



Ministry of Health, Turkey Directorate Healthcare Services

Standards of Accreditation in Health -Laboratory Kit-



Office of Quality and Accreditation in Health-MoH Turkey

Standards of Accreditation in Health
Laboratory Kit v1.0/2015

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Authors-Directorate of Healthcare Services
Office of Quality and Accreditation in Health - MoH Turkey

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We would like to thank you to all institutions that provide laboratory services in SAS Laboratory Kit studies, public associations, other institutional and private stakeholders that set their heart on quality in health.

Department of Quality and Accreditation in Health

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PROLOGUE

Prologue

Nowadays, rapid advances in medical technology and applications have brought significant changes in physical and functional construction of the health services.

Emerging success rates of diagnosis and treatment applications, corresponding increases in number of patients and patient bed turnover, people being more careful about health of themselves and their families can be listed as the cause of the physical and functional changes. These changes affect structural, administrative and designative practices of hospitals and emphasize the need to provide quality health care for patients who need medical care as soon as possible.

So far, a few patient and organizational structure focused accreditation systems have been established for the purpose of development of patient care in the world at an optimal level of quality, creation of a safe patient care environment, minimizing risks concerning patients and employees, a number of quality improvement and patient safety, and performance of healthcare institutions started to be evaluated within these systems.

In Republic of Turkey, foundation of accreditation have been laid in 2003 by studies initiated in the scope of Health Transformation Programme. An important phase of these studies which are conducted in accordance with the “Quality and accreditation for efficient and high quality” objective is development of standard kits which will be used for health institutions by our ministry. One of prepared sets in this context is “SAS Laboratory Kit” which enlightens “Turkey Accreditation in Health System”. This set which was developed for laboratories consists of two parts including standards, assessment criteria and guidelines.

In first part, you can find general information on historical development process relevant to Standards of Accreditation in Health.

Guidelines that include standard requirements which will help interpretation and implementation of standards and assessment criteria can be found in second part.

Standards of Accreditation in Health-Laboratory Kit was developed for medical laboratories such as microbiology, biochemistry, pathology, immunology and genetics.

SAS Laboratory Kit which includes basic accreditation information is provided to all stakeholders for quality improvement in health services.

As we would like to thank you to all stakeholders who contribute to the studies, we wish that SAS Laboratory Kit contributes to national and international laboratory services at an important level.

Department of Quality and Accreditation in Health

Development of the Standards

In Republic of Turkey, foundation of Ministry of Health (MOH) accreditation studies have been laid in 2003 and these studies gained significance among Health Transformation Programme (HTP) principles and MOH policies.

In HTP, planner and assessor roles of MOH, in other words, a ministry structure and practice that determines service standards, sets rules and assesses practice scope and standard implementation level is highlighted. Thus, in line with “Quality and accreditation for efficient and high quality health service” principle, first steps have been taken towards an accreditation system.

Accreditation of health studies which was clearly stated and took place in agenda of Turkey for the first time in 2003, is a result of a long journey. In the first stage of this journey carried out in 2005, determination of quality standards which covers health care services for the first time containing all processes of health care was initiated. Studies in the first stage were aimed to ensure awareness of quality service of managers and employees, determination and documentation of service processes in healthcare institutions. In this context, 100 quality standards were determined in 2005. Number of Quality Standards for Health increased to 150 in 2007, 354 in 2008, and 388 in 2009 with the set for private hospitals and 621 standards in 2011 with last revision. As a result of the standards improving over the years, numerically and the content and scope of standards have developed significantly.

On the basis of the necessity of quality studies having international identity, first steps have been taken for establishment of the Health Accreditation System in Turkey in May, 2012. As a result of studies official co-operation have been initiated by negotiations with ISQua-the accreditor of accreditors on 20.03.2013. In the framework of negotiations and the agreement signed with ISQua, “ISQua International Principles for Healthcare Standards” have been analyzed in detail. In accordance with the inspection of principles, Standards of Accreditation in Health – Hospital Kit was developed taking into account quality needs in Turkey and it was accredited by ISQua on 09th January 2014.

SAS Laboratory Kit

In the scope of on-going health quality studies, first time on 2008, a laboratory services section which consists 19 standards was formed in SKS-Hospital Kit (Version III). On 2011 laboratory related standards have expanded to 3 sections and 65 standards including biochemistry (17), microbiology (24) and pathology (24) laboratory services.

On 2013, Standards of Quality in Health – Tissue Typing Laboratory Kit which consists of 28 standards was developed.

After meetings with ISQua on 2014, studies regarding development of accreditation standards for laboratories have been initiated. SAS – Laboratory Kit was prepared by taking both national and international quality studies, World Health Organization and ISQua principles into account.

This kit has been created taking into account international developments, coverage of all service sections and compatibility for teleological interpretation. Also properties such as service and outcome-oriented approach, encouraging innovation in organizations, highlighting of applicability, being easy to use and inclusive were considered.

Preparation of standard related infrastructure studies covers the first step of standard development process. For this purpose:

- National needs and priorities for quality health service provision is determined.
- Requirements are determined after inspection of ISQua principles.
- Participation of all stakeholders that works on health service provision field is ensured by obtaining their opinion and suggestions.
- Obtained feedback on personal and institutional levels are evaluated.
- Articles such as scientific studies, national and international publications are examined.

It is important to obtain feedback from standard related stakeholders in the terms of ensuring compliance between SAS and field studies in a functional and teleological manner, evaluation of standard applicability and increasing awareness on field.

In this framework, “**SAS Opinion and Suggestion Platform**” has been established and all stakeholders’ feedback is obtained via this platform on determined periods. Thus, regarding SAS Laboratory Kit, following stakeholder feedbacks were obtained via “**SAS Opinion and Suggestion Platform**”.

Institutional Stakeholders:

- TPHI Microbiology Reference Laboratories Department
- TPHI Public Health Laboratories Department
- Provincial Health Directorates
- Hospitals
- Turkish Biochemistry Association
- Clinical Biochemistry Specialists Association

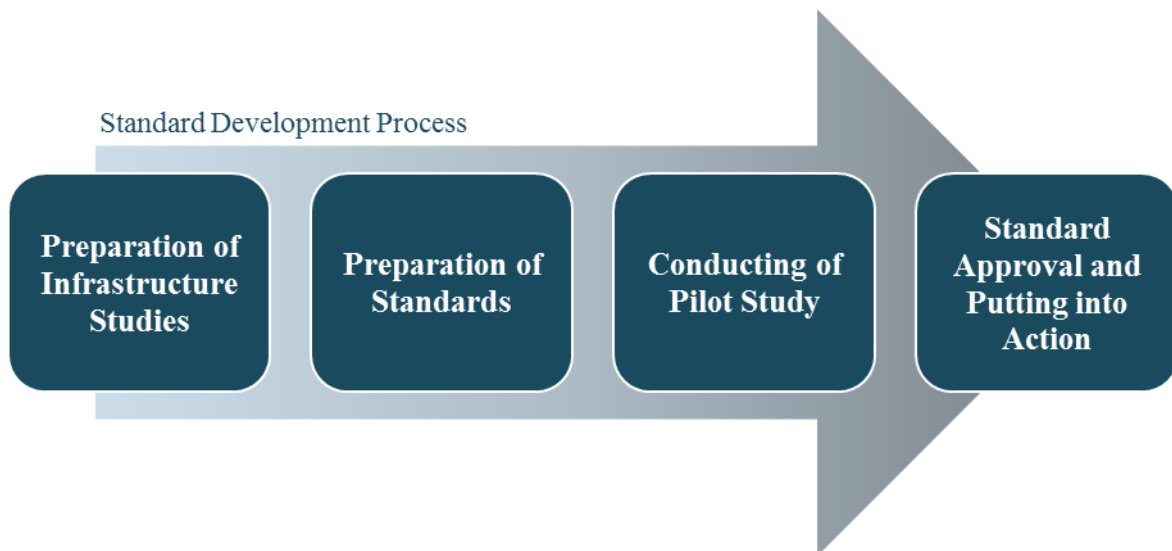
- Turkish Clinical Biochemistry Association
- Clinical Microbiology Specialty Association
- Federation of Pathology Associations
- Turkish Microbiology Society
- Turkish Parasitology Association
- Other Public Associations

Personal Stakeholders:

- Institution Managers
- Provincial Quality Coordination Unit Staff
- Quality Assessors
- Quality Management Directors
- Unit Quality Supervisors

Feedbacks obtained from these stakeholders are evaluated by department employees and used for new standard and revision studies. After studies with experts, pilot studies of developed or revised standards are initiated. After pilot study, obtained data is reflected to standard and final form of the standard is finalized.

Standard development process is shown step by step on scheme below.



Objective and Scope Standards of Accreditation in Health

Standards of Accreditation in Health is structured within the framework of principles of World Health Organization and ISQua such as patient safety, quality improvement, patient and service user focus, corporate planning and performance in accordance with basis of minimum risk, optimum quality, maximum security.

SAS-Laboratory Kit has been prepared for medical laboratories in public, private, university hospitals and private medical laboratories which provide services in microbiology, pathology, tissue typing and genetics fields.

Laboratory Kit of Standards of Accreditation in Health primarily aims to create objectives of success related to standards being met in laboratories. In this context, it has been prepared for all laboratories providing service in Turkey.

Goals of Standards of Accreditation in Health – Laboratory Kit

Standards of Accreditation in Health is prepared to accomplish quality goals shown below for ensuring quality of hospitals in the terms of needs and priorities of Turkey considering WHO Patient Safety goals, principles of ISQua, accreditation programs around the world across the globe.



Goals mentioned above must be achieved in order to accept that services provided by laboratories are in high quality.

These objectives can be addressed in two categories in general, goals contained in the first category defines the methods of service provision of institutions. In other words, it means organizational goals related to how good institutions provide services. (Efficiency, Efficacy, Productivity, and Healthy Work Life)

Goals contained in the second category directly concerns service users. (Patient Safety, Equity, Patient Orientedness, Convenience, Timeliness, Continuity).

Intention of categorization of targets presented here is only for clearance. For example, in an institution which cannot provide a healthy working environment it will be impossible to ensure a patient-focused approach. Besides goals not having priority relations between, achieving goals in accordance with each other is a significant point emphasized by the Standards of Accreditation in Health.

Definitions of SAS goals are shown below:

- **Efficacy:** Measure of achieving planned objectives
- **Efficiency:** Ability to perform tasks in a correct way
- **Productivity:** Relationship between provided service and the amount of resources used, use of minimum resources to achieve planned goals
- **Healthy Work Life:** Providing an ideal and safe working environment and infrastructure for health employees
- **Patient Safety:** Improvement activities and measures to be taken to keep all foreseeable hazards that can lead to harm service users at an acceptable risk level
- **Equity/Fairness:** Ensuring usage of all services depending of treatment and care needs equally without any discrimination
- **Patient Orientedness:** Ensuring participation of patient to diagnosis, treatment and care processes taking into account of his/her requests, needs and expectations for all services provided
- **Convenience:** Implementing more healing than harm of patient during decided medical treatment and processes
- **Timeliness:** Providing diagnosis, treatment and care services according to the needs of the patient in the most appropriate and in an acceptable period of time
- **Continuity/Sustainability:** Ensuring further medical services to go on chronologically and interdisciplinary and after discharge

Structure of SAS Laboratory Kit

Standards of Accreditation in Health – Laboratory Kit includes 7 aspects, 22 chapters, 30 standards and 146 assessment criteria.

SAS Laboratory Kit consists of standards, assessment criteria and related guidelines. In guidelines, goals, objectives and standard requirements can be found. Standards must be interpreted and implemented as a whole including assessment criteria and relevant guidelines.

Aspect Structure of SAS Laboratory Kit

Seven aspects of Standards of Accreditation in Health – Laboratory Kit are as following:

- Management and Organization
- Performance Measurement and Quality Improvement
- Healthy Work Life
- Patient Experience
- Health Services
- Support Services
- Emergency Management

General Objectives and Scope of Aspects

The aspects of SAS Laboratory Kit are determined on the basis of provided services in laboratories, management activities and people involved in service in a way that cover all sections of them.

a. Management and Organization

In the aspect of management and organization, aim is to ensure a management structure which will maintain the continuity of functioning of hospital, along with creating an efficient corporate quality management structure consisting both executive management and employees.

To achieve this goal, hospital need to establish an organizational structure, determine basic policies and values, create a structure of quality management, maintain document management, install safety reporting system, implement risk management and training management, study for the development and improvement of health promotion, and establish a good corporate communication.

b. Performance Measurement and Quality Improvement

Main aim of this aspect is to detect problems in time related to provision of services about especially administrative, financial and medical processes, correct them and conduction interventions for quality improvement. Achievement of this aim can be done by using determined corporate and SAS indicators.

c. Healthy Work Life

In this aspect, for the provision of quality health service it's aimed to provide employees a healthy work environment and inspecting laboratories in employees' perspective.

For this purpose, hospitals need to create a structure for management of human resources, take precautions for factors threatening employee health and security and determine requirements to improve work life.

d. Patient Experience

Patient experience aspect aims to examine services in perspective of patient for ensuring basic patient rights, patient safety and satisfaction.

To achieve this objective, hospital services provided need to be regulated in a way that protects the rights of patients and their caretakers, implements service accessibility in time, ensures comfort, safety and security of patient.

e. Health Services

Ensuring all provision of services in laboratory in the scope of SAS goals is the aim of this aspect. For this purpose, laboratories need to implement studies related to laboratory services, control and prevention of infections, sterilization services chapters.

f. Support Services

In support services aspect, it's aimed to establish required infrastructure for safety and continuity of medical service processes. For this purpose, laboratories need to form a plan about regulations for facility management, waste management, information management, materials and devices management and outsourcing.

g. Emergency Management

This aspect aims laboratories to interfere in fastest and efficient way to prevent dangers and damage in situations such as natural disasters (earthquake, flood, etc.), emergencies (fire, explosion, etc.), baby or child abduction, sudden respiratory or cardiac arrest cases and violence to the employees.

Coding of Standards of Accreditation in Health

Coding system was developed in order to ensure the traceability of standards by providing them an identity.

Coding System

- » Code of standard consists of four parts.
- » First two parts consists of letters and last two parts consists of numbers.
- » Alphabetical parts include two letters, and are abbreviations of related aspect and chapter.
- » Numbers at last two parts (3rd and 4th parts) include two-digit numbers.
 - Third part corresponds to standard number in chapter.

- Fourth part corresponds to assessment criterion number of standard.
- In fourth part, “00” corresponds to standard itself, increasing digits like “01” and so on corresponds to order of assessment criteria.

Codes related to aspects are as following:

Aspect	Code
Management and Organization	YO
Performance Measurement and Quality Improvement	PÖ
Healthy Work Life	SÇ
Patient Experience	HD
Health Services	SH
Support Services	DH
Emergency Management	AD

Codes related to each chapter are as following:

Code	Chapter Name		
YO.OY	Organizational Structure	SÇ.ÇG	Employee Health and Safety
YO.PD	Core Policies and Ethical Values	HD.HD	Patient Experience
YO.KY	Quality Management Structure	SH.LH	Laboratory Services
YO.DY	Document Management	SH.EK	Control and Prevention of Infections
YO.GR	Safety Reporting System	SH.SY	Sterilization Management
YO.RY	Risk Management	DH.TY	Facility Management
YO.EY	Training Management	DH.AY	Waste Management
YO.Kİ	Institutional Communication	DH.BY	Information Management
PÖ.KG	Institutional Indicators	DH.MC	Material and Device Management
PÖ.SG	SAS Indicators	DH.DK	Outsourcing
SÇ.İK	Human Resources Management	AD.AD	Emergency Management

A coding example of a standard is given below:

Standard Code	Standard	AC Code	Assessment Criteria
YO.OY.01.00	An organisational structure to cover all laboratory activities must be established.	YO.OY.01.01	All vertical and horizontal relations in the organisational structure, from senior management to subunits, must be defined.
		YO.OY.01.02	Within the organisational structure, duties, powers and responsibilities of all units and staff must be defined.
		YO.OY.01.03	Responsibilities must be identified for units defined in organisational structure.
		YO.OY.01.04	It must be ensured that policies, procedures, processes and plans are implemented in areas of responsibility defined on the basis of organisational structure.

Measurement System (Determining the Level of Coverage of Standards)

In the scope of measurement system used to determine the level of fulfillment of standards, standard, assessment criteria and related guidelines are addressed as a whole.

Standards of Accreditation in Health covers all service fields with its structure established as aspects and chapters.

All related service areas and processes of organization are inspected according to the assessment criteria of standards.

In accordance with standard/chapter goals and objectives, standard and assessment criteria are evaluated for determination of coverage.

Evaluation Criteria

» **Evidence:** All solid information to determine if standard/assessment criteria is met or not. (Medical records, documents, observations, interviews, images, etc. submitted to or obtained by assessors)

» **Implementation:** Performing processes and actions by planning, defining policies and processes related to standard/assessment criteria.

» **Continuity:** Applications related to standard/assessment criteria being provided continuously, not only during certain periods or periods of time.

» **Scope:** Implementation of standard/assessment criteria in all related parts of laboratory.

» **Traceability:** Accessibility of information retrospectively created or took place in a process related to standard/assessment criteria.

» **Participation of Employees:** Employees awareness, knowledge and implementation of

quality practices in Laboratory related to standard/ assessment criteria.

» **Range of Effect:** Determination of missing elements to be individual or system-wide for the goals of standard/assessment criteria, also refers to magnitude of effect if determined deficiency is system-wide. In practice a low amount of errors compared to general refers to a individual range of effect, determination of high amount of errors in general refers to a system-wide range of effect.

» **Risk Aspect:** Risk of determined missing elements to be hazardous to the patient or staff safety.

Determination of Coverage Level

Determination levels of standards and assessment criteria are defined in three categories shown below:

- » Met
- » Partially Met
- » Not Met

Determination of the level to meet the standard is based on the goals and objectives. At this point, standard, assessment criteria and related guidelines are considered as a whole.

By considering standard requirements mentioned in standard, assessment criteria or guidelines, assessment is conducted taking into account the terms following;

- » Coverage level of provided/obtained evidence to meet standard and assessment criterion
- » Level of implementation of the standard and assessment criterion
- » Level of continuity of the standard and assessment criterion in practice
- » Level of implementation of standard and assessment criterion in all related parts of the Laboratory
- » Level of traceability of the standard and assessment criterion
- » Level of employee participation for related standard and assessment Criterion

After conducted assessment,

In the event of following situations, the standard and assessment criterion is evaluated as 'Met':

- Non-existence of any risk aspect relevant findings
- Meeting minimum 90% of each relevant criteria
- Meeting minimum 90% of assessment criteria
- Detected defects being not at systemical but at individual level and able to be fixed in a short term (1-3 months)

In the event of following situations, the standard and assessment criterion is evaluated as ‘Partially Met’:

- Non-existence of any risk aspect relevant findings or existence of a low risk one
- Meeting minimum 60% of each relevant criteria
- Meeting minimum 60% of assessment criteria
- Detected defects being not at systemical but at individual level and able to be fixed in a short(1-3 months) or middle term (3-6 months)

In the event of following situations, the standard and assessment criterion is evaluated as ‘Not Met’:

- Existence of a detection relevant to risk aspect at medium or high priority level
- Finding of at least one relevant criterion as insufficient
- Not meeting minimum 60% of assessment criteria
- Detected defects being at a systemical level

During determination of the level of coverage whether standards are met or not, level of implementation of goals and objectives related to standard along with coverage of assessment criteria is also to be considered with a holistic perspective. For example, If all of assessment criteria are met, standard is also scored as “Met”. However, in cases when a few

assessment criteria are “Partially Met”, assessors can decide scoring the standard as “Met” with a holistic perspective.

Exclusion in Assessment

In cases when a chapter, standard, assessment criterion or a standard requirement in guidelines isn’t in relevance with laboratory services, related standard, assessment guide or standard requirement is excluded from assessment process.