



# BLOOD SAFETY PROGRAM

MINISTRY OF HEALTH

THIMPHU, BHUTAN



World Health  
Organization



**GUIDELINES FOR NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME**

**IN**

**BLOOD GROUP SEROLOGY (BGS)**

Second Edition 2013

## ACKNOWLEDGEMENT

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## Section I

### General information

#### 1. Definitions:

##### *1a. Quality:*

Quality is the sum-total of all the characteristics of a product that has a bearing on its utilization. It is about consistently producing products that are **'fit' for the purpose**.

A blood unit is 'fit' for purpose (for transfusion) if it is:

- ◆ Safe-which means:
  - ❖ free from infectious agents
  - ❖ free from other contamination
  - ❖ correctly labeled
  - ❖ not expired
  
- ◆ Effective -which means:
  - ❖ contain required bioactive substance
  - ❖ gives clinical benefits to the blood recipient

To avoid confusion, below mentioned are distinct definitions of the commonly used terms related to Quality aspects:

##### *1b. Quality Control (QC):*

It 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, correct techniques etc. It indicates that the test run was valid and has produced 'acceptable' results. It does not guarantee the accuracy of results and reports.

##### *1c. Quality Assurance (QA):*

It is the total process that guarantees the accuracy of the final results and reports. It involves inspecting specimens, reviewing transcriptional details, reliability of assays used and verifying the final reports and results.

##### *1d. External quality assessment (EQA):*

It is a means of determining quality of results. Quality assessment is undertaken at periodic intervals to evaluate the effectiveness of the QA program of a participating laboratory. EQA allows participating laboratories to assess their performance levels in comparison to others in the network so that corrective action and preventive action (CAPA) can be implemented for improvement.

Methods of EQA include:

- a. proficiency testing
- b. testing of samples of known but undisclosed content
- c. on-site evaluation using a checklist and knowledgeable assessors also called as 'audit'

EQA is not.....

- **NOT** a substitute for other quality assurance measures
- **NOT** assessing individual competency
- **NOT** the only assessment of the QS
- Satisfactory performance in EQA is **NOT** a guarantee of 'total quality'

*I.e. External Quality Assessment Scheme (EQAS)*

This is a formal, recognized scheme for organizing EQA. It provides regular, independent assessment of performance and the internal quality control parameters to identify problems and weaknesses with the objective of improving performance and ensuring blood safety.

EQAS for blood transfusion safety focus mainly on blood group serology (BGS) and testing for transfusion transmissible infections (TTI testing).

Benefits of EQAS

*To the participating blood center*

- helps in identification of problems relating to processes, techniques, reagents
- brings in corrective and preventive action
- standards of the blood banks are raised
- exchange of information and provision of education to improve performance
- encouragement of best practice
- uplifts the credibility of the blood bank

*To the national health authorities and the blood safety program*

- establishment of blood banks with a known standard of performance
- helps in developing standards and guidelines
- review of technologies, testing strategies
- use of resources effectively
- identifies need for training and educational program
- improves public confidence in the blood transfusion service
- imparts quality patient care

## **2. The need for quality in blood transfusion service**

- Transfusion chain- it is a complex series of processes right from blood donor selection to administration of blood to the patient, involving different departments, different categories of personnel and clinical areas
- Each process involves risk or there is possibility for errors to take place
- Errors can have serious implications on blood donor or patient care
- Implementation of quality system minimizes errors, detects errors before they occur called near-misses and includes mechanisms for corrective and prevention action

## **3. Types of possible errors**

Errors in the blood center may be due to:

- Pre-analytical
  - inadequate identification procedure of a blood sample, blood donor or patient
  - improper donor or patient preparation
  - inappropriate storage of reagents or blood units
- Analytical-
  - equipment failure, inappropriate calibration
  - use of expired reagents
  - incorrect techniques for testing-not performing cell and serum grouping from ABO testing
- Post-analytical –
  - inaccuracies in reporting (transcription errors)
  - misinterpretation of results

## **Section II**

### **Guidelines on NEQAS in Blood Group Serology**

#### **4. Introduction**

The external quality assessment scheme (EQAS) is a tool to assess the internal control parameters in blood centers or clinical laboratories.

The National Blood Center (NBC), JDW, NR Hospital, Thimphu has been mandated by Ministry of Health to establish the National External Quality Assessment Scheme (NEQAS) for all blood centers in the country.

#### **5. Objective of NEQAS**

The main objective of NEQAS in blood group serology is to conduct an inter-blood center assessment of the performance by comparing the results obtained on the same test items sent from the national blood center to all blood centers.

An evaluation and estimation of the competency of each blood center in blood group serology testing shall be made and then reported back to the respective center.

It is not a competency testing of an individual laboratory technician but rather an effective way of identifying process and procedural problems in a blood center and thereby finding solutions. This shall result in strengthening of the quality assurance program in blood centers.

Blood centers not performing as per expectations and acceptable criteria shall be provided support to improve their quality so that continuous quality improvement (CQI) is achieved for which NEQAS acts an indicator.

NEQAS in BGS shall be conducted in line with the national guidelines.

It shall involve the regular distribution of the sets of test items for the following:

- ABO grouping
- Rh typing
- Cross match testing

#### **6. Organizer**

The NEQAS in BGS shall be conducted by NBC.

Roles and responsibilities:

- Shall have the necessary expertise in the field.
- Shall review, and revise the national guidelines for NEQAS at periodic intervals.
- Shall provide training to the participating blood centers (Pre-NEQAS and Post-NEQAS).



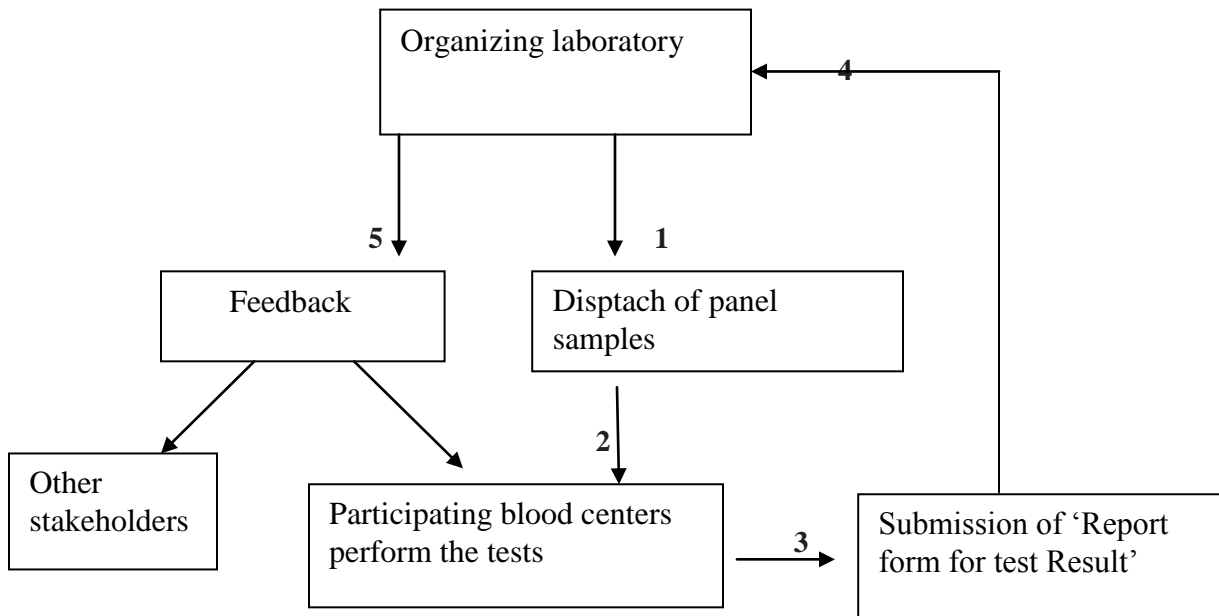
- Shall be responsible for preparation, packaging and distribution of panel samples.
- Shall be receiving, analyzing results and preparing evaluation reports.
- Shall provide necessary feedback, recommendations and conduct follow-up visits.

## 7. Participating blood centers

Roles and responsibilities:

- All the staff of the blood centre shall be well verse with the guidelines and the associated relevant documents.
- Shall treat the panel samples in the same manner as any routine samples.
- Test the panels samples at the earliest possible time.
- On completion and verification of the tests, submit the ‘Report of the Test Results’ (please refer to Annexure 1) to NBC within the deadline indicated.
- Study the feedback report and recommendations of NBC and bring in corrective and preventive actions if advised.

**Figure 1: Flow chart for the scheme**



## **8. Participation in the scheme**

The scheme shall be mandatory for all the blood centers and for all the cycles. The administration of the concerned health facility (CMO/MO-I/C /Medical Superintendent) shall receive prior notification by the Blood Safety Program in Health Care Diagnostic Division, DMS, MoH about the scheme.

Each participating center shall submit a duly filled 'Registration form' and 'Preliminary Questionnaire' (please refer to Annex 2 and Annex 3) to the co-ordinator of the NEQAS at NBC before or during the first cycle.

Each centre shall receive and shall follow the latest edition of the manual on the 'National Guidelines for NEQAS in BGS'

## **9. Confidentiality**

A unique confidential code number assigned to each participant centre shall be used on all documents related to the scheme.

Individual performance will be kept confidential to the other participating blood centers. It is permissible to reproduce any data or reports in an 'unchanged manner' by the blood centre. No additions or deletions shall be made without the approval of the organizer. No information shall be shared to a third party by the organizer other than the concerned stakeholders without prior approval.

## **10. Test Items (EQA samples)**

The test items for EQAS in BGS will comprise of two sets during each cycle.

10.1 The first set will consist of 3 samples which shall be for ABO grouping and for Rh(D) typing (e.g. A101, B101, C 101) :-

'PA 101' and 'SA101',

'PB 101' and 'SB101'

'PC101' and 'SC101'

10.2 The second set will consist of 1 sample for Cross-match test (e.g. D 101):-

'SD101'

The vials with code starting with 'P' will contain 2ml of red blood cell suspension in Alsever's solution and the vials with code starting with 'S' will contain 2ml of plasma/serum.

The information of test items will be included in the instruction sheet that will be sent with the samples. The concerned staff must read the instructions carefully before performing the tests.

## 11. Instructions for the participant

11.1 Tests should be performed IMMEDIATELY upon receipt of the test items. The samples MUST be kept at +2° to +6°C in a refrigerator to maintain good quality. If the red cells are found hemolysed, please wash and re-suspend the cells in normal saline before testing.

Note: Please send a detail feed back if the sample quality is unacceptable, for example if there is complete hemolysis of red cells/leakage/missing sample.

11.2 The test items must be mixed gently for uniformity in the suspensions before performing the tests.

11.3 Universal safety precautions must be strictly followed when performing the tests.

11.4 All test samples received must be treated **as any routine samples** and performed in the manner the blood centre performs the tests on samples of donors and patients. Do not consider these samples in a special way.

11.5 The completed 'Report Form for Test Results' shall be sent to organizer either by email or a hard copy by post. Faxing is NOT RECOMMENDED as the print outs of the reports are not legible at times.

11.6 Forms received after the indicated deadline shall not be evaluated by the organizer.

## 12. Distribution cycle

Test samples shall be delivered to the participating blood centers for two or three cycles to the contact person listed in the 'Registration form' answer no.3.

The dates of dispatch of the test items shall be notified in advance through a phone call /email to the concerned person.

Participants who fail to receive the test items within one week of the dispatch date should inform the organizer.

### 13. Tests

Number of tests per distribution cycle:

Three tests for ABO grouping

Three tests for Rh grouping

Three tests for cross-matching

13.1 **ABO grouping:** ABO grouping shall be performed using red cell suspension for cell grouping and plasma for serum grouping.

13.1.1 For cell grouping, use anti-A, Anti-B and Anti-AB. Report the grades of agglutination/hemolysis reactions in all.

13.1.2 For serum grouping, use standard A, B and O cells prepared in-house. Report the grades of agglutination reactions in all. Then conclude the result of ABO group and enter in the 'Report Form for Test Results'.

**Note:** Use the correct set of test items with the same code letter, for example use PA for cell grouping and SA for serum grouping.

13.2 **Rh D typing:** Rh (D) typing shall be performed using red cell suspension samples with anti-D reagent.

If initial spin 'IS' is negative, proceed to do the weak-D test. Report the results of the agglutination reactions, conclude the results of Rh type and enter in the 'Report Form for Test Results'

13.3 **Cross-matching:** Perform crossmatch using the second set of plasma/serum as patient's sample and first set of 3 red cell suspension used for ABO and Rh. Report the results of the agglutination reactions in all three phases i.e Room Temperature (RT), 37°C and by In-direct Anti-globulin test (IAT). Enter the results in the form provided.

## **14. Grading reactions**

14.1 For ABO groups:

If using tube method, grade agglutination and report as follows:-

4+ = A single large clump of red cells with clear supernatant

3+ = Multiple large clumps of red cells with clear supernatant

2+ = Multiple medium sized clumps of red cells with clear supernatant

1+ = Multiple small clumps of red cells with unclear supernatant

W+ = Many tiny clumps, unclear supernatant which are seen under microscope.

Negative = Homogenous suspension of red cells, no agglutination

If using slide method routinely, record the reaction as 'Agglutination Present' or 'Agglutination Absent'

14.2 For Rh D types:

Report as 'Positive', 'Negative' or 'Weak D'.

14.3 For Cross-match tests:

Interpret the result as 'Compatible' or 'Incompatible'.

## **15. Recording test results**

Record the results in the 'Report Form for Test Result' that will be sent together with the samples each time. Also keep a record of these forms in your blood center for future reference.

## **16. Submitting 'Report Form'**

The completed 'Report Form for Test Result' 'must be sent back to organizer within the closing date indicated.

## 17. Evaluation

Evaluation of the test results is made by the evaluation system recommended below.

### 17.1 Scoring method for ABO grouping

#### 17.1.1 Scores for the test procedure

All participants must perform ABO blood grouping by cell and serum grouping. If done by slide method, marks will be halved.

*Cell grouping:*

- reaction with Anti-A	performed=1	not performed=0
- reaction with Anti-B	performed =1	not performed=0

*Serum grouping:*

- reaction with A cell	performed=1	not performed=0
-reaction with B cell	performed =1	not performed=0

Sub-total performance score =4

#### 17.1.2 Scores for grades of agglutination reactions

Note: The results of agglutination reaction of cell grouping and serum grouping must correlate for scoring. There should be NO discrepancy between cell and serum grouping

-correct reaction	=1
-incorrect reaction	=0
-not recorded	=0
-correct reaction but done by slide method	=0.5

-Subtotal grading score =4

#### 17.1.3 Scores for ABO group interpretation

- correct ABO group	=2
- in-correct ABO group	=0
-ABO group not recorded	=0

Subtotal interpretation score =2

A total score of '10' is assigned for each sample. (10 x3 samples=30 score)

## 17.2 Scoring method for Rh (D) typing

### 17.2.1 Scores for test procedure

- reaction with Anti-D performed=1 not performed=0
- performed procedure is correct & complete =2
- performed procedure is incorrect OR in-complete =0

- Sub total score =3

### 17.2.2 Scores for reaction result in

- correct reaction =3
- incorrect reaction =0
- not recorded =0
- correct reaction but done by slide method =1.5

-Subtotal score =3

### 17.2.3 Scores for Rh (D) interpretation

- correct Rh (D) type =2
- in-correct Rh (D) type =0

Subtotal score =2

A total score of '8' is assigned for each sample. (8 x 3 samples=24)

## 17.3 Scoring method for Cross-matching test

### 17.3.1 Scores for the test procedure

- reaction at 'IS' performed = 1 not performed=0
- reaction at '37°C' performed= 1 not performed=0
- reaction at 'IAT' performed = 1 not performed=0
- reaction with CCC performed when required =1
- not performed when not required =1
- performed when not required=0
- not performed when required=0

Subtotal score =4

### 17.3.2 Scores for the grades of agglutination

-correct agglutination grade at 'IS' =2	incorrect =0
-correct agglutination grade at '37°C' =2	incorrect =0
-correct agglutination grade at 'IAT' =2	incorrect =0
-correct agglutination grade at 'CCC' =2	incorrect =0

Subtotal score =8

### 17.3.3 Scores for interpretation

- correct interpretation = 3
- incorrect interpretation=0
- interpretation not recorded =0

Subtotal interpretation score =3

A total score of '15' is assigned for each sample. (15 x 3 samples=45)

#### REMEMBER:

- Please follow the SOPs on ABO grouping, Rh (D) and Weak (D) testing and crossmatching.
- 1 score shall be given for neat and timely report.

## 18. Acceptable standard score

A total of 100 score is assigned as follows:

- ABO grouping=30
- Rh D typing =24
- Cross matching =45
- Neatness + timely reports=1

Ranges of scores to indicate the level of performance and quality shall be as:

- Unsatisfactory if score  $\leq 80\%$
- Borderline if score is  $> 80\%$  up to  $\leq 85\%$
- Average if score is  $>85\%$  up to  $\leq 90\%$
- Good if score is  $>90\%$  up to  $\leq 95\%$
- Very good if score is  $> 95\%$  up to  $99.9\%$
- Excellent if score is  $100\%$



Participants with standard score of more than 80% shall be accepted as satisfactory quality of laboratory performance.

Minimum of 85% has to be obtained in each set of tests to be considered as a satisfactory result.

- For ABO grouping satisfactory result, the blood centre should score 25.5 out of 30.
- For Rh D typing satisfactory result, the blood centre should score 20.4 out of 24.
- For cross-matching satisfactory result, the blood centre should score 38.25 out of 45.

## **19. Feedback Report**

The feedback report will be sent to the participating centers in two formats; preliminary report and summary report.

In the incidence of discordant results the preliminary report shall be sent immediately. However, summary report shall be sent once analysis and evaluation is completed.

-----**SAMPLE ONLY**-----

ANNEX 1

**'REPORT FORM FOR TEST RESULTS'**

NEQAS in BGS Bhutan
------------------------

Distribution cycle No. XXXX

Date of test item distribution: XXXX

Closing date: XXXXX (The results obtained after the closing date will not be evaluated)

Instructions for distribution XXXX

1. Test items comprise of two sets of samples:  
Set #1 consists of codes: A, B and C for ABO grouping and Rh typing
  - code A : 2 vials containing red cell suspension(PA101) and serum (SA101)
  - code B : 2 vials containing red cell suspension(PB101) and serum (SB101)
  - code C : 2 vials containing red cell suspension(PC101) and serum (SC101)  
Set #2 consists of code D for cross-match tests
  - code D : 1 vial containing of plasma (SD101)
2. Tests should be performed at the earliest upon receipt of the test items. The samples are to be kept at +2° C to +6°C in a refrigerator to maintain good quality. If the red cells are found hemolysed, please wash the cells with normal saline and re-suspend them in normal saline before testing. Please send a feed back if the sample quality is unacceptable to perform the test, mentioning the sample number and the reasons clearly.
3. The test items must be mixed gently for uniformity in the suspensions before performing the tests.
4. Universal safety precautions must be strictly followed when performing the tests.
5. All test samples received must be treated as any routine samples and performed in the same manner . Do not consider these samples in a special way.
6. The completed 'Report form' must be sent to Dr Mahrukh Getshen by email or by post.  
Email address: [getshen@yahoo.com](mailto:getshen@yahoo.com)  
  
Postal address: National Blood Center, JDW,NR Hospital ,Thimphu 001.

-----**SAMPLE ONLY**-----

**'REPORT FORM FOR TEST RESULTS'**

NEQAS in BGS Bhutan
------------------------

Distribution cycle No. XXXX

Date of test item distribution: XXXX

Closing date: XXXXX

Confidential code: XXXX

Quality of test items:

- |        |                                     |
|--------|-------------------------------------|
| PA 101 | satisfactory /unsatisfactory (tick) |
| SA 101 | satisfactory /unsatisfactory (tick) |
| PB 101 | satisfactory /unsatisfactory (tick) |
| SB 101 | satisfactory /unsatisfactory (tick) |
| PC 101 | satisfactory /unsatisfactory (tick) |
| SC 101 | satisfactory /unsatisfactory (tick) |
| SD 101 | satisfactory /unsatisfactory (tick) |

If samples are found unsatisfactory, give details below or reasons for saying so:

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-----SAMPLE ONLY-----

**'REPORT FORM FOR TEST RESULTS'**

NEQAS in BGS  
Bhutan

Distribution cycle No XXXX

Date of test item distribution: XXXX

Closing date: XXXXX

.Blood Bank code no: \_XXXX

**I. ABO grouping (please check  $\sqrt$  in the corresponding block)**

**Test code PA 101& SA 101**

	anti-A	anti-B	Acell	Bcell	A	B	O	AB	UI*
4+	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3+	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
2+	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
1+	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
WR*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Neg*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
ND*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	-				
AP*	<input type="checkbox"/>	<input type="checkbox"/>							
AA*	<input type="checkbox"/>	<input type="checkbox"/>							

**SAMPLE ONLY-----**

**'REPORT FORM FOR TEST RESULTS'**

NEQAS in BGS  
Bhutan

Distribution cycle No XXXX

Date of test item distribution: XXXX

Closing date: XXXXX

Blood Bank code no: \_XXXX

**II. Rh (D) Typing (please check  $\checkmark$  in the corresponding block)**

**Test code PA 101**

	Anti-D			Interpretation of Rh (D)			
	IS	37°C	IAT	Pos	Neg	Weak D	UI*
Pos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Neg*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
NR*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				

-----**SAMPLE ONLY**-----

**'REPORT FORM FOR TEST RESULTS'**

NEQAS in BGS Bhutan
------------------------

Distribution cycle No.\_XXXX

Date of test item distribution: XXXX

Closing date: XXXXX

Blood Bank code no:XXXX

**III. Cross-matching test**

**Test code SD 101**

SD 101	IS	37°C	IAT	CCC	Circle the right answer
PA 101					Compatible/Incompatible
PB 101					Compatible/Incompatible
PC 101					Compatible/Incompatible

**\*Abbreviations:**

UI: Un-interpretable

WR: Weakly Reactive

Neg: Negative

AP: Agglutination present

AA: Agglutination absent

NR: Not required to perform

ND: Not routinely done

-----SAMPLE ONLY-----

**'REPORT FORM FOR TEST RESULTS'**

NEQAS in BGS Bhutan
------------------------

Distribution cycle No: XXXX

Date of test item distribution: XXXX

Closing date: XXXXX

Blood Bank code no: XXXX

**Reagents used for testing**

Names of Reagents	Lot No	Name of Manufacturer/In-house preparation	Expiry date
Anti-A			
Anti-B			
Anti-AB			
Anti-D			
Acell			
Bcell			
Ocell			
Anti-Human Globulin			
Coombs Control Cells			

-----SAMPLE ONLY-----

**'REPORT FORM FOR TEST RESULTS'**

NEQAS in BGS Bhutan
------------------------

Distribution cycle No. XXXX

Date of test item distribution: XXXX

Closing date: XXXXX

Blood Bank code no: XXXX

Questions/Recommendations/Comments

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Tested by (name of the staff who performed the tests) \_\_\_\_\_

Approved by \_\_\_\_\_

Designation: \_\_\_\_\_

Date approved: \_\_\_\_\_



**‘Registration form’**

National External Quality Assessment Scheme for BGS

**CONFIDENTIAL REGISTRATION DETAILS  
BB-XXX**

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**For EQAS use only**

1. Name of laboratory/blood center: \_\_\_\_\_

2. Blood center confidential code no.: \_\_\_\_\_ (shall be filled by the organizer)

**PLEASE COMPLETE USING BLOCK CAPITALS ( To be filled by the above mentioned participant)**

3. Name and address of the identified person to whom test materials shall be dispatched. A survey report and any queries will also be sent to this address.

Name of the contact person: \_\_\_\_\_

Position: \_\_\_\_\_

Telephone number : \_\_\_\_\_(O): \_\_\_\_\_(M)

Fax number: \_\_\_\_\_

E-mail address: \_\_\_\_\_

4. Detailed address with postal code of the facility for sending the test samples:

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5. This laboratory/blood center agrees to abide by guidelines and conditions of participation in the National External Quality Assessment Scheme in BGS(NEQAS in BGS)

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Position: \_\_\_\_\_ Date: \_\_\_\_\_

ANNEX 3

**‘Preliminary questionnaire for participating blood banks’**

(Please complete this questionnaire regarding blood transfusion practice at your blood center )

**Contact Details**

Name of laboratory/blood center: \_\_\_\_\_

Name of person filling this form: \_\_\_\_\_

Telephone number : \_\_\_\_\_(o) \_\_\_\_\_(m)

Fax number: \_\_\_\_\_

E-mail address: \_\_\_\_\_

**Information on Immunohematology tests**

1. Which of the following blood group serology tests are included in your routine testing?  
(Please tick the appropriate answer in the box)

ABO grouping

Rh (D)typing

Cross-matching by direct agglutination (only using IS phase)

OR

Cross-matching by IS, 37°C and IAT phases

2. ABO grouping done routinely by (please tick the appropriate answer in the box)

grouping **and** Serum grouping

grouping only

3. Technique used for **cell grouping routinely** (please tick the appropriate answer in the box)

Slide

Tube

4. Technique used for Rh(D) typing (please tick the appropriate answer in the box)

Slide

Tube

5. Does your blood center perform Weak 'D' test (please tick the appropriate answer in the box)

Yes

No

## NAME LIST OF CONTRIBUTORS

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Blood Safety Program  
Department of Medical Services  
Ministry of Health  
Thimphu