

File reference	W18FOI647
Key words	Trust's Laboratory Information Management System (LIMS)
Date of release	07/03/2019
Attachments	No

Freedom of Information Act Disclosure log - Reply Extract

You asked

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?**

No

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

No

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

Yes

- **Which LIMS is in use?**

iLab

- **When was it last upgraded?**

2014

- **When was the URS last reviewed?**

N/A

- **When did the MHRA last inspect the lab?**

March 2014

- **How much notice did MHRA provide before this inspection?**

Three months

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

No, the Department is prepared.

Attachments included: No