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 mandatory and contractual requirements imposed on healthcare providers who work in the NHS in England.

LAST REVIEW DATE: OCTOBER 2017 - updated to include the 2016/17 NHS Standard Contract and notes on the consultation for the 2017/18 and 2018/19 contracts. Links have been refreshed as necessary.

SOURCE	EXTRACTS AND INFORMATION	COMMENTS
The Health & Social Care Act, 2008 http://www.legislation.gov.uk/ukpga/2008/14/contents 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.	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. http://www.legislation.gov.uk/ukpga/2008/14/notes/division/2/1	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)

The Health & Social Care Act, 2008 – Regulations http://www.legislation.gov.uk/uksi/2010/781/contents/made	(*See extracts below regarding the CQC. These regulations spell out the detail of the CQC regulatory framework.*)	
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.

	investigations are relevant to the regulated activity carried on by the service provider; (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— (i) the analysis of incidents that resulted in, or had the potential to result in, harm to a service user, and (ii) the conclusions of local and national service reviews, clinical audits and research projects carried out by appropriate expert bodies; (d) establish mechanisms for ensuring that— (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 (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 (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. (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. *Regulation 10 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010* http://www.cqc.org.uk/sites/default/files/media/documents/gac_-_dec_2011_update.pdf The CQC publish provider handbooks on how they register, inspect and enforce the regulations for a range of provider types – see http://www.cqc.org.uk/content/provider-handbooks	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 And they must regularly seek the views of service users.

NHS England http://www.england.nhs.uk/ **NHS Standard Contract** https://www.england.nhs.uk/nhs-standard-contract/ NHS England is responsible for the preparation and publication of the NHS Standard Contract. The contract is for use by NHS commissioners when commissioning healthcare services (other than those commissioned under primary care contracts) and is adaptable for use for a broad range of services and delivery models. **NOTE:** The section and paragraph numbers used are taken from the 2016/17 contract, and the content and numbering remains unchanged in the 2017/18 and 2018/19 contracts.	**SERVICE CONDITIONS** **Section SC26 Clinical Networks, National Audit Programmes and Approved Research Studies** 26.1 The Provider must: 26.1.1 participate in the Clinical Networks, programmes and studies listed in Schedule 2F (*Clinical Networks*); 26.1.2 participate in the national clinical audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP) relevant to the Services; and 26.1.3 make national clinical audit data available to support national publication of Consultant-level activity and outcome statistics in accordance with HQIP Guidance. 26.2 The Provider must adhere to all protocols and procedures operated or recommended under the programmes and arrangements referred to in Service Condition 26.1, unless in conflict with existing protocols and procedures agreed between the Parties, in which case the Parties must review all relevant protocols and procedures and try to resolve that conflict. **SC36 Payment Terms** **Operational Standards, National Quality Requirements and Local Quality Requirements** 36.37 Subject to SC36.37A, if the Provider breaches any of the thresholds in respect of the Operational Standards, the National Quality Requirements or the Local Quality Requirements the Provider must repay to the relevant Commissioner or the relevant Commissioner must deduct from payments due to the Provider (as appropriate), the relevant sums as determined in accordance with Schedule 4A (Operational Standards) and/or Schedule 4B (National Quality Requirements) and/or Schedule 4C (Local Quality Requirements). The sums repaid or deducted under this SC36.37 in respect of any Quarter will not in any event exceed 2.5% of the Actual Quarterly Value. 36.37A If the Provider has been granted access to the general element of the Sustainability and Transformation Fund, and has, as a condition of access:	Providers must participate in the NCAPOP audits which are relevant to the services they provide,, and make national clinical audit data available to support the publication of consultant level outcomes Commissioners may charge penalties in respect of any breach of quality requirements

	36.37A.1 agreed with the national teams of Monitor/NHSTDA (as appropriate) and NHS England an overall financial control total and other associated conditions; and 36.37A.2 (where required by those bodies): 36.37A2.1 agreed with those bodies and with the Commissioners specific performance trajectories to be achieved during the Contract Year 1 April 2016 to 31 March 2017 (as set out in an SDIP contained or referred to in Schedule 6D (Service Development and Improvement Plans)); and/or 36.37A2.2 submitted to those bodies assurance statements setting out commitments on performance against specific Operational Standards and National Quality Requirements to be achieved during the Contract Year 1 April 2016 to 31 March 2017 which have been accepted by those bodies (as set out in an SDIP contained or referred to in Schedule 6D (Service Development and Improvement Plans)), no repayment will be required to be made, nor any deduction made, in relation to any breach of any threshold which occurs during that Contract Year in respect of any Operational Standard shown in bold italics in Schedule 4A (Operational Standards) or any National Quality Requirement shown in bold italics in Schedule 4B (National Quality Requirements). **GENERAL CONDITIONS** **GC15 Governance, Transaction Records and Audit** 15.5 Subject to compliance with the Law and Good Practice the Parties must implement and/or respond to all relevant recommendations: 15.5.1 made in any report by a relevant Regulatory or Supervisory Body; or 15.5.2 agreed with the National Audit Office or a Local Auditor following any audit; or 15.5.3 of any appropriate clinical audit; or 15.5.4 that are otherwise agreed by the Provider and the Co-ordinating Commissioner to be implemented. 15.6 The Parties must maintain complete and accurate Transaction Records.	NOTE: Monitor and the NHSTDA are now part of NHS Improvement and the draft wording of the contract for 2017/18 and 2018/19 has been changed accordingly Providers must implement all relevant recommendations of any appropriate clinical audit.

	15.7 The Provider must, at its own expense, in line with applicable Law and Guidance: 15.7.1 implement an ongoing, proportionate programme of clinical audit of the Services in accordance with Good Practice; 15.7.2 implement an ongoing, proportionate audit of the accuracy of its recording and coding of clinical activity relating to the Services; and 15.7.3 provide to the Co-ordinating Commissioner on request the findings of any audits carried out under GC15.7.1 and/or 15.7.2. 15.8 The Co-ordinating Commissioner may at any time appoint an Auditor to audit: 15.8.1 the quality and outcomes of any Service; and/or 15.8.2 the Provider's recording and coding of clinical activity; and/or 15.8.3 the Provider's calculation of reconciliation accounts under SC36 (Payment Terms); and/or 15.8.4 the Provider's recording of performance and calculation of reconciliation accounts in relation to Quality Incentive Scheme Indicators; and/or 15.8.5 the Provider's recording of performance in respect of the Quality Requirements; and/or 15.8.6 the Provider's compliance with Other Local Agreements, Policies and Procedures and/or any Prior Approval Scheme and/or the Service Specifications; and/or 15.8.7 the basis of any Local Prices, taking into account the actual costs incurred by the Provider in providing the Services to which those Local Prices apply; and/or 15.8.8 pass-through costs on high cost drugs, devices and procedures; and/or 15.8.9 the identification of Chargeable Overseas Visitors and collection of charges from them or other persons liable to pay charges in respect of them under the Overseas Visitor Charging Regulations, and subject to any applicable Service User consent requirements, the Provider must allow the Auditor reasonable access to (and the right to take copies of) the Transaction Records, books of account and other sources of relevant information, and any Confidential Information so disclosed will be treated in accordance with GC20 (Confidential Information of the Parties).	And must implement a programme of clinical audit. Findings of any audit must be made available to the co-ordinating commissioner on request. The co-ordinating commissioner can appoint an auditor to audit quality and outcomes and recording and coding of clinical activity.

	Except as provided in GC15.11 and 15.12, the cost of any audit carried out under this GC15.8 will be borne by the Commissioners. 15.9 In respect of any audit carried out under GC15.8, the Co-ordinating Commissioner must share the Auditor's draft report with the Provider, to allow discussion of the findings and the correction of any inaccuracies before the production by the Auditor of a final report. 15.10 In respect of any audit carried out under GC15.8.1 or 15.8.6, if the Auditor's final report identifies any deficiencies in the Services, the Provider must take appropriate action to address those deficiencies without delay. **DEFINITIONS AND INTERPRETATION** **Auditor:** an appropriately qualified, independent third party auditor appointed by the Co-ordinating Commissioner in accordance with GC15.8 (Governance, Transaction Records and Audit) **Clinical Networks:** groups of commissioners and providers of health or social care concerned with the planning and/or delivery of integrated health or social care across organisational boundaries, whether on a national, regional or local basis **Local Quality Requirements:** the requirements set out in Schedule 4C (Local Quality Requirements) as may be amended by the Parties in accordance with this Contract or with the recommendations or requirements of NICE **"National Clinical Audit and Patient Outcomes Programme" or "NCAPOP":** a set of centrally commissioned national clinical audits that measure Provider performance against national quality standards or evidence-based best practice, and allows comparisons to be made between provider organisations to improve the quality and outcomes of care. http://www.hqip.org.uk/national-clinical-audits-managed-by-hqip/	NOTE: The NCAPOP (National Clinical Audit and Patient Outcomes Programme) is a set of national clinical audits, registries and o utcome review programmes which measure healthcare practice on specific conditions against accepted standards. They are commissioned and managed by HQIP. Participation is mandated under this contract.

Department of Health: Quality Accounts

https://www.gov.uk/government/publications/quality-accounts-toolkit-2010-11

Health Act 2009

8. Duty of providers to publish information

(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—

(a)any NHS services that the body provides;

http://www.legislation.gov.uk/ukpga/2009/21/section/8

This Act and these Regulations provide the statutory basis for the requirement for specified healthcare providers to produce Quality Accounts.

The National Health Service (Quality Accounts) Regulations 2010

Schedule

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 [*reporting period*] [*number*] national clinical audits and [*number*] national confidential enquiries covered NHS services that [*name of provider*] 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 [*name of provider*] participated in [*number as a percentage*] national clinical audits and [*number as a percentage*] national confidential enquiries of the national clinical audits and national confidential enquiries which it was eligible to participate in.

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

	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 [*name of provider*] was eligible to participate in during [*reporting period*] are as follows: [*insert list*].		
	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 [*name of provider*] participated in during [*reporting period*] are as follows: [*insert list*].		
	2.4	A list of each national clinical audit and national confidential enquiry that the provider participated in, 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.	The national clinical audits and national confidential enquires that [*name of provider*] participated in, and for which data collection was completed during [*reporting period*], 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. [*insert list and percentages*]		
	2.5	The number of national clinical audit reports published during the reporting period that were reviewed by the provider during the reporting period.	The reports of [*number*] national clinical audits were reviewed by the provider in [*reporting period*] and [*name of* provider] intends to take the following actions to improve the quality of healthcare provided [*description of actions*].		
	2.6.	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.	The reports of [*number*] local clinical audits were reviewed by the provider in [*reporting period*] and [*name of provider*] intends to take the following actions to improve the quality of		

2.7.	The number of local clinical audit reports that were reviewed by the provider during the reporting period.	healthcare provided [*description of actions*].	
2.8.	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.		

http://www.legislation.gov.uk/uksi/2010/279/contents/made

Quality Accounts Toolkit 2010/2011

In December 2010 NHS England published the Quality Accounts Toolkit 2010/2011 to provide advice to providers of NHS services in publishing their June 2011 Quality Account. The Toolkit has not been updated, however, the information contained within remains valid. The toolkit is available at: https://www.gov.uk/government/publications/quality-accounts-toolkit-2010-11.

Quality Accounts List

Since 2012 HQIP has supported the development of the NHS England Quality Accounts List, a list of national projects that NHS services are advised to prioritise participation in during the following financial year and report against as part of their Quality Account. The List is published each January and comprises audits, clinical outcome review programmes and other quality improvement projects. The NHS England Quality Accounts List and further information is available on the HQIP website at: https://www.hqip.org.uk/national-programmes/quality-accounts/.

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

NHS Improvement https://improvement.nhs.uk/ **Monitor is now part of NHS Improvement**	**NHS Improvement regulates providers of NHS services through the NHS provider licence.** Under the Health and Social Care Act 2012 everyone who provides an NHS health care service must hold a licence unless they are exempt under regulations made by the Department of Health. Under the general conditions of the licence (GC7), all providers must be registered with the CQC and therefore must be compliant with the Essential Standards (see above). https://improvement.nhs.uk/resources/apply-for-an-nhs-provider-licence/ **NHS Improvement requires NHS Foundation Trusts to follow an annual planning and reporting cycle.** They use NHS foundation trusts' annual plans and in-year submissions and assign risk ratings for finance and governance under the terms of their Risk Assessment Framework. The reporting requirements are set out in the NHS Foundation Trust Annual Reporting Manual. **NHS Foundation Trust Annual Reporting Manual** https://improvement.nhs.uk/resources/nhs-foundation-trust-annual-reporting-manual-201617/ **Annex 6 to Chapter 7: Model Annual Governance Statement (extract)** **Review of effectiveness** As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of internal control. My review of the effectiveness of the system of internal control is informed by the work of the internal auditors, clinical audit and the executive managers and clinical leads within the NHS foundation trust who have responsibility for the development and maintenance of the internal control framework. I have drawn on the content of the quality report attached to this Annual report and other performance information available to me. My review is also informed by comments made by the external auditors in their management letter and other reports. I have been advised on the implications of the result of my review of the effectiveness	Foundation trusts must report on the quality of care they provide Extract from the Model Annual Governance Statement refers to the use of clinical audit to address weaknesses and ensure continuous improvement

	of the system of internal control by the board, the audit committee [and risk/ clinical governance/ quality committee, if appropriate] and a plan to address weaknesses and ensure continuous improvement of the system is in place. [Describe the process that has been applied in maintaining and reviewing the effectiveness of the system of internal control, including some comment on the role and conclusions of: • the board; • the audit committee; • if relevant, the risk/ clinical governance/ quality committee/risk • managers/risk improvement manager; • clinical audit; • internal audit; and • other explicit review/assurance mechanisms. Include an outline of the actions taken, or proposed to deal with any significant internal control issues and gaps in control, if applicable.]	