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Guidance on the role of the responsible officer

The Role of the Responsible Officer

Prepared by Department of Health in consultation with the Scottish Government Health and Social Care Directorate and the Health Department in Wales

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Summary

The document

This document provides guidance on which responsible officers must have regard to under the Medical Profession (Responsible Officers) (Amendment) Regulations 2013¹. It relates to the role of responsible officers nominated or appointed by bodies designated by the Medical Profession (Responsible Officers) Regulations 2010² (“the 2010 Regulations”) and subsequent amendments.

This document has been produced in collaboration with the Scottish and Welsh governments.

This document is designed for three key audiences:

- doctors licensed with the General Medical Council (GMC) to practise medicine;
- responsible officers and those taking on the role; and
- organisations designated in the regulations.

Sections 1,2 and 6 are likely to be of interest to all three groups. Section 3 is aimed at licensed doctors. Section 4 is aimed at responsible officers or those taking on the role and Section 5 is aimed at designated bodies.

This version of the guidance updates the previous guidance issued by the Department of Health in January 2010 and takes into account changes made by the Medical Profession (Responsible Officers) (Amendment) Regulations 2013³. It also reflects the experience of responsible officers over the first year of implementation.

From April 2013 a new body, NHS England, was given the responsible officer roles that previously sat with Strategic Health Authorities and Primary Care Trusts. Consequently the responsible officers for the majority of doctors in England now have a prescribed connection to NHS England. The remaining responsible officers are connected to either Health Education England, NHS Education for Scotland, the Health Departments in England and Scotland and the Welsh Government

The guidance has been prepared as one document because we consider that each of its three main audiences will want to understand how the system works as a whole.

Coverage of the document

It is important to note that this guidance document relates to the Medical Profession (Responsible Officers) Regulations 2010 as amended by the Medical Profession (Responsible

¹ The Medical Profession (responsible officers) (Amendment) Regulations 2013; TSO

² The Medical Profession (Responsible Officers) Regulations 2010; SI 2010/2841
<http://www.legislation.gov.uk/ukSI/2010/2841/contents/made>

³ Medical Profession (Responsible Officers) (Amendment) Regulations 2013; SI 2013/391
<http://www.legislation.gov.uk/ukSI/2013/391/contents/made>

Officers) (Amendment) Regulations 2013. Parts 1 and 2 of the Responsible Officer Regulations apply to England, Wales, and Scotland, whereas part 3 of the Regulations gives responsible officers in England a further range of duties embracing wider responsibilities relating to clinical governance. Scotland and Wales have not included clinical governance in the role as arrangements were already in place in this regard.

The Responsible Officer Regulations give specified senior doctors (responsible officers) in certain organisations (designated bodies) functions that will ensure that all doctors work within a managed environment, in which their performance, conduct and behaviour are monitored against agreed national standards. Where there are concerns about a doctor's fitness to practise, the Regulations empower responsible officers to instigate investigation of the doctor's performance and to ensure that the appropriate action is taken. Where concerns are raised but are not of the degree at which referral to the GMC is considered necessary, responsible officers have a duty to investigate and to ensure that the appropriate action is taken. If the cause of concern is found to relate to the systems, team or processes as well as, or rather than, an individual doctor, the responsible officer has a duty to ensure that the designated body takes action to address any issues.

Section 1 sets out the background to the role of the responsible officer within the context of other measures aimed at improving the quality and safety of care for patients.

Section 2 sets out the general principles underpinning the system.

Section 3 is aimed at licensed doctors to enable them to understand how they relate to responsible officers. It explains how a doctor can identify his or her own responsible officer.

Section 4 is aimed at licensed doctors taking on the role of responsible officer. It provides guidance on a responsible officer's functions as set out in the Medical Act 1983 (relating to the evaluation of fitness to practise) and, in England only, to their wider statutory role under part 3 of the Regulations (relating to monitoring conduct and performance).

Section 5 is aimed at designated bodies, setting out their responsibilities in the legislation.

Section 6 provides an overview of the checks and balances in place within the system.

It is recognised that designated bodies and their responsible officers will start with very different levels of knowledge and skills in the area of medical management. However, it is essential to the integrity of the system that consistency and rigour of responsible officer decision-making is achieved. One of the purposes of this document is to contribute to the measures that will achieve the necessary levels of consistency, acknowledging that the guidance will evolve, as experience is gained and shared.

Section 1

Background

- 1.1 The role of managers (be they medical or non-medical) and systems in healthcare is to provide the best possible environment in which clinical professionals of all disciplines can deliver high quality, effective and safe care that involves patients in decisions made about them. The care delivered by the majority of doctors registered with the GMC is of a high quality. To support this, on 1 January 2011, a new role, the responsible officer, was introduced in organisations involved in healthcare delivery and policy. The role of the responsible officer is to ensure organisations have in place processes that provide a framework within which doctors are encouraged to maintain and improve their practice.
- 1.2 Responsible officers play a crucial role in improving and maintaining the quality and safety of patient care. They are critical to ensuring that their organisations maintain a focus on the core components of their relevant national quality framework. The following components originate from the Department of Health in England, although other nations will have their own, similar framework:
- **Patient safety** – by ensuring that doctors are maintaining and raising standards of professional performance.
 - **Effectiveness of care** – by supporting an ethos of professionalism, ensuring that clinical care is delivered by practitioners who are fit for purpose, appropriately trained and skilled for the role in which they are employed.
 - **Patient experience** – by ensuring that patients' views are fully integrated into evaluations of a doctor's performance.
- 1.3 Following a series of high profile failings, proposals were made for a system of revalidation for every licensed doctor in the UK. Revalidation enables licensed doctors to demonstrate to patients, the public, colleagues, organisations and the General Medical Council on a regular basis that they are up to date and fit to practise. A key part of that process is the responsible officer who will make recommendations to the GMC about the fitness to practise of doctors connected to them, usually, once every five years (the process of revalidation).
- 1.4 Background on the development of the role can be found in the following documents:
- White Paper *Trust, Assurance and Safety*⁴;
 - Responsible officers and their duties relating to the medical profession – a consultation, July 2008⁵;
 - Response to the consultation - "Responsible officers and their duties relating to the medical profession", May 2009⁶;

⁴ Trust, Assurance and Safety: The Regulation of Health Professionals in the 21st Century; TSO February 2007

⁵ http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Consultations/liveconsultations/DH_086443

⁶ http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/consultations/Liveconsultations/DH_104587

- “The framework for responsible officers and their duties relating to the medical profession” – a consultation on responsible officer regulations and guidance, August 2009⁷; and
- “Responsible officers in the new Health architecture” – a consultation on draft amendment regulations, December 2012⁸

1.5 The role and responsibilities of the responsible officer and the relationship between responsible officers and licensed doctors are described in this document. The responsibilities of organisations delivering healthcare in this regard are also described. The regulations were amended in 2013 and this version reflects those amendments.

1.6 The responsible officer arrangements will apply to the vast majority of practising doctors in the UK, who will relate to a responsible officer nominated or appointed by their designated body.

1.7 The arrangements for confirming the fitness to practise of the small minority of doctors falling outside this framework are set out by the GMC⁹.

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⁷ http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/consultations/Liveconsultations/DH_104587

⁸ <https://www.gov.uk/government/consultations/changes-to-responsible-officer-regulations>

⁹ Doctors without designated bodies; GMC; http://www.gmc-uk.org/doctors/revalidation/designated_body_tool.asp

Section 2

General principles of the Responsible Officer Regulations

This section sets out the principles underlying the responsible officer role as defined by the Regulations.

- 2.1 Decisions about a doctor's fitness to practise are taken only by the GMC and only after specific procedures have been followed. For revalidation the GMC has set out that doctors must demonstrate their fitness to practise across the full scope of their practice.
- 2.2 The Regulations require that designated bodies nominate or appoint a responsible officer, who must be a licensed doctor, and that they provide support to the responsible officer in fulfilling the statutory duties and responsibilities of the role. Organisations defined as designated bodies are set out in the Regulations and can be summarised as:
 - organisations providing healthcare;
 - organisations that set standards and policy for the delivery of healthcare; and
 - some specialist organisations which employ or contract with doctors.
- 2.3 Each designated body, other than NHS England and Health Education England, will have only one responsible officer. Some aspects of the role may be delegated appropriately and some tasks may even be managed outside the direct control of the responsible officer. However, the decision-making of the responsible officer and their role in quality improvement sit at the core of the responsible officer's statutory responsibility.
- 2.4 In England, tasks such as pre-employment or pre-contract scrutiny are often managed outside the direct control of the responsible officer. In such cases the responsible officer must take all reasonable steps to ensure the employing organisation carries out these tasks to the standards required.
- 2.5 Most licensed doctors in the UK relate to the responsible officer of the healthcare organisation in which they are employed or with which they have a contractual arrangement. This is referred to as the prescribed connection. Regulation 10 sets out the way doctors are related to a designated body.
- 2.6 A doctor's prescribed connection is based on the following principles:
 - A doctor with a connection to one or more designated bodies will have only one responsible officer;
 - Where more than one potential prescribed connection exists, a hierarchy illustrated by the diagram on page 10 describes which potential connection takes precedence;
 - If there is more than one equivalent potential prescribed connection (for example a doctor is employed by two designated bodies) the prescribed connection is usually based on where the doctor performs most of their clinical work. If there is no difference in the volume of clinical work performed, then the prescribed connection is to the designated body closest to the doctor's GMC registered address; and

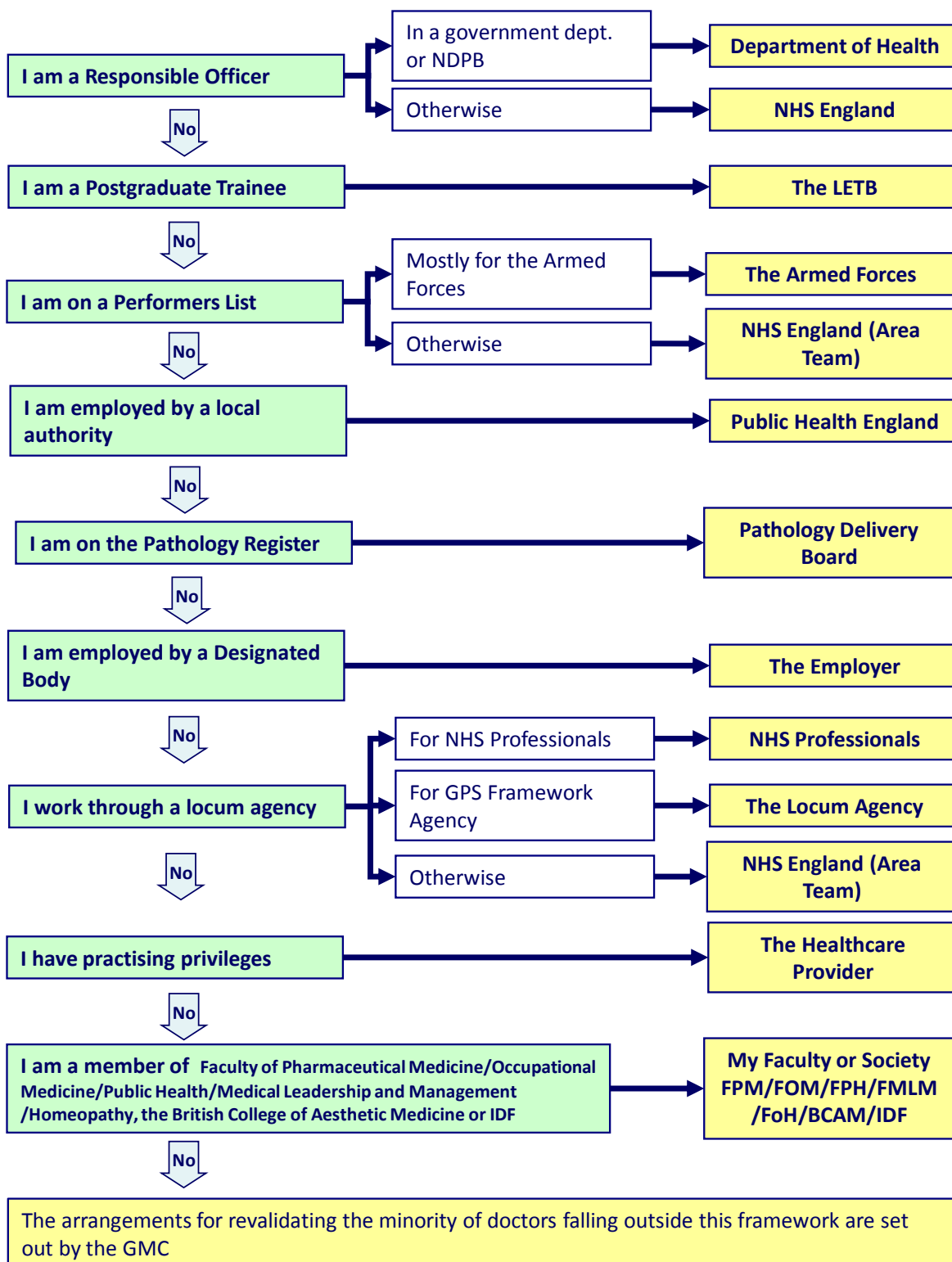
- For doctors with a prescribed connection to NHS England, a process has been developed to link them to a responsible officer.
- 2.7 It is a doctor's responsibility to ensure that they know who their responsible officer is. The [GMC's online tool](#), which can be accessed at the GMC website, has been designed to help doctors identify their correct connection. The diagram on page 10 gives an overview of the hierarchy of connections to aid understanding of the connections set out in the Regulations.
- 2.8 Responsible officers must be doctors who hold a GMC licence to practise and, at the time of appointment, they must have been a fully registered medical practitioner for the previous five years.
- 2.9 The GMC issues each licensed doctor with a date for their revalidation. The GMC will write to each doctor at least three months in advance of the revalidation date to confirm that a recommendation is due by that date. The responsible officer may make a recommendation about the doctor's revalidation to the GMC at any time within three months of the revalidation date. A doctor's next revalidation date is set for five years after the date the GMC confirms revalidation. Responsible officers will need to ensure their systems record the new revalidation date following a recommendation.
- 2.10 The responsible officer can make one of three possible recommendations. They can:
- make a positive recommendation that the doctor is up to date, fit to practise and should be revalidated;
 - request a deferral because they need more information to make a recommendation about the doctor; or
 - notify the GMC that the doctor has failed to engage with any of the local systems or processes (such as appraisal) that support revalidation.
- 2.11 It is important to remember that revalidation sits alongside fitness to practise procedures. If at any stage of the revalidation cycle a responsible officer has concerns that a doctor is not up to date and fit to practise they should refer the doctor into the GMC's fitness to practise process. The responsible officer must not wait until a revalidation recommendation is due.
- 2.12 The responsible officer must take appropriate action when concerns are identified, to ensure that patients are protected and that doctors are supported to improve their practice. If the concerns are sufficiently serious to require the GMC to consider under fitness to practise procedures, the revalidation process may be suspended.
- 2.13 Responsible officers, as licensed doctors, have a responsible officer of their own. In England, for responsible officers of designated bodies other than the Department of Health, Non-Departmental Public Bodies (except NHS England) and other Government departments, this will be a responsible officer in NHS England. NHS England has published guidance¹⁰ on how doctors connected to it will know who their responsible officer is.

¹⁰ Prescribed Connections to NHS England: <http://www.england.nhs.uk/wp-content/uploads/2013/05/prescribed-connections.pdf>

2.14 Responsible officers in Local Education and Training Boards have their responsible officer in Health Education England. In Scotland, it is the responsible officer in the Scottish Government Health Directorate and in Wales the Welsh Government.

2.15 Designated bodies have a duty to provide support to the responsible officer by means of appropriate funding, resources, systems and information. This includes effective systems of appraisal and clinical governance. The responsible officer will use appropriately validated information to make a judgement on the fitness to practise of doctors with a connection to the organisation and, in England, to monitor their conduct and performance.

Prescribed connections for doctors in England



2.16 Note: For locum doctors working through more than one agency the prescribed connection is with the agency the doctor worked for most in the previous calendar year.

Note: Need to add diagrams for Scotland & Wales, or amend the above

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Section 3

Guidance for doctors

The doctor's responsibility

- 3.1 Since the introduction of medical revalidation on 3 December 2012, all doctors with a licence to practise in the UK have a professional duty to engage fully and continuously with all aspects of revalidation. This requires licensed doctors to demonstrate that they are fit to practise across all of their roles.
- 3.2 Doctors must engage fully with the process of appraisal, collate specific information about their practice and comply with both the process and timeframes set out by their responsible officer. The doctor's fitness to practise in the role that they currently hold will be assessed by the responsible officer over a five-year period, on the basis of the outputs of their appraisals. Information from other sources, including wider clinical governance systems, external bodies and patient and colleague feedback will be used to inform the appraisal and the responsible officer recommendation. Ideally this information will be provided to the doctor and appraiser to help inform their discussions.
- 3.3 Every doctor with a licence to practise must participate in medical revalidation. Revalidation requires doctors to have regular appraisals, which for the majority of doctors, will be an annual event. This appraisal will help to demonstrate that their practice meets the standards set by the GMC, as specified in their document *Good Medical Practice Framework for Appraisal and Revalidation*¹¹
- 3.4 The doctor is expected to collate supporting information including complaints, significant events, feedback on their performance and data demonstrating how the doctor has maintained and improved the quality of their practice.
- 3.5 It is the doctor's responsibility to ensure that this portfolio of supporting information complies with GMC requirements and is aligned (in both content and proportionality) with the full scope of their work as a doctor. In order to do this the doctor should inform the responsible officer of all medical roles they undertake, including private practice and non-clinical roles such as public health, administration, management and leadership. Further information on the portfolio and scope of work is available from the GMC and within the *Medical Appraisal Guide*, produced by the NHS Revalidation Support team. For doctors in Wales, information about the Welsh appraisal policy can be found in the *All Wales Medical Appraisal Policy*¹².
- 3.6 Doctors also need to be mindful of their responsibilities under *Good Medical Practice* including taking action if they become aware of any colleague practising or behaving in such a way that could cause harm to patients.

¹¹ Good Medical Practice, General Medical Council,
http://www.gmc-uk.org/doctors/revalidation/revalidation_gmp_framework.asp)

¹² <http://revalidation.walesdeanery.org/index.php/2013-03-18-14-50-18/resources-for-employers>

The revalidation process and the doctor

- 3.7 The vast majority of doctors will be appraised annually. In England and Wales appraisers must be trained to agreed national standards and be subject to a national framework of quality assurance. In Scotland all appraisers are required to attend an NHS Education for Scotland (NES) training course before becoming an appraiser and it will be mandatory that only NES trained appraisers are used from 31 March 2015.
- 3.8 Serious concerns about a doctor's conduct or performance are unlikely to come to light for the first time during appraisal, but if they do, the process will usually be suspended and the responsible officer (or a delegated deputy) informed. The responsible officer will ensure that appropriate action is taken and may take advice from the GMC Employer Liaison Adviser. If there are serious concerns about a doctor's fitness to practice, to the extent that there is a threat to patient safety, the responsible officer must refer the doctor to the GMC's fitness to practise procedures immediately. The responsible officer may also wish to recommend suspension to the doctor's employers and to any other body the doctor contracts with. Decisions regarding a doctor's licence to practise, including suspension from the register, remains, as at present, the sole responsibility of the GMC.
- 3.9 At the appropriate time, the responsible officer will make a recommendation about the doctor's revalidation to the GMC, as described at 2.10 above.

Arrangements for doctors in England

- 3.10 Where any performance concerns are identified, responsible officers will work closely with colleagues in human resources and other parts of the organisation to address those concerns.
- 3.11 Many performance concerns will not be serious enough to result in a referral to the GMC fitness to practise process. Responsible officers will manage these concerns locally under the procedures appropriate to the organisation. For GPs it will be the Performers List Regulations, whilst in other organisations it may be Maintaining High Professional Standards. These processes may involve the responsible officer recommending suspension to the service provider or providers.

Arrangements for doctors in Scotland, Wales and Northern Ireland

- 3.12 Arrangements in Scotland, Wales and Northern Ireland are very similar to those in place in England. However there are some significant differences. For example responsible officers in Scotland do not have clinical governance responsibilities set out in the responsible officer regulations. Guidance and other resources for doctors in Scotland, can be found on the Scottish Government website¹³.

¹³ <http://www.scotland.gov.uk/Topics/Health/NHS-Workforce/Regulation/Medical-Revalidation>

Doctors without a prescribed connection

- 3.13 The designation of organisations that are required to nominate or appoint a responsible officer ensures that the vast majority of doctors will connect to a responsible officer. However, there will be a small number of doctors who do not have a prescribed connection to a designated body. The GMC has set out the possible pathways for these doctors to renew their license to practise. Further details can be found on the GMC's website¹⁴.

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¹⁴ http://www.gmc-uk.org/doctors/revalidation/designated_body_tool.asp

Section 4

Guidance for responsible officers

Who can be a responsible officer?

- 4.1 A responsible officer must, at the time of appointment, be registered and licensed and must have been fully registered for the previous five years. This means they must have held a licence to practise from the time they were introduced on 3 December 2012. They must continue to be registered and licensed throughout the time they hold the role of responsible officer.
- 4.2 In England and Wales, responsible officers should also complete the nationally agreed introductory training programme for responsible officers within 12 months of appointment. See NHS England website¹⁵ for details of this. In Scotland the responsible officers relate to the Responsible Officer Network and are required to attend the national training days.

Roles and responsibilities of the responsible officer in England, Scotland and Wales

- 4.3 Responsible officers play a key role in improving the quality and safety of patient care. They do this through their statutory duties which are described in terms of:
- evaluating the fitness to practise of doctors (regulatory functions); and
 - in England in Wales, monitoring conduct and performance (clinical governance functions).
- 4.4 To ensure that potential harm to patients is minimised, it is crucially important that any concern about a doctor's practice is identified as early as possible. Should a doctor's practice fall below the expected standards, the responsible officer must ensure that appropriate action is taken without delay.
- 4.5 In order to carry out their functions, responsible officers will need to ensure that:
- they maintain a list of the doctors connected to the designated body;
 - effective, quality assured systems and processes for appraisal are in place with sufficient numbers of appraisers, who, in England and Wales, are trained to the agreed national standards and, in Scotland, are trained as described at 4.2.
 - information from the appraisal systems is triangulated against data from other sources, both of internal governance and from external bodies when making a recommendation to the GMC;
 - systems for timely and effective identification, investigation and management of concerns about doctors are in place and functioning effectively;
 - appropriate records are maintained;

¹⁵ <http://www.england.nhs.uk/revalidation/ro/train-net/>

- appropriate internal and external quality assurance processes, including peer review, are in place for all organisational systems of appraisal and quality monitoring; and
- systems are aligned with GMC guidance and process for making recommendations and referral to fitness to practise procedures.

4.6 In order to carry out their additional functions under the regulations, responsible officers in England will need to ensure that:

- pre-employment or pre-contract systems are in place to check that doctors have the appropriate qualifications and experience for the role, including language competence; and
- there is an integrated system for monitoring doctors' performance, recognising good practice, encouraging and supporting development and learning;

4.7 The responsible officer is accountable to the designated body to which they have been appointed or nominated. Whatever the nature of the designated body, the responsible officer must ensure that there are appropriate, quality-assured, systems and processes in place to support doctors' revalidation.

4.8 The designated body is responsible for ensuring that these systems are properly resourced, reviewed and maintained. In order to fulfil this duty, the responsible officer must ensure that the organisation is properly advised of the resource requirements in terms of capacity, expertise and funding needed to support the role

4.9 The responsible officer is responsible for ensuring that an effective system of medical appraisal is in place. Further information on medical appraisal may be found in the following guidance documents that can be found on the NHS England website¹⁶: *Medical Appraisal Guide*, *Quality Assurance of Medical Appraisers* and *Information Management for Medical Revalidation in England*. In Scotland, further guidance may be found in the *Guide to Appraisal for Medical Revalidation*¹⁷ (published July 2012 and updated March 2014) which can be found on the Scottish Government website.

4.10 The responsible officer has a statutory duty to co-operate with the GMC under Regulation 13(5). GMC Employer Liaison Advisors will work closely with responsible officers on matters connected with a doctor's fitness to practise. They will also be able to advise on cases where there is doubt about whether a referral to the GMC is appropriate.

4.11 Under Regulation 13(2)(d) the responsible officer must monitor how doctors comply with conditions imposed by, or undertakings agreed with, the GMC. In practice, when a doctor is under a programme of supervision the responsible officer must ensure they are kept up to date with the progress made by the doctor irrespective of the location of the placement. Where there is doubt that the doctor is continuing to abide by the conditions or undertakings, the responsible officer must report this to the GMC.

¹⁶ <http://www.england.nhs.uk/revalidation/ro/info-docs/>

¹⁷ <http://www.scotland.gov.uk/Topics/Health/NHS-Workforce/Regulation/Medical-Revalidation/GuideAppraisMedRevalMar14>

- 4.12 In addition to the duties outlined above, the responsible officer must ensure that doctors are supported by the organisation in their efforts to improve their performance and the quality of care they provide to patients.
- 4.13 It is important that responsible officers have a high level of understanding of the statutory requirements and good practice in equality and diversity to enable them to ensure that the organisation's systems and processes do not discriminate against any individual doctor or group of doctors.
- 4.14 At the due date the responsible officer makes a recommendation about the doctor's fitness to practise to the GMC as described at 2.10 above.
- 4.15 Further information on the recommendations is available from the Making recommendations about doctors section¹⁸ of the GMC's website
- 4.16 In Scotland and Wales the responsible officer of local responsible officers will be employed by Scottish Government Health Directorates and Welsh Assembly Government respectively.
- 4.17 In addition to their role in making recommendations on doctors' fitness to practise, the responsible officer has a responsibility to provide professional leadership, driving the cultural change that must take place in the organisation to support, celebrate and share good practice. If the organisational culture fails to support honesty, openness and a willingness to rectify mistakes and learn from failings, even the most sophisticated technology available will not deliver a system that works. As in any other organisational system, the effectiveness of governance is dependent upon the prevailing culture and attitudes. The responsible officer has a major role to play in creating and maintaining a culture which not only supports but also encourages good clinical governance.
- 4.18 It is essential that the responsible officer works within the designated body to ensure that it continually learns and adapts its systems on the basis of the findings of any investigations. However, an investigation into a concern about a doctor may also, for example, reveal a system failure, the rectification of which may sit outwith the responsible officer's immediate organisation. Issues such as equipment failure, a design flaw, or poorly labelled drugs from a manufacturer, will need action on the part of the responsible officer to alert the appropriate bodies in addition to the immediate primary action, in order to prevent harm to patients on a wider scale.

Roles and responsibilities of the responsible officer in England and Wales

- 4.19 In relation to contracts of employment or contracts for the provision of services with medical practitioners, the responsible officer must:
- ensure that the doctor has qualifications and experience relevant to the work to be performed;

¹⁸ Making recommendations about doctors; GMC website; <http://www.gmc-uk.org/doctors/revalidation/12394.asp>

- ensure that appropriate references are obtained and checked;
- take any steps necessary to verify the identity of doctors;
- ensure that doctors have sufficient knowledge of the English language for the work to be performed; and
- work closely with the human resources or medical staffing department to ensure these checks are performed and that any further information is obtained about the doctor's fitness to practise in the proposed role.

4.20 Identifying a concern initiates the process to safeguard patients. When a concern arises about a doctor's fitness to practise from any source, the responsible officer must ensure that appropriate action is taken immediately at the time the concern arises. The responsible officer may need to discuss concerns with the GMC Employer Liaison Advisor. At all times patient safety is paramount. The responsible officer has a statutory responsibility to ensure that the designated body takes appropriate action in relation to issues that arise from the conduct and performance of doctors. This action may include:

- initiating an investigation, with appropriately qualified investigators separate from the decision-making process;
- co-ordinating and co-operating with other concurrent investigations into broader systems failure;
- initiating further monitoring;
- developing a plan for remediation, which may include re-skilling and rehabilitation, training and development, mentoring, peer support, coaching or supervision;
- excluding a doctor or placing local conditions or restrictions on their practice pending further appropriate action; and/or
- referral to GMC fitness to practise procedures.

4.21 If an investigation confirms a valid concern, the root cause should also be traced. Cases of apparent poor performance of an individual may in fact be due to a dysfunctional team or wider organisational system. The responsible officer has a duty to investigate the causes of concerns about a doctor's performance, and, under Regulation 16(4)(h)(iv) where necessary, to initiate action to address wider systems or team issues that result in poor performance.

Roles and responsibilities of the responsible officer in England

4.22 The responsible officer must also ensure that there are systems and processes in place, meeting agreed national standards, for investigating any concerns about a doctor's performance or behaviour. There is no legal definition of 'an appropriately qualified investigator' as appropriateness will depend on the issues being investigated. For example allegations of fraud may require an investigator to have different skills from a scenario in which the allegation is sexual impropriety. To help organisations a significant number of case investigators and case managers have been trained. Organisations without access to case investigators or case managers should contact the regional team of NHS England, who have a list of those trained.

- 4.23 When responding to concerns about a doctor, the responsible officer should have due regard for accepted best practice. Further detail of this process can be found in the document *Supporting Doctors to Provide Safer Healthcare*, and a number of publications from the National Clinical Assessment Service (NCAS) website^{19, 20, 21, 22, 23}. For NHS organisations the procedure is described in *Maintaining High Professional Standards in the NHS*²⁴ and the *Performers List Regulations 2013*
- 4.24 Responsible officers, as licensed doctors will need to demonstrate their own fitness to practise in all their medical roles. All responsible officers of designated bodies will have their own responsible officer, the majority of whom will be employed by NHS England. Responsible officers of Government departments, Executive Agencies, Non-departmental Public Bodies (except NHS England) and Public Health England have a prescribed connection to the Department of Health. Demonstrating fitness to practise in the role of responsible officer may include evidence of the effectiveness of organisational systems, training, development, quality assurance and peer review activities

Appraisal of responsible officers

- 4.25 The RO Regulations state that the responsible officers' appraisals should be "carried out by the body for whom the medical practitioner is the responsible officer". However, there is a need to ensure that the appraisal is free from conflicts of interest or appearances of bias. Where a responsible officer is appraised by a doctor for whom they have statutory responsibilities it is difficult to avoid, at least, an appearance of bias.
- 4.26 It is recommended that the appraisal arrangements for responsible officers should be agreed in all cases with their responsible officer. The higher level responsible officer will need assurance that whenever an internal appraiser is proposed, the potential intrinsic conflict of interest or appearance of bias has been adequately managed. In some circumstances, the higher level responsible officer may request that an alternative suitably trained external appraiser is assigned. The choice of appraiser for the responsible officer will be influenced by the doctor's other roles and the structure and line management arrangements of the designated body.
- 4.27 The higher level responsible officers may wish to maintain a list of suitably trained external appraisers to ensure there is adequate capacity for the appraisal of level one responsible officers. The appraiser selected by the higher level responsible officer will

¹⁹ How to conduct a local performance investigation

²⁰ Handling concerns about practitioners' health 1303 A guide for managers

²¹ A guide for managers of performance concerns (in primary and secondary care organisations) through the sequence of an investigation in order to help identify and deal with performance concerns efficiently.

²² Handling performance concerns in primary care 0898

²³ Back on Track: *Restoring practitioners to safe and valued* 1302 practice

²⁴ Maintaining high professional standards in the Modern NHS, a framework for the initial handling of concerns about doctors and dentists in the NHS, Department of Health, February 2005

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4072773

normally be a licensed doctor. For doctors in senior management positions, however, it may be appropriate for the appraiser to be from a non-medical background. The appraiser should therefore:

- be the most appropriate appraiser for the doctor, taking into account their full scope of work
- understand the professional obligations placed on doctors by the GMC
- understand the importance of appraisal for the doctor's professional development
- have suitable skills and training.

- 4.28 In Scotland responsible officers have an appraiser independently allocated to them by NHS National Services Scotland.
- 4.29 The GMC has made clear that to satisfy the requirements of revalidation, appraisers do not need to be licensed doctors and that local decisions should determine the overall suitability of the appraiser workforce. However it is essential that both the doctor and their responsible officer have confidence in the appraiser's ability to carry out the role to the required standard.
- 4.30 Higher level responsible officers will need to be assured that appropriate arrangements are in place and may determine that it is appropriate to make the arrangements for appraisals of responsible officers using a pool of suitably trained appraisers in order to ensure a consistent approach.

Guidance from other sources

- 4.31 In addition to this guidance, responsible officers must have regard to guidance issued by the GMC that relates to their responsibilities, including: *Good Medical Practice*; the *Responsible Officer Protocol*; and *Guidance on Supporting Information for Appraisal and Revalidation*. These can be found on the GMC website²⁵. In England and Wales, Responsible officers should also have regard to relevant guidance from the National Clinical Assessment Service division of the NHS Litigation Authority. .
- 4.32 The responsible officer should ensure that clinicians delivering the service do so on the basis of the best evidence available on the effectiveness of interventions. This means having regard to good practice guidance from recognised sources, recognised national audits and local audits of clinical practice. The responsible officer will want to ensure that this guidance is easily accessible and widely used within his or her organisation. Employers and commissioners should ensure that clinicians have access to the best evidence so that they can practise to the highest standards. The onus is on all parties, as partners in providing and using best practice guidelines and documentation.
- 4.33 The responsible officer's duty to ensure that doctors are fit to practise may be difficult when the doctor is carrying out innovative treatments. In the UK, doctors carrying out procedures that are new, or for which they have no experience, have to gain approval from either the relevant research ethics committee or the clinical governance committee.

²⁵ <http://www.gmc-uk.org/doctors/revalidation/9611.asp>

The processes for ensuring that doctors have the appropriate authority are set out in HSC 2003/1126. In independent hospitals similar arrangements apply and usually approval will be sought from the Medical Advisory Committee

- 4.34 The responsible officer has a relationship with the GMC on matters in connection with fitness to practise, including ethical issues. As a licensed doctor, the responsible officer is bound by the GMC's core guidance, *Good Medical Practice* (see GMC website). The responsible officer is also directly accountable to their designated body's board or its highest level of management.

Information Management

- 4.35 In order for the responsible officer to fulfil their statutory duties, effective mechanisms for sharing relevant information within and between organisations are necessary. Further guidance on this relevant to responsible officers in England²⁷ can be found in the document *Information Management for Revalidation in England*. An electronic template for completion by ROs when there is a need to share information is available via NHS England²⁸.
- 4.36 Information about doctors' fitness to practise is one of the foundations of the revalidation process. Responsible officers must assure themselves that the systems and processes in use within their organisation to store personal information about doctors are secure and comply with relevant legislation and good practice guidance. The sharing of information about a doctor should occur in a way which complies with the principles of data protection and is fair to the doctor concerned, but in determining the information which should be shared, responsible officers, medical directors and employers should regard patient safety as the overriding priority. They must ensure that appropriate auditable governance arrangements are in place to control access to the data and any transfers of that data.
- 4.37 This is particularly important where the responsible officer is employed by a different organisation from that which holds the information about the doctor. The transfer of personal information by secure means is paramount. Responsible officers can find further information from the information governance officer in their organisation or the Information Commissioner's Office.

Education and Support

- 4.38 All responsible officers will need to ensure they are up to date and fit to practise in the role of responsible officer. Support available to responsible officers includes:
- training;
 - networks;

²⁶ HSC 2003/011 - The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation; Department of Health; November 2003

http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4064922

²⁷ http://www.england.nhs.uk/revalidation/wp-content/uploads/sites/10/2014/03/rst_revalidation_information_management_2014v41.pdf

²⁸ <http://www.england.nhs.uk/revalidation/ro/info-docs/mpit-form/>

- the GMC's Employer Liaison Advisers.
- regional teams

4.39 The GMC has appointed a number of Employer Liaison Advisers who work with responsible officers and their teams to:

- support two way exchange of information about under-performing doctors;
- share data about under-performing doctors, including regional trends;
- help responsible officers and their teams understand GMC thresholds and procedures; and
- provide support to responsible officers and employers in relation to revalidation.

4.40 Further information about the role and the names and areas of responsibility for ELAs can be found at: <http://www.gmc-uk.org/concerns/11956.asp>

4.41 The Royal Colleges also provide a source of expertise about clinical practice in their speciality. The Royal Colleges' websites provide information about, and access to, these services.

4.42 In England and Wales, the National Clinical Assessment Service (NCAS) also provides support to resolve concerns about the professional practice of doctors in the UK and overseas. NCAS provides expert advice and support, clinical assessment and training to the NHS and other healthcare partners. In Scotland there is no formal contract between NHS Scotland and NCAS.

4.43 In England, an introductory training programme has been developed for responsible officers and has been rolled out across England. Access to training is through the NHS England Regional Teams. In Scotland the Responsible Officer Network organises training as required.

4.44 In England, Responsible Officer Networks are run by NHS England to provide a mechanism for professional development, quality assurance and calibration of decision-making. If responsible officers choose not to attend these meetings, they must be able to demonstrate how their professional development as a responsible officer is being achieved and how they are calibrating their decision-making with that of other responsible officers to achieve consistency and fairness across the system,

Conflict of Interest and Appearance of Bias

4.45 To provide the assurances that patients and doctors require from the system, the decisions and recommendations of the responsible officer must be impartial and objective. Decision-making influenced by conflicts of interest or bias may breach the standards set out in *Good Medical Practice*. These issues are explored at Section 6 – Checks and Balances.

Section 5

Guidance for healthcare organisations

The duty to nominate or appoint a responsible officer

- 5.1 Designated bodies are defined in the Schedule to the Regulations. The organisations in Part 1 of the Schedule are designated unconditionally, whereas those in Part 2 of the Schedule are only designated if they employ or contract with one or more doctors. Only those designated bodies with a prescribed connection to one or more doctors have to nominate or appoint a responsible officer.
- 5.2 Designated bodies are generally bodies that treat patients or set standards or policy for healthcare. The Schedule to the Regulations sets out the types of organisations that are designated. If there is any doubt about whether an organisation is a designated body legal advice should be sought.
- 5.3 The Regulations require that designated bodies nominate or appoint a responsible officer who is a licensed doctor and provide support to them in fulfilling their statutory duties and responsibilities. These are described in Section 4.
- 5.4 It is essential that organisations allocate sufficient time and resource for the responsible officer to perform the function effectively. The role is complex and demanding. It is likely to require a significant commitment, depending on the size of the organisation. Organisations should ensure that appropriate infrastructures are in place to enable responsible officers to deliver their statutory functions.
- 5.5 The responsible officer is a senior role and should be nominated or appointed by means of a fair and open competition. The Regulations allow for designated bodies to nominate or appoint an external responsible officer.
- 5.6 The responsible officer will need access to organisational information on quality, safety and performance. The designated body has a duty to ensure that information systems are properly resourced and are functioning effectively. The information/data used for this purpose should be kept under review so that the most appropriate information is collected and the quality of the data (for example, coding accuracy) is improved.
- 5.7 A designated body's duty to resource responsible officers includes ensuring they are properly developed and supported by education, skills training and personal development opportunities. The organisation should ensure that the responsible officer takes part in a peer network to ensure sharing of learning, challenge and support in tackling new situations and consistency of decision-making regarding recommendations.

Resourcing responsible officers

- 5.8 The Regulations require designated bodies to provide the responsible officer with sufficient funds and other resources to discharge their duties. This applies to all responsible officers' statutory functions, including the additional (clinical governance) responsibilities that apply in England and Wales under Regulations 14 and 19. In Wales and Scotland this applies only to the statutory functions relating to the evaluation of fitness to practise under Regulation 14.
- 5.9 It is crucial that responsible officers are provided with the appropriate level of administrative and managerial support in order for them to fulfil their role of improving the quality of care across all dimensions, including patient safety. The responsible officer retains personal responsibility but may delegate particular roles and functions covered by the regulations to others. Those acting with delegated authority on behalf of the responsible officer should be appropriately trained, supported and supervised.
- 5.10 Responsible officers must make the recommendations to the GMC. This duty cannot be delegated.
- 5.11 In certain circumstances, the Regulations allow a designated body to recover the cost from a doctor of providing responsible officer services. These include secondary care locums, doctors with practising privileges and doctors who have a prescribed connection with one of the designated faculties or professional organisations. The charge should be reasonable and related to the cost of providing the service.

Section 6

Checks and balances

Responsible officers

- 6.1 Responsible officers, as licensed doctors, will usually be supported and have their own fitness to practise confirmed by a higher level responsible officer. Apart from NHS England this higher level responsible officer will be based outside the responsible officer's own organisation. Assessment of their fitness to practise includes how a doctor carries out his/her role as a responsible officer.
- 6.2 Responsible officers must be able to demonstrate that all associated governance systems are functioning effectively. For example, the responsible officer must ensure that the appraisal system is appropriately quality-assured and that a system of multi-source colleague and patient feedback is in place and functioning effectively. In the event of concerns about the outputs from the appraisal process, there should be a clear procedure in place for these to be raised, either prior to outputs being forwarded to the responsible officer or, if this fails, following submission. It is important to ensure that all processes underpinning the responsible officer's decision-making have safeguards for patients and doctors, and include provision for comments from the doctor to be sought and taken into account.
- 6.3 Where there is justified cause for concern about a doctor's fitness to practise, which cannot be managed through remediation processes, the responsible officer must bring the case to the attention of the GMC, ensuring that the necessary supporting information is available. Final decisions, which may affect the ability of the doctor to continue in practice, will remain as at present, the sole responsibility of the GMC.

Designated bodies

- 6.4 It is the organisation's responsibility to ensure proper governance of the process, challenging the responsible officer appropriately to ensure that a recommendation of fitness to practise is based on appropriate supporting information. Responsible officers will themselves want to be sure that they practise their responsible officer role with consistency. To this end, responsible officer networks for calibrating the decision-making have been put in place and all responsible officers are expected to participate in these activities.
- 6.5 Organisations will continue to operate other systems, such as dispute procedures and the Performers List Regulations (in the case of NHS GPs) where there are fitness for purpose concerns that are not sufficiently serious to trigger GMC action on fitness to practise.

Conflicts of interest or appearance of bias (Regulation 6)

- 6.6 To provide the assurances that patients and doctors require from revalidation, it is important that the evaluation of a doctor's fitness to practise is fair, objective and evidence-based. In some circumstances, doctors will find there is a conflict of interest or an appearance of bias with their appraiser or responsible officer.
- 6.7 A conflict of interest is a situation in which someone in a position of trust has competing professional or personal duties, loyalties, obligations or interests that would either make it difficult to fulfil their duties fairly, or would create an appearance of impropriety or a loss of impartiality that could undermine public confidence. An appearance of bias is an apparent predisposition, prejudice or preconceived opinion that may prevent impartial or objective evaluation
- 6.8 A conflict of interest or appearance of bias may relate to personal relationships, managerial or organisational roles.

Personal relationships

- 6.9 A conflict of interest or appearance of bias may occur:
- where there is or has been a personal relationship between a responsible officer and a doctor, such as family members, marriage or civil partnership, and other close personal relationships;
 - where there is a close financial or business relationship between a responsible officer and a doctor to the extent where the doctors have significant common financial or business interests;
 - where a responsible officer and a doctor have a significant breakdown of their personal relationship;
 - where there is a known and long-standing breakdown of the professional relationship between a responsible officer and a doctor.

Managerial or organisational roles

- 6.10 A conflict of interest or appearance of bias may also occur between the clinical and managerial roles performed by doctors:
- where a responsible officer has responsibility for a medically qualified chief executive;
 - where a responsible officer has responsibility for a doctor who is their medical 'line manager' or employer in another place of work (for example, the medical director or owner of an independent hospital)
 - where the responsible officer is also the employer of a doctor.

Mitigation

- 6.11 There are situations where a potential conflict of interest or appearance of bias can be mitigated through good management practice, for example:
- where a clinical director or service lead is required to oversee the clinical practice of their own responsible officer;

- where the responsible officer has previously handled concerns about a doctor's performance or fitness to practise (unless this has resulted in a known and long-standing breakdown of the professional relationship);
- where there is an ongoing doctor-patient relationship between a doctor and the responsible officer.

- 6.12 In such situations, openness and transparency are key features of any mitigation. It may be helpful to seek advice from the responsible officer's own responsible officer (for example the regional responsible officer) in order to demonstrate this principle.
- 6.13 If a conflict of interest or appearance of bias exists between a doctor and a responsible officer, the designated body should be informed in writing and relevant information should be obtained from the doctor, the responsible officer and other parties. Where appropriate, attempts should be made to resolve any interpersonal or professional issues using existing mediation procedures. If this is not possible, and in the other circumstances described above, an alternative responsible officer should be appointed by the designated body for the doctor. The designated body has a duty to ensure there is no further conflict of interest or appearance of bias when nominating the new responsible officer for the doctor.
- 6.14 Where an alternative responsible officer has to be nominated or appointed for a doctor it is recommended that the designated body seeks advice from the responsible officer's own responsible officer (for example, the regional responsible officer) who will help to ensure there is consistency in decision-making in this area and may also help to identify a suitably experienced alternative responsible officer who has no conflict of interest with the doctor.

Conflict of interest or appearance of bias in appraisal

- 6.15 To avoid a conflict of interest or appearance of bias between a doctor and their appraiser, as well as the personal relationships described above, the following principles should be adopted:
- a responsible officer should not also act as a doctor's appraiser;
 - a doctor's employer should not also act as their appraiser;
 - reciprocal arrangements, where for instance two doctors appraise each other should not occur;
 - a responsible officer should not be appraised by one of the doctors for whom they are responsible;
 - an appraiser should not receive direct payment from a doctor for performing the appraisal (appraisers should be paid by the designated body).
- 6.16 The process for resolving a conflict of interest or appearance of bias between a doctor and their appraiser should be identified in the designated body's appraisal policy along with the particular circumstances where it may occur. A suitable alternative appraiser should be assigned where necessary. In all cases the responsible officer should be assured that the appraisal is fair, objective and impartial.

Equality

- 6.6 Doctors have a professional and ethical duty to treat patients and colleagues with respect whatever their gender, race, life choices or beliefs. There is evidence that doctors from ethnic minorities are disproportionately represented in disciplinary procedures. It is important that responsible officers have a high level of understanding of the statutory requirements and good practice in this area to enable them to ensure that the organisation's systems and processes do not discriminate against any individual doctor or group of doctors. An understanding of equality and diversity issues is therefore a key competence for the role of responsible officer.

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Section 7

Further information

Further information relating to the context of this document can be found at:

GMC website

<http://www.gmc-uk.org/doctors/revalidation.asp>

NHS England website

<http://www.england.nhs.uk/revalidation/>

Scottish Government website

<http://www.scotland.gov.uk/Topics/Health/NHS-Workforce/Regulation/Medical-Revalidation>

Scottish Online Appraisal Resource

<https://online.appraisal.nes.scot.nhs.uk/>

Revalidation in Wales

<http://revalidation.walesdeanery.org/>

Medical Appraisal & Revalidation System in Wales

<http://www.marswales.org/>