# Audit report/ Raport de audit

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|---|---|
| Organisation / Client / Organizație/Client:<br>Street/ Strada:<br>Postcode / City/ Cod poștal/ Oraș: | CENTRUL REPUBLICAN DE DIAGNOSTICARE MEDICALA<br>Str. Constantin Virnav 13<br>MD 2025, Chişinău |
| Client responsible for the audit/ Persoana responsabilă de audit: | Ala HALACU |
| Order number/ Număr de comandă: | 3330/3GJK/A0 |
| Audit target/ Obiectivul auditului: | Determination of conformity with the standard DIN EN ISO 9001:2015 |
| Audit criteria/ Criterii de audit: | DIN EN ISO 9001:2015 Certification procedure TÜV Thüringen and applicable regulations; documentation of the organisation for the management system |
| Audit type/ Tipul de audit: | Certificare |
| Audit date / Data de audit: | 17-22.10.2024 |
| Scope / Domeniu de activitate: | Servicii de medicina specializata de ambulator, de consutanta, de diagnosticare si de laborator. / Specialized outpatient, consultative, diagnostic and laboratory services. |
| EA/ IAF Branch / Category / Bransa/Categorie: | 38-G11 |
| Non-applicability of standard requirements / Neaplicabilitatea cerințelor din standard: | 8.3 |
| Number of employees / Număr de angajați: | 97 |
| Multisite certification / Certificare multisite: | - |
| Lead Auditor / Auditor sef: | Iuliana Bratu |
| Auditor / Auditor: | - |
| Technical expert / Expert tehinic: | Cecilia Stoica |
| Trainee / Stagiar/Auditor in formare: | - |
| Other accompanying persons in the audit / Alte persoane însotitoare la audit: | - |
| Documents applicable to the audit report / Documente aplicabile raportului de audit | Audit plan<br>Annex to the audit report |
| Result of the audit / Rezultatul auditului: | As a result of the audit objectives achieved, the award of the certificate is recommended. |

22.10.2024

**Creation date / Data elaborării**

**Lead Auditor/ Auditor șef**

17.12.2024

**Release date/ Data aprobării**

i.A. U. Lange

**Release of the certification body / Aprobarea Organismului de certificare**

- **Notes on the procedure, evaluation of the audit, distribution list, confidentiality Property rights, restrictions, responsibilities**

The audit result was determined through an on-site assessment of the organisation with interviews of management and staff, through inspection of documents and observation of processes by sampling.
An audit as a sampling procedure cannot examine every detail of the management system. Due to this sampling nature of an audit, it is noted that non-conformities or weaknesses may exist that were not identified during the audit. Auditing is based on a sampling of available information. Needs for improvement identified in one area of expertise or process should in principle be reviewed by the organisation in other areas as well.
The certification body of TÜV Thüringen e.V. examines and evaluates the potential for improvement, non-conformities and the corrections/corrective measures. If necessary, new specifications of the certification body can be made as a result of the examination by the certification body.
The findings of the auditors and thus the audit result do not release the organisation from its responsibility to ensure continuous compliance with the standard requirements and legal requirements. The responsibility for the continued effective operation of the management system always remains solely with the audited and certified organisation.
Should there be any changes to the management system, structures or scope of the certificate during its period of validity, the organisation is obliged to notify the certification body of these changes without delay.
This report is sent to the certification body(ies), on request to the accreditation body, the members of the audit team and the audit representative of the organisation. Annexes to the audit report are used for the certification decision and remain in the certification body. All documents (including this report) relating to this audit and certification process are treated confidentially by the audit team and the certification body. The ownership of this audit report remains with the certification body.

## 1. Summary assessment

As a result of the audit, the audited management system is assessed as complete according to the underlying standard requirements on the basis of the inspected documents and audited processes.

The requirements for the maintenance and further development of the management system are comprehensive given.

The management system is capable of meeting applicable requirements and delivering expected results.

The process of conducting internal audits complies comprehensively the standard requirements. The management assessment is carried out completely compliant with the standard.

## 2. Potential for improvement of the organisation's management system..

Training and continuous skills development of internal auditors is ongoing to enhance the effectiveness of internal audit and the SMC as a whole in accordance with ISO 19011:2018, being a newly implemented SMC.

Continuous awareness of the staff involved in the system.

## 3. Corrective actions on nonconformities from previous audits

There were no deviations from previous audits

## 4. Nonconformities

**Non-critical nonconformity**

See nonconformity report no NA

**Critical nonconformity**

See nonconformity report no NA

## 5. Positive aspects

1. Top management involved and participative in the system in accordance with the requirements of the standards at all levels within the company.
2. Development of new projects from foreign financial funds to implement and maintain the existing quality management system.
3. The person in charge of the system has the necessary competence, qualification and experience in quality management systems to maintain and improve the implemented management system.
4. There is an increasing investment trend for the period 2024-2025.
5. Allocation of necessary resources for the maintenance and continuous improvement of the QMS.
6. Staff employed is competent and responsible for all activities within the company, who actively participate in all SMC related activities.
7. Coherent and well organized team being up to date with the latest news in the field covered by the certification.
8. Top management determined to maintain and improve SMC in accordance with ISO 9001:2015 requirements including resource allocation and involvement in all activities.
9. Promotes and supports the further development of the quality management system by providing the infrastructure with the necessary facilities to achieve quality compliance of the services provided.
10. The defined processes and their interaction correspond to the activities carried out on site.
11. Collaboration with large medical centers in the field abroad.
12. Existence in the quality infrastructure of persons who have worked in the company applying reference standards in the field of health care.

## 6. Information on the organisation:

### 6.1 Description of the organisation and its core activity:

IMSP Republican Center for Medical Diagnosis was founded on the basis of the Provision of the Council of Ministers of the Republic of Moldova no. 148-4 dub 05.08.1988 and the order of the Ministry of Health of the Republic of Moldova no. 281 dim 01.09.1988 "About the organization of the Republican Center for Medical Diagnosis.
The Republican Center for Medical Diagnosis is an institution that operates on the principle of self-financing non-profit, is created and operates in accordance with the legislation in force and its own Statute.
The Center possesses a technical-material base, which allows to implement in practice the most advanced diagnostic technologies.

The subdivisions of the IMSP Republican Center of Medical Diagnostics are equipped with sophisticated medical apparatus and equipment for carrying out the whole spectrum of investigations in the field of activity for functional and laboratory diagnostics.

The structure of the CRDM includes rooms for all the subdivisions indicated in the organizational chart of the Institution, rooms for temporary storage and separation of waste resulting from the medical activity with the respective codification, conference room, storeroom for the storage of goods, including biocides, provided with storage conditions adequate to the requirements of the manufacturer, archive for the storage of documentation, space for the collection and reception of patient samples. Each ward/laboratory has staff rooms equipped with separate wardrobes for the storage of personal protective equipment, sanitary blocks,

bactericidal lamps for the rooms, including waiting areas for patients, furniture made according to the requirements of the medical institution's activity and patient areas.

Medical accessories used in the work process are disposable, medical staff is sufficiently provided with individual protective equipment in accordance with the activities performed (goggles, gowns, pincushions, caps, masks, sterile and non-sterile gloves), detergents, biocides, other.

The institution is equipped with internal and long-distance telephone communication networks from the autonomous station.

The state of the ventilation (including local) and air-conditioning systems are satisfactory. The heating system is centralized with district heating.

The water, sewage and heating networks are centralized with meter. Hot water supply through local sources - electric boilers.

Natural and artificial lighting, microclimate corresponds to the requirements of the Sanitary Regulation approved by HG 663. The electrical installations and medical equipment are operated in accordance with the regulations in force and the Regulation on the operation of electrical installations in compliance with safety and security requirements.

Air ventilation in the rooms is natural and artificial flow-reflow. The ventilation system of the laboratories, Radiology and Computed Tomography and Magnetic Resonance Imaging departments is isolated from the central ventilation system and equipped with HEPA filters.

In order to create proper working conditions and meet technical requirements, a split-type air conditioning system is installed.

The technical-material base is in a permanent process of development, namely: the space for the installation of the water purification and oxygenation system for the proper functioning of the Endoscopy Section has been accommodated; the capital repair of the Nuclear Medicine Section with the installation of the Gamma Camera AnyScan-SPECT (Japanese project); the repair of the facade of the central access in the IMSP CRDM; the construction of the pandus, thus improving access to the building for people with special needs, the equipping of the headquarters and the Center's sections with furniture, the adjacent landscaping and the creation of parking conditions for special transportation and that of the collaborators.

Digitization of the medical institution brings many significant advantages and benefits, both for patients, medical and administrative staff and for the institution as a whole.

In the IMSP Republican Center for Medical Diagnostics an Integrated Medical Information System is implemented for the automation of medical processes and the administration and management of the patient's Electronic Health Record (EHR), being one of the most important links of the institutional computerization.

For the operation of all the information components and information flows, the institution has a local Intranet network, which ensures the interconnection of computing and peripheral equipment and medical devices. More than 170 devices are currently connected, most of which have access to the Internet.

IMSP Republican Center for Medical Diagnosis has access to external networks through 2 separate fiber optic lines, being provided with Internet from 2 companies (Orange and Starnet).

The institution has several high-performance servers used for computer applications and digital data storage managed and administered by the specialists of the Information Technology section.

The institution's staff uses the following Information Systems within the institution: Integrated Medical Information System, Accounting Information System, PACS Imaging Data Management and Archiving System, Medical Services Reporting and Recording Information System, etc. All these Information Systems have enabled the transition from paper to digital data storage on institutional servers, increasing the efficiency of data processing from an organizational point of view.

The institution is equipped with a Modular Video Patient Information System, which consists of a modular video wall and several specialized monitors connected into a single system. It allows the dissemination of digital information in static and/or dynamic mode, informing patients about medical services, modern diagnostic technologies, news.

In the pandemic years we managed to implement a new Information System that allows free access to the Internet for our patients using the new secure internal Wi-Fi network, as a support in viewing appointments, spectrum of investigations, other useful information.

### 6.2 Description of site conditions:

IMSP "CRDM" operates in Chisinau municipality located on Constantin Vîrnav Street 13 and has all the necessary spaces and facilities for the complexity of the activities.

The structure of the territory and the infrastructure as well as the flows are presented in the "General plan of the land and location", code F-PSM-11-04, where all internal and external elements are identified.

The institution carries out its activities in the field of public health, with the provision of services in accordance with the authorization issued by the ANSP, and does not produce environmental pollution (dust, toxic wastewater, gases, bad smells or strong vibrations) in significant quantities that affect the environment.

The design and location of the rooms as well as flows are clearly identified and correspond to all environmental factors (temperature, humidity, noise, vibration) so that the quality of the medical work/analysis performed is not affected due to cross contamination.

All rooms are connected to sources of electricity, water, lighting, heating, air conditioning systems, ensuring an appropriate working environment for all work processes.

Work safety conditions are also ensured which are equipped with all necessary equipment which are represented in the "Emergency Evacuation Plan", approved by the Director and posted on each floor for the information of employees and patients.

CRDM has all the necessary facilities and utilities to ensure the safety, confidentiality, quality and protection of employee and patient/client information.

The institution's infrastructure is designed and built with spaces and facilities that ensure the proper conduct of work processes and ensure an optimal sanitary-hygienic and anti-epidemic regime, to avoid the risk of cross contamination. All offices/offices and work areas have sufficient space to carry out work, cleaning, disinfection and maintenance operations.

All areas and rooms within the institution are categorized according to the principles and sanitary rules to avoid cross-contamination based on the current health regulations of the Republic of Moldova, in order to avoid any risk. The working and auxiliary rooms are divided into floors according to the areas and specificity of the activities carried out and classified as follows:

- Floor 0 - nuclear medicine section, MRI, employee and patient restrooms, laundry;
- 1st floor - the administration with the working offices, each of which includes locker rooms and rest area, biological sampling section, patient results release, meeting room, storage room for medicines/ consumables, staff and patient sanitary groups;
- 2nd floor - the registry, TIC and IB section, ultrasonography, radiology and computed tomography (RTC) section, work desks, where each includes changing rooms and rest area, staff and patient toilets;
- 3rd floor - endoscopy department with sterilization, functional diagnostics, staff and patient toilets;
- Floor 6 - consultation ward, ECG and VM, staff and patient toilets;
- 8th floor - medical laboratory with working offices for investigations, including changing rooms and rest area, waiting room for patients, staff and staff restrooms;

All floors and areas within the facility are properly identified and marked to easily ensure traceability of flows and as a source of information for patients/clients. The rooms and patient reception and consultation rooms are arranged in such a way as to ensure patients' comfort and privacy, appropriate conditions are also created for patients with special needs.

Each ward is equipped with all the necessary machinery, equipment and facilities to carry out its basic activities properly, maintained in good working order and serviced on time by the employees and persons in charge, avoiding any risk.

All maintenance and upkeep works of the infrastructure and facilities are monitored by the Head of Maintenance and Building Operation Service who evaluates and plans the realization of all necessary works to ensure compliance with the sanitary standards specific to medical institutions in conjunction with the Head Nurse

Sanitation works are specific to each area and are carried out by the Nurses, Nurses and Room Attendants according to the specifics of the cleaning and disinfection works. All sanitation requirements to avoid any risk of contamination of the working environment are described in the "Operational Sanitation and Disinfection Program".”.

Each head of section/ laboratory/ department is responsible for maintaining and ensuring an appropriate working environment, monitoring daily all sanitizing and disinfection work carried out by the designated responsible staff and if necessary coming up with proposals and corrective actions to prevent any risk of cross contamination that would have a negative impact on the work processes and results obtained.

### 6.3 Designation of the resources used :

The company's management has established and secured the resources necessary to achieve the quality objectives and customer requirements, the resources necessary to carry out the processes of the management system, as well as those necessary to identify risks, continuously improve its effectiveness. In carrying out the processes it utilizes the following resources: trained human resources; buildings; office furniture; machinery and work equipment; raw materials and materials; energy resources; money; computers; laptops; servers, means and protective equipment, other equipment, including hardware and software; internet connections, mobile and fixed telephony.

### 6.4 Changes to the management system from the previous audit :

Not the case being the first audit.

### 6.5 Objective evidence:

The following objective evidence were given to the audit team during the audit:

| | Proof / Dovezi | | Revision or date / Revizie sau data | Comment / Comentarii |
|---|---|---|---|---|
| x | Extract from the Commercial Register or Central Business Register (or comparable proof) / Extras din Registrul Comerțului - CUI | | MD 0008172-17.12.2004 | |
| x | Organization chart / structure of the organization's documentation / Organigrama / Evaluarea Structurii Documentației Organizației | | Approved on 27.12.2023 | |
| x | Top management policy / Politica de management (Politica in domeniul calitatii, mediului, etc) | | Approved on 28.03.2024 | |
| X | Scope of application for the management system / Domeniul de aplicare al sistemului de management (pagina din Manual în care apare domeniul SMI) | | Report No.01 approved on 30.07.2024 / | |
| X | Latest management review (at least cover sheet, table of contents) / Ultima analiză de management (cel puțin foaia de gardă) | | F-PSM-10-03 / 22.02.2024 | |
| X | Results of the last internal audits / Rezultatele ultimului audit intern | | F-PSM-09-05 / 24.07.2024 | |
| X | Information on the number and subject matter of complaints/appeals / Informații privind numărul și obiectul reclamaţiilor/sesizărilor | | - | |
| X | Relevant required permits, authorizations, registrations - if applicable / Permisele, autorizațiile și cererile relevante necesare - dacă este cazul | | Sanitary authorization for operation no. 018687/2023 Accreditation certificate Nr.1925 issued 28.09.2023, | |
| X | Presentation of the relevant processes - if applicable / Prezentarea proceselor relevante (harta proceselor) - dacă este cazul | | Process map approved on 28.03.2024 | |
| **As well as other documents required by the standards** *(if more documents are required, please add and delete not applicable)* | | | | |
| X | ISO 9001 | non-applicability / neaplicabil | 8.3 | |

Note: Confidential information in the documents can be blacked out. / Notă: Informațiile confidențiale din documente pot fi înnegrite.

## 7. Scope of the management system

**The scope includes the following locations / functional areas:**

The company has determined and documented the scope and certification of SMC:

- Specialized outpatient, consultative, diagnostic and laboratory medicine services.
- Specialized outpatient, consultative, diagnostic and laboratory services.

The location and the office are located in mun. Chisinau, address:

Str. Constantin Virnav 13, MD 2025, Chisinau.

The scope of certification includes all required processes of the management system .

**The following processes are outsourced :**

1. Metrological verification services
2. Audit of financial statements
3. SSM/SU and occupational health services
4. Transportation services
5. Staff training
6. Household waste disposal
7. Partial maintenance services (car and some ventilation and air conditioning equipment)
8. Energy resources and communications
9. Telecommunication services.
10. Evaluation, certification and audit services.

## 8. Complaints about the organization's management system

**There were no documented complaints.**

## 9. Use of the certification mark / certificate

In the final discussion of the audit, the organization was informed in detail about the use of the certification mark and the certificate in accordance with § 6 of the certification contract. It was pointed out in this context that the use of the certification mark and the certificate must in particular not give the impression of a product certification or the certification of areas outside the scope of application.

**The certificate is used as follows:**

**-**

**The certification mark is used as follows**

Distributors:

- ☐ Organisation
- ☐ Certification body