Quality Audit Training Workshop (BSQR)

Learning Objectives

- Explain the purpose and structure of BSQR
- Overview to Quality Standards including ISO 9001
- Describe the principles and practice of internal auditing
- Plan and prepare for an internal audit
- Gather objective evidence during an audit
- Write factual reports that drive improvement of the system
- Verify the effectiveness of corrective actions

Continuous Assessment

Required to show we have met the learning objectives from:

- Contribution from discussions
- Performance in activities
- Feedback throughout the course
- Course Quiz

Do not take up Auditing if ...

- You do not have the authority to question your seniors
- You do not have the time to read documents and write reports
- You do not believe in the concepts of quality management
- You are not looking to improve the practices employed by your organization

Ethos of auditing

- Positive approach
- Aim to help improve the system
- Don’t look to blame
- Aid identification of solutions

Quality Management Systems

Session One

Learning Objectives

- PDCA (continual improvement) cycle
- Process approach to quality management
- Components of an effective quality system
- The 8 principals of quality management

Some Quality Definitions

- ***"Quality"***

  "the essential nature of a thing and the totality of its attributes and properties which bear upon its "***fitness for its intended purpose***"

- ***"Quality Assurance"***

  "covers all matters which individually or collectively influence the quality of a product….***Quality Assurance*** therefore incorporates ***Good Manufacturing Practice***"

Some Quality Definitions

- ***"Quality Control"***

"***Quality Control*** is that part of ***Good Manufacturing Practice*** which is concerned with sampling, specifications and testing, and with the organisation, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their ***quality*** has been judged to be satisfactory"

A Quality Management System must ensure that…

- Products are collected, processed and stored correctly
- Managerial responsibilities are identified
- SOPs are provided for control
- Supply and use of correct starting materials are organised
- Controls for all stages of collection, processing and storage are defined
- Finished products are correctly processed and checked before release
- Storage and distribution is provided and controlled
- Self-inspections are organised
- Issues are identified and fixed in a timely manner

The 8 Principles of Quality Management

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships

4. Quality Management System

- Implement & maintain
- Continually improve
- Reflect size & complexity
- Process based
- Quality manual
- Control of documents
- Control of records

5. (Top) Management Responsibility

- Tangible commitment to quality & continual improvement
- Customer focus
- Quality policy
- Quality objectives (measurable)
- Internal communication
- Management review with a focus on improvement

6. Resource Management

- Provision of necessary resources

  Human Resource:
  - necessary competence & training
  - necessary actions
  - evaluation of effectiveness
  - appropriate records

- Infrastructure affecting product/service
  - surroundings
  - equipment
  - support services

- Work environment affecting product

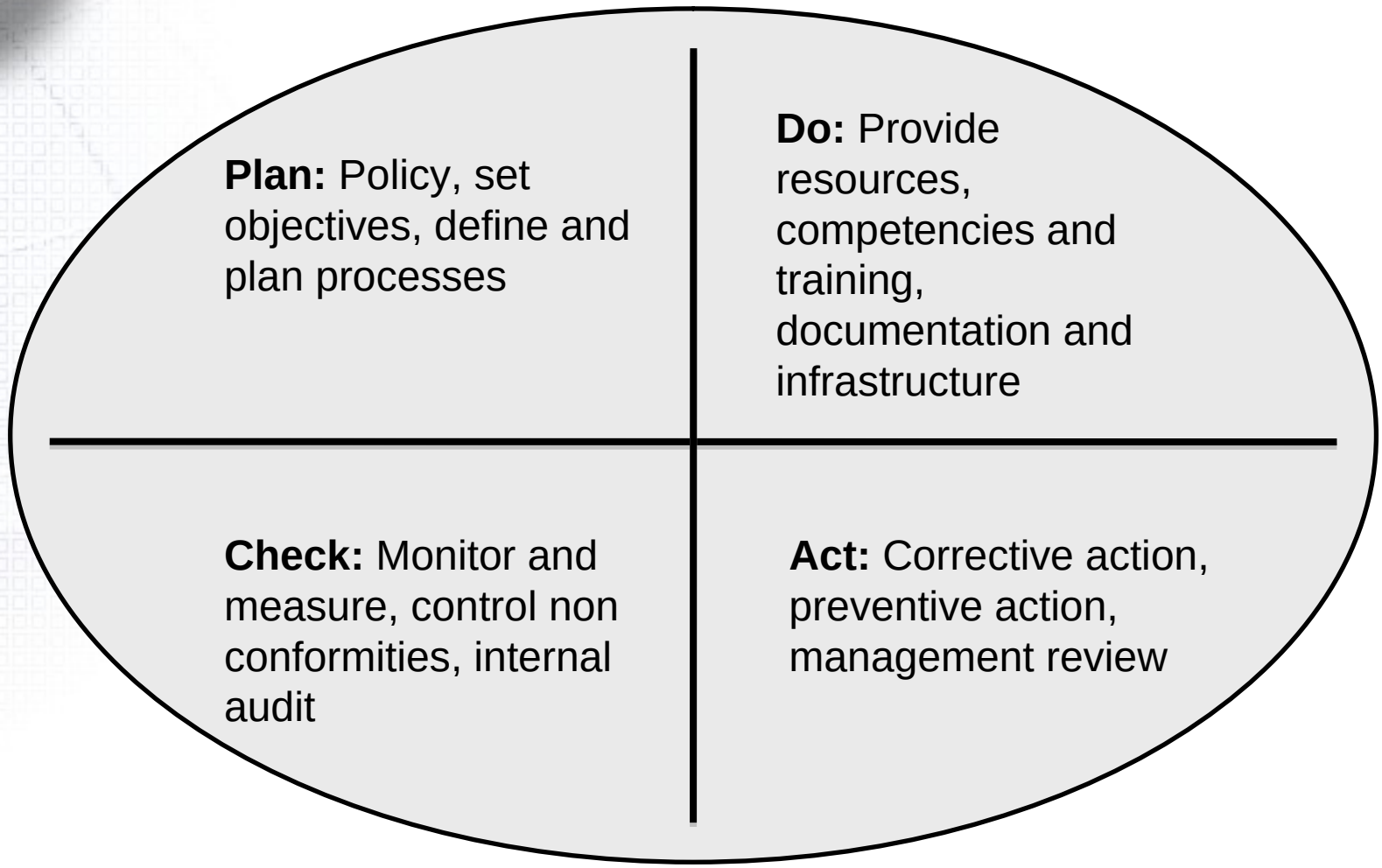
7. Product Realization

- Exclusions allowed in this clause
- Planning operational processes
- Customer related processes (sales)
- Design & development
- Purchasing
- Production/service provision
- Control of monitoring & measurement devices

8. Measurement Analysis & Improvement

- Customer satisfaction (perception!)
- Internal audit
- Monitoring & measurement of processes
- Monitoring & measurement of product
- Control of nonconforming product
- Data analysis
- Continual improvement of QMS
- Corrective action
- Preventive action

Systematic Approach

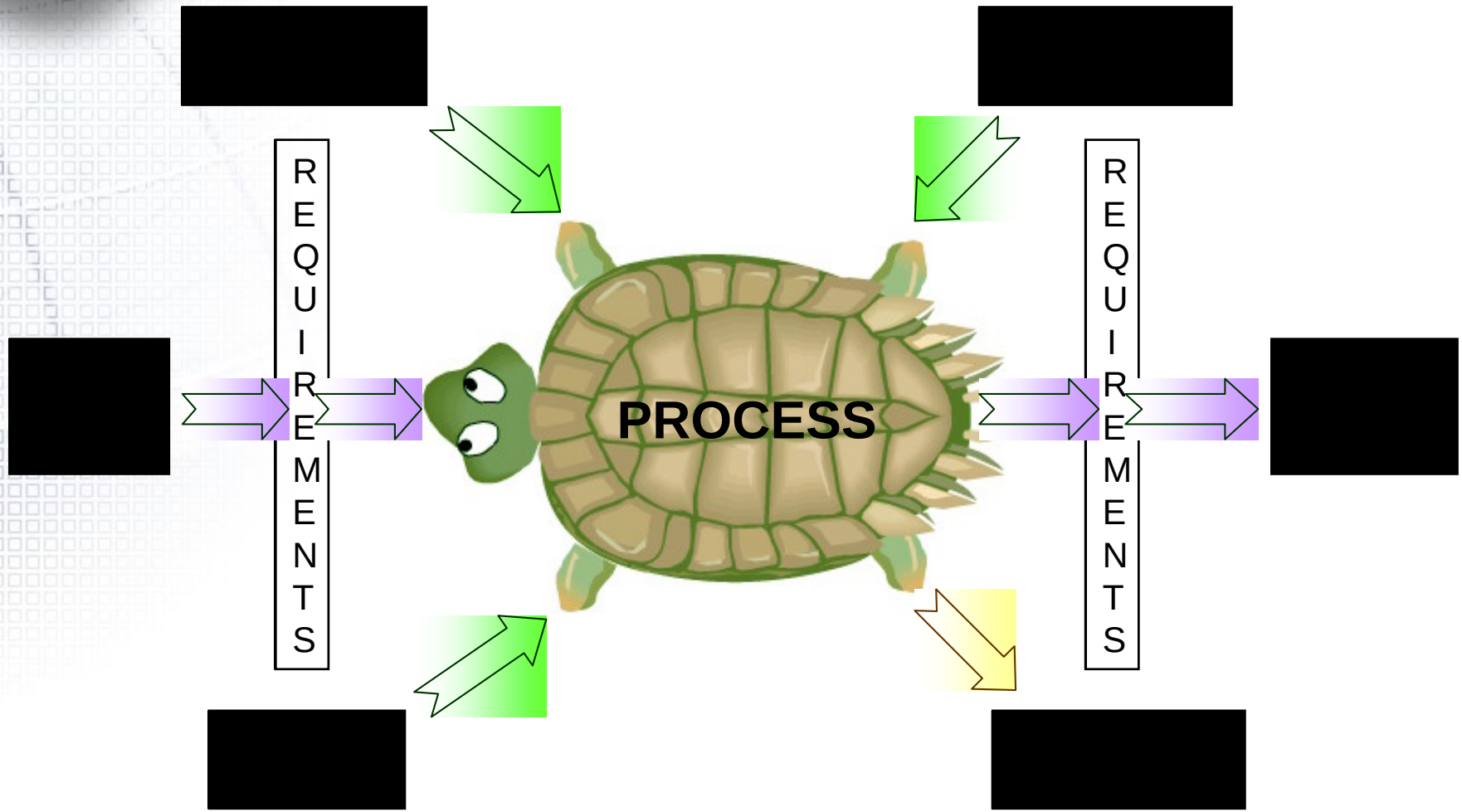


Quality in terms of Blood Components

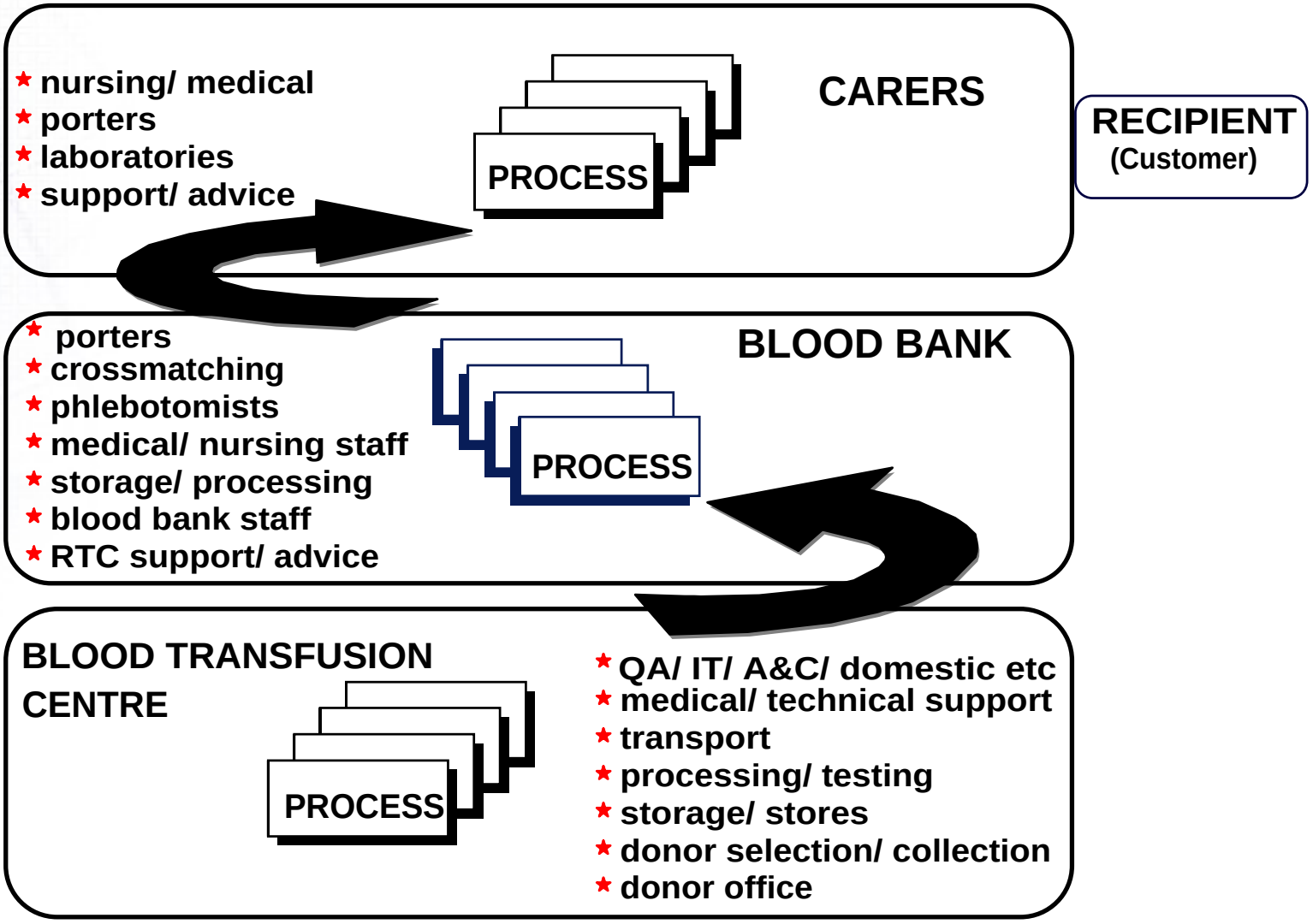
- Safe and effective
- Decrease in errors
- Credibility of test results
- Process and System Controls
- Correctly labelled

- We must have effective processes to provide effective products and services

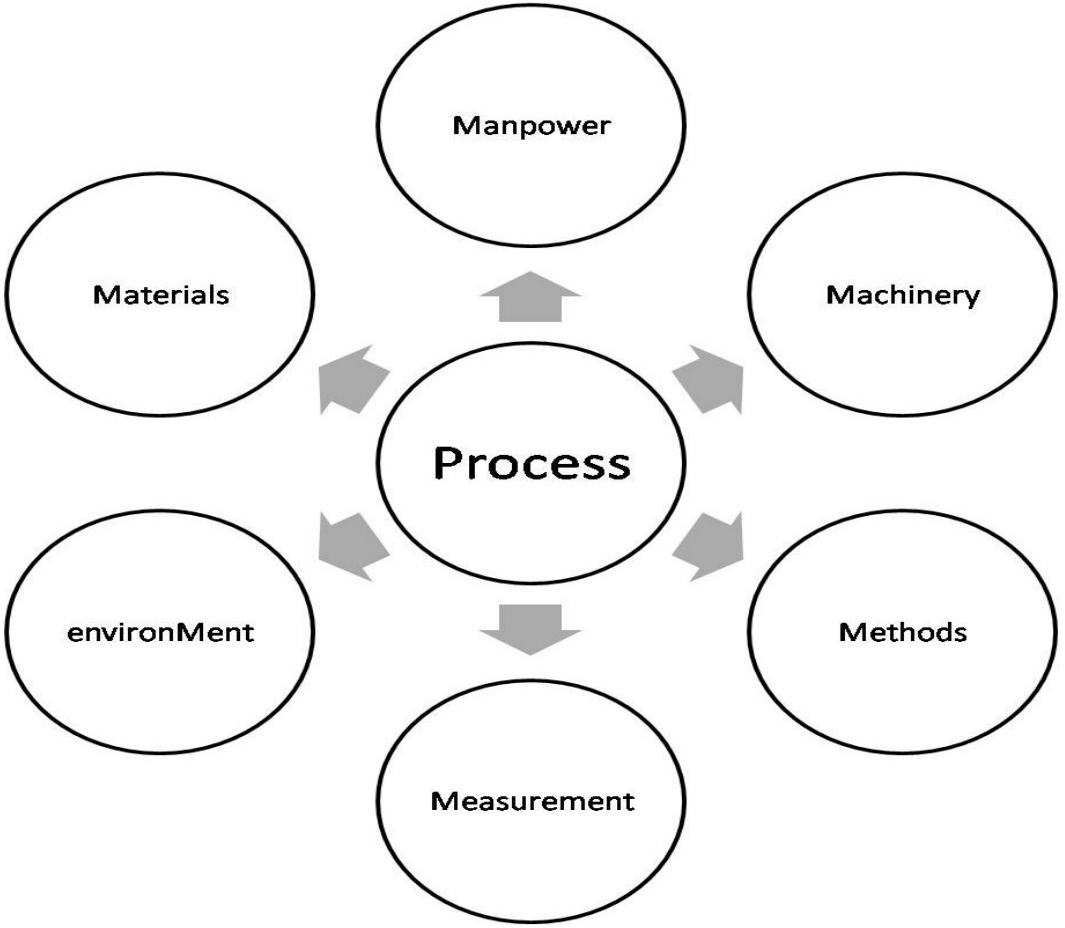
Turtle Diagram - A Controlled Process



Applying The Process Approach



Key Process Factors



Process Based Auditing

- Manpower: Human resources provided including competence and training, authority and responsibilities
- Machinery: Machinery and equipment required including technical and maintenance requirements. Any monitoring and measurement equipment and relevant calibrations
- Methods: Documented procedures (and undocumented) and other documentation including records
- Materials: Materials used in the process (controls placed on suppliers of materials)
- environMent: Work environment (e.g. temperature, cleanliness, noise etc) infrastructure and support requirements

Process Based Auditing

- Measurement: Performance indicators and always ask:
  - How do you know the process is effective and efficient?
  - How does the process deal with nonconforming situations?

Session Two

Blood Safety & Quality Regulations

Learning Objectives

- The BSQR Standard
- The purpose & structure of the BSQR
- Documentation required by the BSQR
- Audit objective evidence

Public Expectations

Blood must be:

- Available whenever needed
- Safe and effective
- Zero risk of disease transmission
- Global Travel – same quality all over the world

What do the regulations say?

Article 1: Objectives of EU Directive 2002/98/EC

Status:-

This directive lays down standards of quality and safety of human blood and blood components in order to ensure a high level of human health protection.

What do the regulations say?

The regulations apply to:

- Collection and testing of blood and blood components whatever their intended purpose
- Processing, storage and distribution of blood and blood components when intended for transfusion

Where does GMP practice apply to Blood Banks

- Purchasing
- Testing
- Quality Control
- IT
- Storage
- Distribution

Blood Safety & Quality Requirements

An Overview to the Requirements

1. Introduction & Principles

- Quality system
  - Responsibility of all and managed systematically
  - Includes quality management systems, processes, people & infrastructure
  - Specify processes in instructions
  - Management reviews & corrective actions
- Quality assurance
  - Provide QA support
  - Procedures, premises and equipment that have an effect on safety shall be validated

Quality - Critical

- Functions include
  - Change management
  - Internal audit and self inspection
  - Non- conformance management
  - Contract management and supplier qualification

2. Personnel& Organisation

- Organisation & Structure
  - Adequate staffing levels
  - Organisation chart
  - Medical officer available

- Training
  - Induction and continuous
  - Recorded and competence assessed
  - Evidence of the effectiveness

- Hygiene
  - Instructions
  - Appropriate PPE

3. Premises

Factors that need to be considered include:

- Location, design, construction, security and maintenance
- Sufficient space for logical sequence of workflow
- Dedicated areas (Storage areas away from clinical areas)
- Environmental, temperature and humidity monitoring & cleaning records
- Adequate storage (segregation of stock)

4. Equipment & Materials

- Equipment shall be validated, calibrated & maintained
- Select equipment to minimise hazards
- Reagents & materials from approved suppliers
  - Critical materials to be released by qualified person
  - Meet Medical Device Directive (where required)
- Retain inventory records
- IT procedures to control use of hardware & software including control & back ups of data

5. Documentation

- Procedures – SOPs
- Records
- Document control
  - review, approval and change control
  - Archiving
- Benefits
  - Standardisation
  - Traceability

6. Blood Collection & Testing

Procedures to include:

- Laboratory testing
- Processing & validation
- Labelling
- Release of blood & blood components

Testing

Mandatory markers

- Minimises risk of disease transmission

Sampling & testing requires

- Defined written procedures
- Validated methods
- Qualified, calibrated , maintained equipment
- Approved reagents and test kits
- Validated data transfer procedures
- Documented acceptance / rejection criteria

ABO & RhD blood group testing

- Performed on first- time, repeat & regular donors
- Subject to requirements set by competent authority

Quality Monitoring

- Provides evidence of:
  - Process control

- Quality Critical Processes must be:
  - Validated
  - Evidence of control

- Monitoring should
  - be carried out on an individual donation (not pooled samples)
  - reflect single donor “batch” nature of components
  - be subject to periodic review

7. Storage & Distribution

- Procedures shall be validated
- Prevent mix ups
- Records of inventory & distribution
- Packaging to maintain integrity & temperature
- Control return of blood back into storage

Review & Release

Product status management
- Quarantine
- Released by authorised (against written specification)
- Accordance with a defined written procedure

Computer generated data
- system validated with access control
- earlier release from donor – consistency check

Rejected donations
- Securely quarantined pending destruction
- Associated components checked

8. Contract Management

- Define any contracted tasks in a written contract

9. Non Conformance

- Any deviation must be released only by exception with agreement of prescribing physician & blood establishment physician
- Complaints and other information including serious adverse reactions and event shall be investigated & controlled
- Effective recall procedure maintained
- Corrective & preventive action system

10. Self Inspection

- Audit system implemented to ensure the compliance with the BSQR
- Document results & close out actions in a timely manner

Audit ‘Objective’ Evidence

‘records, statements of facts or other information which are relevant to the audit standards’

Section 3.9.4

ISO 9000:2005