

Board Meeting in Public

Tuesday, 06 June 2023

Title of Report	Annual Management Quality Review: April 2022 - March 2023	Agenda No.	3.8
Nature of Report (tick one)	<input checked="" type="checkbox"/> Official	<input type="checkbox"/> Official Sensitive	
Author(s)	Tania Wright, Regulatory Affairs Data Analyst Helen Murray, Regulatory Affairs Manager Betty Wickens, Quality System Audit Manager Urenna Kiwanuka, Lead Quality Specialist – Quality Management Systems		
Lead Executive	Helen Gillan, Director of Quality		
Non-Executive Director Sponsor (if applicable)	N/A		
Presented for (tick all that applies)	<input type="checkbox"/> Approval <input checked="" type="checkbox"/> Assurance	<input type="checkbox"/> Information <input type="checkbox"/> Update	
Purpose of the report and key issues			
<p>The Annual Management Quality Review cycle is a regulatory requirement which is designed to provide top management with the information and data required to ensure the continuing suitability, adequacy and effectiveness of the Quality Management System. This report is the annual report which is compiled from the quarterly updates throughout the year</p> <p>Key Issues: Regulatory performance has been positive throughout 2022-23, with no Major or Critical findings from MHRA or HTA inspections, and a reduction in the numbers of SABRE and SAEAR regulator reported events. Work is underway to improve the overall incident management process, with more focus on sustainable management of risk.</p>			
Previously Considered by			
Quality SMT, CGC, Executive Team – Update to Serious Incident figure requested			
Recommendation	The Board is asked to support the management and timely closure of incidents in the QMS as well as the development of a Quality plan for each directorate.		
Risk(s) identified (Link to Board Assurance Framework Risks)			
Continued regulatory compliance is critical for NHSBT to maintain its licences and accreditations, including its Blood Establishment Authorisation (BEA), Human Tissue Authority (HTA) Licences for Tissues, Cells and Organs, Medicinal Products licences, and the Care Quality Commission registrations, all of which are essential to allow us to continue to save and improve more lives. This report provides an annual overview of regulatory activity, key trends, information, and assurances in line with NHSBT's strategic targets for safety and compliance.			

Blood and Transplant

Strategic Objective(s) this paper relates to: [Click on all that applies]		
<input type="checkbox"/> Collaborate with partners	<input type="checkbox"/> Invest in people and culture	<input type="checkbox"/> Drive innovation
<input checked="" type="checkbox"/> Modernise our operations	<input type="checkbox"/> Grow and diversify our donor base	
Appendices:	Appendix A – MQR Q4 2022/23 Appendix B – Acronyms used in this report Appendix C – Internal event severity classifications	