

Job Description of the Blood Bank Staff

A statement of the duties and working conditions for a particular job. It defines the skills, abilities, qualifications and experience required for the job. It also defines the job holder's authority and responsibility within the organization.

The job description sets forth the relevant responsibilities, authorities, basic activities, reporting and constitute an integral part of each employee's employment agreement.

The creation of job specification is not an easy task because sometimes it seems difficult to classify that whether a particular requirement is compulsory or desirable. However, it helps to ascertain that, on what basis a person is recruited and examined. Some common specifications are as under:

- Physical features: Height, weight, vision, etc.
- Demographic features: Age, experience, gender, education, skills, abilities, etc.
- Psychological features: Mental ability, alertness, sharpness, aptitude, reasoning, etc.
- Personal features: Attitude, behavior, etiquette, manners etc.

It clearly defines the job and person specifications. It simplifies interviewing, selection and assessment of candidates. Job description ensures a consistent approach to all appointments and enables to get the staff you want and for the people to get the job they can do. Any tasks outside the job description should be performed only with the knowledge of the employee's supervisor.

The job description should include:-

- Job Title
- Department
- Grade
- Main Function
- Accountable / Responsibilities
- Liaises with
- Authority
- Key Tasks
- General Tasks
- Terms and Conditions

Sample Job Description:

Quality Manager:

- Reports directly to the head of the organization/institution
- Independent of manufacture or service delivery
- Given authority and responsibility for implementing and maintaining the quality system
- To develop, implement and maintain an effective quality system
- To involve all BTS staff in quality
- To develop a culture of quality in the organization
- To train staff in quality and quality systems

- To encourage and support individual departments in implementing their own quality systems

Authority means power or rights assigned to an individual to make decisions.

Responsibility is duty to maintain and manage the assigned authority.

Introduction to Blood Bank:

All selected candidates should undergo orientation training during which he/she should be made aware of the department, facilities occupational safety and health requirements

A pre employment health check should be mandatory before joining the job which should be followed by annual health check ups and vaccination

Training policy and records:

Training implies enhancing the skills and knowledge of the employees for performing a specific job. Training tries to improve employees' performance in current job The crucial consequence of training is learning. As per Policies / procedures /SOP as relevant training should be conducted regularly on the basis of training plan drawn.

Induction / Orientation Training:

Objectives of Orientation/Induction training: To familiarize new employees with the job, the work unit, and the organization as a whole. Training should include:

- Service rules
- Quality management system.
- Assigned work processes and procedures.
- HIS Information System.
- Occupational health and safety, including the prevention or containment of the effects of adverse incidents.
- Ethics.
- Confidentiality of patient information.

In Service Training: Should be imparted to regularly upgrade the skills of the staff so that their performance and satisfaction level improves which should result in higher satisfaction level in the patients and clinicians.

1. Training should be imparted by in house or by external experts
2. Give opportunities to attend CME's and training programs.
3. Conduct additional trainings as infection control practices, waste management, fire safety, violence and mitigation etc time to time for all levels of staff

Competency assessment:

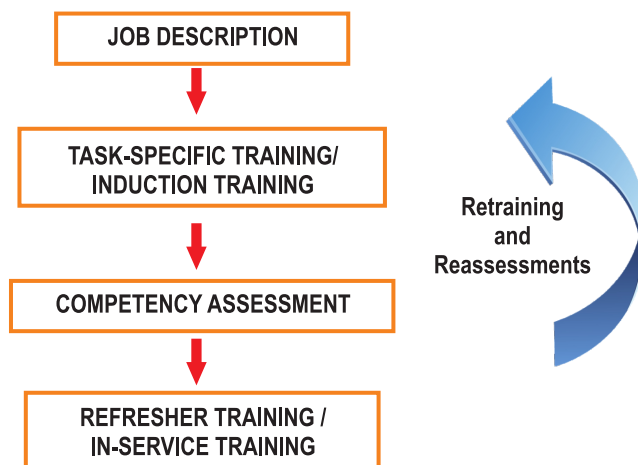
Competence is defined as demonstrated ability to of an individual to do a particular job. It also is the ability of an individual to apply relevant skills and knowledge to the job. Competence is gained by training. Competence assessment of each person to perform assigned managerial or technical tasks according to

established criteria should be assessed at least annually. The methods used for competence assessment may include:

1. **Direct observation** of checklists of routine work processes and procedures, including all applicable safety practices of equipment maintenance and function checks.
2. **Indirect observation**
 - Monitoring the recording and reporting of examination results.
 - Review of work records.
 - Assessment of problem solving skills.

Documentation of competency assessment should be done on designed formats ,dated and kept confidential.

Policy on Retraining for staff failing in competence assessment followed by reassessment at a later date



Disciplinary procedures

Any failure to perform duties, responsibilities or activities as per the employee's job description, any unauthorized performance of duties outside the employee's job description or any insubordination constitute a disciplinary infringement (violation) should be treated according to the applicable disciplinary procedures.

Disciplinary violations may include:

1. Violation of any activity outside the ethical Code of Conduct.
2. Any failure to perform duties, responsibilities or activities as per the job description and or insubordination.
3. Any theft, misappropriation of funds, unethical, illegal or immoral behavior or sexual harassment.
4. Indulgence in alcohol or illegal drug abuse policy

Blood bank should formulate a policy for taking action in the form of a memo/warning against any staff member who commits a disciplinary violation as well as outline a procedure for appeal by the employee.

Grievance /Disputes:

Grievance may be any genuine or imaginary feeling of dissatisfaction or injustice which an employee experiences about his job and its nature, about the management policies and procedures. It must be expressed by the employee and brought to the notice of the management and the organization.

Grievances take the form of collective disputes when they are not resolved. They lower the morale and efficiency of the employees. Unattended grievances result in frustration, dissatisfaction, low productivity, lack of interest in work, absenteeism, etc. Grievance arises when employees' expectations are not fulfilled from the organization as a result of which a feeling of discontentment and dissatisfaction arises.

Awareness of staff should be created during induction training on any grievance and disputes among the staff. Blood bank should develop staff suggestion format, grievance forms and formulate a grievance handling procedure and its redressal with an action plan.

Approach to grievance handling

1. Quick action- As soon as the grievance arises, it should be identified and resolved.
2. Acknowledging grievance- The blood bank incharge must acknowledge the grievance put forward by the employee as manifestation of true and real feelings of the employees.
3. Gathering facts- The blood bank incharge should gather appropriate and sufficient facts explaining the grievance's nature. A record of such facts must be maintained so that these can be used in later stage of grievance redressal.
4. Examining the causes of grievance- The actual cause of grievance should be identified. Accordingly, remedial actions should be taken to prevent repetition of the grievance.
5. Decisioning- After identifying the causes of grievance, alternative course of actions should be thought of to manage the grievance. The effect of each course of action on the existing and future management policies and procedure should be analyzed and accordingly decision should be taken by the manager.
6. Execution and review- The management should execute the decision quickly.

Sexual Harassment

Blood bank should formulate a policy of providing a workplace free from sexual harassment for all employees, to ensure that Sexual harassment of women occurring in the workplace is unlawful and not tolerated by Blood Bank. It is mandatory to constitute an internal complaints committee or equivalent, to consider complaints for their redressal in cases of sexual harassment. Proper complaint and redressal forms should be designed and made available to staff.

Uniform policy / dress code: A white apron should be worn in the blood bank while working in the departments or at the blood donation camps. Staff should use personal protective equipment while working.

Confidentiality of information should be maintained:

- Personnel records (including Training/Health) of staff should be kept secure
- Written policy & code of conduct on confidentiality of donors & patients should be known to staff
- Maintain safe & secure provision of transportation of records within & outside blood bank
- Staff who transport should be aware of confidentiality policy.

Performance Appraisal

Performance Appraisal is the systematic evaluation of the performance of employees and help to understand the abilities of a person for further growth and development.

Objectives of Performance Appraisal

Performance Appraisal should be done with following objectives in mind:

1. To maintain records in order to determine promotions, wage structure, salaries raises, etc.
2. To identify the strengths and weaknesses of employees to place right men on right job.
3. To maintain and assess the potential present in a person for further growth and development.
4. To provide a feedback to employees regarding their performance and related status.
5. As a basis for influencing working habits of the employees.
6. To review and retain the promotional and other training programmes.

Advantages of Performance Appraisal

It is said that performance appraisal is an investment for the organisation which can be justified by following advantages:

1. **Promotion:** Performance Appraisal helps the supervisors to chalk out the promotion programmes for efficient employees. In this regards, inefficient workers can be dismissed or demoted in case.
2. **Compensation:** Performance Appraisal helps in chalking out compensation packages for employees. Merit rating is possible through performance appraisal.
3. **Employees Development:** The systematic procedure of performance appraisal helps the supervisors to frame training policies and programmes. It helps to analyse strengths and weaknesses of employees so that new jobs can be designed for efficient employees. It also helps in framing future development programmes.
4. **Selection Validation:** The management comes to know of the validity and thereby the strengths and weaknesses of selection procedure. Future changes in selection methods can be made in this regard.
5. **Communication:** For an organization, effective communication between employees and employers is very important.
6. **Motivation:** Performance appraisal serves as a motivation tool. Through evaluating performance of employees, a person's efficiency can be determined if the targets are achieved. This very well motivates a person for better job and helps him to improve his performance in the future.

Personnel Records

Personnel Records are records pertaining to employees of an organization. These records are accumulated, factual and comprehensive information related to employees. All information with effect to human resources in the organization should be kept in a systematic order. Personnel records should be maintained for formulating and reviewing personnel policies and procedures. Complete details that should be maintained in personnel records are, name, date of birth, marital status, academic qualifications, professional qualifications, previous employment details.

Sample format for personnel records:

- Name, Address, T. No.
- DOB, Qualifications, Experience
- Date of appointment
- Approval from regulatory authority
- Reference from previous employment
- Record of identification of signature / initials
- Health record (includes immunization record)
- Job description
- Training record
- Competency record
- Leave record
- Record of untoward incident / accident
- Grievance procedure or any disciplinary action taken record

Purpose of Personnel records

Personnel records are really vital for an organization and have benefits as they.

1. Supply crucial information regarding the employees.
2. Keep an update record of leaves, transfers, turnover, etc. of the employees.
3. Help the blood bank in charge / quality manager in framing various training and development programmes on the basis of present scenario.
4. Help the government organizations to gather data in respect to rate of turnover, rate of absenteeism and other personnel matters.
5. Help the management to make salary revisions, allowances and other benefits related to salaries.
6. Also help the researchers to carry in- depth study with respect to manpower development.
7. Help the accreditation agencies to see the factual information pertaining to each staff

Please refer to Annexure - D

CHAPTER 14

Equipment Management

The spectrum of equipment in Blood Bank ranges from a simple pipette to the more sophisticated automated equipment as cell separator. It is difficult to select and obtain the technologically right equipment for the needs of a transfusion service. Equipment availability, functionality and efficiency are the cornerstones for provision of safe blood.

Equipment management is one of the essential elements of a quality management system. Proper management of the equipment is necessary to ensure accurate, reliable, and timely testing.

Following equipment are used in Blood Bank:

Blood Collection

- Donor weighing balance
- Haemoglobinometer
- Sphygmomanometer
- Stethoscope
- Blood mixer and shaker
- Tube stripper and Di-electric tube sealer
- Needle destroyer

Blood Processing

- Refrigerated Centrifuges
- Double pan balance
- Plasma Expresser - Manual/Automated

Blood Storage

- Blood Bank Refrigerator
- -35°C Deep Freezers
- -80°C Deep Freezers
- Platelet Agitator and Incubator
- Cell Separators (Apheresis machine)

Blood Testing

- pH Meter
- Cell Counter (optional)
- Coagulometer (optional)
- Automated Cell Grouping system (optional)
- Equipment for Gel technology (optional)
- Table top centrifuge
- Serological water bath

- ELISA reader (Plate reader/ strip reader)
- VDRL shaker

Blood Distribution

- Transportation vans (optional)
- Insulated blood bags containers with provisions for storage between 2°C to 8°C

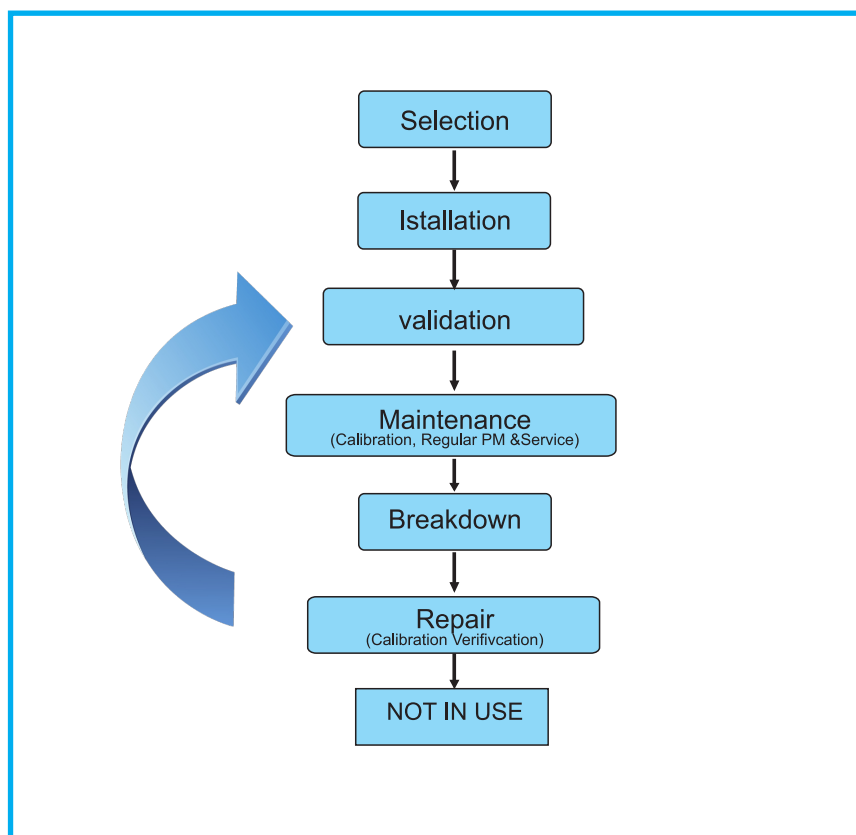
Equipment Management program:

Blood Bank should have a well-organized equipment management program. The strategies for equipment management include scientific need assessment writing specification-Design Qualification (DQ), appropriate selection & procurement by checking Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ), maintenance, repairs, optimum utilization and timely replacement.

The Blood Banks should have Policy, Processes and Procedure to ensure that calibration, maintenance and monitoring of equipment conforms to standards and other specific requirements.

Elements of Equipment management cycle

Selection and purchasing



Equipment Selection: Criteria for selection and procurement of equipment should be as per policy of the institution because it has a strategic and financial impact on the resources. It should be based on DQ, IQ, OQ and PQ.

Need Assessment: A realistic analysis should be done for requirement of an equipment by determination of the use coefficient using the formula $N/M \times 100$, where N is the number of hours the equipment is used per day and M is the maximum number of hours an equipment can be used per day. A use coefficient of less than 50% warrants that equipment would not be economically viable.

Factors that affect selection of equipment: Selection of equipment should be based on the pre-determined specifications (Design Qualification, DQ), best source of supply, acquisition at the most favourable operating criteria, availability of spares, maintenance (covered under AMC/CMC with calibration), environmental issues, and capability of achieving the performance required to comply with standards. Equipment should be procured from approved manufacturers or through their designated suppliers/distributors.

Equipment Qualification

Before installation of equipment all physical requirements (Power, electrical connections, space, doors, ventilation, and water supply) should be met.

Blood bank should confirm the vendor's responsibilities for installation in writing prior to beginning the installation process. A checklist should be drawn of the expected performance specifications to verify performance as soon as the equipment is installed. The equipment should be installed by the manufacturer only. The equipment should not be used before it is completely installed, its performance is verified, and personnel are trained.

Equipment Validation:

Equipment validation should ensure equipment compliance. It should provide a high degree of assurance that equipment consistently produces a result or a product that meets its predetermined and required specifications.

The three protocols used for equipment qualification:

- **Installation Qualification (IQ)** – The equipment, with all its components and documentation, should be placed correctly and checked for performance according to the requirements.
- **Operational Qualification (OQ)** – All the major parts of the equipment should be tested to ensure they all perform correctly and are in synchronization with the entire system.
- **Performance Qualification (PQ)** – The instrument should be monitored over a period of time to check if it consistently delivers results within the required parameters.

Installation Qualification (IQ)

IQ should ensure correct installation of the equipment as per manufacturer's specifications. It should be performed by the manufacturer's field representative who should verify that all component parts are functional, local supply voltages conform to instrument, ambient conditions exist for optimal equipment performance along with correct versions of software. The representative should also set up the instrument parameters (date, time, language, test protocol). Calibration of major equipment, accessory equipment, and/or utilities should also be performed during installation qualification.

Calibration is comparison of a measurement device of known accuracy with another standard of unknown accuracy to confirm, delete, correlate, report or eliminate by adjustment any variation in the accuracy of the item being compared. It should detect and correct any variation from required performance specifications of measurement device. A standard in a measurement is considered the reference which is maintained by the National and International body. Traceability of calibration instrument to the National body assures the users of the confidence and accuracy of the process.

Calibration is important in all phases of blood banks and is required for all measurement devices or equipments that provide information as weight, absorbance, temperature, time, length/width, volume, rpm and pressure.

Calibration is purely an indication that the instrument was found to be performing within the specified specification at the time of calibration only. It provides confidence that the equipment has been and is operating to manufacturer's specifications.

How often to calibrate Equipment: The schedule and standard of calibration should comply with the National standards. Recalibration should be required in between depending on the type and use of equipment, its tendency to wear and drift as well as the uncertainty of measurement. It varies with environmental conditions, recorded history of maintenance and servicing, degree to which the serving personnel are trained and trend data obtained from previous calibration record.

Calibration should also be done whenever the equipment is serviced or its location is changed. Calibration certificates should be maintained as proof of calibration in the equipment maintenance files with date of calibration, calibrator, correction factor, due date of calibration. Calibration, if outsourced, should be done by an NABL accredited calibrating laboratory. This helps in traceability of method.

Equipment Standardized and Calibration with at least the Following Frequencies:-

S.No.	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsourced or in house)
1.	Temperature recorder (Display)	compare against calibrated	Daily	Once in 6months/ year
2.	Refrigerator/ Deep freezer for storage of blood/ components.	Compare against thermometer	Daily	Once in 6 months
3.	Refrigerated blood bag centrifuge	Observe speed temperature and time	Each day of use	Once a year
4.	Hematocrit centrifuge	Observe speed temperature and time	-	Once a year
5.	General lab centrifuge	Observe speed temperature and time	-	Once a year
6.	Automated blood typing	Observe control of correct result(QC samples)	Each day of use	Once a year
7.	Haemoglobinometer	Standardize against Cynamethemoglobin standard	Each day of use	Once a year
8.	Refractio-meter or Urinometer	Standardized against	Each day of use	Once a year
9	Blood container weighing device	Container of known Calibrated weight	Each day of use	Once a year
10	Water bath	Observe temperature	Each day of use	Once a year
11	Autoclave	Observe temperature and Pressure	Each day of use	Once a year
12	Serologic rotators	Observe control for Correct result	Each day of use	Once a year
13	Laboratory thermometer		-	Once a year
14	Electronic thermometer		-	Before initial use and
15	Blood agitator	Observe weight of the first blood filled container for correct results	Once in 15 days	Once year
16	Platelet Shaker cum incubator	Temperature No. of strokes (check in house)	Once a month	Once year (temperature)

Operational Qualification /OQ

Operational Qualification should be performed to demonstrate that the systems and equipment operate correctly as per qualification protocol. It should be performed to verify that the equipment operates consistently within established limits and tolerances over the defined operating ranges. Tests on critical variable should include conditions encompassing upper and lower operating limits and circumstances (i.e. “worst case conditions”).

Operational qualification challenges equipment functionally to verify compliance with manufacturer's specifications and end user defined requirements. It should include verification of operation of all system elements, parts, services, controls, gauges and other components. It should be performed by the field representative and lab technicians together.

There should be documented records for the verification of operation (operational qualification report) to indicate the satisfactory operation. Standard operating procedures for the operation should be finalized and approved. Training of operators for the systems and equipment should be provided, and training records should be maintained. Systems and equipment should be released for routine use after completion of operational qualification.

Performance Qualification (PQ)

The final phase of validation should be performed to verify that the equipment performs according to design specifications and user defined requirements in a reliable and reproducible manner under normal production conditions. It should show satisfactory performance over a period of time i.e. carried out long enough to prove that the equipment is under control and turns out product of specified quality consistently. PQ should be performed by the field representative and technicians to evaluate the performance of new equipment to ensure its working with respect to accuracy and precision. Performance qualification report should be documented as proof of equipment qualification.

Installation certificate should be signed after IQ, OQ and PQ has been successfully done. Authorisation to use the equipment should be given by In-charge blood bank only after validation criteria have been met.

Responsibilities of Blood Bank In-charge for Equipment Management:

- Should oversee all the equipment management systems in the laboratory.
- Ensure training of all persons who would be using the instruments and impart knowledge and understanding on how to operate the instrument and perform all necessary routine maintenance procedures.
- Assign the equipment management responsibility to a technologist in the BTS. It should be assigned to a person who has good skills with equipment maintenance and troubleshooting.
- Develop a system for recording the use of parts and supplies (see implement a written plan for calibration, performance verification, and proper operation of the equipment).
- Establish a scheduled maintenance program that includes daily, weekly, and monthly maintenance tasks.

- Provide training for all operators; only personnel who have been trained specifically to properly use the equipment should be authorized as operators.
- Designate those authorized to use the equipment and when it is to be used.
- Develop written policies and procedures for maintenance of equipment, including routine maintenance plans. The plan should specify the frequency with which all maintenance tasks should be performed.
- Develop formats for records, create logs and forms, and establish the processes to maintain records.

Responsibilities of technologist for equipment maintenance:

- Assure that all personnel are trained on operation and maintenance
- Monitor the equipment management activities
- Review all equipment records routinely
- Update maintenance procedures as necessary
- Ensure that all procedures are followed.
- All users of the equipment should be trained in calibration and daily maintenance

Note: day-to-day maintenance should be the responsibility of the technical operator.

Equipment Log Book

- 1 Each equipment should have a dedicated logbook documenting all characteristics and maintenance elements: Instrument type, make and model number, and serial number .
- 2 Date of purchase of equipment, installation and putting it into service.
- 3 Manufacturer/vendor contact information
- 4 Presence or absence of documentation, spare parts,
- 5 Maintenance contract, warranty's, expiration date
- 6 Specific inventory number indicating the year of acquisition; this is especially useful for larger laboratories.
- 7 Current location
- 8 IQ, OQ, PQ
- 9 An inventory process should be conducted if the Blood Bank does not have an existing inventory system for equipment. During the inventory, the condition of the equipment should be documented as: functional/partially functional, or non-functional. Equipment that is not functioning needs to be evaluated as to whether or not it can be repaired. Non-repairable equipment should be retired, and work should be scheduled for equipment needing repair.

Inventory of spare parts

To ensure that the Blood Bank does not run out of spare parts, an inventory record of most frequently used spares should be kept for equipment. The record should include: part name and number; average use of the part, and the minimum to keep on hand; cost; date when the part is placed into storage, and when it is used (in and out stock log); quantity of each part remaining in inventory.

Maintenance of Equipment

The policies and procedures for maintenance should be defined in appropriate documents. Good equipment records should allow for thorough evaluation of any problems that could arise. A program for regular monitoring and maintenance of equipment should demonstrate their proper calibration, validation and proper functioning at all times.

A maintenance plan should include preventive maintenance procedures as well as routine, cleaning and sanitation, provision for inventory, troubleshooting, and repair of equipment.

Preventive maintenance should include measures such as systematic and routine cleaning, adjustment, and replacement of equipment parts at scheduled intervals.

Equipment maintenance schedule should be fixed at regular intervals: daily, weekly, monthly, or yearly to ensure equipment performance at maximum efficiency as well as to enhance the lifespan of the equipment. A proper maintenance schedule prevents inaccurate test results due to equipment failure, delays in reporting results, lower productivity and large repair costs.

Each major piece of equipment should have its own equipment maintenance document. Smaller, commonly used equipment such as centrifuges and pipettes may be managed with an equipment maintenance file that deals with all such equipment in the Blood Bank.

Equipment maintenance document should include:

- a. Step-by-step instructions for routine maintenance, including frequency of performance, and how to keep records of performance instructions for carrying out function checks, frequency of performance, recording the results.
- b. Directions for calibrating the instrument
- c. Guide for troubleshooting
- d. Any required manufacturer's service and repair
- e. Specific items needed for use and maintenance, such as spare parts.
- f. A label should be attached to the equipment indicating date of calibration, due date of calibration and due date of maintenance or service.

Service contracts

Manufacturers should provide service and repair of equipment that is purchased.

Service contracts should be in place for equipment maintained by the manufacturer or an external agent. A

procedure should be set up for scheduling service to be periodically performed by the manufacturer. All repairs, should be handled by the manufacturer only for major equipment. Service reports should be signed by the service engineer and the responsible person from Blood Bank.

Repair and Breakdown

In the event of a fault or breakdown of the equipment entries should be made in the log book and equipment should be labeled as not in use.

Troubleshooting for Problems with equipment

Failure of the equipment to operate: The technicians should be trained to troubleshoot equipment problems in order to quickly get the equipment functioning and resume testing as rapidly as possible.

Instrument drift: The preventive maintenance procedures should be repeated as a first step to resolve the problem. If failed then troubleshooting processes should be followed.

A flowchart provided by the manufacturer should help to determine the source of problems and its corrective measure.

If problems cannot be identified and corrected in-house, faulty equipment should not be used and help from the manufacturer /service engineer should be sought. Complaint should be logged in the equipment maintenance form giving complete details of the faulty equipment.

Response time of the service engineers to attend to complaints and the time taken for the equipment to be functional should be entered in the breakdown log.

Reuse and Reinstallation

When equipment is removed from the direct control of the Blood Bank or is repaired or serviced, the Blood Bank should ensure that it is checked and shown to be functioning satisfactorily before being returned to Blood Bank use, it should be checked by :

- a. Calibration
- b. Verification or testing to meet specified acceptance criteria (Verification of performance claims should be done in the Blood bank to demonstrate the same results using the kits or equipment in their equipment laboratory, with their personnel). Some of the steps that should be followed to verify performance include testing samples with known values and comparing the results to the expected or certified value e. g. if equipment is temperature controlled, establishing the stability and uniformity of the temperature.

Retiring and disposal of equipment

Blood Bank should have a policy and procedures for retiring older equipment /instrument which is not functioning and is not repairable, or when it is outmoded and should be replaced with new equipment.

It should be disposed of in an appropriate manner and not accumulate, take up valuable space and create a hazard. Consider any potential biohazards, and follow all safety disposal procedures for disposal.

Benefits of equipment management are a high level of performance ,reduction in variation in test results, improvement of the technologist's confidence in the accuracy of testing results and increase safety for workers. It also helps in lower repair costs, as fewer repairs will be needed for a well-maintained instrument reduce interruption of services due to breakdowns and failures.

(Please refer to Annexure - E)

CHAPTER 15

External Supplies and Services

The range of materials and supplies utilized within Blood Bank is wide and has a direct impact on the quality and safety of blood and services provided. Material management refers to planning, acquisition of reagents, materials, consumables, disposables required for effective and efficient operation of Blood Bank.

Blood bank should have a documented policy and procedure for selection, purchase and use of external services, equipment and consumable supplies that affect the quality of services.

Procurement planning

It is important to list out all critical supplies and services. Material that directly affects the quality or safety of blood products or its services are termed as critical and should be procured from vendors, who meet the quality requirements of Blood Bank and are cost effective. Different examples of critical supplies and services for blood banks and patients are as shown.

Supplies and Services - Examples

CRITICAL SUPPLIES	CRITICAL SERVICES
Blood Banks Equipment Consumables <ul style="list-style-type: none"> . Blood Bags . Kits . Reagents 	Blood Banks <ul style="list-style-type: none"> . Testing . Storage . Equipment Maintenance
Patients Blood / Components	Patients Issues of blood / Components

- Procurement of material is the responsibility of management but Blood Bank should be well versed with the procurement procedures of the institution from indent to conclusion of the deal. The demand should be put up in time to avoid delays in procurement as each and every item used in blood bank is essential.
- Prior sanctions for consumables/disposables before installation of equipment should be taken, so that the equipment should not be idle for want of sanction of budget for testing kits.
- Realistic timelines for each and every item should be drawn to avoid non availability of any material at any given time.
- Preparation of technical specifications should be meticulously for the items and the criteria for selection of suppliers to minimize problems in procurement.
- Rate contracts agreement between the purchaser and supplier to supply stores at specified rates during the period of contract, should be atleast one year but renewable. The quantities are not

mentioned in the contract ,but the suppliers should be bound to accept the order during the currency of the contract.

- Staggered supply -the order should be issued once but the supplies may be ordered to be delivered in staggered manner, every quarter or six monthly.

Inventory control –Inventory is sum total of goods in hand and inventory control is a management tool to maintain an economic minimum investment in materials. In the inventory control system, control should be exercised by fixing a minimum and maximum for each item.

The blood bank should have a procedure for inventory control system for supplies. Some definition for inventory control.

Critical / re-order levels- Reorder level denotes the stock level at which fresh order has to be placed. It is the consumption of the item/day multiplied by the lead time and buffer stock.

Lead time is the average duration of time in days between placing of order and receipt of supplies.

Buffer stock is the quantity of material set aside as a safeguard against the variation in demand and procurement.

Blood bank should ensure:

1. No stock-outs – item should be reordered in such a way that stock level at any time never goes beyond minimum level fixed for it.
2. No unnecessary stocking-the quantity reordered should be so adjusted that the stock does not exceed the maximum level.
3. No use of expired material – inventory control to ensure that extra material is not procured and there is no loss due to obsolescence.

Selection of vendor

- Blood bank should have a policy and procedures (QSP/SOP) to select and evaluate the suppliers of critical reagents, supplies and services that affect the quality of examination and maintain records of these evaluations. A list of selected and approved suppliers of equipment, reagents and consumables should be maintained.
- Performance evaluation of suppliers should be monitored to ensure that purchased items consistently meet the laid down criteria e.g.
 - Time between ordering and supply – the lead time
 - Time between supply and installation
 - Timely redressal of break down / complaints
 - Maintenance of cold chain at the time of supply

Receipt and Inspection of stores : Inspection of incoming supplies should be essentially undertaken to maintain the standards and verifies that stores receive supplies which have been ordered for only.

1. The SOP / flowcharts should specify the method for inspection, acceptance/ rejection and storage of consumable materials .e. g sampling procedure for inspection, cold chain for reagents and kits
2. There should be a process for verifying the compliance with standard specification for the purchased material.
3. There should be process for verifying quality using known samples for quality of consumables supplied
4. Ensure supplies should be made within date of delivery.
5. Ensure shelf life of items should be adequate
6. Monitor if cold chain maintenance and document
7. Should reject items not approved by inspection team

Non conforming supply: In case of non conformance of supplies, corrective action should be taken by contacting the supplier. Ask for replacement of supplies if quality is compromised as ascertained by test reports. Should not take supply of short expiry test kit and demand replacement of kits with longer shelf life. Payments should be released only if supplies are acceptable.

Inventory register

The blood bank should have a policy for recording of the following details for consumables including reagents, control materials & calibrators for external supply and also in house production:

- Quantity ordered & received
- Manufacturer's name & address
- Batch no., lot no, manufacturing dates & expiry date
- Date of receipt in the centre
- Date, when it was placed in service
- QC check report

Quality records should be established and maintained as per the policy for the following:

1. External services
2. External supplies

Documentation record of all purchased items required by National/ Regional or local regulations

Storage of reagents and supplies

1. SOP should be available to ensure storage in a safe and hygienic place at proper temperature for supplies and reagents used in collection, processing, compatibility testing, storage and distribution of blood and blood components.
2. The process should ensure that usage of those supplies and reagents that are oldest shall be used first (First expiry first out-FEFO). This should also applicable for those supplies which do not bear

expiry date.

3. Expired supplies and reagents should be discarded as per procedure.
4. Critical level for all reagents and consumables should be defined.
5. There should be a mechanism to ensure use of supplies and reagents as per instructions provided by manufacturer.
6. Blood collection containers and satellite container(s), should be examined visually for damage or evidence of contamination prior to its use and immediately after filling .Examination for breakage of seals should be done. QC check report of blood bags should be preserved as records.

Precautions

It should be ensured that the supplies coming in contact with blood and blood component for transfusion are sterile and pyrogen-free (it shall not interact with the product in a manner as to have adverse effect upon the safety, purity, potency or effectiveness of the product).

(Please refer to Annexure - F)

CHAPTER 16

Process Control

Process mapping is one of the basic quality or process improvement tools used to understand, analyze and document process and activities. Process mapping visually illustrates the work flow. It has acquired more importance in recent times as an approach to quality management to know how each process relates to other processes within the Blood Banks and how those interactions impact quality. It provides a common understanding of the entire process and specific roles and contributions of process participants.

Processes are simply sequences of actions designed to transform inputs into outputs. Blood Banks activities involve processes and procedures. The characteristics of a process are combining several tasks/jobs into one with steps in the process following a natural order. Process mapping displays the sequential steps involved in converting a specific input into required output. Process mapping is the framework for the basis of SOPs and Work instructions and assignment of job responsibilities.

Importance of Process mapping in Blood Banks

It is a quality tool for improvement

1. Process mapping is an exercise to identify all the steps and decisions in a process in diagrammatic form, with a view to continually improving that process. It helps to identify the critical points and helps to delineate responsibilities
2. Process mapping enables Blood Bank to establish what is currently happening, how predictably and why.
3. It identifies gaps in processes and measures how efficiently the process is working and gathers information to understand where waste and inefficiency exist and their impact on stakeholders.
4. Process mapping helps to identify problem areas and opportunities to develop new improved processes to reduce or eliminate inefficiency for process improvement. It helps to identify the focus areas for root cause analysis.

Types of process map

There are two basic types of charts used in process mapping:-

1. Process Flowchart: This chart simply sets out the sequence of activities and decision points. These are useful for capturing the initial detail of the process.
2. Deployment Flowchart: This shows who does what along with the interactions between people and departments.

Preparation for process mapping

- Outline the description of the process and identify the technologist /staff responsible for the process.
- **Assemble** this small team of all those working in and around the process including representatives

for those who do the work and their supervisors / managers of the process.

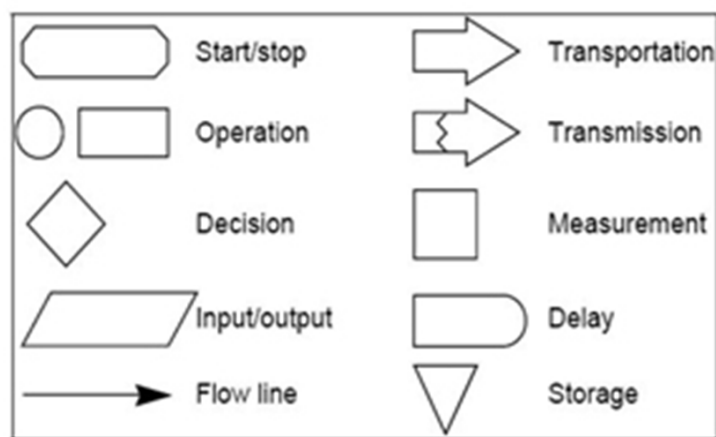
- **Discuss** the Process Objectives, Process risks, Key controls and Measures of success. Use “drill-down” approach (unit, task and action levels). Always review and revise the process.
- **Roughly and simply sketch** the process (without too much detail) describing the sequence of tasks and decision points as they actually happen. The sketch should indicate:
 1. Who does what
 2. What is done and when
 3. What decisions have to be taken
 4. What possible paths follow from each decision.

Symbols used in process mapping

The start and end symbols indicate the start and end points in the map.

Rectangular boxes are used to indicate process steps and diamonds are used for decisions. Decisions usually have two branches – one for yes and another for no, indicated by Y and N respectively.

Circles with a letter or letters are used as page connectors, i.e., if a process spills over onto another page, then a page connector is connected to the last process step in the first page and the first process step in the next page with the same letter.



Draw the flowchart initially to represent the operation, as it actually is and not what you might prefer it to be. Try to layout the sequence by working in a downward direction rather than across. This will help later if you want to convert your process chart to a deployment flowchart.

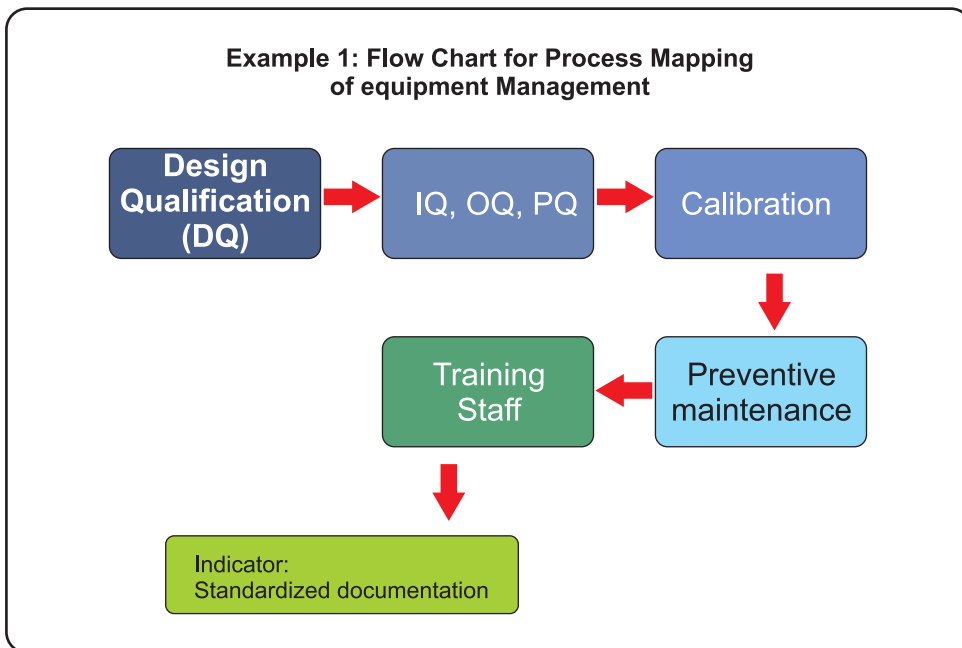
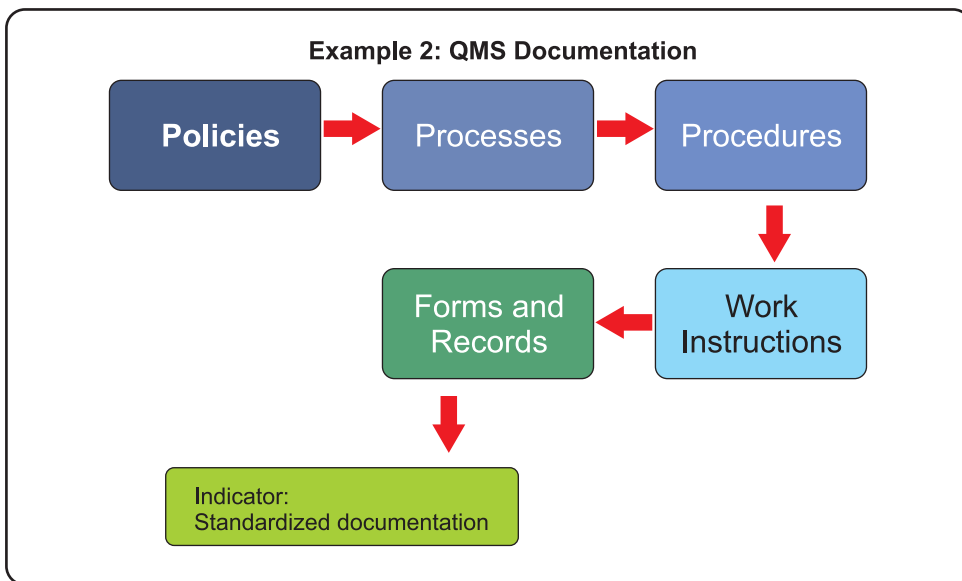
Having thought through the main steps of the process, flowchart them in sequence as they are performed using rectangles for tasks and diamonds for decisions. Use connecting arrows between boxes to represent the direction of the sequence.

It can be helpful to use Post-it notes on a large whiteboard or wall. Each note can represent a step in the process and save a lot of pain when it comes to re-shuffling the sequence to get it right. Use a colour to represent the person carrying out the task if desired.

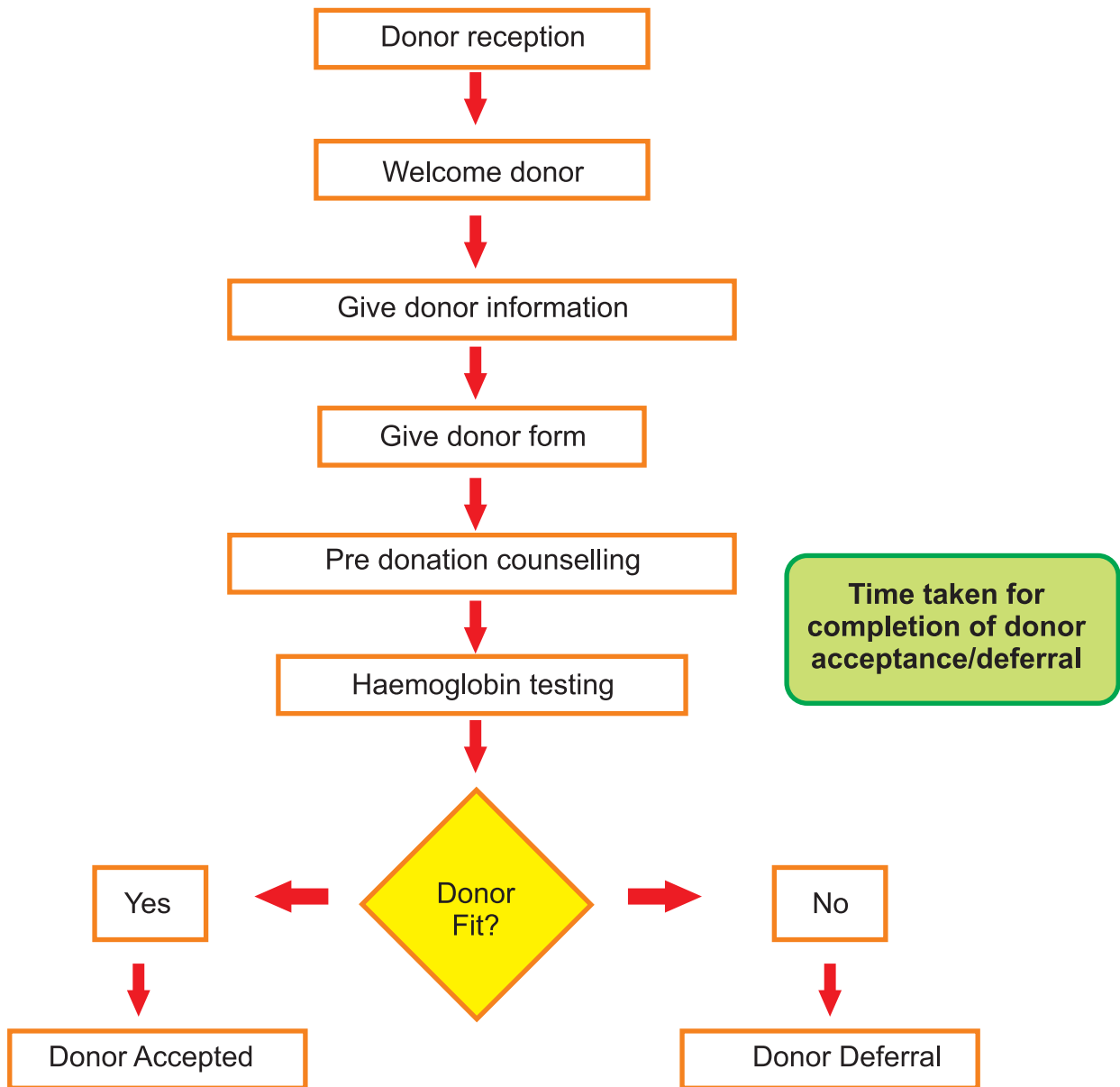
Concisely describe each task or decision in its own box. If necessary, number boxes and provide a key to where the activity is described in more detail.

If the process includes decision points, this will normally imply some return routing causing some boxes to have more than one input.

Decisions often pose questions answerable by YES or NO. It can be convenient to structure the questions so that the preferred answer is YES whereas NO leads to re-routing etc. The most efficient process takes the form of a straight line down the page



Example 3: Voluntary Blood Donation Process Flow - Donor acceptance/deferral



Map Analysis

Review process map and look for any redundant activities and delays between steps/bottlenecks. Look for any duplication or unnecessary steps. Verify if there are any endless do loops where rework is common or bottle necks /backlogs in the process. Activity flow should not go back and forth repeatedly between the staff. There should be no ambiguity between roles and responsibilities of staff.

Finalization of Process

The process flow should be efficient without any bottle necks/loops and duplicates. The procedure should be fast tracking in achieving a desired outcome.

CHAPTER 17

Identification of Deviations and Adverse Events

Deviation is defined as any nonfulfillment of requirement as per laid down procedures (ISO 9000:2005). Other terms frequently used include: accident, adverse event, error, event, incident, and occurrence. Deviations occur in many areas in the Blood Bank and can be identified during different situations:

1. Clinician/Patient Complaints
2. Instrument Calibration, certification of calibration agency
3. Inspection of consumables
4. Internal Quality control
5. Inter lab comparison for EQA
6. Staff satisfaction surveys
7. Reporting
8. During Internal audit/External Audit

Complaint: It is defined as an expression of dissatisfaction made to an organisation related to its services / its products or the complaint handling process itself where the response is explicitly or implicitly expected. Complaints are received when expectations are not met. Received complaints may be only the tip of the iceberg, they should be always investigated.

Adverse Events

These are events such as Accidents, Errors, Incidents and Near Misses. Events that are unusual, unexpected, may have an element of risk, or that may have a negative effect on clients (blood donor / recipient), staff, or the organization (blood services).

Management of Deviations and Adverse Events

1. Detection of deviations and Adverse Events
2. Complaint file
3. Adverse event reporting
4. Investigations
5. Immediate actions

Blood Bank should have policies for detecting, investigating, and responding to events that result in deviations from accepted policies, processes, and procedures in Blood Bank.

These Policies and relevant SOPs should be available to all the staff and the responsibilities of all staff members, including the blood bank in-charge should be defined. The responsibility for analyzing the deviation should also be defined for taking corrective action. The corrective action to be taken should also be determined and documented in formats.

The significance of deviation should be determined and in case it is found to be detrimental for the patient, information to the clinician responsible for using the result or in case non conformity is of incompatibility in blood grouping recall of blood/products issued should be undertaken. Action taken immediately at the time of detecting a deviation like this to mitigate its immediate effect is considered as immediate action.

It is important to define immediate, corrective and preventive actions for better understanding.

Remedial /Immediate action: Action taken to alleviate the symptoms of existing deviation or any other undesirable situation.

Corrective action: Action taken to address the root causes of an existing deviation or other undesirable situation in order to reduce or eliminate recurrence.

Corrective action is taken to protect the customer from receiving or using non conforming product and to prevent recurrence. Blood bank should have policy and procedure to identify, document and eliminate the root causes of such deviation. There should be evidence to prove that the data from this policy can be used for systematic improvement in the blood bank by reviewing the effectiveness of the corrective action taken.

Preventive action: Action taken to reduce or eliminate the potential for a deviation or other undesirable situation in order to prevent occurrence.

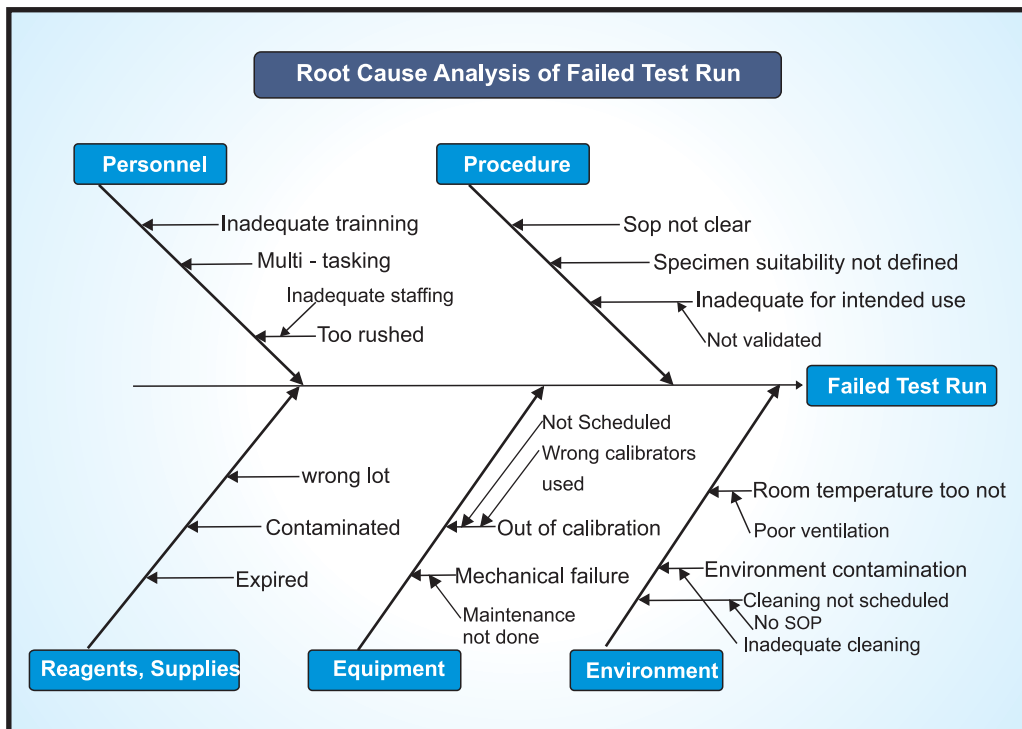
Policy should also define authorization for resumption of the procedure or testing in case of deviation due to equipment failure.

Preventive action is a proactive process for identifying opportunities for improvement, whenever they are identified either technical or concerning the management system. The action plan should be developed, implemented and monitored to reduce the likelihood of the occurrence of such deviations. Procedures for preventive action shall include the initiation of such action and ensure that these are effective. Preventive action should also involve analysis of data, including trends/risk analysis of outliers and EQAS.

Root Cause Analysis (RCA)

RCA helps to identify, document and eliminate the root cause of a problem.

An example of root cause for a failed test run- fish bone / Ishikawa diagram



Questions to be asked before analysis of the root cause	
What is the problem?	Define Problem
Where did it happen?	Which department/units could be responsible
What is the significance?	Benign/Serious/Recurrent
Why did it happen?	Man /Machinery/Training Problem
When did it happen?	Do RCA soon after the problem.

When should RCA be done

- Recurrent problems –Typographical errors, sampling errors
- Serious problems- Near misses, Adverse transfusion reactions
- Sentinel event- A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof eg an Incorrect Blood Transfusion

Approach for RCA

Determine the frequency of error, and area of occurrence to provide clues to the problem. (Quality manager):

- Perform RCA as soon as possible after the error/variance
- Involve all personnel involved in the error in the analysis.
- Focus on the setting of the error and the systems involved. Purpose of the analysis should not to assign blame but to develop confidence amongst staff to detect the problem and find a solution so that it should not recur.

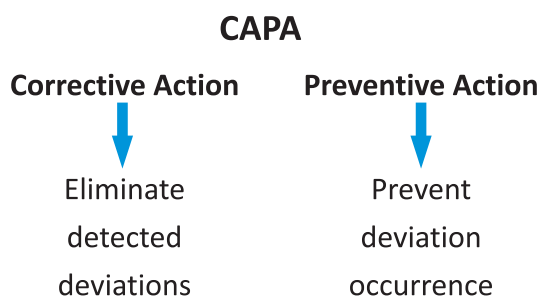
Results of RCA examples

- Sampling errors could be due to shortage of staff or disengagement of staff
- Technical errors could be due to absence of Protocols or training and indicate improper monitoring/supervision
- Near Miss events could be due to absence of checks and balances

RCA of Blood Grouping Error

Wrong Grouping	Sampling error due to untrained staff/defective bar coding
Corrective action	Correction- call for a resample and issue new report Corrective action: issue a warning to technician. Another patient has blood group of this patient which may have been overlooked.
Preventive action	Put a second check for future to prevent any errors. Protocol for grouping needs to be corrected at more places as it can result in a sentinel event if overlooked.

Corrective and preventive action (CAPA)



Steps for CAPA:

- Identification, Investigation & Analysis of potential causes of non conformance of product, processes & quality systems
- Identify actions needed to correct & prevent recurrence
- Verify or validate the corrective & preventive actions to ensure it's effectiveness
- Implement & record changes in methods needed to correct & prevent identified quality problems
- Submit information on CAPA for Management Review

Example of CAPA:

Rupture of a unit of whole blood in the centrifuge

- **Remedial action** : Discard unit, decontaminate centrifuge
- **Corrective action**: Find out the cause if unit was over collected, Calibrate the centrifuge (speed)/biomixer (vol)

- **Preventive action :** Implement proper AMC of equipment and strict adherence to checking of volume of whole blood collected in the bag before centrifugation

Implementation & Monitoring Changes Resulting From Corrective Action

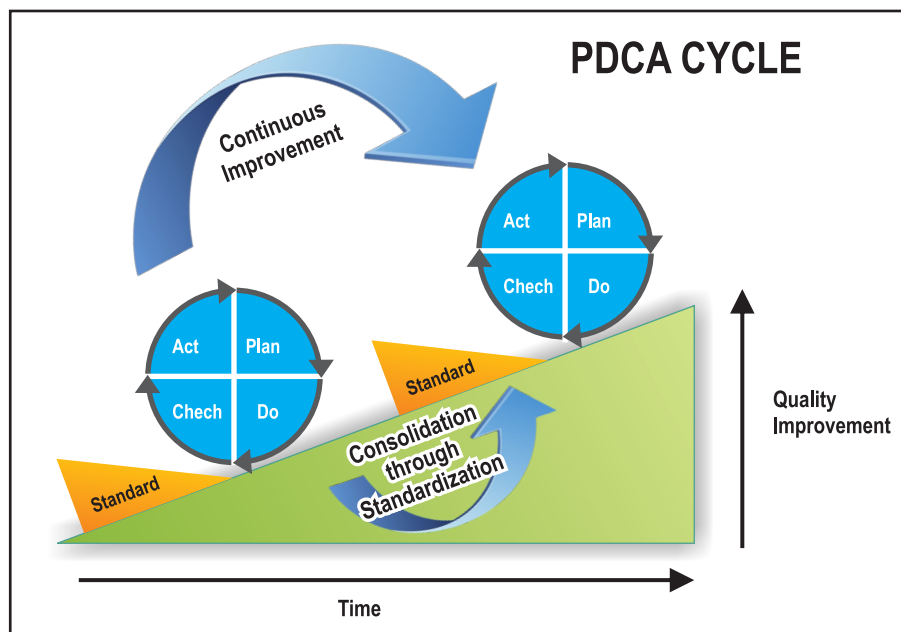
- Document and implement any change required after investigations
- Inform all concerned staff affected by the changes or corrective action taken about the same and retrained if necessary
- Monitor the results of any corrective action taken, in order to ensure that they have been effective in overcoming the identified problems
- Conduct additional audit for the particular area if the investigation casts doubt on compliance with policies and procedures

Procedure for preventive action

- Identify opportunities for improvement in technical or management system whenever they are identified
- Develop Action plan for implementation and monitoring to reduce the occurrence of non-conformities
- Initiate such action and ensure that these are effective

Continual Improvement

Blood Bank should aim for continual improvement as a strategy for effective QMS . Improvement activities should be directed towards highest priority based on risk assessment by developing action plans , documenting them and implementing.



Deming cycle expressed as Plan, Do, Correct and Act cycle (PDCA) strives for continual improvement to maintain quality in BTS. Quality is an ongoing activity and if quality system does not deliver continuous improvement the cycle is not functioning properly. The system should be in place for checks regarding the

services and quality control results which should be investigated to determine the cause of defects and determine what corrective and preventive actions should be taken for further improvement. A problem encountered always presents an opportunity for improvement.

Adverse Events

- **Near Miss**

The potential for harm may have been present, but actual event was prevented because some recovery action was taken

- **No Harm Event**

Event actually occurred but no harm was done

- **Misadventure**

The event actually happened & some level of harm, possibly death occurred

Policy on Adverse events

1. There should be policies and procedures for reporting adverse events

- “Near miss” incidents
- Adverse drug reactions (transfusion reactions)
- Relevant SOPs should be available and known to all staff members of the blood bank.
- Define the responsibilities of all staff members, including the blood bank In-charge for handling adverse events.
- Incident reporting should be a part of induction training for all staff and an incident reporting form should be filled for all events that are reported, analyzed and evaluated for managerial action.
- Incidents should be graded for their degree of risk
- Records should be maintained on all: Accidents / Errors / Incidents / Near Misses

Examples of Adverse events	
Blood donor related	Severe vasovagal reaction Arterial puncture Nerve injury
Recipient related	Incorrect blood / component transfusion Acute transfusion reaction Transfusion transmitted infections
Product related	Haemolyzed blood Contaminated blood
Care management related	Wrong identification Wrong component Death due to ABO mismatch

Components of Event Report	
Who	Identity of reporting individual Identity of person committing, investigating & taking action
What	Brief description of event Effect on donor, patient, product, facility Product number, reagent, equipment
When	Date of report Date of occurrence of the event Date of discovery of the event
Where	Physical location of event Where in process event was detected Explanation of how event occurred
Why & How	Contributing factors to event Root cause (s)
Follow up	Any notification (DCGI), NACO, patient physician) Corrective action, date of implementation Effectiveness of action taken

Example of Event reporting

Wrong blood issued but not transfused	
Event Classification Type Procedure involved Process involved Product involved	Near Miss Product issue Blood administration Red blood cells
Underlying cause Immediate cause	Two patients of same name
Root cause	Inadequate verification of patient identification
Outcome Severity Product no harm, Patient no harm,	Serious Unit returned to inventory Blood not transfused

Policy for issue of non conforming blood

The blood bank should have a policy and procedure for release/ discard of non-conforming blood component and may authorize in-charge of the blood bank for the same. This policy and relevant SOPs should be available and known to all staff members of the blood bank and all such events should be recorded

Prevent Recurrence of Deviations

The Blood Bank should have a policy and procedure to identify, document and eliminate the root cause of a deviations.

Incidents, errors and complaints identified at any stage in a collection, testing, manufacture or distribution process should be reported to a designated individual, These should be corrected on an individual basis. Such reports are a valuable source of information from which to learn and improve.

They should be reviewed and analyzed on a continuous basis with a view to identifying the root cause of system failures, so that error can be minimized or eliminated, and to identify improvements that can be introduced to the system.

The review should be designed to identify trends either adverse or beneficial. Data from this policy should be used for improvement of Blood Bank and linked to the blood banks planning process so that improvements that require resources should be given sufficient consideration and support in their implementation.

(Please refer to Annexure - G)

CHAPTER 18

Quality control of Immunohaematology

Quality Control of Antisera, Reagents and serological tests

Reagents directly contribute to the safety of the blood Supply and ensure reliable results. They should be of high quality BUT also cost-effective selection should be based on requirements, and not cost alone.

List of Reagents used in Blood Bank:

The blood bank reagents depend on the source of antigens & antibody in testing.

- Antisera – anti A, anti B, anti A, B, anti D, anti human globulin (AHG)
- Lectins e.g. anti A1, anti H
- Albumin
- Enzymes
- Saline
- Reagent red cells
- Low ionic strength solution (LISS)

Antisera - Detect an antigen present or absent on RBC (donor/patient red cells)

Reagent Red Cells - Detect antibody present or absent in serum (donor/patient serum)

Reagents may be Monoclonal (single clone of cells specificity) or Polyclonal

(human source: mixture of cells-contains multiple antibodies)

Serological tests in blood banks

- ABO grouping and Rh typing
- Weak D (or Du as earlier named) testing
- Antibody detection and identification
- Cross matching
- Antibody titration
- Direct antiglobulin test
- Haemagglutination inhibition test (for secretor status in saliva)

ANTIBODIES	
POLYCLONAL	MONOCLONAL
Derived from different B Lymphocytes cell lines	Derived from a single B cell clone
Batch to Batch variation affecting Ab reactivity & titre	<ul style="list-style-type: none"> • Reproducible • Predictable • Potentially inexhaustible supply of Ab • with exquisite specificity
NOT Powerful tools for clinical diagnostic tests	Enable the development of secure immunoassay systems.

Monoclonal Antibody

- **Advantages**
 - Not contaminated with other proteins
 - Consistently reproducible affinity & specificity
 - Can be produced indefinitely in unlimited quantities
- **Disadvantages**
 - Difficult preparation
 - High cost

Selection of Antisera

- Antisera must be of high quality with a shelf life of at-least one year of use and should be received in cold chain
- Should contain a preservative to minimize contamination.
- Should be stored in the refrigerator at 2-8°C
- Should be used according to manufacturer's instructions
- Must comply with the standards laid down for potency (titer and avidity) and specificity
- New reagents should not be introduced into routine work until internal QC testing have confirmed that they are satisfactory
- Should be clearly labeled with :
 - Batch number
 - Expiry date
 - Storage temperature

What specifications need to be considered?

Appearance

- Reagent must be clear.
- No turbidity, precipitate, particles on visual inspection

Specificity

- Clear-cut reaction with RBC bearing the corresponding antigen(s)
- Do not contain any other antibody specificity

Potency: it is measured by

A] Titer

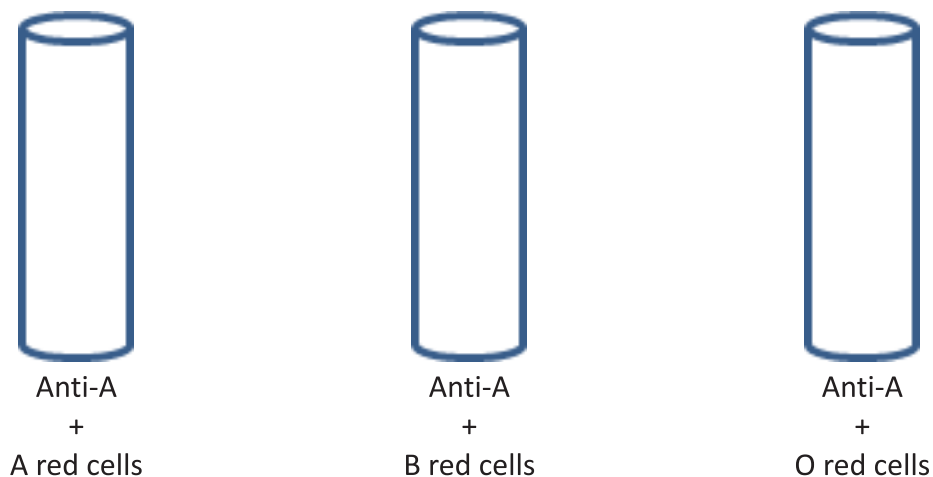
- It is the highest dilution of the antisera at which the macroscopic agglutination is seen at strength of 1+

B] Avidity

- Avidity means the overall strength of reaction between antigen and antibody
- It is measured by the time duration in seconds for the appearance of macroscopic agglutination

Specificity

- Label clean three test tubes for each antisera to be used
- Add 2 drops of antisera to be tested
- Put one drop of 2-5% red cell suspension of known ABO group red cells in respective tubes
- For eg add corresponding red cells suspension in three glass test tubes for testing the specificity of anti A antisera.



Avidity

- Label a clean glass slide for each antisera to be used
- Put one drop of 10% red cell suspension of respective ABO group.
- Put 1 drop of respective antisera adjacent to the drop of red cell suspension
- Mix both the drops using disposable applicator stick
- Start the stop watch simultaneously
- Observe and note the time required for visible agglutination over the view box

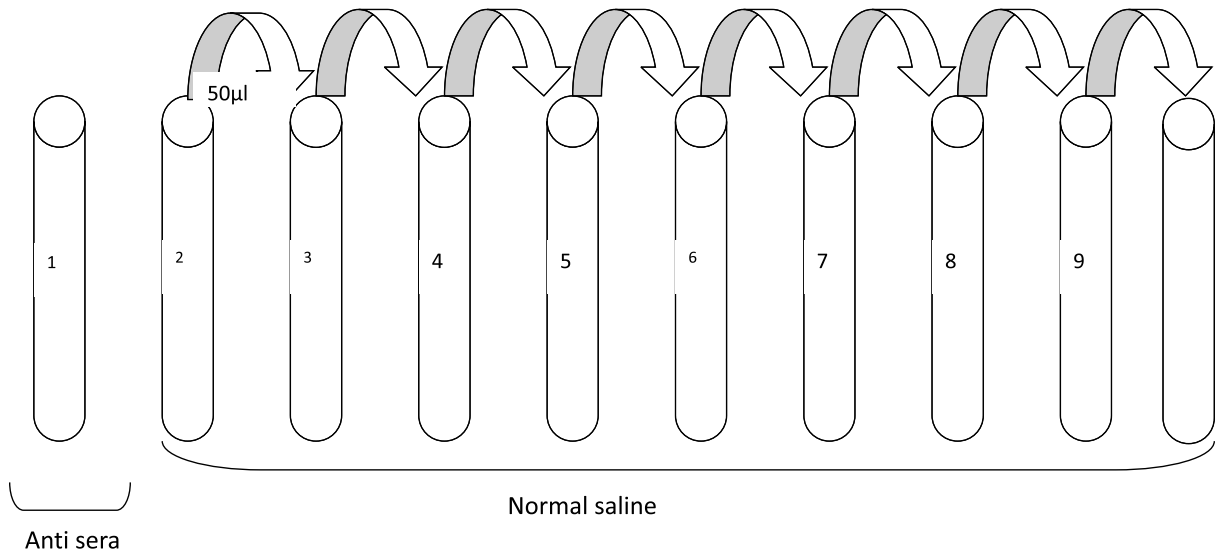
Titer – doubling dilution

- Label 10 test tubes
- Add one volume of saline to all test tubes except the first tube
- Add an equal amount of antiserum to each of the first two tube
- Using a clean pipette mix the contents of the 1 in 2 dilution several times and transfer one volume into the next tube
- Continue the same process for all the dilutions, using a clean pipette to mix and transfer each dilution

- Add 1 drop of the corresponding red cell suspension (5%) into each test tube. Mix well and keep these test tubes at room temperature for at least 15min
- Centrifuge all these test tubes at 1000 rpm for 1min.
- Examine test results macroscopically; grade and record the reactions

Dilution and Titer

- Dilution is expressed as: 1 in 16
which means that the dilution factor is 16
- Titer is simply the inverse of dilution. So, it is the number at which the end point agglutination (1+) is achieved.
e.g. At titer of 16 is recorded for end point agglutination at a dilution of 1 in 16.
- The first tube is a NEAT on i.e. without any dilution
- The second tube contains one part serum and one part of normal saline.
- Hence, it becomes 1 in 2 dilution
(It can be written as 1 : 1 and read as 1 is to 1)



Interpretation

- Observe the highest dilution that produces macroscopic agglutination
- The titer is reciprocal of the dilution level for e.g 32 for 1:32
- If there is agglutination in the tube containing the most diluted serum, the end point has not been reached, and the additional dilution should be prepared and tested

Strength of agglutination

- 4+ One large agglutinate with clear background
- 3+ Several large agglutinates with clear background
- 2+ Medium size agglutinates with clear background
- 1+ Small agglutinates with turbid background
- 0 No agglutination
- Mf Mixture of agglutinated & unagglutinated RBCs
- H Haemolysis

Various areas for QC in serology

- **Reagents**
 - Antisera anti-A, anti-B, anti-AB, anti-D, AHG
 - Red cells A1, B, O cells
 - Medium normal saline
 - Potentiator LISS / Albumin / PEG
- **Equipment**
- **Personnel**
- **Techniques**

ABO ANTISERA

Anti-A, Anti-B, Anti-A,B (Monoclonal Antibodies)

- **Anti-A, Anti-B**
 - blends of 2-3 MoAbs to optimize the intensity of agglutination for a slide tests & the potency for detection of the weaker sub groups e.g. Ax & Bw
- **Anti-A,B**
 - blends of at least 2 MoAbs to optimize both A & B reactions
- **Anti-A+B**
 - blends of Anti-A & Anti-B MoAbs

Quality Assurance in Blood Grouping

- Use of standardized reagents
- Daily QC of reagents
- Tubes should be clean & dry to avoid false positives
- Serum should be added first followed by red cells
- Hemolysis during antigen antibody reaction is considered as positive reaction
- Macroscopic readings may require agglutination viewer
- Negative reactions can be confirmed microscopically

Quality Assurance in ABO Grouping

- Ideally, test should be done using test tubes
- Test should be done at room temperature (22°C)
- Tubes should be clean and properly labeled
- Both, Cell & Serum grouping should be performed
- Anti- AB may be included for confirmation of group O and weak variants of A and B
- Serum grouping using pooled red cells
- Pooled cells should be prepared daily and check for specificity
- Serum grouping helps detect irregular antibodies and Bombay phenotype

Quality Control of ABO Antisera

Parameter	Quality Requirements	Frequency
Appearance	No turbidity , precipitate, particles or gel formation by visual inspection	Each day
Specificity	Clear reaction with red cells having corresponding antigens and no reaction with negative control	Daily and each new lot
Avidity	Macroscopic agglutination with 10% red cells suspension using slide test	Daily and each new lot
Reactivity	No immune hemolysis , rouleaux formation or prozone	Each new lot
Potency	Sera should give 3+ reaction in saline tube test using a 3% red cell suspension at R.T.	Each new lot

Quality control - antisera

Antisera	Titer	Avidity
Anti-A		
A ₁ cells	>256	3 -6 Sec
A ₂ cells	>128	5 – 6 sec
A ₂ B cells	> 64	5 – 6 sec
Anti-B		
B cells	>256	3 – 4 Sec
A ₂ B cells	>128	5 – 6 sec
Anti – AB		
A ₁ cells	>256	3 – 4 sec
B cells	>256	3 – 4 sec
A ₂ cells	>128	5 – 6 sec

Worksheet for QC of Anti-A antisera

Parameters	Required quality control criteria (DGHS)	Name of the firm		
	Date of Manufacture			
	Date of Expiry			
	Lot No.			
Quantity				
Appearance ▪ Turbidity ▪ Precipitate ▪ Particles	No No No			
Specificity ▪ A ₁ cells ▪ A ₂ cells ▪ B cells ▪ O cells	3 – 4+ 3 – 4+ Negative Negative			
Reactivity ▪ Immune hemolysis ▪ Rouleaux ▪ Prozone	No No No			
Avidity ▪ A ₁ cells ▪ A ₂ cells ▪ A ₂ B cells	3 – 4 sec 5 – 6 sec 5 – 6 sec			
Potency (titre) ▪ A ₁ cells ▪ A ₂ cells ▪ A ₂ B cells	1:256 1:128 1:64			
Fulfilling DGHS criteria				

Lectins

- Lectin is a seed extract that has antibody specificity
- Lectins do not contain antibodies, instead they contain proteins that react similar to antibodies
- Used to identify certain types of blood group antigens by binding to the carbohydrate determinant of the antigen, resulting in agglutination
- Other use of Lectin is to investigate red cell polyagglutination
- Some examples
 - Dolichos biflorus (binds A1 antigen)
 - Ulex europaeus (binds H antigen)

QC of anti-A1 and anti-H lectins

Reagent	Red cells	Titer	Avidity (s)
Anti-A ₁	A ₁	1:16	15-20
	A ₂	neg	
	O	neg	
Anti-H	O	1:16	15-20
	A ₁	1:1	
	A ₂	1:8	
	Oh	neg	

Pooled Red Cells

- Pools of red cells from 3–5 blood donors
 - Represent all clinically significant antigens
- Prepared daily
 - Identify and record donor unit number
 - Confirm the group
 - Wash 3 times with saline
 - Add equal volume of washed red cells in a tube
- Prepare working solution (5%)
 - Add 1 drop of pooled cells to 19 drop of saline
- Check specificity
 - Example: B cells should react with anti-B only

QC of reagent red cells - specificity

Known red cells	Anti-A	Anti-B
A	4+	Neg
B	Neg	4+
O	Neg	Neg
O Rh D neg	Neg	Neg

Inclusion of O cells & autocontrol is must in reverse grouping to rule out

- Bombay blood group
- Auto antibodies
- Allo antibodies
- Rouleaux formation

Everyday QC of antisera & reagent red cells

Reagent Red cells	Anti-A Lot /batch	Anti-B Lot / batch	Anti-AB Lot / batch	Anti-D Lot / batch
A1 3 donor Unit no	4+	Neg	4+	Not Applicable
B 3 donor unit no	Neg	4+	4+	Not Applicable
O pos 3 donor unit no	Neg	Neg	Neg	4+
O neg 3 donor unit no	-	-	-	Neg

Anti – D Reagents

Quality Assurance in Rh Grouping

- Anti-D in duplicate for confirmation of Rh D negatives
- Use of one IgM and one blend of IgG + IgM preferable
- If Rh D negative, Weak D test to be done in case of donors

Quality Control of anti-D Antisera

Parameter	Quality Requirements	Frequency
Appearance	No turbidity , precipitate, particles or gel formation by visual inspection	Each day
Specificity	Clear reaction with O positive red cells and no reaction with O negative cells	Daily and each new lot
Avidity	Macroscopic agglutination with 40% red cells suspension using slide test	Daily and each new lot
Reactivity	No immune hemolysis , Rouleaux formation or prozone	Each new lot
Potency	Sera should give 3+ reaction in saline tube test using a 3% red cell suspension at R.T.	Each new lot

Acceptable Titer & Avidity

Type of reagent	Type of red cells	Titer Immediate spin	Titer 30 min incubation	Avidity time (s)	Strength
IgM monoclonal	O positive	1:64-1:128	1:64-1:128 (at RT)	5-10	3+
Blend of IgM+IgG monoclonal	O positive	1:32-1:64	1:128-1:256 (at 37°C)	10-20	3+

Worksheet for QC of anti-D (IgM+IgG) antisera

Parameters	Required quality control criteria (DGHS)	Name of the firm			
	Date of Manufacture				
	Date of Expiry				
	Lot No.				
	Quantity				
Appearance ■ Turbidity ■ Precipitate ■ Particles	No No No				
Specificity ■ O Positive cells ■ O Negative cells	3 – 4+ Negative				
Reactivity • Immune hemolysis ■ Rouleaux ■ Prozone	No No No				
Avidity • O Positive cells (R ₁ R ₁)	10 – 20 sec				
Potency (titre) O Positive cells (R ₁ R ₁) • Immediate spin • 30 to 45 minutes incubation	1:32 – 1:64 1:128 – 1:256				
Fulfilling DGHS criteria					

Anti Human Globulin Reagents

- Detects IgG antibodies and Complement protein that have attached to RBC.
- 2 Types
 - Polyspecific
 - Monospecific

Polyspecific AHG Reagent

- Used in AGT to detect in vivo attachment of IgG and/or complement on the surface of the red cell or in serum
- Usually available as combination of Anti-IgG and Anti-C3d

Monospecific AHG Reagents

- Used in the investigation of positive DAT to determine the nature of molecules attached to the red blood cells
- Differential DAT with monospecific AHG can detect IgG or C3 on the red blood cell surface
- Several formulations exist:
 1. Anti IgG
 2. Anti-C3d

Quality Control of AHG Antisera

- Each vial of a new batch tested for its specificity and sensitivity with IgG coated red cells as positive control and non-sensitized red cells as negative control.
- The potency of anti-IgG of AHG reagents can be estimated by titration using IgG (anti D) sensitized red cells
- Minimum requirements for quality product of AHG :
 - Anti IgG 1:64
 - Anti C₃/C₄ 1:4

Quality Control Of AHG Antisera

Parameter	Quality Requirements	Frequency
Appearance	No turbidity , precipitate, particles or gel formation by visual inspection	Each day
Reactivity & Specificity	No Prozone phenomenon	Each new lot
	No hemolysis or agglutination of unsensitized red cells	Each new lot
	Agglutination of red cells sensitized with anti-D sera	Daily
	Agglutination of red cells sensitized with complement binding antibody	Each new lot
	Agglutination of red cells sensitized with C3b and C3d	Each new lot