



DESKTOP SURVEILLANCE ASSESSMENT (BLOOD BANK)

PREFACE

For an accredited Healthcare Organisation (HCO) to maintain its accreditation status, it is mandatory that the Blood Bank continues to comply with the requirements of Accreditation Standards for Blood Banks (3rd edition: June 2016), for which NABH conducts mid cycle surveillance. The purpose of on-site surveillance is to verify the continued compliance to the accreditation standards.

Due to pandemic COVID-19 crises and complete lock down announced by Government of India, the on-site assessments of NABH have also come to a halt. NABH has decided to develop a methodology to verify the continued compliance of the accredited HCOs to the applicable standards and the first step towards it is “Desktop Surveillance” wherein the HCOs will be required to submit documents as required by NABH.

For the purpose of Desktop Surveillance, the Blood Bank shall provide the information as per this document and the same shall be considered for verifying the continued compliance. The information provided by the Blood Bank shall be evaluated at NABH secretariat and on the basis of this evaluation, decision regarding continuation of accreditation shall be taken.

The Blood Banks are therefore advised to provide the essential information accurately as per the format. Incorrect information provided may lead to adverse decision by National Accreditation Board for Hospitals & Healthcare Providers (NABH).

Note: The format provided for Desktop surveillance is in accordance with 3rd Edition of Blood Bank standard.

Instruction to fill the Format for Desktop surveillance

1. General Information:

Provide relevant information only.

2. Status of Non-Conformities (NC's) of previous on-site assessment:

Mention non-conformities raised in previous on-site assessment along with relevant standard in column no. 2 & 3. In the column no. 4 the blood bank may mention the proposed corrective action taken and in the last column provide the evidence submitted for that non-conformance. For eg. there are two documents submitted as evidence, name of the file shall be DS-2020-Annexure 2.1 a CAPA brief about file & DS-2020-Annexure 2.1 b CAPA brief about file.

3. Details of Manpower: Blood Bank shall provide details in tabular format. More rows in the format shall be inserted to complete the list.

4. New Equipment (if any): Blood Bank shall provide details in tabular format. More rows in the format shall be inserted to complete the list.

5. Indicator Data: Blood Bank shall fill the data in tabular format. The figures shall be inserted in the format. In case the blood bank provide excel sheet, the name of the excel sheet shall be DS-2020-Annexure 5 Indicator. For eg. DS-2020-Annexure 5 Indicator for July to Dec 2019. DS stands for Desktop Surveillance-2020(year)-Annexure 5.

6. Documents/Manuals: Blood Bank shall provide the list of policy & procedure documents with the Issue number, Issue date and date of last review. More rows in the format can be inserted to complete the list.

7. Documents/ Photograph to show the compliance to NABH Standards for blood banks:

Blood Bank shall upload the documents/ pictures as required. The name for the document/ picture shall be as follows:

DS-2020-Annexure 7.1. document name

DS-2020-Annexure 7.1. photo name

DS stands for Desktop Surveillance-2020(year)-Annexure 11 name.

Blood Bank shall attach the geotagged and time stamp photos of various areas as per the given table against each row.

Photographs to be less than 3 MB in jpg format with good resolution.

For geotagged & timestamp: Open 'Camera' App-Head to the 'Settings' of the camera App-Look for the 'time stamp on photos'/'Location tag'/'Save location' option and enable it depending on your OS version.

'GPS Map Ca' App can be used for Geotagging (Can be downloaded and installed from android play store app)

8. Has there been a change in the following aspects of the Blood Bank operations since last assessment:

Blood Bank shall mention the change in Yes/No as per the given table format, in case the answer is 'Yes' give the details of the changes and PDF file as annexure to be attached for example (e.g. DS-2020-Annexure 8.1.doc) DS stands for Desktop Surveillance-2020(year)-Annexure 8 is the number of the title and 1 represents serial number followed by the document name.

9. Self-Declarations

Self - declaration shall be signed by the Head of the blood bank with name, designation, date & place on the letter head of Blood Bank in PDF as DS-2020-Annexure 09 Self Declaration. DS stands for Desktop Surveillance-2020 (year) - Annexure 09 tile number followed by document name.

10. Details of 1st, 2nd and 3rd year Annual Accreditation Fee payment by Blood Bank: The Blood Bank shall provide the details of annual fees paid for 1st, 2nd and 3rd year.

11. Considering the current difficult times and burden on the healthcare institution due to pandemic of COVID 19, NABH has taken a decision to waive of the surveillance desktop assessment fees for time being.



Information to be Furnished by Blood Bank for Desktop Surveillance Assessment

1. General Information

Information		Details
Blood Bank Reference Number		
Blood Bank name		
Blood Bank address		
Accreditation Cycle – Accredited since (mention the year)		
Accreditation Validity Period:		
Previous assessment type: FA/ RA/ Verification/ Focus		
Date of Previous assessment		
Name of Owner/ CEO or equivalent		
Email of Owner/ CEO or equivalent		
Name of Accreditation Coordinator		
Email of Accreditation Coordinator		
Name of the Quality Manager		
Name of the Technical Manager		
No. of units collected/ per annum		
Scope of Services (kindly tick on below)		
Sl.	Facility	Services
1.	Blood bank/Blood Center having component facility (also whole blood)	a. Whole blood b. Whole blood (irradiated) c. Red blood cells d. Deglycerolized RBCs e. Frozen RBCs 40% Glycerol f. RBCs Irradiated g. RBC Leukocytes Reduced h. Rejuvenated RBCs i. Deglycerolised Rejuvenated RBC j. Frozen Rejuvenated RBCs k. Washed RBCs l. Apheresis RBCs m. Apheresis RBCs Leukocytes Reduced n. Platelets o. Platelets Irradiated p. Platelets Leukocytes Reduced q. Apheresis Platelets



		<ul style="list-style-type: none"> r. Apheresis Platelets Leukocytes reduced s. Apheresis Platelets Irradiated t. Apheresis Granulocytes u. Apheresis Granulocytes Irradiated v. Stem cell (PBSC) apheresis w. Cryoprecipitated AHF x. Fresh Frozen Plasma (FFP) y. Plasma Cryoprecipitate Reduced (CPP) z. Liquid Plasma
2.	Blood bank/Blood Center having component facility (also whole blood) with additional facility	<ul style="list-style-type: none"> a. Molecular testing (NAT testing) b. HLA typing & matching
3.	Blood bank/Blood Center having component facility (also whole blood) and additional procedures	Therapeutic Procedures

Kindly specify if there is addition in the scope:

2. Status of Non-Conformities (NCs) of previous on-site assessment:

Sl.	Non-conformities raised during previous on-site assessment	Ref to NABH Standards on Blood Bank Clause No.	Corrective actions taken/ Purposed by the Blood Bank	Evidence of continued compliance of corrective actions to be attached (as on date)
1.				
2.				

3. Details of Manpower:

Sl	Name	Designation /	Qualification	Registration No. and Name of registering authority (if any)	Experience in Blood Bank (yrs)



4. New Equipment (if any):

Sl.	Name of Equipment	Make/ Model	Calibration status	Traceability

5. Quality Indicator:

S.No.	Indicator Name	Data Description	Data field (To be filled by blood bank)	Calculated Value
1	Percentage of Transfusion Transmitted Infection			
1	TTI%	Combine TTI cases (HIV+HBV+HCV+ Syphilis+MP) in whole blood donations	x 100	
		Total no. of whole blood donations		
2	Percentage of Adverse Transfusion Reaction			
2	Transfusion reaction (percentage)	No. of adverse transfusion reactions	x 100	
		Total number of blood/ component units transfused		
3	Percentage of Outdated Whole blood / Concentrated RBC			
3	Wastage Rates	No. of whole blood / Concentrated RBC discarded due to outdating	x 100	
		Total no. of whole blood / Concentrated RBC collected/prepared		
4	Turnaround Time (TAT) of Blood Issues			
4	Turnaround Time (TAT) of Blood Issues	Sum of the Time Taken		
		Total number of blood and blood components crossmatched/reserved		
5	Percentage of Component QC failure (for each component)			
5		No. of component QC failures	x 100	
		Total No. of component tested		



6. **Documents/Manuals:** Blood Bank is required to provide the list of policy & procedure documents alongwith the Issue number, Issue date of last review.

SI	Name & No. of Document	Issue No. & date	Whether reviewed periodically as per the policy of BB	Date of last reviewed

7. **Documents/ Photograph to show the compliance to NABH Standards for blood banks**

- | SI. | Items |
|------|---|
| 7.1 | License Validity (copy of valid license to be attached) |
| 7.2 | Any amendment in the Quality Manual since the last assessment (provide the policy for the same: name of file shall be DS-2020-Annexure 7.2 amended policy) – kindly do not upload the whole Quality Manual |
| 7.3 | Proof of display of processing charges of blood/ blood components (photograph: name of file shall be DS-2020-Annexure 7.3 processing charges) |
| 7.4 | Organogram (pdf document: name of file shall be DS-2020-Annexure 7.4 Organogram) |
| 7.5 | Plan of the facility (photograph with fire exits: name of file shall be DS-2020-Annexure 7.5 fire exit) |
| 7.6 | Photos of the facility (with signages: name of file shall be DS-2020-Annexure 7.6 a counselling room; 7.6 b component area etc.) |
| 7.7 | Copy of updated fire license/NOC/Advisory |
| 7.8 | Proof of installation of extinguishers |
| 7.9 | Schedule of Mock drill for 'Fire Safety' |
| 7.10 | Electricity Backup (proof to be attached – picture/ installation report/ bill of purchase/ logbook) |
| 7.11 | Trainings conducted for Staff working in different section in last 6 months (proof to be attached) |
| 7.12 | Training records of counsellor as per NACO guidelines proof |
| 7.13 | Post training competence evaluation proof (any one training) |
| 7.14 | Evidence of constitution of Anti-sexual harassment committee |
| 7.15 | Evidence of Health check-up & Immunisation Status of new personnel joined blood bank |
| 7.16 | Equipment break down register (for last six months) |

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- 7.17 Evidence of recording of lot numbers of all relevant reagents, control materials and calibrators in the blood bank
 - 7.18 Reagent Storage (maximum 2 photographs) with temperature regulation
 - 7.19 Evidence of evaluation of suppliers (any 2 done in last one year): also annex vendor rating and evaluation forms
 - 7.20 Pre-donation Counselling questionnaire (1 filled in format)
 - 7.21 Proof of provision of transportation from collection site to the component laboratory
 - 7.22 Photo evidence of emergency kits
 - 7.23 Proof of adequate IEC material available/ display with blood bank
 - 7.24 Proof of Blood Donor Records (2 pages of the register)
 - 7.25 Proof of Master records for blood and its components (2 pages of the register)
 - 7.26 Proof of identification and traceability of samples for laboratory tests (2 samples)
 - 7.27 Proof of temperature monitoring and recordings during transportation of whole blood/ components for few samples
 - 7.28 Proof of Component preparation records (2 pages of the register in last 3 month)
 - 7.29 Proof of labelling of blood/ component bags (dully filled)
 - 7.30 Records of Testing of Donated blood in the last 6 months (pertaining to Serological/NAT tests)
 - 7.31 Proof of Issue Register (photograph – atleast 2 pages of filled in format)
 - 7.32 Proof of participation in National Haemovigilance Programme of India (in last 1 year)
 - 7.33 Proof of using Quality Controls (3 random record in last one month)
 - 7.34 Participation in Proficiency Testing Programme (proof to be attached)
 - 7.35 Records of training of staff for Bio-Medical Waste Disposal (random 2 training records)
 - 7.36 BMW consent license (copy to be attached)
 - 7.37 HAZMET kit and evidence of MSDS sheets (photograph)
 - 7.38 MOU with licensed indigenous fractionator for plasma fractionation as applicable



7.39 Complaints Register/ Feedback & Redressal system (Summary of complaints received in last one month to be provided in tabular format, with heading as given below) – name of file shall be DS-2020-Annexure 7.39 Complaints register

Sl.	Date of receipt of Complaints	Issue of complaint	Resolution	Date of disposal

7.40 Date of last two Internal Audit done

7.41 Frequency of Internal Audit as per policy of blood bank

7.42 Last Internal Audit report (provide the following details)
 No of NCs raised:
 Have the Corrective Action and Root Cause Analysis on the NCs been done within the defined time frame:
 Name of Auditor:

7.43 Last Management Review Meeting Minutes (name of file shall be DS-2020-Annexure 7.43 MOM Management Review)

8. Has there been a change in the following aspects of the Blood Bank operations since last assessment:

(Please provide details in tabular format & attach evidence in PDF if any)

Sl.	Items	Yes/ No	If yes, give details thereof
8.1	Blood Bank Premises		
8.2	Key Blood Bank Personnel		
8.3	Legal Status		
8.4	Ownership		
8.5	Policies		
8.6	Scope of services		
8.7	Size of blood bank		
8.8	Top Management		
8.9	Organogram		



9. Self-Declarations (to be submitted on the letter head of HCO, duly signed by Head of HCO)

1. I hereby declare that the Blood Bank (name) is in continued compliance of 3rd Edition of NABH standards for Blood Bank since last on-site assessment.
2. I also declare that each statement and/or contents and /or documents, certificates submitted as Desktop Surveillance documents are true, correct and authentic. I am aware that any wrong information / declaration given therein may lead to adverse actions by NABH.

10. 1st, 2nd and 3rd year Annual Accreditation Fee payment by Blood Bank:

Amount of Fee paid:

Date of payment;

Mode of payment along with complete details.

Signature of Head/ Director/ CEO of Blood Bank

Name & Designation

Date & Place

**NATIONAL ACCREDITATION BOARD FOR HOSPITALS
& HEALTHCARE PROVIDERS (NABH)**

Quality Council of India

5th Floor, ITPI Building; 4 A, Ring Road, IP Estate

New Delhi - 110 002, India

Tel/ Fax: 91-11- 42600600

Website: www.nabh.co

E-Mail: helpdesk@nabh.co