

Request under Freedom of Information Act 2000

Request Ref: NGFOI 18/19: 646

Thank you for your request for information received at Northampton General Hospital NHS Trust (NGH) on 25/02/2019.

I am pleased to be able to provide you with the following information:

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?*
Yes
- *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?*
No
- *Which LIMS is in use?*
DXC APEX / ILAB
- *When was it last upgraded?*
2015/16
- *When was the URS last reviewed?*
The URS is currently under review as part of the replacement process.
- *When did the MHRA last inspect the lab?*
2016
- *How much notice did MHRA provide before this inspection?*
Approximately 1 month.
- *Would you benefit from a review of evidence to assess the transfusion labs "readiness for inspection"?*
A review is not necessary. Inspection is a learning exercise and staff are encouraged to view it as such. We believe we have a comprehensive and safe team.