

Discouraging unethical practices is of utmost importance and challenge for Blood Banks. Commercialisation of Blood Banks and payment to donors should be curbed by and taking necessary steps. Efforts should be made avoid Coercion of donors for replacement and charge excessively from patients.

As part of ethics, confidentiality of donors, testing reports and staff should be maintained for all practical purposes. There should not be any involvement in activities that would diminish confidence in the Blood Banks competence, impartiality, judgment or operational integrity.

Management and personnel should be free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work. Human blood should be treated according to relevant legal requirements.

Management Responsibility

The management should be well aware of applicable regulations, standards and laws and provide commitment, dedication and adherence to the cause of QMS.

The Management should be able to provide a strategic direction to the Blood Bank to develop and grow. This should be enabled through explicit organization structure and lines of communication and accountability. Methods of communication within the Blood Bank and externally should ensure that strategic goals are attained wherever possible and reviewed as necessary, to reflect local needs.

Management responsibility is to ensure establishment of quality policy with an intent, planning, defining responsibilities, authorities and interrelationships. They should also appoint or designate quality manager and ensure availability of competent staff and resources. Management should also conduct management review meetings to address an agenda , deficiencies and scope for improvement of quality.

Quality Policy

It is a document that defines the overall intentions and direction of the quality management system. It demonstrates the Blood Banks commitment to quality with clear leadership by top management.

Quality policy includes commitment to Good professional practice, compliance with standards and continual improvement of quality in Blood Banks. Every blood bank should have a written and current quality policy and all members of staff should be aware of this quality policy. Quality policy should include the scope of services in the blood bank and objectives of quality management systems as well as commitment and compliance with QMS.

It provides a framework for establishing and reviewing quality objectives and should be communicated and understood within the organization. The policy needs to be reviewed for continuing suitability. Head of management should sign the quality policy which should be displayed in the reception area.

Quality Objectives

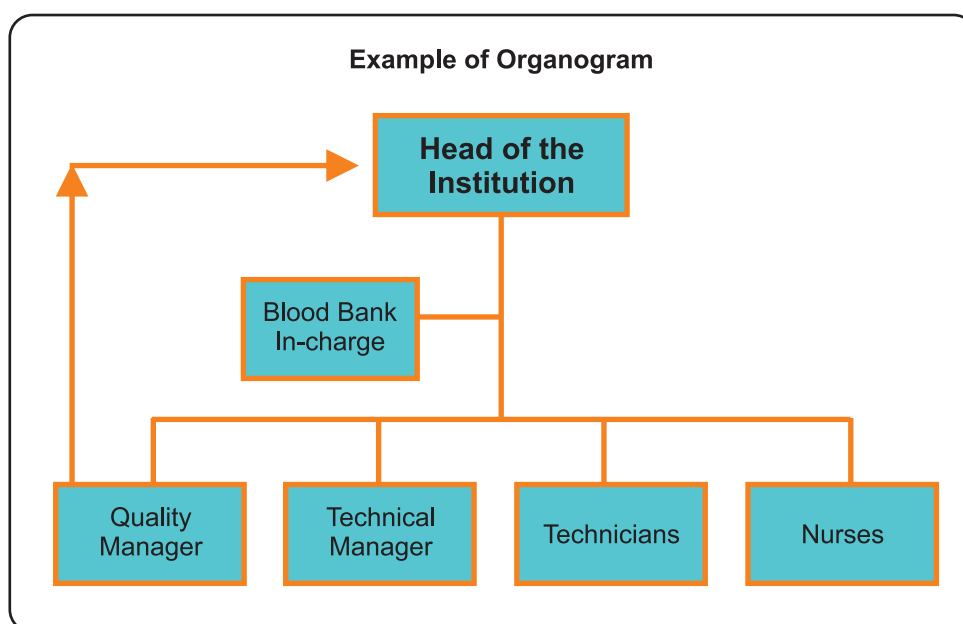
Quality objectives are defined as something sought, or aimed for, related to quality as establishment of QMS. Quality objectives provide services in Blood Banks with applicable standards to satisfy the authorities and blood users. The aim should be to ensure that all staff becomes familiar and complies with the documented quality system and to ensure competence in performing their tasks. The objectives should be Specific, Measurable, Attainable, Retrievable and Time bound. The quality objective are defined by respective blood banks and should be monitored regularly through quality indicators to assess QMS in blood banks.

Organogram

It is a written, dated and signed organizational structure of the Blood Banks, which clearly defines the reporting structures and hierarchies of the management and staff. The organogram should be displayed at a place where it can be viewed by the staff. All staff within the blood bank should have clearly defined lines of authority and responsibility. Responsibility should not be given without authority.

Reporting structures should be developed to assist the blood bank in achieving its objectives and the structure should encourage the organization to work as a coordinated unit, not just as individual sections. The organizational structure should be documented as an organogram. The quality manager should be independent of those having direct responsibility for the work performed.

All staff within the blood bank should have clearly defined lines of authority and responsibility. Responsibility should not be given without authority. Reporting structures should be developed to assist the blood bank in achieving its objectives and the structure should encourage the organization to work as a coordinated unit, not just as individual sections. The organizational structure should be documented as an organogram. The quality manager should be independent of those having direct responsibility for the work performed. It may be as per designation of staff or section /function wise.



Head of Blood bank

The responsibilities of head/director of Blood Banks include professional, scientific, advisory, organizational, administrative and educational matters. Head of blood bank must have competence, authority and resources i. e should have the ability to apply knowledge and skills in practical situation , have the power to get work done with adequate available resources. The head of blood bank should provide effective leadership for design, structure, efficient and effective operation and implementation of quality management systems in Blood Banks. A clear structure enables all staff to understand their role in the organization in terms of whom to report, what are their duties, why they do , what will be the outcome if done incorrectly and how different parts of the organization interact.

The blood bank should have an identified and well-trained **Quality Manager and Technical manager**. Quality Manager and Technical Manager should not be one and the same person if possible & should have their written job descriptions to identify their duties.

Quality Manager is the designated person responsible for directing and coordinating the quality system in the organization with the support of all the staff members who are responsible for the implementation of quality in the organization. QM should ensure compliance to quality, review all records, conduct and coordinate audits, investigate deficiencies and provide information to decision makers. QM reports directly to top management.

Technical manager has the overall responsibility for technical operations and provision of resources needed to ensure the required quality of BB procedures

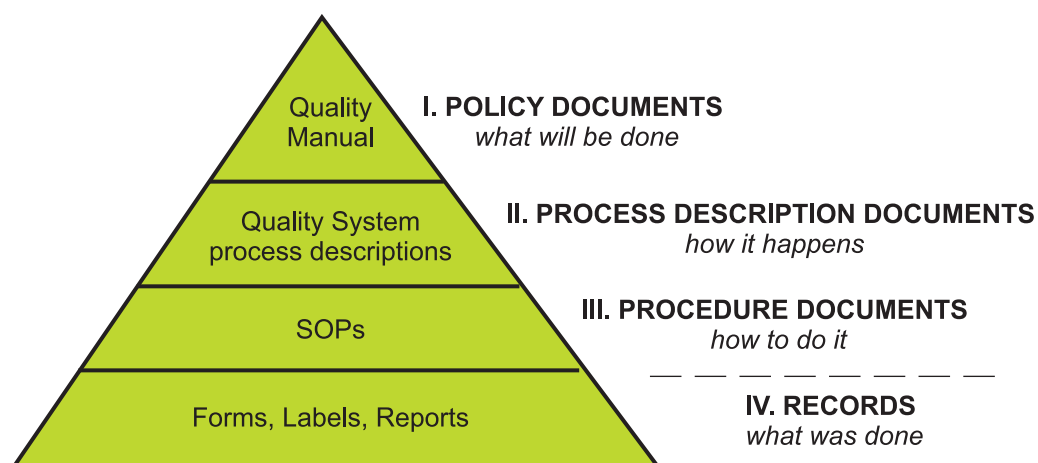
Blood bank Technician is responsible for carrying out Blood Bank procedures in compliance to standards and regulations. He reports to Medical officer or BB In-charge pertaining to all matters of BB and is responsible for interactions with patient/clinicians, wherever applicable.

Every organization needs a formal structure. The structure should maintain and strengthen the organization as a whole. A clear organizational structure is essential for smooth functioning of the blood bank.

Authority and responsibility within the organization must be defined.

Documentation Requirements of QMS

Documentation Hierarchy



Level I: Quality Manual

Level II: Quality system process description documents (QSPs)

Level III: Procedure documents SOP's

Level IV: Forms, Records, Labels

Quality Manual

Quality Manual is an Apex document which establishes the quality policies and objectives of blood bank. The document is a compendium of policies to describe the Blood Bank's quality management system.

Quality Manual describes the overall quality management system of the blood bank. Quality manual provides a road-map to all level of functionaries for achieving the aims & goals of the organization. It provides evidence of what specific controls & monitoring system are implemented to ensure product/service quality. It describes all the applicable elements of the Quality System standards and is supplemented by other documents as quality system procedure documents/supporting procedure, work instructions, forms & formats and reports, reports All Procedures are cross referred in the quality manual.

Outline of Quality Manual

- Title
- Authority under which it is issued (Release Authorization)
- Scope of the Quality Manual
- Amendment record of the manual
- Definitions and abbreviations used
- Contents
- References to other documents
- Distribution record
- Brief description of the Blood Bank and the management system

Quality Supportive / System Procedure in Blood bank- Strategies used to implement the stated polies in quality manual.

These are policy documents which outline all the quality systems that the blood bank should adapt and follow for QMS. These system or supporting procedures should have cross references with the formats used, SOPs etc.

Quality procedure Documents:

1. Blood bank should develop process flow charts also as per list of Processes in the Blood Bank showing critical control points that affect quality of products or services .
2. Blood bank should prepare Standard Operating Procedures (SOPs) for all significant activities of the

BB. The preparation of SOPs is a team effort. Incharge of blood bank should authorize a senior laboratory staff member to coordinate the task for preparation of SOP. SOPs are to be reviewed and updated regularly (at least annually).

Forms , Records and Labels:

They are specific to each blood bank. All Forms, Records and Labels should be clearly identified and traceable in a blood bank. The facility should follow national / state / local regulations for storage and retention of records.

CHAPTER 7

Quality Policy

Quality policy is defined as an overall intention and direction of an organization related to quality as formally expressed by the management. (ISO 9000:2005)

What is Quality policy

It is a written statement which publically states the meaning of quality to Blood Banks and this statement should be communicated to and understood by everyone and must be displayed in all work areas. Quality policy demonstrates the organization's total commitment to quality with clear leadership by top management.

The Quality policy is a:

- Statement of the Blood Bank's intention with respect to its standard of services, including a commitment to meet the needs and requirements of users, donors, staff, general community & other stakeholders
- Statement of the purpose of the quality management system including a commitment to set quality objectives and to achieve continual quality improvement
- Requirement that personnel are familiar with the contents of the quality manual and all procedures relevant to their work
- Commitment to good professional practice
- Commitment to the health, safety and welfare of all staff and visitors to the Blood Bank
- Commitment to comply with relevant legislations & guidelines
- Commitment to continuing compliance with regulatory requirement, National/State guidelines and assessment procedures of the Blood Bank Accreditation Scheme

Quality policy should have a brief description and quality statement of the organization with scope of services it intends to provide.. It should refer to the guidelines and standards for the processes and systems along with the systems used to monitor the effectiveness of QMS. Quality policy should reflect the structure, needs, capabilities of the Blood transfusion services, needs of patients, customer satisfaction and commitment to continuous improvement. Quality policy should also define the quality objectives of QMS with signatures of the management.

Quality objectives are defined as something sought, or aimed for, related to quality (ISO 9000:2005). The objectives should be Specific, Measurable, Attainable, Retrievable and Time bound. e.g Decreasing turn around time to issue blood bags.

It is essential for all personnel concerned with Blood Bank activities to familiarize themselves with the quality policy and ensure its implementation.

Example of Quality policy:

At XYZ BLOOD BANK, it is our mission to be recognized as a supplier of superior quality blood and blood components to the users. To achieve this goal, it is our policy to set and achieve quality standards that allow us to meet the specified requirements and reasonable expectations of our users while conforming to all regulatory requisites. We will deliver to our customers, quality products that meet or exceed requirements, on time and every time. XYZ would implement and maintain, a Quality Management System that conforms to applicable regulatory requirements. We are committed to using this system, to continuously improve our processes and performance.”

CHAPTER 8

Documentation and Document Control

Document: All written procedures, instructions, records, quality control procedures and recorded test results involved in manufacture of a product or in providing a service is called a document. Documents provide a description or instructions of what is supposed to happen. They are live and can be changed by authorized personnel.

Records: Records provide evidence that activities have been performed or results have been achieved. They always document the past. They are dead, fixed and cannot be changed.

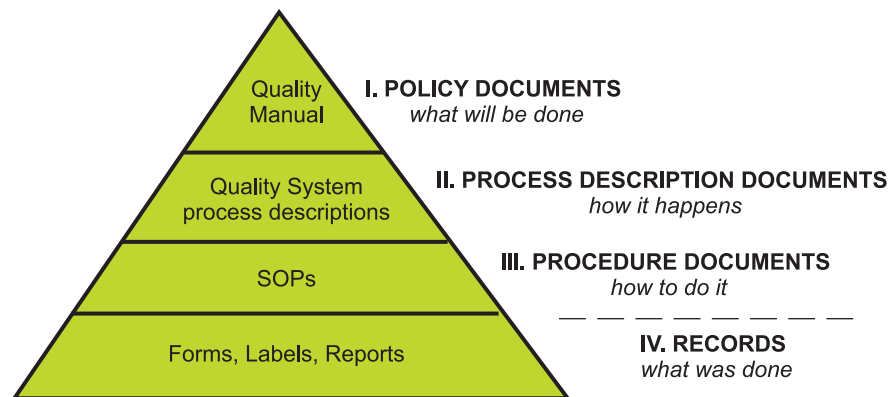
Examples: An unfilled blood request form is a **document**. A filled blood request form is a **record**!

Types of Documents in a Blood Bank

• Policies	• Manufacturer's instructions
• Manuals	• Test data (print outs)
• Standard operating procedures	• Processing data
• Specifications	• QC records
• Datasheets	• Training record
• Forms	• Proficiency records
• Standards	• Incident Reports
• Records	• Fault report (equip)
• Labels	• Non-conformance report (blood bags, reagents, kits)
	• Documents of external origin

A quality system in documentation is used to ensure that the quality level of a product or service is maintained. The documentation system in QMS can be viewed as a hierarchy containing four tiers, as shown in the following illustrations:

Quality Systems Documentation Hierarchy



This hierarchy shows four levels of documentation. All documentation moves from one level to the next in a descending order. The apex level document is Quality Manual consisting Quality policy. Second level are Quality system/supporting procedures (QSPs) which support all clauses of Quality manual. Third level are Standard operating procedures (SOPs) , kit inserts and work desk instructions which describe each and every procedure in detail. The last level of documents are formats and records. If the system is properly structured, changes at one level will seldom affect the level above it, but may affect those below.

Importance of documentation

Documents provide:

- Consistency in procedures
- Reproducibility of all test results
- Traceability of all processes and procedures
- Efficiency in BTS

Important aspects of Documentation in Blood Bank

- To get messages across
- To promote and mobilize resources
- To monitor, evaluate and understand the impact
- To consciously make changes in our work
- To use it for advocacy purposes
- To influence policies and practices
- To add to institutional memory
- To capture events, learning and experiences
- To generate knowledge and be an authority

The different means of documentation

- Photographs
- Videos and documentaries
- Note taking

- Case studies
- Reports
- Articles
- Journals

Policy documents : Quality Manual (Level I)

The first level of documentation is the policy Manual which is also called as Apex manual/ quality manual. Quality Manual is written to state what will be done and why. It should be clear, precise, practical, and easy to understand. It should state quality policy. This statement should be a short, simple definition of the organization's quality intentions.

The remainder of the quality manual should address what will be done to comply with the standards being used. Each element of the standard should be addressed individually and would usually requires a few pages.

Process Description documents: (Level II)

The second level of documentation is the quality system process description documents (QSP). They should indicate the strategies that will be used to implement and perform the stated policies. These procedures (QSPs) define who should perform the specific tasks, when the task should be done, and where the documentation will be made showing that task was performed. Procedures are more detailed than policies and are not required for all the elements. Process documents should have cross linkages with the quality manual as well as with all formats and checklists.

Procedure Documents : (Level III) Standard Operating Procedures

Standard operating procedures (SOPs) are a set of fixed instructions or steps for carrying out these processes. SOP's are usually department, machine, task, or product oriented and spell how a job will be done. The SOP's are the most detailed of the documentation hierarchy. A SOP may be in the form of a detailed drawing, recipe, specific job function, work desk instruction, photograph, video for conformity. The writing of SOP is best carried out by the staff who performs the task. This person knows the process and problems encountered in that process and also creates a pride of ownership in the document, makes it more likely to be carried out.

Not every task requires a SOP. eg you don't need them for a data entry operator to turn on the PC!

Records :(Level IV)

Records are a way of documenting that the policies, procedures, and work instructions have been followed. Records may be forms that are filled out, a label of approval on a product, or a signature and date on some type of document, such as a checklist for cleaning. Records are used to provide traceability of actions taken on a specific product or batch of products. They provide data for corrective actions and a way of recalling products, if necessary. Records therefore provide the output documentation.

	Process Document or QSPs	Output Document
	What you say you will do	What you actually do
Other Names	<ul style="list-style-type: none"> Controlled documents Policies Procedures, Work instructions, Guidelines & Handbooks Forms, Templates & Proformas <p>Eg. Blank case plan template</p>	<ul style="list-style-type: none"> Working documents Records Notes Completed forms <p>Eg. Completed case plan</p>
Purpose	<ul style="list-style-type: none"> Instruct staff & others Ensure consistency 	<ul style="list-style-type: none"> Communication actions Accountability & Evidence
Identifier	<ul style="list-style-type: none"> Living documents - constantly changing. Changes are controlled 	<ul style="list-style-type: none"> Dead documents can not be changed Evidence of the process
	<ul style="list-style-type: none"> Reviewed regularly. Evidence of an integrated and functional system 	Occuring
Creation & Implementation	<ul style="list-style-type: none"> By authorised person only and verified by Management Involvement of all who use. Version & Distribution controlled Electronic - Write protected Hard / Electronic Footered Training to ensure Understanding. 	<ul style="list-style-type: none"> Everybody uses
Retrieval & Storage	<ul style="list-style-type: none"> Controlled to ensure accuracy & currency. Easily accessed. 	<ul style="list-style-type: none"> Privacy & confidentiality Accessed by authorised persons only Locked filing cabinets Password electronic files.
Disposal	<ul style="list-style-type: none"> Outdated - destroyed (both electronic & hard copies) Ensure old documents are not being used. 	<ul style="list-style-type: none"> Kept for stipulated period of time Achieved
Access and Security	<ul style="list-style-type: none"> Every body has access 	<ul style="list-style-type: none"> Only relevant people have access, including clients accessing their own files.

Document control

Document control refers to the documents and records being used only for the respective facility and should not be replicated elsewhere. It is essential for quality management system and a suitable document control procedure should be implemented to define the controls needed to approve, review, update, identify changes, identify revision status and provide access. The document control procedure should clearly define the scope, purpose, method and responsibilities required to implement these parameters.

There should be a unique system of numbering each document by combination of section/organization code, document code and document serial number.

Sample format given below:

Doc Level	Document Type	Numbering Plan
1	Quality Manual	BB-QM
2	Other Manuals	BB - [Name of Manual]
3	Quality System Procedures	BB - QSP - xx
4	Standard Operating Procedures	BB/SOP/ww/xx
5	Forms & Formats	BB / FM / ww/xx

Need for document control?

A document control process is mandated as almost every aspect of auditing and compliance verification is determined through the scrutiny of documented evidence. In order to comply with the document control, it is essential that all personnel understand what type of documents should be controlled and how this control should be exercised.

Document control procedure should communicate the steps necessary to ensure that staff and other users of the Blood Bank documentation understand what they should do in order to manage that information effectively and efficiently.

It should be the responsibility of Quality managers to promote good document and record management practices in Blood Bank and support overall compliance to the document control procedure. Document control log along with distribution list may be maintained.

Individuals and supervisors should be responsible for the documents and records created by them along with their retention and disposal in line with legislative requirements and organisational procedures and practices.

Importance of Document control :

It helps in standardization of procedures and harmonization of steps to be followed by all staff, to get desired output through:

1) Approval for Adequacy: Each document should be approved for adequacy of procedure before use and the staff responsible for approving the document should ensure that the documents for different processes are not contradictory or in conflict with each other.

2) Review and Re-Approve: Gives identification of review of a process and how the reviewed procedure should be approved again for use. It should ensure that the change doesn't affect other processes, like eliminating a record that is essential for another process to work, and ensure that the participants of an earlier process know that they no longer need to create a record, if it is no longer needed in an updated process.

3) Changes and Revision Status: Identifies documents to know the change and that the staff should use the latest version of document.

4) Legible and identifiable: Documents should be readable and easily interpreted by everyone in appropriate languages. (e. g. bilingual consent forms). They should be easy to identify for what process they are meant for.

5) Control of External Documents: Regulatory documents required for processes, also need to be controlled. The outdated versions should be replaced with the newer version always and the same shall be communicated to all staff.

6) Prevents use of Obsolete Documents: It ensures the use of the most recent version of documents, and eliminates use of older version after due changes and approval. A copy of each previous version should be archived and kept as obsolete document. All obsolete documents should be removed from work station.

Controlled document

It means that authorized document have been issued for use after review and approval of an authorized personnel. It has an assigned specific control number, issue/version number a date and distribution that is recorded (master log). The controlled document is subject to authorized revisions and amendments requirements. No unauthorized photocopies of controlled documents should ever be done. Controlled documents should be reviewed regularly (at least once per year) and amended/updated with the approved change.

Implications of unauthorised change or Unauthorized and unexpected events:

- Unexpected events may occur.
- The methodology used will be unauthorized which may be a constraint for quality
 - Lack of control of processes and procedures
 - Negative effects on processes and outputs

- Risk of poor quality outcomes
- Master document and index number retained by Quality Manager

Controlled documents

All documents relating to quality including:

- Quality manual
- QSPs, SOPs, Work instructions
- Forms and records

Controlling distribution: There should be a Document Distribution list to show the distribution of documents to the end users. A Register/Log to locate the current documents should be made. Proof of issue and acknowledgment of receipt of documents should be taken by the quality manager on the document data sheet. Signatures of the responsible designated staff with their full names should be recorded on the document control data sheet. Documentation of all the destroyed copies of outdated document should be maintained.

Revisions: All the revisions should document version control with change in issue number/revision number.

The documentation should show:

- Who made the change
- Each change that was made
- Why the change was made
- When the change occurred
- Who approved the change
- Impact of the change on other processes/procedures
- Was the change communicated to all staff involved?

Amendments: Document control system should allow amendments of documents by hand, pending the reissue of documents, the procedures for such amendments are defined, clearly marked, initialed and dated and the revised document is issued within the specified time. Document may need an urgent or non urgent change depending upon the severity.

Urgent Amendments

- Immediate changes for critical omissions, errors, or change to product information
- Procedure Amendment form
- Tracking document history

Non urgent Amendments: Collection of feedback for next version

History of Document :

It is possible to track the document through either the master index or through master file. Master index/list should have input from all Current titles, Path of workflow, Site specific and Alphabetical wise. Master file should contains copies of new approved version of document, Previous versions , Distribution list with proof of issue & acknowledgment for receipt.

Storage of Documents:

- Documents should be stored carefully and securely for an appropriate period of time
- All the records should be listed and stored with their location and the date of their disposal.
- Should always be stored in a way that ensures security, but allows access to authorized personnel
- Must be protected from physical damage by moisture, heat, fire, sunlight, vermin and chemicals and any deliberate alteration and any other tampering.

Record Retention time

- All records and registers pertaining to the blood bank should be maintained for 5 years (DGCI)
- Finance and accounts records should be maintained as per legal requirements
- Integrity of records (soft & hard) should be ensured
- An authorized person(s) should be responsible for destroying, all records and registers after the prescribed period
- Follow local and state regulations for length of storage of medical records.

Disposal of documents

- No unauthorized person should have access to the confidential information that they contain.
- Should be destroyed immediately, ideally by, by shredding e.g. done by an approved document disposal committee of the facility.
- A monitoring system should be setup, recording the date of disposal and giving details of the disposal
- Maintain record.

The whole purpose of controlling documented information is to make sure it is “available and suitable for use” and also “protected.”

(Please refer to Annexure - A)

CHAPTER 9

Writing a Quality Manual

Quality Manual is a compendium of policies to describe the blood bank's quality management system. It describes the overall quality system used by blood bank and is a mandatory requirement of the QMS. In writing a quality manual, all elements of blood bank standards need to be addressed. The details in quality manual vary according to the activities and level of blood bank.

Blood Bank should do a self assessment of its quality status and understand its existing status and level of competence. It has to be ascertained whether BTS wants to build its quality management system, from basic level/ progress further from an appropriate level to achieve all standards. It is important to draw conclusions from the existing level of documentation in comparison to the standards of NACO/NABH before proceeding ahead. The management shall appoint a quality manager for establishing and maintaining QMS.

Quality Manual should include the following:

- Description of the blood bank
- Quality policy statement
- Policies of the blood bank covering all clauses of standards.
- Quality Objectives, which are measured and reviewed periodically by the executive management of the blood.
- References to supporting processes and procedures, but does not include them
- Policies reflecting actual blood bank practice supplemented by a set of other documents like procedure manuals, work instructions, forms & formats, reports etc.

Outline of Quality Manual:

- **Title page:** The title of the Quality Manual should clearly indicate the name of the blood bank to which the manual has been released with clear legal identity, Issue number, Issue date, Holder name, Copy number, Authority under which it is issued.
- It is recommended that to facilitate ease of handling and updating of the Quality Manual, each page within the manual should have a header and a page footer. The footer should show the issue status, amendment status, copy number, page no. The page no should be written as e. g. 1 of 10, 2 of 10 and so on.
- Signatures of prepared by, approved by, authorised by are also placed on the footer with their full names.

- Sample format as follows:

LOGO Blood Bank	Name Of Blood Bank (License No.)																					
<p>QUALITY MANUAL</p> <p>Or</p> <p><i>Name & Address of Blood Bank</i></p>																						
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="5" style="text-align: left; padding: 5px;">Name of Blood Bank:</td> </tr> <tr> <td style="width: 15%; padding: 5px;">Doc No:</td> <td colspan="4" style="padding: 5px;">Document Name: Quality Manual</td> </tr> <tr> <td style="padding: 5px;">Issue No:</td> <td style="padding: 5px;">Issue Date:</td> <td style="padding: 5px;">Copy No:</td> <td style="padding: 5px;">Section No:</td> <td style="padding: 5px;">Page No:</td> </tr> <tr> <td style="padding: 5px;">Revision No:</td> <td style="padding: 5px;">Revision Date:</td> <td style="padding: 5px;">Prepared by:</td> <td style="padding: 5px;">Approved by:</td> <td style="padding: 5px;">Issued by:</td> </tr> </table>			Name of Blood Bank:					Doc No:	Document Name: Quality Manual				Issue No:	Issue Date:	Copy No:	Section No:	Page No:	Revision No:	Revision Date:	Prepared by:	Approved by:	Issued by:
Name of Blood Bank:																						
Doc No:	Document Name: Quality Manual																					
Issue No:	Issue Date:	Copy No:	Section No:	Page No:																		
Revision No:	Revision Date:	Prepared by:	Approved by:	Issued by:																		
<p>Quality Manual - Confidential Copying of this manual in whole or in part is strictly prohibited</p>																						

Header and Footer																								
Name of blood bank License Number			Logo																					
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="5" style="text-align: left; padding: 5px;">Name of Blood Bank:</td> </tr> <tr> <td style="width: 15%; padding: 5px;">Document No:</td> <td colspan="4" style="padding: 5px;">Document Name: Quality Manual</td> </tr> <tr> <td style="padding: 5px;">Issue No:</td> <td style="padding: 5px;">Issue Date:</td> <td style="padding: 5px;">Copy No:</td> <td style="padding: 5px;">Section No:</td> <td style="padding: 5px;">Page No:</td> </tr> <tr> <td style="padding: 5px;">Revision No:</td> <td style="padding: 5px;">Prepared by:</td> <td style="padding: 5px;">Reviewed by</td> <td style="padding: 5px;">Approved by:</td> <td style="padding: 5px;"></td> </tr> </table>					Name of Blood Bank:					Document No:	Document Name: Quality Manual				Issue No:	Issue Date:	Copy No:	Section No:	Page No:	Revision No:	Prepared by:	Reviewed by	Approved by:	
Name of Blood Bank:																								
Document No:	Document Name: Quality Manual																							
Issue No:	Issue Date:	Copy No:	Section No:	Page No:																				
Revision No:	Prepared by:	Reviewed by	Approved by:																					

Normative references

The quality manual should make reference to the following documents to comply with the requirements of accreditation:

- Drug and Cosmetic Act (D & C Act)
- National Blood Policy
- Regulatory Standards of blood transfusion
- NABH - Accreditation Standards
- ISO 15189: 2012 Quality Management System Requirements

These reference documents are required for proper implementation of the quality system. The blood bank staff should have access to these documents and only the latest versions should be used.

The quality manual should be written using the References to ensure that the requirements of safety and service standards are met. Quality manager should strive for continuous improvement in quality of services for patient care and clinical personnel involved in patient care from requisition, patient information, patient informed consent, donor identification, processes & procedures, interpretation, reporting, safety and ethics in blood banking.

Definitions

Standard definitions should be used, wherever applicable but for quality terminology the standard definitions from the section of the Quality Manual which contains the definition of terms and concepts should be used.

Examples:

'Accuracy of measurement' means closeness of the agreement between the result of a measurement and a true value of the measure.

'Executive Management': The highest level personnel within an organization, including employees and independent contractors, who have responsibility for the operations of the organization and who have the authority to establish or charge the organization's quality policy. Executive management may be an individual or a group of individuals

'Preventive Action': an action taken to reduce the potential for non-conformance or other undesirable situations

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

Abbreviations: The expanded forms of all abbreviations used should be defined in this section of Quality Manual. Examples:

ADSOL Adenine Glucose Mannitol Sodium Chloride

BEQAS	Blood Bank External Quality Assessment Scheme
EDTA	Ethylene Diamine Tetra Acetic Acid
HCV	Hepatitis C Virus
HMB	Hospital Management Board
NAT	Nucleic Acid Test
WBC	White Blood Corpuscles

Distribution of Quality Manual

- The distribution of the authorized manual should provide assurance that all users have appropriate access.
- The distribution record should list the holders of the controlled copies of Quality manual with their allotted copy numbers.
- Copies of Quality Manual distributed as uncontrolled copies, should not be listed.

Introduction page

The introductory pages of a Quality Manual should provide:

- General information about the Blood Bank concerned and the Quality Manual itself.
- Minimum information about the Blood Bank should be its name, site, location and means of communication.
- Additional information about the Blood Bank, such as a brief description of its background, history or size, may also be included.

Information about Quality Manual itself should include:

- Current issue number and date of issue and identification of amended contents.
- Brief description on how the Quality Manual is revised and maintained and who reviews its content and how often, who is authorised to change the Quality Manual and authorised to approve it.
- Brief description on the documented procedures used to identify the status and to control the distribution of the Quality Manual
- Whether the Manual is to be used only for blood bank purposes or it can be shared for external use also.
- Evidence of approval of those responsible for authorisation of the contents of the Quality Manual

Quality policy and Quality objectives:

This section deals with a statement of blood bank quality policy and quality objective, where the blood banks commitment is put forth and its objectives are outlined. It must also be described how the policy will be informed to the staff, understood by them, implemented and maintained.

Elements of Quality Manual

- Quality Manual should describe all the elements of the Quality Management System, to the extent they are applicable.
- The format or method of presentation for the description of management system elements, which can be applied, is unique to each Blood Bank but the sequence similar to standards may be used for ease.
- The quality manual should have the Policy and procedures of all Quality essentials for its BTS defined in terms of the following elements:
 1. Organization
 2. Accommodation
 3. Personnel management
 4. Equipment management
 5. External services & supplies
 6. Process control
 7. Deviations and adverse events
 8. Performance improvement
 9. Document control
 10. Records & reports
 11. Internal Audit & management review

Each of these elements needs to be described under sub sections in reference to policy, scope, responsibility, Quality system procedure, limitations, references to records as formats, checklist. The actual procedure may be written as separate procedure and cross referred to quality manual.

List of documents, records forms

All documents maintained by the Blood Bank records & forms should find reference in the Quality Manual or the associated document.

Annexure

Whenever annexure appears in Quality manual, that supportive data should be provided and attached as an annexure at the end.

The Quality manual should be kept updated under the authority of Director / Incharge responsible for maintaining quality management system.

Quality manual provides a road-map to all level of functionaries for achieving its aims & goals. It should provides evidence of what specific controls & monitoring system are implemented to ensure product/service quality.

It should also help achieve consistency in repeating the best practices and improving those processes which are lacking to ultimately benefit patients, clinicians suppliers, employees and Blood Bank.

CHAPTER 10

How to write an SOP

The standard operating procedures (SOP) is the most vital document for quality management system in any Blood Bank. The use of standard operating procedures (SOP) has become mandatory in blood centres for licensing and accreditation.

Definition of SOP

In Simple terms, an SOP is a written procedure document. SOP is a way for the Blood Bank to perform a task the same way each time it is completed for consistency in results. It is a Controlled document.

SOP is defined by International Conference on Harmonization (ICH) as “Detailed, written instructions to achieve uniformity of the performance of a specific function”

Development of SOP:

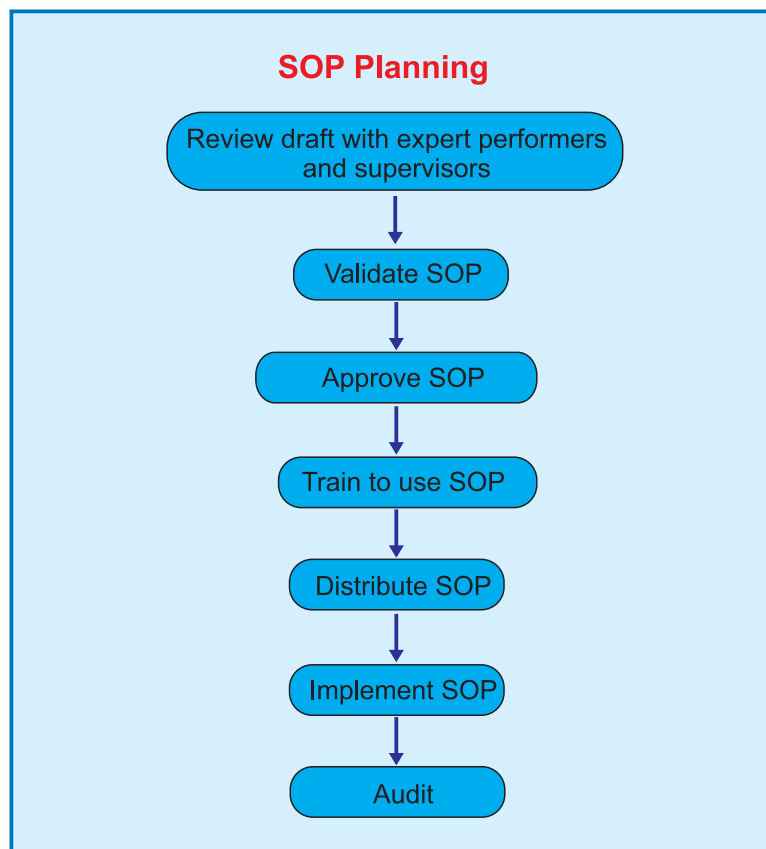
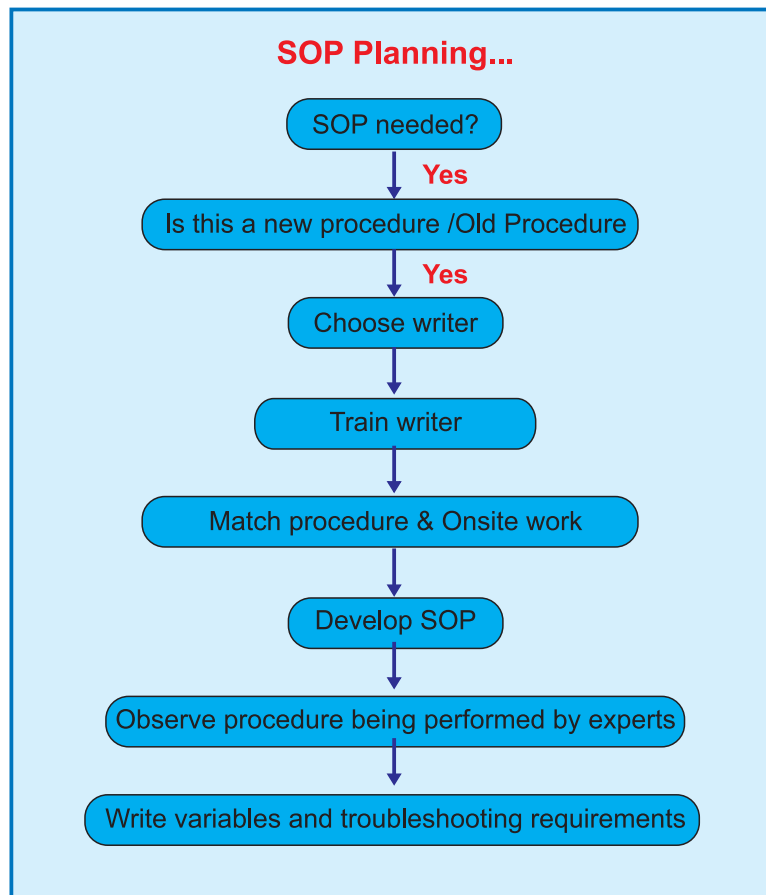
The development of an SOP is a multi-step process that involves preparation, writing, conclusion and training for its use.

- Identify the responsible person for each task
- Plan action (what is to be complete)
- Train staff
- Monitor site performance (work done)
- Ensure regulatory Compliance

Identify the responsible person for each task

The first step is to define the need for a SOP and identify the responsible personnel authorized to write and sign SOPs based on the SOP content and level of importance reflecting the hierarchy of the blood establishment. For example, an SOP describing the management structure of a blood establishment should be written by the senior management and authorized by the institution director him/herself, while an SOP used to describe the testing procedure for ABO blood grouping should be be written by the responsible senior laboratory technician and authorized by the laboratory director. The user should be the person who works in the area covered by the SOP and who is adequately trained for this purpose. The identification of the user varies with respect to the scope and purpose of the SOP.

Plan action (what is to be complete)



A flow-chart should be designed wherever possible before writing SOP to identify working steps and decision points of the process.

It is essential to take staff support and inputs to create SOP in work areas. A team-work approach in writing SOPs enhances the training process in their use. SOPs should be written while performing the activity and not by somebody sitting behind a desk thinking of how the activity is done (especially test methods).

SOP's should be written in first person voice or active voice and describe workflow between functions, and departments. They should be based on the process map with clear, simple & understandable information. The writer should use short, complete sentences and paragraphs with one idea per sentence.

Validation of the draft SOP should be done by qualified personnel. The validation phase allows for 'fine tuning' and introduction of revisions in SOP as required. Upon completion of the validation, SOP should be authorized with signatures of the appropriate qualified senior.

Valid copy of SOP should be available at points of use. Master copy of each SOP shall be with Quality Manager.

Authorisation and change control: This is a critical mechanism for controlling documents, which ensures availability of only those documents that should be currently in use with systematic removal of the previous documents. The authorization should include the effective and expiry date of the document. In addition, the date of writing and respective dates of review and authorization should be included. These dates must document the name and signature of the responsible person for these actions. The responsibilities should be defined in the quality manual. It is also essential to include the distribution of the SOP and to include a clear system for marking copies.

It is not compulsory to include an expiry date on the SOP, but the quality system must define the review interval for all documents including SOPs. This review interval is usually annual and should not exceed more than two years. The review is targeted to improve the quality as well as to incorporate the changes in responsible personnel, general/operational processes, equipment, reagents, premises and methodology (donor collection, analytic testing, etc.). A review should lead to revision indicated by an appropriate revision number ('new' version number). All revised documents should follow the same validation and authorization process as for a new SOP (Document Number and Version). The system used for the document identification code should be described in the quality manual.

The Document-Code may follow the structure of the document system set-up by the quality function using categories such as: - Quality manual chapters (QM) - General Procedures (GP) - Working Processes (WP) - Test Procedures (TP) - Equipment Procedures (EP) - Production Procedure (PP) - Intelligent Technology Procedure (IT) - Administrative Procedure (AP) - Worksheets (WS) - Page Number. These are sample formats. The Blood Bank may adopt its own method for document code for easy and faster retrieval.

The numbering of pages must start with the first page of the document. Each Page number must include the page number and the total number of pages of the document (e.g. 1/8, 2/8, 3/8...). - Distributor (Number of copies).

The original of the SOP should be kept in the quality management office/with Quality Manager, while authorized copies are given to the relevant personal using the SOP. A system to identify 'authorized' copies has to be established (e.g. copies printed on a special paper or using a colour stamps).

Change description (compared to the previous version), should list the relevant changes that have been made in comparison to the previous version of the document and the reasons for these changes (e.g. 'Complete revision of production process due to the introduction of leukocyte depleted blood components'). The minor or major changes/amendments in SOP should be communicated to all staff involved and should be done in all distributed copies. This ensures harmonization of procedures among all staff and areas. Further details on the changes should be given in documenting the training of the new/revised SOPs.

Distribution of SOP is done by the Quality manager to the end user who should be trained to perform the activities within the SOP before the SOP becomes effective.

Once the SOP document is written, completed, reviewed, authorized / approved, it should not be used till training is imparted to the users.

Training of staff

Even with very detailed flow charts and process descriptions, it is necessary to train all personnel, otherwise individuals will interpret the meaning of procedures in different ways, leading to inconsistency in work routines and performance.

Training and retraining of all personnel is the only mechanism to ensure that the SOP and the quality relevant criteria it contains would secure best practice in the blood bank.

The ultimate goal is to convince the Blood Bank staff that SOPs are not only written 'paper-work' but are intended to help the personnel work according to the best quality standards. This should result in optimal blood products issued for the therapeutic use in patients and/or optimal diagnostics to safeguard patients from infections transmitted by blood products.

Personnel involved in transportation and storage should also be trained since they are also key elements in the process chain of blood component production. The training programme should also reflect the idea that training on SOPs should improve the professional competence of the individuals and enhance their personal job qualification including the ability to contribute to future procedure improvements. Training records should be kept and archived.

Ensure Regulatory compliance: Standard operational proceedings (SOPs) should follow strict regulatory guidelines in order to control the precision and actuality of their content. Different types / categories of SOPs should be integrated in the description a quality management system in order to assist in consistency between documents. The quality manager should be responsible for ensuring that basic document standards are defined, that all personnel responsible for writing SOPs are trained to these standards. These standards should also be fulfilled when SOPs are issued or revised.

Implementation

Each concerned department should ensure implementation of SOP. An independent audit of the effective implementation of the SOP should be carried out at appropriate intervals.

The information part of SOP should have following components:

- Name of the blood bank
- Subject of SOP
- Location of SOP
- Function of SOP
- Distribution of SOP
- Unique Number of SOP
- Version and revision
- Date from which SOP shall be effective and the period after which it has to be reviewed
- Number of pages and No of copies (Quality Manager or designated official shall keep a record of those whom SOP has been distributed)
- Name and signature of the author
- Name and signature of the person who has been authorized to approve SOP
- Name and signature of the person who is responsible to authorize the use of SOP from effective date

The descriptive part of SOP should include the following:

Title: Keep the title short and precise to describe the objective of the SOP (e.g. ABO blood group testing of blood donors).

Scope: Define the institution, department or unit using the SOP. This description should be precise and minimal (e.g. Donor screening unit and/or department). This description may be linked to the structural descriptions given in the Quality Manual.

Responsibility: Include who is responsible for oversight of the SOP, performing the activities, or other procedure responsibilities. Staff preparing and complying with SOP - (job description, personnel responsibilities), Job title(s) involved in the process should be covered by the SOP.

Principle of the procedure: Describe the relevant principle for examinations

Materials Used: e. g. Type of container and additives, type of sample, quantity, storage criteria

Equipment : Names of equipment used

Calibration Procedures: For equipment and instruments with (metrological traceability)

Procedural steps: Description of operating procedure - Process Flow-Chart /Description of the work

activities. This section of the SOP should describe the process in clear and concise words. In order to facilitate this process, it is suggested to draw a flow-chart up-front. This flow-chart should describe the process step-wise including the critical decision points. The use of flow-chart will depend on the complexity of the SOP to be written. For example, writing a SOP for typing blood group ABO using a commercial kit will follow the instruction of the manufacturer given in the kit-manual and thus a flow-chart may be useless. In comparison, the production process of red cell concentrates will substantially benefit from a flow-chart giving an clear overview of the process and the decision points including the responsible persons involved. These flowcharts should be displayed at work stations for everyone to follow the same procedure.

Performance specifications (e.g. precision, accuracy expressed as uncertainty of measurement, detection limit, measuring interval, trueness of measurement, analytical sensitivity and analytical specificity) are usually provided by manufacturer in the kit insert. However, it is recommended if the Blood Bank testing personnel should verify the manufacturer's claims by standard procedures. This is essential for Quality Control of procedures and may require use of Statistical Quality Control procedures (SQC) e.g. L J Graph preparation for ELISA tests. These include precision, intermediate precision etc.

Results

- 1 Interferences (e.g. lipaemia, haemolysis, bilirubinemia) and cross reactions;
- 2 Principle of procedure for calculating results, including measurement uncertainty
- 3 Biological reference intervals
- 4 Reportable interval of examination results
- 5 Alert/critical values, where appropriate
- 6 Interpretation of results

Safety precautions: Standard safety precautions are extremely essential for staff and equipment safety. Relevant safety precautions and measures should be highlighted in the SOP.

Potential sources of variability:

The description of effective actions to be performed in case of non conformance is very important in writing SOPs following best practice. The writer should focus on the potential for non-conformance also and quality manager in the blood bank should monitor for any non conformance events. It should include measures or regulation to be taken if there are deviations from the defined working description or in case of unexpected errors. The corrective and preventive action system should ensure that existing product nonconformity or quality problems are corrected and that recurrence of the problem is prevented.

Data should be routinely analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action. All errors and accidents shall be documented and investigated in order to identify system problems for correction.

Annexure :

- 1 The annexure of the SOP should be used to include all attachments relevant for this SOP. eg – Literature or standard guidelines used to cite test principles for laboratory methods used including those that are included in large automated test equipment (e.g. donor screening by EIA technology).
- 2 References should be included in the case of manuals/kit inserts given by manufacturers describing a common commercial test kit. Reference should also include equipment book, such as is used for operating centrifuges, apheresis machines or laboratory test equipment. These references should be cited using the exact description of the manufacturers manual including the version number or the publishing/release date. - Definitions (Terminology) - related SOP documents (e.g. Equipment log-books) - related worksheets or files Records and/or protocols used for documentation, e.g. form sheets used in this SOP, cleaning and disinfection plan, donor recall record.

SOPs should be available at each working area in the blood bank.

List of SOPs For Blood Banks:

Sr. No	SOP No.	Name Of SOP
01		Donor Registration
02		Screening & Selection Of Donor
03		Medical Examination Of Donor
04		Preparation Of Cuso4
05		Hb By Cuso4 Method
06		Hb By Hemocue Method
07		Phlebotomy
08		Collection Of Blood For Component Separation
09		Post Donation Care
10		Adverse Donor Reactions & Management
11		Plasma Exchange
12		Plateletpheresis
13		Blood Donation Camps
14		Pre Donation Counseling
15		Blood Donor Motivation
16		Donor Counseling
17		Recruitment Of Donors
18		Follow Up And Retention Of Donors
19		Receiving Of Blood
20		Baby Blood Grouping
21		Autologous Blood Transfusion

Component Section

Sr. No	SOP No.	Name Of SOP
01		Component Preparation Using Triple Blood Bag with Sagem
02		Component Preparation Using Quadruple Bag
03		Processing of Double Bag
04		Processing of Pediatric Bag
05		Component Preparation by Triple Bag without SAGM
06		Quadruple Bag with Buffy Coat Method
07		Washed Red Cells
08		Component Preparation Using Blood Bags with Filter
09		Leukreduction With Filter
10		Preparation of Bag For Exchange Transfusion
11		Preservation and Storage of Bags
12		Labeling of Bags
13		Traceability of Bags
14		Inventory of Bags and Components
15		Excess Plasma Disposition

TTI Section

Sr. No	SOP No.	Name Of SOP
01		HIV Testing by ELISA Method
02		Hbs Ag Testing by ELISA Method
03		HCV Testing by ELISA Method
04		SYPHILIS TESTING by RPR Method
05		Malaria Testing by Smear
06		Malaria Testing by Card Method
07		Syphilis Testing by ELISA Method
08		Syphilis Testing by TPHA Method
09		Sop For EVOLIS Equipment
10		HIV Testing by Rapid Method
11		HBsAg Testing by Rapid Method
12		HCV Testing by Rapid Method

Immunohematology Section

Sr. No	SOP No.	Name Of SOP
01		Sample Acceptance And Registration
02		Cell Grouping
03		Serum Grouping
04		Rh Grouping
05		Red Cell Suspension
06		Differentiate Between Rouleaux And True Agglutination
07		Weak D Confirmation
08		Pre Transfusion Testing
09		ABO Discrepancy
10		Antibody Screening
11		Cross Match By Column Agglutination Technology
12		Direct Antiglobulin Test
13		Preparation Of Check Cells
14		Indirect Antiglobulin Test
15		Saliva Testing for Grouping
16		Adsorption Technique
17		Low Titer Sera Screening
18		Elution Technique
19		Issue of Blood
20		Issue of PRBC or WB
21		Transportation And Issue Of Different Componentes
22		Received Back Unit
23		Plasma Thawing
24		Blood Transfusion Reaction
25		Exchange Transfusion
26		Issue outside
27		Neonate Sample Processing

QC Section

Sr. No	SOP No.	Name Of SOP
01		QC of Antisera
02		QC of Cuso4
03		Qc of AHG
04		Qc of Albumin
05		QC of Normal Saline
06		QC of Distilled Water
07		QC of Red Cells
08		QC of Platelets
09		QC of FFP
10		QC of Cryoprecipitate
11		Routine Validation of Equipments
12		Cell Counter
13		Preventative Maintenance of Equipments
14		QC of Cryofuge
15		Operation of Ph Meter
16		Operation of Blood Collection Mixer
17		In House Quality Control For ELISA
18		Operation of TSCD
19		Operation of Laminar Air Flow
20		Operation of Tube Sealer
21		Operation of Weighing Balance
22		Operation of Distilled Water Plant

Admin Area

Sr. No	SOP No.	Name Of SOP
01		Biosafety, Disinfection and Waste Disposal
02		Accidents and Spillages
03		Issue and Return of Blood from Storage
04		SOP for Error Handling
05		SOP for Grievience Addressal
06		SOP for Non Conformance Of Results
07		Sop for Record Archival
08		Selection of Material
09		SOP for Purchase of Consumables
10		SOP for Reciept of Consumables
11		Sop For Proficiency Testing
12		External Quality Assessment Scheme
13		SOP in Case Of Power Failure
14		Plan for Internal Audit
15		Procedure Doing an Internal Audit
16		Document Control
17		SOP incase of Fire Breakdown
18		Procedure for Sop Writing
19		Sop for Inventory Control of Consumables
20		SOP for Needle Stick Injury
21		SOP for Housekeeping
22		SOP for Implementing New Process or Change In The Existing Process
23		SOP For Incident Reporting

(Please refer to Annexure - A for sample SOPs)

CHAPTER 11

Accommodation and Environment:

Provision of appropriate, safe and controlled environment is essential for ensuring quality in Blood Bank. Blood bank should be in a highly visible clean hygienic location with good public access. It should be, away from open sewage, drain, public lavatory or similar unhygienic surroundings. The building should not be within a crowded market place or any residential complex.

Cleanliness and Hygiene:

Walls and floors should be smooth, washable and kept clean (plaster in good condition /well painted). Drains should be of adequate size and if connected directly to a sewer, to be equipped with traps to prevent back siphonage. The blood bank should have policies and procedures to maintain hygienic conditions to avoid entry of insects, rodents and flies.

Blood bank should formulate SOP's for cleaning in all areas with time schedule. A checklist for cleaning should be filled daily and records maintained.

(Please refer to Annexure - B)

Environment:

Blood bank should be dust free , well ventilated and well lighted. Daylight should be maximized throughout the facility, particularly in donor areas. As the Blood Bank is more reliant on voluntary donors, it is important that the collection area design is pleasant and non-clinical for the donor, so that it enhances the donation experience.

Open planning should be maximized to improve staff's ability to observe donors. Interview rooms should ensure visual and acoustic privacy. All spaces where blood is handled or materials are stored should conform to relevant standards and manufacturers' instructions.

In addition to existing services, air conditioner with controlled ambient temperature between 20° C to 25° C, diesel powered stand-by generator with adequate power should be available to run ventilation, air conditioning, selected emergency lighting, all donor-connected equipment and refrigerated blood storage.

There should be a provision for positive pressure in component lab and mechanical ventilation (Exhaust) for the autoclaving area , toilets and for pantry area in the donor lounge.

Area

Reference should be made to D&C Act – minimum of 100 square meters for collection, processing and storage of whole human blood and an additional area of 50 square meters for blood components facility and 10 square meters for apheresis. Areas should be reviewed in the light of local practice and regulations

and to accommodate new or additional equipment and processes.

Sections of Blood Bank

- a) Registration and medical examination
- b) Donor motivation and counseling area
- c) Blood collection (air-conditioned)
- d) Refreshment–cum–restroom (air-conditioned)
- e) Laboratory for TTI
- f) Blood component preparation
- g) Laboratory for blood group serology
- h) Sterilization –cum– washing
- i) Store –cum– record room

Component Lab

The component lab is responsible for the reception of all blood for processing into blood components and its storage. This section of blood bank deals with:

- Blood reception and registration
- Blood component preparation
- Quarantine storage
- Labelling of verified blood prior to storage in the inventory and distribution.

The separation of processing activities from inventory and distribution activities is part of the organizational structure required to ensure the effective separation of untested from tested and verified blood. Additional activities include leucocyte filtration, cryopreservation and washing of cellular components.

Appropriate temperature and humidity levels should be maintained for staff comfort and for the integrity of blood components and materials. The temperature recording systems used and humidity control gadget should be calibrated and records of the daily monitoring in temp and humidity control charts should be maintained. Attention should be given to selecting materials for their durability and ease of cleaning and disinfection. Natural light and an external view from all work areas are desirable. No wash basin should be therein processing area. Ambient temperature of storage area should be between 20°C – 25°C.

Quarantine – (Controlled temperature storage in refrigerator/freezer of blood components prior to the verification of test results).

After component preparation, blood components should be held in temperature-controlled storage and quarantined and transferred to inventory and distribution storage or storage prior to completion of testing and verification. Temperature records should be maintained as per checklists. The physical separation of quarantined and inventory blood for release is essential to the maintenance of a safe blood supply.

Labeling and Inventory – After testing verification, each blood component unit should be labeled and

issued to the inventory and distribution unit for inventory storage. Labels should be as per the regulatory requirements. Blood units not suitable for transfusion should be stored separately prior to disposal.

Laboratories

Sample reception area should be designated for receiving samples from donors and requests from wards. Separate testing laboratories to conduct testing of donor blood for blood group serology, cross matching and infectious disease markers, and in-process quality control testing for blood and blood products. The testing laboratories should also provide a range of investigative and diagnostic services for patient testing, including red cell reference laboratory activities, pre-transfusion testing, platelet serology, and tissue typing in some blood banks. Some blood centres may also include haematopoietic stem cell processing.

Blood donation camp

Premises used for outdoor blood donation camp should have sufficient area to divide into waiting area for donors, donation area and post donation care area. It should be a well-lighted and ventilated hall. Indoor like environment should be created at the site of the blood donation camps. Mobile unit should be fully equipped with material and appliances for collection and transportation of blood. For emergency care to donors, emergency box with desired medicines should be always available for handling any donor reaction. Provision for Post-donation care and refreshment should be maintained as per protocol.

All information regarding the camp should be documented.

- List of donors with name, serial donor registration number
- Registration forms
- Statement of expenditure
- Report proforma of staff
- Proforma to note down donor reaction

Registration should be done to note down remarks, suggestions to blood bank by organizers or donors. The collected blood units should be stored in transport boxes during the period of transportation from the venue of camps back to the blood bank. It should be ensured that proper disposal of waste is done at camp site as per recommendation of Biomedical Waste Management Rules 2016 under Ministry of Environment, Forest and Climate Change.

Storage

1. Reagent / kits – Reagents directly contribute to the safety of the blood supply and ensure reliable results. They should be stored at a prescribed temperature in refrigerators with temperature control if required in a safe and hygienic place in a proper manner.
2. Other consumables & provisions - Non A/C store
3. Storage of Blood Bags as per manufacturer's conditions
4. Documents / records – prevent termites and safety from fire , water.

Environment control

Safety for building, equipment & employees and donor should be followed for internal and external environment and it should support to:

- Reduce environmental hazards and risks
- Prevent accident and injuries
- Maintain safe condition for donors, staff and attendants
- Maintain environment that is sensitive to donor needs for comfort, social interaction, and positive distraction
- Maintain environment that minimizes unnecessary environmental stresses for donors, staff and attendants.

Employee Safety

All new employees should be given safety orientation on the information on general safety policies. This is done for the following reasons:

- The staff should be trained in safety issues so that they are able to handle any incidents or accidents.
- To take reasonable care of the health and safety of themselves and other persons who may be affected by their action or omissions.
- To report any hazard or unsafe working practices to their manager or other person in authority, as soon as it is possible to do so, to enable the hazard to be rectified.
- The failure of a member of staff to observe his/her duty in this respect should be regarded as misconduct and should be treated as such in accordance with disciplinary procedure.
- All members of staff should attend induction training and annual update training in health and safety matters (like fire safety drills etc.) as arranged by their department in-charge.

Statutory Requirements to be fulfilled for any Blood Bank

- Fire Safety
- Electrical Safety
- Physical / Chemical / Radiation and Biological Safety
- Pest Control
- Security

Fire safety

Building should be fire safe with all fixtures as smoke alarms and sprinklers. Policy and procedures should be formulated for all aspects of fire prevention & fire safety with an objective to:

- Provide and maintain safe means of escape from premises. Fire exit plan should be developed and displayed at reception and fire exit routes.
- Provide and maintain adequate means of altering staff in the event of fire.
- Provide and maintain adequate firefighting equipment.

- Provide adequate training to all members of staff (organizing fire drills) on use of fire equipment.
- Liaise with local Fire Authorities on all matters concerning fire safety.

Fire protection and prevention

Blood bank should ensure the safety of the donors, patients and employees from fire risk arising from unsafe conditions and practices by providing appropriate measure to control fire hazards in the building.

- Declare blood bank as 'No Smoking' zone.
- Fire protection equipment including fire hydrants, hose reels, automatic sprinkler system, fire detection system / and emergency lighting should be provided in accordance with local regulations. Provision of Fire Extinguishers in appropriate sizes and types (ABC) throughout the Blood Bank.
- Inspection of extinguishers should be regularly undertaken by a qualified contractor.

Fire Fighting & Evacuation Procedure

- Blood Bank should have a general fire fighting and evacuation procedure
- The action to be taken by staff for safety of all users of the Blood Bank especially the high risk areas as Laboratory, Stores, Electrical main board room should be outlined.

R.A.C.E. procedure should be followed for evacuation:

- **Rescue** Remove patients or others in immediate danger. If the person is busy in rescue effort, he should shout "**RED**" so that employees can pull the alarm.
- **Alarm:** Press fire Alarms on the alarm systems placed in different parts of the Blood Bank
- **Contain:** Contain the fire by closing doors and windows so that it does not spread to the other parts
- **Extinguish/evacuate by using** fire extinguisher and evacuate all persons to a safe area, if necessary by following directions of the fire safety officer. Place Fire Evacuation in BLOOD BANKS which indicates the exact location of the fire exits hence in case of any fire accidents; the nearest fire exit in the floor can easily be traced.

Fire Training and Drills:

Training all employees on adequate fire training and fire drills should be conducted. Information. Inform about the fire evacuation procedures including fire exits located in the work places should be provided. Special precautions should also be undertaken to not obstruct front or exit door.

Matching Classes of Fire and Types of Extinguishers

Fuel Sources	Class of Fire	Type of Extinguisher (Extinguishing Agent)
Ordinary combustibles (e.g., trash, wood, paper, cloth)	A	Water; chemical foam; dry chemical*
Flammable liquids (e.g., oils, grease, tar, gasoline, paints, thinners)	B	Carbon dioxide (CO ₂); halon#; dry chemical; aqueous film forming foam (AFFF)
Electricity (e.g., live electrical equipment)	C	CO ₂ ; halon; dry chemical
Combustible metals (e.g., magnesium, titanium)	D	Dry powder (suitable for the specific combustible metal involved)

* Dry chemicals, CO₂ and halon can be used on Class A fires, but may not be effective on their own. They need to be supplemented with water.

#. Halon extinguishers are no longer made, but some may still be in use. Dangerous gases are formed when halon is used to put out fires. Wear proper respiratory equipment, particularly in enclosed spaces. After use, do not allow anyone to enter the area until it has been well ventilated.

(Please refer to Annexure - C)

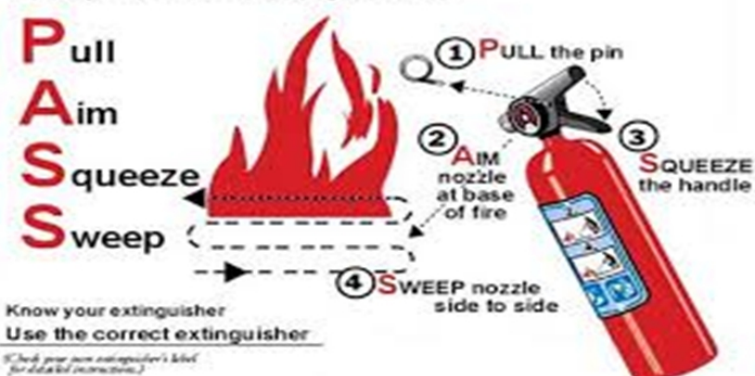
• IF YOU FIGHT A FIRE, REMEMBER THE WORD

PASS

PULL . . . AIM . . . SQUEEZE . . . SWEEP

- **PULL**... the pin. Some extinguishers require releasing a lock latch, pressing a puncture lever or other motion.
- **AIM**... low, pointing the extinguisher nozzle (or it's horn or hose) at the base of the fire.
- **SQUEEZE**... the handle. This releases the extinguishing agent.
- **SWEEP**... from side to side at the base of the fire until it appears to be out. Watch the fire area in case fire breaks out again, and repeat use of extinguisher if necessary
- Read and follow the directions on your extinguisher. If you have the slightest doubt about whether or not to fight a fire – DON'T! Get out and close the door behind you

To operate an extinguisher:



Electricity safety:

Blood bank should define system to prevent electrical hazards as

- **Shock:**

- i. Shock occurs when the human body becomes part of the path through which current flows.
- ii. The direct result can be electrocution.
- iii. The indirect result can be injury resulting from a fall or movement into machinery because of a shock

- **Burns:** Burns can result when a person touches electrical wiring or equipment that is energized.

- **Arc-Blast:** Arc-blasts occur from high- amperage currents arcing through the air. This can be caused by accidental contact with energized components or equipment failure.

- **Explosions:** Explosions occur when electricity provides a source of ignition for an explosive mixture in the atmosphere.

- **Fires:** Electricity is one of the most common causes of fires both in the home and in the workplace. Defective or misused electrical equipment is a major cause.

Effects On The Human Body depends on:

- i. Current and Voltage
- ii. Resistance
- iii. Path through body
- iv. Duration of shock

Effects of AC Electricity:

- i. More than 3 mA- Painful shock- cause indirect accident
- ii. More than 10 mA- Muscle contraction – “No Let Go” danger
- iii. More than 30 mA- Lung paralysis, usually temporary
- iv. More than 50 mA- Ventricular fibrillation, usually fatal
- v. 100 mA to 4 A- Certain ventricular fibrillation, fatal
- vi. Over 4 A- Heart paralysis, severe burns

Electrical Protective Measures

- All laboratory electrical equipment and wiring should conform to national electrical safety standards and codes.

- **Electrical Isolation**

- Insulation on extension cords:
 - Rubber and plastic is put on wires to prevent shock, fires, short circuits and for strain relief.
 - It is always necessary to check the insulation on equipment and cords before plugging them in.
 - Remember, even the smallest defect will allow leakage!

Elevate the conductors e.g. Overhead power lines:

- Remember, never allow yourself, your tools, or the materials you are working with to be within

10 feet of energized lines!

Guard the conductors by enclosing them e.g. receptacle covers, boxes, & conduit:

- Covers, boxes, and enclosures are often put around conductors to prevent worker contact.
- Remember, electric equipment operating at 50 volts or more must be guarded!

It is essential that all electrical installations and equipment are inspected and tested regularly, including earthing / grounding systems.

Equipment Grounding

- Providing a separate, low resistance pathway for electricity when it does not follow normal flow (ground prong).
- Grounding gives the stray current somewhere to go and keeps you from becoming part of the circuit.

The following measures should undertaken to ensure electric safety:

1. Routine inspection of the power outlets throughout the Blood Bank by the electrician.
2. Trip Switches should be located in different parts of the blood bank to prevent short circuit.
3. Periodic inspection of wires should be done to ensure that they are in appropriate conditions.
4. Do a safety inspection before any electrical equipment is brought
5. Switch off electrical equipment not required during night
6. Keep areas around electrical switchboards clear.
7. **Place ABC** type fire extinguishers adjacent to electrical switchboards.
8. In case of temporary Power loss due to Storms, Power disruptions, or damage to the service lines entering or due to maligning of the internal electric wire system of the Blood Bank , ensure that the automatic generator takes over the work load
9. Blood Bank should have an adequate backup facility for maintaining electrical supply round the clock and Emergency electrical supply in case of generator failure

Chemicals Hazard:

- Most of the chemicals which are harmful should be avoided to come in direct contact.
- Washing should be done thoroughly with hand wash solution and water whenever a chemical contacts the skin.
- Should never taste or smell a chemical.
- All container and chemicals should be labeled clearly. No substance in an unlabeled container should be used.
- Flammable solvents should be kept away from heat and sunlight.
- Discard chemicals using safety precautions.
- Should always wear mask during preparing fresh and filling/discarding processing solutions.

Biological hazard:

Infectious Sharp Objects:

Sharps are any medical or non-medical equipment which are capable of cutting and/or puncturing the skin. Sharps' injuries represent the major occupational cause of accidents involving potential exposure to blood borne illness.

Policy on Sharps Handling:

- Sharps be handled carefully at all times and disposed safely in puncture proof containers.
- Sharps should be disposed of at the point of use and generation.

Used needles:

- Should never be recapped after use.
- Should not be removed from syringes by hand.
- Should not be bent, broken or otherwise manipulated by hand.
- Should be destroyed immediately after its use.
- Used disposable sharps should be disposed of in a designated, clearly marked, puncture resistant container.
- Sharps' container should be sealed and replaced.

Blood and body fluid spills:

- Blood and body fluid spills should be cleaned up immediately or as soon as possible.
- Standard precautions should be used when cleaning up spills of blood or body fluids
- Gloves and other personal protective equipment (PPE) appropriate for task Should be worn.

Procedure

The following points should be taken into account while cleaning up body fluids depending on the type of body fluid, Size of spill, Surface type area involved.

- In case of blood spill, place absorbent material and put concentrated sodium hypochlorite on the material and leave for a minimum of 30 min
- Wipe the spill up using absorbent paper towel using gloved hands.
- Wash the area with water and detergent.
- If there is a likelihood of bare skin contact with the surface, the area should be disinfected with sodium hypochlorite solution.
- **Wash Hands properly after the spill has been cleaned up.**

Interventional procedures rooms

- Spills should be attended to as soon as it is safe to do so.
- Area Should be disinfected with sodium hypochlorite. Maintain record of all spills

Bathrooms and toilets

- Spills should be hosed off into sewerage system and are flushed with water and detergent.

- The area should be disinfected with 1% sodium hypochlorite.

Preventive measures taken to control biological hazards can be drawn from the manuals on:

- Infection Control Manual/Lab safety manual
- Biomedical Waste Management Policy and procedures.

Procedure for reporting accidents & incidents - Incident reports / HR exposure report

- Safety is an important issues for donors, staff and the users of the premises
- Blood Bank should strive to ensure the accident, incidents and near misses are identified, reported and action taken to help ensure the safety and the security of all staff.
- Maintain the statutory obligation to maintain safe system of work.
- Corrective actions & Control Measures to reduce, preventive incidents.
- Review and monitor risk management process for continuous quality improvement.
- Emergency telephone nos. for fire/Post Exposure Prophylaxis/medical emergency should be available.

Pest control contracts for should be given for annual services to control all

Rodents / termites / fungus which infest the Blood Bank, if not taken care of . There should be regular observation & cleaning of the premises.

Security Services

Blood Bank functions 24x7. Security arrangement should be made deploying personnel responsible for maintaining

- Safety of the staff, donors and other users of the blood bank
- In situations like violence & aggression, disasters security staff should protect the staff
- Security personnel/guard should maintain a register and keep record of -
 - Incoming & outgoing goods
 - Issue & return of keys
 - ID badges for staff
 - Any untoward incidents occurred & action taken.

Communication

There should be a clear policy & effective mechanism of communication which should be up to date internal & external communication system. It should be protected and should maintain confidentiality.

CHAPTER 12

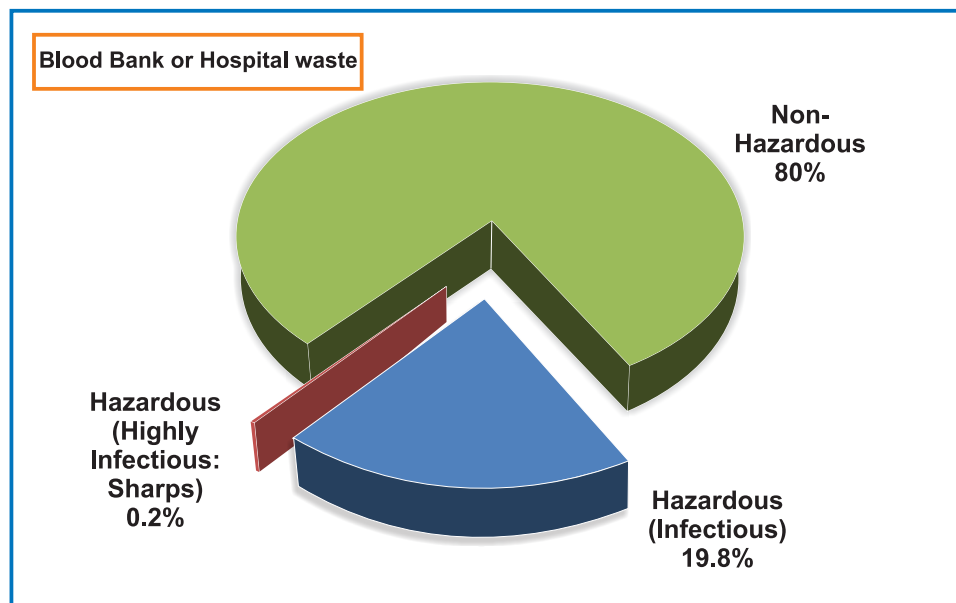
Biomedical Waste Management and Infection Control

What is Bio-Medical Waste?

Any waste generated during:

- Diagnosis, treatment or immunization of human beings or animals
- Research activities
- Production or testing of biological material
- Animal waste from slaughter houses or any other similar establishment.
- All biomedical wastes become highly hazardous if not SEGREGATED AT SOURCE
- In hospital hazardous waste comprises of 20% of total hospital waste.

Why Segregation at source?



Hazards of Poor BMWM

- **Injuries from sharps**
 - Increase in healthcare associated infections
 - Risk of infection outside hospital for waste handlers and at times general public
- **Risk associated with hazardous chemicals and drugs**
 - Disposables & drugs being repacked and sold
 - Environmental pollution

Waste Management Processes



BMW Rules, 2016

These rules that apply to all persons who:

- Generate
- Collect
- Receive
- Store
- Transport
- Treat
- Dispose
- Or handle BMW in any form: hospitals, nursing home, clinics, dispensary, veterinary institutes, labs, research/educational institutes, camps, first aid rooms of schools, **Blood Banks**, Ayush centres
 - Waste Management is Heavily Regulated!
 - The Air (Prevention and Control of Pollution) Act, 1981
 - The Environment (Protection) Act, 1986
 - The Hazardous Waste (Management & Handling) Rules, 1989
 - The National Environmental Tribunal Act, 1995
 - The Biomedical Waste (Management & Handling) Rules, 2015
 - The Municipal Solid Waste (Management & Handling) Rules, 2000
 - E-waste, E-waste Rules, 2011
 - Hazardous microorganisms Rules, 1989



category	Type of Waste	Type of Bag or Container	Treatment and Disposal Options
Yellow	Human /Animal Anatomical Waste	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*
	Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components		Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/hydroclaving followed by shredding or mutilation or combination of sterilization and shredding
	Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs	Yellow coloured non-chlorinated plastic bags or containers	Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200 OC All other discarded medicines shall be either sent back to manufacturer or disposed by incineration

category	Type of Waste	Type of Bag or Container	Treatment and Disposal Options
Yellow	Chemical Waste	Yellow coloured containers or non-chlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility
	Chemical Liquid Waste :	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater.
	Microbiology, Biotechnology and other clinical laboratory waste: Blood bags , Laboratory cultures, stocks or specimens of microorganisms, Vaccines, cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures	Autoclave safe plastic bags or containers	Pre-treat to sterilize with nonchlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for Incineration

Red	Contaminated Waste (Recyclable) (a) Waste generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vaccutainers with their needles cut) and gloves.	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recycles or for energy recovery or plastic to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
White (Translucent)	Waste Sharps including Metals: Needles, syringes with fixed needles, needles from needle tip cutter or bumer, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the state Pollution control Boards of Pollution control Committees) or sanitary landfill or designated concrete waste sharp pit.
Blue	(a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxix watses.	cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

Duties of the occupier

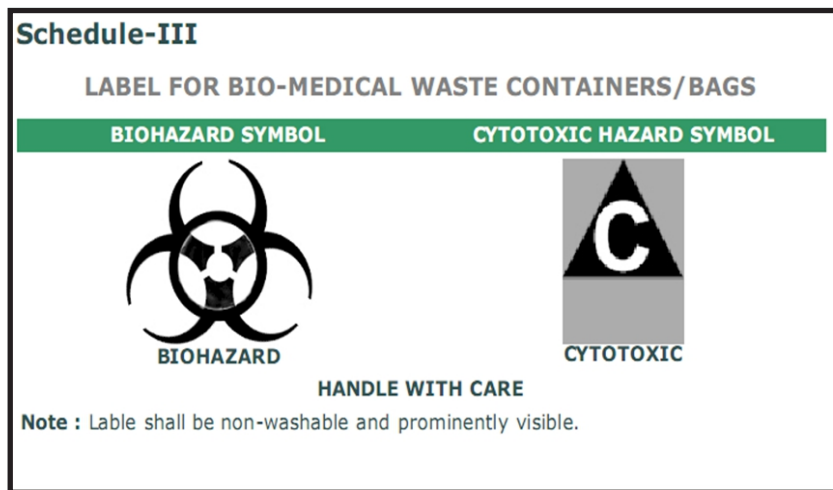
BMW is handled without adverse effect to health and environment

- Safe secure location in premises handle BMW: colour code: Follow Schedule-I
- Pre-treat: disinfection/sterilization on-site (HCFs) Lab waste, microbiological waste, blood samples, blood bags: WHO, NACO, guidelines: CBMWTFD
- Ensure non-chlorinated plastic bags, gloves, blood bags: 2y of notification
- Provide training: all HCW: induction, at least 1/y

- Immunize all HCWs: BMW: HBV, Tetanus
- Establish a Bar- Code System for containers/bags BMW :1 yr
- Conduct health check up: induction, at least 1/y
- Maintain & update daily BMW management register & monthly on website: 2y
- Records: accidents: remedial action: Form I: annual
- Make available: Annual Report: web-site: 2y
- Record: incineration, hydroclaving, autoclaving: 5y

Segregation, packaging, transportation, storage:

- No untreated BMW should be mixed with other wastes.
- BMW segregated into containers/bags: Schedule I
- Containers or bags: labeled as Schedule IV.
- Occupier CBMWTF: barcoded/GPS: 1 y
- Vehicle: GPRS: Motor Vehicles Act, 1988: Schedule IV
- Untreated BMW: shall not be stored >48 hrs:
- Microbiology waste, laboratory, infectious waste: sterilization or disinfection, WHO: CBMWTFs.



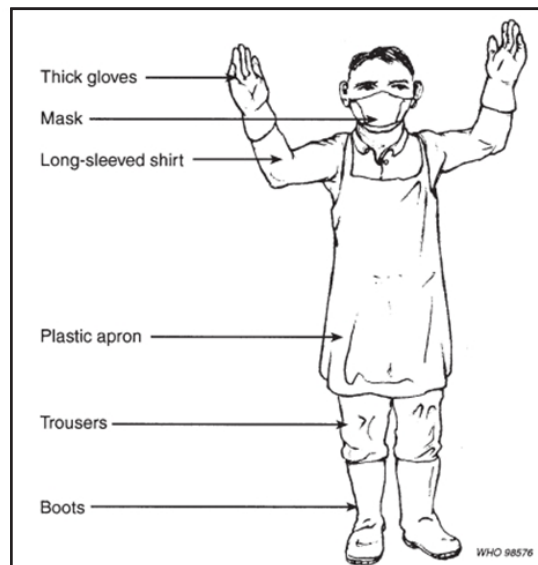
Bio-Medical Waste Transportation:

- Protective clothing
- Personal hygiene
- Immunization
- Management practices
- (Waste segregation, Waste packaging, waste identification , waste storage, Appropriate transportation)
- Special precautions for clearing up spillages of potentially hazardous substances
- Response to injury and exposure

Protection against personal injury essential for all workers at risk:

Protective Clothing

- Helmets, with or without visors depending on the operation.
- Face masks depending on operation.
- Eye protectors (safety goggles) depending on operation.
- Overalls (coveralls) obligatory.
- Industrial aprons obligatory.
- Leg protectors and/or industrial boots obligatory.
- Disposable gloves (medical staff) or heavy-duty gloves (waste workers) obligatory.



Safe Disposal of Sharps:

- Dispose off sharps at the site of generation
- Discard needles in puncture-proof rigid containers
- Don't dispose in any other container
- Dispose when container is 3/4 full

Disinfection:

Reduction in the number of pathogenic microbes so that the material/object/surface becomes safe for handling

Advantages of Sodium hypochlorite

- Bactericidal
- Virucidal
- Easily available
- Affordable

Disadvantages of Sodium hypochlorite

- Corrodes metal
- Deteriorates rapidly

Disinfection of Glassware:

- Blood/plasma/serum/fluids in glass containers can be present in:
 - i Sample vials
 - ii Test tubes
- Discard in plastic bins containing 1% sodium hypochlorite (10, 000 ppm chlorine)
- Disinfected blood/fluids - Wash down with running tap water
- Glassware treated in chromic acid - Dry in hot air oven (Temp160°C)

Blood and Blood Products in Plastic ware:

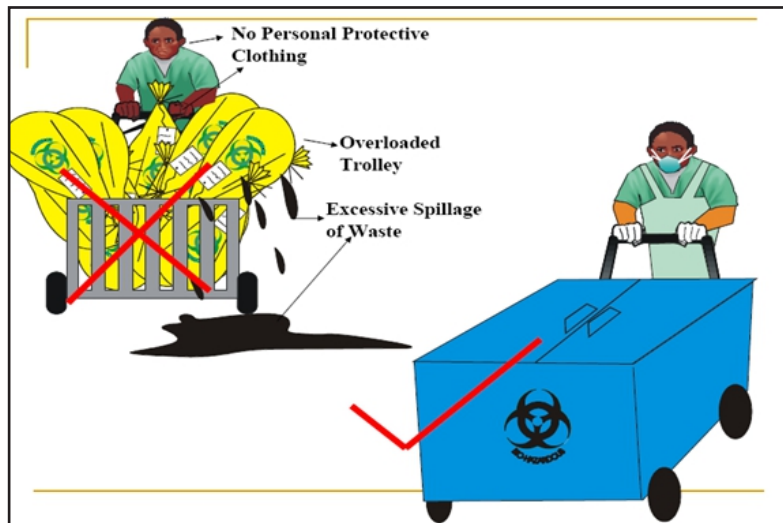
- Blood bags
- Tubings of bags
- Microtips
- Plastic vials
- Microplates
- Used blood bags
- All these products should be disinfected in sodium hypochlorite , autoclaved and shredded.

Steps of transportation:

- Internal Transportation
- Temporary Holding
- External Transport

Internal Transportation:

- Dedicated wheel barrow, trolleys or carts
- Specific routes to reduce the passage of loaded carts through wards and other clean areas
- Carts should be
 - easy to load and unload
 - have no sharp edges that could damage waste bags or containers and
 - easy to clean



Temporary On-site Storage:

- The designated on site storage facility shall be
 - located within the premises close to the treatment
 - away from food storage or food preparation areas.
 - large enough to contain all the hazardous BMW with spare capacity .
 - totally enclosed and secured from unauthorized access.
 - inaccessible to animals, insects and birds.
 - easy to clean and disinfect
 - have an impermeable hard-standing base, good water supply, drainage and ventilation
- Waste should be
 - stored for not more than 48 hours
 - should be packaged securely enough to ensure containment of the waste and to prevent penetration by rodents and vermin
- The universal biological hazard symbol should be posted on the storage, area door, and waste containers



The External (off-site) Transportation:

- All bags to be labeled as prescribed- BAR CODE LABEL
- Waste producer responsible for the proper packaging and labeling of the containers.
- Properly documented and all vehicles to carry a consignment note from the point of collection to the treatment facility - GPS TRACKING
- Vehicles used for the collection of BMW should not be used for any other purpose.
- Easy to load, unload, clean and fully enclosed to prevent any spillage

Schedule II:

SCHEDULE II

[See rule 4(t), 7(1) and 7(6)]

**STANDARDS FOR TREATMENT AND DISPOSAL OF
BIO-MEDICALWASTES**

1. STANDARDS FOR INCINERATION:-

All incinerators shall meet the following operating and emission standards-

A. Operating standards

1). Combustion efficiency (CE) shall be at least 99.00%.

2). The Combustion efficiency is computed as follows:

$$\text{C.E.} = \frac{\% \text{Co}_2}{\% \text{Co}_2 + \% \text{CO}} \times 100$$

3). The temperature of the primary chamber shall be a minimum of 800°C and the secondary chamber shall be minimum of 1050°C + or - 50 °C

4). The secondary chamber gas residence time shall be at least two seconds.

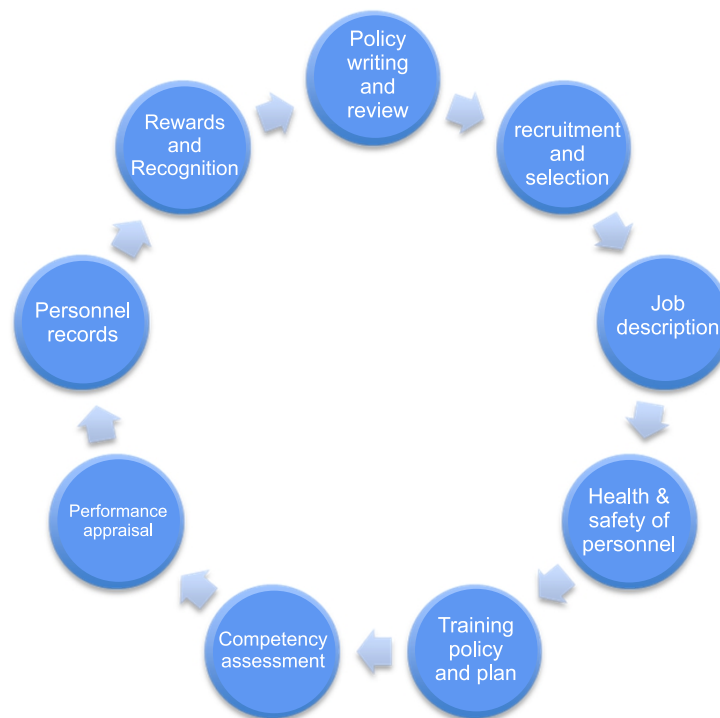
B. Emission Standards

CHAPTER 13

Personnel

Personnel are the most important and critical resource in Blood Banks. Personnel management is also critical to success of a quality management system. There should be a documented procedure of personnel management which includes understanding of policies, and maintenance of records of all personnel in Blood Banks.

Following are the main functions of Personnel Management:



Personnel Policy

The purpose of personnel policy is to ensure availability of right skill mix at right time for efficient & safe service in the blood bank. The policy should outline the essential/desirable skills, qualifications, experience and personal characteristics required for a specific job.

Personnel policies should cover elements as training, health and safety, competence assessment, performance appraisal, promotion, salary, staff benefits, disciplinary procedures, resignation, staff confidentiality and personnel records.

Recruitment / selection guidelines

It should be as per policy to enable sourcing and selection of adequately qualified and competent employees for the requirements of Blood Banks.

Recruitment of staff as per Drug and Cosmetics Act:

- Quality manager – not yet a requirement of Drug rules
- Technical Supervisor /manager

- Technician
- Donor Recruitment Officer (DRO) / MSW
- Registered Nurse
- Counselor
- Lab Attendant

Screening of candidates should be in accordance with the eligibility criteria as under.

Qualification reflects demonstrated skills, training, experience, education and should be appropriate to the tasks performed.

POST NAME	QUALIFICATION	EXPERIENCE
Director / MO - in charge	Medical officer 1. MD pathology/transfusion medicine 2. MBBS with diploma in pathology/transfusion medicine 3. MBBS plus experience in BB (DMC certificate)	Minimum 1 years experience in the respective field
Technical supervisor	Where Blood components are manufactured 1. Degree in Medical Laboratory Technology (M.L.T.) 2. Diploma after 10+2 (D.M.L.T.).	6months experience in component lab. Min. 1 year experience in Blood bank with component lab
Lab Technician	Degree in Medical Laboratory Technology (M.L.T.) with 6 months exp in BB Diploma after 10+2 (D.M.L.T.) From Govt recognised university/institutions	Minimum 6 months experience
Quality Manager	Any of above with specific QMS training	1year of experience.
Technical Manager	Any of (b) and d with specific QMS training (QM and TM can be same in a BB with <5000 units of collection/year	
Staff Nurse	Diploma/BSC Nursing is minimum qualification required	6 months to 1year of experience

Job Description

A simple, organized and brief statement in written form, containing a list of all the essential requirements of the job, along with a summary of duties and responsibilities to be performed by the jobholder is known as Job Description. It is the immediate and the primary output of Job Analysis. In short, it is a statement that captures all the relevant facts related to a specific job.

Job description shows a clear picture of the nature of each job with respect to the tasks and occupational needs. It is an accurate and authorized record of job contents. It incorporates major authorities, duties, scope of work, role and purpose. It is a comprehensive job summary that all the necessary details are extensively curtailed in a concise way. It defines the primary and secondary conditions required for the performance of the concerned job. Roles and responsibilities should be clearly communicated to all staff in written which should include job description and reporting at various hierarchical levels.

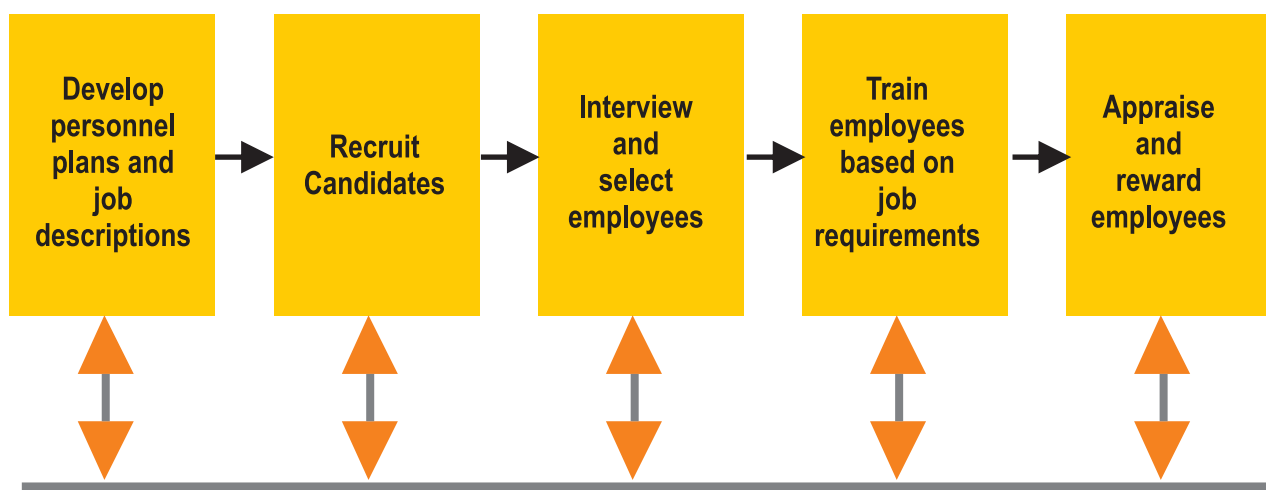
It is easy with the help of the job description to legitimize rewards and punishments if the applicants do not satisfy the job requirements. Moreover, it is also easy to identify the training needs of the job holder.

Job specification

A statement that expresses the minimum qualification and qualities required, for the performance of a particular job . It is also termed as Man Specification or Person Specification or Employee Specification.

Job Specification is prepared on the basis of Job Description, which states the characteristics that an employee should have, to hold the job. It converts the job description in terms of pertinent human qualifications which are demanded by the job. It is developed in consultation with the supervisor and the human resource manager.

Selection Procedure:



Recruitment is a very difficult task, as it involves a chain of activities. The first step for it is job analysis, which is conducted by employing various methods like surveys, questionnaires, interviews, etc. After that, a statement is prepared what a particular job demand and that statement is known as Job Description and this statement is the mirror of Job Analysis.