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Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

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Confidence in Care

Draft Guidance on the Role of Responsible Officers

Closing the Gap in medical Regulation

4 December 2009

CONTENTS

1 INTRODUCTION

1.1 Purpose and Structure of this Document

This is guidance to which responsible officers and designated bodies must have regard under the Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010. It relates to the role of responsible officers to be nominated or appointed by those bodies designated under the Regulations. The guidance is also of relevance to doctors working outside designated bodies.

The guidance has been produced for consultation by the Department of Health, Social Services and Public Safety for Northern Ireland) (the Department) as part of the programme of reform to professional regulation, *Confidence in Care*. In developing the guidance, the Department has drawn on the expertise of those practitioners involved in the programme's workstreams on revalidation and tackling concerns.

This document is designed to provide guidance to 3 key audiences:

- all doctors licensed with the GMC to practise medicine;
- all doctors taking on roles as responsible officers; and
- all organisations designated as having to nominate or appoint a responsible officer in Northern Ireland.

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 aimed at improving the quality of care for patients and sustaining public confidence in doctors.

Section 2 sets out key points on how the system of responsible officers will work.

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.

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 how the role will support wider clinical and social care governance functions.

Section 5 is aimed at designated organisations. It sets out their responsibilities in the legislation.

Appendix 1 provides a response form for feedback on two particular issues on which views are sought in respect of this guidance.

1.2 Coverage of this Guidance

This guidance relates to the Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010. As well as having duties in relation to regulation, responsible officers will be required to undertake a range of duties supporting clinical and social care governance.

1.3 Background

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. It is acknowledged that the vast majority of doctors are competent and conscientious. However, after a series of high profile cases where the required professional standards were not met, 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 specialty 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.

The development of the responsible officer role is part of wide ranging regulatory reform set out in the White Paper *Trust, Assurance and Safety.*[1] In Northern Ireland, the reforms are being taken forward through the programme *Confidence in Care*. That programme values and celebrates the professionalism of the dedicated people who work in health and social care. 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 any concerns are dealt with fairly and effectively and, where appropriate, individuals are supported to get back on track.

In support of this the responsible officer role will:

[1] Trust, Assurance and Safety: The Regulation of Health Professionals in the 21st Century: TSO February 2007

- ensure that those doctors who provide care continue to be safe;
- ensure doctors are properly supported and managed in sustaining and continually 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 action to safeguard patients; and
- increase public and professional confidence in the regulation of doctors.

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 fitness to practice (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. It must also, where appropriate, be sufficient to evidence that the doctor's performance meets the specific standards set by the relevant Royal College or other appropriate body, for the purposes of recertification. The responsible officer, following the appropriate or necessary consultation with College representatives, will decide whether the necessary standards are met. If these are, a recommendation to renew the doctor's licence will ensue. If not the responsible officer may recommend deferral of the revalidation date or, where concerns are serious, refer the doctor to the GMC on fitness to practise grounds; and
- all designated healthcare organisations will be required to nominate or appoint, resource and support a responsible officer. This will be a senior licensed doctor, usually sitting on the Board of the organisation.

The public, the profession and the Health and Social Care sector (HSC) have a right to be assured that licensed doctors are fit to practise. The new regulations are designed to help doctors and the organisations in which they work further improve the quality of care provided to patients.

The roles 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 drawn on work across the UK, as part of the implementation of *Trust, Assurance and Safety,* together with local contributions from a wide range of clinicians, managers and patient groups who have been brought together to support The *Confidence in Care* programme .

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 will therefore bring forward proposals in relation to these doctors at a later date.

2 KEY POINTS

The following section sets out the key messages for all audiences:

2.1 The regulations identify designated organisations. 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.

2.2 Organisations should have only one responsible officer who carries overall accountability, although individual tasks can be delegated.

2.3 Doctors will have one and one only responsible officer at any point in time.

2.4 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 the General Practice Performers List they will relate to the responsible officer in the Health and Social Care Board.

2.5 Doctors should ensure that they know who their responsible officer is.

2.6 Responsible officers must be doctors who are licensed by the GMC.

2.7 As licensed medical practitioners, responsible officers must have a responsible officer.

3 GUIDANCE FOR ALL LICENSED DOCTORS

This section sets out the guidance that is applicable to all doctors with the implementation of the responsible officer role and describes the relationship between a medical practitioner and their responsible officer.

3.1 The Doctors Responsibility to a Responsible Officer

3.1.1 Following the introduction of the new regulations, a responsible officer will have a key role in support of the doctors they are linked to. The role of the responsible officer across the UK is to evaluate doctor's fitness to practise. They will do so based on the evidence that is presented to them, so will have to ensure that their organisation has the necessary systems in place to facilitate this.

3.1.2 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 Practice*[2] and the associated *Framework for Appraisal and Assessment*[3].
- 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.

3.1.3 Designated bodies will be expected to ensure that they have in place robust systems of clinical and social care governance to support the responsible officer in the role. These systems must be fit for purpose and quality assured. The data generated by these systems to support doctors' portfolios and 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. Data 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 by the GMC, and the Royal Colleges and Faculties where appropriate.

3.1.4 The GMC will require each doctor to inform, through the appraisal process, their responsible officer of all relevant practice they undertake. All relevant practice means all work undertaken by the individual in his or her role as a

[2] Good Medical Practice, General Medical Council, November 2006 http://www.gmc-uk.org/guidance/good medical practice/index.asp
[3] Framework for Appraisal and Assessment, General Medical Council, August 2008 http://www.gmc-uk.org/doctors/licensing/docs/explantory note.doc

doctor, both clinical practice and non-clinical roles such as public health, administration, management and leadership.

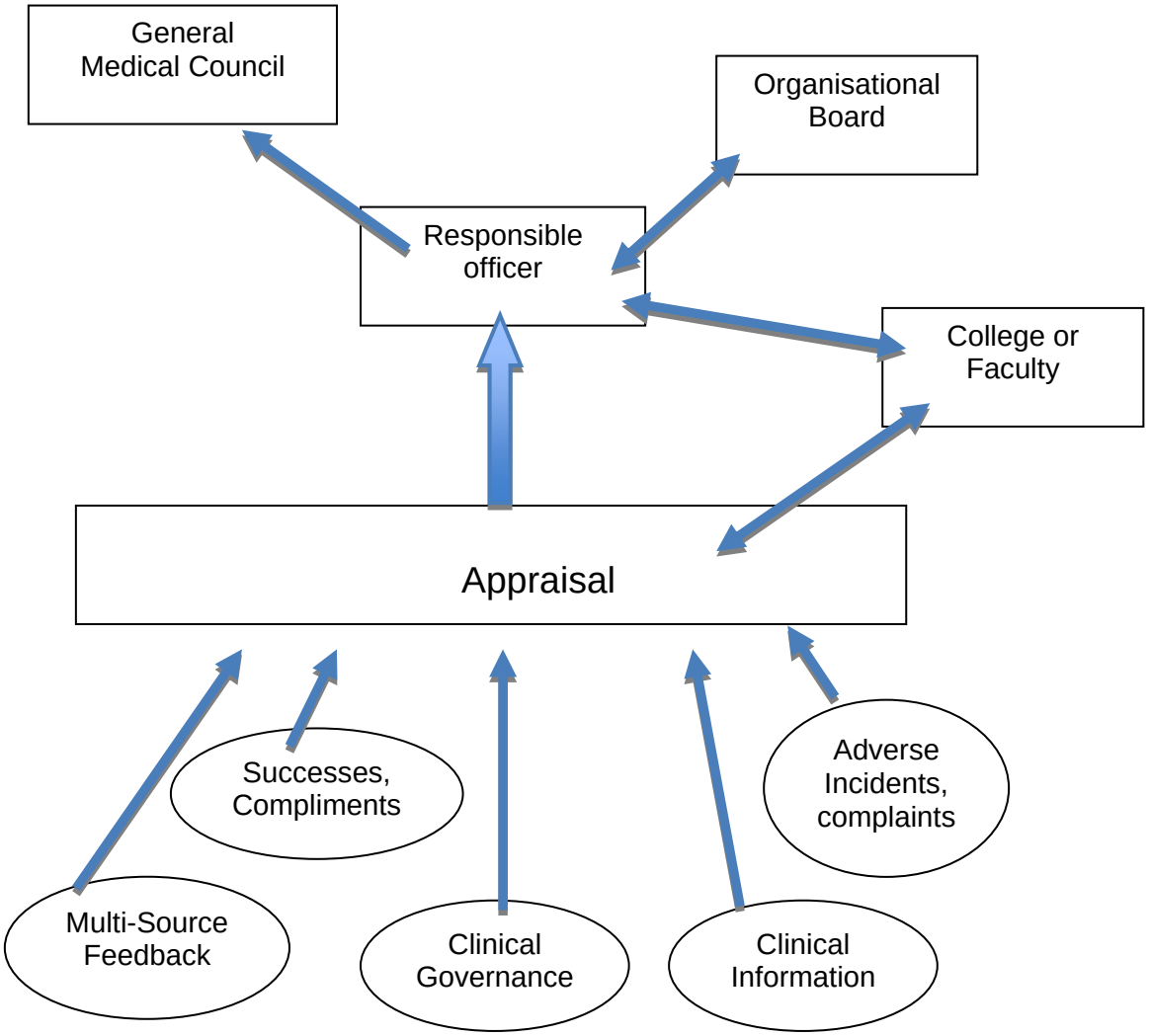
3.2 The Revalidation Process and the Responsible Officer

3.2.1 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 laid 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.

3.2.2 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 practise – see Figure 1.

Figure 1 – Appraisal System



3.2.3 Individual doctors will be responsible for maintaining a portfolio of supporting information to demonstrate maintenance of their clinical and professional standards and, where appropriate, specialist skills. This package of information also provides the basis on which responsible officers will assess fitness to practise.

3.2.4 The appraisal process will draw on 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. Appraisal will also draw on evidence confirming that the doctor

meets the standards set by his/her respective medical Royal College or Faculty.

3.2.5 The responsible officer will be accountable ultimately on behalf of the organisation for ensuring that the systems for appraisal, clinical governance and for gathering and retaining other local relevant information are in place and are effective. He/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.

3.2.6 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 or remediation are appropriate or whether it is serious enough to warrant a referral to the GMC on the grounds of fitness to practise. However, this latter scenario should be a rare event. As appraisal is an annual process within a five year revalidation cycle, it will provide useful punctuation marks to review progress towards revalidation, with opportunities to remediate any potential issues at an early stage.

3.2.7 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 evidence.

3.2.8 It is emphasised that where there is a justified cause for concern about a doctor's fitness to practise which cannot be concluded through local 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.

3.2.9 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 my affect their future licensed status.

3.3 Arrangements for Relating to a Responsible Officer

3.3.1 The 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/she spends the majority of his/her working week. The principle is that, where doctors work in a designated organisation, the organisation will have in place the appropriate systems of strengthened appraisal and clinical governance that will support the revalidation process when introduced. Doctors on the Primary Medical Services Performers List will relate to the responsible officer of the Health and Social Care Board. The arrangements are illustrated in Figure 2 on page 15. At a given point in time, doctors will relate to one responsible officer only. Each designated organisation will have only one Responsible Officer, though responsible officers may delegate support for their responsibilities to other appropriate individuals in their medical management structures i.e. Deputy Medical Director, Clinical Directors etc.

3.3.2 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:

- HSC Trusts
- Independent hospitals
- The Regional Health and Social Care Board
- The Regional Agency for Public Health and Social Well-Being

3.3.3 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:

- The Department of Health, Social Services and Public Safety
- The Health and Social Care Regulation and Quality Improvement Authority (RQIA)
- Northern Ireland Medical and Dental Training Agency (NIMDTA)

3.3.4 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 systems are designated. Currently these are:

- The Faculty of Occupational Medicine of the Royal College of Physicians of London
- The Independent Doctors' Federation
- Faculty of Pharmaceutical Medicine of the Royal College of Physicians of London;
- Faculty of Public Health of the Royal College of Physicians of London;

3.3.5 The arrangement for Doctors in HSC Trusts, the Blood Transfusion Service, the Regional Agency for Public Health and Social Well-Being and Independent Hospitals will be to relate to the Medical Director of the relevant organisation as their responsible officer.

3.3.6 General Practitioners will relate to the lead doctor in the HSC Board as their responsible officer. This may be the Assistant Director of General Medical Services or a doctor at director level within the organisation.

3.3.7 For Doctors in NIMDTA the postgraduate dean will act as the responsible officer for all those doctors fully employed by NIMDTA or employed for the majority of their time by NIMDTA.

3.3.8 For Doctors working in the RQIA, the Medical Director of RQIA will act as the responsible officer for all those doctors fully employed by RQIA or employed for the majority of their time by RQIA.

3.3.9 For Doctors Working in Government Departments across the Northern Ireland Civil Service (NICS) the Chief Medical Officer (CMO) will act as the responsible officer for all doctors employed for all or the majority of their time by Government Departments across the NICS.

3.3.10 Doctors in Training are already subject to detailed assessment and performance review processes to meet the requirements of postgraduate medical training overseen by NIMDTA. It is proposed that NIMDTA, through the postgraduate dean provide the responsible officer for doctors in training.

3.3.11 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 Northern Ireland, the individuals who will need to associate themselves with a responsible officer in another organisation are;

- Trust medical directors;
- The HSC Board's lead doctor;

- The Medical Director of the Regional Agency for Public Health and Social Well-Being ;
- The postgraduate dean;
- The Medical Director of RQIA; and
- The CMO.

The Medical Director of the Regional Agency for Public Health and Social Well-Being will act as the responsible officer for trust medical directors, the medical director of the Blood Transfusion Service, and the HSC Board's lead doctor.

The CMO will act as the responsible officer for The Medical Director of the Regional Agency for Public Health and Social Well-Being, the postgraduate dean and Medical Director of RQIA

The Permanent Secretary in the Department will nominate an appropriate responsible officer for the CMO from outside the Department.

3.3.12 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.

3.3.13 Locum doctors in primary care must be on the Performers List held by the Business Services Organisation (BSO). The view, across the UK is that, a doctor on a Performers List should have a responsible officer in the primary care organisation (in this case the HSC Board) responsible for that list. Therefore, locum doctors in primary care will relate to the Assistant Director of General Medical Services, in the HSC Board, as their responsible officer.

3.3.14 Locum doctors in Secondary Care could relate to the responsible officer in the organisation where they deliver the greatest percentage of their clinical work. Alternatively, responsible officer responsibilities could fall directly to those locum agencies who can demonstrate robust clinical and social care governance systems. **Views are sought via this consultation in respect of which of the above provides the most suitable option for a responsible officer for locum doctors in secondary care.**

3.3.15 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. Examples 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 will work with the GMC to bring forward proposals in relation to these doctors at a later date.

3.4 Conflict of Interest

3.4.1 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. Conflicts of interest may include a business, family or other personal relationship.

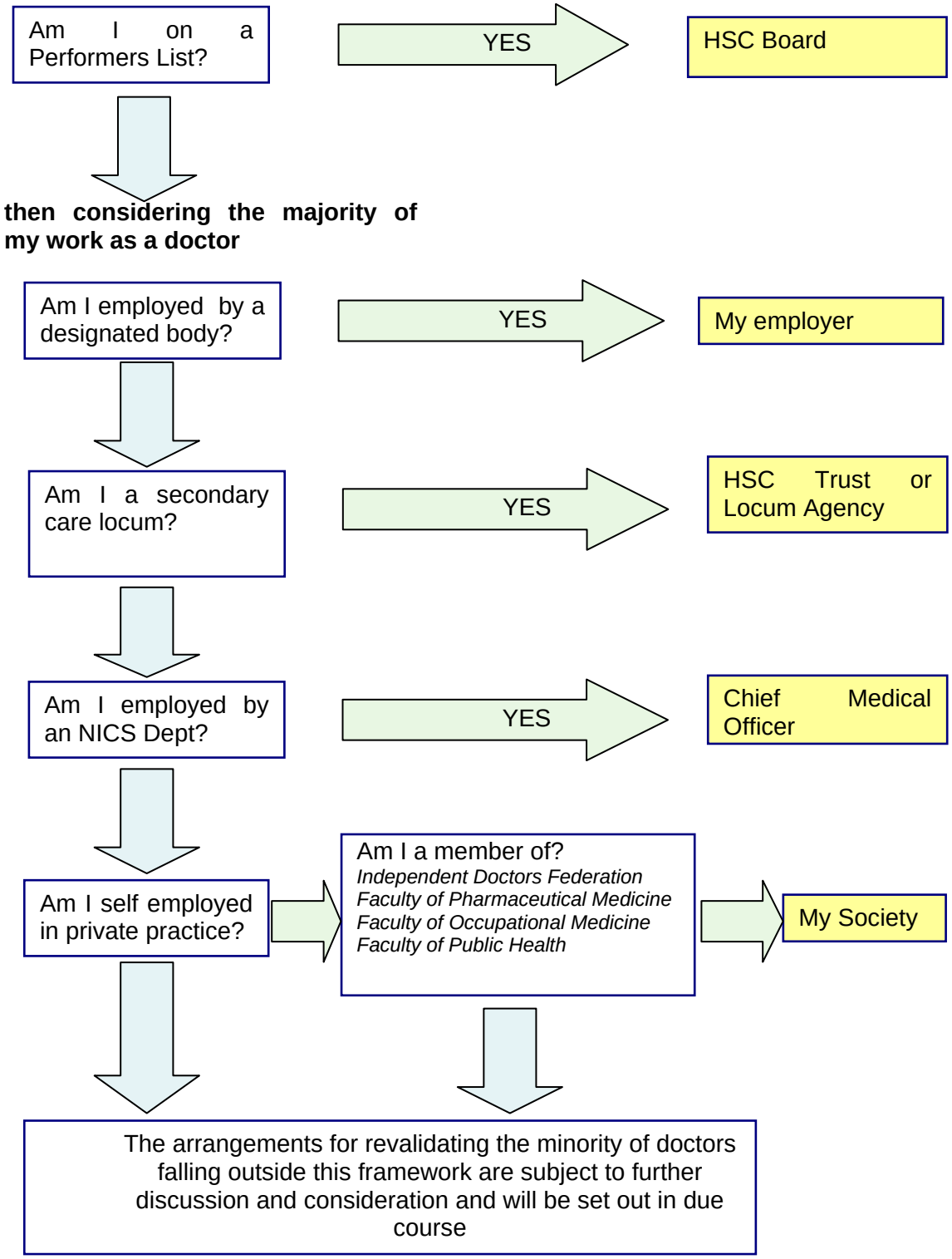
3.4.2 If a conflict of interest is identified between appraisee and appraiser, the responsible officer should be informed in writing, explaining the conflict and providing as much background information as is necessary and relevant. It may also be appropriate to request another appraiser is assigned. The responsible officer will consider the claimed conflict and may assign another appraiser.

3.4.3 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 any 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.

3.4.4 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.

3.5 How to Find Your Responsible Officer

Figure 2 illustrates how individual doctors can find out who their responsible officer is.



4. GUIDANCE FOR RESPONSIBLE OFFICERS

This section, sets out guidance for responsible officers as it relates to their role in evaluating the fitness to practise of doctors, and provides guidance on the additional responsibilities of responsible officers which relate to clinical and social care governance. The section also provides guidance on who should be a responsible officer.

4.1 Roles and Responsibilities of the Responsible Officer

4.1.1 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.

4.1.2 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 as well as systems to identify poor or deteriorating clinical performance and/or conduct 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.

4.1.3 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.

4.1.4 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).

4.1.5 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 required, between their organisation and the relevant Medical Royal Colleges and Faculties to seek their input to the appraisal process, in terms of specialist practice.

4.1.6 The responsible officer has a statutory duty to co-operate with the GMC. Pending the outcome of a pilot project currently underway in England, 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.

4.1.7 Responsible officers in Northern Ireland have a duty to ensure the robust, efficient and reliable functioning of systems of clinical and social care governance. Clinical and social care governance has been defined[4] as "*a framework through which (HSC) organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care.*" This definition reinforces the concept that, for the great majority of doctors, the focus of clinical and social care 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.

4.1.8 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*[5]. The function of appraisal, therefore, remains predominantly formative but concurrently supports them in providing the evidence of the fitness to practise required for revalidation.

4.1.9 As part of 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:

[4] *Best Practice, Best Care: a framework for setting standards, delivering services and improving monitoring and regulation in the HPSS;* DHSSPS (April 2001)

[5] 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

- contracts of employment or for provision of services (admission to the Primary Medical Services Performers' List, 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.

4.1.10 The responsible officer duties in monitoring clinical performance and addressing concerns when they arise will also involve him/her in providing professional leadership and promoting a culture that celebrates and spreads 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 and social care governance is dependent upon culture and attitudes. The responsible officer has a major role to play in creating and maintaining the appropriate culture to support good clinical and social care governance.

4.1.11 Responsible officers have responsibilities relating to the monitoring of conduct and performance of doctors who give rise to concern, but do not require referral to the GMC. 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.

4.1.12 Identifying a concern is merely the start of a process to safeguard patients. The responsible officer's responsibilities relate to the local systems which support local decision-making. For HSC Trusts in Northern Ireland this process is currently described in *Maintaining High Professional Standards in the Modern HPSS*[6]. It is crucially important that appropriate action is taken promptly. 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);

[6] Maintaining high professional standards in the Modern HPSS, a framework for handling of concerns about doctors and dentists in the HPSS, DHSSPS, November 2005 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4072773

- 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 practice;

4.1.13 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.

4.1.14 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 outside 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 – Medicines and Healthcare products Regulatory Authority (MHRA) and the manufacturers, in addition to the immediate primary action needed to prevent harm to patients.

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. 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 is not likely to make the decision to refer a doctor to the GMC in isolation; he/she must ensure that local performance 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). The responsible officer will also be expected to liaise with the appropriate Medical Royal College or Faculty, where appropriate.

4.1.15 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 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.

4.1.16 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.

4.1.17 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.

4.2 The Organisation and Individuals have regard to Guidance

4.2.1 In terms of their responsibilities relating to clinical and social care governance, responsible officers should have regard to guidance issued by specific organisations. These organisations include the Department, the GMC and the NCAS.

4.2.2 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 National Institute of Clinical Excellence (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.

4.2.3 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. Doctors carrying out procedures that are new, or for which they have no experience, have to gain approval through appropriate organisational research governance frameworks.

4.3 Relationships and accountabilities of the responsible officer across the UK

4.3.1 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.

Pending the outcome of a pilot project currently underway in England, this will usually be through a regionally based GMC affiliate.

4.3.2 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. In the case of independent practitioners there may be a need for the responsible officer to relate to a number of organisations which provide these functions.

4.3.3 The responsible officer will also have a crucial set of relationships with the clinical leads of the various service lines of the organisation. This will be with clinical directors, clinical leads or service line leads in secondary care and 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.

4.3.4 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.

4.4 Who should be the Responsible Officer?

4.4.1 It is a basic requirement that a responsible officer must be a licensed doctor.

4.4.2 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.

4.4.3 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 those who will absorb the role of responsible officer (e.g. Trust Medical Directors). 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

4.4.4 The responsible officer will be responsible to the Board/highest level of organisational management 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 responsibility for clinical governance across the organisation may be jointly held with another board member, for example the Executive Nurse Director.

4.4.5 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/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/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 and social care governance and its crucial role in safeguarding quality of clinical care in the NHS.

4.4.6 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/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 and social care governance. He/she will need to understand how to access the resources of the employing organisation to enable the implementation of decisions made about individual doctors.

4.4.7 The responsible officer will need to be able to demonstrate that he/she is trained and skilled in his/her role as a medical manager and leader. He/she must be able to demonstrate to the public, their colleagues and to their organisation that he/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.

4.4.8 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

4.4.9 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.

4.4.10 These competences 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.

4.4.11 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.

4.4.12 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.

4.4.13 The responsible officer will need to demonstrate his/her competence and the consistency of his/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/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

4.4.14 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 and social care governance.

4.4.15 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.

4.4.16 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.

4.4.17 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

4.4.18 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.

4.4.19 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.

4.4.20 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'*.

5. GUIDANCE FOR HEALTHCARE ORGANISATIONS

5.1 The Duty to Nominate or Appoint a Responsible Officer

5.1.1 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.

5.1.2 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. 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 the Performers List.

5.1.3 If there is any doubt about whether you are a designated body you should seek legal advice.

5.1.4 Unconditionally designated bodies include:

- HSC Trusts;
- The Regional Health and Social Care Board;
- The Regional Agency for Public Health and Social Well-Being;
- The Department of Health, Social Services and public Safety;
- Independent Hospitals;
- The Northern Ireland Medical and Dental Training Agency;
- The Regulation and Quality Improvement Authority.

5.1.5 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; and
- other government bodies.

5.1.6 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:

- The Independent Doctors Federation;
- The Faculty of Occupational Health of the Royal College of Physicians of London;
- The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of London; and
- The Faculty of Public Health Medicine of the Royal College of Physicians of London.

5.1.7 It will be an offence for a designated organisation to fail to nominate or appoint a responsible officer.

5.2 Resourcing Responsible Officers

5.2.1 The regulations require designated bodies to provide the responsible officer with sufficient resources to discharge their duties.

5.2.2 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/she is responsible. The regulations require that the organisation provide the resources needed to carry out the statutory duties.

5.3 Alternative Arrangements

5.3.1 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.

5.3.2 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.

5.3.3 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.

5.3.4 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 it is anticipated that organisations will want to nominate an existing senior doctor such as the medical director.

5.3.5 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.

5.3.6 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 4.4.10. The competences of the responsible officer against an agreed and transparent set of standards must be reviewed on a regular basis, as part of his/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.

5.3.7 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 and social care 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.

5.3.8 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.

5.3.9 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.

Appendix 1 – Guidance Consultation Response Questionnaire

1. Locum Doctors in Secondary Care

Section 3.3.14 outlines the two potential models for a responsible officer for locum doctors in secondary care. These are:

Locum doctors in Secondary Care relate to the responsible officer in the organisation where they deliver the greatest percentage of their clinical work.

OR

Locum agencies provide a responsible officer for all doctors registered with them. Only those locum agencies that can demonstrate robust clinical and social care governance systems will be designated to provide a responsible officer.

Question 1
Which of the above options for a responsible officer for locum doctors in secondary care presents the most effective solution?

Response to Question 1

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2. Coverage of Guidance

Question 2
Does the guidance cover all the relevant aspects of the responsible officer role or are there any areas on which guidance is outstanding?

Response to Question 2

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Responses in writing should be sent to:

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