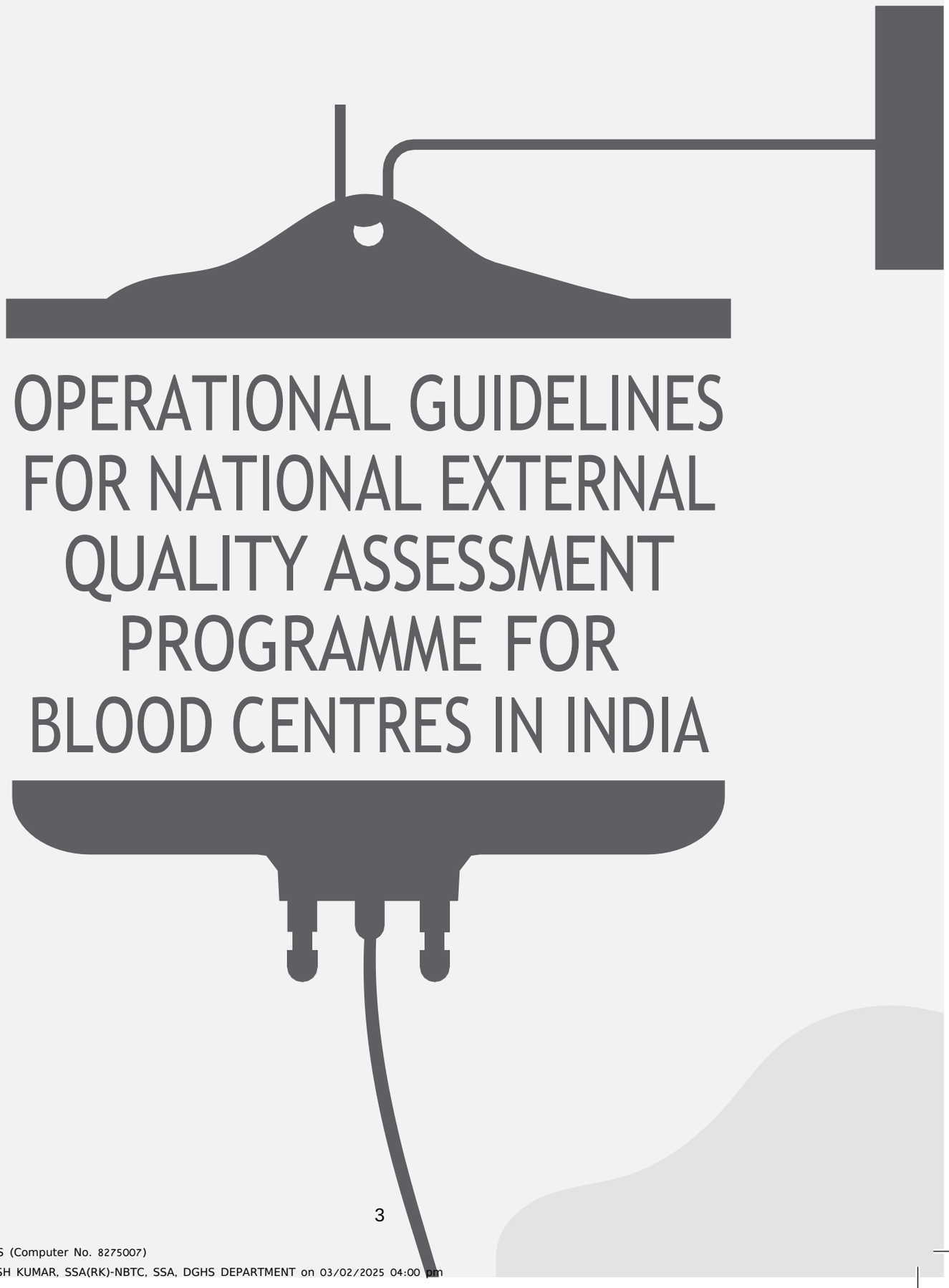
NBTC
राष्ट्रीय रक्त संचरण परिषद
National Blood Transfusion Council

Ministry of Health & Family Welfare
Government of India

World Health Organization
India

OPERATIONAL GUIDELINES FOR NATIONAL EXTERNAL QUALITY ASSESSMENT PROGRAMME FOR BLOOD CENTRES IN INDIA

First Edition - 2024



OPERATIONAL GUIDELINES FOR NATIONAL EXTERNAL QUALITY ASSESSMENT PROGRAMME FOR BLOOD CENTRES IN INDIA

जगत प्रकाश नड्डा
JAGAT PRAKASH NADDA

सत्यमेव जयते

मंत्री
स्वास्थ्य एवं परिवार कल्याण
व रसायन एवं उर्वरक
भारत सरकार
Minister
Health & Family Welfare
and Chemicals & Fertilizers
Government of India

MESSAGE

Ensuring the highest standards of safety and quality in blood transfusion services is a fundamental priority for India's national healthcare system. The National External Quality Assessment (EQA) Programme for Blood Transfusion Laboratory Services stands as a pivotal initiative to elevate the competence, reliability, and integrity of blood testing procedures across the nation.

I would like to acknowledge the commitment of the Blood Transfusion Services Division, Ministry of Health and Family Welfare, Government of India, in expanding the National External Quality Assessment (EQA) Programme nationwide. This initiative unites licensed blood centers under a cohesive quality framework, enhancing self-sufficiency and consistency in blood transfusion services. It also promotes local responsibility, which is crucial for the long-term sustainability and effectiveness of these services.

The Operational Guidelines for the National EQA Programme for Blood Centres will serve as a cornerstone in our mission to standardize and elevate blood transfusion services nationwide. These guidelines provide a structured, adaptable, and user-friendly framework for implementing EQA consistently across diverse regions, while addressing the specific needs of each state and Union Territory. As an indispensable reference for transfusion practitioners, medical officers, and technical staff, the guidelines help unify practices, thus enhancing both the quality and safety of transfusion services.

I hope that the Operational Guidelines for the National EQA Programme for Blood Centres in India will significantly enhance and standardize blood transfusion services nationwide. This resource supports professionals in upholding high standards and contributes to India's goal of providing safe and accessible blood transfusion services to all citizens. Our commitment to excellence advances healthcare quality and strengthens the national healthcare system for a healthier India.

(Jagat Prakash Nadda)

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प्रतापराव जाधव
PRATAPRAO JADHAV

सत्यमेव जयते

आज़ादी का अमृत काल

राज्य मंत्री (स्वतंत्र प्रभार)
आयुष मंत्रालय
व
राज्य मंत्री
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार

MINISTER OF STATE
(INDEPENDENT CHARGE) OF
MINISTRY OF AYUSH AND
MINISTER OF STATE OF
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

MESSAGE

The Government of India plans to expand the National External Quality Assessment Programme (NEQAP) to States and Union Territories (UT) coordinated by the Blood Transfusion Services Division, Directorate General of Health Services, MoHFW, Government of India, to strengthen the quality of blood transfusion services across India. EQA program is expected to achieve the goal of 'Safe Blood Transfusion" as envisaged by the National Blood Policy.

Rapid advancements have been witnessed over the years in the field of transfusion medicine. The introduction of the latest technologies and scientific transfusion practices is necessary for making blood transfusion processes safe, thus stressing the importance of Operational guidelines for the NEQAP for Blood Centres in India.

It is pertinent to emphasize that the Government of India under the visionary leadership of Hon'ble Prime Minister Shri Narendra Modi ji and able guidance of Hon'ble Union Minister of Health and Family Welfare, Shri Jagat Prakash Nadda ji, is taking new initiatives to meet the healthcare needs of the people of India.

I would like to express my appreciation to the Blood Transfusion Services Division, Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, and the technical experts for their immense contributions in developing thes operational guidelines for the NEQAP for Blood Centres in India.

I firmly believe that these guidelines will serve as a valuable repository of knowledge and skills in the practice of transfusion medicine. It will undoubtedly be a significant resource for personnel working in this field, helping them to enhance their expertise and ensure the highest standards in blood transfusion practices, contributing to improved outcomes and patient safety across the healthcare system.

(Prataprao Jadhav)

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NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

सत्यमेव जयते

राज्य मंत्री
स्वास्थ्य एवं परिवार कल्याण
व रसायन एवं उर्वरक
भारत सरकार

अनुप्रिया पटेल
ANUPRIYA PATEL

MINISTER OF STATE
HEALTH & FAMILY WELFARE
AND CHEMICALS & FERTILISERS
GOVERNMENT OF INDIA

Message

The Ministry of Health and Family Welfare, Government of India, is steadfast in its commitment to enhancing the quality of blood transfusion services across the nation. External Quality Assessment (EQA) is a cornerstone in achieving this goal, ensuring the safety, accuracy, and reliability of blood transfusions.

I commend the Blood Transfusion Services Division of Dte.GHS, for their leadership in driving excellence in blood transfusion services. The expansion of the National EQA program is a pivotal step in solidifying India's position as a global leader in blood transfusion safety. By implementing rigorous quality assurance measures and fostering a culture of continuous improvement, the Division is significantly enhancing patient care. This initiative empowers blood centers to identify and address potential deficiencies proactively, leading to improved patient outcomes and public health.

I am confident that the EQA program will not only strengthen the network of licensed blood centers but also elevate the overall standards of blood transfusion practices in India. By setting a high bar for quality and accountability, the program will drive innovation and best practices, ultimately saving lives.

The Operational Guidelines for the National EQA Programme for Blood Centres in India is a critical tool in achieving these objectives. This comprehensive guideline will not only enhance the quality and safety of blood transfusion practices but also ensure consistency in processes and outcomes throughout the country.

By promoting professional development and knowledge sharing, the EQA program will contribute significantly to patient safety and the overall quality of healthcare services nationwide.

The expansion of the National EQA program is a testament to the government's commitment to public health. By investing in this initiative, we are investing in the future of blood transfusion services in India.

(Anupriya Patel)

November 8, 2024
New Delhi

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सचिव
PUNYA SALILA SRIVASTAVA, IAS
Secretary

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

MESSAGE

Efficient Blood Transfusion Service is an indispensable component of the healthcare delivery system in the country.

External Quality Assessment (EQA) in Blood Transfusion Laboratory services is a critical and invaluable tool to assess the performance of the testing system of a laboratory and the quality of its results. It is designed to raise standards of blood transfusion services and helps ensure the provision of appropriate, compatible blood and blood products for safe blood transfusion. EQA provides scope for continuous quality improvement by identifying gaps & errors and implementing measures to prevent their recurrence.

The Operational Guidelines for the National EQA program for Blood Centres in India, prepared by Blood Transfusion Services Division, Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, will establish a harmonized network of competent proficiency testing providers across the country in blood transfusion services It is heartening to know that experts from all over the country have given their valuable inputs for formulation of these guidelines.

I am certain that these guidelines for the National EQA program will serve as a ready reckoner and a useful reference guide for transfusion practitioners, postgraduate students, medical officers, and technical staff working in this field. This will go a long way in further improving the safety and efficacy of Blood Transfusion Services in our country.

Punya Salila

Date : 07.11.2024
Place: New Delhi

(Punya Salila Srivastava)

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स्वास्थ्य सेवा महानिदेशक
DIRECTOR GENERAL OF HEALTH SERVICES

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services

MESSAGE

The Directorate General of Health Services, MoHFW, GoI is committed to strengthening the quality of Blood Transfusion Services and ensure self-sufficiency of Government network of licensed blood centres.

External quality assessment forms an integral part of assessing overall quality system in a blood centre. Overall, integrating EQA into the blood transfusion services framework in India can lead to improved safety, efficiency, and quality of care, benefiting both patients and healthcare providers.

The Operational guideline for the National EQA program for Blood Centres in India encompasses latest scientific and technological aspects of the field. It will be a ready reference and a useful guide that will help establish a harmonized network of competent proficiency testing providers across the country for blood transfusion services. It is heartening to know that experts from all over the country have given their valuable inputs for these operational guidelines.

I acknowledge efforts of Blood Transfusion Services Division, Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India for the successful completion of this arduous task. A special word of appreciation to experts from all over the country for their valuable time and endeavour in creating this very important operational guideline for the National EQA program for Blood Centres in India.

I am optimistic that technical skills outlined in this operational guideline will benefit practitioners, postgraduate students, and technical staff in their daily work within blood centres and related laboratory settings. These guidelines will also play a crucial role in standardizing blood transfusion practices and enhancing blood safety across the country.

(Atul Goel)

29th October 2024.
New Delhi.

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ACKNOWLEDGEMENT

External Quality Assessment in Blood Transfusion laboratory practices is an important component of a quality system for blood transfusion services and plays a pivotal role in making blood safer and ensures the provision of appropriate, and compatible blood and blood products for transfusion. EQA programme is expected to further strengthen Blood Transfusion Services across the country and achieving the goal of 'Safe Blood Transfusion" as envisaged by the National Blood policy.

We would like to appreciate the efforts of Blood Transfusion Services Division, Directorate General of Health Services, Government of India for successful completion of this task. A special word of appreciation for all the technical experts from all over the country for sparing their valuable time, considerable efforts, enriching and contributing immensely in creating this very important Operational guidelines for National EQA programme for Blood Centres in India.

We are thankful to the Technical Advisory Group members of NBTC, Government of India for their key recommendations in expressing the need of expanding the National External Quality Assessment (EQA) Programme country wide and also for providing continued valuable inputs and guidance in the Operational guidelines for National EQA program for Blood centres in the country.

We are grateful to Prof. (Dr) Atul Goel, Director General of Health Services for his unflinching support and leadership in completing the project. The contribution of the technical officers of Blood Transfusion Services division, Directorate General of Health Services including Dr. Megha Pravin Khobragade, Assistant Director General and Dr. Manas Pratim Roy, Assistant Director General are most gratefully acknowledged. We are thankful for the valuable assistance of the WHO India team including Dr. Hilde De Graeve, Dr. Madhur Gupta, Dr. Reba Chhabra, Dr. PS. Chandranand and Ms. Ruchi Rao.

It is envisaged that this Operational guidelines for National EQA program for Blood centres in India will provide the transfusion medicine practitioners, medical technologists, various categories of blood centre staff, residents and postgraduate students, a thorough and concise guidance for improving and standardizing the blood transfusion in the country and keep the personnel in this field abreast of the advances in the field of transfusion medicine. It will further help to establish a harmonized network of competent proficiency testing providers across the country in Blood Transfusion Services and go a long way in further improving the safety and efficacy of Blood transfusion Services in the country.

(Dr Krishan Kumar)
Director, NBTC
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India

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Formats:

Acronyms

AMC	Annual Maintenance Contract
BTS	Blood Transfusion Services
CDSCO	Central Drugs Standard Control Organization
CMC	Comprehensive Maintenance Contract
CME	Continuing Medical Education
Degree C	Degree Centigrade
Dte.GHS	Directorate General of Health Services
ELISA	Enzyme Linked Immunosorbent Assay
EQA	External Quality Assessment
FMEA	Failure Mode & Effects Analysis
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IH	Immunohematology
ILC	Inter Laboratory comparison
IQ	Installation Qualification
IQC	Internal Quality Control
IT	Information Technology
LJ	Levy Jennings
MS	Microsoft
NC	Non-Conformity
NEQAS	National External Quality Assessment Scheme
OEM	Original Equipment Manufacturer
OOS	Out of Specifications
OQ	Operational Qualification
PQ	Performance Qualification
PT	Proficiency Testing
PTS	Proficiency Testing Serology
QC	Quality Control
QMS	Quality Management System
RCA	Root Cause Analysis
RM	Reference material
RPN	Risk Priority Number
SBTC	State Blood Transfusion Council
SOP	Standard Operating Procedure
TAT	Turn Around Time
TTI	Transfusion Transmissible Infection
URS	User Requirement Specification
WI	Work Instructions

Glossary

1. **Accreditation:** Procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks

2. **Assigned value:** value attributed to a particular property of a proficiency test item.

3. **Audit:** Systematic, independent, and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

4. **Blood centre management:** Person(s) manages the activity of a blood centre headed by a blood centre in-charge/director.

5. **Blood product:** A drug manufactured or obtained from pooled plasma of blood drawn from donors by fractionation.

6. **Blood:** Includes whole human blood, drawn from a donor and mixed with an anti-coagulant.

7. **Calibrator:** Measurement standard used in calibration. NOTE: The term "Calibration" is only used in certain fields.

8. **Competence:** Ability of an individual to perform a specific task according to the procedure.

9. **Competence:** Demonstrated ability to apply knowledge and skills.

10. **Competency assessment:** Written policies, instructions and records involved in providing a product or service.

11. **Corrective action:** An activity performed to eliminate the cause of an existing nonconformance or other undesirable situation to prevent a recurrence.

12. **Document:** Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

13. **Documentation:** Written policies, instructions and records involved in providing a product or service.

14. **Effectiveness:** Extent to which planned activities are realized and planned results achieved.

15. **Equipment:** A durable item, instrument or device used in a process or procedure.

16. **Exercise materials:** EQA samples that have been prepared from test samples and that make up an EQA panel.

17. **External Quality Assessment (EQA):** It is an external evaluation of a laboratory's performance using known but undisclosed panel samples. Quality assessment is undertaken at periodic intervals to evaluate the effectiveness of the QA programme of a participating laboratory. EQA allows participating laboratories to assess their performance levels in comparison to others in the networks that corrective action and preventive action (CAPA) can be implemented for improvement.

18. **External Quality Assessment Programme:** A formal programme organized by a recognized institution. This can be a local programme or organized at national, regional, or international level.

19. **Hepatitis B surface antigen (HBsAg):** It is a surface antigen of hepatitis B virus (HBV) which affects the liver. It can cause both acute and chronic infections.

20. **Hepatitis C virus (HCV):** It is a small (55–65 nm in size), enveloped, positive-sense single-stranded RNA virus of the family Flavi viridae. Hepatitis C virus is the cause of hepatitis C and some cancers such as liver cancer (Hepato cellular carcinoma, abbreviated HCC) and lymphomas in humans.

21. **Human immunodeficiency virus (HIV):** It is a Lenti virus, a subgroup of retrovirus that causes HIV infection and over time acquired immunodeficiency syndrome (AIDS). Infection with HIV occurs by the transfer of blood, semen, vaginal fluid, pre-ejaculate, or breast milk. Within these bodily fluids, HIV is present as both free virus particles and virus within infected immune cells.

22. **Immunohematology (IH):** The study of blood and blood-forming tissue in relation to the immune response.

23. **In-charge blood centre/blood centre director:** Competent person(s) with responsibility for, and authority over, a blood centre.

24. **Internal quality control:** Sample material and procedures that verify the attainment of the intended quality of results. These include procedures to monitor the day-to-day reproducibility of test results and detect major errors in the analytical process.

25. **Interlaboratory comparison:** Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.

26. **Label:** An inscription affixed to a unit of blood, component, tissue, derivative or sample for identification.

27. **Labeling:** Information required or selected to accompany a unit of blood, component, tissue, derivative or sample, which may include content, identification, description of the process, storage requirements, expiration date, cautionary statements, or indications for use.

28. **Management system:** System to establish a quality policy and quality objectives and to achieve those objectives.

29. **Marker:** Specific characteristics of exercise materials included in the EQA programme HIV antibody, HIV antigen, Treponema antibody.

30. **Non-conformance:** Failure to meet the requirement.

31. **Organization:** An institution, or part thereof that has its functions and executive management.

32. **Outlier:** Member of a set of values which is inconsistent with other members of that set.

33. **Panel:** A set of EQA exercise materials.

34. **Participant:** Laboratory, organization or individual that receives proficiency test items and submits results for review by the proficiency testing provider.

35. **Policy:** A documented general principle that guides present and future decisions.

36. **Preventive action:** An action taken to reduce the potential for non-conformance or other undesirable situations.

37. **Procedure:** A series of tasks usually performed by one person according to instructions.

38. **Process control:** The efforts to standardize and control processes to produce predictable output, meet standards, and minimize variation.

39. **Process:** A set of related tasks and activities that accomplish a work goal by transforming inputs into outputs.

40. **Product:** A tangible result of a process or procedure.

41. **Proficiency test item:** Specimen, product, artefact, reference material, piece of equipment, measurement standard or data set provided to one or more participants, or submitted by participants, in a proficiency testing round.

42. **Proficiency testing provider:** Organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme.

43. **Proficiency testing round:** Single complete sequence of distribution of proficiency test items, and the evaluation and reporting of results to all participants in a proficiency testing scheme .

44. **Proficiency testing scheme:** Proficiency testing is designed and operated in one or more rounds for a specified area of testing, measurement, calibration, or inspection.

45. **Proficiency testing:** The structured evaluation of laboratory methods to assess the suitability of processes, procedures, equipment, materials, and personnel.

46. **Qualification:** Demonstration that an entity can fulfill specified requirements and verification of attributes that must be met or complied with so that a person or a thing is considered fit for performing a particular function.

47. **Quality assurance:** Activities involving quality planning, control, assessment, reporting and improvements necessary to monitor progress towards changing quality standards and requirements.

48. **Quality control (QC):** Comprises of all those measures that must be taken during each test run to verify that the test is working properly. It includes ensuring correct temperature conditions, kit controls, etc. It indicates that the test run was valid and has produced acceptable results. It does not guarantee the accuracy of results and reports provided to the physician.

49. **Quality management system:** The organizational structure, processes, or procedures necessary to ensure that overall outcome and direction of an organization's quality programme is met, and the quality of the product or service is ensured. This includes strategic planning, resource allocation, and other systemic activities such as quality planning, implementation, and constant evaluation.

50. **Quality management:** Coordinated activities to direct and control an organization about quality.

51. **Quality policy:** Testing performer routinely on materials and equipment, product, and services to ensure their proper function.

52. **Quality:** Characteristics of a unit of blood, component, tissue, derivative, sample, critical material, or service that bear on its ability to meet requirements, including those defined during agreement review.

53. **Quantitative PT scheme:** Where the objective is to quantify one or more measurands for each proficiency test item.

54. **Qualitative PT scheme:** Where the objective is to identify or describe one or more qualitative characteristics of the proficiency test item.

55. **Reference standards:** Reference standards define how or within what parameters an activity shall be performed and are most detailed than management system requirements.

56. **Sample:** A specimen, preferably of large volume, that has been processed, tested, and stored in a sample bank for potential use as exercise material.

57. **Standard operating procedure (SOP):** It is a standard operating procedure, is a set of step-by-step instructions compiled by an organization to help workers carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry.

58. **Test:** Determination of one or more characteristics according to a procedure .

59. **Traceability:** Property of the result of a measurement or the volume of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties.

60. **Transfusion transmitted infections (TTIs):** These are diseases caused by a virus, parasite or other potential pathogen that can be transmitted in donated blood through a transfusion to a recipient.

61. **Validation:** Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome, meetings its predetermined specifications and quality attribute.

62. **Verification:** Confirmation by examination and provision of objective evidence that specified requirements that have been met.

63. **Z score:** Standardized measure of performance, calculated using the participant result, assigned value and the standard deviation for proficiency assessment.

Introduction

External Quality Assessment (EQA) in blood transfusion laboratory practices is an important component of a quality system for blood transfusion services. The term "External Quality Assessment" (EQA) is used to describe a method/process that allows testing conducted by a blood centre, to be compared to that of a reference source outside the blood centre – of a peer group of blood centres or a reference testing laboratory.

Blood Transfusion Services (BTS), Directorate General of Health Services (Dte.GHS) with support of WHO Country Office for India and National Institute of Biologicals organized National Workshop on Blood Safety in India: Roadmap for the Country Blood Transfusion Services on 14 and 15 July 2022.

One of the key recommendations is expanding the National External Quality Assessment Programme countrywide. Working towards the aim, Government of India plans to expand the National EQA Programme to states and union territories (UT) coordinated by Dte.GHS.

BTS, Dte.GHS, Government of India is committed to strengthening the quality of blood transfusion services and making the Government network of licensed blood centres self-sufficient. A risk-based situational analysis of laboratories and other testing services is the basis for planning and implementing an effective strategy for EQA.

A National EQA programme will be more effective for all the critical assays performed in the blood centres within the country and is expected to be very useful in providing data on the accuracy of testing results for national guidelines. To strengthen the testing systems and ensure supply of safe blood and blood products in blood centres, it is essential to participate in international and nationally coordinated EQA programmes as they prove useful in supporting and assessing the performance of laboratories constituting a much-required national EQA programme. Other critical factors in the organization of an EQA programme include the availability of appropriate infrastructure, qualified and trained human resources, approved test kits, well studied proficiency testing (PT) samples and reagents (reference test items), reference standards/IQCs/calibrators, approved standard operating procedures (SOPs), well-maintained equipment, stability of proficiency test items during transit (cold chain), especially in extreme environments, shipment logistics and costs, etc.

The provision of safe, appropriate, and compatible blood and blood products for transfusion involves several processes and there is a risk of error in each of these processes. External quality assessment forms an integral part of the assessment of the overall quality system in a laboratory. EQA is an effective way of identifying process problems within the blood centre and provides with an objective view of its performance relative to other blood centres.

Successful participation of a blood centre in an EQA programme provides objective evidence of the testing services, its associated accrediting bodies, and regulatory agencies, and serves as a unique source of information to the national pool of quality health data in blood transfusion-related testing. Importantly, participation in an EQA programme allows for a

"peer-review" process towards solving technical and methodological problems to improve the quality of service for each individual blood centre as well as to achieve comparability of results among different blood centres. For accrediting bodies and regulatory agencies, EQA provides objective data on the quality of delivered services and has been shown to reflect the quality of testing of test specimens. It is designed to raise standards of performance in blood transfusion services and ensure the provision of appropriate, compatible blood and blood products for transfusion. The information generated by EQA provides an opportunity for continuous quality improvement through the identification of laboratory errors and the implementation of measures to prevent their recurrence. Thus, EQA plays a vital role in making blood safer. The EQA programme is expected to strengthen blood transfusion services across the country and achieve the goal of 'Safe Blood Transfusion" as envisaged by the National Blood Policy.

Government of India aims to improve the performance of testing in blood centres across its blood centres network by engaging the proficiency testing provider blood centres to participate in recognized international EQA programmes. In a country like ours, a hierarchical structure with delegation of responsibilities and supervision to provincial/regional and district laboratories, would be more appropriate for an EQA programme. Responsibilities include distributing the proficiency test items provided by the PT providers identified by the national coordinating centre (Dte.GHS), supervising peripheral laboratories, education, and training, and supporting corrective action at the blood centres.

Communication at different levels is the basis for the success of an EQA programme. The national coordinating centre for EQA programme, BTS, Dte.GHS will maintain communication with all relevant groups including advisory committee members, national and international experts, professional societies for the elaboration of protocols for EQA programmes, ministry-level health authorities responsible for laboratory and testing services at blood centres, and organizations providing proficiency testing materials.

Proficiency test materials/specimens required to conduct the EQA programme may be commercially acquired or locally prepared. The choice of materials should be guided by availability, as well as by funding, appropriate human resources, expertise to prepare the items locally, and the number of participating blood centres.

References:

1. Establishing External Quality Assessment Programmes for Screening of Donated Blood for Transfusion-Transmissible Infections - Implementation Guide - World Health Organization 2016.

2. WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites - World Health Organization 2016.

Aims and objectives

1. Establish a National External Quality Assessment programme across nationwide blood testing centres.
2. Identifying the appropriate organizing centre(s) for the programme.
3. Systemic performance evaluation of nationwide blood testing centres.
4. Identify common errors and provide corrective measures.
5. Harmonization of quality testing system in nationwide blood testing centres.

Scope

1. Scope of testing of participating laboratories.
2. Raising awareness of EQA programme and the need for improvement.
3. Benefits of good laboratory practices.
4. Providing information, education, and support for improvement.
5. Establish continual systems of improvement to measure, maintain and achieve as necessary the quality of performance and standards in each of the blood centre's laboratories.

Testing at blood centres consists of pre-testing, testing, and post-testing processes, which require strict implementation of essential quality management system (QMS). The components of this QMS include internal quality (process) control, proficiency testing, and quality improvement. It is only when these components are implemented together that quality improvement of testing can be achieved and consequently can improve quality testing outcomes in terms of delivering blood and blood components of the highest attainable quality.

The benefits of EQA programme to health and regulatory authorities include establishment of a network of blood transfusion centres with a known standard of performance, training and education of blood centre staff, provision of useful information to assist in:

a. Setting standards
b. Reviewing testing strategies
c. Post-market surveillance of test kits, reagents, instruments
d. Using resources effectively
e. Improving public confidence in the blood transfusion service
f. Supporting systems of accreditation.

A risk-based situational analysis of government network of blood centres will be the basis for planning and implementing an effective strategy for EQA. The assessment should include, but not be limited to, the following aspects:

1. Conceptualization of EQA programme
2. Roles and responsibilities of PT provider
3. Roles and responsibilities of EQA participant
4. NEQA should not get limited to Blood group serology, Immunohematology and TTI testing. Even quality control of blood components should also be involved later if possible.
5. The goal is to improve the quality of blood centres with an aim to improve patient care through education and capacity building.

References:

1. Establishing External Quality Assessment Programmes for Screening of Donated Blood for Transfusion-Transmissible Infections - Implementation Guide - World Health Organization 2016.

2. WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites - World Health Organization 2016.

3. World Health Organization. Guidance on regulations for the Transport of Infectious Substances 2015–2016. Geneva: World Health Organization; 2015 (http://www.who.int/ihr/publications/who_hse_ihr_2015.2/en/, accessed 30 March 2016).

4. TRANSFUSION MEDICINE TECHNICAL Manual, Third Edition 2023, Ministry of Health and Family Welfare, Government of India.

Chapter 1

Operational requirements of blood centres

Chapter 1

Operational requirements of blood centres

A. Valid blood centre license - statutory requirement

1. Blood centres shall be licensed by appropriate licensing authority under the aegis of the Central Drugs Standard Control Organization (CDSCO) and shall be regulated by the Drugs and Cosmetics Act and Rules there under.

2. The blood centre shall have a valid license from CDSCO and approved by Drugs Controller General (India), central license approving authority under the Drugs and Cosmetics Act and Rules.

3. All blood centres should have their own quality policy and prepare a quality manual that addresses the systems in use.

4. Every section responsible for various services will define its own quality control programme including outsourcing services.

5. It is also recommended that blood centres participate in various EQAS programmes.

6. Each blood centre should maintain a detailed standard operating procedure manual, as well as records (forms, registers, labels) in a prescribed format prescribed by the Drugs and Cosmetics Act and Rules.

B. Infrastructure (Accommodation and environment)

The blood centre shall function under the direction of a licensed medical officer qualified by training and by experience as a transfusion medicine specialist who shall be responsible for all medical, technical, and administrative services.

B.1. The blood centre shall:

1. Have minimum operational areas as recommended by the Drugs and Cosmetics Act and Rules and other statutory bodies.

2. Have a suitable space and environment for the operation as per the requirement of the Drugs and Cosmetics Act and Rules.

3. Have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, tests, and visitors.

4. Evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work.

5. Should be located at a place which shall be away from open sewage, drain, public lavatory or similar unhygienic surroundings.

6. Have a continuous and uninterrupted power supply for the equipment used, adequate lighting for all the required activities, hand washing facilities for staff, reliable communication system, furniture and equipment arranged within the available place and availability for proper disposal of biohazardous waste.

C. Trained and qualified personnel

1. The blood centre management shall maintain records of the personnel information, relevant educational and professional qualification, training and experience and competence of all staff members responsible for routine and specialized activities performed at the blood centre.

2. Have a defined process to ensure the employment of an adequate number of individuals qualified by education, training and/or as per applicable regulations.

3. There shall be adequate and competent staff as prescribed in Schedule F Part XII B of the Drugs and Cosmetics Act and Rules. The records of their qualifications, training and competency should be maintained.

4. All blood centres shall provide full-time competent staff ensuring proper cadres for both medical and paramedical personnel.

5. All blood centres should recruit support staff as per recommendations given in the Drugs and Cosmetics Act and Rules.

6. The job descriptions or specifications should be clearly recorded and laid down for all staff members.

7. The staff members should be given induction training soon after the appointment.

8. The training records should be maintained, updated, and reviewed.

9. It is recommended that to evaluate the proficiency and technical competence of all technical staff by ensuring their participation in a national or international coordinated EQA programme applicable to their respective areas of operations.

10. All staff should be provided with necessary trainings, and facilities for implementing universal safety precautions for hospital-acquired infections and applicable biosafety guidelines.

11. It shall be the responsibility of the management to ensure that the personnel in blood centre activities are adequately trained for the tasks undertaken and receive initial and continual training relevant to their need.

12. There shall be a well-devised periodical continuing education programme for staff at all levels.

13. Employees shall be trained to prevent adverse incidents and/or contain the effects of and report adverse incidents. Blood centre employees shall be trained in other regulatory and safety issues of blood centre like biomedical waste and spill management, etc.

14. Personnel records for all staff shall be maintained centrally in case of a hospital-based blood centre or in the blood centre as per the decision of the management.

15. Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.

16. Personnel shall perform assigned activities based on appropriate qualifications. Competency test of all technical staff may be conducted annually in terms of written/ oral/practical tests to ensure the credibility of their technical skills and performance in routine operations.

17. Retraining and reassessment shall be undertaken when necessary.

D. Equipment with annual maintenance/comprehensive maintenance contract

1. The blood centre shall be furnished with all the necessary equipment required for the provision of blood transfusion and testing services.

2. The blood centre shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conform to the blood centre standards and other specified requirements.

3. The records of calibration, maintenance and validation of equipment shall be maintained in the respective logbooks.

4. Blood centre shall have a policy for selection, procurement, and installation of the equipment. It includes the following qualifications:
   a) Installation qualification (IQ)
   b) Operational qualification (OQ) and
   c) Performance qualification (PQ)

5. Only authorized and competent technical personnel shall operate all equipment. Up-to-date instructions on the use and maintenance of the equipment (including relevant manuals and direction for use provided by the original equipment manufacturer (OEM) of the equipment) should be readily available to personnel.

6. Equipment used are maintained in a clean and proper manner and suitably placed to facilitate cleaning and maintenance.

7. The following records shall be maintained for each equipment. These records should include at least the following:

a. Unique identification of the equipment
b. Manufacturer's name, type, identification and serial number or other unique identification
c. Manufacturers/service provider's contact person and contacts details
d. Date of receiving and date of putting into service
e. Current location, where appropriate
f. Condition when received (new, used or reconditioned)
g. Manufacturer's instructions, if available, or reference of their retention
h. Standard operating procedure for each equipment based on the technical manual provided by the OEM, to perform routine operations
i. Equipment performance record that confirms the equipment suitable for use
j. Maintenance carried out and that planned
k. Damage to or malfunction, modification, or repair of the equipment

8. All equipment shall have labels identifying the equipment, calibration status and due date of calibration.

9. All these records shall be maintained and be readily available for the life span of the equipment.

10. Staff must be trained to use and maintain all the equipment available at the blood centres. An equipment logbook should be kept maintaining comprehensive records of operations, AMC/CMC, calibrations, and repairs.

11. Quality manager/in-charge of the blood centre shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents, and analytical system. It should also have a documented and recorded programme of preventive maintenance, which at a minimum, follows the manufacturer's recommendations.

12. The equipment should be observed, standardized, and calibrated regularly on a scheduled basis as described in the standard operating procedure manual and shall operate in the manner for which it was designed to ensure compliance with the legal requirement (the equipment) as stated below for the blood and its component.

13. The blood centre should have a corrective and preventive action(s) system for investigating and follow up of equipment malfunction, failure or adverse event while working. This should minimally include assessment of consequences when equipment is found to be out of calibration, such as effect on donor eligibility and quality of blood components.

14. Blood centre shall have a procedure for replacement or repairing of defective equipment. Whenever equipment is found to be defective, it shall be taken out of service, clearly labelled, and appropriately stored until it has been repaired and shown to be calibrated to meet specified acceptance criteria.

15. The blood centre should have a policy and procedure for appropriate alternate storage of reagents and diagnostic kits in the event of breakdown of equipment.

16. Equipment required for the operation of the blood centre to deliver quality outcome shall be available on the premises in adequate quantities. Additional or advanced equipment may be added if required.

17. There shall be a regular programme for equipment maintenance in all blood centres. All equipment should be maintained to ensure efficient and accurate working at all times.

18. Specifications of acceptable performance should be established for each equipment. Besides IQ, OQ, PQ, Validation of equipment should be done at the time of installation and at regular intervals thereafter.

19. An annual maintenance contract should be undertaken preferably for all equipment with the suppliers, including preventive maintenance and calibration.

20. Records of all maintenance should be kept viz. Equipment Identification, who performed servicing/calibration, when performed servicing/calibration, what was the result/conclusion/outcome, when is the next schedule.

21. Equipment should be used as per manufacturer's instructions.

22. SOP and datasheets regarding records of when and who used the equipment should be available.

23. At the time of installation of new equipment, the installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) should be performed and documented.

24. Dedicated area for Immunohematology, TTI test kits, storage of reagents, test kits and samples are required for NEQA programme.

25. The EQA participant should meet all the criteria as told in Para A, B, C and D. For the initiation as a pilot of this programme with all the criteria as told in Para A, B, C and D and the following additional criteria:

Additional criteria

i. The blood centres, whether NHM-supported or both NHM-supported and private, must include a blood component separation unit (BCSU) and have an annual collection of 5,000 units or more.

ii. This is because only BCSU with 5,000 units or more annual collections will have proper assigned and dedicated technical staff.

iii. First to start with blood centres supported by NHM then all private and charity-based blood centre can be included.

iv. The selected blood centres should be inspected by SBTC technical staff to certify that the respective blood centre has met all the criteria as mentioned in A, B, C, and D.

References:

1. Drugs and Cosmetic Act (and Rules), 1940: Part-XII B; Ministry of Health and Family Welfare (Department of Health), Govt. of India.

2. WHO Manual for Organizing a National External Quality Assessment Programme for Health Laboratories and other Testing Sites, 2016.

3. National Standards for Blood Centres and Blood Transfusion Services, 2nd Edition, 2022, Ministry of Health & Family Welfare, Government of India.

4. Standards for Blood Banks and blood Transfusion Services, National Aids Control Organization, Ministry of Health & Family Welfare, Government of India, New Delhi, 2007.

5. Establishing External Quality Assessment Programmes for Screening of Donated Blood for Transfusion – Transmissible Infections Implementation Guide WHO, 2016.

6. Guidelines for national External Quality Assessment Scheme For STI/TTI(S) Serology, 2nd Edition 2018, Royal Centre for Disease Control, Ministry of Health Royal Government of Bhutan, Thimphu Bhutan.

7. Analytical performance specifications for external quality assessment– definitions and descriptions, DOI, 10.1515/cclm-2017-0151), https://pubmed.ncbi.nlm.nih.gov/28593915/.

Chapter 2

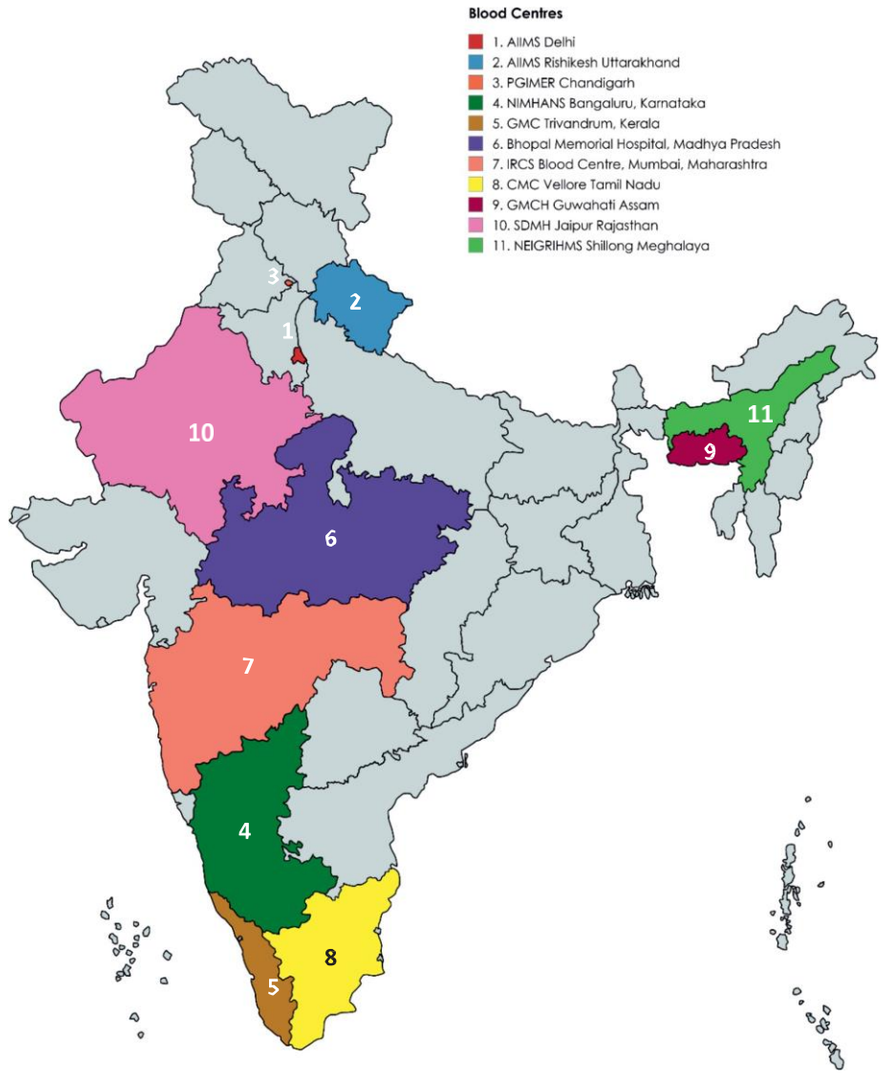
Structure of EQA programme

Chapter 2

Structure of EQA programme

Proficiency testing/External Quality Assessment participant blood centres identified for NEQA programme will be from central government institutions or nominated by respective State Blood Transfusion Council (SBTC). These blood centres shall have a valid blood centre license. The PT providers/EQA participants will participate in the National EQA programme in a phased manner. To begin with, 11 potential proficiency testing providers across states from phase 1 have been identified in the country.

Fig: 1: 11 potential proficiency testing (PT) providers identified by BTS, Dte.GHS for National External Quality Assessment Programme.



Steps in operationalization of National External Quality Assessment Programme

1. National External Quality Assessment (NEQA) programme coordinator (Dte.GHS)
2. Formation of advisory committee
3. Identify organizing institution/programme organizer
4. Participation in international EQA programme by the organizing institution
5. Planning and design of NEQA programme
6. Identification of NEQA samples/reagents resources
7. Identification of participating blood centres
8. Circulation of preliminary questionnaire
9. Preparation of operational guidelines for NEQA
10. Mechanism for preparing and distributing NEQA samples
11. Conduct pilot study
12. Evaluate pilot study and make modifications, if necessary
13. Scale up and expansion of EQA programme
14. Data management - handling results and performance monitoring
15. Periodic monitoring and evaluation of the NEQA programme.

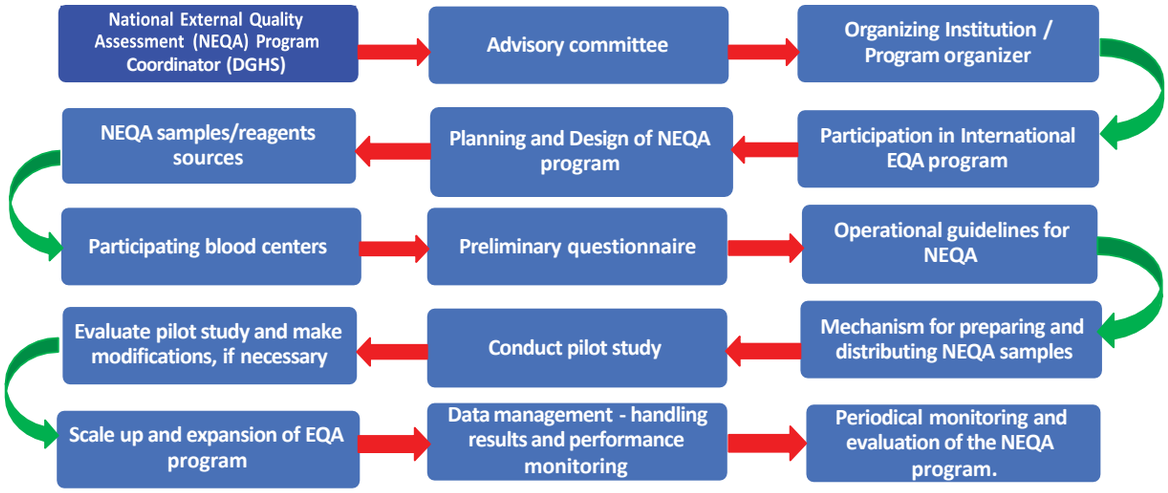
Each nodal centre (NC) will have jurisdiction over two or more states. Further, state representing blood centre (SRBC) to be selected. The nodal centre's will be responsible to train TOT states representing blood centre from each state and also supply EQAS samples, reagents, kits and other logistics through SRBC or directly to blood centre participating EQA programme.

1. The nodal centre will supply EQAS samples to each participating blood centre directly or through SRBC, which will coordinate with NC and EQA participating blood centre

2. The NC will also evaluate the EQAS reports and take necessary action as per the guidelines. It will also arrange training at various blood centres involved through state blood centre

3. Both NC and SRBC will inspect (surprised and pre-planned both type) EQA participating blood centres under their jurisdiction under the guidance of state blood transfusion council.

Figure 2: Flowchart - Operationalization of National External Quality Assessment Programme



A. Composition of an organizing centre/PT provider

For establishing and running a successful EQA programme it is critical to have qualified and trained staff, well-equipped infrastructure, and continual funding. It is recommended for each of the PT organizing blood centre to have the following composition and skills for smooth operationalization of the EQA programme.

i. Each PT organizing/providing blood centre will be under direct supervision of the National Coordinating Centre (NCC) for the EQA programme, i.e., Directorate General of Health Services.

ii. EQA programme in-charge/coordinator of the blood centre (blood centre in-charge).

iii. Quality manager (blood centre in-charge may fulfill the role in absence of a quality manager).

iv. Trained technical staff to prepare, store, distribute and maintain proficiency test items, (laboratory technician(s).

v. Trained and competent technical staff to perform or participate in PT/EQA programmes, (laboratory technician(s)).

vi. Support staff to manage biomedical waste, decontamination, sterilization activities, etc., (laboratory assistants).

vii. Biostatistician/statistician.

viii. Computer operator with experience in Microsoft Office, internet, emailing, etc.

ix. Administrative support for official correspondence.

x. Procurement/supply chain management for procurement and logistics support.

xi. Sample providing centres-

*Sample providing for PT centres may be different. They may or may not be nodal centre. All over India - each PT sample provider (centres for excellence) has to prepare only one set of PT sample for a particular EQAS parameter - to maintain uniformity, standardization and quality of the sample.

Examples

a. Indian Institute of Immunohematology, Mumbai – may prepare samples for basic blood group serology and rare group serology for entire India

b. CMC Vellore - for hemoglobin, malaria or any other test

c. AIIMS New Delhi - any one TTI like HIV or HBV or HCV or any other test

d. PGIMER Chandigarh - antibody screen and identification (advanced IH) or any other test

4. As per the present setup each nodal centre acts as PT organizing centre for 2 or more states and it trains the TOT for each state, coordinates PT testing and also evaluates each blood centre participating in EQAS.

5. There should be SRBC -*For each state there should be SRBC which will work under nodal centre in -
   -Distribution of samples to blood centre and also collect reports from them,
   -Helps in solving problems or shortcomings in the blood centre
   -Conducts training to all blood centre staff about EQAS with the support of nodal centre and also reorientation training.

6. The SRBC will be working along with State Blood Transfusion Council.

7. In conducting of EQAS - in any state all the players who manage Government or EQAS participating blood centres and storage centres should be ideally involved. For example -
   a. The State Blood Transfusion Council which will also coordinate with state health authorities
   b. State drugs controller - They can also ask details of EQAS while inspection
   c. All heads (Director/ Dean/ MS) of the government hospitals who have blood centre attached to their hospital, etc , to provide necessary kits, reagents, equipment, etc., also to frame quality policy.

Roles and responsibilities of PT provider/organizing blood centre.

Blood centres fulfilling all the preliminary screening criteria satisfactorily with respect to administrative, technical, and operational activities will be identified as proficiency testing (PT) organizing/providing blood centres to conduct the EQA programme It is critical that an EQA organizing blood centre/PT provider fulfills the minimum required administrative, technical, and operational expertise.

1. The PT provider/organizing blood centre shall participate in an internationally accredited EQA programme and achieve certification in areas of serology testing for transfusion transmitted infections (TTI) and Immunohematology (IH).
2. Conduct the EQA programme to the EQA participants within the state and to its other allocated blood centres across all the states within the country.
3. Prepare, package, label, and dispense the EQA samples.
4. Document and record results in a confidential manner within the stipulated time for all the EQA participant blood centres within its purview as per applicable quality management systems (QMS).
5. Documentation of test results/test reports in MS Excel spreadsheet.
6. Follow up and monitoring of EQA participants for timely reporting, support in handling out-of-specification (OOS) results, executing Corrective and Preventive Action (CAPA).
7. Procure, store, and maintain stock of PT test items, reference materials (RM), approved testing kits, all laboratory consumables, packaging material, stationary, etc.
8. Prepare and maintain internal quality control material (IQC).
9. Laboratory equipment used in the EQA programme should be calibrated according to the manufacturer's instructions, along with its respective annual or comprehensive maintenance contracts well established and recorded.

10. Organize and participate in pre and post trainings/workshops with support of knowledge partners and WHO Country Office for India.
11. Train, guide, help and try to resolve problems faced by EQAS participating blood centres.

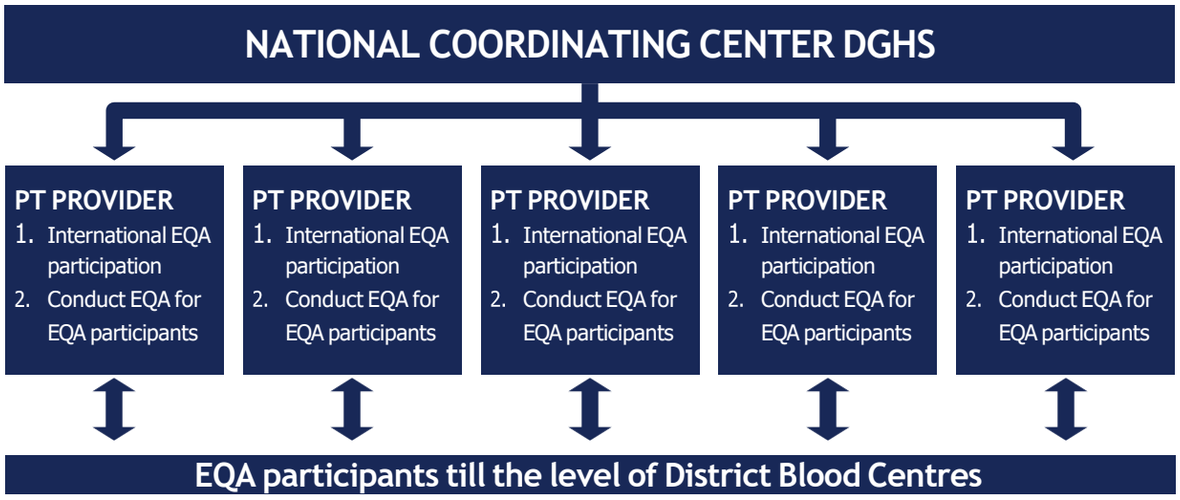
B. Composition of an EQA participating centre

EQA participating centres will be composed of all the regional blood centres within the state, district, and peripheral healthcare network. EQA Participant blood centres should handle proficiency test items for testing in the same way as they handle specimens that are routinely tested in their respective blood centre/laboratory.

Roles and responsibilities of EQA participant centre

1. Each EQA participant blood centre will be under direct supervision of the respective PT provider/organizing blood centre.
2. Participate in EQA with the concerned PT provider blood centre.
3. Test the EQA samples in the same manner as any routine samples.
4. Return the completed test result form to the EQA organizing/PT provider blood centre within the given turnaround time (TAT).
5. Study the feedback report and recommendations provided by the EQA organizing/PT provider blood centre and implement corrective actions and preventive measures.
6. Identification, mapping of potential EQA participant peripheral health centres, including site visits and providing feedback to PT provider.
7. All laboratory equipment used in the EQA programme should be calibrated according to the manufacturer's instructions, and respective AMC/CMC maintenance schedules well established and recorded.
8. Document and record results in a confidential manner within the stipulated TAT for all the EQA participant blood centres as per applicable QMS.
9. Adhere to all the critical documents such as SOPs, QMS, including the EQAS guidelines, instructions accompanying the panel samples and feedback reports.
10. Participate in trainings/workshops with PT providers, knowledge partners and WHO Country Office for India.
11. Documentation of test results/test reports in MS Excel spreadsheet.
12. Procure, store, and maintain stock of internal quality control items (IQC), reference materials (RM), approved testing kits, all laboratory consumables, packaging material, stationary, etc.

Fig. 3: Hub and Spoke Model for Operationalization of National External Quality Assessment Programme



Benefits to participating blood centres

1. Identification of opportunities for improvement relating to blood centre's processes.
2. Comparison of a laboratory's own performance with that of other EQA participating blood centres.
3. Comparison of performance between different testing systems.
4. Provision of information and education to improve performance.
5. Encouragement of best practices.
6. Opportunities to enhance the credibility of the blood centre and increase public confidence.
7. Access to a network of blood centres for the exchange of knowledge and information.
8. Establish harmonized continual systems of improvement to measure, maintain and achieve as necessary the quality of performance and standards in each of the blood centre's laboratories.

References

1. Establishing External Quality Assessment Programmes for Screening of Donated Blood for Transfusion – Transmissible Infections Implementation Guide WHO, 2016.

2. Guidelines for national External Quality Assessment Scheme For STI/TTI(S) Serology, 2nd Edition 2018, Royal Centre for Disease Control, Ministry of Health Royal Government of Bhutan, Thimphu Bhutan.

3. National Standards for Blood Centres and Blood Transfusion Services, 2nd Edition, 2022, Ministry of Health & Family Welfare, Government of India.

4. Standards for Blood Banks and blood Transfusion Services, National Aids Control Organization, Ministry of Health & Family Welfare, Government of India, New Delhi, 2007.

Chapter 3

Budget and finance

Chapter 3

Budget and finance

A. Financial management

The top management is responsible for appropriate planning and effective functioning of a blood centre, about costing, procurement, stocking, supply, and accurate record keeping of all critical items and consumables at any given point of time. It also enables planning for future expansion and mobilization of resources.

Programme owners must ensure allocation of adequate budget and resources for all essential activities including cost estimate cycle per EQAS/PT cycle to ensure the establishment and operationalization of National EQA Programme's sustainability. The budget planning should include:

a) Initial capital cost viz. accommodation, staff including salaries, training and education recruitment, capital equipment, storage, package and dispatch, and Information technology components like computer, printer, internet services, etc.

b) Continuing recurring cost viz. workshop(s) and training(s), laboratory consumables, reagents; kits; general laboratory supplies; stationery and printing; equipment maintenance/replacement; capital assets, for example, vehicles; building maintenance/ expansion; utilities; electricity, telephone, water, etc.; public relations, IEC materials internet facility and other miscellaneous items.

Cost estimation - Financial resources

EQA programme requires specific investment and financial obligations to ensure a sustainable service. The resources may be provided from:

1. An allocated budget from government authorities
2. Twinning with other EQA organizers
3. Fees from participants
4. Commercial suppliers
5. Academic centres
6. Long-term benefactors including trusts
7. Support from development partners as a short-term measure.

B. Cost of operation

Calculation of expenses should include, but not be limited to, the following items:

- General costs (water, communication, electricity, insurance).
- Salaries for personnel or man-hours required.
- Information technology infrastructure and maintenance.
- Costs for maintenance and repair of laboratory equipment.

- Proficiency test items, which can be purchased or produced locally
  - costs of the proficiency test item (serum, plasma, etc.)
  - investments for local production
  - evaluation of proficiency test items (i.e. test kits, reagents, calibrators, consumables, etc.)
  - assessment of stability and homogeneity of the proficiency test items.
- Packaging
  - packaging of proficiency test items
  - envelopes and labels for mailing.
- Administration of PT rounds
  - registration of participants
  - invoicing of participants (if applicable).
- Printing of forms, reports, and catalogue.
- Mailing and/or courier costs
  - of proficiency test items
  - of reports.
- Evaluation of PT rounds
  - reimbursement of costs for experts (as appropriate)
  - costs for use of informatics (as appropriate)
  - costs for organizing meetings of experts and workshops for participants (once or twice a year).
- Training/corrective actions for participants.
- Miscellaneous costs
  - programme development costs
  - programme financial management
  - programme quality management system
  - staff training and development.

C. Subscription fees

Each EQA programme should be financially secure so that it can function in a timely manner. Subscription fees from participants may be the only source of income. In determining the cost of the subscription fee, account should be taken of the number of participants and the number of PT/EQA rounds that are envisaged – the costs of implementation may vary for each PT/EQA round because the number of participants and number of PT/EQA rounds may vary each year, and there may be unforeseen challenges. Thus, it is critical that the budgeting process is risk-based, and takes into consideration the costs of quality control, data analytics, equipment care and maintenance.

References:

1. National Standards for Blood Centres and Blood Transfusion Services, 2nd Edition, 2022, Ministry of Health and Family Welfare, Government of India.

2. Standards for Blood Banks and blood Transfusion Services, National Aids Control Organization, Ministry of Health and Family Welfare, Government of India, New Delhi, 2007.

3. Establishing External Quality Assessment Programmes for Screening of Donated Blood

for Transfusion – Transmissible Infections Implementation Guide WHO, 2016.

4. Guidelines for national External Quality Assessment Scheme For STI/TTI(S) Serology, 2nd Edition 2018, Royal Centre for Disease Control, Ministry of Health Royal Government of Bhutan, Thimphu Bhutan.

Chapter 4

Proficiency testing/ External Quality Assessment Management

Chapter 4

Proficiency testing/ External Quality Assessment Management

A. Prerequisites of PT provider blood centre to undertake EQAs for TTI and IH

A.1. Administrative support:

1. Licensed government blood centre as per prevailing regulations laid down by Government of India.
2. Adequate funding.
3. Reliable source of raw materials (samples/reagents) material for PT programme.
4. Participation in an appropriate recognized national or international External Quality Assessment Scheme or Accreditation by an authorized notified body for appropriate QMS as applicable.
5. Availability of suitable accommodation and environment to undertake infectious disease and immunohematology serology testing.
6. Biosafety level II practices (universal biosafety precautions).
7. Adequate quantity and type of approved quality diagnostic test kits.
8. Standard operating procedures and work instructions.
9. Quality assurance as per QMS (documentation and time bound reporting of test results).
10. Functional equipment with AMC/CMC (including standby).
11. Dedicated human resources (qualified, skilled, trained, and immunized).
12. Technical support/capacity building (trainings and workshops).
13. Administrative support for necessary approvals.

14. Labware, consumables, logistics and storage.
15. Cold chain (refrigerator 2-8 °c and deep freezer -20 °c).
16. Power backup.
17. Computer and internet facility.
18. Data management system (management of test results and reports).
19. Stationary and related consumables.
20. Biomedical waste management.

A.2. Technical support:

1. Technical expertise and resources.
2. Awareness of available screening and diagnostic assays suitable for EQA programmes.
3. Technical know-how of specimen collection, handling, processing, storage, documentation, characterization, and re-characterization of specimens/reagents.
4. Provide training to participating centres (Pre/Post EQAS).
5. Frequency of conducting EQA and number of samples about respective biomarker/ test for each round of EQA must be scheduled appropriately.
6. Prepare, package, and dispense the EQAS samples as per recommended guidelines and biosafety level II practices.
7. Maintenance of cold chain as per recommended guidelines during storage and transit.
8. Receive results, analyze data, and share reports in a confidential manner.
9. Provide feedback to all testing centres in a confidential manner.
10. Certificate of successful participation must be provided to each participant laboratory after the completion of the respective EQA round.
11. Conduct monitoring and on-site supervision (follow up).
12. Periodic review and update of the EQAS guidelines.
13. Participation in appropriate national/international EQA programme.

14. Data management of EQA test results, generate participant wise and group-wise reports post EQA programme and share the same in a confidential manner to the respective EQA participants.

B. Prerequisites of EQA participant blood centre

1. The testing centres should ensure that their staff receive appropriate training.

2. The staff should adhere to all the documents, including the EQAS guidelines, instructions accompanying the panel samples and feedback reports.

3. Test the panel samples in the same manner as any routine samples.

4. Return the completed test result form to organizing laboratory within the stipulated turnaround time.

5. Study the feedback report and recommendations provided by organizing laboratory and implement corrective actions and preventive measures.

6. The participating laboratory must participate and complete all the available rounds of EQA provided by the PT provider successfully in a calendar year.

7. Certificate of successful participation in various EQA programmes must be always available and appropriately displayed in the laboratory.

C. Planning and organization of proficiency testing

1. Discussions with all the concerned stakeholders, participant blood centres, towards preparation, distribution, and testing of one or more proficiency test items, and analysis of the results of a test or groups of tests from several blood centre within a defined period, constitutes a PT round.

2. Competent and pre-identified blood centre shall be assigned the responsibility of a PT provider.

3. The PT provider is entrusted with the responsibility of preparing or acquiring proficiency test items, storage, packaging, labelling, distribution, receiving and analyzing results, and returning results to participants in a timely and confidential manner, thus leading to a successful PT programme.

4. An annual calendar shall be prepared for all the PT programmes for transfusion transmitted infectious diseases (TTI) and immunohematology (IH).

5. PT provider must have adequate access to samples of TTI infectious disease and Immunohematology.

6. Standard operating procedure for collection, processing, labelling/identification, storage, characterization, and stability studies of samples/reagents must be established prior to preparation of PT test items.

7. SOP for the preparation of proficiency test items should be established at least six months in advance of the first PT round.

8. A total of "THREE" PT testing events may be organized in one calendar year period.

9. Each PT programme shall be identified with a specific code along with specific codes for respective blood centres and specimens/samples for that PT round.

C.1 For PT in Serology each cycle/test event will be identified by the following coding system:

C.1.1 Coded: PTSR/ABC/2023/02/TTI/08
For example: PTSR/Blood Centre Code/Year/EQA Cycle number/TTI/Sample number

C.1.2 Decoded:
PTSR = Proficiency Testing Serology
Blood Centre Code = ABC
Year = 2023
EQA Cycle number = 02
Test category = TTI (transfusion transmitted infection)
Test category = IH (Immunohematology)
Sample number = 08

Table 1 Approximate timelines for planning and implementation of a PT round (time for training 1-2 months)

Stage	Tentative timeline*	Action
Planning	1-2 months	Identification of blood centre, TTI markers and IH tests
		Decision on frequency of PT rounds
		Determination of dates of mailing of proficiency test items
		Preparation or ordering of proficiency test items
		Ordering of packing and labeling materials (preferably barcodes)
		Timeline for delivery of proficiency test items to EQA participants

Implementation	2-3 months	General review of preparatory work for the PT round Informing of participants about dispatch and closing dates
		Preparation of participation, reporting and data acquisition, assessment, corrective and preventive action formats, and scoring key, by PT provider
		Sample collection and preparedness towards readiness of proficiency test items (collection, storage, aliquoting, labelling, packing, etc.)
		Readiness about test kits, equipment, consumables, stationary, etc.; for participation in EQA
		Identify technically suitable carrier (with cold chain and data logger capabilities), dispensing of EQA materials
		In-house processing; panel/aliquot dispensing and aliquot testing, in-house validation of panels before dispatch
		Preparation/printing of addresses/labels, forms, etc.
		Packaging of proficiency test items
		Dispensing of proficiency test items in cold chain by courier
		Decision on closing date for reporting for the specific round of EQA
		Decision on sample transit time and data return times
		Data entry completion by EQA participants Data analysis and reporting by EQA participants
		Appropriate storage of leftover proficiency test items by EQA participant, where stability of analyte permits.
		Generation of corrective and preventive actions by PT providers for continual improvement of the programme
		Conclusive meeting of EQA round by National coordinating centre

**The timelines will differ depending on the type of EQA programme, number of participants, volume of data, analysis design, and availability of proficiency test items.*

C.2 The PT provider blood centre will document all the critical steps concerning the PT round in respective data acquisition formats. PT provider will be the custodian of the following formats:

1. PT/EQA participation
2. Samples/reagents shipping/transport
3. Receipt and storage
4. Test result/reporting format for RAPID test method
5. Test result/ reporting format for ELISA/other tests method
6. Test result/ reporting format for Blood grouping and Rh typing of donor/recipient
7. Data analysis for RAPID test method
8. Data analysis for ELISA/other test method

9. Data analysis for Blood grouping and Rh typing of donor/recipient
10. Assessment and scoring key of each EQA participant in the specific round of EQA
11. Corrective and preventive action
12. Feedback and monitoring

Rules of EQA participation

Clear rules of participation in the EQA programme should be determined by the advisory committee. These rules should set out:

1. What is expected of participating blood centre
2. The service to be provided by the scheme
3. How the information collected, including performance data, will be used.
4. Participating blood centre should agree to these rules at the time of registration.

D. General instructions for EQA participant blood centres

1. Participant blood centres are advised to read the instructions of EQA participation thoroughly before undertaking testing of the samples/reagents.

2. All the respective formats must be duly filled in before sharing back the same to the PT provider.

3. EQA participants are advised for strict adherence to turnaround time mentioned for each test event.

4. All the tests on given samples should be as per their respective SOPs and no additional/confirmation tests to be carried out.

E. Criteria for preparation of EQA samples

EQA samples shall be identified and decided upon for each marker/test parameter/reagents by undertaking thorough characterization studies followed by confirmatory testing (identifying true positives for each test parameter/infectious disease and true negatives) using nationally approved diagnostic kits/test methods.

EQA samples shall be prepared following existing policies and current national guidelines. The EQA programme should be designed to assess each participating blood centre on the maximum number of tests, using the minimum number of samples.

1. Biological material can never be guaranteed to be free from infective agents, even when tested and found negative for markers of infection, such as HIV and hepatitis B.

2. EQA material should, therefore, be handled and disposed of in the same way as routine pathological samples.

3. Details of the potential risks of the material should be included with each set of EQA material and sent to EQA participants.

The PT provider blood centre shall provide the EQA participant a turnaround time of at least 4 to 6 weeks for completion of the EQA cycle (sample receipt to reporting of test results)

F. Frequency of EQA cycles for transfusion transmitted infection and immunohematology

At least three test events for both TTI and IH should be distributed each year in order to permit an adequate assessment of laboratory procedures and practices and to gather sufficient data for cumulative performance monitoring.

G. Name/type of marker/test for TTI and IH

G.1. Transfusion transmitted infections (TTI):

1. Antibodies to HIV1&2
2. Hepatitis B surface antigen
3. Antibody to hepatitis C
4. Parasites of plasmodium vivax and P. falciparum
5. Antibody to treponema pallidum

G.2. Immunohematology (IH)

1. ABO grouping (cell and serum grouping)
2. Compatibility testing (crossmatching)
3. Rh(D) typing
4. Antibody screening
5. Antibody identification
6. Red cell phenotyping
7. Direct antiglobulin test (DAT)
8. Hemoglobin

For transfusion transmitted infections - The PT provider blood centre must ensure that EQA samples for each infectious marker (HIV/HBsAg/HCV/Syphilis/Malaria) must contain confirmed true positive and confirmed true negative samples for that particular marker and must be negative for the rest of the markers.

For example: anti-HIV EQA sample must be confirmed true positive only for anti-HIV and must confirmed true negative for HBsAg/HCV/Syphilis/Malaria.

It is recommended that the PT provider blood centre must provide at least 5 to 8 EQA samples of 1.5 mL each.

For immunohematology - The PT provider blood centre will provide a minimum of two EQA samples for ABO and RhD typing, to give variation in blood groups and allow transcription or transposition errors to be identified.

At least one serum sample for crossmatching (and antibody screening and identification, if included) containing atypical antibodies of potential clinical significance.

H. Acknowledgement, receipt and storage of EQA samples/reagents by EQA participant

1. EQA participant must duly acknowledge the receipt and status of samples/reagents to the PT provider as per the prescribed format.

2. PT provider must ship the samples/reagents at appropriate temperatures (2 to 8 0C), enabled with data logger facility if possible (or temperature monitoring labels as used in oral polio vaccine vials called as vaccine vial monitor).

3. The samples/reagents upon receipt by the EQA participant shall be carefully assessed for cold chain maintenance.

4. Leakages, and damages if any to the vials, the same must be reported within 24 hours to the concerned proficiency testing (PT) provider.

5. If all the items are received satisfactorily, necessary documentation must be done immediately by the EQA participant, and the samples/reagents must be stored at recommended temperatures for further usage.

6. Upon satisfactory receipt of EQA samples, it should be stored at their recommended temperature.

I. Stability of EQA Samples

Samples/reagents identified for EQA rounds must be validated for stability studies by the PT provider, before the scheme becomes fully operational to ensure that samples are fit for use when they arrive in participating blood centres.

The stability of samples can be tested by:

1. Sending material to one or more distant participating blood centre which then return it for re-testing.

2. Leaving samples unopened, at ambient temperature, for the length of time that specimens are expected to spend in the postal system, and then re-testing.

3. Results on re-testing should be comparable to the original results and the samples should remain sterile.

J. Additional processing and serological testing of blood grouping samples/reagents for sample suitability and stability:

1. Once the EQA samples/reagents have been finalized by the PT provider, it is important that it is fully characterized.

2. All serum/plasma samples, including those intended to contain no antibodies to red cell antigens other than ABO (inert), should be tested by:
   a. All indirect antiglobulin testing technologies commonly used by participating blood centre
   b. An enzyme technique at 37 °C
   c. Direct agglutination at 4 °C

3. Atypical antibodies which need to be determined in the EQA exercise should be positively identified. The presence of other antibodies to common red cell antigens should be excluded by obtaining a negative reaction with cells having homozygous expression of the required antigen.

4. Donor red cells should be phenotyped for antigens corresponding to those antibodies in the test samples.

5. The presence of antibodies of which the scheme is unaware may cause problems if unexpected (but not necessarily incorrect) results are submitted by participating blood centre. If the problem is not recognized, participants will be penalized unfairly; even if it is recognized, some or all the exercise will have to be withdrawn from performance monitoring. Such problems will prevent the aims of EQA being achieved and may cause the EQA scheme to lose credibility with participating blood centre.

6. Once specificity has been established, it is necessary to dilute antibodies to achieve the reaction strength required to achieve the aims of the exercise. Inert plasma should be used for diluting antibody-containing sera; however, care must be taken to match for ABO group and to consider the effects of dilution on all aspects of the exercise. It is advisable to make and test small volumes of trial dilutions before diluting the bulk of the material.

7. When the specificity and reactivity of the material have been established, the bulk material can be pooled and processed according to the sample presentation required, for example:
   a. Whole blood
   b. Red cells suspended in Alsever's solution
   c. Separate serum samples.

K. Packaging, labelling and transport of EQA samples

1. The transport of infectious substances is regulated under the United Nations regulations for the transport of dangerous goods.

2. Proficiency test items should be classified to determine the appropriate type of packing and transport.

3. The package should be labelled as Category B, UN 3373.

4. Packaging should follow packing instructions P650. Infectious samples/reagents require a triple package, as illustrated in Fig. 4 below.

5. The type of packaging, classification of the material, marking and labelling, and documentation of infectious substances must follow national and/or international packaging and shipping regulations. The type, number, and volume of specimens to be distributed will influence the size of the package.

6. The outer container should be labelled appropriately, for example, "perishable biological material", and a specified set of documents describing the content, intended use and brief objective of the EQA programme should accompany the shipment, as per national recommendations and international regulations.

   A. **Packing list**: A packing list is essential if more than one PT round is included in the distribution and not all participants have the same requirements.

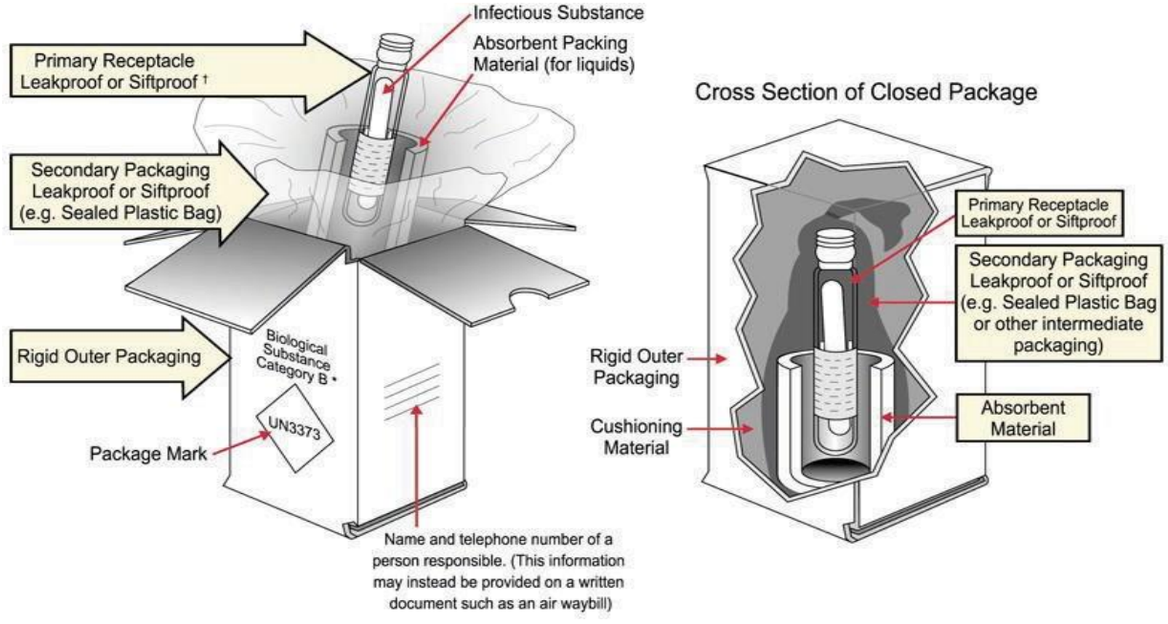
   B. **Address labels**: Address labels should be printed from an up-to-date record of participants' contact names and addresses.

   C. **Instruction sheet**:

      a. Participants should receive adequate instruction regarding proficiency test items characteristics and handling requirements, how to record results, where and how to return results, and the PT round closing date.

      b. Relevant notes and instructions should also be given about infectious agents for which proficiency test items have been screened, other hazard warnings, storage requirements, recommended method for disposal, etc.

Fig. 4: Triple package for transporting biological substances, Category B - CDC classification.



1. Materials should be packaged in a fiberboard box or plastic box to prevent breakage during transportation.

2. Glass or plastic vials containing lyophilized material should be packaged with cushioning material to prevent breakage during transport, and with enough absorbent material to prevent leakage during transport.

3. Vials containing liquid material should be packaged in a leak-proof container and with sufficient absorbent packaging to absorb the entire volume of liquid.

4. Primary and secondary containers should be leak-proof.

5. Stabilized sample preparations should be transported under recommended conditions (for example, frozen for sera, or in a cool box).

6. The international shipment or in-country transportation of proficiency test items must comply with the national and/or international regulations.

7. A courier agent with the required competencies for transporting the proficiency test items should be engaged to work with the EQA organizer to determine optimal arrangements for dispatch and timely delivery of the items, including notifying participants when the proficiency test items are shipped.

8. It should be ensured that local courier/postal services are aware of any recommendations for the safety of the courier and their environment, and, if applicable, of universal precautions for the use of dry ice and the transfer of dangerous goods and/or infectious substances.

9. Stability studies to control for the effect of transportation on the quality of proficiency test items, mimicking the transport conditions and examining possible effects on the specimens should be undertaken and any effects recorded.

L. Documentation of EQA test results/test reports:

The PT provider blood centre and EQA participant blood centre shall document and record the test results/test reports in MS Excel spreadsheet for statistical analysis and reporting.

M. Organizing one EQA cycle pilot study for TTI and IH

1. A pilot study should be undertaken to test the structure of the EQA scheme, proposed methods of operation and design of exercises. The purpose of a pilot study is to identify any unforeseen logistical problems and provide solutions before scaling up the operation of the scheme and offering formal larger participation.

2. The design of the format for EQA exercises should be based on the information collected from potential participating blood centre. Systems will need to be developed for:
   a. Registration of participating blood centre
   b. Preparation and distribution of exercises
   c. Collation and analysis of results and other information from participating blood centre
   d. Performance monitoring.

3. One EQA cycle pilot study should be undertaken for at least ten government licensed blood centres. These blood centre should be selected to represent different groups of participants in terms of their distance from the organizing centre, the size of their blood centre or the techniques they use.

4. The pilot study should include the following steps.

5. Establishment of an information management system to:
   a. Hold details of participating blood centre
   b. Collate and analyze data
   c. Generate reports

6. Serological testing of material for:
   a. Initial suitability
   b. Validation of sample stability throughout the duration of the exercise
   c. Determination of the expected results on the closing date of the exercise

7. Processing, dispensing, and labelling of the exercise material and preparation of the required documentation.

8. Distribution of the exercise to selected blood centre and to a recognized, competent laboratory for the confirmation of expected results.

9. Analysis of the results and preparation of exercise reports.

10. Internal trials of the performance monitoring system (this does not need to be shared with participants at this stage).

11. Monitoring of problems in areas such as the preparation of exercise material, sample stability, clarity of instructions, return of results, use of results forms and suitability of the exercise format.

12. Analysis of feedback from participating blood centre

13. Implementation of changes required to solve any problems that have been identified.

14. Review of recurrent operating costs.

15. Participating blood centre should be asked to comment on any problems they encountered and to make suggestions for improvement. At the completion of the pilot study, a review should be made of problems experienced in the operation of the scheme and comments from participants. Adjustments can then be made to the design of the scheme and to the estimate of operating costs, if necessary.

N. Submission of results and turnaround time

1. Participant blood centres are advised to read the instructions of EQA participation thoroughly before undertaking testing of the samples/reagents.

2. Participant blood centres should handle proficiency test/samples/reagents for testing in the same way as they handle samples/reagents that are routinely tested in their laboratory or testing site.

3. Samples/reagents received by participating EQA blood centres for specific markers/ tests must be tested as per their current standard operating procedures being practiced at the respective blood centre by trained and experienced laboratory personnel.

4. Strict adherence to turnaround time as per the timelines given by the PT provider is must.

5. Fill up the test results and prepare the EQA round reports as per the specific formats provided by the PT provider.

6. Leftover samples/reagents must be stored at recommended temperature by the PT provider.

7. Upon successful receipt of test results and reports from the respective EQA participating blood centre, the "PT provider shall compile the test results received from all the participant blood centres, analyze the test results and report using appropriate MS Excel spreadsheet template or validated statistical software for both individual blood centre and for the group of EQA participating blood centres for that EQA round".

8. The outcome of the EQA round is reported back by the PT provider to the respective EQA participant blood centres in a confidential and timely manner.

9. Appropriate time bound corrective and preventive actions if any for a specific blood centre is conducted in a time bound manner.

10. The PT provider shall ensure that the EQA round is initiated, conducted, closed, monitored, and take necessary feedback in a time bound manner.

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Chapter 5

Quality Management Systems (QMS) for EQA providers and participants

Chapter 5

Quality Management Systems (QMS) for EQA providers and participants

Quality management system (QMS) comprises of organizational structure, responsibilities, procedures, processes, and resources for the EQA programme. Implementing appropriate QMS in blood centres is essential to ensure safe blood. The objective of QMS is to continuously improve the quality of processes and products related to blood donation, production, and transfusion. QMS covers all aspects of the EQA programme, from receipt of EQA samples to release of EQA test reports.

To achieve consistency, all staff should always implement approved standard quality procedures and work instructions. QMS provides a framework for the collection, processing, testing, distribution, and timely reporting of EQA test results.

Continuous quality monitoring by conducting periodical internal and external audits is essential to compare current and expected quality level and to identify opportunities for improvement. It is suggestive that all blood centres have themselves certified for an appropriate QMS like ISO 15189:2022. Additionally, ISO standard 17043:2023, mentions about general requirements for the competence and impartiality of proficiency testing (PT) providers and consistent operation of all proficiency testing schemes. It is recommended to adhere to the standard practices prescribed in the standard while executing proficiency testing by proficiency testing providers (PTPs).

A. An ideal QMS for blood centre shall have the following components

1. Organization's quality policy and objectives
2. A quality manual
3. Risk assessment plan
4. Procedures, work instructions, and records
5. Personnel and training
6. Equipment calibration and maintenance
7. Internal quality controls
8. Participation in EQA
9. Information and data management

10. Validations (methods/processes)
11. Quality analysis (control charts)
12. Customer satisfaction
13. Environmental monitoring
14. Equipment calibration and maintenance
15. Biomedical waste management
16. Corrective and preventive action(s)

B. Risk based assessment of blood centres

The risk-based assessment shall be included in the planning to implement a quality management system in blood centres, given that it makes it possible to identify, characterize, and quantify the potential problems associated with the processes developed to classify them afterwards according to their importance and to elaborate an action plan for each of them. Dynamic risk management tools like Failure Mode and Effects Analysis (FMEA) can be generated (matrix) from the impact or severity of the failure, the probability of occurrence, and the detection capacity. The information obtained from the analysis can be used to calculate the risk priority number (RPN) whose value indicates if the process is under control or if some measures must be incorporated to keep the process under control. The results obtained are expected to demonstrate that knowing the Risk Priority Number of each activity in a planning stage favors the design of a preventive and corrective action plan well in advance.

B.1. Key objectives of risk assessment of blood centres

1. Identify the risks of each activity and quantify them.
2. Analyze the causes associated with identified risks.
3. Design a plan of recommended action for each risk.

C. Standard operating procedures and work instructions

SOPs and WIs are documents that help ensure consistency and quality in a company's processes. The main difference between the two is their purpose and level of detail.

SOPs are top-level documents that describe what actions to take in certain circumstances. They create detailed guides to help employee(s) complete tasks in the most efficient manner.

Work instructions are the lowest-level documents. They provide detailed instructions on how to perform procedures. They outline the proper methods for carrying out tasks, with detailed explanations of the tasks that must be completed.

SOPs are about reinforcing a positive top-down structure that ensures consistency, quality, and control. Work instructions should be developed as needed alongside any new task or function added to the workplace. SOPs serve to ensure compliance with internal policies

and regulations, while work instructions provide detailed instructions on how to perform a specific task.

D. Internal quality control

The laboratory shall have a procedure for monitoring the validity of EQA results. The resulting data shall be recorded in such a way that trends and shifts are detectable and, where practicable, appropriate statistical techniques such as control charts shall be applied to review the results. This monitoring shall be planned and reviewed.

1. The laboratory shall have an IQC procedure for monitoring the ongoing validity of EQA, according to specified testing SOP, that verifies the attainment of the intended test results while maintaining both quality and validity.
    a. The laboratory SOP should also allow for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method. To enable this, the laboratory SOP should avoid lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both.

    b. The use of third-party IQC material should be considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer.

2. The EQA participant laboratory shall select IQC material that is fit for its intended purpose. When selecting IQC material, factors to be considered shall include:
    a. Stability with regard to the properties of interest.

    b. The matrix is as close as possible to that of test samples.

    c. The IQC material reacts to the examination method in a manner as close as possible to routine test samples.

    d. The IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near decision limits and when possible, covers the measurement range of the examination method.

3. If appropriate IQC material is not available, the participant laboratory shall consider the use of other methods for IQC. Examples of such other methods may include:
    a. Trend analysis of routine test results, for example, with moving average of test results, or percentage of samples with results below or above certain values or associated with a diagnosis.

    b. Comparison of results for test samples on a specified schedule to results for test samples examined by an alternative procedure validated to have its calibration metrologically traceable to the same or higher order references as specified in ISO 17511.

    c. Retesting of retained test samples.

4. IQC shall be performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the test from an erroneous result.

5. The resulting data shall be recorded in such a way that trends and shifts are detectable and, where applicable, statistical techniques shall be applied to review the results.

6. IQC data shall be reviewed with defined acceptability criteria at regular intervals, and in a timeframe that allows a meaningful indication of current performance.

7. The laboratory shall prevent the release of test results in the event that IQC fails the defined acceptability criteria.
   a. When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain significant errors, the results shall be rejected and relevant test samples re-examined after the error has been corrected.

   b. The results from test samples that were examined after the last successful IQC event shall be evaluated.

E. Nonconforming work

The laboratory shall have a process for when any aspect of its laboratory activities or examination results do not conform to its own procedures, quality specifications, or the user requirements (for example, equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The process shall ensure that:

1. The responsibilities and authorities for the management of nonconforming work are specified.

2. Immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory.

3. Testing is halted, and reports withheld when there is a risk of erroneous test results.

4. An evaluation is made of the significance of the nonconforming work, including an impact analysis on test results.

5. A decision is made on the acceptability of the nonconforming work.

6. When necessary, test results are revised, and the user is notified.

7. The responsibility for authorizing the resumption of work is specified.

8. The laboratory shall implement corrective action commensurate with the risk of recurrence of the nonconforming work.

9. The laboratory shall retain records of nonconforming work and actions.

F. Key performance indicators of provider and participant laboratories for quality monitoring of EQA

1. Design of the EQA
2. Turnaround time
3. Infrastructure, accommodation, and environment
4. Sample handling and management
5. Good laboratory practices
6. Good documentation practices
7. Skilled and trained human resource
8. Functional equipment with valid calibration and maintenance records
9. Internal quality control
10. Universal biosafety practices
11. Biomedical waste management practices
12. Continual training program
13. Monitoring, evaluation, and feedback

G. EQA records, documentation and quality assurance

Quality assurance personnel assess each step of the transfusion process. They perform audits, monitor quality measures, report incidents, and ensure all areas of the blood centres are operating in compliance with national guidelines, prescribed standards, and applicable government regulations. There would be proper procedures for data and document control at all levels of work undertaken with traceability

H. Data entry, statistical analysis, and evaluation

EQA reports act as an important feedback tool in external quality assessment (EQA). Their main role is to score laboratories for their performance in an EQA round. The most common scores that apply to quantitative data is Z score. To calculate these scores, EQA providers need to have an assigned value and standard deviation for the EQA assessment. Both assigned values and standard deviations can be derived statistically. When derived statistically, different anomalies against the normal distribution of the data must be handled. Z scores are calculated by using the formula as below:

$$Z = \frac{x - \mu}{\delta}$$

Where, x is the participants result,
μ is the EQA participants population mean
δ is the EQA participants population standard deviation

H.1. Recording formats

1. Participants should be provided with a recording format to record results. The forms should be as simple as possible to minimize confusion in entering and reading the data and to facilitate data entry.

2. Control data such as participant reference number, PT round number, proficiency test item(s) number(s), test method, etc., may be pre-printed if facilities permit, or can be completed by the participant.

3. Pre-printing information will reduce transcription and omission errors. The participant's unique identifier should be placed on all protocol forms; this should be confidential to the participant and the EQA centre and not divulged to any third party.

4. The units or status in which results are reported should be clearly shown.

5. The protocol sheet may also include a list of codes (for example, for methods and/or reagents); participants should enter the appropriate code for the method and/or reagent, and results of the measurement, into the protocol form, and should have space to note problems or other comments.

6. The mechanisms by which results may be returned to the organizing centre (for example, post, email) should also be shown in the protocol form.

7. Return log: It is essential to record the date of reception of each report at the EQA organizing centre, and if appropriate, the method of return, for example, email or by post.

8. PT round record: For retrospective control, the blood centre should have a standard hard copy or electronic record form, which should be completed for each dispatch. Any problems encountered should be noted on the PT round record, which should be signed and dated by the member(s) of staff completing each item.

9. To ensure that participants receive their reports promptly, the methodology for data entry and analysis should be established and evaluated by the PT provider / EQA organizer.

10. Data shall be entered into an MS Excel spreadsheet for ease of statistical calculations and analysis.

11. If data are being handled in any manner that requires transcription from one form to another, a procedure to minimize the risk of transcription errors needs to be in place.

12. The format of the PT round reports will depend on the method of analysis and computing facilities available at the PT provider/EQA organizing centre.

13. The PT round to which a report refers should be clearly shown; the report should indicate performance for each analyte being studied, and the deviation of the laboratory results from the consensus value and from the appropriate method (instrument) consensus mean.

14. Individual reports for each participant should show their performance in relation to the total group of participants (without indicating any other laboratory information) along with an assessment of their performance. If multiple page reports are produced, each page should be identified as belonging to the report.

15. Small programmes with limited resources can send the same summary report to all participants with individual notes attached to unsatisfactory performers.

16. If there are blood centre that demonstrate unacceptable performance, the report must recommend that these are investigated, and appropriate corrective action be taken, or advice sought.

17. Long-term performance for each analyte should be provided when appropriate.

18. Reports including the results of the evaluation should be sent by email or post.

19. The confidentiality of information should be assured.

20. The PT provider must essentially maintain a well-organized record system including for PT round records, data analysis and EQA participant performance.

21. It will be necessary at intervals to select information to be included in reports such as the annual report to participants, reports to expert committees and steering committees overseeing performance, etc.

22. It is recommended that the EQA test results must be well documented and maintained to avoid any discrepancy between the EQA participating blood centre and the organizing centre.

I. Test conformity

Every EQA sample tested accurately will be awarded "1" point for those EQA blood centres conforming accurately and "0" will be awarded for those EQA blood centres NOT conforming accurately including Grey Zone (Equivocal) with the PT provider blood centre results as depicted in the following table.

S. No	EQA Sample ID	PT Provider Blood Centre Results	EQA participant blood centre results	Score on conformity / Non-conformity
1	PTSR/ ABC/2023/02/ TTI/03	Positive	Reactive	1
			Grey Zone	0
			Non-reactive	0
2	PTSR/ ABC/2023/02/ TTI/07	Negative	Reactive	0
			Grey Zone	0
			Non-reactive	1

Accuracy is calculated using the following formula:

II. Accuracy in (%) = $\dfrac{\text{Total number of correct results x 100}}{\text{Total no of panel samples}}$

III. Scoring of EQA test results: (transfusion transmitted infections)

i. Accuracy of test results (25%). Accurate filling up of all the information related to the test kit, its reagents, consumables, and accessories, etc., as required by the respective formats/annexures.

ii. Inadequate/wrong test kit information in the forms/annexures will cause loss of scores and affect the overall outcome of an individual EQA participant blood centre.

iii. Upon satisfactory performance conforming the status of EQA test samples with that to the PT provider blood centre for the specific test event/survey (TTI) as per the current standard operating procedure being followed by the respective EQA test participant blood centre (75%).

iv. Overall performance score for transfusion transmitted infection (A+B) = 25 + 75 = 100 marks.

III. Part A: EQA test kit information - 25 marks

Test Kit Information	Maximum Marks
Name of the kit	5
Name of the manufacturer	5
Date of manufacturing	5
Date of expiry	5
Batch/lot number	5

Fig. 5: Numerical scoring scheme for TTI test kit information for EQA participants by PT provider.

III. Part B: EQA test results score - 75 Marks

Test Parameter	Maximum marks
HIV	15
HBsAg	15
HCV	15
Syphilis	15
Malarial parasite	15

Fig. 6: Numerical scoring scheme for TTI marker tests for EQA participants by PT provider.

IV. Scoring of EQA test results: (Immunohematology)

i. Accuracy of test results (25%). Accurate filling up of all the information related to the test kit, its reagents, consumables, and accessories, etc., as required by the

respective formats/annexures.

ii. Inadequate/wrong test kit information in the forms/annexures will cause loss of scores and affect the overall outcome of an individual EQA participant blood centre.

iii. Upon satisfactory performance conforming the status of EQA test samples with that to the PT provider blood centre for the specific test event/survey (IH) as per the current standard operating procedure being followed by the respective EQA test participant blood centre (75%).

iv. Overall performance score for Immunohematology (A+B) = 25 + 475 = 500 marks

IV. Part A: EQA Test kit information - 25 marks:

Test Kit Information	Maximum Marks
Name of the kit	5
Name of the manufacturer	5
Date of manufacturing	5
Date of expiry	5
Batch/lot number	5

Fig. 7: Numerical scoring scheme for IH test kit information for EQA participants by PT provider.

IV. Part B: EQA Test Results Score - 475 Marks

Test Parameter	Maximum Marks
Test Donor Identification	50
Donor Hemoglobin	25
Blood Group	150
Compatibility Testing	
Donor Identification	75
Compatibility Testing	75
Comments	
Direct Coombs Test	50
Indirect Coombs Test	50

Fig. 8: Numerical scoring scheme for immunohematology tests for EQA participants by PT provider.

I. Turnaround time, feedback, and monitoring by the PT provider

1. Ensure timely generation and reporting of EQA reports to its participants.

2. Gather periodic (immediately after every EQA round) feedback about the programme from the participants.

3. Take necessary corrective, preventive actions, gap analysis and guide the participants as and when concerns are identified or raised from the side of EQA participants.

J. Out-of-specifications test results, root cause analysis, Corrective and Preventive Action

i. The objective of an investigation into out of specification results is to identify the root cause and take appropriate corrective and preventative action. A full-scale investigation should include a review of all the steps involved in the EQA programme beginning from EQA sample receipt to reporting of EQA test results.

ii. Corrective actions are taken in response to non-conformities or perceived non-conformities within the operation of EQA programme. Preventive actions are taken to reduce the likelihood of problems occurring or reoccurring.

iii. Root cause analysis (RCA) is a systematic approach used for problem solving aiming at identifying the root causes of a non-conformity (NC).

J.1. Root cause analysis is a process of five major steps involving the following

1. Documentation of the non-conformant (NC) proficiency testing serology (PTSR) result.

2. Investigation of man, machine, method, material, and environment involved in the NC.

3. Documentation of the root cause analysis.

4. Closure by implementing necessary corrective and preventive actions.

5. Monitoring and follow-up for a specific period depending on the type of NC.

J.1.1. Preliminary verification such as verification of

1. Data transmission or transcription

2. Quality controls

3. Calibration and maintenance of the instrument

4. Qualification of the instrument and validation of the assay and reagents

5. Alarms of the instrument

6. Expiry date and integrity of the reagents

7. Storage conditions of samples and reagents

With a view to facilitating root-cause identification, and wherever needed a deeper investigation should be performed.

J.1.2. Investigations shall include

1. Prints/logs/records of the assays/instruments used
2. Prints/log/records of the results obtained on the same run and/or day
3. Prints/log/records of the results obtained with the same batch of reagent, on the same instruments
4. Prints/log/records of results of the internal and external quality control obtained on the same run/day
5. Work plans
6. Computer logs/records.

J.1.3. Corrective and Preventive Action(s) process includes

1. Identifying and defining the problem
2. Root cause analysis
3. Preparing an action plan
4. Implementing the action plan
5. Following up on the action plan

K. Archiving of records

1. All information on PT rounds, participants and all quality documents should be archived either in hard copy or electronically as specified by national regulations.
2. EQA participants should also maintain records of their EQA performance.
3. It is recommended that the individual records generated by both PT provider and EQA participants be archived for a minimum period of one year (serology) to two years (molecular).

References:

1. https://ieomsociety.org/proceedings/2022india/58.pdf (Development of Risk Assessment Framework for Blood centre Operations During Emerging Infectious Diseases like Covid-19).
2. https://www.nabl-india.org/wp-content/uploads/2019/02/NABL-112_Issue-No.-04.pdf.

3. Guidelines for national External Quality Assessment Scheme For STI/TTI(S) Serology, 2nd Edition 2018, Royal Centre for Disease Control, Ministry of Health Royal Government of Bhutan, Thimphu Bhutan.

4. TRANSFUSION MEDICINE TECHNICAL Manual, Third Edition 2023, Ministry of Health & Family Welfare, Government of India.

Chapter 6

Information management system and education

Chapter 6

Information management system and education

1. The requirements for information processing will depend on the scale and scope of the programme participated by each blood centre. It is possible to operate an EQA programme without any information technology by manually maintaining registers/technical files and spreadsheets for all the critical and routine operations. However, the use of a computerized system makes essential tasks such as producing results forms much easier and allows for a more complex analysis of results.

2. It is essential to be able to: create a database (manual or electronic) of the details of participating laboratories, including contact names, addresses, confidential registration codes and tests to be assessed.

3. Prepare EQA exercise documentation, including letters, instructions, results forms, and address labels; record the results from participating laboratories, using confidential registration codes; perform basic analyses, including comparison of each individual participating laboratory's results with the expected results and the collation of the overall results.

4. Analyze results within defined groups, such as laboratories using a particular statistical technique.

5. Prepare reports with the expected results, the individual results of each participating laboratory and other overall analyses or comments.

6. It is desirable to be able to: report data in different formats, such as histograms and scatter charts; generate scores for performance monitoring and cumulative scoring; search the database using specified criteria.

7. Procedures should be established and implemented for always protecting the integrity of data. Appropriate information technology systems and automation should be maintained to ensure the proper functioning and be provided with environmental and operating conditions necessary for maintaining the integrity of data.

8. Computer programmes and routines shall be adequately protected to prevent access, alteration, and destruction by unauthorized persons.

9. An alternative system that ensures continuous operation shall be available if computerized data and computer functions are unavailable. The alternatives systems should be tested periodically.

10. Using Microsoft Excel spreadsheet, analytical data management will be devised after identifying the key indicators for capturing EQA data with the following in perspective.
    a. Understanding user requirement specifications (URS) and workflow.
    b. Develop and digitize test results and reporting formats.
    c. Develop pathway for performance monitoring and evaluation.
    d. Provision for preparation of infographics.

11. There will be a website and electronic data submission.

12. The submission of data should be made within a specified deadline.

References:

1. National Standards for Blood Centres and Blood Transfusion Services, 2nd Edition, 2022, Ministry of Health & Family Welfare, Government of India.

2. Establishing External Quality Assessment Programmes for Screening of Donated Blood for Transfusion – Transmissible Infections Implementation Guide WHO, 2016.

3. Guidelines for national External Quality Assessment Scheme For STI/TTI(S) Serology, 2nd Edition 2018, Royal Centre for Disease Control, Ministry of Health Royal Government of Bhutan, Thimphu Bhutan.

Chapter 7

Trainings and workshops for EQA provider and EQA participant

Chapter 7

Trainings and workshops for EQA provider and EQA participant

1. Training of the state representing blood centre and/or participating blood centre is very important during different stages of operations specially in how to do the testing and its documentation. All personnel shall have training specific to blood centre operations and QMS.

2. The staff members should be given induction training soon after the appointment. It should include training and acclimatization in different areas/sections of the blood centre or organization.

3. The training records should be maintained, updated, and reviewed.

4. It shall be the responsibility of the management to ensure that the personnel in blood centre activities are adequately trained for the tasks undertaken and receive initial and continual training relevant to their needs.

5. There shall be a continuing education programme for staff at all levels and all staff should be encouraged to participate in CME programme at regular intervals

6. Employees shall be trained to prevent adverse incidents and/or contain the effects of and report adverse incidents.

7. Blood centre employees shall be trained in other regulatory and safety issues of blood centre like biomedical waste management and fire safety, etc.

8. Competency test of all technical staff may be conducted annually in term of written/oral/ practical tests to ensure the reliability of their performance.

9. The proficiency of technical staff (Each month one or more technical staff to be selected) can also be evaluated by reviewing the quantity and quality of work performed by one or more technical staff each month. Evaluation of all technical staff in one year to be done confidentially (without their knowledge). This can assess the candid skill of each technical staff.

10. The competency of each person to perform the assigned tasks shall be assessed following training and periodically thereafter.

11. Retraining and reassessment shall be undertaken when necessary.

12. The PT provider(s) and/or SRBC and the EQA participant(s) shall identify gaps and needs and regularly conduct on a periodic basis general and specific training(s) and workshops for various categories of staff for its proper resolution which could be done online.

13. After the training and workshop there shall be a mechanism of feedback and performance evaluation.

14. There should be uniformity among all the EQAS providers with respect to documentation.

References:

1. National Standards for Blood Centres and Blood Transfusion Services, 2nd Edition, 2022, Ministry of Health & Family Welfare, Government of India.

2. Standards for Blood Banks and blood Transfusion Services, National Aids Control Organization, Ministry of Health & Family Welfare, Government of India, New Delhi, 2007.

3. Establishing External Quality Assessment Programmes for Screening of Donated Blood for Transfusion – Transmissible Infections Implementation Guide WHO, 2016.

4. Guidelines for national External Quality Assessment Scheme For STI/TTI(S) Serology, 2nd Edition 2018, Royal Centre for Disease Control, Ministry of Health Royal Government of Bhutan, Thimphu Bhutan.

Chapter 8

Monitoring and evaluation

Chapter 8

Monitoring and evaluation

1. Performance monitoring involves setting standards of acceptable performance and identifying participating laboratories that fail to reach these standards.

2. The EQA programme's objective in identifying unsatisfactory performance is to offer advice and support to assist theselaboratories in improving their performance.

3. The need for monitoring of the performance of individual laboratories – and the initiation of appropriate corrective and preventive action in cases ofpersistent unsatisfactory performance – will be determined by the placeof EQA within the existing national quality system.

4. The first step in performance monitoring is to define standards of satisfactory, unsatisfactory and, possibly, "borderline" performance. The potential clinical significance of errors must be considered whendefining standards of acceptable performance.

5. When establishing an EQA programme, it is therefore advisable to operate the programme for a defined period, such as one year, with initial follow-up of errors as described below, but with no formal performance monitoring or scoring. During this time, information can be gathered on current levels of performance within each category of testing, such as rapid or test kit performance for TTI. This process will allow realistically achievable standards of acceptable performance to be set whilst ensuring that major errors, such as a false negative TTI result, are defined as unsatisfactory.

6. For performance monitoring, there should be no differentiation between incorrect results due to technical or procedural errors (such as the incorrect transcription of results or the transposition of exercise materials), although they may be analyzed and reported separately.

7. An incorrect result in the blood transfusion laboratory or hospital blood centre can have the same serious consequences, regardless of the reason for the error. For this reason, it is advisable to base performance monitoring – and numerical scoring, if used – on interpretations made rather than on serological reactions recorded for each test. Along with incorrect results, non-return or late return of results also constitutes unsatisfactory performance.

8. Performance standards should be agreed independently by the advisory committee, which includes representatives of participating laboratories and experts in the field. The advisory committee should also be responsible for regularly reviewing the definitions of unsatisfactory performance and making changes, where necessary, to reflect improvements in overall performance.

9. Scoring systems can be developed to allow the performance of individual laboratories to be monitored. While such scoring systems can objectively show what progress is being achieved, scoring can have the disadvantage of causing laboratories to collude or "cheat" for fear of obtaining an inadequate score. Such behavior severely limits the value of EQA programme participation. Therefore, it is important for the EQA programme provider to emphasize, to participating laboratory staff, their supervisors and their heads, the importance of non-punitive approaches to EQA performance.

10. A scoring system using penalty points is easiest to weight for clinical significance and to use for the identification of unsatisfactory performance on a cumulative basis. Scoring can be "weighted" to reflect the potential clinical significance of errors made. The scoring system should be determined up front and communicated to participating laboratories as part of the EQA programme information manual.

11. Cumulative scores can be used to identify persistent unsatisfactory performance as well as laboratories with "borderline" performance. Once the system is established, cumulative scores should be given with each exercise report. If this is not possible, cumulative scores can be provided for each laboratory in an annual summary to show trends in individual performance.

A. Follow-up of unsatisfactory performance

1. Any follow-up actions by the EQA programme should comply with the procedures laid down by the advisory committee. While it is the role of an EQA programme to perform follow-up actions, the extent of these interventions should be documented and consistent with the resources available to the EQA programme provider. For example, an initial contact could be made by the EQA provider to determine possible causes of error and offer advice.

2. If the EQA programme provider's interventions yield no subsequent improvement in performance, a letter should be sent to the head of the laboratory to report the situation, formalize the advice that has been offered and suggest possible solutions. Procedures should be put in place to ensure that, once a laboratory becomes an unsatisfactory performer, its progress is then monitored until consistent satisfactory performance is achieved.

3. Programme personnel should be non-judgmental and constructive regarding unsatisfactory performance. Any advice offered should be evidence based and in line with national standards or guidelines, where these exist.

   Examples of severe errors include false negative results for any markers or multiple false positive results, failure to identify an intentional clerical error or sample mix-up. Options for ongoing assistance may include:

   a. providing specific, long-term, and recurrent advice on improvement opportunities
   b. providing additional EQA exercise material for troubleshooting
   c. providing hands-on laboratory training
   d. facilitating a supervisory visit or audit at the participating laboratory to identify deficiencies, including communication with the laboratory's head

4. The programme provider's ability to undertake these activities will depend on the resources allocated to them. The advisory committee should advocate strongly that these resources be provided, as the benefit of participation in EQA can be maximized only when these support activities are available.

5. On an annual basis, a longitudinal review of performance of participating laboratories should be conducted. This will ensure that any participating laboratory with consistent problems from one EQA exercise to another is followed up adequately. To help monitor the performance of participating laboratories, the EQA programme provider may choose to keep a log of performance of participating laboratories in a logbook or spreadsheet for ease of review.

6. In the absence of any performance monitoring or follow-up by the EQA programme, a comparison of an individual laboratory's results with those obtained by other laboratories is a useful means of highlighting the need for improvement. This process can often raise standards with no intervention from an external source.

7. The main purpose of an EQA programme is to improve performance and to provide assistance to address any problems detected. Education should therefore be inherent in all activities of an EQA programme it can be provided to laboratories on an individual basis as well as to all participating laboratories and other relevant professionals.

8. The programme has a particularly important educational role regarding errors made in EQA exercises by individual participating laboratories. When resources are available, EQA programme personnel can help laboratories identify the root causes of errors and make suggestions for changes in practice and procedures to prevent their recurrence. Errors in EQA exercises may be due to specific technical issues; however, apparently simple errors, such as transcription errors resulting in the recording of an incorrect TTI result, can be indicative of wider problems and deficiencies in a laboratory's quality system.

9. Education can be provided more widely in the form of reports on the overall performance of different techniques and technologies, which provide specific learning points on best practice. Once a programme is well established it may also be possible, with the help of the advisory committee, to organize an annual scientific meeting or a workshop for participating laboratories to address issues highlighted by the EQA exercises.

10. The programme provider should, where possible, communicate information generated by the programme not only to participants but also to a wider audience, by making presentations at local, national, and international meetings and through publications. EQA programme data can also be used as a basis for the writing and review of guidelines, making education accessible to all those working in the field of blood transfusion.

11. For an EQA programme to progress, it is important to monitor its development and evaluate its impact on a regular basis. This evaluation will also provide objective evidence in support of the programme's continuation and be crucial for its sustainability. Evaluation should be undertaken at least once a year and a report produced. For effectiveness of EQA programme the PT provider (s) shall follow up, take feedback, monitor reporting of test results within Turnaround Time (TAT).

B. Indicators

Process and outcome indicators that could be used to assess the successof a programme are listed below. It should be recognized, however, thatan improvement in relation to outcome indicators could be influenced byfactors not directly related to participation in an EQA programme, such asthe introduction of improved reagents or technology.

B.1. Process and output indicators

Examples of process and output indicators to be collected annuallyinclude:

a. frequency of advisory committee meetings and attendance.
b. proportion of participating laboratories.
c. proportion of laboratories returning results for each exercise –late and not at all.
d. number of laboratories registering for assessment of results onadditional tests.
e. number of problems recorded in relation to the operation of theprogramme.
f. number of complaints received and resolved regarding theoperation of the programme.
g. number of times exercise material fails to meet documented requirements.
h. positive feedback from participants.
i. troubleshooting and educational activities undertaken.
j. publications or presentations by the programme.

Outcome indicators

Examples of outcome indicators include:

1. Proportion of satisfactory and unsatisfactory performance change in overall scores, if applicable.
2. Trends in performance with the same material over several exercises.
3. Improvement or changes in testing used by participating laboratories.
4. Participating laboratories receiving accreditation

C. Impact

By analyzing outcomes, the impacts that the programme has over a period can be determined. For example, the proportion of satisfactory versus unsatisfactory performance or the change in overall scores can infer the reduction in erroneous results on donor specimens obtained and therefore the minimization of transmission risk; the improvement in testing practices can be translated into savings in costs and in technologist time. When stakeholders and those providing the funding for the programme learn of these impacts, continued funding of the programme becomes simple to justify.

D. Annual report

An annual report on the programme should be compiled and distributed to stakeholders, including ministry of health, advisory committee, and other interested parties, such as participating laboratories. Its contents may include:

a. summary of the exercises distributed.
b. summary of overall performance, highlighting any trends.
c. summary of process indicators.
d. learning points from the exercises.
e. details of developments and challenges within the programme.

f. overall assessment of the impact of the programme.
g. human and financial resources, if appropriate and applicable.

References:

1. WHO Manual for Organizing a National External Quality Assessment Programme for Health Laboratories and other Testing Sites, 2016.

2. Establishing External Quality Assessment Programmes for Screening of Donated Blood for Transfusion – Transmissible Infections Implementation Guide WHO, 2016.

3. Guidelines for national External Quality Assessment Scheme For STI/TTI(S) Serology, 2nd Edition 2018, Royal Centre for Disease Control, Ministry of Health Royal Government of Bhutan, Thimphu Bhutan.

Annexures

Format 1

Questionnaire format for participating institute/blood centre for National External Quality Assessment Programme.

Please complete this questionnaire regarding blood transfusion laboratory practice and general quality measures in your laboratory to enable the National EQA Programme to plan appropriate exercises and developments.

Part 1: Contact details

Name of blood centre:

Name of contact person:

Address:

Telephone number:

Fax number:

E-mail address:

Please tick the correct information for Part 2 to Part 7 regarding availability of resources for running of programme

Part 2: License

1. Is your institution/blood centre licensed under Drugs and Cosmetics Act?
   ☐ Yes ☐ No

Part 3: Human resource

1. Please provide information regarding availability of qualified and trained at your institution/blood centre:

Laboratory technician	☐ Yes ☐ No	If, yes, please provide staff strength
Laboratory assistant	☐ Yes ☐ No	If, yes, please provide staff strength
Data entry operator	☐ Yes ☐ No	If, yes, please provide staff strength
Clerical staff	☐ Yes ☐ No	If, yes, please provide staff strength
Quality manager	☐ Yes ☐ No	If, yes, please provide staff strength

Part 4: Accommodation and environment

1. Is there availability of a dedicated area for TTI in your institution/blood centre?
   ☐ Yes ☐ No
2. Is there availability of a dedicated area for immunohematology in your institution/blood centre?
   ☐ Yes ☐ No

3. Is there availability of a dedicated area for storage of samples, test kits and reagents in your institution/blood centre?
   ☐ Yes ☐ No

Part 5: Administrative and IT support

1. Is there availability of a computer in your institution/blood centre?
   ☐ Yes ☐ No
2. Is there availability of a printer in your institution/blood centre?
   ☐ Yes ☐ No
3. Is there availability of internet facility in your institution/blood centre?
   ☐ Yes ☐ No
4. Is there availability of 24/7 power back in your institution/blood centre?
   ☐ Yes ☐ No

Part 6: Equipment availability (dedicated for EQA programme)

1. Is there availability of a refrigerator (2 – 8 0C) in your institution/blood centre?
   ☐ Yes ☐ No
2. Is there availability of a deep freezer (-20 0C) in your institution/blood centre?
   ☐ Yes ☐ No
3. Is there availability of diagnostic test kits for immunohematology?
   ☐ Yes ☐ No
4. Is there availability of diagnostic test kits for TTI testing?
   ☐ Yes ☐ No
5. Are the equipment used for TTI testing and immunohematology functional with AMC/ CMC (including standby equipment)
   ☐ Yes ☐ No

Part 7: Quality system

1. Is there a staff training policy?
   ☐ Yes ☐ No
2. Is competency assessment undertaken for all laboratory staff?
   ☐ Yes ☐ No
3. Are written standard operating procedures (SOPs) in place?
   ☐ For all tests, procedures and practices
   ☐ For some tests, procedures and practices
   ☐ No
4. Is there a system for equipment calibration?
   ☐ Yes ☐ No
5. Is there a record of equipment usage, maintenance, and repair?
   ☐ Yes ☐ No
6. Are all reagents used according to the manufacturers' instructions?
   ☐ Yes ☐ No
7. Are all reagents validated in-house?
   ☐ Yes ☐ No

8. Are all reagents used within their expiry date?
   ☐ Yes ☐ No
9. Is there a mechanism for reporting and investigating errors?
   ☐ Yes ☐ No
10. Is there a mechanism for handling biomedical waste?
    ☐ Yes ☐ No

Format 2

National External Quality Assessment Programme
EQA participant registration form

EQA cycle code:	
Name of blood centre:	
Name of HOD/in-charge:	
Address for correspondence:	
Email ID* **Official email is preferable*	-
Landline number: **Mobile number:**	

Please √ the EQA programmes in which your laboratory would like to enroll. Each test event includes _____ number of EQA test samples.

EQA cycle Number	HIV	HCV	HBV	Syphilis	Malaria
1					
2					
3					

Name of HOD/In-Charge Signature & Seal

Dated:

Format No: 3A

National External Quality Assessment Programme

General instructions for EQA participant blood centres for transfusion transmitted infectious disease testing

A. Intended use

The package consists of coded panel of external quality assessment (EQA) test samples each with known reactivity status for transfusion transmitted infectious (TTI) diseases. It is intended to be used for the EQA assessment of the performance of laboratories undertaking routine TTI screening of blood donations.

A.1. EQA test samples provided

a. _____ vials each of 1.5mL, labelled appropriately.
b. Result sheets

B. Instructions for storage, handling, and testing of EQA samples

a. Vortex gently, then centrifuge all EQA samples prior to testing.
b. Process the EQA samples alongside routine test/donor specimens and in the same way as they would usually be processed by your laboratory.
c. Note: The EQA test samples are potentially infectious and should be handled using biosafety level 2 safety precautions.
d. EQA test samples are to be stored at 2 – 8 °C for the duration of the programme.

C. Instructions for testing of EQA samples

- Test the EQA test samples in the same way as routine donor specimens would normally be tested using the testing strategy in use in your laboratory.

D. Instructions for completing the results form

a. Please tick the relevant box where you have been given a choice of response.
b. Report only the results of one test kit on each page. Photocopy the relevant page(s) for additional results.
   — Definitions of abbreviations used in the form: (example)
   ➔ R: Reactive, NR: Non-Reactive, INC: Inconclusive

E. Instructions for returning the results

a. Retain the original result entry form and send a photocopy of the same to PT provider.
b. Results received in any format other than the one provided will not be included for analysis.
c. Results received after the closing date will not be included for analysis.

Format No: 3- B

National External Quality Assessment Programme
General instructions for EQA participant blood centres for immunohematology testing

A. Intended use

This involves biological samples and specimens. Though the status of certain infections might be known pertaining to the samples, the materials cannot be labeled as non-infectious. Hence advised to follow universal precautions while handling, storage, and testing like any other blood sample. It is intended to be used to assess the performance of laboratories performing some or all of the listed immunohaematological tests.

A.1. EQA test samples provided

a. _____ vials each of 1.5mL, labelled appropriately.

b. Result sheets

B. Instructions for storage, handling, and testing of EQA samples

a. Vortex gently, then centrifuge all serum/plasma EQA samples prior to testing. Red cell specimens may be mixed well as per laboratory protocol.

b. Process the samples alongside routine test/donor specimens and in the same way as they would usually be processed by your laboratory by the same technical staff as will be performed routinely.

c. Note: The EQA test samples are potentially infectious and should be handled using biosafety level 2 safety precautions.

d. Samples are to be stored at 2–8°C for the duration of the program.

C. Instructions for testing protocol of EQA samples

- Test the EQA test samples in the same way as routine donor/test specimens would normally be tested, using the testing strategy in use in your laboratory.

D. Instructions for completing the results form

a. Please tick the relevant box where you have been given a choice of response.

b. Grading (0 to 4+) can be used uniformly for describing the agglutination reaction strength by all centres depending on the platform.

c. Final results may be mentioned as group of the test/donor in respective block and positive/negative for DCT/ICT/Ab-S/Ab-ID in addition to other details as to the methodology and reagents followed by your laboratory.

E. Instructions for returning the results

a. Retain the original result entry form and send a photocopy of the same to PT provider.

b. Results received in any format other than the one provided will not be included for analysis

c. Results received after the closing date will not be included for analysis.

Format 4

National External Quality Assessment
Checklist for receipt of EQA samples/reagents

1. Name and correspondence address of the EQA participant blood centre:

2. EQA participant code:
3. EQA cycle code:
3. Date of sample receipt:
4. Total number of samples received:

5. No. of samples rejected (if any) Tick (√) appropriate box

   Hemolyzed ☐ Lipemic ☐ Insufficient ☐
6. No. of vials damaged / leaking:
7. No. of vials with labeling issues (please attach photographs)
8. Cold chain maintained: Yes ☐ No ☐
9. General instructions received: Yes ☐ No ☐
10. Reporting form received: Yes ☐ No ☐

Verified by (name): Date (Signature)

Name of HOD/In-Charge: Date: (Signature & Seal)

Format 5

National External Quality Assessment
Test results form- rapid test

EQA cycle code: Blood centre EQA registration ID:

Name of the test kit: Name of manufacturer: Date of manufacturing:

Lot/Batch number: Date of expiry: Date of testing:

EQA sample ID	Analyte	Operator				Observer / Verifier				Test Result interpretation • Reactive • Non-reactive • Invalid
		Operator initials	Ab line / spot	Ag line / spot	Control line / spot	Observer/ verifier initials	Ab line / spot	Ag line / spot	Control line / spot	

Name of HOD/In-Charge Signature & Seal

Dated:

Format 6

National External Quality Assessment
TEST RESULTS FORM- ELISA/CLIA

EQA Cycle Code:		**Blood center EQA registration ID:**
Name of Test Kit		Name of Manufacturer:
Date of Manufacturing	**1st run** Operator Initials: Date of testing: Lot/Batch number: Date of Expiry: **2nd run** Operator Initials: Date of testing: Lot/Batch number: Date of Expiry: **3rd run** Operator Initials: Date of testing: Lot/Batch number: Date of Expiry:	

	Results												
EQA sample ID	**Analyte**	**S/Co ratio (1st run)**			**S/Co ratio (2nd run)**			**S/Co ratios (3rd run)**			**Test Results interpretation (Tick √ appropriate box)**		
		Sample OD	Cut-off (CO)	S/Co (OD÷CO)	Sample OD	Cut-off (CO)	S/Co (OD÷ CO)	Sample OD	Cut-off (CO)	S/Co (OD÷ CO)			
											☐ R	☐ NR	☐ INC
											☐ R	☐ NR	☐ INC
											☐ R	☐ NR	☐ INC
											☐ R	☐ NR	☐ INC
											☐ R	☐ NR	☐ INC
Comments:													

Test Result Interpretation: Reactive (R); Non-Reactive (NR); Inconclusive (INC)

Name of HOD/In-Charge: Dated: Signature & Seal

Format 7

National External Quality Assessment
Immunohematology results entry format

1. EQA cycle code:
2. Blood centre EQA registration ID:
3. Date of testing:
4. Name of the kit
5. Name of the manufacturer
6. Batch/Lot number
7. Date of manufacturing
8. Date of expiry

Test parameters to be performed by each of the EQA participant blood centres:

i. ABO and Rh on test
ii. ABO and Rh on donors
iii. Compatibility testing
iv. Direct coombs test
v. Indirect coombs test
vi. Antibody screening (optional)
vii. Antibody identification (optional)

Sample	Group and type	DAT	IAT	Comp. testing	Ab Screen	Ab ID
Test 1						
Donor 1						
Donor 2						
Test 2						

Confidentiality:

All the EQA participants must be allocated an EQA number by the PT providers. Identity of EQA participants is CONFIDENTIAL and will not be shared without the written permission of the participant.

Note:

a) Process the EQA samples as you would do in your lab/blood centre and record your results in the table below.
b) Enter the results in the appropriate columns in the answer sheets provided
c) Retain the original result entry form and send a photocopy of the same to PT provider.
d) Results received in any format other than the one provided will not be included for analysis.
e) Results received after the closing date will not be included for analysis.

ABO Rh(D) and typing technique used (Tick √ in appropriate test method)								
Test Method	Slide [ ]	Tile [ ]	Tube [ ]		Column (Gel) [ ]	Column (Bead) [ ]	Micro Plate [ ]	Other* (Specify) [ ]
Test identification	**Cell (Forward) typing**				**Serum (Reverse) group**			**ABO and Rh (D) result**
Test 1 ID:	Circle as appropriate				Circle as appropriate			
	Anti A	**Anti B**	**Anti AB +**	**Anti D**	**A1 Cells**	**B Cells**	**O Cells**	
Name:								
	Anti A	**Anti B**	**Anti AB+**	**Anti D**	**A1 Cells**	**B Cells**	**O Cells**	
Test 2 ID:								
Name:								
Donation Unit	**Cell (Forward grouping)**				**Serum (Reverse) group**			
	Anti A	**Anti B**	**Anti AB+**	**Anti D**	**A1 Cells**	**B Cells**	**O Cells**	**ABO and Rh (D) result**
D Donation Unit 1 ID details:								
D Donation Unit 2 ID details:								

* (Other test method/s):

Compatibility Testing					
Donation Unit Number	Saline-Major (Room Temperature)	AHG-Major	Saline-Minor (Room Temperature)	AHG-Minor	Is the Blood unit fit for transfusion?
Coombs Tests, Antibody Screening, and Identification					
Method used					
Screening cells					
Sample Name	Test 1	Donor 1	Test 2	Donor 2	
Direct Coombs test					
Indirect Coombs test					
AHG reagent used					
Probable Antibody/ies detected on screening					
Antibody identification performed					
Antibody/ies identified					
Date of sample processing					
Date of sample receipt					
Date of submission					

Comments/Remarks:

Name of HOD/In-Charge Signature & Seal Dated:

Format 8

National External Quality Assessment
Test results final compilation form for
EQA compilation of test results for transfusion transmitted Infections -
To be filled by PT provider blood centre

EQA cycle code: **Date of Compilation:**

Overall performance scores for TTI parameters										
S.No.	EQA participant blood centre	HIV code	HBsAg	HCV	Syphilis	Malaria	EQA participants population mean (m)	EQA participants population standard deviation (d)	Standard deviation index of EQA participant blood centre (m / d)	Z score and overall performance status of blood centre

SDI = Interlaboratory mean ÷ Interlaboratory SD; Z score ≤ 2 Satisfactory; Z score ≥ 2 needs improvement.

Name of HOD/In-Charge: Signature & Seal: Dated:

Format 9

National External Quality Assessment
Test results final compilation form for
EQA compilation of test results for immunohematology- To be filled by PT provider blood centre.

EQA cycle code: Date of compilation:

Overall performance Scores for IH parameters											
S.No.	EQA participant blood centre code	Test donor identification	Donor hemoglobin	Blood group	Compatibility testing	Direct coombs test	Indirect coombs test	EQA participants population mean (m)	EQA participants population standard deviation (d)	Standard deviation index of EQA participant blood centre (m / d)	Z score and overall performance status of blood centre

SDI = Interlaboratory mean ÷ Interlaboratory SD; Z score ≤ 2 Satisfactory; Z score ≥ 2 needs improvement.

Name of HOD/In-Charge: Signature & Seal: Dated: