

Division of Blood Transfusion Services

Ministry of Health and Family Welfare



Record Keeping & Documentation

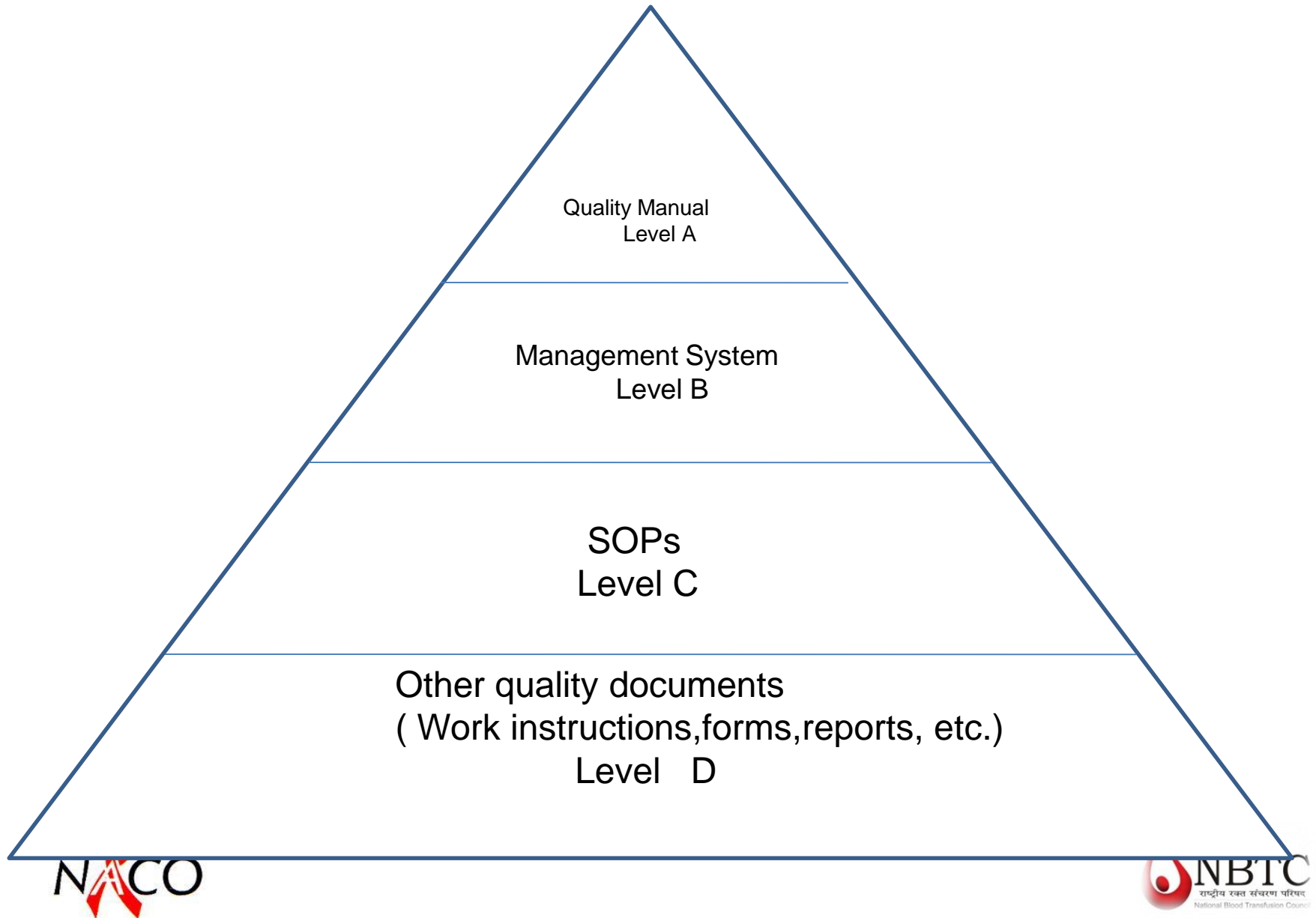
Documentation

- Helps to create System Dependent Organization (not a person dependent one)
- Enables communication of Intent.
- Ensures consistency of action.
- Avoids differing perception of how to do work.
- Helps in making employees to understand their role within the organisation

Documentation

- Helps in providing mutual understanding between employees and the management.
- It provides clear, efficient framework for operation.
- It provides a ready basis for training new employees and periodic re-training of current employees.
- Provides a basis for continual improvement.

Types of Documents



Documentation

- Quality Manual
- Standard operating procedures
- Work instructions
- Forms
- Specifications
- Office manuals

Documentation (contd...)

- Documents like quality plans, charts, text books, software, drawings, memos, notices etc.
- Complaints handling
- External documents e.g. Legislative documents, rules, instructions issued by Government.
- Records.

Document (contd...)

- Written or electronically generated information and work instructions.
- Examples of documents include Quality manual, policies, procedures or forms.

Standard Operating Procedures

- Current version of SOPs should be written by technologist who performs it, verified by supervisor, Quality Assurance Manager & Authorised by Medical Officer In Charge.
- All SOPs should be validated.
- SOPs should be available on work bench & used by all.
- One copy of all SOPs should be maintained in a master file.
- The obsolete versions of all SOPs should be archived.

Record

- Information captured in writing or through electronically generated media that provides objective evidence of activities that have been performed or results that have been achieved such as test records or audit results.
- Records do not exist until the activity has been performed and documented.

Records (contd...)

- Record system should make it possible to trace a unit of blood/component from source to final destinations.
- The system should ensure confidentiality of donor and patient records.
- Records should be legible & corrections should be initialed.
- Date of performance of procedures, tests and interpretation should be recorded.

Blood Donor Record

- Serial number
- Date of phlebotomy
- Name, Address & signature of donor
- Age, weight, hemoglobin, blood group.
- Blood pressure, Medical Examination.
- Bag number
- Category of donation (voluntary/replacement)
- Deferral records
- Signature of Medical Officer In-Charge.



Donor's blood collection record

- Date of collection
- Batch number & bag manufacturer's name
- Segment number on the donor tubing
- Particulars of donor
- Identification number
- Amount of blood collected
- Time and duration of collection
- Signature of phlebotomist & medical officer.

Donor reactions

- Date, time
- Description
- Management details
- Action taken for prevention in future.

Master Records

- Bag serial number
- Date of collection, Date of Expiry
- Quantity in ml.
- ABO/Rh Group
- Results of HIV, HBsAg, HCV, VDRL, Malaria tests.
- Irregular antibodies (if any)
- Name & address of the donor with particulars
- Utilisation issue number
- Components prepared or discarded
- Signature of the Medical Officer In Charge.

Issue Register

- Serial number
- Date & Time of Issue
- Bag serial number
- ABO/Rh Group
- Total quantity in ml.
- Name & address of the recipient
- Group of recipient
- Unit/ Institution
- Details of cross-matching report
- Indication for transfusion.

Blood Component records

- Identification number
- Name and volume of component prepared
- Date, time and mode of preparation
- Disposition record.

Records of blood/components from outside source

- Identification number
- Name of component
- Name of collecting facility
- Date of collection & expiry
- Disposition record.

Record of processing of donor blood

- ABO(cell & serum grouping) & Rh(D) type
- Antibody screening & identification.
- Anti-HIV 1&2, Anti-HCV, HBsAg, VDRL, Malaria tests and its interpretation.

Grouping

- Reaction results,
- Batch number
- Manufacturer's name of reagents
- Details of reagent red cells.

TTI testing

- ELISA printouts showing results & interpretation.
- Batch number, expiry date, manufacturer's name of the kit.
- Rapid tests/spot tests should be interpreted by two individuals and recorded.

Records

- Quality control records indicating testing of components, reagents & equipment.
- Records of apheresis procedures.
- Records of all blood/components discarded.

Record of Recipient

- Blood requisition form with full particulars of recipient & identification number.
- Results of ABO & Rh(D) tests & their interpretation.
- Interpretation of compatibility tests.
- Compatibility record.
- Report of adverse reaction & record of their investigation.

Issue Register

- Date & Time of issue
- Particulars of patient & his ABO & Rh type.
- Identification number & segment number of red cell units issued, ABO & Rh(D) type, blood component issued.
- Signature of person issuing & receiving.

Other records

- Daily group wise blood stock register showing its receipt, issue & balance, units discarded with reason of discarding.
- Record showing the daily temperature recordings of the temperature dependent equipment.
- Stock register of non-consumable articles.
- Stock register of consumable articles.

Other records

- Documentation of staff qualifications & training.
- Documentation of staff competency & proficiency tests.
- Staff signature register.
- Record of quality assurance (internal & external audits)

Other records

- Record of incident reports.
- Record of equipment maintenance.
- Record of document control.

Computer System

- Blood Bank management ensures the availability of data and information required to provide a service that meets the needs and requirements of users.
- Blood Bank management has established a procedure(s) for the management of data and information, that includes:
 - Security
 - Access
 - Confidentiality & data protection
 - Backup systems
 - Storage, archive, retrieval
 - Secure disposal.

Computer System – contd...

- The computerized systems include:
 - hardware
 - software
 - peripheral devices
 - personnel
 - documentation
- End-user validation of computer systems and the interfaces between systems should be conducted in the environment where they will be used.

Computer system

- SOP should be made available for use.
- An alternative method to be used during system breakdowns must be known.
- Hard copies should be available even when documentation is electronically maintained.
- Maintenance and continuous operations must be ensured.

Computer system (contd...)

- Personnel must be trained.
- Validation of system and integrity and security of data entry should be ensured.
- Back up should be available.
- The records required by Drugs & Cosmetics Act should also be maintained as hard copies.

Records of components supplied.

- Quantity
- Compatibility report
- Details of recipient
- Signature of issuing person.

Records of CPD/CPD-A/SAGM bags

- Details of manufacturer
- Batch number
- Date of supply and of testing.

Records of CPD/CPD-A/SAGM bags (contd...)

- Register for diagnostic kits and reagents
 - Name of the kits/reagents.
 - Details of batch number
 - Date of expiry
 - Date of use.
- Blood bank must issue cross matching report of the blood to the patient together with the blood unit.
- Transfusion adverse reaction records.

- Records of Consumables
 - Purchase,
 - Use
 - stock in hand
- The above mentioned records must be kept for a period of five years.
- For donor retention program, donor records should be maintained for a longer term.
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References

- CDSCO guidelines : ‘Regulatory requirements of blood and/or its components including blood products’
- Standards for Blood Banks & Blood Transfusion Services, NACO. 2007.
- Quality Council of India : Training Manual – Implementation of Assessment-Improvement Framework (IS: 15700)