

## CQC Registration Annual Assurance

**Trust Board**  
**28 May 2026**

<b>Presented for:</b>	Information and assurance
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<b>Previous Committees:</b>	Quality Assurance Committee, 16 April 2026

<b>Freedom of Information Act (FOIA) Exemption</b>	<input type="checkbox"/> <b>YES</b> (restricted from the FOIA) <input checked="" type="checkbox"/> <b>NO</b> (available to the public under the FOIA)
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<b>Link to Strategic Objective</b>	Focus on care quality, effectiveness and patient experience
<b>Link to Provider Capability Assessment</b>	Governance, risk and regulatory
<b>Link to CQC Well-led Statement</b>	Governance, Management and Sustainability
<b>Regulatory Impact</b>	Regulation 17: Good governance

<b>Key points</b>	
1. This report provides an annual update on compliance with CQC standards and the outcomes of CQC visits, inspections and engagement during the year 2025/26.	Assurance
2. The Trust's current registration status is registered with the CQC without conditions (compliant).	Assurance
3. During 2025/26, the Trust was subject to two routine planned inspections by the CQC: a Trust-wide Well-Led inspection on 17, 18 and 19 June 2025 and an IR(ME)R inspection of the external beam radiotherapy service at St James's University Hospital on 9 July 2025. The year also included continued regulatory follow-up in relation to the unannounced maternity and neonatal inspections undertaken in December 2024 and January 2025.	Information
4. The Trust continued to engage with the CQC through routine enquiries and inspection follow-up during 2025/26. Regular engagement meetings were paused during active inspection activity and organisational change, executive engagement meetings were re-established in quarter 3.	Information

<b>Risk Appetite Framework</b>			
<b>Level 1 Risk</b>	<b>Level 2 Risks</b>	<b>(Risk Appetite Scale)</b>	<b>Impact</b>
Clinical Risk	Patient Safety & Outcomes Risk - We will provide high quality services to patients and manage risks that could limit the ability to achieve safe and effective care for our patients.	Minimal	Outside risk appetite
External Risk	Regulatory Risk - We will comply with or exceed all regulations, retain its CQC registration and always operate within the law.	Averse	Outside risk appetite

## 1. Summary

This report provides an annual assurance update on compliance with Care Quality Commission (CQC) standards and the outcomes of CQC inspections, visits, enquiries, notifications and engagement during 2025/26.

The year included significant regulatory activity and follow-up, including publication and ongoing response to findings arising from the maternity and neonatal inspections undertaken in December 2024 and January 2025, a Trust-wide Well-Led inspection in June 2025, and an IR(ME)R inspection of external beam radiotherapy in July 2025. The Well-Led inspection resulted in a rating of requires improvement, with breaches of Regulations 16, 17 and 18 identified.

Across the year, the Trust continued to respond to routine CQC enquiries and statutory notifications, strengthened oversight of improvement activity, re-established executive engagement meetings with the CQC, and further developed its arrangements for self-assessment and inspection readiness.

The IR(ME)R inspection identified no recommendations or required improvements.

## 2. Findings

Leeds Teaching Hospitals NHS Trust was required to register with the Care Quality Commission (CQC) under Section 10 of The Health and Social Care Act 2008 from 1 April 2010. The Trust is required to be compliant with the fundamental standards of quality and safety.

The new health and social care regulations came into force on 1 April 2015 setting out new fundamental standards for all care providers, to replace the previous standards and outcomes. Two new regulations came into place on 27 November 2014; a fit and proper person requirement for Directors, and Duty of Candour for NHS bodies.

The Trust's current registration status is registered with the CQC without conditions (compliant). The Care Quality Commission has not taken enforcement action against Leeds Teaching Hospitals NHS Trust during 2025/26. However, following the inspection of Maternity Services in December 2025 CQC issued a section 29A warning notice in relation to staffing.

### 2.1 CQC inspections, visits and key outcomes in 2025/26

During quarter 1 2025/26, there were two routine planned inspections undertaken by the CQC and no responsive unannounced inspections. These were the Trust-wide Well-Led inspection on 17, 18 and 19 June 2025, and the IR(ME)R inspection of the external beam radiotherapy service at St James's University Hospital on 9 July 2025.

The year also included continued regulatory follow-up in relation to maternity and neonatal services arising from the unannounced inspections undertaken in December 2024 and January 2025. In response, the Trust established a Perinatal Improvement Assurance Committee reporting directly to the Board, with full detail of regulatory scrutiny relating to maternity and neonatal services being overseen through that route from December 2025.

### 2.2 Trust-wide Well-Led inspection

The Trust was notified on 18 May 2025 of CQC's intention to carry out a provider-level Well-Led inspection. Prior to inspection, the CQC requested evidence submissions, interview schedules and staff focus groups, and the Trust put in place a range of preparatory actions and staff guidance. Written feedback was provided on 20 June 2025 and shared with Trust Board.

Following the inspection, the CQC rated leadership at Leeds Teaching Hospitals NHS Trust as requires improvement. The inspection was undertaken following concerns identified during inspection activity in maternity and neonatal services where enforcement action had been taken and a warning notice had been issued. The CQC identified breaches of:

- Regulation 16(2), complaints response times
- Regulation 17(2)(a), good governance
- Regulation 18(2)(a), staffing and training compliance.

The CQC also identified a mixed picture in relation to leadership and culture. Findings included that the Board was not working as cohesively as it should, that openness and culture at Board level was mixed, and that leadership culture was inconsistent across services and at Board level. The report also recognised positive aspects, including partnership working to improve discharge, the diverse skills and lived experience of Board members, and organisational ambition in relation to sustainability.

## **2.3 IR(ME)R inspection of radiotherapy**

The CQC informed the Trust on 9 June 2025 of its intention to inspect the external beam radiotherapy service within the radiotherapy department at St James's University Hospital for compliance with the Ionising Radiation (Medical Exposure) Regulations 2017. A self-assessment questionnaire and supporting evidence were submitted in advance.

The inspection took place on 9 July 2025. Initial feedback was positive, with excellent practice identified, particularly in relation to improvements in incident management processes. The final report was confirmed on 4 August 2025. There were no recommendations or areas for improvement.

## **2.4 CQC engagement**

During the period of active inspection activity, routine engagement meetings with the CQC were paused, in line with CQC's approach during live inspection processes. However, the Trust continued to engage with the CQC in relation to inspection matters and non-inspection-related enquiries.

In quarter 3, executive engagement meetings with the CQC were re-established. A meeting took place on 18 December 2025 between Trust Executives and the CQC to reset stakeholder relationships and discuss improvements, key risks and mitigation. Areas discussed included maternity cases, Board quality and performance indicators, inpatient and maternity survey findings, NHS Staff Survey results, complaints performance, and arrangements for future CQC development sessions with the Board and senior leaders, which took place in March 2026.

## **2.5 Routine CQC enquiries**

The Trust continued to receive routine enquiries from the CQC throughout 2025/26, including concerns raised by patients and families, members of staff and members of parliament. These enquiries were managed with the local CQC engagement lead and relevant CSUs and were tracked by the Trust Quality Team and Head of Quality Governance.

In quarter 1, 10 enquiries were received; in quarter 2, 10 enquiries were received, including three enquiries relating to review and additional evidence requests for investigations completed by MNSI; in quarter 3, this reduced significantly to three enquiries. In quarter 4, 10 enquiries were received. Across the year, the annual report records 33 enquiries from the Trust CQC Inspector, which is similar to the amount received in the previous year. Responses and supporting evidence were provided in all cases, and the majority of enquiries were closed.

## **2.6 Management and oversight of improvement plans**

Oversight of regulatory improvement activity was strengthened during the year. The weekly Chief Executive-led Improvement Steering Group continued to oversee progress against the Perinatal and Well-Led Improvement Plans, including preparation for the independent inquiry into maternity services. In addition, the Trust reported to the monthly Integrated Quality Improvement Group, chaired by NHS England, with membership including the ICB, commissioners, national maternity improvement advisers and the CQC.

## **2.7 CQC quality statements and preparation for future inspection**

The Trust continued to develop its approach to inspection readiness during 2025/26. The Quality Team had developed and implemented an online self-assessment system against the CQC quality statements, launched on 4 February 2025 for CSU Tri Teams, Quality Leads and Corporate Senior Leaders. The system supports services to assess their position, record methods of assurance, identify gaps in control and plan actions. It also enables oversight by core service, site and domain, and supports identification of transferable learning and priority improvement work.

By quarter 3, all CSUs had registered on the system and 12 were actively using it to self-assess and identify areas of risk and improvement. The Quality Team also supported Cardio-Respiratory CSU to undertake self-assessment with additional independent challenge. Alongside this, preparation for inspection was reinforced through staff resources, leadership sessions and Safe Care GO Week, including a dedicated session for CSU Tri Teams and senior leaders on inspection readiness, regulatory expectations, learning from previous inspections and the use of the self-assessment system.

## **3. Quality and performance implications**

The regulatory activity described within this report has significant quality and performance implications for the Trust. CQC inspection, enquiry and notification activity provides an external measure of compliance with the fundamental standards of care and highlights areas where the Trust must demonstrate sustained improvement. The outcomes of regulatory scrutiny during 2025/26, particularly in relation to maternity and neonatal services and the Trust-wide Well-Led inspection, indicate that quality assurance,

governance oversight and organisational leadership arrangements required strengthening during the year.

The Well-Led inspection outcome is particularly important from a quality and performance perspective. The rating of requires improvement, together with breaches of Regulations 16, 17 and 18, has implications for complaints management, governance systems, dissemination of learning, and training compliance. These are not isolated regulatory issues; they are indicators of wider organisational effectiveness and the extent to which assurance systems are operating consistently across the Trust.

At the same time, the year has also demonstrated areas of strengthened assurance and improvement. The Trust maintained its CQC registration without conditions throughout 2025/26 and continued to respond to all routine enquiries and statutory notifications. Oversight of improvement activity was strengthened through the Chief Executive-led Improvement Steering Group and reporting to the Integrated Quality Improvement Group. Re-established executive engagement with the CQC has also supported clearer oversight of risks, progress and mitigation.

There is also evidence during the year of work to improve organisational readiness and strengthen assurance against the CQC framework. This includes the implementation and use of the CQC quality statement self-assessment system, structured support to CSUs and corporate teams, staff guidance and learning resources, and wider inspection-readiness activity. In quarter 3, Safe Care GO Week provided an additional focus on strengthening assurance against the safe domain, reinforcing consistent safety practices, multidisciplinary engagement and follow-up of improvement activity. No adverse quality impacts were identified from that initiative.

The IR(ME)R inspection outcome also provides positive assurance within the year. The external beam radiotherapy inspection identified no recommendations or required improvements, which indicates effective local governance and compliance within that service.

Overall, the quality and performance implication is that 2025/26 has been a year of heightened regulatory scrutiny, with clear areas requiring improvement, but also with demonstrable progress in strengthening oversight, inspection readiness and quality governance arrangements across the Trust.

#### **4. Financial Implications**

There are no financial implications detailed within this paper.

#### **5. Risk**

During 2025/26, the Trust's position in relation to External Risk – Regulatory Risk and Clinical Risk – Patient Safety and Outcomes is outside the risk appetite set by the Board during periods of active inspection, regulatory scrutiny and quality assurance intervention. This reflected the impact of the maternity and neonatal inspections, the subsequent Well-Led inspection outcome, and the wider assurance activity required in response.

The Well-Led inspection outcome, including breaches of Regulations 16, 17 and 18, reinforced the significance of the regulatory and clinical risks faced by the Trust during the year. These findings indicated risks relating not only to compliance with CQC

requirements, but also to governance effectiveness, complaints management, dissemination of learning, and training compliance.

However, by quarter 3 the position had begun to improve in line with the Board's risk appetite. This reflected the fact that the Trust remained compliant with CQC registration requirements, executive engagement meetings with the CQC had been re-established, routine enquiries had reduced, and oversight of improvement plans and inspection readiness had been strengthened through the Chief Executive-led Improvement Steering Group, the Integrated Quality Improvement Group, and the CQC quality statement self-assessment process.

Overall, the principal risk remains that failure to sustain and embed improvement could result in continued regulatory concern, further deterioration from the Board's risk appetite, and impact on patient safety, organisational assurance and external confidence. Ongoing oversight through established governance arrangements is therefore required to ensure that regulatory risks are identified, managed and escalated appropriately.

## **6. Communication and Involvement**

During inspection activity, the Trust co-ordinated communication with services, corporate teams and senior leaders to support evidence collation, staff interviews, focus groups and inspection preparation. Following inspection feedback and report publication, findings were shared through the Trust's governance arrangements, including reporting to Trust Board and relevant oversight groups. Improvement activity has since continued through established governance routes, including the Chief Executive-led Improvement Steering Group, the Integrated Quality Improvement Group, and the Perinatal Assurance Group.

The Trust has also continued routine communication with the CQC in relation to enquiries, notifications and inspection follow-up. During quarter 3, executive engagement meetings with the CQC were re-established, supporting direct discussion of key risks, progress and mitigation.

In addition, communication and involvement have supported wider inspection-readiness work across the organisation. The Quality Team has provided staff guidance, resources and leadership sessions to support understanding of the CQC quality statements, self-assessment arrangements and expectations during inspection. This has included engagement with CSU Tri Teams, Quality Leads, Corporate Senior Leaders and frontline teams through inspection-readiness sessions and Safe Care GO Week activity.

## **7. Equality Analysis**

Not applicable.

## **8. Publication Under Freedom of Information Act**

This paper has been made available under the Freedom of Information Act 2000

## **9. Recommendation**

Trust Board is asked to note the annual report on CQC registration, and the assurance provided.

