

# STRENGTHENING QUALITY MANAGEMENT SYSTEMS IN BLOOD BANK



# FACILITATOR'S GUIDE 2016





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# STRENGTHENING QUALITY MANAGEMENT SYSTEMS IN BLOOD BANK

### **FACILITATOR'S GUIDE**







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Dr. C. V. Dharma Rao Joint Secretary



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#### Foreword

Blood Transfusion Service is an essential component of health care system that has a responsibility of ensuring availability, accessibility, adequacy, quality and safety of blood supply. The availability and safety of blood depends on multiple steps in the transfusion chain. This starts with a healthy and motivated population, retention of voluntary non-remunerated repeat donors, processing and testing of all donated blood, availability of blood and blood products, rational use of blood and its components and post-transfusion monitoring of the patient. At every step, any lowering of quality would reflect adversely on the final product. Therefore, capacity building for strengthening the Quality Management Systems of Blood Banks is very important wherein emphasis is laid on ensuring consistency in performing various activities so that the safety and quality of blood is guaranteed. The performance of any procedure will yield desired quality results only if Standard Operating Procedures (SOP's) are followed. The recently conducted baseline assessment of NACO supported Blood Banks revealed that many Blood Banks in the country are not aware of the Standard Quality Management practices for various procedures that are commonly performed in Blood Transfusion Services, hence NBTC/ NACO has developed this Module. Individual Blood Banks need to adapt these and develop their own blood bank-specific Quality Policy and Quality Manual based on the infrastructure available, test procedures to be followed and availability of reagents. I am sure the Blood Banks will find this Module of Quality Management System useful to help them in achieving their objective of continuously providing adequate, safe and quality blood.

(Dr. C.V. Dharma Rao)

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National Blood Transfusion Council Ministry of Health and Family Welfare Government of India

#### **Preface**

A Quality Management System can be described as a set of key quality elements that must be in place for an Organization's work operations to function in a manner that meets the Organization's stated quality objectives. This system provides the means to direct and control the Organization with regard to quality. The purpose of this Quality Module is to define and document a Blood Bank's Quality Management System.

There has been growing awareness about quality in Blood Transfusion Services with the objective of releasing only those blood products and blood which fulfill the desired standards in terms of safety and efficacy. Consistency is the hallmark of quality and can be achieved only by implementing standard Quality procedures by all staff engaged in Blood Banks at all times. Following Quality procedures is also essential for licensing and accreditation. Each Blood Bank has to develop its own set of Quality Policy and Quality Manual matching their requirement and resources. To attain maximum safety, the requirements of Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), use of Standard Operating Procedures (SOP) and moving towards total Quality Management is vital for organization and management of Blood Transfusion Services.

The Strengthening Quality Management System in Blood Banks Module is intended to act as a guide and help all Blood Banks in writing and validating their own Quality Policy and Quality Manual. We are hopeful that these Modules will also stimulate Blood Transfusion Services in adapting Standard Quality procedures strengthening their Quality Systems.

(Dr. R.S. Gupta)

#### **Acknowledgement**

Blood Transfusion is a lifesaving intervention that has an essential role in the total patient management within the health care delivery. Based on the principle of delivering quality health care services, the National Blood Transfusion Council (NBTC) and Blood Transfusion Services Division, NACO has developed a Module on "Strengthening Quality Management Systems in Blood Banks" with an objective to maintain and enhance the quality and safety of Blood Transfusion Services in India. This Quality Module is based on Internationally-accepted standards and focuses on good quality principles and best practices. It shall be a template to provide guidance to Blood Banks on writing policies and procedures that support a Quality Management System.

Keeping in mind the guiding principle of consistency, this Module emphasizes on the adherence to Quality Standards in the entire Transfusion chain from "Donor to Recipient", encompassing the selection of Blood donors from low-risk population, safe blood collection, testing of donated blood for Transfusion Transmissible Infections and Blood group serology, preparation, storage, issue and transportation of Blood components for appropriate clinical use and lastly safe administration of Blood to the recipients.

The constant encouragement of Shri N.S. Kang, President NBTC / Secretary NACO, Dr C.V. Dharma Rao, Joint Secretary, NACO and Dr R.S.Gupta, Director NBTC/DDG (BTS), NACO have greatly helped in undertaking this important activity.

A special thanks to Dr Shanoo Mishra PO (QC), NBTC and other team members for their constant effort and hard work in overall supervision and guidance for development of this module.

It is commendable to note that the document has been prepared and compiled by Dr Veena Doda and reviewed with the coordinated and concerted efforts of various experts from the Transfusion Medicine fraternity especially Dr Gajendra Gupta, Dr Joy Mammen, Dr Sunita Upadhyaya and Dr Sarika Mohan. I gratefully acknowledge the contributions made by all the experts.

I extend my sincere thanks to the U.S. Centers for Disease Control and Prevention, Division of Global HIV/AIDS & TB (CDC-DGHT), India and Christian Medical Association of India (CMAI) for supporting the development and printing of this publication.

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#### **Purpose And Scope**

Quality Management Systems in Blood transfusion service are essential to ensure safe blood. One of the fundamental objectives of this initiative is to help participants to develop a realistic plan of action for establishing an effective quality system in their own Blood banks. This Training manual provides information on all the essential elements of quality and is designed as a road map to establish and adopt quality management systems in blood banks.

This manual is directed to the staff working in blood banks for creating awareness on the importance of quality management systems, strengthening their existing skills and planning ways of introducing improved and systematic approaches and procedures for safe and efficacious blood.

Session	Timings	Duration	Methodology
Registration	0.00 0.00	00	A . (2.2)
Pre-course Assessment	9:00 am- 9:30 am	30 min	Activity
Introduction	9:30 am - 10:30 am	60 min	
Introduction of Participants		30 min	Ice breaker
Brief of Development and Expected		30 min	Presentation
Outcomes of the 03 day Training Programme <b>TEA BREAK</b>	10.20 10.45	4.F	
	10:30am - 10:45 am	15 min	
Programmatic Overview	10:45 am- 11:25 am	40 min	
Standards and Guidelines in Blood Banking, Regulations, National Policy		20 min	Presentation
National and State level Reporting systems (SIMS and NHP)		10 min	Presentation
Haemovigilance		10 min	Presentation
Basic Principles of Quality	11:25 am-12:25pm	75 min	
The importance of quality in the Blood Transfusion Service		10 min	Presentation
Quality Management Systems in Transfusion service		15 min	Presentation
Flow charting as a tool for mapping processes		15 min	Presentation
Developing a process flow chart		25 min	Group Activity
Presentation of group work on flow chart		10 min	Group Presentation
Organization and Management	12:40pm -1:30 pm	140 min	r
Organization and Management	- 1	15 min	Presentation
Developing a quality policy		15 min	Presentation
Write a quality policy and prepare an organogram		30 min	Activity
Presentation of group work on quality policy and organogram		20 min	Group Presentation
LUNCH	2:00pm-2:30pm	30 min	
Preliminary visit to Blood Bank	2:30 pm-3:30pm	60 min	Activity
Personnel	3:30pm-4:00pm	30 min	7 10 11 11 1
Job description, responsibility and delegation	0.00pm 1.00pm	15 min	Presentation
Writing a job description		15 min	Activity
TEA BREAK	4:00pm-4:30pm	30 min	
Accommodation and Environment	4:30pm-5:00pm	30 min	
Requirement of Accommodation and Environment in Blood Bank		15 min	Presentation
Questionnaire on Accommodation and Environment		15 min	Activity
Waste Management	5:30pm-6:10pm	40 min	
Waste Management Guidelines and management of spills and needle-stick injury		20 min	Presentation
Segregation of waste as per pollution control guidelines		20 min	Role Play

Recap of Day 1	8:50am-9:00 am	10 min	Interactive Discussion
Documentation	9:00am-11:00 am	120 min	
Documentation and Document Control		15 min	Presentation
Writing a Quality Manual		15 min	Presentation
Writing an SOP		15 min	Presentation
Controlling a document		30 min	Activity
Write an SOP		15 min	Activity
Presentation of group work		30 min	Group discussion
	11:00 am-11:15am	00 1	
Equipment management in	11:15am-12:30am	90 min	
Blood Bank		30 min	Presentation
Prepare the calibration and maintenance plan of equipment		15 min	Activity
Prepare a equipment log			15 mir
Presentation of individual work activity		30 min	Group discussion
	12:30pm-1:30pm	60 min	
External Services and supplies		20 min	Presentation
Inventory Management in Blood Bank		10 min	Interactive Discussion
Questionnaire on inventory management		30 min	Individual activity &Group discussion
	1:30pm-2:30pm		
	2:30pm-4:00pm	90 min	
Identification of Nonconformities		40 min	Presentation
Scenario of Nonconformity for Root- cause Analysis (RCA) and CAPA		20 min	Group activity
Identifying non-compliance against a set of standards		30 min	Group Activity
	4:00pm-4:15pm		
	4:15pm-6:00pm	120 min	
Quality Control Immunohaematology		30 min	Presentation
Quality Control Components		30 min	Presentation
Quality Control TTI and Preparation and Interpretation of LJ Graph		60 min	Presentation and Individual activities & group discussion

Session	Timings	Duration	Methodology
Recap of Day 2	8:50am-9:00am	10 min	Interactive Discussion and homework discussion
EQA and Performance Improvement	9:00am-10:15am	80 min	
EQA for Blood Banks		15 min	Presentation
EQA Roll out Plan		5 min	Presentation
Root Cause Analysis		30 min	Activity
Quality Indicators for performance improvement		15 min	Presentation
Quality Indicators for performance improvement		15 min	Activity and Discussion
Internal Audit and Management Review	10:15am-12:45pm	65 min	
Internal Audit		30 min	Presentation
TEA BREAK	10:55am-11:10am		
Visit to Blood bank- Mock exercise-Internal Audit		90 min	Visit f/b Interactive Discussion
Management Review		30 min	Presentation
Internal Audit and Management Review		15 min	Discussion
Quality Manual and Implementation Plan	12:45pm-2:15pm	90 min	
Inadequacy in quality manual		60 min	Group Activity
LUNCH	1:45pm-2:15pm		
Implementation plan for respective Blood Bank		30 min	Group discussion
Conclusion	2:15pm-3:15pm	70 min	
Post-Evaluation on QMS, Feedback and Discussion		20 min	Activity and Discussion
Accreditation-form, website		10 min	Presentation
Valediction		15 min	Activity
Concluding remarks		15 min	
TEA BREAK	3:15pm- 4:00pm		

#### **Note for Master Trainers**

The national guidelines on Blood Bank Quality Management System are a major initiative taken by NACO to support the blood bank network in ensuring an overall quality and safety of blood transfusion practice. The NACO Quality Management System (QMS) training tool kit consist of QMS module, facilitator's guide, and agenda on the course content that are designed for use by the trainers, quality coordinators and program managers.

The facilitator guide outlines the training methods for facilitators for handling each session of QMS training. The Facilitator's Toolkit is provided on CD-ROM which contains the training materials in the form of PowerPoint presentations and activity notes for participants.

For the purpose of effective training, the master trainers are expected to meet the following requirements:

- 1. To be well-versed with the essential elements of QMS and be competent to implement QMS in blood banks.
- 2. To be well versed with the training methods outlined in the facilitators guide.
- 3. Undertake assessments and reassessments of Blood Banks using Self-Assessment Quality checklist (refer annexure A of QMS module) for evaluating baseline and progress made on QMS.
- 4. Use the standard power point presentations, QMS module, Facilitator's Guide, Formats and checklists for further roll-out of training.
- 5. Based on the level of Quality systems in Blood Banks, prioritize the essential elements of QMS for Blood bank training and adopt appropriate training methods as outlined in the facilitator guide.

# \_\_

Day - 1

#### **Session 1: Introduction**

#### **Activity 1& 2: Introduction of Participants and facilities**

#### **Objective:**

• To help participants to get to know each other.

Time: 15 Minutes

Material: Soft ball – 1 No.

#### Methodology

#### Instructions to the Facilitator:

- Ask the participants to sit in a circle
- The facilitator can introduce him/herself first
- Throw the ball to one of the participants
- The participant who holds the ball has to introduce him/herself to the group by saying out aloud their name, designation, workplace & hobby.
- The participant holding the ball will now throw it to anyone in the group. The person who gets the ball now introduces him/herself.
- The activity continues till all the participants have introduced themselves.

#### **Session 1: Introduction**

#### **Activity 3: Pre course assessment**

#### Objective:

• To understand the knowledge and understanding of subject among participants about QMS in Blood Banks

Time:10 Minutes

Material: Paper, Pens

#### Methodology

Individual Activity

#### Instructions to the Facilitator:

- The facilitator distributes pre-course assessment questionnaire to all participants.
- At the end, collect the questionnaire sheets within allotted time.

Note: Remember to collect answered sheets from all participants

#### Summarize:

• The facilitator has to distribute and collect questionnaire

#### Reference:

♦ Day 1: Pre- and post- course assessment questionnaire

# Session 1: Discussion on entire module and expected outcome of three days training

**Activity 4: Interactive discussion** 

#### Objective:

 To give an overview of entire module and expected outcomes at the end Time:10 minutes

Material: Projector, slides

#### Methodology

♦ Power point presentation f/b Interactive Discussion

#### Instructions:

• The facilitator needs to hold an interactive discussion with participants with an overview of entire program with understanding of expected outcomes.

#### Summarize:

- Quickly recap the program.
- Clarify any questions by the participants.

#### Reference:

- ♦ Kindly refer to QMS Module
- Day 1: PPT NO.2: An overview of QMS Training

#### **Session 1: Programmatic Overview**

Activity 4: Standards & Guidelines in Blood Banking, Regulations, National Policy

#### Objective:

 To create awareness of the standards & Guidelines in Blood Banking, Regulations, National Blood Policy Time:20 Minutes

Material: Projector, slides

#### Methodology

♦ Power Point Presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries

#### Summarize:

- 1 What are the core points discussed in this presentation?
- 2 How does it relate to your work?

- National Blood policy 2002, Revised version 2007
- Day 1: PPT No: 3: Standards and guidelines in BB, regulations, national policy

## Session 2: National and State level reporting systems Activity 4: Haemovigilance, NHP and SIMS

#### Objective:

 To create awareness of the National and state reporting systems including Haemovigilance, NHP and SIMS Time:30 Minutes

Material: Projector, slides

#### Methodology

♦ Three Power Point Presentations

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

#### Reference:

• Day 1: PPT No. 4: National and state level reporting systems

## Session 3: Basic Principles of Quality Activity 1: The importance of Quality in the blood transfusion service

#### Objective:

• To illustrate the importance of quality in blood transfusion service

Time:10 Minutes

Material: Projector, slides

#### Methodology

♦ Power Point Presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries

#### Note:

• Refer to standards and guidelines while describing quality

#### Summarize:

• What are the core points discussed in presentation?

#### Reference:

◆ Day 1: PPT No: 5: Importance of Quality in BTS

# Session 3: Basic Principles of Quality Activity 2: Quality Management systems in Transfusion service

#### Objective:

♦ To define and explain QMS in blood transfusion service

Time:15 Minutes

Material: Projector, slides

#### Methodology

♦ Three Power Point Presentations

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries.

#### Note:

• Refer to standards and guidelines while describing quality

#### Summarize:

• What are the core points discussed in presentation?

#### Reference:

◆ Day 1: PPT No: 6: Importance of Quality in BTS

# Session 3: Basic Principles of Quality Activity 3: Flow charting as a tool for mapping process

#### Objective:

• To illustrate the flow charting as a tool for mapping process in a blood bank.

Time:15 Minutes

Material: Projector, slides

#### Methodology

♦ Power Point Presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries.

#### Note:

• Please explain with the help of general examples

#### Summarize:

What are the core points?

- Kindly refer to QMS module
- ◆ Day 1: PPT No: 7: Process Mapping

# Session 3: Basic Principles of Quality Activity 4: Developing a process flow chart

#### Objective:

 To describe and develop process flow chart of critical areas of blood bank Time:15 Minutes

Material: Paper, pens

#### Methodology

#### Instructions:

- Prepare a blood donation process map in Blood Bank
- Prepare a process map of blood from collection to inventory in a Blood bank
- Prepare a process map for issue of blood
- Prepare a process map for Blood donation camp
- ♦ Presentation from each group
- ♦ Open Discussion

#### Summarize:

- 1. What are the core points discussed in this activity?
- 2. How does it relate to your work?

#### Reference:

◆ Day 1: Activity no: 1

# Session 3: Basic Principles of Quality Activity 2: Presentation of group work on flow chart

#### Objective:

 To allow each group to present the respective process flow charts Time:20 Minutes

Material: Projector, Screen, Pointer

#### Methodology

♦ Power Point Presentation

#### Instructions:

- Each group to depute one speaker
- Brief presentation by each speaker

#### Summarize:

- 1 What are the core points discussed in these presentations?
- 2 How does it relate to your work?

#### Reference:

Day 1: PPT No. : 7Day 1: Activity No: 1

# **Session 4:Organization and Management Activity 1: Organization and Management**

#### Objective:

 To describe and explain organization structure and chart. Time:15 Minutes

Material: Projector, Slides

#### Methodology

♦ Power Point Presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries

#### Summarize:

- 1 What are the core points discussed in this presentation?
- 2 How does it relate to your work?

#### Reference:

- ♦ Kindly refer QMS module
- ◆ Day 1: PPT No: 8: Organization and Management

# Session 4: Organization and Management Activity 2: Developing a Quality Policy

#### Objective:

♦ To explain importance and formulation of Quality policy

Time: 15 Minutes

Material: Projector, slides

#### Methodology

♦ Power Point Presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- How does it relate to your work?

- ♦ Kindly refer QMS Module
- ◆ Day 1: PPT No. 9: Developing a Quality Policy

# Session 4: Organization and Management Activity 3: Write a quality policy and prepare an organogram

#### Objective:

 To write a quality policy and prepare an organogram of your facility Time: 30 Minutes

Material: Paper, pens

#### Methodology

#### Instructions:

- Write an Organogram & Quality Policy of your Blood Bank.
- ◆ Activity (QM and TM from each BB)

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 1: Activity no: 2

# Session 4: Organization and Management Activity 4: Presentation of group work on flow chart

#### Objective:

• To describe and explain quality policy and organization structure on flow chart.

Time: 20 Minutes

Material: Paper, pens, projector,

slides

#### Methodology

#### Instructions:

- Allow and encourage each member from each group to present their respective work
- ♦ Discussion

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 1: Activity no: 2

## **Session 4: Organization and Management Activity 5: Preliminary Visit to Blood Bank**

#### Objective:

◆ To visit Blood Bank for understanding organization and management

Time: 60 Minutes

Material: none

#### Methodology

#### Instructions:

- Allow and encourage each participant to understand organization and management of the blood bank being visited.

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

Day 1

# Session 5: Personnel Activity 1: Job description, responsibility and delegation

#### Objective:

• To describe the methods and importance of job description, responsibility and delegation in a Blood Bank.

Time: 15 Minutes

Material: Projector, slides

#### Methodology

• Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

- ♦ Kindly refer QMS module
- ♦ PPT no:11

# Session 5: Personnel Activity 2:Writing a Job description

#### Objective:

 To understand and write job description of staff (esp. Head, QM, TM, technician) in a Blood Bank. Time: 15 Minutes

Material: Paper, pens

#### Methodology

Group Activity

#### Instructions:

- Divide into 4 groups
- Write a Job description of Following
- ♦ Head of Blood Bank
- Quality Manager
- ♦ Technical Manager
- ♦ Blood Bank Technician
- Answer the questionnaire (Individual Activity)- 10 min

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 1: Activity no: 3

# Session 5: Accommodation and Environment Activity 1: Requirement of Accommodation and Environment in Blood Bank

#### Objective:

• To understand standards required for accommodation and environment in a Blood Bank.

Time: 15 Minutes

Material: Projector, slides

#### Methodology

• Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

- ♦ Kindly refer QMS module
- Day 1: PPT no:12: Accommodation and Environment

# Session 5: Accommodation and Environment Activity 2: Questionnaire on Accommodation and Environment in Blood Bank

#### Objective:

 To answer relevant questions on accommodation and environment in a Blood Bank. Time: 15 Minutes

Material: Paper, pens

#### Methodology

#### Instructions:

- ♦ Individual activity: 5min

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 1: Activity no: 4

#### **Session 6: Waste Management**

# Activity 1: Waste management guidelines and management of spills and needle-stick injury

#### Objective:

 To understand waste management guidelines and management of spills and needle-stick injury in a Blood Bank. Time: 20 Minutes

Material: Projector, slides

#### Methodology

♦ Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide.
- Do not just read out the points. Please clarify the participant's queries.

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

- ♦ Kindly refer QMS module
- ♦ PPT no:13

# Session 6: Waste Management Activity 2: Segregation of waste as per pollution control guidelines

#### Objective:

- ◆ To answer relevant questions on Bio Medical waste management in a Blood Bank.
- ♦ To hold game "Bin in a minute!"

Time: 15 Minutes

Material Game - Colour coded bins, 15 Yellow colored balls with names oflab consumables / waste to be pasted on it (Gloves, Used syringe, test tubes, etc.)

#### Methodology

Group Activity

#### Instructions:

- Divided into 2 activities:
- ♦ Questionnaire: 10 min
- ♦ Role play activity:10 min
  - o Bin in a Minute:

#### Game: Bin It In a Minute

- Arrange the colour coded bins. Ask participants to come in batches of 5.
- Hand over three balls to each of the participants.
- Ask the participants to come forward and throw the balls in the appropriate coloured bins.
- Ensure all participants participate. Rectify the mistakes if participants throw the ball in the wrong bin
  - o Spill management
- Role play on spill management for an assumed blood spill on the floor
- ♦ Individual activity

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 1: Activity no:5

Day - 2

#### Recap

#### **Activity 1: Recap of Day-1**

#### Objective:

♦ To recap and briefly outline

Time: 10 Minutes

Material: nil

#### Methodology

♦ Interactive Discussion

#### Instructions:

- Please try to explain the outline of day 1.
- Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in the recap?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 1 agenda

#### **Session 1: Documentation**

#### **Activity 1: Documentation and Document Control**

#### Objective:

• To describe and outline the importance of documentation and document control in a Blood Bank.

Time: 15 Minutes

Material: Projector, slides

#### Methodology

• Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- ♦ Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

- ♦ Kindly refer to QMS Module
- ◆ Day 2 : PPT No: 1

# Session 1: Documentation Activity 2: Writing a Quality Manual

#### Objective:

 To describe and understand the importance of Quality Manual.

♦ Contents of a Quality Manual

Time: 15 Minutes

Material: Projector, slides

#### Methodology

• Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 2 : PPT No: 2

# Session 1: Documentation Activity 3: Writing an SOP

#### Objective:

• To describe and outline importance of an SOP

♦ Contents of an SOP

Time: 15 Minutes

Material: Projector, slides

#### Methodology

• Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries.

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

#### Reference:

♦ Day 2 – PPT NO. 3

# Session 1: Documentation Activity 4: Controlling a document

### Objective:

 To describe and understand the importance of controlling a document

♦ List of control documents in a Blood Bank

Time: 30 Minutes

Material: : Paper, pens

### Methodology

#### Instructions:

- ♦ Divide into 4 groups
- Distribute questionnaire

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 2 : Activity No: 7

# Session 1: Documentation Activity 5: Write an SOP

### Objective:

• To write an SOP in the prescribed format.

Time: 15 Minutes

Material: Paper, pens

### Methodology

Group Activity

## Instructions:

- ♦ Instructions:
- ♦ Individual Activity: 15 min
- Competency Evaluation for Writing a Standard Operative Procedure
  - 1. List the area which needs Standard Operative Procedure
  - 2. Draw header and footer of SOP with required field
  - 3. Write steps used to develop SOP
  - 4. Advantages for SOP and how will you implement in blood bank
  - 5. Write Properties of SOP
  - 6. Write Standard Operative Procedure on any one procedure:
    - a. Donor Selection
    - b. Donor Screening
    - c. Post Donation Counseling
    - d. ABO blood grouping
    - e. Investigation of Transfusion Reaction
    - f. Labeling of blood bags and blood components
    - g. Equipment maintenance: Calibration

- h. Hemoglobin estimation of donor
- i. Management of adverse reactions in a donor
- j. Document Control

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 2 : Activity No. 6

# Session 1: Documentation Activity 6: Presentation of group work

# Objective:

• To encourage each group to present their SOPs.

# Time: 30 Minutes

**Material:** Projector, slides, flipchart, marker pens

#### Methodology

• Power point presentation or write on a flipchart (depends on comfort level of participant)

#### Instructions:

- Each participant will present one of their SOP
- One minute for one participant for presentation

#### Summarize:

- What are the core points discussed in this activity?
- How does it relate to your work?

#### Reference:

♦ Kindly refer to Activity No: 6

# Session 2: Equipment Management Activity 1: Equipment management in Blood Bank

# Objective:

• To describe and understand the importance of equipment management in a Blood Bank.

# Time: 30 Minutes

Material: Projector, slides

# Methodology

• Power point presentation or write on a flipchart (depends on comfort level of participant)

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

# Summarize:

- What are the core points discussed in this presentation?
- How does it relate to your work?

# Reference:

◆ Day 2 : PPT NO. 6

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# Session 2: Equipment Management Activity 2: Prepare the calibration and maintenance plan of equipment

### Objective:

• To prepare the calibration and maintenance plan of equipment in a Blood Bank.

Time: 15 Minutes

Material:

## Methodology

#### Instructions:

#### Sub activities:

1.Individual activity: 10 min:

a) Questionnaire of 4 questions: Calibration and maintenance plan of Equipment

b) Questionnaire of 5 questions : Equipment management

### Summarize:

• What are the core points discussed in this activity?

♦ How does it relate to your work?

#### Reference:

◆ Day 2: Activity No: 8

# **Session 2: Equipment Management Activity 3: Prepare an Equipment Log**

# Objective:

• To prepare an equipment log.

Time: 15 Minutes

Material: Paper, pens

# Methodology

Activity

#### Instructions:

♦ Individual activity: 5 min: Equipment log card

#### Summarize:

What are the core points discussed in this activity?

How does it relate to your work?

# Reference:

• Day 2 : Activity No. 9

# Session 3: Inventory Management Activity 1: External services and supplies

# Objective:

• To describe and understand the importance and methods of evaluation of suppliers in a Blood Bank.

Time: 20 Minutes

Material: Projector, slides

### Methodology

• Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- How does it relate to your work?

#### Reference:

◆ Day 2 : PPT No: 7

# Session 3: Inventory Management Activity 2: Inventory management in Blood Bank

## **Objective:**

• To describe and understand the importance and methods of evaluation of suppliers in a Blood Bank.

Time: 10 Minutes

Material: nil

# Methodology

♦ Interactive Discussion

#### Instructions:

- Please try to encourage participation from each member regarding evaluation of suppliers .
- Please clarify the participant's queries

## Summarize:

- What are the core points discussed in this discussion?
- ♦ How does it relate to your work?

#### Reference:

# Session 3: Inventory Management Activity 3: Questionnaire on inventory management

### Objective:

 To answer key questions on evaluation of suppliers in a Blood Bank. Time: 30 Minutes

Material: Paper, pens

## Methodology

♦ Individual activity f/b group discussion

### Instructions:

- ♦ Individual activity: 10 min
- Distribute questionnaire on inventory management
- Collect answer sheets from everyone
- ♦ Group discussion: 20 min
- Please answer all queries raised by participants

# Summarize:

- What are the core points discussed in this discussion?
- How does it relate to your work?

#### Reference:

◆ Day 2: Activity No: 10

# **Session 3: Inventory Management Activity 1: Identification of Nonconformities**

### Objective:

- To describe and understand the nonconformities identified in a Blood Bank.
- ◆ To understand how to control the nonconformities to achieve quality.

Time: 40 Minutes

Material: Projector, slides

#### Methodology

Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 2 : PPT No: 8

# Session 4: Identification and Control of Nonconformities Activity 2: Scenario of nonconformity for root-cause analysis (RCA) and CAPA

# Objective:

 To describe and understand the various scenarios of nonconformities and their RCA and CAPA. Time: 20 Minutes

Material: : paper, pens

# Methodology

Group activity

#### Instructions:

Total time : 20 minDivide into 4 groups

- ♦ 4 scenarios :
  - 1. Equipment failure
  - 2. Infection control
  - 3. Personnel management
  - 4. Complaints/Feedback
- ♦ Each group will perform activities in 10 min
- ♦ F/B open discussion : 10 min

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 2: Activity No: 11 (8a)

# Session 4: Identification and Control of Nonconformities Activity 3: Identifying non-compliance against a set of standards

### **Objective:**

 To describe and identify the nonconformities in a Blood Bank. Time: 30 Minutes

Material: Paper, pens

#### Methodology

#### Instructions:

• Group activity: 30 min

• f/b open discussion

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

#### Reference:

- ♦ Day 2 : Activity No: 8b
- ♦ Homework of the day: Activity no: 8c, 8d,8e

# **Session 5: Quality Control**

# **Activity 1: Quality control Immunohaematology**

### Objective:

• To describe and understand the Quality control of IH procedures in a Blood Bank.

Time: 30 Minutes

Material: Projector, slides

### Methodology

♦ Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

# Reference:

• Day 2 : PPT No: 9a

# **Session 5: Quality Control**

# **Activity 2: Quality control Components**

#### Objective:

 To describe and understand the Quality control of Component procedures in a Blood Bank. Time: 30 Minutes

Material: Projector, slides

# Methodology

• Power point presentation

# Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

# Reference:

• Day 2 : PPT No: 9b

# Session 5: Quality Control Activity 3: Quality Control for TTI and Preparation and Interpretation of LJ Chart

# Objective:

• To describe and understand the Quality control of TTI procedures in a Blood Bank.

#### Time: 60 Minutes

Material: Projector, slides

# Methodology

• Power point presentation and activity based learning

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

### **Activity:**

- ♦ Two individual sub-activities:
  - o Questionnaire on TTI: 25 questions: 10 min
  - o Preparation and Interpretation of LJ chart: 12 questions: 20 min
- f/b group discussion: 30 min
- Please encourage every member to participate
- Please resolve all participants' queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 2: PPT NO. : 9c

• Day 2: Activity No: 13 (9a)

Day-3

# Recap of Day-2

# Activity 1: Recap and homework discussion

# Objective:

♦ Recap day-2

♦ NC Homework discussion

## Time: 10 Minutes

Material: nil

# Methodology

♦ Interactive Discussion

#### Instructions:

- Please try to explain the contents of day-2.
- Do not just read out the points.
- Please clarify the participant's queries

#### Summarize:

- What was the core points discussed in day-2?
- ♦ How does it relate to your work?

# Reference:

♦ Kindly refer to Agenda of Day-2

# **Session 1: EQA and Performance Improvement**

Activity 1: EQA for Blood Banks and roll-out plan by NACO

# Objective:

• To describe and understand the importance of EQA in Blood Banks.

Time: 20 Minutes

Material: Projector, slides

# Methodology

♦ Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

# Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

#### Reference:

- ◆ Day 3: PPT No : 1

# Session 1: EQA and Performance Improvement

**Activity 3: Quality Indicators for performance improvement** 

### Objective:

• Describe the quality indicators in a Blood Bank

Time: 15 Minutes

Material: Projector, Slides

# Methodology

• Power point presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

# Reference:

◆ Day 3 : Activity No: 15

# Session 1: EQA and Performance Improvement Activity 2: Root Cause Analysis

#### Objective:

• To understand the steps of RCA for outliers in EQA for performance improvement.

Time: 30 Minutes

Material: paper, pens

### Methodology

Individual Activity

#### Instructions:

- Please try to explain the crux of the contents of RCA form. Do not just read out the points.
- Please clarify the participant's queries
- Please ask questions related to RCA form randomly
- Please encourage that they prepare RCA form when they go back to their facilities
- Explain it as an important tool for performance improvement

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

### Reference:

◆ Day 3: Activity No: 14

# **Session 1: EQA and Performance Improvement**

**Activity 3: Quality Indicators for performance improvement** 

#### Objective:

• Describe the quality indicators in a Blood Bank

Material: Paper, pens

# Methodology

♦ Group Activity

### Instructions:

- ♦ Group Activity :15 min
- Divide into 4 groups
- Questionnaire

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

◆ Day 3: Activity No. 15

# Session 2: Internal audit and Management Review Activity 1: Internal Audit

# Objective:

♦ Explain Internal audit in a Blood Bank

Time: 30 Minutes

Material: Projector, Slides

## Methodology

♦ Power Point Presentation

# Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- ◆ Please clarify the participant's queries

# Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

#### Reference:

- ♦ Kindly refer QMS Module
- ◆ PPT No: Day 2 Session 1 3

# Session 3: Visit to Blood Bank Activity 2: Mock exercise- Internal Audit

#### Objective:

♦ Mock exercise – Internal Audit

Objective: Mock exercise

- Internal Audit

# Methodology

♦ Visit to Blood Bank

#### Instructions:

- Please try to explain the crux of visit to Blood Bank for the purpose of understanding Internal Audit through Mock exercise.
- ♦ Divide into 4 groups:

1st group: Donor area

2nd group: Sample collection area

3rd group: TTI and IH

4th group: Component separation and inventory stock management

• Please clarify the participant's queries

#### Summarize:

- What are the core points in this mock exercise?
- ♦ How does it relate to your work?

#### Reference:

- Day 3: Activity No: 3

# Session 2: Internal Audit and Management Review Activity 3: Management Review

# Objective:

• To describe the importance and process of Management

Time: 30 Minutes

Material: projector, slides,

pointerlides

### Methodology

♦ Power Point Presentation

### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- ♦ How does it relate to your work?

#### Reference:

# Session 4: Quality Manual and Implementation Plan Activity 1: Inadequacy in Quality Manual

#### Objective:

• To identify inadequacies in Quality Manual

Time: 60 Minutes

Material: Paper, pens, Sample

Quality manual

# Methodology

♦ Group activity

#### Instructions:

- Please try to explain the crux of the activity.
- Divide the batch into institution-wise groups
- Each institution will find inadequacies in sample Quality manual
- Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this activity?
- ♦ How does it relate to your work?

#### Reference:

- ◆ Day 2: Activity no: 17

# Session 4 : Quality Manual and Implementation Plan Activity 2 : Implementation plan for respective Blood Bank

### **Objective:**

• To understand and formulate the implementation plan for respective Blood Banks

Time: 30 Minutes

Material: Paper, pens.

# Methodology

♦ Group discussion

## Instructions:

- Please encourage each participating institution to formulate their QMS implementation plan.
- Ensure activities are shortlisted in a flowchart pattern
- Ensure timelines created for implementation- e. g through Gantt chart
- Give 2 minutes to each institution to present their implementation plan with activities and timelines on a flipchart
- f/b interactive discussion

# **Session 5: Conclusion**

# **Activity 1: Post-evaluation on QMS**

### Objective:

Post-training evaluation questionnaire

♦ Feedback

Time: 20 Minutes

**Material:** paper, pens, post-evaluation questionnaire,

feedback forms

### 

- Post-training evaluation
- ♦ Feedback

#### Instructions:

- Please introduce the post-evaluation questionnaire and distribute feedback forms.
- ♦ Please give 20 minutes to the batch
- Collect feedback forms at the end of the session.
- Please clarify the participant's queries

#### Summarize:

• Please collect filled post-evaluation questionnaire from every participant.

#### Reference:

◆ Agenda – Day3 – post assessment questionnaire

# Session 5 : Conclusion

# **Activity 2: Accreditation**

# Objective:

Explain importance of accreditation in QMS

Time: 15 Minutes

Material: Projector, Screen and

Pointer

### Methodology

Power Point Presentation

#### Instructions:

- Please try to explain the crux of the contents in each slide. Do not just read out the points.
- Please clarify the participant's queries

#### Summarize:

- What are the core points discussed in this presentation?
- How does it relate to your work?

#### Reference:

Day 3 : PPT No : 7

# Session 6: Valediction Activity 1: Valediction

### Objective:

• To distribute certificates to participants and resource persons.

Time: 30 Minutes

Material: Certificates

# **♦ Methodology**

Distribution of certificates

#### Instructions:

- Please invite dignitaries
- Distribution of certificates
- ♦ Ensure no participant/resource person left out
- Please invite dignitary for address

## Summarize:

### Reference:

♦ Agenda- Day3

Session	6: Concluding Remarks
Activity	: Concluding remarks

# Objective:

• To deliver concluding remarks for training.

Time: 15 Minutes

Material: nil

**♦ Methodology** 

♦ Address

### Instructions:

• Please invite nominated person to deliver concluding remarks

## Summarize:

Concluding remarks

#### Reference:

♦ Agenda- Day 3



