# Quality Audit Training Workshop (BSQR)

# Welcome to the Workshop

- Fire precautions & exit routes
- Please take valuables with you at break
- Keep cell phones switched off
- Any problems, please let us know
- Above all, relax & enjoy the course

# 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

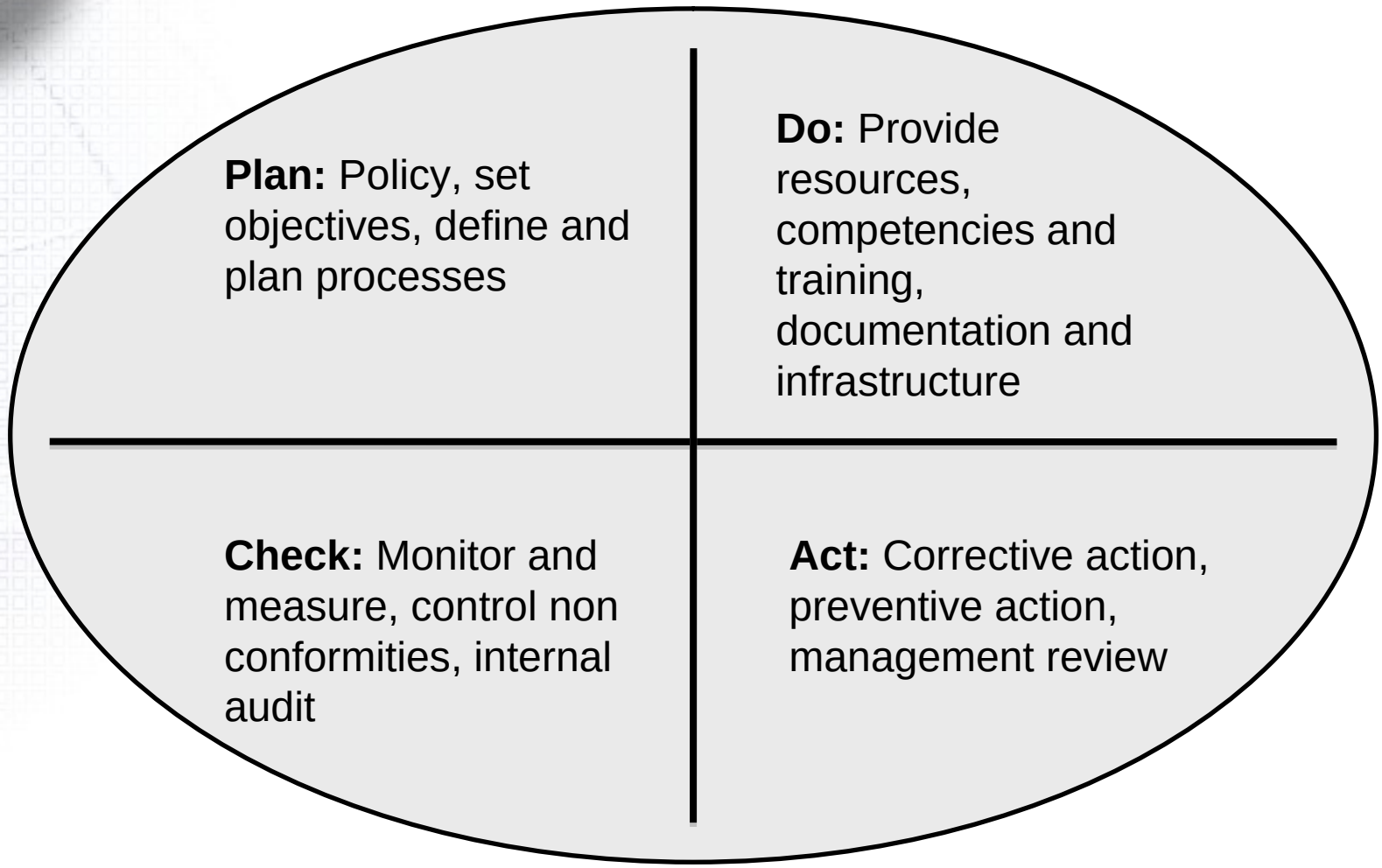
# 7. Product Realization

- 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

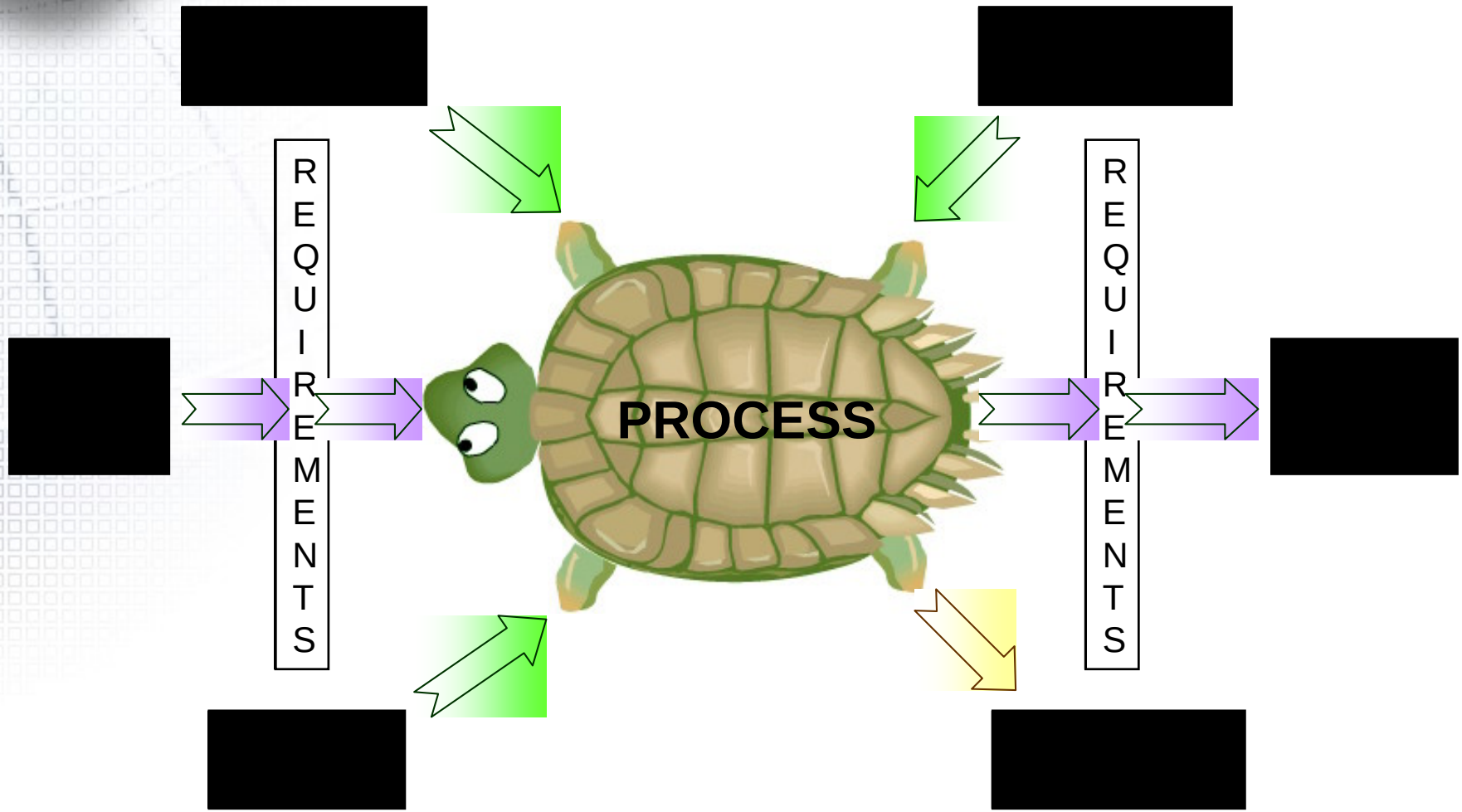


# Quality in terms of Blood Components

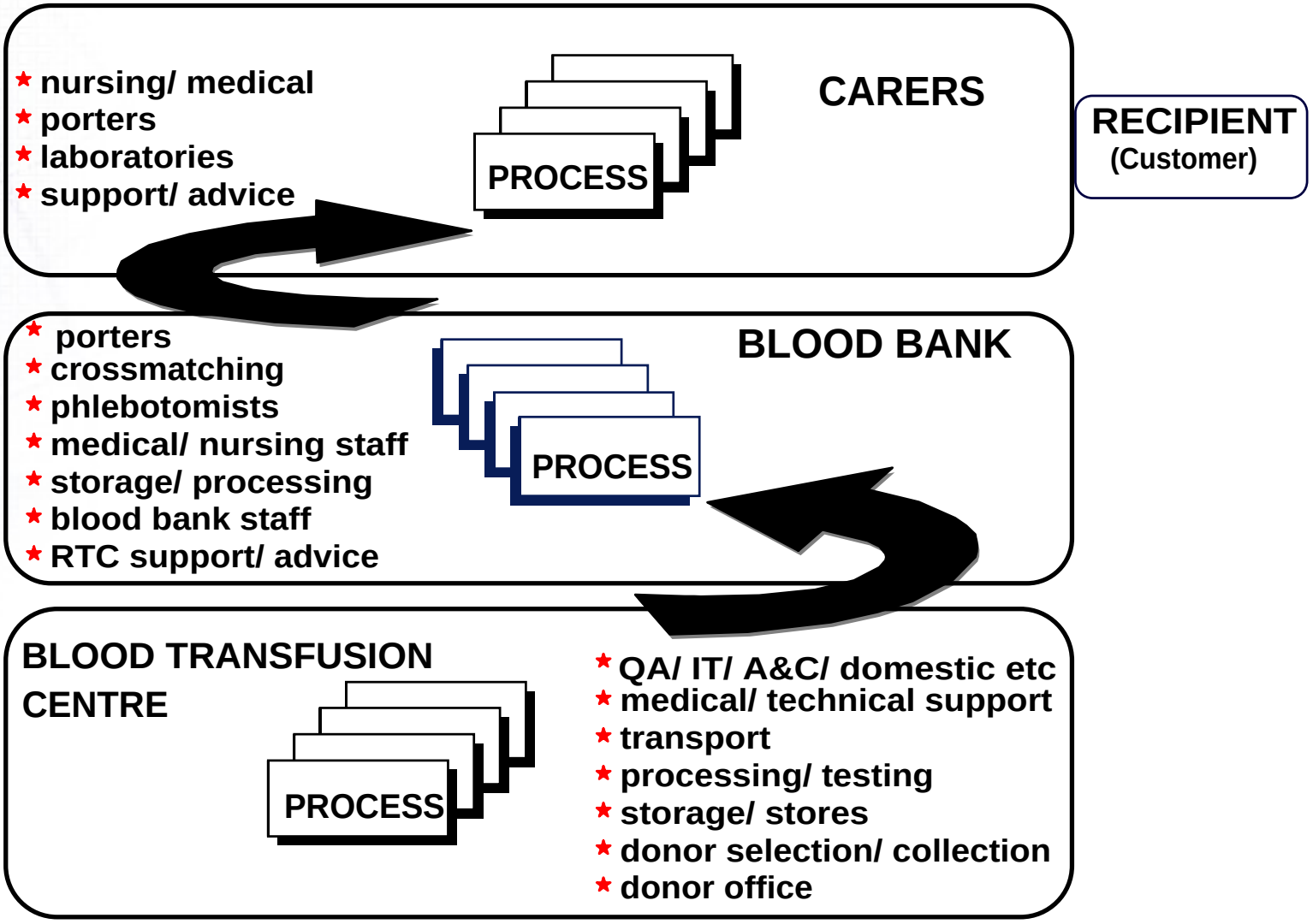
- Safe and effective
- Decrease in errors
- Credibility of test results
- Process and System Controls
- Correctly labelled

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

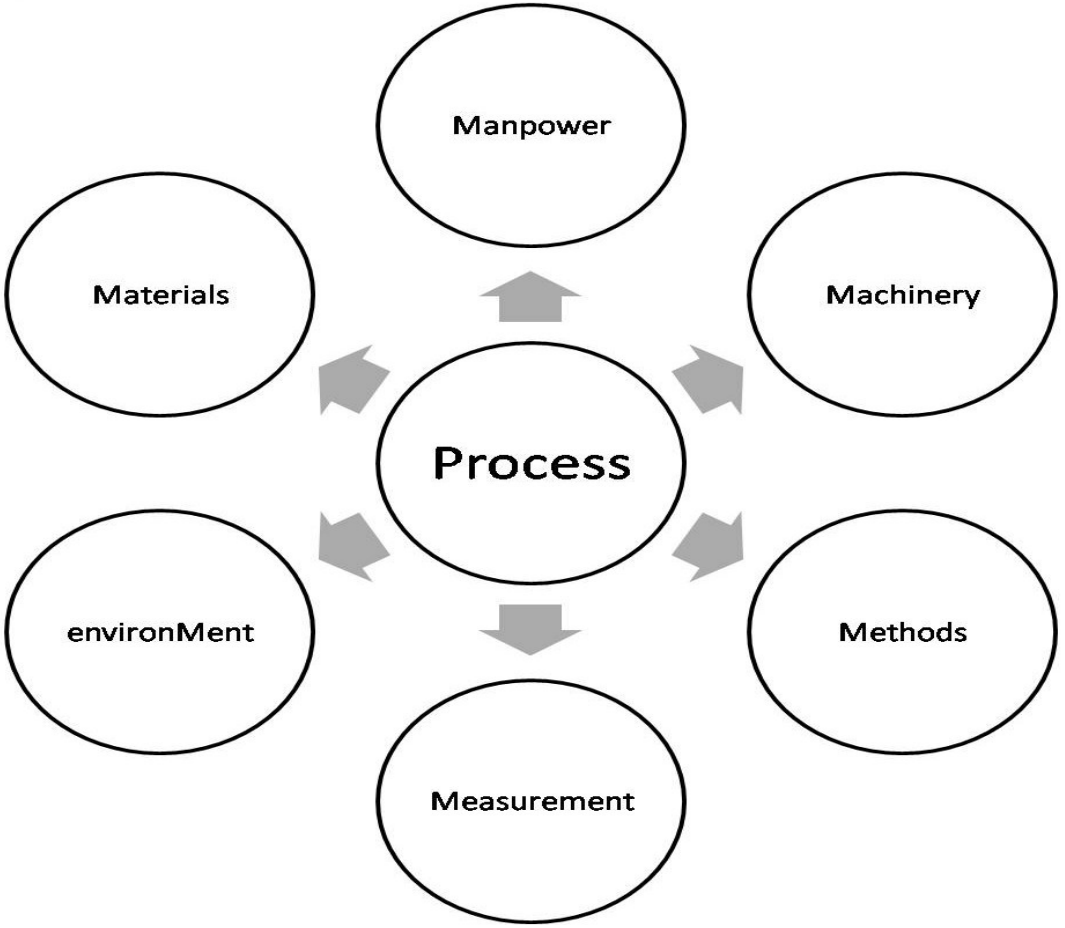
# Turtle Diagram - A Controlled Process



# 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?