



A Framework of Quality Assurance for Responsible Officers and Revalidation

Annex A – Core Standards

NHS England INFORMATION READER BOX

Directorate

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Document Purpose	Guidance
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Description	The Framework of Quality Assurance (FQA) provides an overview of the elements defined in the Responsible Officer Regulations, along with a series of processes to support Responsible Officers and their Designated Bodies in providing the required assurance that they are discharging their respective statutory responsibilities.
Cross Reference	The Medical Profession (Responsible Officers) Regulations, 2010 (as amended 2013) and the GMC (Licence to Practise and Revalidation) Regulations 2012
Superseded Docs (if applicable)	A Framework of Quality Assurance for Responsible Officers and Revalidation, Annex A – Core Standards – 4 April 2014
Action Required	Designated Bodies to receive annual board reports on the implementation of revalidation and submit an annual statement of compliance to their higher level responsible officers.
Timings / Deadline	From December 2015
Contact Details for further information	england.revalidation-pmo@nhs.net http:// www.england.nhs.net/revalidation/
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A Framework of Quality Assurance - Annex A: Core Standards

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1. Executive summary

Medical revalidation was launched in 2012 to strengthen the way that doctors are regulated, with the aim of improving the quality of care provided to patients, improving patient safety and increasing public trust and confidence in the medical system.

The Framework of Quality Assurance for Responsible Officers and Revalidation (FQA) has been designed to assist responsible officers in providing assurance to their organisation's board (or an equivalent governance or executive group) that the doctors working in their organisations remain up to date and fit to practise.

The process, and collection of information it requires, supports responsible officers in the preparation of their own appraisal portfolios, giving an overview of their performance as responsible officers, whilst also providing a formal record of compliance, which will be helpful in the event of a designated body's systems and processes becoming subject to challenge at any stage.

2. Purpose of the Paper

2.1 Core Standards

The Responsible Officer Regulations make clear that as part of their respective roles as set out in statute, the responsible officer and the designated body must provide assurance that all systems and processes, including those of clinical governance, underpinning the responsible officer's recommendation to the GMC on a doctor's continuing fitness to practise, are functioning effectively. In order to provide this assurance the responsible officer will want to be able to demonstrate that:

- the underpinning systems and processes are in place and functioning effectively, in compliance with nationally agreed standards;
- their own decision-making, and also that of appraisers and case investigators, is robust and consistent, not only at the individual level and internally within the designated body, but also that they are in alignment with the decision-making of peers in other organisations, from all sectors, across the country; and
- the board (or an equivalent governance or executive group) of the designated body is engaged in the process of revalidation, taking active steps to integrate the systems and processes underpinning medical revalidation into the organisation's broader quality and safety agenda.

The elements defined by the Responsible Officer Regulations can be considered in the following categories, as being related to:

- the designated body and the responsible officer;
- appraisal;
- monitoring performance and responding to concerns; and

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- recruitment and engagement.

Within each standard, Annex A currently describes 2 levels:

- Essential/core standards, minimum requirements, as set out in legislation and mandated guidance.
- Standards considered as good practice, identified in guidance and other key sources.

The FQA provides a single resource for responsible officers, enabling them to check the extent of their progress towards achieving robust quality assurance of all their systems, from achieving the basic mandatory standard to working at the level of good and, in time, towards excellent practice, whilst also highlighting any areas presenting cause for concern at a stage where effective action may be taken.

Framework of Quality Assurance for Responsible Officers and Revalidation, Annex A - Core Standards

1	The Designated Body and the Responsible Officer	Mandatory	Good Practice
1.1.1	The designated body has nominated or appointed a responsible officer in compliance with the Responsible Officer Regulations. The responsible officer is a licensed doctor who has been licensed continuously for the previous five years and continues to be licensed throughout the time they hold the role of responsible officer.	X	
1.1.2	The designated body has nominated or appointed an alternative responsible officer in all cases where there is a conflict of interest or appearance of bias between the responsible officer and a doctor with whom the designated body has a prescribed connection	X	
1.1.3	The responsible officer has sufficient time to carry out the role including the training, support and quality assurance requirements	X	
1.1.4	The designated body provides the responsible officer with sufficient funds, capacity and other resources to enable the responsible officer to carry out the responsibilities of the role.	X	
1.1.5	The responsible officer ensures an accurate record is maintained of all doctors with a prescribed connection to the designated body.	X	
1.1.6	The responsible officer is appropriately trained and remains up to date and fit to practise in the role of responsible officer	X	
1.1.7	The responsible officer is actively involved in peer review and networking for the purposes of calibrating decision-making and organisational systems and processes	X	
1.1.8	The responsible officer makes timely recommendations to the GMC about the fitness to practise of all doctors with a prescribed connection to the designated body, in accordance with the GMC requirements and the <i>Responsible Officer Protocol</i> . Ideally at the beginning of the 4 month notice period.	X	
1.1.9	The responsible officer considers all relevant information from the doctor's full scope of work and through the complete revalidation cycle in making a recommendation about a doctor's fitness to practise.	X	
1.1.10	The responsible officer ensures that accurate records are kept of all relevant actions and decisions relating to the responsible officer role	X	
1.1.11	The responsible officer has mechanisms in place to assure the quality of the processes underpinning the Responsible Officer Regulations	X	

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1.1.12	The responsible officer provides a report to the designated body's board (or an equivalent governance or executive group) and the higher level responsible officer, on compliance with the Responsible Officer Regulations and any other statutory requirements.	X	
1.1.13	The responsible officer provides the designated body's board (or an equivalent governance or executive group) with a development plan that addresses any identified weaknesses or gaps in compliance with the Responsible Officer regulations to agreed timelines.	X	
1.1.14	The responsible officer includes the report on compliance and resulting development plan in their own appraisal and revalidation portfolio.	X	
1.1.15	The responsible officer ensures that the designated body's medical revalidation policies and procedures comply with equality and diversity legislation.	X	
1.1.16	Where the responsible officer role is outsourced, the designated body must be satisfied that the service specification for the role (including responsible officer training, support and review) meets the required core standards.	X	
1.1.17	The responsible officer has completed a recognised training programme before making revalidation recommendations.		X
1.1.18	The responsible officer attends three out of four regional networking events each year.		X
2	Appraisal	Mandatory	Good Practice
2.1	Policy, Leadership and Governance		
2.1.1	The responsible officer ensures that a medical appraisal policy is in place which is ratified by the designated body's board (or an equivalent governance or executive group), with core content which is compliant with national guidance (GMC Guidance, Medical Appraisal Guide, Responsible Officer Guidance, etc.)	X	
2.1.2	The responsible officer ensures that every doctor participates in the annual medical appraisal process	X	
2.1.3	The responsible officer ensures that every doctor with a missed or incomplete medical appraisal have an explanation recorded	X	
2.1.4	The responsible officer ensures that appraisals will be undertaken according to professional standards (as laid out in <i>Providing a Professional Appraisal, RST</i>)	X	
2.1.5	The responsible officer ensures that there is a written protocol for the handling of information for appraisal and revalidation which complies with information governance, confidentiality and data protection requirements.	X	

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2.1.6	There is a process in place for the responsible officer to ensure that key items of information (such as specific complaints, significant events and outlying clinical outcomes) are included in the appraisal portfolio and discussed at the appraisal meeting, so that development needs are identified	X	
2.1.7	The responsible officer ensures that there is a process for the allocation of appraisers and the scheduling of appraisals.	X	
2.1.8	The responsible officer ensures that no appraisals are carried out by an appraiser who is not trained to undertake the role.	X	
2.1.9	The responsible officer ensures that steps are taken to ensure the objectivity of the appraisal.	X	
2.1.10	The responsible officer ensures that the appraiser submits the completed appraisal outputs within 28 days of the appraisal meeting.	X	
2.1.11	The responsible officer ensures that there is a process for quality assuring the inputs and outputs of appraisal to ensure that they comply with GMC requirements and other national guidance.	X	
2.1.12	The responsible officer ensures that all doctors with whom the designated body has a prescribed connection are able to obtain structured feedback from patients and colleagues in compliance with GMC criteria	X	
2.1.13	Where some or all of the functions required for the medical appraisal system are commissioned externally (e.g. from an appraisal provider), the responsible officer must be satisfied that the service specification including appraiser training, support and review meets the required core standards.	X	
2.1.14	The responsible officer ensures that the designated body's medical appraisal policy is reviewed to ensure continued alignment with national guidance.		X
2.1.15	The responsible officer ensures that a doctor should normally have no more than three consecutive appraisals with the same appraiser and must then have a period of at least three years before being appraised again by the same appraiser		X
2.1.16	The designated body has guidance on the expected time requirements to prepare for, undertake and complete documentation for appraisals (for both doctors and appraisers).		X
2.1.17	The responsible officer ensures that there is a named clinical appraisal lead.		X
2.2	Capacity and Capability		
2.2.1	The responsible officer ensures that the designated body has access to sufficient numbers of trained appraisers to carry out annual medical appraisals for all doctors with whom it has a prescribed connection	X	

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2.2.2	The responsible officer ensures that medical appraisers are recruited and selected in accordance with national guidance (Quality Assurance of Medical Appraisers).	X	
2.2.3	The responsible officer ensures that medical appraisers have completed a suitable training programme, with core content compliant with national guidance (Quality Assurance of Medical Appraisers), including equality and diversity and information governance, before starting to perform appraisals.	X	
2.1.4	The responsible officer ensures that all appraisers have access to medical appraisal leadership and support.	X	
2.2.5	The responsible officer ensures that there is a system in place to obtain feedback on the appraisal process from the doctors being appraised.	X	
2.2.6	The responsible officer ensures that medical appraisers participate in ongoing performance review and training/development activities, to include peer review and calibration of professional judgements (Quality Assurance of Medical Appraisers)	X	
2.2.7	The responsible officer ensures that there is a process for responding to concerns about appraisers and the appraisal process.	X	
2.2.8	The responsible officer ensures that the initial training programme is competency based and those who cannot demonstrate the competencies do not become/are not appointed as medical appraisers.		X
2.2.9	The responsible officer ensures that there is an initial review of performance for appraisers covering the first three appraisals followed by an initial review.		X
2.2.10	The responsible officer ensures that appraiser to doctor ratios lower than 1:20 and higher than 1:5 are recorded and justified.		X
2.2.11	The responsible officer ensures that there is a written role description, person specification and terms of engagement for medical appraisers		X
2.2.12	The responsible officer ensures that appraisers have access to regular appraiser assurance groups or networks, which will include agreement about expectations of attendance.		X
3	Monitoring Performance and Responding to Concerns	Mandatory	Good Practice
3.1	Policy, Leadership and Governance		
3.1.1	The responsible officer ensures that there is a system for monitoring the fitness to practise of doctors with whom the designated body has a prescribed connection.	X	

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3.1.2	The responsible officer ensures that a responding to concerns policy is in place (which includes arrangements for investigation and intervention for capability, conduct, health and fitness to practise concerns) which is ratified by the designated body's board (or an equivalent governance or executive group), with core content which is compliant with national guidance (Supporting Doctors to Provide Safer Healthcare: Responding to Concerns about a Doctor's Practice), and where necessary compliant with Maintaining High Professional Standards in the Modern NHS (Department of Health, 2003)	X	
3.1.3	The responsible officer ensures that there are formal procedures in place for colleagues to raise concerns.	X	
3.1.4	The responsible officer identifies any issues arising from routinely collected information (such as complaints, significant events and outlying clinical outcomes) and ensures that the designated body takes steps to address such issues.	X	
3.1.5	The responsible officer ensures that there is an agreed mechanism for assessing the level of concern that takes into account the risk to patients.	X	
3.1.6	The responsible officer ensures there is a process established for initiating and managing investigations of capability, conduct, health and fitness to practise concerns which complies with national guidance (<i>How to conduct a local performance investigation</i> , NCAS)	X	
3.1.7	The responsible officer ensures that a doctor who is subject to investigation procedures is kept informed about progress, the doctor's comments are taken into account and appropriate support mechanisms are in place.	X	
3.1.8	The responsible officer ensures that there is a mechanism to seek advice from expert resources, including: GMC employer liaison advisers, the National Clinical Assessment Service, specialty and royal college advisers, regional networks, legal advisers, HR and occupational health.	X	
3.1.9	The responsible officer ensures that there is a process in place for key items of information (such as complaints, significant events and outlying clinical outcomes) to be included in the doctor's appraisal portfolio and discussed at the appraisal meeting.	X	
3.1.10	The responsible officer ensures that any steps necessary to protect patients are taken.	X	
3.1.11	The responsible officer ensures that the locally agreed approach and actions are a proportionate response to a concern and take into account patient safety, the doctor's needs and the needs of the service or designated body.	X	

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3.1.12	The responsible officer ensures that where issues have been identified, measures are initiated to address concerns which may include re-skilling, re-training, rehabilitation services, supervision, mentoring, coaching etc. in line with relevant national guidance	X	
3.1.13	The responsible officer ensures that where necessary a recommendation is made to the designated body that the doctor should be suspended or have conditions or restrictions placed on their practice.	X	
3.1.14	The responsible officer ensures that where necessary measures are taken to address systemic issues within the designated body that may contribute to concerns identified.	X	
3.1.15	The responsible officer is proactive in sharing relevant information relating to a doctor's fitness to practise with other parties, in particular the new responsible officer should the doctor change their prescribed connection.	X	
3.1.16	The responsible officer refers serious concerns about a doctor's fitness to practise to the GMC	X	
3.1.17	The responsible officer ensures that where a doctor is subject to conditions imposed by, or undertakings agreed with, the GMC, systems are in place to monitor compliance with these conditions or undertakings.	X	
3.1.18	The designated body's board (or an equivalent governance or executive group) makes provision for the cost and impact of investigating and responding to concerns about doctors' practice	X	
3.1.19	The responsible officer ensures that arrangements for the sharing of relevant information about a doctor's practice exist between all organisations in which a doctor works, which complies with information governance, confidentiality and data protection requirements	X	
3.1.20	Where some or all of the functions required for the responding to concerns system are commissioned externally (e.g. from a Professional Support Unit, etc.), the responsible officer must be satisfied that the service specification including case investigator and case manager training, support and review meets the required core standards.	X	
3.1.21	The responsible officer ensures that the Responding to Concerns policy and pathway are shared within the designated body and are publicly available.		X
3.1.22	Systems are in place to monitor data about a doctor's practice on an on-going basis to enable the early identification of trends, and to respond appropriately when variation in individual performance is identified.		X
3.1.23	The responsible officer ensures that frameworks are in place to describe the process for categorising risk and thresholds for investigations.		X

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3.1.24	The responsible officer ensures that individuals monitoring, supervising or supporting practitioners are appropriately qualified and indemnified		X
3.1.25	The responsible officer or appointed case manager takes the lead in drafting, implementing and monitoring action plans to address the identifiable needs.		X
3.1.26	The responsible officer ensures that appropriate arrangements are in place to support for the re-entry of appropriate practitioners to the designated body		X
3.1.27	The responsible officer compares patterns of handling and concerns through their responsible officer network.		X
3.1.28	The responsible officer co-ordinates a quality assurance look back process of cases.		X
3.1.29	The responsible officer ensures that there are mechanisms are in place to define the success criteria for interventions and processes and to demonstrate that the organisation learns from experience.		X
3.2	Capacity and Capability		
3.2.1	The responsible officer ensures that the designated body has access to sufficient numbers of trained case investigators and case managers, whether they are sourced internally or externally.	X	
3.2.2	The responsible officer ensures that case investigators and case managers are recruited and selected in accordance with national guidance (<i>Supporting Doctors to Provide Safer Healthcare, Responding to concerns about a Doctor's Practice, RST</i>)	X	
3.2.3	The responsible officer ensures that case investigators and case managers have completed a suitable training programme, with essential core content (Ref RST training specification - including equality and diversity, information governance) before starting to perform investigations.	X	
3.2.4	The responsible officer ensures that individuals (such as case investigators, case managers) and teams involved in responding to concerns participate in ongoing performance review and training/development activities, to include peer review and calibration (ref RST guidance)	X	
3.2.5	The responsible officer ensures that personnel involved in responding to concerns have sufficient time to undertake their responsibilities	X	
3.2.6	The responsible officer ensures that case investigators and case managers have a regular programme of updates and skills development.		X

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3.2.7	The responsible officer ensures that case investigators and case managers undertake quality assurance of their roles and receive feedback on their performance.		X
3.2.8	The responsible officer ensures that case investigators and case managers participate in peer networks to learn and share good practice.		X
4	Recruitment and Engagement	Mandatory	Good Practice
4.1	The responsible officer ensures that when entering into contracts of employment or contracts for the provision of services, the designated body has policies and procedures in place to ensure that:	X	
4.1.1	The doctor has qualifications and experience relevant to the work being performed	X	
4.1.2	Appropriate references are obtained and checked	X	
4.1.3	Any steps necessary to verify the identity of doctors are taken	X	
4.1.4	Doctors have sufficient knowledge of the English language for the work to be performed	X	
4.1.5	All pre-employment checks recommended In national guidance are performed (ref NHS Employers Guidance)	X	
4.1.6	Any other relevant information is obtained from the doctor, the previous responsible officer, the GMC or other sources to enable a judgement to be reached about the doctors suitability for the proposed role	X	