

## QUALITY MANAGEMENT IN PUBLIC HEALTH: ORGANIZATION, FUNCTIONING, RULES AND SOME RESULTS

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### Abstract

*The purpose of this paper is to highlight the most significant aspects of quality management in the public health sector in Romania, with a particular focus on the organization, functioning, existing regulations, and outcomes achieved to date in this area. Our motivation stems from the fact that adequate control and good quality assurance in public health can significantly contribute to improving patient outcomes, reducing costs, and increasing trust in the healthcare system. By implementing rigorous evaluation and improvement methods, health systems can ensure better and safer care for all patients. Based on the most recent literature, we address issues such as the establishment of the organization responsible for quality management in Romania's health sector (including the national regulatory context and organizational form, as well as the main aims and objectives of this organization). We then focus on the activities of the hospital accreditation office within the National Authority for Quality Management in Health (NAQMH / ANMCS) and the exercise of specific competencies by the North-East Territorial Office in Iași. The conclusion of our paper is dedicated to the most important findings regarding the studied topic.*

**Keywords:** *Quality Management; Public health; Hospital (or Inpatient Health Facility/IHF); Hospital accreditation; Accreditation categories.*

**JEL Classification:** H51; I18

### I. INTRODUCTION

Quality control and assurance in public health have recently gained significant importance due to the desire to provide medical services that are as safe, efficient, and high-quality as possible. From a conceptual perspective, quality in public health refers to the extent to which health services increase the likelihood of desired outcomes for patients and are consistent with current professional knowledge (Boghian, 2021; Gheorghe, 2006; Chiru, 2006; Armean, 2002). In the same vein, the Council of Europe Recommendation of September 30, 1997, states: "The quality of health care is the degree to which the treatment provided increases the chances of the patient achieving the desired outcomes and reduces the chances of undesirable outcomes, considering the current state of knowledge" (<https://rm.coe.int/>).

Continuous and improving quality assurance requires that at certain intervals, specialized personnel apply specific methods and use particular tools (Donabedian, 2005). These include: (i) clinical audits (a systematic process of reviewing medical services to ensure they meet quality standards and identifying areas for improvement), (ii) performance evaluation (using performance indicators to monitor and assess the quality of medical services), and (iii) patient feedback, which involves collecting and analyzing patient opinions to understand their experiences and identify opportunities for improvement. Additionally, ongoing training is essential, aiming to ensure that medical personnel are up-to-date with the latest knowledge and practices through continuous education and training programs (Enăchescu & Marcu, 1998).

In this context, Romania, like other European Union (EU) member states, has implemented a hospital accreditation system, which involves periodic evaluation and certification of medical institutions according to rigorous quality standards. In 2016, the first cycle of hospital accreditation was completed, initiated after 2011. Based on accumulated experience, quality standards and accreditation methodology were reviewed and approved in 2017.

Following changes in the approach to quality in the health system promoted at the governmental level (RG, 2015), the development of quality management in health accelerated, including the regionalization of monitoring accredited health facilities and adverse events associated with medical procedures. These initiatives were further reinforced by the adoption of a law (RP, 2017) concerning quality assurance in the health system.

The evolution of regulations in the quality of health services, reflected in amendments to Law No. 95/2006, is as follows: (i) initially, quality assurance of health services was the responsibility of the National Health

Insurance House (NHIH / CNAS), which accepted contracts only with authorized and evaluated providers according to the law; (ii) CNAS / NHIH and the Ministry of Health were responsible for developing quality evaluation criteria; (iii) in 2015, Law No. 126/2015 transferred this responsibility to the newly established National Agency for Quality Management in Health (NAQMH / ANMCS) (RP, 2015); (iv) since the enactment of Law No. 126/2015, NAQMH / ANMCS is the only legally competent body to evaluate the quality of health services.

Our work aims to address problems of this nature ("Quality management in public health: Organization, functioning, rules, and some results"), and is structured as follows: (1) Introduction; (2) Strategic coordinates regarding quality in the public health sector; (3) Establishment of the body ensuring quality management in health in Romania (3.1. National regulatory context; 3.2. National Agency for Quality Management in Health (NAQMH / ANMCS): Organizational structure, purpose, and main objectives; 3.3. Activity of the hospital accreditation office within NAQMH / ANMCS (2022); (4) Findings in the competence area of NAQMH / ANMCS - North-East Territorial Office in Iași; and (5) Conclusions.

In preparing this work, we have considered the most recent bibliographic resources, including reports from prestigious institutions in the field, policy/strategy documents, and the legislative framework in force at the time of completing this endeavor

**II. STRATEGIC COORDINATES REGARDING QUALITY IN THE PUBLIC HEALTH SECTOR**

In 2008, the National Hospital Accreditation Commission (Co.NAS) was established through a government decision (RG, 2008), which defined its structure, responsibilities, and modes of organization and operation. The primary objective of Co.NAS was to accredit hospitals in Romania to implement governmental health policies and programs and to align national legislation with European standards, with the aim of continuously improving the quality of hospital medical services (RG, 2018).

Currently, the National Agency for Quality Management in Health (NAQMH / ANMCS) is implementing the National Quality Assurance Strategy for the Health System for the period 2018-2025, which focuses on specific action areas and competencies, concentrating on several major directions (Table 1).

**Table 1.** Action areas and specific competencies

<b>Quality management standards in the national health system</b>	<b>Implementation of quality management in the national health system</b>	<b>Transversal and zonal measures</b>
<ul style="list-style-type: none"> <li>• improving the quality regulatory system, including by integrating the concept of clinical governance;</li> <li>• stimulating the development and updating of clinical guidelines;</li> <li>• stimulating the development and updating of clinical protocols on levels of medical assistance and "therapeutic pathway" procedures (clinical pathway);</li> <li>• the implementation of a formal mechanism to guarantee the involvement of patients / patient associations and representatives of civil society in quality issues in health, to increase the degree of satisfaction of patients and the population with health services.</li> </ul>	<ul style="list-style-type: none"> <li>• the preparation of health units, in order to increase the quality of medical services;</li> <li>• evaluation of the structure, processes, performances, measurement of the level of quality achieved and accreditation of health facilities;</li> <li>• development of measures to maintain and improve the quality level of health facilities;</li> <li>• the implementation of a unitary/standardized monitoring mechanism for the performance of health facilities, focused on quality and on providing feedback for quality improvement (with an emphasis on continuity of care, on the doctor-patient relationship, on communication between professionals and on respecting the patient's rights).</li> </ul>	<ul style="list-style-type: none"> <li>• strengthening the institutional capacity;</li> <li>• streamlining the quality assessment system;</li> <li>• the development of the regional infrastructure in order to monitor the quality management system;</li> <li>• research and innovation to increase quality in health;</li> <li>• research for necessary documentation at the administrative level;</li> <li>• creating the premises for the continued evolution of the quality field, through the training of specialists.</li> </ul>

Source: National Quality Assurance Strategy for the Health System, 2018-2025

The implementation of the "Quality in Health" strategy is carried out through the Action Plan, which defines the responsibilities and roles of healthcare professionals, ensuring the monitoring and evaluation of progress toward achieving the set objectives for the medium term and by 2025. Specialists in the field, quality managers, patients, and patient associations play a crucial role in this implementation. These groups, adhering to the values of NAQMH / ANMCS, will understand and support the vision of "quality in health", thereby contributing to the improvement of health services through quality, efficiency, and performance, ensuring patient safety and

satisfaction for the patient, family, and community.

The implementation of the strategy is complemented by the development and application of subsequent strategies that establish specific and complementary objectives. These provide the necessary support for achieving NAQMH / ANMCS’s mission, aligning with the requirements of similar organizations in the European Union and introducing performance and outcome indicators for the international recognition of NAQMH / ANMCS and its standards. It is important to allocate adequate financial resources and ensure the efficient use of funds, particularly public funds, to enhance health services (Bostan & Bostan, 2023ab; Bostan et al., 2022ab; Asalos et al., 2022).

Monitoring and evaluating performance in the implementation of the Strategy and Action Plan depend on: (i) the quality and clarity of the indicators used; (ii) the structures involved in data collection and reporting; (iii) the speed of response for completing missing or irrelevant information.

Developing a culture of quality within organizations implementing the strategy is essential for ensuring objective feedback and assessment. Additionally, surveys, studies, and research, whether quantitative or qualitative, can be used to evaluate the results of the strategic measures applied in healthcare facilities. The indicators included in the Action Plan will be monitored throughout the strategy's implementation. Their progress will be analyzed annually and during stage evaluations, with final conclusions being formulated in the 2026 assessment.

### III. CREATION OF THE ORGANIZATION RESPONSIBLE FOR QUALITY MANAGEMENT IN THE HEALTH SECTOR IN ROMANIA

In the field of health quality and its management, NAQMH / ANMCS collaborates with other national bodies, including the Ministry of Health, the National Health Insurance House, the Health Insurance House of the Ministry of Defense, and at the county level or in the municipality of Bucharest, with the Health Insurance Houses and Public Health Directorates.

Given the subject of our paper, we will focus specifically on the role of NAQMH / ANMCS. According to Law No. 95/2006 on health reform and Law No. 185/2017 on ensuring quality in the health system, NAQMH / ANMCS is nationally responsible for establishing quality standards for healthcare facilities, evaluating and accrediting them, as well as developing the regulatory framework in the field of health quality. Article 249 (1) of Law No. 95/2006 states that "the evaluation of the quality of health services for the purpose of accrediting healthcare units falls to the National Authority for Quality Management in Health" and according to Article 249 (2), "the evaluation and accreditation of healthcare units are carried out based on the standards, procedures, and methodology developed by the National Authority for Quality Management in Health" (RP, 2006).

It is important to note that "evaluation represents the process through which a commission of independent, specially trained, and accredited evaluators checks the conformity of processes within the healthcare unit with the requirements of the standards" (ANMCS, 2018). This process includes three main stages (Table 2).

**Table 2.** The stages of the evaluation process

Stage I - Scheduled	Stage II - Visit	Stage III - Post-visit
The team of evaluators analyzes the documents requested by ANMCS / HAONAQMH and sent by the medical units in the CaPeSaRo application and requests clarifications from the management, when necessary.	The evaluation commission moves to the headquarters of the health unit and to validate the data on the basis of which compliance with the requirements of the standards is established, pursuing the previously mentioned objectives.	The evaluators draft the evaluation report, any objections or ambiguities raised by the management of the unit are answered and the evaluation report is drawn up, based on which the accreditation report is drawn up.

Source: ANMCS, 2018

Evaluators focus on determining whether quality management is fully understood and accepted by the leaders and staff of the structures, whether there is a genuine concern for quality, and whether procedures and protocols are designed to address identified issues (ANMCS, 2018).

Additionally, it is essential for the evaluation team to verify whether the unit has a self-assessment system intended for the continuous improvement of its activities. Following the identification of non-conformities, the evaluators must work with the management of the healthcare unit to develop a compliance plan.

#### 3.1. National regulatory context

Accreditation is an essential requirement for all healthcare facilities, whether they provide services within

the public health insurance system or not, with the exception of family medicine practices, dental practices, and specialized outpatient units regulated by Government Ordinance no. 124/1998 (RG, 1998). This requirement does not apply to pharmaceutical units, such as pharmacies and open circuit drugstores.

Previously, regulations regarding the quality of healthcare services were scattered across various normative acts with variable legal force, and until 2017, these norms were only partially complete, sometimes contradictory, or redundant. Some of these shortcomings were due to the introduction of new provisions without the repeal of previous regulations, leading to implementation difficulties and repeated legislative corrections.

In this context, Law no. 185/2017 on ensuring quality in the healthcare system (RP, 2017) was adopted. The law establishes that the responsibility for ensuring the quality of healthcare services and patient safety lies with healthcare facilities, according to the policies and strategies promoted by the Ministry of Health and the National Authority for Quality Management in Health (NAQMH / ANMCS). According to the law, the standardization and evaluation of healthcare services are carried out by NAQMH / ANMCS, and its regulations are mandatory for healthcare facilities seeking accreditation.

Subsequently, new amendments were introduced to clarify the obligations of healthcare facilities in the domain of healthcare service quality. These amendments aimed to clarify the general applicability of provisions regarding healthcare service quality and to define more clearly the obligations of healthcare facilities, regardless of their funding source. Additionally, the obligations of public authorities for monitoring and controlling compliance with these obligations and the methods for performing quality control were established.

Furthermore, the amendments improved the regulation of staffing requirements by setting criteria for determining staff needs and ensuring the continuity of medical activities under conditions of patient safety. Measures were also introduced for the periodic analysis of human resource utilization and flexible use of staff to maintain the continuity of medical and patient care services.

### **3.2. National Authority for Quality Management in Health (NAQMH / ANMCS): Organizational structure, purpose, and main objectives**

NAQMH / ANMCS is a public institution with legal personality, operating as a specialized body within the central public administration, with the primary responsibility of managing quality in the healthcare sector. Directly subordinate to the Government and coordinated by the Prime Minister, the agency's governance structure includes the Board of Directors, its Permanent Office, the President of NAQMH / ANMCS, and the General Director (RP, 2017).

The agency plays a crucial role in the standardization and objective evaluation of healthcare services, with its central responsibility being the accreditation and monitoring of healthcare facilities. Its independence from all involved parties ensures the impartiality of the evaluation process. The agency is funded by its own resources, supplemented by subsidies allocated through the budget of the General Secretariat of the Government.

The main purpose of NAQMH / ANMCS is to ensure and continuously improve the quality of healthcare services and patient safety by establishing rigorous standards and conducting ongoing evaluations of healthcare facilities (ANMCS, 2023). Additionally, NAQMH / ANMCS is tasked with identifying dysfunctions in the healthcare system, analyzing their causes, and proposing solutions to the competent institutions.

The key objectives of NAQMH / ANMCS include (ANMCS, 2023): (i) systematic evaluation of the quality of medical services and patient safety across all healthcare facilities (with the results map presented in Figure 1); (ii) development of an effective methodology for identifying, analyzing, and reporting adverse events in medical care in a non-punitive manner, with the aim of collecting relevant national data; (iii) continuous training and information for staff responsible for quality management in health; (iv) ongoing professional development in quality management and patient safety for healthcare personnel; (v) transparent information to patients about the quality of services provided by healthcare facilities to increase public trust in the healthcare system.

Through these activities, NAQMH / ANMCS aims to raise the standards of medical services and strengthen the trust relationship between patients and the healthcare system, contributing to a safer and more efficient medical system for all citizens.

In accordance with Law No. 185/2017 (RP, 2017), NAQMH / ANMCS is responsible for providing central authorities with essential information regarding the quality of healthcare services and patient safety. Additionally, NAQMH / ANMCS promotes the concept of quality management in healthcare and patient safety through the publication of informational materials, the development of promotional content, and the organization of scientific events.

To ensure effective management of healthcare service quality and patient safety, NAQMH / ANMCS has established eight territorial offices (RG, 2018), which were fiscally registered in 2019. However, NAQMH / ANMCS's own revenue has not been sufficient to cover the operational costs of these offices (ANMCS, 2023).

A consistent objective of NAQMH / ANMCS has been the standardization and optimization of data

collection and transmission in electronic format, using uniform reporting forms, since the institution's establishment.

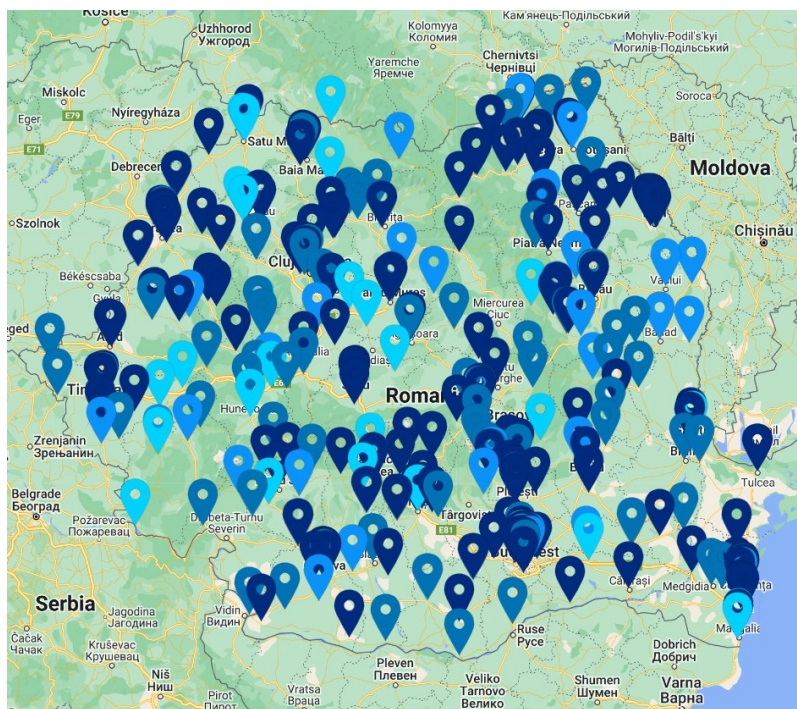






Figure 1. Accreditation map USP / IHF (RO-2023)

Symbols:

-  Category II - Accredited with recommendations
-  Category III - Accredited with reservations
-  Category IV - Accredited with low confidence
-  Fifth Category - Decision to extend the accreditation process

Source: <https://anmcs.gov.ro/web/harta-acreditarii>

### 3.3. Activity of the Hospital Accreditation Office within NAQMH / ANMCS (2022)

In 2022, the Hospital Accreditation Office produced 47 accreditation reports. These included 27 initial accreditation reports and 20 reclassification reports, based on the analysis of the Non-Conformity Remediation Chart (ANMCS, 2023). As a result, in 2022, 47 healthcare facilities were classified into accreditation categories, with their status according to the accreditation category detailed in Table 3.

Table 3. The situation of the 47 USP / IHF s according to the accreditation category

Name of the accreditation category	No. USP / IHF	Public	Privat
Category I - Accredited	-	-	-
Category II - Accredited with recommendations	19	8	11
Category III - Accredited with reservations	11	9	2
Category IV - Accredited with reduced confidence	6	6	-
Category V - Decision to extend the accreditation process	9	6	3
Category VI - Unaccredited	2	1	1
Total	47	30	17

Source: ANMACS, 2023

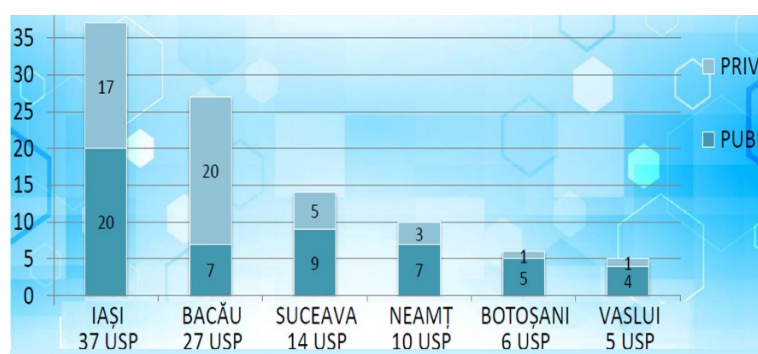
The classification of the Healthcare Facility (USP / IHF) into Category V and the decision to extend the accreditation process were determined by non-compliance with over 51% of the standards. According to regulations, the USP must request a change to a new accreditation category within a maximum of 1 year from receiving the results (ANMCS, 2023). After addressing the non-conformities identified in the Non-Conformity Chart and the indicators with a score of (-10), the USP / IHF will be re-evaluated to determine the new accreditation

category.

**IV. FINDINGS WITHIN THE COMPETENCE AREA OF NAQMH / ANMCS NORTH-EAST TERRITORIAL OFFICE (IAȘI)**

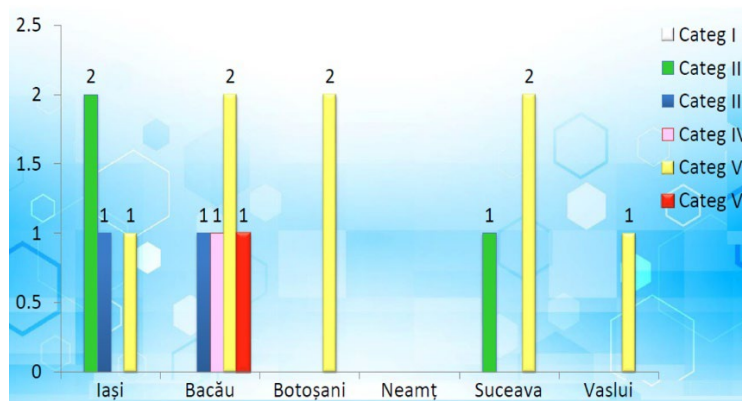
The North-East Territorial Office, an integral part of NAQMH / ANMCS with legal personality, was established to enhance the efficiency of guiding healthcare facilities in implementing the quality management and patient safety system, as well as to monitor the maintenance of accreditation standards across all healthcare facilities in the region (ANMCS, 2019a).

The North-East Territorial Office oversees 99 healthcare facilities with inpatient beds (USP / IHF), of which 52 are public and 47 are private. Based on the type of hospitalization, the region includes 52 USP / IHFs for continuous and day hospitalization, 18 USP / IHFs for continuous hospitalization, and 29 USP / IHFs for day hospitalization (ANMCS, 2019b). The distribution of these facilities across the counties of the region is illustrated in Figure 2.



**Figure 2.** Distribution of USP / IHF by counties of the North-East Region  
Source: <https://anmcs.gov.ro/web/wp-content/uploads/2019/09/prezentare-ot-ne.pdf>

In the II accreditation cycle, 24 USP / IHFs were evaluated, until the outbreak of the Covid-19 pandemic, of which 15 were included in accreditation categories (Figure 3), for the rest (9) the procedure of accreditation.



**Figure 3.** Classification by accreditation categories of the 15 USP / IHFs in the North-East Region at the level of each county (until the outbreak of the Covid-19 pandemic)  
Source: <https://anmcs.gov.ro/web/wp-content/uploads/2019/09/prezentare-ot-ne.pdf>

Regarding the Significance of Accreditation Categories, Category I indicates that the hospital management, the medical team, and the overseeing authority or governing body collaborate effectively to ensure the quality of medical services and patient safety. In Categories II, III, and IV, the overall score and the proportion of indicators with a (-10) score reflect the quality of hospital management and the work of the medical team. Additionally, the presence of a compliance plan primarily highlights the support from the overseeing authority and, to a lesser extent, the activities of the hospital management. Category V suggests that certain aspects of the quality of medical services have not been sufficiently addressed by hospital management, but there is an opportunity to correct them. Conversely, Category VI indicates significant deficiencies in management and a lack of proper oversight from the

authorities.

For example, before the Covid-19 pandemic, there were three healthcare facilities in the North-East Region categorized as Category II (Accredited with recommendations), two in Category III (Accredited with reservations), one in Category IV (Accredited with low confidence), eight in Category V (Accreditation extension decision), and one in Category VI (Not accredited), representing 6.67% of the national total (Rotaru, 2019).

Up until the onset of the pandemic, there were no national healthcare facilities categorized as Category I – Accredited. To obtain accreditation, a hospital must correct the identified deficiencies according to a compliance plan approved by NAQMH / ANMCS, thereby meeting the necessary criteria. These criteria must be cumulatively met within 12 months of receiving the accreditation report and include: (i) achieving an overall compliance score with accreditation standards of at least 51%; (ii) obtaining a score of over 51% for all accreditation standards; (iii) reducing the proportion of indicators with a (-10) score below 50%.

Within one year of receiving the results, healthcare facilities can request that NAQMH / ANMCS analyze and verify the non-conformities that led to a score below 51% in order to be reclassified into a different accreditation category. This reclassification will take place after the healthcare facility addresses the indicators specified in the Non-Conformity Remediation Plan.

## V. CONCLUSION

Quality management in the health sector focuses on identifying issues within the healthcare system and analyzing their root causes, providing well-founded recommendations to the relevant institutions to address deficiencies. Through NAQMH / ANMCS, a quality management system is promoted based on international best practices, which includes objective and independent evaluation of medical services, continuous monitoring, and ongoing professional development of healthcare workers to ensure and enhance the quality and safety of services for patients.

In the first half of 2022, NAQMH / ANMCS resumed the evaluation of healthcare facilities with beds (USP / IHF) as part of the second accreditation cycle and made progress in developing the necessary tools for the first stage of accreditation of outpatient healthcare facilities.

In the future, NAQMH / ANMCS must play an active role in implementing quality assurance mechanisms and accreditation processes for healthcare providers in both the public and private sectors. Therefore, key priorities include:

- Improving institutional capacity for the evaluation and promotion of quality and evidence-based medicine in health policies.
- Reviewing and enhancing the quality regulatory system, including updating the regulatory framework for the evaluation and accreditation of all healthcare facilities with beds.
- Developing an integrated performance evaluation system, with a particular focus on quality and control of healthcare services at all levels of care.
- Implementing the concept of clinical governance to support better organization and accountability of clinical processes.
- Introducing and strengthening quality management mechanisms among healthcare providers, with an emphasis on monitoring, quality improvement, continuity of care, the doctor-patient relationship, and the respect of patient rights.
- Strengthening the capacity for monitoring and evaluating the performance of healthcare providers, including standardizing procedures for analyzing and responding to deviations from minimum standards.

We found that important objectives of the institution analyzed include completing the second accreditation cycle for hospitals and developing partnerships with medical universities to integrate quality management and patient safety into the educational curriculum, thereby promoting excellence in the education and training of future healthcare professionals.

## VI. ACRONYMS OF SOME EXPRESSIONS USED IN THE WORK:

- CE** – Council of Europe
- Co.NAS** – National Hospital Accreditation Commission
- EU** – European Union
- GO** – Government Ordinance
- IHF / USP** – Inpatient Health Facility
- MH** – Ministry of Health

NAQMH – National Agency for Quality Management in Health  
NHH – National Health Insurance House  
RG – Romanian Government  
RP – Romanian Parliament

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