

# **Enforcement decision tree**

February 2015

# Introduction

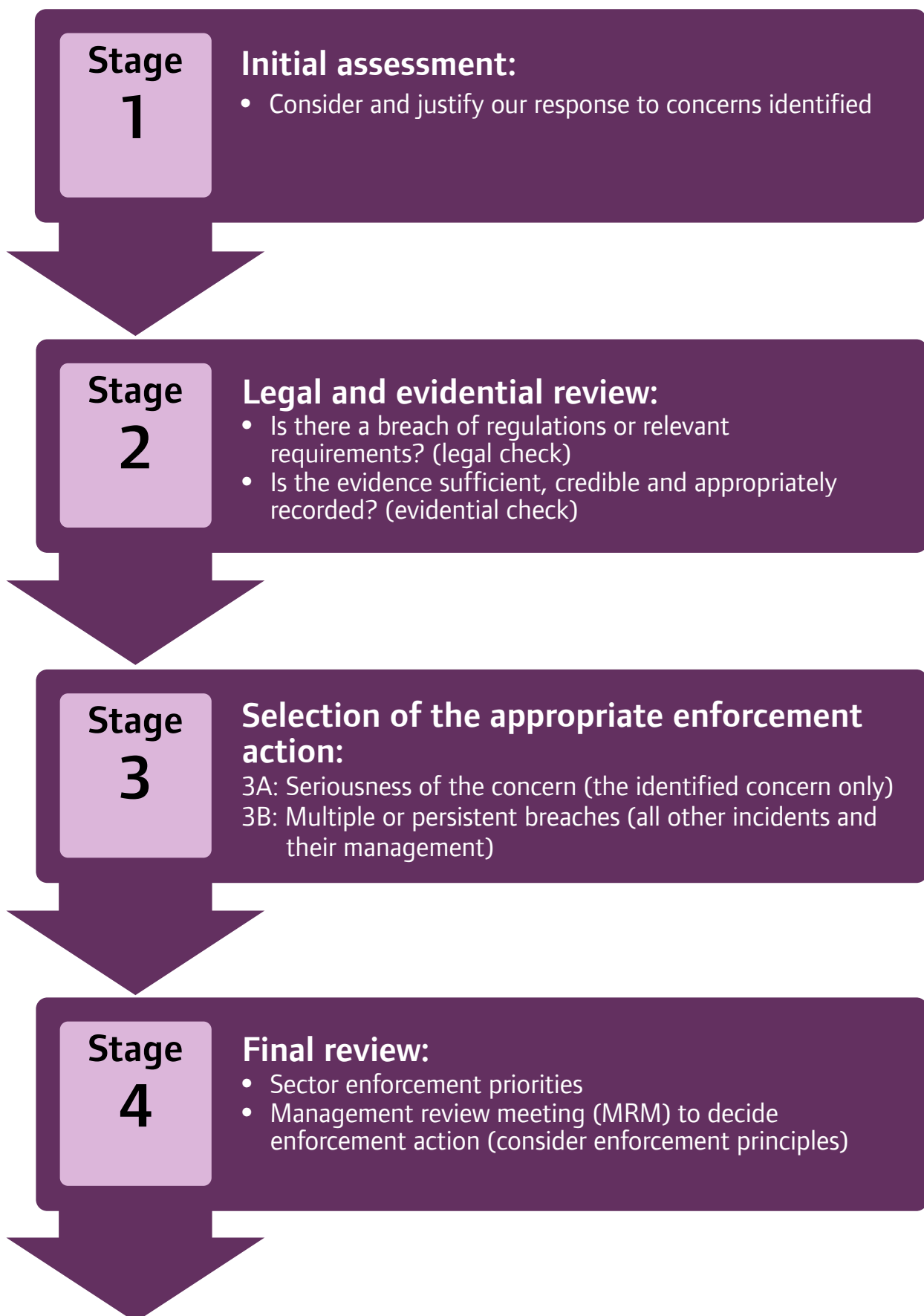
The enforcement decision tree is at the core of how the Care Quality Commission (CQC) applies its enforcement policy. The decision tree describes the process that guides inspectors to a decision on whether to use enforcement powers and, if so, which ones are proportionate. By setting a structured decision-making process, it will drive both consistency and proportionality.

The decision tree has four stages:

1. Initial assessment.
2. Legal and evidential review.
3. Selection of the appropriate enforcement action.
4. Final review.

The decision tree forms the basis for the enforcement guidance for inspectors, the detailed training that each inspector will receive, and the tools available to inspectors to support their decision making on enforcement. The decision tree has been developed and tested with input from across CQC's directorates, in particular with representatives from the operations team to ensure it is robust and effective. It should also be used alongside the [enforcement policy](#), which provides further guidance on which enforcement powers are appropriate for different scenarios.

# Enforcement decision tree



# Stage 1: Initial assessment

CQC becomes aware of incidents and events that could potentially warrant enforcement from a number of sources. These include notifications by providers, safeguarding alerts, instances of whistle-blowing, coroners' reports, complaints, comments from the public, and concerns identified during inspection.

When this occurs, the first stage of the process is to conduct an initial assessment to consider what response may be appropriate from the full set of options available to inspectors. The options at this stage include us taking action short of formal enforcement (for example, by bringing forward a comprehensive inspection or referring the issue to another oversight body). Another option is for us to take formal enforcement action.

During the assessment stage we need to ensure that we respond properly to any information about a possible breach in standards. We recognise that each case will be different and so we have a wide range of options we can use where there are possible breaches, including enforcement, inspection or referral. It is not feasible or proportionate to follow up every single breach of standards. However, information about every potential breach should result in some level of initial enquiry. For example:

- All safeguarding alerts should be reviewed.
- Notifications should be triaged and more serious (non-administrative) ones forwarded to the relevant inspector to consider.
- Any concerns identified during an inspection should be looked at in more detail before decisions are made.

Where these initial enquiries do not provide sufficient assurance that people using regulated services are reasonably protected from harm, or that a provider or individual may need to be held to account, escalation to enforcement should be considered.

Where a matter is escalated, a management review meeting (MRM) should be convened to decide on the most appropriate next step.

The MRM follows a defined decision-making structure including mandatory steps and a quality framework to help drive consistency. The MRM is an iterative process that continually reviews decisions about what, if any, enforcement action should be taken until a decision is reached by a CQC decision maker identified in the scheme of delegation. The MRM also ensures there is a documented rationale for all decisions thus assisting us to operate a clear decision-making process and to provide an audit trail to show how decisions were reached.

In the most serious cases we may move straight to collecting evidence with a view to urgent procedures or prosecution, without first going through the initial assessment. Such cases will usually be where people who use services are at risk of immediate harm unless we act, or where robust evidence is only available for a short time.

In all cases we will have regard for the criteria set out in our enforcement policy. These include acting on breaches of fundamental standards of care, and prioritising cases with the potential to 'send a message' to the provider community or which could have a broader impact in influencing improvements across a sector.

The MRM will consider the full range of possible responses but should recognise the importance of working cooperatively with providers and our limited enforcement resources. We expect that relatively few cases will move straight to stage 2, which involves the collection of evidence with a view to commencing a prosecution. However, in making the decision to move to stage 2:

- We will have regard to criteria set out at stages 2 and 3.
- We will have regard to any current sector enforcement priorities in our business plan.
- We will check whether the facts as we understand them support a case where there has been a serious breach of the provider's legal duties, where we are best placed to take the lead, and where it is feasible to collect evidence.

## Stage 2: Legal and evidential review

Where a case progresses from stage 1 to stage 2, the inspector will conduct a legal and evidential review of the case.

This involves an assessment of the legal and evidential basis to determine whether there is sufficient evidence of a breach of the regulatory standards, or other breach of the legal requirements by a provider, to justify progressing to stage 3.

- The review must identify: What breach of the regulations or other legal requirement appears to have taken place?
- Whether enforcement action may be appropriate in the light of CQC's statutory guidance and considering any other relevant legislation.
- Do we possess or can we obtain sufficient, credible and appropriately recorded evidence to support enforcement action? It will usually be necessary to create an 'evidence bundle' at this stage, which may later become the evidence to be disclosed.

The stage 2 review will be conducted by inspectors who will seek advice where necessary.

If the inspector considers the evidence demonstrates an identifiable breach of the regulations or other legal requirements, and that it is likely to be sufficient and robust to prove the breach, the case will usually continue to stage 3.

## Stage 3: Selection of appropriate enforcement action

Stage 3 uses a structured decision-making process to decide the appropriate enforcement action. Our enforcement criteria take account of CQC's duty to protect and promote the health, safety and welfare of people who use regulated health and social care services by encouraging improvement and focusing on the needs and experiences of people using services. The criteria also consider the need for CQC to hold providers and individuals to account for compliance with their legal obligations.

The decision-making process seeks to ensure we take consistent and proportionate decisions without being too prescriptive. It should not result in mechanistic recommendations but should guide individuals nominated in the scheme of delegation to reach an appropriate decision.

This stage consists of two criteria that assist CQC decision makers to choose which enforcement powers we should use. The criteria are:

- Seriousness of the concerns.
- Evidence of multiple and/or persistent breaches.

### Stage 3A: Seriousness of the concerns

We will seek to take progressively stronger action in proportion to the scale of the impact on people using a service as well as the number of people affected. Similarly, we will take stronger action where a service is carried on in an inappropriate way without effective management of risk.

For example, a service would be carried on in an inappropriate way if policies (such as controls, safeguards, precautions or good practice standards) are in place but they are not implemented, despite being reasonably practicable. This would also be the case where there is disregard for legal requirements, attempts to avoid them or provision of false or misleading information.

#### 3A(1): Impact of the concerns

Inspectors should assess the level of impact that would result if the concerns identified about a service were to happen again. The focus here is on reoccurrence in order that we can assess if we should act to protect people using regulated services from harm in the future. Accountability for previous issues is considered as part of the next stage (stage 4), which determines whether a prosecution should be commenced.

Impact of the concerns	Definition
<b>Major</b>	<p>Serious risk to a person's life, health or wellbeing, that is:</p> <ul style="list-style-type: none"> <li>• Has or would have a significant current or long-term impact on a person's life and health which may result in a permanent or irreversible condition.</li> <li>• Has or would significantly reduce a person's quality of life.</li> </ul> <p>Care being provided that is considerably poorer than would be required to meet the fundamental standards.</p>
<b>Moderate</b>	<p>Risk of significant harm to a person's life, health or well-being, that is:</p> <ul style="list-style-type: none"> <li>• Has or would have a moderate impact on a person's life and health which may result in a non-permanent or reversible condition or temporary disability that lasts less than 28 days.</li> <li>• Has or would moderately reduce a person's quality of life although it is reasonably manageable by the individual concerned.</li> <li>• Has or would significantly infringe a person's rights or welfare.</li> </ul>
<b>Minor</b>	<p>People using the service have experienced care that has had a negative impact on their health, quality of life, personal rights and welfare, but not to a level included above.</p>



### 3A(2): Likelihood that the facts giving rise to concerns will happen again

Inspectors should assess the likelihood that the facts which gave rise to the incident or concerns about a service will happen again. The likelihood should be based on the control measures and processes in place to manage the concerns identified, including changes in practice (such as recruiting additional staff or replacing equipment).

Likelihood facts giving rise to concerns will happen again	Definition
<b>Probable</b>	The facts which gave rise to concerns are likely to happen again because there are minimal or ineffective control measures or processes in place to manage the risks so people using services may be exposed to risk of harm.
<b>Possible</b>	The facts which gave rise to concerns will probably happen again but, if they do, the control measures and processes in place mean that people using services should be protected from the risk of significant harm in all or most cases.
<b>Remote</b>	The facts which gave rise to concerns are unlikely to happen in the future. Control measures and processes are in place to manage the risks and/or the potential for reoccurrence is time-limited (for example, new equipment has replaced failing equipment that caused harm).

#### Example 1

Some controls address likelihood, such as the [World Health Organisation \(WHO\) Surgery safety checklist and implementation manual](#). This reduces the likelihood of surgery on the wrong patient or wrong site. Therefore, where it is not being used it increases the likelihood that there will be a moderate or major impact on people using a service.

**3A(3): Seriousness of the concerns**

Inspectors should use their assessments of the impact of the concerns about a service, and the likelihood the facts giving rise to the concerns will happen again. They should then apply them to the table below to determine whether the seriousness of the concern is low, medium, high or extreme.

		Likelihood the facts giving rise to concerns will happen again		
		Remote	Possible	Probable
Impact of the concern	Minor	Low	Low	Medium
	Moderate	Low	Medium	High
	Major	Medium	High	Extreme

### 3A(4): Initial recommendation

Inspectors should use the results of 3A(3) to reach an initial recommendation about which civil powers should be used to protect people using the service from harm or the risk of harm.

This recommendation only takes account of the impact of the concerns and the likelihood of the circumstances that gave rise to the concerns occurring again. A final decision will not be reached until the multiple and persistent criteria, and our sector enforcement priorities, have been considered.

Seriousness of the concern	Recommended initial civil enforcement action
<b>Extreme</b>	Urgent cancellation Urgent suspension Urgent imposition, variation or removal of conditions
<b>High</b>	Cancellation Suspension More significant conditions (impose, vary or remove)
<b>Medium</b>	Conditions (impose, vary or remove) Warning Notice
<b>Low</b>	Requirement Notice

Our enforcement policy describes when we tend to consider use of each of these powers and should be taken into account. In particular, conditions can range from formalising administrative details, to restricting risky services or requiring specific improvement. Therefore there are principles for the use of these powers, and for their urgent use.

## Stage 3B: Identifying multiple and/or persistent breaches

Once a decision has been made under stage 3A, inspectors should apply the tests under stage 3B to consider whether a more or less serious level of enforcement is appropriate.

This part of the decision-making process considers whether the identified concerns are part of a pattern of concerns about the provider, demonstrating systemic failings. It also considers the provider's ability to identify risks and make the necessary improvements, or whether they are not able to do this due to management failures.

This stage considers any evidence of multiple or persistent failings. This includes a review of whether there are repeated breaches, the provider's overall history of performance, whether there was a failure to assess or act on risk, and whether there is adequate leadership and governance.

Decisions made under stage 3B can result in a change to the recommended enforcement action by increasing or decreasing the severity. A decision can also be made to recommend holding an individual or provider to account by commencing a criminal prosecution.

The enforcement criteria prompt consideration of 'prosecution powers'. The criteria do not differentiate between full prosecution, caution or fixed penalty because there are common features at the start of all criminal proceedings (notably, the need for a high standard of evidence). The eventual outcome will depend on consideration of the specific evidence and circumstances of each case and, on occasion, how the provider responds to any civil proceedings. The only exception is where a specific scenario is singled out for consideration of fixed penalties (for example, absence of a registered manager) or as an annual sector enforcement priority set out in CQC's current business plan.

For this stage, inspectors should work through each of the questions below to identify any adjustments to the recommendation made under stage 3A(4). Inspectors should also consider whether criminal powers should be recommended to hold a provider or an individual to account.

### **3B(1): Has there been a failure to assess or act on past risks?**

Inspectors should consider:

- Is there a history of not assessing risks to people using services, either on purpose, through neglect or because ineffectual/inadequate action has been taken?
- Is there a history of not acting on identified risks for people using services (including a failure to act on previous CQC requirements or enforcement actions)?

#### **Example 2**

A provider of services for people with a learning disability has clear policies for managing patients with epilepsy. However, when a patient is admitted, the service does not carry out a needs assessment in line with its own policy. It then fails to take account of the specific risks associated with epilepsy, even though the patient's notes flagged this as a key issue that should be reflected in the care plan. Care plans may be generic rather than individual and, although observations of the patient were carried out, they were done in line with the general observation policy, without any member of staff questioning whether additional observations might be needed for a person with a history of frequent fits. The patient's death, after an apparent fit while taking a bath, raises questions about the provider's systems for risk assessment and management overall.

### **3B(2): Is there evidence of multiple breaches?**

Inspectors should consider:

- Is there more than one breach of a regulation or relevant requirements at the same location, different locations, or across the whole or part of the service, which may indicate that the current incident is part of a pattern of concerns?
- Is there more than one core service, key question or population group rated inadequate?
- Are there multiple breaches in a small service? (This may be of greater concern than multiple breaches in a large service, for example, three people affected in a six-bed care home compared with a 600-bed NHS foundation trust.) Inspectors should take account of the proportion of breaches compared with the size of the service and population receiving care.

#### **Example 3**

A mental health service provides a range of services in a number of different settings. However, it is identified that there is no central system for managing incident reporting and that the overall governance processes are disjointed. The lack of effective governance has resulted in patterns of issues across the service and ratings of inadequate overall for safety and responsiveness. These ratings require the initial recommendation to be reviewed and criminal proceedings to be considered.

### **3B(3): Does the provider's track record show repeated breaches?**

Inspectors should consider:

- Are there repeated breaches of the regulations during an inspection cycle (for example, within the last three years) by the provider or at location level?
- Are there requirements or enforcement actions that have not been complied with and have the necessary improvements not been made?
- Has a provider been placed in special measures and been unable to improve services, such that it still has one or more ratings of inadequate at the end of the time-limited period?

If the answer to the third question is 'yes', consideration should be given to cancelling the registration unless there is good reason not to do so.

Inspectors should note that a provider's history is from the first date of registration of the provider or manager to carry on the regulated activity. If a provider has de-registered and then re-registered (for example, with a new name), the history should still be taken into account but with caution so as not to make unwarranted assumptions.

#### **Example 4**

A resident of a care home dies from choking after being helped to eat inappropriate food, despite the risk being clear in her care plan. This is the fourth incident of differing severity at the home in the last few months, in which lack of induction and basic information for agency staff have resulted in them not following care plans. This constitutes a pattern of repeated breaches. Therefore, we would review the initial recommendation and consider criminal proceedings.

A GP practice had recruited office staff without carrying out disclosure and barring service (DBS) checks as part of their recruitment. When this was raised with the practice manager, they amended their procedures immediately to include a DBS check for all staff and stipulated that staff that had been recruited previously without a DBS check must now apply for one. When reviewing their history, the practice had maintained compliance with the regulations and relevant requirements consistently and it was performing well. As the issue was rectified immediately, issuing a requirement that recruitment of office staff involves a DBS check would be appropriate, rather than issuing a Warning Notice or imposing conditions.

### **Stage 3B(4): Is there adequate leadership and governance?**

Inspectors should consider:

- What are the previous ratings or findings for the well-led key question and the competency and capability of the provider's management?

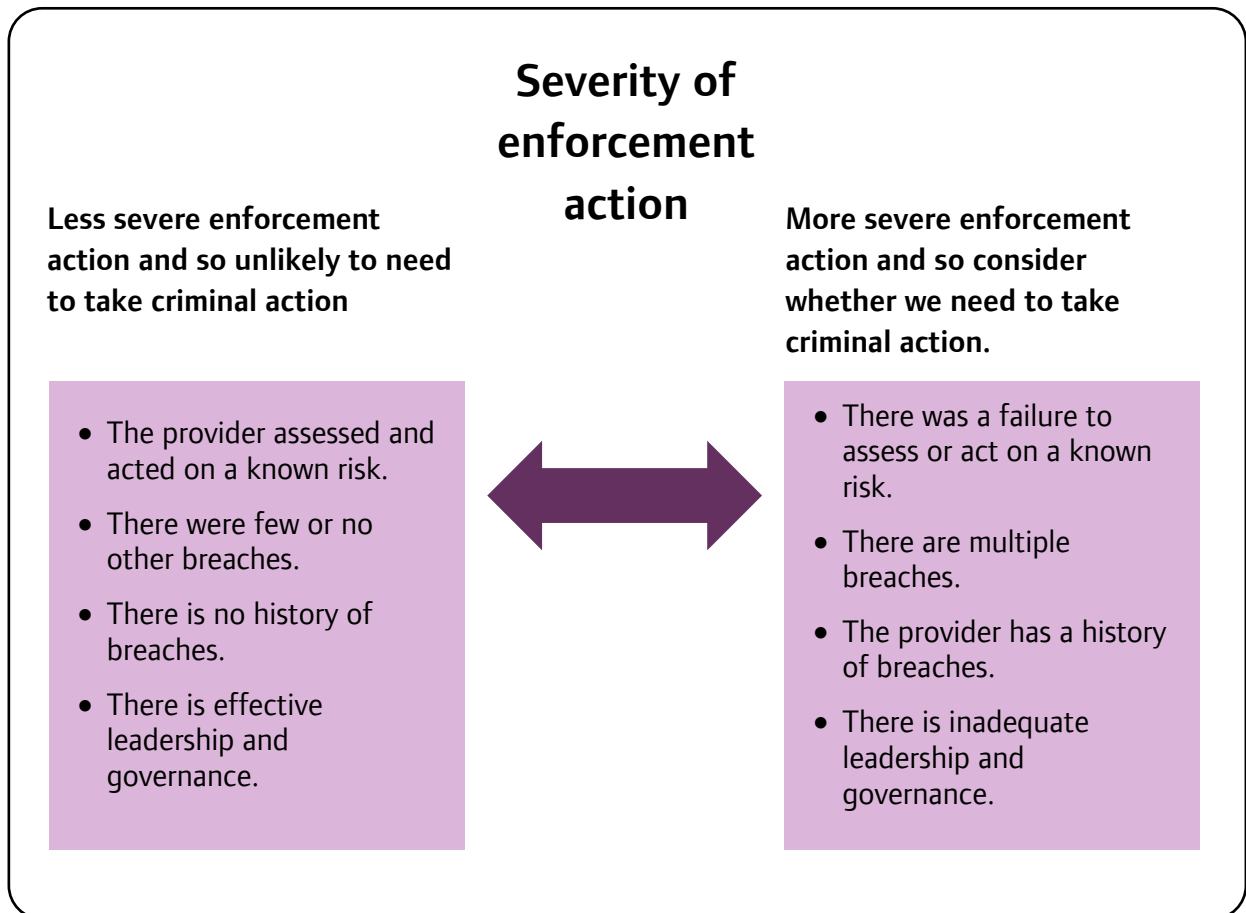
### Example 5

The chief executive of an NHS trust leads from the top with a clear mantra that staff work “for the trust” not “at the trust” and with the concept of a “trust family” throughout the hospital. Staff were encouraged to, and rewarded for, improving patient experience. All levels of staff were empowered to develop their own solutions to enhance the services. And there was strong support and alignment between clinicians and managers, who worked together to achieve their aim of providing quality patient care. The trust’s recent comprehensive inspection rated it outstanding for well-led at trust level and overall. This demonstrates effective leadership. Therefore, a review of the initial recommendation should be carried out to consider decreasing the severity of the recommended enforcement action.

### Stage 3B(5): Change to enforcement action due to multiple and persistent criteria

Depending on the answers to each of the above questions, 3B(1) to 3B(4), inspectors should make an overall assessment about the most appropriate enforcement action for us to take.

The answers to the questions may increase or decrease the severity of any recommended enforcement action as well as include a recommendation to take criminal action.



## Stage 4: Final review

Each year, as part of developing the coming year's business plan, we will review enforcement activity and consider whether there are priorities that should be reflected in our business plan. There will not necessarily be priorities every year, and priorities may differ by sector. Priorities will be agreed by the CQC Board when it agrees the business plan.

### **Sector enforcement priorities and management review**

These sector enforcement priorities are a final check to assist decision making about what enforcement action we should take.

Enforcement priorities can set expectations as part of our overall approach to enforcement. They do not dictate decisions under this approach but are factors to be taken into account in our decision making:

- They can enable transparent messaging, as guidance on broad issues of current interest to CQC's Board – for example, to build up our capability in using new powers at a manageable pace, or to spread learning from examples such as using an enforcement case to 'send a message' and influence all providers.
- They can enable transparent notification of areas of recurrent concern, which inspectors are likely to have regard to over the year, in order to drive up standards – for example, absences of registered managers, or failure to submit timely notifications.
- They can enable CQC's Board to ensure inspectors are carrying out the Board's priorities – for example, if inspectors do not appear to be using the full range of powers available to them or if there is unexplained variation in time taken for certain procedures.

A final decision on enforcement action should be taken at an MRM. The MRM should review the decision making by inspectors at each stage and decide:

- Whether civil enforcement action should be taken and if so in what form.
- Whether criminal enforcement action should be taken and if so in what form.

The MRM is the audit trail of the decision-making process for all stages.