



Revalidation Support Team

Information Management for Medical Revalidation in England

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1. Introduction

This document describes the information management and information governance processes required to ensure revalidation is effective in its primary aims. It is targeted at responsible officers and those responsible for designing information systems to support clinical governance and revalidation. It may also be of interest to doctors, appraisers, Caldicott guardians and managers.

Revalidation

Revalidation of doctors is a key component of a range of measures designed to improve the quality of care for patients; it is the process by which the General Medical Council (GMC) confirms the continuation of a doctor's licence to practise in the UK. The purpose of revalidation is to assure patients and the public, employers and other healthcare professionals that licensed doctors are up to date and fit to practise.

Through a formal link with an organisation, determined usually by employment or contracting arrangements, doctors relate to a senior doctor in the organisation, the responsible officer. The responsible officer makes a recommendation about the doctor's fitness to practise to the GMC. The recommendation will be based on the outcome of the doctor's annual appraisals over the course of five years, combined with information drawn from the organisational clinical governance systems. Following the responsible officer's recommendation, the GMC decides whether to renew the doctor's licence.

The responsible officer is accountable for the quality assurance of the appraisal and clinical governance systems in their organisation. Improvement to these systems will support doctors in developing their practice more effectively, adding to the safety and quality of health care. This also enables early identification of doctors whose practice needs attention, allowing for more effective intervention.

All doctors who wish to retain their GMC licence to practise need to participate in revalidation.

NHS Revalidation Support Team

This publication was written by the NHS Revalidation Support Team (RST), part of Guy's and St Thomas' NHS Foundation Trust. Funded by the Department of Health (England), the RST delivered a wide range of projects between 2008-2014 that helped pave the way towards the implementation of medical revalidation.

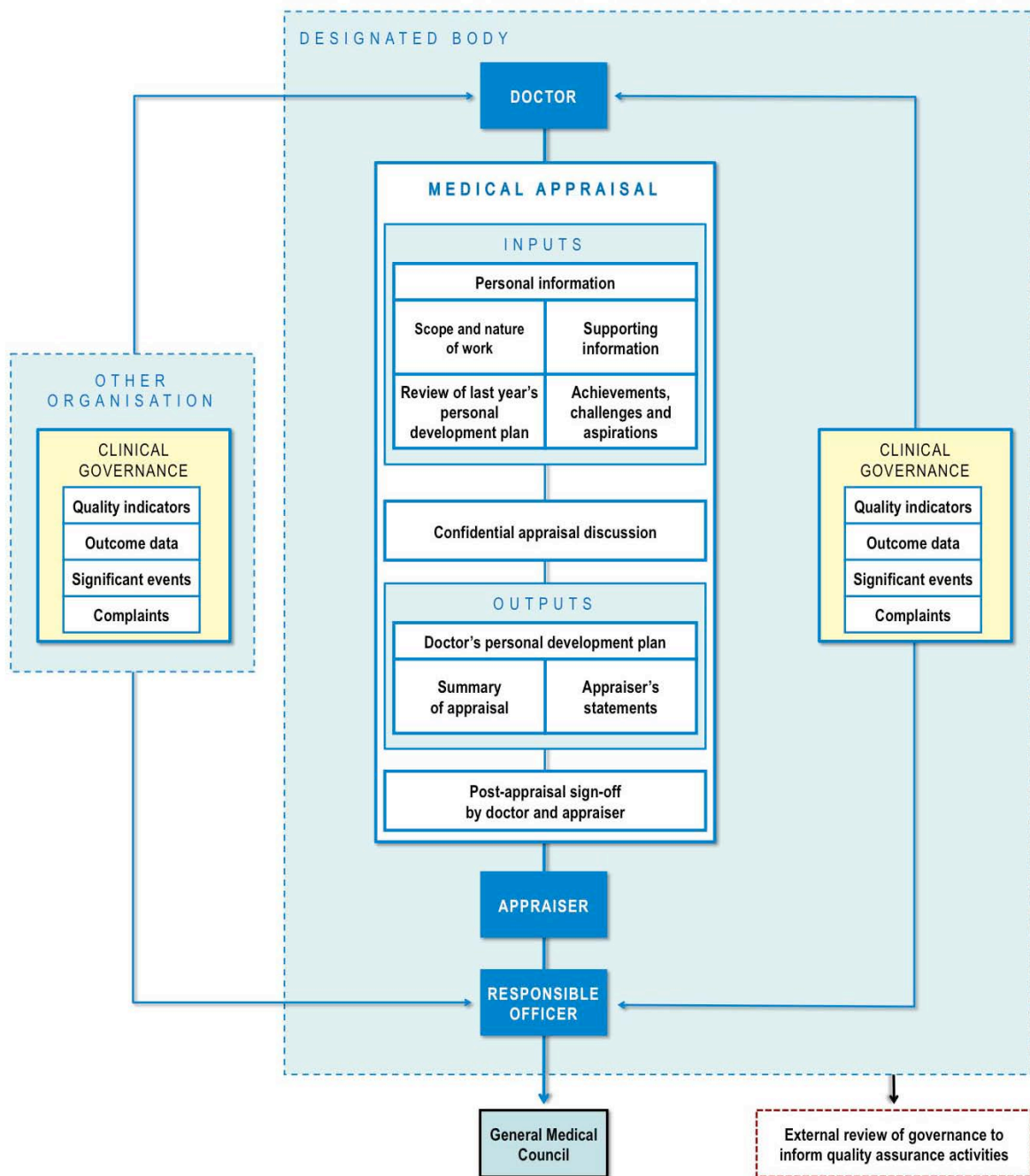
The knowledge, expertise and functions of RST are currently being transferred to NHS England, prior to the closure of the RST on 31 March 2014.

All RST publications were created in collaboration with partners and stakeholders.

2. Information flows

This diagram illustrates the overall information flows in appraisal and revalidation:

Figure 1: Information flows to support revalidation



The doctor

It is the doctor's professional responsibility to produce a portfolio of supporting information. The GMC has published guidance on the required supporting information in *Supporting Information for Appraisal and Revalidation* (GMC, 2012). The guidance describes the following six types of supporting information to be collected by the doctor over the five-year revalidation cycle:

1. continuing professional development
2. quality improvement activity
3. significant events
4. feedback from colleagues
5. feedback from patients (or alternative as agreed with responsible officer)
6. review of complaints and compliments.

The supporting information is presented and discussed at the doctor's annual appraisal, using the process described in the *Medical Appraisal Guide* (NHS Revalidation Support Team, 2013). Supporting information collected over the revalidation cycle, together with the doctor's reflections and commentary, constitute the doctor's portfolio. The doctor has a professional responsibility to include in the portfolio all complaints and significant events in which they have been involved as well as relevant information from all their medical roles.

The nature of the supporting information under each category will reflect the doctor's particular specialist practice and other professional roles. For example, appropriate quality improvement activities will vary across different specialties and roles. The Academy of Medical Royal Colleges has published advice from the medical royal colleges and faculties contextualising the GMC's supporting information guidance for specialist practice¹.

The doctor should comply with reasonable requests for information relating to their performance and fitness to practise from those entitled to ask for it.

¹ *Supporting Information for Appraisal and Revalidation: Core Guidance Framework* (Academy of Medical Royal Colleges, 2013)

The appraiser

The doctor's supporting information is shared with the appraiser prior to the appraisal meeting in sufficient time for the appraiser to consider the content. The portfolio is reviewed by the appraiser and provides the basis for the appraisal discussion. The appraiser should be satisfied that the doctor has included all relevant information.

Following the appraisal, the outputs of appraisal (the personal development plan, appraisal summary and appraiser's statements as described in the *Medical Appraisal Guide*) are agreed and signed-off by the doctor and appraiser. The outputs of appraisal are forwarded to the responsible officer as a record of the completed appraisal.

If agreement cannot be reached on the content of the outputs of appraisal, the responsible officer should be informed. In this instance, the appraiser should still submit the disputed outputs of the appraisal, clearly indicating the area on which consensus has not been achieved. The responsible officer should then take steps to establish the facts objectively.

The responsible officer²

The Medical Profession (Responsible Officers) Regulations 2010 and *The Medical Profession (Responsible Officers) (Amendment) Regulations 2013* – otherwise known as the responsible officer regulations – describe the statutory duties of the responsible officer. These fall under the following broad headings:

- ensuring that appraisals are carried out to the appropriate standard and information from all the doctor's roles is considered
- monitoring doctors' conduct and performance
- evaluating the fitness to practise of all doctors with whom the designated body has a prescribed connection
- identifying and investigating concerns about doctors' conduct or performance
- ensuring that appropriate action is taken in response to concerns
- ensuring that, when designated bodies enter into contracts of employment or contracts for the provision of services with doctors, those doctors have the appropriate qualifications and experience for the work to be performed, their identities are verified and appropriate references are obtained and checked.

² The responsible officer may delegate particular roles and functions covered by the regulations to others. For the purposes of this document, the term responsible officer should be interpreted as including those acting with appropriate delegated authority.

The responsible officer will have access to the outputs of each annual appraisal for monitoring the doctor's progress within the revalidation cycle. The outputs of appraisal will also inform the responsible officer's recommendation. They should therefore enable the responsible officer to be satisfied that the doctor's appraisals have considered the full scope of work and that the accumulating portfolio addresses the full range of supporting information outlined in the GMC guidance.

In some circumstances, such as where a concern is raised, the responsible officer may require access to completed appraisal portfolios to review the doctor's supporting information and their commentary and reflection. The responsible officer may also need access to completed appraisal portfolios for quality assurance purposes.

The responsible officer will require information regarding all the doctor's roles and places of work to enable them to:

- ensure the doctor's prescribed connection is correctly identified
- establish a reliable process for information-sharing when a doctor works in more than one organisation
- monitor the doctor's fitness to practise in all medical roles
- make fitness to practise recommendations to the GMC which cover all the doctor's medical roles.

Information relating to the doctor's scope of work is detailed in the forms completed for appraisal, but may also be obtained directly from the doctor.

New contracts

The responsible officer has specific responsibilities when the designated body enters into contracts of employment or contracts for the provision of services with doctors. This applies to locum agency contracts, membership contracts and also to the granting of practising privileges by independent health providers. The prospective responsible officer must:

- ensure doctors have qualifications and experience appropriate to the work to be performed
- ensure that appropriate references are obtained and checked
- take any steps necessary to verify the identity of doctors
- where the designated body is a primary care trust, manage admission to the medical performers list in accordance with the regulations
- maintain accurate records of all steps taken.

It is also important that the following information is available:

- GMC information: fitness to practise investigations, conditions or restrictions, revalidation due date
- Criminal Records Bureau check (although delays may prevent these being available to the responsible officer before the starting date)
- Gender and ethnicity data (it is voluntary for the doctor to provide this information, but it should be included when available, in order to monitor fairness and equality).

It may be helpful to obtain a structured reference from the current responsible officer which complies with GMC guidance on writing references – see *Writing References* (GMC, 2012) – and includes factual information relating to:

- the doctor's competence, performance or conduct (see *Good Medical Practice*, paragraph 41)
- appraisal dates in the current revalidation cycle
- local fitness to practise investigations, local conditions or restrictions, and any unresolved fitness to practise concerns.

When a doctor moves to a new designated body without a contract of employment or for the provision of services (for example, through membership of a faculty), the information needs to be available to the new responsible officer as soon as possible. This will usually involve a formal request by the new responsible officer for information to be forwarded from the previous designated body.

When more detailed information is required relating to outputs of appraisal, specific concerns, investigations or unresolved issues, this may be obtained directly from the doctor or from the previous responsible officer on request.

Responding to concerns

Specific information will need to be available to the responsible officer to enable them to monitor a doctor's fitness to practise, take appropriate action in response to any concerns and to make revalidation recommendations taking all relevant information into account. This information will need to be made available by all the organisations in which the doctor works and will include:

- any fitness to practise concerns including relevant complaints, significant events and outlying performance or clinical outcomes
- all measures taken to address concerns, including investigations, formal action plans or remediation processes
- any local disciplinary procedures
- any conditions, restrictions or undertakings relating to the doctor's practice.

Individual learning from events is an important part of resolving concerns. The appraisal meeting is often the most appropriate setting to ensure that this learning is planned and prioritised. As part of their role in resolving concerns, the responsible officer may therefore wish to ensure certain key items of supporting information (such as certain complaints or significant events) are included in the doctor's portfolio and discussed at appraisal, so that development needs are identified and addressed. In these circumstances, the responsible officer may require the doctor to include certain key items of supporting information in the portfolio for discussion at appraisal and may subsequently wish to check in the appraisal summary to confirm that the discussion has taken place.

In some settings (for example, where the doctor and the appraiser work in the same organisation and the information can be sent through secure internal transfer) it may be appropriate, with the doctor's knowledge, for this information to be sent to both the doctor and the appraiser to discuss in the appraisal. The method of sharing key items of supporting information should be described in the appraisal policy. It is important that information is shared in compliance with principles of information governance and that transfer is undertaken through secure channels to safe environments (see chapters 4 and 5).

The responsible officer must decide how to respond to reports and concerns which are unsubstantiated, hearsay or opinion (previously referred to as 'soft concerns'). The responsible officer may choose to:

- take no action at this time (although it is advisable to record the event and the reasons for taking no action)
- record the information and take steps to verify or triangulate the reports
- undertake a preliminary investigation of the report or concern
- pursue other formal procedures (such as a full investigation, capability assessment, suspension or referral to GMC fitness to practise procedures).

In choosing which course to follow the responsible officer is obliged to "take any steps necessary to protect patients"³ and needs to take into consideration the nature, source and reliability of the report and any other relevant information. The responsible officer should record factual information, decisions and actions ensuring that any explanatory notes (from the responsible officer or the doctor) are accurate and adequate for future purposes. The handling of these reports and concerns should comply with local whistleblowing policies.

The General Medical Council (GMC)

At the point of submitting a revalidation recommendation to the GMC in terms of the doctor's fitness to practise, the responsible officer must be satisfied that:

- the doctor's appraisals have considered the whole of the doctor's practice
- the portfolio contains the full range of supporting information described in the GMC guidance
- there are no unaddressed concerns.

When submitting a recommendation, the responsible officer has three options:

1. a positive recommendation
2. agreeing a deferral with the GMC for a specified period of time so that further information can be obtained, or an investigation or remedial process can be completed
3. a notification of non-engagement where the doctor has not engaged in the revalidation process.

³ *Medical Profession (Responsible Officers) Regulations 2010*, 16(g) (i)

Option 3 is not a mechanism for addressing concerns about a doctor's fitness to practise. Responsible officers should use existing mechanisms to refer fitness to practise concerns to the GMC at the time they emerge, not at the point of revalidation. However, if a doctor fails to engage in the revalidation process, a responsible officer may make a notification of non-engagement to the GMC before the revalidation date is due. The GMC is then at liberty to bring forward the doctor's recommendation dates in order to address this⁴.

Following a positive recommendation, the GMC will undertake any necessary checks and quality assurance measures. Then, taking all relevant information into account, the GMC will reach a decision on the renewal of the doctor's licence to practise.

⁴ See Section 3 in [Making Revalidation Recommendations: the GMC responsible officer protocol \(GMC, 2012\)](#)

3. Information for quality assurance

It is important that the systems underpinning the responsible officer recommendations are fit for purpose and delivering the intended outcomes. There is therefore a need for periodic flows of information to support quality assurance of the systems supporting the revalidation process and the revalidation recommendations. There are four broad layers of quality assurance:

1. The overarching quality assurance framework which should be integrated with the requirements of the GMC.
2. Assurance to be provided by the national healthcare regulators (the Care Quality Commission and Monitor) regarding the governance of healthcare providers.
3. The higher-level responsible officer, who makes recommendations about the fitness to practise of the responsible officers in their area, needs assurance that each responsible officer has effective systems in place which enable them to fulfil their statutory duties.
4. Each responsible officer should take steps to assure themselves that their local systems of appraisal, clinical governance and responding to concerns are functioning effectively, consistently and fairly. This is an internal management activity but may be enhanced by external or independent validation or verification.

There is no single external regulatory or governance framework for designated bodies in England. The majority of designated bodies are healthcare providers and are registered and regulated by the national healthcare regulators. These organisations will be required to demonstrate compliance with the regulator's registration criteria, which include relevant statutory requirements.

There are also a number of organisations such as faculties, locum agencies, local education and training boards (LETBs) and non-departmental public bodies, which are not registered with or regulated by the national healthcare regulators. Many of these bodies have some form of external governance framework. (For example, the local education and training boards are inspected and reviewed by the GMC and Health Education England and locum agencies are audited by the Government Procurement Service audit team.) It is important that all designated bodies are able to demonstrate in a consistent way that their systems are fit for purpose.

Designated bodies in England will demonstrate that their systems are sufficient to support the responsible officer's recommendations by complying with the framework for quality assurance for revalidation defined by NHS England in its role as the Senior Responsible Owner for the revalidation programme in England. This framework has at

its core an annual organisational audit which designated bodies will complete to provide assurance that they are compliant with the requirements of the responsible officer regulations. For each designated body the annual organisational audit will be the centrepiece of the organisational report to the board (or equivalent governance or executive group) on revalidation. The board report will describe the results of the annual organisational audit, and indicate the actions that the organisation will subsequently undertake to generate improvements in their revalidation systems. It should also be included in an NHS organisation's quality account. The outputs of the annual organisational audit from all designated bodies will be collated into a single annual report by NHS England in its role as Senior Responsible Owner for the revalidation programme in England.

4. Information governance

Information management processes must be supported by and be applied within existing legislative frameworks. These include:

- *The Medical Profession (Responsible Officers) Regulations 2010*
- *The Medical Profession (Responsible Officers) (Amendment) Regulations 2013*
- *The Data Protection Act 1998*
- *The Freedom of Information Act 2000*

In addition to this legislation, designated bodies should aim to comply with a range of professional guidance and operational codes relating to information governance and handling of personal information, including:

- *Confidentiality: NHS Code of Practice* (Department of Health, 2003)
- *Records Management: NHS Code of Practice* (Department of Health, 2006)
- *Joint Guidance on Protecting Electronic Patient Information* (British Medical Association and NHS Connecting For Health, 2008)
- *Good Medical Practice* (General Medical Council, 2013)
- *Confidentiality* (General Medical Council, 2009)
- *Medical Appraisal Guide* (NHS Revalidation Support Team, 2013)
- *The Role of Responsible Officer: Closing the Gap in Medical Regulation – Responsible Officer Guidance* (Department of Health, 2010)

The information governance principles described in this paper are intended to achieve the purposes of revalidation while meeting the requirements of this legislation and guidance. Local processes of information management should appropriately protect the rights of patients, individual doctors and organisations.

The Role of Responsible Officer: Closing the Gap in Medical Regulation – Responsible Officer Guidance (Department of Health, 2010) states:

“Responsible officers will want to assure 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. This will be particularly important where the responsible officer is employed by a different organisation to that which holds the

information about the doctor. The transfer of personal information by secure means is paramount.”

Much of the information held for the purpose of appraisal and revalidation is personal information; it is therefore protected by the *Data Protection Act 1998* and is generally exempt from requests under the *Freedom of Information Act 2000*. However, in certain unusual circumstances (for example, in civil or criminal litigation) personal information held by the doctor or the designated body may need to be released under the order of a court or tribunal. In these circumstances, the legal obligation overrides any objection the individuals may have.

Responsible officers can obtain further information relating to information governance, the *Data Protection Act 1998* and the *Freedom of Information Act 2000* from the information governance officer in their organisation or the Information Commissioner's Office website at www.ico.gov.uk. Detailed information about governance standards for NHS organisations and all organisations accessing the NHS National Network is available in the *Information Governance Toolkit* from the Health & Social Care Information Centre at <https://www.igt.hscic.gov.uk>

In managing information for appraisal and revalidation the designated body and the responsible officer should apply the following broad principles:

- The information within a doctor's appraisal and revalidation portfolio is confidential and access should be limited to the doctor, the appraiser and the responsible officer (or an appropriate person with delegated authority).
- Doctors are entitled to view information held about them in clinical governance or responsible officer systems (unless there is an exemption under the *Data Protection Act 1998*) and they may request that this information is:
 - amended, where there are factual inaccuracies
 - qualified, so that their comments are attached
 - deleted.

The doctor does not have an absolute right to have information amended, qualified or deleted. Before any information is removed, it is important that all patient safety and fitness to practise considerations are taken into account. Information relevant to the current or future evaluation of fitness to practise should be retained (see retention of information, page 18). Some information relating to doctors may need to be retained indefinitely.

- Prior to appraisal, the appraiser has access to the doctor's revalidation portfolio, which includes supporting information for the current appraisal and

the outputs of appraisal from the current revalidation cycle (including personal development plans, appraisal summaries and appraiser statements).

- The discussion in the appraisal meeting is confidential unless fitness to practise or patient safety issues arise.
- After the appraisal, the appraiser submits the outputs of appraisal to the responsible officer, highlighting any patient safety or fitness to practise issues. The doctor should be aware of any information highlighted in this way.
- All information presented by the doctor at appraisal should be retained by the doctor and made available to the responsible officer on request; no information relating to the doctor or the portfolio is retained by the appraiser.
- When quality assurance of the doctor's portfolio and the responsible officer's recommendation is undertaken, it should be performed on anonymised records wherever possible.
- The General Medical Council can access all information relevant to the licensure of doctors.
- The higher-level responsible officer has access to information relating to the fitness to practise of the responsible officer and to the quality assurance of the organisational systems (appraisal and clinical governance) underpinning the responsible officer's recommendations.

Each responsible officer should consider whether records within the control of the designated body are sufficient to fulfil the statutory duties of the role both now and in the future. Information within doctors' portfolios or held by other organisations may be lost or deleted and all information required by the responsible officer to fulfil their statutory role should be retained by the designated body until it is no longer relevant. As the prescribed connection is with the designated body, the records relating to individual doctors should usually be held and retained by the designated body and not held independently by the responsible officer.

Information-sharing

In order to fulfil the statutory obligations, the responsible officer will commonly need to consider relevant information held within other organisations or may need to share information with other organisations in which the doctor works. The responsible officer needs to establish a reliable process for information-sharing when a doctor works in more than one organisation or information needs to cross organisational boundaries. The sharing of personal information must comply with the *Data Protection Act 1998* and organisational policies.

Specific types of information (such as complaints and significant events) relating to work undertaken in other organisations can be obtained in one of two ways:

1. A direct request to the doctor, specifying the information to be forwarded to the responsible officer or to be included in the appraisal portfolio. The doctor should co-operate with reasonable requests for information; deliberate withholding of relevant information may be regarded as a probity issue.
2. A direct request to the organisation: when seeking information from another organisation, the responsible officer should make a formal written request for the relevant information explaining the statutory grounds and the reason for the request (for example investigation, fitness to practise evaluation or recommendation). The request should be sent to the responsible officer, medical director, chief executive or someone in an equivalent senior management role.

The following situations require routine transfer of information across organisational boundaries and effective information-sharing arrangements need to be put in place to enable this:

- In primary care, information relating to general practitioners' fitness to practise is not routinely collected from GP practices; arrangements should be put in place to ensure the responsible officer receives relevant fitness to practise information from the practices.
- For doctors in training, arrangements need to be agreed between the deanery responsible officer and the training host to ensure relevant information is available in both settings.
- For locums and other doctors who move frequently between organisations, ensuring relevant information is available from a sample of the doctor's places of work may be sufficient. Organisations employing locums should always comply with requests for relevant information from the locum doctor's responsible officer.
- Many responsible officers are linked to doctors not directly employed within or contracted to the designated body and therefore relevant information about these doctors will need to be transferred to the designated body.

The sharing of information held by a responsible officer or the designated body should occur in a way which is fair to the doctor concerned, but in determining which information should be shared, responsible officers, medical directors and employers should regard patient safety as the overriding priority.

NHS Employers has published useful guidance on information-sharing between organisations⁵. The NHS Revalidation Support Team has also published the *Medical Practice Information Transfer (MPIT) Form*⁶. The *MPIT Form* provides a template for sharing a concern about a doctor's practice with their responsible officer and passing information relevant to the doctor's fitness practice to the new responsible officer when a doctor's prescribed connection changes. It may also be useful in sharing routine governance information about a doctor with their responsible officer.

Consent

The sharing of information collected to support the statutory role of the responsible officer is normally exempt from the restrictions of the *Data Protection Act 1998*. Therefore, when sharing information relating to the doctor's fitness to practise, the doctor's consent is not normally required. When information is shared for these purposes it is important that only relevant factual information is shared and that this information is only shared with those who have a right to know, for example, the responsible officer, the employer or the GMC. The information shared should not contain personally identifiable information relating to patients or other staff.

When deciding whether information is relevant and sharing can be justified, the medical director/responsible officer or other senior manager from the organisation should consider whether the information:

- relates to fitness to practise or patient safety
- is factual or has been generated or validated through a formal process (for example, the findings or recommendations of an investigation process)
- has already been shared with the doctor.

The doctor should be informed when information from another organisation relating to a fitness to practise concern is shared with the doctor's responsible officer. The implications of not sharing potentially important information should be carefully considered and, if necessary, discussed anonymously with other senior colleagues before a decision is made.

⁵ *Guiding Principles for Sharing Information on Healthcare Workers* (NHS Employers, 2012)

⁶ *Medical Practice Information Transfer Form* (NHS Revalidation Support Team, 2013)

Retention of information

All appraisal and revalidation information required by the responsible officer should be retained by the designated body (within legal parameters and safeguards) until it is agreed that it is no longer relevant.

The *Data Protection Act 1998* states that information shall be obtained only for one or more specified and lawful purposes and shall not be kept for longer than is necessary for that purpose. The retained information may be used:

- to support the designated body and responsible officer in complying with their statutory obligations
- for the management and quality assurance of medical appraisal and revalidation processes
- for evaluating and monitoring the doctor's fitness to practise
- to safeguard the public.

Before any information is deleted, it is important that all patient safety and fitness to practise considerations are taken into account. Information relevant to the current or future evaluation of fitness to practise should be retained. Some information may need to be retained indefinitely.

Personal information

Personal information is information from which individuals (for example, patients, carers, relatives or staff) can be identified.

The supporting information used for appraisal and revalidation should be anonymised. Doctors must therefore ensure that all personal identifiers (for example names, dates of birth, addresses, hospitals or NHS numbers) are removed and patients, carers, relatives and staff are not directly identifiable. Despite this, it is possible that, in some unusual circumstances, information contained in appraisal and revalidation portfolios may allow those with local knowledge to identify key individuals. While all information used within appraisal and revalidation portfolios is held and shared in confidence, it is important that appropriate safeguards are in place to minimise the use of information which may identify individuals.

This can be achieved by:

- Anonymised information – this is information which does not identify an individual directly, and which cannot reasonably be used to determine identity. Anonymisation requires the removal of name, address, full post code and any other detail or combination of details that might support identification.
- Pseudonymised information – this is like anonymised information in that in the possession of the holder it cannot reasonably be used by the holder to identify an individual. However it differs in that the original provider of the information may retain a means of identifying individuals. This is often achieved by attaching codes or other unique references to information so that the data will only be identifiable to those who have access to the key or index. Pseudonymisation allows information about the same individual to be linked in a way that true anonymisation does not.
- Consent – where practical, the consent of those identified should be sought.
- Notification – patients may be notified in leaflets and notices that all records are stored and processed confidentially and that anonymised information may be used for professional development and revalidation.⁷

⁷ Information taken from *Confidentiality: NHS Code of Practice* (Department of Health, 2003)

5. Computerised support for appraisal and revalidation

The purpose of this section is to describe the functionality required for computer systems to support the processes of appraisal and revalidation, to assist the responsible officer and designated body in making decisions to purchase or commission a system.

There are likely to be significant management advantages if all the doctors in a designated body use the same computerised appraisal and revalidation support system. The choice of computerised systems is increasing and before responsible officers or designated bodies commission a system they should consider the advice in this section carefully. Where decisions are made to purchase a computerised support system, collective commissioning through regional procurement network collaboratives is likely to improve value for money. At the point of publication of this guidance the purchasing or commissioning of computerised support systems is a decision for individual designated bodies and internal policies determine their use.

It is important to ensure that the selected system has the necessary appraisal, revalidation, management and security functionality. In particular, the appraisal function must be consistent with the *Good Medical Practice Framework for Appraisal and Revalidation* (GMC, 2013) and *Supporting Information for Appraisal and Revalidation* (GMC, 2012) and should also support the model of medical appraisal described in the *Medical Appraisal Guide* (NHS Revalidation Support Team, 2013).

The supplier should provide credible assurance that the system will be developed to satisfy the evolving needs of doctors and responsible officers.

At the commencement of revalidation the NHS Revalidation Support Team produced two simple electronic tools to support implementation which are available for download:

- *The Medical Appraisal Guide Model Appraisal Form* (NHS Revalidation Support Team, 2012) is an interactive pdf form which allows the doctor and the appraiser to enter and review supporting information, learning and reflection and agree and sign-off the outputs of appraisal.
- *The Responsible Officer Dashboard* (NHS Revalidation Support Team, 2012) is a stand-alone application (an Excel database) which allows the responsible officer to maintain a list of doctors for whom they have responsibility and track their progress through the revalidation cycle. It enables important information, such as records of appraisals and the presence of fitness to practise concerns, to be highlighted and ensures that all relevant information is considered when fitness to practise recommendations are made. The dashboard can also provide simple ORSA compliance reports.

These solutions are not components of a national revalidation system; they were designed to support readiness and implementation in the short-term and their use is voluntary. User guides are available, though no support or training is provided. The availability of these tools allows responsible officers and designated bodies time to consider their needs in relation to computer support systems and also allows suppliers time to develop fully functional solutions.

In addition, the General Medical Council provides an online portal, GMC Connect⁸, which lists the doctors with whom responsible officers are linked and via which the responsible officer submits revalidation recommendations to the GMC.

Commissioning appraisal and revalidation support systems

There are a number of issues to bear in mind when considering a computerised support system for appraisal and revalidation.

Commissioning process

The commissioning of a computerised support system should be carried out in consultation with the doctors who will be using it. This is especially important if use of the system is to be regarded as obligatory by the organisation for compliance with its appraisal policy. Good communication during the commissioning and decision-making process is important and doctors will usually prefer that once the system is commissioned it is not changed frequently. The initial decision is therefore important and the responsible officer should have organisational commitment and a strong degree of certainty regarding the availability of recurrent funding.

The commissioning of systems for supporting appraisal and revalidation in the NHS may be arranged jointly on behalf of a number of designated bodies through the NHS procurement collaboratives or 'hubs' to ensure value for money.

⁸ GMC Connect can be accessed at: www.gmc-uk.org/publications/GMCConnect

Supplier selection

The designated body needs to be satisfied that the provider has the technical expertise and other resources to manage such a system and will continue to improve and develop it, upgrading hardware and functionality, as required. Appropriate arrangements for the back-up of information should be in place.

The commissioner needs to be assured that the supplier is sufficiently reliable and financially robust to be able to maintain the system for a reasonable lifespan and that it carries adequate insurance. The supplier should have appropriate arrangements for managing risk and ensuring business continuity.

Remote access

Systems are commonly web-based with storage of data on an external server so that the user can access it from different settings. Since many doctors maintain their portfolios for appraisal outside office hours, access from the doctor's home within a robust code of connection⁹ is essential. The desirability of mobile access may also be considered.

Compatibility

The selected system will need to function on current organisational systems. Many organisations have firewall or security settings which may interfere with access or functionality. Compatibility with other software including operating systems and internet browsers in current use must also be taken into consideration.

Training and support

Training for users is usually needed and the provider or the designated body should be able to provide training which is flexible, timely and focused on the needs of the user. Some individual training may be necessary.

Doctors, appraisers and responsible officers using a computerised system to support appraisal and revalidation need access to appropriate guidance and support, including a help desk with suitable hours of access, response times and the skills to resolve the majority of problems on the first contact.

⁹ A code of connection is a description of the security standards that doctors and organisations must adhere to in order to connect to the system. The purpose is to safeguard the system and those who are connected to it.

Maintenance and system administration

The capacity and capability of on-site administrative functions should be considered, as should the need for any additional hardware, such as computer terminals, scanners and printers.

All systems require downtime for maintenance, upgrades and system administration. Suppliers should ensure that downtime is at a regular, predictable time or is notified to users in advance. It is important that downtime is for the shortest possible period and is at times of minimal system use (for example in the early morning).

The commissioner will need to be assured that the functionality of the system will not be affected by increased numbers of users or at peak usage times and that there are appropriate failover arrangements. There should be agreed standards for access times, upload times, error notifications, screen refresh and other measures of system responsiveness, which should apply at all times including times of peak use.

Functionality

It is important that the system functions to support appraisal and revalidation in an integrated way so that information entered by the doctor and the appraiser at appraisal is also available to the responsible officer for revalidation. The management, appraisal and revalidation functions are described separately but the main advantage of a computerised support system is the effective integration of these functions.

Administrative and management functionality

The administrative functions of a computerised appraisal and revalidation support system should include simple tasks such as renewing passwords, managing registration processes and the ability to send email reminders. The system should also support the management of the appraisal and revalidation processes. The management function should allow:

- matching of an appraiser with an individual doctor
- monitoring usage statistics and information regarding quantity, type and volume of attachments
- managing planned appraisal dates, making and tracking appraisal appointments
- monitoring completion of appraisal and managing the sign-off process
- search functions for doctors by name, GMC number, department etc.

A computerised appraisal and revalidation support system should provide management reports including:

- doctors awaiting appraisal in the current appraisal year
- doctors with scheduled appraisal dates in the current appraisal year
- doctors with a completed appraisal in the current appraisal year
- doctors with a revalidation due date in the current appraisal year
- doctors who have participated in a patient and colleague feedback questionnaire in the current year or current revalidation cycle
- doctors undergoing investigation, or with unresolved concerns or formal action plans
- doctors with local restrictions, conditions or undertakings on their practice
- doctors with GMC restrictions, conditions or undertakings on their practice, or subject to GMC fitness to practise procedures
- doctors with satisfactory or unsatisfactory portfolio progression.

Quality assurance activities, including quality assurance of the doctor's portfolio, the outputs of appraisal and the responsible officer recommendation should be possible on a sample of anonymised records. It should be possible to view the records and outputs of appraisals performed by individual appraisers.

Appraisal functionality

The computerised appraisal and revalidation support system should be able to store, present and share information for medical appraisal in the context of revalidation. The system should support the requirements of the *Good Medical Practice Framework for Appraisal and Revalidation* (GMC, 2013), *Supporting Information for Appraisal and Revalidation* (GMC, 2012) and the model of annual appraisal described in the *Medical Appraisal Guide* (NHS Revalidation Support Team, 2013). Relevant speciality-based advice from the medical royal colleges should also be considered. When evaluating a system, the following functions should be considered:

- The doctor should be able to enter their scope of work, relevant data, supporting information, commentary and reflection directly into forms and tables within the system and by uploading attachments. Attachments should be accepted in all common electronic file formats and should be scanned for viruses before uploading. All data should be encrypted.
- Any file size limits for attachments should be sufficient for the vast majority of doctors and warnings should be given when limits are close to being breached.
- Where commentary and reflection relates to a specific item of supporting information, a direct link should be clear.

- A timeout function is required to reduce the risk of unauthorised access. During data entry, an auto-save or 'save alert' function should operate to minimise data loss.
- The doctor should be able to share the supporting information, the associated written commentary and their reflection confidentially with their allocated appraiser. The system should also allow sharing with more than one appraiser where joint appraisal is required. The appraiser will require access to the supporting information submitted for previous appraisals and to the outputs of each appraisal in the current revalidation cycle.
- It should be possible to save the full portfolio for each appraisal, including all attachments, and to export it to another appropriate secure system.
- It should also be possible to save parts of the portfolio so they can be reviewed separately offline.
- The appraiser may need to comment on or highlight certain areas of the portfolio for discussion.
- At agreed points in the process (usually when the portfolio is forwarded to the appraiser and at the point of post-appraisal sign-off) the content of the appraisal portfolio should be locked so that it cannot be altered or edited. It may be useful for the doctor or the appraiser to add comments or explanatory notes after the appraisal meeting. After the post-appraisal sign-off, the portfolio and the outputs of appraisal should be locked so that they cannot be altered or edited.
- It is important for the system to ensure key parts of the appraisal process are completed within specific time limits (for instance, the post-appraisal sign-off should be completed within four weeks of the appraisal meeting).
- The outputs of appraisal need to be shared confidentially with the responsible officer or those acting with appropriate delegated authority (such as the deputy responsible officer or appraisal lead).

When a doctor moves from using one computerised appraisal system to another, some parts of the doctor's information may need to be transferred to the new system. It is important to consider whether key items of information (such as personal development plan, appraisal summary, statements and sign-off) should be exported or transferred to another system in their original form. This requires these items to be entered and coded in a common format (for example see the *Medical Appraisal Guide Model Appraisal Form* format for personal development plan, appraisal summary and sign-off statements).

Many doctors record their continuing education or learning logs on secure internet sites and use other systems, such as those provided by some medical royal colleges, to record activity and reflection. Wherever possible, to reduce duplication of data recording, the doctor should be able to transfer information or summaries from these systems into their appraisal portfolio.

Revalidation functionality

When evaluating a proposed system, the following functions should be considered:

- the ability to keep a complete list of all doctors for whom the responsible officer has responsibility (with relevant identifiers), irrespective of where the doctor works or whether the doctor uses the system to support their appraisal
- the ability to track the progress of individual doctors through the five-year revalidation cycle
- appropriate search functions to identify individual doctors and groups of doctors (for example, those who have an ongoing concern or investigation, or those who have yet to complete an appraisal or a patient or colleague feedback exercise)
- a summary of the outputs of appraisal and relevant governance information relating to individual doctors (especially information relating to appraisal, concerns and fitness to practise)
- the ability to view the doctor's full scope of work, to enable the responsible officer to monitor and make recommendations on all the doctor's medical roles and to share relevant information appropriately
- direct access to key items of information, such as information regarding concerns, complaints or significant events, in order to monitor the doctor's fitness to practise and for quality assurance of the process and outputs of appraisal
- the ability to identify individual doctors whose progress towards revalidation is not satisfactory, including those whose appraisal outputs are unsatisfactory or about whom there are fitness to practise concerns
- export and transfer functionality, to facilitate the transfer of information to the new responsible officer if the doctor moves to a new designated body
- the ability to transfer revalidation recommendations effectively and securely from the responsible officer to the GMC
- the ability to allow access to an alternative responsible officer, who may be external to the organisation, in cases where the designated body needs to nominate or appoint an alternative, external responsible officer, for example where a conflict of interest or appearance of bias exists.

Information storage and security

The principles of information security require that all reasonable care is taken to prevent inappropriate access, modification or manipulation of data from taking place. In practice, this is applied through three cornerstones – confidentiality, integrity and availability:

1. Confidentiality – information must be secured against unauthorised access
2. Integrity – information must be safeguarded against unauthorised modification
3. Availability – information must be accessible to authorised users at times when they require it.

The principles of information security apply equally to paper records and computerised systems. Paper records relating to individuals should be maintained in secure storage with records kept of all named key-holders. All information should be protected against accidental loss, destruction or damage. It is important that those people acting on behalf of the responsible officer act only within the scope of their authority.

Computerised support systems must comply with high standards of security to safeguard the personal information held within them. The supplier should comply with the following:

- The supplier must undertake a recognised information assurance process, involving risk analysis, mitigation definition, testing and accreditation.
- The supplier should be accredited with ISO 27001¹⁰, thus ensuring that the processes, personnel controls and physical controls are in place and of sufficient quality to assure the protection of the information in their care. This includes virus-scanning of uploaded attachments and an audit trail of individuals accessing the system and changes made to the data, along with appropriate back up procedures. The data itself should be encrypted. The service should adopt standard practices from initiatives such as the Health & Social Care Information Centre.¹¹
- The security of the service should be independently tested by an accredited organisation on a regular basis and after significant changes. The supplier should undertake routine penetration testing to check the system is secure against unauthorised access and regular monitoring to guard against attempts to breach data protection controls. When any changes are enacted, risk-

¹⁰ ISO/IEC 27001:2005 specifies the requirements for establishing, implementing, operating, monitoring, reviewing, maintaining and improving a documented Information Security Management System within the context of the organisation's overall business risks. It specifies requirements for the implementation of security controls customised to the needs of individual organisations or parts thereof. For further information please visit www.iso.org/iso/home.htm

¹¹ The Health and Social Care Information Centre (HSCIC) is the trusted national provider of high-quality information, data and IT systems for health and social care. For further information see www.hscic.gov.uk

assessment and security considerations should be revisited to ensure that security standards are maintained or improved.

- Designated bodies should ensure that information assurance and governance policies are followed. This includes the secure disposal of decommissioned computers and hard drives.

It is important that users are vigilant to potential risks and that all risks are reported to the site administrator. For doctors, appraisers and responsible officers, the key security features should, at a minimum, include:

- access controls
- password protection
- guidance.

Access controls

Access should only be provided to named individuals formally approved by the responsible officer. The level of access for each individual (for example, access to management information, portfolio information) should be described. Access controls should include registration and authentication. All users should register on the system and receive authorisation from the administrator before accessing information and using its functions. Acceptance of terms and conditions, code of connection⁷, security standards and consent for sharing information with key individuals and retention of records should be required for registration.

Password protection

Users will need to supply a unique username and password and identify information such as their name, email address and employing organisation as part of effective password creation and management. The mechanism for updating passwords and advising users of forgotten passwords should comply with good practice in this area. Advice on this subject will be available from the organisation's information governance lead and/or IT department.

Guidance

Guidance should be issued to appraisers and doctors regarding the use of personal email accounts, personal computer systems and memory sticks for access to, storage and transfer of information for appraisal and revalidation.

Appendix 1

Useful documents

Relevant legislation

- *The Data Protection Act 1998 The Freedom of Information Act 2000*
- *The Medical Profession (Responsible Officer) Regulations 2010*
- *The Medical Profession (Responsible Officers) (Amendment) Regulations 2013*

Guidance documents

- *Confidentiality* (GMC, 2009)
- *Confidentiality: NHS Code of Practice* (Department of Health, 2003)
- *Good Medical Practice* (GMC, 2013)
- *Good Medical Practice Framework for Appraisal and Revalidation* (GMC, 2013)
- *Guiding Principles for Sharing Information on Healthcare Workers* (NHS Employers, 2013)
- *Joint Guidance on Protecting Electronic Patient Information* (British Medical Association and NHS Connecting For Health, 2008)
- *Medical Appraisal Guide* (NHS Revalidation Support Team, 2013)
- *Records Management: NHS Code of Practice* (Department of Health, 2006)
- *The Role of Responsible Officer: Closing the Gap in Medical Regulation – Responsible Officer Guidance* (Department of Health, 2010)
- *Supporting Information for Appraisal and Revalidation* (GMC, 2012)
- *Writing References* (GMC, 2013)

Electronic tools

- *Medical Appraisal Guide Model Appraisal Form* (NHS Revalidation Support Team, 2012)
- *Responsible Officer Dashboard* (NHS Revalidation Support Team, 2012)
- *Medical Practice Information Transfer (MPIT) Form* (NHS Revalidation Support Team, 2013)