

# Audit process and guidelines

Auditing the initial stages of the health professional regulatory bodies' fitness to practise procedures

Revised 2011

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# 1. Introduction

## Purpose of this document

- 1.1 Since 2009 we have carried out annual audits of cases that the nine health professional regulators that we oversee have closed without holding a formal hearing in front of a Fitness to Practise ('FTP') committee (or panel).
- 1.2 The purpose of these audits is to ensure that the regulators have not closed cases that should have been referred for a formal hearing in front of an FTP committee, and that the regulators' procedures for investigating cases are appropriate and are being followed correctly.
- 1.3 Our focus in carrying out these audits is to make sure that:
  - the regulators' decisions to close cases have not exposed patients (or service users) to unacceptable safety risks,
  - public confidence in the regulation of the profession is maintained.
- 1.4 This document sets out the process that we use when carrying out those audits.
- 1.5 We also have separate legal powers to review all the decisions that are made at formal FTP committee hearings<sup>1</sup>. More information about our review of final FTP hearing decisions is available on our website.

## Background

- 1.6 We were given the legal power to carry out these audits in 2008. Further information about this power is set out in Annex 1.
- 1.7 The process that we use to carry out the audits was developed in 2008 with input from patient groups, the regulators that we oversee, and other stakeholders. We carried out the first set of audits in 2009. The reports of all our audits are available on our website<sup>2</sup>.
- 1.8 In January 2011 our Council decided that we should make the audit process more risk-based and proportionate, and that we should audit each regulator only once every three years, unless there are specific risks justifying more frequent audits. More detail about how we decide on the frequency of each audit is set out later in this document.

## Scope of the audit

- 1.9 The number of cases that we audit depends on the size of the regulator's caseload, and our assessment of the risks within each regulator's processes. Usually we audit 100 of the cases that the regulator has closed during a set period of months immediately before the audit starts ('the audit period'). Some regulators have smaller caseloads and will not have closed 100 cases during the audit period – we will audit all the cases that those regulators have closed within that period.

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<sup>1</sup> Under section 29 of National Health Service Reform and Health Care Professions Act 2002 we can appeal final decisions of FTP panels to the courts if we think they are 'unduly lenient' and it is 'desirable for the protection of members of the public'.

<sup>2</sup> [www.chre.org.uk](http://www.chre.org.uk)

- 1.10 Although we select the cases to be audited at random, we often weight the selection so that we audit more cases that fall within categories that we think may have higher risks of significant errors. Sometimes we may need to audit more than 100 cases in order to check a large enough sample of cases in higher-risk categories.
- 1.11 More detail is given below of how we select which cases to audit.

### Scope of reporting

- 1.12 Our powers of audit are limited to looking at individual cases for the purposes of making 'general reports' or 'general recommendations affecting future cases'.<sup>3</sup>
- 1.13 We only audit cases that have been closed without a hearing by an FTP panel. This means that the only evidence that we consider is the documentary evidence that will have been considered by the decision-maker within the regulator (such as the investigating committee or the case examiner). Typically such evidence might include a written complaint, witness statements, or healthcare records.
- 1.14 As no FTP panel hearing will have been held, none of the information about the case will be in the public domain. We take care to ensure that we protect personal data and maintain confidentiality when we carry out the audits, and we avoid publishing any information that might identify the people involved in the case. All our audit team have to comply with our 'Code of Conduct for FTP Auditors' (see Annex 3). We ask the regulators that we audit to sign up to agreements with us that set out how we will handle the information that we receive or gather during the audits.
- 1.15 Our powers do not allow us to require a regulator to formally review or re-open any individual cases as a result of our audit – even if our view is that the regulator should have referred the case for a formal FTP panel hearing.

### Encouraging improvement

- 1.16 We will work with the regulators that we oversee to help them continuously improve their ways of working. Where those improvements require the law to be changed, we will work with the regulator and the government to help ensure that the necessary changes happen.
- 1.17 Where we identify areas where we think a regulator needs to improve, we will make appropriate recommendations in the report that we publish about our audit findings. We will also encourage the other regulators to consider their own processes in the light of our audit findings. We will also highlight any particular strengths that we identify within individual regulators' processes, so that other regulators can consider adopting the same practices.

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<sup>3</sup> Sections 26(1) and 26(2) of the National Health Service Reform and Health Care Professions Act 2002 as amended.

## 2. The Audit process in more detail

### Procedural guidance

- 2.1 Each of the regulators has provided us with a document that summarises their investigation procedures and identifies any guidance that they use ('the regulator's procedural guidance'). We ask the regulators to update those documents when they make changes to their procedures, so that we have accurate information about their current and past procedures. This helps us when auditing individual cases and making recommendations about possible areas for improvement. .

### Scheduling audits and assessing risks

- 2.2 We will audit each regulator at least once every three years. The audit cycle for each regulator will be reviewed annually, and any such review will take into account the level of probable risk.
- 2.3 We will consider auditing a regulator more frequently than once every three years, where:
- Information suggests that a regulator's actions may be failing to mitigate unacceptable risks to: patients or service users; or to public confidence in the regulated profession; or to the system of regulation
  - Information suggests that a regulator's performance in certain casework areas is not meeting an acceptable standard or is deteriorating
  - There has been a significant change in the policy or practice of the regulator that we consider may create risks to: patients or service users; or to public confidence in the regulated profession; or to the system of regulation
  - The regulator is new, or its governance has changed significantly, or exceptional events have taken place that may affect the performance of its fitness to practise function, and we consider that an audit may reassure the public or other stakeholders
  - The regulator requests us to carry out an audit.

### Risk factors

- 2.4 In assessing the acceptability of possible risks arising from a regulator's actions, we will compare information about the regulator to:
- The basic acceptable standard of casework that is described our document *FTP Casework Framework – an audit tool* (see Annex 2); and
  - The quality of work of the regulators that have been found to be performing well.
- 2.5 Evidence, including from our most recent CHRE audit, that a regulator is not meeting basic acceptable casework standards may include:
- Specific examples of cases closed at the initial stages of the fitness to practise process where we consider that those closures took place before adequate investigation had been completed, or where the regulator's communications about the investigation or the reasons for its closure were

inadequate, or where there has been poor 'customer' care or any significant unjustified delay.

- The existence of unclear or unacceptable policies and procedures to be used by investigators, caseworkers or decision-makers.
- Apparent weaknesses in the regulator's fitness to practise infrastructure, including those that negatively affect the quality of its case management system, the effectiveness of its management controls, the quality of its decision-making, and/or the resources available to conduct the fitness to practise process.

2.6 These criteria will be regarded as non-restrictive guidelines to be used by us in assessing how best to be proportionate and targeted in carrying out audits of cases closed at the initial stages of the regulators' fitness to practise process.

2.7 In reaching decisions about the targeting of these audits, our overriding aim will be to ensure that our initial stages audits support the regulators in delivering the objectives of their fitness to practise processes, which are:

- protecting patients (and service users)
- upholding professional standards, and
- maintaining public confidence in the healthcare professions and their regulation.

2.8 Where appropriate, in reaching decisions about the initial stages audits we will apply the principles of the Performance Review Risk Assessment Tool (see Annex 4).

2.9 As part of the information needed for our review of the audit cycle each year we will write to each regulator to ask for:

- The regulator's own assessment of areas of risk in its FTP processes. We will also ask whether the regulator has any concerns about the current procedures and whether there are any improvements it wishes to make, or intends to make, in its current procedures or legislative framework.
- A summary of significant changes to its processes or policies since the previous year.

### Selecting the sample

2.10 We usually audit cases closed within a set period of months ending immediately before the start of the audit ('the audit period'). This means that we can be sure that the audit demonstrates the regulator's current practice.

2.11 The number of cases sampled at any audit will be proportionate to our assessment of the risks and the resources available to conduct any audit. We usually audit 100 of each regulator's cases (unless the regulator closed fewer than 100 cases during the audit period – in which event we will audit the entirety of the cases that the regulator closed). However we may decide to audit more or fewer cases, where the information that we have about risks within that regulator's processes supports a smaller or larger-scale audit.

## Preparation for each audit

- 2.12 Shortly before we start each individual audit we will.
- 2.13 Write to the regulator to:
- Confirm that the audit will take place and provide information about: the estimated length of the audit; the anticipated timetable for the drafting of our audit report (including any timescales for provision of information and comments by the regulator); the names of the individual auditors who will be taking part in the audit.
  - Ask the regulator for an up-to-date version of its procedural guidance.
  - Ask the regulator to confirm that it has not changed its assessment of risks or identified any new concerns since we finalised our audit cycle.
  - Ask for information about cases that have been closed during the audit period. We will ask the regulator to give us information about the numbers of cases that were closed at different stages of its investigation process during the audit period. We will ask the regulator to refer to case reference numbers wherever possible, and not to pass on to us any information that might identify particular individuals (for example their names or registration numbers). This information will allow us to calculate the number of cases that we need to audit, and to identify the individual cases to be audited.
  - Ask the regulator to identify a key contact person within their organisation. The key contact will be responsible for ensuring that the necessary arrangements are in place for the audit to proceed, and will act as the point of contact for the auditors throughout the period of the audit.
- 2.14 We will notify the regulator which cases we wish to audit in good time for them to retrieve the relevant files from storage/archives.

## During the audit

- 2.15 We carry out each audit at the regulator's offices. We will require access to all relevant paper and electronic files and relevant policies and procedures.
- 2.16 We will not remove any documents or information from the regulator's offices.
- 2.17 Our auditors will assess each case using a standard audit form (which we will if necessary tailor to each regulator's processes and the risks within those processes).
- 2.18 The audit will assess whether individual case closure decisions protect the public (by this we mean whether the decision protects patients/service users and maintains public confidence in the profession and its regulation). This means that we need to consider some or all of the following issues:
- Does the decision to close each audited case appear to be in line with the regulator's written procedures?
  - What other outcomes or decisions were available to the regulator in each case?
  - Is there evidence that any decision to close individual cases poses a threat to patients'/service users' safety?

- Will the decisions to close the individual cases maintain public confidence?

2.19 We will also assess:

- Whether we think that there are weaknesses in the handling of any cases which indicate that other cases may be handled inappropriately in the future; and
- Whether the regulator’s processes (as demonstrated within individual cases that we audited) meet the standards of our ‘FTP Casework Framework’ document (see Annex 2)

2.20 If the audit of any case identifies any particular areas of concern, we may seek to adapt or extend the audit to include other cases that may raise similar concerns.

**After the audit**

2.21 We will produce a report at the end of each audit that summarises our key findings and any recommendations we are making to the regulator about areas for improvement.

2.22 We will work with the individual regulator throughout the audit to ensure that the content of our draft report is accurate. We will also give the regulator an opportunity to respond to any concerns raised in the report before it is published, as well as giving the regulator an opportunity to publish a formal response to the report. We will follow a four-stage process:

<b>Stage 1</b>	Verbal or written clarification of issues – this will take place during the audit or shortly afterwards. If necessary, we will write to the regulator identifying particular cases that raise concerns, and asking for the regulator’s comments.
<b>Stage 2</b>	Draft report – after clarification of any issues we will prepare our draft report and send it to the regulator. The regulator will be given an opportunity to highlight any inaccuracies in the draft report and comment on our draft findings.
<b>Stage 3</b>	Reviewing the draft report – we will consider any comments made by the regulator and, if necessary, seek further clarification
<b>Stage 4</b>	The final report – we will send the final report to the regulator, giving the date on which we will publish the report. If the regulator wishes to express disagreement with the final report, we will publish any statement that the regulator wishes to make explaining its views (provided it is of a reasonable length) alongside our final report.

2.23 Where appropriate we may reproduce some or all of our findings in our other publications, such as our annual Performance Review.

### 3. Annex 1 – Legislative Framework

3.1 We undertake the audits using powers contained in Sections 26(1) and 26(2) of the National Health Service Reform and Health Care Professions Act 2002. These are set out below:

26(1) except as mentioned in subsections (3) to (6), the Council may do anything which appears to it to be necessary or expedient for the purpose of, or in connection with, the performance of its functions.

26(2) The Council may, for example, do any of the following-

- a) investigate, and report on, the performance of each regulatory body of its functions;
- b) where a regulatory body performs functions corresponding to those of another body (including another regulatory body), investigate and report on how the performance of such functions by the body in question compares;
- c) recommend to a regulatory body changes in the way it performs any of its functions.

3.2 It should be noted that Section 26(3) of the 2002 Act, which would have prevented us from doing the audits, was amended by Section 115 of the Health and Social Care Act 2008, which states:

115 In section 26 of the 2002 Act (powers and duties of the Council: general), for subsection (4) substitute –

“(4) Subsection (3) does not prevent the Council from –

- a) taking action under section 28,
- b) where section 29 applies, taking action under that section after the regulatory body’s proceedings have ended, or
- c) investigating particular cases with a view to making general reports on the performance by the regulatory body of its functions or making general recommendations to the regulatory body affecting future cases.”

## 4. Annex 2 – FTP casework framework: an audit tool

- 4.1 The purpose of this document is to provide us with a standard framework as an aid in reviewing the quality of regulators' casework and related processes. The framework will be adapted and reviewed on an ongoing basis.

### Stage specific principles

Stage	Essential elements
1 Receipt of information	<ul style="list-style-type: none"> <li>• There are no unnecessary tasks or hurdles for complainants/informants.</li> <li>• Complaints/concerns are not screened out for unjustifiable procedural reasons.</li> <li>• Provide clear information.</li> <li>• Give a timely response, including acknowledgements.</li> <li>• Seek clarification where necessary.</li> </ul>
2 Risk Assessment	<p><u>Documents/tools</u></p> <ul style="list-style-type: none"> <li>• Guidance for caseworkers/decision makers.</li> <li>• Clear indication of the nature of decisions that can be made by caseworkers and managers, including clear guidance and criteria describing categories of cases that can be closed by caseworkers, if this applies.</li> <li>• Tools available for identifying interim orders/risk.</li> </ul> <p><u>Actions</u></p> <ul style="list-style-type: none"> <li>• Make appropriate and timely referral to IO panel or equivalent.</li> <li>• Make appropriate prioritisation.</li> <li>• Consider any other previous information on registrant as far as powers permit.</li> <li>• Record decisions and reasons for actions or for no action.</li> <li>• Clear record of who decided to take action/no action.</li> </ul>
3 Gathering information/evidence	<p><u>Documents/tools</u></p> <ul style="list-style-type: none"> <li>• Guidance for caseworkers/decision makers.</li> <li>• Tools for investigation planning.</li> </ul> <p><u>Actions</u></p> <ul style="list-style-type: none"> <li>• Plan investigation/ prioritise time frames.</li> <li>• Gather sufficient, proportionate information to judge public interest.</li> <li>• Give staff and decision makers access to appropriate expert advice where necessary.</li> <li>• Liaise with parties (registrant/complainant/key witnesses/employers/other stakeholders) to gather/share/validate information as appropriate.</li> </ul>

Stage	Essential elements
4 Evaluation/ Decision	<p><u>Documents/tools</u></p> <ul style="list-style-type: none"> <li>• Guidance for decision makers, appropriately applied.</li> </ul> <p><u>Actions</u></p> <ul style="list-style-type: none"> <li>• Apply appropriate test to information, including when evaluating third party decisions and reports.</li> <li>• Consider need for further information/advice.</li> <li>• Record and give sufficient reasons.</li> <li>• Address all allegations and identified issues.</li> <li>• Use clear plain English.</li> <li>• Communicate decision to parties and other stakeholders as appropriate.</li> <li>• Take any appropriate follow-up action (e.g. warnings/advice/link to registration record)</li> </ul>

### Overarching principles

Stage	Essential elements
1 Protecting the public	<ul style="list-style-type: none"> <li>• Every stage should be focused on protecting the public and maintaining confidence in the profession and system of regulation.</li> </ul>
2 Customer Care	<ul style="list-style-type: none"> <li>• Explain what the regulator can do and how, and what it means for each person.</li> <li>• Create realistic expectations.</li> <li>• Treat all parties with courtesy and respect.</li> <li>• Assist complainants who have language, literacy and health difficulties.</li> <li>• Inform parties of progress at appropriate stages.</li> </ul>
3 Risk Assessment	<ul style="list-style-type: none"> <li>• Systems, timeframes and guidance exist to ensure ongoing risk assessment during life of case.</li> <li>• Take appropriate action in response to risk.</li> </ul>
4 Guidance	<ul style="list-style-type: none"> <li>• Comprehensive and appropriate guidance and tools exist for caseworkers and decision makers, to cover the whole process.</li> <li>• Evidence of use by decision makers resulting in appropriate judgements.</li> </ul>
5 Record keeping	<ul style="list-style-type: none"> <li>• All information on a case is accessible in a single place.</li> <li>• There is a comprehensive, clear and coherent case record.</li> <li>• There are links to the registrations process to prevent inappropriate registration action.</li> <li>• Previous history on registrant is easily accessible.</li> </ul>
6 Timeliness and monitoring of progress	<ul style="list-style-type: none"> <li>• Timely completion of casework at all stages</li> <li>• Systems for, and evidence of, active case management, including systems to track case progress and to address any delays or backlogs.</li> </ul>

## 5. Annex 3 – Code of conduct for auditors

### Introduction

- 5.1 Our<sup>4</sup> aim is to carry out the audits in a way that promotes the public interest and safety. To do this effectively, we aim to:
- foster a constructive and co-operative relationship with all the organisations that we audit;
  - assure ourselves and our stakeholders that we always act with the highest standards of professionalism.
- 5.2 For this reason, any staff involved in conducting audits on the premises of audited organisations are expected to sign and comply with this code of conduct (“the code”). For the purposes of this document, the term “staff” includes employees, contractors, people seconded to work with us, or working under our direction.
- 5.3 Failure to comply with the terms of this code as well as endangering our reputation and vital external relationships may also result in a failure to comply with other specific policies for example in relation to data handling. Breaches of this code therefore have the potential to be considered as serious disciplinary offences/contractual breaches.

### General conduct

- 5.4 When carrying out an audit, you will be expected to conduct yourself with utmost integrity, honesty, objectivity, professionalism and courtesy; and to consider yourself as our ambassador.
- 5.5 You must familiarise yourself with our policies and rules on staff conduct, and the terms of any memorandum of understanding that has been agreed between us and the organisation being audited. You must keep within the spirit and letter of these policies, rules and agreements.
- 5.6 You must take special care to protect and keep confidential any information, including paper and electronic documents, which you acquire during an audit. You must not discuss such information with anyone except those who legitimately need to know about it as part of the auditing process. If you have any doubt about when you may divulge information, you should consult your line manager or a member of the senior management team.

### Actual and perceived conflicts of interest

- 5.7 It is important that our activities are free from bias, or suspicions of bias, and are seen to be so. For this reason you must avoid any perceptions of bias that might arise from personal interests or the receipt of gifts or entertainment or other benefit.

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<sup>4</sup> References in this document to ‘our’, ‘us’, ‘we’, are to CHRE or any successor body. ‘You’, ‘your’ refers to any of our staff (including contractors etc) to whom this code of conduct applies.

### *Personal interests*

- 5.8 Staff taking part in audits should declare any personal interest relating to the regulator being audited. This should be done by completing the 'Register of interests relating to FTP audits/performance reviews/investigations of regulatory bodies'. New registered interests should be drawn to the attention of your manager. In good time, before starting work on an audit of a particular organisation, you should consider whether you have any personal interests that you have not already registered. You should err on the side of caution, in favour of declaring a possible personal interest. You should register and declare the interest as soon as it becomes apparent to you.
- 5.9 If you think it may not be appropriate to take part in a particular audit you should discuss this with your manager.
- 5.10 A personal interest would include any personal friendships, or family or business relationships, you have with individual members of staff of the audited organisation; or employment or contractual relationship you have had with the audited organisation within the five years before the start of the audit. A personal interest may also arise if you have had a significant negative experience with an individual or organisation.
- 5.11 You may also discover during an audit that you have a personal connection with a case. Again you should err on the side of caution and stop work on that case until you have consulted your manager. Where there is a personal interest to declare, a record will be made. The record will be in general terms such as "declared a personal connection with someone closely involved in the case that was being audited, and discontinued any consideration of that case", or "prior knowledge of case...".
- 5.12 During the period of an audit you should normally not take part in social activities, on or off the premises, with staff of the organisation being audited. If you are invited to such an activity and consider that you should attend for professional reasons, you should consult your manager where possible, or a member of the senior management team. You must always act professionally and avoid talking about the progress or detail of the audit, and should not subsequently reveal any information that has not been published in a report.

### *Gifts and entertainment*

- 5.13 You should avoid accepting any gift, entertainment or other benefit from any person who is employed or associated with an organisation that we audit. This is before, during or after an audit. You may accept light refreshments such as non-alcoholic drinks and biscuits (but not a free meal) offered during the course of a normal working day – this will not be regarded as a gift or entertainment or benefit.
- 5.14 If you consider, in your professional judgment, that it has been necessary to accept a gift or entertainment or benefit, you should declare this in writing to your line manager. Agreement must be reached in writing on how a gift should be treated. It may be decided that a gift can be kept by you; or it may be kept by us for communal use; or otherwise donated or returned, where this will not cause offence. Any gift or entertainment that is received will be recorded, along with the gift's final destination, on the register of interests.

### Safety of self and others

- 5.15 You must comply with our health and safety policies when conducting an audit. You must also comply with any health and safety instruction given to you by a member of the audited organisation's staff.
- 5.16 Working away from our offices alone or in small groups presents greater risks and gives rise to a greater duty to look after each other and yourself. You should familiarise yourself with our lone worker policy.
- 5.17 In particular you should not place yourself in a situation where you will be at risk. If you feel you are at risk, for instance due to the location of the offices or your workplace within the office, you should discuss this with your line manager or other manager.
- 5.18 You must not work at the premises outside that organisation's normal working hours, other than in exceptional circumstances and by agreement with the organisation and your line manager.
- 5.19 If unexpectedly you will not be attending work, you must notify your line manager as well as a member of the audit team who will be on the premises of the audited organisation.
- 5.20 If a member of the audit team unexpectedly does not attend the premises, and does not make contact with the audit team by 10am, you should contact your line manager or another manager as soon as possible. The manager should decide how to establish whether that team member is safe.

### Protecting property

- 5.21 You must take special care to protect our property, the property of the organisation you are auditing, and your own property. Take all reasonable precautions to protect from theft or loss any valuable equipment, or equipment giving access to data.

### Computer use

- 5.22 You must comply at all times with our "Code of Conduct on IT use" and any other of our policies or rules relating to the use of computers, phones and similar devices. This applies both when you are using equipment (including computer and internet access facilities) provided by the audited organisation and when you use your own or our equipment to access the audited organisation's internet provision (which you should only do in exceptional circumstances and with prior agreement).
- 5.23 You must also comply with any additional requirements that the audited organisation may communicate to you. If these appear to be unreasonable or to interfere with your ability to conduct the audit, you should consult with your line manager as soon as possible.
- 5.24 You should assume that you may not use the audited organisation's computer or phone equipment (other than when accessing agreed parts of the organisation's database for the purposes of the audit). If exceptionally it is agreed that you may use the audited organisation's computer and phone equipment, you must not use it for personal use or to access the internet or to send emails. You may only use such phone equipment in an emergency, after receiving permission.

- 5.25 When conducting an audit, you must connect to our server only through equipment provided by us. You must always use the secure settings available on our equipment.
- 5.26 You must always password-lock your computer screen when leaving it, or when not using it. The automatic password lock should be set to operate within 5 minutes of the equipment being idle.
- 5.27 You must password-protect your PDA and ensure that it automatically locks within 5 minutes of the PDA being idle.
- 5.28 Portable data storage devices (such as data sticks, disks and laptops) create a significant risk of loss of data and you must avoid storing data on these devices. You must never copy confidential information onto such storage media. This includes identifiable information from cases we have audited and any other personal and sensitive data. Any original document acquired during an audit should be treated as confidential and not copied in this way.
- 5.29 Where it is necessary to work 'offline' you must only save data on a laptop that we have provided. You may only store documents that meet all the following criteria:
- The document has been created by a member of our staff (including yourself);
  - The document does not contain easily identifiable personal information about another person (for example it contains only a case reference number and does not contain any names/addresses/dates of birth); and
  - The document is password protected.
- 5.30 You should upload the information, and remove it from your laptop, as soon as reasonably practical.

### Handling of information

- 5.31 You should not seek to access any information that does not fall within the limits of the audit.
- 5.32 If information is divulged to you in error, you must stop reading the information and consider whether you should notify the audited organisation's nominated representative and your line manager.
- 5.33 You must not remove or send (either physically or electronically) from the premises of the audited organisation any information that you acquire during an audit. Usually only general information (such as information that is not specific to an individual case) may be collected and removed from the organisation's premises. The only exception to this is information that has been legitimately collected as part of the audit and that is in a form that we and the audited organisation have agreed may be removed, or information that it is envisaged in the established audit process will be removed from the organisation's premises. Usually we will have agreed with the audited organisation that case documents will not be removed from their premises - and then only with permission, and with any personal identifying information redacted. If you do need to remove case documents (including copies) you must make sure that you have the permission of your line manager or a member of the senior management team. The manager should ensure that we have appropriate permission from the audited organisation.

- 5.34 You must not send case-related documents by email unless there are exceptional circumstances. Documents that are emailed must be password-protected.
- 5.35 You must take care not to mark or alter any of the audited organisation's physical files, or the information held on their computer or other electronic systems. If this happens accidentally, you must tell the organisation's representative as soon as possible.

### **Confidentiality agreement**

- 5.36 This code of conduct incorporates our standard confidentiality agreement terms and, by signing to agree to be bound by the code of conduct, you also agree to the terms of the confidentiality agreement. These are reproduced (and expanded for the purposes of the audits) in the following paragraphs.
- 5.37 It is a condition of your contract with us that you do not reveal confidential information gained during the course of your work with us, either during or after termination of your work for us.
- 5.38 You may have access to personal and/or confidential information belonging to third parties during your work for us. You must not access this information except with our permission.
- 5.39 If you suspect that personal or confidential information has been disclosed to you in error, you must cease to view that information as soon as you become aware of this possibility and you must bring to your line manager's attention the fact of this disclosure.
- 5.40 You must not disclose personal or confidential information accessed during the course of your work to third parties unless this is expressly authorised by us.
- 5.41 All records, reports, documents, publications and other papers written or acquired by you in the course of your work will remain our property and must be returned to us on termination of your work for us. You must not make copies of any documents for your personal use.
- 5.42 Confidential information belonging to us includes all information which has been specifically designated as confidential as well as information relating to our financial and business activities.
- 5.43 You owe this same duty of confidentiality in respect of any information you acquire from another organisation during the course of your work with us. This applies whether or not such information is specifically designated as confidential. You agree that we may take the same actions against you for breach of confidentiality as though the information originally belonged to us.
- 5.44 You must not use information gained through your engagement or experiences of your work for us, including anecdotal and statistical information, for the purpose of publishing or disseminating any article, essay or research, including non-pecuniary and academic work, without our express written permission. Such permission will, unless otherwise stated, be subject to our giving approval for the finished document to be used, and will not be unreasonably withheld.
- 5.45 You must provide us with three business days' notice of any intention to disclose any matters relating to your work with us to any third party, including information not relating to personal or confidential information. You agree not to disclose any such matters without our consent.

- 5.46 You accept in signing this Agreement that damages will not be an adequate remedy in respect of any breach of this Agreement and that we will be entitled to seek an injunction to prohibit use of any information obtained in this way by you or any third party, in addition to our right to seek other common law remedies.
- 5.47 This Agreement excludes information which has lawfully entered the public domain by reason other than your breach of this Agreement.

**Agreement to comply with code of conduct**

- 5.48 I agree to comply with the terms of this code of conduct (including the terms of the confidentiality agreement).
- 5.49 I understand that breaches of this code may lead to disciplinary action against me.
- 5.50 I agree that after signing this document, unless I promptly inform the Chief Executive in writing, I will be deemed to have accepted any future changes to this code of conduct, and any related policies and rules, that are notified to me or to staff generally.

**Signed:** \_\_\_\_\_

**Name:** \_\_\_\_\_

**Current job title:** \_\_\_\_\_

**Date:** \_\_\_\_\_

## 6. Annex 4 – The Risk Assessment Tool

### Introduction

- 6.1 If concerns about a regulator's performance arise during the performance review, because of information that has been provided by the regulator and/or other information that we hold, we will carry out a risk assessment to determine what action to take.
- 6.2 The purpose of the risk assessment is to provide a framework through which we can explain to our key stakeholders our decision to take or not to take any further action on the area of concern.

### Evaluation of concerns

- 6.3 When evaluating the concern we have identified we will consider the following four fundamental questions:
1. How robust is the information supporting our concern?
  2. How likely is it that the public, patients, employers and registrants will be affected as a result of this?
  3. How severe would the impact be on the public, patients, employers and registrants?
  4. How confident are we that the regulator is aware of this area of concern and is already making the necessary improvements?
- 6.4 When addressing the above questions, we will consider a number of different factors as outlined in the attached tables. However, these questions and factors are only guidance and we may consider other factors where necessary. We will not have to satisfy all of the factors to make a judgement. The factors are to be used merely as a guide for staff when considering the risk assessment.

### What action should we take?

- 6.5 Having evaluated our concerns, we will determine what action we should take. The three possible options outlined at table 5:
1. No action to be taken
  2. Note in the performance review report the efforts being made by the regulator to address the concerns. Concerns will be followed up throughout the year and in the next performance review.
  3. Investigate the area (s) of concern
- 6.6 When we have decided what action to take, we will share this with the regulator. We will work with the regulator on how to take the proposed action forward.

**Table 1: Prompts to help us address the five questions**

Question	Factors to consider	Answer
How robust is the information supporting our concern?	<ul style="list-style-type: none"> <li>• What are our sources of information?</li> <li>• Is there sufficient information to make a decision?</li> <li>• How up to date is our information?</li> </ul>	<b>Robust/Not robust</b>
How likely is it that the public, patients, employers and registrants will be affected as a result of this?	<ul style="list-style-type: none"> <li>• What would be the impact?</li> <li>• How often are they likely to occur?</li> </ul>	<b>Rare, unlikely, possible, likely, almost certain (modified by confidence level)</b>
How severe would the impact be on the public, patients, employers and registrants?	<ul style="list-style-type: none"> <li>• How long would the impact be felt for?</li> <li>• Who would be most affected?</li> <li>• What impact would this have on the public's confidence in health professions regulation?</li> <li>• What affect would this have on the effectiveness of the organisation?</li> </ul>	<b>Negligible, minor, moderate, major, catastrophic</b>
How confident are we that the regulator is aware of this area of concern and is already making the necessary improvements?	<ul style="list-style-type: none"> <li>• Is the concern restricted to one function, one aspect of a function or is it spread across the functions?</li> <li>• Has the regulator identified this as a concern?</li> <li>• Has the regulator began to take action to address the concern?</li> <li>• Is the regulator capable of responding to this concern?</li> </ul>	<b>Not confident, confident, very confident</b>
What action should we take?	<ul style="list-style-type: none"> <li>• What is the risk to the noted groups and therefore, what is our level of concern?</li> </ul>	<ul style="list-style-type: none"> <li>• <b>No action to be taken</b></li> <li>• <b>Note in the performance review report the efforts being made by the regulator. Concerns will be followed up throughout the year and in the next performance review.</b></li> <li>• <b>Investigate the area (s) of concern</b></li> </ul>

**Table 2: Evaluating the likelihood of an occurrence**

The likelihood grading system is taken from the NPSA’s guidance for risk managers, clinicians and health care staff and is in line with the Healthcare Commission’s guidance. This supports a consistency of analysis across healthcare regulation and review.

Likelihood score	1	2	3	4	5
Descriptor	Rare	Unlikely	Possible	Likely	Almost certain
Frequency How often are they likely to occur?	This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting issue	Will undoubtedly happen/recur, possibly frequently

**Table 3: Evaluating the impact**

When considering the impact, we need to consider the consequence level

Consequence	1	2	3	4	5
<b>Descriptor</b>	<b>Negligible</b>	<b>Minor</b>	<b>Moderate</b>	<b>Major</b>	<b>Catastrophic</b>
How long would the impact be felt for?	No impact felt	Less than 6 months	6 months to 12 months	12 months	Over 12 months
Who would be most affected?	No one	No one group in particular	Some groups notably, patients and the public	All groups	All groups
What impact would this have on the public's confidence in the regulator?	No impact felt	Limited impact -short term loss of confidence  Few elements of public expectation not met	Medium term loss of confidence  Some elements of public expectation not met	Long term loss of confidence  Significantly below public expectation	Permanent loss of confidence  Significantly below public expectation
What affect would this have on the effectiveness of the organisation?	No impact felt	Would have a small impact on the effectiveness of the organisation	Would have a significant affect on the effectiveness of the organisation.	Would prevent the organisation from running effectively	Would prevent the organisation from running effectively

**Table 4: Evaluating our confidence in the regulator**

When considering risk we need to evaluate our level of confidence in the regulator to address the concern we have identified, to ascertain whether improvement can occur without our intervention.

<b>Confidence</b>			
<b>Question</b>	<b>Not confident</b>	<b>Confident</b>	<b>Very confident</b>
Is the concern restricted to one function, one aspect of a function or is it spread across the functions?	Concern covers one or more function or aspect of function	Concern is restricted to one to two aspects of a function	Concern is restricted to one small aspect of a function
Has the regulator identified this as a concern?	The regulator does not consider this to be an area of concern	The regulator has insight into this area	The regulator expresses clearly that this is a cause for concern
Has the regulator began to take action to address the concern?	The regulator has taken no steps to address the concern nor are steps planned	The regulator has action to address the concern planned. Willing to modify plans to speed up or better enable improvement	The regulator is already taking action to address the concern
Is the regulator capable of responding to this concern?	Few or unsatisfactory systems in place. Inadequate levels of support from the Council and the Executive	Systems are in place and improvement is ongoing. Has the support of the Council and the Executive	Systems are in place and fully implemented. Has the support of the Council and the Executive

**Table 5: Evaluating the action, we should take**

We use the common risk assessment format:

**(Likelihood) x (consequence) = risk**

**Risk +/- confidence = action to take**

There is no predetermined formula for applying the modification of confidence – it is a judgement call as to whether the current management of the regulator affects our consideration of risk.

Likelihood score	1	2	3	4	5
	Rare	Unlikely	Possible	Likely	Certain
<b>5 Catastrophic</b>	5	10	15	20	25
<b>4 Major</b>	4	8	12	16	20
<b>3 Moderate</b>	3	6	9	12	15
<b>2 Minor</b>	2	4	6	8	10
<b>1 Negligible</b>	1	2	3	4	5

**1. No action to be taken**

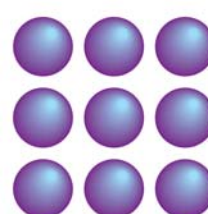
**2. Note in the performance review report the efforts being made by the regulator to address the concerns. Concerns will be followed up throughout the year and in the next performance review.**

**3. Investigation**

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