

Ref: FOIA Reference 2018/19-720

Royal Stoke University Hospital
Quality, Safety and Compliance Department
Newcastle Road
Stoke-on-Trent
Staffordshire
ST4 6QG

Date: 5th April 2019

Email foi@uhnm.nhs.uk

Dear

I am writing in response to your email dated 25th February 2019 requesting information under the Freedom of Information Act (2000) regarding LIMS (Laboratory Information Management System).

As of 1st November 2014 University Hospitals of North Midlands NHS Trust (UHNM) manages two hospital sites – Royal Stoke University Hospital, and County Hospital (Stafford). Therefore the response below is for the two sites combined from that date where appropriate.

Q1 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?

A1 UHNM does not hold a URS in relation the LIMS

Q2 Do you have a full (requirements) traceability matrix (RTM) to drive validation for LIMS

A2 UHNM Pathology work with UKAS (accreditation) to ensure validation of the LIMS is achieved.

Q3 Do you have full validation evidence ready for review and fully referenced on your local QMS for LIMS?

A3 Yes

Q4 Which LIMS is in use?

A4 Clinisys LabCentre is the LIMS used by UHNM Pathology services

Q5 When was it last upgraded?

A5 March 2017

Q6 When was the URS last reviewed?

A6 UHNM does not hold a URS in relation the LIMS

Q7 When did the MHRA last inspect the lab?

A7 Please see below:

- RSUH = April 2009
- County = March 2012

Q8 How much notice did MHRA provide before this inspection?

A8 County hospital was inspected under Mid Staffordshire Foundation Trust (MSFT) prior to the acquisition of the Trust (UHNM). We do not have any evidence available regarding notice provided for this visit.

RSUH – Information not held, however, MHRA have always been able to attend the site without any notice. Although we are usually given two weeks' notice to ensure that the appropriate person(s) would be available.

Q9 Would you benefit from a review of evidence to assess the transfusion labs “readiness for inspection”?

A9 The FOI Act 2000 is for the release of information that is held/recorded and does not cover the opinions of persons regarding suppliers, systems or procedures, therefore this information is not held.

*Please note that any individuals identified do not give consent for their personal data to be processed for the purposes of direct marketing.

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An anonymised copy of this request can be found on the Trust's disclosure log, please note that all requests can be found at the following link: <http://www.uhnm.nhs.uk/aboutus/Statutory-Policies-and-Procedures/Pages/Freedom-of-Information-Disclosure-Log.aspx>

This letter confirms the completion of this request. A log of this request and a copy of this letter will be held by the Trust.

If you have any queries related to the response provided please in the first instance contact my office.

Should you have a complaint about the response or the handling of your request, please also contact my office to request a review of this. If having exhausted the Trust's FOIA complaints process you are still not satisfied, you are entitled to approach the Information Commissioner's Office (ICO) and request an assessment of the manner in which the Trust has managed your request.

The Information Commissioner may be contacted at:

Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF or via www.ico.org.uk.

If following review of the responses I can be of any further assistance please contact my secretary on 01782 676474.

Yours,



Leah Carlisle
Deputy Head of Quality, Safety & Compliance