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Document Authorisation

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CROSS REFERENCES

This Policy refers to the following documents:

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Key Change From Previous Revision:

1. This policy has been reformatted.
2. Inclusion of specific Statement at 1.
3. Update to reference Governance and Risk Committee
4. Inclusion of Supplier Performance, staff suggestions and Risk Management agenda items
5. Inclusion of Corporate Quality Management Review
6. Reference to Annual Quality Report as required by Q2020

STATEMENT
Quality is regarded as of paramount importance at the Northern Ireland Blood Transfusion Service. This commitment is demonstrated by the development of a quality management system, which will ensure the provision of safe, efficacious and timely blood products and services for both patients and donors. This system will comply with all relevant legislation including Blood Safety and Quality Regulations, Human Tissue Quality and Safety Regulations, Environmental legislation, and CPA Accreditation standards.

This effectiveness of this policy and systems to support will be continually reviewed by management.

Objectives of management review are:-
- To establish that the Quality Assurance System is achieving the expected results, continuing to conform to the standard, and functioning in accordance with the established Operating Procedures.
- To expose irregularities or defects in the System, identify weaknesses and make recommendations for continual improvement.
- To review the effectiveness of previous corrective actions including those related to subcontractor and supplier performance.
- To review the adequacy and suitability of the Quality Assurance System for current and future operations.
- To review any complaints received, identify the cause and recommend corrective action if required including customer feedback.
- To review the finding of internal / external audits and identify any areas of recurring problems.
- To review the reports of non-conformities and evaluate trend information.
- To review training requirements. Analyse all the above for trends and make appropriate improvements.
2 OVERVIEW

2.1 Within relevant quality standards, it is recommended that there are procedures to ensure adequate management review of the quality systems in place. The NIBTS also recognise that such reviews are an important part of meeting the requirements of Clinical Governance. This document outlines the approach, which will be used for Quality Management Review within the NIBTS.

3 RESPONSIBILITY

3.1 Board, Chief Executive, Senior Management Team and Departmental/Section Heads

4 POLICY

4.1 QUALITY IMPROVEMENT REVIEW MEETINGS

These meetings are held monthly. The Terms of Reference for this meeting are set out in TOR:QD:007. A Quality metrics report, collated by the Regulatory Affairs and Compliance Manager is reviewed at this meeting. Issues reviewed at this meeting include:

- **Audit**
  
  Internal and External with information on the status of each audit against the agreed plan.

- **Quality Incident Reports**
  
  The status of investigations, reports, recommendations and agreed corrective actions will be summarised.

- **Document Control**
  
  The status of document issues and review will be summarised.

- **Training**
  
  The report will include details of quality training provided within and without the quality department.

- **Equipment Maintenance**
  
  Outstanding issues relating to equipment, e.g. poor performance will be discussed.
Recalls

Recalls completed in any month will be summarised.

Change Control

A procedure for the management of change control will be developed. The status of changes pending and implemented will be listed.

External Quality Assessment Schemes –

Results of exercises will be collated.

Component Monitoring

The results of blood components monitoring will be summarised.

Where performance fails to meet the specified minimum level the Quality Improvement Review committee will consider and escalate issues in keeping with specific procedures including referral to the NIBTS Agency Board

4.2 DEPARTMENTAL MEETINGS

These meetings currently include:

- Quality Control Laboratory
- Blood Donation Co-ordinating Group
- Microbiology
- Hospital Services
- Cord Blood Bank
- Serology
- IM&T Steering Group

The appropriate departmental manager chairs each meeting

At each meeting relevant quality issues will be discussed. Aspects including as Quality Incident reports, audit reports, documentation, change, EQAS schemes, training and equipment maintenance will be discussed. Where departments are involved in the provision of patient testing services sample turn round times will be considered.

Action arising from discussing will be logged on an action list for that meeting along with the identity of those responsible for the completion of the action and a target date for the same.

This action list will be reviewed at each meeting.

4.3 ANNUAL REVIEW OF QUALITY SYSTEMS
A number of specific reports will be collated. This will include a report, which covers the activities undertaken in the Laboratories within NIBTS, which are accredited by the CPA/UKAS. This “CPA/UKAS” Annual Quality Management Review will be use the Agenda at appendix 1. An executive summary of the meetings will be provided to the CPA/UKAS on the form provided by the CPA/UKAS on the Website http://www.cpa-uk.co.uk/.

An organisation wide Corporate Annual Quality Management Review will be held Annually. The Agenda for this meeting is set out in Appendix 2. In keeping with requirements defined in Q2020(DHSSPS) a full year report will be issued annually. This will highlight areas for improvement in the quality system and recommendations on how they can be addressed. This report will be presented to the Senior Management Team and Board. The Chief Executive will review this report and agree appropriate actions.

4.4 GOVERNANCE AND RISK COMMITTEE

The NIBTS are required to have in place systems, which ensure quality assurance principles are applied to all activities including clinical activities. The quality systems in place in the NIBTS cover many of the necessary aspects and as such it is considered essential that reports produced by the Regulatory Affairs and Compliance and the Quality Department are reviewed within the forum of the Governance and Risk Committee. The committee will review the status of the quality system by reference to the monthly quality Improvement Review meetings.

4.5 SENIOR MANAGEMENT TEAM

Key Quality KPIs are established for NIBTS. These are reviewed by the Senior Management Team. Any required actions relating to Regulatory Affairs, Compliance and Quality are recorded with responsibility and target dates for completion of activities being confirmed. An action list will be generated within the SMT forum and reviewed at each meeting.

4.6 REFERENCES

1. Clinical Pathology Accreditation (UK)Ltd – Standards for the Medical Laboratory
2. ISO15189 Medical Laboratories – Particular requirements for quality and competence
3. Blood Safety and Quality Regulations - 2005
4. Human Tissue(Quality and Safety)Regulations 2007
5. ISO 9000 Series
6. Guidelines for Blood Transfusion Services in the UK
7. Rules and Guidance for Pharmaceutical Manufacturers and Distributors
5 EQUALITY SCREENING OUTCOME

This policy has been drawn up and reviewed in light of the statutory obligations contained within Section 75 of the Northern Ireland Act (1998). In line with the statutory duty of equality this policy has been screened against particular criteria. If at any stage of the life of the policy there are any issues within the policy which are perceived by any party as creating adverse impacts on any of the groups under Section 75 that party should bring these to the attention of the Head of HR & Corporate Services.

The Northern Ireland Blood Transfusion Service is committed to the promotion of equality of opportunity for staff, donors and service users. We strive to ensure that everyone is treated fairly and that their rights are respected at all times. We believe that it is important that our policy is understood by all those whose literacy is limited, those who do not speak English as a first language or those who face communication barriers because of a disability. On request it may be possible to make this policy available in alternative formats such as large print, Braille, audio file, audio cassette, Easy Read or in minority languages to meet the needs of those not fluent in English.

6 TRAINING REQUIREMENTS

All staff involved in provision of patient testing services must read and understand this policy.
APPENDIX 1

CPA Annual Quality Management Review Meeting

Date, time and location

Agenda

1. Reports from managerial and supervisory personnel - Assessment of user satisfaction and complaints
2. Internal audit of quality management system
3. Internal audit of examination processes
4. External quality assessment reports
5. Reports of assessments by outside bodies
6. Status of preventive, corrective and improvement actions
7. Quality indicators that monitor the laboratory’s contribution to patient care – staff suggestions
8. Major changes in organisation and management, resource (including staffing) or process –
9. Performance of Suppliers
10. Risk Management
11. Minutes and Follow up of previous management reviews
12. Review of Quality Policy
13. Review of Quality Objectives/Key Performance Indicators
Appendix 2

NIBTS Corporate Annual Quality Management Review Meeting
Date, time and location

Agenda

1. Reports from department managers (Senior Management Team) - Assessment of user satisfaction and complaints
2. Internal audit of quality management system
3. Internal audit operational activities
4. External quality assessment reports
5. Reports of assessments by outside bodies
6. Status of preventive, corrective and improvement actions
7. Quality indicators that monitor the contribution to patient care – staff suggestions
8. Major changes in organisation and management, resource (including staffing) or process –
9. Performance of Suppliers
10. Management of Assets
11. Risk Management
12. Minutes and Follow up of previous management reviews
13. Review of Quality Policy
14. Review of Quality Objectives/Key Performance Indicators