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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

Confidence in Care

Guidance on the Role of Responsible Officers for Doctors and Employers

February 2011

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PURPOSE AND STRUCTURE OF THIS DOCUMENT

1. This is guidance to which responsible officers and designated bodies must have regard to 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.
2. The guidance has been produced by the Department of Health, Social Services and Public Safety for Northern Ireland) (the Department) as part of the programme of reform (*Confidence in Care*) to professional regulation. 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. Comments were also sought on the guidance during the legislative consultation process.
3. This document is designed to provide guidance to 3 key audiences:
 - all doctors licensed with the GMC to practise medicine;
 - all doctors taking on the role of responsible officer; and
 - all organisations designated as having to nominate or appoint a responsible officer in Northern Ireland.
4. Section 1 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. It also defines the key areas of the responsible officer role.
5. Section 2 provides guidance for licensed doctors on how they relate to, and can identify, their responsible officer.
6. Section 3 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 their wider role under the Health and Social Care Act 2008.
7. Section 4 is aimed at designated organisations and defines their responsibilities in the legislation.

Coverage of this Guidance

8. 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.

Review of this Guidance

9. It is acknowledged that the role of the responsible officer will evolve as experience of the role is gained and shared. With this in mind the guidance will need to evolve to reflect developments and will be reviewed in light of operational experience.

SECTION 1 BACKGROUND AND KEY POINTS

Background

10. 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.
11. 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.
12. The purpose of revalidation, when it is introduced, will be to assure patients and the public, employers and other healthcare professionals that licensed doctors are up to date and are practising to the standards defined by *Good Medical Practice*¹.
13. The development of the responsible officer role is part of wide ranging regulatory reform set out in the White Paper *Trust, Assurance and Safety*.² In Northern Ireland, these reforms are being taken forward through the programme *Confidence in Care*. This programme values and celebrates the professionalism of the doctors who work in health and social care. In addition, it seeks to raise the already high standards of the overwhelming majority of doctors whilst ensuring that the small number of staff who are not meeting those standards are swiftly identified and any concerns are dealt with fairly and effectively.
14. 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 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.

¹ Good Medical Practice Framework for Assessment and Appraisal (GMP)

² Trust, Assurance and Safety: The Regulation of Health Professionals in the 21st Century: TSO February 2007

Revalidation

15. The responsible officer will play a crucial role in the process of medical revalidation when it is introduced. This new process, and the role of the responsible officer, has major implications for every doctor and healthcare organisation. The 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 for revalidation will be based on the outcome of a doctor's annual appraisals over a number of years, combined with supporting information drawn from the organisation or organisations in which the doctor has worked;
 - this supporting information must provide robust, accurate evidence about all aspects of the doctor's practice, including that resulting from any investigations already completed. It should be scrutinised through the clinical arm of corporate governance and be sufficient evidence that the doctor's performance meets the standards of *Good Medical Practice*
16. 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.
17. 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 Regulations are designed to help doctors and the organisations in which they work further improve the quality of care provided to patients.
18. 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 the outcomes of work undertaken 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 .
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.
20. The arrangements for revalidation for the small minority of doctors falling outside this framework are subject to further discussion with stakeholders,

and possibly piloting. The GMC, in partnership with all UK Health Departments and Medical Royal Colleges, are developing policy in relation to this group of doctors. When agreed, further guidance on the policy will be issued by the Department.

KEY POINTS

21. The following points provide the key messages in relation to responsible officers for all audiences.
22. A licensed doctor should normally relate to the responsible officer of the healthcare organisation most relevant to their principle area of practice.
23. The Regulations list designated bodies. All such organisations must nominate or appoint a responsible officer. The designated bodies are identified in the Regulations but they can broadly be summarised as:
 - Organisations that provide healthcare;
 - Organisations that set standards and policy for the delivery of healthcare;
 - Some specialist organisations.
24. These organisations should have only one responsible officer who carries overall accountability although individual tasks can be delegated.
25. A licensed doctor will have one, and only one, responsible officer at any point in time.
26. As a rule of thumb, a doctor will relate to the responsible officer in the organisation where they undertake the majority of their clinical work.
27. Doctors should ensure that they know who their responsible officer is.
28. Responsible officers must be doctors who are registered with the GMC and have a licence to practise medicine.
29. As licensed medical practitioners, responsible officers must relate to a responsible officer.

SECTION 2: GUIDANCE FOR ALL LICENSED DOCTORS

This section sets out the guidance that is applicable to all doctors in relation to the implementation of the responsible officer role and describes the relationship between a medical practitioner and 'his' or 'her' responsible officer.

A Doctors responsibility to a Responsible Officer

29. With the introduction of the new Regulations, a responsible officer will have a key role in supporting the doctors who are linked to the designated organisation to which they have been appointed. 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. To support doctors in compiling the necessary evidence, responsible officers will ensure that their organisation has the appropriate systems in place.

30. 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⁽³⁾
- Expectations of their managed healthcare organisation in safely undertaking the clinical role for which they are employed or contracted.

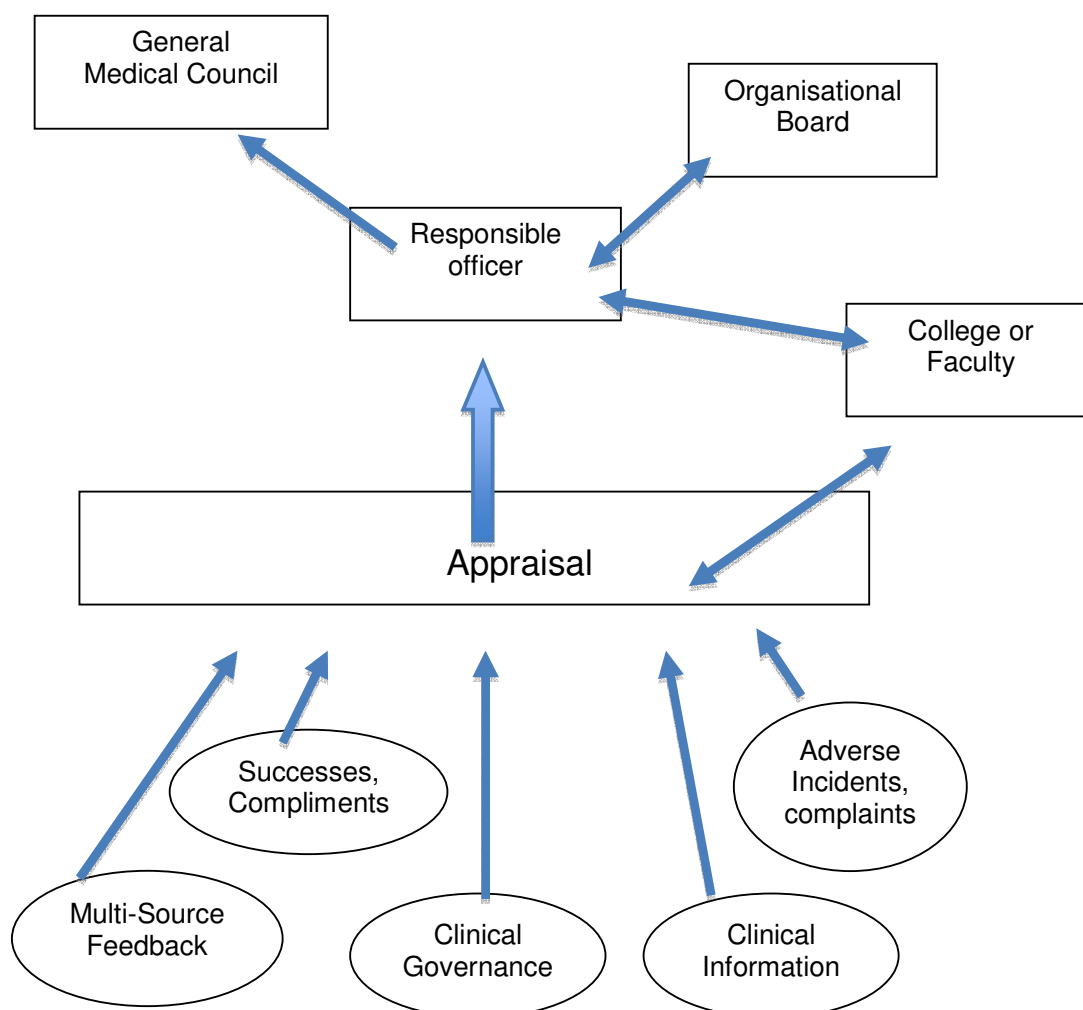
31. These systems must be fit for purpose and quality assured; the data generated by these systems will continue to be used to support doctors' portfolios, inform appraisal and will be the basis on which a recommendation on revalidation is made to the GMC. Therefore, this information must be properly assured, appropriately validated and reviewed where appropriate. It should also be accurate, timely, relevant to the full span of the individual's clinical practice and meet the standards set by the GMC.

³ Good Medical Practice, General Medical Council, November 2006
http://www.gmc-uk.org/guidance/good_medical_practice/index.asp

Appraisal

32. 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.
33. The core mechanism underpinning revalidation will be a strengthened appraisal system, which is being designed to elicit the necessary information about a doctor's practice – see Figure 1.

Figure 1 – Appraisal System



34. Individual doctors will be expected to fully engage in the appraisal process and will be responsible for maintaining a portfolio of supporting information to demonstrate maintenance of their clinical and professional standards. .
35. The GMC have consulted on their proposals to 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 doctor, both clinical practice and non-clinical roles such as public health, administration, management and leadership.
36. Failure to do so may become a fitness to practise issue and may affect their future licensed status.
37. Supporting information for revalidation will be largely the same as the information doctors currently bring to their annual appraisal. It will include outcomes from patient and colleague feedback (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. This range of supporting information should confirm the doctor is practising to the standards defined in the GMP framework and should include information required by the doctor's Medical Royal College where applicable and available.
38. 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.
39. Information from the outcomes of appraisal and the above organisational systems will be required by the responsible officer.
40. The responsible officer, having assessed all the information and, if necessary, 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, with concerns related to the small number of doctors with performance or conduct issues having been identified and addressed as they arise through existing processes.
41. Appraisal is an annual process within a five year revalidation cycle, and, as such, it will provide useful points at which a doctor's progress towards revalidation can be reviewed, and identify any gaps identified in evidencing that a doctor is meeting the requirements of Good Medical Practice.

Concerns about a doctor's Performance

42. When a concern is raised about a doctor's performance, the responsible officer will 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.
43. 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.
44. 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.**

Arrangements for Relating to a Responsible Officer

45. The arrangements are illustrated in Figure 2, Page 15. Doctors will relate to one responsible officer only. Each designated organisation will normally have only one responsible officer.
46. Doctors in postgraduate training will hold licenses to practise. Doctors in training are already subject to detailed assessment and performance review processes to meet the requirements of postgraduate medical training overseen by Northern Ireland Medical and Dental Training Agency (NIMDTA). NIMDTA will provide the responsible officer for doctors in training. Clearly both employers and NIMDTA have information that will be pertinent to confirming the fitness to practise of doctors in training. The effective flow of information between employer and the postgraduate dean will therefore be important to ensure a fair and robust process of revalidation, when introduced.
47. General Practitioners will relate to the Responsible Officer in the HSC Board. Where a doctor is also on a Performers List in another UK country, the doctor will relate to the Responsible Officer of the organisation where most of their work is carried out.
48. Doctors in HSC Trusts, the Blood Transfusion Service and the Regional Agency for Public Health and Social Well-Being will relate to the Responsible Officer of the employing organisation.

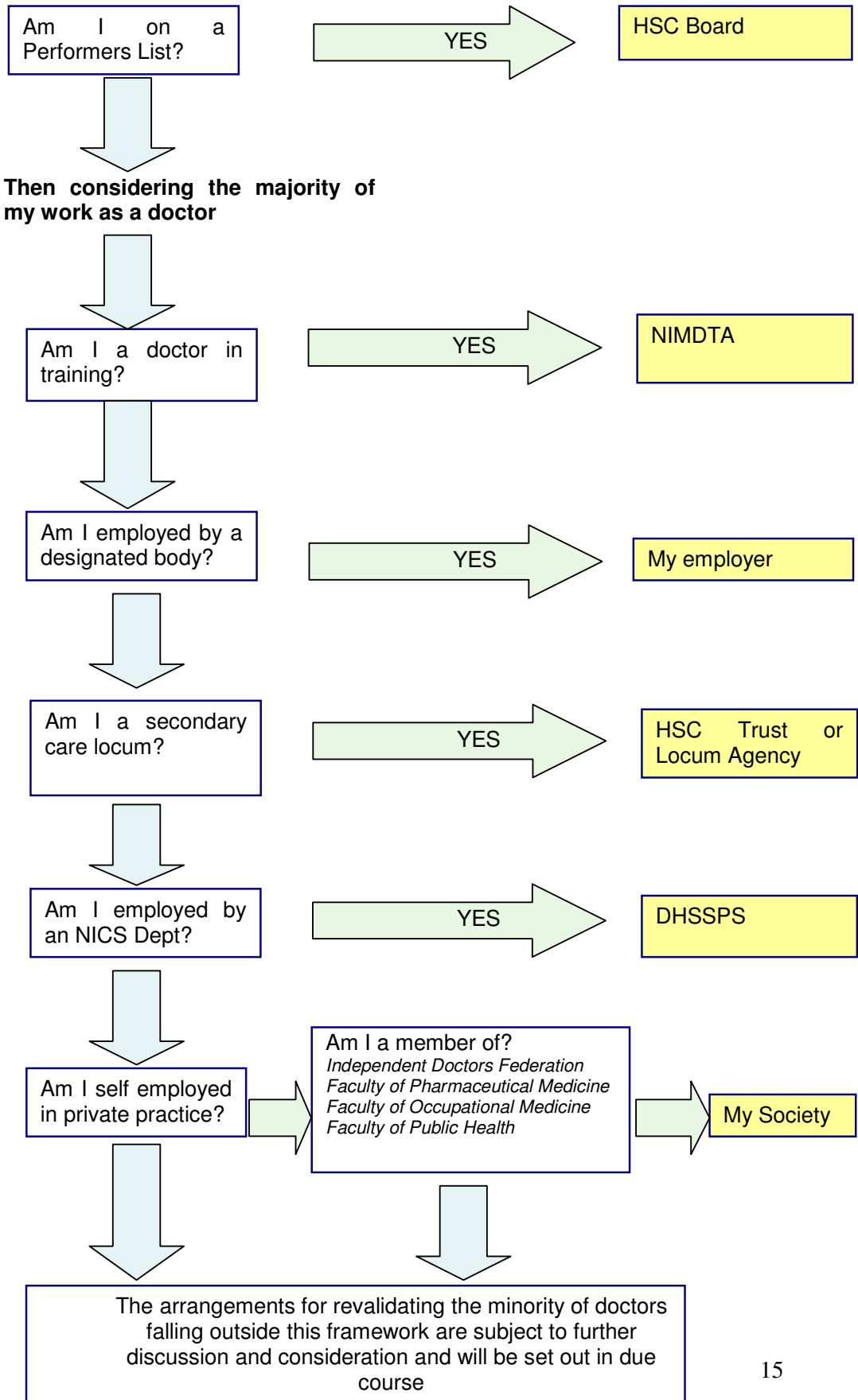
49. NIMDTA will also provide the Responsible Officer for all doctors employed by NIMDTA or employed for the majority of their time in NIMDTA. Similarly, RQIA (The Regulation & Quality Improvement Authority) will provide the Responsible Officer for all those doctors fully employed by RQIA or employed for the majority of their time by RQIA.
50. The Department of Health, Social Services and Public Safety (DHSSPS) will provide the Responsible Officer for all doctors employed for all or the majority of their time by Government Departments across the Northern Ireland Civil Service (NICS).
51. 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. If there is no significant difference between the amount of work a doctor carries out for each designated body, then the doctor relates to the responsible officer of the organisation nearest to the doctor's registered address.
52. Responsible officers, as licensed doctors will also be required to have their fitness to practise confirmed and go through the revalidation process. As senior doctors in their organisations they will use the same systems as the doctors for whom they are responsible. They will have a responsible officer, outside their own organisation, who will ensure they are supported in the same way as those for whom they are responsible (regulation 10). 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). For some doctors this will be the same speciality.
53. The Regional Agency for Public Health and Social Well-Being will provide the Responsible Officer for Responsible Offices of HSC Trusts, the Blood Transfusion Service, and the HSC Board.
54. The Department will provide the Responsible Officer for the Responsible Officers of the Regional Agency for Public Health and Social Well-Being, NIMTDA and RQIA.
55. The Permanent Secretary in the Department will nominate an appropriate responsible officer for the CMO from outside the Department.
56. For all other responsible officers, who cannot link to a responsible officer as set out in paragraphs 52-55, the Responsible Officer of RQIA will act as the Responsible Officer.
57. 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.

58. Locum doctors in primary care must be on the Performers List held by the HSC Board. The view across the UK is that a doctor on a Performers List should have a Responsible Officer in the primary care organisation responsible for that list. Therefore, locum doctors in primary care will relate to the Responsible Officer in the HSC Board.
59. Many locum doctors who provide services in secondary care are also employed by a designated organisation and will relate to the responsible officer of that designated organisation. Similarly, many Northern Ireland based doctors in training also act as locum doctors in secondary care but will relate to the Responsible Officer in NIMDTA.
60. There will remain a small number of doctors who practise exclusively in a locum capacity within the secondary care sector. They have a number of options in relating to a responsible officer. They may;
- link to a responsible officer in one of the organisations listed at paragraph 50
 - by virtue of the extent of work they perform for a single Trust, link to that Trust's Responsible Officer; or
 - by virtue of registration with a locum agency on the Office of Government Commerce Buying Solutions framework agreement ⁽⁴⁾, link to that agency's Responsible Officer.
61. It is recognised however that these arrangements may not facilitate this entire group of doctors in linking with a responsible officer. This will be the subject of further guidance.
62. 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. We recognise however 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.

⁴ Contract reference number CM/AMN/07/4820; period of contract 1 July 2008 to 30 June 2011; responsibility for this agreement transferred from the NHS Purchasing and Supply Agency to Buying Solutions, an executive agency of the Office of Government Commerce, in October 2009. The agreement can be viewed at the following web site: <http://www.buyingsolutions.gov.uk/healthcms/Productsandservices/Agencystaffandoutsourcedservices/temporarystaff/Medicallocums/>.

How to Find Your Responsible Officer

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



SECTION 3: GUIDANCE FOR THE RESPONSIBLE OFFICER

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.

Roles and Responsibilities of the Responsible Officer

63. 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.

64. 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.

65. 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, at an early stage, poor or deteriorating clinical performance and/or conduct. 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.

66. 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.

67. The responsible officer has to ensure that the organisation is advised 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).

68. Medical Royal Colleges and Faculties may offer support to responsible officers if required to assist them to evaluate the specialist practice of doctors. The responsible officer may wish to avail of this resource, when required, to seek their input to the appraisal process, in terms of specialist practice.
69. The responsible officer has a statutory duty to co-operate with the GMC. The responsible officer will liaise with the GMC on matters connected with fitness to practise issues. In Northern Ireland it is likely that this liaison will build from the current arrangements where contact is made through the local GMC office.

Clinical and Social Care Governance

70. Responsible officers in Northern Ireland have a duty to ensure that the system of clinical and social care governance in their organisation is capable of supporting doctors in meeting the requirements of revalidation. Clinical and social care governance is defined ⁽⁵⁾ 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.
71. 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⁾. The function of appraisal, therefore, remains supportive and developmental but concurrently supports them in providing the evidence of the fitness to practise required for revalidation.
72. 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:
 - contracts of employment or for provision of services (admission to the Primary Medical Services Performers’ List, for example)

⁵ *Best Practice, Best Care: a framework for setting standards, delivering services and improving monitoring and regulation in the HPSS*; DHSSPS (April 2001)

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

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.

73. 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.

Revalidation of Doctors

74. In its consultation document, *The Way Ahead*, The GMC sets out instances where a responsible officer may not be able to make a recommendation that the doctor is fit to practise. These are;

- a. Where a doctor has not been in active practice and has clearly not engaged with any appraisal process or with his or her Responsible Officer. In these circumstances, there will be little or no evidence on which a Responsible Officer could make a positive recommendation that a doctor is up to date and fit to practise. In these circumstances the doctor will need to take an alternative route for revalidation or can expect to have his or her licence to practise withdrawn.
- b. If there are gaps in the evidence provided by the doctor, the GMC, based on the recommendation of the Responsible Officer, may decide to defer revalidation to enable the doctor to collect the necessary information. In the absence of negative information indicating that the doctor's fitness to practise is impaired, there would be insufficient grounds for referring the case to the GMC's fitness to practise procedures, but, equally, it would not be appropriate to renew the doctor's licence where there were significant gaps in the evidence required to show that the doctor was competent and fit to practise.
- c. Where there are concerns about a doctor's practice these should be identified as early as possible and, addressed through local processes in the first instance as set out in the next paragraph.

Conduct and Performance of Doctors

75. Responsible officers have responsibilities relating to the monitoring of conduct and performance of doctors who give rise to concern. Identifying a concern is merely the start of a process to safeguard patients. The responsible officer's responsibilities relate to the organisational 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*⁷. Analogous guidance for the primary care sector is *Investigating Performance Concerns*⁸. 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);
- 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;

76. 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.

77. 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.

⁷ http://www.dhsspsni.gov.uk/hrd_suspensions_framework.pdf

⁸ INVESTIGATING PERFORMANCE CONCERNS: Primary Medical Services February 2009

http://www.dhsspsni.gov.uk/investigating_performance_concerns_guidance.pdf

Referral to the General Medical Council

78. 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.
79. 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).
80. 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.
81. 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 doctor's 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.
82. 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.

Guidance from other sources

83. In addition to this guidance, responsible officers have a duty to have regard to guidance issued by specific organisations. These organisations include the Department, the GMC and the NCAS.

84. The responsible officer should ensure that clinicians delivering the service do so on the basis of the best evidence available on the effectiveness of interventions. This means having regard to 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 practise 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.
85. 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.

Relationships and accountabilities of the responsible officer across the UK

86. 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.
87. 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.
88. 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.
89. 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?

90. It is a basic requirement that a responsible officer must be a licensed doctor.
91. 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.
92. 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

93. The responsible officer will be responsible to the Board/highest level of organisational management for assuring clinical performance in respect of doctors and, as a senior doctor, will also provide leadership to the medical workforce. As set out earlier, the discharge of this role will rely heavily on adequate clinical and social care governance systems across the organisation which may be the responsibility of another board member, for example the Executive Nurse Director.
94. The responsible officer must have practical experience as a senior doctor and have a licence to practise.
95. 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 HSC.
96. 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.

97. 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. In addition to data management, a sound knowledge of the principles of data protection are essential. 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.
98. 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.
99. The responsible officer will need to demonstrate the ability to communicate beyond the local organisation, with the public, GMC, medical Royal Colleges and Faculties.

Competences

100. 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.
101. 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.
102. 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.
103. 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.

104. 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

105. 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.

106. 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.

107. 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.

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

108. 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 may find there is a conflict of interest or appearance of bias with their appraiser or responsible officer. The following are examples of where a conflict of interest or appearance of bias may occur:

Personal relationships:

- where there is or has been a personal relationship (marriage, partnership etc) between a responsible officer and a doctor or where the two are related in any other way;
- where there is a financial or business relationship between a responsible officer and a doctor;
- instances where a third party is involved e.g. an affair or marriage breakdown;
- where there is a known and long-standing personal animosity between a responsible officer and a doctor.

Managerial or organisational roles

The different roles of managers and clinicians might create a situation where a conflict of interest or appearance of bias might need further consideration:

- a clinical director might be called on to comment on the clinical practice of their own responsible officer; or
- a responsible officer who is appraised by a medical chief executive might then have to make a fitness to practise recommendation in respect of the chief executive.

109. If a conflict of interest or appearance of bias 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 be appropriate for the responsible officer to request that another appraiser is assigned. The responsible officer will not themselves assign the new appraiser. It will be the responsibility of the appropriate clinical director or appraisal lead to assign a new appraiser in such cases.

110. If a conflict of interest or appearance of bias exists between a doctor and a responsible officer, the designated body should be informed in writing 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. In such circumstances, the designated body

should seek advice from the responsible officer's own responsible officer and the decision should be recorded in writing.

111. 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.
112. 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, this is recognised, made explicit and other arrangements 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.
113. 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 4: GUIDANCE FOR HEALTHCARE ORGANISATIONS

This section is aimed at designated bodies or organisations and defines their responsibilities in the Regulations.

The Duty to Nominate or Appoint a Responsible Officer

114. The Regulations require that designated bodies nominate or appoint a responsible officer. The designated bodies are either organisations providing healthcare or those with a role in setting the policy or standards for healthcare.
115. Some bodies always employ or contract with doctors and have been designated unconditionally while others will only have to nominate or appoint a responsible officer when they employ or contract with doctors. Some of the latter 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.
116. If there is any doubt about whether you are a designated body you should seek legal advice.
117. 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;
 - The Northern Ireland Medical and Dental Training Agency.
118. Bodies that have to nominate or appoint a responsible officer only if they employ or contract with licensed doctors, as listed in Part 2 of Schedule 1 to the Regulations, include other providers of healthcare services and other government bodies.
119. In addition, the following organisations are also designated to provide responsible officer services to their members if they 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.

Resourcing Responsible Officers

120. The Regulations require designated bodies to provide the responsible officer with sufficient resources to discharge their duties.
121. 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.

Alternative Arrangements

122. If an organisation is designated to nominate or appoint a responsible officer, but considers 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.
123. Where organisations are making a charge for providing the responsible officer function to doctors with whom they do not contract, nor employ, 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.
124. It is also essential that the organisation provides sufficient time for the responsible officer to perform his or her 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.
125. 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 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 who by virtue of that position will meet the above conditions.

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. There will

undoubtedly be a learning curve and employing organisations must ensure that the Responsible Officer is as well supported and developed as possible. However since much of the role of the responsible officer is already undertaken by medical directors, the foundation for this support should on the whole come from existing procedures and systems.

126. 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.

127. 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 clinicians 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.

128. 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.

129. 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.