Quality Management

Training for

Blood

Transfusion

Services

Modules 6–8
PART 1: BASIC PRINCIPLES OF QUALITY

MODULE 6
Documentation

QMT 6.1: Presentation
Documentation in quality systems

QMT 6.2: Presentation
Standard operating procedures

QMT 6.3: Activity
Writing an SOP

QMT 6.4: Activity
Validating an SOP

QMT 6.5: Presentation
Document control

QMT 6.6: Activity
Controlling a document

MODULE 7
Training

QMT 7.1: Presentation
Training in the quality system

QMT 7.2: Presentation
Training needs and plans

QMT 7.3: Activity
Creating a training plan

QMT 7.4: Presentation
Monitoring and evaluation of training

MODULE 8
Assessment within the Quality System

QMT 8.1: Presentation
Assessment within quality systems

QMT 8.2: Presentation
Validation
QMT 8.3: Activity
Preparing a validation plan

QMT 8.4: Presentation
Maintenance and calibration of equipment

QMT 8.5: Activity
Designing a maintenance and calibration plan

QMT 8.6: Presentation
Quality monitoring tools

QMT 8.7: Activity
Analysing data and monitoring performance

QMT 8.8: Presentation
Error management

QMT 8.9: Activity
Preparing an SOP on error reporting

QMT 8.10: Presentation
Audits and auditing

QMT 8.11: Presentation
The audit process

QMT 8.12: Activity
Developing an audit plan

QMT 8.13: Activity
Identifying non-compliances against a set of standards

QMT 8.14: Activity
Audit of work area

QMT 8.15: Activity
Analysing quality system failures

QMT 8.16: Activity
Mid-course assessment
PART 1

BASIC PRINCIPLES OF QUALITY

Modules 6–8
Module 6
Documentation
<table>
<thead>
<tr>
<th>QMT 6.1</th>
<th>Documentation in Quality Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To explain the role of documentation in quality systems</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Definitions relating to documentation  
♦ Value of documentation  
♦ Basic types of documents  
♦ Relationship between documents  
♦ Dangers of too much documentation |
| **Key points** | ♦ Documentation is key to a quality system  
♦ Documentation helps to ensure consistency of processes and procedures  
♦ Documentation provides traceability  
♦ Good documentation indicates a good quality system  
♦ Training is easier if there is good documentation to train to |
| **Teaching focus** | ♦ Illustrate the importance of documentation by using examples from your own experience  
♦ Use scenarios where a lack of documentation may have/has caused problems |
| **Learning outcomes** | Participants should be able to:  
♦ Explain the role and need for documentation in a quality system  
♦ List different types of documents used in a quality system |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Definitions (1)  
5 Definitions (2)  
6 Definitions (3)  
7 Definitions (4)  
8 Value of Documentation (1)  
9 Value of Documentation (2)  
10 Types of Documentation  
11 Layers of Documentation  
12 Documentation  
13 Quality Manager’s Responsibilities for Documentation (1)  
14 Quality Manager’s Responsibilities for Documentation (2)  
15 Documentation – Corrective Loop  
16 Use of Documentation in Decision Making  
17 Dangers of Too Much Documentation (1)  
18 Dangers of Too Much Documentation (2)  
19 Key Points  
20 Learning Outcomes |
<table>
<thead>
<tr>
<th>Presentation notes and handling the session</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Slides 4 - 7</strong></td>
</tr>
<tr>
<td>Definitions (1), (2), (3) &amp; (4)</td>
</tr>
<tr>
<td>♦ These four slides give definitions of terms related to documentation</td>
</tr>
<tr>
<td><strong>Slides 8 - 9</strong></td>
</tr>
<tr>
<td>Value of Documentation (1) &amp; (2)</td>
</tr>
<tr>
<td>♦ These two slides list the main reasons for establishing a documentation system within the quality system</td>
</tr>
<tr>
<td><strong>Slide 10</strong></td>
</tr>
<tr>
<td>Types of Documentation</td>
</tr>
<tr>
<td>♦ This slide lists the various types of documents required in a quality system</td>
</tr>
<tr>
<td>♦ Ask the participants to suggest more</td>
</tr>
<tr>
<td><strong>Slide 11</strong></td>
</tr>
<tr>
<td>Layers of Documentation</td>
</tr>
<tr>
<td>♦ This slide gives a diagrammatic representation of the main categories of documents according to the ISO classification</td>
</tr>
<tr>
<td>♦ Discuss each level with the participants</td>
</tr>
<tr>
<td><strong>Slide 12</strong></td>
</tr>
<tr>
<td>Documentation</td>
</tr>
<tr>
<td>♦ Emphasize the points on this slide so that participants fully understand that documents must reflect what actually happens</td>
</tr>
<tr>
<td><strong>Slides 13 - 14</strong></td>
</tr>
<tr>
<td>Quality Manager’s Responsibilities for Documentation (1) &amp; (2)</td>
</tr>
<tr>
<td>♦ These two slides list the responsibilities of the quality manager for documentation</td>
</tr>
<tr>
<td>♦ Emphasize that the quality manager is not responsible for writing every document, but is responsible for the establishment and maintenance of an effective documentation system</td>
</tr>
<tr>
<td><strong>Slide 15</strong></td>
</tr>
<tr>
<td>Documentation – Corrective Loop</td>
</tr>
<tr>
<td>♦ The slide shows a diagrammatic representation of quality improvement for documents which, in turn, assists overall quality improvement</td>
</tr>
<tr>
<td><strong>Slide 16</strong></td>
</tr>
<tr>
<td>Use of Documentation in Decision Making</td>
</tr>
<tr>
<td>♦ The slide shows how good documentation can help in decision making through the analysis of data collected from actual processes/procedures</td>
</tr>
<tr>
<td>♦ This concept of constant action, analysis and decision making is further developed in Module 8</td>
</tr>
<tr>
<td><strong>Slides 17 - 18</strong></td>
</tr>
<tr>
<td>Dangers of Too Much Documentation (1) &amp; (2)</td>
</tr>
<tr>
<td>♦ It is essential that participants understand the dangers of too much documentation</td>
</tr>
<tr>
<td>♦ Discuss each point with the participants, using examples of situations that would result in poor quality outcomes due to poor documentation or too much documentation</td>
</tr>
</tbody>
</table>
**Teaching Aim**

- To explain the role of documentation in quality systems

**Core Topics**

- Definitions relating to documentation
- Value of documentation
- Basic types of documents
- Relationship between documents
- Dangers of too much documentation
### Definitions (1)

**Documentation**
- All written production procedures, instructions, records, quality control procedures and recorded test results involved in providing a service or the manufacture of a product

**Standard operating procedure (SOP)**
- Written instructions for the performance of a specific procedure

### Definitions (2)

**Document control**
- Formal control of the issue, use and review of authorized documents within the quality system

**Specification**
- Document that states requirements

### Definitions (3)

**Guidelines**
- Document stating recommendations or suggestions

**Quality manual**
- Document specifying the quality management system of an organization
Definitions (4)

Quality plan
- Document specifying the elements of the quality management system and the resources to be applied in a specific case

Records
- Documents that state results achieved or provide evidence of activities performed

Value of Documentation (1)

- Provides specific instructions
- Ensures processes and outcomes are traceable
- Processes can be audited and external assessments can therefore take place
- Tool for training

Value of Documentation (2)

- Helps in:
  - Making decisions
  - Investigating problems
- Improves efficiency
- Improves quality
Types of Documentation

- Policies
- Standards
- Manuals
- Standard operating procedures
- Specifications
- Datasheets
- Forms
- Records
- Labels
+ Others

Layers of Documentation

ISO 9000: 1994 (E)
Level 1: Quality manual (policies)
Level 2: Quality procedures
Level 3: SOPs
Level 4: Records

Documentation

- Documents must relate to what actually happens
- Documents are usually fictitious when:
  - Quality manager writes the documentation
  - People carrying out procedures are not asked how they operate
  - Documents do not reflect actual practice
Quality Manager’s Responsibilities for Documentation (1)

- Ensure written approval of all documents before implementation
- Maintain an index
- Review document content to assess impact
- Ensure ongoing access to the documents, as required

Quality Manager’s Responsibilities for Documentation (2)

- Ensure validation protocols are designed prospectively
- Control changes to documents
- Ensure documents exist for all key activities
- Maintain on-going review

Documentation — Corrective Loop

- Write what you will do
- Do what is written
- Record what you did
- Revise what you do

Corrective loop
Use of Documentation in Decision Making

- Collect accurate data from the process/procedure (records)
- Analyse the data
- Use analysis to determine if changes are needed
- Plan and decide on the changes
- Validate the changes
- Introduce the changes

Dangers of Too Much Documentation (1)

- How much is too much?
  - Quality is not measured by the number of documents, but by their impact on the quality outcomes
- Staff must be able to produce, use and manage the documents

Dangers of Too Much Documentation (2)

- Do you need to document everything?
  - No, only those things that need documenting
  - What needs documenting? How do you decide?
  - What types of document to use? e.g. datasheets/SOPs
- Make sure the system works and is not choked by too much documentation

How much is too much?

- Quality is not measured by the number of documents, but by their impact on the quality outcomes

Staff must be able to produce, use and manage the documents

Do you need to document everything?

- No, only those things that need documenting
- What needs documenting? How do you decide?
- What types of document to use? e.g. datasheets/SOPs

Make sure the system works and is not choked by too much documentation
Key Points

- Documentation is key to a quality system
- Documentation helps to ensure consistency of processes and procedures
- Documentation provides traceability
- Good documentation indicates a good quality system
- Training is easier if there is good documentation to train to

Learning Outcomes

You should now be able to:

- Explain the role and need for documentation in a quality system
- List different types of documents used in a quality system
# QMT 6.2 Standard Operating Procedures

## Teaching aim
To describe how to plan and write an effective standard operating procedure (SOP).

## Core topics
- Planning and writing SOPs
- Validation of SOPs
- Use of SOPs

## Key points
- SOPs are an essential part of the quality system
- SOPs should be written for all the key procedures in an organization
- SOPs must be clear, concise and easy to follow
- SOPs should be used for staff training
- SOPs should be validated
- SOPs should be living documents
- Staff must have easy access to the SOPs
- SOPs must be followed by all staff at all times

## Teaching focus
- Focus in general terms on the value and use of SOPs
- Do not be too prescriptive about the layout and design of SOPs

## Learning outcomes
Participants should be able to:
- Identify key characteristics of an effective SOP
- Describe how to plan SOPs
- Prepare SOPs
- Explain the use of SOPs

## Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Procedure
5. SOPs (1)
6. SOPs (2)
7. SOP Planning Map (1)
8. SOP Planning Map (2)
9. Preparing an SOP
10. Format of an SOP
11. Purpose
12. Responsibilities
13. Scope/Restrictions
14. Definitions
15. Materials Required
16. Procedure
17. Writing the SOP
18. Do’s and Don’ts of SOPs (1)
<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Procedure</th>
<th>♦ The slide outlines what a procedure is and the four essential elements of a written procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slides 5 - 6</td>
<td>SOPs (1) &amp; (2)</td>
<td>♦ These two slides outline some basic principles of SOPs</td>
</tr>
</tbody>
</table>
| Slides 7 - 8 | SOP Planning Map (1) & (2) | ♦ These two slides provide a simple flowchart on developing an SOP  
♦ Discuss each step in the planning map with the participants  
♦ Emphasize that each step in the development of an SOP is critical and outline what can go wrong if a step is omitted |
| Slide 9 | Preparing an SOP | ♦ The slide outlines the important points that need to be considered as the SOP is developed |
| Slide 10 | Format of an SOP | ♦ The slide outlines the common format for an SOP  
♦ Discuss why those points marked as minimum requirements are considered as such, while keeping in mind the need to avoid being too prescriptive  
♦ Some points on the slide are dealt with in detail on slides 11–16 |
| Slide 11 | Purpose | ♦ The slide outlines the meaning of “purpose” in relation to SOPs  
♦ Emphasize that this should be a short statement regarding the task and outcome, and should preferably contain some wording that indicates a reflection of the quality policy  
♦ Give some examples of a procedure (generic or BTS) and ask participants to suggest various sentences that would serve as the “purpose” of those SOPs |
<table>
<thead>
<tr>
<th>Slides 12 – 13</th>
<th>Responsibilities &amp; Scope/Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Emphasize that SOPs should state who supervises the performance of a particular procedure, and who can or cannot perform it</td>
<td></td>
</tr>
<tr>
<td>♦ Point out to participants how responsibilities overlap with the scope of an SOP</td>
<td></td>
</tr>
<tr>
<td>♦ Give some examples of procedures and the agreed positions or conditions for someone using the SOPs</td>
<td></td>
</tr>
<tr>
<td>♦ Give some examples of procedures that would apply to one area, but not another: e.g. cleaning of the offices compared with cleaning of the laboratory</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the kind of words that should be defined in the SOP</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 15</th>
<th>Materials Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Stress the importance of including in the SOP all the materials required to carry out a procedure</td>
<td></td>
</tr>
<tr>
<td>♦ Give some examples of consumables and equipment that may be required</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 16</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Remind the participants about the basic rules applied to a flowchart of a process or procedure</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that first designing a flowchart and then writing down the actual procedure, based on the flowchart, will ensure logical step-by-step instructions that do not omit critical points</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 17</th>
<th>Writing the SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Involve the participants by asking them who should write SOPs, using a few examples either from the BTS or a generic scenario</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the fact that the best person to write an SOP is the person who does the work</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 18 – 20</th>
<th>Do's and Don'ts of SOPs (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The three slides lists some tips on writing effective SOPs</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 21</th>
<th>Reviewing Draft Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The next four slides deal with the review of the draft SOP and its validation</td>
<td></td>
</tr>
<tr>
<td>♦ Ensure participants understand that reviewing the draft is essential and that this should be completed before validation</td>
<td></td>
</tr>
<tr>
<td>♦ The slides list some simple steps in identifying who should review the draft SOP and what the review should include</td>
<td></td>
</tr>
<tr>
<td>♦ Ensure participants distinguish between this review and regular review which is undertaken as part of document control, as discussed in QMT 6.5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 22</th>
<th>Review by Those Involved in the Use of the SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Emphasize the need for both the worker and supervisor to review the SOP</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 23</th>
<th>Review by Relevant Departments</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Emphasize the importance of review by other departments that are affected by the SOP, reminding participants how an output from one process or procedure can be the input for another process or procedure</td>
<td></td>
</tr>
<tr>
<td>Slide 24</td>
<td>Final Validation of SOPs</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------</td>
</tr>
<tr>
<td></td>
<td>♦ The general principles of validation are dealt with in Module 8</td>
</tr>
<tr>
<td></td>
<td>♦ Ensure that participants understand the reasons for validation, as stated on the slide</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 25</th>
<th>Validation Protocols</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ Explain how a written protocol provides another layer in the documentation system, ensuring that every step in the quality system has been covered</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 26</th>
<th>Managing SOPs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide lists the important information that should be included in the SOP to ensure that the document is managed correctly</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 27</th>
<th>Using SOPs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide outlines some important points regarding the use of SOPs</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss each point with the participants</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 31</th>
<th>Write your own SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ This slide, showing a cup of coffee, introduces the next activity</td>
</tr>
</tbody>
</table>
1 Purpose
1 To ensure that the current revisions of documents are accessible to staff at the appropriate locations.
2 To ensure an audit trail of the revision of documents is maintained.
3 To control changes to master documentation.
4 To include provision for regular review and revision of master documents.
5 To prevent inadvertent use of superseded documents.

2 Scope
This procedure covers the issue, control and revision of master documents.

3 References
◆ PMA Guide to GMP 1992 Update
◆ ISO 9000 (1994)
◆ Standards for the practice of blood transfusion.

4 Definitions
◆ Master documentation: all documents that are authorized and approved by designated individuals.
5 Procedure

DOCUMENT CONTROL PRIOR TO ISSUE

Responsible personnel: QA Secretary

5.1 On approval of master document by the designated person (NBS–QP–1), the QA Secretary shall:

5.1.1 Allocate an effective date to the master document. The effective date should allow enough time, from the date of issue to the implementation date, for the training of staff in the new or revised procedure.

5.1.2 Print or copy the required number of copies, as determined by the distribution list.

5.1.3 Check the copies against the master to ensure that it is reproduced in full and that they are legible copies.

5.2 Stamp the copies with a unique copy number and “Controlled copy or “Working copy”.

5.2.1 Use the following criteria:
   All Master documents:  No copy number
   No “Controlled copy or “Working copy” stamp.

5.2.2 Copies of MMI/Specifications/disposition forms or any other set of documents used for traceability of a process or test results.

5.2.2.1 The copy sent to the Manager/Head of Department responsible for the process or testing of products shall be stamped “Working copy”. Managers will control the issue of the document by copying the working document and issuing the document for a production batch or tests on a batch of product.

5.2.2.2 All other copies shall be stamped “Controlled copy” and allocated a unique copy number.

5.2.3 Copies of standard operating procedures, standard test procedures:

5.2.3.1 Stamped “Controlled copy” and allocated a unique copy number.

5.2.3.2 However, Appendices of these documents which are used as records are stamped “Working copy”.

Responsible personnel: Department Manager/Departmental Head/Branch Manager

5.3 Controlled copies may not be reproduced in anyway whatsoever. If additional copies are needed, they shall be requested in writing from the Quality Department.

Working copies may be reproduced, but the manager must ensure that the most recent revision is used at all times.
DOCUMENT STORAGE

Responsible personnel: QA Secretary

5.4 The current master shall be stored in the safe within the Quality Department and adequately indexed.

5.5 Where the master is superseded by a more current revision, the previous revision shall be removed from the master file, stamped “Archived copy” and filed in the archived file with the revision summary and index updated.

5.6 DISTRIBUTION

Responsible personnel: QA Secretary

5.6.1 Distribute (Refer SOP-ADM-4) all the approved documents to managers in the branches and departments as per distribution list (refer to Appendix III).

Responsible personnel: Department Manager/Departmental Head/Branch Manager

5.6.2 Distribute to the person indicated on the Issue Note (refer to Appendix II). Recipient of the document must sign for receipt of document and return Document Issue Note to Quality Department.

5.6.3 If the document received is the initial version, place the new document at the workplace.

5.6.4 If the document is a revision of a previously approved copy, remove the previous approved copy from circulation, discard these obsolete documents and record this (refer to Appendix IV) before placing the current revision at the workplace.

5.6.5 Ensure that all outdated versions of documents are removed from circulation and destroyed, their destruction is recorded (refer to Appendix IV) and filed in the department or branch.

5.6.6 Ensure that the Document Issue Note is returned to the Quality Department.

Responsible personnel: QA Secretary

5.7 Maintain records to identify that documents issued have been received by the individuals indicated on the distribution lists.

5.8 DOCUMENT REVIEW AND REVISION

All documents must be reviewed at least every 2 years. The date of review and who reviewed the document must be submitted to QA Secretary who keeps an index of master documents, with the effective date, revision number and review date of every master document.
Responsible personnel: Department Manager/Departmental Head/Branch Manager

5.9 Review
Ensure standard operating procedures are revised when there is a process change. All master documents should be reviewed at least once every 2 years. The review is normally performed by the author.

5.10 If the review of master documentation leads to the revision of a document, refer to NBS-QP-1.

Responsible personnel: QA Secretary

5.11 Co-ordinate the review of documents by drawing up a list every 3 months of documents older than 18 months without review and circulated to the necessary departments.

6 RECORDS

6.1 Current master documentation is kept in the Quality Department under strict control of the QA Secretary until such time that these documents are superseded.

6.2 Previous revisions of master documentation are kept in the Quality Department under strict control of the QA Secretary for an indefinite period of time.

6.3 All forms that identify the control of documentation (i.e. Document Issue, Distribution List), shall be kept in the Quality Department under strict control of the QA Secretary for an indefinite period of time.

6.4 Computer records of document issue and control are backed-up on tapes and stored off the premises.

7 APPENDICES

7.1 Appendix I – Flowchart

7.2 Appendix II – Document Issue Note

7.3 Appendix III – Document Distribution list

7.4 Appendix IV – Record of destruction of obsolete documents
APPENDIX I
Flowchart

1. Document written and approved (NBS-QP-1)
2. Allocate effective date of current document
3. Note distribution list
4. Print or copy required number of copies
5. Check copies against master
6. Allocate copy number stamp controlled copy / working copy
7. Revision? YES NO
   - Remove previous master from file
   - Stamp master archived copy
   - Place in archived file with revision summary
   - Update index of archived file
   - Review every 2 years
5. Revision? YES NO
   - Discard obsolete document and record
   - Place new document at workplace
   - Refer NBS-QA-1
5. Revision? YES NO
   - Place new document at workplace
   - Issue note returned
   - Acknowledgement of document receipt
   - File document – issue note
   - End

AUTHORIZED BY
APPENDIX II

Document Issue Note

Name:
The document detailed below has been issued to you as being on the distribution list for the document. Please indicate receipt of the document by signing and dating this note below and return to the Quality Department at your earliest convenience.

<table>
<thead>
<tr>
<th>Serial no.</th>
<th>Title</th>
<th>Revision</th>
</tr>
</thead>
</table>

I acknowledge receipt of the above document issue and confirm that:
i) If applicable, all obsolete documents superseded by this issue have been removed from circulation and destroyed.

ii) If applicable, the document has been inserted into the appropriate manual and all obsolete issues have been destroyed.

Signature: ________________________________________________________________

Name: _________________________________________________________________

Date: _________________________________________________________________

RETURN IMMEDIATELY TO THE QUALITY DEPARTMENT
APPENDIX III

Distribution List

I hereby request a single controlled/non-controlled copy to be distributed to:

<table>
<thead>
<tr>
<th>Procedure document no.</th>
<th>Revision no.</th>
<th>Distribution list</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

Signature: ________________________________________________________________

Name: ________________________________________________________________

Date: ________________________________________________________________
APPENDIX IV

Procedure Document No. NBS-QP-2  

Record of Destruction of Obsolete Documents

All obsolete documents superseded by a revised document must be removed from circulation and destroyed by the recipient.

<table>
<thead>
<tr>
<th>Procedure document no.</th>
<th>Date of destruction</th>
<th>Destroyed by</th>
<th>Department / Branch</th>
<th>No. of copies destroyed</th>
<th>Revision number of document destroyed</th>
<th>Effective date of document destroyed</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

Retain document within Department/Branch for internal audit purposes.

AUTHORIZED BY

QMT/Module 6
Standard Operating Procedures

Teaching Aim

- To describe how to plan and write an effective standard operating procedure (SOP)

Core Topics

- Planning and writing SOPs
- Validation of SOPs
- Use of SOPs
Procedure

- A procedure is a clear, precise, documented description of any activity, including:
  - Sequence of operation
  - Methods to be used
  - Equipment to be used
  - Records to be kept

SOPs (1)

- Key element of documentation
- Define precisely how a procedure is to be performed
- Should be simple, logical and easy to follow

SOPs (2)

SOPs need to be:
- Appropriate
- Up-to-date
- Comprehensive
- Concise
- Validated
- Followed
Preparing an SOP

- **Preparation**
  - Understand the purpose of the SOP
  - Understand the terms and words used
  - Identify the equipment, consumables and documentation needed

- **Writing the SOP**
  - Prepare a flowchart
  - Give detailed step-by-step instructions on how to perform the procedure
Format of an SOP

Format of an SOP varies, but commonly includes:
- Purpose *
- Responsibilities *
- Scope/restrictions *
- Definitions
- Materials required (including associated controlled documents) *
- Procedure *
- Appendices
- References * Minimum requirements

Purpose

The task
The specified outcome
The reason why an SOP is required

Responsibilities

Authorized users
- Who the authorized users of the SOP are
  (not normally named individuals)
- What they are permitted to do

Supervision
- Who supervises the process or the part of the process managed by this SOP
Scope/Restrictions

- Who can use this SOP and where
  - Category of staff permitted to perform the task
  - Category of staff not permitted to perform the task
  - Work areas in which the SOP must or must not be used

Definitions

- Definition of any word or phrase that a user might misinterpret
- Types of word
  - Define abbreviations
  - Define acronyms
  - Define unfamiliar words
  - Define familiar words with multiple meanings

Materials Required

- Everything the user will need to perform the task safely and efficiently
  - Cross-referenced documents: e.g. forms, datasheets, other SOPs and labels
  - Consumables
  - Equipment
Procedure

- Step-by-step instructions
  - Use direct instructions: e.g. “do” rather than “ensure that”
- Logical progression
- Each SOP should cover only one specific procedure

Writing the SOP

- Writers
  - Who should write an SOP?
  - Manager/supervisor/worker

Do's and Don'ts of SOPs (1)

Do
- Organize first, phrase later
- Know your reader and objective
- Use short, complete sentences and paragraphs
- Use one idea per sentence
- Be simple, clear and concise
- Use illustrations to add clarity
- Define all unusual terms and symbols
### Do's and Don'ts of SOPs (2)

**Do**
- Pay attention to spelling, punctuation, and capitalization
- Ensure that paragraphs deal with one subject only
- Ensure continuity in an instruction or procedure
- Close loops in the procedure

### Do's and Don'ts of SOPs (3)

**Avoid**
- Long, vague phrases — say what you mean
- Use of ambiguous expressions
- Use of slang and colloquial expressions
- Use of adverbs and empty modifiers: (e.g., relevant, appropriate, suitable)
- Use of overworked words or phrases
- Omitting important words
- Use of jargon of any discipline, if possible

### Reviewing Draft Procedures

- The draft procedure should be reviewed and comments/changes made by:
  - The persons who do the work
  - The departments/individuals at the interface who may be directly or indirectly affected by the SOP
- **BUT** involvement of all relevant staff may result in too many different views and slow down implementation
Review by Those Involved in the Use of the SOP

- Make use of the experience of those who are doing the job
- This increases the probability of support from the workers, who now have to follow the SOP
- Review process
  - Drafts reviewed for accuracy, clarity and relevance
  - Reviewed by both worker and supervisor

Review by Relevant Departments

- Able to identify activities/procedures that may affect other departments, perhaps adversely
- Department knowledge may enhance efficiency
- Able to identify communication gaps
- Increased probability of support from departments that are affected by the SOP

Final Validation of SOPs

- To demonstrate that the outcomes of the SOP are as expected
- Responsibility
  - The quality manager should guide heads of departments in setting up the validation plan
- Ask the following questions
  - Are all the steps included?
  - Is the outcome reproducible?
Validation Protocols

- Criteria for approval
- Method used
- Perform procedure and report the outcome
- Review the results
- Acceptance of the SOP

Managing SOPs

- Elements for managing SOPs
  - Name of organization
  - Title of procedure
  - Unique document number, including revision number
  - Page numbers/number of pages
  - Date on which the SOP becomes effective
  - Approval signature(s)
  - Name of author
  - Review date
  - Revision number

Using SOPs

- To perform the activity
- To demonstrate a quality-based approach to the work
- Training
  - Training against individual SOPs
  - Basis of training record
Key Points (1)

- SOPs are an essential part of the quality system
- SOPs should be written for all the key procedures in an organization
- SOPs must be clear, concise and easy to follow
- SOPs should be used for staff training

Key Points (2)

- SOPs should be validated
- SOPs should be living documents
- Staff must have easy access to the SOPs
- SOPs must be followed

Learning Outcomes

You should now be able to:

- Identify key characteristics of an effective SOP
- Describe how to plan SOPs
- Prepare SOPs
- Explain the use of SOPs
Write a Standard Operating Procedure for making a cup of instant coffee
**ACTIVITY**

<table>
<thead>
<tr>
<th>QMT 6.3</th>
<th>Writing an SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aims</strong></td>
<td>To provide practice in preparing an SOP for a simple, familiar activity</td>
</tr>
<tr>
<td><strong>Core topics</strong></td>
<td>♦ Identifying the components of an activity ♦ Preparation of a usable SOP</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>♦ SOPs define the way in which a procedure is to be carried out ♦ SOPs must be written to be used</td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Ensure the SOPs follow the principles taught in QMT 6.2 ♦ Keep the SOPs focused on simply making the coffee ♦ Ensure that the SOPs reflect the actual procedure</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td>Participants should be able to: ♦ Write an SOP for a simple familiar activity ♦ List the key components of an SOP</td>
</tr>
<tr>
<td><strong>Type of activity</strong></td>
<td>Group work</td>
</tr>
<tr>
<td><strong>Materials required</strong></td>
<td>♦ QMT 6.2: Slide 31 ♦ QMT 6.2: Example of an SOP ♦ QMT 6.3: Example of an SOP Template ♦ Flipcharts ♦ Pens</td>
</tr>
<tr>
<td><strong>Preparation</strong></td>
<td>♦ If the activity of making a cup of instant coffee is not used, select a simple everyday activity that involves several steps and some decision-making</td>
</tr>
<tr>
<td><strong>Instructions</strong></td>
<td>1 Describe the activity and instruct participants to create a flowchart in preparation for writing the SOP. 2 Instruct the participants to write an SOP for the activity, using the template as an example. 3 Instruct participants to: ♦ Identify the critical steps in the procedure ♦ Include all “headings” recommended for a SOP ♦ Follow all the general instructions given during the presentation QMT 6.2 ♦ Include records for the traceability of the procedure.</td>
</tr>
<tr>
<td><strong>Review of the activity</strong></td>
<td>♦ Ensure that all steps in the procedure have been included and are in a logical sequence ♦ Discuss the logical steps in the flowchart, the procedure and its related SOP</td>
</tr>
<tr>
<td><strong>Time span</strong></td>
<td>1½ hours</td>
</tr>
</tbody>
</table>
Write your own SOP ......

Write a Standard Operating Procedure for making a cup of instant coffee
Standard Operating Procedure for:

1 Purpose
   Reason for writing the SOP.

1 Scope
   The section or department that will use this SOP.

2 References
   Books, journals.

3 Definitions
   Meaning of words used in the SOP.

5 Procedure
   Responsible personnel: e.g. Biochemistry/Reagent Department and all Blood Bank Staff.
   5.1 Step 1
   5.2 Step 2
   5.3 Step 3
   5.4 Step 4

6 Records
   How long records are kept, where the records are kept.

7 Appendices
   7.1 Appendix I: Flow chart
### QMT 6.4 Validating an SOP

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To demonstrate how SOPs are validated</th>
</tr>
</thead>
</table>
| **Core topics**  | ♦ Creating a validation protocol for an SOP  
♦ Identifying and understanding any problems with the validation of SOPs  
♦ Correcting any problems identified |
| **Key points**   | ♦ No SOP should be introduced without first being validated  
♦ The procedure must result in an acceptable product |
| **Teaching focus** | ♦ Ensure that the SOPs are followed as written  
♦ Ensure that all aspects of the SOPs are reviewed |
| **Learning outcomes** | Participants should be able to:  
♦ Validate an SOP  
♦ Identify missing steps in an SOP through the validation process |
| **Type of activity** | Group work |
| **Materials** | ♦ SOPs prepared by each group in QMT 6.3: these should be exchanged so that each is validated by a different group  
♦ Materials required for the selected procedure: e.g. kettle, water, instant coffee, sugar, milk, mug, teaspoon  
♦ Templates of validation procedures |
| **Instructions** | 1 Give each group an SOP prepared by a different group.  
2 Instruct them to:  
♦ Create a validation protocol and form for the SOP, using the example given in QMT 6.2: Example of an SOP  
♦ Select one member of the group to carry out the SOP, as written  
♦ Select at least one different member of the group to carry out the same SOP, as written  
♦ Identify any missing steps  
♦ Ensure that the outcome of the SOP is consistent and expected  
♦ Complete the validation form that they have designed. |
| **Review of the activity** | Discuss the outcome of the validation, examining:  
♦ Applicability of the validation protocol and report form  
♦ Any reported missing steps  
♦ Any unexpected outcomes  
♦ Any inconsistencies between outcomes when different members of the group carry out the SOP |
<p>| <strong>Time span</strong> | 1 hour |</p>
<table>
<thead>
<tr>
<th>QMT 6.5</th>
<th>Document Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To introduce the mechanisms and reasons for the control of documents</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ The importance of document control  
♦ Mechanisms of document control  
♦ Distribution of documents  
♦ Document revision |
| **Key points** | ♦ All key documents related to quality should be controlled  
♦ Control mechanisms cover:  
  ─ Distribution  
  ─ Review  
  ─ Change |
| **Teaching focus** | ♦ Emphasize the kind of problems likely to occur without a document control system  
♦ Stress the need for simplicity in document control systems  
♦ Make clear the distinction between revision of a document and a new document |
| **Learning outcomes** | Participants should be able to:  
♦ Identify the key aspects of document control  
♦ State the documents that must be controlled and how |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Rationale  
5 Importance of Document Control  
6 Controlled Document  
7 Requirements (1)  
8 Requirements (2)  
9 Document Control  
10 Documents to Control  
11 Document Distribution  
12 Controlling Distribution  
13 Document Locations  
14 Revisions  
15 Implications of Uncontrolled Change  
16 Key Points  
17 Learning Outcomes |
| **Materials** | QMT 6.5 Example of an SOP Revision Summary  
QMT 6.5 Example of an SOP Index |
<p>| <strong>Related activity</strong> | QMT 6.6 Controlling a Document |</p>
<table>
<thead>
<tr>
<th>Time span</th>
<th>½ hour</th>
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<tbody>
<tr>
<td><strong>Presentation notes and handling the session</strong></td>
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<tr>
<td><strong>Slide 4</strong> Rationale</td>
<td>✦ The slide outlines the main reasons for document control</td>
</tr>
<tr>
<td><strong>Slide 5</strong> Importance of Document Control</td>
<td>✦ This slide asks what the impact of a lack of documentation control might be in specific situations ✦ Involve participants in the discussion on each situation</td>
</tr>
<tr>
<td><strong>Slide 6</strong> Controlled Document</td>
<td>✦ This slide gives a definition of a controlled document</td>
</tr>
<tr>
<td><strong>Slides 7 – 8</strong> Requirements (1) &amp; (2)</td>
<td>✦ These two slides state the important characteristics of controlled documents and the activities that can or cannot be carried out with regards to them</td>
</tr>
<tr>
<td><strong>Slide 9</strong> Document Control</td>
<td>✦ This slide lists some of the mechanisms for controlling documents</td>
</tr>
<tr>
<td><strong>Slide 10</strong> Documents to Control</td>
<td>✦ This slide lists all the documents that should be controlled in a quality system ✦ It also gives some suggestions on how to distinguish between controlled and uncontrolled documents</td>
</tr>
<tr>
<td><strong>Slide 11</strong> Document Distribution</td>
<td>✦ The slide states the three main requirements for document distribution</td>
</tr>
<tr>
<td><strong>Slide 12</strong> Controlling Distribution</td>
<td>✦ This slide lists some mechanisms for controlling the distribution of documents</td>
</tr>
<tr>
<td><strong>Slide 13</strong> Document Locations</td>
<td>✦ Stress the importance of maintaining a copy of all controlled documents within the Quality Department ✦ Ensure that participants understand that each department should take responsibility for their controlled documents</td>
</tr>
<tr>
<td><strong>Slide 14</strong> Revisions</td>
<td>✦ Stress the importance of fully documenting changes to any controlled document and retaining the record of changes and the various versions of the document for a set period of time ✦ Discuss the fact that the period of time for which documents should be retained is controlled by the quality standards used and remind participants that there may be regulations regarding this</td>
</tr>
<tr>
<td><strong>Slide 15</strong> Implications of Uncontrolled Change</td>
<td>✦ The slide summarizes some of the points that should have arisen in the discussion on slide 5 ✦ Re-emphasize the poor outcomes that will occur with a lack of control of change</td>
</tr>
</tbody>
</table>
QMT 6.5  EXAMPLE OF AN SOP REVISION SUMMARY

Procedure Document No:

SOP REVISION SUMMARY

Document Title:

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision</th>
<th>Reason for Revision</th>
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<tbody>
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AUTHORIZED BY
## STANDARD OPERATING PROCEDURES FOR PATERNITY TISSUE TYPING

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<th>Code</th>
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<th>Written by</th>
<th>Effective date</th>
<th>Revision no.</th>
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<tr>
<td>SOP-PT-1</td>
<td>For the reading, comparison and printing of a report of tissue typing results</td>
<td>A de Aguiar</td>
<td>11-02-98</td>
<td>0</td>
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<tr>
<td>SOP-PT-2</td>
<td>For interpretation of HLA tissue typing results</td>
<td>A de Aguiar</td>
<td>11-02-98</td>
<td>0</td>
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<tr>
<td>SOP-PT-3</td>
<td>For recording of patient details</td>
<td>A de Aguiar</td>
<td>11-02-98</td>
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<td>SOP-PT-4</td>
<td>For the microscopic reading of HLA tissue typing results</td>
<td>A de Aguiar</td>
<td>11-02-98</td>
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<tr>
<td>SOP-PT-5</td>
<td>For injection of lymphocytes, complement and Fluoro Quench onto Terasaki Trays</td>
<td>A de Aguiar</td>
<td>11-02-98</td>
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<tr>
<td>SOP-PT-6</td>
<td>For the programming, maintenance, calibration and operation of the Lambda Jet III automatic dispenser</td>
<td>J Letsolo</td>
<td>17-03-98</td>
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<tr>
<td>SOP-PT-7</td>
<td>For the compiling and final collating of paternity investigation reports</td>
<td>D McLinden</td>
<td>31-08-99</td>
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<tr>
<td>SOP-PT-8</td>
<td>For the calculation of the plausibility of paternity</td>
<td>D McLinden</td>
<td>11-02-98</td>
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<tr>
<td>SOP-PT-9</td>
<td>For the quality control of HLA antisera using the Lambda Scan Plus II programme</td>
<td>A de Aguiar</td>
<td>07-03-01</td>
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<tr>
<td>SOP-PT-10</td>
<td>For identification and venepuncture of parties for disputed paternity investigations</td>
<td>A de Aguiar</td>
<td>11-02-98</td>
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<tr>
<td>SOP-PT-11</td>
<td>For the use of the automatic oiler</td>
<td>J Letsolo</td>
<td>11-02-98</td>
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<tr>
<td>SOP-PT-12</td>
<td>For programming, needle head maintenance and operation of the Lambda Dot III automatic dispenser</td>
<td>J Letsolo</td>
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<td>SOP-PT-13</td>
<td>For the reading, analysis and interpretation of panel reactive antibody results</td>
<td>J Letsolo</td>
<td>11-02-98</td>
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<td>SOP-PT-14</td>
<td>For the operation of the electrostatic mixer</td>
<td>J Letsolo</td>
<td>11-02-98</td>
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<tr>
<td>SOP-PT-15</td>
<td>For tissue typing antisera selection and Terasaki tray preparation</td>
<td>J Letsolo</td>
<td>11-02-98</td>
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<tr>
<td>SOP-PT-16</td>
<td>For the preparation of serum to be tested for panel reactive antibodies and for HLA crossmatching</td>
<td>P Scheepers</td>
<td>11-02-98</td>
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<tr>
<td>SOP-PT-17</td>
<td>For the preparation of 10% cryoprotective medium for the freezing of lymphocytes</td>
<td>J Letsolo</td>
<td>11-02-98</td>
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<tr>
<td>SOP-PT-18</td>
<td>For the assignment of cell ID's blood samples on tubes and Terasaki trays</td>
<td>A de Aguiar</td>
<td>26-02-01</td>
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<tr>
<td>SOP-PT-21</td>
<td>For the billing of test results on the Meditech system conducted in the Tissue Immunology Department</td>
<td>A de Aguiar</td>
<td>26-02-01</td>
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<tr>
<td>SOP-PT-22</td>
<td>For the updating of a transplant patient's details on the patient management programme</td>
<td>A de Aguiar</td>
<td>26-02-01</td>
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<tr>
<td>SOP-PT-23</td>
<td>For the monthly compiling of private and provincial renal transplant list</td>
<td>A de Aguiar</td>
<td>07-03-01</td>
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<tr>
<td>SOP-PT-25</td>
<td>For the search for a best match on the Lambda Scan Utility programme</td>
<td>A de Aguiar</td>
<td>26-02-01</td>
<td>0</td>
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<tr>
<td>SOP-PT-26</td>
<td>For the relaying of cadaver donor test results and the billing of tests</td>
<td>A de Aguiar</td>
<td>26-02-01</td>
<td>0</td>
</tr>
<tr>
<td>SOP-PT-27</td>
<td>For the labelling of Terasaki trays for the injecting of HLA antisera</td>
<td>A de Aguiar</td>
<td>26-02-01</td>
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<tr>
<td>SOP-PT-28</td>
<td>For the preparation of Flourobeads-T-Developer</td>
<td>A de Aguiar</td>
<td>26-02-01</td>
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<tr>
<td>SOP-PT-29</td>
<td>For the preparation of rabbit complement</td>
<td>A de Aguiar</td>
<td>22-04-01</td>
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<tr>
<td>SOP-PT-30</td>
<td>For cadaver transplant study methodology</td>
<td>A de Aguiar</td>
<td>07-03-01</td>
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</tr>
<tr>
<td>SOP-PT-31</td>
<td>For the billing, updating on patient management and processing of provincial hospital requisition forms for panel reactive antibody testing</td>
<td>A de Aguiar</td>
<td>22-04-01</td>
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</tr>
<tr>
<td>SOP-PT-32</td>
<td>For purchasing critical material from approved vendors</td>
<td>A de Aguiar</td>
<td>07-03-01</td>
<td>0</td>
</tr>
</tbody>
</table>

AUTHORIZED BY
Document Control

Teaching Aim

- To introduce the mechanisms and reasons for the control of documents

Core Topics

- The importance of document control
- Mechanisms of document control
- Distribution of documents
- Document revision
Rationale

- The job is not done until the paperwork is complete
- Do what is documented; document what you do

Importance of Document Control

- Current documents
  - Consider the consequences of an old and incorrect version of an SOP being used in the workplace
- Regular review
  - Consider the consequences if an SOP no longer reflects what is actually done
- Archiving
  - Consider a look-back where no previous versions of an SOP have been kept

Controlled Document

- A distributed document that
  - Has been assigned a specific control number
  - Is subject to authorized revisions and changes
Requirements (1)
- No photostat copies of controlled documents
  - Working copies may be photocopied
- Review regularly (at least once per year)
- Latest version must be used in the workplace

Requirements (2)
- Archive a copy of each previous version
  - Destroy all other previous versions
- No unauthorized changes

Document Control
- Changes to documents must be authorized and recorded
- Regular review and revision
  - Use a unique document number for each procedure
- Master document and index number retained by Quality Department
Documents to Control

- All documents relating to quality including:
  - Quality manual
  - Quality procedure manual
  - Written procedures
  - Raw material specifications
  - List of approved suppliers
- Organization may wish to distinguish between controlled and uncontrolled documents: e.g.
  - Different colour paper
  - "Controlled Copy" stamp

Document Distribution

- Systematic
- Controlled
- Timely

Controlling Distribution

- Distribution list
- Register to locate current documents
- Proof of issue and acknowledgement of receipt
- Documentation of final destruction of previous versions
Document Locations

- Each department maintains its own documents in its work area
- Document Control (within the Quality Department) retain a copy

Revisions

- Version control via a revision number
- Documentation showing:
  - 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

Implications of Uncontrolled Change

- Unauthorized and unexpected events
- Unauthorized methodology
- Lack of control of processes and procedures
- Negative effects on processes and outputs
- Risk of poor quality outcomes
Key Points

- All key documents related to quality should be controlled
- Control mechanisms cover:
  - Distribution
  - Review
  - Change

Learning Outcomes

You should now be able to:

- Identify the key aspects of document control
- State the documents that must be controlled and how
<table>
<thead>
<tr>
<th>QMT 6.6</th>
<th>Controlling a Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching aim</td>
<td>To illustrate the process of document control</td>
</tr>
</tbody>
</table>
| Core topics | ♦ Identifying a simple revision required to an SOP  
♦ Incorporating the revision into a new version of the SOP  
♦ Correct annotation of the revised SOP  
♦ Ensuring document control procedures have been followed |
| Key points | ♦ Revision of documents is an ongoing activity  
♦ Document control systems ensure that the correct document is in use  
♦ Revisions must be validated before the release of the document |
| Teaching focus | ♦ Ensure that the revision is correctly identified  
♦ Ensure that the key changes needed have been identified  
♦ Ensure that the control system is simple and easy to follow  
♦ Review the difference between the revision of a document and the need for a new document |
| Learning outcomes | Participants should be able to:  
♦ Identify the errors that result from lack of document control.  
♦ Identify how to take corrective action |
| Type of activity | Group work |
| Materials | ♦ Case study. See QMT 6.6: Role Play – Document Control  
♦ Flipcharts  
♦ Pens |
| Instructions | 1 If the participants are willing to act out the role play, ask them to do so. Instruct those observing to note down immediately any problems they identify during the role play.  
2 Ensure the participants have a hard copy of the case study.  
3 Instruct the participants to:  
♦ Read through the case study and identify all the errors in the document control system  
♦ Examine the validity and effectiveness of the document control system and justify their answers  
♦ Identify potential quality failures  
♦ Suggest how the document control system could be improved to prevent the errors and potential failures. |
| Review of the activity | ♦ Ensure that the participants recognize that the document control system is not efficient  
♦ Ensure that they identify the errors that can occur and that their suggestions on solutions to the errors and improving the control system are simple and easy to follow |
| Time span | 1½ hours |
Background

The quality manager of a national chain of coffee shops has received a revised SOP for making cappuccinos (a type of coffee drink) that the chain sells. The previous version of the SOP had to be amended because they are now using a new brand of coffee beans – the quality of the beans used before had declined. However, the previous method resulted in a very bitter drink when used with the new beans.

The new version of the SOP has been properly document controlled and logged in the master document index. The copies issued have also been entered into the index.

The quality manager visits each of the coffee shops in turn to put the revised documents in place.

Characters

♦ Quality Manager: Tom
♦ Coffee shop manager: Mary
♦ Coffee shop workers: Sue, Mike, Dave

Role play

Tom: Good morning Mary!
Mary: Good morning Tom. It’s nice to see you again. Is there something that we need to discuss?
Tom: A simple thing, that’s all. I’ve got a new version of the Cappuccino SOP that needs to be introduced. I’ve got four copies of the SOP and records of receipt for you and your staff with me today. Could we deal with this now?
Mary: Yes, that’s not a problem. We’re all here today so it should be quick and easy.
Tom: Good, I’ll get the paperwork out and we’ll get it done then.
Mary: (Calls out to her three staff) Are you all free for a minute? Before the shop opens, we just need to update some documents.

Sue, Mike and Dave appear and they all sit down.

Tom: Right, we’ve had to amend the cappuccino SOP because, as you all know, the new coffee beans that we have changed to need to be brewed in a different way – otherwise the cappuccinos are so bitter that people can’t drink them.

I need you all to replace the current SOP, SOP/TCS/CAP/001/01 with the new version, SOP/TCS/CAP/001/02. I’ve got all the documents here and you can see that the new versions are clearly marked with the new version number and date on which it was put into use. I’ve also got the master index receipt forms that you each need to sign to acknowledge receipt of the new versions.

Are there any problems with this?
Mary: No, I don’t think that any of us have any problems with this. (Her staff all agree with her.) What do you want us to do?

Tom: I’ve got a copy of the new SOP here for each of you. You will see that the receipt forms have already been filled in with your name and the copy number issued to you. Please take the SOP, check the details on the form, sign it and give it back to me.

They all take the new SOPs and sign the receipt forms.

Tom: All I need you to do now is to replace your existing SOP with this new one. This is very important. I want you to destroy the old ones. Is that clear?

They all say yes.

Tom: Right, if there are no problems I’ll be off to the next shop. Nice to see you all again. Keep up the good work. Goodbye.

They all say goodbye to Tom.

Mary: Can you all read the new SOPs and make sure that you understand them. We need to introduce them immediately to coincide with the introduction of the new coffee beans today.

Dave: Look, I’m in a real hurry. Because of Tom coming, I’ve not had time to get the ovens ready and cook the croissants and we open in 10 minutes. You know that the early morning rush is a really important time for us. I’ll sort everything out later.

Mary: OK. Just make sure you don’t forget to sort things out when it has quietened down a bit.

Dave: No, I won’t.

Mary, Sue and Mike read the new SOP, go to their training files and replace the old versions with the new one. They all destroy their copies of the old version.

Later in the day, Dave remembers the new SOP and puts it in his training file. He can’t find the previous version and is too busy to bother to spend time looking for it. He also doesn’t have time to read the new version, but will remember to have a look at it the next day.

A few days later, only Dave and Sue are working in the shop. They are very busy and Dave has to make the coffee as well as doing his normal job of looking after the food and the money.

Sue: We’ve had a lot of complaints about the coffee today, Dave.

Dave: Yes, we have. I can’t understand why as we have these wonderful new beans to use. Thinking about it, you know, I’ve only had complaints about the Cappuccinos, nothing else. What about you?

Sue: Yes, you’re right. It’s only the cappuccinos that have been a problem. I wonder why because I’ve not been doing anything different today. (Pause) Wait a minute! You’ve not made the coffee for a long time – are you doing it properly?

Dave: What do you mean? I’ve been making coffee for years. I know how to make perfect coffee, perfect every time.
Sue: Yes, but have you forgotten that the method changed a few days ago? You know we had a new SOP for the Cappuccinos. You have been following it, haven't you?

Dave: (Pause) … Well, now you mention it, I'd forgotten that the method had changed and I've been using the old method, the one we've been using for the last couple of years.

Sue: But we all had the new SOP. You read it, didn’t you? We introduced it that day that Tom came.

Dave: Actually, I was very busy and didn’t get around to it. Sorry, it's my fault. I was still using the old method.
Module 7
Training
## Teaching aim
To highlight the importance of training in the quality system

### Core topics
- Importance of training
- The organization’s responsibility for training
- Types of training

### Key points
- Staff are a major variable in processes
- Training of staff is essential to ensure consistent performance of duties
- Every organization should take responsibility for the continuing training of its staff
- The organization benefits from having a skilled and motivated workforce

### Teaching focus
- Emphasize that quality problems are likely to occur if staff are not trained
- Reinforce the value of training to the organization and the individual

### Learning outcomes
Participants should be able to:
- Explain why training is a requirement of quality systems
- List the benefits of staff training to the organization and to the staff themselves

### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Need for Training
5. Importance of Training to the Organization
6. Importance of Training to the Individual
7. Organization’s Responsibility for Training (1)
8. Organization’s Responsibility for Training (2)
9. Types of Training Programme
10. Methods of Training
11. Key Points
12. Learning Outcomes

### Materials
None

### Related presentations
- QMT 7.2  Training Needs and Plans
- QMT 7.4  Monitoring and Evaluation of Training

### Time span
½ hour

### Presentation notes and handling the session
- Slide 4  Need for Training: The presentation is simply an introduction to training in the quality system. QMT 7.2 and QMT 7.4 address these issues in more detail
<table>
<thead>
<tr>
<th>Slides 5 - 6</th>
<th>Importance of Training to the Organization and to the Individual</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slides state why training is essential and the benefits to both the organization and staff</td>
</tr>
<tr>
<td></td>
<td>♦ Emphasize the fact that trained staff are the major foundation of a culture of quality</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 7 - 8</th>
<th>Organization’s Responsibility for Training (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ These two slides list the responsibilities of an organization in relation to training and the associated activities needed to develop a culture of quality</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Types of Training Programme</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide lists the important areas that should be covered in the organization’s training plan</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss each area and invite participants to suggest various activities in the BTS that fall into the areas covered</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Methods of Training</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>♦ The slide lists various ways in which training can be provided</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss the merits and disadvantages of each</td>
</tr>
</tbody>
</table>
Training in the Quality System

Teaching Aim

- To highlight the importance of training in the quality system

Core Topics

- Importance of training
- The organization's responsibility for training
- Types of training
## Need for Training

So you've validated all your methods, and procedures!

Where do you go now?

---

## Importance of Training to the Organization

- Lack of variation = controlled process
- To control a process — remove the variables
- Personnel are the major variable in any process. To remove variation — TRAIN THEM!
- Adequate training and competence are essential to ensure good process control
- Higher employee satisfaction/morale

---

## Importance of Training to the Individual

- Increases individuals' knowledge and understanding of processes and procedures
- Improves skills needed to do their work
- Increases awareness of their responsibilities within the process
- Develops staff in their areas of expertise

---
### Organization's Responsibility for Training (1)

- Identify skills needed by personnel who perform activities that affect quality
- Provide training to satisfy these needs
- Evaluate the effectiveness of the training provided

### Organization's Responsibility for Training (2)

- Develop organized training programme that includes
  - Ensuring that employees are trained for the tasks they perform
  - Developing a training plan to qualify new employees (certification) and re-certify existing employees
  - Documentation of all training programmes and training
  - Assessment of training
  - Improvement, when necessary

### Types of Training Programme

- New employee orientation
- Skills-based training
- Technical training
- Safety
- Managerial/supervisory training
- Quality system training
- Computer training
- Continuing education
- Others
### Methods of Training

- Lectures/presentations
- Interactive teaching and learning
  - Small group discussions
  - Role play
- Practical demonstrations
- Direct observation of performance
- Self-directed learning, including computer-based training

### Key Points

- Staff are a major variable in processes
- Training of staff is essential to ensure consistent performance of duties
- Every organization should take responsibility for the continuing training of its staff
- The organization benefits from having a skilled and motivated workforce

### Learning Outcomes

You should now be able to:

- Explain why training is a requirement of quality systems
- List the benefits of staff training to the organization and to the staff themselves
<table>
<thead>
<tr>
<th>QMT 7.2</th>
<th>Training Needs and Plans</th>
</tr>
</thead>
</table>
| **Teaching aim** | ♦ To examine the importance of assessing the training needs of all categories of staff and preparing training plans  
♦ To introduce the distance learning approach |
| **Core topics** | ♦ Identifying the need for job-specific training  
♦ Planning the training  
♦ Resources required  
♦ The trainer and the trainee  
♦ Training materials  
♦ How to impart training  
♦ The distance learning approach |
| **Key points** | ♦ Training must be well planned  
♦ The required resources must be provided  
  ─ Funds  
  ─ Appropriate trainers  
  ─ Materials  
♦ The trainer must be able to impart his/her knowledge to trainees  
♦ Distance learning offers a cost-effective alternative to conventional approaches to training  
♦ WHO distance learning materials, *Safe Blood and Blood Products*, have been specially designed for training in blood safety |
| **Teaching focus** | ♦ Highlight the need to identify all job-specific training needs  
♦ Emphasize the need to ensure training plans are realistic |
| **Learning outcomes** | Participants should be able to:  
♦ Identify training needs in the BTS  
♦ Develop a plan to meet identified training needs  
♦ Identify the skills required to train others effectively |
| **Slides** | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Assessment of Training Needs (1)  
5 Assessment of Training Needs (2)  
6 Assessment of Training Needs (3)  
7 Assessment of Training Needs (4)  
8 Planning the Training  
9 Trainers  
10 Training Materials  
11 Trainees  
12 Delivering Training (1)  
13 Delivering Training (2)  
14 Common Constraints on Providing Training |
<table>
<thead>
<tr>
<th>Slide</th>
<th>Description</th>
</tr>
</thead>
</table>
| Slides 4 - 7 | Assessment of Training Needs (1), (2), (3) & (4)  
- These four slides list the basic steps in assessing training needs within an organization  
- Stress the importance of compliance with regulatory requirements  
- Discuss the need to state training standards within the quality system  
- Stress the difference between re-training and updating |
| Slide 8 | Planning the Training  
- This slide lists the elements that should be included and documented in the training plan |
| Slide 9 | Trainers  
- This slide lists the essential qualities of a good trainer  
- Ensure that participants understand that good knowledge is not the only characteristic of a good trainer  
- Emphasize the need for the trainer to share their knowledge with trainees |
| Slide 10 | Training Materials  
- This slide lists some of the materials that will be needed for staff training  
- Emphasize the need for good visual aids  
- Discuss some of the characteristics of a good visual teaching aid: e.g. simple, not over-crowded |
| Slide 11 | Trainees  
- This slide lists the main points that must be considered regarding the trainees |
| Slides 12 - 13 | Delivering Training (1) & (2)  
- These two slides provide advice on how to be an effective trainer  
- Discuss each point with participants and ask them to comment on training they have received that has been particularly effective |
<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Common Constraints on Providing Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists some examples of constraints faced by many organizations when training plans are designed</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss these points with participants and ask them to suggest possible solutions to these problems</td>
<td></td>
</tr>
<tr>
<td>♦ The next slides outline the value of using the distance learning approach and how this has been assisted by the development of the WHO distance learning materials: <em>Safe Blood and Blood Products</em></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 15 – 16</th>
<th>Distance Learning – An Alternative Approach to Training (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides list some important aspects of setting up a distance learning programme in blood safety</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 17</th>
<th>Components of a Distance Learning Programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide contains a simple diagrammatic representation of the important components that contribute to trainees’ learning</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 18</th>
<th>Structure of a Distance Learning Programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide shows one suggestion for the basic structure of a distance learning programme in blood safety</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 19 – 21</th>
<th>Benefits of Distance Learning (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These three slides outline the major benefits of distance learning for trainers, trainees and the organization as a whole</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 22 – 23</th>
<th>WHO Distance Learning Materials (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The first slide shows the series of WHO distance learning materials, <em>Safe Blood and Blood Products</em></td>
<td></td>
</tr>
<tr>
<td>♦ The second slide lists the modules for use by trainees</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 24</th>
<th>WHO Materials for Trainers</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide lists the materials developed for coordinators and trainers of a distance learning programme in blood safety</td>
<td></td>
</tr>
</tbody>
</table>
Training Needs and Plans

Teaching Aim

- To examine the importance of assessing the training needs of all categories of staff and preparing training plans
- To introduce the distance learning approach

Core Topics

- Identifying the need for job-specific training
- Planning the training
- Resources required
- The trainer and the trainee
- Training materials
- How to deliver training
- The distance learning approach
Assessment of Training Needs (1)

Identify the need for training
- Regulatory requirements
- Quality standards regarding training

Assessment of Training Needs (2)

Identify the need for re-training
- Results of:
  - Recording and analysing errors: e.g. errors related to lack of knowledge and/or skills
  - Direct observations
  - Proficiency testing
  - Audits

Assessment of Training Needs (3)

Perform skills evaluation
- Identify the categories of staff to be evaluated
- Define level of competency for each job function
- Identify the skills needed to perform the job
- Assess level of staff performance in relation to job function
- Determine whether a gap exists between the level of skill acquired by staff and the level needed
Assessment of Training Needs (4)

- Develop a training plan to meet identified needs
- Comply with regulatory requirements
- Comply with quality standards related to training
- Close any gaps between actual and required skills
- Ensure staff are certified as competent

Planning the Training

- Allocate resources: e.g. funds
- Define training specifications
  - Skills
  - Knowledge
- Select training methods and activities
- Plan assessment
  - Theoretical, practical or both
  - Pass mark
- Monitor and evaluate

Trainers

- Select trainers in accordance with the knowledge and skills to be imparted
  - Knowledge and experience in the area of work
  - Teaching experience
  - Good communication skills
  - Enthusiastic, flexible and adaptable
  - Appropriate language skills
Training Materials

- Select training materials that are appropriate for the identified needs
  - SOPs for job-specific training
  - Quality manual/standards for quality awareness training
  - Practical exercises
- Attractive visual aids, where appropriate

Trainees

- Plan the training curriculum and activities with the trainees in mind
  - Type of training required: e.g. new employees, skills-based training
  - Operators of new technology or equipment
  - All staff — regular competency training
  - Those assigned to training as corrective action for non-compliance

Delivering Training (1)

- Ensure the language is appropriate
- Ensure the information is appropriate
- Deliver training in an interesting manner
- Deliver training in the time available
Delivering Training (2)

- Offer opportunities for feedback from trainees
- Facilitate the exchange of information
- Allow sufficient time for all trainees
- Encourage interaction between trainees

Common Constraints on Providing Training

- Variations in training needs
- Shortage of experienced trainers
- Limited training facilities
- Inadequate training budget
- Geographical dispersal of staff needing training
- Shortage of training materials

Distance Learning
An Alternative Approach to Training (1)

- Most teaching is delivered through specially-designed learning materials
- A learner support system provides ongoing tutorial support and guidance through:
  - Regular communication between the trainer and trainees by post, telephone, e-mail or website
  - Supporter/mentor in the trainee’s own workplace
  - Supervised practical training
Distance Learning
An Alternative Approach to Training (2)

Practical work takes place in:
- Designated study centres:
  - National/regional/provincial blood centres
  - Large hospital blood banks
  - Education and training institutions
- Individual learner's own workplace

Components of a Distance Learning Programme

Structure of a Distance Learning Programme
**Benefits of Distance Learning (1)**

- A comprehensive training programme can be made widely available through a combination of:
  - Specialized learning materials
  - Local expertise
- Increased access to training, particularly for staff in remote hospital blood banks
- Large numbers can be trained at the same time

**Benefits of Distance Learning (2)**

- Fewer trainers needed
- More cost-effective than conventional courses
- Flexible, work-based training approach promotes improved staff performance
- Less disruption to services because most of the training takes place in the workplace

**Benefits of Distance Learning (3)**

- Uniformly high quality teaching through learning materials written by international experts
- Modular approach accommodates variations in knowledge, skills, experience and current work
- Distance learning materials can also be used for in-service training and conventional courses
WHO Distance Learning Materials (1)

WHO Distance Learning Materials (2)

Safe Blood and Blood Products
- Introductory Module: Guidelines and Principles for Safe Transfusion Practice
- Module 1: Safe Blood Donation
- Module 2: Screening for HIV and Other Infectious Agents
- Module 3: Blood Group Serology

WHO Materials for Trainers
- Establishing a Distance Learning Programme in Blood Safety: A Guide for Programme Coordinators
- Safe Blood and Blood Products: Trainer’s Guide
Key Points (1)

- Training must be well planned
- The required resources must be provided
  - Funds
  - Suitably qualified and experienced trainers
  - Training materials
- Trainers must be able to impart their knowledge to trainees

Key Points (2)

- Distance learning offers a cost-effective alternative to conventional approaches to training
- WHO distance learning materials, Safe Blood and Blood Products, have been specially designed for training in blood safety

Learning Outcomes

You should now be able to:
- Identify training needs in the BTS
- Develop a plan to meet identified training needs
- Identify the skills required to train others effectively
## QMT 7.3 Creating a Training Plan

### Teaching aim
To provide practice in preparing a training plan

### Core topics
- Identifying key skills required for the job
- Developing an appropriate, effective and deliverable training programme
- Reviewing training plans to ensure that all aspects have been covered

### Key points
- Training plans must be designed to meet identified training needs
- Review and assessment of training plans are essential

### Teaching focus
- Check that training plans are appropriate and comprehensive
- Check that they are effective and complete
- Ensure that the training plans are deliverable

### Learning outcomes
Participants should be able to:
- Identify specific job needs
- Create a training plan for BTS staff
- Critically review a training plan to ensure it is suitable and deliverable

### Type of activity
Group work

### Materials
- Flipcharts
- Pens

### Instructions
1. Instruct each group of participants to select one type of staff member from the list below. Do not allow duplicate choices.
   - A donor motivator
   - A new laboratory worker in the TTI testing laboratory
   - A phlebotomist who needs competency assessment
   - A cleaner who needs training in quality awareness.

2. Instruct each group to draw up a training plan, including:
   - Documentation of the probable needs of the trainee
   - Training materials to be used
   - Who will do the training
   - What the training programme will cover
   - Where training will take place
   - Method of assessment
   - Timetable.

### Review of the activity
- Ensure that participants have included all necessary elements in the plan
- Ensure that the needs they have identified can be justified

### Time span
1 hour
# QMT 7.4 Monitoring and Evaluation of Training

<table>
<thead>
<tr>
<th><strong>Teaching aim</strong></th>
<th>To establish the importance of documentation and records in training and the need to monitor and evaluate training</th>
</tr>
</thead>
</table>
| **Core topics**  | ♦ Documenting the training programme  
♦ Training records  
♦ Monitoring the effectiveness of training |
| **Key points**   | ♦ Quality principles apply to training as much as any other BTS process  
♦ All training should be documented  
♦ Training procedures should be defined, agreed on and documented  
♦ Both the overall training plan and the actual training need to be monitored and evaluated  
♦ Evaluation should be used to improve training in the future |
| **Teaching focus** | ♦ Emphasize the importance of training records  
♦ Highlight the importance of regular reviews of training and their documentation |
| **Learning outcomes** | Participants should be able to:  
♦ Demonstrate an understanding of the need for documentation and training records  
♦ Produce effective documentation covering the training syllabus and its delivery  
♦ Develop a training programme that includes monitoring and evaluation |
| **Slides**       | 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Documentation  
5 Training Records  
6 Need for Assessment of Training  
7 Monitoring Training  
8 Monitoring Trainees  
9 Evaluating the Training Process (1)  
10 Evaluating the Training Process (2)  
11 Evaluating the Training Process (3)  
12 Key Points (1)  
13 Key Points (2)  
14 Learning Outcomes |
<p>| <strong>Materials</strong>    | None |
| <strong>Related activity</strong> | None |
| <strong>Time span</strong>   | ½ hour |</p>
<table>
<thead>
<tr>
<th>Presentation notes and handling the session</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Slide 4</strong></td>
</tr>
<tr>
<td>Documentation</td>
</tr>
<tr>
<td>♦  This slide lists the types of document that should be generated and maintained in relation to training</td>
</tr>
<tr>
<td><strong>Slide 5</strong></td>
</tr>
<tr>
<td>Training Records</td>
</tr>
<tr>
<td>♦  Emphasize the need to maintain accurate records of all training for each individual staff member</td>
</tr>
<tr>
<td><strong>Slide 6</strong></td>
</tr>
<tr>
<td>Need for Assessment of Training</td>
</tr>
<tr>
<td>♦  This slide lists the reasons for the assessment of training and what should be assessed</td>
</tr>
<tr>
<td><strong>Slide 7</strong></td>
</tr>
<tr>
<td>Monitoring Training</td>
</tr>
<tr>
<td>♦  This slide lists the aspects of training that should be monitored</td>
</tr>
<tr>
<td><strong>Slide 8</strong></td>
</tr>
<tr>
<td>Monitoring Trainees</td>
</tr>
<tr>
<td>♦  This slide lists various methods of monitoring trainees and assessing their performance</td>
</tr>
<tr>
<td><strong>Slides 9 - 11</strong></td>
</tr>
<tr>
<td>Evaluating the Training Process (1), (2), &amp; (3)</td>
</tr>
<tr>
<td>♦  These three slides list some basic elements that should be evaluated to ensure that the training process is effective</td>
</tr>
<tr>
<td>♦  Stress the importance of applying quality principles to training, particularly the need for continual improvement</td>
</tr>
</tbody>
</table>
Monitoring and Evaluation of Training

Teaching Aim

- To establish the importance of documentation and records in training and the need to monitor and evaluate training.

Core Topics

- Documenting the training programme
- Training records
- Monitoring the effectiveness of training
### Documentation

- Training plan
- Training programme
- Training sessions
  - Trainer and trainees
  - Duration of the session
  - Training methods
  - Available training materials
  - Training facilities and venue
- Review and evaluation of training

### Training Records

- Records of relevant education, qualifications, experience and training of each member of staff
- Continuing Professional Development file for each member of staff, recording all training undertaken
  - Name of trainer
  - Date and duration
  - Type of training: e.g. presentations, workshops
  - Verification of competence

### Need for Assessment of Training

- Does the training process do what it is supposed to do?
- Have information/skills been transferred effectively?
- Are there validation methods to ensure a quality process?
Monitoring Training

- Training plan
- Training sessions
- Training material
- Trainees

Monitoring Trainees

- Methods
  - Questionnaires
  - Examinations or tests (theoretical and practical)
  - Assessment of practical performance
  - Comment forms to elicit feedback
  - Discussions

Evaluating the Training Process (1)

- Communication
- What was liked
- What was disliked
- Whether the objectives were achieved
- Ways in which the training could be improved
Evaluating the Training Process (2)

Are the training materials:
- Appropriate?
- Relevant to the aims of teaching?
- Appropriately detailed?
- Relevant to current work?

Evaluating the Training Process (3)

- What did the trainees learn?
- Have they acquired new skills?
- Is there an attitude change?
- Is there an improvement in their performance?
- Did the trainer learn anything?

Key Points (1)

- Quality principles apply to training as much as any other BTS process
- All training should be documented
- Training procedures should be defined, agreed on and documented
### Key Points (2)

- Both the overall training plan and the actual training need to be monitored and evaluated
- Evaluation should be used to improve training in the future

### Learning Outcomes

You should now be able to:

- Demonstrate an understanding of the need for documentation and training records
- Produce effective documentation covering the training syllabus and its delivery
- Develop a training programme that includes monitoring and evaluation
Module 8
Assessment within the Quality System
## QMT 8.1 Assessment within Quality Systems

### Teaching aim
To introduce assessment of the quality system

### Core topics
- The need for assessment
- Elements of assessment
  - Evaluation
  - Validation
  - Monitoring
  - Quality assessment schemes
  - Errors and error management
  - Audits

### Key points
- Continual assessment is essential for the maintenance and improvement of the quality system
- There are a number of interrelated tools that should be used for quality assessment

### Teaching focus
Emphasize the value and importance of monitoring and evaluation in the maintenance of a quality system

### Learning outcomes
Participants should be able to:
- List key elements of assessment and their use within quality systems

### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. The Need for Assessment
5. Evaluation
6. Validation
7. Monitoring
8. Quality Assessment Schemes
9. Terms Related to Errors
10. Errors and error management
11. Audits (1)
12. Audits (2)
13. Key Points
14. Learning Outcomes

### Materials
None

### Related activity
None

### Time span
½ hour

### Presentation notes and handling the session
<table>
<thead>
<tr>
<th>Slide 4</th>
<th>The Need for Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The presentation is an introduction to later presentations in this module which cover the topics introduced here in depth. Do NOT give too much detail at this point</td>
<td></td>
</tr>
<tr>
<td>♦ The slide lists the basic reasons why assessment of the quality system is essential</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that assessment should lead to improvement</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide states two facts about evaluation</td>
<td></td>
</tr>
<tr>
<td>♦ Ensure participants understand that evaluation is a process that is undertaken before validation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide states the definition of validation</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the difference between evaluation and validation</td>
<td></td>
</tr>
<tr>
<td>♦ Validation is dealt with in detail in QMT 8.2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Emphasize that monitoring is the collection, analysis and use of data</td>
<td></td>
</tr>
<tr>
<td>♦ The analysis of data is dealt with in detail in QMT 8.6 and QMT 8.7</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>Quality Assessment Schemes</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide gives the definitions of internal and external quality assessment</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss some of the other activities that could fall under internal quality assessment</td>
<td></td>
</tr>
<tr>
<td>♦ External quality assessment (EQA) is dealt with in detail in QMT 12.6</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Terms Related to Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Discuss with the participants the concept of analysing quality incidents for the purposes of improvement</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the differences between the various terms used to describe &quot;errors&quot;</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 10</th>
<th>Errors and Error Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide gives a simple definition of an error and some important information regarding error management</td>
<td></td>
</tr>
<tr>
<td>♦ Errors and error management are dealt with in detail in QMT 8.8 and QMT 8.9</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 11 – 12</th>
<th>Audits (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slides give a definition of an audit and some important information regarding audits</td>
<td></td>
</tr>
<tr>
<td>♦ Audits are dealt with in detail in QMT 8.10 – 8.14</td>
<td></td>
</tr>
</tbody>
</table>
Assessment within Quality Systems

Teaching Aim

- To introduce assessment of the quality system

Core Topics

- The need for assessment
- Elements of assessment
  - Evaluation
  - Validation
  - Monitoring
  - Quality assessment schemes
  - Errors and error management
  - Audits
The Need for Assessment

- Quality is not a static process
- The Deming cycle describes the process of continuous quality improvement
- Assessment is a way of identifying where improvement is needed
- Assessment of all activities is central to maintaining quality systems

Evaluation

In quality terminology, evaluation has a VERY SPECIFIC MEANING:

- Evaluation is a specific selection process to determine the suitability of a procedure or material (e.g. reagent, blood bag, equipment)
- Evaluation should reflect how the procedure/material will be used

Validation

- Validation is the specific activity performed to ensure that, following evaluation, new procedures/material work as required
- All changes need to be validated before being implemented
Monitoring

- Monitoring is an ongoing activity
- The appropriate parameter(s) need to be pre-selected: e.g.
  - Number of donations collected
  - Number and type of components produced
  - Number of test failures
- Data need to be analysed and used/acted on

Quality Assessment Schemes

- Internal quality assessment (IQA)
  - The assessment of a laboratory's overall quality system by the process of halving a sample, analysing each half in the same manner and comparing the results
- External quality assessment (EQA)
  - The external assessment of a laboratory's performance using samples of known, BUT undisclosed, content and comparison with the performance of other laboratories
- Both are specifically designed to assess laboratories

Terms Related to Errors

- Different terminology may be used to describe similar occurrences
  - Errors
  - Mistakes
  - Quality incidents
  - Nonconformity
  - Non-compliance
- The definitions are not all identical but, for simplicity, the terms 'error' and 'error management' are used in this course
Errors and Error Management

- **Error**
  An incident where the quality system has failed

- **Analysis of errors and their outcomes and resolution** is part of monitoring the quality system

- **Error management** examines the failure rate rather than the success rate of the quality system

Audits (1)

- **Audit**
  A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled (ISO 2000)

Audits (2)

- **Regular inspections of the quality system**

- **Performed against** referential standards or other specifications: e.g. GMP, ISO

- **An important part of the quality improvement cycle**. Identifying areas where improvement is needed

- **Can be general or focus only on specific areas**
Key Points

- Continual assessment is essential for the maintenance and improvement of the quality system.
- There are a number of interrelated tools that should be used for quality assessment.

Learning Outcomes

You should now be able to:
- List key elements of assessment and their use within quality systems.
### QMT 8.2 Validation

**Teaching aim**
To explain the importance of validation within the quality system

**Core topics**
- Basic principles of validation
- Principles of validation of processes, equipment, reagents and software
- Planning validations

**Key points**
- Validation ensures that:
  - Everything to be used in a process, including the process itself, is working to documented specifications before use
  - Everything used remains within specifications (re-validation)
- Validation controls the impact of change

**Teaching focus**
- Emphasize the risks of a failure to validate new activities/changes
- Clarify the distinction between validation and evaluation

**Learning outcomes**
Participants should be able to:
- Describe the main purposes of validation
- Develop a validation plan

**Slides**
1. Title
2. Teaching Aim
3. Core Topics
4. Validation
5. What Should Be Validated?
6. Why Validate?
7. General Principles
8. What Does Validation Involve?
9. Processes and Procedures
10. Equipment (1)
11. Equipment (2)
12. Reagents and Consumables
13. Software
14. Planning Validation (1)
15. Planning Validation (2)
16. Performing the Validation
17. Responsibility for Validation
18. Documentation Required
19. Key Points
20. Learning Outcomes

**Materials**
Examples of validation documentation

**Related activity**
QMT 8.3 Preparing a Validation Plan

**Time span**
1 hour
**Presentation notes and handling the session**

<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide gives a simple description of validation</td>
<td></td>
</tr>
<tr>
<td>♦ Two definitions (one from ISO and one from GMP) are given</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>What Should Be Validated?</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide poses the question &quot;What should be validated?&quot;</td>
<td></td>
</tr>
<tr>
<td>♦ Ask the participants for some examples of each category</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Why Validate?</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide states several reasons for carrying out validation</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that the most important reason is to control change; show how, if change is controlled, fewer errors occur</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>General Principles</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide lists some important aspects of the validation process</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to plan all validations</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>What Does Validation Involve?</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Use an example to explain each aspect of the validation process</td>
<td></td>
</tr>
<tr>
<td>♦ A simple example is the oven used to bake biscuits. The oven is designed to generate a temperature of 400°C and should have a timer that can time up to one hour in one-minute intervals</td>
<td></td>
</tr>
<tr>
<td>♦ An example of validating the oven would be as follows.</td>
<td></td>
</tr>
</tbody>
</table>

**Components parts**

♠ Does the thermostat ensure that the temperature stops increasing at 400°C and remains stable throughout the selected time period?  
♠ Does the temperature indicator actually show the correct temperature?  
♠ Does the timer really time correctly?  

**Oven**  
♠ Assess the overall performance of the oven including other requirements: e.g. size, capacity, ease of cleaning, etc.  
♠ Is the temperature evenly distributed horizontally within the oven? Even if the thermostat and temperature indicator, etc., are working perfectly, if the temperature is not evenly distributed, those biscuits baked at the side will be burnt and those in the middle of the rack will be uncooked!  

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Processes and Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the basic principles of validating a process or procedure</td>
<td></td>
</tr>
<tr>
<td>♦ Remind participants of the steps they took to validate the SOPs in QMT 6.3 and QMT 6.4</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 10 – 11</th>
<th>Equipment (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The two slides lists some essential questions that should be asked and answered during the calibration process</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 12</th>
<th>Reagents and Consumables</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists some questions to ask and answer during the validation of reagents and consumables</td>
<td></td>
</tr>
<tr>
<td>♦ The validation of test kits and blood grouping reagents is dealt with in more detail in QMT 12.2 and QMT 12.3</td>
<td></td>
</tr>
<tr>
<td>Slide 13</td>
<td>Software</td>
</tr>
<tr>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>♦ Since computer software is increasingly being used in BTSs, discuss a few of the aspects of software validation, as listed on the slide</td>
<td></td>
</tr>
<tr>
<td>♦ Remember that some participants may not be familiar with the terminology you use</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 14 – 15</th>
<th>Planning Validation (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The two slides state the logical process of planning a validation for any item</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point on the slides, giving examples, where appropriate</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 16</th>
<th>Performing the Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the main steps in carrying out a validation</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to carry out the validation as planned and to base all decisions on documented specifications and/or acceptance criteria</td>
<td></td>
</tr>
<tr>
<td>♦ Use some examples to illustrate the points</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 17</th>
<th>Responsibility for Validation</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Emphasize the role of the quality manager in the validation process</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that decisions made by the quality manager should be based only on documented and analysed evidence</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 18</th>
<th>Documentation Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the basic documents that should be maintained for each validation undertaken</td>
<td></td>
</tr>
</tbody>
</table>
Validation

WHO/QMT 8.2

Teaching Aim

- To explain the importance of validation within the quality system

Core Topics

- Basic principles of validation
- Principles of validation of processes, equipment, reagents and software
- Planning validations
Validation

- Validation determines whether something does what it is supposed to do
- Definitions
  - Confirmation and provision of objective evidence that the requirements for a specific intended use or application have been fulfilled — ISO 9000 (2000)
  - That part of a quality system that evaluates in advance the steps involved in operational procedures or product preparation to ensure quality, effectiveness and reliability (GMP)

What Should Be Validated?

New or changed:
- Processes and procedures
- Equipment
- Reagents and other consumables
- Software

Why Validate?

- Quality system requires it
- Regulatory requirement
- To control changes
  - Ensure something is working before it is used
  - Ensure something new does not interfere with existing processes
- As a result of error reporting or poor assessment results
  - Review procedure or equipment
General Principles

- Validation
  - Should be planned carefully
- Validate
  - Before introducing anything: e.g. procedure or equipment
- Re-validate
  - After its introduction

What Does Validation Involve?

- Systematically looking at a process, procedure, equipment, reagent or software
  - Breaking it down into its smallest working parts
  - Checking that each part works as expected
  - Checking that each part works as needed
  - Looking at it in its entirety and checking that it works as expected and as needed
  - Identifying and minimizing the effect on other activities

Processes and Procedures

- Have the critical control points been identified?
- Has a standard operating procedure been written?
- Is the outcome as expected?
  - Specifications
  - Acceptance criteria
- Have staff been trained?
- Does the process/procedure affect another process/procedure?
Equipment (1)

- Does it do what it is supposed to do?
- Does it meet specifications?
- Are the correct services (power, water, etc.) available, if required?
- Are there quality control procedures?

Equipment (2)

- Is it safe to use?
- Are consumables/disposables readily available, if required?
- Are calibration, maintenance, servicing and repair available?

Reagents and Consumables

- Are there specific procedures for validating essential reagents and consumables?
- Do they include re-validation on a regular basis?
- Does the outcome meet the specifications and/or acceptance criteria?
Software

- Does it run on the available hardware?
- Does it do what it is supposed to do?
- Does it meet specifications?
- Does it conflict with other software/systems?
- Does it have security?
  - Password protection
  - Different user levels

Planning Validation (1)

- Is the aim of the validation clear?
- Identify requirements: e.g.
  - Method of validation
  - Equipment
  - Skills
- Define specifications
  - Required features
  - Desired features
  - Acceptance criteria

Planning Validation (2)

- Define other requirements: e.g.
  - Sample size
  - Health and safety
- Identify specific tests that need to be performed
  - Quality control of specific outputs
  - Break complex activities into smaller ones
  - Challenge the system
- Document the entire validation process
Performing the Validation

- Carry out pre-selected method
- Collect, analyse and interpret data
- Compare data against specifications and/or acceptance criteria
- Accept or reject
- Document all steps

Responsibility for Validation

- Head of department has overall responsibility
- Some activities should be delegated to junior staff
- Quality department guides the heads of departments in the validation process to ensure:
  - It is planned and documented correctly
  - It is carried out according to the plan
  - The relevant issues are addressed
  - The correct decision is made, based on data generated

Documentation Required

- Validation plan
- Written and approved procedure
- Collected data (recorded in appropriate format)
- Validation form
Key Points

- Validation ensures that:
  - Everything to be used in a process, including the process itself, is working to documented specifications before use.
  - Everything used remains within specifications (re-validation).
- Validation controls the impact of change.

Learning Outcomes

You should now be able to:
- Describe the main purposes of validation.
- Develop a validation plan.
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 8.3</th>
<th>Preparing a Validation Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To provide practice in producing an effective and appropriate validation plan</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Identifying critical validation points  
♦ Appropriate validation  
♦ The difference between validation and evaluation  
♦ Examples of validation plans |
| **Key points** | ♦ Planning is essential  
♦ No matter how small the change, validation is needed |
| **Teaching focus** | ♦ Focus on validation, not evaluation  
♦ Ensure participants keep validation plans simple  
♦ Ensure understanding of the difference between validation and evaluation |
| **Learning outcomes** | Participants should be able to:  
♦ Describe the main activities when validating reagents, processes, equipment and software  
♦ Identify the use of documentation in validation procedures |
| **Type of activity** | Group work |
| **Materials** | ♦ Flipcharts  
♦ Pens |
| **Instructions** | Allocate each group an item from one of the lists below. Avoid duplication between groups and try to use an example from each of the lists. |

**List A**  
♦ Platelet agitator  
♦ Electronic balance for weighing reagents  
♦ Refrigerated centrifuge  
♦ Mechanical pipette that delivers a variable range from 5-200 µl

**List B**  
♦ Anti-A antisera  
♦ Anti-human globulin reagent  
♦ HBsAg test kit  
♦ Red cell antibody detection panel

**List C**  
♦ Addition of HCV testing to enhance blood safety  
♦ Introduction of FFP production

**List D**  
♦ Introduction of new donor records software  
♦ Introduction of a new automated HIV test with software interface
<table>
<thead>
<tr>
<th>2</th>
<th>Tell the groups to follow the instructions given in the presentation and: ♦ Identify critical validation points for the item ♦ Prepare an appropriate validation plan, including specifications and/or acceptance criteria for the item ♦ Identify the documentation required.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Review of the activity</strong></td>
<td>♦ Ensure that the validation points are appropriate to the item ♦ Ensure that the plans are feasible ♦ Ensure that key documentation is identified</td>
</tr>
<tr>
<td><strong>Time span</strong></td>
<td>2 hours</td>
</tr>
<tr>
<td><strong>QMT 8.4</strong></td>
<td><strong>Maintenance and Calibration of Equipment</strong></td>
</tr>
<tr>
<td>-------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To introduce the reasons for, and the basic principles of, the maintenance and calibration of equipment</td>
</tr>
<tr>
<td><strong>Core topics</strong></td>
<td>♦ Need for equipment maintenance</td>
</tr>
<tr>
<td></td>
<td>♦ Organizational and user responsibilities</td>
</tr>
<tr>
<td></td>
<td>♦ Principles of calibration</td>
</tr>
<tr>
<td></td>
<td>♦ Action in the event of calibration failure</td>
</tr>
<tr>
<td></td>
<td>♦ Records/documentation</td>
</tr>
<tr>
<td><strong>Key points</strong></td>
<td>♦ Prevention is better than cure</td>
</tr>
<tr>
<td></td>
<td>♦ An effective maintenance and calibration programme is required for all equipment that has any impact on the quality of the final product</td>
</tr>
<tr>
<td></td>
<td>♦ Maintenance and calibration should be regular, appropriate and comprehensive</td>
</tr>
<tr>
<td></td>
<td>♦ Staff must be trained in the correct use, maintenance and calibration of equipment</td>
</tr>
<tr>
<td></td>
<td>♦ All maintenance and calibration must be documented</td>
</tr>
<tr>
<td><strong>Teaching focus</strong></td>
<td>♦ Emphasize the value of preventive maintenance</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss in depth action to be taken in the event of calibration failure</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss the importance of the reliability of previous results obtained with that equipment</td>
</tr>
<tr>
<td><strong>Learning outcomes</strong></td>
<td>Participants should be able to:</td>
</tr>
<tr>
<td></td>
<td>♦ List the main reasons for the maintenance and calibration of equipment</td>
</tr>
<tr>
<td></td>
<td>♦ Discuss the value of preventive maintenance</td>
</tr>
<tr>
<td></td>
<td>♦ Outline the basic principles of calibration and how to apply them</td>
</tr>
<tr>
<td></td>
<td>♦ Develop documentation for the maintenance and calibration of equipment</td>
</tr>
<tr>
<td><strong>Slides</strong></td>
<td>1 Title</td>
</tr>
<tr>
<td></td>
<td>2 Teaching Aim</td>
</tr>
<tr>
<td></td>
<td>3 Core Topics</td>
</tr>
<tr>
<td></td>
<td>4 Need for Maintenance and Calibration</td>
</tr>
<tr>
<td></td>
<td>5 Equipment Maintenance/Calibration System</td>
</tr>
<tr>
<td></td>
<td>6 Organizational Responsibilities</td>
</tr>
<tr>
<td></td>
<td>7 User Responsibilities (1)</td>
</tr>
<tr>
<td></td>
<td>8 User Responsibilities (2)</td>
</tr>
<tr>
<td></td>
<td>9 Maintenance</td>
</tr>
<tr>
<td></td>
<td>10 Preventive Maintenance</td>
</tr>
<tr>
<td></td>
<td>11 Benefits of Preventive Maintenance</td>
</tr>
<tr>
<td></td>
<td>12 Definition of Calibration</td>
</tr>
<tr>
<td></td>
<td>13 Calibration</td>
</tr>
</tbody>
</table>
### Materials
None

### Related activity
QMT 8.5 Developing a Maintenance and Calibration Plan

### Time span
¾ hour

### Presentation notes and handling the session

<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Need for Maintenance and Calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide lists the reasons why maintenance and calibration should be carried out</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Equipment Maintenance / Calibration Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>This slide lists some simple steps in establishing a maintenance or calibration schedule for each piece of equipment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Organizational Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide lists the responsibilities of the organization to ensure that maintenance and calibration of equipment is carried out</td>
</tr>
<tr>
<td>♦</td>
<td>Emphasize the need to train staff and give ownership in order to increase staff commitment to maintaining equipment</td>
</tr>
<tr>
<td>♦</td>
<td>As the point on health and safety is discussed, stress to participants that dirty or dusty equipment will not give an impression of quality, even if the equipment is fully functional</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 7 – 8</th>
<th>User Responsibilities (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>Emphasize the need to make all staff responsible for the equipment they use</td>
</tr>
<tr>
<td>♦</td>
<td>Stress that, even if there is a contract for servicing from an outside agency, it is essential to monitor equipment at the planned frequency</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The slide simply states the most important reason for the regular maintenance of equipment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 10 – 11</th>
<th>Preventive Maintenance &amp; Benefits of Preventive Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>The two slides list some important facts regarding preventive maintenance and the main benefits of ensuring a comprehensive maintenance programme for all critical equipment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 12 – 13</th>
<th>Definition of Calibration &amp; Calibration</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦</td>
<td>These two slides give a definition of calibration and the main benefits of carrying out regular calibration of equipment</td>
</tr>
<tr>
<td>Slides 14 – 15</td>
<td>When to Calibrate &amp; How to Calibrate</td>
</tr>
<tr>
<td>---------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>♦ The two slides give advice on when to calibrate and how to calibrate</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss these points with the participants, asking them to give some examples for each one</td>
<td></td>
</tr>
<tr>
<td>♦ Stress the problems that may arise if a BTS does not calibrate because of constraints such as non-availability of reference standards</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss possible mechanisms for solving the problems identified, such as liaising with other organizations who use similar equipment</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss the problem of determining a calibration interval if no advice is given from the manufacturer</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss how arbitrarily set intervals should be stringent and have the shortest time within which calibration could alter at the given intensity of usage</td>
<td></td>
</tr>
<tr>
<td>♦ Involve the participants in the discussion by asking them how they would go about extending the period between calibrations</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 16 – 17</th>
<th>Calibration Failure – Equipment and Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The two slides give some advice on what to do when calibration fails</td>
<td></td>
</tr>
<tr>
<td>♦ The first slide describes what should be done with the equipment</td>
<td></td>
</tr>
<tr>
<td>♦ The second slide advises on what to do with the &quot;products&quot; from a piece of equipment that has failed calibration</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that equipment that has failed calibration should never be used</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 18 – 19</th>
<th>Documentation Required &amp; Maintenance and Calibration Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These two slides list the various types of documents and records that must be kept in relation to maintenance and calibration</td>
<td></td>
</tr>
</tbody>
</table>
Maintenance and Calibration of Equipment

Teaching Aim

- To introduce the reasons for and the basic principles of maintenance and calibration of equipment

Core Topics

- Need for equipment maintenance
- Organizational and user responsibilities
- Principles of calibration
- Action in the event of calibration failure
- Records/documentation
Need for Maintenance and Calibration

- All equipment needs to be maintained to ensure it works efficiently and reliably at all times
- Some items of equipment require particular attention due to their critical function and the need for absolute accuracy: e.g.
  - Pipette (volumes)
  - Blood cold chain equipment (temperature)
- Calibration is required to ensure the accuracy of quantitative activities of the equipment

Equipment Maintenance/Calibration System

- Establish an inventory of equipment
  - Devise a system for unique identification of equipment
- Set up maintenance, calibration and servicing schedules
  - What is required; when it is required; who is responsible
- Establish specifications for acceptable performance
  - For each item/category of equipment
- Document

Organizational Responsibilities

It is the responsibility of the organization to ensure:

- Staff are properly trained to use and maintain equipment
- Training records are kept for both the use and maintenance of the equipment
- Regular maintenance contracts are in place
- Health and safety aspects are addressed
User Responsibilities (1)

It is the responsibility of the user to:

- Keep equipment in good condition at all times
- Ensure it is safe to operate
- Perform and document regular maintenance in accordance with manufacturers’ instructions

User Responsibilities (2)

It is the responsibility of the user to:

- Perform and document regular calibration in accordance with agreed procedures
- Ensure scheduled servicing is performed and documented
- Keep an up-to-date error/breakdown log

Maintenance

Prevention is better than cure
Preventive Maintenance

- Maintenance is usually a preventive action
- Is a proactive system of regular checks and activities to ensure continuous proper functioning of equipment and minimize the risk of breakdown
- Should be incorporated into daily start-up and shut-down procedures
- Provides a system for monitoring critical functions

Benefits of Preventive Maintenance

Contributes to uniformity and quality of processes
- Ensures that equipment always operates within specifications
- Prevents minor problems from becoming major
- Reduces errors and down-time
- Reduces cost of equipment breakdown/replacement
- Provides a history of equipment performance

Definition of Calibration

- The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or system and the corresponding known value of a reference standard
Calibration

- Ensures accuracy and precision of those functions where quantitative steps are performed
- Permits comparison of actual performance versus required performance
- Adjusts output to within acceptable/specified limits

When to Calibrate

- At regular intervals
  - Based on usage and critical importance of function
- When routine monitoring shows performance outside defined specifications
- When equipment is new and no calibration certificate is provided
- When equipment undergoes traumatic events
  - e.g. moving over long distances

How to Calibrate

- Use validated methods
  - Gravimetric/spectrophotometric
  - May need to be performed externally with complex equipment
- Use validated equipment
  - Measuring equipment calibrated against standards or references
  - Thermometers
  - Standard weights
Calibration Failure - Equipment

- Temporarily remove equipment from use and label appropriately until:
  - Cause of problem is identified and rectified
  - New calibration shows compliance with specifications
- Permanently remove equipment from use if calibration cannot be attained

Calibration Failure - Products

- Determine action for those products/results produced since the previous calibration
  - Review potential impact of calibration failure
  - Develop plan to investigate
  - Assess each product/result individually
  - Determine what further action to take

Documentation Required

- Manufacturer's instructions for each item of equipment
- Specific instructions on how to use the equipment
  - SOPs/datasheets
  - Specifications for acceptable performance
- Maintenance/calibration/servicing schedule
**Maintenance and Calibration Records**

- Identification of equipment
- Who performed the maintenance/calibration/servicing
- When it was performed
- What the results were
- What the conclusion/outcome was
- Any action taken

**Key Points (1)**

PREVENTION IS BETTER THAN CURE

- An effective maintenance and calibration programme is required for all equipment that has any impact on the quality of the final product
- Maintenance and calibration should be regular, appropriate and comprehensive

**Key Points (2)**

- Staff must be trained in the correct use, maintenance and calibration of equipment
- All maintenance and calibration must be documented
## Learning Outcomes

You should now be able to:

- List the main reasons for the maintenance and calibration of equipment
- Discuss the value of preventive maintenance
- Outline the basic principles of calibration and how to apply them
- Develop documentation for the maintenance and calibration of equipment
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 8.5</th>
<th>Designing a Maintenance and Calibration Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To provide practice in producing appropriate maintenance and calibration plans</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Identifying the maintenance and calibration needs of equipment  
♦ Determining appropriate calibration methods |
| **Key points** | ♦ There are different approaches to maintenance and calibration  
♦ Maintenance and calibration plans must be sustainable |
| **Teaching focus** | ♦ Emphasize the importance of designing simple and appropriate maintenance and calibration plans  
♦ Ensure participants understand the value and use of documentation and records for maintenance and calibration |
| **Learning outcomes** | Participants should be able to:  
♦ Produce an appropriate maintenance and calibration schedule  
♦ Identify key documentation for the maintenance and calibration of equipment |
| **Type of activity** | Group work |
| **Materials** | ♦ Flipcharts  
♦ Pens |
| **Instructions** | 1 Allocate one piece of equipment from the list below to each group:  
♦ Scales to weigh blood bags at collection sites  
♦ Components preparation centrifuge  
♦ Mechanical pipette  
♦ Blood storage refrigerator.  
2 Instruct participants to prepare a maintenance AND calibration plan for the piece of equipment.  
3 Identify the relevant documentation and records needed. |
| **Review of the Activity** | ♦ Ensure the key maintenance and calibration aspects of each piece of equipment have been identified  
♦ Ensure the maintenance and calibration plans are realistic  
♦ Ensure the following have been included in the calibration plans:  
  – Calibration method  
  – Calibration frequency  
  – Action to be taken if there is a calibration failure  
♦ Ensure that all appropriate documentation and records have been identified |
<p>| <strong>Time span</strong> | 1½ hours |</p>
<table>
<thead>
<tr>
<th>QMT 8.6</th>
<th>Quality Monitoring Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To introduce quality monitoring and some examples of quality monitoring tools</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Monitoring performance  
♦ Monitoring tools  
♦ Benchmarking |
| **Key points** | ♦ Quality monitoring is a way of looking at what is actually happening  
♦ Looking at indicators can identify trends and help prevent problems occurring  
♦ Monitoring is an active process that requires appropriate data analysis to make best use of the monitoring system  
♦ Visualization of data is one of the best ways of looking at what is going on |
| **Teaching focus** | ♦ Emphasize that there are different approaches to quality monitoring  
♦ Encourage participants to try different methods |
| **Learning outcomes** | Participants should be able to:  
♦ List some simple tools for data analysis  
♦ Describe how these simple tools may be used to monitor performance |

<table>
<thead>
<tr>
<th>Slides</th>
</tr>
</thead>
</table>
| 1 Title  
2 Teaching Aim  
3 Core Topics  
4 Understanding Monitoring  
5 Quality Monitoring  
6 Why Monitor?  
7 What to Monitor?  
8 How to Monitor  
9 Simple Visualization Tools  
10 Examples of Charts (1)  
11 Examples of Charts (2)  
12 Examples of Charts (3)  
13 Normal Distribution of Data  
14 Normal Distribution  
15 Statistical Process Control (SPC) (1)  
16 Statistical Process Control (SPC) (2)  
17 SPC Rules  
18 Performance Monitors – SPC (1)  
19 Performance Monitors – SPC (2)  
20 Control Chart  
21 Benchmarking  
22 Key Points (1)  
23 Key Points (2)  
24 Learning Outcomes |
<table>
<thead>
<tr>
<th>Materials</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related activity</td>
<td>QMT 8.7  Analysing Data and Monitoring Performance</td>
</tr>
<tr>
<td>Time span</td>
<td>¾ hour</td>
</tr>
</tbody>
</table>

**Presentation notes and handling the session**

<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Understanding Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The presentation is designed to demonstrate to participants that simple visual tools will assist them in monitoring and should result in rapid responses, when necessary</td>
<td></td>
</tr>
<tr>
<td>♦ The slide lists the main reason why monitoring is essential</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the fact that monitoring leads to improved quality through increased control</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Quality Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide gives a definition of quality monitoring</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that data collection without review and analysis is of no value</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need for continuous appraisal</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Why Monitor?</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide gives some further reasons for carrying out quality monitoring</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 7</th>
<th>What to Monitor?</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists what should be monitored</td>
<td></td>
</tr>
<tr>
<td>♦ Recap on presentation QMT 3.2 in which indicators were discussed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 8</th>
<th>How to Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists some advice on how to monitor</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with participants and ask them to provide some examples</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 9</th>
<th>Simple Visualization Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Slide 9 introduces the next three slides which contain various examples of charts</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 10 – 12</th>
<th>Examples of Charts (1), (2), &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These slides show three examples of simple charts that demonstrate data better than numbers</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each type of chart and ask participants how they could analyse or interpret the charts</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>Normal Distribution of Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide explains normal distribution</td>
<td></td>
</tr>
<tr>
<td>♦ Ensure participants understand this, using slide 14 as an illustration, before proceeding to statistical process control (SPC) in slide 15 onwards</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Normal Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ This slide shows the graph of normal distribution</td>
<td></td>
</tr>
<tr>
<td>♦ Use the slide to demonstrate how a concept is more easily understood as a graph rather than in words or numbers</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 15 – 16</th>
<th>Statistical Process Control (SPC) (1) &amp; (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The two slides list some facts about SPC and why it is used</td>
<td></td>
</tr>
<tr>
<td>♦ Explain each statistical term: e.g. drift</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 17</th>
<th>SPC rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the rules of SPC</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point and then move to slides 18–20 to demonstrate what is meant</td>
<td></td>
</tr>
<tr>
<td>Slides 18 - 19</td>
<td>Performance Monitors – SPC (1) &amp; (2)</td>
</tr>
<tr>
<td>----------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td>♣ The three slides show different examples of what can be observed when monitoring a process or procedure with SPC</td>
<td></td>
</tr>
<tr>
<td>♣ Discuss each example with the participants and ask them to suggest possible causes of the patterns that are observed</td>
<td></td>
</tr>
<tr>
<td>♣ Emphasize the need to monitor patterns and to make decisions based on several observations</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 20</th>
<th>Control Chart</th>
</tr>
</thead>
<tbody>
<tr>
<td>♣ The slide shows a control chart for a particular process</td>
<td></td>
</tr>
<tr>
<td>♣ Ask the participants to describe what is happening to the process, as demonstrated by the control chart</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 21</th>
<th>Benchmarking</th>
</tr>
</thead>
<tbody>
<tr>
<td>♣ The slide lists some simple facts about benchmarking</td>
<td></td>
</tr>
<tr>
<td>♣ Discuss each point and how benchmarking can assist in monitoring the quality system</td>
<td></td>
</tr>
</tbody>
</table>
Quality Monitoring Tools

Teaching Aim

- To introduce quality monitoring and some examples of quality monitoring tools

Core Topics

- Monitoring performance
- Monitoring tools
- Benchmarking
Understanding Monitoring

- Look at what you already have
  - What you see you understand
  - What you understand you can control

Quality Monitoring

- The ongoing collection, review and analysis of data enabling objective, continuous appraisal of the quality of a process/procedure
- Facilitates the continuous appraisal of the overall quality system of the organization

Why Monitor?

- Confirms compliance and consistency
- Alerts to unexpected changes
- Enables assessment of the impact of changes to processes or procedures
- Helps to identify opportunities for improvement
What to Monitor?

- Any indicators that could help predict change in the quality of an output
  - Decide what you need to know
  - The change may be positive (improvement) or negative (deterioration)

How to Monitor

- Collect data
  - Define what needs to be collected
  - Ensure this does not interfere with the procedure
- Use simple tools to visualize/analyse the data
  - Graphing or charting: e.g. histogram, pie chart
  - Statistics/trend analysis
- More complex statistical tools

Simple Visualization Tools

- Graphs and charts
- Simple presentation of raw data
- Look at the overall picture: e.g.
  - Number of donations/session
  - Number of test failures/day
  - Number of discarded products
Examples of Charts (1)

Types of donor

- 25% Voluntary
- 25% Family
- 50% Paid

Examples of Charts (2)

Platelet concentrates issued/ordered

- Ordered
- Issued

Examples of Charts (3)

No. donors

Nov. and Dec. 2001 and 2002: Donor numbers could be analysed by a statistical test to determine whether the increase is significant and the reason for the difference.
Normal Distribution of Data

- Visualized as a bell-shaped curve
- Symmetrical and continuous
- Defined by the 68-95-99.7 rule:
  - 68% of the values should lie within 1 SD of the mean
  - 95% of the values should lie within 2 SD of the mean
  - 99.7% of the values should lie within 3 SD of the mean

SD = Standard deviation

Statistical Process Control (SPC) (1)

- Also referred to as Statistical Process Monitoring
- SPC is a way of picturing data
- Problem-solving tools
  - To identify change/drift
  - To reduce variation
  - Achieve process stability
Statistical Process Control (SPC) (2)

- SPC charts
  - Ongoing recording of data
  - Plot mean +/- 2 or 3 standard deviation
  - Standard rules are applied to identify outliers

SPC Rules

- Points +/- 2 or 3SD from the mean
- Runs of 5 or 7 up or down
- Runs of 5 or 7 above or below the mean
- Cyclic patterns
- 2/3 of all points within +/- 1SD from the mean

Performance Monitors – SPC (1)
Performance Monitors - SPC (2)

Cyclic pattern

2/3 within +/- 1 SD

Control Chart

x = 1.640

2 SD = 1.274

Benchmarking

- A comparison of measurable values
- An integral part of the improvement process
- Comparison against others
- Looks for ideas to borrow from those who are doing better
- Benchmark against other BTSs or other departments in the same BTS
Key Points (1)

- Quality monitoring is a way of looking at what is actually happening
- Looking at indicators can identify trends and help prevent problems occurring

Key Points (2)

- Monitoring is an active process that requires appropriate data analysis to make best use of the monitoring system
- Visualization of data is one of the best ways of looking at what is going on

Learning Outcomes

You should now be able to:
- List some simple tools for data analysis
- Describe how these simple tools may be used to monitor performance
### QMT 8.7 Analysing Data and Monitoring Performance

<table>
<thead>
<tr>
<th>Teaching aim</th>
<th>To illustrate the value of monitoring the data that are generated</th>
</tr>
</thead>
</table>
| Core topics  | ♦ Using different types of data  
♦ Appropriate analysis of data  
♦ Critical analysis of data  
♦ Recognizing potential problems  
♦ Statistical process control (SPC)/statistical process monitoring (SPM)  
♦ Identifying and monitoring trends |
| Key points   | ♦ Many BTS activities generate data  
♦ Not all data are a measure of performance  
♦ Monitoring focuses on what is actually happening  
♦ Visual presentation of data is an effective method of analysis and understanding |
| Teaching focus | ♦ Explain why certain data have little monitoring value  
♦ Give examples of different types of analysis and their advantages and disadvantages  
♦ Keep the work focused on a simple analysis of the data  
♦ Explore possible reasons for trends in data |
| Learning outcomes | Participants should be able to:  
♦ Analyse some typical laboratory data  
♦ Prepare simple charts to monitor and evaluate performance  
♦ Use SPC/SPM to demonstrate and monitor trends |
| Type of activity | Group work |
| Materials     | ♦ QMT 8.7: Examples of Monitoring Data  
♦ Flipcharts  
♦ Pens  
♦ Graph paper  
♦ Calculators |
| Instructions  | 1 Instruct the participants to follow the instructions on each set of data.  
2 Instruct them to plot a chart for each set of data, using the data given.  
3 Instruct them to analyse and draw a conclusion from the graphs they have drawn. |
| Review of the activity | ♦ Ensure that the charts are correctly drawn  
♦ Ensure that the correct conclusions are drawn |
| Time span     | 1½ hours |
# Pack weights

<table>
<thead>
<tr>
<th>Data given</th>
<th>The range for acceptable pack weights is 505 to 595 grams</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data gathered from two mobile teams (A and B)</strong></td>
<td><strong>Team A (average)</strong></td>
</tr>
<tr>
<td></td>
<td>Weight</td>
</tr>
<tr>
<td></td>
<td>540</td>
</tr>
<tr>
<td></td>
<td>525</td>
</tr>
<tr>
<td></td>
<td>530</td>
</tr>
<tr>
<td></td>
<td>528</td>
</tr>
<tr>
<td></td>
<td>560</td>
</tr>
<tr>
<td></td>
<td>555</td>
</tr>
<tr>
<td></td>
<td>540</td>
</tr>
<tr>
<td></td>
<td>504</td>
</tr>
<tr>
<td></td>
<td>532</td>
</tr>
</tbody>
</table>

**Instructions**

1. Calculate the mean.
2. Plot charts for both teams.
3. Draw conclusions from the charts.
New donor selection criteria

The BTS has introduced new criteria for donor selection to reduce the number of HIV positive units collected.

Data gathered from the selection exercise over a 10-month period

<table>
<thead>
<tr>
<th>Month</th>
<th>Pre-change 2000</th>
<th>Post-change 2001</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of donors screened</td>
<td>No. of donors deferred</td>
</tr>
<tr>
<td>January</td>
<td>2500</td>
<td>205</td>
</tr>
<tr>
<td>February</td>
<td>2510</td>
<td>210</td>
</tr>
<tr>
<td>March</td>
<td>2440</td>
<td>240</td>
</tr>
<tr>
<td>April</td>
<td>2480</td>
<td>200</td>
</tr>
<tr>
<td>May</td>
<td>2560</td>
<td>230</td>
</tr>
<tr>
<td>June</td>
<td>2540</td>
<td>220</td>
</tr>
<tr>
<td>July</td>
<td>2510</td>
<td>250</td>
</tr>
<tr>
<td>August</td>
<td>2470</td>
<td>220</td>
</tr>
<tr>
<td>September</td>
<td>2520</td>
<td>210</td>
</tr>
<tr>
<td>October</td>
<td>2530</td>
<td>215</td>
</tr>
</tbody>
</table>

Instructions

1. From the data given, determine whether the use of the new donor selection criteria has had an impact on the number of HIV positive units collected.
2. What other conclusions can be drawn from the data?
## Platelet counts

### Data given

Platelet counts performed on single donor platelet concentrates over a 25-day period.

The mean and standard deviations are based on the previous three months’ data.

Mean = 3.5  Standard deviation = 0.2

<table>
<thead>
<tr>
<th>Data</th>
<th>Day</th>
<th>Platelet count</th>
<th>Day</th>
<th>Platelet count</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>3.7</td>
<td>14</td>
<td>3.2</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>3.5</td>
<td>15</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>3.6</td>
<td>16</td>
<td>3.8</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>3.3</td>
<td>17</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>3.4</td>
<td>18</td>
<td>3.7</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>3.6</td>
<td>19</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>3.5</td>
<td>20</td>
<td>3.8</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>3.6</td>
<td>21</td>
<td>4.2</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>3.4</td>
<td>22</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>3.4</td>
<td>23</td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>3.3</td>
<td>24</td>
<td>3.5</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>3.3</td>
<td>25</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>3.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Instructions

From the data given, analyse the trend over the 25-day period.
# QMT 8.8 Error Management

## Teaching aim
To demonstrate the importance of putting systems in place to deal with errors

## Core topics
- Defining errors
- Error policy
- Error reporting
- Error analysis
- Correction, corrective action and preventive action

## Key points
- Errors (quality incidents) must be defined clearly
- Systems to report quality incidents need to be in place so that they can then be investigated
- Systems of correction, corrective action and preventive action need to be in place
- All staff and users of products/services need to be aware of the systems that are in place
- Incidents must be used to improve processes/procedures, not to punish staff

## Teaching focus
- Define "errors"
- Discuss the boundary between mistakes and errors
- Discuss the differences between mistakes, errors and non-compliance

## Learning outcomes
Participants should be able to:
- Demonstrate an understanding of errors and their reporting
- Explain the importance of taking action to correct errors and prevent further occurrences

## Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Definitions (1)
5. Definitions (2)
6. Definitions (3)
7. Error Policy
8. Error Reporting (1)
9. Error Reporting (2)
10. Error Analysis
11. Quality Incident
12. Investigating Errors/Quality Incidents (1)
13. Investigating Errors/Quality Incidents (2)
15. Key Points (1)
16. Key Points (2)
17. Learning Outcomes
<table>
<thead>
<tr>
<th>Materials</th>
<th>QMT 8.8 Example of a Quality Incident Report Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Related activity</td>
<td>QMT 8.9 Preparing an SOP on Error Reporting</td>
</tr>
<tr>
<td>Time span</td>
<td>¾ hour</td>
</tr>
<tr>
<td><strong>Presentation notes and handling the session</strong></td>
<td></td>
</tr>
<tr>
<td>Slides 4 - 6</td>
<td>The three slides list various definitions related to error management</td>
</tr>
<tr>
<td>Definitions (1), (2) &amp; (3)</td>
<td>Stress the difference between corrective action and preventive action</td>
</tr>
<tr>
<td>Slide 7</td>
<td>The slide lists the steps or actions required to maintain a system that incorporates error management</td>
</tr>
<tr>
<td>Error Policy</td>
<td></td>
</tr>
<tr>
<td>Slides 8 - 9</td>
<td>The two slides deals with various aspects of error reporting</td>
</tr>
<tr>
<td>Error Reporting (1) &amp; (2)</td>
<td>Emphasize the need to have a firm system in place to ensure that a report leads to an investigation and, ultimately, to improvement</td>
</tr>
<tr>
<td>Slide 10</td>
<td>The slide states the two main types of error</td>
</tr>
<tr>
<td>Error Analysis</td>
<td>Stress the importance of analysing and categorizing errors</td>
</tr>
<tr>
<td>Slide 11</td>
<td>Discuss the use of the term &quot;quality incident&quot; as opposed to &quot;error&quot;</td>
</tr>
<tr>
<td>Quality Incident</td>
<td>Emphasize the need to identify failures in the quality system in both product and service delivery</td>
</tr>
<tr>
<td>Slides 12 - 14</td>
<td>The slides list the steps involved in investigating errors</td>
</tr>
<tr>
<td>Investigating Errors/Quality Incidents (1), (2) &amp; (3)</td>
<td>Discuss each step with the participants, using an example of a simple error that requires investigation</td>
</tr>
</tbody>
</table>
**NATIONAL BLOOD SERVICE**

**Incident Report Form**

<table>
<thead>
<tr>
<th>Type of incident</th>
<th>Donor complaint / User complaint / Internal complaint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date requested</td>
<td>Incident report number</td>
</tr>
<tr>
<td>Description of incident</td>
<td></td>
</tr>
<tr>
<td>Signed</td>
<td>Date</td>
</tr>
<tr>
<td>Corrective action taken</td>
<td></td>
</tr>
<tr>
<td>Signed by responsible person</td>
<td>Date of completion</td>
</tr>
<tr>
<td>Approved by Head</td>
<td>Date</td>
</tr>
<tr>
<td>Verified as acceptable by Quality Department</td>
<td></td>
</tr>
<tr>
<td>Signed by Quality Manager</td>
<td>Date</td>
</tr>
</tbody>
</table>
Error Management

Teaching Aim

To demonstrate the importance of putting systems in place to deal with errors

Core Topics

- Defining errors
- Error policy
- Error reporting
- Error analysis
- Correction, corrective action and preventive action
### Definitions (1)

**Error**
- Something that is wrong, an incident where the quality system has broken down (quality incident)

**Reporting**
- Documenting an error so that it has been noted and so that action can be taken

### Definitions (2)

**Correction**
- Correcting the actual error

**Corrective action**
- Correcting the cause of the error

**Preventive action**
- Procedures put in place to prevent potential errors from occurring

### Definitions (3)

**Compliance**
- Meeting requirements

**Non-compliance**
- Not meeting requirements
Error Policy

- A clear policy on the identification, reporting and investigation of errors
  - Appropriate procedures in place
  - All staff have a responsibility to report errors
  - Senior/supervisory staff must take note of reports and follow the procedure for formal notification and investigation
  - Formal logging of errors, results of investigation, action taken
  - Generates a culture of awareness — not blame

Error Reporting (1)

- What do you report?
- How do you report quality incidents?
- Who do you report quality incidents to?
- Why do you report quality incidents?
  - Action needs to be taken to correct the problem
  - Deficiencies need to be corrected

Error Reporting (2)

- Quality incident reporting system
  - Documented system
  - Triggers an investigation
  - Leads to a conclusion
Error Analysis

- Random errors
  - No pattern
  - Due to ‘one-off’ mistakes
  - Often due to poor training

- Systematic errors
  - Pattern
  - Occur regularly
  - Common cause
  - Often due to poor systems/procedures

Quality Incident

- Any occasion when anything has gone wrong: e.g.
  - A donor has an accident at a blood collection session
  - A wrongly labelled sample
  - Running out of a stock item
  - Failure of a test
- Might involve donors, members of the public, staff, patients
- Can range from trivial to serious

Investigating Errors/Quality Incidents (1)

- Who investigates?
  - The person who finds/reports the incident
  - The manager of the section/department in which the incident occurred
  - The quality department
- Find out what has happened
- Determine what should have happened
Investigating Errors/Quality Incidents (2)

- Determine what needs to be done to correct the problem - correction
  - May require input from quality department/manager
- Determine what needs to be done to deal with the cause of the problem - corrective action
- Determine what needs to be done to prevent any other potential problems - preventive action
  - May require additional review

Investigating Errors/Quality Incidents (3)

- Ensure that all those involved agree with the actions
- Complete the actions and monitor
- Document all steps
- Close the incident

Key Points (1)

- Errors (quality incidents) must be defined clearly
- Systems to report quality incidents need to be in place so that they can then be investigated
- Systems of correction, corrective action and preventive action need to be in place
Key Points (2)

- All staff and users of products/services need to be aware of the systems that are in place
- Quality incidents must be used to improve processes/procedures, not to punish staff

Learning Outcomes

You should now be able to:
- Demonstrate an understanding of errors and their reporting
- Explain the importance of taking action to correct errors and prevent further occurrences
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 8.9</th>
<th>Preparing an SOP on Error Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aim</strong></td>
<td>To provide practice in preparing an SOP on dealing with errors</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ Identifying errors  
♦ Reporting and recording errors  
♦ Analysing errors  
♦ Corrective and preventive action |
| **Key points** | ♦ Reporting of errors is essential  
♦ Staff need to feel able to report errors without fear of punishment |
| **Teaching focus** | ♦ Focus on the benefits of error reporting  
♦ Ensure feedback mechanisms are included  
♦ Reinforce the definition of errors and their reporting  
♦ Emphasize the need for corrective and preventive action |
| **Learning outcomes** | Participants should be able to:  
♦ Write an SOP on error reporting for their BTS  
♦ Clearly define errors, reporting mechanisms and action required |
| **Type of activity** | Group work |
| **Materials** | ♦ QMT 8.8: Example of a Quality Incident Report Form  
♦ Flipcharts  
♦ Pens |
| **Instructions** | 1 Instruct each group of participants to construct a flowchart and SOP for the process of reporting errors.  
2 Instruct them to include appropriate documentation and records for the SOP. |
| **Review of the activity** | ♦ Ensure that the SOPs clearly define errors, their reporting and recording  
♦ Ensure that the SOPs assist users to distinguish between random and systematic errors  
♦ Ensure that the SOPs include steps for corrective and preventive action  
♦ Ensure the SOPs have appropriate documentation and records |
| **Time span** | 1½ hours |
### Audit and Auditing

#### Teaching Aim
To introduce the importance of audits within the quality system

#### Core Topics
- Audits and auditing
- Audit definitions
- Audit planning
- Benefits and value of audits

#### Key Points
- Audits are essential to maintain and improve quality
- Audits should be performed and received as positive events
- Audits should be viewed as "improvement opportunities"
- Appropriate and relevant standards must be used
- All staff should become involved and be able to contribute to the audit and its outcome

#### Teaching Focus
- Reinforce the importance and value of audits
- Stress the importance of preparing for audits
- Consider any relevant national standards

#### Learning Outcomes
Participants should be able to:
- Define quality audit
- List the different types of quality audit
- Describe the audit planning process
- Outline the benefits and value of an audit

#### Slides
1. Title
2. Teaching Aim
3. Core Topics
4. Always Remember!
5. Definitions (1)
6. Definitions (2)
7. General Rules of Audits
8. Types of Quality Audit (1)
9. Types of Quality Audit (2)
10. Characteristics of Quality Audits
11. Audit Planning (1)
12. Audit Planning (2)
13. Audit Planning – Auditor
14. Audit Planning – Auditee
15. Audit Standards (1)
16. Audit Standards (2)
17. What Questions are Answered? (1)
18. What Questions are Answered? (2)
19. The Benefits and Value of Audits
20. Key Points (1)
21. Key Points (2)
22. Learning Outcomes

#### Materials
None
<table>
<thead>
<tr>
<th>Related activity</th>
<th>QMT 8.12 Developing an Audit Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time span</td>
<td>1 hour</td>
</tr>
</tbody>
</table>

**Presentation notes and handling the session**

| Slide 4  | Always Remember! | ♦ The slide states the most important thing to consider regarding audits  
♦ Emphasize that, like everything else in the quality system, audits are of no value if they do not result in improvement or fail to identify problems |
|-----------|------------------|------------------------------------------------------------------|
| Slides 5 - 6 | Definitions (1) & (2) | ♦ The two slides list the definitions of an audit  
♦ The first slide gives a simple explanation; the second gives the ISO definition  
♦ Ensure participants understand the definition of audit and evaluation in the context of quality |
| Slide 7  | General Rules of Audits | ♦ The slide emphasizes the characteristics of an audit that are contained in the ISO definition |
| Slides 8 - 9 | Types of Quality Audit (1) & (2) | ♦ The two slides list the various types of quality audit that can be carried out  
♦ Emphasize that the QMT course focuses on internal auditing |
| Slide 10  | Characteristics of Quality Audit | ♦ The slide contains a "checklist" of the main characteristics of an audit  
♦ Encourage the participants to use the list when planning and carrying out an audit |
| Slides 11 - 12 | Audit Planning (1) & (2) | ♦ The slides provide some general tips on planning an audit  
♦ The point on good preparation is expanded in slides 13 and 14 |
| Slide 13  | Audit Planning – Auditor | ♦ The slide lists the questions that should be asked by the auditor before the audit is conducted |
| Slide 14  | Audit Planning – Auditee | ♦ The slide lists the questions that should be asked and answered by the department being audited |
| Slides 15 - 16 | Audit Standards (1) & (2) | ♦ These two slides remind the participants about the use of quality standards in an audit, as covered in QMT 5.1 and QMT 5.2 |
| Slides 17 - 18 | What Questions are Answered? (1) & (2) | ♦ These two slides list some questions that help to simplify the audit process |
| Slide 19  | The Benefits and Value of Audits | ♦ The slide lists the benefits and value of audits  
♦ Stress the need for involvement of all staff and that audits contribute to continuous improvement of the quality system |
Audits and Auditing

Teaching Aim

- To introduce the importance of audits within the quality system

Core Topics

- Audits and auditing
- Audit definitions
- Audit planning
- Benefits and value of audits
Always Remember!

Audit is a process in which we engage — not a goal that we reach

Definitions (1)

Audit
- Listening and gathering information
- A defined searching examination

Definitions (2)

Quality audit
- Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled — ISO 9000 (2000)
- Systematic, independent and documented examination to determine whether activities comply with the planned and agreed quality system
General Rules of Audits

- Audits are systematic inspections of systems
- Audits are performed against standards appropriate for the organization and activities
- Auditing is a skill that should be taught and developed in a range of staff to augment their specialist skills
- Audits can be performed of any BTS activity

Types of Quality Audit (1)

Internal audit (first party)
  - By staff from the same organization

External audit (second party)
  - Audit of supplier

External audit (third party)
  - Audit by regulatory/statutory body

Types of Quality Audit (2)

System (adequacy) audit
  - Audit of the quality management system

Compliance audit
  - Audit of the implementation of the quality management system
Characteristics of Quality Audits

- Actual practice versus planned practice
- Independent and objective
- Performed by trained, competent staff
- Quantifiable results
- Performed with co-operation
- Proactive

Audit Planning (1)

- Internal audits should be planned on a regular basis as part of an ongoing programme, with all departments aware of the expected timescale.
- External audits are conducted as required by local regulations and should be expected.

Audit Planning (2)

- Good preparation by both auditor and auditee is essential.
- Help and support from the quality department for both auditors and auditees is important.
Audit Planning - Auditor

- What work area is being audited?
- What do they do in this work area?
- What type of audit is appropriate?
- What is the scope of the audit?
- What standards to audit to?
- What is the objective of the audit?
- Has this work area been audited before and have previous findings been taken into account?

Audit Planning - Auditee

- What is to be audited?
- What standards am I being audited to?
- When will the audit take place?
- Who is the auditor?
- What is going to happen?
- Am I prepared?

Audit Standards (1)

- Audits are performed against standards
- The standards must be relevant for the organization and the part of the organization being audited
Audit Standards (2)

- Appropriate BTS standards may include
  - International quality standards such as ISO
  - Good manufacturing practice (pharmaceuticals)
  - Clinical guidelines/practice
  - Agreed international blood transfusion standards

What Questions are Answered? (1)

- Audits ask and answer specific questions
- What should I be doing?
  - Standards
  - Research
  - Common sense

What Questions are Answered? (2)

- Am I doing what I should be doing?
  - Audit (only then do you find out what is happening)
  - Is what I think is happening actually happening?
  - Does what is happening meet the required standards?
The Benefits and Value of Audits

- Continuous improvement
- Independent view
- Communication
- Means of discussing problems
- Increases staff confidence
- Improved understanding of the use and value of standards
- Focuses minds on quality

Key Points (1)

- Audits are essential to maintain and improve quality
- Audits should be performed and received as positive events
- Audits should be viewed as "improvement opportunities"

Key Points (2)

- Appropriate and relevant standards must be used
- All staff should become involved and be able to contribute to the audit and its outcome
<table>
<thead>
<tr>
<th>Learning Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>You should now be able to:</td>
</tr>
<tr>
<td>- Define quality audit</td>
</tr>
<tr>
<td>- List the different types of quality audit</td>
</tr>
<tr>
<td>- Describe the audit planning process</td>
</tr>
<tr>
<td>- Outline the benefits and value of an audit</td>
</tr>
</tbody>
</table>
## QMT 8.11 - The Audit Process

### Teaching aim
To describe the audit process and how to report on the findings.

### Core topics
- Audit process
- Audit reports

### Key points
- The audit process involves the following steps:
  - Preparation
  - Performance
  - Conclusion
  - Report
  - Follow-up
- Audit findings must be documented in the form of a report which should be controlled and follow a defined format
- The audit is incomplete until any corrective action required is taken

### Teaching focus
- Emphasize the need for the auditors to prepare carefully before the audit
- Stress the importance of auditing to the standards
- Emphasize the importance of making the audit a positive experience

### Learning outcomes
Participants should be able to:
- Describe the steps in the audit process
- State the main elements of an audit report

### Slides
- **1** Title
- **2** Teaching Aim
- **3** Core Topics
- **4** Audit Cycle
- **5** Audit Process
- **6** Preparation
- **7** Performance (1)
- **8** Performance (2)
- **9** Performance (3)
- **10** Performance (4)
- **11** Auditing Do’s and Don’ts – Don’ts
- **12** Auditing Do’s and Don’ts – Do’s
- **13** Concluding an Audit
- **14** Reporting
- **15** Report Format (1)
- **16** Report Format (2)
- **17** Report Format (3)
- **18** Follow-Up
- **19** Audit Outcomes
- **20** Key Points (1)
### Key Points (2)

### Learning Outcomes

### Materials

None

### Related activity

QMT 8.12 Developing an Audit Plan

### Time span

¾ hour

### Presentation notes and handling the session

<table>
<thead>
<tr>
<th>Slide 4</th>
<th>Audit Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide provides a diagrammatic representation of the steps in the audit cycle</td>
<td></td>
</tr>
<tr>
<td>♦ The cycle starts with the top right-hand box (set standards)</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that this is a cycle that contributes to continuous quality improvement</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 5</th>
<th>Audit Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The steps listed on this slide are expanded on in detail over the next few slides</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 6</th>
<th>Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Stress the importance of preparing for an audit</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 7 - 10</th>
<th>Performance (1) — (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The four slides list the basic steps in performing an audit</td>
<td></td>
</tr>
<tr>
<td>♦ Involve the participants by asking them what could be done to ensure that each of the steps actually takes place</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 11 - 12</th>
<th>Auditing Do's and Don'ts</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The two slides list the do's and don'ts of an audit</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize that they are both equally important in ensuring a successful audit</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 13</th>
<th>Concluding an Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Stress the importance of concluding an audit in an appropriate manner</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss each point with the participants and review the benefits of carrying out each step in the conclusion</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 14</th>
<th>Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists important points regarding the report of an audit</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to produce the audit report in a timely manner</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slides 15 - 17</th>
<th>Report Format (1), (2) &amp; (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ These slides list the main headings that should be incorporated into an audit report</td>
<td></td>
</tr>
<tr>
<td>♦ Emphasize the need to standardize the report format to prevent confusion</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 18</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ Stress the need to follow-up an audit to ensure continuous improvement</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Slide 19</th>
<th>Audit Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>♦ The slide lists the outcomes of a successful audit</td>
<td></td>
</tr>
<tr>
<td>♦ Discuss with the participants what may happen if the audit is not conducted correctly</td>
<td></td>
</tr>
</tbody>
</table>
The Audit Process

Teaching Aim

- To describe the audit process and how to report on the findings

Core Topics

- Audit process
- Audit reports
Audit Cycle

- Review standards
- Introduce changes
- Agree agenda for changes needed
- Set standards
- Observe practice
- Compare with standards

Audit Process

- Preparation
- Performance
- Conclusion
- Reporting
- Follow-up

Preparation

- Gain the confidence and cooperation of the auditee
  - Plan
  - Obtain background information to review
  - Prepare a checklist
  - Arrange a date and time for the audit
  - Send an agenda
  - Have a pre-audit meeting, if necessary
Performance (1)

- Follow the flow of work
- Promote positive interaction
- Minimize interruptions

Performance (2)

- Review management system
- Review quality assurance system
  - SOPs
  - Records
- Review quality control system
  - QC results
  - Maintenance and calibration records

Performance (3)

- Work with the supervisor
  - Share impressions of compliance and quality during the audit
- Include the workers in the area, but keep this to a minimum
Performance (4)

- Provide feedback during the audit
  - Positive observations will reinforce compliance and quality
  - Negative observations can provide more information and identify areas for improvement

Auditing Do's and Don'ts - Don'ts

Don't
- Make unnecessary criticism
- Make insignificant observations
- Antagonize staff
- Make inappropriate comments
- Use personal beliefs instead of the agreed standards

Auditing Do's and Don'ts - Do's

Do
- Ensure that the purpose of the audit is clear
- Be open and polite
- Be prompt and efficient
- Be constructive
- Thank the staff
Concluding an Audit

- Hold a concluding session with the auditee to:
  - Review observations
  - Reinforce positive findings
  - Agree on negative findings
  - Eliminate vague or subjective observations
  - Agree on action needed and the timescale to correct non-compliances or quality deficiencies
  - Agree on follow-up visit and/or audit date

Reporting

- Documenting the audit findings is essential
- The report contains the findings of the audit presented in a factual and accurate way
- Audit reports:
  - Should be shared with the auditee
  - Should be produced to an agreed common format and within an agreed timeframe
  - Are controlled and confidential documents

Report Format (1)

A common format for audit reports includes:

- An executive summary
  - Indicates the general quality status
  - Highlights positive and negative findings

- Findings
  - Objective
  - Measured against the agreed standards
  - Quantifiable
Report Format (2)

- Recommendations/requirements for corrective action
  - Specific to the problem reported
  - Cross-reference to the standards
  - Include recommended resources needed to correct the problem
  - Person responsible for corrective action

Report Format (3)

- Timeframe for final review of:
  - Completed corrective actions
  - Follow-up visit
  - Next audit

Follow-Up

- Writing the audit report does not mean you have reached the end of the process
- Monitor the corrective actions that have been planned and the agreed time frame
- When the corrective actions have been completed, the audit is complete
- Re-visit the area
Audit Outcomes

- Continuous quality improvement
- The organization's operations become more efficient
- The strength of the organization increases
- Staff motivation improves
- Everyone is happy

Key Points (1)

- The audit process involves the following steps
  - Preparation
  - Performance
  - Conclusion
  - Report
  - Follow-up

Key Points (2)

- Audit findings must be documented in the form of a report which should be controlled and follow a defined format
- The audit is incomplete until any corrective action required is taken
# Learning Outcomes

You should now be able to:

- Describe the steps in the audit process
- State the main elements of an audit report
<table>
<thead>
<tr>
<th>QMT 8.12</th>
<th>Developing an Audit Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aims</strong></td>
<td>To provide participants with practice in preparing an audit plan</td>
</tr>
</tbody>
</table>
| **Key Points** | ♦ Audit plans should be simple  
♦ Audit plans should reflect the standards being used  
♦ Pre- and post-audit meetings are essential |
| **Core topics** | ♦ Types of audit  
♦ Using standards as a basis for an audit |
| **Teaching focus** | ♦ Remember that the course does not aim to train auditors, but to give participants a tool for monitoring their quality system  
♦ Ensure participants’ plans are simple and appropriate |
| **Learning outcomes** | Participants should be able to:  
♦ Design an audit plan |
| **Type of activity** | Group work |
| **Materials required** | ♦ Flipcharts  
♦ Pens  
The participants will have to use a certain amount of creativity, but it would be helpful if you can provide examples of the following:  
♦ SOPs from each relevant area  
♦ BTS quality policy and/or standards  
♦ Specifications, where relevant  
♦ Testing strategies |
| **Instructions** | 1 Allocate one of the following areas to each group:  
♦ Blood collection  
♦ ABO and RhD typing of donated blood  
♦ Production of packed red cells  
♦ HIV testing.  
2 Instruct them to design an audit plan for the area, deciding on the following:  
♦ Type of audit  
♦ Standards that will be used. |
| **Review of the activity** | Ensure that the plans include the following features:  
♦ Selection of the audit team and leader  
♦ A timeframe  
♦ A pre-audit meeting  
♦ Standards for the audit  
♦ The type of audit  
♦ The scope of the audit  
♦ Objectives  
♦ A checklist for the audit  
♦ A concluding meeting |
| **Time span** | 1 hour |
### ACTIVITY

<table>
<thead>
<tr>
<th>QMT 8.13</th>
<th>Identifying Non-Compliances Against a Set of Standards</th>
</tr>
</thead>
</table>
| **Teaching aims** | ♦ To illustrate a typical audit situation  
♦ To provide practice in identifying non-compliances and observations in an audit situation |
| **Core topics** | ♦ Identifying non-compliances  
♦ Relating non-compliances to audit standards  
♦ Defining observations |
| **Key points** | ♦ The auditor must be able to identify and understand the key quality elements in a procedure  
♦ It is important to be very specific about non-compliances identified and document them carefully |
| **Teaching focus** | ♦ Ensure that participants understand the aim of the activity  
♦ Encourage questions about the players’ audit technique  
♦ Ensure all non-compliances are identified |
| **Learning outcomes** | Participants should be able to:  
♦ Identify non-compliances from observations made during an audit |
| **Type of activity** | Role play |
| **Materials required** | ♦ Scenario  
♦ Local standard for use in audit  
♦ Flipchart  
♦ Pens |
| **Instructions** | 1 Identify two people to assist with the acting of the scenario.  
2 "Act" out the scenario without interruptions.  
3 Split the class into two groups:  
♦ The first group stays in the training room and carries out the instructions in point 4  
♦ The second group goes with the facilitator and carries out QMT 8.14: Audit of a Work Area  
♦ When the second group completes the activity, they return to the training room and carry out the instructions in point 4  
♦ The first group proceeds with the facilitator for their audit of a work area.  
4 Instruct the participants to analyse the scenario step-by-step and identify and document the non-compliances, noting the appropriate standard.  
5 Distribute the standard for use in the audit. |
| **Review of the activity** | ♦ Ensure that any non-compliance identified is based on objective observation  
♦ Ensure that the standard is used as the reference point  
♦ Allow discussion to encourage participants to recognize that observations can relate to non-compliance against several separate standards |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time span</strong></td>
<td>1½ hours</td>
</tr>
</tbody>
</table>
Identifying Non-Compliances against a Set of Standards

A Hospital Services Department is being audited at South Colinbridge Blood Centre

**Auditor** Can you tell me what you are doing?

**Bob:** I’m entering the hospital requests that were received this morning on the computer. You see, they phone in and we write it on these pads, then we enter them on here.

**Auditor:** I notice some of the forms have been altered. Why is that?

**Bob:** Well, we have to add some extra ABs to all the requests, otherwise they will go out of date.

**Auditor:** How do you know how many extra the hospitals need?

**Bob:** Oh, we guess – we know roughly what they’ll accept and besides they are getting more for the same money! If they don’t use them, we give them credit.

**Auditor:** So you don’t check with the hospitals first?

**Bob:** No.

The auditors move on to the Issues cold room

**Auditor:** Why are some of these red cell units in boxes and some in crates?

**Shirley:** The ones in the boxes have been issued to hospitals and the ones in the crates are stock.

**Auditor:** Some crates are stacked with the boxes. Are they issued or stock?

**Shirley:** Oh, they’ve been issued, but we’ve run out of boxes.

**Auditor:** All the boxes have labels on, with the hospital destination printed on. What about the crates?

**Shirley:** Oh, I’ve got the labels here – I’ll put them on as soon as some more boxes turn up. I issued them all, so I know which are which.

**Auditor:** Why did you run out of boxes?

**Shirley:** I ordered them ages ago, but when they came the inserts didn’t fit, so we sent them back.

**Auditor:** Didn’t anyone check them when they arrived?

**Shirley:** Well, I know the stores manager checks the deliveries against the purchase order, but I think I ordered the wrong inserts. I don’t usually do the ordering, but the boss was away at the time. I followed the correct procedure. Just a silly mistake.
Auditor: It's very cold in here, what's the temperature?
Shirley: It's 4 degrees.
Auditor: How do you know?
Shirley: There's a thermometer on the wall – there, it reads 7.5.
Auditor: How do you know it's reading correctly?
Shirley: It's brand new!!
Auditor: Has it been checked at all?
Shirley: It will be checked by QA when it's a year old.
Auditor: Are there any other temperature monitoring devices here?
Shirley: Yes, every storage area has a thermometer. I'll show you. They all have a sticker from QA to show that they're working and I have a list in the office that shows when they were last checked.
Auditor: Can you show me?
Shirley: Yes, here it is. I have to sign each time it's checked. Look.
Auditor: I see Bob has checked some. Is that allowed?
Shirley: Well, I think so. He's always ready to help out if I'm not here.
Auditor: How do you know what to do, for example, if the results are out of limits?
Shirley: Oh well, QA left an SOP here and showed me what to do. I had to sign this form to show that I had been trained.
Auditor: What about Bob? His name isn't here.
Shirley: I showed Bob what to do because QA were too busy.
Auditor: Going back to the thermometer on the wall, how warm does it have to get before someone does something?
Shirley: What do you mean?
Auditor: Isn't 7.5 degrees too warm?
Shirley: Yes, but QA will tell us what to do if it gets warm or cold for too long. They've got their own system.
Auditor: What do you use that thermometer for then?
Shirley: Oh, that's just for us. We check the temperature every day.
Auditor: Is that recorded?
Shirley: Yes, there's a form in the office.
Auditor: Can you show me?
Shirley: Yes, here we are – oh, I see that it's been the same for the last two days.
Auditor: Should those boxes on the form be signed?
Shirley: Yes, but Bob sometimes forgets.
Auditor: Is there anything written down that tells you what to do if the refrigerator is too warm?
Shirley: I’m not sure. We wait for QA to tell us. They may have something.
Auditor: OK. Can I watch something being issued?
Shirley: Yes, follow me. Bob’s doing some now. He’s new to this, but I showed him what to do last week.
Auditor: Is the procedure written down anywhere?
Shirley: Yes, that’s the SOP that Bob’s looking at now.
Auditor: I notice there are some hand-written changes.
Shirley: Yes, we had some new software delivered last week, so we had to make some small changes.
Auditor: I see.
Auditor: You mentioned earlier that some ABs get wasted. How many?
Shirley: Hardly any at all. We manage to get rid of most of them.
Auditor: Do you keep any statistics on how much goes to waste?
Shirley: I keep a complete list. We have to know what happens to every unit.
Auditor: Does anybody else look at the list?
Shirley: No, I don’t think so.
Auditor: Shirley, thank you very much. You have been very helpful – please thank Bob for me too.
### ACTIVITY

**QMT 8.14 Audit of Work Area**

<table>
<thead>
<tr>
<th>Teaching aims</th>
<th>To illustrate the experience of an audit from the perspective of an auditor</th>
</tr>
</thead>
</table>
| Core topics   | ♦ Using an audit plan to conduct an audit  
♦ Identifying non-compliances |
| Key points    | ♦ Audits must be performed in a professional, sensitive and positive way  
♦ Successful audits are systematic  
♦ It is essential to have pre- and post-audit meetings to outline the process and review the findings |
| Teaching focus| ♦ Ensure the participants understand the aim of the activity  
♦ Ensure that all members of the groups are involved  
♦ Reinforce the importance of recording observations  
♦ Invite the auditees to participate in the review of the audit |
| Learning outcomes | Participants should be able to:  
♦ Demonstrate an understanding of the audit process |
| Type of activity | Group work |
| Materials required | The facilitators must prepare the following materials:  
♦ An audit plan  
♦ A checklist for the audit |
| Preparations   | ♦ In order for this activity to succeed, collaboration with the course coordinator is necessary to identify an area in the BTS that can be audited within the rules given to the participants  
♦ Prepare an audit plan and checklist for a section of the area in the BTS, as agreed with the course coordinator  
♦ Ensure that you have met with the supervisor and that timings and the plan and checklist are acceptable to them |
| Instructions   | 1 Conduct the audit according to the plan and checklist.  
2 Ensure that you remain in control of the audit. Do not let the participants take over the process. If they wish to ask questions, they may do so, but only through you as the auditor.  
3 Invite the supervisor to attend the review session. |
| Review of the activity | ♦ Use the review as a summary session, as follows:  
− Comment on positive findings  
− Discuss negative findings with the supervisor  
♦ Discuss the observations that you have made and invite the participants to add any they feel you have omitted  
♦ Ensure observations participants are objective; explain why you, as an auditor, would reject them if they are not  
♦ Ensure that the observations concentrate on the standards that have been used for the audit |
<p>| Time span      | 1½ hours |</p>
<table>
<thead>
<tr>
<th>QMT 8.15</th>
<th>Analysing Quality System Failures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Teaching aims</strong></td>
<td>To illustrate the problems that can occur without good quality systems</td>
</tr>
</tbody>
</table>
| **Core topics** | ♦ System failures affect quality  
♦ Minor errors can combine to create one serious failure in the quality system |
| **Key points** | ♦ The consequences of quality failure can be serious  
♦ An analysis of failures often identifies a number of minor errors as the cause |
| **Teaching focus** | ♦ Explain the activity clearly  
♦ Ensure all participants take part  
♦ Keep the role-play light-hearted and fun  
♦ Ensure that all the quality failures are identified |
| **Learning outcomes** | Participants should be able to:  
♦ Explain how system failures can affect the quality of products and services  
♦ Demonstrate an ability to identify errors and potential errors in processes |
| **Type of activity** | Role play |
| **Materials required** | ♦ In this activity, small sweets (candy) called "Smarties", or an equivalent type called "M&Ms", are used. If Smarties or M&Ms are unavailable, use coloured sweets of uniform size that come in at least two different colours  
♦ Scenario: Smartosis Cocoanaemia  
♦ Activity Summary  
♦ Player Briefs  
♦ Smartie Issue Log  
♦ Urgent Recall Notice  
♦ Transfusion Record  
♦ Hospital Bank Issue Log  
♦ Clinical Outcomes  
♦ Flipcharts  
♦ Pens |
| **Preparations** | ♦ Smarties: prepare 6 containers that hold the appropriate number and colour of Smarties marked, as detailed in the Activity Summary, with:  
− Patient number  
− Batch number  
− Hospital name  
− Donation number  
♦ All Smarties must be the same colour, except those for Patient 3 |
♦ All Smarties for Patient 3 must be the same colour as each other, BUT a different colour from the other patients: e.g. the Smarties for Patients 1, 2, 4, 5 and 6 are red and the Smarties for Patient 3 are blue

♦ The box of Smarties for Patient 4 should contain only 5 Smarties

♦ Photocopy the following materials for use by participants:

<table>
<thead>
<tr>
<th>Item</th>
<th>No. of copies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario: Smartosis Cocoanaemia</td>
<td>1</td>
</tr>
<tr>
<td>Player brief: Smartie Bank Issue Clerk</td>
<td>1</td>
</tr>
<tr>
<td>Player briefs: Patients 1–5</td>
<td>5</td>
</tr>
<tr>
<td>Player brief: Patient 6</td>
<td>1</td>
</tr>
<tr>
<td>Player briefs: Doctors 1–5</td>
<td>5</td>
</tr>
<tr>
<td>Player brief: Doctor 6</td>
<td>1</td>
</tr>
<tr>
<td>Player briefs: Nurses 1–5</td>
<td>5</td>
</tr>
<tr>
<td>Player brief: Nurse 6</td>
<td>1</td>
</tr>
<tr>
<td>Player briefs: Hospital Bank Clerks</td>
<td>2</td>
</tr>
<tr>
<td>Player briefs: Delivery Drivers</td>
<td>2</td>
</tr>
<tr>
<td>Player brief: Quality Manager</td>
<td>1</td>
</tr>
<tr>
<td>Smartie Issue Log</td>
<td>1</td>
</tr>
<tr>
<td>Urgent Recall Notice</td>
<td>1</td>
</tr>
<tr>
<td>Transfusion Record</td>
<td>6</td>
</tr>
<tr>
<td>Hospital Bank Issue Log</td>
<td>2</td>
</tr>
</tbody>
</table>

♦ Cut the page containing the clinical outcomes into six pieces, so that there is a small slip of paper showing the outcome for each individual patient. Place the pieces of paper in sealed envelopes or fold them so that they cannot be easily read

Instructions

1 Identify a "player" for each of the following:
   ♦ 1 Smartie Bank clerk
   ♦ 6 patients
   ♦ 6 doctors
   ♦ 6 nurses
   ♦ 2 hospital bank clerks
   ♦ 2 drivers
   ♦ 1 quality manager.

   You will need a maximum of 24 players and a minimum of 17 (you can omit the nurses and 1 driver, if necessary).

2 Arrange the participants according to their roles:
   ♦ Seat the doctors, patients and nurses together
   ♦ Seat the hospital bank clerks so that they are fairly close to their respective hospital patients, but separate from them
   ♦ Place the quality manager and Smartie Bank clerk together.
3 Instruct each player on their roles, distributing the appropriate Player Briefs (written instructions).

4 Go through participants’ roles on an individual basis, ensuring they fully understand what they are meant to do and the importance of compliance with what is written in their individual briefs.

5 Hand the slips of paper with the clinical outcomes to the respective patients, reminding them not to open their piece of paper until you tell them to and not to show it to anyone else.

6 Explain the activity and make sure that each player understands what is required. Stress that the acting and accuracy of the scenario are not critical, but getting the message across and understanding the issues are.

7 Keep the role play fun and control the activity at all times; make it run smoothly.

8 Read out the scenario and talk through the activity, giving all the participants their individual cues.

9 Begin the role play:

   ♦ Instruct the "patients" to be ill
   ♦ Once the doctors have made the diagnosis of Smartosis Cocoanaemia, they must instruct the nurses to contact their hospital’s bank clerk and order a dose of Smarties; this can be done by "telephone"
   ♦ The hospital bank clerks then phone the Smartie Bank and order the appropriate number of doses
   ♦ The Smartie Bank clerk tells them to send a driver to collect the Smarties
   ♦ The drivers are then sent to the Smartie Bank to collect the doses
   ♦ The doses are delivered to the hospital bank clerks and duly noted in their issue logs
   ♦ The nurses collect the appropriate patients’ doses
   ♦ Smarties are then given to the patients, except Patient 6 who gets better before receiving his/her treatment
   ♦ About halfway through the Smarties being given, draw the attention of the participants to the quality manager who will – in a panic – report to the Smartie Bank clerk that a batch is defective; between them, they decide to recall the batch
   ♦ The Smartie Bank clerk phones the hospital and gives the recall notice and number
   ♦ The hospital clerk, in turn, calls the ward who inform him/her that the dose was not used and agree to return it
   ♦ The driver returns the dose to the Smartie Bank clerk
   ♦ At this point, Patients 1– 5 should have completed their treatment
   ♦ Call everyone’s attention to the patients; instruct the patients to open their slips of paper with their individual clinical outcomes and carry out what it says on the paper
   ♦ Allow the participants a little time to absorb the fact that some of the patients have died.

10 Review the outcomes as below.
| Clinical outcomes | Patient 1 – Patient dies, faulty batch of product not recalled, no record of dispatch of the batch to that hospital  
Patient 2 – Patient survives: no errors  
Patient 3 – Patient dies: contaminated individual product  
Patient 4 – Patient dies: wrong dose given  
Patient 5 – Patient survives: no errors  
Patient 6 – Patient survives: product recalled before transfusion |
| Review of the activity | ♦ Ensure that the discussion focuses on the whole series of events, starting from the issue of the Smarties from the Smartie Bank  
♦ Discuss each patient’s outcomes, analysing the details of the Smartie transfusion and identifying any quality failures  
♦ In each case of quality failure, discuss the quality system elements that could have prevented the failure  
♦ Ensure the following issues are raised:  
  – Training  
  – SOPs  
  – Records of issue and transfusion  
  – General documentation  
  – Poor GMP resulting in a contaminated batch |
SCENARIO

SMARTOSIS COCOANAEMIA

Read out the following paragraphs just before instructing the patients to be ill.

Smartosis Cocoanaemia is a serious condition affecting up to 50% of the population. It is caused by a lack of chocolate, brought on by a severe Smartie deficiency. If left untreated, the condition causes damage to the nervous system, resulting in death. The progress of this disease is rapid, with many patients dying within 6 hours of diagnosis. Fortunately, there is a simple and readily available cure in the form of Smartie transfusion. The success rate of the treatment is 100%.

There are six patients who have just been admitted to hospital. Five patients are in St Helpus, a large teaching hospital, and one patient is in a small private clinic, St Saveus.
# Activity Summary

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Hospital</th>
<th>Donation number</th>
<th>Lot number</th>
<th>Smarties</th>
<th>Outcome</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>St Helpus</td>
<td>G07359911237</td>
<td>B9812</td>
<td>Box of 6, correct colour</td>
<td>Patient dies</td>
<td>Faulty batch, batch recalled, Smartie Bank issue system does not indicate that this product was issued to the hospital as it was not logged</td>
</tr>
<tr>
<td>2</td>
<td>St Helpus</td>
<td>G07359911240</td>
<td>A9812</td>
<td>Box of 6, correct colour</td>
<td>Patient recovers</td>
<td>No errors</td>
</tr>
<tr>
<td>3</td>
<td>St Helpus</td>
<td>G07359911241</td>
<td>A9812</td>
<td>Box of 6, wrong colour</td>
<td>Patient dies</td>
<td>Batch OK, but product contaminated</td>
</tr>
<tr>
<td>4</td>
<td>St Helpus</td>
<td>G07359911242</td>
<td>A9812</td>
<td>Box of 5, correct colour</td>
<td>Patient dies</td>
<td>Wrong dose given</td>
</tr>
<tr>
<td>5</td>
<td>St Helpus</td>
<td>G07359911243</td>
<td>A9812</td>
<td>Box of 6, correct colour</td>
<td>Patient recovers</td>
<td>No errors</td>
</tr>
<tr>
<td>6</td>
<td>St Saveus</td>
<td>G07359911238</td>
<td>B9812</td>
<td>Box of 6, correct colour</td>
<td>Patient recovers</td>
<td>Recalled in time, patient given different batch</td>
</tr>
</tbody>
</table>
PLAYER BRIEF

Smartie Bank Issue Clerk

You are responsible for taking requests for Smarties from hospitals, preparing the orders and issuing them to the hospital. To issue the Smarties, they must be logged out through the computer system. The record of this has been produced for you as the Smartie Issue Log. All you have to do when you issue the Smarties is to put the date in the space provided at the top of the form.

You hold telephone conversations with the hospital Smartie Bank clerks. They both phone up to order their routine stocks of Smarties. You need to find out which hospital they are calling from and how many doses they each need. Instruct the hospitals to send their drivers to collect the dose(s).

Give the driver the prepared Smartie doses and ask him to deliver them to the hospital. If there is only one driver, the player will be the Smartie Bank’s driver. When you have received all the orders, send your driver to the appropriate hospitals to deliver the doses. Make sure that the right doses get to the right hospitals: Patients 1–5 are at St Helpus Hospital and Patient 6 is at St Saveus Hospital.

The Quality Manager will then tell you there has been a recall of the batch of Smarties and gives you the Recall Notice. You don’t know what to do and have to ask him/her what action to take. He/she does not know either, so you look at your issue log and find out the hospital(s) to which you have issued that batch of products.

You telephone the hospital clerk at the hospital(s) that have received the products to try and get them back before they are used. You have to make sure that the hospital Smartie Bank clerk(s) phones the ward(s) urgently to find out if the Smarties have been used. Make sure that the clerk gets the products back and calls you back to let you know that they have them.

Send the driver to collect the products and log the donation number(s) of the retrieved products on the Recall Sheet. Tell the Quality Manager that you have retrieved the products issued from the defective batch.

You have no SOPs for the issue or recall of products, but you have done the job for many years and it has developed around you.

You need:
♦ These instructions
♦ Smartie Issue log
♦ Recall Notice and Recall Log
♦ Pen.
PLAYER BRIEFS

Patients (1–5)

You are critically ill with an acute condition that can be successfully treated with the administration of a dose of 6 Smarties. You only have to act as though you are suffering when told to do so. At the beginning of the activity you will be given a number from 1–6. Do not forget this number as you need to partner with the doctor (and nurse if there are enough "players") who has the same number as you.

You should eat your Smarties as instructed by your doctor. You will be given a folded piece of paper at the beginning of the activity with the final clinical outcome for you written on it. Do not open it until told to. Don’t show anybody else what is written on your piece of paper.

Patient 6

You are critically ill with an acute condition that can be successfully treated with the administration of a dose of 6 Smarties. You only have to act as though you are suffering when told to do so. At the beginning of the activity you will be given Number 6. Do not forget this number as you need to partner with the doctor (and nurse if there are enough "players") who has the same number as you.

When the doctor has received your dose of Smarties from the hospital issue clerk, you suddenly start to feel better and the doctor will decide that he has made the wrong diagnosis and will not give you the Smarties to eat. You will be given a folded piece of paper at the beginning of the activity with the final clinical outcome for you written on it. Do not open it until told to. Don’t show anybody else what is written on your piece of paper.
Doctors 1–5

Your patient becomes ill and you will make a diagnosis of Smartosis Cocoanaemia. Instruct the nurse, if you have one, to order one dose of 6 Smarties for your patient.

When you receive the dose of Smarties and a Transfusion Record form, instruct the nurse to record the details on the Transfusion Record form. If there is no nurse, record these details yourself.

The Smarties must be given to the patient one at a time and the transfusion of each one should be recorded on the Transfusion Record as detailed in the nurse’s instructions. All Smarties must be given within 2 minutes of starting transfusion.

Doctor 6

Your patient becomes ill and you will make a diagnosis of Smartosis Cocoanaemia. Instruct the nurse, if you have one, to order one dose of 6 Smarties for your patient.

When you receive the dose of Smarties and a Transfusion Record form, instruct the nurse to record the details on the Transfusion Record form. If there is no nurse, record these details yourself.

However, your patient will become better and, on reassessment, you decide that his/her condition is not as serious as you first thought and that the transfusion is not necessary at this time. You keep the Smarties on the ward for a while until you decide whether you need to use them or not. You, or the nurse, will receive a call from the hospital bank clerk requesting you to verify that you have received the batch they are asking about. He/she will then ask you to return the dose, which you do.
Nurses 1–5

On instruction from the doctor, you contact the hospital Smartie Bank to order a dose of Smarties for your patient. When they are received from the Smartie Bank, the hospital clerk will contact you and you will fetch the Smarties. When you return to the ward, you record the required information on the Transfusion Record about the dose of Smarties given and their transfusion, ensuring that all the required information is recorded:

- Hospital
- Patient identification number
- Smartie donation number
- Smartie batch number
- Colour of the Smarties

Give the dose of Smarties to your patient. It is important that you tick each box on the Transfusion Record as you give each Smartie to the patient.

Nurse 6

On instruction from the doctor, you contact the hospital Smartie Bank to order a dose of Smarties for your patient. When they are received from the Smartie Bank, the hospital clerk will contact you and you will fetch the Smarties. When you return to the ward, you will record the required information on the Transfusion Record about the dose of Smarties, ensuring that all the required information is recorded:

- Hospital
- Patient identification number
- Smartie donation number
- Smartie batch number
- Colour of the Smarties

Your patient will get better. Do not give the dose of Smarties. Record this information on the Transfusion Record.
PLAYER BRIEFS

Hospital Bank Clerk, St Helpus

You are the liaison between the hospital and the Smartie Bank. You will receive an order for Smarties from five different patients whose "names" are "Patient 1" to "Patient 5", from the nurses or doctors.

You phone through to the Smartie Bank clerk to make your order. You ask for 5 doses of Smarties giving your hospital details. The Smartie Bank clerk will ask you to send the driver to collect the doses. Ask the driver to do this. **If there is only one driver in the role play, the Smartie Bank clerk will tell you that he will send the dose.**

When the driver returns, enter the Smartie donation number, batch number and the date received on the Hospital Bank Log. When the doctors or nurses come to the bank for the Smartie doses, you hand the dose over after recording the issue date and appropriate patient number on the issue log. The doses will already be marked with the patient numbers. Ensure you enter the correct details and hand the correct patient dose to the appropriate nurse/doctor.

You have no SOPs for the receipt or issue of Smarties, but have done the job for many years and it has developed around you.

Hospital Bank Clerk, St Saveus

You are the liaison between the hospital and the Smartie Bank. You will receive an order for Smarties for Patient 6 from the nurse or doctor.

You phone through to the Smartie Bank clerk to make your order. You ask for 1 dose of Smarties, giving your hospital details. The Smartie Bank clerk will ask you to send the driver to collect the dose. Ask the driver to do this. **If there is only one driver in the role play, the Smartie Bank clerk will tell you that he/she will send the dose.**

When the driver returns, enter the Smartie donation number, batch number and the date received on the Hospital Bank Log. When the doctor or nurse comes to the Smartie Bank for the Smartie dose, you hand the dose over after recording the issue date and patient number (6) on the issue log.

Later in the role play, you will receive a phone call regarding the recalled batch. You do not know what to do, but eventually decide to phone the ward. Phone the doctor/nurse and inform them that the batch has been recalled. When they tell you that they have not used it, ask them to return the dose to you. When you receive the batch back, ask the driver to return it to the Smartie Bank.

You have no SOPs for the receipt or issue of Smarties, but have done the job for many years and it has developed around you.
PLAYER BRIEF

Delivery Driver(s)

You will collect the Smartie doses and deliver them to the appropriate hospital.

If you are the only driver in the role play, you will belong to the Smartie Bank and will follow the clerk’s instructions.

You are on an emergency and are expected to use sirens.
Quality Manager

When the Smarties have been delivered and have already been given to the patients, you will initiate the recall. However, you don’t actually have a documented system and don’t really know what to do as this is the first time that this has happened.

You check the issue log with the Smartie Bank clerk and identify the only hospital in the log that has received the problem batch. When the dose is identified and returned, you assume that the problem is solved as the only issued product has been retrieved.
SMARTIE ISSUE LOG

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Donation number</th>
<th>Batch number</th>
</tr>
</thead>
<tbody>
<tr>
<td>St Saveus</td>
<td>G07359911238</td>
<td>B9812</td>
</tr>
<tr>
<td>St Barts</td>
<td>G07359911239</td>
<td>A9812</td>
</tr>
<tr>
<td>St Helpus</td>
<td>G07359911240</td>
<td>A9812</td>
</tr>
<tr>
<td>St Helpus</td>
<td>G07359911241</td>
<td>A9812</td>
</tr>
<tr>
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<td>G07359911242</td>
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</tr>
<tr>
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<td>G07359911243</td>
<td>A9812</td>
</tr>
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<td>G07359911244</td>
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<td>G07359911245</td>
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</tr>
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<td>G07359911247</td>
<td>A9812</td>
</tr>
<tr>
<td>St Barts</td>
<td>G07359911248</td>
<td>A9901</td>
</tr>
<tr>
<td>The Middlesex</td>
<td>G07359911249</td>
<td>A9901</td>
</tr>
<tr>
<td>The Middlesex</td>
<td>G07359911250</td>
<td>A9812</td>
</tr>
<tr>
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<td>C9812</td>
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<tr>
<td>The Middlesex</td>
<td>G07359911254</td>
<td>A9812</td>
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<tr>
<td>St Barts</td>
<td>G07359911255</td>
<td>A9812</td>
</tr>
<tr>
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<td>G07359911258</td>
<td>C9812</td>
</tr>
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<td>Basildon</td>
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<td>Basildon</td>
<td>G07359911260</td>
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</tr>
<tr>
<td>Basildon</td>
<td>G07359911261</td>
<td>A9812</td>
</tr>
</tbody>
</table>
URGENT RECALL NOTICE

The following batch of Smarties has failed to meet required specifications and has been withdrawn from stock: **Batch: B9812**.

No Smarties from this batch must be used. They must be returned to the Smartie Bank immediately. Record all return or usage details below.

(Signed)

Quality Manager: Date:

<table>
<thead>
<tr>
<th>Log of Returned Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donation number</td>
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<tr>
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</tbody>
</table>
## Transfusion Record

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>Patient number</td>
<td></td>
</tr>
<tr>
<td>Smartie donation number</td>
<td></td>
</tr>
<tr>
<td>Smartie batch number</td>
<td></td>
</tr>
<tr>
<td>Smartie colour</td>
<td></td>
</tr>
</tbody>
</table>

Dose record (tick boxes in turn after the administration of each dose to the patient)

- [ ]
- [ ]
- [ ]
- [ ]
- [ ]

**Comments**

Transfusion performed by:  

Date:  

Signature:
### HOSPITAL BANK ISSUE LOG

<table>
<thead>
<tr>
<th>Donation number</th>
<th>Batch number</th>
<th>Date received</th>
<th>Date issued</th>
<th>Issued to</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
CLINICAL OUTCOMES

Patient 1  Dies

Patient 2  Recovers

Patient 3  Dies

Patient 4  Dies

Patient 5  Recovers

Patient 6  Recovers
### Teaching aim
To assess participants' broad understanding of Modules 1–8

### Core topics
- Determining participants’ knowledge and understanding of quality principles in comparison with the pre-course assessment

### Key points
- The mid-course assessment is not an examination
- It will help facilitators to identify participants' particular needs in relation to Part 2 of the course

### Teaching focus
- Ensure that participants understand that the assessment is not an examination

### Learning outcomes
Participants should be able to:
- Demonstrate improved knowledge and competence in the topics covered in Modules 1–8

### Type of activity
Multiple-choice questions

### Materials
- QMT 8.16: Mid-Course Assessment Questions
- QMT 8.16: Mid-Course Assessment Answers
- Pens

### Instructions
1. Instruct the participants to answer the questions on the questionnaire.
2. Encourage them not to guess the answers.

### Review of activity
- During your next available free time, mark the participants' responses, using the grid in QMT 8.16: Mid-Course Assessment Answers, to identify participants’ further learning needs
- Note the results
- Return the marked sheets to participants

### Time
½ hour
1. The quality of a product or a service denotes:
   a. High cost
   b. Fitness for the purpose
   c. Quick results and efficacious products
   d. Sophistication and complexity of the process

2. ISO is:
   a. Internal Services Office
   b. International Organisation for Standardisation
   c. International Safety Organization
   d. Instant Solutions Offer

3. The relationship between the results achieved and the resources used is:
   a. Efficiency
   b. Effectiveness
   c. Precision
   d. Verification

4. The initial draft of a standard operating procedure should be written by:
   a. Person performing the procedure
   b. Quality manager
   c. Technical head of the blood bank
   d. An expert committee

5. A system of activities that uses resources to transform inputs into outputs is defined as:
   a. Procedure
   b. Process
   c. Plan
   d. Performance
6. The fulfilment of a requirement is defined as:
   a. Conformity
   b. Characteristic
   c. SOP
   d. Audit

7. The implementation of quality in blood banks is the responsibility of:
   a. The quality manager only
   b. The technical head of the blood bank only
   c. External auditors
   d. All staff members of the blood bank

8. A quality policy is officially endorsed and approved by the:
   a. Top management of the blood bank
   b. Quality Manager
   c. Customer
   d. Technical professionals of the blood bank

9. The overall intentions and direction of an organization in relation to quality, as formally expressed by top management is:
   a. Quality objective
   b. Quality policy
   c. Quality management system
   d. Quality planning

10. A document stating the quality policy and describing the quality system of an organization is called:
    a. Quality manual
    b. Guidelines
    c. Specifications
    d. Quality plan

11. A job description includes all of the following except:
    a. Key tasks to be performed
    b. Minimum qualifications and experience
    c. Position in the organization’s organogram
    d. Career advancement prospects
12 **Standard operating procedures (SOPs):**
   a. Are guidelines for screening of transfusion-transmissible infections
   b. May be used by some staff members sometimes
   c. Are designed to help newly recruited and inexperienced technical staff to develop confidence and acquire skills
   d. Must be followed strictly by all staff members at all times

13 **SOPs should be accessible to:**
   a. Senior staff only
   b. All relevant staff all the time
   c. Staff when they encounter problems in performing procedure
   d. All staff only on demand

14 **The following documents need to be controlled:**
   a. Quality manual
   b. Standard operating procedures
   c. Donor records
   d. List of approved suppliers
   e. All of the above

15 **The part of quality assurance that ensures that products are consistently produced and controlled to quality standards appropriate to their intended use is called:**
   a. Good Manufacturing Practice (GMP)
   b. Good Laboratory Practice (GLP)
   c. Good Clinical Practice (GCP)
   d. Internal quality control

16 **A quality audit is:**
   a. A systematic, independent and documented examination to determine whether quality activities comply with planned arrangements
   b. An evaluation of conformity by observation and judgement
   c. An activity that ensures correct financial procedures

17 **Competency assessment of staff includes all the following except:**
   a. Written evaluation
   b. Review of work records
   c. Testing of unknown samples
   d. Gross salary received
   e. Problem solving skills
18 A stock card is characterized by the following except:
   a A simple and efficient stock control system
   b A record of the order, delivery and use of each item
   c Decides next order and quantity to order
   d Ensures excessive stocks are always available
   e Helps at each time of issue, order or delivery of stock

19 The following essential information should be retained for stock control except:
   a Minimum stock level
   b Minimum order
   c Code number of consumables
   d Test in which consumable is to be used

20 The method most suitable for ordering consumables with a long expiry period if you have sufficient resources and storage space is:
   a Bulk order
   b Standing order
   c Order as required

21 Which of the following does not apply to an external quality assessment (EQA) scheme?
   a Organized by an external agency
   b Does not require follow up
   c Periodic
   d Compares performance at different sites

22 Material received by a participating blood bank for external quality assessment should be analyzed:
   a By the quality manager alone
   b By the most skilled worker
   c With specially procured and exclusive reagents
   d In the same manner as routine work

23 A unique number must be assigned to each donation of blood. To which of the following should this number be attached?
   a The primary collection bag only
   b The primary and all secondary collection bags only
   c The primary, all secondary collection bags and all specimen tubes used only
   d The primary, all secondary collection bags, all specimen tubes used and donation record
24 The following applies to storage areas for blood and blood components:
   a Quarantined components should be stored with non-conforming blood components
   b Tested (available) units should be stored separately from partially tested or untested (quarantined) blood components
   c Quarantined components should be stored with expired blood components

25 Quality monitoring of processed blood components is performed to:
   a Find reasons not to make blood components
   b Research new techniques for making blood components
   c Ensure that the final product meets specifications and that the process is "in control"
   d Keep the quality manager happy

26 The identification of a patient receiving transfusion should be carried out:
   a By the patient’s bedside immediately before transfusion
   b At the nurses’ station before transfusion
   c During the transfusion
   d After the transfusion

27 The documentation required in the preparation of blood components includes:
   a Approved SOPs and records of all key activities ranging from the receipt of whole blood to the distribution of released components to hospitals and blood banks for compatibility testing
   b Validation protocol for testing for transfusion-transmissible infections
   c Crossmatching results
   d Training records for staff working in the Quality Department

28 Documented procedures for the recall of blood components must enable:
   a Recall of all components/component pool related to the donation that caused an adverse reaction
   b Recall of the initial component that caused the adverse reaction
   c Awareness that the component caused an adverse reaction

29 Recall of a product should lead to:
   a Notification of the donor staff
   b No further action
   c An investigation, with corrective action to prevent recurrence
   d Notification of the components preparation staff
30 It is important to have a stock control system for reagents because:
   a. It ensures that reagents are validated properly
   b. It helps you in monitoring the rate of usage of items, and the reliability of your supplier which, in turn will help prevent an out-of-stock situation
   c. It is an extra system to keep people busy
   d. It is a new system that management wants implemented

31 Record-keeping in the laboratory is essential in meeting the requirements of:
   a. Good laboratory practice
   b. Good record-keeping practice
   c. Good testing practice
   d. Good housekeeping practice

32 A "blood cold chain" is:
   a. A metal link that is kept in the refrigerator
   b. The storage of products in a refrigerator and/or freezer
   c. A system for storing and transporting blood and plasma in an appropriate way to maintain all its functions
   d. A cold climate

33 The following are NOT essential parts of the blood cold chain:
   a. Equipment for the storage and transportation of blood
   b. People who manage the storage and transportation of blood
   c. People and equipment, resulting in an adequate blood cold chain
   d. Maintenance of blood storage equipment
   e. Control of the stock of blood available for use

34 A haemovigilance programme is concerned with:
   a. Investigation of transfusion-related incidents
   b. Haemoglobin level of a donor
   c. Haemoglobin test
   d. Efficiency of staff

35 The customers of the BTS at the clinical interface are:
   a. Patients
   b. Clinicians
   c. Patients and clinicians
   d. Donors
## QMT 8.16 MID-COURSE ASSESSMENT ANSWERS

### Answers

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<table>
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<tr>
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