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Darlington Memorial Hospital
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Request for Information Reference: 02.19.60

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Email only

22 March 2019

Freedom of Information Act 2000 – Request for Information

Thank you for your request for information received on 26 February 2019 in relation to the County Durham and Darlington NHS Foundation Trust (Trust). We are dealing with your request under the provisions of the Freedom of Information Act 2000.

You requested information regarding the laboratory Information management system. Specifically you requested information as follows:

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

- 1. Do you have a full User Requirement Specification (URS) within your LIMS service?***

Answer: Full URS from initial procurement, in process of developing new URS for future requirements.

- 2. Do you have a full (requirements) traceability matrix (RTM) to drive validation for LIMS***

Answer: Yes - The Trust have user acceptance testing scripts.

- 3. Do you have full validation evidence ready for review and fully referenced on your local QMS for LIMS?***

Answer: Previously not stored on local electronic QMS, is planned to be on current validation cycle.

- 4. Which LIMS is in use?***

Answer: WINPATH 5.28

5. When was it last upgraded?

Answer: March 2015

6. When was the URS last reviewed?

Answer: March 2019

7. When did the MHRA last inspect the lab?

Answer: March 2019

8. How much notice did MHRA provide before this inspection?

Answer: 1 Week

9. Would you benefit from a review of evidence to assess the transfusion labs "readiness for inspection"?

Answer: No

In line with the Information Commissioner's directive on the disclosure of information under the Freedom of Information Act 2000 your request will form part of our disclosure log. Therefore, a version of our response which will protect your anonymity will be posted on the County Durham and Darlington NHS Foundation Trust website.

If you have any queries or wish to discuss the information supplied, please do not hesitate to contact me on the above telephone number or at the above address.

If you are unhappy with the way your request for information has been handled, you can request a review by writing to:

The Chief Executive
County Durham & Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
DL3 6HX

If, you remain dissatisfied with the handling of your request or complaint, you have a right to appeal to the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House

Water Lane
Wilmslow
Cheshire
SK9 5AF

Telephone: 0303 123 1113
Website: www.ico.gov.uk.

There is no charge for making an appeal.

Yours sincerely

Joanna Tyrrell
Freedom of Information Officer