



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 The Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010

Public Consultation Results and Departmental Response

April 2010

Background

On 4th December 2009, the Department launched a consultation on the content of the Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010. The consultation ended on 5th February 2010. This report provides an analysis of responses to the consultation and outlines the way forward.

In total, 19 responses were received, 13 in questionnaire format and 6 free format responses. All responses were on behalf of organisations and the full list of respondents is provided at Appendix A. Respondents are categorized as follows: -

Health and Social Care providers/commissioners	8 responses
Professional organisations	6 responses
Educational/regulatory organisations	3 responses
Non-health organisations	2 responses

Appendix B contains a list of the members of the *Confidence in Care* workstreams who contributed to the formulation of policy in relation to the responsible officer role in N Ireland and who have provided substantial input into the model for the medical profession here.

These regulations are subject to draft affirmative resolution. Appendix C outlines the next steps in terms of the legislative process.

The Department would like to thank all of the participants in this process for their time and assistance. Generally feedback has been supportive of the proposals.

Background

Proposals for a major reform in the regulation of the medical profession were first set out in *Good doctors, safer patients*. The development of the responsible officer role is part of the programme of reform set out in the White Paper *Trust, Assurance and Safety*. This programme seeks to build on the professionalism of 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 numbers 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.

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

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, fit to practise and complying with the relevant professional standards – is not new and the legislative basis already exists. The Department of Health, Social Services and Public Safety (the Department) believes that this model will achieve the original objectives of revalidation namely 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.

The responsible officer will be accountable for ensuring that local appraisal systems, and other relevant supporting information, will be 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. For these arrangements to work well, healthcare organisations need to have robust clinical and social care governance processes.

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. 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. 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.

The legal basis

Provisions for responsible officers are set out in the Medical Act 1983 (Medical Act), which was amended by the Health and Social Care Act 2008 (2008 Act). 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).

Section 120 of the 2008 Act allows the appropriate authority to give responsible officers additional functions in relation to clinical and social care governance (for example, relating to systems for investigating concerns). 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). The Department will make Regulations for Northern Ireland.

Therefore the Regulations which were 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.

Main issues raised by the consultation

- Need for clearer definition of conflict of interest and mechanism for appeal in cases of conflict;
- Concerns over the proposed arrangements to determine the responsible officer for responsible officers; and
- Outstanding issue of RO model for secondary care locums.

Consultation feedback

The report follows the questionnaire structure. A short piece of explanatory text sets out the context for the subsequent questions. Only comments which suggest changes to the legislation or highlight issues to be addressed have been included in this report.

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

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.

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

Yes	9	69%	No	2	17%	Did not respond	2	17%
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Comments received

Two thirds of responses were positive with comments such as -
“it is important that all doctors have the opportunity to relate to an appropriate responsible officer for the purposes of revalidation and that mechanisms are in place as soon as possible to support this so that these relationships can be established.”

Educational/regulatory organisation

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

Comments received

“While regulation 3(3) designates clinics/residential accommodation treating alcohol/drug misuse, this does not seem to be extended to include those similar clinics treating persons with eating disorders.”

Professional organisation

“We are satisfied that the proposed designation of organisations will enable the vast majority of doctors to link with an RO. However, as the consultation acknowledges, there remain unresolved questions about how this will work for certain groups.These doctors need to be supported in meeting the requirements of revalidation and the regulations must therefore facilitate their link with an appropriate RO.”

Educational/regulatory organisation

DHSSPS Position

The legislation, as drafted, covers the majority of doctors who will need to link with an RO and it is therefore felt the position is adequately covered.

ACTION While it is not practicable or appropriate to designate all organisations, the list of designated bodies has been reviewed in light of the comments made during consultation. We consider that the list, which is now a Schedule to the draft Regulations, provides a comprehensive description of the majority of bodies which licensed doctors would hold contracts with, be employed by, or be associated with.

Duty to nominate or appoint additional responsible officers in cases of conflicts of interest (regulation 4)

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

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.

Yes 7 54% **No** 5 38% **Unsure** 1 8%

Comments received

Just over half the respondents felt sufficient safeguards are being provided in the event of a conflict of interest arising. Comments about what further measures should be provided included -

“Consideration could be given to having the second responsible officer from outside the organisation. This could be a responsible officer of another designated body if the conditions are met as set out in regulation 6.”

Educational/regulatory organisation

“One option would be an appeal process to the GMC. It should be agreed that patient safety overrides loyalty or responsibility to an organisation. More guidance on this area would be welcomed.”

Professional organisation

“Although Regulation 4 provides for another responsible officer to be appointed in the event of a conflict of interest, there is no definition of such a “conflict of interest”. As we suspect that conflicts will arise more often than anticipated, we recommend the guidance should be more robust and detailed as to how conflict will be minimised and addressed, to prevent legal challenges.

Professional organisation

DHSSPS Position

In the consultation, we explained that we are aware of the potential for conflicts of interest arising between the responsible officer and either the doctor, or the organisation. A conflict of interest should not affect the evaluation of fitness to practise. The draft Regulations have provided for organisations to nominate or appoint a second responsible officer where a conflict of interest existed.

One theme of a number of responses to the consultation was that the safeguards provided in the draft Regulations were insufficient. There was a view that organisations would have too much power to deny that a conflict of interest existed.

ACTION We have recognised the concerns raised by respondents and, in order to address the issue, we have amended the Regulations to allow for an “appearance of bias” to also be a cause for nominating or appointing a second responsible officer. The guidance document will also be strengthened to give more clarity on this issue and will include examples of where a conflict of interest or appearance of bias may occur. The guidance document will also stress the important role designated organisations need to play in ensuring proper governance of the process.

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

It is our view 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.

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

Yes	12	100%	No	0	0%
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Comments Received

All who responded to the consultation were in support of responsible officers having a license to practise.

DHSSPS Position

By definition, the responsible officer will almost certainly not be in clinical practice. It is clear from the wider consultation conducted by the Department of Health in England on the UK wide policy that the full breadth of medical practice had to be encompassed in the responsible officer role.

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

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.

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

Comments Received

“There is a need to formalise the arrangements between one organisation offering RO services for another, perhaps through a memorandum of understanding. We would suggest that a model memorandum of understanding might be helpful in this regard. Further clarity on the relationship between the RO (who is likely to be NHS-based) and the higher education sector employers of clinical academics would also be helpful.”

Professional organisation

“No, as the responsible officer will need to have the capacity to carry out the full responsibilities as designated in Regulation 8.”

Educational/regulatory organisation

DHSSPS Position

This issue will not require any change to the draft Regulations but the issues raised will be covered in the associated guidance.

Functions of a responsible officer (regulation 8)

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.

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

Yes 10 83% No 2 17%

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

Comments Received

“It is not clear however how an RO would assess the work of a doctor that was undertaken in the private sector. Clarification on regulation 8.2b would be helpful as it seems to give ROs the power to investigate a doctor’s practice in the private sector. If that is the case, there would need to be an appropriate understanding and/or agreement with the private sector.”

Professional organisation

“We consider the functions in Regulation 8 are inappropriate as they will lead to a huge volume of work for the responsible officer, particularly bearing in mind that junior doctors and locums move around quite frequently.”

Professional organisation

DHSSPS Position

Private health care organisations are designated under regulation 2. The focus of the White Paper *Trust Assurance and Safety* was on greater transparency and having good governance systems in place.

In the guidance document it clearly states that the regulation of doctors is, and will remain, a matter for the GMC who are responsible for setting the standards of practice for medical practitioners.

ACTION The draft Regulations have been amended to clarify that the responsible officer is responsible for monitoring compliance.

Responsibilities of responsible officers

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. In some cases, the tasks underpinning the conduct and performance 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.

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

Yes 9 90% No 1 10%

Comments Received

Almost all agreed that the functions set out in regulation 8 were appropriate.

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

Comments Received

“There is no explicit mention of the need to ensure that there are robust systems of clinical governance to support doctors in demonstrating that they are fit to practise so as to meet the requirements of revalidation (although regulation 14(2) hints at this). As we outline at the beginning of our consultation response, this emphasis is unhelpful because it implies that the principal function of the RO is to root out poor practice rather than the wider purpose of contributing to the quality agenda by supporting good practice.”

Educational/regulatory organisation

DHSSPS Position

The requirements for fitness to practise are clearly defined by the regulator, the GMC and many of the governance systems are already in place.

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

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.

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

Yes 9 75% No 2 17% Unsure 1 8%

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?

Yes 10 83% No 2 17%

Q12 If the answer to either Q10 or Q11 is NO please explain?

Comments Received

“Currently, Regulation 9(1) appears incomplete as it does not accommodate, for example, academic doctors who are employed by universities and who hold an honorary contract with an NHS organisation. This is to some extent recognised in the guidance at paragraph 3.3.15. Whilst the DH/GMC proposals may be brought forward at a later date, this could potentially leave a cohort of doctors out of cycle regarding revalidation with other doctors in the same clinical team.”

Professional organisation

“The underlying principle governing the connection between doctors and ROs should be that every doctor is able to relate to an RO who works for an organisation that has a meaningful link with the work that the doctor carries out on a day to day basis.

For the most part, the prescribed connections between doctors and organisations are sound. However, for some situations the connections are at odds with the principle of the meaningful link.

Regulation 9 also provides that where doctors are employed or contracted by more than one organisation, the prescribed connection is with the body where they undertake most of their ‘clinical practice’ with patients. The regulations do not define ‘clinical practice’. However, there are many disciplines and roles within medicine that involve no clinical practice whatsoever. It would be more helpful, therefore, if the regulations referred to medical practice or professional practice.”

Educational/Regulatory organisation

DHSSPS Position

Universities will be designated for the purpose of these regulations under a schedule to regulation 2.

It is implicit that if an individual wishes to continue as a licensed medical practitioner he/she must relate to a responsible officer.

The requirements under the performers list Regulations, provides an opportunity for a wide range of practitioners to access appraisal and, thus facilitates their revalidation.

ACTION The Regulations will be altered to define clinical practice.

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

Yes 4 44% No 3 37% Unsure 2 25%

Comments Received

The response to this question was mixed and some of the comments were –

“Further work needs to be undertaken to clarify the situation for doctors based overseas (including as part of their training).”

Professional organisation

“A possible alternative before using the address as the final decision tool would be “by agreement between the responsible officers of the respective bodies and the medical practitioner”

Educational/regulatory organisation

DHSSPS Position

The regulations seek to prescribe the link between individual doctors and the designated organisation, rather than rely on the agreement of either party.

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

Comments Received

“..... believes that the hierarchy for trusts should be the Department. The basis on which there would be a 3 tier hierarchy is not clear. It is not clear why NIMDTA and Trusts would have a different connection.”

Service provider/commissioner

“Each responsible officer must themselves be linked to a responsible officer who will ensure they are subject to the same evidence-based assessment as those they are responsible for. We support the hierarchy set out in regulation 10 for this to happen”

Educational/Regulatory organisation

DHSSPS Position

From the comments received, there appeared a perception that the responsible officer would appraise all those staff for which he/she is responsible. This is not the case. They will evaluate their fitness to practise and makes recommendations to the General Medical Council, largely based on evidence that appraisal has taken place satisfactorily.

The relationship between respective responsible officers was proposed to reflect the relationship between parent organisations following the Review of Public Administration. The Department considers that, following further discussion involving potential responsible officers that the arrangements proposed meet this intention.

ACTION A further connection has been added to the regulation. Where body A in regulation 10(2) is none of the bodies named, body B will be the HSC Regulation and Quality Improvement Authority.

The remaining regulations relate to resourcing responsible officers, having regard to guidance and offences under the regulations.

Q15 Please comment on the extent to which regulations 11-13 and 15-17 achieve the policy objectives set out in the previous consultation paper on the role of the responsible officer.

Comments Received

“This is and will be a significant cost pressure for Trusts, resourcing revalidation will require recognition of this from commissioners.”

Service provider/commissioner

“We note that the RO is responsible for ensuring that sufficient resources are put in place to support the function. This is a rather invidious position for the RO, particularly if there is not clear guidance on the subject.”

Professional organisation

“The proposed approach does appear to meet the policy objectives. It would be useful to have indicative guidance as to the nature and levels of support organisations should provide to a responsible officer.”

Educational/regulatory organisation

“They also make explicit the duty of organisations to ensure that the RO role is properly resourced. We have some doubt as to whether the best means of ensuring that ROs are able to carry out their duties is by making it a criminal offence to prevent them from doing so. A more positive approach would be to provide incentives to encourage compliance and good practice.”

Educational/regulatory organisation

DHSSPS Position

The costs associated with the responsible officer role are the subject of pilots underway across the UK. However, a principal underpinning this role is the need to build on processes and infra-structure that are already in place.

Further consideration has been given to the creation of offences in the draft Regulations and in particular, to the way in which an offence would be brought before the courts and what evidence would be required to secure a conviction. As a result it has now been decided not to proceed with the original proposal to create offences in Regulations.

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.

Comments Received

The general view was that the guidance document was well presented, easy to follow and helpful. Some matters which did raise concern are contained in the following comments:-

“Background (1.3)

It is not clear where the RO’s responsibility lies in making a decision on an individual. Potentially it could be to the individual doctor, employing organisation, GMC or a combination of all three.”

Professional organisation

“Notwithstanding our earlier comments about the sometimes negative description of the RO role in parts of the consultation, we were pleased to note that the guidance highlights the more positive contribution of ROs to supporting doctors and advancing the quality agenda.”

Educational/regulatory organisation

“In our view the draft guidance was helpful and clear”

Professional organisation

DHSSPS Position

The responsible officer will not be making a decision on an individual but a recommendation on their fitness to practise to the regulator, the General Medical Council who will decide on whether a licensed medical practitioner remains on the register.

The legislation seeks to strengthen existing clinical and social care governance systems. The responsible officer will have parallel responsibilities to individual doctors, the system, the organisation and him/herself.

ACTION The guidance document has been reviewed and updated to take account of feedback from the consultation and the proposed changes to the draft Regulations. In particular, further information has been provided on how conflicts of interest or appearance of bias should be managed. We have also added a section covering frequently asked questions to the document.

Appendix A – List of Respondents

The consultation received 19 responses. The respondents were: -

The Royal College of Radiologists
Northern Ireland Medical and Dental Training Agency (NIMDTA)
DRC Locums
Central Medical Advisory Committee, Northern Health and Social Care Trust
Northern Ireland Ambulance Service Health and Social Care Trust
Medical Protection Society
The Regulation and Quality Improvement Authority
Child and Adolescent Mental Health in the Belfast Health and Social Care Trust
General Medical Council
Royal College of Nursing Northern Ireland
Royal College of General Practitioners
British Medical Association
Belfast Health and Social Care Trust
Western Health and Social Care Trust
Northern Ireland Judicial Appointments Commission
Southern Health and Social Care Trust
Belfast City Council
Primary Care, Health and Social Care Board
Independent Healthcare Advisory Services

Appendix B – Membership of the Confidence in Care workstream team

Dr Paddy Woods, DHSSPS (Joint Workstream Lead)
Diane Taylor, DHSSPS (Joint Workstream Lead)
Mervyn Barkley, Co-Director HR, Belfast HSC Trust
Dr Tony Stevens, Medical Director, Belfast HSC Trust
Colleen Stirling, NI Social Care Council
Denis Morrison, Pharmacy, HSC Board
Catherine McQuillan, Dental, DHSSPS
Dr Kathryn Booth, Primary Care Advisor, HSC Board
Dr Stephen Austin, British Medical Association
Dr Paul Darragh, British Medical Association
Joyce Cairns, HR DHSSPS
Sean Scullion, Safety, Quality and Standards, DHSSPS
Bronagh Scott, Director of Primary Care and Community Care for Older People's Services
and Executive Director of Nursing, Northern HSC Trust
Gill Smith, Programme Manager, DHSSPS
Ruth Hutchison, Programme Support Officer, DHSSPS
Jane Lindsay, Programme Manager, DHSSPS
Dr Claire Loughery, Northern Ireland Medical and Dental Training Agency
Dr Terry McMurray, Northern Ireland Medical and Dental Training Agency
Dr Michael Mannion, Northern Trust
Dr Steven Bergen, PHA
Dr Kathryn Booth, HSC Board
Lisa Rutherford, General Medical Council
Alan Walker General Medical Council
Dr David Stewart, Regulation and Quality Improvement Authority
David Bingham, Business Services Organisation

APPENDIX C

Statutory Rule to be printed and laid in draft subject to affirmative resolution.

Consider comments, finalise policy and prepare consultation report	End March 2010
Notify Minister and Health Committee re outcome of consultation	Mid-April 2010
Proof read, full validation of SR and send for printing	Late April 2010
Arrange for laying in draft at the Assembly Business Office	Late April
Arrange for Motion to be tabled at the Business Office	End May/early June
Following debate arrange for making (sealed & signed)	Late June
Arrange for SR registration, numbering, printing and publication	Late June/early July 2010
Regulations coming into operation	1 st October 2010