

Annual Quality Report 2015 -16



Northern Ireland
Blood Transfusion Service

Introduction

The Northern Ireland Blood Transfusion Service (NIBTS) is the sole supplier of blood components and products to Health and Social Care (HSC) in Northern Ireland. All blood components prepared from donations are provided by our voluntary, non-remunerated donors. In addition to supplying blood components and products, NIBTS provides a Regional Antenatal Testing Service and Regional Reference Laboratory Service for Northern Ireland.

NIBTS staff have a strong commitment to quality as demonstrated by our mission statement:

“To collect, process and deliver high quality blood and blood products and appropriate advice to the HSC in Northern Ireland to the standard required by the Regulators”.

The following statements set out the vision and strategic direction for NIBTS based on five themes.

The corporate goals, service improvement plans for individual departments and individual staff development reviews are linked to these themes:

- **Quality** – Patient safety and maintenance of licences
- **Donor/ Customer** – Improving the donor and customer experience
- **People** – Engage, empower and encourage learning and development
- **Improvement** – Constantly seeking to improve our service
- **Resources** – Maximising the use of resources allocated to us and minimising waste

NIBTS is required to maintain a Blood Establishment Authorisation licence in order to continue to supply blood and blood products. In order to retain this licence the organisation is required to maintain a Quality Management System to ensure the safety and quality of blood products in line with the Blood Safety and Quality Regulations 2005 (as amended).

This system includes the following elements which contribute to quality improvement; by the identification of:

- Non-conformances
- Observations, suggestions etc. (opportunities for quality improvement)
- Risks

These in turn drive the process of Root Cause Analysis through to the implementation, monitoring and review of corrective and or preventative actions.

NIBTS has developed and maintains processes which ensure effective management of:

- Internal Audit – Assessment of user satisfaction
- Processing of complaints
- External quality assessment schemes
- Quality incidents
- Assessments by external bodies
- Change control
- Risk management

In 2011, “Quality 2020: A 10-year Strategy to Protect and Improve Quality in Health and Social care in Northern Ireland” was launched by the Department of Health, Social Services and Public Safety.



This Strategy has identified five strategic goals to be achieved by 2020 that will turn the vision of being “recognised internationally, but especially by the people of Northern Ireland, as a leader for excellence in health and social care” into a reality.

The five strategic goals are:

- 1. Transforming the Culture**
- 2. Strengthening the Workforce**
- 3. Measuring the Improvement**
- 4. Raising the Standards**
- 5. Integrating the Care.**

The five strategic themes for NIBTS can be mapped to the strategic goals of Q2020 with some NIBTS themes encompassed by more than one of the Q2020 strategic goals:

Q2020 Goal	Corresponding NIBTS theme
1. Transforming the Culture	People/Quality
2. Strengthening the Workforce	People
3. Measuring the Improvement	Quality/Improvement/Resources
4. Raising the Standards	Donor/Customer/Improvement/Quality
5. Integrating the Care	Donor/Customer/Resources

Many of the quality improvement initiatives undertaken by NIBTS are consistent with the strategic goals of Q2020. This report will demonstrate progress made under the five strategic headings during 2015/16. A further review of quality objectives will be undertaken during 2016/17.

Transforming the Culture



We recognise that key to transforming the culture of an organisation is staff involvement in changes and the recognition that these changes will improve the quality of products and services provided.

We continue to develop our incident management system to ensure that when errors occur they are addressed and investigated to identify actions and improvements which can be implemented to avoid recurrence and further improve quality.

We strive to ensure a 'no blame' culture, with the incident management system used to address each incident in a fair and just manner. To ensure learning across the organisation, incidents and their outcomes

are reviewed on a monthly basis by the Incident Management Group with representatives from all areas of the organisation. These representatives then disseminate the learning points to staff throughout the organisation.

We recognise that change sometimes can be challenging. To minimise the risk and impact of change to staff, products or services we have developed a Change Control Process which aims to assess the impact of each change, put in place appropriate action plans to implement the change involving all stakeholders, monitor progress of the change and, after implementation, review the change to identify any learning points and determine if the desired benefits were delivered.

A Change Control Group representative of the organisation continued to meet on a weekly basis throughout 2015/16 to review new changes or revision of action plans for existing changes. This supports dissemination of information regarding change throughout the organisation and encourages team working.

We continue to involve staff in the business planning process of the organisation with comments and suggestions invited from all members of staff.

We participated in a HSC- wide staff survey process conducted during the latter stages of 2015 with a tailored report provided to NIBTS. The outcomes of this survey are being incorporated into actions plans associated with initiatives being carried out by the organisation such as Investors in People.

We recognise that users of our service must also have the opportunity to voice any suggestion for improvements or concerns.

During 2015/16, we carried out user surveys for the patient testing and blood supply aspects of our organisation. Follow up user meetings after the completion of analysis of the surveys allowed opportunity for further discussion of potential service developments.

We recognise that communication is key to ensuring staff are informed of service developments. The organisation has therefore sought to improve its communication channels by:

- Redesigning the staff intranet to a more user friendly format
- Use of screensavers to communicate information to staff
- Provision of data terminals in various locations for those staff who do not routinely interact with computers during their daily duties

These will be further improved during 2016/17 with the introduction of regular staff briefings and newsletter.

Strengthening the Workforce

Our staff are paramount to the delivery of quality products and service. We recognise the importance of staff being trained for the roles they fulfil whether this be with regard to clinical expertise, laboratory, processing, communication or management skills.

During 2015/16, we continued our commitment to support staff training by:

- 1. Delivery of mandatory training in:**
 - a. Good Manufacturing Practice
 - b. Fire Awareness
 - c. Health and Safety
 - d. Disability Awareness
 - e. Risk Management
 - f. Manual Handling
 - g. Recruitment and Selection Refresher Training
 - h. Data Protection Awareness
- 2. Induction for new staff**
- 3. Bullying & Harassment Awareness Training for managers**
- 4. Deaf Awareness Training for frontline staff**
- 5. Disciplinary, Grievance and Investigation Awareness Training**

A further nine members of staff were supported in the completion of post entry qualifications.

NIBTS participate in GMC Revalidation procedures for medical staff. The revalidation process for Medical Staff is up to date with one doctor obtaining revalidation during the 2015/16 period. All Nursing Staff employed by NIBTS have achieved NMC revalidation by the required date.

NIBTS Biomedical Staff are required to maintain registration with the Health and Care Professions Council. A condition of this registration is participation in continued professional development which is subject to audit. All Biomedical Scientists employed by NIBTS maintained their registration during 2015/16.

Our staff are required to participate in an annual staff development review process during which training needs are identified. During 2015/16 98% of staff were reviewed which is an improvement on the previous year's figure

We strive to reduce staff absence rates both due to long term and short term illness. The target for 2015/16 was < 6% and this was achieved.

Allied to reducing staff absence is improving the health and wellbeing of our staff. During 2015/16, NIBTS ran a number of programmes aimed at improving staff wellbeing including:

- Health and Safety Week – June 2015 – displays with information and talk on 'Stress Reduction and Well Being'
- First aid courses
- Health Fair – checking of blood pressure, cholesterol and general medical advice for staff
- Flu Vaccination Programme

Measuring the Improvement



We recognise the importance of gathering data and statistics as a means of examining performance and identifying areas of strength and where improvements are required.

Information is gathered throughout the organisation and presented at a number of fora to monitor performance. These include regular departmental and interdepartmental meetings and monthly meetings attended by the Senior Management Team. Reports are also provided for each Agency Board Meeting.

During 2015/16, the key aspects of NIBTS service objectives have been achieved. The service maintained an adequate panel of blood donors as well as collecting, testing, processing and issuing high quality blood components. In addition the demand for blood components from hospitals was met and the various regulatory requirements and relevant licences were met or maintained. We achieved financial breakeven and paid suppliers in accordance with prompt payment requirements.

Corporate Quality

A corporate quality document with Key Performance Indicators and targets is reviewed on a monthly basis at the Senior Management Team Meeting with targets stated for collection figures, donor satisfaction and complaints, waiting times, financial targets, staff absence and SDR completion.

Effectiveness of Quality Management System

A set of corporate quality metrics data for various elements of the Quality Management System .- product quality, incidents, documents, change management, audit, external assurance exercises and recall - is produced on a monthly basis and reviewed by the Senior Management Team. This data is shared at the Agency Board meeting.

Quality of products and services

Progress on quality objectives and other quality indicators relevant to each department are reviewed during departmental and interdepartmental meetings with a standard quality metric template completed for each meeting. This template captures data such as progress on change controls, departmental incidents, equipment maintenance, audit progress, document review completion and turnaround times for reports. Targets are set for each of these areas and the capture data reviewed in line with these targets.

One of the more visible measures of the antenatal patient testing service to users is the turnaround time for samples to be tested and the report issued.

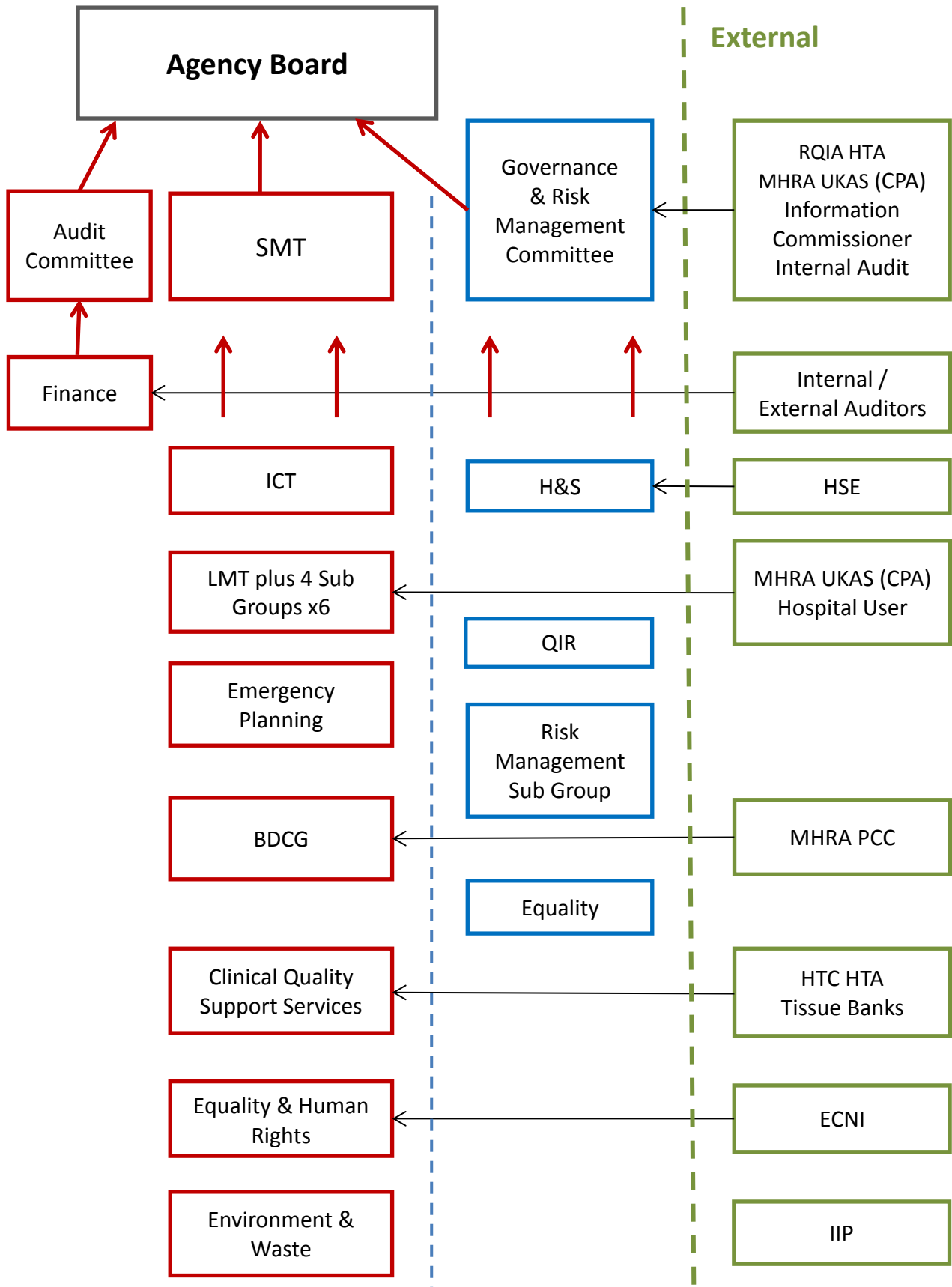
Improvements in turnaround times for Antenatal Serology report issue was noted when comparing the end of year figure i.e. 2014/15 and 2015/16 with an improvement in both mean days for report issue 2.77 days for 2014/15 improving to 2.58 days in 2015/16 and in the % of reports issued within three days (89.43% in 2014/15 and 92.88% in 2015/16)

Turnaround times for Antenatal Virology report issue maintained a performance level which exceeded the set targets with 94.92% being issued within three days with a mean day for report issue of 2.29 days.

Quality of the products produced is monitored via a sampling programme on an ongoing basis with reports provided to the production department on a daily basis. A monthly report focussing on quality monitoring of the components produced is reviewed by senior staff from within collection, clinical, production and quality.

The following diagram diagrammatically shows how performance is monitored and managed throughout the organisation.

Figure 3 – Performance Management



Through the Incident Management System, we have the opportunity to assess and improve working practices where appropriate. The organisation investigates all errors and incidents. The level of investigation required is determined by the risk level of the incident. Incident investigations, actions taken as a result and any learning opportunities can be viewed by staff in electronic format and are discussed at various fora including the monthly incident management meeting attended by staff from throughout the organisation to share any learning points.

The change management process allows full consideration of any changes to be made, what benefits are anticipated and the impact on all areas of the service and its users. Where appropriate, a review step is built into the process to allow an assessment of the completed change, any learning points and to determine if the benefits have been delivered.

We, as part of our Quality Management System, have implemented a programme of internal audits. During 2015/16 a total of 28 internal audits were performed with no critical or major findings identified.

External Regulation

NIBTS are subject to inspection by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the CPA (UKAS). MHRA carried out an inspection of NIBTS during February 2016 with no critical or major findings identified. No UKAS inspections were performed during 2015/16 and NIBTS has maintained its accredited status.

The external audits confirm that the Quality Management System is operating at an effective level. However we recognise that it is essential to both maintain and improve performance of the system with the change control process identified as a particular area of focus in the forthcoming year.

NIBTS is also subject to audit by the Business Services Organisation Internal Audit function which completes an annual plan of work which includes a review of financial management, governance and risk management. For each of these areas in

2015/16, satisfactory assurance was reported and the linked controls assurance standards externally verified. Implementation of Internal Audit recommendations are the subject of detailed action plans and progress is assessed by the auditors at their mid-year and end of year reviews. The Chief Executive prepares a Governance Statement for the Annual Report which is supported by an opinion from the Head of Internal Audit. In 2015/16, a Mid-Year Assurance Statement was completed for Department of Health (DoH). There were mid-year and end of year accountability review meetings with Department of Health, both of which had satisfactory outcomes.

Raising the Standards

NIBTS is one of four blood services in the United Kingdom. It also has links with other blood services within Europe through the European Blood Alliance.



Within the UK Blood Services, there are a wide range of groups which support bench marking and identify best practice and shared learning. Two overarching committees are the UK Forum and the UK Blood Services Joint Professional Advisory Committee. Both these committees have a number of sub-groups and advisory committees which focus on specialised areas of Blood Transfusion Practice.

The UK Blood Service Business Information Committee produces an annual report benchmarking comparison data for key processes within blood services. Notable developments during 2015/16 arising from these groups is the addition of Hepatitis E screening to the suite of mandatory screens for infectious disease markers for certain recipients and initiation of a communication process with the MHRA, CPA (UKAS) and HTA regulatory and accreditation bodies to improve consistency of standards and potential reduction of audit overlap.

Within NIBTS, where incidents have occurred or findings identified via audit, these are logged and investigated to determine the root cause and other causal factors and any actions to be taken or potential improvements which can be made to prevent any recurrence.

Key Achievements

NIBTS Laboratory Departments identify a series of quality objectives each year to improve service delivery/quality. The Laboratory objectives/achievements for 2015/16 are included in the following table:

Department	Activities	Key Achievements 2015/16
Hospital Services	<p>Preparation and manufacture of blood components</p> <p>Hospital issues department</p> <p>Belfast Cord Blood Bank</p>	<p>Improvements in staff and product security via new dispatch protocols</p> <p>Validation and implementation of new equipment for segmenting blood packs</p> <p>Commencement of project to cease provision of cord blood bank service in line with Department of Health decision</p>
Automated Serology	<p>Blood grouping of all donations</p> <p>Blood grouping and antibody screening of all donations including medical reporting of at risk pregnancy results</p>	<p>Validation and installation of new testing platform for blood grouping and antibody screening which provides a robust modern test platform</p> <p>Merge of Antenatal and Donor Grouping Departments providing more robust contingency</p>

Department	Activities	Key Achievements 2015/16
<p>Blood Group Reference Laboratory</p>	<p>Specialist referral service for hospital blood banks for complex red cell investigations and cross matching red cell units for difficult clinical cases: Includes on call service</p>	<p>Training of additional staff to the level of competence required for participation in the NIBTS On Call rota</p> <p>This allows the provision of a more robust service and improve rota viability</p>
<p>Transfusion Microbiology Laboratory</p>	<p>Testing of all donations for infectious diseases markers</p> <p>Antenatal screening for infectious diseases in pregnancy</p>	<p>Validation and Implementation of new testing platforms for infectious disease markers. Development provides a robust modern test platform and delivers cost savings</p> <p>Validation and implementation of more secure archiving system for samples</p>
<p>Quality Control Laboratory</p>	<p>Quality monitoring of blood components</p> <p>Bacteriological testing of platelet components</p> <p>Environmental monitoring of component production areas</p>	<p>Participation in regional media tender delivering cost savings</p> <p>Formation of quality monitoring report review group to ensure proactive approach to any slippage in product quality</p>

Donor Satisfaction

Donors give blood on a voluntary, non-remunerated basis and are critical to the success of our service. We have a system to record complaints from donors or members of the public to allow analysis, investigation and improvement to the service. We also record and monitor donor satisfaction levels with a 98.2% satisfaction level recorded for 2015/16. Donor complaints for this period were 4.0 per 10,000 donor attendances (total of 26 complaints received).

We are a member of the Regional Forum for Personal and Public Involvement Forum (PPI), and central to our programme of engagement with users is the Blood Transfusion Service Communities Partnership (BTSCP)

BTSCP has two main groups – one for Greater Belfast, and another in Dungannon. There is a further group, the Youth Forum, set up to focus on the views and needs of younger people. Target areas for all groups relate to donor recruitment, session organisation, and also a platform for consultation.

In 2015/16, BTSCP groups met on a seven occasions, and discussed the development of a new donor strategy for 2016 to 2020, blood collection activity and complaints. The groups were also kept informed about the introduction of new donor eligibility criteria relating to men who have sex with men (MSM), and the new double-pod BloodMobile Unit.

Integrating the Care

We work with colleagues in Trusts throughout Northern Ireland and other UK and Ireland Blood Transfusions Services to achieve mutual benefits and improvements in service.

We host the Northern Ireland Transfusion Committee. The work plan for this committee identified a number of projects over the next five years which are designed to reduce red cell demand by a minimum of 8%. The projects and their status are listed in the table below.

Project	Status
Current	
Single unit red cell transfusion	Piloted and implemented in SEHSCT (18% reduction in red cell issues 2015/16)
Preoperative assessment including use of infusible iron	Piloted in BHSCT
Targeted intervention in acute upper gastrointestinal haemorrhage patient category	Transfusion care pathway agreed and to be implemented in BHSCT
Future	
Targeted intervention in care of the elderly patients reducing red cell transfusions	Scheduled for 2018/19
Diagnosis treatment and management of anaemia pre admission to hospital	Scheduled for 2019/20

In addition, there are a number of workstreams including competency assessment for *Right Patient Right Blood*, documentation of bloodless pathway, implementation

of checklist for assessing Transfusion Associated Circulatory Overload (TACO), electronic tracking and traceability of blood components transfused.

The NIBTS Medical Team have led an initiative to extended maintenance phlebotomy to community blood donor clinics to improve access to this service. The team are liaising with the Belfast Trust hepatology service to provide monitoring of serum ferritin as it is easier for the patient to have these samples drawn when he or she is attending as a donor.

The NIBTS medical team also works closely with the Public Health Agency on implementation of antenatal screening programme for infectious diseases in pregnancy to ensure appropriate testing regimes are available for these service users.

We work closely with colleagues in the three other UK Blood Services with representation in the UK Quality Managers group and linked subgroups which concentrate on Quality Monitoring and Validation. This allows sharing of expertise, information and learning throughout the four services and assists benchmarking similar process such as recall rates, SABRE reportable incident occurrence and bacterial positivity rates in platelet components. Regulatory audit outcomes for all services are shared as are any actions taken to address non-conformances. Each group aims to meet four times per year either face to face or by teleconferencing. Participation in these groups ensures each service is aware of changes and developments in service provision and maintains consistency of service across the UK.

Notable workstreams for the UK Quality Managers Group during 2015/16 include:

- Analysis of data integrity
- Exploratory discussions regarding a shared UK Audit group
- Leading discussions between blood services and UKAS regarding the implementation of ISO 15189 standards.

The Quality Monitoring and Validation subgroup's workstreams include:

- Analysis of revised EU Good Manufacturing Guide Annex 15 (Validation and Qualification).
- Validation approaches to joint tender exercises - Potential methods of file sharing to assist information exchange.
- Standardising discard limits for non-conforming components between services.
- Analysis of Statistical Process Control (SPC) used in each service with view to adopting a common approach.