

Clinical Audit – Statutory and Mandatory Requirements

When carried out in accordance with best practice standards, clinical audit:

- Provides assurance of compliance with clinical standards;
- Identifies and minimises risk, waste and inefficiencies;
- Improves the quality of care and patient outcomes.

This table summarises the current statutory and mandatory requirements imposed on healthcare providers who work in the NHS in England. It will be kept under review and updated as necessary. **LAST REVIEW DATE: 7 December 2011.**

| SOURCE | EXTRACTS AND INFORMATION | COMMENTS |
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| <p>The Health & Social Care Act, 2008 http://www.legislation.gov.uk/ukpga/2008/14/contents</p> <p>NOTE: throughout this table, text in black has been taken directly from the referenced source documents. Text in blue has been written by HQIP. Web links to source documents are underlined and in blue.</p> | <p>Chapter 2 of Part 1 creates a system of registration for providers and, in some cases, managers of health and adult social care. Regulations will set out the health and social care activities (referred to as ‘regulated activities’), which a person will not be able to carry on unless that person is registered to do so. The intention is that all providers, including, for the first time, NHS providers, will be brought within the ambit of registration. The new registration system replaces (in England) the current requirement for certain establishments and agencies providing independent health care or adult social care to be registered under the Care Standards Act 2000. The Commission will need to be satisfied that applicants for registration comply with registration requirements, which will be set out in regulations. Once a provider or manager has been registered, the Commission will be responsible for checking continued compliance with these requirements, and will have a range of sanctions so that it can take appropriate action where providers or managers fail to meet the requirements. The Commission will have a wider range of powers than its predecessor organisations, including the power to issue penalty notices for non-compliance with regulatory requirements and the power to suspend registration.</p> <p>http://www.legislation.gov.uk/ukpga/2008/14/notes/division/2/1</p> | <p>This is the statutory basis for the system of registration and regulation which the Care Quality Commission (CQC) operates. Full details of who is required to register and the process of monitoring and assessment are given on the CQC website (see below)</p> |
| <p>The Health & Social Care Act, 2008 – Regulations http://www.legislation.gov.uk/ukdsi/2009/9780111487006/contents</p> | <p><i>(See extracts below regarding the CQC. These regulations spell out the detail of the CQC regulatory framework.)</i></p> | |

Care Quality Commission (CQC)

<http://www.cqc.org.uk/>

CQC Guidance about compliance: Essential Standards of Quality and Safety

Outcome 14 Supporting workers

Extract from the regulations:

23.—(1) The registered person must have suitable arrangements in place in order to ensure that persons employed for the purposes of carrying on the regulated activity are appropriately supported in relation to their responsibilities, to enable them to deliver care and treatment to service users safely and to an appropriate standard, including by—

(a) receiving appropriate training, professional development, supervision and appraisal; and

(b) being enabled, from time to time, to obtain further qualifications appropriate to the work they perform.

(2) Where the regulated activity carried on involves the provision of health care, the registered person must (as part of a system of clinical governance and audit) ensure that healthcare professionals employed for the purposes of carrying on the regulated activity are enabled to provide evidence to their relevant professional body demonstrating, where it is possible to do so, that they continue to meet the professional standards which are a condition of their ability to practise.

(3) For the purposes of paragraph (2), “system of clinical governance and audit” means a framework through which the registered person endeavours continuously to—

(a) evaluate and improve the quality of the services provided; and

(b) safeguard high standards of care by creating an environment in which clinical excellence can flourish.

Regulation 23 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

Healthcare providers must ensure healthcare professionals are enabled to participate in clinical audit in order to satisfy the demands of the relevant professional bodies (for example, for revalidation)

Outcome 16 Assessing and monitoring the quality of service provision

Extract from the regulations:

10.—(1) The registered person must protect service users, and others who may be at risk, against the risks of inappropriate or unsafe care and treatment, by means of the effective operation of systems designed to enable the registered person to—

- (a) regularly assess and monitor the quality of the services provided in the carrying on of the regulated activity against the requirements set out in this Part of these Regulations; and
- (b) identify, assess and manage risks relating to the health, welfare and safety of service users and others who may be at risk from the carrying on of the regulated activity.

(2) For the purposes of paragraph (1), the registered person must—

- (a) where appropriate, obtain relevant professional advice;
- (b) have regard to—
 - (i) the complaints and comments made, and views (including the descriptions of their experiences of care and treatment) expressed, by service users, and those acting on their behalf, pursuant to sub-paragraph (e) and regulation 19,
 - (ii) any investigation carried out by the registered person in relation to the conduct of a person employed for the purpose of carrying on the regulated activity,
 - (iii) the information contained in the records referred to in regulation 20,
 - (iv) appropriate professional and expert advice (including any advice obtained pursuant to sub-paragraph (a)),
 - (v) reports prepared by the Commission from time to time relating to the registered person’s compliance with the provisions of these Regulations, and
 - (vi) periodic reviews and special reviews and investigations carried out by the Commission in relation to the provision of health or social care, where such reviews or

Healthcare providers must regularly assess and monitor the quality of the services provided.

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| | <p>investigations are relevant to the regulated activity carried on by the service provider;</p> <p>(c) where necessary, make changes to the treatment or care provided in order to reflect information, of which it is reasonable to expect that a registered person should be aware, relating to—</p> <p>(i) the analysis of incidents that resulted in, or had the potential to result in, harm to a service user, and</p> <p>(ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies;</p> <p>(d) establish mechanisms for ensuring that—</p> <p>(i) decisions in relation to the provision of care and treatment for service users are taken at the appropriate level and by the appropriate person (P), and</p> <p>(ii) P is subject to an appropriate obligation to answer for a decision made by P, in relation to the provision of care and treatment for a service user, to the person responsible for supervising or managing P in relation to that decision; and</p> <p>(e) regularly seek the views (including the descriptions of their experiences of care and treatment) of service users, persons acting on their behalf and persons who are employed for the purposes of the carrying on of the regulated activity, to enable the registered person to come to an informed view in relation to the standard of care and treatment provided to service users.</p> <p>(3) The registered person must send to the Commission, when requested to do so, a written report setting out how, and the extent to which, in the opinion of the registered person, the requirements of paragraph (1) are being complied with, together with any plans that the registered person has for improving the standard of the services provided to service users with a view to ensuring their health and welfare.</p> <p><i>Regulation 10 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010</i> http://www.cgc.org.uk/db/documents/Essential_standards_of_quality_and_safety_March_2010_FINAL.pdf</p> | <p>They must use the findings from clinical and other audits, including those undertaken at a national level, and national service reviews to ensure that action is taken to protect people who use services from risks associated with unsafe care, treatment and support</p> <p>And they must regularly seek the views of service users.</p> |
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| | <p>SEE ALSO Guidance about compliance: Judgement Framework (http://www.cqc.org.uk/db/documents/Judgement_framework_March_2010_FINAL_201010083115.pdf) for case studies demonstrating the use of clinical audits to provide evidence on assessment.</p> <p>Quality and Risk Profiles (QRP) are essential tools for providers, commissioners and CQC staff in monitoring compliance with the Essential standards of quality and safety. The QRPs do this by drawing in data from a number of sources which are analysed to identify areas of potential non compliance within a provider.</p> <p>The CQC has produced ‘Data source documents’ for each of the five types of NHS provider, which specify the sources of data used to feed into the profiles for each essential standard. This includes National Clinical Audit Datasets. These documents should be updated regularly and reference should be made to the most recent versions, available from the CQC website.</p> <p>http://www.cqc.org.uk/organisations-we-regulate/registered-services/quality-and-risk-profiles-qrps</p> | |
| <p>Department of Health:</p> <p>The NHS standard contracts for acute hospital, mental health, community and ambulance services and supporting guidance 2011-12 (effective from 1 April 2011)</p> <p>http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_124324</p> | <p>The NHS standard contracts cover agreements between PCTs and all of provider delivering NHS funded services. The contract will apply to new agreements from April 2011 for:</p> <ul style="list-style-type: none"> NHS Trusts NHS Foundation Trusts Independent Sector providers Charitable and Voluntary sectors Social Enterprises <p>The provisions relating to clinical audit are the same for all service providers – the following extracts are from the Acute Contract Terms.</p> | |

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| | <p>12.1 The Provider shall:</p> <p>12.1.1 participate in the Clinical Networks and Screening Programmes listed in Schedule 20 (<i>see below</i>)</p> <p>12.1.2 participate in the national clinical audits within the National Clinical Audit Patients Outcome Programme (NCAPOP) relevant to the Services; and</p> <p>12.1.3 where it deems it to be appropriate having regard to its obligations under clause 6 (<i>Co-operation</i>), participate in such other partnership arrangements as may be in place in the relevant local health economies,</p> <p>and the Provider shall adhere to all protocols and procedures they operate or recommend, unless they conflict with existing protocols and procedures agreed between the Parties, in which case the Parties shall review any such conflict and resolve it.</p> <p>19.4 Subject to compliance with the Law and Good Clinical Practice and Good Health and/or Social Care Practice or unless otherwise agreed with the Co-ordinating Commissioner, the parties shall implement all relevant recommendations:</p> <p>19.4.1 in any report by the Care Quality Commission or Monitor;</p> <p>19.4.2 agreed with the National Audit Office or the Audit Commission following any audit;</p> <p>19.4.3 of any appropriate clinical audit, and</p> <p>19.4.4 that are otherwise agreed by the Provider and the Co-ordinating Commissioner to be implemented.</p> | <p>Providers must participate in the NCAPOP audits which are relevant to the services they provide</p> <p>and must implement all relevant recommendations of any appropriate clinical audit.</p> |
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| | <p style="text-align: center;">SCHEDULE 1 – DEFINITIONS AND INTERPRETATION</p> <p>“National Clinical Audit Patients Outcome Programme” or “NCAPOP” means a set of centrally-funded national projects that provide provider organisations with a common format to collect data for central analysis and provides comparative findings feed back to help participants identify necessary improvements for patients.</p> <p style="text-align: center;">SCHEDULE 20 – CLINICAL NETWORKS AND SCREENING PROGRAMMES</p> <p style="text-align: center;">(For local agreement and not to conflict with any information in Service Specifications)</p> <p>http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_124518.pdf</p> | <p>NOTE: the National Joint Registry (NJR), which is commissioned and managed by HQIP, forms part of the NCAPOP. Participation is therefore mandated under this contract.</p> <p>Providers and commissioners must agree locally which clinical networks and screening programmes the provider is required to participate in.</p> |
| <p>Department of Health: Quality Accounts</p> <p>http://www.dh.gov.uk/en/Healthcare/Qualityandproductivity/Makingqualityhappen/Qualityaccounts/index.htm</p> | <p>Health Act 2009</p> <p>8. Duty of providers to publish information</p> <p>(1) Each of the bodies listed in subsection (2) must, in accordance with regulations made by the Secretary of State, publish in respect of each reporting period a document containing prescribed information relevant to the quality of—</p> <p style="padding-left: 40px;">(a) any NHS services that the body provides;</p> <p>http://www.legislation.gov.uk/ukpga/2009/21/section/8</p> | <p>This Act and these Regulations provide the statutory basis for the requirement for specified healthcare providers to produce Quality Accounts.</p> |

The National Health Service (Quality Accounts) Regulations 2010

Schedule

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| 2. | The number of national clinical audits(1) and national confidential enquiries(2) which collected data during the reporting period and which covered the NHS services that the provider provides or sub-contracts. | During [<i>reporting period</i>] [<i>number</i>] national clinical audits and [<i>number</i>] national confidential enquiries covered NHS services that [<i>name of provider</i>] provides. |
| 2.1. | The number, as a percentage, of national clinical audits and national confidential enquiries, identified under entry 2, that the provider participated in during the reporting period. | During that period [<i>name of provider</i>] participated in [<i>number as a percentage</i>] national clinical audits and [<i>number as a percentage</i>] national confidential enquiries of the national clinical audits and national confidential enquiries which it was eligible to participate in. |
| 2.2 | A list of the national clinical audits and national confidential enquires identified under entry 2 that the provider was eligible to participate in. | The national clinical audits and national confidential enquiries that [<i>name of provider</i>] was eligible to participate in during [<i>reporting period</i>] are as follows: [<i>insert list</i>]. |
| 2.3 | A list of the national clinical audits and national confidential enquiries, identified under entry 2.1, that the provider participated in. | The national clinical audits and national confidential enquiries that [<i>name of provider</i>] participated in during [<i>reporting period</i>] are as follows: [<i>insert list</i>]. |
| 2.4 | A list of each national clinical audit and national confidential enquiry that the provider participated in | The national clinical audits and national confidential enquires that [<i>name of provider</i>] participated in and for which data collection |

Section 2 of the schedule to the regulations specifies the content required in respect of clinical audits

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| | <p>and which data collection was completed for during the reporting period, alongside the number of cases submitted to each audit, as a percentage of the number required by the terms of the audit or enquiry.</p> | <p>was completed during [<i>reporting period</i>], are listed below alongside the number of cases submitted to each audit or enquiry as a percentage of the number of registered cases required by the terms of that audit or enquiry. <i>[insert list and percentages]</i></p> | |
| <p>2.5</p> | <p>The number of national clinical audit reports published during the reporting period that were reviewed by the provider during the reporting period.</p> | <p>The reports of [<i>number</i>] national clinical audits were reviewed by the provider in [<i>reporting period</i>] and [<i>name of provider</i>] intends to take the following actions to improve the quality of healthcare provided [<i>description of actions</i>].</p> | |
| <p>2.6.</p> | <p>A description of the action the provider intends to take to improve the quality of healthcare following the review of reports identified under entry 2.5.</p> | <p>The reports of [<i>number</i>] local clinical audits were reviewed by the provider in [<i>reporting period</i>] and [<i>name of provider</i>] intends to take the following actions to improve the quality of healthcare provided [<i>description of actions</i>].</p> | |
| <p>2.7.</p> | <p>The number of local clinical audit(3) reports that were reviewed by the provider during the reporting period.</p> | | |
| <p>2.8.</p> | <p>A description of the action the provider intends to take to improve the quality of healthcare following the review of reports identified under entry 2.7.</p> | | |
| <p>http://www.legislation.gov.uk/uksi/2010/279/contents/made</p> | | | |

Quality Accounts Toolkit 2010/2011

This toolkit is aimed at providers of NHS services, in order to offer advice as they set out to produce their Quality Accounts for June 2011. It seeks to consolidate the understanding of the purpose of Quality Accounts and to guide their production based on what the public, NHS staff and other interested parties have said during the national engagement and testing processes.

<http://www.dh.gov.uk/en/Healthcare/Qualityandproductivity/Makingqualityhappen/Qualityaccounts/index.htm>

Presentation of the data

4.48 The clarity of reporting Trusts participation in national clinical audits in 2009/10 Quality Accounts was variable. Whilst some of you prepared information in a clear and easy to understand format, others fell short for the criteria set out in the mandated requirements.

4.49 For 2010/11 you should set out in tabular form all the national clinical audits and national confidential enquiries that were recommended for 2010-11. For each audit or enquiry, show those that applied to services provided by your Trust and those that did not, stating whether or not you participated and the proportion of registered cases submitted, against the total number of cases you could have submitted, or those required by the terms of that audit or enquiry, as in the following example:

| Audit | Participation | % Cases submitted |
|--|---------------|-------------------|
| Acute care | | |
| Emergency use of oxygen (British Thoracic Society) | Yes | X% |
| Adult community acquired pneumonia (British Thoracic Society) | Yes | X% |
| Non invasive ventilation (NIV) - adults (British Thoracic Society) | Yes | X% |
| Pleural procedures (British Thoracic Society) | No | NA |
| Cardiac arrest (National Cardiac Arrest Audit) | Yes | X% |
| Vital signs in majors (College of Emergency Medicine) | Yes | X% |

There is an extensive section on the requirements around clinical audit – this is an extract but the full document should be consulted.

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| Adult critical care (ICNARC CMPD) | Yes | X% |
| Potential donor audit (NHS Blood & Transplant) | Yes | X% |

For each national audit or confidential enquiry that you are not currently participating in, you are encouraged to explain your reasons for not doing so; or if you intend joining in the future, you may wish to set a projected date for commencement of participation.

Reviewing reports of national clinical audits

4.50 It is essential that providers, clinicians and managers reflect on the findings of national clinical audits and national confidential enquiries. Where necessary, they should take the lead on instigating changes to improve processes and/or change practice, and review the impact of these changes through participating in subsequent re-audit or other review.

4.51 In your statement, you should state the number of national clinical audit reports (published in the calendar year 2010) that were reviewed by your Board and, for each of those audits, the actions taken to improve the quality of services and the outcomes of care.

4.52 Last year most Trusts failed to present details of any actions to improve quality following the review of a national clinical audit reports. To support you in 2011 we will provide a list of national clinical audit reports published during the 2010 calendar year. The Quality Account should set out which of these your Trust has reviewed during 2010/11 and the actions taken to improve quality.

See the HQIP portal <http://www.hqip.org.uk/national-clinical-audits-for-inclusion-in-quality-accounts/> for access to the list of national clinical audits to be included in quality accounts, latest reports and access to the project websites.

Reviewing reports of local clinical audits

4.54 Local clinical audit can also be important in measuring and benchmarking clinical practice against agreed markers of good professional practice, stimulating changes to improve practice and re-measuring to determine any service improvements.

4.55 In your statement, you should state the number of local clinical audit reports reviewed by your Board and provide details of actions taken to improve the quality of local services and the outcomes of care.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_122545

Monitor

<http://www.monitor-nhsft.gov.uk/home>

Compliance Framework 2011/2012

Quality

57. Quality is a key responsibility of the board and is primarily monitored by third parties, in particular by the Care Quality Commission. Monitor does not intend to duplicate existing regulation in this area.

58. However, Monitor considers that maintaining and improving quality is an important indicator of governance at a trust. Boards will make two quality-related board statements to Monitor to:

- certify annually that, to the best of their knowledge and using their own processes, they are satisfied that plans in place are sufficient to ensure ongoing compliance with the Care Quality Commission’s registration requirements; and
- certify that, to the best of their knowledge and using their own processes, they are satisfied that their NHS foundation trust has and will keep in place effective arrangements for the purpose of monitoring and continually improving the quality of healthcare provided to patients.

(For the full text of the statements, see extracts from Appendices C3 and D2 below.)

59. For the purposes of this certification, ‘quality’ comprises:

- patient safety;
- clinical effectiveness; and
- patient experience.

In order to make this statement, boards are expected to have regard to Monitor’s Quality Governance Framework and be able to:

- describe their own objectives for improving quality;
- identify metrics to monitor quality in terms of clinical outcomes, patient or service user safety and experience, and expected levels of performance;

Foundation Trust Boards must certify that they have effective arrangements in place for the purpose of monitoring and continually improving the quality of healthcare provided to patients.

- confirm that the board is satisfied that, to the best of its knowledge and using its own processes (supported by Care Quality Commission information and including any further metrics it chooses to adopt), its NHS foundation trust has, and will keep in place, effective arrangements for the purpose of monitoring and continually improving the quality of healthcare provided to its patients; and
 - certify that actions will be taken in order to be in a position to make the revised statement by the time of the trust's quarter two submission.
- The board will certify annually that, to the best of its knowledge and using its own processes, it is satisfied that plans in place are sufficient to ensure ongoing compliance with the Care Quality Commission's registration requirements.

Appendix D2: in-year quality board statement

For quality, that:

- The board is satisfied that, to the best of its knowledge and using its own processes and having had regard to Monitor's Quality Governance Framework (supported by Care Quality Commission information, its own information on serious incidents, patterns of complaints, and including any further metrics it chooses to adopt), its NHS foundation trust has, and will keep in place, effective arrangements for the purpose of monitoring and continually improving the quality of healthcare provided to its patients.

This statement has changed in 2011/12. If an NHS foundation trust board is unable to make this revised statement at quarter one, the board must:

- confirm that the board is satisfied that, to the best of its knowledge and using its own processes (supported by Care Quality Commission information and including any further metrics it chooses to adopt), its NHS foundation trust has, and will keep in place, effective arrangements for the purpose of monitoring and continually improving the quality of healthcare provided to its patients; and
- certify that actions will be taken in order to be in a position to make the revised statement by the time of the trust's quarter two submission.

See Also Appendix H, Monitor's Quality Governance Framework, section 3B:

- There is a well-functioning, impactful clinical and internal audit process in relation to quality governance, with clear evidence of action to resolve audit concerns
 - Continuous rolling programme that measures and improves quality
 - Action plans completed from audit
 - Re-audits undertaken to assess improvement

http://www.monitor-nhsft.gov.uk/sites/default/files/COMPLIANCE%20FRAMEWORK_final.pdf

Schedule 6 - The link below is to the latest version of Schedule 6 of the NHS foundation trusts' Terms of Authorisation. (7 July 2011).

Schedule 6 was created as a result of work between Monitor, the Department of Health (DH) and the Healthcare Commission to streamline requests for information which do not comply with the following principles:

- only necessary information should be collected;
- collection should be performed at least cost;
- duplication should be avoided; and
- information should be made available quickly and usefully.

Building on the work to streamline existing reporting, Monitor and the DH developed an approval process for future requests for information based on the principles set out above. Approved requests are reviewed periodically. All requests for information, which NHS foundation trusts do not have a legal or statutory obligation to complete, require Monitor approval through this process before becoming mandatory. They are then added to Schedule 6.

<http://www.monitor-nhsft.gov.uk/sites/default/files/Schedule%206%20-%207%20July%202011.pdf>

Lists all mandatory data collections from NHS Foundation Trusts.

The NHS Litigation Authority (NHSLA) Clinical Negligence Scheme for Trusts (CNST)

<http://www.nhsla.com/>

The Clinical Negligence Scheme for Trusts handles all clinical negligence claims against member NHS bodies where the incident in question took place on or after 1 April 1995 (or when the body joined the scheme, if that is later). Although membership of the scheme is voluntary, all NHS Trusts (including Foundation Trusts) and Primary Care Trusts (PCTs) in England currently belong to the scheme. While Independent Sector Treatment Centres cannot join the scheme in their own right, they can benefit from cover when treating NHS patients via the membership of their referring PCT.

The costs of the scheme are met by membership contributions. The projected claim costs are assessed in advance each year by professional actuaries. Contributions are then calculated to meet the total forecast expenditure for that year. Individual member contribution levels are influenced by a range of factors, including the type of trust, the specialties it provides and the number of “whole time equivalent” clinical staff it employs. Discounts are available to those trusts which achieve the relevant NHSLA risk management standards and to those with a good claims history.

<http://www.nhsla.com/Claims/Schemes/CNST/>

A key function for the NHSLA, as set out in our Framework Document, is to “contribute to the incentives for reducing the number of negligent or preventable incidents”. We aim to achieve this through an extensive risk management programme.

NHSLA standards and assessments

The core of our risk management programme is provided by a range of NHSLA standards and assessments. Most Healthcare organisations are regularly assessed against these risk management standards which have been specifically developed to reflect issues which arise in the negligence claims reported to the NHSLA. There is a set of risk management standards for each type of healthcare organisation incorporating organisational, clinical, and health & safety risks.

<http://www.nhsla.com/RiskManagement/>

Explaining the background to the scheme and the Risk Management Standards.

NHSLA Risk Management Standards for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care 2011/12

<http://www.nhsla.com/NR/rdonlyres/3A954C45-1178-4202-86AF-04FAD75471D7/0/NHSLAAcuteCommunityMHLdandIndependentSectorStandards201112.doc>

NHSLA Risk Management Standards for Ambulance Trusts 2011/12

<http://www.nhsla.com/NR/rdonlyres/1B62FFA1-C5FC-49B5-BEF1-0C3025201A40/0/NHSLAAmbulanceStandards201112.doc>

5.7 All of the criteria require an approved document to be in place. These documents could include strategies, policies, guidelines, standard operating procedures or protocols. Such evidence provided in support of a criterion must be in place and effective at the time of assessment and have been approved by the agreed method as per the organisation's policy on procedural documents. Draft documentation, or planned or proposed systems that have not been implemented, will not be admissible.

5.8 The Level 1 assessment is only concerned with the existence of the minimum requirements for each criterion in the approved documentation, and as such the quality of these will not be rigorously tested until the Level 2 assessment. Therefore compliance at Level 1 should not be seen as an indication that the organisation will be able to demonstrate compliance at Level 2 or that it is effectively managing risks.

At Level 1 the evidence presented at assessment must be in use and reflective of day to day practice within the organisation. To test this, the assessor(s) will randomly select ten documents from the organisation's evidence portfolio and ask to see evidence of their approval. Additionally, the assessor(s) will review the organisation's intranet and/or policy folders to ensure that the ten documents are readily available for use by staff. If the organisation is unable to evidence that all ten documents have been approved and are in use, it will be deemed to be at Level 0 and placed under improvement measures.

The basic principles of the CNST are outlined in the Risk Management Standards. The extracted text appears in both sets of standards.

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| | <p>5.9 Audits and other monitoring tools will be acceptable as evidence of implementation at Level 2 but as they do not demonstrate practical evidence of implementation assessors may also need to view health records, risk assessments, incident reports, meeting minutes, training records etc.</p> <p>5.10 At Level 2, the assessors will in most cases look for 12 months of evidence to demonstrate compliance. In such instances the 12 month period must reflect one of the following:</p> <ul style="list-style-type: none"> • 12 calendar months preceding the assessment - if this option is chosen, the last month in the data collection period must be no later than 12 months before the assessment, e.g. if the organisation is being assessed in December 2011, the last month in the data collection period must not pre-date December 2010; • the financial year immediately preceding the assessment; • the calendar year immediately preceding the assessment. <p>The organisation should indicate to the assessors on the evidence template the data collection period being used.</p> <p>The evidence presented to the assessors must be reflective of the full time period, i.e. in presenting evidence for a calendar year it would not be acceptable to present training records for September to December only. Failure to provide such evidence will result in non-compliance being awarded.</p> <p>In circumstances where processes are new, evidence of previous processes may be acceptable. The organisation should discuss such instances with the assessors prior to the assessment.</p> <p>For any of the Level 2 criteria, the assessors may ask to interview staff to seek clarification on the evidence reviewed and may also ask to visit clinical and non-clinical areas to verify whether systems are in place.</p> <p>5.11 At Level 3, the assessors will require organisations to demonstrate through monitoring that their processes to manage risk have been implemented.</p> <p>Monitoring should reflect all areas of the organisation and where applicable all staff groups and all patient groups.</p> <p>Where deficiencies have been identified action plans must have been drawn up and changes made to reduce the risks.</p> <p>For any of the Level 3 criteria, the assessors may ask to interview staff to seek clarification on the evidence reviewed and may also ask to visit clinical and non-clinical areas to verify whether systems are in place and working.</p> | |
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| Standard 5 - Criterion 1: Clinical Audit | |
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| The organisation has an approved documented process for ensuring that all clinical audits are undertaken, completed and reported on in a systematic manner that is implemented and monitored. | |
| Level 1 | Minimum Requirements |
| 1.5.1 | <p>As a minimum, the approved documentation must include a description of the:</p> <ol style="list-style-type: none"> a. duties b. process for setting priorities for a clinical audit programme including participation in local and national clinical audit c. process for ensuring that audit tools reflect the standards set out in the organisation's approved documents d. process for disseminating audit results/reports e. format for all audit reports, i.e. methodology, conclusions, action plans, etc. f. process for making improvements g. process for monitoring action plans and carrying out re-audits h. process for monitoring compliance with all of the above. |
| Level 2 | Minimum Requirements |
| 2.5.1 | <p>The organisation can demonstrate compliance with the objectives set out within the approved documentation described at Level 1, in relation to the:</p> <ul style="list-style-type: none"> • process for ensuring that audit tools reflect the standards set out in the organisation's approved documents • process for making improvements. |
| Level 3 | Minimum Requirements |
| 3.5.1 | The organisation can demonstrate that it is monitoring compliance with the minimum requirements contained within the approved documentation described at Level 1, in |

Standard 5.1 applies to all providers who are part of the scheme.

NOTE: the original document includes hyperlinks which have been removed in this version for ease of reading.

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| | <p>relation to the:</p> <ul style="list-style-type: none"> • process for ensuring that audit tools reflect the standards set out in the organisation's approved documents • process for making improvements. <p>Where the monitoring has identified deficiencies, there must be evidence that recommendations and action plans have been developed and changes implemented.</p> | |
| | <p>Clinical Negligence Scheme for Trusts: Maternity Clinical Risk Management Standards Version 1 2011/12</p> <p>The NHSLA is aware of concerns raised by some maternity services about the Level 3 audit requirements for maternity records. It has been suggested that for audits to be useful they need to cover a short timescale to allow for any deficiencies to be identified and rectified at an early stage. Thus the NHSLA's requirement for audits to cover a twelve month period prohibits their usefulness. The NHSLA does not, however seek to prevent audits from being carried out on a more frequent and regular basis and would encourage maternity services to audit practice in accordance with their own predetermined timescales. Nevertheless for the NHSLA to award its highest level of compliance (Level 3) to a maternity service it needs to be assured that the systems and processes described within a service's guidelines have been in place and working for a minimum of twelve months. The NHSLA will continue to look at alternative ways of seeking assurance that systems are in use and would welcome suggestions on how this can be achieved from maternity services or other stakeholders.</p> <p>http://www.nhsla.com/NR/rdonlyres/48887534-BC71-4355-BE6E-482C3238E7CE/0/CNSTMaternityStandards201112.doc</p> | <p>In addition to Standard 5.1 the CNST Risk Management Standards for Maternity Services included specific requirements for audit. Any provider of maternity services should review them in detail. This extract is from the overview.</p> |

Mandatory requirements for individuals

| SOURCE | EXTRACTS AND INFORMATION | COMMENTS |
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| <p>General Medical Council</p> <p>www.gmc-uk.org</p> | <p>From ‘Supporting information for appraisal and revalidation’</p> <p>Review of your practice - evaluating the quality of your professional work</p> <p>2. Quality improvement activity</p> <p>For the purposes of revalidation, you will have to demonstrate that you regularly participate in activities that review and evaluate the quality of your work.</p> <p>Quality improvement activities should be robust, systematic and relevant to your work. They should include an element of evaluation and action, and where possible, demonstrate an outcome or change.</p> <p>Quality improvement activities could take many forms depending on the role you undertake and the work that you do. If you work in a non-clinical environment, you should participate in quality improvement activities relevant to your work.</p> <p>Examples of quality improvement activities include:</p> <ul style="list-style-type: none"> • Clinical audit - evidence of effective participation in clinical audit or an equivalent quality improvement exercise that measures the care with which an individual doctor has been directly involved • Review of clinical outcomes - where robust, attributable and validated data are available. This could include morbidity and mortality statistics or complication rates where these are routinely recorded for local or national reports • Case review or discussion - a documented account of interesting or challenging cases that a doctor has discussed with a peer, another specialist or within a multi-disciplinary team • Audit and monitor the effectiveness of a teaching programme • Evaluate the impact and effectiveness of a piece of health policy or management | <p>Revalidation is the process whereby, from 2012, all doctors who hold a license to practice will have to demonstrate to the GMC that they are fit to practice, and are doing so in accordance with the relevant professional standards.</p> |

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| | <p>practice</p> <p>If you work in a non-clinical role you might find it helpful to discuss options for a quality improvement activity with your appraiser, or a relevant professional association.</p> <p>Medical Royal College and Faculty guidance</p> <p>The medical Royal Colleges and Faculties will provide guidance on the type of activity that would be most appropriate for doctors working in particular specialties or general practice. Many specialties have in place robust and validated quality measures, such as national specialty databases. If you are in specialist practice, you should consult your College or Faculty guidance.</p> <p>Frequency</p> <p>Involvement in quality improvement activities is expected at least once every revalidation cycle; however the extent and frequency will depend on the nature of the activity. For example, participation in a full national clinical audit might be appropriate once per revalidation cycle, whereas a case review might be expected to take place more regularly. You should discuss and agree the frequency of the quality improvement activity with your appraiser.</p> <p>Discussing quality improvement activities at your appraisal</p> <p>Active participation relevant to your work</p> <p>You will need to demonstrate that you have actively participated in a quality improvement activity or a clinical audit relevant to your work.</p> <p>Evaluate and reflect on the results</p> <p>You need to demonstrate that you have evaluated and reflected on the results of the activity or audit. This might be through reflective notes about the implications of the results on your work, discussion of the results at peer-supervision, professional development or team meetings and contribution to your professional development.</p> <p>Take action</p> <p>You will need to demonstrate that you have taken appropriate action in response to the</p> | <p>As at 10 August 2011, medical Royal Colleges and faculties are still developing and / or consulting on specific guidance.</p> |
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| | <p>results. This might include the development of an action plan based on the results of the activity or audit, any change in practice following participation, and informing colleagues of the findings and any action required.</p> <p>Closing the loop - demonstration of outcome or maintenance of quality</p> <p>You should consider whether an improvement has occurred or if the activity demonstrated that good practice has been maintained. This should be through the results of a repeat of the activity or re-audit after a period of time where possible.</p> <p>http://www.gmc-uk.org/doctors/revalidation/9260.asp</p> | |
| <p>HQIP has produced a 'Guide to Involving Junior Doctors in Clinical Audit' (http://www.hqip.org.uk/assets/5-HQIP-CA-PD-026-Guide-to-Involving-Junior-Doctors-in-Clinical-Audit-19-April-2010.pdf) which describes the Foundation Programme curriculum requirements for participation in clinical audit, and the Postgraduate Medical Education and Training Board mandatory requirements for doctors training at Registrar levels.</p> | | |