

Addressing Compliance in NHS Pathology Services

All NHS Pathology Services are obliged to implement a Quality Management system compliant with the Clinical Pathology Accreditation (UK) Ltd's Standards for the Medical Laboratory. The 'CPA' Standards demand evidence of robust pre-examination, examination and post examination processes and are based on a range of International Standards and Essential Criteria that seek ultimately to reduce risk to the patient.

Formal recognition of competency through accreditation is mandatory for NHS Trust laboratories. Failure to achieve accreditation can impact access to funding and the Trust's liability insurance premiums. Verification of a laboratory's compliance requires evidence and documentation forms the major part of this evidence.

Documentation includes mission statements, policies, detailed laboratory procedures, meeting minutes and worksheets. *"The preparation of this documentation is perhaps the most lengthy and time consuming part of the accreditation process for laboratories, but because of the evidential nature of many standards it is essential that this is undertaken in a systematic and structured way."* (David Burnett, Understanding Accreditation in Laboratory Medicine, ACB Venture Publications 1996).

The time required to locate, review, update and distribute documentation impacts the stretched resources of most laboratories. Paradoxically, many Pathology Services are concerned that the document management effort inhibits their ability to focus on the continuous improvement of their services.

Leeds Teaching Hospitals NHS Trust Pathology Directorate

The Leeds Teaching Hospital Directorate of Pathology provides Pathology laboratory services to The Leeds Teaching Hospitals and Bradford Hospitals NHS Trusts.

There are eight main departments based on nine sites in seventeen buildings across Leeds and Bradford. The Directorate employs 900 staff and processes over 3 million patient sample requests a year.

All departments were CPA accredited or seeking accreditation and had in place systems and processes in order to comply with CPA standards. However, each department operated these systems and processes independently of each other, making change control and audit, although under the control of a Quality Co-ordinator for each department, problematical and inconsistent.

Tackling the Compliance Headache

The Directorate of Pathology decided that a common quality management system across all departments would reduce duplication and contribute towards an integrated approach across all Pathology disciplines.

A common system would also positively contribute to the Pathology CNST and Clinical Governance agenda by:

Standardising quality improvement processes

Systematically disseminating innovation

Detecting adverse events and learning from them

Learning from complaints

Recognising and managing poor performance

Reflecting the above in professional development

Developing high quality systems to support all clinical governance activity

Involving service users in planning decisions

Mark Davy, the Quality Manager of the Haematology Department was tasked with co-ordinating the procurement project. With support from the Directorate's IT team Mark set about investigating potential solutions. A detailed statement of requirement for a Quality Management Document System was produced by a Quality Steering Committee that comprised representatives of each discipline.

The chosen system had to address key issues and risks:

- The system had to make information instantly accessible, prompt regular update and record approval by appropriate staff.
- Delivery and acknowledgement of new or changed documents had to be fully traceable to reduce the risk of staff using out of date procedures or even ignoring procedures.
- The system had to underpin continuous improvement by prompting regular review and update of content. Analysis of improvement activity had to be automatically generated.
- The system had to reduce the risk of liability by automating the production of evidence to demonstrate compliance with due process and standard operating procedures.
- The system had to facilitate CPA Accreditation and reduce the ongoing administrative and financial burden of compliance.

The specification was sent to a number of potential suppliers and those shortlisted were invited to demonstrate their systems and provide a detailed response to the Pathology team's specification. The evaluation process took place in Autumn 2004 and a decision was reached and an order placed in November 2004.

The myEQMS.com Solution

The myEQMS.com solution from Qualsys was selected as the product that best matched the Pathology team's specification.

Robert Oakley, commercial director at Qualsys commented, *"myEQMS.com is used in a range of industries to support compliance with regulations and standards. We already work with a number of NHS Trusts, supporting clinical governance initiatives in a range of departments. This project was an exciting opportunity to demonstrate how myEQMS.com can simplify CPA compliance, streamlining administration and ensuring all staff have access to the right document when they need it."*

The myEQMS.com system provides a repository for all types of computer files and applications, and has allowed all eight Pathology Departments to load existing documentation (predominantly Microsoft Word documents) and providing scope for introducing alternative formats such as video and audio at a later stage. A hierarchical navigational structure, has been tailored to each pathology departments' requirements, allows users to browse relevant, 'live' documents. The search engine permits detailed search on the content of the repository.

The system incorporates document control and approval, versioning and archiving functionality. Definitive versions of files are accessible to end-users but only those staff with appropriate administrative permissions can make alterations. Security controls allow administrators to tailor the view of content down to an individual user level if necessary.

Additional functionality automates review and approval, prompting action by email and system messages. This means that a new SOP is only released by the system once it has been signed off by the appropriate members of staff in the appropriate sequence. Groups of users are notified of the release of critical content and are asked to record their acknowledgement. Non-compliance with action requests triggers escalation messages to management. The EQMS database maintains comprehensive audit trails of all system activity as evidence of compliance. EQMS is equipped with a full Report Suite that permits Managers to monitor the effectiveness of documented processes and procedures. *"This is an important component of any quality system"* says Oakley.

The Advantages of Web Services Deployment

A key advantage influencing selection was that myEQMS.com is deployed as a fully functional Web Service. This meant that system-use is easily extended as widely as required across all Trust sites, with the potential for remote access for POC (Point Of Care) testing. Furthermore, the Pathology IT team were concerned about implementing, supporting and maintaining another new system on their own network infrastructure.

Keith Gailer, IT Operations manager said, *"We were very keen to exploit the Web Service concept as a cost-effective way of introducing new solutions quickly and efficiently. Currently, the NHS and the Trust are rolling out new systems, updating hardware and software platforms and training staff continuously. This places significant demands on my team and leaves little time to support new initiatives."*

Accordingly, the my.EQMS.com Web Service platform proved an ideal fit, providing the resilience and security required by the Trust without tying up valuable support resource. Keith was enthusiastic about the web service as it provided benefits beyond the functional:

- Stable hosting environment managed by experienced professionals;
- State of the art security infrastructure to protect the Trust's data;
- Data held in an environment with 100% track-record for availability;
- 24/7 technical support;
- Regular updates and maintenance;
- No burden on the Trust's IT department.
- No need to purchase additional hardware or software

All Trust staff access the system and do their work via standard browser technology on their desktops.

The Benefits to the Trust

All Pathology staff now have access to online SOPs, policies, forms and reports. All content is now in a controlled environment where it cannot be amended without the approval of the appropriate members of staff. All superseded versions are auto-archived providing a complete audit trail for external assessors. Users have confidence that they are always using the right policy, SOP or form and the scope for error has been significantly reduced.

The Pathology Department are able to administer and maintain their own system completely independently with no need to draw on valuable IT support. The system has reduced paper usage and the effort expended in making sure staff are up to date with latest SOPs. All appropriate staff are notified via email of a new SOP. The system records acknowledgements for each new SOP. This provides complete traceability and removes a huge amount of unproductive work associated with the CPA compliance effort.

"myEQMS.com has dramatically reduced the amount of time spent searching for information. Ease of access to our SOPs makes them far more usable than before. This has helped standardise our laboratory processes and minimise the risk of error." says Mark Davy.



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