing and checking the implementation in laboratory of corrective and preventive actions and of the execution of assigned tasks,
- keeping quality records and permanent control of these records,
- monitoring the compliance with the adopted rule of the confidentiality of tests and test results,
- proposals of changes and amendments introduced to the existing test procedures, instructions and quality manual,
- organising and monitoring the development of test procedures and instructions,
- preparing schedules of training,
- establishment of a policy and procedure for the resolution of complaints and participation in actions dealing with complaints.
Considering the above, the Quality Manager becomes “owner” of the following processes:

- management of system documentation,
- audits,
- corrective actions,
- preventive actions,
- management reviews (preparation),
- system improvements,
- resolution of complaints,
- process benchmarking (including actions related with self-evaluation), and
- investigation of customer’s feedback and seeking satisfaction of other parties concerned.

The tasks of Laboratory Management are, for example, the following:

- establishment of the laboratory employment policy ensuring, within the scope of the activities of this laboratory, full satisfaction of the qualification needs of the personnel,
- documentation of the applied methods of tests/calibrations and their implementation when satisfactory and reliable results are obtained,
- cooperation with customers at all stages of mutual relations,
- supervision of the way in which objects are handled for testing,
- quality control to monitor the reliability of the undertaken tests/calibrations.

The responsibilities of Laboratory Manager, resulting from the above mentioned tasks and duties, can be described in the following way.

The Laboratory Manager is responsible for all substantial problems related with the laboratory activities, and within this scope of the activities his authorities and duties shall specifically include:

- close cooperation with the top management, i.e. with the Quality Manager and Technical Manager, as regards observance of the quality policy and measures taken to enable the laboratory operate as an entirely impartial body,
- active participation in solution of problems related with the correct functioning of a management system in laboratory,
- proper policy regarding laboratory personnel affairs and remuneration,
- efforts to ensure financial means for the correct functioning of a laboratory,
- promotion and acquisition carried out for and on behalf of the laboratory,
- supervision of all testing done by the laboratory,
- supervision of implementation and improvement of test procedures and instructions used by the laboratory,
- inspiring and animating actions for the development and improvement of testing methods, especially as regards the methodologies recommended for use by the PN, EN and ISO standards,
- initiating and organising the verification of testing methods, including interlaboratory studies to evaluate the skills of personnel and to examine and verify the accuracy of laboratory methods,
- approval of test procedures and instructions,
- participation in audits and management reviews,
- demanding the corrective and preventive actions and checking if they have been effective,
- approval of training programmes,
- direct contacts with the customers of laboratory,
- contacts with the customers when receiving and accepting orders,
- analysis of orders for tests to verify the completeness of requirements and possibility of satisfying them,
- permanent control of the accuracy and reliability of performed tests,
- permanent control of laboratory records,
- punctual execution of orders, satisfying the customer’s requirements,
- approval of test reports,
- determination of the laboratory personnel duties and responsibilities regarding the confidentiality of test results,
- supervision of complaint procedures.

The tasks of the Technical Manager are, for example, the following:

- ensuring proper accommodation (measuring fields) and environmental conditions most appropriate for the type of the carried out activities,
- ensuring and maintaining the suitability of equipment used for the carried out activities,
• protection of technical and auxiliary materials used for the carried out activities, and
• supervising the operation of equipment.

The responsibilities of Technical Manager, resulting from the above mentioned tasks and duties, can be described in the following way.

The Technical Manager is responsible for all technical problems related with the activities of the laboratory and in this scope his authorities and duties shall specifically include:
• evidencing of equipment, scheduling its calibration and control checks, organisation of these activities and keeping records,
• monitoring the technical state of equipment and providing adequate auxiliary materials for testing,
• observance of punctuality of the dates of calibration and control checks of the equipment,
• participation in implementation work, and improvement of test procedures and instructions valid in a laboratory, elaboration of service manuals,
• withdrawal from use and protection from casual use of equipment in which an inefficiency and/or inaccuracy of measurements has been detected, or which has exceeded the validity date of the calibration or control check,
• permanent supervision of the proper use of the testing equipment, including its maintenance and repairs,
• taking care of the condition of the laboratory compartments and test stands,
• supervision and observance of the laboratory health and safety regulations, fire protection and sozology,
• participation in implementation of new methods and equipment, and acceptance of new personnel,
• making Laboratory Manager aware of the needs of personnel training,
• training of newly employed staff, participation in the scheduled audits, and monitoring of corrective actions,
• participation in the resolution of complaints,
• direct contacts with the customers of laboratory,
• supervising and observance of provisions of the confidentiality of tests and relevant results,
• proper organisation of test stands and measuring fields in the case of a third party being present during the test.

Considering the above, the Technical Manager becomes “owner” of the following processes:
• providing proper accommodation (measuring fields) and environmental conditions,
• purchase of deliveries and services,
• equipment,
• reference standards and reference materials, and also
• measurement traceability.

3. Improvements of the management system efficiency – tools, means, areas and methods

According to the provisions of the standard, the tools used for an improvement of the management system efficiency include quality policy, quality-related objectives, the results of audits, data analysis, corrective and preventive actions, and management reviews.

As practice teaches us, the management system efficiency can be improved through:
• documentation (regarding declaration and specification of procedures) – ensuring proper communication with the parties concerned, and
• the use of system records collected as proofs of the consistency of procedures applied in the analysis of real events.

An improvement of the efficiency of a laboratory management system is, among others, related with the following most important spheres of the laboratory activity:
• competences, including technical competences of the personnel,
• test methods/calibration,
• operation (control) of equipment – maintaining the equipment in the state of permanent readiness.

A method for improvement of the management system efficiency is optimisation of:
• individual processes identified in the scope of laboratory activities,
• conditions under which these processes are running, and
• awareness of customer requirements.

3.1. Improvements of competences, including technical staff competences – actions and measures

To improve the staff competences, among others, the following actions and measures can be adopted:
• determination of a framework of qualification requirements (education, special skills and experience),
• accurate determination of authorities and responsibilities,
• outlining the individual path of professional career,
• preliminary and upgrading training,
• determination of communication means and tools and partnership cooperation in solution of current personnel problems,
making personnel aware, through presentation and explanation, of tactic and strategic objectives in the currently adopted laboratory policy – formation of attitudes,

• „sharing” with personnel on even basis both failures and successes,

• documentation and propagation of personnel professional achievements,

• continuous monitoring of tests/calibrations performed by the personnel and proceeding with items for testing,

• organising parallel and comparative tests,

• supervising compliance with provisions of the management system documentation,

• supervision of records, including intermediate records and data transfer,

• “open” attitude to initiatives submitted by the personnel in the field of improvements and „rectifying” the process run,

• actions for personnel integration,

• fair remuneration.

3.2. Improvements of research methods / calibrations – actions and measures

The following measures are recommended as elements of improvement of the research methods/calibrations:

• detailed analysis of the customer requirements and choice of the test methods most “useful” for the customer,

• documentation of test/calibration procedures adapted to the real needs and possibilities of laboratory (development of test procedures „suitable” for the scope of the laboratory activities),

• verification of test procedures before their actual use in laboratory,

• „monitoring” update of the test procedure provisions (allowing for the changing parameters and ambient conditions of the carried out tests).

3.3. Improvements of equipment operation (control) – ensuring permanent readiness of the equipment - actions and measures

Improvements in the control of equipment are, among others, obtained through:

• analysis of the current needs of laboratory and proper choice and specification of properties during purchase of basic and complementary equipment (reference standards, reference materials, auxiliary materials),

• plans regarding the implementation of equipment in use and the accompanying training of operators,

• determination of the frequency and means of random and periodical control checks of the equipment (to ensure measurement traceability and usability),

• evidencing and recording the „history” of the equipment,

• step-by-step determination and supervision of the equipment operation.

4. Summary

As related above, the improvement of a management system in laboratory can refer to different fields of the laboratory activities which, according to internal regulations, can be supervised by different members of the laboratory management personnel. In large laboratories, the initiation and supervision of improvement can be the responsibility of the following staff members: Laboratory Manager, Quality Manager and Technical Manager, each of them proceeding in accordance with the scope of the internally determined authorities, responsibilities and tasks. In small laboratories, it is usually the Laboratory Manager who is supposed to perform all these duties.

Improvement is achieved through optimisation of processes carried out by the laboratory; the responsibility is with the “owners” of individual processes, that is, with the individual managers functioning in an organisation structure of the laboratory. They can initiate and perform actions improving the management system. Examples of these actions have been mentioned above for the three previously established main areas of improvement.

References


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