Paper I

To:	**Trust Board**
From:	Medical Director
Date:	**4 August 2011**
CQC regulation:	As applicable

Title:	**MEDICAL REVALIDATION**

Author/Responsible Director: Medical Director

Purpose of the Report: To describe the process for strengthened appraisal and revalidation, outline progress to date, and describe the role of the Responsible Officer (Medical Director).

The Report is provided to the Board for:

Decision		Discussion	
Assurance	√	Endorsement	

Summary / Key Points:

Medical Director to report verbally at the 4 August 2011 Trust Board meeting.

Recommendations:

Medical Director to report verbally at the 4 August 2011 Trust Board meeting.

Previously considered at another corporate UHL Committee ? yes – Executive Team 26 July 2011

Strategic Risk Register	**Performance KPIs year to date**
N/A	N/A

Resource Implications (eg Financial, HR)
N/A

Assurance Implications
Yes

Patient and Public Involvement (PPI) Implications
N/A

Equality Impact
N/A

Information exempt from Disclosure
N/A

Requirement for further review ? No

Paper I

CONSULTANT APPRAISAL & REVALIDATION

1.0 INTRODUCTION

1.1 This paper describes the process for strengthened appraisal and revalidation and will describe the system and progress to date. Consultant appraisal covers consultants, associate specialists, staff grades and locum consultants.

1.2 It should be recognised at the outset that appraisal and revalidation is not a replacement for good ongoing clinical management which should address issues in a prompt manner. Appraisal does not replace Fitness to Practice guidance.

2.0 BACKGROUND

2.1 In 2010 The Trust participated in a Pathfinder Pilot to test the Strengthened Appraisal process in preparation for revalidation. The overarching aim of the pilot was to identify areas where the Trust could identify any further work to enable the Trust to be an early adopter site.

2.2 Revalidation is expected to start in 2012 and will be based on a five yearly cycle. Once introduced it will be the process by which doctors will have to demonstrate to the GMC, normally every 5 years that they are up to date and fit to practice and complying with the relevant professional standards. The core mechanism 'underpinning revalidation' is a strengthened appraisal system.

2.3 This paper covers the following areas:

- Roles and Responsibilities
- The Appraisal System
- Current Performance

3.0 ROLES AND RESPONSIBILITIES

3.1 There are a number of roles identified in the appraisal process, each having specific responsibilities. These include the Responsible Officer (RO), the Assistant Medical Director for Revalidation and Appraisal, Senior Appraisers, Appraisers and Appraisees.

3.2 The Department of Health in July 2010 produced guidance on the Role of the Responsible Officer (The Role of Responsible Officer; Closing the gap in medical regulation – Responsible Officer Guidance) and this is attached in full at Appendix 1. Responsible officers must have regard to this guidance under the Medical Profession (Responsible Officers) Regulations 2010. It relates to the role of responsible officers to be nominated or appointed by those bodies designated under the Medical Act 1983 (as amended by the Health and Social Care Act 2008). The regulations came into force on 1st January 2011; however the processes underpinning revalidation are still being developed.

3.3 Dr K Harris, Medical Director has been appointed as the Responsible Officer by the SHA Medical Director and he meets all of the requirements as laid out in the Responsible Officer (RO) Legislation. The Responsible Officer is responsible for ensuring that all

doctors in the Trust are up to date and fit to practice. He will be expected to communicate to the GMC the results of appraisal over the five year cycle.

3.4 The overarching role of the RO is to protect patients by ensuring that the GMC's standards are met by licensed doctors.

3.5 The RO will be expected to participate in appropriate on-going RO training and development and have a PDP related to the role of RO as part of annual appraisal.

3.6 The RO is expected to start to identify doctors who will be early adopters for positive revalidation recommendations expected to take place between 1 April 2012 and 31 March 2013.

3.7 The RO has access to, and reviews, minutes of the quarterly Revalidation Support Network meetings chaired by Mr A Banerjee, Assistant Medical Director for Consultant Appraisal and Revalidation and has access to the appraisal system and dashboard.

3.8 The Assistant Medical Director for Revalidation and Appraisal (Mr A Banerjee) supports the RO in relation to his role in the design, management and delivery of the appraisal system. The AMD has operational responsibility for the appraisal system escalating issues to the RO where required. He also acts as Deputy RO when the RO is unable to review an individual's appraisal/revalidation due to a conflict of interest.

3.9 Four Senior Appraisers have been appointed to resolve, facilitate non-agreement at appraisal. These individuals have all held medical management posts in the past but are not currently line managers of appraisees providing an 'arbitration' role. A Senior Appraiser will be allocated by the Assistant Medical Director for Appraisal and Revalidation where there is non-agreement at appraisal (see Appendix 2).

3.10 There are 106 appraisers who have undergone training. They receive information from the appraisee 2 weeks before the appraisal in addition to the CBU lead confirming there is no reason to not go ahead with the appraisal. If there are any particular issues that the CBU lead advises should be included in the appraisal both the appraiser and appraisee are informed.

3.11 The appraisee undertakes preparatory work for the appraisal gathering information and selects a date and an appraiser. Pre-appraisal information includes patient complaints, clinical audit information and details of mandatory training as well as completion of the main appraisal form. It is advised that the appraiser should be from the same speciality although the same appraiser cannot be used each year thus preventing subjectivity/bias.

4.0 APPRAISAL SYSTEM

4.1 The strengthened appraisal process covers three aspects; pre-appraisal, appraisal and post appraisal.

4.2 The appraisal is divided into a summative and a formative assessment. The summative part relates to the pre-appraisal information with the majority of the appraisal meeting being used for the formative element resulting in a PDP with both parties signing off the completed document. Appendix 3 provides a schematic on the appraisal process.

4.3 Post appraisal the Assistant Medical Director for Appraisal and Revalidation and Responsible Officer are able to see a dashboard which indicates which consultants have successfully completed appraisal. This is depicted as green for no concerns and amber for issues to be addressed. Where required support and/or advice is sought from the Human Resources Team.

4.4 The 'Appraisal & Revalidation Guidelines' document was last updated, reviewed and signed off in June 2011.

4.5 Participation in the pilot for strengthened appraisal has led to access of a number of sources of national support including NCAS, GMC liaison Officer, Royal Colleges, the Department of Health Revalidation Support Team, BMA and other local Trusts.

5.0 CURRENT PERFORMANCE

5.1 There are currently 128 doctors who have participated in strengthened appraiser training in 2010. Most of these doctors facilitated a pilot appraisal and are familiar with the strengthened appraisal process.

5.2 There are 578 'active' accounts with 476 signed off on the electronic system. The remaining have required corporate sign off for a variety of reasons, for example staff having left, long term sickness and maternity leave.

5.3 A list of doctors who had not completed a successful appraisal was compiled by the Assistant Medical Director for Revalidation and shared with the four Senior Appraisers. These individuals were discussed at the Steering Group on 6th July. The Responsible Officer has written to those individuals to access appraisal as a priority. These individuals will be targeted and will undergo an appraisal with an appraiser approved by the AMD.

5.4 A number of consequences are in place for those individuals who do not complete a successful appraisal and these include lack of progression for Clinical Excellence Awards and withholding the summary form (signifying completed appraisal) for private practicing privileges.

5.5 Some of the reasons for non-completion include maternity or other extended absence.

5.6 The CBU medical leads have been asked to provide assurance that none of those individuals who have failed to complete an appraisal are subject to investigation/cause for concern.

6.0 FUTURE DEVELOPMENTS

6.1 Systems will need to be developed for new appointees to facilitate revalidation. This will need to include obtaining information relating to new doctors from previous employers. This is likely to include:

- Pre-employment information or information regarding suitability for role – this needs to be available to the RO before the doctors starts work and should include references, qualifications, verification of ID, gender/ethnicity data, experience, current RO, revalidation due date, GMC conditions or restrictions and CRB.

- RO information or fitness to practise information – this needs to be available to the RO within three months of the start date and should include previous appraisal records, relevant performance monitoring information, records of all investigations, disciplinary procedures, conditions/restrictions, patient and colleague feedback and unresolved concerns.

6.2 Revalidation will also need to include systems for locums and temporary appointments. An approach could be where these individuals are appointed for more than 6 months the supervising consultant will need to complete an exit report. This exit report will need to be available to the locum or the locum's RO.

7.0 CONCLUSION

7.1 UHL has participated in the national pilot for strengthened appraisal to facilitate revalidation (anticipated 2012).

7.2 New roles, electronic systems and processes have had to be introduced to support this strengthened appraisal. This continues to require further data validation.

7.3 Strengthened appraisal has resulted in a more robust process and increased uptake from previous years.

7.4 Non-participation is being actively managed by the Responsible Officer.

Paper I

Appendix 2

Non-agreement Process

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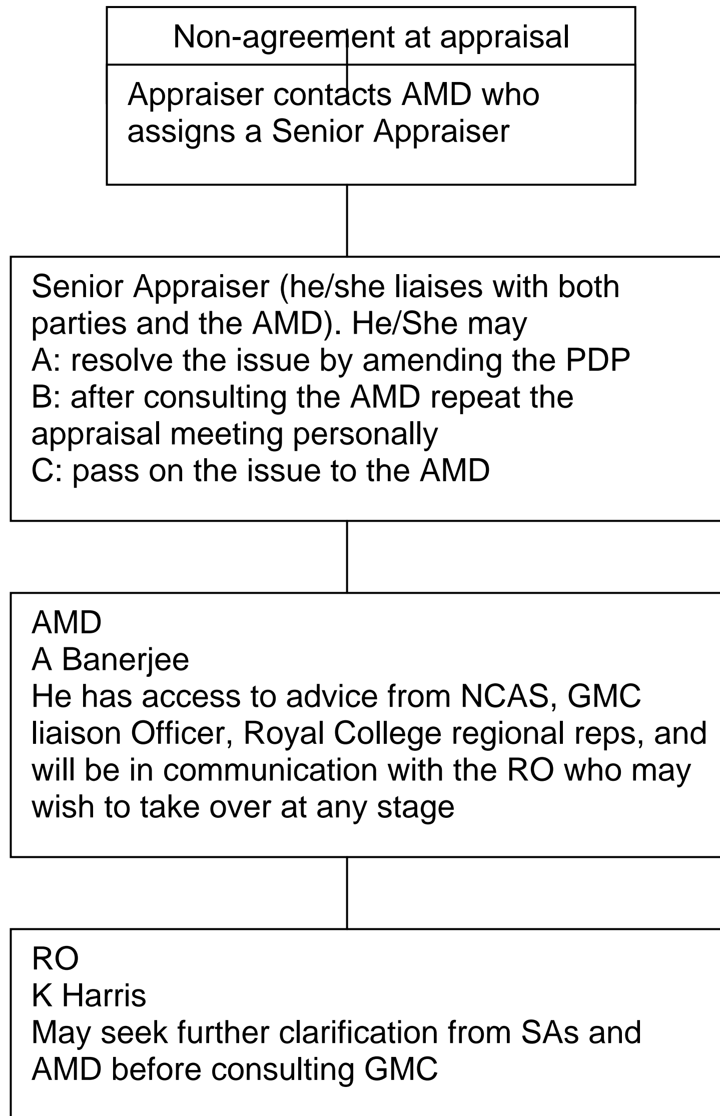

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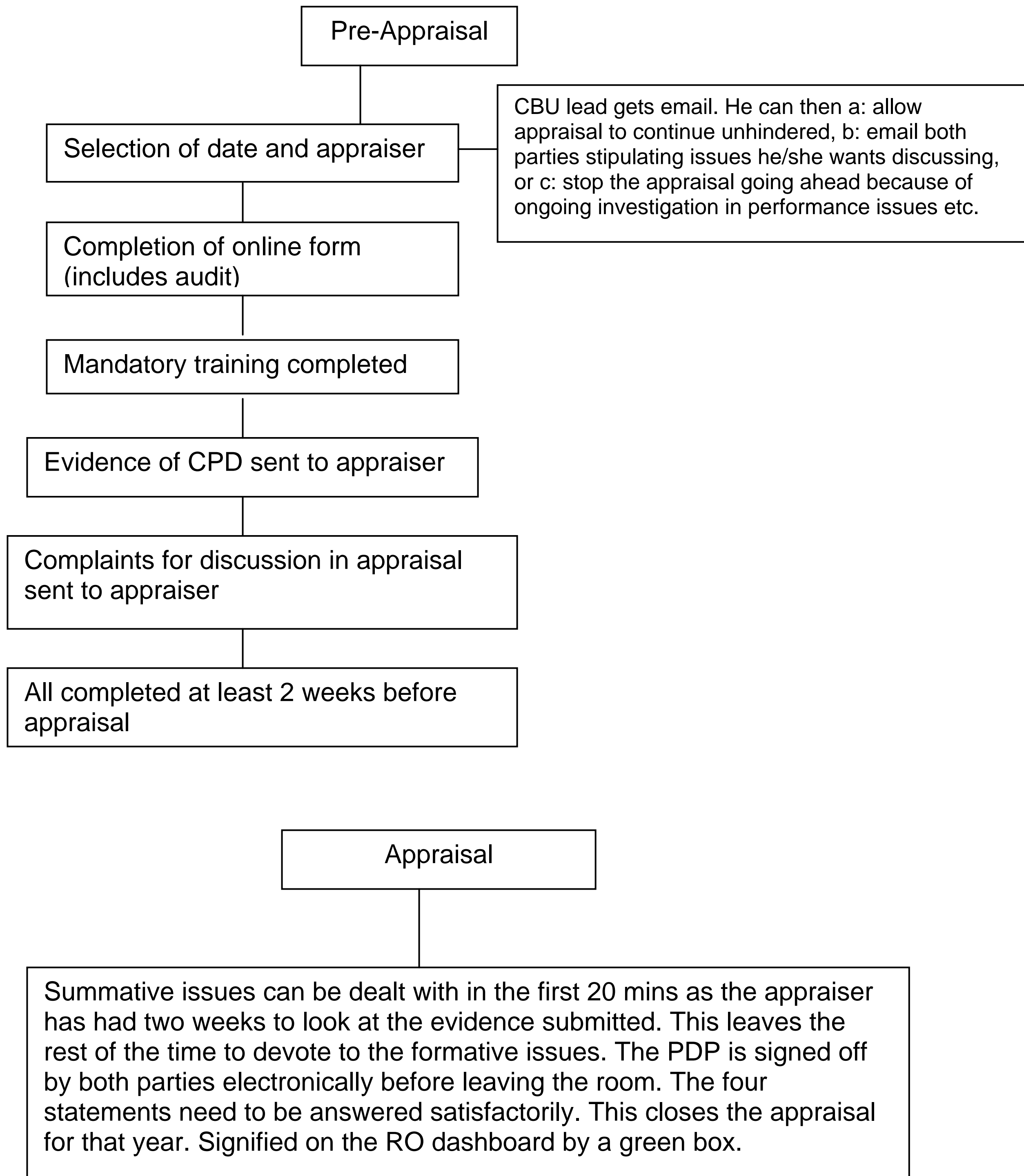
Appendix 3

Appraisal Process



DH Department of Health

The Role of Responsible Officer

Closing the gap in Medical Regulation - Responsible Officer Guidance

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Clinical	Social Care / Partnership Working

Document Purpose	Best Practice Guidance
Gateway Reference	14375
Title	The Role of the Responsible Officer - Closing the Gap in Medical Regulation - Responsible Officer Guidance
Author	DH/NHS Medical Directorate/Clinical Governance Team
Publication Date	26 Jul 2010
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, Foundation Trust CEs , Medical Directors, PCT Chairs, NHS Trust Board Chairs, Special HA CEs, Directors of HR, GPs, Doctors, Employers of doctors
Circulation List	Directors of HR, Trade Unions, Defence societies, Regulators, Deaneries, GMC, Royal Colleges, Universities
Description	Guidance on the role of responsible officer for doctors, organisations, and responsible officers.
Cross Ref	A Consultation on Responsible Officer Regulations and Guidance. DH, August 2009
Superseded Docs	
Action Required	N/A
Timing	**N/A**
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For Recipient's Use	

The role of the Responsible Officer

Closing the gap in medical regulation – Responsible Officer guidance

Prepared by **Clinical Governance Team**
NHS Medical Directorate

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Executive Summary

The document

This is guidance which responsible officers must have regard to under the Medical Profession (Responsible Officers) Regulations 2010[1]. It relates to the role of responsible officers to be nominated or appointed by those bodies designated under the Medical Act 1983 (as amended by the Health and Social Care Act 2008).

Both this document and the regulations it refers to have been the subject of public consultation. In addition the guidance document has been produced as a collaborative endeavour between the Department of Health, the Scottish and Welsh governments, the British Association of Medical Managers (BAMM), the Medical Managers Committee of the British Medical Association (BMA) and NHS Employers.

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

- doctors licensed with the General Medical Council (GMC) to practise medicine;
- all doctors taking on roles as responsible officers; and
- all organisations designated (by the Secretary of State for Health) as having to nominate or appoint a responsible officer in England, Scotland and Wales.

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

Coverage of this guidance document

This guidance document relates to the Medical Profession (Responsible Officers) Regulations 2010. Parts 1 and 2 of the regulations apply to England, Wales, and Scotland. Part 3 of the regulations gives responsible officers in England a further range of duties embracing wider responsibilities relating to clinical governance. Wales will make its own regulations on the clinical governance aspects, whilst Scotland is considering what, if any, improvements are needed in the area of clinical governance and will bring forward its own guidance and/or legislation if necessary.

The regulations give senior doctors in certain organisations (designated bodies) functions for specified doctors that will ensure doctors are appraised annually and where there are concerns about a doctor's fitness to practise they are investigated and referred to the GMC. In England where the concerns are below the level where referral to the GMC is considered necessary responsible officers will investigate, identify the cause and take the appropriate action to bring the doctor back on track.

This guidance document relates for the most part to England, Wales and Scotland unless specifically stated. However paragraphs 4.14 - 4.18 relate to England only and paragraphs 3.22 - 3.23 to Scotland only.

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

Section 1 sets out the background to the role of the responsible officer and describes it in the context of other measures that are aimed at improving the quality of care for patients and the confidence the public has in doctors. It also explains how the legislation applies to different parts of the United Kingdom.

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, in England only, to their wider statutory role under the Health and Social Care Act 2008 (relating to monitoring conduct and performance).

Section 5 is aimed at designated bodies. It sets out their responsibilities in the legislation. It also provides guidance on best practice.

Section 6 is aimed at all readers. It sets out the measures that exist for ensuring that the system operates fairly and equitably for all doctors.

It is recognised that designated bodies and their newly appointed responsible officers will start with very different levels of knowledge and skills in the area of medical management. It is nevertheless essential, if we are to achieve consistency and rigour of responsible officer decision-making, to set out guidance on the role of responsible officers, whilst acknowledging that the role will evolve as real experience of the role is gained and shared. Initially that experience will come from the revalidation pilots that are currently underway.

The guidance document will need to evolve to reflect these developments in the role of responsible officer, and will be reviewed one year after the regulations come into force on 1 January 2011.

Section 1: Background

1.1 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. The care delivered by the majority of doctors registered with the GMC is generally of a high quality. However, after a series of high profile failings, proposals were made for a system of revalidation for every doctor. Revalidation is a new way of regulating the medical profession that provides a focus for doctors' efforts to maintain and improve their practice. The purpose of revalidation is to assure patients and the public, employers and other healthcare professionals that licensed doctors are up to date and are practising to the appropriate professional standards. Although it is widely understood that the delivery of medical care to patients will always involve an element of risk, revalidation will help doctors, employers and the GMC to provide further assurance to patients and the public that doctors working in the UK are fit to practise.

1.2 The processes underpinning revalidation are still being developed. The GMC has consulted on them[2]. When the Government published its proposals for revalidation in 2007, it divided revalidation into two elements – relicensing and recertification. A single system is now proposed as maintaining relicensing and recertification as separate elements within revalidation risks complexity and confusion. Revalidation should be a single set of processes with a clear outcome, which doctors, their patients and those who employ or contract doctors' services can understand. Doctors who are no longer working in the specialty for which they were originally listed in the specialist or GP registers will not lose their register entry if their revalidation has been secured on the basis of supporting information of practice in another field. The specialist or GP register entry will remain as a historical record of a doctor's achievement. But the register will also show the field in which a doctor most recently demonstrated fitness to practise through revalidation.

1.3 Responsible officers, in England, are integral to improving the quality of care and ensuring a focus on the three core components of quality described in *High quality care for all*[3]:

- **Patient Safety** – by ensuring that doctors are maintaining, and raising further, professional standards.

- **Effectiveness of care** – by supporting professional ethos to improve further the effectiveness of clinical care.

- **Patient experience** – by ensuring that patients' views are integral to evaluations of a doctor's fitness to practise.

1.4 The development of the responsible officer role across the UK is part of the programme of reform set out in the White Paper *Trust, Assurance and Safety*[4]. That programme values and celebrates the professionalism of the dedicated people who work in healthcare. It

[2] Revalidation: The way ahead, GMC, March 2010, http://www.gmc-uk.org/doctors/licensing/5786.asp
[3] High quality care for all, Department of Health, September 2008
[4] Trust, Assurance and Safety: The Regulation of Health Professionals in the 21st Century; TSO February 2007

seeks to raise the already high standards of the overwhelming majority of professionals, whilst ensuring that the small number of staff who are not able to meet those standards are swiftly identified and then dealt with fairly and effectively and, where appropriate, are supported to get back on track.

1.5 In support of this, the responsible officer role will:

- ensure that those doctors who provide care continue to be safe;
- ensure doctors are properly supported and managed in sustaining and, where necessary, raising their professional standards;
- for the very small minority of doctors who fall short of the high professional standards expected, ensure that there are fair and effective local systems to identify them and ensure appropriate remedial, performance or regulatory action to safeguard patients; and
- increase public and professional confidence in the regulation of doctors.

1.6 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 connection 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 practise (as a positive statement of assurance, not simply an absence of concerns);
- this recommendation must be determined on the basis of robust, accurate supporting information about all aspects of the doctor's practice, including that resulting from any investigations already completed. That supporting information must be scrutinised through the clinical arm of corporate governance and appraisal/capability/remediation processes. It must also be, where appropriate, sufficient to evidence that the doctor's performance meets the specialist or general practitioner standards that may be required by the GMC to demonstrate a doctor's fitness to practise. The responsible officer, following the appropriate or necessary consultations with Medical Royal College representatives and where necessary the National Clinical Assessment Service[5] (NCAS), will decide whether the necessary standards are met and if not will refer the doctor to the GMC on fitness to practise grounds. If the concerns do not merit referral to the GMC the responsible officer will also consider whether local remediation is appropriate; and
- all designated healthcare organisations (Regulation 4 & Schedule of designated bodies) will be required to nominate or appoint, resource and support a responsible officer. In the NHS in England this will be a senior licensed doctor, usually sitting on the Board. In NHS Scotland this will be a Health Board Medical Director who is an executive member of the Board. In NHS Wales this will be a Local Health Board or NHS Trust Medical Director.

1.7 The public, the profession and the NHS have a right to be assured that licensed doctors are fit to practise. The new regulations are designed to help doctors, and the organisations where they work, to further improve the quality of care provided to patients.

[5] In Scotland NCAS services are delivered through NCAS Scotland.

1.8 The role and responsibilities of the responsible officer are described in this document as is the relationship between licensed doctors and a responsible officer and the duty of designated healthcare organisations to nominate or appoint to the role and resource it. The guidance document has been produced following the conclusions of a working group established by the Department of Health as part of the implementation of *Trust, Assurance and Safety.* It also reflects developments to the regulations following consultations[6,7,8] on the role of the responsible officer and contributions from a wide range of clinicians, managers and patient groups.

1.9 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 (such as those using their medical knowledge in the IT, insurance, or other industries that are not healthcare services), are subject to further discussion with stakeholders, and possibly piloting. The Department of Health and the GMC will therefore bring forward proposals in relation to these doctors at a later date.

[6] Consultation on Responsible Officers and their duties relating to the medical profession http://collections.europarchive.org/tna/20100509080731/http://dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098851

[7] Response to the Consultation on Responsible Officers and their duties relating to the medical profession http://collections.europarchive.org/tna/20100509080731/http://dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098851

[8] Consultation on Responsible Officer regulations and guidance http://collections.europarchive.org/tna/20100509080731/http://dh.gov.uk/en/Consultations/Closedconsultations/DH_104587

Section 2. Key messages

2.1 The following section sets out key messages for all audiences.

2.2 All designated bodies 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 who employ or contract with doctors.

2.3 Organisations should have only one responsible officer who carries the overall accountability, although individual tasks can be assigned to others.

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

2.5 In most cases, doctors will connect to the responsible officer in the organisation where they undertake the majority of their clinical work. In England and Wales postgraduate trainees will relate to a responsible officer in their deanery. In Scotland trainees will relate to the NHS Education for Scotland (NES) responsible officer. Doctors on a General Practice Performers List (except those that work for the armed forces for the majority of their time) will relate to the responsible officer in the organisation that manages that Performers List. In England, this is the Primary Care Trust, in Scotland the Health Board and in Wales the Local Health Board.

2.6 Doctors should ensure they know who their responsible officer is.

2.7 Responsible officers must be doctors who hold a license to practise issued by the GMC.

2.8 Responsible officers will have a responsible officer. In England, this will normally be the Strategic Health Authority responsible officer. In Scotland and Wales, it will be the responsible officer in the Scottish Government Health Directorates and the Welsh Assembly Government.

Section 3. Guidance for licensed doctors

The doctor's responsibility to a responsible officer

3.1 Following the introduction of the new regulations, a responsible officer nominated or appointed by an organisation designated by the Secretary of State for Health will have a key role for the doctors he or she is connected to. The role of the responsible officer across the UK is to evaluate doctors' fitness to practise. They will do so based on the supporting information that is presented to them, so will have to ensure that the organisation has necessary systems in place to facilitate this. Under the regulations, in England, the responsible officer's role will support doctors as they strive to improve the quality of care.

3.2 Every doctor who has a connection with a designated body under the regulations (Regulation 10 & 12) will be required to participate in regular appraisal[9] 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[10] and the associated Framework for Appraisal and Assessment[11];
- specialist or general practitioner standards as set out by the appropriate Medical Royal College or Faculty[12]; and
- expectations of their managed healthcare organisation in safely undertaking the clinical role for which they are employed or contracted.

3.3 Designated bodies have a duty under Regulation 14 and, in England, also under Regulation 19 to support the responsible officer in the role by appropriately resourcing them. This is likely to require robust systems of clinical governance and ensuring these systems are fit for purpose and quality assured. The data fed into these systems and made available to support doctors' portfolios, and to inform appraisal, are the basis on which recommendations will be made to the GMC and must be properly assured, appropriately validated and reviewed where appropriate. They will include multi-source feedback, information from clinical governance and information relating to the doctor's clinical performance as required by the GMC for revalidation. The information from these systems, which will inform the responsible officer's decision-making, must be accurate, timely, relevant to the full span of the individual's clinical practice and meet the standards set out by the GMC, and the Medical Royal Colleges and Faculties where appropriate.

3.4 The GMC have consulted on the proposals for 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

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[9] http://www.revalidationsupport.nhs.uk/Strengthened_Medical_Appraisal.asp
[10] Good Medical Practice, General Medical Council, November 2006 http://www.gmc-uk.org/guidance/good_medical_practice/index.asp
[11] Framework for Appraisal and Assessment, General Medical Council, August 2008 *http://www.gmc-uk.org/doctors/licensing/docs/explanatory_note.doc*
[12] Revalidation: The way ahead, Annex 2 Specialty and General Practice Frameworks, GMC, March 2010, http://www.gmc-uk.org/static/documents/content/Revalidation_way_ahead_annex2.pdf

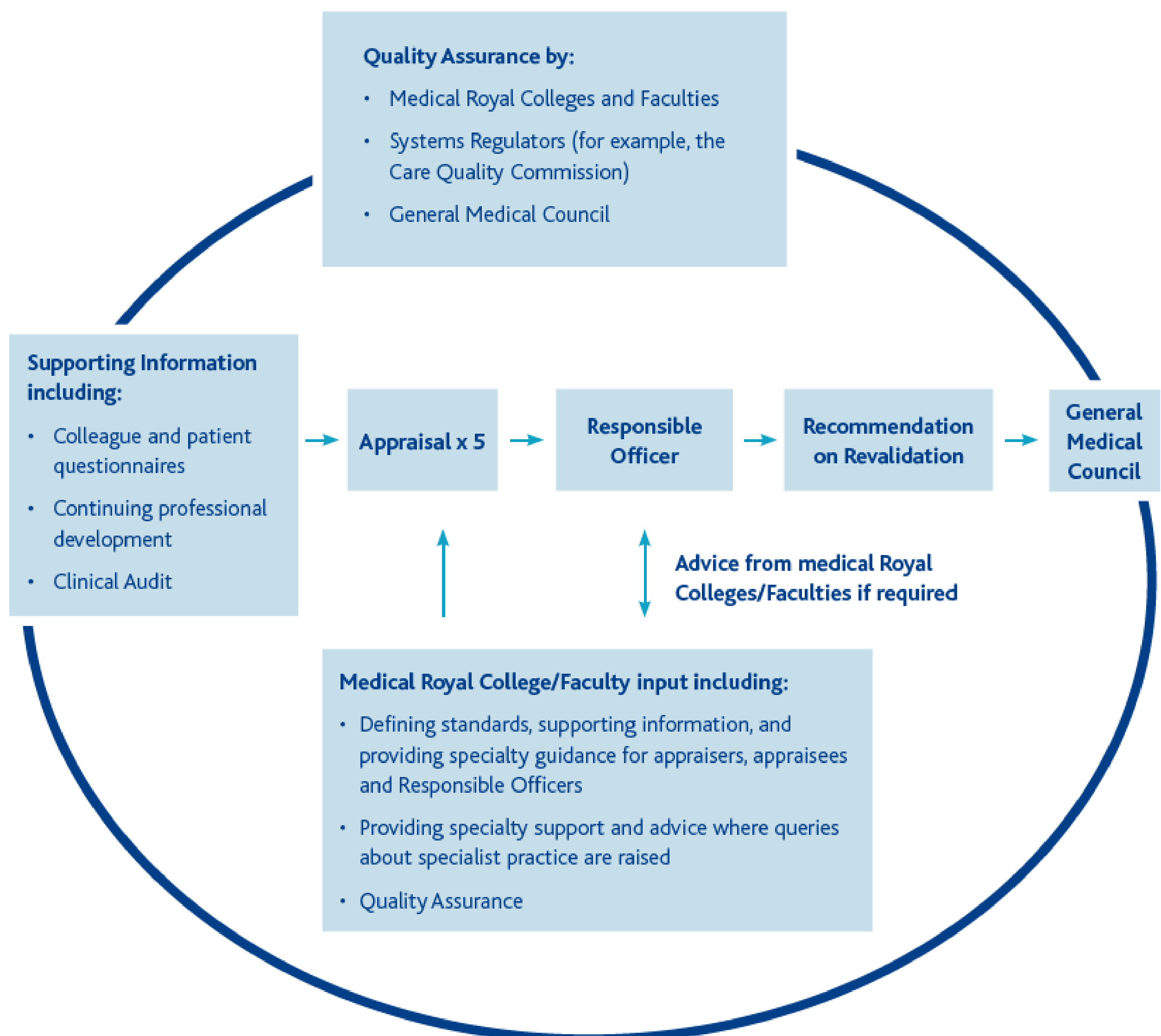
doctor, both clinical practice and non-clinical roles such as public health, administration, management and leadership.

The revalidation process and the responsible officer

3.5 Revalidation, when introduced, will be the process by which doctors will have to demonstrate to the GMC, normally every five years, that they are up to date and fit to practise and complying with the relevant professional standards.

3.6 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 Revalidation Process Diagram:



Source: GMC: Revalidation the way ahead Appendix A

3.7 Individual doctors will be responsible for maintaining a portfolio of supporting information to demonstrate the maintenance of their clinical and professional standards and, where applicable, their specialist skills. This package of information also provides a basis of evidence that responsible officers can use to help assess fitness to practise.

3.8 The appraisal process will include information from multi-source feedback, Continuing Professional Development (CPD) portfolios and verified clinical performance information, along with the outcomes of any investigation of complaints, concerns, patient safety incidents and other available indicators that can be reliably related to the performance of the individual doctor. Supporting information confirming the doctor's performance against the clinical standards as set out by his or her respective Medical Royal College or Faculty, where applicable, should be included in their appraisal.

3.9 The responsible officer will be accountable for ensuring that the systems for appraisal, clinical governance and for gathering and retaining other local relevant supporting information are in place and are effective. He or she will also be responsible for ensuring that systems are in place to record and collate all the necessary information, including a record of any practice undertaken by the doctor outside of the organisation.

3.10 Every doctor will be appraised annually by a trained appraiser[13]. Concerns about conduct or performance are unlikely to come to light for the first time during the appraisal process itself, but if they do, they will obviously need to be dealt with there and then. The responsible officer should be informed by the appraiser about any significant concerns that arise, i.e. those of a sufficiently serious nature to call into question the doctor's fitness to practise, as these are likely to require specialist input from the appropriate Medical Royal College or Faculty, NCAS or other relevant body. Arrangements for remediation, supervision or suspension may also need to be put in place. If the responsible officer is concerned at any time, including at the time of appraisal, that the doctor might present a risk to patients, the responsible officer will refer the doctor to the GMC.

3.11 At the time of revalidation, 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, concerns on the small number of doctors with performance or conduct issues having been identified and addressed through the appraisal process. Where there is a concern about a doctor at the revalidation stage, the responsible officer must decide whether local processes are appropriate or whether the concern is serious enough to warrant a referral to the GMC on the grounds of fitness to practise.

3.12 It is emphasised that where there is justified cause for concern about a doctor's fitness to practise which cannot be managed through remediation processes, the role of the responsible officer is limited to drawing the case to the attention of the GMC and to ensuring that the necessary supporting information 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.

[13] In certain circumstances, eg where a doctor is on a career break, the interval between appraisals may vary.

3.13 To provide the supporting information 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. In England, further information is available from the Revalidation Support Team's Strengthening Medical Appraisal[9]. Failure to do so may become a fitness to practise issue and may affect their future licensed status. The GMC is expected to set out the detailed requirements and processes following its consultation *Revalidation: The way ahead*[2].

Arrangements for relating to a responsible officer

3.14 The overarching role of the responsible officer is to protect patients by ensuring that the GMC's standards are met by licensed doctors. A licensed doctor should normally relate to the responsible officer of the healthcare organisation in which he or she spends the majority of his or her working week. The principle is that, where doctors work in a designated body, that organisation will have in place the appropriate systems of strengthened appraisal and clinical governance that will support the revalidation process when it is introduced. Regulation 10 sets out the way doctors are connected to a designated body. Doctors on a Performers List will relate to the responsible officer in the organisation whose Performers List they are on. The arrangements are illustrated in Figure 2 on page 13. Doctors will relate to one responsible officer only. Each designated body will normally have only one responsible officer. In the NHS, we expect that this will be the Medical Director.

3.15 Providers of healthcare will be required to nominate or appoint responsible officers. These organisations either:

- provide or arrange for the provision of healthcare by doctors; or
- employ or contract with doctors;

and include:

- NHS hospitals and mental health trusts;
- Foundation Trusts;
- Independent sector hospitals in England and Wales;
- Primary Care Trusts and provider organisations;
- Health Boards in Scotland; and
- Local Health Boards and NHS Trusts in Wales.

3.16 Organisations that have a role in setting policy and standards for the provision of healthcare that employ or contract with licensed doctors will also have to nominate or appoint a responsible officer. These currently include:

- Special Health Authorities in England;
- Special Health Boards in Scotland; and
- Government departments.

3.17 Doctors may also work independently of organisations either as independent providers or self-employed contractors. These doctors are generally members of specialist societies. These doctors do not relate to a responsible officer because they are a trainee, on a Performers List, employed or have practising privileges with an independent hospital. A small number of these organisations that have demonstrated appropriate clinical governance system are designated. Doctors who are members of these organisations will relate to their responsible officer if they have no other connection. Currently these are the:

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

3.18 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.

General practitioners

3.19 General practitioners, in England, will relate to the responsible officer of the PCT holding the Performers List on which the individual is named. In Scotland this will be the Health Board and in Wales, the Local Health Board. In England where there are conflicts of interest the doctor may make a case to relate to another responsible officer nominated or appointed by the PCT (see paragraph 6.6 - 6.8). In Scotland the case would be made to the Health Board and in Wales to the Local Health Board.

3.20 General Practitioners working in the armed forces will have their responsible officer in the appropriate force, if they spend the majority of their time working for the armed forces. Most GPs in these circumstances work full-time for the forces but are required to be on a Performers List for activities such as providing training.

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

Arrangements for doctors in Scotland

3.22 Doctors in Health Boards in Scotland (both primary care and acute sector) will relate to the responsible officer for the Health Board who will be an executive member of the Board. In cases of conflict of interest or appearance of bias a doctor in a Health Board may relate to another responsible officer.

3.23 As indicated above, general practitioners will relate to the responsible officer of the Health Board holding the Performers List on which the individual doctor is named. Again, in cases of conflict of interest or appearance of bias the doctor may relate to the responsible officer of another Health Board. Where a doctor is also on a Performers List in another part of the UK, the doctor will relate to the Performers List where most of their work is carried out.

Doctors working in management roles

3.24 As with other medical practitioners, doctors in management roles should relate to the responsible officer of the organisation for whom they undertake the majority of their work.

3.25 Responsible officers, as licensed doctors will also have to have their fitness to practise confirmed. As senior doctors in their organisations they will use the same systems as the doctors they are responsible for. They will have a responsible officer, outside their own organisation, who will ensure they are supported in the same way as those they are responsible for (Regulation 12). The GMC have set out that 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.

Doctors in training

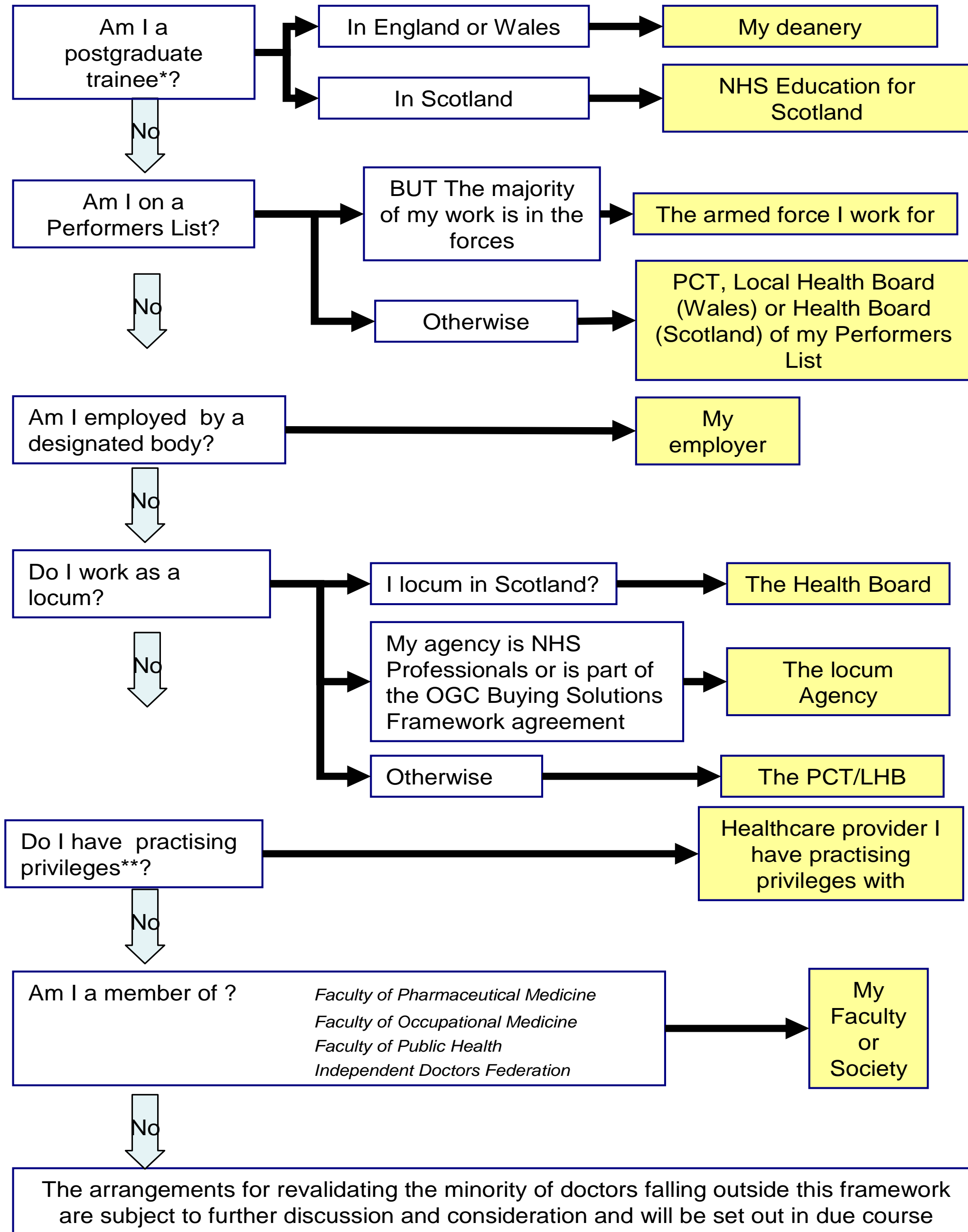
3.26 Doctors in postgraduate training will hold licences to practise. In England and Wales trainee doctors will connect to a responsible officer in their postgraduate medical deanery. In Scotland, they will relate to the responsible officer at NHS Education for Scotland. Clearly, both employers and deaneries have information that will be pertinent to confirming the fitness to practise of trainees. The effective flow of information between employer and deanery (and in Scotland, NES, the employer, and the deanery), will therefore be important to ensuring a fair and robust process for confirming trainees are fit to practise and to support revalidation, when introduced.

UK doctors working overseas or offshore

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

How to find your responsible officer

3.28 Figure 2 below shows how individual doctors can find out who their responsible officer is. It is intended as a guide to supplement the regulations (Regulation 10).



* The medical practitioner is a doctor in training who is a member of a foundation or specialty training programme managed by a postgraduate medical deanery

** "Practising privileges" means the grant, by a person managing a hospital, to a medical practitioner of permission to practise as a medical practitioner in that hospital

3.29 Many doctors work across a number of settings and may be considered to have a connection to more than one designated body. Figure 2 sets out the hierarchy where doctors have different types of connection. Where the doctor has a connection to more than one organisation within a connection type the general principle is that the organisation where the doctor carries out the majority of their clinical work provides the responsible officer. More details are given in the following paragraphs.

3.30 Where a doctor is on more than one Performers List the responsible officer will be in the primary care area where they undertake the majority of their clinical work. Where that is equally split then the responsible officer is in the primary care organisation nearest to the doctor's address that is registered with the GMC.

3.31 When a doctor has more than one employer, the responsible officer will be in the organisation where the doctor carries out the majority of their clinical practice. If this cannot differentiate and if one of them is an NHS body that body will provide the responsible officer. If that fails to identify the responsible officer the organisation which is closest to the doctor's registered address will provide the responsible officer.

3.32 For locum doctors working through more than one agency the responsible officer will be provided by the agency the doctor worked with most in the previous calendar year.

Locum doctors

3.33 This section only applies to locum doctors in secondary care. Locum doctors in primary care are on a Performers List and should read the relevant section relating to general practitioners in England, Wales or Scotland.

3.34 In England and Wales locum agencies are designated if they are on the NHS Purchasing and Supply Agency (PASA) (now the Office of Government Commerce (OGC) Buying Solutions) framework agreement[14]. The framework agreement includes conditions of clinical governance that are already audited by the OGC. NHS Professionals Ltd, a private company wholly owned by the Secretary of State for Health that provides locum doctors to the NHS but is not party to the current framework is also designated. Locum doctors in England and Wales who contract through a locum agency on the PASA framework agreement, or NHS Professionals Ltd. will relate to a responsible officer in that organisation.

3.35 Locum doctors who work solely outside the structure set out above will relate to a responsible officer in the PCO nearest to the doctor's registered address.

3.36 In Scotland, locum agencies will not have their own responsible officer and locum doctors will relate to the responsible officer in the Health Board in the area of their registered address.

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[14] 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.pasa.nhs.uk/PASAWeb/Productsandservices/Agencystaffandoutsourcedservices/Agencyandtemporarystaff/Medicallocums/

Doctors without a prescribed connection to a responsible officer

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

Section 4. Guidance for responsible officers

4.1 This section, in paragraphs 4.2 to 4.13, sets out guidance for responsible officers in England, Scotland and Wales and specifically relates to their role in evaluating the fitness to practise of doctors. Paragraphs 4.14 to 4.22 provide guidance on the additional responsibilities, relating to clinical governance, of responsible officers in England only.

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

4.2 The role of the responsible officer will primarily be to ensure that systems within his/her organisation support doctors in delivering quality care that is constantly improving. Where a doctor falls below the standards set, the responsible officer will need to ensure that appropriate action is taken to bring the doctor back on track while ensuring the safety of patients.

4.3 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.

4.4 The responsible officer will be answerable to the GMC and his or her nominating or appointing organisation for ensuring that there are appropriate systems and processes in place for collecting and holding information that informs the evaluation of fitness to practise. This will include ensuring there are robust systems of appraisal in place to support doctors in improving their practice. Where conduct or performance is falling below the usual high standards that doctors are expected to work to, it is important to identify them early and take the appropriate action 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.

4.5 To carry out their functions, responsible officers will need to ensure:

- 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; and
- appropriate action is taken to remedy identified areas of weakness.

4.6 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).

4.7 Medical Royal Colleges and Faculties will offer support to responsible officers in evaluating the specialist practice of doctors. The responsible officer will want to ensure that there is appropriate liaison between their organisation and the relevant Medical Royal Colleges and Faculties to seek their input to the appraisal process as required, in terms of specialist practice. The responsible officer will decide when he or she needs advice on specialist practice. In cases where there are concerns relating to general practice or specialist clinical practice advice may be available from the Medical Royal Colleges.

4.8 The responsible officer has a statutory duty to co-operate with the GMC under Regulation 13(5). In England, pending the outcome of a second pilot project currently underway, this may be through a regionally based GMC affiliate. The responsible officer will liaise with the GMC on matters connected with fitness to practise issues.

4.9 In the event of concerns being raised about a doctor of a sufficiently serious nature to call into question the doctor's fitness to practise, the responsible officer will need to consider referral of the doctor to the GMC. Responsible officers will be accountable for the oversight of all associated processes. The responsible officer is expected to co-operate with the GMC in establishing the appropriateness of the referral and will oversee the collation of the relevant information. The responsible officer will also be expected to liaise with the appropriate Medical Royal College or Faculty, where appropriate, through the College Regional Advisors or identified college contacts for independent advice on the relevant specialist practice and also, in cases of concern, for advice on the performance of the doctor.

4.10 The responsible officer is also accountable for overseeing 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 monitor the compliance of the doctors they are responsible for with any conditions imposed upon the doctor 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 progress monitoring process.

4.11 The responsible officer is unlikely to make the decision to refer a doctor to the GMC in isolation; he or she will want to seek advice from appropriate sources, for example from the medical Royal Colleges and Faculties or the National Clinical Assessment Service (NCAS) or other relevant body. The responsible officer must also ensure that remediation and disciplinary procedures, where appropriate, are followed.

4.12 The responsible officer's responsibilities relate to the local systems which support local decision-making. For secondary care organisations in England this process is described in *Maintaining High Professional Standards in the NHS*[15]. PCTs in England are advised to follow guidance from NCAS. These new arrangements do not in any way affect the right of patients or members of the public to refer cases directly to the GMC.

4.13 Responsible officers are licensed doctors. It follows then that they must each also have a responsible officer. In England, the responsible officer at a local level will relate to a responsible officer at the appropriate Strategic Health Authority, who will ensure that the relevant supporting information is collected and make any recommendation about fitness to practise to the GMC. The SHA responsible officer in England will relate to the Department of Health's responsible officer. In Scotland and Wales the responsible officer of local responsible officers will be at the Scottish Government Health Directorates and Welsh Assembly Government respectively.

[15] Maintaining high professional standards in the Modern NHS, a framework for the initial handling of concerns about doctors and dentists in the NHS, Department of Health, February 2005 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4072773

Additional responsibilities relating to clinical governance for responsible officers in England

4.14 Responsible officers in England have a duty to ensure the robust, efficient and reliable functioning of systems of clinical governance. Clinical governance has been defined[16] as "*a framework through which healthcare organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish*". This definition reinforces the concept that, for the great majority of doctors, the focus of clinical governance systems should be on quality improvement, in terms of the quality of care not only as delivered by each doctor but also by the entire team of which the doctor is part. The function of appraisal, therefore, remains formative – but only after an objective and confident judgement has been made about the quality of the doctor's practice. In the vast majority of cases, this judgement will be affirmative, but, in the small number of instances where there is cause for concern, robust processes must be in place to ensure early identification and rapid remedial action.

4.15 In addition to the duties outlined above, the responsible officer must ensure that doctors are supported by the organisation in their efforts to improve their own performance and the quality of care they provide to patients. They must also ensure that:

- medical practitioners have qualifications and experience appropriate to the work to be performed and that appropriate references are obtained and checked;
- doctors' performance and conduct is monitored; and
- appropriate, timely action is taken when concerns about shortcomings in performance or conduct are identified.

4.16 The responsible officer duties in monitoring clinical performance and reporting concerns when they arise will also involve him or her in providing professional leadership and leading the cultural change that must take place in the organisation to support and allow the systems of celebrating and spreading best practice. If the culture does not support honesty, openness and a willingness to rectify and learn from failings, even the most sophisticated technology available will not deliver a system that works. Like any other system and process, the effectiveness of clinical governance is dependent upon the culture and attitudes of the organisation. The responsible officer has a major role to play in creating and maintaining the appropriate culture to support good clinical governance.

4.17 Safeguarding patients begins when doctors are appointed (or admitted to a Performers List). The responsible officer will have a statutory responsibility to ensure that there are robust systems within the organisation for:

- undertaking appropriate employment checks for medical appointments;
- obtaining appropriate references and resolving any issues that may arise; and
- recording the results of the checking process.

4.18 Responsible officers in England have a broader set of responsibilities under Regulations 16 and 17 relating to the monitoring of conduct and performance of doctors who give rise to concern, but do not require referral to the GMC. It is likely that the systems for monitoring performance and conduct will be common to both the revalidation and the

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

fitness to practise processes and will reflect good employment practice. There will be a range of outcomes and pathways, but broadly, doctors will either have their fitness to practise confirmed, be subject to appropriate local action or remediation to improve the doctor's practice or be referred to the GMC.

4.19 Identifying a concern is merely the start of a process to safeguard patients. It is crucially important that appropriate action is taken at the appropriate time. The responsible officer has a personal responsibility for initiating the action in relation to issues that arise from the conduct and performance of doctors. These actions may include:

- initiating an investigation, with appropriately qualified investigators separate from the decision-making process;
- co-ordinating and co-operating with other concurrent investigations into broader systems failure;
- initiating further monitoring;
- initiating 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 pending further appropriate action.

4.20 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.

4.21 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 investigate the causes of concerns about a doctor's performance, and where necessary, to initiate action to address wider systems or team issues that result in poor performance.

4.22 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 out of 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 – National Patient Safety Agency, Medicines and Healthcare Regulatory Agency and the manufacturers, in addition to the immediate primary action needed to prevent harm to patients.

Guidance from other sources

4.23 In addition to this guidance responsible officers must have regard to guidance issued by the GMC that relates to their responsibilities (Regulation 15). This will primarily be Good Medical Practice and the associated specialist standards but may extend to other guidance.

4.24 In England responsible officers must also have regard to guidance issued by NCAS that relates to their responsibilities (Regulation 18). This includes guidance about the proper procedures for investigating concerns.

4.25 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 best practice guidance from recognised sources, to recognised national audits and to local audits of clinical practice. The responsible officer therefore will want to ensure that this guidance is easily accessible and widely used within his or her organisation. Employing organisations should 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.

4.26 The responsible officer has a duty to ensure that doctors are fit to practise. That may be difficult when the doctor is carrying out innovative treatments. In England, doctors carrying out procedures that are new, or for which they have no experience, have to gain approval from either a Research Ethics Committee or a Trust's Clinical Governance Committee. The processes for ensuring that doctors have the appropriate authority are set out in *HSC 2003/11*[17].

Relationships and accountabilities of the responsible officer across the UK

4.27 The responsible officer has a relationship with, and is accountable to, the GMC on matters in connection with fitness to practise, including ethical issues. The responsible officer should also be directly accountable to the organisation's Board or the highest level of management.

4.28 Key relationships for the responsible officer at Executive Board level will be with the Chief Executive, Director of Human Resources and Director of Nursing or their equivalents. Within the organisation, the responsible officer will relate closely to the organisation's medical management, appraisal and clinical governance infrastructure.

4.29 The responsible officer will also have a crucial set of relationships with the clinical leads of the various service lines of the organisation. In the NHS in England, this will include clinical directors, clinical leads or service line leads in secondary care and Professional Executive Committee (PEC) chairs, clinical governance leads and clinical service leads in primary care.

4.30 Other key relationships will be 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.

4.31 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.

Data protection

[17] HSC 2003/011 - The interventional procedures programme: working with the National Institute for Clinical Excellence to promote safe clinical innovation; Department of Health; November 2003 http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4064922

4.32 Responsible officers will want to ensure themselves that the systems and processes that are in use by themselves and their staff that contain personal information comply with the principles of data protection and that appropriate auditable governance arrangements are in place to control access to the data and any transfers of that data.

4.33 This will be particularly important where the responsible officer is employed by a different organisation to that which holds the information about the doctor for example the responsible officer's responsible officer. The transfer of personal information by secure means is paramount. Responsible officers can get further information from the information governance officer in their organisation or the Information Commissioner's Office.

Who should be the responsible officer?

4.34 It is a basic requirement that a responsible officer must be a registered with the GMC with a licence to practise. The responsible officer will be expected to be able to demonstrate the competencies required by the role, for England and Wales these will be laid out in the Department of Health document *A Competency Framework for Responsible Officers*. For Scotland, this will be demonstrated through the existing NHS Scotland leadership behaviours and competencies for the executive cohort, which will be expanded as required. It is recognised that not all responsible officers will be able to demonstrate all of the competencies before taking on the role. Doctors will bring their own experiences of medical management and leadership skills gained during the course of their careers to the role, and will acquire responsible officer knowledge, skills and experience as they develop in the role. Responsible officers will, however, need to be able to demonstrate the competencies identified for senior-level medical managers and their development of the required competencies will be monitored against the country-specific frameworks through their own appraisal processes.

4.35 In Scotland, all Medical Directors, who will be the responsible officers in NHS Scotland, are already required to comply with the behaviours in the NHS Scotland leadership development framework and this compliance is already monitored, through individual performance management arrangements, by Chief Executives of Health Boards.

4.36 In many cases when concerns are raised about a doctor's fitness to practise they will reveal an issue with the systems in place in the organisation. The responsible officer will have to ensure that appropriate action is taken as a result of the evaluation of fitness to practise. That may require the organisation to change the systems that have given rise to the concern and that is why those we consulted thought the responsible officer should be a senior doctor in their organisation. In NHS organisations across the UK, we expect that the role will be undertaken by the Medical Director with a seat on the Board.

4.37 Each designated body will normally have only one responsible officer. He or she may assign 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 statutory responsibility of the responsible officer.

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

Person specification

4.39 In the NHS in England, the responsible officer will be responsible to the board for clinical performance and clinical governance in respect of doctors and, as a senior doctor, will also provide leadership to the medical workforce. In some organisations across the UK, responsibility for clinical governance across the organisation may be jointly held with another board member, for example the Director of Nursing.

4.40 The responsible officer should 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, we expect that he or she will be able to demonstrate an ability to lead and manage change in complex healthcare organisations and have significant experience of medical management, including, practical experience of performance management of colleagues, appraisal processes and audit. He or she will be expected to be able to demonstrate the ability to translate findings into remediation plans and to introduce new policies and strategies throughout an organisation. This will require being able to demonstrate knowledge both of the practicalities of clinical governance and its crucial role in safeguarding quality of clinical care in the NHS.

4.41 In terms of special areas of skills and knowledge, the responsible officer will need to demonstrate an accurate and up-to-date knowledge of the law as it relates to medical regulation and interfacing structures and processes. He or she will need to be able to demonstrate expert knowledge and skills in appraisal, quality assurance of appraisal systems and of appraisers, mediation, negotiation, remediation and rehabilitation. The responsible officer will need to have an acute grasp of the management and interpretation of information gathered from the various reporting systems underpinning clinical governance. He or she will need to understand how to access the resources of the employing organisation to enable the implementation of decisions made about individual doctors.

4.42 The responsible officer will need to be able to demonstrate that he or she is trained and skilled in his or her role as a medical manager and leader. He or she will be expected to be able to demonstrate to the public, their colleagues and to their organisation that he or she has the competencies, skills, knowledge and attitudes required to deliver this important role. In addition to qualifications, it is expected that responsible officers will be able to demonstrate their on-going development and training, with annual appraisals and assessments of performance.

4.43 The responsible officer will need to demonstrate the ability to communicate outside the local organisation, with the public, GMC, Medical Royal Colleges and Faculties.

Competencies

4.44 It is recognised that designated bodies and their newly appointed responsible officers will start with very different levels of knowledge and skills in the area of medical management.

It is nevertheless essential, to achieve consistency and rigour of responsible officer decision-making, to set out a framework of recommended core competencies for responsible officers. It is further recognised that the competency framework will evolve as doctors take on the role and as real experience of the role is gained and shared.

4.45 Recommended competencies cover:
- communication skills;
- mediation and arbitration skills;
- evidence handling skills;
- an understanding of the principles of investigation; and
- an understanding of equality and diversity issues.

4.46 These core competencies are grouped into six domains, and are aligned with competency frameworks for medical management, appraisers, and appraiser trainers in England:

- Communication;
- Managing the process of medical revalidation, appraisal, quality assurance of appraisers, remediation, mediation, negotiation, investigation and rehabilitation, equality and diversity issues, dealing with colleagues about whom there is concern;
- Knowledge of regulation and the law as it relates to medical revalidation and of the specific underpinning processes. Understanding of principles of natural justice and the legal process, accountability and governance;
- Maintaining the knowledge and skills needed for the role, consistency, rigour and accountability;
- Strategic responsibilities of the RO, building and maintaining external relationships, accessing the organisation's resources; and
- Clinical governance, quality improvement and quality assurance of systems underpinning revalidation, information flows.

4.47 There is evidence that doctors from ethnic minorities are disproportionately represented in disciplinary procedures. It is important that responsible officers have a high level of understanding of equality and diversity issues to enable them to ensure that the organisation's systems and processes do not discriminate against any individual doctor or group of doctors (see section 6).

Education and support

4.48 Every responsible officer will need to undergo initial and on-going education, assessment and support. Initial educational interventions will vary in scale and scope according to the needs of the individual and the context within which each operates. There may be significant differences in terms of needs between those who have been in medical director positions in large complex organisations for many years, with a wide range of experience and a well-developed medical management infrastructure, as opposed to those who are taking on the role in an organisation with a developing medical management infrastructure and less experience of management or clinical governance.

4.49 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 competencies. 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.

4.50 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

4.51 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.

4.52 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 (see section 6).

4.53 Every responsible officer must be a senior, licensed doctor and, as such, will be professionally accountable to the GMC for his or her ethics and decision-making. Influence by conflicts of interest represents a breach of the standards set out in *Good Medical Practice*.

Section 5. Guidance for Healthcare Organisations

The duty to nominate or appoint a responsible officer

5.1 Regulation 5 requires that designated bodies nominate or appoint a responsible officer. The bodies that are being designated can be considered as either organisations that provide healthcare or those that have a role in setting the policy or standards for healthcare.

5.2 Some organisations always employ or contract with doctors and have been designated unconditionally, others will only have to nominate or appoint a responsible officer when they employ or contract with doctors that have a connection with them (see Figure 2 on page 13). Some bodies may find that they do not need to nominate or appoint a responsible officer because the doctors they employ have connections with other organisations, for example, an out of hours provider of healthcare whose doctors are all on a Performers List.

5.3 If there is any doubt about whether your organisation is a designated body you should seek legal advice.

5.4 Unconditionally designated bodies include:
- NHS Trusts and Foundation Trusts;
- PCTs in England;
- Local Health Boards in Wales;
- Health Boards in Scotland; and
- Strategic Health Authorities in England.

5.5 Bodies that only have to nominate or appoint a responsible officer if they employ or contract with licensed doctors include:
- other providers of healthcare services;
- government departments and other government bodies;
- NHS Professionals Ltd. and locum agencies which are participants in the NHS PASA framework agreement for the supply of medical locums;
- Special Health Authorities;
- Special Health Boards in Scotland;
- The Common Services Agency in Scotland;
- Providers of independent healthcare services as defined in the Regulation of Care (Scotland) Act 2001;
- Royal Colleges; and
- the GMC.

5.6 In addition, the following organisations are also designated to provide responsible officer services to their members who are not connected to any other designated body:
- Faculty of Public Health;
- Faculty of Occupational Health;
- Faculty of Pharmaceutical Medicine; and
- Independent Doctors Federation.

Resourcing responsible officers

5.7 The regulations require designated bodies to provide the responsible officer with sufficient funds and other resources to discharge their duties. In England this applies to all responsible officers' statutory functions, including the additional (clinical governance) responsibilities under Regulations 14 and 19. In Wales and Scotland this applies only to the statutory functions relating to the evaluation of fitness to practise under Regulation 14.

5.8 It is crucial that responsible officers are supported at the appropriate level in order for them to fulfil their role of improving the quality of care across all its dimensions, including patient safety. In the majority of organisations, the responsible officer will be employed by the same healthcare organisation as that which employs the doctors for whom he or she is responsible.

Alternative arrangements

5.9 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 body or appropriate person to provide the responsible officer function. Regulations 14 and 19 require designated bodies to provide the responsible officer with funds and other resources to carry out their statutory duties.

5.10 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 cost of providing the service.

5.11 There are particular resource issues involved with the provision of remediation, re-skilling and rehabilitation. In alignment with NCAS guidance outlined in *Back on Track*[18], for doctors who are in a contractual relationship with an NHS healthcare organisation, the agreed remediation action plan should set out the relative contribution of each party towards the costs. For example in primary care the contribution of the PCO, the practice and the doctor. Where an organisation is providing its services to another organisation or to an individual doctor, it would be up to the organisations and/or the individual concerned to agree the best way of meeting these costs; for example by paying the costs directly to the supplier or for the provider to pay the supplier and then to claim the costs in full.

5.12 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.

5.13 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

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

assessment of the individual's competencies. Initially in England, and certainly in Scotland and Wales, we anticipate that organisations will want to nominate an existing senior doctor such as the Medical Director. In such cases, we expect that doctors will have been appointed to their post through an open competitive process.

5.14 The employing organisation will want to ensure that, on nomination or appointment to the responsible officer role, the responsible officer has the competencies set out in paragraph 4.45. The competencies of the responsible officer against an agreed and transparent set of standards must be reviewed on a regular basis, as part of his or her appraisal process. The responsible officer's appraisal process could include review by another responsible officer from a similar organisation, or by a clinical or academic colleague, with any recommendation arising from the evaluation of fitness to practise being made by the responsible officer's responsible officer.

5.15 Organisations will have to ensure that the responsible officer is properly developed and supported by education, skills training and personal development opportunities. The organisation should ensure that the responsible officer takes part in a peer network to ensure sharing of learning, challenge and support in tackling new situations. Although much of the role of the responsible officer is already undertaken by medical directors there will be a learning curve and employing organisations must ensure that they are as well supported and developed as possible.

5.16 The effectiveness of the responsible officer will necessitate timely access to the appropriate information. This means that the employing organisation will have to ensure that information systems underpinning the clinical elements of corporate governance and any other relevant processes (for example multi-source feedback) are properly resourced and functioning. Much of the data will already be held on systems of clinical governance and the task will be mainly one of collation. It is essential that the staff charged with the responsibility of inputting or collating sensitive data concerning individual clinician's performance are of high calibre, have credibility in the organisation, understand the absolute need for security of the information, are well trained and are regularly assessed. They will also be able to understand when patient identifiable information is used and ensure that it has explicit patient consent or is anonymised. They will be expected to work very closely with both those collecting the data and those using it.

5.17 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.

5.18 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 Medical 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.

Section 6. Checks and Balances

Responsible Officers

6.1 Responsible officers, as licensed doctors, will be supported and have their own fitness to practise confirmed by a responsible officer outside their own organisation (see Section 3). Assessment of fitness to practise will include how a doctor carries out his/her role as a responsible officer.

6.2 Responsible officers must be able to demonstrate that all associated governance systems are functioning effectively. For example, the responsible officer must ensure that the appraisal system is appropriately monitored and that a system of multi-source peer and patient feedback as part of the appraisal is in place and functioning effectively. In the event of concerns about the outputs from the appraisal process, there should be a clear procedure in place for these to be raised, either prior to outputs being forwarded to the responsible officer or, if this fails, following submission. It is important to ensure that all processes underpinning the responsible officer's decision-making have safeguards for patients and doctors, and include provision for comments from the doctor to be sought and taken into account.

6.3 In cases where a responsible officer is unable to make a recommendation that the doctor is fit to practise, this is likely to be as a consequence of concerns being raised about a doctor through the appraisal process and/or other local clinical governance processes. In the unlikely event that a responsible officer decides not to make a recommendation of fitness to practise, **and where no relevant concerns have been raised through the appropriate processes**, the doctor should be able to ask the responsible officer's own responsible officer (for example in England the SHA Medical Director) to review the decision not to make a recommendation.

Designated bodies

6.4 It is the organisation's responsibility to ensure proper governance of the process, challenging the responsible officer appropriately to ensure that a recommendation of fitness to practise is based on appropriate supporting information. Responsible officers will themselves want to be sure that they practise their responsible officer role with consistency and, to this end, responsible officer "networks" and other coaching or "buddying" arrangements should be considered.

6.5 It is emphasised that where there is justified cause for concern about a doctor's fitness to practise which cannot be managed through remediation processes, the role of the responsible officer is limited to drawing the case to the attention of the GMC and to ensuring that the necessary supporting information is available. Final decisions which may affect the ability of the doctor to continue in practice will remain, as at present, the sole responsibility of the GMC.

Conflicts of interest or appearance of bias (Regulation 6)

6.6 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 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.

6.7 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.

6.8 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 (for example the appropriate SHA Medical Director in England, or in Wales the Medical Director of NHS Wales and in Scotland, the Chief Medical Officer) and the decision should be recorded in writing.

Equality

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

GMC Audit

6.10 The GMC will need to be confident that the recommendations they receive are robust, fair and consistently applied. Both the processes leading to the recommendations and the recommendations themselves will, once revalidation is in place, therefore be subject to quality assurance by the GMC.

Section 7. The Document and Further Information

7.1 This document sets out the background to the role of the responsible officer and describes the context of measures that are aimed at improving the quality of care for patients and the confidence the public has in doctors. It also explains how the legislation applies to different parts of the United Kingdom and how the system of responsible officer will work.

7.2 If you require further information relating to the context of this document it can be found at:

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

Alternatively you can contact:

In England: The Clinical Governance Team, Room 423, Wellington House, 133-155 Waterloo Road, London SE1 8UG, Tel 0207 972 1323 or by e-mail to responsibleofficer@dh.gsi.gov.uk

In Wales: Workforce & Organisational Development Division, HSSDG, Welsh Assembly Government Tel:029 2082 3487

Section 8. Frequently Asked Questions on the Role of the Responsible Officer

Logistics

Q: When will the first responsible officers be in place?
A: Subject to Parliament approving the regulations, designated organisations will be required to nominate or appoint responsible officers in January 2011.

Q: How did you decide which organisations to designate?
A: In considering which organisations should be designated in the regulations, we have considered the risks to patient safety and public protection. The designated organisations are those that deliver healthcare and organisations with a role in setting policy and standards for the delivery of healthcare.

Q: I have a connection to more than one designated body - can I choose between my responsible officers?
A: No. The regulations set out the hierarchy that decide which responsible officer you relate to.

Q: How will some Deans in England and Wales who may not have been in active clinical practice for 5 years act as a responsible officer for trainees?
A: The designated connection is between a doctor and a designated body. A doctor in training is connected to the postgraduate medical deanery that manages his/her training programme. The postgraduate medical deanery will nominate or appoint a responsible officer for their organisation in line with the regulations.

Q: What happens if I move to another organisation or if the balance of my work changes?
A: On moving or changing the balance of work, the doctor should inform their appropriate responsible officer of the change.

Q: What are the arrangements for clinical academics?
A: Doctors working in academic roles will relate to the NHS organisation in which they work.

The Role

Q: What will be the role of responsible officers?
A: The Medical Act 1983 (as amended by the Health and Social Care Act 2008) enables regulations to provide for the responsible officer to be given duties that include the evaluation of fitness to practise. The Health and Social Care Act 2008 also enables regulations to provide for the monitoring of the conduct and performance of doctors. Responsible officers will also liaise with the GMC over fitness to practise procedures.

Q: Who will be expected to take on the role of responsible officer?
A: The responsible officer will be a licensed senior doctor in a healthcare organisation, who takes personal responsibility for those aspects of the local clinical governance systems which deal with the performance and conduct of doctors. He/she must be fully involved in local clinical governance arrangements, able to understand the medical issues involved in issues of

professional competencies and conduct, and with the authority to make changes wherever necessary including changes in the wider systems. In many cases, particularly in the NHS, it will be appropriate for it to be a medical director or equivalent, but we are not being prescriptive that it has to be a medical director**.**

Q: What is the line of accountability?
A: The core role of the responsible officer is to ensure those aspects of the local clinical governance arrangements that relate to the conduct and performance of doctors. They will therefore be accountable to the board of the healthcare organisation (or organisations) to which they provide responsible officer services. Clearly, responsible officers will need to work very closely with the GMC over issues relating to the evalution of fitness to practise of individual doctors. However, the responsible officer has a line of professional accountbility to the GMC for the recommendations.

Q: What will responsible officers need in the way of indemnity?
A: The GMC recommends that all doctors have indemnity appropriate to the work they do. The responsible officer is a doctor and should be indemnified in the same way.

Q: I am a medical director with three clinical sessions. If I am appointed as the responsible officer, will I be able to continue my clinical work – and who will be my responsible officer?
A: There is no technical or legal reason why a responsible officer cannot continue to work clinically, providing that there is a robust medical management infrastructure supporting him or her and that there is sufficient delegation of duties to enable both the roles to be delivered to a high standard. The responsible officer's responsible officer will be the SHA Medical Director in England, who will need to receive supporting information from the individual's management role as responsible officer and also from all clinical activity.

Responsible Officer Decision-making

Q: How will the responsible officer know whether the information presented by the doctor accurately represents all their clinical activity?
A: It is the doctor's responsibility to list all the areas in which they work clinically and to provide appropriate information about each area. Failure to do so will give rise to concern and be a breach of probity.

Q: Will responsible officers have the right to analyse individual appraisees' information or just appraiser summaries?
A: The responsible officer will have to be able to see all the relevant information needed to form a judgement about a doctor's fitness to practise.

Q: What happens if there is a concern about a colleague at appraisal – does the appraiser deal with this or is the doctor referred to the responsible officer at this stage?
A: If a doctor gives rise to serious concern at appraisal and leads the appaiser to believe that the doctor poses a risk to patient safety, the appraiser will, as they do now, stop the appraisal and refer to the investigative processes of GMC, informing the responsible officer.

Q: If there are concerns about a doctor who may need to undergo remediation, what happens to the status of that doctor's licence to practise while this is being undertaken?

A: The doctor remains licensed to practise througout the remediation process. A doctor's licence can only be removed by the GMC.

The Organisation's Reponsiblilties

Q: What is the likely cost for implementing responsible officers?
A: We have outlined the likely financial impact for the implementation of this policy in the responsible officer impact assessment. It is estimated that there will be around 975 responsible officers across England, Scotland and Wales. It is expected that these will be existing staff, such as Medical Directors, and many of their functions are those that should already be carried out in most organisations.

We estimate that in the first year the total cost will be £26.8m. Thereafter, we estimate that the total average annual cost will be £22m but it is worth noting that these estimates are of economic impact and include (non-financial) opportunity costs.

Q: Will additional funding be provided to the NHS for responsible officers?
A: NHS organisations will be expected to meet the costs of responsible officers out of the additional resources that have been provided. Where a responsible officer is employed by another organisation or has responsibilities for individuals outside their own organisation, those organisations or individual doctors may be required to contribute to the cost of providing the responsible officer.

Q: How can the responsible officer make recommendations about doctors' fitness to practise if the clinical governance systems in the organisations are not robust?
A: It is the responsibility of the organisation to resource and put in place effective, robust systems of clinical governance. The responsible officer must ensure that these systems are functioning and that they are effective.