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PA/PH/BLOOD-QM (26) 3 DEF

Strasbourg, February 2026

BLOOD QUALITY MANAGEMENT PROGRAMME

Final report: B-MJV039

The National Blood Transfusion Center, Chişinău, Republic of Moldova

18 - 20 November 2025

EDQM Scientific Programme Managers: I. Teeuwen & C. Loos

**Distribution
For action :**

DEFINITIVE

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B-MJV039 A Auditors

B-MJV039 E Entity

B-QM_WG Quality_Management_Working_Group

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- 1 The Council of Europe is not responsible for and will not notify to national competent authorities any
2 observations made in a Blood Mutual Joint Visit (B-MJV) organised by EDQM. According to *Directive 2002/98/EC*
3 *of the European Parliament and the Council of 27 January 2003 setting standards of quality and safety for the*
4 *collection, testing, processing, storage and distribution of human blood and blood components and amending*
5 *Directive 2001/83/EC*, in particular article 15 and its implementing Directive 2005/61/EC of the European
6 Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions
7 and events, in particular article 5 and 6, it is the obligation of EU Member States to ensure that blood
8 establishments notify to the national competent authority any serious adverse events and/or reactions.

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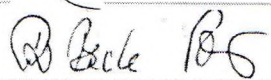
1. GENERAL INFORMATION ON THE BLOOD ESTABLISHMENT (BE)

Name of the BE	The National Blood Transfusion Centre
Address	11 Academiei street, Chisinau, Republic of Moldova
Date of B-MJV	18 to 20 November 2025

2. DISSEMINATION LIST & APPROVAL OF THE REPORT

	Name	Signature
Director of the BE	Silvia Roșca	
Quality Manager	Igor Rimbu	
Responsible person	Doina Banari-Chisinau	

3. B-MJV TEAM

	Name	Signature
Lead Auditor	Marielle VAN ROOSMALEN	
Auditor	Beate ROTHE	
Team Co-ordinator	Iola TEEUWEN	

4. CONFIDENTIALITY

The information contained in this report is confidential and should not be communicated to third parties without the written approval of the BE and the EDQM-ICND. The BE has received a copy of the confidentiality statements, concerning all the information (written and oral) received in relation to the B-MJV, and declarations of absence of conflict of interest, signed by all auditors. The originals are confidentially archived at the EDQM-ICND.

5. OBJECTIVES OF THE SCHEME

The aim of the B-MJV was:

To observe the Quality Management System (QMS) under development at the blood establishment (BE), to provide recommendations for improvement and/or advice on the implementation of the QMS and to observe the level of implementation of the EU legislation, the Good Practice Guidelines (GPG) and the Council of Europe *Guide to the preparation, use and quality assurance of blood components* (Blood Guide).

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6. SCOPE OF THE B-MJV

Processes to be included in the B-MJV Whole process from collection to issuing of blood components, including the Quality System

Sites

BE main site: 11 Academiei street, Chisinau, Republic

Mobile site: Center of Excellence in Medicine and Pharmacy "Raisa Pacalo"

Standards and requirements against which the B-MJV was conducted:

- EU Blood legislation;
- Good Practice Guidelines;
- Council of Europe's *Guide to the Preparation, Use and Quality Assurance of Blood Components*;
- Others, please specify: N/A

The declared standards and guidelines used in the BE for the implementation of the QMS are the following:

On a mandatory basis: The standards of the quality system for the activity of the blood service units, approved by the order of the Ministry of Health of the Republic of Moldova no. 581/2024

On a voluntary basis: N/A

7. LIST OF DOCUMENTS PROVIDED BY THE BLOOD ESTABLISHMENT

• Before the scheme

- Quality Manual,
- organisation chart with names,
- list of Standard Operating Procedures (SOPs),
- list of equipment,
- SOPs on Internal Audits,
- report of the last qualification performed,
- last Quality Management Review report,
- list of Non-Conformances (NCs) raised during the previous 12 months.
- other documents:
 - o Ministry of Health regulation on the organization and functioning of the National Blood Transfusion Centre
 - o List of Operational Qualifications for Medical Devices within CNTS
 - o Ministry of Health order on the approval of donated blood test algorithms
 - o Policy on risk management
 - o SOP on non-conformance management activity

• On-site: N/A

All documents provided/presented are confidentially archived at the EDQM-ICND.

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1 8. PLAN OF THE B-MJV

2 The final plan, as modified onsite, was as follows:

Day 1 - 18 November 2025		
Time	Activity	Assessors
09:00 – 09:20	Opening meeting Presentation of the scheme, auditors and BE main staff	All
09:20 – 10:05	Overall Quality Management - presented by the BE Overview of organisational aspects, policies and objectives of the BE, explanation on how the national regulation incorporates the GPG	All
10:15 – 11:45	Selection of donors from registration to donor selection, including medical interviews Blood collection	All
11:45 – 12:35	Processing and Labelling	All
14:00 – 15:00	Testing (donor and patient testing)	All
15:00 – 15:35	Release, Distribution and Issuing	All
15:35 – 16:30	Equipment management	All
16:30 – 17:15	Qualification and Validation	All

Day 2 – 19 November 2025		
Time	Activity	Assessors
08:45 – 10:50	Visit of the mobile collection site Address: <i>Centre of Excellence in Medicine and Pharmacy "Raisa Pacalo"</i>	All
10:50 – 11:20	Qualification and Validation (follow up)	All
11:20 – 12:30	Quality Documentation Management	All
14:20 – 14:50	Change Control	All
14:50 – 15:45	Quality Control and SPC	All
15:45 – 16:05	Risk Management	All
16:05 – 17:10	Haemovigilance and recall management	All
17:10 – 17:30	Non-Conformances and CAPA Management	All

Day 3 – 20 November 2025		
Time	Activity	Assessors
09:05 – 10:10	IT systems	BR
	Procurement, Supply and Contract management	MVR, IT
10:15 – 11:00	Internal audit	BR, IT
	Human resources From recruitment to training	MVR
11:00 – 12:00	Assessment team debriefing	Assessment team only
12:00 – 13:10	Closing meeting	All

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9. FINDINGS

For B-MJVs and B-MJAs, the findings are classified according to their level of criticality, as follows:

CRITICAL	Any non-conformance which directly affects the safety of the patient or the donor.
MAJOR	A serious non-conformance but does not on its own affect the safety of the patient or the donor.
MINOR	A non-conformance that cannot be classified as either critical or major but does constitute a deviation from the standard.
OTHER	A finding which is not a non-conformance but may result in a future non-conformance or is a deviation from good practices.

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Ref.	Concerned Issue	Findings	Requirements	Criticality and Risk(s)	Recommendations
MANAGEMENT PROCESSES					
QD1	Quality documentation	Whilst notable efforts have been made for SOPs, the quality documentation structure is not fully streamlined: - The layout and structure of the different forms used in the blood establishment is not homogenised. For example: - The NC form is identified as an annex to POS nr PS-HV/25/08. - The donor registration form does not have any identification. - Some forms are identified as being approved by the ministry of health (code "E") or authorised internally (code "MC"). - Printed copies of SOPs are well controlled; however, the same level of oversight does not apply to forms. For example, whilst the donor questionnaire is reviewed annually, there is no mechanism to ensure that the most current version is consistently in use.	Good Practice Guidelines 5.3.1. All types of documents should be defined and adhered to. Requirements apply equally to all forms of document media types. Complex systems need to be understood, well documented and validated, and adequate controls should be in place. Many documents (instructions and/or records) may exist in hybrid forms (i.e. some elements are electronic and others are paper-based). Relationships and control measures for master documents, official copies, data handling and records need to be stated for both hybrid and homogeneous systems. 5.3.2. [...] Appropriate controls for electronic documents, such as templates, forms and master documents, should be implemented. Appropriate controls should be in place to ensure the integrity of the record throughout the retention period.	Minor to Major Risk of lack of clarity in the document management system and of not having a complete overview of all documentation available or in use. Risk of data errors or omissions due to inconsistency of documentation structure. Risk that the forms used in the establishment are not up to date.	Create a document register which includes information on all forms used in the establishment, with unique identifiers and version numbers. An online documentation system would greatly benefit this establishment to track and maintain all types of documents. Standardise the layout and structure of all forms and harmonise identification codes (e.g., for annexes, internal forms and ministry approved forms). Ensure a controlled system is in place for printed forms, and ensure that only the latest versions are available for use.

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QD2	Quality documentation	Although the risk of storing the anti-B solution in a warm room is managed through daily quality control testing, this risk is not formally documented.	5.3.3. Documents should be designed, prepared, reviewed and distributed with care. Reproduction of working documents from master documents should not allow errors to be introduced through the reproduction process. Good Practice Guidelines 1.4.2. The quality system should ensure that processes are in place to ensure the control of outsourced activities and quality of purchased materials. These processes should incorporate the principles of quality risk management and systematically ensure that: [...] 1.4.2.2. the level of effort, formality and documentation of the quality risk management 5.2.2.2 Testing instructions detail all the starting materials, equipment and computerised systems (if any) to be used and specify all sampling and testing instructions. If applied, in-process controls should be specified, together with their acceptance criteria.	Minor Risk of loss of traceability of decisions made regarding checks on materials. Risk that quality control is not systematically implemented by new staff and/or that the risk of non-compliance is not fully understood.	Document the risk assessment for the daily quality control testing and add it to the risk register that is under development.	Ensure all associated SOPs are up to date and train the affected personnel.
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QD3	Quality documentation	The <i>Lista de Calificari Operationale la dispozitivi medicale</i> is not fully unambiguous. For example, certain instruments are indicated as requiring maintenance every 12 months, although this is not applicable. Additionally, the corresponding table entries for these instruments are left blank.	5.4.2. Records should be made or completed at the time each action is taken and in such a way that all significant activities concerning the donation, collection, processing, testing and distribution of blood and blood components are traceable. Good Practice Guidelines 4.1.3. All validated processes should use qualified equipment. Qualification results should be documented. Regular maintenance and calibration should be carried out and documented according to established procedures. The maintenance status of each item of equipment should be available. 5.3.4. Documents containing instructions should be approved, signed and dated by appropriate and authorised persons. This may also be undertaken electronically. Documents should have unambiguous content and be uniquely identifiable. The effective date should be defined.	Minor Risk of compromised traceability. Risk that maintenance is not performed according to internal processes. Risk of non-compliance with regulatory standards.	Revise and revalidate the <i>Lista de Calificari Operationale la dispozitivi medicale</i> to ensure clear and unambiguous formatting. Verify that all instruments have complete entries, and that no table entries are left blank (i.e. write "not applicable" rather than leaving it blank).
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NC1	Non-conformances (NC) and CAPA management	Following the NC on blood clotting, the CAPA plan execution was not signed off by the Quality Manager.	Good Practice Guidelines 4.6.3. Changes should be authorised and approved by the responsible persons or relevant functional personnel in accordance with the blood establishment's quality system.	Minor Risk that there is no appropriate quality oversight to changes, which can introduce errors to actions and processes.	It is recommended to update the form to include a signature field and a due date for CAPA implementation, and also clearly define the Quality Manager's role in approving the CAPA plan.
HR1	Human Resources Training	There is no systematic training programme for every job position. For example, the head of QC laboratory did not require a formal training plan, as the competency for the position is based on an initial questionnaire.	Directive 2005/62/EC Annex 2.3. All personnel must receive initial and continued training appropriate to their specific tasks. Training programmes must be in place and must include good practice.	Major Risk that personnel may perform tasks without having completed all required training for those responsibilities.	Define mandatory training plans for every role within the organisation, signed off by the member of staff.
HR2	Human Resources Training	There is no systematic process for continued training. For example, knowledge and skill is assessed on a yearly basis, but if staff performs well, there is no plan for continuous training.	Directive 2005/62/EC Annex 2.4. The contents of training programmes must be periodically assessed and the competence of personnel evaluated regularly.	Major Risk that members of staff do not stay up to date with evolving procedures, regulatory changes or best practices.	Develop and implement a structured training programme that includes mandatory continuous and refresher training for all relevant staff, with defined frequency, documentation of completion, and periodic review of training effectiveness.

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HR3	Human Resources Training	Good practice training (GPG) is not incorporated into staff training programs.	Directive 2005/62/EC Annex 2.3. All personnel must receive initial and continued training appropriate to their specific tasks. Training programmes must be in place and must include good practice.	Major Risk of misinterpretation of the GPG and inappropriate implementation of the principles and guidelines.	Add a general mandatory GPG training to the training programme for all staff as well as specific training sessions for the different sections of the GPG to the appropriate positions within the establishment.
SUPPORT PROCESSES					
PR1	Premises, hygiene and safety Premises	The premises were not adequately protected to afford protection against the entry of insects or other animals. For example: - Nets on windows in processing area were broken - Windows were open in blood collection areas	Good Practice Guidelines 3.1.3. Premises should be designed and equipped so as to afford protection against the entry of insects or other animals.	Major Risk of a contamination of blood collected and blood components processed.	All windows should be kept closed unless unbroken nets are applied to prevent the entry of insects or other animals.

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PR2	Premises, hygiene and safety <i>Temperature control</i>	There is no systematic temperature monitoring in place. For example, the rooms used for the blood collection (both in the transfusion centre and the mobile collection site) did not have temperature monitors, and some blood processing and testing areas did not either.	Good Practice Guidelines 3.1.2. Lighting, temperature, humidity and ventilation should be appropriate and such that they do not adversely affect (directly or indirectly) blood components during their processing and storage, or the accurate functioning of equipment. 3.1.6. Requirements for the temperature and, if necessary, for humidity of the preparation areas should be defined according to the operations undertaken within them and taking into account the external environment.	Major Risk to the integrity of the blood components left outside the fridges, and to the correct functioning of the equipment in the rooms.	Implement systematic temperature monitoring and control for all blood collection and processing areas starting by defining temperature requirements, installing temperature monitoring devices, and continuous monitoring. Update affected quality documents and train personnel. Windows should be kept closed as it could modify the temperature and humidity of the room.
EM1	Equipment management <i>Labelling</i>	The labelling applied to instruments is ambiguous. For example: - Some instruments were not properly identifiable: only one of the two cobas 5800 instruments was identified. - The external servicing date is not on the cobas 5800 instruments, which creates uncertainty of operational status for regular users. Reliance on the servicing company is currently too implicit.	Good Practice Guidelines 6.7.3. Labels applied to containers, equipment or premises should be clear, unambiguous and in the agreed format of the blood establishment.	Minor Risk of loss of traceability regarding equipment history and status. Risk that personnel assumes equipment is fit for use (or not fit for use) without knowing its status. Risk of delays in blood processing and testing.	Add separate visual identifiers to all instruments, which should also be defined in the associated equipment register and other affected quality documentation. Add a visible label with the external servicing date as a visual reminder for staff.

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QV1	Qualification and Validation <i>User Requirements</i> User requirements specifications (URS) are not systematically checked after equipment installation or equipment maintenance/repair. For example: - After the external maintenance of the cobas 5800 instruments, there is no confirmation that the report provided by the service provider is reviewed and accepted by the establishment's technician. - The validation of the new NEO Iris instruments did not include an internal check against requirements.	Good Practice Guidelines 4.2.3. The regulated user should take all reasonable steps, to ensure that the system has been developed in accordance with an appropriate quality management system. The supplier should be assessed appropriately. 4.3.4.2. User requirements specification (URS). The specification for equipment, facilities, utilities or systems should be defined in a URS and/or a functional specification. The essential elements of quality need to be built in at this stage and any good practice risks mitigated to an acceptable level. The URS should be a point of reference throughout the validation life cycle.	Major Risk that equipment does not fully comply with internal requirements. Risk that equipment does not function as intended.	Verify equipment readiness through internal (re)validation and ensure specifications are met internally, possibly by implementing a checklist. Have a qualified staff member check and sign off on the external provider's validation report to confirm that the instrument is ready for use.
QV2	Qualification and Validation For the cooling chamber, IQ and OQ were completed in 2022, while process qualification (PQ) was performed in 2024, as seen in <i>Registrul general al dispozitivelor medicale aflate in dotare si utilizare in cadrul CNTS</i>. This delay was due to reliance on the CE mark, considered sufficient to defer checks for two years.	Good Practice Guidelines 4.3.1.1. Facilities and equipment need to be qualified prior to implementation. [...] 4.3.4.7. Performance qualification (PQ). Although PQ is described as a separate activity, in some cases it may be appropriate to perform it in conjunction with OQ or process validation. PQ should follow successful completion of IQ and OQ.	Major Risk that the cooling chamber is not performing as intended over time. Increased risk of undetected failures or deviations.	Systematically implement all qualification and validation steps before putting equipment into use.

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QV3	Qualification and Validation	There was no technical validation of the transportation boxes, even though the temperature is monitored.	Directive 2005/62/EC Annex 4.1. All equipment must be qualified, calibrated and maintained to suit its intended purpose. Operating instructions must be available and appropriate records kept. Good Practice Guidelines 4.3.1.2. The principles of qualification and validation are applicable to the preparation, distribution and issuance of blood components. It is a requirement of good practice that blood establishments and hospital blood banks control the critical aspects of their operations throughout the life cycle of the blood components and the associated processes. Any planned changes to the facilities, equipment, utilities and processes should be formally documented and the impact on the quality of blood components should be validated.	Major Risk that transportation boxes do not maintain temperature requirements under real conditions. Risk of loss of traceability, as there is no documented evidence that the transportation boxes meet the set requirements.	Validate the transportation boxes prior to use, by testing them under extreme temperature conditions (both high and low). Document the validation steps in the quality system.
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10. STRONG POINTS AND POINTS FOR IMPROVEMENT

Strong points

General Principles

- The organisation maintains a strong quality culture, embraced by all staff.
- Top management is very involved in QM and stays very informed, using available tools to their advantage (e.g. EDQM B-QM assessment schemes and proficiency testing schemes).
- There is a strong commitment to improvement, and staff are very open and receptive to feedback (e.g. high level of implementation of EDQM recommendations since the previous assessment in 2022).
- The opening presentation gave a strong, insightful overview of blood transfusion services in Moldova; it was very detailed and well-prepared.
- There is an open line of communication with the Ministry of Health (MoH), as well as with the hospitals in the country. For example, the MoH certifies the National Blood Transfusion Centre every five years, and the Transfusion Centre audits the hospitals on a regular basis.
- There is country-wide self-sufficiency for all blood products.
- There is a functioning Transfusion Committee made up of representatives of MoH, the national agency of public health, the agency of medicines, and the national transfusion centre that meets once a month. In addition, each main site of the National Transfusion Centre has its own separate committee.

Personnel and organisation

- New staff is informed on all processes within the National Transfusion Centre, which fall outside the scope of their own department.

Premises

- Good spatial organisation: Well-organised and clean, with clearly labelled equipment and storage spaces.
- Simple yet very effective design of the reception desks, which ensure data confidentiality.
- Reliable backup systems for equipment, e.g., two compressors in the cold chamber operate alternatively but one is sufficient if needed.
- The mobile donation site is well organised, with volunteers, a smooth and efficient workflow, clear media communication, overall cleanliness, and efficient scheduling.

Equipment and materials

- Data processing systems:
 - Well-developed access management on IT systems.
 - There is a yearly check on data transmission between systems.

Documentation:

- Document retention periods (archiving) are defined by type of document.
- Paper documentation system is very well organised.

Blood collection, testing and processing

- Good donor management:
 - Extensive and well-coordinated donation campaigns, including partnerships with the Ministry of Defence and the Ministry of Justice. Demonstrated strong time management by scheduling National Donor Day in June, strategically placed before the holiday season to maintain adequate blood supply.
 - Achieved nearly 100% voluntary donations within just a few years.
 - Electronic booking system for donations.
 - Robust national traceability system ensuring donor information is accessible throughout the entire transfusion chain via a nationwide online platform.
- Regular monitoring of effectiveness of disinfection of venipuncture site.

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- Well-designed change management process with thorough planning and risk analysis, including change requests, implementation plans, and validation of implementation (e.g. change implementing the new NEO Iris instruments)

Self-inspection, audits and improvements

- The internal audit plan and report are very well developed, very comprehensive and informative.
- There is sufficient and well-trained staff to carry out internal audits.

Points for improvement

General Principles

- The Quality Management Review (QMR) is very qualitative. It is recommended to include more quantitative data. For example, the information and conclusions of the internal audit reports could be included, as well as the number of NCs, changes, discarded products, etc.

Equipment and materials

- Improve label readability on blood bags by increasing font size.
- In the change validation reports (e.g., for the NEO Iris instruments), it is recommended to reference supporting documents that confirm changes have been implemented (e.g., updated SOPs) to enhance traceability.

Documentation

- Avoid unnecessary work by eliminating multiple printed copies when information is already available on the IT system.
- For training on SOPs, include a list of individuals required to acknowledge 'read and understood' to ensure no one is missed, rather than having everyone write their own names and signatures.
- Conduct a risk assessment for SOP revisions to avoid mandatory annual updates for all documents, in order to reduce workload.
- Make revisions to SOPs more noticeable by highlighting changes or adding a summary table of updates at the start or end of the procedure.

Blood collection, testing and processing

- Enhance post-donation care by encouraging a longer resting period, donor monitoring, proper hydration, and improving the comfort and appeal of post-donation areas.
- At the mobile collection site, donors carry their questionnaires openly. It is recommended to provide anonymising covers to protect confidentiality.

Storage and distribution

- Complete risk assessments on the following processes:
 - Retention of plasma samples for only 12 months, rather than the entirety of the shelf life plus one year.
 - Storage of materials (i.e. blood bags) that are used in the collection area, in line with the lack of temperature monitoring in those rooms.

Outsourced activity management

- Implement a systematic and documented process to evaluate the suppliers that are set up on a national level (by the Ministry of Health), to ensure the suitability of the supplier for the purposes of the National Transfusion Centre.
- Contingency planning for suppliers could be further elaborated based on a risk assessment. For example, the contingency plan for the supply of blood bags could include a plan in case all products are recalled due to a product defect.

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- 1 Self-inspection, audits and improvements
- 2 • The elaboration of the audit plan should be based on a formal risk assessment. It is also
- 3 recommended to have an overview of the audited process over several years to ensure that all
- 4 processes are being appropriately audited.
- 5 • It is recommended to implement risk management to the audit results as well to be able to determine
- 6 the urgency of action implementation.
- 7 Quality monitoring and control
- 8 • Statistical Process Control (SPC) is under development; current progress is strong, and the team
- 9 should maintain their approach.

11. OVERALL ASSESSMENT

The assessment highlighted many strong points within the organisation. The robust quality culture is evident; dedication to quality is embraced by all staff and supported by a highly engaged top management. There is a clear commitment to continuous improvement, highlighted by the implementation of EDQM recommendations from the previous assessment in 2022 and the openness of staff to feedback. Effective communication channels exist with the Ministry of Health and hospitals nationwide. The facilities visited are very well-organised and clean. Donor management is strong, with extensive and well-coordinated donation campaigns contributing to operational excellence.

During the visit, the assessment team also identified key opportunities for improvement. These include the implementation of an online documentation management system to streamline and standardise all types of documentation, ultimately reducing workload over time. Risk management could be further developed and integrated into all processes (e.g., internal audit management) and incorporated into the QMS through the establishment of clear documentation of risk assessments. Additionally, post-donation care could be enhanced by encouraging longer resting periods, monitoring donors, ensuring proper hydration, and improving the comfort and appeal of post-donation areas. Implementing these changes could further reinforce the organisation's ongoing commitment to excellence.

12. TIMELINES

The list of observed findings was presented during the closing meeting.

According to procedure IR24/02 Managing Blood Mutual Joint Audits, Mutual Joint Visits, Training Visits and Tailored Expert Support Schemes, the preliminary report shall be submitted to the BE within eight weeks after B-MJV takes place.

The BE is entitled to submit comments on the preliminary report in order to clarify editorial misunderstandings provided that the comments are in accordance with the findings agreed upon during the closing meeting.

The final report is finalised within three weeks after receiving feedback from the BE.

Milestones	Deadline
Date of closing meeting	20 November 2025
Preliminary report submitted to BE	13 January 2026
Comments on preliminary report	15 January 2026
Final report submitted to BE	02 February 2026

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13. ACKNOWLEDGEMENTS

The assessment team extends its sincere appreciation to all personnel at the National Blood Transfusion Centre for their cooperation, professionalism and hospitality throughout the visit. Special acknowledgement is given to Silvia Roşca, Director of the National Blood Transfusion Centre, for her expertise, invaluable input and dedication to the smooth running of the visit. Her leadership was evident in the enthusiasm demonstrated by the highly motivated and knowledgeable staff.

It is the team's sincere hope that the observations and recommendations shared during this assessment will serve as a constructive foundation to further strengthen the establishment's QMS. The EDQM team wishes the executive management, quality team, and all staff continued success in their efforts to advance best practices and uphold the highest standards of quality. We look forward to collaborating again in the future.

14. COMMENTS RECEIVED ON THE PRELIMINARY REPORT PA/PH/BLOOD-QM (26) 3

An explanatory note was received from the director of the National Blood Transfusion Centre on 15 January 2026. The document has been automatically translated into English using the European Commission's eTranslation tool and is attached as an appendix to this report for information.

The EDQM team did not address the comments in the explanatory note as they are in accordance with the findings raised in this report and agreed upon the closing meeting. Corrective and preventive actions are not requested from the BE in the case of a B-MJV.

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15. APPENDIX

B-MJV040 - Explanatory note regarding the preliminary report PA/PH/BLOOD-QM (26) 3

Ref.	CNTS reasoning/measures
QD1	In the Republic of Moldova, the document management system has a specific approach because a centralized automated information system that would manage document management is not approved and implemented at national level. The encoding of the generated documents is done manually. Therefore, these codings of the documentation were divided in the following way: - The primary record documentation of the blood service, which applies to the activity of all blood service units in the country, was approved by order of the Ministry of Health and encoded with the form/E number (example: form 404/E, form 405/E, form 406/E, etc); - The documentation specific to the production process within our institution was approved by order of the National Blood Transfusion Center and encoded with the form/MC number (example: form 01/MC, form 02/MC, etc); - The specific documentation, which is part of the operational procedures, which are also approved by order of the institution, and the form in question is coded with the number/code of the operational procedure. Forms are applied in activity from the date of approval of the internal order. When an amendment/adjustment of a form is required, it shall be approved by another internal order and shall take effect from the date of approval of the newly approved order. The previous version of the form is repealed and decommissioned. The record of these versions of forms is made manually, by updating the lists and the structure of the approved new forms. The list of forms with the newly approved structure of the forms is placed in the intranet system of the institution and the heads of subdivisions take these forms and apply them in the activity of the subdivision. The responsible for updating and disseminating the approved new forms is the quality vice-director.
QD2	Laboratory reagents are stored in refrigerators at the appropriate temperature regime. They are placed on the worktable, at the room temperature, only during the period of activity (8.00-14.30). At the same time, each day, at the beginning of the working day, the internal control shall be carried out for each reagent, which shall be notified in the form set out in Annex 11.
QD3	The register of medical devices with all the information in the table has been duly completed. The duly completed Register of Medical Devices is attached in Annex 21.
NC1	The form contains the field for the signature of the Vice-Director of Quality. The lack of signature of the vice-director of quality is explained by the fact that he/she is on holiday.
HR1	Currently, the systematic training program is being implemented, with all stages: program development, training by confirming it in the training monitoring form, knowledge assessment by means of a questionnaire and the final decision assigned to the employee: accepted to start work, It requires repeated training, Removing from activity. To this objection we inform you that continuous training plans for both doctors and nurses/laboratories exist. Annually a contract is concluded with the University of Medicine and Pharmacy and the Center of Excellence in Medicine and Pharmacy and based on the continuous training plans, which are approved annually by the director of the institution, the staff, according to the list, discipline and period is sent for continuous medical training, In Annex 31 you will find contracts and programmes for doctors and nurses
HR2	
HR3	
RP1	All the windows of the institution are secured with nets. The defective mesh was found in the separate product documentation room. At the moment this net has been changed. Non-conformity removed. The windows in the blood collection area are secured with non-defective nets, which provide protection against insects and animals.

¹ For the purposes of this report, the annexes to the appendix are not provided. They are available at the BE.

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PR2	Non-conformity removed. All rooms with testing/production significance were provided with temperature thermometers. Temperature monitoring is recorded in the room temperature monitoring sheets. Annex 41 application of thermometers in rooms
EM1	Non-conformity removed. The label has been placed on the device. The maintenance report of the Cobas 5800 is present. Maintenance sheets approved by the servicing company are taken over by the institution's bio-engineering service by signature with the presence of the phrase 'known/informed/accepted'. Annex 51 documents confirming the activity mentioned above.
QV1	The label has been placed on the device. The maintenance report of the Cobas 5800 is present. Maintenance sheets approved by the servicing company are taken over by the institution's bio-engineering service by signature with the presence of the phrase 'known/informed/accepted'. Non-conformity removed. NEO Iris medical devices have been qualified and validated. Annex 61 contains the protocols for qualification at reception and operational qualification.
QV2	The recommendation is already implemented in the activity and the initial and operational qualifications will be made for each medical device at the reception stage in the institution. Proof of implementation are the qualification protocols for NEO Iris devices, Annex 61.
QV3	Contaminations are inspected and validated before use. At the same time, we are at the stage of purchasing calibrated thermometers for temperature validation during transportation.