

INDEPENDENT AGENCY FOR ACCREDITATION AND RATING

**INTERNATIONAL
STANDARDS AND
GUIDELINES FOR
ACCREDITATION OF
HOSPITAL TYPE MEDICAL
ORGANIZATIONS**

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2021



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(I) INTRODUCTION

The organization of the provision of quality health care to the population is a global challenge to all healthcare systems. In the existing global healthcare practice, the concept of “quality” is inextricably linked with the concept of “safety of medical activity”. This process is reflected in the publication by the World Health Organization (WHO) of technical reports on key issues in the field of ensuring the safety of health care, the introduction of international standards of the ISO 9000 series “Quality Management Systems” in the field of healthcare, etc.

Experts of the World Health Organization have proven that improving the quality and increasing life expectancy of the population accelerates the economic development of the state, increases the growth of the gross national product. However, increasing life expectancy is impossible without creating an effective system for providing quality health care.

If we consider the quality of health care from different angles, then it is adequate to use three approaches to its assessment - structural (the quality of the structure, reflecting the organizational and technical quality of the resources used: material and technical base, equipment, staffing, etc.), process (process quality, indicating the correctness of the diagnosis, the choice of an adequate treatment technology, compliance with norms and standards, correctly adopted treatment tactics) and effective (the quality of the result, evaluating the degree of approximation to the maximum possible result of treatment).

In many countries, ensuring patient safety is seen as a general potential condition for providing health care. The use of modern practices to ensure the quality and safety of medical activities, the introduction of effective quality management systems, the formation of a mature patient-oriented corporate culture of medical organizations is aimed at continuous improvement of the level of health care.

The Tandem of "quality" and "safety of medical activity" includes:

- safe performance of any medical intervention, including surgery;
- safe provision of emergency and urgent care, including in the conditions of the admission department of a hospital;
- safe use of medical devices (MD);
- safe use of medications (MCT);
- prevention of healthcare-associated infections (HAIs);
- protection of information from unauthorized access;
- creation of a safe environment;
- ensuring a safe environment for medical activities, including the correct identification of patients, the continuity of care and the transfer of clinical responsibility for the patient

In other words, the provision of any type and volume of health care should be carried out in a safe environment of a medical organization, regardless of its organizational and legal form, size and direction of activity, with a minimum likelihood of developing existing risks.

Accreditation in medicine is a guarantee for healthcare organizations to remain competitive in the medical services market, and it also serves as an indicator of the quality and safety of health care provided.

Therefore, during accreditation, in addition to professional specific assessments, such assessment criteria can be taken into account as: the ability to choose a priority problem and justify it; ability to organize work; ability to make decisions; psychomotor

abilities; communication skills; the ability to cooperate; the capacity for compassion; generosity; intellectual curiosity; behavioral abilities; interpersonal relationships; ethical factors; commitment.

The Independent Agency for Accreditation and Rating (IAAR) is a leading international accreditation agency, established in 2011, which conducts international institutional and specialized (program) accreditation and awards the Quality Mark.

IAAR is the first accreditation agency from the CIS countries to receive a high recognition status from the World Federation for Medical Education (WFME).

The activities of the IAAR comply with the quality assurance standards of the European Higher Education Area (ESG) and the World Federation for Medical Education (WFME).

Purpose of standards and guidelines:

The standards and guidelines have been developed to provide medical organizations with a universal tool for assessing the quality of health care, the ability of medical organizations to ensure the safety of health care, the implementation of the principle of patient-centeredness, development and continuous improvement to ensure the improvement of the process of quality health care, to improve public health indicators, to optimize health care and costs associated with the provision of health care to patients who are on inpatient treatment.

Benefits for medical organizations:

Medical organizations receive a tools containing quality criteria presented in quantitative terms. The use of standards will make it possible to assess the existing quality and safety of health care in a particular medical organization and determine ways to improve it. The use of standards will improve the quality and safety of health care through the effective management of a medical organization, increasing the responsibility and personnel education qualifications. Accreditation provides competitive advantages, since obtaining the status of an accredited medical organization is an independent recognition of quality health care, which attracts patients to use the services of a particular organization. Standardization of procedures allows you to optimize the activities and financial capabilities of a medical organization and determine the best way for the organization to develop. Accreditation will allow building a system of effective interaction with other medical organizations to further improve the quality and safety of health care to the population.

Principles underlying the development of standards and guidelines:

professionalism and public accessibility of the assessment; voluntariness; independence; objectivity and professionalism; transparency, reliability and relevance of information on accreditation procedures; collective decision-making, dissemination of information about positive and negative results.

Process for developing standards and guidelines

The process of developing standards and guidelines included several stages: analysis of scientific and practical literature to determine the need and possibility of creating tools that meet international requirements for ensuring the high quality and safety of health care, studying the guidelines of the ISQua agency, examples of international standards, discussing with stakeholders the need and the relevance of developing universal tools for assessing the quality and safety of health care; involvement in the development of standards of a wide range of stakeholders, in

particular employers, professional associations, medical education organizations, health experts, representatives of patient groups, approbation of standards on the basis of practical healthcare organizations, making changes taking into account the discussion of the developed standards and testing them in a pilot mode.

(II) ABBREVIATIONS LIST

ISQua - International Society for Quality in Health Care

EEC - external expert commission

WHO - World Health Organization

MCT - medications

MC - medicines

HAI - healthcare-associated infections;

MD - medical devices

MO - medical organization

IAAR - Independent Agency for Accreditation and Rating

SU - structural unit

CIS - Commonwealth of Independent States

WFME - World Federation for Medical Education

ESG - Standards and Guidelines for Quality Assurance in the European Higher Education Area

SAR - self-assessment report

SN - social networks

SOP - standard operating procedures

(III) GLOSSARY

Accreditation	A self-assessment and external peer review process used by healthcare organizations to assess their level of performance in relation to established standards and to implement ways to continuously improve the healthcare system.
Adverse Events	Unintended injuries or complications that are caused by the management of patient/service user's care, rather than by the underlying medical condition. Such complications can lead to death, disability, or a long hospital stay.
Appropriate	The degree to which something is fit for a particular purpose.
Assessment	The process by which the characteristics and needs of patients/service users, groups, communities or situations are evaluated or determined so that they can be addressed. The assessment forms the basis of a plan for services or actions.
Audit	A systematic independent examination and review to determine whether actual activities and results comply with planned arrangements.
Client/patient	Individuals or organizations being served by the organization.
Code of Behavior	A documented set of agreed principles that informs all parties of responsibilities and expectations under the code.
Community	Individuals, families, groups, and organizations that typically reside in the same locality.
Competency	The knowledge, skills, abilities, behaviors, experience and expertise necessary to perform a specific task and activity
Complaint	Expression of an issue or dissatisfaction with services, which may be verbal or in writing.
Confidentiality	The right of individuals to keep information about patient from being disclosed.
Consent	Voluntary agreement or approval given by an individual.
Data	Numbers, symbols, words, images, graphics that have yet to be organized or analyzed.
Efficiency	The degree to which resources are brought together to achieve desired results most cost effectively, with minimal waste, rework and effort.
Ethics/Ethical	Acknowledged set of principles which guide professional and moral conduct.
Evaluation	A formal process to determine the extent to which the planned or desired outcomes of an intervention are achieved.
Expert	An expert is a specialist with extensive knowledge or

	ability based on education, research, experience and profession in a particular area of study.
Governing body	Individuals or groups with ultimate authority and accountability for the overall strategic directions and modes of operation of the organization.
Health Professionals	Medical, nursing or allied health staff members who provide clinical treatment and care for patients who have legal rights to perform certain manipulations within their qualifications.
Human resources	The staff members necessary to ensure a certain process and the functioning of a medical organization.
Information	Data that is organized, interpreted and used. Information may be presented in paper and/or electronic form.
Information Management	Collection, management and dissemination of information.
Licensing	The process by which a government agency grants permission to an individual practitioner or healthcare organization to work.
Mission	A broad written statement that articulates the purpose and scope of the organization. In general, the purpose of a medical organization.
Operational plan	A plan that clearly defines the actions an organization will take over a specified period of time to achieve its stated goals and enable the organization to achieve its long-term strategic goals.
Vocational guidance	The process by which employees become familiar with the professional position and work environment.
Patient Safety Incident	Any unintentional or unexpected incident that may or may have resulted in harm to one or more patients.
Performance evaluation	An ongoing process by which a manager and an employee evaluate an employee's performance, set performance goals, and evaluate progress towards those goals.
Policy	A written operational statement, a document(s) approved at the level of a medical organization, formalizing an approach to tasks that corresponds to the goals of the organization.
Procedure	A written set of instructions containing approved and recommended steps for a particular action or series of actions. Treating or caring for a patient while providing health care
Process	A series of actions or steps taken to achieve a specific goal.
Quality Improvement Plan	A plan that outlines quality improvement initiatives, including proposed actions, timelines, and responsible persons.
Research	Contribution to the existing body of knowledge through an investigation aimed at discovering and interpreting facts.

Risk	The likelihood of danger, loss or injury.
Risk management framework	A set of components that provide the foundations and organizational mechanisms for the development, implementation, monitoring, analysis and continuous improvement of risk management throughout the organization.
Safety	The degree to which potential risk and unintended outcomes are prevented or minimized.
Scope	The range and type of services offered, as well as any conditions or restrictions on service coverage.
Staff	Employees of the organization, including temporary and permanent employees.
Strategic plan	A formalized plan that establishes the general goals, tasks of the organization for a certain period of time.
Expert	An external expert in evaluating the performance of a medical organization in accordance with approved standards.
Values	Principles, beliefs, or philosophies that guide behavior, which may include social or ethical issues.
Vulnerable populations/persons with special needs/persons with disabilities	Individuals who may be limited in their ability to protect themselves from harm and who need extra help.
Disease prevention	Activities designed not only to prevent disease - such as reducing risk factors - also activities aimed at stopping the development of diseases and reducing their consequences in the event of a disease.
Promotion and protection of healthcare interests; advocacy and promotion of healthcare interests	A combination of actions and measures at the individual and societal levels to achieve commitment and curious attitude, with the adoption of appropriate commitments in the "policy-strategic" plan, supporting appropriate societal acceptance and systemic support for a specific health goal or program.
Providing Opportunities to Protect and Promote Health	Taking action in partnership with individuals or groups to provide them – through the mobilization of human and material resources – with opportunities to protect and promote their health.
Administrative staff	Employees in the management of structural units responsible for administrative support for the formation of policies and the implementation of policies and plans.
Advance directive for health care	A document detailing the therapy and procedures to be followed at the time of deterioration, signed by the patient
Anamnesis	Information about symptoms, recent or previous illnesses and treatments, as well as previous surgeries or procedures, medication use, and the person's family history
Nurses (paramedical	Medical personnel that provide basic medical and

personnel)

personal care to people who need such care due to aging, illness, injury or other physical or mental impairment.

Medicines

Substances or their combinations that come into contact with the human body, penetrate the organs, tissues of the human body, used for the prevention, diagnosis, treatment of a disease, rehabilitation, for the maintenance, prevention or termination of pregnancy and obtained from blood, blood plasma, from organs, tissues human or animal organism, plants, minerals by synthesis methods or using biological technologies. Medicinal products include pharmaceutical substances and medications

Medications

Medicinal products in the form of dosage forms used for the prevention, diagnosis, treatment of a disease, rehabilitation, for the maintenance, prevention or termination of pregnancy

Medical device

A device that is used to diagnose, prevent, or treat various diseases. Includes tools, apparatus, implants, vitro reagents, consumables, fixtures, appliances, furniture, and other items.

Quality of health care

The degree, to which health services delivered to individuals and populations increase the likelihood of achieving desired health outcomes and are consistent with actual evidence (WHO).

The quality of health care is the level of compliance of the health care provided with the standards for the provision of health care (Health Code of the Republic of Kazakhstan dated July 7, 2020 No. 360-VI).

Principles of health care quality

Efficiency, safety, people orientation, timeliness, fairness, integration, efficiency.

Components of health care quality

Technological quality - performance of professional functions.

Technical quality - use of resources.

Danger of injury or disease as a result of medical interventions - control of the degree of risk.

Patient satisfaction with health care.

Audit of a medical organization

Quality improvement cycle, which should include an assessment of the actual care provided in relation to approved standards of high quality, the development of a Plan to bring the actual level of health care in line with the declared standards, and the improvement of this care to achieve the best health outcomes.

Document, documented information

Information recorded on a material carrier with details that allow it to be recorded.

Quality Management System	A set of practices, processes and resources that are necessary for the overall management of the quality of services provided by an organization.
Risk Management	The process of making and implementing managerial decisions aimed at reducing the likelihood of an adverse outcome and minimizing possible losses caused by its implementation. Risk management is a tool to ensure patient safety.
Clinical protocol of a medical organization	A normative document that defines the requirements for the provision of health care to a patient with a certain disease, with a certain syndrome, or in a certain clinical situation in a medical organization.
Authorized body in the field of healthcare	The central executive body that conducts management and intersectoral coordination in the field of public health, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare of the population, circulation of medicines and medical devices, quality of medical services (assistance).
Evidence-based medicine	Appropriate, consistent and meaningful use of current best clinical trial evidence in decision making for prevention, diagnosis, treatment, medical rehabilitation and palliative care for a specific disease or patient condition
Clinical Guidance	Recommendations on the use of preventive, diagnostic, therapeutic and rehabilitation measures in the treatment of patients, based on evidence-based medicine
Medical intervention	Direct or indirect impact and (or) other manipulation performed by a medical professional in the provision of health care to patients for the purpose of prevention, diagnosis, treatment, rehabilitation, research aimed at restoring or improving health
Medical rehabilitation	A set of medical services aimed at maintaining, partial or complete restoration of impaired and (or) lost functions of the patient's body
Palliative care	A complex of medical services aimed at relieving pain and severe manifestations of the disease (condition) of a terminally ill patient in the absence of indications for radical treatment
Algorithm for diagnosis and treatment	A clear sequence of actions in terms of diagnostic, therapeutic and rehabilitation measures
Healthcare technology	Application of knowledge and skills that are used for health promotion, prevention, diagnosis, treatment of disease, rehabilitation of patients and provision of palliative care, including vaccines, medicines and medical devices, procedures, manipulations, operations, screening, prevention programs, including information systems
Healthcare Technology Assessment	Comprehensive assessment of the comparative proven clinical and clinical-economic (pharmaco-economic)

effectiveness and safety of healthcare technologies, as well as the economic, social and ethical consequences of their use, carried out for decision-making in the field of healthcare

Conflict of interest

A situation, in which a health professional or a pharmaceutical professional, in the course of their professional activities, has a personal interest in obtaining material benefits or other advantages that affect or may affect the proper performance of their professional duties due to a conflict between the personal interest of a health professional or a pharmaceutical professional and the interests of a patient

Medical procedures and manipulations

Diagnostic, therapeutic and curative measures with the main goal of helping people with health problems.

Patient orientation

A model of interaction between medical staff members and a patient, based on friendliness, respect, non-conflict, understanding of the patient's needs and the ability to solve them, attention to the emotional state of a person.

Triage system

Medical sorting (triage) - distribution in the admission department of a medical organization of incoming patients into groups, based on the priority of urgent medical aid. Triage is aimed at providing timely assistance in the optimal amount to the largest possible number of patients in emergency conditions.

Urgent medical aid

Medical assistance provided in case of sudden acute diseases, conditions, exacerbation of chronic diseases that pose a threat to the life of the patient, which is provided by any medical organization and health professional to a citizen immediately and free of charge, and no refusal to provide such aid is allowed.

Emergency health care

Health care provided in case of sudden acute diseases, conditions, exacerbation of chronic diseases without obvious signs of a threat to the patient's life.

(IV) INTERNATIONAL ACCREDITATION PROCEDURE

Goals and objectives of international accreditation

The purpose of international accreditation (accreditation) is to assess and recognize the high quality of the activities of a medical organization (MO) and the proposed health care in accordance with international accreditation standards.

The procedure for international accreditation serves the general purpose of assessing the quality of a medical organization's activities and compliance with international standards. When conducting international accreditation, the specific legislation of the respective countries is taken into account.

The main principles of international accreditation are:

- professionalism and public accessibility of the assessment;
- voluntariness;
- independence;
- objectivity and professionalism;
- transparency, reliability and relevance of information on accreditation procedures;
- collective decision-making, dissemination of information about positive and negative results.

The procedure for conducting international accreditation

The procedure includes the following steps:

❖ **Applying for accreditation.**

Submission of an application for accreditation by a medical organization with copies of title and permit documents attached. Consideration by IAAR of the application of a medical organization.

❖ **Conclusion of an agreement between the MO and IAAR.**

Adoption of the IAAR decision on the commencement of the procedure for accreditation of a medical organization. The schedule for visiting a medical organization, the conditions and financial issues of accreditation are determined by an agreement between the IAAR and a medical organization.

IAAR organizes training to explain the criteria and procedures for international accreditation to representatives of a medical organization at special seminars on the theory, methodology and technology of accreditation. This seminar procedure is not a mandatory component of the accreditation process.

❖ **Preparing a self-assessment report**

The medical organization independently organizes and conducts a self-assessment of the organization in order to establish compliance with international accreditation standards, and also prepares a self-assessment report. The medical organization is provided with standards and guidelines for preparing a self-assessment report.

The MO sends the self-assessment report and all required attachments to the IAAR at least eight (8) weeks prior to the visit of the External Expert Commission (EEC).

IAAR sends the self-assessment report to reviewers for review at least 6 (six) weeks prior to the visit after an internal review of compliance with the requirements of the standards. The expert examines the self-assessment report for compliance with IAAR international standards, prepares and sends a review to IAAR within 10 (ten) calendar days. In case of non-compliance with IAAR requirements, the review is sent to the expert for revision. In case of repeated non-compliance, IAAR has the right to remove this expert from participation in the EEC.

Based on the analysis of the self-assessment report of the medical organization, IAAR has the right to make one of the following decisions:

- develop recommendations for finalizing the self-assessment report;
- to carry out subsequent accreditation procedures (visit of the EEC to the Medical Organization);
- Postpone the dates for subsequent accreditation procedures due to non-compliance of the self-assessment report with international IAAR standards.

❖ Visit of the EEC to a medical organization

In case of continuation of subsequent accreditation procedures, the IAAR forms an External Expert Commission (EEC), which is approved by the General Director of the IAAR. An external assessment of the quality of the organization and implementation of the medical organization's activities for compliance with international IAAR standards is carried out by the EEC during a visit to a medical organization.

The composition of the EEC is formed depending on the scope of the external evaluation. The EEC is composed of independent experts with experience in expert activities in quality assurance.

In case of continuation of accreditation, IAAR will agree with the MO on the timing of international accreditation and the EEC visit program.

The EEC visit program is developed by the IAAR coordinator and the EEC Chairman with the participation of the MO. The agreed program of the EEC visit is approved by the IAAR General Director at least 1 (one) week before the visit to the Medical Organization. The structure and content of the program is developed taking into account the specifics of the MO.

The duration of the commission's visit is usually 3-5 days. During the visit, the Medical Organization creates conditions for the work of the EEC in accordance with the Service Agreement:

- submits for each of the members of the commission an electronic and paper version of the self-assessment report;
- provides the necessary office equipment in agreement with the IAAR representative, according to the number of EEC members;
- organizes an inspection of infrastructure and resources, meetings, interviews and other types of work of the EEC in accordance with the Program of the visit;
- provides the requested information.

The results of the visit to the MO are reflected in the report on the results of the external evaluation.

The draft EEC report is reviewed by the IAAR and sent to the MO for approval. In the event that the MO reveals actual inaccuracies, the Chairman coordinates with the members of the EEC and makes the necessary changes to the EEC report. In case of disagreement with the comments of the MO made to the EEC report, the Chairman, together with the IAAR coordinator, prepares an official response with justification.

The report contains a description of the EEC visit, a brief assessment of the compliance of the activities of the medical organization in the context of international IAAR standards, recommendations of the medical organization for improving performance and quality assurance, recommendations to the Accreditation Council. Proposals to the Accreditation Council contain a recommendation for accreditation (including the recommended period of accreditation) or non-accreditation.

The EEC report, including recommendations, is developed collectively by the members of the EEC.

❖ IAAR Decision Making

The basis for the Accreditation Council to make a decision on accreditation are the EEC reports on the assessment of a medical organization and the report on the self-assessment of a medical organization.

The Chairman of the External Expert Commission speaks before the Accreditation Council on the results of the visit of the External Expert Commission.

The exclusive competence of the IAAR Accreditation Council includes making decisions on accreditation or refusal to accredit a medical organization. The composition of the Accreditation Council is determined in accordance with the Regulations on its activities. The meeting is held if there is a quorum. The Accreditation Council has the right to make a reasoned decision that does not comply with the recommendation of the external expert commission.

The Accreditation Council has the right to take one of the following decisions:
- "to accredit":

- **1 year** - if the criteria are met in general, but if there are some shortcomings and opportunities for improvement (when assessing criteria that require improvement of more than 20%, no strengths);

- **3 years** - with positive results in general, but with some minor shortcomings and opportunities for improvement (when evaluating criteria that require improvement from 10 to 20%, in the presence of strengths);

- **5 years** - with positive results in general (when evaluating criteria that require an improvement of no more than 10%, in the presence of strengths).

- **“denial of accreditation”** (when at least one criterion is assessed as “unsatisfactory”, in the absence of strengths).

If the Accreditation Council makes a positive decision, the IAAR sends an official letter to the MO with the results of the decision and a certificate of accreditation of the medical organization. Further, the decision on accreditation of the Medical Organization is sent to the authorized body in the field of healthcare of the respective country and posted on the IAAR website. Also, the Report of the external expert commission can also be accessed on IAAR website.

If the Accreditation Council makes a negative decision, the IAAR sends an official letter to the MO about the decision.

The MO, following the established procedure in accordance with the Service Agreement and the Regulations on the Appeals and Complaints Review Committee, may file an appeal with the IAAR against the decision of the Accreditation Council. In case of doubt about the competence of the external expert commission and representatives of the Agency, or a gross violation committed by the members of the external expert commission, the MO may file a complaint with the IAAR.

❖ Subsequent procedures

If the Accreditation Council of the IAAR makes a positive decision, the MO submits to the IAAR the Action Plan of the MO for the implementation of the recommendations of the EEC, which is signed by the first head of the MO and certified with a seal, and also concludes a Service Agreement with the IAAR. The Agreement and the Plan are the basis for post-accreditation monitoring.

In accordance with the Regulations on the procedure for post-accreditation monitoring of accredited organizations, the MO must prepare interim reports in accordance with the Plan. Interim reports are sent to IAAR before the expected date of post-accreditation monitoring.

Post-accreditation monitoring of MO is carried out in accordance with the Regulations on the procedure for post-accreditation monitoring of MO.

In case of non-fulfillment of the Plan and the requirements put forward by the IAAR in relation to the MO, as well as the lack of awareness raising about the changes carried out in the MO the Accreditation Council has the right to take one of the following decisions:

- temporarily suspend the accreditation of the Medical Organization;
- revoke the accreditation of the Medical Organization, which may entail the cancellation of all previously achieved results of accreditation.

In the event that the MO refuses to conduct post-accreditation monitoring, expressed in the non-signing of the Service Agreement with the IAAR, the IAAR Accreditation Council has the right to decide to terminate and revoke the accreditation status of the MO.

In case of early termination and deprivation of accreditation status, the MO has the right to apply for accreditation to IAAR after 6 months from the date of the decision to revoke the accreditation of a medical organization.

External expert commission (group of experts on external evaluation)

The external evaluation of the MO is carried out by an External Expert Commission (External Evaluation Expert Group), consisting of independent experts with clinical experience in quality assurance activities.

The EEC is formed based on the order of the IAAR General Director from among the certified representatives of the professional community included in the database of IAAR experts.

IAAR, in order to exclude a conflict of interest, 14 (fourteen) calendar days before the visit, sends an official letter to the MO on the composition of the EEC.

The MO has the right to notify the IAAR by official letter of the existence of a conflict of interest with justification within 3 (three) business days. IAAR will replace the expert if necessary.

All EEC members sign the Declaration of Commitment of No Conflict of Interest and the IAAR External Expert's Code of Ethics on each visit.

The expert is required to notify the IAAR coordinator of any association with the MO or self-interest that could lead to a potential conflict related to the external evaluation process.

Each member of the EEC must perform its functions and responsibilities in a quality manner. Non-compliance and refusal without a valid reason is considered a violation of the IAAR External Expert's Code of Ethics and may result in exclusion from the IAAR Expert Database.

Information about the MO obtained during the external evaluation is presented as confidential and is not subject to disclosure.

EEC members should not disclose or comment on the recommended terms of accreditation before the decision of the Accreditation Council.

The composition of the External Expert Commission includes:

- Chairman of the EEC, responsible for coordinating the work of experts, preparing and verbally presenting preliminary conclusions formed during the visit to the Medical Organization, and also responsible for preparing the final report on the results of the external evaluation of the Medical Organization.

- External experts - representatives of the professional community.

The IAAR appoints a coordinator from among its staff who is responsible for coordinating the work of the expert group. The MO, for its part, appoints an authorized person responsible for the process of international accreditation of the MO.

(V) SELF-ASSESSMENT REPORT

The self-assessment report (SAR) is one of the main documents for international accreditation.

Basic principles for preparing the report

1. Structuring: strict compliance of the presented material with the sections of the document.
2. Readability: the text of the document should be easy to read in terms of printing, semantic and stylistic features of the text.
3. Analyticity: analysis of advantages and disadvantages, analysis of the development dynamics of the MO.
4. Criticism: objectivity of the assessment.
5. Persuasiveness: providing facts, data, information as arguments to be used to make conclusions.

The final document should be well structured, numbered (including annexes).

Report Format

The report should be drawn up in the form of a coherent and logical text with tables, graphs, figures, where appropriate, and annexes that contain large tables (occupying more than half of an A4 sheet) and other large-scale sources of information.

The self-assessment report includes an introduction, body and conclusion. All statements, judgments, assumptions of the report must be supported by the necessary documents in the body of the text and annexes.

The report should be written in the following format: font type - Times New Roman, font size - 12, space between lines - 1.0, paragraph spacing before and after headings - no more than 6 pt, at the beginning of the report there should be an automatically edited built-in table of contents, numbers pages. The report is printed in A4 format with portrait orientation, as for the annexes the landscape orientation can also be used. The first annex to the report must contain a text confirming the reliability, exhaustive nature and accuracy of all the data presented, signed by the head of the MO and the executors who compiled the report, including the contact details of the report compilers for further consultations if necessary: "I, [full name of the head of the organization], confirm that in this self-assessment report [name of the MO] containing [number of pages of the main part of the report, i.e. without annexes] pages, was provided absolutely reliable, accurate and comprehensive data that adequately and fully characterize the activities of the Medical Organization.

The length of the Self-assessment report should not exceed 100 pages in terms of the main text. A package of documents in the form of annexes (in a separate file not exceeding 100 pages) is separately attached to the Self-Assessment Report. Graphics must be compressed to 96 dpi before being exported to appendix text. To reduce the volume of annexes, it is recommended that in the text of the self-assessment report, as many references as possible be made to supporting documents located on the electronic resources of the Medical Organization.

The report and its annexes are submitted to IAAR in English, unless otherwise specified, in electronic form at the email address iaar@iaar.kz.

Contents of the Self-Assessment Report

The self-assessment report consists of an introduction, three main sections and annexes. The structure of the report is presented in Appendix 1.

It is recommended that the introduction include information about the conditions and organization of self-assessment, its goals and objectives.

The first section provides general information about MO:

- brief information;
- organizational and legal support of activities;
- organizational structure and management system;
- the number and categories of patients at the time of preparation of the report;
- dynamics of the patients over the past 3-5 years.

The second section includes an analysis of the compliance of the MO with international accreditation standards. The section articles should be organized according to the order given in the instruction. The report should provide answers to all major questions and include all necessary documentary evidence in the annexes.

The MO should provide information on achievements in the quality of health care over the past 3-5 years individually for each article to be presented in the second section of the report. It is also expected that the report will highlight the issues and areas for improvement identified through the SWOT analysis of each standard.

The third section of the report should include general conclusions and a conclusion about the self-assessment process, giving grounds for applying for an external quality assessment procedure.

Appendices should include tables, general information about the MO and a list of materials and documentary evidence submitted for consideration by the external expert group during the visit to the MO.

The self-assessment report should be submitted on behalf of the head of the MO and should be signed by him/her.

The main provisions and conclusions of the report should be brought to the attention of all participants in the self-assessment process; published on the Internet resource of the Medical Organization. All those responsible for self-assessment and reliability of the material presented in the report should participate in filling out the table "Conclusion of the self-assessment commission".

At the beginning of the Self-Assessment Report, general information (profile) is provided, reflecting the name of the MO, legal details, full name of the head, contact information, date of submission of the self-assessment report, full name of the contact person for preparing the report, output data of the Standard according to which the assessment is carried out, information about the group, conducting a self-assessment.

The introduction indicates the basis for passing the external assessment, the result of the previous accreditation (Accreditation body, accreditation standards, according to which the external assessment was carried out and the status of accreditation) in case of re-accreditation. A brief description of the methods used in the development of the MO Self-Assessment Report (appointment of a working group, involvement of stakeholders, etc.) is reflected.

The main part of the self-assessment report should consistently reflect the results of the self-assessment of the MO against the criteria of each standard. At the end of the self-assessment on the criteria of each standard, a quantitative conclusion is given.

The final part of the self-assessment report should include the table "Conclusion of the self-assessment commission", which reflects the evaluation of the criteria for all standards.

The self-assessment report must follow the structure of the IAAR standards and can be compiled in form and content based on the responses given by the medical organization to all items of the IAAR standards. The following sections provide guidelines for compiling a self-assessment report by individual IAAR standards, with brief comments on each standard and criterion.

(VI) INTERNATIONAL STANDARDS FOR ACCREDITATION

The International Accreditation Standards of the Medical Organization consist of the following sections: “Leadership and management of a medical organization”, “Staff”, “Resource management”, “Safety management”, “Safety of medicines (MC) and medical devices (MD)”, “Patient: safety, rights and obligations”, “Treatment and care of patients”, “Organization of anesthesia, resuscitation (intensive care) and surgical care”, “Laboratory diagnostic service and blood service”, “Diagnostic imaging service”.

Each standard has sub-standards and criteria according to which the performance of the MO is evaluated. For the correct interpretation of the standard and criteria, a guideline and a list of expected documents, which MOs can present as evidence, are used.

Below is the structure of a single standard.

- | | |
|-------|--------------------|
| 1. | Standard |
| 1.1 | Substandard |
| 1.1.1 | Criterion |
| ➤ | Guidance |
| ➤ | Suggested Evidence |



1 STANDARD “LEADERSHIP AND MANAGEMENT OF A MEDICAL ORGANIZATION”

1.1 Management body, functions and powers

1.1.1 A hospital type MO must have a management body, the structure, functions and powers of which are described in the policy of the organization.

Guidance

The governing body of a medical organization can be represented in various forms. The governing body of a medical organization must comply with the legal documents governing this process at the domestic level.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents, approved structure of the organization.

1.1.2 The policy, containing the responsibility, rights, powers, functions of the management body, is approved by the organization and its original copy is stored in the relevant department.

Guidance

The governing body of a medical organization functions on the basis of permits of a medical organization approved and corresponding to the legal documents of the country. In a medical organization, all provisions, rules, regulations defining the powers, duties, rights of the governing body must be developed and approved. A medical organization should have a unit that has the authority and responsibility to collect and store documents of this type.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents, approved structure of the organization;
- ✓ approved functions of the unit responsible for the storage of documents regulating the activities of the governing body.

1.1.3 The MO is headed by a governing body or the top officer, who is responsible for the activities of the MO in accordance with the legislation of the country and acts on the basis of regulatory documents.

Guidance

The MO is headed by default by the top officer who has the authority. Sometimes a collegial body is provided for the management of the MO, which is a management body headed by an authorized person.

Suggested Evidence:

- ✓ management structure;
- ✓ powers of the head of the organization;
- ✓ qualification requirements for the head of the organization;
- ✓ documented evidence of compliance of the top officer of a medical organization with the qualification requirements established at the domestic level and accepted by the medical organization.

1.1.4 The governing body is responsible for the development of the mission, vision, development plan of the MO and its implementation.

Guidance

The mission, vision, goals, objectives, development plan of a medical organization are important fundamental documents for the functioning of a medical organization, compliance with its purpose. The governing body is responsible for the development, coordination and approval of the fundamental documents of the MO.

Suggested Evidence:

- ✓ Charter;
- ✓ documented evidence of the statement of the mission, vision, goals and objectives of the MO, development plan.

1.1.5 The governing body determines the types of health care provided to the population, regulates and manages the process of implementing types of services.

Guidance

All types of activities provided by the MO should be specified in the fundamental documents. The MO must have permits from the authorized body of the country to conduct certain types of activities with a definition of the types of health care provided.

Suggested Evidence:

- ✓ MO licenses;
- ✓ Charter of the MO with a list of medical and other types of assistance and services provided.

1.1.6 The governing body ensures the openness of the management system, demonstrates communication skills when disseminating information about the activities of the MO both inside and outside the organization.

Guidance

A medical organization needs to ensure transparency of management and decisions made by publishing basic documents on the organization's website, posting information on social networks, and providing a report from the management body to the staff of the medical organization. A medical organization should ensure transparency of management and decisions made by posting information on the website, in bulletins, etc. on an ongoing basis.

Suggested Evidence:

- ✓ publications of a medical organization;
- ✓ organization's website.

1.1.7 The governing body is responsible for ensuring the necessary human resources to provide quality health care.

Guidance

The Medical Organization should have a service or unit for accounting, recruiting staff members. The Medical Organization must provide the necessary staff members for the organization of the full scope of health care. Staff are subject to qualification requirements according to their positions. Admission to the MO is carried out on a competitive basis. The MO should hold a competition that meets the principles of openness and objectivity. The competition documentation is approved by the Medical Organization and posted on the website of the organization. Competition announcements are posted on the website, in social networks (if necessary) if there are vacancies.

Suggested Evidence:

- ✓ legal documents of the country regulating these processes;
- ✓ internal regulatory documents;
- ✓ competition documents;
- ✓ orders for employment based on the results of the competition;
- ✓ organization staffing.

1.2 Strategic and operational management

1.2.1 The medical organization must have a strategic development plan that meets the needs of society in obtaining health care, consistent with the mission and vision of the medical organization.

Guidance

MO should develop a plan for the strategic development of the organization. The plan for the strategic development of the Medical Organization should include the main directions for the development of the organization, contain the expected results, ways to achieve, expressed through tasks and activities. The strategic plan should provide resources for the implementation of all activities and the achievement of the MO goal. The strategic development plan must be approved by the collegiate body (if any) and the governing body.

Suggested Evidence:

- ✓ legal documents of the country regulating these processes;

- ✓ internal regulatory documents;
- ✓ organization's strategic development plan;

1.2.2 The strategic plan should be developed in accordance with the country's regulations and communicated to all internal stakeholders.

Guidance

The strategic plan is developed on the basis of the country's legal documents using established rules and standards. All internal stakeholders should be involved in developing the strategic development plan. The plan should be communicated to internal stakeholders by posting the strategic development plan on the organization's website, reviewing it during meetings with employees, reports from the management body on the results of the organization's activities and development plans.

Suggested Evidence:

- ✓ documented evidence informing the staff about the strategic development plan of the Medical Organization in the form of meeting minutes and etc.

1.2.3 The MO and all structural divisions must develop operational plans in accordance with the strategic plan.

Guidance

On the basis of the adopted strategic development plan, the heads of structural divisions develop plans for the development of divisions. These plans are developed for the current calendar year and are components of the MO's operational plan. The plans are approved by the governing body of the Medical Organization.

Suggested Evidence:

- ✓ operational plans of the MO.

1.2.4 The MO should identify responsible persons for the implementation of strategic and operational plans in each structural unit and at the level of the entire organization.

Guidance

In addition to developing development plans, the MO should identify employees responsible for the implementation of strategic and operational plans in each structural unit and at the level of the entire organization. The usual practice is that the heads of departments and the governing body are responsible for the implementation of both the strategic and operational plans of the departments and the entire organization. Employees responsible for the implementation of plans should have experience in management, planning, organization, monitoring and control, and receive appropriate training.

Suggested Evidence:

- ✓ documents of the Medical Organization, indicating the appointment of employees responsible for the implementation of plans;
- ✓ documented evidence of the implementation of the plan by structural units under the control of responsible employees.

1.2.5 MO should review on an ongoing basis and make changes/adjustments to the strategic and operational plans depending on changes in the country's legal documents, the needs of society.

Guidance

The strategic development plan and operational plans should be reviewed periodically due to changing environmental conditions, new challenges for the healthcare system, changes in the country's legal and regulatory documents, and the influence of other factors. The standard review period for plans is one calendar year.

Suggested Evidence:

- ✓ protocols, documented evidence of the revision of the strategic development plan and operational plans of the organization and its structural divisions;
- ✓ documented evidence of informing and familiarizing the staff members about the changes/additions/adjustments made.

1.3 Organizational structure and management of structural divisions

1.3.1 MO should have an organizational structure that meets the mission of the organization and aimed at the implementation of the main tasks of the organization.

Guidance

MO must have an organizational structure that meets the requirements established at the domestic level, the purpose of the medical organization. The components of the organizational structure are management units, clinical departments, diagnostic, laboratory, auxiliary and other units.

Suggested Evidence:

- ✓ organizational structure.

1.3.2 The organizational structure must be discussed and approved at a meeting of the collegial body and is available to all stakeholders.

Guidance

The organizational structure is developed on the basis of the country's legal documents using established rules and standards. All internal stakeholders should be involved in the development of the organizational structure. The structure should be communicated to internal stakeholders by posting the structure on the organization's website, familiarizing with it during meetings with employees.

Suggested Evidence:

- ✓ documented evidence informing staff about the organizational structure of a medical organization in the form of minutes of meetings, etc.

1.3.3 MO should define the structural units, responsibilities and functions of each unit, and the interaction between them.

Guidance

Each structural unit, designated in the organizational structure, must have a position, functional duties of the staff. All departments should interact with each other, which should be written in internal regulatory documents (quality management systems), for example, in a process matrix.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;

- ✓ internal regulatory documents of a medical organization containing the purpose of the unit, the functions of the staff members;
- ✓ documented evidence of compliance of units with the organizational structure.

1.3.4 The MO should periodically evaluate the management of structural units to ensure the quality of the assistance provided.

Guidance

The management and proper organization of the activities of a medical organization is based on the observance of the principles and technologies of management. Any cycle of activity of any structure includes several mandatory stages - analysis, planning, organization, monitoring and control. The quality of the assistance provided is the main goal of the activities of the units. Control and monitoring of the quality of the activities of structural units must be carried out on an ongoing basis at regular intervals, as well as control in cases of violation of certain procedures, complaints and other incidents.

Suggested Evidence:

- ✓ plan for monitoring the management and activities of structural units;
- ✓ the results of the assessment of the management of structural divisions - documented evidence;
- ✓ taken management decisions in case of revealed violations - documented evidence.

1.3.5 The MO should clearly define the terms of reference of responsible persons for the management of structural units.

Guidance

The powers of the heads of structural units are prescribed in the internal regulatory documents of the medical organization, which are developed and comply with the legal documents of the country. Each head of a structural unit, when managing, is guided by certain powers and determines the amount of work according to the powers. Certain decisions can be made by the manager at his/her level, some decisions are made by top managers.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulations.

1.4 Rights and obligations of staff members, organizational and clinical ethics

1.4.1 The MO should have a policy in the field of determining the rights and obligations of the staff members of all structural divisions.

Guidance

The policy of the Medical Organization in the field of determining the rights and obligations of the staff members of structural divisions should be developed on the basis of the legal documents of the country, approved and brought to the attention of the staff members. The policy is presented in the form of an employment contract between the organization and the employee, which spells out the rights and obligations of the staff.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;

✓internal regulations.

1.4.2 The MO must ensure that the staff members meet the regulatory, legal and qualification requirements for their professional positions.

Guidance

When hiring, an assessment is made of the applicant's compliance with the qualification requirements that apply to certain job positions. Qualification requirements are set at the country level and are mandatory for compliance with the MO.

Suggested Evidence:

- ✓legal documents of the country regulating this process;
- ✓internal regulations.

1.4.3 The head of the structural unit is responsible for the effectiveness of the work of the staff members, periodically evaluates the staff members.

Guidance

The powers and responsibilities of the head of the structural unit include control and monitoring of the activities of staff members, the quality of their work. To solve this problem, managers should periodically assess the staff members by checking the skills and abilities in providing diagnostic, health care, filling out medical documentation, monitoring the work of staff members, and attesting staff members.

Suggested Evidence:

- ✓normative/regulatory documents of the MO;
- ✓the results of staff members assessment - documentary evidence;
- ✓taken management decisions in case of revealed violations - documented evidence.

1.4.4 The MO must implement ethical policies/principles that are consistent with business, financial, ethical and legal standards and the protection of the rights of patients, on the basis of which management and other decisions are made.

Guidance

Medical activity is connected with ethical and legal norms, observance of the rights of patients. The MO must have a policy (regulations/orders/directives) for ethical compliance. Ensuring compliance with ethical principles through the functioning of the ethics commission/committee/council or other bodies or structural units.

Suggested Evidence:

- ✓legal documents of the country regulating this process;
- ✓internal regulations.

1.4.5 The ethics policy should be aimed at resolving the operational aspects of the activities of the Medical Organization, including staff members issues.

Guidance

An important aspect of the implementation of ethical principles should be the observance of the rights of patients, the implementation of ethical standards in relation to the staff members of the medical organization and other aspects. All processes that require compliance with ethical principles must be prescribed in the internal regulatory documents of the Medical Organization and comply with the regulatory legal documents of the country.

Suggested Evidence:

- ✓ legal documents of the country regulating this process
- ✓ internal regulations
- ✓ the results of the activities of the ethical bodies of the MO - documented evidence

1.4.6 The ethics policy should be communicated to all stakeholders, as well as participants in the course of providing health care.

Guidance

All internal stakeholders should be involved in the implementation of the policy in the field of compliance with ethical and legal standards, protection of the rights of patients and staff. Ethical principles and rules should be brought to the attention of all participants in the course of health care. This is achieved by informing staff and patients about ethical principles and norms, monitoring the implementation of policies and compliance with ethical standards.

Suggested Evidence

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ the results of the activities of the ethical bodies of the MO - documented evidence.

1.5 Quality management and quality improvement

1.5.1 The MO should have a quality policy that should be documented and communicated to all interested parties.

Guidance

The quality of health care for patients is the main priority of the MO. All processes implemented in the MO are ultimately aimed at achieving a high quality of health care in all departments of the organization. The quality policy should contain the main regulatory documents of the MO, based on the approved legal documents of the country.

Suggested Evidence

- ✓ legal documents of the country regulating this process;
- ✓ internal regulations.

1.5.2 The MO should identify a qualified person responsible for ensuring and controlling the quality of health care and patient care both at the level of the entire organization and in each structural unit.

Guidance

The system for providing and controlling the quality of health care should be built at the level of the entire organization and a single structural unit. The MO should provide for the position of a responsible employee for the provision and quality control of health care at the organization level, as well as employees responsible for quality assurance and quality control. Employees responsible for the provision and quality control of health care must have certain competencies, certificate in quality management in healthcare.

Suggested Evidence

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ staffing schedule.

1.5.3 All interested parties (medical staff members, management staff members, patients, professional communities, etc.) should take part in the development of a quality policy.

Guidance

The quality policy affects all aspects of the activities of the Medical Organization and, of course, the participation of all interested parties in the development of the policy is absolutely necessary. A working group for the development of a quality policy is being created in the Medical Organization, which necessarily includes employees with competencies in the field of quality management, as well as representatives of the medical community of the Medical Organization, professional organizations, and patients. All policy documents should be discussed at collegiate meetings and brought to the attention of each employee of the MO.

Suggested Evidence:

- ✓ order/instruction on the composition of quality policy developers;
- ✓ meeting minutes.

1.5.4 The Medical Organization is responsible for collecting, monitoring, analyzing processes that affect the quality of health care and makes scientifically based management decisions.

Guidance

MO should establish procedures for the continuous collection of information, the results of the activities of structural units to ensure the quality of all processes. Data should be collected through questionnaires, quality assurance data collection, incident analysis and other sources. The data is analyzed, on the basis of which management decisions are made. All processes are documented.

Suggested Evidence:

- ✓ quality monitoring plan;
- ✓ results of data analyses - documented evidence;
- ✓ taken management decisions - documented evidence.

1.5.5 Heads of structural units improve the quality of health care for patients through participation in the formation of general hospital priorities and monitoring of patient care in the supervised unit.

Guidance

All staff members should be involved in improving the quality of health care. To understand and accept the concept of continuous quality improvement, it is necessary to achieve the commitment of the heads of structural divisions to the principles of organization, their active participation in the formation of general hospital priorities, constant monitoring of the provision of health care in the division. Managers have certain powers, as well as obligations, in relation to the provision of quality health care.

Suggested Evidence:

- ✓ the results of the analysis of quality assurance in each unit of the MO – documented evidence;

✓ the actions taken by the heads of structural units to provide quality health care to patients are documented evidence.

1.5.6 The MO should have quality improvement procedures developed based on the results of the analysis of processes affecting quality.

Guidance

All data that is collected through routine collection, reviews, complaints from patients and stakeholders, assessments of staff actions and data from other sources should be collected in the unit or from the responsible employee, analyzed, on the basis of which decisions are made to improve quality. Quality improvement procedures should be comprehensive, systematic, for their implementation a plan should be developed with the definition of expected results, measures and necessary resources.

Suggested Evidence:

✓ a plan to improve the quality of health care;
✓ the results of the implementation of the measures included in the plan on the improvement of the quality of health care - documented evidence.

1.6 Resource management

1.6.1 The MO must have sufficient material and technical base that meets the requirements for the safety of patients and staff, to ensure adequate receipt of health care; manage their resources, including technological, material and technological, human.

Guidance

The medical organization must have sufficient material and technical base to ensure the adequate implementation of medical procedures, provide a safe environment for employees, patients and those who care for them, including providing the necessary information and protection from harmful substances, microorganisms, compliance with safety regulations in the laboratory and when using the equipment. MO **should** improve the material and technical base through regular renewal, expansion and strengthening. Resources need to be managed to provide quality health care. For this purpose, the relevant units and qualified staff members function in the MO; responsible for the processes of providing certain resources. The staff has the appropriate competencies in the field of resource management.

Suggested Evidence:

✓ material and technical means used by the Medical Organization;
✓ plan for the development of the material and technical base.

1.6.2 MO in the development plan of the organization (strategic, operational) should provide for the development of resources in accordance with the needs of the population, regulatory and legal aspects, professional needs and challenges of our time and improve resources through regular updating, expansion and strengthening of the material and technical base, which must correspond to the development of the organization.

Guidance

The process of regular updating is an integral part of the MO activities. The renewal process should be based on an assessment of the population's need for quality health care, the introduction of new technologies, changes in the regulatory sphere of

the healthcare system and other aspects. The MO should develop a plan to improve the material and technical base in accordance with the identified needs and priorities.

Suggested Evidence:

- ✓ a plan to improve the material and technical base with the necessary funding;
- ✓ accounting, report on acquired resources;
- ✓ documented evidence of updating the material and technical base.

1.7 Risk Management

1.7.1 The MO should have a risk management program/plan.

Guidance

The risk management program is a detailed system that identifies, classifies, evaluates and controls risks in order to prevent, limit and reduce future hazards and losses. The program is an integral part of the policy of providing high quality health care.

The risk management program focuses on resources, patients, staff, technology, etc. to implement the risk management program, the MO must have a plan included in the strategic and operational plan of the organization and each structural unit.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ approved program/risk management plan;
- ✓ responsible employees of the Medical Organization for risk management.

1.7.2 The risk management program should aim to identify and proactively reduce adverse events and other risks to patients and staff.

Guidance

The risk management program should contain the ranking of risks as they affect the quality of care. Risk ranking allows the Medical Organization to determine the highest priority risks and develop preventive measures to mitigate them. It is important to identify the main measures and provide funding.

Suggested Evidence:

- ✓ risk management program;
- ✓ documented evidence of risk ranking, the presence of a risk prevention program, financial support.

1.8 Educational process management

1.8.1 In the case of the participation of the MO in the educational process and the training of medical staff members, there must be a document on the rights and obligations of the MO.

Guidance

MO can act as a clinical base. In this case, the MO must have certain contractual evidence with educational organizations.

Suggested Evidence:

- ✓ agreements with educational organizations.

1.8.2 The MO should have a policy for the participation of patients and staff in the educational process.

Guidance

Serving as a clinical base, the MO should have a policy for the participation of patients and staff in the educational process. The policy includes internal regulations based on the country's regulations governing this process. The internal regulatory documents must spell out the rights and obligations of patients and staff.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ informed consent.

1.8.3 The MO must provide services in accordance with contractual obligations and the educational program.

Guidance

To fulfill the terms of the contract between educational organizations and a medical organization, a medical organization must provide services in the form of allocation of special places (rooms) for training, access to patients, manipulations, operations and other health care processes. All services must be provided in accordance with the educational program, which is developed by the educational organization and coordinated with the clinical base.

Suggested Evidence:

- ✓ agreements with educational organizations;
- ✓ documented evidence of the provision of educational services.

1.8.4 The MO must identify an employee responsible for the implementation of the educational process, taking into account the safety of students, academic staff and patients.

Guidance

For the qualitative conduct of the educational process, it is important to manage this process. For this purpose, the Medical Organization should allocate a responsible employee who coordinates the organization of the educational process, the safety of students, the provision of the necessary resources, as well as monitoring the safety of patients.

Suggested Evidence:

- ✓ order/instruction on the appointment of a responsible employee;
- ✓ powers of the responsible employee;
- ✓ accounting, report on the activities of the employee responsible for the implementation of the educational process, taking into account the safety of students, academic staff and patients.

1.9 Scientific process management

1.9.1 The MO can independently conduct/participate in scientific research, which must be reflected in the Charter or other legal documents.

Guidance

The MO can and/or should be involved in scientific research. The rules of participation are regulated by the legal documents of the country in this area. The MO must have permits, for example, a license/accreditation for scientific activities. Scientific research conducted by the MO should be regulated by the rules and regulations of the country and the MO.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ research projects (if any).

1.9.2 The MO should have a qualified person/structural unit responsible for scientific research, which oversees all research involving people.

Guidance

For the implementation of scientific research/projects in the MO, there must be a structural unit or an employee responsible for the management of scientific activities in the organization. Staff must be qualified. The Medical Organization should have a local ethical commission to determine the safety and protect the rights of patients when conducting scientific research involving people.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ research projects (if any);
- ✓ order/instruction on the profile structural unit/employee responsible for the management of scientific activities in the organization;
- ✓ qualification requirements, powers and responsibilities of the structural unit/employee responsible for the management of scientific activities in the organization.

1.9.3 The MO must have and apply the rules for informing patients and also gathering their and their families consent about the possibility of participating in clinical, scientific research or clinical trials, provide documentary confirmation/refusal to participate in scientific research conducted by the MO.

Guidance

In order to participate in scientific research, the MO must obtain the informed consent of patients/family members/legal representatives, which is provided on a voluntary basis. The MO must explain in detail all the effects that may occur during the study so that the patient can make a conscious choice.

Suggested Evidence:

- ✓ regulations for informing and consenting of patients and their families about the possibility of participating in clinical, scientific research or clinical trials;
- ✓ informed consent/refusal of patients/family members/legal representatives;
- ✓ accounting, reporting on the work done and analysis of activities.



2 STANDARD “STAFF”

2.1 Human resources management

2.1.1 MO must have a policy in the field of human resources, taking into account the specifics of the provision of health care to patients, the needs of society in the provision of quality health care.

Guidance

Human resource management includes the following elements:

- Planning, selection and adaptation of staff members. The MO is developing measures to attract specialists.

- Operational work with staff members, training and development. When hiring, an employee is assigned a probationary period (internship) lasting no more than three months. During this time, the employer checks the employee's ability to perform imputed professional duties in the environment of the Medical Organization.

Suggested Evidence:

- ✓ an internal regulatory document based on the model rules for the admission of professionals approved at the domestic level, adopted in this MO;
- ✓ hiring regulations.

2.1.2 The MO defines the qualification requirements for positions and the responsibilities of each employee, which are prescribed in the job description.

Guidance

The MO should have an internal qualifications policy based on the country's regulations. These requirements should be brought to the attention of all employees of the organization.

Suggested Evidence:

- ✓ an internal regulatory document containing qualification requirements for the MO employees;
- ✓ internal regulatory documents that contain job descriptions for all positions approved in this MO;
- ✓ evidence of bringing to all employees the requirements for job positions.

2.1.3 MO must have a structural unit responsible for accounting, admission, selection, development of human resources.

Guidance

Each MO should have a structural unit (SU) responsible for the accounting and development of human resources. The SU has its own staff members, carries out accounting, selection, development of staff members, organizes the search for applicants for vacancies.

Suggested Evidence:

- ✓ the structure of the MO with the presence of a specialized SU;
- ✓ functional responsibilities of the SU;
- ✓ evidence of the processes of selection and admission of professionals in the MO.

2.1.4 The HR strategy is reviewed on an ongoing basis and updated as necessary.

Guidance

The MO should review staff members policy based on changes in the country's legal and regulatory documents. Updates should be made on a regular basis and based on the development strategy of the MO.

Suggested Evidence:

- ✓ protocols/documents proving the revision of the HR strategy.

2.2 Recruitment and selection of staff members

2.2.1 The MO must ensure that the recruitment of staff members is carried out in accordance with the principles of openness, accessibility of information, objectivity and equality.

Guidance

MO should carry out the reception of professionals, providing equal rights to all volunteers. The MO must provide evidence of vacancies. Information should be available to external applicants, posted on the website/other open sources.

Suggested Evidence:

- ✓ vacancy announcements in print/electronic formats;
- ✓ competition documents must contain the requirements for applicants;
- ✓ proof of acceptance (orders, protocols and other documents).

2.2.2 The MO should determine the desired level of staff training, taking into account the needs and categories of patients.

Guidance

MOs must determine the level of training of staff or determine the "Input Level" in order to be able to provide an adequate level of quality and safety of health care to patients.

Suggested Evidence:

- ✓ proof of minimum/threshold requirements for all positions;
- ✓ evidence of the absence of permanent vacancies for certain positions.

2.3 Staff development

2.3.1 The MO should have a human resources development policy.

Guidance

Describe the policies of the MO on ensuring proper recognition and adequate remuneration of employees. Are there any additional institutional or government policies or rules in this area?

Provide data on staff turnover: by employee category (doctors, nurses, etc.); in large MOs - by divisions. Staff turnover characterizes the effectiveness of staff members policy, including the effectiveness of mentoring programs, adaptation of new employees, feedback with staff members, etc. Including the indicator allows to define "unfavorable divisions". Target indicator - within 3-5% (the so-called natural turnover - is necessary for the timely renewal of the team and does not require intervention from the administration.

Suggested Evidence:

- ✓ an internal regulatory document regulating the development policy of employees of the MO;
- ✓ evidence of the implementation of the human resources development policy;

- ✓ staff turnover rates for the last 5 years.

2.3.2 The HR policy should be aimed at developing professional qualities, motivating and stimulating staff members, and guaranteeing the recognition of the professional achievements of staff members.

Guidance

Describe what mechanisms exist to develop and support the potential of employees and evaluate their performance. List the professional development programs for employees that employees have completed or are planning to undergo, under which they could improve their skills and receive an objective assessment of their clinical performance? How are staff encouraged to participate in professional development programs?

Suggested Evidence:

- ✓ internal regulatory document containing the regulation on staff members development;
- ✓ evidence of staff incentives for the last 5 years.

2.3.3 The MO should have a staff promotion policy.

Guidance

Describe how staff are encouraged to participate in professional development programs. Provide examples of how medical staff have been able to move up the career ladder in the last five years.

Suggested Evidence:

- ✓ internal regulatory document regulating the rules for the promotion of employees;
- ✓ evidence of employee promotion over the past five years.

2.3.4 HR policy should be reviewed based on changes in the legal documents of the country, the Medical Organization and the results of an analysis of the quality of health care for patients.

Guidance

Describe the process of reviewing the HR policy. What formed the basis for the revision of the internal regulatory document? How were the results of assessing the quality of consumer health care used in the transformation of HR policy?

Suggested Evidence:

- ✓ evidence of a revision of HR policy, protocols, results of feedback from patients, medical staff members.

2.3.5 The MO should have a process for the participation of staff in improving the quality of health care, managing the MO.

Guidance

The MO must provide evidence of the involvement of internal stakeholders in the processes for improving care and managing the MO.

Suggested Evidence:

- ✓ minutes of meetings to discuss the quality of health care provided;

- ✓ evidence in the form of orders, instructions, which indicates the membership of clinical staff members in the management of the MO;
- ✓ feedback results with the participation of clinical staff.

2.4 Training and certification of staff members (clinical skills, advanced training)

2.4.1 The MO should have and implement a staff training policy to match its current capabilities.

Guidance

The MO must provide evidence of the presence in the organization of a policy of training, advanced training of staff members. Provide evidence of staff training over the last five years. Provide the proportion of staff covered by in-house training programs. The learning target is 100%. Calculated for basic training programs such as CPR, individual SOPs, new technologies, etc.

Suggested Evidence:

- ✓ internal regulatory document in the field of staff members training;
- ✓ staff development plan;
- ✓ copies of certificates of advanced training of staff members, reports.

2.4.2 The MO should use a defined process to assess the performance of staff in accordance with their job responsibilities and professional positions, the quality and safety of patient care.

Guidance

The MO must provide evidence of the existence of a process for evaluating medical, administrative, managerial, and support staff members. The process should be regular, have an evidence base. Documents should contain clear evaluation criteria and should be accessible to internal stakeholders.

Suggested Evidence:

- ✓ internal normative document regulating the process of regular assessment;
- ✓ minutes of meetings/results of staff evaluation.

2.4.3 The MO should have a unified process for collecting information on the professional qualifications of staff members, confirmed by staff members documents on qualifications, certification, licensing, level of education, etc.

Guidance

The MO should identify the structural unit responsible for collecting routine information on the professional qualifications of staff. The collection process should be organized on an ongoing basis, documents should be stored in a specific place.

Suggested Evidence:

- ✓ rules/procedure governing the process of collecting documents on the professional training of staff members.

2.4.4 The results of the analysis of professional training and the level of professionalism of the staff members should be taken into account in the development of HR policy.

Guidance

MOs should conduct and review staff members policies, taking into account the level of preparedness of the staff. The level of preparedness of the staff members should be discussed at collegiate bodies and the results should influence the transformation of HR policy. The MO should provide funding for staff members, if necessary. The MO should conduct a review of staff competencies and performance evaluation of staff, in accordance with procedures approved by the management of the organization.

Suggested Evidence:

- ✓ reports, protocols on the level of staff members preparedness
- ✓ revised staff members policy based on the analysis of the level of staff training

2.5 Staff health and safety

2.5.1 The MO should have a policy in the field of maintaining and promoting the health of staff members, both physical and mental.

Guidance

The MO must provide evidence of the existence of a regulatory document (regulations, rules, etc.) to strengthen and maintain the health of staff members. The MO should monitor the health status of professionals and have a health maintenance and promotion plan.

Suggested Evidence:

- ✓ regulations/rules for promoting a healthy lifestyle, promoting the health of staff members;
- ✓ documents for periodic assessment of the health status of staff members;
- ✓ recovery plan.

2.5.2 The MO should pay special attention to staff members safety.

Guidance

The MO must have a policy in the field of staff members safety, conduct safety briefings for each employee when familiarizing themselves with the organization.

Suggested Evidence:

- ✓ safety briefing;
- ✓ documents confirming the passage of safety briefing by employees;
- ✓ cases of safety violations and the results of their elimination.

2.6 Freelance Management

2.6.1 The Medical Organization has the right to attract freelance professionals to provide medical or other assistance regulated by the legal documents of the organization.

Guidance

The MO should have a policy to engage freelancers to provide clinical, diagnostic, and support services. The policy should contain rules for the admission of freelancers, their rights and obligations, as well as labor relations between the MO and the freelancer.

Suggested Evidence

- ✓ the presence of an internal regulatory document regulating the relationship between the Medical Organization and a freelancer;
- ✓ the number of freelancers and the number of labor contracts.

2.6.2 MO should have a policy in the field of recruitment, requirements for their qualifications, duties, rights, functions, instructions for freelancers.

Guidance

MO in its policy of attracting freelance professionals should clearly spell out the basic requirements for qualifications, the availability of the necessary training and experience for this category of professionals, their rights and obligations. Freelancers must be instructed in safety, ethics of conduct.

Suggested Evidence:

- ✓ an internal regulatory document containing requirements for the qualification of freelancers;
- ✓ instructions for freelance professionals should be brought to their attention;
- ✓ evidence of training for freelance professionals.

2.6.3 The MO should determine the requirements for the quality and volume of work of freelancers, monitor and control their activities within the organization.

Guidance

The MO should determine the requirements for freelancers depending on the position for which the freelancer is invited or applying. The requirements for freelancers should specify the amount of work and the quality of its performance. The monitoring process should be provided by the MO on an ongoing basis.

Suggested Evidence:

- ✓ documents, evidence of assessment of the quality of services provided by freelancers;
- ✓ in case of non-compliance with the requirements, how the relationship between the organization and freelancers was regulated.

2.6.4 The MO should review its policy in the field of attracting freelancers, taking into account the results of the analysis of their activities.

Guidance

The MO should periodically review its policy of recruiting freelancers to provide certain types of services and ensure high quality and safety of health care.

Suggested Evidence:

- ✓ updated policy (internal legal document) that has been revised in the last 5 years;
- ✓ Evidence that the MO has reviewed its recruitment policy for freelancers based on an analysis of their performance.



3 STANDARD “RESOURCE MANAGEMENT”

3.1 Financial management

3.1.1 Financing of the MO is aimed at implementing the mission and development strategy of the organization.

Guidance

The MO must provide funding adequate to the implementation of the mission and development strategy of the MO. In the strategic, operational plan of organizing the event, the measures are supported by financial resources.

Suggested Evidence:

- ✓ strategic development plan;
- ✓ operational plan and reports for past periods;
- ✓ plan of financial and economic activity.

3.1.2 Financing of the MO provides for the conditions in which the organization will operate, and is based on an assessment of the needs of staff members and management in the development of the organization.

Guidance

The Medical Organization should regularly assess the need for the provision of high-quality and safe health care, forecast financial opportunities to ensure quality improvement. The SU responsible for planning the MO financing should determine the budget, taking into account the forecast based on the need for staff, inflation and other external factors, in which the organization will operate.

Suggested Evidence:

- ✓ plan of financial and economic activity;
- ✓ dynamics of changes in funding over the past five years;
- ✓ list of acquired material and logistics support.

3.1.3 In the case of the provision of paid medical services, information on pricing policy should be open to the public.

Guidance

The Medical Organization must necessarily determine the pricing policy in the case of the provision of paid medical services. The pricing policy is based on an assessment of the needs of the population for certain types of health care and the capabilities of the municipality. Without fail, the pricing policy in the form of a price list, a list of medical services must be posted on the organization's website and updated on an ongoing basis.

Suggested Evidence:

- ✓ approved regulation/rules/regulations on paid services;
- ✓ a document approved at the level of the Medical Organization with a list of medical services and costs;
- ✓ evidence of the placement of up-to-date information about the pricing policy posted on the organization's website.

3.1.4 The MO should review funding on an ongoing basis, taking into account the need for development, justify budget changes and report back to the community.

Guidance

The MO should conduct an annual assessment of the funding of its own organization. The administration or management body annually reports to the team on financial and economic activities.

Suggested Evidence:

- ✓ minutes of meetings of collegial bodies with the management report results of the Medical Organization on financial and economic activities;
- ✓ MO reports on financial and economic activities.

3.2 Financial audit and accounting

3.2.1 MO should have a system of internal control over financial activities.

Guidance

The MO should have an internal audit system, including financial audit. Internal audit allows MO to control the financial activities of the organization and helps to achieve the development goals of MO using a systematic approach to assessing and improving the effectiveness of risk management processes, corporate governance.

Suggested Evidence:

- ✓ internal document on the creation of a financial audit;
- ✓ acts of financial audits;
- ✓ decisions taken based on the results of financial audit reports.

3.2.2 Accounting is kept taking into account the transparency of processes and should be fully automated.

Guidance

The MO should ensure the transparency of accounting processes by using automated processes and providing access to accounting results to certain categories of employees.

Suggested Evidence:

- ✓ approved accounting policy;
- ✓ tax and financial reports;
- ✓ automated accounting system adopted at the domestic level and used in the MO.

3.2.3 The MO should engage independent auditors to assess financial performance.

Guidance

Conducting an independent audit allows the organization to obtain independent and objective information about accounting and financial activities. An independent audit is mandatory.

Suggested Evidence

- ✓ an order to conduct an independent audit;
- ✓ conclusions with the results of independent audits.

3.2.4 Financial reporting should be strictly regulated and reports should be provided to the governing body/chief executive.

Guidance

The MO structural unit should generate financial statements on a regular basis and submit them to the governing body/chief executive officer for review and approval. Usually, the reporting period is 3 months, but sometimes it can be shorter, for example - a month. This process is determined by the management of the MO itself.

Suggested Evidence:

- ✓ reports provided to management.

3.3 Salary

3.3.1 The MO should have a policy on staff remuneration.

Guidance

The Medical Organization pursues a clear policy in matters of remuneration. Remuneration of staff members should be carried out within the established time limits, about which the staff members are informed.

Suggested Evidence:

- ✓ internal regulatory document, staff remuneration policy.

3.3.2 The MO must ensure that the remuneration of staff members is regulated by the legal documents of the country and local documents of the organization.

Guidance

The MO should develop internal regulations on staff remuneration, focusing on the legal documents governing labor relations and the remuneration system at the domestic level.

Suggested Evidence:

- ✓ internal regulatory document, staff members remuneration policy
- ✓ regulatory and legal documents confirming the labor activity.

3.3.3 The remuneration process must be communicated to each employee to avoid conflicts of interest.

Guidance

MOs need to demonstrate the openness of the remuneration process. Employees must be informed of pay dates that must be observed. The MO must ensure individual confidentiality in relation to employees.

Suggested Evidence:

- ✓ methods of remuneration;
- ✓ employee survey.

3.3.4 The MO should have a system of staff incentives in the form of financial payments, of which each employee should be informed.

Guidance

MO must have an approved internal regulatory document on staff incentives. Describe how the MO has provided financial incentives and rewards to its employees over the past five years. What finances were allocated by the Medical Organization to stimulate and encourage employees? How does the governing body communicate to staff information about the incentive system?

Suggested Evidence:

- ✓ internal regulatory document on the staff members incentive system, approved at the level of the Medical Organization;
- ✓ evidence of informing staff about the existence of a staff incentive system;
- ✓ documents proving payments to staff as incentives and rewards.

3.4 Information management and protection, information technology

3.4.1 MO should have a qualified employee/unit responsible for the development of information technology, protection and information management.

Guidance

The MO should use information technology to exchange information with proper protection and management. The MO should provide in the structure of the organization a structural unit responsible for the functioning of information technologies, the implementation of information protection, including personal information about patients.

Suggested Evidence:

- ✓ the structure of the organization with the definition of the location of the structural unit responsible for information technology or an employee in a particular structural unit;
- ✓ position/job descriptions of employees of this structural unit;
- ✓ an internal regulatory document regulating this process in the MO.

3.4.2 The MO must guarantee sufficient quantity and quality of technical means for the activities of the staff members.

Guidance

MO should determine on an ongoing basis the need for staff members in technical means by collecting applications, analyzing and summarizing them. Technical means should be updated as they wear out and break down.

Suggested Evidence:

- ✓ a list of technical means on the balance sheet of the organization;
- ✓ system of collection, analysis of the need for technical means;
- ✓ documents confirming the acquisition of technical equipment over the past five years;
- ✓ plan for the purchase of technical equipment with the allocation of finance.

3.4.3 The MO must guarantee the privacy, confidentiality, data security and integrity of information.

Guidance

The MO ensures compliance with the principles of a clear definition of the level of access depending on the position held, which is spelled out in the internal documents of the organization.

Suggested Evidence:

- ✓ an internal regulatory document containing information security measures and the level of access depending on the position;
- ✓ list of staff members by access levels.

3.4.4 The MO should plan and establish processes for managing trustworthy information for all staff members and external parties of the organization.

Guidance

The MO should have a plan or process for managing trustworthy information in accordance with local law, managing incoming and outgoing documentation.

Suggested Evidence:

- ✓ availability of an internal regulatory document regulating the process of document management;
- ✓ compliance with the rules for registering internal and external documentation and the algorithm for its movement.

3.4.5 For patients, the MO should have a standardized data coding system for diagnosis, procedures.

Guidance

MO, according to the quality management system, must have a system for coding patient data. The system is usually unified for a certain country and must be applied by the MO in accordance with established rules.

Suggested Evidence:

- ✓ availability of a documented system for coding patient data and their identification;
- ✓ demonstration of case histories, prescription sheets with coded data.

3.4.6 The MO should provide the necessary information in a timely manner, depending on the need.

Guidance

According to the regulatory rules, certain requirements are established for the provision of information to both external organizations and internal structural divisions, and employees. The MO is obliged to provide up-to-date reliable information at the request of external organizations, patients and their relatives and other consumer groups on the basis of clear regulations and rules

Suggested Evidence:

- ✓ regulations for the provision of information from the Medical Organization to external organizations/bodies;
- ✓ documents used to record the provision of the necessary information.

3.4.7 MO staff members should be trained in working with information, information systems, the principles of information use, information security and information management.

Guidance

The MO must necessarily train all staff members to work with documentation. Training depends on the level of staff members access to certain processes and their level of responsibility.

Suggested Evidence:

- ✓ plan and training programs for staff members to work with documentation;
- ✓ evidence of staff training (certificates, lists, instructions, etc.).

3.5 Management of internal documents and medical records

3.5.1 The MO should have unified document management processes.

Guidance

According to the requirements for information management in MO, a document management system should be developed. The implementation of the records management system should be the responsibility of a specific structural unit or an employee. The Medical Organization should provide training for all staff members on working with internal documents and medical records.

Suggested Evidence:

- ✓ documents regulating records management;
- ✓ staff training programs/plan.

3.5.2 MO should introduce rules, procedures, plans that are aimed at regulating all processes in the organization.

Guidance

In any MO, a quality management system should function, the functions of which include the creation of standards of procedures, training of staff members, control of implementation in the field.

Suggested Evidence:

- ✓ current regulations covering all processes related to the activities of the Medical Organization;
- ✓ evidence of the use of the SU regulations.

3.5.3 The MO uses a standard medical record for patients and has a clear layout for each medical record.

Guidance

The MO must have and comply with the rules for managing medical records, in particular, the patient's medical record. The MO must implement a clear algorithm for filling, storing and moving the patient's medical record. The format of the patient's medical record is usually approved at the country level and is used as a unified one in each MO.

Suggested Evidence:

- ✓ standard medical record of the patient;
- ✓ a document regulating the storage, movement of a patient's medical record.

3.5.4 The medical record must contain accurate and sufficient information about the patient, diagnosis, treatment regimen, and the dynamics of the condition.

Guidance

When developing a medical record, mandatory sections should be taken into account, including information about the patient, diagnosis, ongoing diagnostic treatment procedures, mandatory recording of the patient's condition in dynamics, and the outcome of the disease.

Suggested Evidence:

- ✓ standard filled out medical record of the patient.

3.5.5 The MO should define the powers and responsibilities for maintaining medical records on the part of clinical and non-clinical staff members.

Guidance

The MO should provide training to staff members who, by virtue of their authority, use the medical record. Training should be ongoing. The MO should define the responsibility of the staff for maintaining the medical record.

Suggested Evidence:

- ✓ plan/program/instruction for staff training on maintaining a medical record;
- ✓ regulations defining the responsibility of staff members for maintaining medical records and medical records.

3.5.6 The MO should ensure regular review, evaluation and analysis of the quality of medical records, including the patient's medical record.

Guidance

The MO should have a structural unit responsible for internally ensuring the quality of health care. Trained experts analyze the maintenance of medical records on a regular basis and provide the results of the analysis to the governing body for management decision-making

Suggested Evidence:

- ✓ the structure of the MO, the functions and responsibilities of the structural unit for internal quality assurance;
- ✓ results of examination of medical records of patients.

3.6 Databases and their analysis

3.6.1 MO should have a database of patients, the activities of the organization itself.

Guidance

Medical organization should have an electronic/paper system for collecting and storing data of patients, employees and other data on the activities of the MO. All MO documents must be preserved and stored in accordance with the requirements for such processes. The MO should provide a procedure for verifying the reliability of published and provided data

Suggested Evidence:

- ✓ database of patients;
- ✓ database on the main activities of the MO.

3.6.2 The database must have protection that ensures the protection of personal data of patients and staff, the activities of the medical organization, subject to non-disclosure.

Guidance

Describe how information is protected, what protection programs are used by the Medical Organization.

Suggested Evidence:

- ✓ up-to-date information security agreements;
- ✓ obligations of the staff on non-disclosure of confidential information.

3.6.3 Staff, depending on the level of authority, must have access to the database for data analysis and management decision-making.

Guidance

Each employee of the Medical Organization must have access to certain official information for the implementation of their functions, the exchange of information with other employees and structural divisions. At the same time, access and use of information should be differentiated depending on the position of the staff or employee. This is important for proper information management and protection.

Suggested Evidence:

- ✓ a document regulating certain access to information for staff members, depending on their position;
- ✓ a document that concretely defines the level of staff members access to a certain level of information.



4 STANDARD “SAFETY MANAGEMENT”

4.1 Infection safety management and infection control

4.1.1 MO must have a policy in the field of infection prevention and control, use a risk-based approach with the identification of areas with a high risk of infection to develop preventive measures and monitor their implementation and effectiveness.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention. The MO should use a country regulation or an internal regulation developed on the basis of a country's regulations governing the prevention and control of nosocomial infections. Usually, to ensure the control and prevention of infections, a certain set of documents (rules, regulations, orders) is used that regulate these processes. The organization must have a plan, carry out constant monitoring and control, generate a report, and also develop accounting forms to collect up-to-date information. A risk-based approach should be implemented based on principles such as ensuring separation of patients, early recognition and control of the source of infection, applying standard precautions for all patients, implementing additional precautions based on practical considerations, implementing administrative controls, implementing environmental controls and engineering systems.

Suggested Evidence:

- ✓ normative documents regulating the issues of control and prevention of infections;
- ✓ plan, program for infection prevention and control;
- ✓ reports, registration forms and other documents on the registration of cases of infections.

4.1.2 The MO should identify a qualified person/unit responsible for infection prevention and control.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention. The MO may have a structural unit responsible for infection prevention and control, in some cases this function may be performed by a certain employee. The professional(s) should have an appropriate education in the field of infection control, undergo competency assessment and continuously improve their skills. A Structural Unit or an employee is responsible for all processes related to the implementation of preventive measures against infections, carries out internal control in the MO, organizes training for clinic staff and implements other issues related to infection control.

Suggested Evidence:

- ✓ MO structure;
- ✓ functional duties/job description of an employee(s);
- ✓ documents confirming the qualifications of an employee(s).

4.1.3 MO staff members should be trained in infection safety rules, as well as participation in coordinated infection prevention and control activities.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention. The MO should train all staff in infection prevention and control on an

ongoing basis. Each employee of the Medical Organization must know the rules of infection safety, have the skills to conduct infection control and follow the rules of infection safety.

Suggested Evidence:

- ✓ staff members training plan for infection safety rules
- ✓ documents proving that the staff members of the Medical Organization have received training on infection safety and control
- ✓ documents confirming that the staff has passed certification/control of the level of knowledge, skills, abilities in the field of infection safety and infection control

4.1.4 The MO should periodically screen staff members for infections.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention. In order to implement infection safety, MO staff members must be periodically tested for the absence of infections. This check should be carried out initially when new employees are hired, and also periodically for all staff members engaged.

When staff members are found to be infected, the MO must take steps to eliminate the risk of infection to other professionals and patients.

Suggested Evidence:

- ✓ documents proving that staff members have been screened for infections;
- ✓ facts of detection of infections among staff members;
- ✓ measures implemented by the Medical Organization and documents confirming this process, as well as the result of the implementation of these measures.

4.1.5 The MO should allocate the necessary resources to an infection prevention and control program.

Guidance

MOs should have an infection prevention and control program that is reflected in the organization's strategic and operational plans. Certain finances should be allocated to the program, including covering the costs of ensuring the infection safety of buildings, communications, equipment, consumables, personal and patient protection equipment.

Suggested Evidence:

- ✓ funded prevention plan/program;
- ✓ reports on allocated finances for a five-year period.

4.1.6 The MO should provide training to staff, patients and their families on infection prevention.

Guidance

Important in order to achieve the required quality of health services is the training of both staff and patients and their families in the prevention of infections. MOs should ensure compliance with infection prevention rules by organizing staff training, testing their knowledge and skills, raising patient awareness during their stay in the MO, providing recommendations on infection prevention, and using visual materials to increase awareness.

Suggested Evidence:

- ✓ infection prevention training plan for staff and patients;
- ✓ accounting, report on the implementation of training;
- ✓ assessment of staff knowledge and skills on infection prevention.

4.2 Safety of medical equipment, devices and consumables

4.2.1 The Medical Organization must ensure the safety of medical equipment, including surgical, resuscitation, etc.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention. MO must use medical equipment (instruments, apparatus, etc.) that meets safety requirements. Certain requirements are imposed on medical equipment: ensuring the protection of the patient and user from mechanical damage, from an increased level of vibration, noise, thermal and ionizing radiation; ensuring electromagnetic compatibility, electrical, chemical safety of use; the medical equipment used must be made of safe materials; contain the necessary amount of information on the safety of operation and use specified in the operational document of medical equipment, instructions for the medical use of medical devices, labeling; contain materials with physical properties that exclude the possibility of harm to the health of the patient or user during use, transportation, storage, due to loss of tightness, strength, contamination and environmental factors; safe to use with the materials, substances and gases with which they come into contact.

The MO should have trained staff members to work with medical equipment. Medical staff members must know and apply safety precautions. The MO should identify an employee/structural unit responsible for managing and reducing the risks associated with the safety of medical equipment. To ensure the safety of medical equipment, medical organizations must comply with the requirements and rules established at the domestic level, if necessary, develop their own documents on the regulation of this area.

Suggested Evidence:

- ✓ legal documentation governing this process;
- ✓ program/plan for managing/renovating/replacing medical equipment;
- ✓ accounting, reporting documents for the operation, regular checks of medical equipment, operating instructions;
- ✓ documents defining the procedures for the maintenance of medical equipment;
- ✓ accounting and reporting documents for the registration of defects, malfunctions, repairs;
- ✓ documentary evidence of staff training to work with medical equipment, including safety precautions, the availability of certificates, diplomas and other supporting documents;
- ✓ documented evidence of the qualifications of the responsible person/structural unit for managing and reducing risks associated with the safety of medical equipment.

4.2.2 The MO must ensure the safety of consumables.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention.

Consumables include a medical group of goods that are intended for single use only, and after the treatment and diagnostic process they are disposed of. These include the following types of products:

- ✓ protective materials or PPE - disposable gloves, caps, shoe covers, three-layer masks;
- ✓ means for bandaging and processing seams - bandages, cotton wool, gauze, tampons, balls;
- ✓ syringes and infusion systems - transfusion systems, syringes, needles, scarifiers, catheters;
- ✓ antiseptics - alcohol wipes, hygienic hand gels;
- ✓ devices for laboratory research - spatulas, containers for collecting tests, dilators, gels for ultrasound and ECG;
- ✓ disposable sheets and towels.

They must be sterile and reliable, meet all necessary safety standards.

MOs must ensure the safety of consumables by ordering them from trusted suppliers, accounting for them, using and storing them correctly, and properly disposing of them.

Medical staff members must know and apply the rules for the use and disposal of consumable medical supplies. The MO should identify a responsible person/structural unit responsible for the safety of medical consumables. To ensure the safety of consumables, the Medical Organization must comply with the requirements and rules established at the domestic level, if necessary, develop their own documents on the regulation of this area.

Suggested Evidence:

- ✓ legal documentation governing this process;
- ✓ documents on the accounting of consumables;
- ✓ documents on the disposal of consumables;
- ✓ documents for the supply of consumables;
- ✓ plan for the purchase of consumables;
- ✓ documentary evidence of the knowledge and skills of medical staff members in the use of consumables.

4.3 Workplace, surface and hospital linen safety

4.3.1 The Medical Organization in the policy on prevention and control of infections should provide for standards for ensuring the safety of workplaces and surfaces from infections.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention.

One important aspect of safety is infection prevention and control. Workplaces and various surfaces of the MO are the most frequently polluted places, which determines the mandatory rules for ensuring their infection safety. The MO must have an infection safety program that includes documented procedures, instructions for the treatment of workplaces and surfaces, depending on their purpose, the level of contamination and the required level of cleanliness and sterility. To ensure the safety of workplaces and surfaces, the Medical Organization must comply with the requirements and rules established at the domestic level, if necessary, develop their own documents on the regulation of this area.

Suggested Evidence:

- ✓ legal documentation governing this process;
- ✓ rules/instructions for processing workplaces and surfaces;
- ✓ schedule for processing workplaces and surfaces;
- ✓ documented procedures for checking compliance with the infection safety of workplaces and surfaces;
- ✓ documented cases of violation of the infection safety of workplaces and surfaces and measures taken;
- ✓ documents on the training of staff members to ensure the infection safety of workplaces and surfaces.

4.3.2 The MO should ensure the safety of hospital linen by developing and enforcing generally accepted rules and regulations and strictly enforcing them.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention.

Hospital linen is one of the important aspects of MO, which can be a potential risk factor for the spread of infection and therefore is subject to mandatory safety control.

MO must have documented procedures for storage, replacement, processing and decontamination, disposal. In structural subdivisions, specially trained staff members store, replace hospital linen, process, disinfect, usually a separate unit (laundry) within the MO or use outsourcing in some cases.

Suggested Evidence:

- ✓ legal documents governing this process;
- ✓ documented procedures for ensuring the safety of hospital linen;
- ✓ documented evidence of staff training/skills to ensure the safety of hospital linen;
- ✓ recorded cases of violation of safety rules by staff members, appropriate decisions.

4.4 Human Waste and Tissue Safety

4.4.1 MO should have standards for the handling and disposal of medical waste, human tissues, items containing human tissues and fluids.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention.

The standards for the handling and disposal of medical waste, human tissues, objects containing human tissues and fluids contain the rules and requirements for the implementation of these processes in the MO. They help ensure the safety of patients and staff. The MO must comply with the rules adopted at the domestic level, determine the responsibility of staff members, train staff members, conduct periodic quality control checks, record and analyze each case of violation of established rules.

Suggested Evidence:

- ✓ legal documents governing this process;
- ✓ documented procedures for ensuring the safety of medical waste, human tissues, objects containing human tissues and fluids;

- ✓ documented confirmation of the training/skills of staff members to ensure the safety of medical waste, human tissues, objects containing human tissues and fluids;
- ✓ recorded cases of violation of safety rules by staff members, appropriate decisions.

4.4.2 Staff must be trained to work with waste, tissues, human fluids

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention.

All staff members must be trained to work with waste, tissues, human fluids. MOs must ensure 100% training of staff members and periodic assessment of their competence. The Medical Organization should appoint an employee responsible for infection safety, who controls the level of preparedness of staff members in the field of infection safety.

Suggested Evidence:

- ✓ documented staff members training procedures based on country requirements in this area;
- ✓ documented evidence of staff members competence assessment;
- ✓ competencies and functional duties of the employee responsible for infection safety.

4.4.3 The MO must ensure the safety of staff and patients from pathogens associated with contact with human tissues and fluids.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention. The MO must ensure the safety of staff and patients based on the implementation of the requirements adopted at the domestic level. Infection safety guarantees should be built on the basis of informing patients about the safety measures that they must comply with; ensuring the correct operation of all systems related to and/or influencing the spread of pathogens through continuous monitoring and control; observance of hygiene rules by the employees of the Medical Organization.

Suggested Evidence:

- ✓ program/plan/instructions for the safety of patients, staff;
- ✓ documented informing procedure of patients on the prevention of infections and risks of infection;
- ✓ documented evidence of the implementation of preventive measures with patients;
- ✓ availability of visual materials for working with patients;
- ✓ documented evidence of assessment of the knowledge and skills of staff members;
- ✓ accounting, reporting documents for checking systems related to and/or affecting the spread of pathogens in the Medical Organization;
- ✓ measures taken following the detection of cases of violation of safety rules.

4.5 Food safety

4.5.1 The MO must ensure the safety of patients' nutrition.

Guidance

The MO should carry out risk assessment and monitoring of their reduction and prevention in the field of nutrition. Patient nutritional safety is one of the important mechanisms for ensuring the quality of services provided in the MO. On the other hand, nutrition can be one of the risk factors for violating infection safety. Many medical organizations have their own catering units, where food for patients is made, some use outsourcing services.

MOs must ensure food safety by complying with sanitary and hygienic norms and rules for food objects of MOs. Food facilities staff members should be periodically tested for the absence of infections, pathogens that are dangerous to patients and staff. Food must be tested for safety and quality. The MO should provide for a qualified employee/structural unit responsible for food safety issues. The MO should provide funding to improve food quality and safety.

Suggested Evidence:

- ✓ program/plan/instructions for the safety of patients, staff members in the field of nutrition;
- ✓ documented informing of patients on the prevention of infections and the risks of infection associated with nutrition;
- ✓ documented evidence of the implementation of preventive measures with patients;
- ✓ availability of visual materials for working with patients;
- ✓ documented evidence of assessment of the knowledge and skills of food facilities staff members;
- ✓ accounting, reporting documents for checking systems related to and/or influencing the spread of pathogens through food in the MO;
- ✓ measures taken following the detection of cases of violations of security rules and documentary evidence.

4.5.2 The MO must ensure the safety of food for staff members.

Guidance

Many MOs have catering facilities for staff. In addition to the food safety of patients, the Medical Organization must ensure the food safety of staff without fail.

The MO should conduct risk assessment and monitoring of their reduction and prevention in the field of staff members nutrition, since nutrition can be one of the risk factors for violating infection safety. Many medical organizations have their own catering units, where food is made for both patients and staff, some use outsourcing services.

MOs must ensure food safety by complying with sanitary and hygienic norms and rules for food objects of MOs. Food facilities staff members should be periodically tested for the absence of infections, pathogens that are dangerous to patients and staff. Food must be tested for safety and quality. The MO should provide for a qualified employee/structural unit responsible for food safety issues. The MO should provide funding to improve food quality and safety.

Suggested Evidence:

- ✓ program/plan/instructions for staff members safety in the field of nutrition;
- ✓ documented evidence of the implementation of preventive measures with staff members;
- ✓ documented evidence of assessment of the knowledge and skills of food facilities staff members;

- ✓ accounting, reporting documents for checking systems related to and/or influencing the spread of pathogens through food in the MO;
- ✓ measures taken following the detection of cases of violations of security rules and documentary evidence.

4.6 Safety of engineering, utility systems, repair work, reconstruction and construction

4.6.1 MO must ensure the safety of engineering, utility systems through the use of controls.

Guidance

MO, in addition to providing quality patient care, must also ensure the safety of engineering and utility systems. In order to ensure the safety of engineering, utility systems, the MO must have a program based on the legal documents of the country, have a system audit/inspection plan, identify a qualified employee responsible for ensuring safety, regularly update systems, train staff members in safety and proper response to in the event of incidents with an assessment of knowledge and skills.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ safety program for engineering and utility systems;
- ✓ audit/inspection plan, reports/audits on inspections, conclusions on violations and adopted acts on them;
- ✓ documented proof of renovation of engineering and utility systems, including the allocation of financial resources;
- ✓ functional responsibilities and qualification requirements for the employee(s) responsible for the security of systems, and compliance with them;
- ✓ instructions, memory aids for patients on safety and proper response in case of incidents;
- ✓ program/plan for training staff members in safety and proper response in case of incidents with an assessment of knowledge and skills;
- ✓ availability of contracts and execution when third-party organizations are involved for the reconstruction of systems, ensuring security.

4.6.2 MO must ensure the safety of buildings, repair work.

Guidance

The MO must ensure the safety of buildings, structures, including during reconstruction and demolition, redevelopment by having a safety program/plan, a plan for the reconstruction of buildings, structures, repair work with the allocation of financial resources, attracting third-party organizations to carry out repair, construction work that have official permits for such types of work, the use of an independent and well-documented process for accepting the results of the activities of third-party organizations, having a qualified employee(s)/structural unit responsible for the safety of buildings, structures, repair work, reconstruction, mandatory training of staff members in safety issues, correct response in case of an incident, availability of a notification system in case of an incident. It is important to comply with safety rules and reduce the risk of infection during the reconstruction and demolition of units or buildings.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ a program for the safety of buildings, structures, repair work;

- ✓ audit/inspection plan, reports/audits on inspections, conclusions on violations and adopted acts on them;
- ✓ documented evidence of repair work, including the allocation of financial resources;
- ✓ functional duties and qualification requirements for the employee(s) responsible for the safety of buildings, repair work, and compliance with them;
- ✓ instructions, memory aids for patients on safety and proper response in case of incidents;
- ✓ program/plan for training staff members in safety and proper response in case of incidents with an assessment of knowledge and skills;
- ✓ availability of contracts and execution when third-party organizations are involved for the reconstruction, demolition, construction of security buildings.

4.7 Fire safety

4.7.1 MO must ensure fire safety

Guidance

The MO should implement a program to reduce the risk of fire and smoke. The MO should have a functioning system for early fire detection; adequate firefighting equipment must be available and regularly inspected and renewed as necessary.

Suggested Evidence:

- ✓ legal documents regulating this process
- ✓ fire safety program;
- ✓ audit/inspection plan, reports/audits on inspections, conclusions on violations and adopted acts on them;
- ✓ documented evidence of firefighting work, including the allocation of financial resources;
- ✓ functional responsibilities and qualification requirements for the employee(s) responsible for fire safety, and compliance with them;
- ✓ instructions, memory aids for patients on fire safety and proper response in case of incidents;
- ✓ availability of contracts and execution under them when third-party organizations are involved to ensure fire safety;
- ✓ availability of a fire warning system and all necessary resources (equipment, materials).

4.7.2 The MO should conduct fire safety training for staff members.

Guidance

One of the important points in ensuring the fire safety of staff members, patients, risk management is trained staff members and sufficient informing of all participants in the medical process, which should be provided with training of staff members on an ongoing basis, determining the skills and abilities of staff members, building a system for continuous improvement of this process. The employee(s)/structural unit must have a program, a plan for staff training and informing patients for the correct response in case of incidents with an assessment of knowledge and skills.

Suggested Evidence:

- ✓ program and plan for training fire safety staff members and the correct response in case of incidents with an assessment of knowledge and skills, including simulations;

✓ accounting, reporting documentation for assessing the knowledge and skills of staff members.

4.7.3 The MO must have an evacuation plan in case of a fire threat.

Guidance

MOs should develop and implement a system for evacuating patients and staff members in the event of a fire threat, including an evacuation scheme that is located in open areas in sufficient numbers. The evacuation scheme should be understandable, developed in the state language and languages of interethnic communication for the convenience of studying it by all patients and staff. The MO should provide enough exits from buildings to avoid crowding and congestion.

Suggested Evidence:

- ✓ evacuation scheme for staff and patients;
- ✓ the presence of signs, the openness of the exits.

4.8 Water and electricity safety

4.8.1 MO must ensure the safety of water and electricity.

Guidance

The safety of water and electricity is a key aspect of the risk management program. The MO must ensure safety through continuous access to water and electricity, including their alternative sources, have a system for assessing the level of water safety, evaluating processes and equipment to ensure the continuity and safety of the provision of water and electricity, identifying units for which continuity of water and electricity supply is a priority, the presence of a structural unit or employee(s) responsible for the continuity and safety of water and electricity.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ water and electricity safety program;
- ✓ audit/inspection plan, reports/audits on inspections, conclusions on violations and adopted acts on them;
- ✓ documented evidence of work on the continuity and safety of water and electricity, including the allocation of financial resources;
- ✓ functional responsibilities and qualification requirements for the employee(s) responsible for the safety of water and electricity, and compliance with them;
- ✓ availability of contracts and execution with the involvement of third-party organizations to ensure the safety of water and electricity;
- ✓ availability of an alternative water and electricity supply system and all necessary resources (equipment, materials).



5 STANDARD “SAFETY OF MEDICINES (MC) AND MEDICAL DEVICES (MD)”

5.1 Management of medicines and medical devices

5.1.1 MO must ensure the management and safe handling of medicines (MC) and medical devices (MD) in the organization

Guidance

The Medical Organization must ensure that medicines and medical devices are used depending on the need, are regulated by the legislative and regulatory documents of the country. Management of medicines and medical devices consists of the following processes: planning, purchasing, storage, ordering medicines, preparation/packaging, prescription/use, monitoring and control, error and side effect reports, evaluation.

The MO should have a plan for the required number of medicines and medical devices based on forecast data of the required amount, and financial resources should be planned for this. The purchase of medicines and medical devices is carried out from reliable sources. Storage of medicines and medical devices is carried out strictly according to the rules and requirements approved at the domestic level. The MO must order medicines and medical devices taking into account the need, within the MO departments/subdivisions must order medicines and medical devices depending on the needs of the unit. In the Medical Organization, subdivisions, only trained staff members prepare and pack medicines. The prescription of medicines is carried out by medical staff members by documenting this process. Medical staff members should monitor the use of medicines by patients. The circulation of medicines and medical devices must be controlled by constant monitoring of circulation. It is important to register all the negative aspects associated with side effects from taking medicines and medical devices, as well as incorrect prescription.

Suggested Evidence:

- ✓ legal documentation regulating this process;
- ✓ internal regulatory documents, rules, regulations, orders of the Medical Organization;
- ✓ plan for the purchase of medicines and medical devices;
- ✓ contracts for the supply of medicines and medical devices;
- ✓ compliance of medicines and medical devices with the established requirements of the regulatory documents of the country;
- ✓ MO documents used to manage the procurement process, ordering medicines and medical devices;
- ✓ monitoring plan, supporting documents;
- ✓ accounting, reporting documents used in MO.

5.1.2 The MO should identify a qualified person responsible for the management and control of the use of medicines and medical devices at the organization level, as well as at the level of each unit.

Guidance

MO should have a service/employees responsible for the quality and safe handling of medicines and medical devices. The employee(s) must have appropriate training, have competencies, undergo periodic testing of knowledge and skills in handling medicines and medical devices. The employee(s) has(have) the rights to monitor and control the circulation of medicines and medical devices. In the MO, employees responsible for the circulation and control of medicines and medical devices should

work both at the level of the entire organization and in each unit. Employees must have all permits that give them the right to work in this direction and in this position, must undergo training, confirm their competencies and keep records and responses to the movement of medicines and medical devices. It is also important that the MO should have a process for collecting negative effects and medical errors in prescriptions.

Suggested Evidence:

- ✓ legal documents regulating the requirements established at the country level for the qualifications of the employee(s) responsible for the management of medicines and medical devices;
- ✓ documents confirming the qualifications of the employee(s), assessment of competencies, training in the relevant field;
- ✓ the work plan of this employee(s) or structural unit;
- ✓ reporting documentation on the analysis, monitoring and control over the circulation of medicines and medical devices.

5.1.3 The MO should have a program for the prudent and safe use of antibiotics.

Guidance

MO should pay special attention to the circulation of antibiotics, since their excessive prescription leads to negative consequences, such as resistance, treatment failure, development of side effects, etc. All this together determines a special approach to the use of antibiotics to prevent unnecessary complications, side effects and the development of resistance, which can lead to a decrease in the quality of treatment and a deterioration in the health status of patients.

Suggested Evidence:

- ✓ antibiotic management program;
- ✓ a program for monitoring and controlling the effectiveness of the program;
- ✓ methodological materials on the rational use of antibiotics.

5.2 Storage of medicines and medical devices

5.2.1 The Medical Organization needs to provide appropriate and safe storage conditions for medicines and medical devices in accordance with the legal documents of the country and local documents.

Guidance

Ensuring the safety of medicines and medical devices is a prerequisite for ensuring the quality of health care. The Medical Organization accepts and stores medicines and medical devices, in connection with which, safety is particularly relevant. MO must have the necessary material and technical resources and conditions for the storage of medicines and medical devices, depending on the appropriate requirements.

The requirements include the following: the conditions specified by the manufacturers of medicines and medical devices must be observed, the accounting of medicines and medical devices must be carried out on an ongoing basis, the labeling of medicines and medical devices must be mandatory, a risk assessment system must function, including against loss.

Suggested Evidence:

- ✓ legal documents regulating this process;
- ✓ system of accounting and reporting on the movement of medicines and medical devices;

- ✓ internal regulatory documents regulating the storage conditions for medicines and medical devices;
- ✓ documentary evidence of the compliance of material and technical resources with the storage conditions for medicines and medical devices, including for medicines for special circulation (dangerous medicines, radioactive medicines, medicines undergoing approbation);
- ✓ availability of a labeling system for medicines and medical devices;
- ✓ program for monitoring the safe and circulation of medicines and medical devices.

5.2.2 MO must have a pharmacy for the storage of all medicines and medical devices, as well as conditions for the storage of medicines and medical devices in the departments of the organization.

Guidance:

The MO must have a pharmacy for the storage of medicines and medical devices, trained staff members responsible for storing and issuing medicines and medical devices to units. The pharmacy must be equipped with all the necessary equipment, the places allotted for the storage of medicines and medical devices must comply with the conditions for the proper storage of medicines and medical devices. All processes for storage, issuance, disposal and other processes are strictly regulated and all processes are documented. Only certain employees, who have permits, have access to and permission to move medicines and medical devices, disposal, acceptance and other actions.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ system of accounting and reporting on the movement of medicines and medical devices;
- ✓ internal regulatory documents regulating the storage conditions for medicines and medical devices;
- ✓ documentary evidence of the compliance of material and technical resources with the storage conditions for medicines and medical devices, including for medicines for special circulation (dangerous medicines, radioactive medicines, medicines undergoing approbation).

5.2.3 MO must ensure the storage of medicines and medical devices, depending on their level of access.

Guidance

MO uses medicines and medical devices of different effects and different groups. Depending on the category of medicines, different requirements are imposed on storage conditions. In the Medical Organization, medicines and medical devices should be divided into certain groups depending on the level of their access and distributed among departments also according to this logic. This is to provide a standard approach to the storage of medicines and medical devices, depending on the level of their access, not only at the pharmacy level, but also in all clinical divisions of the MO. Pharmacy staff periodically inspect medicine storage locations in the organization to ensure proper medicine storage.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;

- ✓ system of accounting and reporting on the movement of medicines and medical devices;
- ✓ internal regulatory documents regulating the storage conditions for medicines and medical devices, depending on the level of their access;
- ✓ documentary evidence of the compliance of material and technical resources with the storage conditions for medicines and medical devices, including for medicines for special circulation (dangerous medicines, radioactive medicines, medicines undergoing approbation).

5.3 Prescription of medicines

5.3.1 The MO should have a formal procedure for assigning medicines and verifying medicine assignments.

Guidance

The procedure for prescribing and verifying medicine prescriptions adopted by the Medical Organization should be based on the country's legal documents, meet the requirements of safety, timeliness, strict accounting and compliance with clinical recommendations and/or protocols/standards of treatment.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ accounting and reporting system for medicine prescriptions;
- ✓ completed accounting documents that comply with the universal rules and filling requirements;
- ✓ program/plan for internal verification of the correctness and compliance of the prescription of medicines and reporting documentation on the implementation of the program/plan;
- ✓ acts of inspections, revealed violations and decisions taken.

5.3.2 The MO must identify and document the persons who are allowed to prescribe medicines.

Guidance

In all countries, the main professionals who are allowed to prescribe medicines and medical devices are doctors with the necessary qualifications, special knowledge and experience. In some cases, nursing staff has the right to prescribe medicines. In addition to these categories of health professionals, employees, who ensure the provision of units of medicines and medical devices, can issue medicines.

Suggested Evidence:

- ✓ a list of staff members who are allowed to prescribe medicines, divided into access levels;
- ✓ accounting and reporting documentation that provides an objective verification of the correctness and correctness of prescribing medicines.

5.3.3 Staff eligible to prescribe medicines are required to use the standard prescription and prescribing requirements.

Guidance

The issuance of medicines and medical devices is a rather important part of providing quality health care to the population. Prescriptions must be correctly spelled out; all requirements are met. When a violation of the requirements for prescribing

medicines is detected, the MO must make appropriate decisions: training of staff members, use of instructions. For a rational solution of such issues, the Medical Organization should conduct staff training on an ongoing basis.

Suggested Evidence:

- ✓ standard for prescribing medicines and medical devices;
- ✓ facts of incorrect prescribing of medicines, decisions on them documented;
- ✓ plan/program for training in the process of safe prescribing of medicines;
- ✓ a documented process for the management of incomplete, illegible and incomprehensible assignments, including measures to prevent their subsequent occurrence;
- ✓ Prescribed medicines are documented in the patient's medical record or are attached to the patient's medical record upon discharge or transfer.

5.4 Preparation of medicines

5.4.1 The MO must ensure the safety and appropriate conditions for the preparation of medicines.

Guidance

Medicine preparation is an important aspect of medicine supply. Medicinal preparations must be prepared under certain conditions, which must be provided and observed in the MO. Employees with appropriate education and skills prepare and dispense medicines in a clean and safe environment, in accordance with the requirements of the country's legal and regulatory documents and internal documents.

Suggested Evidence:

- ✓ legal documents of the country regulating these processes at the domestic level;
- ✓ internal regulatory documents;
- ✓ qualification of staff members working on the preparation of medicines, documents proving the training of staff members;
- ✓ sanitary and epidemic requirements for fulfilling the conditions for the preparation of medicines in the Medical Organization;
- ✓ accounting, reporting on the preparation of medicines, compliance with standards, registering the facts of violations and decisions taken.

5.4.2 Staff admitted to the preparation of medicines must have appropriate training.

Guidance

The MO must ensure the availability of qualified staff members with access to the preparation of medicines. The Medical Organization must, on an ongoing basis, check the skills and abilities of staff members admitted to the preparation of medicines. The Medical Organization should improve the qualifications of staff members by constantly training them in accordance with the new requirements for the rules of preparation, as well as new medicines.

Suggested Evidence:

- ✓ qualification requirements for employees admitted to the preparation of medicines;
- ✓ compliance of documents of employees admitted to the preparation of medicines with the requirements of the country and the Medical Organization;
- ✓ staff development/training plan;

✓ assessment of the level of preparedness of staff members admitted to the preparation of medicines.

5.4.3 Written prescriptions should be checked for validity, interactions of several medicines when prescribing.

Guidance

MOs should provide a process for checking the validity of prescribing medicines, the possibility of interaction of several medicines when prescribing. The MO should have a qualified employee responsible for verifying the validity of prescribing medicines. Most often, the presence of a clinical pharmacologist is a mandatory requirement for the functioning of the medical organization and ensuring the necessary level of quality in the provision of health care. It is imperative that the verification of the validity of prescribing medicines is carried out in the Medical Organization on an ongoing basis and management decisions are made based on the results of such verification.

Suggested Evidence:

- ✓ the structure of the Medical Organization with the presence of a department, an employee responsible for verifying the validity of prescribing medicines;
- ✓ legal documents regulating this process in the country;
- ✓ internal regulatory documents;
- ✓ acts of inspections and, in case of revealed violations, decisions taken;
- ✓ documents (accounting, reporting), proving the constancy of checks and their registration, as well as decisions taken;
- ✓ qualifications of the staff members responsible for carrying out inspections and assuring compliance.

5.5 Monitoring and training in medicines handling

5.5.1 The MO must ensure control over the circulation and monitoring of the prescription of medicines to exclude unreasonable and excessive prescribing.

Guidance

Verification, monitoring and control are one of the important aspects of quality assurance in health care. MO, to ensure the control and monitoring of the MC prescription should have established procedures that meet the requirements of the country in this area. To control and monitor the circulation of medicines, the correctness and validity of their prescription in the Medical Organization, a structural unit or a qualified employee with such powers is usually determined. Staff who are authorized to conduct an appropriate review are considered competent to do so, are given appropriate privileges or job descriptions, and receive resources to support the review process.

In addition to the authorized staff members, all participants in the medical process jointly monitor patients taking medications. The purpose of monitoring is to evaluate the effect of medicines on the patient and on the symptoms of the disease, as well as for certain medicines, to assess the effect that indicators have on the state of individual organs and systems, the development of side effects.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents of the Medical Organization;
- ✓ a plan for monitoring and controlling the validity of prescribing medicines;

- ✓ accounting, report on the implementation of the plan and related documents;
- ✓ facts of unreasonable prescription of medicines and decisions taken.

5.5.2 The MO should provide training for staff members working with medicines and medical devices on an ongoing basis.

Guidance

The Medical Organization should ensure continuous professional development and training of staff members working with medicines and medical devices. Training should be carried out on an ongoing basis with all the staff members of the MO related to medicines and medical devices. Training should be differentiated depending on the functions performed by a particular employee. Assessment of the knowledge and skills of staff should be carried out on an ongoing basis, based on which decisions are made on the implementation of adequate training courses/seminars for staff.

Suggested Evidence:

- ✓ a plan for advanced training/training of staff members working with medicines and medical devices;
- ✓ training programs approved by the MO;
- ✓ accounting, report on staff development/training;
- ✓ accounting, a report on testing knowledge, skills and decisions made based on the results of the assessment.

5.5.3 Based on the results of monitoring, the MO should conduct an analysis of the mistakes made.

Guidance

It is important that the Medical Organization conducts constant monitoring and control of the facts of violation of the correct prescription of medicines. To this end, an analysis of the mistakes made, their validity, analysis of cases with the identification of factual errors and further actions to eliminate and prevent the errors in the future are carried out on an ongoing basis. Data should be recorded and communicated to all interested parties.

Suggested Evidence:

- ✓ legal documents regulating this process;
- ✓ internal regulatory documents in this area;
- ✓ accounting, report on the results of the analysis of errors;
- ✓ corrective actions based on the results of the analysis of the mistakes made.



6 STANDARD “PATIENTS: SAFETY, RIGHTS AND OBLIGATIONS”

6.1 Patient safety management

6.1.1 The medical organization must have a policy in the field of the rights and obligations of patients.

Guidance

MOs must respect the rights of patients to receive quality health care. The policy should be based on the legal documents of the country that regulate this process. The policy should spell out the rights and responsibilities of patients. The rights of patients, as well as their family members, are fundamental to the provision of health care, interaction between the patient/family and the medical organization. Therefore, it is imperative for the staff members to be trained and have sufficient knowledge of patients’ rights and obligations and their family members to ensure the correct behavior on the part of staff members, the development of procedures in accordance with the accepted rules.

Suggested Evidence:

- ✓ legal documents of the country regulating these processes at the domestic level;
- ✓ internal regulatory documents regulating this process in a medical organization;
- ✓ policy, expressed in the rules, regulations that are adopted in a particular medical organization, adopted in a medical organization;
- ✓ the level of staff knowledge about the rights and obligations of patients and their families.

6.1.2 A Medical Organization should have a system for informing patients and feedback to determine the possibility of providing health care.

Guidance

The MO should provide evidence-based and high-quality information to patients about prescriptions, manipulations, diagnostics and other medical procedures. The staff members of the medical organization must make sure that the patient perceives the information correctly by receiving feedback, analyzing it and, if necessary, additionally explaining and informing the patient. Without obtaining informed consent, medical staff members have no right to carry out any actions in relation to the patient. In some cases, the family may decide for the patient if this is customary at the domestic level. The Medical Organization informs patients and their families on a mandatory basis about their rights and responsibilities in case of refusal of treatment or termination of treatment, refusal of resuscitation and provision or refusal of artificial life support.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ accounting forms containing the informed consent of the patient;
- ✓ a report on the facts of refusal of patients from health care and the actions of staff members with patients.

6.1.3 The medical organization must have a process for identifying patients, including at least two identifiers, by which the patient can be identified also in the case of a coma, must have and apply established methods for identifying patients

Guidance

It is important to correctly identify patients, which is an integral part of the quality of health care. In conditions of unpredictability, when it is unclear which patients and their condition can enter a medical organization, the possibility of admission of patients with the same last name, first name, etc., a medical organization should use a patient identification system, which should consist of at least two independent identifiers, for example, last name, first name, patronymic and date of birth. A medical organization may use additional indicators to correctly identify patients, for example, an individual identification number or something else and enter data into patient records.

Suggested Evidence:

- ✓ patient identification system in a medical organization;
- ✓ documents proving compliance with this requirement;
- ✓ report on inspections and facts of violation of compliance with patient identification and decisions taken.

6.1.4 Identifiers must be used in all documents, materials owned and/or used by the patient

Guidance

MO must ensure universal identification of patients throughout the entire period of their stay in a medical organization, regardless of which department they are located in, whether they move, if necessary, to receive health care in different departments of a medical organization. When moving, as well as when receiving health care in the same department, treatment and care are carried out by different medical teams, and therefore, the correct identification of the patient is very important for the quality of health care and the elimination of violations. In this regard, a single (universal) patient identification system must be adopted in a medical organization, which is mandatory for use in all departments. All staff members must be trained in patient identification and apply it correctly.

Suggested Evidence:

- ✓ legal documentation of the country in this area;
- ✓ internal documents of a medical organization;
- ✓ registration forms of various departments of a medical organization;
- ✓ documents proving compliance with this requirement;
- ✓ report on inspections and facts of violation of compliance with patient identification and decisions taken.

6.1.5 A medical organization should have identification processes for any interventions, including diagnostic, therapeutic, rehabilitation, etc.

Guidance

MO uses a universal patient identification system, which consists of at least 2 identifiers, one of which can be a surname, name, patronymic, and the second - the date of birth, including the day, month, year of birth.

Suggested Evidence:

- ✓ a patient identification system used for any interventions, including diagnostic, therapeutic, rehabilitation;
- ✓ a system for recording, monitoring and analyzing cases of violation of the rules for identifying patients and decisions taken.

6.2 Transfer of information

6.2.1 The medical organization should have standard procedures for communicating information

Guidance

The MO should have standard procedures for transferring information that reduce the risk of data loss during transfer. The transfer of information can be carried out both in writing, using electronic means of communication, and orally. Each form of information transfer must have its own rules and requirements. Staff must be trained in the rules and requirements adopted by the medical organization. To improve patient safety, the medical organization monitors the procedure for transmitting information through indicators

Suggested Evidence:

- ✓ legal documents of the countries regulating this process;
- ✓ internal regulatory documents of a medical organization;
- ✓ accounting, reporting documentation proving the existence of this procedure in a medical organization.

6.2.2 Standard procedures should be applied when communicating information in writing

Guidance

MO should have standard rules, requirements governing procedures for the transfer of information in writing.

Suggested Evidence:

- ✓ standards/rules/procedures for communicating information in writing;
- ✓ a system for registration of the written exchange of information or the transmission of information in writing;
- ✓ evidence of compliance with the rules for the transfer of information in writing.

6.2.3 Standard procedures should be applied when communicating information orally

Guidance

MO should have standard rules, requirements governing procedures for the transmission of information orally.

Suggested Evidence:

- ✓ standards/rules/procedures for the transmission of information orally;
- ✓ a system for registering the written exchange of information or the transmission of information orally;
- ✓ evidence of compliance with the rules for the transmission of information orally.

6.2.4 Standard procedures should be applied when transmitting information through the use of electronic means of communication

Guidance

MO should have standard rules, requirements governing procedures for the transfer of information through the use of electronic means of communication.

Suggested Evidence:

- ✓ standards/rules/procedures for the transmission of information through the use of electronic means of communication;
- ✓ a system for registering the written exchange of information or the transmission of information through the use of electronic means of communication;
- ✓ evidence of compliance with the rules for the transfer of information through the use of electronic means of communication.

6.3 Surgical safety

6.3.1 The medical organization must ensure the safety of the patient at the stage of preparation for surgery

Guidance

Patient safety is a priority for any clinic. Medical organizations should have resources (financial, human, logistical) to ensure patient safety, including at the stage of preparing the patient for surgery. Surgical care for each patient is planned based on the results of their examination and is documented in the patient's medical record; for all procedures, the standard patient identification adopted in the medical organization is used. All risks associated with the upcoming surgery should be discussed with the patient, their family or people who are authorized to make decisions regarding a particular patient. Only with informed consent can surgery be performed.

Suggested Evidence:

- ✓ a patient's medical record with a preoperative epicrisis containing the rationale for surgical intervention, main and alternative routes;
- ✓ a patient's informed consent to surgical intervention;
- ✓ documented evidence of the patient making a decision together with the attending physician and informing the patient about the main plan for surgical intervention, alternative routes, possible complications;
- ✓ accounting and control of the implementation of pre-surgical intervention;
- ✓ analysis of the implementation of pre-surgical intervention, facts of violation of standard procedures and decisions made.

6.3.2 Staff are required to verify the intervention site by using a standard designation.

Guidance

MOs should have a system for identifying or verifying the surgical site. This place is marked by standard marking methods established by the MO. Each medical professional involved in the preparation and surgical intervention must understand the symbols. Markings on the patient's body are carried out with the consent and understanding of the patient. Usually, site verification is carried out before the operation (for example, in the evening) and again before the actual start of the operation.

Suggested Evidence:

- ✓ standard procedures for verifying the site of surgical intervention established in a medical organization;
- ✓ a medical record containing data on the verification of the site of surgical intervention before the start of the operation;
- ✓ accounting and control of the verification of the site of surgical intervention;

✓ analysis of the verification of the site of surgical intervention, facts of violation of standard procedures and decisions made.

6.3.3 The patient must be verified before surgery according to identifiers, confirmation of informed consent, intervention site, re-questioning for allergic reactions, airway problems

Guidance

MO employees must necessarily verify the patient, the site of surgical intervention, obtain the patient's informed consent before the operation, make sure that there are no known allergic reactions and problems with the respiratory tract. All procedures must be carried out strictly in accordance with the standards adopted in the medical organization, violations must be recorded, management decisions are made on them, such as determining the level of knowledge and skills of staff members, training of staff members, administrative measures up to removal from these procedures.

Suggested Evidence:

✓ internal regulatory documents regulating this process;
✓ accounting, report on the implementation of these procedures in accordance with accepted standards;
✓ analysis of the facts of violation of the implementation of these procedures in accordance with accepted standards and decisions taken.

6.3.4 The staff is obliged to carry out the time-out procedure and document this process in the patient's medical record

Guidance

The basic principles of surgical safety are the right body site, the right procedure, and the right patient. Patient safety is enhanced by standardized preoperative verification and timeout. Time-out - checking the readiness of medical staff members for a high-risk operation or invasive procedure to ensure that the correct procedure is performed on the correct area of the body for the correct patient. The entire surgical team participates in the time-out procedure, which consists of the following steps: identification of the patient, confirmation of the name of the surgical intervention or invasive procedure, confirmation of the site and side of the surgical intervention or invasive procedure, readiness of the surgical team for the surgical intervention. The entire timeout procedure is recorded in the medical record. Pre-op verification and time-out procedures are monitored through indicators that are applied to improve patient safety

Suggested Evidence:

✓ standards adopted in the medical organization for the implementation of the time-out procedure;
✓ medical records containing information on the implementation of the time-out procedure;
✓ accounting, report on the implementation of these procedures in accordance with accepted standards;
✓ analysis of the facts of violation of the implementation of these procedures in accordance with accepted standards and decisions taken.

6.4 Safety of High-Risk Medicines

6.4.1 The medical organization must have procedures for increasing safety of high-risk medicines

Guidance

The use of medicines in a medical organization is inevitable in the implementation of health care. Medicines are divided into different risk groups. All medicines are subject to strict accounting and reasonableness of the prescription, the correctness of the fulfillment of the prescriptions and the monitoring of the impact. There is a group of high-risk medicines, which include insulin, antithrombotic agents, anticoagulants, epidurals, thrombolytics, neuromuscular blocking agents, chemotherapy medicines, opioids, etc., which can cause great harm to the patient if used incorrectly and/or uncontrolled. One of the important aspects that can reduce the safety in the field of high-risk medicines is that some medicines are similar in names, packaging and other data. A medical organization must have and implement a process for the safety of high-risk medicines by delimiting the storage locations for high-risk medicines, restricting access to such medicines, and additional labeling if necessary. The safety process should be written in standard documents, brought to the attention of medical staff members and steadily implemented.

Suggested Evidence:

- ✓ lists of high-risk medicines;
- ✓ standard procedures for handling high-risk medicines;
- ✓ accounting, report on the movements of high-risk medicines;
- ✓ facts of violations of the treatment of high-risk medicines, accounting and decisions taken.

6.4.2 The medical organization must ensure that the staff members are aware of the standards for handling high-risk medicines

Guidance

To ensure safety when using high-risk medicines, it is important for the staff members to know the standards for handling high-risk medicines. To achieve this goal, the Medical Organization must provide training for staff members in handling high-risk medicines, determine the level of knowledge and skills of staff members in handling high-risk medicines. The process of training, testing knowledge and skills should be carried out on an ongoing basis, the analysis of the results should be used to improve the process of proper handling of high-risk medicines by staff members.

Suggested Evidence:

- ✓ results of determining the level of knowledge and skills of staff members in handling high-risk medicines;
- ✓ plan, training program for staff members in handling high-risk medicines;
- ✓ accounting, report on the work done with staff members on handling high-risk medicines.

6.4.3 The medical organization must have a process for the safe use of concentrated electrolytes

Guidance

High-risk medicines also include concentrated electrolytes. The danger of improper handling of these medicines can lead to the death of the patient, disability, deterioration in the results of treatment of the underlying disease. These medicines

must be diluted before use, for which many medical organizations use additional markings and inscriptions. Storage of concentrated electrolytes is preferably in separate departments, for example, in a pharmacy of a medical organization or a pharmaceutical department. Restriction of access of medical staff members to medicines of this category.

Suggested Evidence:

- ✓ lists of concentrated electrolytes;
- ✓ standards for handling concentrated electrolytes;
- ✓ accounting, report on the movements of concentrated electrolytes;
- ✓ facts of violations of the handling of concentrated electrolytes, accounting and decisions taken.

6.4.4 A medical organization must have a system for monitoring the circulation of high-risk medicines

Guidance

The MO is responsible for handling high-risk medicines. To ensure the safety of high-risk medicines, each medical organization should have a monitoring system for the circulation of high-risk medicines, including several stages, evaluating the process and final results. Monitoring should be included in the activity plan of the medical organization; reporting should be provided to management on an ongoing basis to make adequate management decisions.

Suggested Evidence:

- ✓ program/plan for monitoring the handling of high-risk medicines;
- ✓ results of monitoring the handling of high-risk medicines;
- ✓ facts of violations in the handling of high-risk medicines and decisions made on them in a medical organization.

6.5 Clinical protocols/recommendations

6.5.1 The medical organization must provide health care in accordance with the clinical protocols/recommendations recommended at the domestic level

Guidance

A medical organization provides health care using certain procedures, practices, methods, etc. Currently, in all countries there are standard procedures for providing health care for certain diseases, which are developed on the basis of the principles of evidence-based medicine, best practices that have proven their effectiveness and safety for patients. The MO should use clinical protocols/recommendations permitted at the domestic level (approved by authorized bodies, commissions, etc.).

Suggested Evidence:

- ✓ legal documents of the country regulating this process at the domestic level;
- ✓ standards, clinical protocols, clinical guidelines approved for use at the domestic level.

6.5.2 Clinical protocols/recommendations should be up-to-date and accessible to all participants in the provision of health care

Guidance

MO should use clinical protocols/recommendations that are relevant, procedures, methods of diagnosis, treatment and rehabilitation should be substantiated and

scientifically proven. The medical organization should have access to updated clinical protocols/recommendations on an ongoing basis.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ clinical protocols/recommendations of the latest revision, updated;
- ✓ documented evidence of receipt of updated, up-to-date clinical protocols/recommendations.

6.5.3 Clinical staff should be trained and have knowledge of clinical protocols/recommendations

Guidance

The MO should organize staff training on relevant clinical protocols/recommendations on an ongoing basis. Staff should be checked to determine the level of knowledge and skills in applying clinical protocols/recommendations by testing, passing practical skills, for example, in a simulation center. Staff training should be organized on its own, as well as with the use of invited specialists, including the developers of updated clinical protocols/recommendations. Training can be organized in the form of master classes, seminars, advanced training courses and in other forms and formats, including on-the-job and on-the-job training.

Suggested Evidence:

- ✓ plan/program for training clinical staff in clinical protocols/recommendations;
- ✓ accounting, report on the activities carried out to train staff members in clinical protocols/recommendations;
- ✓ the results of testing the level of knowledge and skills of clinical staff;
- ✓ plan of corrective measures based on the results of testing the level of knowledge and skills of clinical staff, implementation report.

6.5.4 The medical organization must ensure control and monitoring of the provision of health care in accordance with clinical protocols/recommendations

Guidance

It is important that the MO should ensure the provision of health care in accordance with accepted clinical protocols/recommendations, which is an integral part of ensuring patient safety. The provision of safe and quality health care is ensured through continuous monitoring and control of the provision of health care in accordance with clinical protocols/recommendations. To do this, the medical organization must develop a control and monitoring plan, implement it, analyze the results obtained and take corrective actions in a timely manner.

Suggested Evidence:

- ✓ a plan for control and monitoring of compliance by clinical staff with the rules and requirements of clinical protocols/recommendations;
- ✓ accounting, reporting on the measures taken to implement monitoring and control over the implementation of clinical protocols/recommendations by the staff;
- ✓ results of monitoring analysis and corrective actions taken.

6.6 Managing the risks associated with the provision of health care through handwashing

6.6.1 The medical organization should have procedures aimed at ensuring safety by staff handwashing

Guidance

Compliance with the rules for hand washing is one of the important aspects of ensuring patient safety, as well as the quality of health care provided. Hands are the main sources of transmission/carrying of infectious agents. The MO should have rules for the processing of hands for all staff members and certain categories of health professionals, and train staff members in the accepted rules. The rules must be strictly followed.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents (rules, regulations, standards) adopted in accordance with the legal documents of the country and used by the medical organization;
- ✓ instructions, reminders of hand treatment in places of hand washing;
- ✓ documented evidence of staff training in hand handling.

6.6.2 The medical organization must provide staff with the necessary resources

Guidance

The Medical Organization must allocate the necessary resources (financial, material) to create conditions for compliance with the rules for hands preparation. All handwashing sites should have leaflets/instructions, adequate water resources for handwashing, chemicals for handwashing and decontamination, personal protective equipment (gloves) and other necessary supplies.

Suggested Evidence:

- ✓ instructions, reminders of hand treatment in places of hand washing;
- ✓ list of consumables to ensure the correct processing of hands and their availability.

6.6.3 The medical organization should monitor this process to prevent complications after medical procedures and the spread of infections among patients

Guidance

When monitoring compliance with handwashing rules, the MO should adhere to the basic principles of timeliness, objectivity, achievability and regularity. Monitoring should be carried out on an ongoing basis by trained employees in parallel in all departments to maintain objectivity. Monitoring should assess not only the handwashing skills of the staff, but also the availability and functionality of all necessary resources for proper handwashing, for which the healthcare organization is responsible.

Suggested Evidence:

- ✓ plan for monitoring required resources and compliance with staff handwashing rules;
- ✓ accounting, monitoring report;
- ✓ measures taken based on the monitoring results;

✓ facts of violation of the handwashing rules, facts in the form of complications, infection with evidence of non-compliance with the rules for hand washing and decisions taken.

6.7 Fall Risk Management

6.7.1 The medical organization must have procedures for managing the risks of falling patients and monitoring this process

Guidance

The fall of patients is one of the important causes of traumatization of patients, deterioration of their condition. Falls of patients can be caused by various reasons, the physical condition of the patient, the mental state of the patient. MOs should develop and implement procedures to prevent falls. The procedures must be communicated to all employees of the medical organization and observed by all participants in the medical process.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents (rules, regulations, standards) adopted in accordance with the legal documents of the country and used by the medical organization;
- ✓ instructions, memory aids on the prevention of falls.

6.7.2 The medical organization must create the necessary conditions for the safety of patients and reduce the risk of their falling

Guidance

The MO creates conditions to reduce the risk of falling patients by developing a safe environment plan using zoning, dividing patients into risk groups and other conditions, using various means of informing, etc.

Suggested Evidence:

- ✓ a plan with allocated funding to provide the necessary resources;
- ✓ documented evidence of the presence in the medical organization of all resources for the prevention of falls in patients, differentiated depending on risk groups.

6.7.3 The medical organization should train staff in the prevention of falls in patients with a clear distribution of responsibilities

Guidance

The Medical Organization mandatorily trains all staff members in the prevention of falls in patients with the determination of responsibilities in providing assistance in the event of an incident. In addition to training, the medical organization should evaluate the knowledge and skills of patient care staff through testing and acceptance of skills in a simulation center. The MO should have a qualified employee/unit responsible for the prevention of falls in patients, performing the functions of control and monitoring, as well as staff training.

Suggested Evidence:

- ✓ staff members training plan/program;
- ✓ the results of assessing the knowledge and skills of staff in providing assistance in case of a fall;

✓ corrective actions based on the results of assessing the knowledge and skills of staff members in the provision of assistance in case of a fall.

6.7.4 The medical organization should create a system for informing and educating patients about the prevention of falls

Guidance

Patient awareness is an important aspect of fall prevention. In this regard, staff should provide information and education to patients. This is especially important for patients who have undergone surgical interventions that have led to a certain limitation of movement. For such patients, training by trained professionals and monitoring of compliance with the rules and requirements should be carried out.

Suggested Evidence:

- ✓ documented evidence of a patient information system in place;
- ✓ patient education programs for fall prevention.

6.8 Access to health care for persons with special needs

6.8.1 The medical organization should provide physical access to the organization to patients with disabilities/special needs by having a policy and trained staff.

Guidance

Persons with special needs are frequent patients of medical organizations. For such people, it is necessary to create certain conditions aimed at realizing their right to receive quality health care. Medical organizations should have a policy (rules, regulations, instructions) aimed at working with this category of patients. The staff of the medical organization must be trained and have the skills to work with patients with special needs.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ plan and its implementation for training staff to work with patients with special needs.

6.8.2 The medical organization must create the necessary conditions for access to the organization of patients/special needs with disabilities

Guidance

A medical organization needs to create and constantly improve conditions for people with special conditions. This process requires funding, which should be provided in the plan of the medical organization.

Suggested Evidence:

- ✓ a plan of a medical organization with the allocation of the necessary funding to create conditions for people with special needs;
- ✓ a list of equipment, fixtures and other structures for patients with special needs;
- ✓ contracts for the purchase of necessary resources.

6.9 Patient Rights Procedures

6.9.1 The medical organization must have a policy in the field of the rights and obligations of patients

Guidance

The MO should have a policy on the rights and obligations of patients that is in line with the country's legal and regulatory documents.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulations.

6.9.2 Patient Rights and Responsibilities Policy should be available to patients

Guidance

Openness of information about the rights and obligations of patients is an essential rule for the provision of quality health care. Patients should be aware of their rights and responsibilities.

Suggested Evidence:

- ✓ availability of documents containing information about the rights and obligations of patients;
- ✓ documented evidence of the availability of information about the rights and obligations of patients in accessible places.

6.9.3 During hospitalization, the staff must inform the patient about his/her rights and obligations.

Guidance

The MO should have a system for correctly informing patients about their rights and obligations. This should be done by medical staff members, starting with the admissions room.

Suggested Evidence:

- ✓ Accounting for the patients informing about their rights and obligations;
- ✓ medical record, signed informed consent.

6.9.4 The medical organization is obliged to respect the right of the patient and his/her legal representatives to reliable information about the state of health, procedures, costs, risks, treatment options

Guidance

The MO must ensure the process, and all employees of the organization must respect the rights of patients, including reliable information about the state of health, procedures, costs, risks, treatment options. This is achieved by interviewing patients and signing informed consent.

Suggested Evidence:

- ✓ informed consent;
- ✓ medical card.

6.9.5 Staff must be fully informed about the rights and obligations of patients

Guidance

The MO should provide a process to educate staff about the rights and responsibilities of patients, and ensure ongoing compliance.

Suggested Evidence:

- ✓ rights and obligations of patients;
- ✓ training/informing staff about the rights and obligations of patients;
- ✓ documented evidence of compliance with rights and obligations.

6.10 Information privacy

6.10.1 The medical organization must have procedures for maintaining the confidentiality of information

Guidance

The confidentiality of information about patients is one of the important rules that must be observed in a medical organization. MO must have procedures, including rules, regulations, to ensure compliance with this requirement. All patient data must be kept confidential.

Suggested Evidence:

- ✓ documented procedures for maintaining the confidentiality of information;
- ✓ accounting, report on compliance with information confidentiality requirements.

6.10.2 Staff must be aware of and comply with the requirements for maintaining the confidentiality of information

Guidance

Rules requiring staff members to maintain the confidentiality of information are binding. The MO should ensure that staff are trained in confidentiality requirements and that they comply with these requirements. In case of violation of the requirements, an internal investigation and determination of managerial/administrative decisions should be carried out.

Suggested Evidence:

- ✓ rules for maintaining the confidentiality of information adopted in a medical organization;
- ✓ documented evidence of staff training;
- ✓ monitoring the process of maintaining confidentiality and in case of violation of requirements - documented solutions.

6.11 Appeals of patients and their legal representatives

6.11.1 A medical organization must have procedures for accepting applications, appeals from patients and their legal representatives in case of violation of their rights or other circumstances

Guidance

The procedures for accepting applications from patients, legal representatives in case of violation of their rights must be strictly observed in every medical organization. Procedures should be prescribed, information about procedures should be available to patients, and staff should not interfere with the appeals of patients or their legal representatives.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ documented evidence of the existence of a procedure for accepting applications, appeals from patients and their legal representatives in case of violation of their rights or other circumstances approved by the medical organization.

6.11.2 The medical organization must provide public information about contact officials who can be contacted

Guidance

All participants in the medical process should have information about contact officials who can be contacted if necessary. To inform patients and their legal representatives, contact details should be posted in open, accessible places.

Suggested Evidence:

- ✓ documented evidence of the availability of contact details of officials of a medical organization;
- ✓ staff members, if necessary, must provide the necessary information about the contact details of officials.

6.11.3 The medical organization must consider the appeals of patients and their legal representatives within a certain period of time and provide a response in a timely manner

Guidance

All appeals from patients and their legal representatives must be considered within a certain time frame, responses must be prepared and provided. This process has its own rules and requirements for the timing of execution and response.

Suggested Evidence:

- ✓ procedures for preparing responses on behalf of a medical organization to inquiries/complaints and other appeals from patients and their legal representatives, prescribed in the documents of the Medical Organization;
- ✓ documented evidence of registration of applications from patients and their legal representatives;
- ✓ documented evidence of registration of responses to requests from patients and their legal representatives in a timely manner.

6.11.4 The results of the analysis of applications should be used to improve the quality of health care

Guidance

A medical organization should analyze the appeals of patients and their legal representatives, which will allow it to identify problems that are of a systemic nature. In the future, on the basis of appeals, the Medical Organization should develop a corrective action plan to eliminate systemic problems in the medical organization.

Suggested Evidence:

- ✓ documented evidence of changes to the activity plan of the medical organization based on the appeal of patients and their legal representatives (if any).

6.12 Awareness and voluntariness of decision-making by patients to receive health care

6.12.1 The medical organization must have procedures for voluntary decision-making by patients on receiving health care

Guidance

MOs must respect patients' rights and have procedures for patients to voluntarily decide to receive health care. Only the patient or his/her legal representative should decide whether to receive or refuse health care.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ documented evidence of the existence of decision-making procedures by the patient or his/her legal representative.

6.12.2 The receipt of health care should be determined by informed written consent, which should be signed directly by the patient, if this process is impossible - by his/her legal representatives, with identification

Guidance

The Medical Organization must provide a document to the patient or his/her legal representative, which spells out the main manipulations that will be carried out by the staff in the provision of health care. The patient must read and sign this document. This is regarded as an evidence of a patient's informed consent. In some cases, the patient must sign multiple informed consents for separate processes.

Suggested Evidence:

- ✓ informed consent.

6.12.3 The patient must be informed about this procedure, his/her rights and obligations must be explained to him/her, the decision must be voluntary on the basis of reliable and complete information.

Guidance

Medical staff members must explain to the patient his/her rights and obligations, describe in detail the procedures that the patient will undergo in a medical organization, explain the essence of all manipulations for the patient to make an informed decision.

Suggested Evidence:

- ✓ informed consent;
- ✓ documentary confirmation of the conformity of the originality of the signed informed consent and the manipulations performed.

6.12.4 Medical staff should be trained to work with patients to obtain informed consent

Guidance

Medical staff should be trained to work with patients to obtain informed consent and their responsibilities should be delineated. The doctor conducts a conversation with the patient and his/her competence includes obtaining informed consent, the nurse is engaged in registering this procedure.

Suggested Evidence:

- ✓ a plan/program for staff training in obtaining informed consent;
- ✓ the results of an assessment of knowledge and skills in working with patients in this area.

6.13 Refusal of treatment

6.13.1 The patient has the right to refuse treatment, and the medical organization must have procedures for registering this process

Guidance

Any patient has the right to refuse treatment. This may be due to many reasons, the main of which are fear and anxiety for one's life, lack of financial resources, distrust of medical staff members. If the patient is indicated for health care, it is necessary to inform him/her of the possible risks. In the event that a patient or their legal representative refuses treatment, the MO should have procedures for registering the refusal. The patient or his/her legal representative must sign a written waiver of health care. These documents are recorded and stored in a medical organization.

6.13.2 The staff of the medical organization is obliged to inform the patient about the risks associated with refusing treatment and the possibility of refusing a particular procedure.

Guidance

The medical organization is obliged to provide complete and reliable information to the patient or legal representatives in order to obtain a different opinion in case of refusal of treatment. The staff must always explain the need for treatment, a certain procedure to the patient, explain all the risks that may arise in case of refusal.

Suggested Evidence:

- ✓ documented evidence of staff informing patients.



7 STANDARD "TREATMENT AND CARE OF PATIENTS"

7.1 Hospital admission

7.1.1 The medical organization must conduct a screening / primary examination of the patient for his/her need for health care provided by this medical organization

Guidance

Upon admission to a hospital, the patient must be screened to determine the need for the health care that is provided by a particular medical organization. The staff conducts patient identification, screening of the patient, filling out a medical record and referring the patient to a specific specialized department.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ screening program and documented evidence;
- ✓ patient record;
- ✓ triage system.

7.1.2 Staff must inform the patient about the screening/initial examination procedure

Guidance

The medical organization should always inform the patient about all the manipulations that will be performed on the patient. Informing about the initial examination is mandatory and is carried out with the informed consent of the patient or his/her legal representative.

Suggested Evidence:

- ✓ assessment of staff competencies in conducting primary examination/screening;
- ✓ patient record;
- ✓ triage system.

7.1.3 The medical organization must have a system for sorting patients as an emergency, the staff must comply with the requirements of the system, when emergency patients arrive, they receive priority in examination and treatment

Guidance

Patients in need of emergency, urgent care receive priority in examination and treatment. To this end, algorithms have been developed for the actions of the staff, early notifications about the delivery of such patients in the case of using the ambulance service, emergency care, and other mechanisms for providing timely health care.

Suggested Evidence:

- ✓ documented evidence of the priority of hospitalization of patients in need of emergency, urgent care;
- ✓ triage system.
- ✓ patient record.

7.1.4 Patients undergo laboratory and instrumental studies in accordance with local regulatory requirements

Guidance

The medical organization should provide the necessary resources for laboratory and instrumental studies in the admission room for the timely establishment of the correct diagnosis and the appointment of adequate treatment.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ documented evidence of instrumental and laboratory studies;
- ✓ patient record;
- ✓ triage system.

7.1.5 The medical organization should have procedures for dealing with patients with special needs at the time of admission to the hospital

Guidance

The medical organization should have all the necessary resources and procedures to deal with patients with special needs. Procedures must be documented and applied by staff. Staff should be trained to work with patients with special needs.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ documented evidence of the implementation of the procedure for working with patients with special needs;
- ✓ patient record;
- ✓ triage system.

7.1.6 The medical organization should have procedures for working with high-risk patients

Guidance

High-risk patients require comprehensive care, which may result in multi-specialist care. This process should be standardized and spelled out in internal official documents.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ documented evidence of the implementation of the procedure for working with high-risk patients;
- ✓ patient record;
- ✓ triage system.

7.1.7 Upon admission, patients and their families receive training and instructions on the inpatient unit, information about the intended treatment and any expected costs of treatment, as well as the expected results of treatment

Guidance

During admission and hospitalization, patients and their families should be given sufficient information to make informed decisions. Staff should provide information about the intended treatment, expected outcomes, and the expected cost of treatment for the patient and family in cases where treatment is not paid from the state budget or private sources. In cases where the patient has financial difficulties associated with paying for services, the organization seeks ways to overcome them. The information provided can be given in writing or communicated to the patient orally with a corresponding entry in the medical record.

Patient safety is an important aspect of patient care. Information about hospital accommodation and equipment related to the provision of health care and services is an important component of patient safety.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ documented evidence of the implementation of the procedure for working with high-risk patients;
- ✓ patient record.

7.1.8 The medical organization fills out the medical documentation upon admission of the patient, which is subsequently used in the departments as a single record document

Guidance

Prepared documents, a completed medical record is opened in the admission room, where all data on patient identification, results of screening / initial examination, data from laboratory and instrumental studies are entered. This medical record is transferred to the department where the patient is transferred. The use of a single record document ensures the continuity of the provision and quality of health care

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ documented evidence of the implementation of the procedure for working with high-risk patients;
- ✓ patient record.

7.2 Continuity of care for patients

7.2.1 The medical organization must have a policy in the field of continuity of care delivery

Guidance

The medical organization must ensure the continuity of the provision of health care to patients as one of the basic principles of quality health care. The medical organization should have a policy that includes certain procedures, rules, regulations, instructions to ensure the continuity of the provision of health care. First of all, it is said that the medical organization must determine the need for the amount of health care that the patient needs; identify structural divisions / departments, medical staff providing such types of assistance within the same organization; have an algorithm for providing continuous health care and be able to control and monitor the entire medical process. Secondly, continuity must also be ensured when it is necessary to transfer a patient

from one department to another. It is important to use one document that includes all the patient's medical records to ensure continuity in the provision of health care, a unified system for identifying the patient, determining the staff responsible for a certain period and type of health care.

Suggested Evidence:

- ✓ A policy approved by the medical organization, including rules for transferring between departments, instructions for transferring information about a patient, compliance with clinical protocols/recommendations, etc.;
- ✓ the algorithm of actions of staff in the provision of health care, including plans for treatment and care, guidelines and other measures;
- ✓ patient record.

7.2.2 The staff of the department determines the plan and tactics of treatment on the basis of a collegial decision individually for each patient, taking into account the initial examination, the availability of examination results upon admission

Guidance

Upon admission of a patient to a certain department, the state of his/her health, the results of screening / initial examination upon admission to the medical organization, the results of preliminary examinations, laboratory, instrumental and other studies at the outpatient level during planned hospitalization are considered and a collegial decision is made on the plan and tactics of treatment. Each patient is assigned a specific doctor responsible for his/her treatment, who, taking into account the collegial decision, his/her own experience, develops a plan and tactics of treatment and agrees with the head of the department. The treatment plan prescribes the main manipulations that are assigned to the patient and, if necessary, are determined consultants from other departments, other departments where the patient will be transferred, etc.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ medical record with a description of the examination of the patient with the participation of the medical staff of the department.

7.2.3 Examinations of patients are carried out depending on the diagnosis, severity of the condition, medical interventions performed

Guidance

The medical organization should have clear rules for examining patients, depending on the severity of the condition, diagnosis, and medical interventions. In different clinical units, the number of examinations may vary. For example, in intensive care units, patients are examined by doctors much more often than in units providing routine health care. This mechanism should be spelled out in the algorithms for the actions of the medical staff of each department.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record with a description of the examination of the patient.

7.2.4 Each patient is assigned qualified clinical staff responsible for the entire period of receipt of inpatient care by the patient

Guidance

Each patient must have an attending physician who is responsible for the full cycle of health care in a particular department. Nursing staff may change depending on job changes. An exception may be observed in individual units, if this is prescribed in the regulatory documents of the medical organization. If the patient receives treatment in only one department, the attending physician will also organize the discharge and the necessary documents for further follow-up at the outpatient level. If the patient is transferred to another unit within the same medical organization, the attending physician is responsible for preparing the necessary documents and transmitting correct information about the patient to ensure the continuity and portability of health care.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record.

7.2.5 Medical records must be completed correctly, reliably and objectively

Guidance

It is important to correctly fill out the medical documentation, for which the medical staff of the department is responsible. All information must be objective, evidence-based, relevant and legible. Abbreviations, the use of informal abbreviations that can be interpreted incorrectly are not allowed. Qualified staff with such authority should only make prescriptions. The medical organization must periodically check medical records and identify facts of incorrect filling in medical records, make certain management decisions.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record;
- ✓ results of internal audits of medical records and decisions made on them.

7.2.6 The medical organization is obliged to respect the rights of patients and their families during treatment

Guidance

Medical organizations are obliged to respect the rights of a patient, their family members in terms of coordinating the plan and tactics of treatment, mandatory informed consent for all types of manipulations. Qualified medical staff should carry out explanatory work with patients and their family members, legal representatives in order to correctly inform and perceive the treatment, change the treatment if necessary. It also increases adherence to treatment.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record;
- ✓ informed consent;

- ✓ documented evidence of interviews with patients and their families and other tools;

7.2.7 Patients and legal representatives are full participants in treatment decisions through continuous information, health literacy and participation in the patient care process

Guidance

This criterion is closely related to the previous one (Section 7.2.1). The clinical staff of the medical organization should involve patients, their family members, legal representatives in the discussion and making a joint decision about the plan, treatment tactics, changes that need to be made during treatment, taking into account the results of additional examinations, etc. Therefore, it seems important to improve the quality of health care to include work with patients, their family members, legal representatives in the work of medical staff. These can be conversations, lectures, the use of visual information materials to improve medical literacy and jointly make the right decision about the treatment of a patient.

Suggested Evidence:

- ✓ patient record;
- ✓ informed consent;
- ✓ documented evidence of interviews with patients and their families and other tools.

7.2.8 The medical organization determines the process of meeting the religious and spiritual needs of patients (requests of the patient and his family for the provision of religious services, etc.).

Guidance

The healthcare organization recognizes and respects the values and beliefs of patients by educating staff about different cultures and faiths, and by providing care and treatment that takes into account the values, personal beliefs and religion of the patient. Staff provide care in a manner that is respectful of the patient's values and beliefs. The staff identifies any special cultural or spiritual preferences of patients and does not restrict patients' access to spiritual assistance. Patients' particular cultural or spiritual preferences can make it difficult to access and provide care. The organization identifies such barriers in the provision of medical care, takes measures to eliminate them and creates conditions for reducing the impact of these barriers on the process of providing medical care. Religious service or services may be provided by a member of the organization's staff, local services, or a person suggested by the patient's family.

Suggested Evidence:

- ✓ internal regulatory documents;
- ✓ documented evidence of interviews with patients and their families and other tools.

7.2.9 The medical organization must have patient training programs and implement them depending on the categories of patients and needs

Guidance

Training of patients, their families and legal representatives is a process that should be carried out on an ongoing basis. The best option for implementing this

direction is the development and implementation of training programs in the medical organization. Training programs can be aimed not only at making the right decision regarding treatment, but also at improving medical literacy, the correct behavior of patients, their families and increasing the commitment of this category to the recommendations of qualified medical staff after discharge from the medical organization. This will undoubtedly have an impact on obtaining positive results of treatment, improving the quality of health care. Such programs can also be run by nurses.

Suggested Evidence:

- ✓ internal regulatory documents;
- ✓ training programs for individual departments;
- ✓ patient record;
- ✓ documented evidence of training with patients and their families and other tools.

7.2.10 The medical organization should have procedures for the provision of donor services

Guidance

Donation is one of the integral parts of health care. The medical organization should have a service responsible for the provision of donor services. This service should be headed by a qualified person with appropriate education and experience. Procedures related to the provision of donor services should be strictly regulated and subject to close control and monitoring.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record;
- ✓ informed consent;
- ✓ documented evidence of functioning of the donor service delivery service.

7.3 Transfer of patients

7.3.1 The medical organization should have procedures and practices for transferring patients from one department to another or to another organization

Guidance

For the continuity and portability of the provision of health care, the medical organization must ensure, if necessary, procedures for transferring a patient from one department to another. The medical organization must have internal regulatory documents governing this process. The staff members must be familiar with all transfer procedures.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record.

7.3.2 The transfer process must be agreed with the host and documented

Guidance

When transferring from one department to another, the medical organization must have regulations (instructions, rules) and must coordinate its actions with the receiving party (another department). The transfer can be carried out only if there are free places in the receiving department, the treatment plan complies with the need to continue treatment in another unit, and the transfer is coordinated with the head of another unit.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory document;
- ✓ patient record;
- ✓ informed consent;
- ✓ documented evidence of agreement.

7.3.3 A patient must be informed about the transfer and give voluntary informed consent

Guidance

The medical organization must obligatorily obtain the informed consent of a patient to transfer him/her to another unit. This is achieved by talking with a patient, explaining the reasons for the transfer to the patient, family members and legal representatives. Only if there is a voluntary written informed consent, the medical organization transfers the patient to another unit

Suggested Evidence:

- ✓ internal regulatory documents;
- ✓ patient record;
- ✓ informed consent.

7.3.4 A staff must ensure patient transport, using mobility aids if necessary.

Guidance

Some patients, for health reasons, cannot move independently from one department to another. The medical organization must have and provide the departments with the necessary resources. Such resources may include mobile chairs, mobile wheelchairs, means for sheltering patients in case they are transported to other buildings of the medical organization through external channels, to other medical organizations, and more. The department responsible for proper transport is the department from which the patient is transferred, unless otherwise specified. Some medical organizations use a single patient transportation service.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record;
- ✓ documented evidence of the availability of the necessary means for transportation.

7.3.5 When transferring to another organization, the medical organization must provide a discharge record containing complete and reliable information about the diagnosis, treatment and condition of the patient, or transfer a patient record in case of transfer to another department within this medical organization

Guidance

When transferring, if necessary, to another organization, the medical organization must submit a detailed transfer document (epicrisis) containing all the necessary data on the diagnosis, treatment plan and tactics, changes in the patient's condition, collegiate examinations and discussions, a reasoned decision to transfer to another organization. In case of transfer to another department within the same medical organization, the patient record is mandatory transferred.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record;
- ✓ informed consent;
- ✓ documented evidence of transfer to another organization.

7.4 Discharge record

7.4.1 The medical organization should have standard procedures for discharging patients based on criteria for assessing the condition of the patient and his/her readiness for discharge

Guidance

The medical organization should have and use standard procedures for discharging patients at the end of health care. The procedures include an objective assessment of the patient's health status and the possibility of his/her discharge from the medical organization, the patient receiving qualified assistance in accordance with clinical protocols/recommendations that led to an improvement in the state of health or recovery, and preparing documents for discharge.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ discharge epicrisis;
- ✓ documented evidence of compliance with the clinical protocol/recommendation/instruction.

7.4.2 The medical organization is obliged to instruct / train the patient, his/her legal representatives, on the recommendations that must be followed after discharge

Guidance

It is important that the patient adheres to the recommendations given to him/her by qualified staff after discharge. To increase patient adherence to recommendations, qualified medical staff should explain to each patient on an ongoing basis the need for all recommendations, instruct patients and their families on how to implement certain recommendations. If necessary, provide visual information materials.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ discharge epicrisis with recommendations;
- ✓ documented evidence of briefing with patients, their family members, legal representatives.

7.4.3 The medical organization provides the patient with a discharge record (discharge epicrisis) - a document containing complete information about the diagnosis, the state and dynamics of the patient's health status, diagnostic and medical interventions performed with an assessment of the results, further recommendations, including care

Guidance

The medical organization should have standard procedures, documents that are provided to patients, legal representatives upon discharge. The main document that the patient or his/her legal representative receives is a discharge epicrisis or conclusion. The document has certain filling requirements that must be strictly observed. The discharge epicrisis contains basic information about the diagnosis, plan, treatment tactics, results obtained, changes in the patient's health status and reasonable actions of medical staff. Without fail, this document contains recommendations to the patient, outpatient organization, under the supervision of which the patient is transferred. Like all processes/procedures, the discharge record is subject to internal audit.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ discharge epicrisis/conclusion;
- ✓ taking into account the facts of incorrect filling of the discharge epicrisis and the decisions made on them.

7.4.4 The medical organization should have a process for monitoring and managing patients who notify hospital staff of their intention to leave the hospital despite medical advice, and who leave the organization despite medical advice without warning staff about it.

Guidance

Sometimes patients refuse hospitalization or treatment. The medical organization must respect the rights of patients to refuse/interrupt treatment. The medical organization should have standard procedures for handling patient refusals of further treatment, and medical staff should try to convince the patient to end treatment if there are medical recommendations to do so. When interviewing such patients, it is desirable to involve family members and legal representatives as well. If the patient refuses further treatment, the medical organization must ensure that a written refusal is received from the patient or legal representative. Sometimes there are situations when patients arbitrarily leave the medical organization without notifying the medical staff. The medical organization should also have standard procedures for recording such cases.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record;
- ✓ informed refusal of treatment;
- ✓ documented evidence of fixing cases of unauthorized departure from the medical organization without warning the staff;
- ✓ accounting for the facts of treatment interruption, their analysis and decisions made on them.



8 STANDARD "ORGANIZATION OF ANESTHETIC, RESUSCITATION (INTENSIVE CARE) AND SURGICAL CARE"

8.1 Organization and management of services

8.1.1 The medical organization must provide anesthetic and sedation services in accordance with professional standards, local standards, laws and regulations.

Guidance

The use of professional standards for the administration of anesthetic and sedation is mandatory when providing these types of health care to patients. Anesthesia and sedation are complex processes, including the introduction to anesthesia, the state during the period of being in anesthesia, the awakening or exit from sedation, anesthesia. In the medical organization, these processes are quite frequent in the clinical practice of medical staff.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient record;
- ✓ informed consent of the patient;
- ✓ facts of complications of anesthesia and sedation, their analysis and decisions made on them.

8.1.2 Anesthesia and sedation are performed by qualified staff who are responsible for the quality of care provided

Guidance

For anesthesia and sedation, the medical organization attracts qualified medical staff with the necessary training. Usually, the medical organization has a resuscitation and anesthesiology department, where qualified medical workers work. Sometimes the medical organization may outsource these types of services. Important for ensuring the quality of health care is the level of qualification of medical staff, the availability of the necessary resources. Medical staff must confirm their competence and improve their skills, and the medical organization must provide control and monitoring.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ plan for advanced training/education of medical staff;
- ✓ results of determining the level of preparedness of medical staff conducting anesthesia and sedation;
- ✓ audit and accounting of the facts of improper anesthetic management and sedation, their analysis and decisions made on them.

8.1.3 Sedation is standard for all departments of the medical organization

Guidance

The medical organization should use the standards for the provision of anesthesia care and sedation, adopted and approved in the country. Every worker involved in the anesthetic management and sedation should be familiar with and apply standards for anesthesia and sedation care. These standards, prescribed in clinical

protocols/recommendations, are universal for all departments and are mandatory for all employees.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulations/standards for the provision of anesthetic care and sedation;
- ✓ documented evidence of the application of standards for the provision of anesthesia care and sedation in all departments;
- ✓ audit and accounting of the facts of improper anesthetic management and sedation, their analysis and decisions made on them.

8.2 Anesthetic care

8.2.1 Anesthetic care is provided by suitably qualified staff

Guidance

To provide anesthetic care, medical staff must have the appropriate training and experience. In the medical organization, requirements for the competencies of anesthetic care staff should be developed. This applies to both doctors and nurses. Qualification requirements should be approved at the country level and mandatory for all medical organizations.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ personal files of medical staff;
- ✓ results of determining the level of preparedness of medical staff conducting anesthesia;
- ✓ audit and accounting of the facts of improper anesthetic management, their analysis and decisions made on them.

8.2.2 Prior to anesthesia and induction, the patient is examined by qualified staff and documented

Guidance

In the medical organization, there are clear mechanisms for preparing a patient for anesthesia and sedation. These mechanisms are prescribed in clinical protocols/recommendations, their observance is mandatory for all medical staff. Qualified medical staff examines the patient, determines the need, the amount of anesthetic care, and possible alternative solutions. Conducts a conversation with the patient, explains the effect of anesthesia or sedation, secures informed written consent. Anesthetic status is recorded in the patient's medical record and taken into account in the preoperative period.

Suggested Evidence:

- ✓ standards for the provision of anesthetic care;
- ✓ patient record;
- ✓ audit and recording of the facts of improper execution of the examination of the patient with documentation of the status, their analysis and decisions made on them.

8.2.3 Before administering anesthesia, qualified staff discuss anesthesia tactics with the patient and enter information into the patient's record.

Guidance

Paragraph 8.2.3 already states that qualified staff must conduct a conversation with the patient. An important point of the conversation is that the medical staff should explain to the patient the entire process of anesthesia: what and how will be administered to the patient, how anesthetics affect the state of health, how the patient will come out of anesthesia, what should not be taken before and after anesthesia, and other aspects. Explain all reactions and possible side effects of drugs used for anesthesia, the doctor should also find out the presence of allergic reactions and other questions. All necessary information is entered into the medical record.

Suggested Evidence:

- ✓ standards for the provision of anesthetic care;
- ✓ patient record;
- ✓ audit and recording of the facts of improper execution of the examination of the patient with documentation of the status, their analysis and decisions made on them.

8.2.4 The anesthesiologist is obliged to monitor the patient's condition during anesthesia, promptly respond to changes in the patient's condition, provide qualified assistance and document the entire process

Guidance

The functions of the anesthesiologist include introducing the patient into a state of anesthesia or sedation, monitoring him/her during narcotic sleep, correcting tactics when the patient's condition changes, and responding promptly in cases of emergency. All manipulations, changes in the patient's condition should be entered into the medical record and analyzed.

Suggested Evidence:

- ✓ standards for the provision of anesthetic care;
- ✓ patient record;
- ✓ audit and recording of the facts of improper anesthetic management, monitoring and control of the patient's health status with documentation of the status, their analysis and decisions made on them.

8.2.5 In the postoperative period, the anesthetist must monitor the post-anesthetic status and wake the patient from the state of anesthesia sleep and document the process of awakening

Guidance

Obligatory process should be the observation of the patient after the end of the operation. Each patient may wake up from anesthesia sleep differently. During this period, it is important to control his/her condition, since unpredictable reactions of the body may occur, the doses of anesthetics also vary from the level of intervention and other factors that may affect the patient's health. All processes occurring with the patient, procedures, manipulations carried out by the patient should be reflected in the medical record.

Suggested Evidence:

- ✓ standards for the provision of anesthetic care;
- ✓ patient record;
- ✓ audit and recording of the facts of improper anesthetic management, monitoring and control of the patient's health status with documentation of the status, their analysis and decisions made on them.

8.3 Resuscitation

8.3.1 Resuscitation services should be available around the clock in the medical organization

Guidance

A hospital-type medical organization must have an intensive care unit that provides emergency health care around the clock. Patients entering the medical organization have various indicators of health status and may need emergency health care. Patients in the medical organization may deteriorate their health and need emergency health care. All this determines the standardization of this process and the observance of the quality of health care.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ standards for the provision of resuscitation care;
- ✓ patient record;

8.3.2 The medical organization must have resources in constant readiness for the provision of resuscitation health care

Guidance

The medical organization must provide all the necessary resources for the adequate functioning of the division and the provision of emergency health care around the clock for all patients who are or are admitted for treatment. Resources must be planned and secured for the proper functioning of the relevant division and the timely provision of emergency care if necessary.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents, development plan of the specialized subdivision;
- ✓ standards for the provision of resuscitation care;
- ✓ documentary evidence of the purchase of the necessary equipment, medicines, consumables.

8.3.3 The medical organization implements procedures that reflect the procedure for providing resuscitation health care

Guidance

Resuscitation health care is provided according to strictly prescribed rules and must comply with quality standards. Medical staff must have certain competencies and provide health care in accordance with developed and approved standards. Procedures should reflect the amount of care, the sequence of care.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ standards for the provision of resuscitation care;
- ✓ patient record;
- ✓ audit and accounting of the facts of improper performance of resuscitation procedures, monitoring and control of the patient's health status with documentation of the status, their analysis and decisions made on them.

8.3.4 The medical organization approves qualified staff for conducting resuscitation health care

Guidance

Resuscitation care is provided only by qualified workers with certain skills and experience. The medical organization establishes the requirements for the qualification of staff, determines the procedures for confirming qualifications.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ personal files of medical staff;
- ✓ results of determining the level of preparedness of medical staff providing resuscitation care;
- ✓ audit and accounting of the facts of improper performance of resuscitation care, their analysis and decisions made on them.

8.4 Surgery

8.4.1 Surgical care is provided by suitably qualified staff

Guidance

To provide surgical care, medical staff must have the appropriate education and experience. In the medical organization, requirements for the competencies of the staff of the surgical service of the organization should be developed. This applies to both doctors and nurses. Qualification requirements should be approved at the country level and mandatory for all medical organizations.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ personal files of medical staff;
- ✓ results of determining the level of preparedness of medical staff providing resuscitation care;
- ✓ audit and accounting of the facts of improper performance of resuscitation care, their analysis and decisions made on them.

8.4.2 Prior to surgery, qualified staff will examine the patient and document the status

Guidance

In the medical organization, there are clear mechanisms for preparing a patient for surgical intervention. These mechanisms are prescribed in clinical

protocols/recommendations, their observance is mandatory for all medical staff. Qualified medical staff examines the patient, determines the need, the amount of surgical care, and possible alternative solutions. Conducts a conversation with the patient, explains the course of the operation, secures informed written consent. The status is recorded in the patient's medical record and taken into account during the surgical period.

Suggested Evidence:

- ✓ standards for the provision of surgical care;
- ✓ patient record;
- ✓ audit and recording of the facts of improper execution of the examination of the patient with documentation of the status, their analysis and decisions made on them.

8.4.3 Before performing a surgical intervention, qualified staff discuss the treatment tactics with the patient, entering information into the patient's record

Guidance

Paragraph 8.4.2 already states that qualified staff should conduct a conversation with the patient. An important point of the conversation is that the medical staff should explain to the patient the entire process of surgical intervention: what operation and how will be performed on the patient, what manipulations will be performed on the patient, what should not be taken before and after the operation, and other aspects. Also, the doctor should find out the presence of allergic reactions and other questions. All necessary information is entered into the medical record.

Suggested Evidence:

- ✓ standards for the provision of surgical care;
- ✓ patient record;
- ✓ audit and recording of the facts of improper execution of the examination of the patient with documentation of the status, their analysis and decisions made on them.

8.4.4 The surgeon is obliged to monitor the patient's condition during the operation or manipulation, promptly respond to changes in the patient's condition, provide qualified assistance and document the entire process

Guidance

The functions of the surgeon include performing an operation on a patient and monitoring his/her condition during surgery, monitoring him/her during drug induced sleep, correcting tactics when the patient's condition changes, and responding promptly in cases of emergency. All manipulations, changes in the patient's condition should be entered into the medical record and analyzed.

Suggested Evidence:

- ✓ standards for the provision of surgical care;
- ✓ patient record;
- ✓ audit and accounting of the facts of improper performance of surgical care, monitoring and control of the patient's health status with documentation of the status, their analysis and decisions made on them.

8.4.5 In the postoperative period, the surgeon is obliged to monitor the status of the patient, monitor his/her condition, if necessary, correct the treatment and document the entire process

Guidance

Obligatory process should be the observation of the patient after the end of the operation. During this period, it is important to control his/her condition, since unpredictable reactions of the body may occur, the doses of anesthetics also vary from the level of intervention and other factors that may affect the patient's health. All processes occurring with the patient, procedures, manipulations carried out on the patient should be reflected in the medical record.

Suggested Evidence:

- ✓ standards for the provision of surgical care;
- ✓ patient record;
- ✓ audit and accounting of the facts of improper performance of surgical procedures, monitoring and control of the patient's health status with documentation of the status, their analysis and decisions made on them.



9 STANDARD "SERVICE OF LABORATORY DIAGNOSTICS AND BLOOD SERVICE"

9.1 Organization of laboratory services

9.1.1 The medical organization must identify a qualified employee/staff responsible for the activities of the laboratory service

Guidance

The laboratory service is an integral part of the process of providing health care to patients. The laboratory service should be headed by a qualified person responsible for its activities and the quality of the laboratory services provision. Staff must have appropriate education, certain skills and experience.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ qualification requirements for laboratory service workers;
- ✓ functional duties of laboratory service staff.

9.1.2 The medical organization must determine the place for the implementation of laboratory activities, which must comply with the requirements adopted in the country

Guidance

For the activities of the laboratory service, certain conditions are necessary to ensure the timeliness, continuity of the provision of laboratory services, the quality of these services and the safety of laboratory research. Therefore, the determination of a place that meets the sanitary and epidemiological requirements is important for the proper functioning of the laboratory service.

Suggested Evidence:

- ✓ legal documents regulating this process and requirements;
- ✓ internal regulatory documents;
- ✓ documentary evidence of compliance of the place for laboratory activities with sanitary and epidemiological safety standards.

9.1.3 The medical organization must provide the necessary resources for the functioning of this service

Guidance

The medical organization must ensure the continuity of the laboratory service. To comply with these requirements, the medical organization must provide the necessary resources, which must be planned, funded, purchased in advance.

Suggested Evidence:

- ✓ laboratory service financing plan;
- ✓ accounting, report on the purchase of necessary resources;
- ✓ audit of laboratory service resources, facts of violations in this area, analysis and decisions made on them.

9.1.4 The medical organization must provide qualified staff with appropriate education and experience in conducting laboratory research

Guidance

To provide laboratory care, medical staff must have the appropriate education and experience. In the medical organization, requirements for the competencies of the laboratory service staff of the organization should be developed. This applies to both doctors and nurses. Qualification requirements should be approved at the country level and mandatory for all medical organizations.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ personal files of laboratory service staff;
- ✓ the results of determining the level of preparedness of the laboratory service staff;
- ✓ audit and recording of the facts of improper provision of laboratory assistance, their analysis and decisions taken on them.

9.1.5 The medical organization must guarantee a process in which laboratory tests are carried out strictly within a certain time frame, the results of laboratory tests are reported in a timely manner

Guidance

It is important to observe time management when conducting laboratory research. In this regard, the medical organization should have rules for the division and distribution of flows of laboratory applications, priority is given to patients in need of resuscitation, emergency care.

The medical organization should have rules that define the processes for delimiting the flow of laboratory applications, the time frame for performing laboratory tests.

In the case of the medical organization contacting third-party organizations for the provision of laboratory services, the medical organization must establish rules that must be observed by the parties to the process.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ standards, rules for performing laboratory tests, approved at the level of the medical organization;
- ✓ results of audits of the timeliness of laboratory tests, revealed facts of violations and decisions taken on them;
- ✓ contracts with third parties, audit of compliance with the terms of contracts and, in case of violation of the terms, decisions taken.

9.2 Handling of patient biomaterials

9.2.1 The medical organization must have standard procedures for the appointment of a laboratory test and issuing a referral

Guidance

The medical organization should have standard procedures for assigning a laboratory test, which include patient identification, type of test, type of biomaterial, type of test, and other necessary criteria and indicators. Referrals must be issued by the doctor as an entry in the medical record or as a separate document if the test is conducted in another organization.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ rules for issuing referrals for laboratory tests approved at the level of the medical organization;
- ✓ contracts with third parties, audit of compliance with the terms of contracts and, in case of violation of the terms, decisions taken.

9.2.2 The medical organization must have and implement procedures for the collection, labeling and identification, registration, acceptance, storage and processing of biomaterial

Guidance

The medical organization should have biomaterial labeling procedures for which it is desirable to use patient identification data.

Suggested Evidence:

- ✓ rules for labeling, registration, acceptance, storage, processing of biomaterial;
- ✓ audit and, if facts of violation of the rules are found, decisions are made on them.

9.2.3 The medical organization must have and implement procedures for the safe transportation of biomaterial

Guidance

The medical organization must have standard procedures for transporting biomaterial to ensure the safety and security of biomaterial

Suggested Evidence

- ✓ rules for transportation of biomaterial;
- ✓ audit and, if facts of violation of the rules are found, decisions are made on them.

9.3 Laboratory safety

9.3.1 The medical organization should have and implement laboratory safety procedures

Guidance

The medical organization must have laboratory safety standards and comply with all necessary procedures. Safety procedures include the need for the medical organization to ensure and use personal protective equipment by staff.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ laboratory safety rules;
- ✓ audit and upon detection of violations of the rules, decisions taken on them;
- ✓ documented evidence of the acquisition of protective equipment in sufficient quantities.

9.3.2 The medical organization must train staff in laboratory safety measures, monitor the implementation of these measures. Incidents related to violation of laboratory safety measures are analyzed and documented with the adoption of corrective actions.

Guidance

The medical organization must train staff in laboratory safety measures and their strict observance. The person responsible for laboratory safety must provide training, provide advisory services, and monitor the implementation of safety measures. All cases of violation of laboratory safety are recorded, analyzed and lead to management decisions.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ laboratory safety rules;
- ✓ plan, training program for laboratory safety of staff;
- ✓ accounting, report on the conduct of training with the determination of the level of knowledge and skills of the staff;
- ✓ audit and, if facts of violation of the rules are found, decisions are made on them.

9.4 Quality control in the laboratory

9.4.1 The medical organization needs to carry out internal quality control based on rechecking the results of laboratory tests

Guidance

It is mandatory to ensure the quality of laboratory research. This result can be obtained in several ways: the use of good equipment, tested for compliance with laboratory safety and quality standards, qualified staff, the availability of all necessary reagents and consumables. All these processes are the essence of one result - the correct result of laboratory research. The medical organization must ensure the required quality of laboratory services in various ways, of which the most objective is to recheck the results of laboratory tests. The rechecking of laboratory tests should be carried out by the internal audit service.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ rules for ensuring the quality of laboratory diagnostics;
- ✓ audit and, if facts of violation of the rules are found, decisions are made on them.

9.4.2 The medical organization needs to organize external quality control with process documentation

Guidance

In addition to internal audit, the medical organization should use the possibilities of an external independent audit or verification of laboratory equipment, the correctness of laboratory tests and other components of the laboratory test cycle. The results obtained must be communicated to all responsible employees and documented. Based on the results of external audits, the medical organization should make management decisions.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ rules for ensuring the quality of laboratory diagnostics;
- ✓ audit and, if facts of violation of the rules are found, decisions are made on them.

9.5 Laboratory equipment

9.5.1 The medical organization must ensure that laboratory equipment is tested, maintained and calibrated in accordance with the requirements of regulatory documents

Guidance

Laboratory safety assurance is provided by testing of laboratory equipment. For this procedure, standards have been developed that should be used by the medical organization. This allows you to keep the equipment in good condition. The medical organization must ensure that laboratory equipment is maintained as required and updated with adequate funding.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ rules/standards for checking laboratory equipment;
- ✓ plan for the audit of laboratory equipment and its implementation and, if facts of violation of the rules are found, decisions made on them;
- ✓ plan for the purchase of laboratory equipment and components, consumables, reagents; allocated finances and budget execution.

9.5.2 The staff of the medical organization must be able to work on laboratory equipment within their qualifications

Guidance

Only trained staff can and should work on laboratory equipment. When hiring, employees with the appropriate level of education and training should be accepted. The medical organization should have procedures for recruiting in accordance with the legal documents of the country governing this process, as well as provide advanced training for laboratory staff.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ qualification requirements for laboratory equipment staff;
- ✓ documented evidence of the assessment of the knowledge and skills of the staff of the medical organization for admission to work with certain laboratory equipment;
- ✓ plan/program for training laboratory service staff to enable them to work on laboratory equipment.

9.6 Organization of the blood service

9.6.1 The medical organization should have policies/procedures for the receipt, storage, movement and use of blood and blood components

Guidance

The blood service is one of the important components of providing full-fledged and high-quality health care and has its own requirements and rules for functioning. The

medical organization must have a blood service that is responsible for the storage, receipt, movement and use of blood and its components. If the medical organization uses the services of third-party organizations, it must have agreements with organizations that have permission to conduct such activities. The medical organization must have a policy (regulatory, internal documents such as regulations, orders, instructions, rules, etc.) for the proper functioning of this service.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal documents;
- ✓ documented evidence of the activity of the service (plans, program);
- ✓ measures to audit the service;
- ✓ contracts with third-party organizations providing blood services.

9.6.2 The medical organization should identify a qualified worker/staff responsible for the activities of the blood service

Guidance

The medical organization must have staff with appropriate qualifications and experience in this area. Staff/qualified worker must have the authority to manage this service in accordance with the requirements established in the country.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulations, requirements for staff qualification;
- ✓ personal files of blood service staff;
- ✓ results of determining the level of preparedness of blood service staff;
- ✓ audit and recording of the facts of improper provision of assistance, their analysis and decisions taken on them.

9.6.3 The medical organization must provide the necessary resources for the functioning of this service

Guidance

The medical organization must ensure the continuity of the blood service. To comply with these requirements, the medical organization must provide the necessary resources, which must be planned, funded, purchased in advance.

Suggested Evidence:

- ✓ blood service financing plan;
- ✓ accounting, report on the purchase of necessary resources;
- ✓ audit of blood service resources, facts of violations in this area, analysis and decisions made on them.

9.6.4 The medical organization must provide qualified staff with appropriate education and experience in transfusion of blood and its components

Guidance

To provide care using blood and its components, medical staff must have the appropriate education and experience. In the medical organization, requirements for the competencies of the organization's blood service staff should be developed. This

applies to both doctors and nurses. Qualification requirements should be approved at the country level and mandatory for all medical organizations.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ personal files of blood service staff;
- ✓ results of determining the level of preparedness of blood service staff;
- ✓ audit and recording of the facts of improper provision of assistance, their analysis and decisions taken on them.

9.6.5 The medical organization must have and implement a procedure for identifying a patient, determining the need and possibility of transfusion of blood and its components

Guidance

The correct identification of the patient, the possibility and need for transfusion of blood and its components is important in providing care with the use of blood and its components. First of all, it is necessary to determine the need for this procedure, obtain informed consent from the patient for this procedure, identify the patient according to the indicators established in the medical organization, determine the appropriate drug according to the criteria, and document all manipulations.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ patient identification standards;
- ✓ documented evidence of recording all examinations and their results before transfusion and manipulations;
- ✓ audit and recording of the facts of improper provision of assistance, their analysis and decisions taken on them.

9.6.6 The medical organization must have and implement procedures for monitoring patients during transfusion and after transfusion with the definition of responsible employees

Guidance

The functions of the staff include manipulating the patient and monitoring his/her condition during the transfusion of blood and its components, monitoring him/her after the transfusion, correcting tactics when the patient's condition changes, and responding promptly in cases of emergency. All manipulations, changes in the patient's condition should be entered into the medical record and analyzed.

Suggested Evidence:

- ✓ standards for the provision of blood transfusion procedures and its components;
- ✓ patient record;
- ✓ audit and accounting of the facts of improper execution of the procedure, monitoring and control of the patient's health status with documentation of the status, their analysis and decisions made on them.



10 STANDARD “DIAGNOSTIC IMAGING SERVICE”

10.1 Organization of diagnostic imaging service

10.1.1 The medical organization should have a policy for the organization and operation of the diagnostic imaging service

Guidance

The diagnostic imaging service is one of the important components of providing a complete and high-quality diagnosis of pathological conditions in patients. The medical organization must have a diagnostic imaging service in its composition or conduct such examinations using third-party organizations. The medical organization must have a policy (regulatory, internal documents such as regulations, orders, instructions, rules, etc.) for the proper functioning of this service.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal documents;
- ✓ documented evidence of the activity of the service (plans, program);
- ✓ measures to audit the service;
- ✓ contracts with third-party organizations providing diagnostic imaging services.

10.1.2 The medical organization should identify a qualified person/staff responsible for the operation of the diagnostic imaging service.

Guidance

The medical organization must have staff with appropriate qualifications and experience in this area. Staff/qualified worker must have the authority to manage this service in accordance with the requirements established in the country.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulations, requirements for staff qualification;
- ✓ personal files of the staff of the diagnostic imaging service;
- ✓ results of determining the level of preparedness of the staff of the diagnostic imaging service;
- ✓ audit and accounting of the facts of improper provision of diagnostics, their analysis and decisions made on them.

10.1.3 The medical organization must determine the location for the implementation of the diagnostic imaging service, which must comply with the requirements adopted in the country

Guidance

For the operation of the diagnostic imaging service, certain conditions are necessary to ensure the timeliness, continuity of the provision of diagnostic services, the quality of these services and the safety of research. Therefore, the determination of the location that meets the sanitary and epidemiological requirements is important for the correct functioning of the diagnostic imaging service.

Suggested Evidence:

- ✓ legal documents regulating this process and requirements;
- ✓ internal regulatory documents;
- ✓ documented evidence of the compliance of the location for the implementation of the diagnostic imaging service with sanitary and epidemiological safety standards.

10.1.4 The medical organization must provide the necessary resources for the functioning of this service

Guidance

The medical organization must ensure the continuity of the diagnostic imaging service. To comply with these requirements, the medical organization must provide the necessary resources, which must be planned, funded, purchased in advance.

Suggested Evidence:

- ✓ financing plan for the diagnostic imaging service;
- ✓ accounting, report on the purchase of necessary resources;
- ✓ audit of the resources of the diagnostic imaging service, facts of violations in this area, analysis and decisions made on them.

10.1.5 The medical organization should provide qualified staff with appropriate education and experience in performing diagnostic imaging

Guidance

To provide diagnostic tests, medical staff must have the appropriate education and experience. The medical organization should develop requirements for the competencies of the organization's diagnostic imaging service staff. This applies to both doctors and nurses. Qualification requirements should be approved at the country level and mandatory for all medical organizations.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ internal regulatory documents;
- ✓ personal files of the staff of the diagnostic imaging service;
- ✓ results of determining the level of preparedness of the staff of the diagnostic imaging service;
- ✓ audit and recording of the facts of improper provision of diagnostic care, their analysis and decisions taken on them.

10.1.6 The medical organization must guarantee a process in which research is carried out strictly within a certain time frame, research results are reported in a timely manner

Guidance

It is important to observe time management when conducting diagnostic studies. In this regard, the medical organization should have rules for the division and distribution of application flows, priority is given to patients in need of resuscitation, emergency care.

The medical organization should have rules that define the processes for delimiting the flow of applications, the time frame for performing diagnostic studies.

In the case of the medical organization contacting third-party organizations for the provision of diagnostic services, the medical organization must establish rules that must be observed by the parties to the process.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ standards, rules for performing diagnostic studies, approved at the level of the medical organization;
- ✓ results of audits of the timeliness of the implementation of diagnostic studies, revealed facts of violations and decisions taken on them;
- ✓ contracts with third parties, audit of compliance with the terms of contracts and, in case of violation of the terms, decisions taken.

10.2 Radiation safety

10.2.1 The medical organization must ensure the safety of staff working in the diagnostic imaging service

Guidance

It is important to ensure the radiation safety of staff working in a specialized subdivision. Safety guarantees for staff are the availability of a policy in this area (regulations, rules, instructions, etc.), which are mandatory for all participants in the process. The medical organization must create conditions for compliance with the level of safety through constant monitoring and control, checking equipment, using equipment testing for compliance with safety levels, upgrading the site, equipment.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ standards, rules for performing diagnostic studies, approved at the level of the medical organization;
- ✓ results of diagnostic equipment audits, revealed facts of violations and decisions made on them.

10.2.2 Service staff must be trained in safety measures; the medical organization must monitor compliance with safety measures

Guidance

The medical organization must train staff in safety measures, monitor their strict observance. The employee responsible for radiation safety must provide training, provide advisory services, and monitor the implementation of safety measures. All cases of violation of radiation safety are recorded, analyzed and lead to management decisions.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ radiation safety rules;
- ✓ plan, training program for staff radiation safety;
- ✓ accounting, report on the conduct of training with the determination of the level of knowledge and skills of the staff;
- ✓ audit and, if facts of violation of the rules are found, decisions are made on them.

10.2.3 The medical organization must ensure the safety of patients receiving diagnostic imaging services

Guidance

The medical organization must train staff in safety measures, monitor their strict observance.

Patient safety is a priority for the work of the staff of the specialized division. Patients must be informed and agree to conduct this kind of diagnosis, they must be provided with full information about diagnostic procedures, with informed consent, explain and control the correct behavior of patients in order to comply with safety measures during diagnostic procedures. The employee responsible for radiation safety must train staff in working with patients, provide advisory services, and monitor the implementation of safety measures. All cases of violation of radiation safety are recorded, analyzed and lead to management decisions.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ radiation safety rules;
- ✓ instructions, visual information materials, including aspects of radiation safety for patients;
- ✓ accounting, report on informing patients;
- ✓ audit and, if facts of violation of the rules are found, decisions are made on them.

10.2.4 Safety incidents are investigated and documented and corrective action taken

Guidance

All incidents related to the violation of radiation safety must be documented without fail. All cases of violation of radiation safety should be investigated to identify problems and level them in the future. Responsible is a qualified person with appropriate training and authority. To record incidents, a response standard / instruction should be provided, which should be known and applied by all staff of the relevant service.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ radiation safety rules;
- ✓ accounting, report on incidents related to violation of safety measures;
- ✓ documented evidence of decisions made on incidents.

10.3 Radiological equipment

10.3.1 The medical organization must ensure that radiological equipment is tested, maintained and calibrated in accordance with the requirements of regulatory documents, the whole process is documented

Guidance

Radiation safety guarantees are provided by checking the equipment. For this procedure, standards have been developed that should be used by the medical organization. This allows you to keep the equipment in good condition. The medical

organization must ensure that equipment used for diagnostic imaging is maintained as required and updated with adequate funding.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ rules/standards for testing diagnostic imaging equipment;
- ✓ audit plan for diagnostic imaging equipment and its implementation and, if facts of violation of the rules are found, decisions made on them;
- ✓ plan for the purchase of diagnostic imaging equipment and components, consumables, reagents; allocated finances and budget execution.

10.3.2 The staff of the medical organization must be able to work on radiological equipment within their qualifications

Guidance

Only trained staff can and should operate diagnostic imaging equipment. When hiring, employees with the appropriate level of education and training should be accepted. The medical organization must have recruitment procedures in accordance with the country's legal documents governing this process, as well as provide advanced training for diagnostic imaging staff.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ qualification requirements for staff working on diagnostic imaging equipment;
- ✓ documented evidence of the assessment of the knowledge and skills of the staff of the medical organization for admission to work with diagnostic imaging equipment;
- ✓ training plan/program for the staff of the diagnostic imaging service to enable them to work on the appropriate equipment.

10.4 Quality control in radiology

10.4.1 The medical organization needs to carry out internal quality control on an ongoing basis

Guidance

It is mandatory to ensure the quality of diagnostic studies. This result can be obtained in several ways: the use of good equipment, tested for compliance with radiation safety and quality standards, qualified staff, the availability of all necessary reagents and consumables. All these processes are the essence of one result - the correct result of radiation research. The medical organization must ensure the required quality of diagnostic imaging services in various ways, which are stipulated in the standards approved at the country level and adopted by the medical organization.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ rules for ensuring the quality of visual diagnostics;
- ✓ audit and, if facts of violation of the rules are found, decisions are made on them.

10.4.2 The medical organization needs to organize external quality control with process documentation

Guidance

In addition to internal audit, the medical organization should use the possibilities of an external independent audit or verification of radiation equipment, the correctness of diagnostic tests, and other components. The results obtained must be communicated to all responsible employees and documented. Based on the results of external audits, the medical organization should make management decisions.

Suggested Evidence:

- ✓ legal documents of the country regulating this process;
- ✓ rules for ensuring the quality of visual diagnostics;
- ✓ audit and, if facts of violation of the rules are found, decisions are made on them.

10.4.3 The results of monitoring and quality control are used to improve the quality of diagnostic procedures, patient and staff safety

Guidance

The results of monitoring the activities of the service and the quality of diagnostic care for patients should be used to improve the functioning of the service. The results of audits / checks must be communicated to the staff without fail, and the management decisions taken must be based on the results of control and monitoring.

Suggested Evidence:

- ✓ plan for monitoring and quality control of visual diagnostics;
- ✓ results of monitoring and quality control of visual diagnostics;
- ✓ documented evidence of development / improvement in the quality of diagnostic procedures, safety of patients, staff.

(VII) ANNEXES

Annex 1

The report must be presented according to the following structure:

- Title page indicating the name of the medical organization and the Accreditation body **(1 page)**
- Statement confirming the authenticity and accuracy of the submitted data, signed by the first head of the medical organization **(1 page)**
- Table of contents (with automatically edited table of contents) **(1 page)**
- The medical organization profile **(1-2 pages)**
- **I Symbols and abbreviations (1-2 pages)**

A list of designations and abbreviations used in the text of the Self-Assessment Report is provided.

- **II Introduction (1 page)**

The basis for passing the external assessment, the result of the previous accreditation (Accreditation body, accreditation standards, according to which the external assessment and the status of accreditation was carried out) in case of re-accreditation are indicated.

A brief description of the methods used in the development of the medical organization Self-Assessment Report (appointment of a working group, involvement of stakeholders, etc.) is reflected.

- **III Presentation of the organization of education (1-2 pages)**

A brief history, type of ownership, main permits of the medical organization, information on the types of activities of the medical organization, directions and types of health care are given, current quantitative indicators of the organization of health care are given (number of beds, including those occupied; turnover, bed occupancy; staff; number of structural divisions / departments, etc.) and indicators of the health status of patients indicating quantitative data (number of patients by disease groups, average stay of patients in the medical organization by departments; mortality rates, etc.) by structural divisions / departments.

The uniqueness of the internal quality assurance system functioning in the medical organization is noted.

➤ **IV Previous accreditation (1-5 pages)**

In the case of passing the previous accreditation, a brief description of the results of the previous accreditation is provided with an analysis and the degree of implementation of each recommendation of the EEC.

➤ **V Compliance with Accreditation Standards (70-80 pages)**

Evidence and analytical material is presented, developed on the basis of self-assessment of the medical organization for compliance with the criteria of each accreditation standard. The result of the analysis of the current state of the activities of the medical organization is reflected, material is presented on the effectiveness of the functioning of the internal quality assurance system and the effectiveness of its mechanisms in accordance with the criteria of the standards.

Each Standard contains evidentiary and analytical materials on the compliance of the medical organization with the criteria of this standard, thus consistently reflecting the results of self-assessment.

The substantiation of the positions of the medical organization (strong, satisfactory, suggests improvement, unsatisfactory) is given in accordance with the assessment of the criteria by the working group on self-assessment of the medical organization. In the case of an assessment of “suggests improvement” and “unsatisfactory”, the proposed measures to strengthen the position are indicated.

At the end of each section, the conclusions of the medical organization working group on the criteria are given, for example, “According to the standard “.....”, 7 criteria are disclosed, of which 3 are in a strong position, 3 are satisfactory and 1 suggests improvement.”

➤ **VI Conclusion of the self-assessment commission (12-14 pages)**

An assessment table "Parameters of the organizational profile" (section "Conclusion of the self-assessment commission") is provided with a mark on the compliance of the medical organization with the criteria (strong / satisfactory / suggest improvements / unsatisfactory) of the assessment table, considered as the conclusions of the self-assessment working group.

➤ **Annexes to the self-assessment report.**

The annexes to the report contain all documented evidence, which must be numbered in accordance with the standards (for example, standard 1 - numbering 1.1).

Organization Profile Settings

Item Nos.	No.	Criterion	Compliance level/position			
			Strong	Satisfactory	Suggests	Unsatisfactory
1 STANDARD “LEADERSHIP AND MANAGEMENT OF A MEDICAL ORGANIZATION”						
1.1 Management body, functions and powers						
1	1	The medical organization of a stationary type should have a governing body, the structure, functions and powers of which are prescribed in the policy of the organization				
2	2	The policy containing the responsibility, rights, powers, functions of the governing body is approved by the organization and is stored in the original in the relevant unit.				
3	3	The medical organization is headed by a governing body or the first head, who is responsible for the activities of the medical organization in accordance with the legislation of the country and acts on the basis of regulatory documents				
4	4	The governing body is responsible for developing the mission, vision, development plan of the medical organization and its implementation				
5	5	The governing body determines the types of health care provided to the population, regulates and manages the process of implementing types of services				
6	6	The governing body ensures the openness of the management system, demonstrates communication skills when disseminating information about the activities of the medical organization both inside and outside the organization				
7	7	The governing body is responsible for ensuring the necessary human resources to provide quality health care				
1.2 Strategic and operational management						
8	8	The medical organization must have a strategic development plan that meets the needs of society in obtaining health care, consistent with the mission and vision of the medical organization				
9	9	The strategic plan should be developed in accordance with the country's regulations and				

		communicated to all internal stakeholders				
10	10	The medical organization and all structural divisions should develop operational plans in accordance with the strategic plan				
11	11	The medical organization should identify responsible persons for the implementation of strategic and operational plans in each structural division and at the level of the entire organization				
12	12	The medical organization should be reviewed on an ongoing basis and changes / adjustments to the strategic and operational plans should be made depending on changes in the legal documents of the country, the needs of society				
1.3 Organizational structure and management of structural divisions						
13	13	The medical organization must have an organizational structure that meets the mission of the organization and is aimed at the implementation of the main tasks of the organization				
14	14	The organizational structure must be discussed and approved at a meeting of the collegial body and is available to all stakeholders				
15	15	The medical organization should define the structural divisions, responsibilities and functions of each unit, and interaction between them				
16	16	The medical organization should periodically assess the management of structural divisions to ensure the quality of the assistance provided.				
17	17	The medical organization should clearly define the terms of reference of responsible persons for the management of structural divisions				
1.4 Rights and obligations of staff members, organizational and clinical ethics						
18	18	The medical organization should have a policy in the field of determining the rights and obligations of staff of all structural divisions				
19	19	The medical organization must ensure that the staff meet the regulatory, legal, qualification requirements for professional positions held				
20	20	The head of the structural division is responsible for the effectiveness of the work of the staff, periodically evaluates the staff				
21	21	The medical organization must implement ethical policies/principles that are consistent with business, financial, ethical and legal standards and protect the rights of patients, on the basis of which management and other decisions are made				
22	22	The policy in the field of ethics should be aimed at resolving the operational aspects of the activities of the medical organization, including staff issues				
23	23	The ethics policy should be communicated to all				

		stakeholders, as well as participants in the course of providing health care.				
1.5 Quality management and quality improvement						
24	24	The medical organization should have a quality policy that should be documented and communicated to all interested parties				
25	25	The medical organization should identify a qualified person responsible for ensuring and controlling the quality of health care and patient care both at the level of the entire organization and in each structural division				
26	26	All interested parties (medical staff, management staff, patients, professional communities, etc.) should take part in the development of a quality policy.				
27	27	The medical organization is responsible for collecting, monitoring, analyzing processes that affect the quality of health care and makes scientifically based management decisions				
28	28	Heads of structural divisions improve the quality of health care for patients through participation in the formation of general hospital priorities and monitoring of patient care in the supervised division				
29	29	The medical organization should have quality improvement procedures developed based on the results of the analysis of processes affecting quality.				
1.6 Resource management						
30	30	The medical organization must have sufficient material and technical base that meets the requirements for the safety of patients and staff, to provide adequate health care; manage own resources, including technological, material and technological, human				
31	31	The medical organization in the organization development plan (strategic, operational) should provide for the development of resources in accordance with the needs of the population, regulatory and legal aspects, professional needs and the challenges of our time and improve resources through regular updating, expansion and strengthening of the material and technical base, which must correspond to organization development				
1.7 Risk management						
32	32	The medical organization must have a risk management program/plan				
33	33	The risk management program should aim to identify and proactively reduce adverse events and other risks to patients and staff				
1.8 Educational process management						

34	34	In the case of the participation of the medical organization in the educational process and the training of medical staff, there must be a document on the rights and obligations of the medical organization				
35	35	The medical organization should have a policy of participation of patients and staff in the educational process				
36	36	The medical organization must provide services in accordance with contractual obligations and educational program				
37	37	The medical organization should determine the employee responsible for the implementation of the educational process, taking into account the safety of students, academic staff and patients				
1.9 Scientific process management						
38	38	The medical organization can conduct independently or participate in scientific research, which should be reflected in the Charter or other title documents				
39	39	The medical organization should have a qualified person/structural division responsible for scientific research that oversees all research involving humans.				
40	40	The medical organization must have and apply the rules for informing and consenting to patients and their families about the possibility of participating in clinical, scientific research or clinical trials, provide documentary confirmation / refusal to participate in scientific research conducted by the medical organization				
Total as per the Standard						
2 STANDARD "STAFF"						
2.1 Human resources management						
41	1	The medical organization must have a policy in the field of human resources, taking into account the specifics of the provision of health care to patients, the needs of society in the provision of quality health care				
42	2	The medical organization defines the qualification requirements for positions and the responsibilities of each employee, which are spelled out in the due instructions				
43	3	The medical organization must have a structural division responsible for accounting, recruitment, selection, development of human resources				
44	4	The staff strategy is reviewed on an ongoing basis and updated as necessary.				
2.2 Recruitment and selection of staff members						
45	5	The medical organization must ensure that the				

		recruitment of staff is carried out in compliance with the principles of openness, accessibility of information, objectivity and equality				
46	6	The medical organization should determine the desired level of staff training, taking into account the needs and categories of patients				
2.3 Staff development						
47	7	The medical organization should have a human resource development policy				
48	8	Staff policy should be aimed at developing professional qualities, motivating and stimulating staff, guaranteeing recognition of the professional achievements of staff				
49	9	The medical organization should have a staff promotion policy				
50	10	Staff policy should be reviewed based on changes in the legal documents of the country, the medical organization and the results of an analysis of the quality of health care for patients				
51	11	The medical organization must have a process for the participation of staff in improving the quality of health care, managing the medical organization				
2.4 Training and certification of staff members (clinical skills, advanced training)						
52	12	The medical organization should have and implement a staff training policy to match its modern capabilities				
53	13	The medical organization should use a defined process to assess the performance of staff in accordance with their job responsibilities and professional positions, the quality and safety of patient care				
54	14	The medical organization should have a unified process for collecting information on the professional qualifications of staff, confirmed by documents of staff on qualifications, certification, licensing, level of education, etc.				
55	15	The results of the analysis of professional training and the level of professionalism of the staff should be taken into account in the development of staff policy				
2.5 Staff health and safety						
56	16	The medical organization should have a policy in the field of maintaining and promoting the health of staff, both physical and mental				
57	17	The medical organization should pay special attention to staff safety				
2.6 Freelance Management						
58	18	The medical organization has the right to attract				

		freelance workers to provide medical or other assistance regulated by the legal documents of the organization				
59	19	The medical organization must have a policy in the field of recruitment, requirements for their qualifications, duties, rights, functions, instructions for freelancers				
60	20	The medical organization should determine the requirements for the quality and volume of work of freelancers, monitor and control their activities within the organization				
61	21	The medical organization should review its recruitment policy for freelancers, taking into account the results of the analysis of their activities.				
Total as per the Standard						
3 STANDARD “RESOURCE MANAGEMENT”						
3.1 Financial management						
62	1	Financing of the medical organization is aimed at the implementation of the mission and development strategy of the organization				
63	2	Financing of the medical organization provides for the conditions in which the organization will operate, and is based on an assessment of the needs of staff and management in the development of the organization				
64	3	The medical organization must review funding on an ongoing basis based on development needs, justify budget changes, and be accountable to the community				
65	4	The medical organization must review funding on an ongoing basis based on development needs, justify budget changes, and be accountable to the community				
3.2 Financial audit and accounting						
66	5	The medical organization must have a system of internal control over financial activities				
67	6	Accounting is kept in view of the transparency of processes and should be fully automated				
68	7	The medical organization should engage independent auditors to assess financial performance				
69	8	Financial reporting should be strictly regulated and reports should be provided to the governing body/chief executive				
3.3 Salary						
70	9	The medical organization must have a policy in the field of remuneration of staff				
71	10	The medical organization must ensure that the remuneration of staff is regulated by the legal				

		documents of the country and local documents of the organization				
72	11	The remuneration process must be communicated to every employee and avoid conflicts of interest				
73	12	The medical organization should have a system of staff incentives in the form of financial payments, of which each employee should be informed				
3.4 Information management and protection, information technology						
75	13	The medical organization must have a qualified employee / division responsible for the development of information technology, protection and management of information				
76	14	The medical organization must guarantee sufficient quantity and quality of technical means for the activities of staff				
77	15	The medical organization must ensure privacy, confidentiality, data security and integrity of information				
78	16	The medical organization should plan and establish processes for managing trustworthy information for all organization staff and external parties.				
79	17	For patients, the medical organization should have a standardized data coding system for diagnosis, procedures				
80	18	The medical organization should provide the necessary information in a timely manner, depending on the need				
81	19	The medical organization staff should be trained in working with information, information systems, principles of information use, information security and information management				
3.5 Management of internal documents and medical records						
82	20	The medical organization should have unified document management processes				
83	21	The medical organization must implement rules, procedures, plans that are aimed at regulating all processes in the organization				
84	22	The medical organization uses a standard medical record for patients and has a clear layout for each medical record				
85	23	The patient record must contain accurate and sufficient information about the patient, diagnosis, treatment regimen, state dynamics				
86	24	The medical organization should define the powers and responsibilities for maintaining medical records on the part of clinical and non-clinical staff.				
87	25	The medical organization should ensure regular review, evaluation and analysis of the quality of medical records, including the patient's medical				

		record				
3.6 Databases and their analysis						
88	26	The medical organization must have a database of patients, the activities of the organization itself				
89	27	The database must have protection that ensures the protection of personal data of patients and staff, the activities of the medical organization, subject to non-disclosure				
90	28	Staff, depending on the level of authority, must have access to the database for data analysis, management decision-making				
Total as per the Standard						
4 STANDARD “SAFETY MANAGEMENT”						
4.1 Infection safety management and infection control						
91	1	The medical organization must have an infection prevention and control policy, use a risk-based approach with the identification of areas with a high risk of infection to develop preventive measures and monitor their implementation and effectiveness				
92	2	The medical organization should identify a qualified person/division responsible for infection prevention and control				
93	3	The medical organization staff should be trained in infection safety rules, as well as participation in coordinated infection prevention and control activities				
94	4	The medical organization should periodically screen staff for infections				
95	5	The medical organization should allocate the necessary resources to the infection prevention and control program				
96	6	The medical organization should provide training to staff, patients and their families on infection prevention				
4.2 Safety of medical equipment, devices and consumables						
97	7	The medical organization must ensure the safety of medical equipment, including surgical, intensive care equipment, etc.				
98	8	The medical organization must ensure the safety of consumables				
4.3 Workplace, surface and hospital linen safety						
99	9	The medical organization in the infection prevention and control policy should provide standards for ensuring the infectious safety of workplaces and surfaces				
100	10	The medical organization should ensure the safety of hospital linen by developing and enforcing generally accepted rules and regulations and strictly				

		enforcing them.				
4.4 Human waste and tissue safety						
101	11	The medical organization must have standards for the handling and disposal of medical waste, human tissues, objects containing human tissues and fluids				
102	12	Staff must be trained to work with human waste, tissues, fluids				
103	13	The medical organization must ensure the safety of staff and patients from pathogens associated with contact with human tissues and fluids				
4.5 Food safety						
104	14	The medical organization must ensure the safety of food for patients				
105	15	The medical organization must ensure the safety of food for staff				
4.6 Safety of engineering, utility systems, repair work, reconstruction and construction						
106	16	The medical organization must ensure the safety of engineering, utility systems through the use of controls				
107	17	The medical organization must ensure the safety of buildings, repair work				
4.7 Fire safety						
108	18	The medical organization must ensure fire safety				
109	19	The medical organization must conduct fire safety training for staff				
110	20	The medical organization must have an evacuation plan in case of a fire threat				
4.8 Water and electricity safety						
111	21	The medical organization must ensure the safety of water and electricity				
Total as per the Standard						
5 STANDARD “SAFETY OF MEDICINES (MC) AND MEDICAL DEVICES (MD)”						
5.1 Management of medicines and medical devices						
112	1	The medical organization must ensure the management and safe handling of medicines (MC) and medical devices (MD) in the organization				
113	2	The medical organization should identify a qualified person responsible for the management and control of the use of medicines and medical devices at the organization level, as well as at the level of each division				
114	3	The medical organization should have a program for the prudent and safe use of antibiotics				
5.2 Storage of medicines and medical devices						
115	4	The medical organization need to provide appropriate and safe storage conditions for medicines and medical devices in accordance with the legal documents of the country and local				

		documents				
116	5	The medical organization must have a pharmacy for storing all medicines and medical devices, as well as conditions for storing medicines and medical devices in the departments of the organization				
117	6	The medical organization must ensure the storage of medicines and medical devices, depending on their level of access				
5.3 Prescription of medicines						
118	7	The medical organization should have a formal procedure for assigning medicines and verifying medicines prescriptions				
119	8	The medical organization must identify and document the persons who are allowed to prescribe medicines				
120	9	Staff entitled to prescribe a medicine must use the standard requirements for prescribing a medicinal remedy				
5.4 Preparation of medicines						
121	10	The medical organization must ensure the safety and appropriate conditions for the preparation of medicines				
122	11	Staff authorized to prepare medicines must have appropriate training				
123	12	Prescriptions issued should be checked for validity, interactions when prescribing multiple medicines				
5.5 Monitoring and training in medicines handling						
124	13	The medical organization must ensure control over the circulation and monitoring of the prescription of medicines to exclude unreasonable and excessive prescribing				
125	14	The medical organization must provide training for staff working with medicines and medical devices on an ongoing basis				
126	15	Based on the results of monitoring, medical organization should analyze the mistakes made				
Total as per the Standard						
6 STANDARD "PATIENTS: SAFETY, RIGHTS AND OBLIGATIONS"						
6.1 Patient safety management						
127	1	The medical organization must have a policy on the rights and obligations of patients				
128	2	The medical organization should have a system for informing patients and feedback to determine the possibility of providing health care				
129	3	The medical organization must have a process for identifying patients, including at least two identifiers by which the patient can be identified also in the case of a coma, must have and apply established methods for identifying patients				

130	4	Identifiers must be used in all documents, materials owned and/or used by the patient				
131	5	The medical organization should have identification processes for any interventions, including diagnostic, therapeutic, rehabilitation, etc.				
6.2 Transfer of information						
132	6	The medical organization should have standard procedures for communicating information				
133	7	Standard procedures should apply when communicating information in writing				
134	8	Standard procedures should be applied when communicating information orally				
135	9	Standard procedures should apply when communicating information through the use of electronic means of communication				
6.3 Surgical safety						
136	10	The medical organization must ensure the safety of the patient at the stage of preparation for surgery				
137	11	Staff are required to verify the surgical site by using a standard designation				
138	12	A patient should be verified before surgery according to identifiers, confirmation of informed consent, surgical site, re-questioning for allergic reactions, airway problems				
139	13	Staff are obliged to carry out the time-out procedure and document this process in the patient's medical record				
6.4 Safety of High-Risk Medicines						
140	14	The medical organization must have procedures for improving the safety of high-risk medicines				
141	15	The medical organization must ensure that the staff are aware of the standards for handling high-risk medicines				
142	16	The medical organization should have a process for the safe use of concentrated electrolytes.				
143	17	The medical organization must have a system for monitoring the circulation of high-risk medicines				
6.5 Clinical protocols/recommendations						
144	18	The medical organization must provide health care in accordance with clinical protocols/recommendations recommended in the country				
145	19	Clinical protocols/recommendations should be up-to-date and accessible to all participants in the provision of health care				
146	20	Clinical staff should be trained and have knowledge of clinical protocols/recommendations				
147	21	The medical organization must ensure the control and monitoring of the provision of health care in accordance with clinical protocols / recommendations				

6.6 Managing the risks associated with the provision of health care through handwashing				
148	22	The medical organization should have procedures in place to ensure safety by sanitizing hands by staff		
149	23	The medical organization must provide staff with the necessary resources		
150	24	The medical organization should monitor this process to prevent complications after medical procedures and the spread of infections among patients		
6.7 Fall risk management				
151	25	The medical organization must have procedures for managing the risk of falling patients and monitoring this process		
152	26	The medical organization must create the necessary conditions for the safety of patients and reduce the risk of their falling		
153	27	The medical organization should train staff in the prevention of falls of patients with a clear distribution of responsibilities		
154	29	The medical organization should establish a system for informing and educating patients about the prevention of falls		
6.8 Access to health care for persons with special needs				
155	30	The medical organization should ensure physical access to the organization for patients with disabilities/special needs through policies and trained staff		
156	31	The medical organization must create the necessary conditions for access to the organization of patients with special needs / disabilities		
6.9 Patient rights procedures				
157	32	The medical organization must have a policy in the field of the rights and obligations of patients		
158	33	Patient rights and responsibilities policy should be available to patients		
159	34	On admission, staff must inform the patient of his/her rights and obligations		
160	35	The medical organization is obliged to respect the right of the patient and his/her legal representatives for reliable information about the state of health, procedures, costs, risks, treatment options		
161	36	Staff should be fully informed about the rights and obligations of patients		
6.10 Information privacy				
162	37	The medical organization must have procedures for maintaining the confidentiality of information		
163	38	Staff must be aware of and comply with confidentiality requirements.		
6.11 Appeals of patients and their legal representatives				

164	39	The medical organization must have procedures for accepting applications, appeals from patients and their legal representatives in case of violation of their rights or other circumstances				
165	40	The medical organization must provide public information about contact officials who can be contacted				
166	41	The medical organization must consider the appeals of patients and their legal representatives within a certain period of time and provide a response in a timely manner				
167	42	The results of the analysis of applications should be used to improve the quality of health care				
6.12 Awareness and voluntariness of decision-making by patients to receive health care						
168	43	The medical organization must have procedures for the voluntary decision of patients to receive health care				
169	44	Receipt of health care should be determined by informed written consent, which should be signed directly by the patient, if this process is impossible - by his/her legal representatives, with identification				
170	45	A patient must be informed about this procedure, his/her rights and obligations must be explained to him/her, the decision must be voluntary on the basis of reliable and complete information				
171	46	Medical staff should be trained to work with patients to obtain informed consent				
6.13 Refusal of treatment						
172	47	A patient has the right to refuse treatment, and the medical organization should have procedures for fixing this process				
173	48	The staff of the medical organization is obliged to inform the patient about the risks associated with refusing treatment and the possibility of refusing a specific procedure				
Total as per the Standard:						
7 STANDARD "TREATMENT AND CARE OF PATIENTS"						
7.1 Hospital admission						
174	1	The medical organization must conduct a screening / primary examination of the patient for his/her need for health care provided by this medical organization				
175	2	Staff must inform patient about screening/initial examination procedure				
176	3	The medical organization must have a system for sorting patients as an emergency, the staff must comply with the requirements of the system, when emergency patients arrive, they receive priority in examination and treatment				

178	4	Patients undergo laboratory and instrumental examinations in accordance with local regulatory requirements				
179	5	The medical organization must have procedures for dealing with patients with special needs at the time of admission to the hospital				
180	6	The medical organization must have procedures for dealing with high-risk patients				
181	7	On admission, patients and their families receive training and instruction on the inpatient unit, information about the intended treatment and any expected costs of treatment, and the expected outcomes of the treatment				
182	8	The medical organization fills out medical documentation upon admission of the patient, which is used later in the departments as a single record document				
7.2 Continuity of care for patients						
183	9	The medical organization must have a policy in the field of continuity of health care				
184	10	The staff of the department determines the plan and tactics of treatment on the basis of a collegial decision individually for each patient, taking into account the initial examination, the availability of examination results upon admission				
185	11	Examinations of patients are carried out depending on the diagnosis, severity of the condition, medical interventions performed				
186	12	Each patient is assigned a qualified clinical staff responsible for the entire period of the patient's inpatient care				
187	13	Medical records must be completed correctly, reliably and objectively				
188	14	The medical organization is obliged to respect the rights of patients and their families during treatment				
189	15	Patients and legal representatives are full participants in treatment decisions through continuous information, health literacy and participation in the patient care process				
190	16	The medical organization determines the process of meeting the religious and spiritual needs of patients (requests of the patient and his family for the provision of religious services, etc.).				
191	17	The medical organization must have patient training programs and implement them depending on the categories of patients and needs				
192	18	The medical organization should have procedures for the provision of donor services				
7.3 Transfer of patients						

193	19	The medical organization should have procedures and practices for transferring patients from one department to another or to another organization.				
194	20	The transfer process must be agreed with the host side and documented				
195	21	Patient must be informed of transfer and provide voluntary informed consent				
196	22	Staff must ensure patient transport, using mobility aids if necessary.				
197	23	When transferring to another organization, the medical organization must provide a record containing complete and reliable information about the diagnosis, treatment and condition of the patient, or transfer the patient record in case of transfer to another department within this medical organization				
7.4 Discharge record						
198	24	The medical organization should have standard procedures for discharging patients based on criteria for assessing the patient's condition and readiness for discharge.				
199	25	The medical organization is obliged to instruct / train the patient, his/her legal representatives, on the recommendations that must be followed after discharge				
200	26	The medical organization provides the patient with an extract (discharge record) - a document containing complete information about the diagnosis, the state and dynamics of the patient's health status, diagnostic and medical interventions performed with an assessment of the results, further recommendations, including care				
201	27	The medical organization should have a process for monitoring and managing patients who notify hospital staff of their intention to leave the hospital despite medical advice, and who leave the organization despite medical advice without warning staff about it.				
Total as per the Standard:						
8 STANDARD "ORGANIZATION OF ANESTHETIC, RESUSCITATION (INTENSIVE CARE) AND SURGICAL CARE"						
8.1 Organization and management of services						
202	1	The medical organization must provide anesthesia and sedation services in accordance with professional standards, local standards, laws and regulations.				
203	2	Anesthesia and sedation are performed by qualified staff who are responsible for the quality of care provided.				
204	3	Sedation is standard for all departments of the medical organization				
8.2 Anesthetic care						

205	4	Anesthetic care is provided by suitably qualified staff				
206	5	Prior to anesthesia and induction, the patient is examined by qualified staff and documented				
207	6	Before anesthesia is administered, qualified staff discuss anesthesia tactics with the patient and enter information into the patient's record.				
208	7	The anesthesiologist is obliged to monitor the patient's condition during anesthesia, promptly respond to changes in the patient's condition, provide qualified assistance and document the entire process				
209	8	In the postoperative period, the anesthesiologist must monitor the post-anesthetic status and wake the patient from anesthesia sleep and document the process of awakening				
8.3 Resuscitation						
210	9	Resuscitation services should be available around the clock in the medical organization				
211	10	The medical organization must have resources in constant readiness to provide resuscitation health care				
212	11	The medical organization implements procedures that reflect the procedure for providing resuscitation health care				
213	12	The medical organization approves qualified staff for conducting resuscitation health care				
8.4 Surgery						
214	13	Surgical care is provided by suitably qualified staff				
215	14	Prior to surgery, qualified staff examine the patient and document the patient's status				
216	15	Before performing a surgical intervention, qualified staff discuss the treatment tactics with the patient, entering information into the patient's record				
217	16	A surgeon is obliged to monitor the patient's condition during the operation or manipulation, promptly respond to changes in the patient's condition, provide qualified assistance and document the entire process				
218	17	In the postoperative period, the surgeon is obliged to monitor the status of the patient, monitor his/her condition, if necessary, correct the treatment and document the entire process.				
Total as per the Standard:						
9 STANDARD "SERVICE OF LABORATORY DIAGNOSTICS AND BLOOD SERVICE"						
9.1 Organization of laboratory services						
219	1	The medical organization must identify a qualified worker/staff responsible for the activities of the laboratory service				
220	2	The medical organization must determine the location for the implementation of laboratory activities, which				

		must comply with the requirements adopted in the country				
221	3	The medical organization must provide the necessary resources for the functioning of this service				
222	4	The medical organization must provide qualified staff with appropriate education and experience in conducting laboratory research				
223	5	The medical organization must ensure a process in which laboratory tests are carried out strictly within a certain time frame, the results of laboratory tests are reported in a timely manner				
9.2 Handling of patient biomaterials						
224	6	The medical organization must have standard procedures for ordering a laboratory test and issuing a referral				
225	7	The medical organization must have and implement procedures for the collection, labeling and identification, registration, acceptance, storage and processing of biomaterial				
226	8	The medical organization must have and implement procedures for the safe transportation of biomaterial				
9.3 Laboratory safety						
227	9	The medical organization must have and implement laboratory safety procedures				
228	10	The medical organization must train staff in laboratory safety measures, monitor the implementation of these measures. Incidents related to violation of laboratory security measures are analyzed and documented with the adoption of corrective actions.				
9.4 Quality control in the laboratory						
229	11	The medical organization needs to carry out internal quality control based on rechecking the results of laboratory tests				
230	12	The medical organization needs to organize external quality control with process documentation				
9.5 Laboratory equipment						
231	13	The medical organization must ensure that laboratory equipment is tested, maintained and calibrated in accordance with the requirements of legal documents				
232	14	Staff of the medical organization must be able to work on laboratory equipment within the framework of their qualifications.				
9.6 Organization of the blood service						
233	15	The medical organization must have policies/procedures for the receipt, storage, movement and use of blood and blood components.				
234	16	The medical organization must identify a qualified employee/staff responsible for the activities of the blood service				

235	17	The medical organization must provide the necessary resources for the functioning of this service				
236	18	The medical organization must provide qualified staff with appropriate education and experience in transfusion of blood and its components				
237	19	The medical organization must have and implement a procedure for identifying a patient, determining the need and possibility of transfusion of blood and its components				
238	20	The medical organization must have and implement procedures for monitoring patients during transfusion and after transfusion with the definition of responsible employees				
Total as per the Standard:						
10 STANDARD “DIAGNOSTIC IMAGING SERVICE”						
10.1 Organization of diagnostic imaging service						
239	1	The medical organization must have a policy for the organization and operation of the diagnostic imaging service				
240	2	The medical organization must identify a qualified person/staff responsible for the operation of the diagnostic imaging service.				
241	3	The medical organization must determine the location for the implementation of the diagnostic imaging service, which must comply with the requirements accepted in the country				
242	4	The medical organization must provide the necessary resources for the functioning of this service				
243	5	The medical organization must provide qualified staff with appropriate training and experience in performing diagnostic imaging				
244	6	The medical organization must ensure a process in which research is carried out strictly within a certain time frame, research results are reported in a timely manner				
10.2 Radiation safety						
245	7	The medical organization must ensure the safety of staff working in the diagnostic imaging service				
246	8	Service staff must be trained in security measures, the medical organization must monitor compliance with security measures				
247	9	The medical organization must ensure the safety of patients receiving diagnostic imaging services				
248	10	Security incidents are investigated and documented and corrective action taken				
10.3 Radiological equipment						
249	11	The medical organization must ensure that radiological equipment is tested, maintained and				

		calibrated in accordance with the requirements of legal documents, the whole process is documented				
250	12	Staff of the medical organization should be able to work on radiological equipment within the framework of their qualifications				
10.4 Quality control in radiology						
251	13	The medical organization needs to carry out internal quality control on an ongoing basis				
252	14	The medical organization needs to organize external quality control with process documentation				
253	15	The results of monitoring and quality control are used to improve the quality of diagnostic procedures, the safety of patients and staff				
Total as per the Standard:						
TOTAL BY STANDARDS:						

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