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Accreditation of forensic science laboratories in Turkey in the scope of TS EN ISO/IEC 17025:2017 standard

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Abstract

The identification and interpretation of evidence are important in criminal disclosure. In addition to analyzing the investigated evidence using scientific and credible methods, it must be documented that the processes are carried out in accordance with nationally and internationally accepted scientific criteria. This can only be achieved with accreditation. Accreditation of test laboratories according to the 17025 standard in forensic sciences is an assurance that the expertise for courts is acceptable throughout the world. Compliance with the 17025 standard ensures that every detail of the laboratory operation is in accordance with an unchanging and understandable procedure, the workflow processes are always the same, thus minimizing possible errors and improving the efficiency of the laboratory service. For accreditation in laboratories, the requirements of TS EN ISO / IEC 17025 must be applied. It is possible to separate TS EN ISO / IEC 17025 into two main parts. The first part is the management requirements and the second part is the technical competence. Documentation, audits and quality management constitute an integral part of the terms of the management. The concept of technical competence includes personnel competence, test methods and devices. Appropriate equipment, selection of methods, implementation, competent personnel selection and training, continuous improvement of the practices in the laboratory to ensure quality are also parts of the accreditation process. The first accreditation is received by the Institute of Forensic Medicine of The University of Istanbul, which operates in the field of forensic science in Turkey as one of the four accredited institutions. In this study, the laboratories that want to apply the accreditation process are informed about the points that they should pay attention to, the attainments of accreditation in forensic sciences and the objectives such as expansion of scope for the future are mentioned briefly, suggestions are given to increase the number of accredited laboratories connected to universities as well as ensuring sustainability. Also designing the Forensic Science Laboratories in compliance with ISO / IEC 17025 standards, examining the technical requirements in this context, as well as the accreditation of laboratories in the field of forensic science in Turkey, have been addressed.

Keywords: ISO / IEC 17025:2017, accreditation, forensic science laboratory, qualification

Introduction

Accreditation according to Turkish EC is a quality infrastructure established to support the reliability and validity of the work carried out by conformity assessment bodies and consequently the conformity confirmation documents (test and inspection reports, calibration certificates, management system documentation, product documentation, staff documentation etc.) Accreditation of conformity assessment bodies is carried out on the basis of internationally recognized requirements set out to determine the eligibility criteria for the conformity assessment bodies, the relevant sector specific requirements and the internationally accepted requirements in the guidance documents specified by the regional or international accreditation bodies [1-5].

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According to definitions within the scope of international accreditation organizations; Accreditation in the CITAC / Eurochem (Cooperation on International Traceability in Analytical Chemistry) guidelines is a procedure for recognition by the public authorities that the unit provides specific services and is competent. The definition of accreditation for a laboratory is the process during which the laboratory's technical competence is assessed, approved and periodically audited by an internationally recognized authority in accordance with certain standards, for the reliability of the tests and analyzes. Quality assurance, on the other hand, is a measure of the quality of all precautions, procedures in the laboratory and is a system of quality assurance of the work to be carried out [1]. Another organization, ILAC (International Laboratory Accreditation Cooperation), is an international organization who aims at developing a communications network among accredited laboratories that deliver accurate and reliable results. It combines many worldwide laboratory accreditation systems and it operates on a voluntary basis. This mutual recognition system results in the

acceptance of test results acquired from accredited laboratories for the goods of the companies who export to foreign markets. This is a cost-reducing factor for both sides, since the need for retesting is eliminated [2]. IAF (International Accreditation Forum), is an organization that monitors the reliability and appropriateness of accredited certification bodies [3] EA (European Co-operation for Accreditation) is a nonprofit organization where the members are the accreditation agencies of European Union countries and countries with candidate status [4]. These organizations provide communication by gathering the established agencies in various countries to accredit the conformity assessment activities in the world. Accreditation activities in our country are provided by Türk Akreditasyon Kurumu (TÜRKAK).

In addition to the accreditation bodies, there are organizations who publish guidelines to establish standardization and ensure agreement on applications and terms used in various fields. For standards of test laboratories, ISO (International Organization for Standardization) and ASTM (formerly American Society for Testing and Materials) are the most preferred organizations. ASTM is the world's largest voluntary organization who develops standards. TSE is providing service in standardization, conformity assessment, testing and calibration, in Turkey. It also provides service in countries such as Uzbekistan, Kazakhstan and Azerbaijan. In the field of chemistry IUPAC (International Union of Pure and Applied Chemistry) works especially on compatibility of terminology. Many different organizations work together in the field of metrology (ISO, IEC, BIPM, OIML, IUPAC, IUPAP, IFCC). These organizations came together to form a structure called VIM (International Vocabulary of Metrology). NIST (National Institute of Standards and Technology) publishes standards on measurement and methods. Organizations such as CITAC (Cooperation on International Traceability in Analytical Chemistry) and EUROLAB (Organization for Testing in Europe) provide useful guides for test laboratories [20]. In the world, ISO 17025 standard is used for the accreditation of testing and calibration laboratories. Accreditation in compliance with 17025 increases the competitiveness of a testing laboratory, develops its management system and increases the effectiveness and efficiency of its services [21]. 17025 accreditation in forensic science is a guarantee that the courts of the whole world would accept the testing laboratory's expert services.

Compliance with 17025 standards ensures that every detail of the laboratory process is carried out according to fixed procedures and the workflow process is always the same. In this way, possible errors are minimized, the efficiency of the laboratory increases in terms of operation and service. Being accredited enables mutual recognition and even research results to be internationally comparable, through guidelines on both the standards and the activities of other research laboratories. Nowadays, accreditation is a process based on sometimes a necessity, sometimes voluntariness. In countries that implement free market economies, laboratories; have to be accredited to prove their independence and credibility as well as to increase their competitive power. The standard named TS EN ISO/IEC 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" have two main sections. These sections are named as "administration requirements" and "technical requirements". While the administration requirements are primarily concerned with the operation and effectiveness of the quality management system in the laboratory, the technical requirements address the competence of the personnel, the methodology and the test / calibration equipments. In the quality system, regardless of anything, "do what you write" and "write what you do" motto is important [21]. For a correct application, the standard must also be correctly interpreted. In interpreting the standard correctly, it is important to get ideas from experienced laboratories and inspectors.

The most important reasons of why standardization is required in forensic laboratories [20-22]:

1. The worldwide acceptance of the report of the forensic laboratories,
2. The increasing pressure of competition among companies and to have a place among the worldwide laboratories in international competition,
3. To realize the potential of employees and to increase the quality of workforce,
4. To satisfy the increasing expectations of customers in terms of services provided,
5. Globalization around the world,
6. To increase confidence in forensic laboratories,
7. To provide rapid production of laboratory services while ensuring quality.

Application Process in Turkey

Within the discipline of forensic sciences, quality assurance is important since the results affect the decision given in the justice system. In Turkey, TS EN ISO 17025 standard is used for the accreditation of laboratories. In Turkey, with the Law on Turkish Accreditation Authority and Establishment and Duties No. 4457, the tasks to accredit domestic and foreign institutions that will carry out laboratory, certification and inspection services and to ensure that these institutions are working in accordance with the determined national and international standards, and thus provide that the products / services system, personnel and laboratory documents are internationally accepted, were given to the Turkish Accreditation Agency. As of 2008, TÜRKAK, which started to provide accreditation services in 2001, has signed a mutual recognition agreement with the European Accreditation Association in all the accreditation fields subject to mutual recognition agreements. TÜRKAK is a full member of Europe Accreditation Association (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) [5].

Accreditation application file is prepared by the laboratory. Documents in the file are; quality handbook, organization chart, procedures, instructions, forms, etc. For the purposes of a preliminary audit, the file is sent to a specified auditor by TÜRKAK.

RKAK. The auditor's report as a result of his review on the file is forwarded to the laboratory, by the Agency. Laboratory fulfills the requirements and recommendations in this report and reapplies to the agency. The parties agree on the audit date of the laboratory and the auditors. After the audit, the auditors prepare the report and present it to the accreditation agency, for approval. Accreditation enters into force with the agency's approval of the report. After that, there are probation controls each year and a full accreditation audit at four year periods.

Following the declaration of accreditation decision, the first thing that the laboratory should do is to carry out a comprehensive inventory work on all main items such as their processes, personnel and equipment. For all tests, the laboratory should outline detailed

workflows and the relationship of all units must be presented in a clear manner in this plan [9,16].

TS EN ISO/IEC 17025 standards

The TS EN ISO / IEC 17025 standards are intended to be used for the development of management systems for the laboratory's quality, administrative and technical operations. The use of this standard will help to establish cooperation between laboratories and other organizations, mutual exchange of knowledge and experience and will also help to harmonize standards and procedures [7,10]

The purpose of the standard is to establish a management system open to constant improvement, to set up and follow up the goals of the management system, to provide traceability in technical and documentation aspects, as well as to achieve reliable testing and calibration results [6].

ISO/17025 laboratory accreditation is divided into two main sections. Management requirements and technical requirements. Quality management requirements is similar to ISO 9000 quality standards specified for quality management but an adapted version for the laboratory conditions. For this reason, the institutions or laboratories who have implemented quality systems in compliance with ISO 9000 standards can adapt easier to provide these conditions. There is a reason for all the conditions included in this section and they constitute a management system with adequate systems to maintain control. These requirements require a minimum amount of documentation to be generated in order to be available for the use of the laboratory which is a legal entity or a unit of a legal entity, as well as for its customers. It is required that the proposed system should be sustainable and leverageable in an appropriate manner. For the fulfillment of the conditions in this article as well as demonstrating its administration, there are detailed descriptions for various elements of the quality system [6,9-13]

Technical competence shows the requirements that the laboratory must comply with in order to demonstrate its technical adequacy when performing various tests and/or calibrations. According to the General Conditions for the adequacy of laboratories for testing and calibration; the laboratory should have quality control procedures to monitor the validity of its test results and this monitoring process should be planned.

Many factors determine the accuracy and reliability of tests and / or calibrations made by a laboratory. These factors include contributions from any of the following [6]:

- Human factor
- The layout and environmental conditions
- Testing and calibration methods and validation of these methods
- Equipments
- Measurement traceability
- Sampling
- Movement of test and calibration materials
- Assurance of the quality of test and calibration results
- Reporting of the results

Starting from how the samples coming to the forensic laboratories are collected, how they are transferred, how the reporting process work and up to how the report will be forwarded; all the phases should be described one by one and the task definitions of each personnel involved in these phases should be prepared very clearly. Procedures should be defined and written down for the activities which are an integral part of these tasks as well as for the activities which can be defined separately from them. Procedures should be written according to the functioning of the laboratory. If we group them under the main headings, they include procedures such as admissions and registration of sampling, test methods and validation of methods, provision of the quality of the analysis results, reporting of results, on the job training [13]. Each procedure should include the written instructions about the defined tasks. The instructions must contain all the details related to that topic and must provide the capability to perform that activity for the assigned personnel without the need of another person. In the meantime, the forms and schedules to be used should be prepared and put into practice after the approval of the management [9-10].

Personnel: It is one of the most important requirements of the standard and it includes authorization of the personnel who use the devices for calibration and test services, make measurements, calculate uncertainties, prepare reports and interpret measurement results when necessary as well as evaluating and recording their knowledge and skill, education status and training needs. Personnel competence is important and fundamental. The adequacy of all the personnel, who does the tests, evaluates data, interprets, and writes expert reports, must be maintained by the management of the laboratory. In evaluating the adequacy of all employees, primarily their education, training, skills and experience must be sufficient and acceptable. Even if the education records of the personnel are complete and sufficient during the audits, that they perform tasks which comply with calibration /test instructions and evaluating the competence of their knowledge and experience during implementation is essential for the audit results.

Personnel's job definitions of designated fields, the authorities and responsibilities should be defined and declared to them.

Trainings and their timings must be specified in the annual training plan, in accordance with the tasks, applications and work processes in the laboratory. Training activities should be carried out in line with the specified plans and programs. At the end of these trainings, it should be determined if the personnel has acquired the desired qualifications and if shortcomings are identified, corrective actions must be taken. These activities are such as; retraining of the personnel, change of duty, expert assistance, and so on. The effectiveness of corrective actions should be measured [9-14].

Layout and Environmental Conditions: The infrastructure of the laboratory (energy sources, lighting etc.) and the environmental conditions should enable the tests to be carried out and should not affect the measurement results in the negative direction [14].

Documentation of technical conditions related to the layout and environmental conditions that may affect the calibration results for internal and external services that the laboratory serves, monitoring and controlling the environmental conditions affecting the calibration or testing, the requirement of stopping the calibration / testing if the environmental effects are adversely affecting the measurements must be all stated in the documents [10,14].

Testing and calibration methods and validation of these methods

Forensic science laboratories are places where evidences are

analyzed and interpreted with scientific methods. Therefore, the measurement results should be accurate and reliable. The measurement results of the method depend on many factors such as the conditions of the laboratory, equipment, chemicals used, personnel experience, etc. For this reason, the parameters affecting the measurement result of the method should be measured and the effects should be determined.

Validation of the Method is; the measuring and testing operations to demonstrate that a device, a method, a measuring procedure or a system performance complies with the specified conditions. Validation parameters are; precision, accuracy, repeatability, reproducibility, determination limit, authenticity and selectivity, linear region, measurement range and substantiality [9-12].

Validation process; is applied when the method is going to be used for the first time in the laboratory, when a change is applied to a currently used method, when a validated method is going to be used in a different laboratory, when a different person is going to do it or a different device is going to be utilized and when a method parameter is changed.

Laboratory must use appropriate methods and instructions within the scope of accreditation activities; such as sampling, handling, and transporting, storing, preparation of the materials to be tested/ calibrated, the analysis of the test/calibration data if appropriate as well as the budget of uncertainty measuring. The applied methods and instructions must be chosen to meet the needs of customers (9-11). Validated methods should all be documented in writing within the quality management system. Under some special conditions if non-standard methods are used, the customer should be informed that the obtained results may not be valid and the necessary validation processes would be carried out prior to the use of such methods [11-12].

Devices: Suitable devices to provide the necessary accuracy and uncertainty for laboratory, testing and calibration must be used. Calibration and intermediary control programs must be created when necessary and implemented for devices that may impact the results. The information should be recorded and maintained about the calibration, maintenance, repair etc. of devices. Implementations must be defined to prevent the use of devices, which are broken down or their validity of calibration has been expired, in tests/calibrations [13-15].

Traceability of Measurements: All devices used in tests and / or calibrations must be calibrated before starting to be used. The laboratory should have a program and procedures created for calibration of the devices.

Sampling: If the laboratory is collecting samples from the scene of crime or from the materials or products directly transferred to the laboratory, it should have a sampling plan and procedures. Sample records should include the sampling procedure used, the definition of the sample, environmental conditions and the details to determine the location of the sample.

Process implemented on the tested samples: The laboratory must take the necessary measures to avoid damage of the incoming sample for test/calibration. In this context, procedures should be established for the transfer, admission to the lab, handling, preservation, storage, retaining and handing-over of samples [12,14-15].

Quality Assurance of Testing and Calibration Results: Laboratory should establish control procedures to follow up and maintain the validity of its calibration/testing services. In order to ensure accuracy and consistency of results, reference material should be used, interlaboratory comparison or proficiency test (LAC / PT) programs should be taken and appropriate results should be obtained and the consistency of the results should be evaluated by repeating tests and calibrations using the same or different methods [15].

The Preparation of the Reports on Results: Laboratory should turn the data, obtained from the calibration and test measurements it performed, into results and should report them. The results should be prepared accurately, clearly, objectively and in compliance with the test/calibration instructions and national/international standards. The content and format of the calibration certificates / test reports must comply with the requirements specified in the TS EN ISO / IEC 17025 standards and to the notifications of the institution issuing the accreditation document [13-15].

The standard is revised in 2017. In the last revision the following changes are done; configuration of the standardization items in line with ISO/CASCO document structure (item 4-8), defining the laboratory activities of testing, calibration and sampling (associated with testing or calibration) in the context of the standard, risk and opportunity-based approach adoption, more emphasizing on impartiality and confidentiality, replacing the phrase of laboratory management by the phrase management of laboratory, merging under one item the article on purchase of service and materials and the article on outsourcing testing and calibration to a subcontractor, adding the decision rule for making conformity assessment and introducing more clarity into metrological traceability.

Advantages of Being an Accredited Laboratory

Accreditation is the expression of national and international reputation demonstrating the reliability of technical proficiency. Accreditation certificate, in addition to the official recognition of the adequacy of the laboratory, also offers the customers the convenience of choosing reliable test, analysis and calibration services. Thanks to the common approach used for accreditation, reports issued by accredited laboratories are internationally accepted. Thus, in evaluating evidence of international offenses, repetition of evidence-related tests and analysis are avoided, providing benefits in terms of both time and cost [13,15]. Our laboratory's accreditation in the scope of forensic science includes tests on materials/products which constitute Forensic Genetics Review Blood (liquid), cheek epithelial cells, blood stain (dried blood) and extending the scope of the laboratory is undertaken. The laboratory also started the extension of its scope by including intra-analysis methods used in the field of toxicology, in addition to the work it is currently conducting for the purpose of improving individual and corporate quality of the laboratory one step further, maintaining the international validity of its analysis results and reports and ensuring the sustainability of the currently attained standards. Scope expansion studies have started in toxicology by including the methods of heavy metal analysis in urine with ICP-MS and methods of alcohol analysis in the blood with HS-GC-MS. When the required financial resources are provided, the next steps considered include drug analysis methods with GC-MS and LC-MS-MS. Besides these methods, new methods are constantly being developed and validated through scientific research. If the analysis demanded by the customer is not within the scope, then an in-house analysis method would be developed, validated and the

sample is processed with this method.

Accredited Organizations in the Field of Forensic Sciences in Turkey

A drawback or an error occurring in any step of the work in forensic science lab may negatively affect the criminal investigation and maintaining justice. We are confronted with the fact that the following applications are indispensable in order to achieve a fair and impartial trial. The evidence which may be found at the crime scene should be investigated using modern scientific techniques and methods as well as duly collecting and recording the evidence. Also, it should be documented that the evidences are analyzed with validated and reliable methods and that the services are provided using national and internationally accepted scientific criteria by the accredited laboratories. Crimes of international dimension can only be processed if the analysis of the evidence is also valid at an international dimension. As a result, the laboratories working in this field needed accreditation in order to be traceable according to international standards and in order to be open to internal and external audit. Therefore Turkey's first accredited laboratory is the T. C. Ministry of Interior Gendarmerie General Command Gendarmerie Criminal Department Afterwards, there are subsequently, the Forensic Medicine Institute of the Ministry of Justice of the Republic of Turkey, T. C. the Ministry of Interior, General Directorate of Security Criminal Department, İstanbul University Institute of Forensic Medicine Forensic Sciences Laboratory and KA-MİR Forensic Consulting Expertise and Consulting Co. Ltd.

Conclusion

The contribution of the forensic science to shed light on the crime depends on the reliability of the analysis done in the laboratory and the validation of the data interpretation. For that reason, from the arrival of the evidence to the lab up until the reporting process, each phase should comply with scientific validation, objectivity and auditability. In the accredited forensic institutions in Turkey, each stage from the admission of the sample until the reporting process can be monitored and the results of the analysis is open to internal and external audit. However, this is not the case in the recently opened non-accredited forensic science centers. This situation creates doubt about the operations and impartiality of these institutions as well as the substantiality of their tests. To eliminate this drawback and for the laboratories to meet on a common ground, it should be a requirement for the newly opened centers in the field of forensic science to apply for accreditation. Accredited laboratories which implement ISO 17025 standard; are the laboratories which best meet the expectations of the customers, provide the best quality service, has the quality system which has an audited documentation and backed up by proper maintenance, calibration and work instructions, as well as the current reference materials, ongoing quality control tests and trained personnel. These laboratories are operating independently and impartially, and consequently the test reports they issue achieve international validity. When a laboratory uses the same standards, the same test methods and the same documentations which are valid in every country, it means that accreditation results in worldwide acceptability. The quality management would become a demotivating activity for the personnel where the burden is more than the return only if the standard is misinterpreted. For this reason, the correct interpretation of the standard is the key to quality.

Competing interests

The authors declare that they have no competing interest

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