

Board Meeting in Public Thursday, 06 June 2024

Title of Paper	Annual Annual Management Quality Review (MQR)		Agenda No.	3.5	
Nature of Paper	□ Official Sensitive				
Author(s)	Tania Wright – Regulatory Affairs Data Analyst, Jenny Chan – Regulatory Affairs Manager, Betty Wickens – Quality System Audit Manager, Heli Belfield – Lead Quality Specialist				
Lead Executive	Helen Gillan – Director of Quality				
Non-Executive Director Sponsor	N/A				
Presented for (tick all that applies)	''			* See Note i	
Executive Summary (max 300 word count)					
The Annual Management Quality Review (MQR) 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 (QMS). There has been a lot of positive performance this year. Overall external inspection performance has been positive, with no Critical findings and only one Major finding from any of NHSBT's three regulators. However, overdue events and overdue supplier reviews have been a challenge throughout the year, and all KPIs related to overdue QMS events were missed at the end of the year.					
Previously Considered by					
Not previously reported					
Recommendation Complying with Notes i and ii	 The Board is asked to: Support the ongoing work to improve management of the incidents in the QMS. Encourage and support teams to log incidents promptly when they do occur, so that the risk can be assessed, and any regulatory reporting can be completed in a timely manner. Engage with the relevant Lead Quality Specialists and/or local QA teams to ensure that Quality Plans are progressed. Support preparations for future regulatory inspections, as required. 				
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 a quarterly overview of regulatory activity, key trends, information, and assurances in line with NHSBT's strategic targets for safety and compliance. Strategic Objective(s) this paper relates to: [Click on all that apply]					
□ Collaborate with partners □ Invest in people and culture □ Drive innovation					
 ☑ Modernise our operations ☐ Grow and diversify our donor base 					
Appendices:					