

Freedom of Information Request

Ref: UHB 17-442

Date 27 July 2017



Thank you for your request for information under the Freedom of Information Act 2000. The Trusts response is as follows:

1. Does your EBME department have ISO 9001 quality management system registration?

MEMO Clinical Engineering (EBME, Mechanical Services, Radiation and Imaging) holds the EN ISO 13485:2012 QMS certified by BSI which is based on ISO 9001.

2. If so which extension 2008 or 2015?

We are working towards achieving the upgrade to EN ISO 13485:2016 by February 2018

3. When did you achieve this?

We were originally registered to ISO 13485 on 16/02/2004; the certificate will expire on 05/02/2018.

This concludes our response. We trust that you find this helpful, but please do not hesitate to contact us directly if we can be of any further assistance.

If, after that, you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of receipt of the response to your original letter and should be addressed to:

Trust Secretary
University Hospitals Bristol NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
BS1 3NU

Please remember to quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

To view the Freedom of Information Act in full please click [here](#).

Yours sincerely,

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