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Guidance on the Accreditation of Medical Laboratories

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TURKISH ACCREDITATION AGENCY

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1. INTRODUCTION

In accordance with TS EN ISO 15189 standard, a medical laboratory is the laboratory that is capable of conducting biological, microbiological, immunological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, genetic or other analyses with the aim of providing information on diagnosis, management, prevention and treatment of diseases and assessing health status of a person, and that provides consultation services which contain interpretation of results and all laboratory research, including recommendations regarding appropriate future research.

TURKAK provides accreditation service to medical laboratories according to TS EN ISO 15189 standard. Purpose of the accreditation assessments is to decide whether or not the medical laboratory has a system that meets the requirements of TS EN ISO 15189 standard and applicable guidance standards. In case of an accreditation request regarding point of care testing, requirements of TS EN ISO 15189 and those in ANNEX-A of the standard requestioned during the assessment.

Medical laboratory services are essential for patient care, and should meet needs and expectations of all patients and all clinical personnel in charge of caring for these patients. Such services can be listed as arrangement of the analysis requests in medical laboratory study as well as safety and ethical evaluations, and preparation and identification of patient, sampling, and carriage, storage and processing of samples, their interpretation with an eye to their analysis, reporting of the samples and providing recommendations.

2. RELATED DOCUMENTS

- TS EN ISO 15189 Medical Laboratories - Requirements for Quality and Competence
- R10.08 Guidance on Complaints and Appeals
- P701 Procedure for the Accreditation of Conformity Assessment Bodies
- P704 Procedure for Proficiency Testing and Interlaboratory Comparison Programs
- R10.01 Rules for Professional Liability Insurance Obligation of Accredited Organizations

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- R10.06 Requirements on the Use of TURKAK Accreditation Mark by Accredited Organizations
- R10.12 Guidance on Metrological Traceability
- R20.09 Guidance on the Accreditation of Laboratories Providing Services Through Branches
- R20.21 Guidance on TURKAK Marked Medical Analysis Reports
- R20.28 Guidance on Flexible Scope Accreditation of Testing and Medical Laboratories
- R20.36 Guidance on Scope Statement to be Accredited for Medical Laboratories
- EA-4/17 M Description of Scopes of Accreditation for Medical Laboratories
- ILAC G26:11/2018 Guidance for the Implementation of a Medical Accreditation Scheme

3. APPLICATION

The procedures related to the receipt of the application for Medical Laboratories are executed as specified in TURKAK P701 Procedure for the Accreditation of Conformity Assessment Bodies, Section 3.1.3 Receipt and Review of Application. In addition:

a) Medical examination and sampling field for which the applicant laboratory requests accreditation are confirmed by contacting the organization. The confirmation process also includes the compliance of the scope requests in the applied field with the field documents to be specified in the relevant scope declaration. If the organization performs internal calibration, it declares the field/range/method for which internal calibration is performed.

Note 1: Internal calibration is a calibration activity which is not covered by the scope of the laboratory's own accreditation, but provides its own metrological traceability only for its own devices and does not provide this service to another laboratory. The assessments of the organizations performing internal calibration activities are conducted by adding a calibration expert in the relevant field to the assessment team.

b) The scope of accreditation applied by the organization is assessed in terms of its accreditability. This assessment includes, but is not limited to, the following steps:

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i. Has accreditation earlier been granted domestically/internationally within the scope of the application?

ii. Is there a domestic/foreign accreditation practice in the domain applied?

The assessment of the application is recorded by F701-085 Application Review Form. If needed, technical expert opinion may be consulted in the relevant field.

When determining the laboratory scope, the issues above and the issues specified in Article 4.1 shall be taken into consideration.

The laboratory, which applies for accreditation, is required to establish a management system in line with TS EN ISO 15189 standard and to be operating such system for at least three months.

Laboratories applying for the initial accreditation perform internal audit and management review for the entire system, and submit their records to TURKAK.

When the laboratory accesses the relevant area in the TÜRKAK e-Portal, it selects its scope from the scope catalogue as stated above and/or edits and adds it in accordance with the R20.36 Guidance on Scope Statement to be Accredited for Medical Laboratories, and then approves the application.

4. IMPLEMENTATION OF TS EN ISO 15189 IN LABORATORY ACCREDITATION

In laboratory applications of TS EN ISO 15189 standard, organizations that want to be accredited or are already accredited by TURKAK must comply with the following matters.

4.1. Determination of Laboratory Scope

The laboratory specifies in its documentation that it declares to comply with the requirements of TS EN ISO 15189 and the related documents.

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R20.36 Declaration of the Scope to Be Accredited for Medical Laboratories shall be referred for more detailed information regarding scope.

The laboratory cannot declare compliance with TS EN ISO 15189 standard during the test activities that are continuously outsourced. Accreditation is not granted in these scopes.

Calibration activities performed internally shall also be included in this declaration. Accreditation assessment is planned based on the declaration of the laboratory.

4.2. Ethical Conduct

A laboratory shall not engage in practices restricted by law and shall try to avoid situations that cause conflict of interests. Protection of ethical standards is the common responsibility of the laboratory and all the healthcare providers such as laboratory manager phlebotomist or nurse. All of the patient samples shall be treated equally. There should be no discrimination based on gender, age or race in the analysis of patient samples. It is expected that all samples will be analysed for the right patient at the right time and with the right result.

Confidentiality should be maintained in every phase of the process, including transport of samples and data entry. Confidential information about patients and details about tests should only be given to appropriately competent, sufficient and relevant personnel. In case of the tests where devices are mostly used, confidentiality is ensured by automation. However, in manual tests, utmost care should be shown towards the matters about the protection of confidentiality. Confidentiality should be observed and maintained at any laboratory stage, because patients have the right to reject the analysis of their samples even after their collection and processing. Also in point of care testing, attention should be paid to protect confidentiality as much as possible. In order to ensure permanent protection of the confidentiality of patient information, the laboratory should own a documented procedure and effective implementation of the procedure should be verified.

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Patients have a reasonable expectation that their samples will be used only for the laboratory tests which are requested by a clinician. They have the right to decide on when and how their records or samples will be used for the purposes other than the usual medical care for which they give consent. If leftover samples are used for different test(s) for clinical or research purposes, approval from the patient, a local ethics committee, or management must be obtained. Additional samples should not be collected for research procedures without informed consent from the patient and approval from the appropriate ethics committee.

The laboratory should set and implement policies on retention and destruction of medical records and storage and disposal of samples. The personnel authorized to have access to medical records such as physicians, patients and laboratory personnel should be designated and such designation should be documented.

4.3. Impartiality and confidentiality

The laboratory shall conduct its activities in a way to assure issues related to impartiality and confidentiality. The laboratory conducts risk assessment to ensure the impartiality of its activities, and evaluates it continuously.

Risk assessment is not tied to any methodological condition in the standard, and conducted in accordance with the level of impartiality (first, second and third parties) declared by the laboratories, the legislation and other mandatory documents to which they are subject to, and the risk caused by impartiality hazard. The laboratory designs the entire system by evaluating the hazards and possible risks that may affect its impartiality.

Risk assessment identifies potential hazards/scenarios/threats related to impartiality, control measures in place to prevent the occurrence of such circumstances, and how to manage the process in the event of a hazard, and specifies these in relevant documents. It must determine

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how to eliminate the identified hazard related to impartiality or how to minimize the risk in all cases.

Risk assessment of impartiality should at least consider the hazards that may arise from situations such as property, administration, management, personnel, shared resources, financial transactions, contracts, marketing (including branding), sales commission payments or other incentives for the guidance of new users.

The laboratory is responsible for the management of all information obtained or generated during the course of its activities in line with legal obligations. The laboratory secures the issues related to user confidentiality by a method that can hold it legally accountable, such as a contract with the user. However, when the requirements of law, legislation etc. conflict with the requirements of the standard, legislative provisions are valid. If the legal authority wishes to access user/patient information without notifying the user/patient, the user/patient will not be informed about the fact that the information was shared. This should be specified in user contracts.

4.4. Structural Requirements

Organizations should define managerial functions responsible for laboratory activities. No matter how it is expressed, the function that provides the resources needed by the laboratory, that initiates the final process for the procurement of resources, and that is responsible for laboratory activities should be accepted to be the laboratory management.

The laboratory must be a legal entity or a defined part of a legal entity that can be held legally accountable for its activities, or the purposes of this standard, a public laboratory is considered to be a legal entity with public status. In the assessment of the laboratories with public legal entity status, it is enough to see the document showing the public legal entity status such as the institutional act, regulation, Decree-Law etc. Organizations with public legal entity status are required to make declaration of assurance instead of professional liability insurance.

The laboratories with private law legal entity status must have registered under the Turkish Commercial Code. Associations, foundations and chambers of professions can establish

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enterprises to perform laboratory activities that are registered under the Turkish Commercial Code. It is sufficient for organizations having such legal entity status to show their Trade Registry as document and record for their legal entity status. Organizations having such legal entity status are required to have a professional liability insurance.

In case of the organizations which provide services through branches, requirements to hold the branches legally accountable are follows: pursuant to the Turkish Commercial Code, the branches are required to be registered or in the absence of registration, the branches are required to have tax office record so that their content can be examined. Detailed information on accreditation with branches is provided in R20.09 Guidance on the Accreditation of Laboratories Providing Services Through Branches.

While providing service, accredited bodies may experience legal issues originating from the possibility of damage in goods and items which may lead to liabilities due to human factor, and from decisions of clients taken based on the services they provide. In such cases, TURKAK aims to safeguard interests of itself and its clients with professional liability insurance. Such insurance should be prepared as a result of the assessment made by the laboratory depending on the possible damages and scope of the projected risk, and should contain the test activities that it undertakes. Laboratories with private legal entity status are required to have professional liability insurance whereas organizations with public legal entity status are not. Mandatory liability insurance against medical malpractice, which is obligatory in medical laboratories, does not supersede professional liability insurance.

Detailed information on professional liability insurance is provided in R10.01 Rules for Professional Liability Insurance Obligation of Accredited Organizations.

In case of any change in its organizational structure, “F701-105 Structural Change Notification Form” and its annexes should be sent to TURKAK at a reasonable time before the change, if possible. Otherwise, they should be delivered to TURKAK within 15 days at the latest after the change.

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4.5. Personnel

The laboratory employs all personnel (internal or external personnel) in accordance with its management. Employment contracts for all personnel must be written in all cases and must comply with the provisions of the Labour Law No. 4857. A contract stating issues such as impartiality, confidentiality, working conditions etc. is executed in writing between the laboratory and related personnel for the types of work that are not required to be executed in writing pursuant to the Labour Law No. 4857. For personnel employed abroad, a contract including the above-mentioned issues is executed in writing that takes into consideration the local legislation of the relevant country. Contracts are executed directly with the personnel, recorded and made available for the assessment teams. SGK (Social Security Institution) notifications made by taking into account the work period of the personnel in charge of managerial functions are kept available to be shown to the assessment team.

Personnel involved in quality management duties in medical laboratories are employed full time. laboratory; The full-time personnel in question is expected to receive the "SGK Service Report" with a QR code via e-Government every six months in accordance with the Personal Data Protection Law No. 6698 and to keep its records. In TÜRKAK assessments, records taken at most one week before the assessment date are shown to the assessment team. In cases where it is not possible to employ the personnel involved in quality management full-time, TÜRKAK is contacted, the reasons are stated and the decision of TÜRKAK is acted upon.

Apart from the issues mentioned above; If the laboratory does not take responsibility for the social security of its personnel, it keeps the social security records showing the other working relationships of the personnel in question to be presented to the assessment team during TÜRKAK assessments. In addition, the laboratory specifies the arrangements that will ensure these issues in its contracts.

Different assessments do not exist with regards to competence, monitoring etc. between the internal or external personnel in the laboratory. All personnel should be monitored. Contributions due to personnel performance should be included in verification or validation studies, without

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regards to the involvement of internal or external personnel. When a different case is concerned, the reasons should be presented to the assessment team.

Competence monitoring should be determined in accordance with the status of the laboratory activity (risk, frequency, etc.).

In order to fulfill the requirements of the TS EN ISO 15189 standard, a medical laboratory must be managed by a laboratory management consisting of a person or persons named "laboratory manager" who has certain qualifications, competence, delegated authority, responsibility and resources. These manager(s) may delegate duties to sufficient and competent personnel, provided that documentation is provided.

TS EN ISO 15189 standard specifies the duties that need to be fulfilled for quality management and technical management. There is no difference between the assignment of these tasks to a single person and naming that person “quality manager, etc.”, and the division of duties and the fulfilment of the activities in question by multiple personnel. It should be considered that if a division of duties is made, an additional control element must be defined in the system to check whether the activities are conducted consistently.

The laboratory can designate its personnel in critical positions for activities for which they are accredited. Communication channels should be established to ensure continuous access to said personnel. Appointment of appropriate agents is also an option to ensure the continuity of these functions. When the laboratory identifies critical personnel, it should also consider personnel whose absence may cause an activity in the scope of accreditation to stop (e.g., a single analysis person authorized in a scope).

In all cases, as stated in Article 4.1.10 of the Accreditation Agreement, personnel changes affecting activities within the scope of accreditation is notified in writing to TURKAK within the time period specified in the agreement. After this notification, TURKAK assesses the status of the laboratory, and depending on the content of the change, may choose not to make any changes

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in accreditation status, or may partially or completely suspend or withdraw the accreditation, or request on-site assessment.

4.6. Equipment, Reagents and Consumables

Medical laboratories need to possess all equipment required to provide service. The laboratory equipment consists of any equipment that has an impact on activities of the laboratory. It can be listed as hardware and software of devices, measurement systems and laboratory information systems or sample transport systems. Under normal circumstances, the organization should only use the equipment that it owns, or the equipment that was leased or loaned to the organization on a long-term basis. In the event that a laboratory needs to utilize the equipment which is out of its permanent control, it should show conformity of the equipment with TS EN ISO 15189 standard, and demonstrate that the equipment used was considered in verification/validation studies (if necessary).

In all cases, as stated in Article 4.1.10 of the Accreditation Agreement, changes (equipment change, equipment location change, etc.) affecting activities within the scope of accreditation is notified in writing to TURKAK within the time period specified in the agreement. After this notification, TURKAK assesses the status of the laboratory, and depending on the content of the change, may choose not to make any changes in accreditation status, or may partially or completely suspend or withdraw the accreditation, or request on-site assessment.

Medical laboratories should keep an inventory list including entire equipment that they have and use throughout their activities. This inventory list should meet all requirements of TS EN ISO 15189 standard. This list should be updated when a new device is purchased or an existing device is decommissioned.

To assure the quality of analysis results, TS EN ISO 15189 standard stipulates replacement of the device, if necessary. Still, there is no obligation to have spares for the equipment in use. Nevertheless, laboratories may choose to keep spares of some equipment depending on the risk status of the activities they perform. In cases where spare equipment is kept, such information

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should be included in the inventory list and similar to all devices, relevant records related to spare equipment should be made ready for sharing with TURKAK.

The medical laboratory is required have a documented procedure for calibration of the equipment which affects results of analysis directly or indirectly. Besides, the laboratory needs to follow the requirements in R10.12 Guidance on Metrological Traceability in order to ensure metrological traceability of the devices it uses. The cases mentioned in R10.12 Guidance on Metrological Traceability are of first priority. However, in the event where they cannot be applied based on a valid reason, the medical laboratory may implement the tools specified in TS EN ISO 15189 standard with the aim of achieving reliability in results.

4.7. Referral Laboratories

A referral laboratory is a laboratory to which laboratory management chooses to send a sample or subsample for analysis, data for analysis or interpretation, or a sample to use when routine analyses cannot be performed.

A laboratory may temporarily outsource the work to an external service provider (to referral laboratory) due to unpredictable reasons (e.g. workload, temporary capacity decrease, etc.). Laboratories cannot constantly use external service providers within the scope of their accreditation.

Except for force majeure, the laboratory receives outsourced laboratory activity services, in accordance with the work to be done, from an organization accredited for the activity requested by TÜRKAK or by an accreditation body that has a medical examination recognition agreement or recognition agreements to which TÜRKAK is a party.

Forces majeures are cases such as legal provisions, non-existence of another accredited organization in the same domain, etc. In such cases, the laboratory receiving the external service assures the compliance of the services received. This assurance may be provided by an assessment of the reference laboratory or by other laboratory-developed procedures. In such

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cases, in order to see the compliance of the laboratory receiving the service, TURKAK may supervise assessments conducted by the laboratory receiving the service in relation to assuring the compliance of the external service received. The laboratory receiving external services includes the necessary provisions in its contract that will allow the reference laboratory to ensure the above-mentioned supervision in the laboratory. In any case, the laboratory receiving the service must ensure compliance of the reference laboratory for the work to be done. The fact that the reference laboratory is accredited is an important criterion to ensure such assurance, but whether such assurance is enough or not should be determined by the organization receiving the service.

The medical laboratory should keep a list of the reference laboratories or the consultants that provide opinions and comments in any domain (pathology, cytology, genetics, etc.) to them. Laboratories should convey the procedures, analyses, reports and consultancy services, management of critical outcomes, necessary personnel qualifications and requirements for demonstrating competence to reference laboratories and consultants.

4.8. Sample Collection and Sample Receipt

Within the scope of TS EN ISO 15189, accreditation cannot be given only for the sampling activity, but if a medical laboratory is also accredited for the primary sampling activity, this activity will be defined within the scope of accreditation. In cases where it is not stated that the primary sample collection is done by the laboratory, it shall be assumed that the samples have been supplied externally. will be assumed to come from outside.

In the medical laboratories where sample collection is conducted, sufficient space should be allocated for pre-analytical activities in order to ensure that work quality, safety of personnel and patient care services are not put at risk. Laboratory equipment and essential materials are required to be able to support activities of the facility as well as being functional and reliable. Standard working instructions should be applied and trained personnel should be employed to avoid adverse events during the sampling process. Patients, personnel and visitors should be protected from identified hazards. Sampling spaces should be designed with an eye to accessibility,

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comfort, safety, privacy and confidentiality of the patients and personnel. Laws and regulatory requirements need be taken into account, if available.

The laboratories, which do not conduct primary sample collection activities and only receive samples, should assure appropriate delivery of samples and their storage under appropriate conditions for a period until the analysis phase. Processes of recording sampling data need to be included in internal audit and assessment cycle of the facility.

Samples should be labelled with unique identifiers. This is applicable also to all aliquot tubes. Furthermore, samples should be carried in laboratory in a way that their integrity will be preserved.

4.9. Advisory Services

Advisory services in medical laboratories include informing of users and/or providing users recommendations about scientific and logistic subjects such as selection and utilization of analyses, and professional opinions (professional judgements) regarding the necessary sample type, sample quantity, frequency of analysis requests, clinical symptoms, limitations of analysis procedures and interpretation of test results, and durations of giving result, promoting effective use of laboratory services and acceptance/refusal criteria of samples.

The laboratory is required to make sure that the analyses requested are compatible with the needs of patients and users. Recommendations on secondary or affirmative tests (if available) should be given to users duly. Laboratory should acquaint the users with limitations of tests and conditions and/or situations which may assist in interpreting results of the confirmatory or complementary tests.

Results of several analyses (e.g., certain genetic analyses or analyses on contagious diseases) may require special consultancy. Laboratory management should regard that such results containing serious implications are not directly communicated to patient without receiving adequate consultancy service. Requirements of personnel qualifications and competence

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assessments laid down in Article 6.6.2 of TS EN ISO 15189 standard should be taken into consideration also for the personnel who will provide advisory service in interpretation of the analysis results.

Laboratory management should review quality management system also in view of all test activities as well as consultancy services, if available.

4.10. Proficiency Tests and Interlaboratory comparison

As a minimum, laboratories undertake internal and external quality control activities prescribed by the standard that are suitable for their activities. As an external quality control activity, proficiency testing or participation in inter-laboratory comparisons are undertaken in line with the requirements of P704 Procedure for Proficiency Testing and Interlaboratory Comparison Programs.

In order to acknowledge the undertaken quality control activity as an external quality control activity, it is necessary that the evaluation criteria for the results are predetermined and that an assessment outside of the laboratory is performed. The studies and assessments conducted by the laboratory after the final external quality control activity report is submitted are not considered as external quality control activity.

Laboratories need to primarily choose schemes of accredited proficiency testing providers which operate domestically and/or internationally in accordance with TS EN ISO/IEC 17043 standard. In other cases, PT/ILC programs in which the laboratory participates, should be evaluated based on TS EN ISO/IEC 17043 standard, and records of the evaluation should be kept available for presentation to TURKAK.

Laboratories should evaluate their plans in domains where they would like to request a scope extension by the methods specified in P704 Procedure for Proficiency Testing and Interlaboratory Comparison Programs and include them in the relevant TURKAK form.

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4.11. Risk Management

Risk management is the identification, assessment and prioritization of risks followed by the coordinated and economical application of resources to minimize, monitor and control the likelihood and/or impact of undesirable events or maximize the realization of opportunities.

The depth of risk assessment or which cases will be identified as risk relates to and varies by organizational structure, personnel composition and competence level, infrastructure etc. of laboratories. The laboratory should assess pre-analysis, analysis and post-analysis processes and the possible risks in case of emergency.

Risk assessment is a process that contains continuous monitoring and reassessment of the improvement actions which should be updated depending on the changing circumstances. Risk management is not a one-off activity.

Risk assessment should contribute to continuous improvement and target the preferred fields on the basis of the risk assessments.

A risk management system consists of the following steps:

a) Making risk plan,
b) Identifying risk and its effects,
c) Developing strategies to cope with risks, and
d) Monitoring for risk control.

These steps comply with the management requirements in TS EN ISO 15189, including the following ones:

- Identifying and controlling noncompliance,
- Planning preventive and corrective activities,
- Conducting internal audits and management reviews, and
- Applying continuous improvement.

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The laboratory should evaluate the effects of work processes and potential mistakes in analysis results which have an impact on patient safety, arrange the processes for mitigating or eliminating the identified risks and ensure documentation of the decisions and activities undertaken. The risk assessment made should contribute to continuous improvement and the improvements should be made for the preferred fields based on risk assessments.

Risk and opportunity assessment involves identifying, analysing and evaluating risks/opportunities. The purpose of risk assessment is to help decide whether risks need to be reduced and/or improved as a priority, based on the results of the risk analysis.

This is the most basic level of management expected from the implementation of risk and opportunity assessment. The laboratory can execute an advanced risk assessment process. In all cases, the laboratory should practically determine how the risks and opportunities associated with testing, calibration and sampling activities will be managed in a reactive and proactive manner.

The laboratory can evaluate risks and opportunities on the basis of the scope for which it is accredited, taking into account the quality management system in its entirety. While making risk and opportunity assessments, the laboratory can also go through the articles of the standard, focusing on the laboratory activity. There is no restriction on specifying a similar/identical risk monitoring/prevention method for the process approach of laboratories or for risks that may be common to more than one laboratory activity (more than one experiment).

4.12. Quality Indicators

Quality indicators are the parameters originating from the need for reducing failure rate regarding laboratory activities. These parameters contribute to systematic monitoring and assessment of such activities and identification of strategic direction.

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In a medical laboratory, all errors need to be measured and controlled through quality indicators. Utilization of quality indicators is useful for defining the critical phase of each process. Thus, it will be possible to assess medical processes continuously with the aim of detecting the errors. According to TS EN ISO 15189 standard, laboratory management should apply the quality indicators to periodically track and evaluate involvement of the laboratory in patient care.

Laboratories need to set the critical indicators that may influence pre-analytical, analytical and post-analytical processes. The quality indicators set should be auditable and measurable as well as focusing on critical problems and/or processes.

While setting the quality indicators, it is useful to make identification (identification of acceptable/unacceptable limits etc.) in a way that meets needs of the laboratory ideally.

Data collection methods for quality indicators (outputs from database of the laboratory operating system, user and personnel feedbacks, risk analyses, corrective and preventive activities etc.) should be specified in order to assure continuous improvement. Throughout data collection and reporting processes, software can be utilized to facilitate the matters such as measurement of all parameters which should be recorded, shortening of record and process time, comparison of the data measured in different time intervals, application of the procedures etc. Moreover, the objectives associated with the collected data on quality indicators, analysis management, improvement approaches for laboratory activities, review periods and activity plan should be identified.

Quality indicators can be accepted as some kind of internal assessment system. A well-designed internal assessment system allows for identification and systematic monitoring of critical activities. Support of the laboratory management helps application of the quality indicators, which successfully enhance the awareness of the need for executing an improvement process among laboratory personnel. For this reason, the quality indicators should be incorporated in a consistent and integrated quality improvement strategy.

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4.13. Laboratory Management Systems

Medical laboratories may establish and manage a quality management system (e.g. ISO 9001) to implement clause 8.1.1 of the standard. Even if there is a management system that is documented and operated in accordance with the requirements of any standard, assessment teams will check whether a management system that meets the requirements of the TS EN ISO 15189 standard has been created during the accreditation assessment.

Laboratories can submit documentation that they will prepare to ensure the integrity of the quality management system and to demonstrate compliance with TS EN ISO 15189 standard through a Quality Manual.

Laboratories should establish their management systems in accordance with TS EN ISO 15189 and accreditation rules, and document their procedures as necessary to consistently apply their quality management systems in accordance with the standard. When establishing the boundaries of documentation, organizations should also consider that the above-mentioned compliance can be shown to the assessors of the accreditation body, and also ensure the auditability of their systems. For example, as a requirement of the standard, the laboratory management should communicate with the personnel about their duties, powers and responsibilities, but although the standard does not define a method for this communication, it should demonstrate that this requirement is fulfilled, and specify the suitable method of recording (in writing etc.) for this part of the system to be auditable.

4.14. Laboratory Information Management Systems

A laboratory information management system contains all processes needed to effectively manage the data such as patient information, analysis requests, analysis results, evaluation and comments which are sent from external resources or which are sent externally by the laboratory. The information management system can be in the form of a fully non-computerized (paper-based), fully computerized or hybrid system, namely the combination of both.

The laboratory information management system is usually divided into five laboratory phases.

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- Receipt a sample and user/patient data related to this sample and entering it into the system, Assignment, programming and monitoring of the sample and relevant analytical work load,
- Processes and quality control regarding sample, the equipment used and documentation,
- Storage of the data on sample analysis,
- Review, approval and compilation of the sample data for reporting and/or analysis at a higher level.

The functionality of modified commercial off-the-shelf software and exclusive, expedient or custom software, including appropriate running of the interfaces in the laboratory information management system should be validated before starting to use them. For commercial off-the-shelf software, software verification studies should be conducted and records of the software should be kept. In case of any change, including the laboratory-specific software configuration or modifications in the commercial off-the-shelf software, such changes need to be approved, documented, and assessed based on the risk level of the usage areas, and then validated before their implementation.

The laboratory information management system should be designed to protect the created records against deletion by users. Users can edit or disable such records only within their span of authorization. Computerised laboratory information systems need to monitor all records of users (audit trail) and form time stamps of all significant events (generation, editing) for each record. Besides, a risk assessment should be conducted on the functions of the software used in the laboratory, and the deviations observed.

It is important to create a tool for securing the system against data loss. For non-computerized systems, the said tool is the use of safe materials and spaces in order to record and store all information appropriately whereas computerized systems require scheduled or regular backups. Preserving confidentiality of patient information is vital, therefore the laboratory needs to take safety and security measures to protect confidentiality of data.

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Between systems used in the laboratory, between a manual process and a computerized system, between cloud-based applications and storage, across organizational boundaries, for example between production, quality control and quality assurance (internal boundaries), between the laboratory and third parties, for example, service providers (Risks that may be associated with data transfers between external borders should be taken into account. At the same time, appropriate controls should be established to prevent data loss or modification.

In cases where the laboratory information management system is outsourced or operated by an external supplier, the laboratory should ensure that the supplier or system operator complies with requirements (agreement, confidentiality, access and updating, etc.) of the relevant standard.

5. ASSESSMENT PROCESS

TÜRKAK confirms the different branches where medical testing activities are carried out and in which of them important activities are carried out. Important activities are generally processes that affect the competence of the medical laboratory, such as policy formulation, process and/or procedure development and review of the contract when appropriate, planning of conformity assessment activities, review, approval and decision of the results of conformity assessment activities. Based on this, all activities carried out by the laboratory to meet the requirements of the TS EN ISO 15189 standard are considered important activities. The compliance of important activities with the requirements is confirmed through various assessment techniques.

In the selection of the personnel who will perform the assessed activity during the assessment, the "Personnel List and Authorization Matrix" data submitted by the organization to TÜRKAK is taken as basis. These data must be presented in a way that will show which personnel are authorized in which field and activity (analysis, sampling, reporting, etc.) and include all issues such as work experience requested to be reported by TÜRKAK.

If the medical laboratory uses a referral laboratory, TÜRKAK may supervise the assessments carried out by the medical laboratory to ensure the suitability of the activities carried out by the reference laboratory.

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Risk Based Assessment Approach

In accordance with the "P701 Procedure for Accreditation of Conformity Assessment Bodies", an accreditation cycle program is prepared for each medical laboratory, which will ensure that the activities included in the scope of accreditation (scope in the annex to the accreditation certificate) are assessed at the relevant locations, together with the management system throughout the cycle. Changes in the management system and organization are reviewed within the framework of a risk-based approach. The assessment period may be increased depending on the significance of the changes.

When planning assessments within the accreditation cycle of medical laboratories, the risk factors to consider may include, but are not limited to the following:

- Personnel change
- Change of device used in analysis
- Changes in locations
- Nonconformities identified in the previous assessment, observation and/or scopes to examine proposed by the assessment team
- Changes in subcontractor use and subcontractor information
- Unsatisfactory PT/ILC results
- Revised standards, in-house methods, etc. within the scope of the medical laboratory
- Changes in requirements of legal authority, regulations, legislation etc.
- Corrective actions taken by the medical laboratory for nonconformities
- Frequency of conformity assessment activities carried out within the scope of accreditation and the number of medical analysis reports they produce
- Feedback or complaints received from the relevant parties

In the initial accreditation assessment, all scopes and locations of the medical laboratory are assessed. The re-assessments are carried out to include a comprehensive review of medical

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laboratory activities and quality system. Where possible, scope extension assessment conducts with surveillance assessment or re-assessment.

6. OTHER ISSUES

The laboratory should notify TURKAK of the intended changes in its legal status and its address of operation, in writing and 15 days in advance. Following such notification, the laboratory accepts evaluation of the related situation and re-determination of accreditation by TURKAK. Following the address change, TURKAK suspends the scopes found to be affected by moving. The laboratory informs TURKAK in writing when it is ready for the assessment after the suspension decision. TURKAK conducts the assessment as soon as possible and lifts the suspension if there is no noncompliance that hinders maintenance of the accreditation.

Any change, including in the locations where tests are conducted, within scope of the accreditation, should be regarded as scope extension.

In the following cases that may be considered as critical changes, affect process management and accordingly, analysis results, the laboratory is requested to notify TURKAK of such changes that it has made.

- Inclusion or removal of parameters in sub-domains within the scope of the accreditation,
- Change in kits/antibodies in manual technical processes etc. in cases where a new testing method is introduced to Standard Operating Procedure (SOP)'s,
- Change in the basic testing methods the laboratory refers (new version of the same method), or the intra-organizational testing method applied,
- Intraorganizational change in the basic method,
- Change in the device and relevant processes (change in the main device-support device/process management, change in the kit/antibody),
- Starting/stopping of primary sampling activity by CAB,

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On the other hand, minor changes in SOPs, modifications in template of quality documents, revisions of word in documents, spelling errors etc. which do not affect the test result shall be evaluated during routine assessments and there is no need to report to TURKAK separately.

By definition, the laboratories should plan and conduct internal audits in periods of at most 12 months for the whole system including the laboratory activities by persons who are independent of the work being assessed and have the competence required by the work. Management review processes should also be planned and conducted in periods of at most 12 months.

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