NHSBT Board Meeting
31st May 2019

Annual Management Quality Review
April 2018 – March 2019

1. Status – Official

2. Executive Summary

2.1 Continued regulatory compliance is critical for NHSBT to maintain its licences and accreditations, including its Blood Establishment Authorisation, Human Tissue Authority (HTA) licences for Tissues, Cells and Organs, medicinal products licences and the Care Quality Commission registrations, all of which are essential for us to save and improve lives. This report provides an annual overview of regulatory activity/information, key trends and performance in line with NHSBT's strategic targets for safety and compliance. The report is a key element of our quality management review process, it satisfies the requirement for NHSBT to continue to comply with a number of standards, regulations and guidelines and provides assurance on regulatory performance to the Board.

2.2 There were a total of 19 external regulatory and accreditation inspections during the year. There were no critical non-compliances received in any of the inspections. Two major non-compliances were raised, both by the Medicines and Healthcare products Regulatory Agency (MHRA) in one inspection against our Investigative Medicinal Products (IMP)/Specials Manufacturing licence. Feedback from the MHRA during inspections demonstrated that our medicines manufacturing regulatory performance has positively improved this year. Overall, there has been a significant improvement on 17/18 when 12 majors were raised during external inspections.

2.3 Following considerable effort across the organisation there has been significant success in reducing the number of overdue quality management system (QMS) events. Overdue levels across all directorates are now at record low levels.

2.4 There has been a significant decrease in the number of Serious Adverse Blood Reactions and Events (SABRE) reports to MHRA this year. Serious Adverse Events and Adverse Reactions (SAEARs) reported to the Human Tissue Authority (HTA) remained at similar levels when reporting changes were taken into account.

2.5 A significant number of regulatory licence changes were submitted and processed this year. All were completed as required to support important new and changing operational and business needs, such as product trials, new contracts and importation to support EU Exit. A number of changing or new regulations have been reviewed and actions taken, or are ongoing where necessary, to put in place action plans to ensure continued or future compliance.

2.6 A number of quality improvement actions have resulted in reductions in repeat adverse events such as missing units and discretionary and haemoglobin testing errors.

2.7 NHSBT successfully achieved immune effector cell (IEC) accreditation for four sites during 2018/2019. This was challenging from a regulatory point of view, but the first patient for the

new NHS therapy Chimeric Antigen Receptor (CAR) T cell treatment commenced treatment in December 2018 and the first CAR-T product was returned to Filton in early 2019. We expect this work to increase as more NHS Trusts bring the treatment online.

2.8 To complement the wider organisational response to the UK's impending departure from the EU, a QA EU Exit team was formed this year. The team has developed a specific process for management and escalation of no-deal EU Exit issues to ensure that NHSBT is able to quickly adapt to potential unpredictable changes that may arise as a result of EU exit, whilst still remaining within the confines of the QMS and ensuring that we continue to meet our regulatory obligations.

2.9 Work to simplify our quality management system is continuing with the priority focus being on introducing new documentation formats. This work is integrated with our Human Factors programme and takes into account learning styles and "what works for colleagues" in carrying out their day to day activities. Further work is following in areas such as quality incident management, root cause analysis and how we complete and record task based training.

3. Actions Requested

The NHSBT Board is asked to;

- Note the regulatory activity and performance across NHSBT during the year.
- Note the plans for development and improvement activities in 2019/20.
- Comment and feedback on this report and recommend any areas for future improvement.

4. Purpose of the paper

4.1 The report is a key element of our quality management review process, it supports the requirement for NHSBT to fully implement and maintain an effective Quality Management System and hence demonstrate compliance with a number of standards, regulations and guidelines, including Good Manufacturing Practice. The report is a key element of our framework in providing assurance on regulatory performance to the Board.

See detailed report and information in the attached Appendix.

NED Scrutiny N/A

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Appendix: Management Quality Review – Annual Report 2018/19

1. External Inspection Performance and External Reports

1.1 There were six MHRA inspections in 2018/19. Four were routine Blood Supply inspections at Oxford, Filton, Liverpool and Southampton and there was one combined Investigational Medicinal Products (IMP) and Manufacturing "Specials" (MS) inspection, also at Liverpool. One further ad hoc audit was performed by the MHRA at Birmingham New Street – this concentrated exclusively on the Pulse and IT Management Systems. The Human Tissue Authority (HTA) performed two inspections (Liverpool and Southampton); and our diagnostic laboratories performed well during four surveillance visits by the United Kingdom Accreditations Services (UKAS) (NBL, IBGRL, all RCI and all H&I laboratories), a European Federation of Immunogenetics (EFI) inspection (Sheffield) and a Joint Accreditation Committee ISCT-Europe & EBMI (JACIE) visit to SCI-Birmingham. There was also an inspection of our CE Marked Reagents programme by Underwriter's Laboratory and a further four inspections performed by JACIE which resulted in new Immune Effector Cell certification for Filton, Birmingham, TAS at GOSH and Manchester (see 3.2.1). There were no Critical inspection findings, however two Major findings were raised by MHRA, both at the IMP/MS inspection at Liverpool. These were attributed to gaps in supplier management and inadequate measures in place to minimise the risk of product contamination within the clean room. Agreed action plans are in progress to address both issues. All other inspection findings have been or are in the process of being addressed. The findings from all inspections have been shared across the organisation and where appropriate all non-compliances have been dealt with nationally.

1.2 Serious Adverse Blood Reactions and Events (SABRE) reports; during 2018/19 a total of 36 events were reported to the MHRA, which is a reduction on 2017/18 (47). The reports included a variety of event types, with the most frequent due to testing errors (6), unsuitable donations delivered (6), discretionary testing omissions (5), irradiation errors/omissions (4) delivery errors (4) and donor screening checks (failure to follow donor acceptance guidelines) (3). The remaining eight were all individual events with no common cause. All events have been investigated and are being managed to conclusion on an individual or national basis as appropriate.

1.3 Human Tissue Authority (HTA) Tissue and Cells Serious Adverse Events and Adverse Reactions (SAEARs): there were 106 Tissue and Cells SAEARs reports made to the HTA in 2018/19 compared with 41 in 2017/18. This is a significant increase, however as noted in earlier reports this year, this is primarily due to a change in reporting requirements instigated in December 2017, when we were asked by the HTA to report positive sterility test results as SAEARs. There were 58 (55%) SAEAR events due to positive sterility test results this year. It should be noted that the majority of these positives are caused by donor or retrieval contamination (i.e. outside NHSBT control) rather than by poor NHSBT processing practices. From April 2019, sources of contamination will be reported in more detail, to provide better trends and management information on the quality of our clean room processing practices. The remaining SAEARs (48) were due to: failure to engraft or delayed engraftment (13) (non NHSBT fault), serious adverse reactions (9), patient adverse reactions (8) and a mix of one-off causes with no significant trends evident (18). All events have been investigated and are being managed to conclusion on an individual and national basis as appropriate.

1.4 Under our delegated HTA Assisted Function to manage Organ Donation and Transplantation (ODT) SAEARs reporting, 45 incidents were submitted to NHSBT that required onward

reporting to the HTA. Following a request from the HTA, we now submit a SAEARs report for each recipient affected (one event may affect one or more recipients depending on the casual factors of the event), making it difficult to compare overall figures in 2018/19 to 2017/18. We can compare rates of retrieval damage where in 2018/19, 19 SAEs were due to retrieval damage resulting in no transplantation of the organ which is comparable to the previous year (17). There was only one SAEAR that could be directly attributed to NHSBT – this concerned a delay to the transportation of a heart, resulting in a lost transplant. This incident has been investigated as a Serious Incident and managed and reported through the CARE system.

2. Quality Management System Performance Update

2.1 Critical and Major Internal Quality Events: there were no internal events classified as Critical during 2018/19. The number of Major events raised in blood and tissues has increased by 53% from 544 in 2017/18 to 831 in 2018/19. The higher rate reflects the agreed change in classification from Other to Major for both donor arm pain events (90) and microbiology positive events (206) detected during clean room environmental monitoring (EM). Action plans to lower the incidence of both arm pain events and EM failures are outlined in sections 3.1.3 and 3.4.1 respectively.

2.2 Patient Adverse Events (PAEs): numbers have decreased slightly to 137 in 2018/19 from 147 in 2017/18. No new or significant trends have been identified among the reports received, with the majority (80%) being reported as clinical events. All PAEs have been reviewed by the CARE groups and no significant issues have been noted.

2.3 Serious Adverse Events of Donation (SAED): there were 34 events in 2017/18, a decrease on the 46 raised during 2017/18. The SAED causes were similar to last year with; 11 fractures within 24 hours of donation, 10 hospital admissions within 24 hours, 8 needle insertion problems lasting more than 12 months, 1 acute coronary syndrome within 24 hours, a road traffic collision within 24 hours, 1 death within seven days; and two “other” events. Trending has identified a reduction in long-term needle insertion injuries of 50%. Benchmarking has demonstrated that in comparison to other UK Blood Services NHSBT report a higher number of SAEDs, this is thought to be related to our thorough donor awareness campaign which results in increased reporting of illness/events post-donation.

2.4 This year 75% of internal self-inspections were completed within one month of the target date, this is a small improvement on the 73% achieved in 2017/18. Two audits were more than three months delayed. At the end of the year there were four outstanding inspections comprising; two risk-based audits, one Tissue Quality and Safety Regulations (TQSR) audit (delayed due to auditor availability) and one audit against the In-Vitro Diagnostics Directive (IVDD) which has been delayed while we upskill auditors. A QI has been raised and these audits were progressed during April 2019. Self-inspection is a key requirement of Good Manufacturing Practice and in order to improve schedule completion a group of new internal auditors was trained this year. Trending of inspection findings demonstrates the top 5 areas for improvement are poor documentation, record/report issues, procedure not being followed, training and environment/premises. Work will be done with Senior Management Teams to ensure appropriate actions are taken to improve performance in these areas in 2019/20.

2.5 Eight supplier audits were completed in the year, four for new contracts, two to review new premises, one routine re-audit and one due to an increased number of reported quality issues. The latter concerned the first batches of Non-UK plasma received from Poland, all

issues have now been resolved. Following investigations in relation to the supplier management finding by MHRA during their inspection in Liverpool a QI has been raised as there are a significant number of critical suppliers (31%) which have not been reviewed as required by our current documented process. An action plan is in place which prioritises the review of the outstanding suppliers and looks to improve the current process.

2.6 Product Recalls: There has been a slight decrease in the number of recalls in 18/19 (2262) compared with 17/18 (2346). The most common cause ofrecalls was bacteriology screen positive results (37%), followed by donor-related recalls (27%) and repeat-reactive infectious disease markers (20%). This is comparable to last year's levels of 44%, 27% and 18% for the same recall categories. The improved bacteriology recall rate is a result of the new air-conditioning system installation in Manchester in May 2018.

2.7 Document Management: The percentage of overdue document reviews at the end of 2018/19 was 23 (0.2%). This is a significant improvement on last year (1.3%) and the lowest rate recorded in recent years. The overdue rate across every directorate is now under 1%. This is an outstanding effort, given the large number of controlled documents in use across the organisation.

2.8 Change Control Management: the percentage of overdue change controls ended the year at 3.2%, a very significant improvement on the 12.8% overdue at the end of 2017/18. This rate has consistently been at 5% or lower since November 2018, indicating that this improved level is being sustained.

2.9 Event Management (Quality Incidents, Hospital Complaints and Audit Findings): at the end of 2018/19 the number of overdue events had significantly decreased to 66 – more than a threefold decrease from the end of 2017/18 (215), further highlighting the progress made this year in improving overdue performance. As a result of the improvements made in management of overdue QMS items the MHRA has asked us to cease sending them monthly reports. This is important and has rebuilt our credibility and relationship with the regulator in this area.

3. Quality and Compliance Issues/Trends

Many quality and compliance issues/trends have been successfully dealt with over the year, these include:

3.1 Blood Supply

3.1.1 The new system of logging of pre-validation potential missing blood donations started in October 2018 and has now been running for 6 months. The latest six-month data review indicates that of 64 units initially missing 42 were ultimately found leaving 22 with an unknown fate (unknown fates include labelled empty packs and underweight donations probably discarded into clinical waste bags in error). The improved reconciliation procedures in Blood Donation were implemented in February with the Processing procedure improvements were effective from end of March; final changes to the process involving dedicated NHSBT security ties are due in May 2019. A downward trend in overall numbers has been noted over the last three months and with the final interventions in place it is planned that the improvements will continue and be sustained.

3.1.2 The on-going issue of failure to perform donor haemoglobin (Hb) testing prior to donation was thought to have been resolved, with no events logged in Q3. Since then, three events were noted in January, prompting a further review of the guidance. This resulted in a pilot

of a laminated donor check list. This is a list of key activities given to the donor while donating which encourages them to speak up if any of the tasks have not been completed (including not having their Hb done). There has been one subsequent event in March and monitoring of the process continues.

3.1.3 Trend analysis has demonstrated that there were 90 donor arm pain events during 2018/19, only slightly less than the 95 in 2017/18. A change control has been raised to implement a pilot of a new multi-stage causal investigation process for arm pain events with the aim of streamlining the management for these events and to reduce the number overall. All nurses have in the last year been required to complete a new arm pain management training package and the standard operating procedure has been updated to tighten and clarify needle adjustment guidelines. There is also now renewed focus and monitoring via Regional Lead Nurses who are reviewing performance regularly. Trends will continue to be monitored and further interventions made if performance does not improve.

3.1.4 In June 2018 the revised approach to risk-based management of Discretionary Testing (DT) errors went live. This utilises an automated BOBs report to review event trends and to only accept a QI when local interventions are required to address either a higher risk issue or an adverse trend. Post implementation, only five QIs have been logged in the QMS which has significantly reduced the workload while retaining the focus on improved performance. Trending across 2018/19 shows a downward trend in DT incidents with the effort now being focussed on the higher risk event types. In Q1 2019/20 a performance summary will be presented to BSCARE, where this approach will be reviewed again to see if it has delivered the expected improvement.

3.2 **Diagnostic and Therapeutic Services**:

3.2.1 Chimeric Antigen Receptor (CAR) T cell Treatment: 2018/19 saw the introduction of this new therapy by the NHS and four NHSBT sites (Filton, Birmingham, TAS at GOSH and Manchester) were inspected by JACIE and received their Immune Effector Cells (IEC) certification under the FACT-JACIE Standards, allowing us to participate in the CAR-T therapy programme. The first NHS patient started their treatment in December 2018, and the first CAR-T product was returned to Filton in early 2019. A significant amount of regulatory work was completed to enable this novel treatment to commence including direct liaison with the pharmaceutical company involved and with regulators (HTA and MHRA).

3.2.2 Therapeutic Apheresis Services (TAS) - NHSBT partnered with Sheffield teaching hospitals to expand the stem cell and bone marrow collection services by adding collection from DKMS (Delete Blood Cancer based in Germany) donors from 1 April 2019. Until now, TAS and SCI Sheffield have provided registry donor collection services for the British Bone Marrow Registry and the Anthony Nolan. Providing services for DKMS will establish NHSBT as the only NHS provider to all three stem cell and bone marrow registries operating in England. Negotiating regulatory compliant agreements and ensuring appropriate QMSs were in place was crucial to establishing the new relationship and gaining approval from the HTA.

3.2.3 Serum Eyedrops – During 2018/19, QA worked with laboratory staff at Liverpool to validate the process and obtain MHRA approval for the new closed manufacturing system for serum eyedrops. This new process increases production throughput, reduces contamination risk and allows us to supply product more quickly to patients currently on the waiting list.

3.2.4 Tissue and Eye Services (TES) are currently in discussions with the Scottish National Blood Transfusion Service (SNBTS) for SNBTS to retrieve eye donations in Scotland and send them to NHSBT for subsequent processing, storage and distribution. Regulatory work is ongoing in conjunction with SNBTS and the HTA to understand the options for licensing this arrangement. Agreements and processes will be put in place to ensure the arrangements are compliant with the necessary regulations and guidance.

3.2.5 During our work to implement the requirements for Single European Code (SEC) labelling of tissues and cells brought in by the new Import and Coding Directive, a number of issues have been encountered, some in interpretation of the new requirements and some with the software system changes required (to Hematos). The issues have been discussed with the HTA and also reviewed at recent inspections in Southampton, Birmingham and Sheffield. Action plans have been agreed with the HTA and work is ongoing to address the issues. The HTA raised a Minor shortfall in the Southampton inspection to capture the issue and to formally record our corrective action plan. The two main areas that need to be addressed are; 1) Tissues/cells, or the accompanying paperwork, must have the SEC-DI (Donation Identification) applied whenever the tissues/cells are released for circulation, such as when tissues/cells are procured by one establishment and transferred to another establishment for processing, 2) The SEC-DI must not be altered once it is allocated to tissues/cells released for circulation – the SEC-DI assigned by the initial establishment must endure throughout procurement, processing and distribution for human application.

3.3 **Organ Donation and Transplantation (ODT):**

3.3.1 The project to Increase the Number of Organs Available for Research (INOAR) has required significant quality and regulatory input, including many discussions with the HTA. ODT QA will continue to work closely with the research team to provide support and advice and to ensure that a compliant solution is implemented.

3.3.2 Quality and regulatory activity to ensure we are in a position to effectively implement the proposed new opt out legislation has commenced. Working with operational leads we have identified a significant number of quality system changes/updates that will be required. Plans are now being developed to ensure that we have the appropriate resources on the project to implement the changes in a compliant manner.

3.3.3 Retrieval of tissues by NORS teams - significant progress has been made to resolve the regulatory issues associated with continued NORS team collection of various tissues during organ donation. ODT QA have worked with stakeholders and the HTA to agree responsibilities for pancreatic islets, liver hepatocytes and other tissues for procurement and testing under NHSBTs Tissues and Cells licence. NORS teams now work under a Third Party Agreement, approved by the NHSBT Designated Individual, for procurement of islets, hepatocytes and any ad hoc tissue requests for specific patients. Changes to consent and authorisation forms have been agreed to remove the current ambiguity between tissues and organs. These changes will be implemented when the associated electronic changes are complete. An action plan has been created and agreed with the HTA.

3.4 **Advanced Therapy Medicinal Products (ATMPs**):

3.4.1 Environmental Monitoring (EM) improvement strategies – following discussions with MHRA, failures of EM specifications are now recorded as Major quality incidents. This reflects the potential impact that EM failures could have on products processed in clean rooms and the importance of thorough investigation of these events. This has resulted in 206 extra events being reported as Majors this year. There has been a significant focus on our EM

management processes, specifically to support the investigation of the events and implementation of effective CAPA. Considerable effort has gone into training and competency assessment of clean room operators and the use of Human Factors (HF) day to day check lists has been instigated. Work has also commenced to standardise the procedural documents that support EM activities, clean room operations, and aseptic processing, with the aim of adopting standardised, national best practise across all relevant functions. Training and awareness sessions have been held to improve knowledge about clean room environment design and equipment, ensuring that they are fit for purpose. QA will be leading on bringing all of the aforementioned improvement activities into a Contamination Control Strategy which will provide greater assurance in terms of regulatory performance and ultimately patient safety.

3.4.2 During 2018/19, we contracted the services of a professional Qualified Person (QP), who will be responsible for the final approval of ATMP products prior to release. This will ensure NHSBT continues to comply with requirements for ATMP product release while we develop our own internal cohort of QPs for the future.

3.4.3 During 2018/19 a record number of IMP batches, approximately 30, have been manufactured, tested, certified and released for Clinical use across our ATU sites at Liverpool, Birmingham and CBC. In response to growing workloads at CBC the QA ATMP team has recruited an additional AQAM, based at Filton to support this workload and ensure we can maintain regulatory compliance and assure the quality and safety of our products.

3.5 QA Technical Assurance - QATA are increasing oversight of ICT incident and change management processes in response to MHRA expectations and to ensure that IT incidents with the potential to impact safety and compliance are managed and documented with the appropriate level of rigor.

3.6 Data Integrity Guidelines: high level plans have been formulated and are being implemented to address the compliance gaps identified on review of the updated MHRA guidelines. To improve governance and integration, data integrity is to be included in the terms of reference for the Master Data Management Council and the Information Governance Committee. In addition, a data integrity process audit is included in the 2019/20 internal audit programme, a Data Integrity Risk Assessment steering group has been established, QA have developed a risk assessment for NHSBT's approach to the control of blank forms; and data integrity has been included in the updated mandatory training package for all staff. NHSBT's Data Integrity lead has met with the other UK Blood Transfusion Services and continues to work collaboratively with them to understand MHRA's expectations and to ensure a consistent approach.

3.7 Falsified Medicines Directive – this new EU Directive was adopted in 2011 and introduced new harmonised measures which aim to prevent falsified medicines entering the pharmaceutical supply chain, to ensure that medicines in the EU are safe and that trade in medicines is properly controlled. The final part of the Directive, which concerns the implementation of safety features such as tamper proof packaging and a unique identifier, came into force in February 2019. The requirements apply to almost all Prescription Only Medicines unless exempt under certain circumstances within the Directive. A gap analysis has been completed and we have concluded that the impact of the Directive on NHSBT is very limited as the medicines held/used are either exempt or are supplied to NHSBT as an 'end user'. However, some minor changes to procedures for medicines management will be required to reflect the requirements of the Directive. Public Health England are seeking

confirmation from the MHRA regarding our obligations under the Directive for medicines in emergency PODs held by Hospital Services under our Wholesale Dealers Licence.

3.8 QA EU Exit Team - QA formed a dedicated, senior team to manage EU Exit related risks and activities. Working with M&L, QA has reviewed our routine QMS processes to ensure that we have flexibility to manage the potential volume of issues NHSBT might face under a no-deal scenario. QA has developed a specific process for escalation and management of no-deal EU Exit issues in a timely manner, whilst maintaining compliance and safety. There is a dedicated Change Control record in Q-Pulse to capture all related issues, actions, their rationale and approvals.

3.9 Regulatory Licence changes – there have been a number of regulatory licence changes during the year including:

3.9.1 MHRA**:**

- addition of importation to the Blood Establishment Authorisation (BEA) for the three blood manufacturing sites. This authorisation was necessary for the import of plasma from Europe to continue, following the UK's expected exit from the EU.
- modification of the Colindale BEA to permit processing of a new trial component, leuco-depleted whole blood, to enable NHSBT to participate in a study trialling the use of a whole blood component in the treatment of trauma in the field.
- modification of the West End Donor Centre BEA, to permit the increase of apheresis donor chairs from one to three.

3.9.2 HTA:

- addition of a new HTA Import Certificate for Liverpool to comply with the recent EU Import Directive requirements. This will permit Liverpool to import specified tissues from nominated third (non-EU) countries.
- updates to HTA licences for Filton to include procurement, storage, processing and distribution; and Colindale and Liverpool for testing of starting material for CAR-T therapy.
- authorisation to export was added to the Sheffield HTA licence to facilitate the DKMS arrangements.

4. Continuous Improvement Plans for 2019-2020

4.1 Simplification and Modernisation of Document Management Systems - As part of the QA Strategy Deployment initiative to simplify and modernise the document control system, Microsoft Office 365 SharePoint has been identified as the replacement platform for the Controlled Documents Library. SharePoint will provide better end user navigation, improved accessibility of documents and facilitate remote access to Controlled Documents. Methods for improving NHSBT's procedural document formats through use of Microsoft Office 365 Sway have also been identified and standardised formats are being drawn up. These formats are designed to take the user into account by making them more engaging and easier to follow, e.g. by including pictures and video clips. Prototypes have been developed and presented to users in a project within Manufacturing and feedback on their design has been positive. The finalised versions of the new formats will maintain compliance to the applicable quality regulations and standards and be intuitive for authors to use in writing controlled documents. The new formats for SOPs will be implemented over the next 6 months.

4.2 New Medical Devices Regulations – these apply from 26th May 2020 and 26th May 2022 for medical devices and in vitro diagnostic medical devices respectively. NHSBT has

contributed to the draft guidance and continues to be represented at the MHRA IVDR External Strategy Group. An initial 'discovery' phase is underway which will assess the impact on NHSBT operations and inform actions required to ensure compliance; this work will be completed by end October 2019. Workshops were held in January to assess the impact on each function and to determine the actions required. The workshops identified approximately 180 devices within the scope of the new Regulations. Further workshops are being held during June 2019 to determine the work required either to CE mark or exempt each of the devices under the Regulation. NHSBT has engaged with the other UK Blood Transfusion Services to share plans and to ensure a consistent approach.

4.3 RESTORE Clinical Trial of Manufactured Red Blood Cells (mRBC) – MHRA Clinical Trial Authorisation and other approvals required to commence the trial have now been received. The project was delayed from 2017/2018 due to difficulties in establishing satisfactory air flows in Filton ATU clean rooms. These issues have now been resolved and the clean rooms have passed external validation, smoke testing, installation and operational qualification (pending QA sign off). Performance qualification is expected to be complete in June 2019 in readiness to update the MHRA and request an inspection date.

4.4 QA Direct - The implementation of QA Direct has begun in line with the recommendation in the QA Workforce review completed in 2017/18. We have taken key steps towards establishing the new service, with the appointment of the National QA Manager for Service Delivery, and the Assistant QA Manager for Service Delivery. As part of the change process a series of consultative workshops are being held with QA staff and stakeholders to review and agree the required QMS processes. It is intended that QA Direct will go-live across Q2/Q3 of 2019.

5. Benchmarking

During 2018/19 QA participated in a deep dive into quality metrics coordinated by the Alliance of Blood Operators (ABO). A number of measures were considered but rejected due to difficulty in collection of consistent data, however the exercise will result in a recommendation that the following 3 metrics are taken forward for benchmarking across the ABO; Individual components recalled (due to process failure) per 10,000 units issued, product related complaints per 10,000 units issued and order fill rate (how well we are supplying what is requested by our customers i.e. OTIF). The recommendation will be published by the ABO and if agreed taken forward. Meanwhile QA are reviewing the data available and looking for further opportunities to benchmark the QMS.