

Request under Freedom of Information Act 2000

I am pleased to confirm the following.

- **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?** Each department has validation for each upgrade of the LIMS
- **Which LIMS is in use?** Winpath v5.32
- **When was it last upgraded?** 11th July '09
- **When was the URS last reviewed?** N/A
- **When did the MHRA last inspect the lab?** 8th Nov' 11
- **How much notice did MHRA provide before this inspection?** Not known
- **Would you benefit from a review of evidence to assess the transfusion labs "readiness for inspection"?** No

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If you are unhappy with the information received in response to this request, please address your complaint to the Patient Affairs Office at Milton Keynes Hospital NHS Foundation Trust, Standing Way, Eaglestone, Milton Keynes MK6 5LD. If, after exhausting our internal process, you are still unhappy with the information received, you may write to the Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

If you need any further assistance, please do not hesitate to contact us at the address above.

Yours sincerely,

Freedom Of Information Co-ordinator
For and on behalf of Milton Keynes Hospital NHS Foundation Trust

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