Department of
Health, Social Services and Public Safety
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AN ROINN
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

MÄNNYSTRIE O
Poustie, Resydènter Heisin an Fowk Siccar

Confidence in Care

Responsible Officers Consultation

4th December 2009

Contents

CHAPTER ONE

Introduction

The consultation

1.1 It has been decided that, following a previous public consultation across the UK on the roles and responsibilities of the responsible officer, this consultation will run for a period of 9 weeks. The consultation period will run from **4th December 2009** and will close on 5th **February 2010**. Details of how to respond to the consultation are set out in Chapter Four.

1.2 This Chapter reviews the background and the rationale for the responsible officer proposals; describes how they link to the broader programme of reform of professional regulation in healthcare; and sets out the proposed legal basis for implementation through regulations to be made under provisions in the Health and Social Care Act 2008 ("the 2008 Act").

1.3 Chapter Two discusses key aspects of the draft regulations (published alongside this consultation) in the context of the response to the previous consultation.

1.4 Chapter Three introduces the statutory guidance, what it aims to achieve and seeks views on the document.

Background

1.5 The role of managers, both medical and non-medical, and systems in healthcare is to provide the best possible environment in which clinical professionals of all disciplines can deliver high quality, effective and safe, care to patients. It is acknowledged that the vast majority of doctors are competent and conscientious. However, after a series of high profile cases where the required professional standards were not met, proposals were made for a system of revalidation for every doctor. The purpose of revalidation, when it is introduced, is to ensure that licensed doctors remain up to date and continue to be fit to practise. Revalidation will have three main aims:

- To confirm that licensed doctors practise in accordance with the General Medical Council's (GMC's) generic standards (relicensure);
- For doctors on the specialist register and General Practitioner (GP) register, to confirm that they meet the standards appropriate for their speciality or general practice (recertification); and
- To identify for further investigation, and remediation, poor practice where local systems are either not robust enough to do this or do not exist.

1.6 Proposals for a major reform in the regulation of the medical profession were first set out in *Good doctors, safer patients*[1]. The development of the responsible officer role is part of the programme of reform set out in the White

[1] *Good doctor, safer patients* (Department of Health, July 2006)

Paper *Trust, Assurance and Safety*[2]. That programme seeks to build on the professionalism and dedicated people who work in healthcare. It seeks to raise the already high standards of the overwhelming majority of professionals, whilst ensuring that the small number of individuals who are not able to meet those standards are swiftly identified and concerns dealt with fairly and effectively and, where appropriate, individuals are supported to get back on track.

1.7 The Department of Health (DH) in England undertook a UK-wide public consultation, on behalf of the 4 UK health departments, on the role of the responsible officer[3] from July to October 2008. DH published the response[4] to that consultation on 5 May 2009.

1.8 The public, the profession and the health and social care (HSC) sector have the right to be assured that licensed doctors are fit to practise. These new regulations are designed to help doctors, and the organisations where they work, to further improve the quality of care provided to patients.

How the responsible officer fits into the wider reform of medical regulation

1.9 Two key concepts underpin the proposed reform of medical regulation:

- a more effective liaison between local healthcare organisations and the GMC through the new roles of responsible officer and, where they are in place, GMC affiliates; and
- robust implementation of medical revalidation.

1.10 *Liaison between local healthcare organisations and the GMC*. When concerns are raised over the conduct, performance or health of a doctor, the initial responsibility for action to protect patients usually lies with a local healthcare organisation or with an individual clinical team within the organisation. The need for swift local action to address these concerns, supported where appropriate by the National Patient Safety Agency's National Clinical Assessment Service (NCAS), is well recognised; there is good evidence that early identification of problems, with remediation (action to address the problem) and reskilling where appropriate, can both protect the safety of patients and help doctors to get their career back on track[5]. However, in a minority of cases further action is needed beyond the options available locally. The responsible officer will then need to consider referral to the GMC for possible action under the national "fitness to practise" processes, with a range

[2] *Trust Assurance and Safety – The Regulation of health professionals in the 21st Century* (The Stationery Office, February 2007).

[3] *Responsible officers and their duties relating to the medical profession* (Department of Health July 2008) http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_086443

[4] *The role of the responsible officer – response to consultation* (Department of Health May 2009) http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_098851

[5] See for instance *BACK ON TRACK Restoring doctors and dentists to safe professional practice Framework Document* (National Clinical Assessment Service October 2006) http://www.ncas.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=9418

of sanctions available including conditions on registration, suspension of registration and 'erasure' (removal from the register) as the ultimate sanction.

1.11 For these arrangements to work well, healthcare organisations need to have robust clinical and social care governance processes, and there needs to be close liaison in the more serious cases between local healthcare organisations and the GMC. The evidence presented in *Good doctors, safer patients* suggests that this close liaison does not always occur – a problem sometimes referred to as the "regulatory gap". The responsible officer will have a key role in the evaluation of the fitness to practise of doctors and in improving co-ordination with the GMC.

1.12 *Implementation of medical revalidation.* The concept of medical revalidation – a continuous process in which every practising doctor will have to demonstrate to the GMC that they are up to date and fit to practise and complying with the relevant professional standards – is not new and the legislative basis already exists. The White Paper, *Trust, Assurance and Safety* describes an approach to implementing medical revalidation involving two strands: "relicensing" (confirming that a doctor's practice is in accordance with the GMC's generic standards); and "recertification" (confirming that a doctor who is also on the specialist or GP register conforms to the relevant standards for those areas of practice). These two strands will be brought together into a single process using enhanced appraisal as the primary vehicle.

1.13 This model was reaffirmed in the report[6] of a working party chaired by England's Chief Medical Officer and including input from Northern Ireland. The Government believes that this model will achieve the original objectives of revalidation – to give assurance to patients that doctors remain fit to practise – without imposing an excessive burden on doctors. As the first stage in revalidation the GMC has issued licences to doctors on the register.

1.14 In this model, individual doctors will be responsible for maintaining a portfolio of evidence to demonstrate that they have continued to maintain their specialist skills. However, the responsible officer will be accountable for ensuring that local appraisal systems and other relevant evidence – for instance, evidence from investigations into concerns and patient safety incidents – are available to support evaluations of fitness to practise. In addition, it is envisaged that the responsible officer will take personal responsibility for the recommendations he or she will make to the GMC regarding the fitness to practise of individual doctors.

1.15 These 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 an appropriate healthcare organisation. The arrangements for revalidating the minority of doctors falling outside this framework are subject to further discussion and consideration and will be set out in due course.

[6] *Medical Revalidation – Principles and Next Steps: The Report of the Chief Medical Officer for England's Working Group* (Department of Health July 2008)

1.16 A minority of doctors may choose to maintain their registration with the GMC but allow their licence to practise – and with it certain legal privileges such as the right to prescribe – to lapse. Such doctors will not have a licence to renew and evaluations of their fitness to practise will not be undertaken.

1.17 It is important to stress that, in relation to fitness to practise, the role of the responsible officer is to make recommendations to the GMC and provide evidence to support these recommendations. Final decisions which could affect the ability of doctors to continue practising as doctors will remain, as at present, the sole responsibility of the GMC.

1.18 There is evidence of differences in the proportion of doctors who become involved in local and central disciplinary processes and in the eventual outcomes. These differences have been shown in relation to country of initial qualification as a doctor, ethnicity and gender. Although there is no detailed evidence and broader cultural and social factors may be in part responsible, we cannot rule out the possibility of some form of hidden discrimination in the way in which the current processes operate. The programme of reform to professional regulation, of which the responsible officer proposals form a key part, offers an opportunity to address these issues.

The legal basis

1.19 Provisions for responsible officers are set out in the Medical Act 1983, which was amended by the Health and Social Care Act 2008. Section 119 of the 2008 Act inserted a new Part 5A (including new sections 45A, 45B and 45C) into the 1983 Act, which applies in all parts of the UK. It sets out the framework for the functions of the responsible officer in relation to the evaluation of the fitness to practise of individual doctors (recommendations on revalidation and referrals to the GMC).

1.20 Section 120 of the 2008 Act, which applies to Northern Ireland, allows the appropriate authority to give responsible officers additional functions in relation to clinical and social care governance (for example, relating to systems for the recruitment of doctors). Both Part 5A of the Medical Act and section 120 of the 2008 Act enable specific details to be set out in secondary legislation (regulations). This Department (Department of Health, Social Services and Public Safety) will make regulations for Northern Ireland.

1.21 Therefore the regulations which are the subject of this consultation contain provisions on responsible officers under Part 5A of the Medical Act and under section 120 of the 2008 Act.

CHAPTER TWO - REGULATIONS

2.1 As yet the rules that will set out the processes for the revalidation of doctors have not been established. These regulations are therefore framed in the wider context of evaluating the fitness to practise of doctors.

Organisations required to nominate or appoint responsible officers (regulation 2)

2.2 Doctors registered with the GMC work in a wide variety of settings and ways. While most doctors work in HSC, many also work in other organisations. Some doctors work entirely outside the HSC, while others choose to work as locum doctors filling in as and when needed. Some doctors work outside clinical settings, for example in insurance companies and law firms, but have retained registration. These doctors may also choose to be issued with a licence to practise medicine. The GMC has recently began to issue licences to members.

2.3 The response to the consultation on the role of the responsible officer stated that the proposal is to designate in regulations the widest range of organisations that employ or contract with doctors. The draft regulations seek to put this into practice to ensure that responsible officers are in all settings where that approach is necessary and appropriate. There are three broad categories of organisations that we propose to designate in the regulations:

- Key organisations, including HSC Trusts and other agencies, that employ or contract with doctors to provide healthcare are covered in regulation 2(2);
- Other organisations with a role in the provision of services that affect the treatment of individual patients – but only if they employ or contract with doctors are covered in regulation 2(3)
- a range of organisations that do not treat patients but which provide advice or make decisions that affect large numbers of patients. This range includes other Northern Ireland Departments and non-departmental public bodies. Not all of these organisations employ doctors, but where they do we are proposing that they nominate or appoint a responsible officer. These are also included in regulation 2(3).

2.4 Not all doctors are employed or contract with healthcare organisations. Some work outside organisational structures treating patients in either their own practices or in other settings e.g. sports clubs. For these doctors we are in discussion with the relevant professional societies such as the Independent Doctors Federation and the Faculty of Occupational Health about providing a responsible officer. These organisations already provide access to appraisal and will help to support underperforming doctors to bring them back on track. We have therefore designated them in the draft regulation 2(3) to provide the responsible officer for their members that work independently and are not employed.

2.5 Other doctors contract through locum agencies to provide healthcare services. Many locum doctors have portfolio careers and are employed for only some of their time. 65% of respondents to the consultation on the role of the responsible officer agreed that locum agencies should be designated organisations, subject to their demonstrating good clinical and social care governance systems. These will ensure thorough checks are carried out on a doctor's qualification and suitability for any placement, that they are appraised and that when concerns are identified appropriate action is taken to protect patients. Whilst it is still our intention that appropriate locum agencies should be designated and have their own responsible officers, we are still in discussion with relevant stakeholders regarding the best way of assessing their clinical and social care governance systems. We have therefore not designated locum agencies in these draft regulations. Once we have resolved the issues about clinical and social care governance we intend to bring locum agencies within the regulations.

2.6 In setting out the designation of bodies in the way proposed, we think we have ensured 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 include doctors working in law firms, universities, research companies and insurance companies. We do not believe that it would be either practical or appropriate to designate these types of organisations in the regulations. There will also be other doctors, including those on career breaks and those working for non UK organisations overseas, that will not be linked to a responsible officer. The arrangements for confirming the fitness to practise of these doctors are subject to further discussion with stakeholders and possibly piloting. The Department and the GMC will therefore bring forward proposals in relation to these doctors at a later date.

Q1 Do you agree that regulation 2 designates all those organisations that need to have a responsible officer?

Q2 if you answered NO to Q1 which other organisations should be designated?

<u>Duty to nominate or appoint responsible officers (regulation 3)</u>

2.7 While regulation 2 sets out the bodies that have to nominate or appoint a responsible officer, regulation 3 places the duty on them to do so. It also places a duty on them to fill a vacant post as quickly as possible, minimising the possibility that the evaluation of a doctor's fitness to practise will be unfairly affected.

Conflicts of interest

2.8 In developing proposals for the role of the responsible officer we have been aware of the potential for conflicts of interest that may impact on the way the role is performed. Conflicts may occur between:

- The doctor and the responsible officer; and
- The responsible officer and the organisation

2.9 Sometimes individuals come into conflict with each other over professional matters, sometimes the conflict occurs over personal issues. In these circumstances it may be difficult to retain an objective judgement. We do not think that it is right to put either the doctor or the responsible officer in a position whereby a conflict of interest could affect an evaluation of fitness to practise. Regulation 4 provides for organisations to nominate or appoint an alternative responsible officer where a genuine conflict of interest exists.

2.10 We are also aware of concerns that responsible officers may find they have a conflict between their professional responsibilities and the demands of the organisation. Such conflicts already exist for medical managers who, as doctors, are accountable to the GMC for their professional actions. We do not think it is appropriate to address these concerns through regulations.

Q3 Do you think regulation 4 provides sufficient safeguards in the event of a conflict of interest arising? If not, please explain what further measures should be considered.

Conditions for nomination or appointment of responsible officers (regulation 5)

2.11 In the consultation on the role of the responsible officer we asked whether responsible officers themselves should be required to have a licence to practise. 82% of those who responded were in favour of this proposal. It has since been suggested that responsible officers should instead have the option of having a licence. This is on the grounds that Medical Directors are likely to be nominated as responsible officers and some have no clinical element to their role.

2.12 The view has been expressed that the licensing of doctors with no clinical role is not in keeping with the principles of regulation and that this could lead to a situation where, for example, a medical manager undertaking no clinical work would be legally entitled to prescribe and issue death certificates. The alternate view, held by the GMC and DH, is that medical managers play an important role in ensuring the safety of patients and that they should, and will be able to provide evidence to demonstrate they are fit to practise.

2.13 After further consideration our view is that responsible officers should be medical practitioners licensed as fit to practise medicine and who themselves will be up to date in medical practice in order to be credible with the public and colleagues when considering a doctor's fitness to practise. We have therefore included this in draft regulation 5(a)

Q4 Do you agree that regulation 5 should requires responsible officers to have a license to practise?

Nomination or appointment of one person as responsible officer for two or more designated bodies (regulation 6)

2.14 The consultation on the role of the responsible officer, proposed that organisations could contract out the responsible officer function to other organisations that are required to have responsible officers if they feel that this option is more appropriate. Regulation 6 puts that into practice by allowing a responsible officer to be nominated or appointed for more than one body. Regulations 11 and 16 enable the transfer of resources to the employer of the responsible officer. In doing so, it requires both organisations to ensure that the responsible officer meets the requirements, that they will not be overburdened and that there are not likely to be any conflicts of interest in taking on the role.

Q5 In circumstances where the responsible officer acts for another body are additional criteria to those in regulation 6 needed?

Nomination of responsible officer by the Department (regulation 7)

2.15 Although the process we have outlined should ensure that every doctor can link appropriately to a responsible officer, there could, in theory, be cases where a designated organisation fails to nominate or appoint a responsible officer. There may be other occasions when a person proposed as the responsible officer does not meet the criteria set out in the regulations but the employer nominates or appoints that person as a responsible officer anyway.

2.16 In response to the consultation on the role of the responsible officer it was proposed to give power to the appropriate authority to nominate or appoint a responsible officer where a designated organisation:

- repeatedly refuses to nominate or appoint a responsible officer; or
- nominates or appoints a responsible officer who does not meet the criteria.

2.17 Regulation 7 enables the Department to step in to nominate a responsible officer, should these circumstances ever happen, so that doctors' fitness to practise status and their livelihood cannot be threatened by the unfair actions of their employer.

2.18 In N Ireland, medical directors in HSC organisations will be appointed as responsible officers. This power would effectively give the Department the power of appointment to senior posts in the HSC sector. We think it is extremely unlikely that this power will be used.

Responsibilities of a responsible officer (regulation 8)

2.19 Under Part 5A of the Medical Act 1983, the regulations will give functions for responsible officers in N Ireland that relate to the evaluation of fitness to practise. In practice these are the functions that support the regulation of doctors by the GMC.

2.20 We think that the functions fall into three areas:

- ensuring the organisation has systems in place to support the evaluation of conduct and performance, and in particular, revalidation when it is introduced;
- preparing evidence based recommendations to the GMC on the fitness to practise of doctors linked to the designated organisation; and
- ensuring that action is taken when concerns are raised by that evaluation.

Q6 Are the functions set out in regulation 8, relating to the evaluation of a doctor's fitness to practise, appropriate?

Q7 If you think there are other functions that should be specified please explain what they are?

2.21 The power to make regulations that give additional functions to responsible officers that relate to the monitoring of conduct and performance is given in section 120 of the 2008 Act.

2.22 To protect patients it is important that the evaluation of fitness to practise is supported by systems that ensure that doctors are managed and supported throughout their careers. The organisation needs to ensure that, where there are concerns about a doctor that fall below the level for referral to the GMC under fitness to practise procedures, the doctor is brought back on track as quickly as possible.

2.23 The following functions of the responsible officer relate to conduct and performance :

- initiating an appropriate investigation;
- arranging for further monitoring;
- considering the need to share information with other healthcare organisations directly through alert systems;
- considering the need for suspension or restrictions on practice;
- considering the potential for remediation or reskilling;
- initiating action in relation to wider systems issues; and
- referral to the police.

2.24 In some cases, the tasks underpinning these functions are carried out by different parts of the organisation. It is not intended that the tasks themselves should be moved, or that they should be carried out by the responsible officer. We draw a distinction between the tasks to be undertaken and accountability

for them in relation to doctors. In our view, the accountability for ensuring the systems are in place and working satisfactorily in relation to doctors should be with the responsible officer.

2.25 The functions listed in paragraph 2.24 were considered to be the most significant functions**.** The remainder of functions will be covered in guidance.

Q8 Do you agree that the functions of a responsible officer relating to conduct and performance set out in regulation 8 are appropriate?

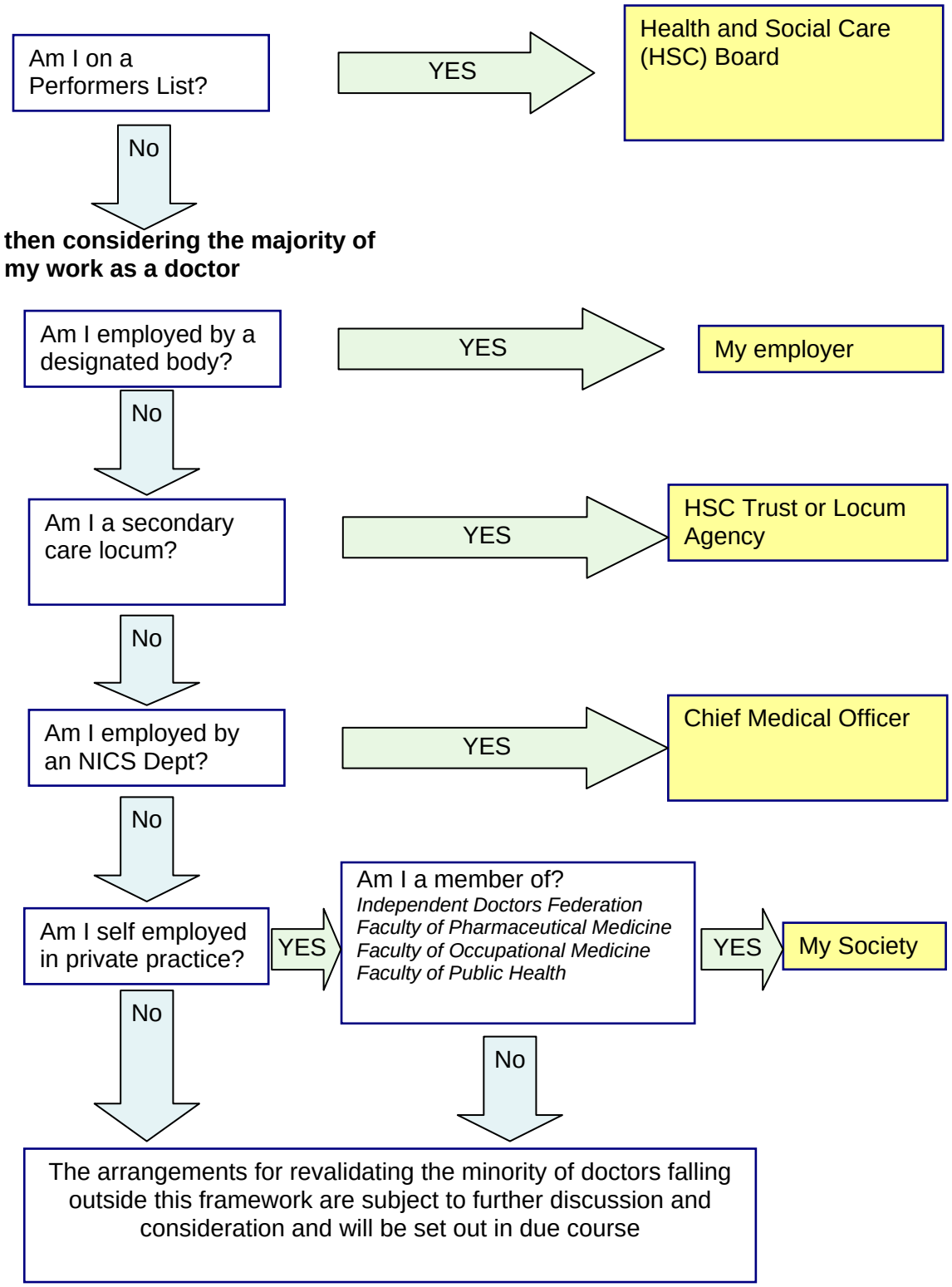
Q9 If you think there are other functions that should be specified please explain what they are.

Linking doctors with a responsible officer (regulations 9 and 10)

2.26 Regulation 3 designates the organisations that have to nominate or appoint a responsible officer. As already stated, doctors work in a wide variety of settings, some with portfolio careers encompassing a number of different roles and employers. Organisations need to know which doctors they are responsible for and doctors need to know who their responsible officer is. Regulation 9 sets out the connections between doctors and designated organisations. These reflect the key principles that a doctor should have only one responsible officer and that the organisation overseeing the majority of an individual doctor's work should be the one that the doctor is linked to. Regulation 10 establishes the connection between a responsible officer and their own responsible officer.

2.27 In the consultation on the role of the responsible officer, an illustration was included of how the links between doctors and responsible officers would be achieved. 87% of respondents thought that the proposed connections were appropriate. These linkages are illustrated in Figure 1 below.

Figure 1: Linking doctors to a responsible officer



2.28 To practise as a general practitioner in the HSC sector, a doctor, including a locum doctor, must be on the Primary Medical Services Performers List held by the Regional Business Services Organisation (RBSO). The Performers List system provides a framework within which the HSC can take action if a medical practitioner's personal and/or professional conduct, competence, performance or health gives cause for concern. The view, across the UK is that, a doctor on a Primary Medical Services Performers List should have a responsible officer in the primary care organisation (in this case the HSC Board) responsible for that list.

2.29 Regulation 9(1) also sets out the following connections:

- to the employer where a doctor is employed;
- a doctor providing services to patients at an independent hospital (i.e. the doctor has practising privileges) who is not linked to a responsible officer by the Performers List or employment;
- where the doctor is a member of a designated organisation and is not linked to a responsible officer by other means.

2.30 Many doctors practise medicine in a variety of settings, often with different roles. Some are employed by more than one organisation, others combine roles in hospitals with academic roles teaching or research. Other doctors that work in the HSC sector also have an independent practice. Regulation 9(2) sets out how the connection to a responsible officer will be made in such cases. The underlying principles of the *Confidence in Care* programme are to ensure that quality care is given to patients. With this in mind we have defined the principal criterion for deciding which responsible officer a doctor relates to as where they carry out the majority of their clinical work with patients.

2.31 The variations we have come across in the way doctors work suggest that in some cases it will not be possible to decide which responsible officer a doctor will relate to based on the majority of their clinical work.

2.32 In paragraph 2.5 we explained our intention to designate locum agencies once arrangements have been agreed regarding how the clinical and social care governance systems in these organisations will be assessed. We will set out the connection for these doctors at that time.

2.33 In paragraphs 2.11 – 2.14 we set out the arguments in support of the requirement for responsible officers to be licensed. We think that they should therefore also be linked to a responsible officer who will ensure they are subject to the same evidence based assessment as those they are responsible for. Regulation 10 sets out the hierarchy in order for this to happen.

2.34 Doctors in HSC Trusts, the Regional Agency for Public Health and Social Well-Being and Independent Hospitals will relate to the Medical Director of the relevant organisation as their responsible officer. The lead doctor in the HSC Board will act as responsible officer for all doctors fully employed by the HSC Board or employed for the majority of their time by the HSC Board.

2.35 General Practitioners will relate to the Assistant Director of General Medical Services in the HSC Board as their responsible officer.

2.36 For Doctors in the Northern Ireland Medical and Dental Training Agency (NIMDTA) the postgraduate dean will act as the responsible officer for all those doctors fully employed by NIMDTA or employed for the majority of their time by NIMDTA.

2.37 For Doctors working in the HSC Regulation and Quality Improvement Authority (RQIA) the Medical Director of RQIA will act as the responsible officer for all those doctors fully employed by RQIA or employed for the majority of their time by RQIA.

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

2.39 For Doctors in the Northern Ireland Medical and Dental Training Agency (NIMDTA) the postgraduate dean will act as the responsible officer for all those doctors fully employed by NIMDTA or employed for the majority of their time by NIMDTA. Doctors in Training are already subject to detailed assessment and performance review processes to meet the requirements of postgraduate medical training overseen by NIMDTA. It is proposed that NIMDTA, through the postgraduate dean, provide the responsible officer for doctors in training.

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

2.41 The responsible officer for locum doctors in secondary care is subject to ongoing work. Locum doctors in secondary care could relate to the responsible officer in the organisation where they deliver the greatest percentage of their clinical work. Alternatively, responsible officer responsibilities could fall directly to locum agencies who can demonstrate robust clinical and social care governance systems.

2.42 Providing the responsible officer role for responsible officers - 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.

2.43 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.

2.44 In Northern Ireland the individuals who will need to associate themselves with a responsible officer in another organisation are: -

- Trust Medical Directors;
- Medical Director of the Northern Ireland Blood Transfusion Service;
- The HSC Board's Assistant Director for General Medical Services;
- The Medical Director of the Regional Agency for Public Health and Social Well-Being;
- The postgraduate dean;
- The Medical Director of HSC RQIA; and
- The CMO.

The preferred arrangements are –

- for Trust responsible officers (Medical Directors) the Medical Director of the Regional Agency for Public Health and Social Well-Being will be the responsible officer;
- for the Medical Director of the Northern Ireland Blood Transfusion Service the Medical Director of the Regional Agency for Public Health and Social Well-Being will be the responsible officer;
- for the HSC Board's lead doctor, the Medical Director of the Regional Agency for Public Health and Social Well-Being will be the responsible officer;
- for the Medical Director of the Regional Agency for Public Health and Social Well-Being, the postgraduate dean and the Medical Director of HSC RQIA the CMO will be the responsible officer;
- for the CMO the Department will nominate an appropriate responsible officer for the CMO from outside the Department.

2.45 Many of the functions of a responsible officer relate to ensuring that their organisation has the systems in place to enable them to evaluate doctors' fitness to practise. Generally, those same systems will be used to collect information relating to the responsible officer. Therefore, the functions of the responsible officer's responsible officer will mainly be to ensure that those systems apply equally to the responsible officer. The key responsibility will be to make a recommendation on the responsible officer's fitness to practise.

Q10 Do you agree that regulation 9(1) sets out the appropriate connections for doctors?

Q11 Do you think regulation 9(2) enables doctors in designated organisations to be linked to an appropriate responsible officer regardless of their working pattern?

Q12 If the answer to either Q8 or Q9 is NO please explain?

Q13 In particular, do you think there are any other alternatives to using the doctor's registered address as a final report to decide?

Q14 Please comment on the appropriateness of the system set out in regulation 10 to manage the conduct and performance of responsible officers?

Other regulations

2.46 The remaining regulations relate to resourcing responsible officers, having regard to guidance and offences under the regulations. These areas apply to both the evaluation of fitness to practise and to the monitoring of conduct and performance.

Provision of resources (regulations 11 and 16)

2.47 The response to the consultation on the role of the responsible officer stated the intention to specify explicitly in Regulations each of the areas that should be resourced. Following further consideration, it has been decided that such an approach would not be appropriate and the intention is therefore to set a general duty on designated organisations to provide responsible officers with sufficient funds and other resources. The Department remains committed to ensuring that responsible officers have the necessary resources to ensure that the management of the conduct and performance of doctors is improved and that appropriate action is taken where there are concerns about a doctor. The N Ireland draft regulations reflect this position.

Duty to have regard to guidance (regulations 12 and 15)

2.48 As part of the consultation on the role of the responsible officer views were sought on whether there were key pieces of guidance from other organisations that responsible officers should take into account when undertaking their role. A large majority of respondents were of the view that responsible officers should have a statutory duty to take into account guidance from the GMC and the National Patient Safety Agency's National Clinical Assessment Service (NCAS).

2.49 In our view the guidance that relates to the evaluation of fitness to practise is issued by the GMC and we have specified that it must be taken into account in regulation 12. We think that the guidance issued by NCAS is relevant to the management of underperforming doctors in a wider sense than purely fitness to practise and have set the requirement for it to be taken into account in regulation 15.

Offences (regulations 13 and 17)

2.50 The intention has always been that these offences should be aimed at organisations rather than individuals and this is reflected in the draft regulations. This is to ensure that doctors' livelihoods are not put in jeopardy

because they are prevented from being linked to a responsible officer or because they are not given the appropriate support.

2.51 Both regulations 13 and 17 create offences where a designated body fails to provide resources for a responsible officer or a responsible officer is prevented from carrying out their statutory duties. In addition regulation 13 creates an offence where there is a failure to nominate or appoint a responsible officer.

2.52 Consideration was given as to whether to create an offence by preventing a doctor from being linked to a responsible officer. This has been considered unnecessary as the connection is set out in the regulations and cannot be prevented.

Q15 Please comment on the extent to which regulations 11-13 achieve the policy objectives set out in the previous consultation paper on the role of the responsible officer.

CHAPTER THREE - GUIDANCE

Purpose of the guidance

3.1 The powers in the Medical Act 1983 and the Health and Social Care Act 2008 enable the appropriate authority to require designated bodies and responsible officers to have regard to guidance on the nomination or appointment of responsible officers and the role and responsibilities of responsible officers. The draft guidance relates to N Ireland only. Separate regulations are being taken forward by the Department of Health in England for England, Scotland and Wales. It is intended to provide practical guidance to responsible officers for their evaluation of doctors' fitness to practise and also their statutory clinical and social care governance role and through them to all those who have a role in the management of the conduct and performance of doctors.

3.2 The guidance has been produced for consultation by the Department as part of the programme of reform to professional regulation, *Confidence in Care*. In developing the guidance, the Department has drawn on the expertise of those practitioners involved in the programme's workstreams on revalidation and tackling concerns.

3.3 You are asked to read the draft guidance and comment on the content, structure, style and layout of the document. Your input will help shape the guidance and ensure it is both relevant and appropriate to the needs of responsible officers, their organisations and the doctors that relate to them.

Q16 Please comment on the content, structure, layout and 'useability' of the draft guidance. Comments on the guidance can be submitted either as track changes or clearly annotated with paragraph numbers.

CHAPTER FOUR

Responding to the consultation

The consultation runs from **4th December 2009** and will close on **5th February 2010.**

You can respond to this consultation on the web at

www.dhsspsni.gov.uk/liveconsultations or in writing.

Responding on the web

If you wish to respond online the questionnaire can be found at:

www.dhsspsni.gov.uk/liveconsultations

The online questionnaire will be available from Friday 4th December**:**

Responding by e-mail or in writing

If you wish to respond by e-mail please use the consultation questionnaire. Once it is completed please e-mail to:

ruth.hutchison@dhsspsni.gov.uk

If you wish to respond in writing it would be helpful if you could do so by completing the consultation questionnaire form and sending it to the address below. If you do not want to use the consultation response form or are unable to do so, then please write with your answers and comments to the address below.

Consultation on responsible officer regulations
Ruth Hutchison
Programme Support Officer
Confidence in Care Programme
Room 12, Annex 2, Castle Buildings
Belfast BT4 3SQ

If you have any complaints or comments about the consultation process (but not responses to the consultation itself), please send them to:

Consultation Coordinator
Department of Health, Social Services and Public Safety
Room 12
Annex 2
Castle Buildings
Stormont
Belfast
BT4 3SQ

Please do not send consultation responses to this address

Summary of the consultation

A summary of the response to this consultation will be made available within three months of the end of the live consultation period and will be placed on the Consultations website at

http://www.dhsspsni.gov.uk/en/Consultations/Responsestoconsultations/index.htm”

Freedom of Information

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000, the Data Protection Act 1998 and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.