



# Standards of Accreditation in Health

Laboratory Kit v1.1/2016



**Standards of Accreditation in Health  
Laboratory Kit v1.1/2016**

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**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**

# DEFINITIONS



**Accommodation Service:** In the health facility, except of the scope of medical services, they are services offering the accommodation, cleaning, washing services for patient's relatives and staff, also food service for employees and ensuring to give these services in a safety environment which provides life and property safety.

**Adverse Event:** Events that may or does affect the safety of patient, relatives, employees or the other people negatively in health facilities.

Adverse events related to patient safety may occur in the terms of drug safety, transfusion safety, facility safety, falls and information security.

Adverse events related to employee safety may occur in the terms of stab wounds, facility safety, occupational infections, contact with blood and body fluids.

**Analytic Period:** Test processes between sample analysis and approval of the results

**Antisepsis:** Killing of microorganisms in or on living tissue or inhibition of reproduction of these microorganisms is called antisepsis.

**Asepsis:** The measures taken to avoid the migration of germ to clean surface, medium or material is called asepsis.

**Basic Policy:** Determining the health facility's mission and vision with corporate goals and objectives.

**Calibration:** A number of processes correlating between the values which a measuring device or measuring system show and known values of measured ones under certain circumstances.

**Chemical Waste:** Gas, solid or liquid waste of chemicals used in medical fields such as treatment or diagnosis and which may be harmful to the health of humans and the environment with various effects.

**Code of Document:** Providing traceability of the document, the document management system directory refers to the identification system established in accordance with the rules set by institutions and organizations.

**Consent Document:** Applied for medical Treatment, process will be transferred to the patient by health care providers with information and documents are created to get the consent of the patient.

**Container:** Temporary storage unit with 0,8 m3 volume at least, wheel, cap, caps lock, made of stainless metal, plastic or material and so on.

**Contamination:** Being infected with foreign matter. Transition of bacteria and virus from contaminated surface to another.

**Contraindication:** Situation that prevents a treatment administration or discovery of patient status/complication that prevents treatment or intervention

**Corporate Communications:** In the process of production and management; institution that make up the information flow between departments and elements, motivation, integration, education, decision making and control functions such as implemented in the framework of certain rules in order to ensure, and the process carried out taking into consideration the reputation of the institution while interacting with the external communication.

**Date of Publish:** The documents was refered to date of publish.

**Decontamination:** As well as, as a word includes all applications for removal of micro-organisms or organic soils (cleaning, disinfection, sterilization), it is used

in the meaning of removal of organic substances and pathogens from a surface or material by pre-cleaning process comprising physical and / or chemical methods and making the surface or material useable without using any personal protective before sterilization or disinfection in practice.

**Dialysis:** General term for dialysis method practices in order to remove residual liquid and toxic matters accumulated in body due to kidney failure or other reasons

**Dialysis Center:** In general, defines one day treatment institutions formed in comply with relevant legislation in which hemodialysis and/or peritoneal dialysis methods are practiced on adult and child dialysis patients.

In Turkey, consists of the following units:

- Dialysis Units in Public Hospitals
- Dialysis Units in University Hospitals
- Private Dialysis Centers

**Disinfection:** The process of destruction or stopping reproduction of the majority or all of the pathogenic microorganisms (except bacterial spores) on inanimate surfaces. Disinfection process is considered in three groups high, medium and low disinfection according to the affect levels of bacterial spores and mycobacteria.

**Document:** Environments containing the information.

**External Document:** Document not prepared by the institution itself, but benefited from the realization of the activities.

**External Quality Assessment Programme:** Programmes in which laboratory analytic performances are assessed in determined periods

**External Quality Assessment Test Sample:** In the scope of external quality assessment programmes, unknown test sample which is prepared by quality assessment center and is sent to participant laboratories in regular intervals

**Facility Management:** For health facility in order to achieve its purpose, it is coordination of all activities related to planning, application and management of necessary working environment physical and functional arrangements which provides the best way to meet the growing health care needs.

**Fire Detection Systems:** Indoorsystems that protect life and property against fire via early warnings

**Form:** Document prepared for filling write the desired data or information.

**Goal:** Refers to the general results that the organisation wants to reach in the long term.

**Guide:** The document was created for informational purposes and guiding activities.

**Hand Hygiene:** It is a general term referring to any action of handcleansing.

**Handover:** In order to ensure the patient safety and continuity of care, it is a transfer of patient's special information from a caregiver to another or from a system featured in an organized team to another with a modern interaction process transferred in an interactive way.

**Hazardous Waste:** Genotoxic, pharmaceutical and chemical wastes arising from units and wastes containing heavy metals and pressured containers.

**Healthcare Associated Infection:** These infections are the ones which develop after

the patient is admitted to the health facility and which are not on incubation period on admission. Service associated infections after discharge and occupational infections are included in the matter.

**Hemodialysis:** Standard, hemodiafiltration and other dialysis methods practiced at dialysis centers or home via hemodialysis device by the use of artificial membranes

**High Risk Medicine:** These are the medicines that are therapeutics and maximum dosages are close to each other. When used in a wrong way, these can affect the patient negatively irreversibly or permanently.

**High-Level Disinfection:** Some of the chemicals may kill all spores by long term (3-12 hours) treatment. In similar concentrations but in a shorter treatment period (e.g. 20 minutes with glutaraldehyde) the same disinfectant kills all microorganisms except bacterial spores. This process is called high-level disinfection.

**Household Waste:** Non-contaminated wastes, which is mainly originated from kitchen, garden, and administrative units

**IMS:** Information Management System. Trained users and devices connected to the computer through a network of institutions, every effort is made to perform with electronic software to maintain the record.

**Indication:** It is a term, which refers that situations, in which should be done an application, a treatment or a process.

**Indicator:** When a topic becomes digitized and measured, this is a tool that contributes to making improvement activities.

**Infectious Waste:** All kinds of body fluids and human tissues, organs and other pathological material; blankets, sheets, bandages, adhesive tape, tampons, swab and other wastes; bacteria and virus retaining air filters which known as infectious agents carriers or likely to carry them.

**Information Security:** It means to protect the information from damages and to prevent obtaining the information by unwanted users in any environment using the appropriate technology in the right way for the right purpose.

**Institution:** Dialysis Centers which provides service actively in Republic of Turkey

**Institutional Structure (Design):** Institutional structure includes authorities and responsibilities in institution and forming communication channels. Organizational structure of the health institution is formed after these studies. This structure is shown in the organization scheme. In the organization schemes, positions in the institution, units, departments and authority, responsibility and communication relations between them are shown.

**Instruction:** A single document containing the steps of the activity.

**Intended Population:** Employees of the company, people who get the service and all the people that interact with the organization and institutions (media, insurance agencies, suppliers, government agencies, non-governmental organizations, universities, local government units, community leaders, experts, etc.)

**Internal Quality Control:** Control of measurement performance against known samples

**Isolation Precautions:** Activities carried out and measures to prevent transmission of a pathogen microorganism from person to person, from person to environment or vice versa.

**List:** Similar items listed consecutively document.

**Low Level Disinfection:** In this process, in a short time (less than 10 minutes) most of the vegetative bacteria, some fungi and some viruses dies.

**Matrix Structure:** Matrix structure is the use of both functional and sectional structure at the same time in the health institution. For example, services provided in operation room require coordination of people and units that have different functions and from different departments.

**Measurement Uncertainty:** A parameter which defines value distribution which can be equal to measure, that defines reference range

**Medical Gas:** Gas that is produced and packed to be used in anesthetic processes or diagnosis and treatment interventions.

**Medical Intervention:** In the purposes of disease diagnosis/treatment and protecting health, physical and psychological interventions within medicine limits in accordance with occupational responsibilities and standards by people who have authority to practice medicine.

**Medical Waste:** Infectious, pathologic and penetrating wastes which results from units.

**Method Validation:** A collection of studies for determining laboratory test method's desired performance conditions, checking that tests give results in comply with desired quality goals and keeping tests under control

**Mission:** It is the pure and general object, which determines the reason of health facility's being, its philosophy with provided products and services that lays down their unique differences and separate them from other health institutions.

**Morbidity:** incidence of disease

**Narcotic Medicine:** These are medicines that are like morphine and has painkiller specifications, natural, semi artificial and artificial and these may cause strong physical and psychological addiction.

**Objective:** States short term processes for reaching the goals. Objectives are more open and has measurable features comparing to goals.

**Organization Scheme:** It is a graphic that shows institutional structure as a whole and it also shows various relations between service units in a comprehensive order.

**Outsourcing:** It's the method of providing some services which take part in the hospital but not offered from an institution or organization out of the facility.

**Panic/Critical Value:** Result values that are in a high risk range for patient's condition that his/her doctor must be informed of as soon as possible and following diagnostic/therapeutic/protective intervention is required without delay

**Pathological Waste:** Materials that are used for pathological examination and disposed of during surgical operations including tissue, organ, body parts, human fetus etc.

**Patient Care:** Patient care is all of provided health services to patient which encompasses the whole health service processes starting from admission of the patient to monitoring of the patient after treatment.

**Performance:** A term that defines output of an action qualitatively or quantitatively. In the terms of performance assessment in an institution, it means that how much employees contribute to organizational objectives.

**Peritoneal Dialysis:** Via peritoneal cavity and peritoneal membrane, continuous out-

patient peritoneal dialysis, peritoneal dialysis by the use of devices and combinations of these

**Personal Hygiene Area:** In accordance with the hygiene rules, these are the areas like toilets, baths or sinks, which provides body cleaning and meets hygiene needs.

**Personal Protective Equipment:** Equipment used by employee such as clothing, tool or materials against the risks and threats in working environment. Various personal protective equipment may be needed to be procured in line with unit specialities.

**Plan:** the intended purpose ensure achievement of steps, what, when, why and document that shows how to do it.

**Post-analytic Period:** Post-analysis processes after approval of the results

**Post-postanalytic Period:** Interpretation of the results for patients' benefit and determination of additional test requirements, and also in the term of making the right decision for diagnosis, treatment and follow-up of patients, provision of information and guidance support by laboratory

**Pre-analytic Period:** Covers all steps consisting of taking sample, transfer, sample acceptance to laboratory, storage and analysis preparation after patient test order until analysis period

**Pre-preanalytic Period:** Period for patient test order

**Primary Facility Resources:** It expresses the need of minimum formation of the infrastructure of technologies which will be used in the provision of health care (water, electricity, air conditioning and medical gas systems, etc.).

**Privacy:** Represents the living area of the patient that has to be clarified for the patients care, treatment (test results, information about the disease and treatment) or for any other reason but hiding them from all other individuals in the society.

**Procedure:** Document describing how the execution of the activities of a process.

**Promotion and Enhancement of Health:** is the course in which people increase the control on their health and are able to enhance it. Promotion and enhancement of health represents a social and political progress. It does not only mean the activities that increases the skill and capacity of individuals but also changing social, environmental and economic conditions, thus it also means the activities aimed at easing their impact on the health of society and individuals. Promotion and enhancement of health is the course of increasing the control on health determiners (such as biological, environmental, economical, social and life style elements) and thus it is the progress of enhancing their own health.

**Psychotrope Medicine:** these are the medicines that affect central nervous system and cause some temporal changes in sense, mood, consciousness and behaviors by changing the functions of the brain. And also these may cause physical addiction when used for a long time.

**Quantitative Tests:** Tests that measures analysis component amount in a matter. In these tests, analyses are conducted quantitatively.

**Reference Range:** Lowest and highest value that a test can give as result by taking community profile as reference

**Revision Date:** The document was last updated refers to the date.

**Revision Number:** The document is updated refers to the number of times.

**Risk analysis:** It refers to identification of risks using methods allowing a comprehensive understanding of the risks, assessment of the severity of the damage in case of risks that may arise. In this context, risk analysis includes following processes; Identification of dangers which patients may be exposed to Determination of the frequency and level of exposure to hazards Assessment of which patient or patient groups are affected.

**Risk:** It refers to the probability of occurrence and the severity of an event that can damage human health as a result of exposure to a hazard.

**Root Cause Analysis:** Root causes are real reasons of problems. Root cause analysis is a study for determining these real reasons. In other words, it is a process practice for permanent solutions instead of temporary ones.

**Sample:** Biological material extracted that is convenient for ordered laboratory examination and which can provide information about source organ or tissue

**Self-Assessment:** An assessment in institution based on Standards of Accreditation in Health which is carried out by Quality Management Director

**Sharp Waste:** Wastes such as injection, injection syringe and all other subcutaneous venture injections, cylinders, cartridges and cans enclosing all the gases used in procedure, lancets, scalpel, knife, serum kit needles, surgical suture needles, biopsy needles, intracath, broken glass, bulbs, solid-lamellae, broken glass tubes and petri dishes and these waste may cause stinging, punching, scrape and injuries.

**Side Effect:** All pharmacological effects, that are unintended, without taking the harm of the medicine into consideration.

**Sterilization:** Killing all microorganisms found on anybody or substance by physical or chemical methods including spores.

**Supporting Document:** Procedure, Direction, Guide, Form, Plan, List, Consent Document, and External Document or this document is supportive documents.

**Temporary Storage:** The process of keeping waste wait in units built in the unit or containers for a temporary period not to exceed 48 hours before the transportation

**Test:** All applications in order to determine an analyte, cause or properties in a sample

**Transportation:** The process of transporting waste by convenient transportation vehicles from temporary storage units to disposal area.

**Ultimate Disposal:** Destruction or disarmament through incinerating or storing the waste in plants where all measures provided in applicable legislation are taken without any damage to the environment and human health.

**Value:** Defined rules and principle series which directs their members to certain acts for securing the survival of institution.

**Verbal Request:** verbal request is defined as the doctor's conveyance of the request to the nurse in a verbal way in the obligatory cases which the physician can not give a written request.

**Vision:** Expression of health facility's hope to reach the status under current conditions and its main philosophy for the future with sentences that features excellence and being ambitious

**Waste Management Plan:** Determining the general principles for not harming the environment and human health when the process of composing waste till disposal of them.