

The Role of Responsible Officer

Responsible Officer Guidance – Closing the Gap in Medical Regulation

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Section 1. Introduction

The document

- 1.1 This is guidance to which responsible officers and designated bodies must have regard under the Medical Profession (Responsible Officers) Regulations 2010¹. It relates to the role of responsible officers to be nominated or appointed by those bodies designated under the Act. The document is also of relevance to doctors working outside designated bodies.
- 1.2 The guidance has been produced for consultation as a collaborative endeavour between the Department of Health, the Devolved Administrations, the British Association of Medical Managers (BAMM), the Medical Managers Committee of the British Medical Association (BMA) and NHS Employers.
- 1.3 This document is designed to provide guidance to 3 key audiences:
 - doctors licensed with the General Medical Council (GMC) to practise medicine;
 - all doctors taking on roles as responsible officers; and
 - all organisations designated (by the Secretary of State for Health) as having to nominate or appoint a responsible officer in England, Scotland and Wales.
- 1.4 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.
- 1.5 This section of the guidance sets out the background to the role of the responsible officer and describes it in the context of other measures that are aimed at improving the quality of care for patients and the confidence the public has in doctors. It also explains how the legislation applies to different parts of the United Kingdom.
- 1.6 Section 2 sets out key points on how the system of responsible officers will work.
- 1.7 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 responsible officer.

¹ The Medical Profession (responsible officers) Regulations 2010; TSO

- 1.8 Section 4 is aimed at licensed doctors taking on the role of responsible officer. It provides guidance on a responsible officer's functions under the Medical Act 1983 (relating to the evaluation of fitness to practise) and, in England only, to their wider statutory role under the Health and Social Care Act 2008 (relating to monitoring conduct and performance).
- 1.9 Section 5 is aimed at designated organisations. It sets out their responsibilities in the legislation. It also provides guidance on best practice.

Coverage of this guidance

- 1.10 This guidance relates to the Medical Profession (Responsible Officers) Regulations 2010. These regulations apply to England, Wales, and Scotland. In England, as well as having duties in relation to regulation, responsible officers will be required to undertake a range of duties embracing wider responsibilities relating to clinical governance. Wales will make their own regulations on the clinical governance aspects, whilst Scotland is considering what, if any, improvements are needed in the area of clinical governance and will bring forward its own guidance and/or legislation if necessary.
- 1.11 This guidance relates for the most part to England, Wales and Scotland. However paragraphs 4.15 - 4.26 relate to England only and paragraphs 3.24 - 3.26 to Scotland only.

Background

- 1.12 The role of managers, both medical and 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 to patients. As Ministers have recognised, the care delivered by the majority of doctors registered with the GMC is generally of a high quality. However, after a series of high profile failings, proposals were made for a system of revalidation for every doctor. The purpose of revalidation when it is introduced will be to ensure that licensed doctors remain up to date and continue to be fit to practise. When introduced, revalidation will have three aims:
- to confirm that licensed doctors practise in accordance with the GMC's generic standards (relicensure);
 - for doctors on the specialist register and GP register, to confirm that they meet the standards appropriate for their speciality or general practice (recertification); and
 - to identify for further investigation, and remediation, poor practice where local systems are either not robust enough to do this or do not exist.

- 1.13 The role of responsible officers, in England, is integral to improving the quality of care and ensuring a focus on the three core components of quality described in *High quality care for all*²:
- **Patient Safety** – by ensuring that doctors are maintaining, and raising further, professional standards.
 - **Effectiveness of care** – by supporting professional instincts to improve further the effectiveness of clinical care.
 - **Patient experience** – by ensuring that patients' views are integral to evaluations of a doctor's fitness to practise.
- 1.14 The development of the responsible officer role is part of the programme of reform set out in the White Paper *Trust, Assurance and Safety*³. That programme values and celebrates the professionalism of the dedicated people who work in healthcare. It seeks to raise the already high standards of the overwhelming majority of professionals, whilst ensuring that the small number of staff who are not able to meet those standards are swiftly identified and then dealt with fairly and effectively and, where appropriate, are supported to get back on track.
- 1.15 In support of this, the responsible officer role will:
- ensure that those doctors who provide care continue to be safe;
 - ensure doctors are properly supported and managed in sustaining and, where necessary, raising their professional standards;
 - for the very small minority of doctors who fall short of the high professional standards expected, ensure that there are fair and effective local systems to identify them and ensure appropriate remedial, performance or regulatory action to safeguard patients; and
 - increase public and professional confidence in the regulation of doctors.
- 1.16 The responsible officer will play a crucial role in the process of medical revalidation when it is introduced. Introducing the new processes of revalidation, and putting responsible officers in place, has major implications for every doctor and for every healthcare organisation. The new regulations mean that:
- licensed doctors with a prescribed link to a designated body will relate to one and only one responsible officer. The responsible officer, will make a recommendation to the GMC about the doctor's

² High quality care for all, Department of Health, September 2008

³ Trust, Assurance and Safety: The Regulation of Health Professionals in the 21st Century; TSO February 2007

fitness to practise (as a positive statement of assurance, not simply an absence of concerns);

- this recommendation must be founded on the basis of robust, accurate evidence about all aspects of the doctor's practice, including that resulting from any investigations already completed. That evidence must be scrutinised through the clinical arm of corporate governance and appraisal/capability/remediation processes. It must also, where appropriate, be sufficient to evidence that the doctor's performance meets the specialist or general practitioner standards set by the relevant medical Royal College or other appropriate body, as required for recommendation as being fit to practise. The responsible officer, following the appropriate or necessary consultations with College representatives and/or NCAS, will decide whether the necessary standards are met and if not will refer the doctor to the GMC on fitness to practise grounds. In England if the concerns do not merit referral to the GMC the responsible officer will also consider whether local remediation is appropriate; and
- all designated healthcare organisations will be required to nominate or appoint, resource and support a responsible officer. In the NHS in England this will be a senior licensed doctor, usually sitting on the Board. In NHS Scotland this will be a Health Board Medical Director who is an executive member of the Board.

- 1.17 The public, the profession and the NHS have a right to be assured that licensed doctors are fit to practise. The new regulations are designed to help doctors, and the organisations where they work, to further improve the quality of care provided to patients.
- 1.18 The role and responsibilities of the responsible officer are described in this document as is the relationship between licensed doctors and a responsible officer and the duty of designated healthcare organisations to nominate or appoint to the role and resource it. The guidance has been produced following the conclusions of a working group established by the Department of Health as part of the implementation of *Trust, Assurance and Safety*. It also reflects responses to a consultation on the role of the responsible officer and contributions from a wide range of clinicians, managers and patient groups.
- 1.19 The responsible officer arrangements will apply to the vast majority of practising doctors in the UK who will need to relate to a responsible officer nominated or appointed by a designated body. The arrangements for confirming the fitness to practise of a small minority of doctors falling outside this framework are subject to further discussion with stakeholders, and possibly piloting. The Department of Health and the GMC will therefore bring forward proposals in relation to these doctors at a later date.

Section 2. Key messages

- 2.1 The following section sets out key messages for all audiences.
- 2.2 All designated organisations must nominate or appoint a responsible officer. The designated bodies are set out in the regulations, but they can be broadly summarised as:
 - organisations that provide healthcare;
 - organisations that set standards and policy for the delivery of healthcare; and
 - some specialist organisations
- 2.3 Organisations should have only one responsible officer who carries the overall accountability, although individual tasks can be delegated.
- 2.4 Doctors will have one and only one responsible officer at any point in time.
- 2.5 As a rule of thumb, doctors link to the responsible officer in the organisation where they undertake the majority of their clinical work. For doctors on a General Practice Performers List they will relate to the responsible officer in the organisation that manages that Performers List. In England, this is the Primary Care Trust, in Scotland the Health Board and in Wales the Local Health Board.
- 2.6 Doctors should ensure they know who their responsible officer is.
- 2.7 Responsible officers must be doctors who are licensed by the GMC.
- 2.8 Responsible officers will have a responsible officer. In England, this will be the Strategic Health Authority responsible officer. In Scotland and Wales, it will be the responsible officer in the Scottish Government and Welsh Assembly.

Section 3. Guidance for licensed doctors

The doctor's responsibility to a responsible officer

- 3.1 Following the introduction of the new regulations, a responsible officer nominated or appointed by an organisation designated by the Secretary of State for Health will have a key role for the doctors they are linked to. The role of the responsible officer across the UK is to evaluate doctors' fitness to practise. They will do so based on the evidence that is presented to them, so will have to ensure that the organisation has necessary systems in place to facilitate this. Under the regulations, in England, the responsible officer's role will support doctors as they strive to improve the quality of care.
- 3.2 Every doctor who has a link with a designated body under the regulations will be required to undergo a strengthened process of appraisal in order to be able to demonstrate, by production of a portfolio of supporting information, that their practice meets:
- standards set by the GMC as laid out in Good Medical Practice⁴ and the associated Framework for Appraisal and Assessment⁵;
 - specialist or general practitioner standards as set out by the appropriate medical Royal College or Faculty; and
 - expectations of their managed healthcare organisation in safely undertaking the clinical role for which they are employed or contracted.
- 3.3 Designated bodies will be expected to ensure that they have in place robust systems of clinical governance to support the responsible officer in the role and that these systems are fit for purpose and quality assured. The data fed into these systems and made available to support doctors' portfolios, and to inform appraisal, must be of the highest quality, and include multi-source feedback, information from clinical governance and information relating to the doctor's clinical performance. It must be properly assured, appropriately validated and reviewed where appropriate. The information from these systems, which will inform the responsible officer's decision-making, must be accurate, timely, relevant to the full span of the individual's clinical practice and meet the standards set out by the GMC, and the medical Royal Colleges and Faculties where appropriate.
- 3.4 The GMC will require each doctor to inform, through the appraisal process, their responsible officer of all relevant practice they undertake. All relevant

⁴ Good Medical Practice, General Medical Council, November 2006

http://www.gmc-uk.org/guidance/good_medical_practice/index.asp

⁵ Framework for Appraisal and Assessment, General Medical Council, August 2008

http://www.gmc-uk.org/doctors/licensing/docs/explanatory_note.doc

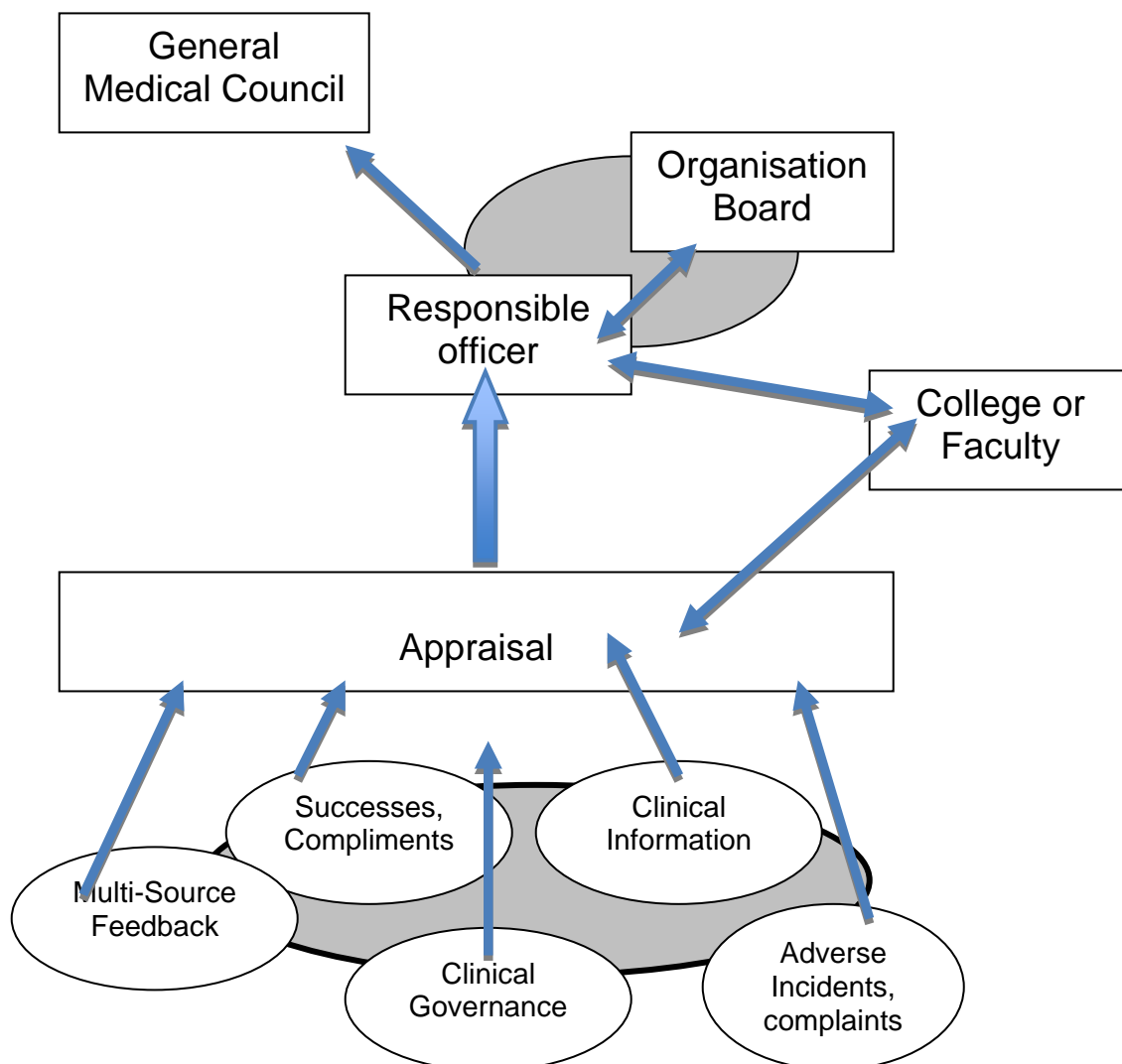
practice means all work undertaken by the individual in his or her role as a doctor, both clinical practice and non-clinical roles such as public health, administration, management and leadership.

The revalidation process and the responsible officer

3.5 The purpose of medical revalidation, when introduced, will be to assure patients, employers, commissioners and colleagues that licensed doctors are up to date and fit to practise. *Trust, Assurance and Safety* describes an approach to medical revalidation involving two key strands:

- relicensing – to confirm that licensed doctors practise in accordance with the GMC’s generic standards as set out in ‘Good Medical Practice’; and
- recertification – to confirm that doctors on the specialist and GP registers continue to meet the standards appropriate for their area of practice.

Figure 1



- 3.6 The core mechanism underpinning these two strands of revalidation will be a strengthened appraisal system, which is being designed to elicit the necessary information about a doctor's practice - see Figure 1.
- 3.7 Individual doctors will be responsible for maintaining a portfolio of supporting information to demonstrate the maintenance of their clinical and professional standards and, where applicable, their specialist skills. This package of information also provides a basis of evidence that responsible officers can use to help assess fitness to practise.
- 3.8 The appraisal process will include information from multi-source feedback, Continuing Professional Development (CPD) portfolios and verified clinical performance information, along with the outcomes of any investigation of complaints, concerns, patient safety incidents and other available indicators that can be reliably related to the performance of the individual doctor. Evidence confirming the doctor's performance against the clinical standards as set out by his or her respective medical Royal College or Faculty, where applicable, should be included in their appraisal.
- 3.9 The responsible officer will be accountable on behalf of the organisation for ensuring that the systems for appraisal, clinical governance and for gathering and retaining other local relevant evidence are in place and are effective. He or she will also be responsible for ensuring that systems are in place to record and collate all the necessary information, including a record of any practice undertaken by the doctor outside of the organisation.
- 3.10 The responsible officer, having assessed all the information and, if appropriate, consulted the relevant medical Royal College or Faculty, will make a recommendation to the GMC regarding the doctor's fitness to practise. It is anticipated that the majority of doctors will be positively recommended in this way, but, where there is a concern about a doctor, the responsible officer must decide whether local processes of remediation are appropriate or whether it is serious enough to warrant a referral to the GMC on the grounds of fitness to practise.
- 3.11 It is the designated organisation's responsibility to ensure the proper governance of the process, challenging the responsible officer appropriately to ensure that any recommendation is based on the evidence.
- 3.12 It is emphasised that where there is justified cause for concern about a doctor's fitness to practise which cannot be managed through local remediation processes, the role of the responsible officer is limited to drawing the case to the attention of the GMC and to ensuring that the necessary supporting evidence is available. Final decisions which may affect the ability of a doctor to continue in practice will remain, as at present, the sole responsibility of the GMC.

- 3.13 To provide the evidence that will enable the responsible officer to make a recommendation based on all the evidence, doctors will be required to make the responsible officer aware of all relevant work, both clinical and non-clinical. Failure to do so may become a fitness to practise issue and may affect their future licensed status.

Arrangements for relating to a responsible officer

- 3.14 The overarching role of the responsible officer is to protect patients by ensuring that the GMC's standards are met by licensed doctors. A licensed doctor should normally relate to the responsible officer of the healthcare organisation in which he or she spends the majority of his or her working week. The principle is that, where doctors work in a designated organisation, that organisation will have in place the appropriate systems of strengthened appraisal and clinical governance that will support the revalidation process when it is introduced. Doctors on a Performers List will always relate to the responsible officer in the organisation whose Performers List they are on. The arrangements are illustrated in Figure 2. Doctors will relate to one responsible officer only. Each designated organisation will normally have only one responsible officer. In the NHS, we expect that this will be a Board Medical Director.
- 3.15 Providers of healthcare will be required to nominate or appoint responsible officers. These organisations either:
- provide or arrange for the provision of healthcare by doctors; or
 - employ or contract with doctors;
- and include:
- NHS hospitals and mental health trusts;
 - Foundation Trusts;
 - Independent sector hospitals in England and Wales;
 - Primary Care Trusts and provider organisations; and
 - Health Boards in Scotland and Local Health Boards in Wales.
- 3.16 Organisations that have a role in setting policy and standards for the provision of healthcare that employ or contract with licensed doctors will also have to nominate or appoint a responsible officer. These include:
- Special Health Authorities in England;
 - Special Health Boards in Scotland
 - The Common Services Agency in Scotland; and
 - Government departments.
- 3.17 Doctors may also work independently of organisations either as independent providers or self employed contractors. These doctors are generally members of specialist societies. A small number of these

organisations that have demonstrated appropriate clinical governance system are designated. Currently, in England, these are the:

- Independent Doctors Federation;
- Faculty of Occupational Medicine;
- Faculty of Pharmaceutical Medicine; and
- Faculty of Public Health.

Arrangements for doctors in NHS Trusts, Foundation Trusts and independent hospitals in England and Wales

3.18 Doctors in NHS Trusts, Foundation Trusts and independent hospitals in England and Wales will relate to the responsible officer for the organisation. We expect that for the NHS the responsible officer will sit on the organisation's board. In exceptional circumstances, where there is a conflict of interest, a doctor in an NHS organisation may make a case for relating to another responsible officer nominated or appointed by the NHS organisation. Such circumstances may include a family or other personal relationship. Managing conflicts of interest is discussed in more detail in paragraphs 3.33 - 3.36.

General practitioners

3.19 General practitioners, in England, will relate to the responsible officer of the PCT holding the performer's list on which the individual is named. In Scotland this will be the Local Health Board and in Wales, the Health Board. Again, where there are conflicts of interest the doctor may make a case to relate to another the responsible officer nominated or appointed by the PCT.

3.20 In England, many PCTs are splitting their provider and commissioning functions into separate bodies. Where a doctor not on a Performers List works in both these bodies the principle is still that the doctor relates to the responsible officer of the designated organisation in which he or she works for the majority of his or her time.

Arrangements for doctors in Scotland

3.21 Doctors in Health Boards in Scotland (both primary care and acute sector) will relate to the responsible officer for the Health Board. We expect that the responsible officer will be an executive member of the Health Board. In exceptional circumstances a doctor in a Health Board may make a case for relating to another responsible officer.

3.22 As indicated above, general practitioners will relate to the responsible officer of the Health Board holding the Performers List on which the individual doctor is named. Again, in exceptional circumstances the doctor may make

a case to relate to the responsible officer of another Health Board. Where a doctor is also on a Performers List in another country the doctor will link to the Performers List where most of their work is carried out.

- 3.23 Where a doctor has more than one employer the principle will be that each doctor relates to the responsible officer of the organisation in which he or she works for the majority of his or her time.

Doctors working in management roles

- 3.24 As with other medical practitioners, doctors in management roles should relate to the responsible officer of the organisation for whom they undertake the majority of their work.
- 3.25 Responsible officers, as licensed doctors will also have to have their fitness to practise confirmed. As senior doctors in their organisations they will use the same systems as the doctors they are responsible for. They will have a responsible officer, outside their own organisation, who will ensure they are supported in the same way as those they are responsible for. In England, responsible officers will be at the appropriate Strategic Health Authority (SHA). In Scotland and Wales they will be at the Scottish Government and the Welsh Assembly respectively. The SHA responsible officer will relate to the Department of Health's responsible officer. Doctors must demonstrate their fitness to practise in the areas in which they work, rather than in the specialty in which they originally gained their Certificate of Completion of Training (CCT) or which they practice for only a minority of the working time.

Doctors in training

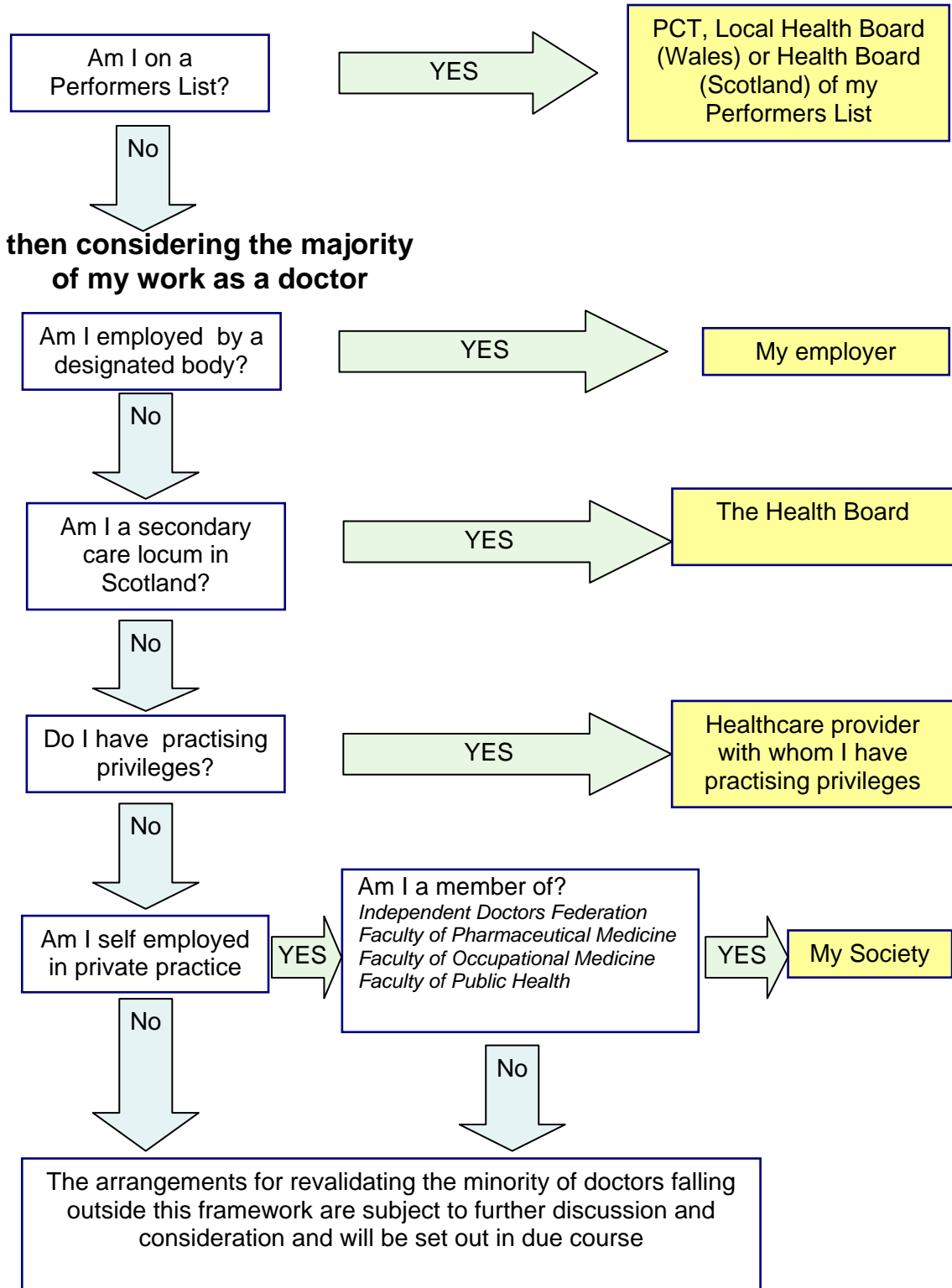
- 3.26 All doctors in training posts must relate to the responsible officer of the organisation they are employed by. All discussions concerning the performance of doctors in approved UK training (Speciality and Foundation Programmes) must involve the trainee's Post-Graduate Dean.

UK doctors working overseas or offshore

- 3.27 Doctors registered in the UK but working overseas or offshore should relate to the responsible officer of their employing or contracting organisation, where this is a designated body under the regulations. For example, doctors in military service will relate to the responsible officer for the Defence Medical Services, regardless of where they happen to be at any particular time.

How to find your responsible officer

3.28 Figure 2 below shows how individual doctors can find out who their responsible officer is. It is intended as a guide to supplement the regulations.



Locum doctors

- 3.29 This section only applies to locum doctors in secondary care. Locum doctors in primary care are on a Performers List and should read the relevant section relating to general practitioners in England, Wales or Scotland.
- 3.30 One issue where opinions were most polarised in the discussions of our expert group was whether locum agencies, not employing doctors but contracting with them to supply services to healthcare providers, should have their own responsible officer. It was agreed that they should have a responsible officer if they could demonstrate good clinical governance systems are in place.
- 3.31 It is the Department of Health's intention that appropriate locum agencies in England should be designated organisations and have their own responsible officer. Discussions with relevant stakeholders in England are still ongoing regarding the best way of assessing locum agencies' clinical governance systems in order to enable this to happen. In Scotland, locum agencies will not have their own responsible officer and locum doctors will relate to the responsible officer in a Health Board.

Doctors without a prescribed connection to a responsible officer

- 3.32 The designation of organisations that are required to nominate or appoint a responsible officer ensures that the vast majority of doctors, and particularly those whose work affects the safety of patients, will relate to a responsible officer. However, we recognise that there will be a number of doctors who do not work in clinical settings, and are not involved in direct patient care, but who nevertheless will wish to maintain a licence to practise. These will include doctors working in law firms, universities, research companies and insurance companies. It is not considered either practical or appropriate to designate these types of organisation in the responsible officer regulations. The arrangements for confirming the fitness to practise of these doctors are subject to further discussion with stakeholders, and possibly piloting. The Department of Health and the GMC will therefore bring forward proposals in relation to these doctors at a later date.

Conflicts of interest

- 3.33 It is important that the evaluation of a doctor's fitness to practise is fair, honest and evidence based if it is to provide the assurances that patients and doctors require from the system. In some circumstances, doctors will find they have a conflict of interest with their appraiser or responsible officer.

- 3.34 If a conflict of interest is identified between appraisee and appraiser, the responsible officer should be informed in writing, explaining the conflict and providing as much background information as is necessary and relevant. It may also be appropriate to request another appraiser is assigned. The responsible officer will consider the claimed conflict and may assign another appraiser.
- 3.35 If a conflict exists between the doctor and the responsible officer, the designated organisation should be informed in writing giving as much information as possible. It is important that every attempt is made to resolve the issue using the existing mediation procedures. If, after all processes are exhausted, a satisfactory resolution is not possible the evaluation of fitness to practise may be overseen by another responsible officer.
- 3.36 In the same way that conflicts of interest must not be allowed to affect a doctor's career they should not be a route that allows a doctor to undergo a less rigorous assessment of his or her fitness to practise.

Section 4. Guidance for responsible officers

- 4.1 This section, in paragraphs 4.2 to 4.14,, sets out guidance for responsible officers in England, Scotland and Wales and specifically relates to their role in evaluating the fitness to practise of doctors. Paragraphs 4.15 to 4.23 provide guidance on the additional responsibilities, relating to clinical governance, of responsible officers in England only.

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

- 4.2 There are two principal processes for which the responsible officer has prime responsibility. These are:
- processes that will underpin the retention of doctors' licences; and
 - processes underpinning referral of doctors to the GMC in those cases where there are doubts concerning fitness to practise.

The regulation of doctors is, and will remain, a matter for the GMC. Decisions about a doctor's fitness to practise will be taken by the GMC only after the appropriate procedures have been followed.

- 4.3 The responsible officer will be answerable to the GMC and their nominating or appointing organisation for ensuring that there are appropriate systems and processes in place for collecting and holding information that informs the evaluation of fitness to practise. This will include ensuring there are robust systems of appraisal in place to identify poor or deteriorating clinical performance and/or conduct is identified at an early stage. Where conduct or performance is falling below the usual high standards that doctors are expected to work to, the appropriate action must be taken to avoid potential harm to patients and to support doctors to get back on track. It is the responsibility of the organisation to ensure that these systems are properly resourced, reviewed and maintained.
- 4.4 Specifically, the responsible officer must ensure that:
- they maintain a list of doctors they are responsible for;
 - there is an integrated system for monitoring doctors' performance, recognising good practice, encouraging and supporting development and learning;
 - effective systems and processes of appraisal are in place;
 - appropriate action is taken to remedy identified areas of weakness; and
 - progress against doctors' personal development plans is monitored.

- 4.5 The responsible officer has to ensure that the organisation is advised properly of the resource consequences in terms of time, the processes for collection of relevant supporting information, the staff and funds needed for rigorous processes of appraisal and for continuing professional development (CPD).
- 4.6 Medical Royal Colleges and Faculties will offer support to responsible officers in evaluating the specialist practice of doctors. The responsible officer has a responsibility to ensure that there is appropriate liaison, when appropriate, between their organisation and the relevant Medical Royal Colleges and Faculties to seek their input to the appraisal process, in terms of specialist practice. The responsible officer will decide when he or she needs advice on specialist practice. It is envisaged that this should happen only where there are concerns about fitness to practise .
- 4.7 The responsible officer has a statutory duty to co-operate with the GMC. In England, pending the outcome of a pilot project currently underway, this may be through a regionally based GMC affiliate. The responsible officer will liaise with the GMC on matters connected with fitness to practise issues.
- 4.8 In the event of concerns being raised about a doctor of a sufficiently serious nature to call into question the doctor's fitness to practise, the responsible officer will need to consider referral of the doctor to the GMC. Responsible officers will be accountable for the oversight of all associated processes. The responsible officer is expected to co-operate with the GMC in establishing the appropriateness of the referral and will oversee the collation of the relevant information. The responsible officer will also be expected to liaise with the appropriate Medical Royal College or Faculty, where appropriate, through the College Regional Advisors for independent advice on the relevant specialist practice and also, in cases of concern, for advice on the performance of the doctor.
- 4.9 The responsible officer is also accountable for overseeing the process by which doctors whose practice is supervised and/or limited under conditions imposed by, or undertakings given to, the GMC. It is up to the responsible officer's to ensure that the doctors they are responsible officer for comply with any conditions imposed upon them by the GMC. It is essential that good communication channels are set up and maintained to ensure that, for example, if a doctor is placed within an organisation for remediation, the host responsible officer is informed and oversees the monitoring process.
- 4.10 Whilst the responsible officer will, under normal circumstances, have a personal involvement in, and responsibility for, referral to the GMC where there is doubt about a doctors fitness to practise, it is recognised that there may be specific circumstances in which another responsible officer should undertake the role. There may be a conflict of interest for the responsible

- officer – for example, a friendship, marriage, a business arrangement outside the organisation or long-standing acrimony. Whilst it is envisaged that these situations will be uncommon, it is important that appropriate governance arrangements are in place to address these.
- 4.11 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 monitored and that a system of multi-source peer and patient feedback is in place and functioning effectively, as described in *Assuring the Quality of Medical Appraisal for Revalidation*⁶. 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 rights of appeal as part of good governance.
- 4.12 The responsible officer is not likely to make the decision to refer a doctor to the GMC in isolation; he or she must ensure that capability, remediation and disciplinary procedures, where appropriate, are followed and that advice is sought from appropriate sources, for example from the medical Royal Colleges and Faculties or the National Clinical Assessment Service (NCAS).
- 4.13 The responsible officer's responsibilities relate to the local systems which support local decision-making. For secondary care organisations in England this process is described in *Maintaining High Professional Standards in the NHS*⁷. PCTs in England are advised to follow guidance from the NCAS. These new arrangements do not in any way affect the right of patients or members of the public to refer cases directly to the GMC.
- 4.14 Responsible officers are licensed doctors. It follows then that they must each also have a responsible officer. In England, the responsible officer at a local level will relate to a responsible officer at the appropriate Strategic Health Authority, who will ensure that the relevant evidence is collected and make any recommendation about fitness to practise to the GMC. The SHA responsible officer in England will relate to the Department of Health's responsible officer. In Scotland and Wales the responsible officer of local

⁶ Assuring the Quality of Medical Appraisal for Revalidation (AQMAR); Revalidation Support Team; May 2009
http://www.revalidationsupport.nhs.uk/Assuring_the_Quality_of_Medical_Appraisal_for_Revalidation.asp

⁷ 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

responsible officers will be at the Scottish Government and Welsh Assembly Government respectively.

Additional responsibilities relating to clinical governance for responsible officers in England

- 4.15 Responsible officers in England have a duty to ensure the robust, efficient and reliable functioning of systems of clinical governance. Clinical governance has been defined⁸ as “*a framework through which healthcare organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish*”. This definition reinforces the concept that, for the great majority of doctors, the focus of clinical governance systems should be on quality improvement, in terms of the quality of care not only as delivered by each doctor but also by the entire team of which the doctor is part. The function of appraisal, therefore, remains summative – but only after an objective and confident judgement has been made about the quality of the doctor’s practice. In the vast majority of cases, this judgement will be affirmative, but, in the small number of instances where there is cause for concern, robust processes must be in place to ensure early identification and rapid remedial action.
- 4.16 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 own performance and the quality of care they provide to patients. They must also ensure that:
- contracts of employment or for provision of services (admission to Performers’ Lists, for example) are appropriate, effective, robust and designed to safeguard the patient;
 - doctors’ performance and conduct is monitored; and
 - appropriate, timely action is taken when concerns about shortcomings in performance or conduct are identified.
- 4.17 The responsible officer duties in monitoring clinical performance and reporting concerns when they arise will also involve him or her in providing professional leadership and leading the cultural change that must take place in the organisation to support and allow the systems of celebrating and spreading best practice. If the culture does not support honesty, openness and a willingness to rectify and learn from failings, even the most sophisticated technology available will not deliver a system that works. Like any other system and process, the effectiveness of clinical governance is dependent upon the culture and attitudes of the organisation. The responsible officer has a major role to play in creating and maintaining the appropriate culture to support good clinical governance.

⁸ *Clinical governance and the drive for quality improvement in the new NHS in England*; G. Scally and L. J. Donaldson, BMJ (4 July 1998): 61-65

- 4.18 Safeguarding patients begins when doctors are appointed or admitted to a Performers List. The responsible officer will have a statutory responsibility to ensure that there are robust systems within the organisation for:
- undertaking appropriate employment checks for medical appointments;
 - obtaining appropriate references and resolving any issues that may arise; and
 - recording the results of the checking process.
- 4.19 Responsible officers in England have a broader set of responsibilities relating to the monitoring of conduct and performance of doctors who give rise to concern, but do not require referral to the GMC. It is likely that the systems for monitoring performance and conduct will be common to both the revalidation and the fitness to practice processes and will reflect good employment practice. There will be a range of outcomes and pathways, but broadly, doctors will either have their fitness to practise confirmed, be subject to appropriate local action or remediation to improve the doctor's practice or be referred to the GMC.
- 4.20 Identifying a concern is merely the start of a process to safeguard patients. It is crucially important that appropriate action is taken at the appropriate time. The responsible officer has a personal responsibility for initiating the action in relation to issues that arise from the conduct and performance of doctors. These actions may include:
- initiating an appropriate investigation, with trained investigators separate from the decision-making process;
 - co-ordinating and co-operating with other concurrent investigations into broader systems failure;
 - further monitoring;
 - sharing information with, or seeking information from, other healthcare organisations (other organisations will be expected to share information appropriately);
 - remediation, which may include re-skilling and rehabilitation training and development, mentoring, peer support, coaching or supervision; and
 - excluding a doctor or placing local conditions or restrictions on their practise;
- 4.21 External organisations in a sub-contracting relationship with the responsible officer function will need mechanisms in place locally to deliver the above actions, in accordance with the responsible officer's recommendations following a rigorous process of investigation.
- 4.22 If an investigation confirms a valid concern, the root cause should also be traced. Many cases of apparent poor performance of an individual may in

fact be due to a dysfunctional team or a wider organisational system. The responsible officer has a duty to support the quality of the environment and, if necessary, to initiate action to address wider systems or team issues that result in poor performance.

- 4.23 It is essential that the organisation continually learns and adjusts its systems on the basis of the findings of investigations. An investigation may reveal a system failure, the rectification of which may lie outwith the responsible officer's or organisation's immediate control. 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 – NPSA, MHRA and the manufacturers, in addition to the immediate primary action needed to prevent harm to patients.

The organisation and individuals have regard to guidance

- 4.24 In terms of these wider responsibilities relating to clinical governance, responsible officers should have regard to guidance issued by specific organisations. These organisations include the Department of Health, GMC, NCAS and NPSA.
- 4.25 The responsible officer has a duty to 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 NICE guidance, to best practice guidance from recognised sources, to recognised national audits and to local audits of clinical practice. The responsible officer therefore also has a duty to ensure that this guidance is easily accessible and widely used within their organisation. It is the employing organisation's responsibility to ensure that clinicians have easy access to the best evidence so that they can practice to the highest standards. The onus is on both the clinician and the employer as partners in providing and using best practice guidelines and documentation.
- 4.26 The responsible officer has a duty to ensure that doctors are fit to practise. That may be difficult when the doctor is carrying out innovative treatments. In England, doctors carrying out procedures that are new, or for which they have no experience, have to gain approval from either a Research Ethics Committee or a Trust's Clinical Governance Committee. The processes for ensuring that doctors have the appropriate authority are set out in *HSC 2003/11*⁹.

⁹ 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

Relationships and accountabilities of the responsible officer across the UK

- 4.27 The responsible officer should be directly accountable to the organisation's Board or the highest level of management. The responsible officer also has a relationship with the GMC, in terms of a duty of co-operation on matters in connection with fitness to practise, including ethical issues. In England, pending the outcome of a pilot project currently underway, this will usually be through a regionally based GMC affiliate.
- 4.28 Key relationships for the responsible officer at Executive Board level will be with the Chief Executive, Director of Human Resources and Director of Nursing. Within the organisation, the responsible officer will relate closely to the organisation's medical management, appraisal and clinical governance infrastructure.
- 4.29 The responsible officer will also have a crucial set of relationships with the clinical leads of the various service lines of the organisation. In England, this will be with clinical directors, clinical leads or service line leads in secondary care and PEC chairs, clinical governance leads and clinical service leads in primary care, along with appraisal leads and trainers who will oversee the information processes and flows within the organisation. These individuals will be responsible for collating information on the performance of individual doctors to present to the responsible officer. The responsible officer will want to ensure that they are properly trained in appraisal and multi-source feedback and demonstrate that they are of the highest calibre and integrity.
- 4.30 The responsible officer will liaise, where appropriate, with the medical Royal Colleges and Faculties for information and support regarding specialist and GP practice and potential recommendations.

Who should be the responsible officer?

- 4.31 It is a basic requirement that a responsible officer must be a licensed doctor.
- 4.32 In many cases when concerns are raised about a doctor's fitness to practise they will reveal an issue with the systems in place in the organisation. The responsible officer has to ensure that the appropriate action is taken as a result of the evaluation of fitness to practise. That may require the organisation to change the systems that have given rise to the concern and that is why the advisory group and those we consulted thought the responsible officer has to be a senior doctor in their organisation. In NHS organisations, we expect that the role will be undertaken by the Medical Director with an Executive seat on the Board.
- 4.33 Each designated organisation will normally have only one responsible officer. He or she may devolve some aspects of the wider role to an

assistant medical director or other medical manager as an “associate” to the responsible officer. However, the decision-making of the responsible officer, and recommendations made, are the responsibility of the responsible officer.

- 4.34 Organisations will need to make decisions as to how best to deliver the additional duties of the responsible officer on top of those already carried out by the Executive Medical Director. This may necessitate some restructuring and strengthening of the organisation’s medical management infrastructure but this will vary according to existing arrangements that are in place and gaps that need to be filled.

Person specification

- 4.35 In England, the responsible officer will be responsible to the board for clinical performance and clinical governance in respect of doctors and, as a senior doctor, will also provide leadership to the medical workforce. In some organisations across the UK, responsibility for clinical governance across the organisation may be jointly held with another board member, for example the Executive Nurse Director.
- 4.36 The responsible officer must have practical experience as a senior doctor and have a licence to practise. The responsible officer will be able to demonstrate evidence of continuing personal and professional development. Specifically, he or she must be able to demonstrate an ability to lead and manage change in complex healthcare organisations and have significant experience of medical management, including, practical experience of performance management of colleagues, appraisal processes and audit. He or she must be able to demonstrate the ability to translate findings into remediation plans and to introduce new policies and strategies throughout an organisation. This will require being able to demonstrate knowledge both of the practicalities of clinical governance and its crucial role in safeguarding quality of clinical care in the NHS.
- 4.37 In terms of special areas of skills and knowledge, the responsible officer will need to demonstrate a detailed, accurate and up-to-date knowledge of the law as it relates to medical regulation and interfacing structures and processes. He or she will need to be able to demonstrate expert knowledge and skills in appraisal, quality assurance of appraisal systems and of appraisers, mediation, negotiation, remediation and rehabilitation. The responsible officer will need to have an acute grasp of the management and interpretation of information gathered from the various reporting systems underpinning clinical governance. He or she will need to understand how to access the resources of the employing organisation to enable the implementation of decisions made about individual doctors.

- 4.38 The responsible officer will need to be able to demonstrate that he or she is trained and skilled in his or her role as a medical manager and leader. He or she must be able to demonstrate to the public, their colleagues and to their organisation that he or she has the competences, skills, knowledge and attitudes required to deliver this important role. In addition to qualifications, responsible officers must be able to demonstrate their on-going development and training, with annual appraisals and assessments of performance,
- 4.39 The responsible officer will need to demonstrate the ability to communicate outside the local organisation, with the public, GMC, medical Royal Colleges and Faculties.

Competences

- 4.40 There are also competences specific to the role of responsible officer, which are not appropriate to set out in the regulations. Instead they are set out in this guidance as competences that individuals must have before they can be nominated or appointed to the role of responsible officer.
- 4.41 These competencies are:
- communication skills;
 - mediation and arbitration skills;
 - evidence handling skills;
 - an understanding of the principles of investigation; and
 - an understanding of equality and diversity issues.
- 4.42 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 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.
- 4.43 A suitable range of skills, knowledge and behaviours is outlined in various competency frameworks for medical leaders. Across the broad competency domains of communication, managing and developing people, managing and developing the business (service), personal effectiveness, understanding the wider context of healthcare and improving quality, the responsible officer would be expected to function at the highest levels of competency.
- 4.44 The responsible officer will need to demonstrate his or her competence and the consistency of his or her decision-making, both within their organisation and in terms of supporting the decision-making of peer responsible officers. Regular assessments against an agreed set of standards should be undertaken to ensure that his or her decision-making is properly aligned with the regulations, with the GMC and with standards set by the

appropriate professional bodies. Peer review with other responsible officers should also be undertaken on a regular basis.

Education and support

- 4.45 Every responsible officer will need to undergo initial and on-going education, assessment and support. Initial educational interventions will vary in scale and scope. There are significant differences in terms of needs between those who have been in medical director positions in large complex organisations for many years, with a wide range of experience and a well-developed medical management infrastructure, as opposed to those who are taking on the role in an organisation with a developing medical management infrastructure and less experience of management or clinical governance.
- 4.46 For some, taking on the responsible officer role will mean adding on a new knowledge-base and a set of skills to already well-developed and honed medical management competences. For others it will mean a steep and rapid learning curve against a background of organisational change as the necessary structures and processes are put in place.
- 4.47 As a minimum, in addition to education and development in management and leadership required to the equivalent of the medical director, the responsible officer will need to develop an understanding of the following:
- the law underpinning medical regulation;
 - the process of medical revalidation as it is introduced;
 - natural justice and other legal processes and principles;
 - the processes underpinning, and resulting from, performance management of medical colleagues;
 - handling colleagues about whom there is concern, from investigation through to local remedy or referral to the GMC;
 - monitoring organisational systems of clinical governance, both in terms of the information output and the rigour of the systems themselves;
 - monitoring other associated information systems;
 - quality assurance and education of appraisers, the quality assurance of systems of appraisal and audit; and
 - structures of accountability, both within the organisation and externally.
- 4.48 Organisations should ensure that their responsible officer is facilitated to take part in peer networking and other forms of support and learning, including periodic formal assessment of their performance in the role as it feeds into their own appraisal.

Conflict and its resolution

- 4.49 Whilst for the most part doctors will relate to the responsible officer in a non-confrontational manner, there may be occasions when there is conflict between an individual doctor and the responsible officer. This could be as a result of the decisions a responsible officer has made about an individual practitioner, or it may be a long-running conflict on an unrelated matter. There may be underlying conflicts of interest, business arrangements or close friendships and relationships.
- 4.50 It is essential to ensure that there are checks and balances on the decision-making of the responsible officer so that where there is a conflict of interest that may sway the process, and thereby potentially cause harm to patients, that this is recognised, made explicit and that other arrangements are put in place. For example, if there is a conflict of interest, a responsible officer from another organisation may be sought to handle the evaluation of fitness to practise of the doctor concerned.
- 4.51 Every responsible officer must be a senior, licensed doctor and, as such, will be professionally accountable to the GMC for his or her ethics and decision-making. Influence by conflicts of interest represents a breach of the standards set out in '*Good Medical Practice*'.

Section 5. Guidance for Healthcare Organisations

The duty to nominate or appoint a responsible officer

- 5.1 The regulations require that designated bodies nominate or appoint a responsible officer. The bodies that are being designated can be considered as either organisations that provide healthcare or those that have a role in setting the policy or standards for healthcare.
- 5.2 Some organisations always employ or contract with doctors and have been designated unconditionally, others will only have to nominate or appoint a responsible officer when they employ or contract with doctors that have a connection with them (see page 12). Some bodies may find that they do not need to nominate or appoint a responsible officer because the doctors they employ have connections with other organisations, for example, an out of hours provider of healthcare whose doctors are all on a Performers List.
- 5.3 If there is any doubt about whether you are a designated body you should seek legal advice.
- 5.4 Unconditionally designated bodies include:
 - NHS Trusts and Foundation Trusts;
 - PCTs in England;
 - Local Health Boards in Wales;
 - Health Boards in Scotland;
 - Strategic Health Authorities in England; and
 - Special Health Boards in Scotland.
- 5.5 Bodies that only have to nominate or appoint a responsible officer if they employ or contract with licensed doctors include:
 - other providers of healthcare services;
 - government departments;
 - other government bodies;
 - Special Health Authorities;
 - Special Health Boards in Scotland;
 - The Common Services Agency in Scotland;
 - Independent healthcare services as defined in the Regulation of Care (Scotland) Act 2001;
 - Royal Colleges; and
 - The GMC.

- 5.6 In addition, the following organisations are also designated to provide responsible officer services to their members who are not linked to any other designated body:
- Independent Doctors Federation;
 - Faculty of Occupational Health;
 - Faculty of Pharmaceutical Medicine; and
 - Faculty of Public Health.
- 5.7 It will be an offence for a designated organisation to fail to nominate or appoint a responsible officer.

Resourcing responsible officers

- 5.8 The regulations require designated bodies to provide the responsible officer with sufficient funds to discharge their duties. In England this applies to all responsible officers' statutory functions, including the additional (clinical governance) responsibilities. In Wales and Scotland this applies only to the statutory functions relating to the evaluation of fitness to practise.
- 5.9 It is crucial that responsible officers are supported at the appropriate level in order for them to fulfil their role of improving the quality of care across all its dimensions, including patient safety. In the majority of organisations, the responsible officer will be employed by the same healthcare organisation as that which employs the doctors for whom he or she is responsible. The regulations require that the organisation provide the resources needed to carry out the statutory duties.

Alternative arrangements

- 5.10 If an organisation is designated to nominate or appoint a responsible officer, but thinks that it is not feasible to provide the function internally, the organisation may ask another designated body to provide the responsible officer function. The regulations require designated organisations to provide the responsible officer with funds and other resources to carry out their statutory duties.
- 5.11 Where organisations are making a charge for providing the responsible officer function to doctors they do not employ or contract with, these charges should be reasonable and related to the marginal costs of providing the service. If the additional work of providing the responsible officer function escalates, however, and consumes significant time, then marginal costs will not suffice. A portion of the full costs of the responsible officer and the establishment may also be charged.
- 5.12 There are particular resource issues involved with the provision of remediation, re-skilling and rehabilitation. In alignment with NCAS guidance

outlined in '*Back on Track*¹⁰, for doctors who are in a contractual relationship with an NHS healthcare organisation, the agreed remediation action plan should set out the relative contribution of each party towards the costs. For example in primary care the contribution of the PCT, the practice and the doctor. Where an organisation is providing its services to another organisation or to an individual doctor, it would be up to the organisations and/or the individual concerned to agree the best way of meeting these costs; for example by paying the costs directly to the supplier or for the provider to pay the supplier and then to claim the costs in full.

- 5.13 It is also essential that the organisation provides sufficient time for the responsible officer to perform their function effectively. The role is complex and demanding. It is likely to require a significant commitment, depending on the size of the organisation, the number of doctors its responsible officer is responsible for and the level of support for them. Organisations may have to strengthen and re-arrange medical management infrastructures to enable responsible officers to deliver their responsibilities.
- 5.14 The responsible officer is a senior role and should normally be nominated or appointed by means of a fair and open competition, with a rigorous process, involving external assessment of the individual's competences. Initially in England, and certainly in Scotland, we anticipate that organisations will want to nominate an existing senior doctor such as the Executive Medical Director.
- 5.15 Organisations will have to ensure that the responsible officer is 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. Although much of the role of the responsible officer is already undertaken by medical directors there will be a learning curve and employing organisations must ensure that they are as well supported and developed as possible.
- 5.16 The employing organisation has a responsibility to ensure that, on nomination or appointment to the responsible officer role, the responsible officer has the competences set out in paragraph 4.41. The competencies of the responsible officer against an agreed and transparent set of standards must be reviewed on a regular basis, as part of his or her appraisal process. The responsible officer's appraisal process could include review by another responsible officer from a similar organisation, or by a clinical or academic colleague, with any recommendation arising from the evaluation of fitness to practise being made by the responsible officer's responsible officer

¹⁰ Back on Track Restoring doctors and dentists to safe professional practice, NCAS, October 2006
<http://www.ncas.npsa.nhs.uk/aboutus/whatwedo/bot/>

- 5.17 The effectiveness of the responsible officer will necessitate timely access to the appropriate information. This means that the employing organisation will have to ensure that information systems underpinning the clinical elements of corporate governance and any other relevant processes (for example multi-source feedback) are properly resourced and functioning. Much of the data will already be held on systems of clinical governance and the task will be mainly one of collation. It is essential that the staff charged with the responsibility of inputting or collating sensitive data concerning individual clinician's performance are of high calibre, have credibility in the organisation, understand the absolute need for security of the information, are well trained and are regularly assessed. They will be expected to work very closely with both those collecting the data and those using it.
- 5.18 Information will also be required from other organisations and individuals. These include:
- other employers, immediately past and present;
 - all organisations in which the doctor works, including independent practice;
 - commissioners of services where appropriate; and
 - organisations and individuals who undertake appraisals of doctors.
- 5.19 The supporting information required will relate to concerns about the conduct or performance of individual doctors, and information from the individual's appraisals. Such information may include:
- information on the quality of the doctor's performance;
 - information tailored to the minimum standards required by the relevant Royal College for certification;
 - feedback/letters from patients or colleagues;
 - multi-source feedback;
 - participation in clinical audit;
 - training and CPD activity;
 - records of complaints about the doctor; and
 - the outcomes of such complaints.

The document and further information

- 5.20 This document sets out the background to the role of the responsible officer and describes the context of measures that are aimed at improving the quality of care for patients and the confidence the public has in doctors. It also explains how the legislation applies to different parts of the United Kingdom and how the system of responsible officer will work.
- 5.21 If you require further information relating to the context of this document it can be found at:

http://www.dh.gov.uk/en/Managingyourorganisation/Humanresourcesandtraining/Modernisingprofessionalregulation/DH_397

Alternatively you can contact:

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