

Enforcement decision tree

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Updates in January 2017

The main changes from the 2105 version are:

- Definitions of both the ‘impact of the breach’ and ‘likelihood that the breach will happen again’ at stage 3A have been updated for greater clarity.
- Increased information on criminal enforcement, and links to relevant guidance such as CQC’s prosecution criteria and list of offences (stage 3C).
- Clearer, more consistent language and terminology. The decision tree refers to a ‘breach’ rather than a ‘concern’ and to ‘legal requirements’ rather than referring to ‘fundamental standards’.
- Amendments to the examples included in stage 3.

Introduction

The Care Quality Commission (CQC) has civil and criminal enforcement powers. Civil powers focus on reducing risk to people who use regulated services and criminal powers hold registered persons to account for serious failures. In some cases it will be appropriate to use both civil and criminal enforcement powers at the same time.

The enforcement decision tree is at the core of how CQC applies its enforcement policy. The decision tree describes the process that guides CQC's decision on the use and selection of enforcement powers. By setting a structured decision-making process, it drives 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 is the basis of the enforcement guidance for inspectors, the detailed training that each inspector will receive, and the tools available to inspectors to support their role in the enforcement decision making process.

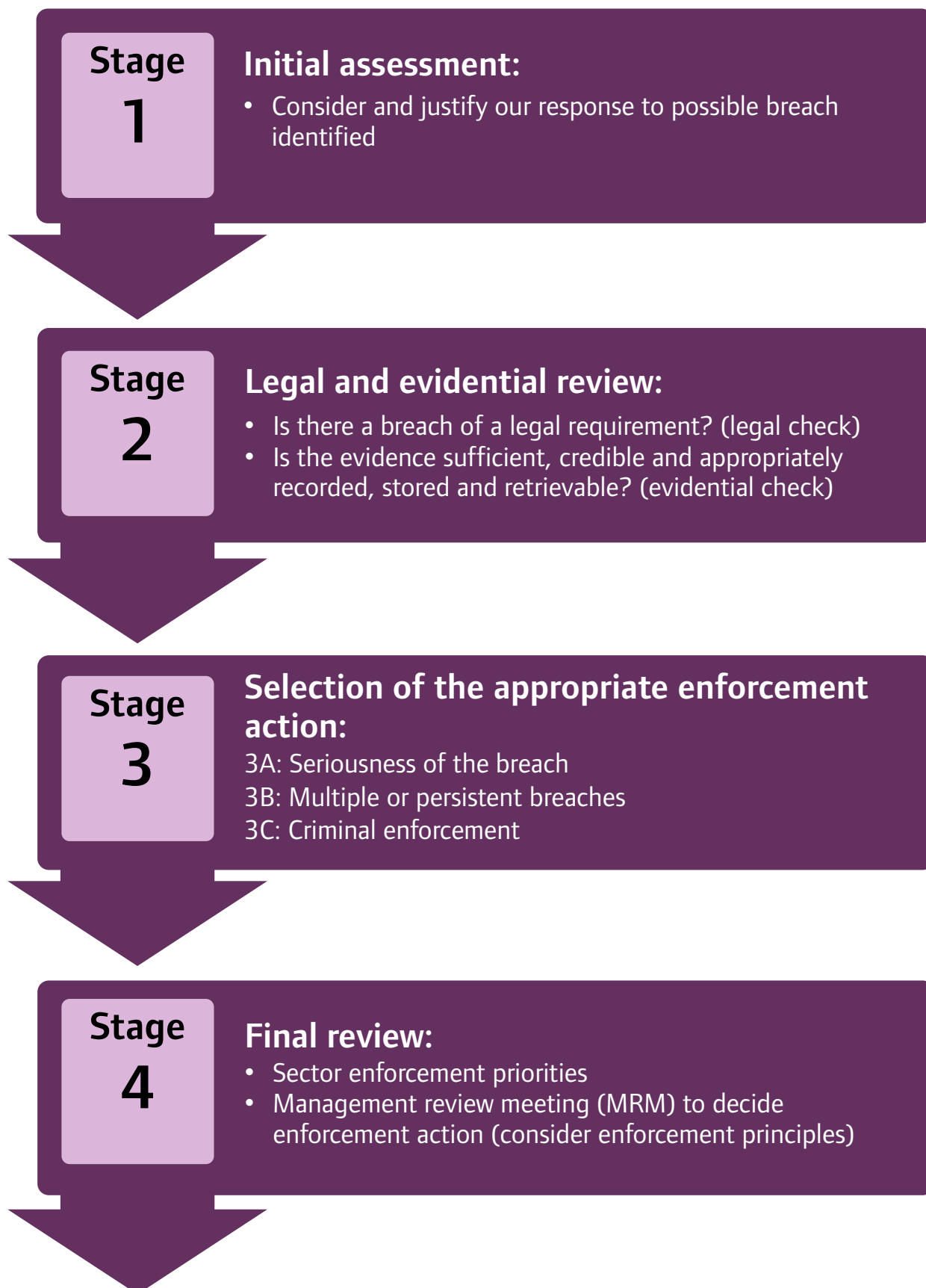
The decision tree has been developed and tested with input from across CQC's directorates, in particular with representatives from inspection teams to ensure that it is robust and effective. It should be used alongside the [enforcement policy](#), which provides further guidance on which enforcement powers are appropriate for different scenarios.

The decision tree refers throughout to a breach or breaches of legal requirements as this is the legal basis for most civil and all criminal enforcement action.

Legal requirements mean requirements that are contained in CQC Regulations and/or the Health and Social Care Act 2008.

However, inspectors need to be aware that some civil enforcement powers are not dependent on a breach of a legal requirement, for example a Section 29A Warning Notice (for further information, see the guidance on [Section 29A Warning Notices](#)). In such cases, as well as considering any breach of legal requirement, inspectors and decision-makers should also consider the specific legal test for the civil enforcement and any separate specific guidance on a topic (i.e. the evidence to support a conclusion that significant improvement is required).

Enforcement decision tree



Stage 1: Initial assessment

CQC becomes aware of incidents and events that could warrant civil and/or criminal enforcement action from a number of sources. These include notifications by providers, safeguarding alerts, instances of whistle-blowing, RIDDOR or coroners' reports, complaints, information 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 is appropriate from the full set of options available to inspectors.

The options at this stage include:

- carrying out a focused or comprehensive inspection
- gathering more information
- referring the concern or sharing the information of concern with another public body
- progressing to Stage 2 of the decision tree and considering what enforcement action to take.

During the initial assessment stage we need to ensure that we respond properly to information about a possible breach of a legal requirement. We recognise that each case is different and so we have a wide range of options that we can use where there are potential breaches. It is not feasible or proportionate to follow up every potential breach of a legal requirement. However, information about every potential breach should prompt some action. For example:

- all safeguarding alerts should be reviewed
- notifications and/or incident reports should be reviewed by the relevant inspector
- any concerns identified during an inspection should be assessed in more detail before making a decision.

Where initial enquiries do not provide assurance that people using regulated services are reasonably protected from harm, or that a provider or individual may need to be held to account for the breach, escalation to enforcement and Stage 2 of the decision tree 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 that there is a documented rationale for all decisions, therefore helping us to operate a clear decision-making process and to provide an audit trail to show how decisions were reached.

In all cases we will have regard for the criteria set out in our enforcement policy. These include acting on breaches of legal requirements and prioritising cases with the potential to 'send a message' to registered persons or highlighting cases that 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 registered persons and our limited enforcement resources. We expect that relatively few cases will move from initial assessment straight to Stage 2 as most concerns will require further enquiries to be made.

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 legal requirements by a registered person.

The review must identify:

- The breach of legal requirement that appears to have taken place.
- Whether enforcement action may be appropriate having regard to relevant guidance and the Enforcement Policy.
- Whether we possess or can obtain sufficient, credible and appropriately recorded evidence that is stored and retrievable 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 usually be conducted by inspectors and inspection manager who will seek advice where necessary.

If the inspector considers that the evidence demonstrates an identifiable breach of a legal requirement and the evidence is sufficient and robust to prove the breach, the case will 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. At this stage decision-makers should consider all civil and criminal enforcement options.

Sections 3A and 3B provide a framework for reaching a decision about what civil enforcement action is appropriate while 3C provides a framework for deciding whether it is appropriate to take criminal 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 highlight the need for CQC to hold registered persons to account for non-compliance with their legal obligations.

The decision-making process seeks to ensure that we take consistent and proportionate decisions without being too prescriptive. It should not result in mechanistic recommendations but should guide decision makers to reach appropriate decisions.

This stage uses two criteria to assist CQC decision makers to decide which enforcement powers we should use. The criteria are:

- seriousness of the breach.
- evidence of multiple and/or persistent breaches

Stage 3A: Seriousness of the breach

We will take progressively stronger action in proportion to the seriousness of the breach and the potential 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 registered provider would be ineffective in managing risk if policies and procedures are in place to control risk but these are not implemented despite this being reasonably practicable. A registered provider would also be ineffective if there is a disregard for legal requirements, an attempt to avoid them or if false or misleading information is provided.

3A(1): Potential impact of the breach

For civil enforcement, inspectors should assess the level of potential impact that would result if the breach of legal requirements identified was repeated.

The focus for civil enforcement is on reoccurrence to assess if we should act to protect people using regulated services from harm in the future.

Potential impact of the breach	Definition
Major	<p>The breach, if repeated, would result in a serious risk to any person’s life, health or wellbeing including:</p> <ul style="list-style-type: none"> • permanent disability • irreversible adverse condition • significant infringement of any person’s rights or welfare (of more than one month’s duration); and/or • major reduction in quality of life.
Moderate	<p>The breach, if repeated, would result in a risk of harm including:</p> <ul style="list-style-type: none"> • temporary disability (of more than one week’s but less than one month’s duration) • reversible adverse health condition • significant infringement of any person’s rights or welfare (of more than one week’s but less than one month’s duration); and/or • moderate reduction in quality of life.
Minor	<p>The breach, if repeated, would result in a risk of:</p> <ul style="list-style-type: none"> • significant infringement of any person’s rights or welfare (of less than one week’s duration); and/or • minor reduction in quality of life • minor reversible health condition.

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

Inspectors should assess the likelihood that the facts that led to the breach will happen again. The likelihood should be based on the control measures and processes in place to manage the risks identified, including changes in practice (such as recruiting additional staff or replacing equipment).

Likelihood that the facts giving rise to the breach will happen again	Definition
Probable	It is more probable than not that the facts that gave rise to the breach will happen again as there are insufficient or ineffective control measures in place to manage the risk identified.
Possible	It is possible that the facts or circumstances that led to the breach will happen again as some control measures have been put in place but these are not effective.
Remote	It is unlikely that the facts or circumstances that led to the breach will happen again as control measures have been put in place to manage the risk identified, although they may be newly implemented and/or not embedded.

3A(3): Seriousness of the breach

Inspectors should use their assessment of the potential impact of the breach and the likelihood that the facts giving rise to the breach will happen again. They should then apply them to the table below to determine whether the seriousness of the breach is low, medium, high or extreme.

		Likelihood that the fact giving rise to the breach will happen again		
		Remote	Possible	Probable
Potential impact of the breach	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 enforcement powers should be used to protect people using the service from harm or the risk of harm.

This recommendation only takes account of the potential impact of the breach and the likelihood that the facts giving rise to the breach will happen again. A final decision on what civil enforcement action to take will not be reached until the multiple and persistent criteria, and our sector enforcement priorities, have been considered.

Seriousness of the breach	Recommended initial civil enforcement action
Extreme	Urgent cancellation Urgent suspension Urgent imposition, variation or removal of conditions
High	Cancellation Suspension More significant conditions (impose, vary or remove)
Medium	Conditions (impose, vary or remove) S29 Warning Notice
Low	Requirement Notice

Our enforcement policy describes use of each of these powers and should be taken into account. In particular, conditions can range from minor amendments to registration to significant restrictions on the carrying on of a regulated activity.

Stage 3B: Identifying multiple and/or persistent breaches

Once an initial recommendation has been reached under Stage 3A, inspectors should apply the test under Stage 3B to consider whether a more or less serious level of enforcement than the initial recommendation is appropriate.

This part of the decision-making process considers whether the identified breach and conduct is part of a pattern demonstrating systemic failings.

Where enforcement against a registered provider is being considered the provider’s ability to identify risks and make and sustain necessary improvements should be assessed.

This stage considers evidence of multiple or persistent failures. 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 known risk, and whether there is adequate leadership and governance.

Conclusions reached under Stage 3B can result in a change to the recommended enforcement action by increasing or decreasing the severity.

At this stage, inspectors should work through each of the questions below to identify any adjustments to the initial recommendation made under Stage 3A(4).

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

Inspectors should consider:

- Is there a history of failing to adequately assess risks to people using services, either deliberately, recklessly, through neglect or because ineffective or inadequate action has been taken to make improvements?
- Is there a history of failing to act on identified risks to people using services, including a failure to act on previous CQC inspection reports, requirements or enforcement actions?

Example 1

A provider of services for people with a learning disability has clear policies for managing patients with epilepsy, including a requirement to carry out an epilepsy risk assessment on admission. A person is admitted to the service with a history of regular and serious epileptic seizures but an epilepsy risk assessment is not carried out. The person drowns in a bath while being observed in line with the service's general observation policy.

A post-mortem examination report concludes that the person drowned as a result of an epileptic seizure. His care plan records that he has epilepsy. 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 conduct is part of a pattern?
- 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 2

A mental health service provides a range of services in different settings and locations.

There is no central system for managing incident reporting and investigation. The overall governance processes are disjointed. The lack of effective governance has resulted in patterns of risk across the service not being properly identified and action taken. Ratings of inadequate have been awarded overall and for safe and responsive. The initial recommendation should be reviewed in light of this information.

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?
- Have necessary improvements been made following breaches identified in reports or enforcement actions?
- 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 fourth question is 'yes', consideration should be given to cancelling the registration or taking action to remove relevant locations unless there is good reason not to do so.

Inspectors should note that a provider's history is taken from the first date of registration of the provider or manager to carry on the regulated activity. If a provider has registered under a new entity the history should still be taken into account, but with caution so as not to make unwarranted assumptions.

Example 3

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 has 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.

Example 4

A GP practice had recruited office staff without carrying out disclosure and barring service (DBS) checks as part of their recruitment and without having a risk assessment in place to determine why a DBS check was not necessary. When this was raised with the practice manager, they amended their procedures immediately to include a DBS check for all staff and stipulated that any member of staff who had been recruited previously without a DBS check must now apply for one. A review of its history showed that the practice had met the regulations and complied with relevant requirements consistently and it was performing well. As the issue was rectified immediately, it would be appropriate to issue a requirement for recruitment of office staff to involve a DBS check, 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 improve patient experience and rewarded for doing so. All levels of staff were empowered to develop their own solutions to enhance the services. There was also 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 civil 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 civil enforcement action for us to take.

The answers to the questions may increase or decrease the severity of any recommended civil enforcement action.



Section 3C: Consider whether we need to take criminal enforcement action

Criminal enforcement action should be considered in every case where CQC proposes civil enforcement and/or identifies a specific incident of suspected avoidable harm.

Decisions about the most appropriate criminal enforcement action to take will be made in consultation with legal services and following a review of the two-stage test set out in the Code for Crown Prosecutors. This two-stage test requires the decision-maker to consider both the sufficiency of evidence gathered and the public interest to be served in taking criminal enforcement action.

The decision-maker should have regard to CQC's [prosecution criteria](#) (page 27 of the enforcement policy) and consider:

- the seriousness of the breach or breaches identified
- the potential impact of the breach or breaches identified on a service user and/or the ability of CQC to perform its regulatory functions (breach of conditions or failures to notify).

Example 5

A resident of a care home dies from choking after being helped to eat inappropriate food, despite the risk being clear in their care plan. The lack of induction and basic information for agency staff has resulted in them not following care plans. We should decide whether to gather additional evidence to support criminal enforcement and identify further lines of enquiry.

There is more information about our criminal enforcement powers in the [enforcement policy](#) and the [list of criminal offences](#).

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 CQC's 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 that 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 the time taken for certain procedures.

A final decision on civil enforcement action and further consideration of criminal enforcement 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 pursued.

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