



Framework for managing concerns about Responsible Officers who have a prescribed connection to a higher level Responsible Officer of NHS England

A guidance document for use by higher level Responsible Officers of NHS England

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NHS England

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February 2016

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1. Purpose of document

This NHS England guidance document seeks to ensure that the handling of concerns about Responsible Officers (ROs) who have a prescribed connection to an NHS England higher level RO (HLRO) is undertaken fairly, proportionately, in alignment with statutory obligations, in partnership with other agencies where necessary and in a way that drives up quality and safety of healthcare. This is a new process and the framework will be kept under review and defined as needed.

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

2. Background

Revalidation

Revalidation is the process by which doctors demonstrate to the GMC that they are up to date and fit to practise. The cornerstone of the revalidation process is that doctors will participate in annual medical appraisal. On the basis of this and other information available to the RO from local clinical governance systems, the RO will make a recommendation to the GMC, normally every five years that the doctor should be revalidated, or otherwise that the decision be deferred pending the provision of more information, or that there has been non-engagement in the revalidation process. The GMC will consider the RO's recommendation and decide whether the doctor is fit for revalidation and to continue to hold a license to practise.

RO regulations

The Medical Profession (ROs) Regulations 2010¹ as amended by the Medical Profession (ROs) (Amendment) 2013² (“the Regulations”) require each body designated under the regulations to appoint an RO. Regulations 13 and 17 are applicable for this framework.

¹http://www.legislation.gov.uk/ukdsi/2010/9780111500286/pdfs/ukdsi_9780111500286_en.pdf

²http://www.legislation.gov.uk/ukdsi/2013/391/pdfs/ukdsi_20130391_en.pdf

3. Scope

This framework is to guide the processes for managing concerns about ROs who have a prescribed connection to the HLRO in the four regions of NHS England (North, South, Midlands & East, and London).

The Regulations set out the relevant prescribed connections between a designated body and its doctors and an RO. In accordance with these, the NHS England HLRO is the RO for a doctor if he/she is an RO in England, but who is *not* any one of the following:

- an RO for a Local Education and Training Board (LETB),
- an RO for either a Government department or executive agency of a Government department or a Non Departmental Public Body (NDPB) – except NHS England.

In addition the regional HLRO is the RO for any doctor employed in the regional team of NHS England who has no other employer or prescribed connection. If concerns are identified about a HLRO the framework will be followed in line with relevant regulations and regulators.

This framework guides the processes in relation to identifying concerns, storage of records and managing concerns brought to the attention of the HLRO and the oversight of investigation into ROs for relevant concerns. This framework does not cover the processes for pre-employment checks and routine management of appraisal and revalidation recommendations for ROs by the HLRO.

4. Aim of this guidance

For the HLRO there are complexities, in that a large number of the doctors who are ROs with a prescribed connection to him or her are employed by an organisation out-with NHS England. Therefore if there are concerns about ROs and there is no line management relationship, there is relevance in establishing a local decision making group (refer to section 7) to include

representatives from the HLRO and the employing organisation. The RO regulations, however, require the HLRO to monitor the performance of all connected ROs, and take the appropriate action in line with relevant regulations should a concern arise.

This guidance identifies the framework for managing concerns by the HLRO and aims to bring a consistent, fair, proportionate approach in line with the Regulations, enacting changes or imposing sanction where necessary in order to improve patient safety and the quality of healthcare services.

5. Key principles

All those who are involved should ensure HLROs receive appropriate information about the performance of first tier ROs whose connection is to the HLRO. The key objectives of any actions undertaken by NHS England staff at all levels will be:

- protecting patients and the public, and enhancing their confidence in the NHS;
- identifying the possible causes of concern;
- ensuring equality and fairness of treatment and avoiding discrimination;
- being supportive of all those involved;
- safeguarding information, maintaining confidentiality and protecting whistleblowing identity as necessary;
- ensuring that action is based on reliable evidence; and
- keeping accurate records, remaining transparent in process and being open to scrutiny.

The HLRO may delegate these responsibilities to a named deputy within NHS England but will retain overall responsibility for the process.

6. The nature of concerns

By way of examples, concerns about a doctor with a prescribed connection to the HLRO may arise in the form of:

- Complaints made by patients, carers or relatives of patients;
- Concerns expressed by colleagues, including whistle-blowing concerns;
- Serious incident and never event reports;
- Adverse quality and performance measurements pertaining to individuals or the organisation of the first tier RO;
- Concerns by other agencies, including regulatory agencies, that the RO is not addressing their statutory responsibilities within their own organisation with due attention;
- System failures or leadership failures in the organisation's appraisal and revalidation or clinical governance processes, including any information of concern coming to light through the Framework for Quality Assurance, including the Annual Organisation Audit, Board Statement of Compliance, independent verification visit or any other method;
- Insufficient engagement with or insufficient presentation of evidence at annual appraisal;
- Referral of an RO to the GMC, which may not require the HLRO to be involved but the HLRO will respond appropriately.

7. Investigation

Concerns may be raised about an RO by/within an employing organisation as well as by a HLRO. If the concerns are raised by/within the employing organisation the CEO must contact the HLRO to notify them of the concern. In the case of a HLRO becoming aware of a concern about an RO, the HLRO will contact the CEO of the employing organisation to ensure they are aware of this. If a concern arises about an RO, an investigation may be deemed necessary and dealt with in the following way:

Initial Assessment Phase

The HLRO should:

- Ascertain if the CEO, General Manager, and/or Director of HR of the ROs designated body are aware of concerns;
- Ascertain if the RO works in other healthcare organisations and if they require informing;
- Ascertain the involvement of the GMC ELA and The National Clinical Assessment Service (NCAS) and involve where necessary;
- For designated bodies where the RO is also the owner, the CEO/board of the designated body (or equivalent) of the organisation will be consulted to ascertain the correct individuals
- In discussion with the above, and with appropriate colleagues establish a local decision making group, constituted from those recommended below*, and taking into account all that is known in relation to the RO and designated body, take a judgment as to whether:
 - An investigation is required, this judgement may include the use of a risk assessment relevant to the employing organisation
 - The RO should continue undertaking RO duties

*Resources for this group may include; CEO, Chair, HR Director, Lay person, Medical Director if different from RO and an external RO if not. The group should usually include at least 3 out of 4 of the above with the option for one to nominate a deputy. NCAS and the GMC ELA (may / could) be used in an advisory manner and informed of relevant investigations in line with the designated body's policy.

Where possible and practical given the nature of the concern the local decision making group should meet face to face as a group. However, in some circumstances a teleconference may be a suitable alternate. It is the responsibility of the designated bodies CEO to ensure the appropriate participation of the membership to inform the decision of the group and assure the HLRO of this action.

- Should an investigation be necessary the HLRO must ensure the CEO of the employing organisation has the necessary resources to implement such an investigation.

Investigation Phase

The designated body's policy on concerns management where the RO is employed/contracted should be followed while appropriate investigation by the organisation is implemented.

If an investigation is advised, the HLRO should ensure that an appropriate investigation takes place overseen by a case manager. The HLRO should advise the designated body on appointment of an appropriate case manager, an agreed Case Manager will keep all relevant parties up to date. NHS England will advise on the suitability of an investigator to carry out investigations regarding ROs and may provide assistance in sourcing a suitable investigator. Only in exceptional circumstances should the HLRO be the case manager.

The HLRO can advise if the investigation should be under existing Trust or designated body policies (such as those for Maintaining High Professional Standards or Acceptable Behaviour at work policies), or by exception if a separate investigation of an RO with distinct terms of reference is required and later adopted by the local decision making group.

Organisations may have a number of policies to support and manage RO concerns. In the absence of such policies or in circumstances of non-compliance by the organisation the HLRO may refer the concern to the Care Quality Commission or other regulator.

The HLRO will advise on the terms of reference, and these should be agreed with all parties including the HLRO and the local decision making group.

It is the responsibility of the HLRO and the local decision making group to facilitate robust communications with the employing or contracting body of the RO at all stages of the investigation and to work collaboratively throughout the process following the employing organisations responding to concerns policy.

Restriction of RO duties

The regulations allow for a HLRO to recommend to the RO's employer/contractor that the practitioner should be excluded or have conditions or restrictions placed on their practice, should this be necessary. The HLRO cannot mandate this; however the organisation should consider carefully the HLRO's recommendation.

A judgement can be made as to whether any restrictions on duties apply to RO duties, and/or management practice, and/or clinical practice of the RO in the context of him/her being a medical manager and practitioner. These decisions will be case specific and will be guided by:

- any perceived risk to or threat to public/staff safety;
- where the presence of the RO might hamper an investigation;
- the estimated time for an investigation to take place;
- reputational risk to RO or designated body and the perceived seriousness of the concerns being investigated;
- views of GMC ELA, and in particular their confidence in receiving valid recommendations from the RO's office;
- views from other agencies, for example NCAS.

Ongoing monitoring of an RO, or monitoring of the response to a concern, maybe carried out via the agreed action plan or if appropriate via the medical appraisal outputs.

The HLRO can advise with regards to the appointment of an interim replacement should this be requested. The prescribed connection should continue between the RO and HLRO if still the formal RO with an interim RO in place, whilst the investigation is ongoing. On a case by case

basis it will be decided whether an interim RO is to be appointed, whilst an investigation is ongoing the HLRO role will be advisory to the CEO.

The HLRO will speak to the RO to keep him/her up to date with the information shared at all times as appropriate.

Decision making

The HLRO is empowered by the Regulations to take action and instigate necessary actions in association with the local decision making group. He/she may be required to do this with expediency in some instances.

Some smaller designated bodies may struggle to establish a local decision making group. In such circumstances in addition to an external RO; membership may be supported by the inclusion of appropriate external senior regional resources. This will ensure that the local decision making group has the appropriate membership whilst also providing an independent view and ensuring consistency.

Possible Recommendations or Actions

Once case investigation is complete the HLRO and local decision making group may recommend or take action pertinent to the context of the concerns:

- In relation to the recommendation for revalidation of the RO:
 - The HLRO may need to recommend the deferral of an RO's revalidation date in order to consider the outcome of ongoing or recently concluded local disciplinary processes or investigation, where this is material to the evaluation of the ROs fitness to practise. These processes are likely to relate to an RO's conduct or performance
 - The HLRO may inform the GMC of non-engagement

- In relation to restriction of RO duties
 - The HLRO may advise the designated body management /CEO that the RO should be supervised in clinical roles within the organisation, alternatively the HLRO may

seek information from the GMC around confidence in the recommendations being made by the RO

- In relation to the seriousness of concerns identified, referral to other agencies may be indicated
 - The HLRO may refer the matter to the GMC or to the police
 - The HLRO may alert the CQC if it is viewed that clinical governance systems are poor in the designated body
- To the employing or commissioning organisations of the doctor consider action as appropriate regarding the doctor in line with their relevant policy.

In the event that an RO under investigation chooses to step down from RO duties, whilst the remit of the HLRO in essence ends due to there being no prescribed connection, there is a professional duty with regard to patient safety which justifies the HLRO in continuing to be involved in the investigation and/or informing relevant agencies. In such circumstances guidance from the GMC ELA and NCAS may be appropriate.

Appeals process

As the HLRO is not directly accountable for decisions determining the employment or livelihood or contractual status of the RO, appeals procedures will be in line with the relevant designated body.

8. Scope of responsibilities of the Higher Level Responsible Officer

The scope of responsibilities of the RO are identified in Regulation 17 (4) and 13. As Regulation 13 refer mainly to appraisal, Regulation 17(4) is most pertinent to this framework as it relates to conduct and performance.

9. Remediation

Remediation is a broad term covering a range of options including:

- reskilling or retraining to address an identified lack of knowledge;
- refresher or re-entry training to enable return to work after a period of absence;
- supervised clinical placements, possibly at a centre removed from the practitioner's normal place of clinical practice;
- occupational health referral and/or rehabilitation after an episode of ill health.

In principle, the responsibilities for remediation and support lie with the employing/contracting organisation. The HLRO and the local decision making group is able to advise on this process.

10. Ongoing review, learning and consistency

If there is a complex situation/investigation being handled by a specific NHS England region it may be helpful to seek advice from another regions' advisory group to ensure processes and decisions are consistent. Once an investigation is complete the learning should be shared across regions to ensure consistency, this will also inform the continuation of managing concerns framework development.

Appendix 1 - Abbreviations and acronyms

CEO	Chief Executive Officer
CQC	Care Quality Commission
ELA	Employer Liaison Advisor
GMC	General Medical Council
HLRO	Higher Level Responsible Officer
MHPS	Maintaining High Professional Standards
NCAS	National Clinical Assessment Service
PDP	Personal Development Plan
RO	Responsible Officer