

Clatterbridge Road Bebington Wirral CH63 4JY

Tel: 0151 556 5000 Web: www.clatterbridgecc.nhs.uk

Date: 25 March 2019

Re: Freedom of Information Request

Ref: 62- 2019

Thank you for your email dated 25th February 2019 requesting information with regards to LIMS (Laboratory Information Management System).

The information that you require is as follows:

Under the freedom of information act please could you answer the following questions around your Trust's LIMS (Laboratory Information Management System)

- Do you have a full User Requirement Specification (URS) within your
 LIMS service?
- Do you have a full (requirements) traceability matrix (RTM) to drive validation for LIMS
- Do you have full validation evidence ready for review and fully referenced on your local QMS for LIMS?
- Which LIMS is in use?
- When was it last upgraded?
- When was the URS last reviewed?
- When did the MHRA last inspect the lab?
- How much notice did MHRA provide before this inspection?
- Would you benefit from a review of evidence to assess the transfusion labs "readiness for inspection"?

We do not have a laboratory at The Clatterbridge Cancer Centre and therefore do not use LIMS. All Laboratory Services are provided to us by Wirral and Liverpool Laboratories.

Should you require any further information please do not hesitate to contact me on the email address provided below.

Please remember to quote the reference number above in any future communications.

If you are dissatisfied with the handling of your request, you have the right to ask for this to be investigated internally.

If you are dissatisfied with the information you have received, you have the right to ask for an internal review.

Both processes will be handled in accordance with our Trust's Freedom of Information Policy and the Freedom of Information Act 2000.

Internal investigation and internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to: Freedom of Information Review, The Clatterbridge Cancer Centre NHS Foundation Trust, Clatterbridge Road, Bebington, Wirral, CH63 4JY

If you are not satisfied with the outcome of the internal investigation/review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

In order for us to ensure customer satisfaction and to monitor compliance with the Freedom of Information Act 2000, we would be grateful if you could take a couple of minutes to complete a short feedback form via the link below:

https://www.surveymonkey.co.uk/r/H39RFMM

Version: 1.0 Ref: ECGMFOIRE