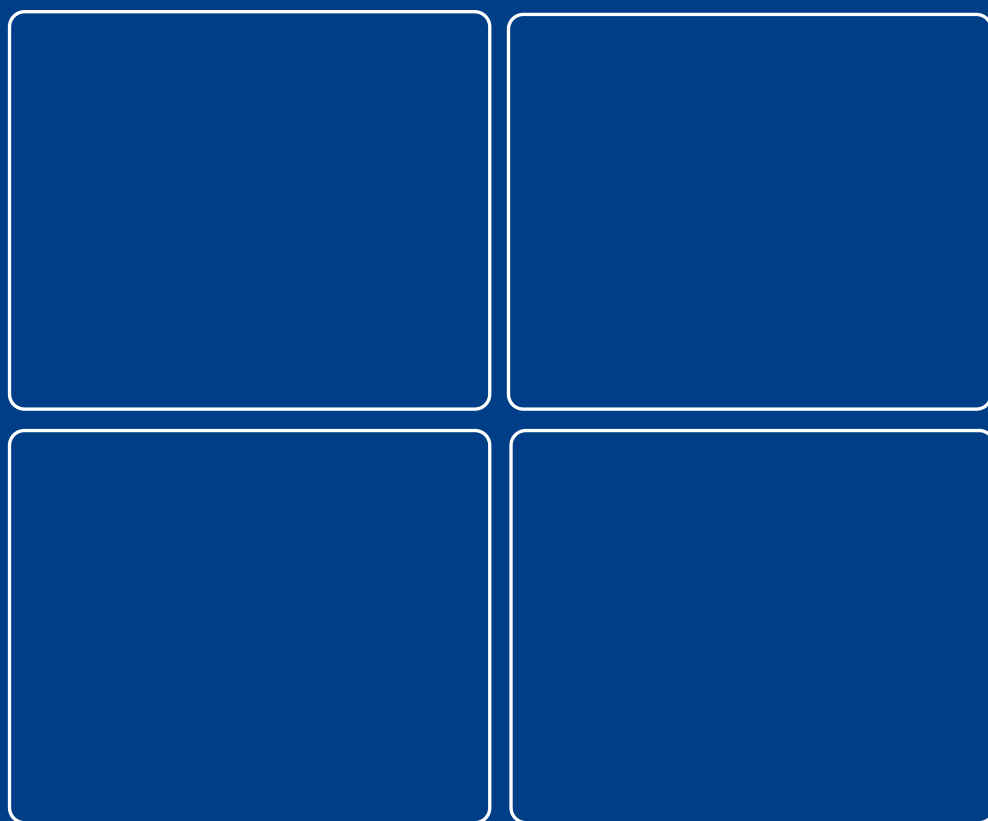


Judgement framework



How we judge providers' compliance with the section 20 Regulations
of the Health and Social Care Act 2008

April 2012

About the Care Quality Commission

The Care Quality Commission is the independent regulator of health care and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act.

Whether services are provided by the NHS, local authorities or by private or voluntary organisations, we make sure that people get better care. This is because we:

- Focus on quality and act swiftly to eliminate poor quality care, and
- Make sure care is centered on people's needs and protects their rights.



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Our regulatory model

The aim of our regulatory model is to ensure that providers and managers who carry on regulated activities are registered, and that the care people receive from these providers and managers meets the essential standards of quality and safety. Our approach is outcome-focused and it places the views and experiences of people who use services at its centre. Gathering and understanding the views and experiences of people using services is a key focus of our inspections.

The regulations that govern registration, and that we regulate against, are the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. These regulations describe the essential standards of quality and safety that people who use health and social care services have a right to expect.

Where we judge that a provider is non-compliant with one or more regulations, we will act quickly, working closely with commissioners of services and others, and using our enforcement powers (as described in the Enforcement policy) if necessary.



The Judgement framework

The Judgement framework is concerned with Regulations 9-24 in Part 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These are the regulations that most directly relate to the quality and safety of care (see appendix A for a list of these regulations).

The Judgement framework is written for staff of the Care Quality Commission to help them reach judgements about whether a provider or a manager is meeting the essential standards (providers and managers are described as 'registered persons' in the Enforcement policy) and to decide our regulatory response when they are not.

The Judgement framework promotes consistency in judgements and provides transparency to providers about the methods we use to reach our judgements. It is not a substitute for the professional judgement of our staff, and the individual circumstances of the provider or manager will always be taken into account.

Within the Judgement framework, we talk about making a judgement about whether a provider or manager is compliant or non-compliant with one or more of Regulations 9-24, which describe the essential standards of quality and safety. When people who use services (and others, where appropriate) are not experiencing the outcomes described in the essential standards of quality and safety, we carry out further activity to identify whether this is the result of non-compliance with one or more of the regulations (this is described as not complying with legal requirements in the Enforcement policy). In some cases the outcomes may be met; however there may still be non-compliance with the regulations. Where we make a judgement of non-compliance with a regulation, we use the Judgement framework and Enforcement policy to decide what is appropriate regulatory action.

The Judgement framework should be used alongside:

- The *Guidance about compliance: Essential standards of quality and safety*, which describes the outcomes we expect people using a service to experience when a provider is compliant with the regulations.
- The case studies available on our website, which provide real-life examples of what compliance, non-compliance and the impact of non-compliance looks like for different service types.
- The Enforcement policy, to help determine our regulatory response where non-compliance with one or more of the regulations is identified. This policy directly supports the Judgement framework.

The framework is split into four stages:

Stage 1	Determining whether we have enough evidence to make a judgement.
Stage 2	Making a judgement about whether the evidence demonstrates non-compliance with one or more of the regulations.
Stage 3	Determining the level of impact of non-compliance on people.
Stage 4	Determining our regulatory response (which includes referring to the Enforcement policy).

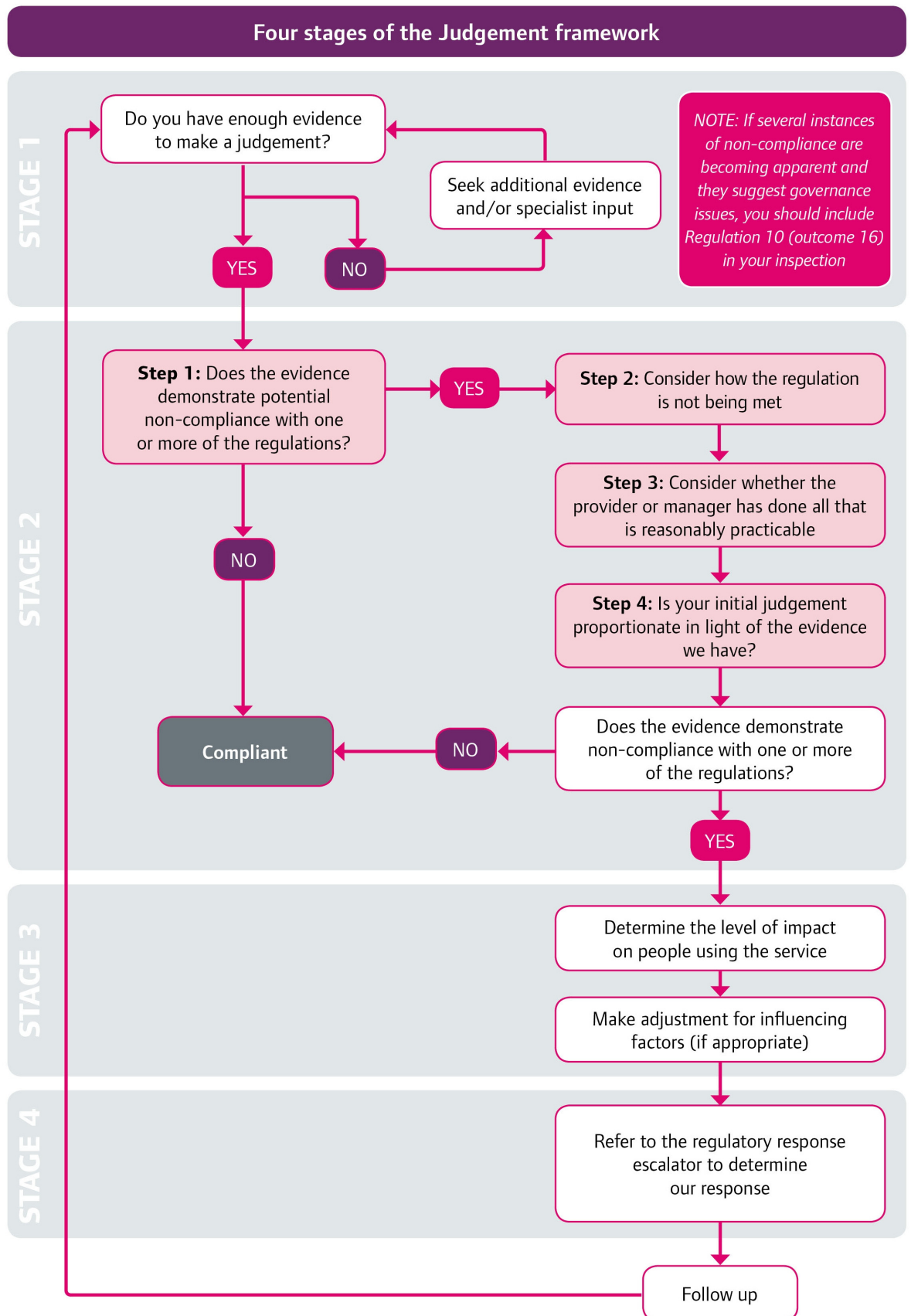
The stages are illustrated in the flowchart on the next page.

If we judge the provider and/or manager is compliant (this is described as complying with legal requirements in the Enforcement policy), we will only use stage 1 and stage 2 of the framework.

If we judge that the provider and/or manager is non-compliant, we will progress to stage 3 and stage 4 of the framework, using the Enforcement policy to help determine our regulatory response.

Although the Judgement framework is split into stages, the process will not always be linear. For example, during any part of stage 2 or stage 3, we may find we do not have enough evidence. In this instance, we can refer back to stage 1 to gather more evidence. We may also find it helpful to consider stage 2 and stage 3 together in order to come to a judgement.

Figure 1:



What do our judgements look like?

We will judge a provider or manager to be either:

- Compliant¹, or
- Non-compliant²

with one or more of the regulations. Where a provider or manager is judged to be non-compliant with a regulation, we assess the impact of this on people who use the service (and others, where appropriate) and judge it to be either:

- Minor
- Moderate
- Major

How do our judgements affect our regulatory response?

If we reach a judgement that the provider or manager is non-compliant with one or more of the regulations, we use the Enforcement policy to help determine our regulatory response.

What does compliance look like?

The *Guidance about compliance: Essential standards of quality and safety* describe in detail the expected outcomes that people who use services (and other people, where applicable in the regulations) experience when a provider or manager complies with the regulations. Providers and managers are also expected to act in accordance with other relevant legislation, codes of practice and guidance documents etc, some of which are described in Appendix B of the *Guidance about compliance*.

The prompts within the *Guidance about compliance* should not be used as a checklist to demonstrate compliance. The detailed outcomes and prompts indicate what a provider or manager should do to ensure compliance with the regulations. However, providers and managers are not legally bound to use these and may decide to use alternative arrangements. We are not seeking compliance with the outcomes and prompts, but with the regulations.

If we consider that we have collected enough evidence and have found no evidence of non-compliance with a regulation, our judgement will be that the provider and/or manager are compliant.

¹ A 'compliant' judgement is reflected in our inspection reports and website as 'Met the standard'.

² A 'non-compliant' judgement is reflected in our inspection reports and website as 'Action needed' if we set compliance action(s), or 'Enforcement action taken' if we have taken enforcement action.

What if we identify multiple non-compliance?

When undertaking an inspection, we may identify multiple instances of potential non-compliance across more than one regulation.

Where we identify this in the early stages of our inspection, we will normally include an assessment of Regulation 10: Assessing and monitoring the quality of service provision (Outcome 16) in our inspection. This is because Regulation 10 focuses on the effective operation of systems designed to enable the provider and manager to regularly assess and monitor the quality of the service provided and to identify, assess and manage risks from carrying on one or more regulated activities.

Stage 1

Determining whether we have enough evidence to make a judgement

In stage 1, we determine whether we have sufficient robust evidence to make a judgement of compliance or non-compliance about the regulations that we are inspecting against.

To determine whether we have sufficient evidence, we consider the following questions when looking at our evidence:

- Does it demonstrate the outcomes and/or experiences of people who use services?
- Is it current? (this may vary depending on the data source).
- Is it reliable? (is the source credible?)
- Is it usable? (is it good quality, and have we obtained consent to use it, if applicable?)
- Is it relevant? (is it specific to the regulations, the regulated activities and CQC's remit?)
- Is it sufficient? (is there an adequate amount of evidence with enough detail to make a judgement about the provider, manager, location?)
- Does it demonstrate what processes and governance the provider or manager has in place?
- Is specialist input needed to analyse the evidence? (This includes written advice, guidance and briefings that can be accessed anytime, as well as input from individuals or groups where it is deemed appropriate. Further guidance is available about when and how to access specialist input.)

We consider the evidence we have collected in relation to its relevance to the regulation being assessed and gather sufficient evidence to enable us to reach a robust judgement.

How do we weight the evidence?

We consider the weight of each piece of relevant evidence and make our judgements in light of its strength. It may be that one single piece of evidence is sufficient to make a judgement. For example, we visit a small dental provider in the afternoon and find that the autoclave has not been used to sterilise the four sets of instruments used that day, despite the fact that 12 people received oral examinations or treatment. Based on this, we have enough evidence to make a judgement of non-compliance with Regulation 12(2) (c) (ii) (Outcome 8).

However, in most cases we need to corroborate our evidence with other sources to support our findings and enable us to make a robust judgement. For example, during an inspection a person working in or using the service comments that they thought there were not enough numbers of staff on duty. We corroborate this with other evidence before making a judgement about Regulation 22 (Outcome 13).

Corroborating evidence strengthens, adds to, or confirms evidence that already exists.

What if we have conflicting evidence?

When we have conflicting evidence, we consider the weight we have given to each piece of evidence. We consider the source of each piece of evidence, how robust it is and which is the strongest. We may conclude that we need to seek additional evidence or specialist advice in order to make a judgement.

If we conclude **'yes'** we do have enough evidence to make a judgement, we progress to stage 2.

If we conclude **'no'**, we don't have enough evidence to make a judgement, we seek further information and then repeat stage 1.

Stage 2

Making a judgement about whether the evidence demonstrates non-compliance with one or more of the regulations

In stage 2, we use the evidence we have collected and the *Guidance about compliance: Essential standards of quality and safety* to make a decision about whether the provider and/or manager is potentially non-compliant with one or more of the regulations (step 1).

If the provider or manager is potentially non-compliant, we consider the following: which part of the regulation is not being met (step 2); what is reasonably practicable for the provider and/or manager to be expected to do in order to comply with the regulation (step 3); and whether our initial judgement is proportionate in the light of the evidence we have (step 4).

Step 1: Does the evidence demonstrate potential non-compliance with one or more of the regulations?

If we are satisfied that we have found no evidence of non-compliance, our judgement will be that the provider or manager is compliant.

If we think that the provider or manager is potentially non-compliant with one or more of the regulations, we consider how the regulation is not being met, what is reasonably practicable and what is proportionate, in steps 2, 3 and 4 below.

Step 2: How is the regulation not being met?

We consider the questions below alongside the *Guidance about compliance: Essential standards of quality and safety* to determine whether the provider or manager is non-compliant:

- Is part or all of the regulation not being met?
- How has the provider and/or manager fallen short of meeting the regulation/part of the regulation?

It is important we are clear about which part of the regulation is not being met for any instances of non-compliance, and how it is not being met. This is so we can determine the impact of non-compliance on people who use the service (and other people, as applicable in some of the regulations).

Step 3: Has the provider or manager done all that is reasonably practicable in relation to one or more of the regulations?

Forming a decision about what is 'reasonably practicable' involves evaluating the risk against the effort, time and money needed to control the risk. It is the standard of behaviour we expect from a provider or manager who is meeting the regulations that describe the essential standards of quality and safety. Evidence of a lack of effort, time or money will not, in itself, be accepted as a rationale for a provider or manager failing to achieve and maintain compliance with regulations. However, where complete control of a risk would require a disproportionate and unjustifiable expenditure or resource, partial mitigation of the risk may be acceptable.

For example, Regulation 15 (Outcome 10) sets out the requirements for suitability of premises. What is reasonably practicable or expected in respect of the layout of premises in a single-handed dentist surgery will differ from a hospital or large purpose-built dental premises because of the different nature of their functions. If a small dentist surgery is located in a listed building that was previously a private house, the accessibility for the people who use the service may not meet the requirements of the Disability Discrimination Act and the provider may not be able to change the structure to accommodate wheelchair users. However, if the provider has made alternative premises available or offers a home visit where appropriate, and has advertised that this can be arranged, then they have done what is reasonably practicable and, in this example, would be judged as compliant.

Step 4: Is our initial judgement that there is evidence of non-compliance proportionate in light of the evidence that we have?

The judgements we make must be proportionate to the evidence and our regulatory response must be proportionate to all of the facts and circumstances.

For example, during an inspection we may find an isolated example of one badly-handled complaint but, overall, the evidence indicates an effective complaints system where people are supported to make complaints, and complaints are handled and responded to effectively. In this instance (and depending on the outcome of the badly-handled complaint), it would not be proportionate for us to judge the provider as non-compliant with Regulation 19 (Outcome 17) based on this specific evidence.

However, when inspecting another provider we may find 10 complaints logged but no records of what action was taken to manage them, and evidence showing that not all staff were aware of how to handle complaints, no process or policy in place for them to follow and no evidence of staff learning from complaints. In this instance, it would be proportionate for us to judge the provider as non-compliant with Regulation 19 (Outcome 17).

Next steps

If, having considered steps 2, 3 and 4, we conclude that the provider or manager is compliant, we take no further action.

If we conclude that the provider or manager is non-compliant with one or more of the regulations, we progress to stage 3.

Stage 3

Determining the impact on people who use services

In stage 3 we determine what impact the non-compliance we have identified in stage 2 will have on people using the service (and other people, as applicable in some of the regulations). The impact can be minor, moderate or major:

- **Minor impact** – people who use the service experienced poor care that had an impact on their health, safety or welfare or there was a risk of this happening. The impact was not significant and the matter could be managed or resolved quickly.
- **Moderate impact** – people who use the service experienced poor care that had a significant impact on their health, safety or welfare or there was a risk of this happening. The matter may need to be resolved quickly.
- **Major impact** – people who use the service experienced poor care that had a serious current or long-term impact on their health, safety and welfare, or there was a risk of this happening. The matter needs to be resolved quickly.

As part of our consideration of impact, we also take into account who is using the service and what their circumstances are, as these factors may result in a greater impact. For example:

- **Capacity** – a lack of staff who understand, and are able to apply, the Mental Capacity Act would have more of an impact on a service providing care to people with dementia than it would in a health screening service that primarily deals with fit, healthy adults.
- **Diversity** – failing to have information readily available as audio recordings or Braille would have more of an impact on people using a service that specialises in care for those with impaired vision than a service that doesn't (although all services should be able to produce information in accessible formats in response to specific requests if this is reasonable and proportionate).
- **Vulnerability** – a poor and uncomfortable environment would have more of an impact on people who are detained or are staying in a service long term due to chronic illness, than for people using an outpatient clinic.

The case studies on our website provide real-life examples of what compliance, non-compliance and the impact of non-compliance look like for different service types for each of Regulations 9-24. The case studies are not a definitive list that we use prescriptively or take to describe all of the potential impacts or exposures to risk. We use them as a proportionality check to test our findings; however it does not replace our professional judgement that takes account of the evidence and specific circumstances.

The examples below describe a minor, moderate and major impact on people using a service for one of the regulations.

Care and welfare of people who use services: Regulation 9 (Outcome 4)

Minor impact

Information from a clinical record screening exercise at a dental practice has raised concerns that four out of 10 records considered showed that patients did not receive a full oral health assessment that included teeth, gums and soft tissue, in line with evidence-based guidance. When following this up with the practice, they told us that they had taken on a newly-qualified dentist who was struggling to complete full assessments within the allocated appointment time. The practice had picked up the problem through their monitoring. They have begun to take steps to ensure the dentist has good access to peer support and they have adjusted the appointment allocations slightly to give him a bit more time. This has a **minor impact** on people using the service, as their health needs are not fully assessed; however the matter is being managed and can be resolved fairly quickly.

Moderate impact

When Mr B was transferred to his local community hospital for rehabilitation, his care plan identified that he was at risk of falling. The community hospital did not put protective rails on his bed and Mr B had a fall during the night and bruised his arm. Although there was a policy of reassessing people's risk of falling on admission, feedback from staff indicated that these assessments can be delayed. This has a **moderate impact** on people using the service, because their needs are not being accommodated following admission. This has a significant impact on Mr B's and other patients' safety and there is a risk that this will happen again.

Major impact

A care home provides care for older people with a variety of needs. Some have long-term illnesses that are managed by the district nurse or GP. The home has recently appointed a 'care manager' with a vocational qualification in care as its clinical lead; the registered manager does not have a clinical background. The care manager has made amendments to the care plans (previously developed with input from the district nurse). This has included changing the times that medication is given and not changing dressings of leg ulcers as recommended. Members of staff and some residents have raised concerns with our inspector that the care manager is not suitably qualified to make alterations in the planning and delivery of care and those alterations are putting residents at serious risk. They had previously raised these concerns with the registered manager, who had supported the care manager. This has a **major impact** on people using the service, because these changes compromise the health, safety and welfare of the residents. No serious impact has been uncovered yet, however there is a risk that this will happen.

Once we have determined the impact of non-compliance on people who use services, we progress to stage 4.

Stage 4

Determining our regulatory response

In stage 4, we use the judgements we have reached in stages 2 and 3 and the Enforcement policy to determine what regulatory response we should take.

The table below is an example of the judgements we may have reached.

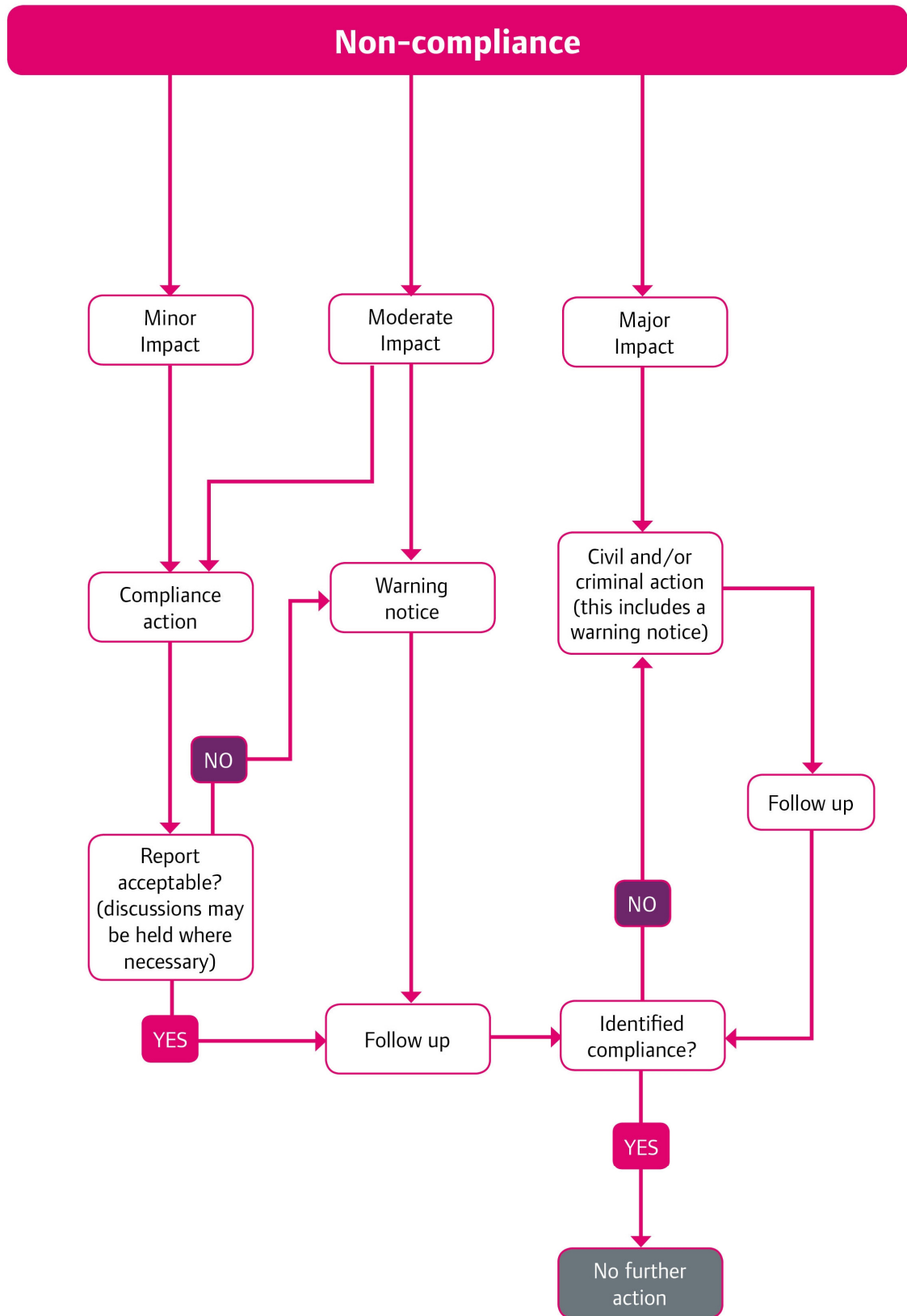
Essential standard of quality and safety	Compliant	Non-compliant		
		Minor impact	Moderate impact	Major impact
Regulation 17 (Outcome 1): Respecting and involving people who use services			✓	
Regulation 9 (Outcome 4): Care and welfare of people who use services		✓		
Regulation 11 (Outcome 7): Safeguarding people who use services from abuse	✓			
Regulation 22 (Outcome 13): Staffing		✓		

We use the impact of non-compliance that we identified in stage 3 and the 'regulatory response escalator' to select a proportionate response. We always consider what response would be the most effective in securing compliance while protecting the health, safety and welfare of people who use services.

The regulatory response we take may differ where a provider and/or manager is non-compliant with more than one regulation or where we have concerns about their capacity. We consider these factors as contextual information when we consider our regulatory response.

The following diagram is the 'regulatory response escalator' model – an overview of the process for determining our regulatory response to non-compliance.

Figure 2: Determining our regulatory response – the 'regulatory response escalator' model



What kinds of regulatory response can we take?

The Enforcement policy sets out the range of regulatory responses that we can take. Where we identify non-compliance, we use the most appropriate response to promote change. We take different action for different types of services depending on the issues and context. The following table outlines the different options for regulatory response; the full regulatory response escalator is reproduced in Appendix B.

Regulatory response	Outcome from the action
Formal regulatory action:	
Compliance action	<ul style="list-style-type: none"> Provider and/or manager submits a robust report detailing the actions they intend to take to become compliant within the timeframe that they have agreed with us. An update is required from the provider and/or manager on progress and upon completion of actions to become compliant. Follow-up is either through a desktop review or an inspection.
Enforcement action:	
Warning notice	<ul style="list-style-type: none"> Provider and/or manager implements the necessary changes to become compliant within the timeframe imposed. Follow-up visit to check compliance.
Criminal law:	
Fixed penalty notice	<ul style="list-style-type: none"> Registered person pays a fine and makes the necessary changes.
Simple caution	<ul style="list-style-type: none"> Registered person admits offence and the caution is accepted.
Prosecution	<ul style="list-style-type: none"> Registered person is prosecuted.
Civil enforcement:	
Conditions/urgent conditions	<ul style="list-style-type: none"> To restrict activity to ensure the health, welfare and safety of people. Follow-up visit to check compliance.
Suspension of registration/urgent suspension of registration	<ul style="list-style-type: none"> Provider and/or manager implements the necessary changes to become compliant so temporary restrictions can be lifted. Follow-up visit to check compliance.
Cancellation/urgent cancellation of registration	<ul style="list-style-type: none"> Provider and/or manager is no longer registered to carry on regulated activities.

Factors we may consider when determining our regulatory response

How do we decide which regulatory response to take when we identify a moderate impact?

We have the option of issuing a compliance action or a warning notice when we identify a moderate impact. When deciding which to use, we consider the following:

- Is there urgency for changes to be implemented? and
- Do we need to follow up directly by carrying out an inspection?

If the answer is **'yes'** to both of these questions, we will usually impose a warning notice. If the answer is **'no'** to one or both questions we will usually issue a compliance action, depending on the individual circumstances and the professional judgement of our inspectors.

What do we expect from a report submitted when a compliance action has been set?

Providers and/or managers have to send a report showing how they intend to achieve compliance and any action needed to do so in response to a compliance action. We check the robustness of the report using the 'SMART' approach:

- **Specific** – does the report identify the details of what the issue is, and what action needs to be taken? Does it explicitly say what they want to achieve and who is going to make these changes?
- **Measurable** – does it say how they are going to ensure that changes have been made? What measures are they going to put in place? Who will do this?
- **Achievable** – are the measures they are going to put in place achievable, attainable and sustainable? Has the provider described the resources needed to implement the changes? Are these in place?
- **Relevant** – is the action appropriate to the issue identified?
- **Time bound** – is there an appropriate date by which the changes will have been made? How will this date affect people who use services?

Where a report is not SMART, we can ask the provider and/or manager to amend the document or provide further information. If a report does not offer assurance that the necessary changes will be implemented to achieve compliance, we will normally escalate our action. We will normally issue a warning notice imposing a timescale for when we require compliance to be achieved.

If the necessary changes are not implemented and the provider remains non-compliant, this demonstrates continued non-compliance with the regulation(s) and we will take further action.

How do we check that the necessary changes have been implemented?

All enforcement action is followed up through an inspection. Where we request compliance actions, we will also follow up through an inspection except where we can gather the necessary information to provide assurance through a desktop review. In this situation we would not need to visit the provider or manager to check they had made the necessary improvements.

How do we respond when non-compliance continues or we identify repeated non-compliance?

Continuous non-compliance is when a provider and/or manager does not implement the necessary changes to be able to demonstrate compliance during follow-up checks and within the timescale agreed or imposed.

Repeated non-compliance is when a provider and/or manager demonstrates non-compliance over a short period of time with different regulations or where the provider and/or manager briefly becomes compliant but does not sustain this.

Where non-compliance continues and is identified in follow-up checks, or a provider and/or manager demonstrates multiple non-compliance across different regulations, we follow the regulatory response escalator, even when the identified impact is minor or moderate.

If we have identified non-compliance when inspecting a location, what additional checks do we make if the provider has more than one location?

Where we have identified non-compliance, depending on the types of issues and the significance of the issues, we may want to carry out additional checks of the provider.

Where a provider has locations across different regions, we will need to inform the relevant inspector(s) and/or provider relationship lead of our concerns and coordinate any further checks through the provider relationship lead.

Checks of a provider with multiple locations within a single region may include sampling other locations to see if the same concern is across other locations.

For example, we may carry out responsive inspections, contact the regional intelligence and evidence officers to carry out some trend analysis, and inform the provider relationship lead.

If we identify the same non-compliance across other locations, we should consider taking action on the regulated activity for the provider, rather than the regulated activity at each location.

What do we do if we identify concerns that relate to one regulated activity, but not to any other regulated activities carried on at a location?

If we identify non-compliance during an inspection, we need to determine whether the concern is across the location or specific to a regulated activity. Where it is specific to one regulated activity, we have to act proportionately and take the appropriate regulatory response for the relevant regulated activity only. The impact identified should be used to determine what regulatory response to take by applying the same rules as we would when deciding what regulatory response should be taken across a location.

For example, during an inspection we may find non-compliance with Regulation 9 (Outcome 4): Care and welfare of people who use services, which is due to issues with the care plans in place for those receiving palliative care. The choices people made about end-of-life care were not recorded and there was little evidence of informed decision-making processes.

The location is registered to carry on the following regulated activities:

- Accommodation for people who require nursing or personal care
- Treatment of disease, disorder or injury.

In this situation our regulatory response would be against the regulated activity of 'treatment of disease, disorder or injury' as the concerns only relate to the palliative care offered as part of this regulated activity, not the ongoing nursing care offered to people.

Appendix A: Regulations covered by the framework

The Judgement framework is concerned with Regulations 9-24 in Part 4 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. These are the regulations that most directly relate to the quality and safety of care.

When reviewing a provider's compliance, we focus on one or more of these 16 regulations depending on the type of inspection and service provided.

Outcome	Regulation	Regulation descriptions
1	17	Respecting and involving people who use services
2	18	Consent to care and treatment
4	9	Care and welfare of people who use services
5	14	Meeting nutritional needs
6	24	Cooperating with other providers
7	11	Safeguarding people who use services from abuse
8	12	Cleanliness and infection control
9	13	Management of medicines
10	15	Safety and suitability of premises
11	16	Safety, availability and suitability of equipment
12	21	Requirements relating to workers
13	22	Staffing
14	23	Supporting staff
16	10	Assessing and monitoring the quality of service provided
17	19	Complaints
21	20	Records

Appendix B: Regulatory response escalator table

	Type	When to use	Aim of use	Next step if aim is not achieved (or other action where more appropriate)
Formal regulatory action	Compliance action	First breach/offence with minor impact First breach/offence with moderate impact	To gain an acceptable report and achieve compliance through least punitive action	If the report is not acceptable, following discussion with provider and where required, carry out a site visit and issue a warning notice If non-compliance is identified when followed up, issue a warning notice and/or civil enforcement action
Enforcement action	Warning notice	First breach/offence with moderate impact Multiple breaches/offences with moderate impact Any breach/offence with a major impact	To demand compliance within timescale (where appropriate)	Civil enforcement and/or criminal law action
Criminal law	Penalty notice	Non-compliance with warning notice Direct offences Multiple breaches/offences with moderate impact Breach/offence(s) with major impact	To dispose of liability for offence or breach efficiently and cost effectively without restricting the registered person's registration	If not accepted, move to prosecution and/or consider civil enforcement action

		Carrying on a regulated activity without registration		
	Simple caution	Non-compliance with warning notice Direct offences Carrying on a regulated activity without registration	To gain an admission of the offence and dispose of liability for offence/breach efficiently and cost effectively without restricting the registered person's registration	If refused move to prosecution and/or consider civil enforcement action
	Prosecution	Non-compliance with warning notice Direct offences Carrying on a regulated activity without registration	To hold registered person to account for the breach/offence without restricting registration	Consider civil enforcement action or further prosecution
Civil enforcement	Imposition, variation, removal of conditions	Non-compliance with warning notice Non-compliance with compliance actions Multiple breaches/offences with moderate impact Breach/offence(s) with major impact With/after prosecution Direct offences	To restrict the registered person's activity	Cancellation of registration Prosecution Further imposition/variation/removal of conditions (which includes variation to remove location)
	Suspension of registration	Non-compliance with warning notice Non-compliance with compliance actions Multiple breaches/offences with moderate impact Breach/offence(s) with major impact	To prevent the registered person from carrying on the regulated activity/activities for a period of time	Extend suspension Vary to remove regulated activity(ies) Cancellation Prosecution

		With/after prosecution		
	Cancellation of registration	Non-compliance with warning notice Non-compliance with compliance actions Multiple breaches/offences with moderate impact Breach/offence(s) with major impact Continued non-compliance Variable compliance over time	To prevent the registered person from carrying on regulated activities	Prosecution if regulated activities continue after the cancellation is confirmed
	Urgent imposition, variation, removal of conditions	Non-compliance that will or may expose any person to the risk of harm	To immediately restrict or prevent some regulated activities being provided immediately	Prosecution if registered person fails to abide by the restriction or prevention of regulated activities
	Urgent cancellation of registration	Non-compliance where there is an immediate risk to a person's life, health or wellbeing	To immediately prevent all regulated activities being provided immediately	Prosecution if regulated activities continue after cancellation confirmed

Note

The use of this escalator table may not follow a linear order, as every breach is judged on an individual basis and is proportionate to the risk for people using the services. CQC has the right to exercise discretion.



Appendix C: Glossary of terms

Corroborate: Corroborating evidence strengthens, adds to or confirms already existing evidence.

Essential standards of quality and safety: These standards are described in the publication *Guidance about compliance: Essential standards of quality and safety*. They consist of a significant number of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. The regulations describe the essential standards of quality and safety that people who use health and adult social care services have a right to expect.

People who use services: These are people who receive services from a provider who is carrying on a regulated activity. This is the definition of 'service user' provided in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. A number of the regulations also refer to other individuals, for example Regulation 15 (Outcome 10) and Regulation 16 (Outcome 11) refer to others who may be at risk, Regulation 17 (Outcome 1) refers to those acting on behalf of service users and Regulation 12 (Outcome 8) refers to persons employed and others who may be at risk.

Proportionality: The concept of proportionality means that as a regulator, we must not go further than necessary to achieve our aim of ensuring compliance with the essential standards. This is key when considering how judgements are reached in Stage 2, and the appropriate regulatory response in Stage 4. Judgements must be proportionate to the evidence and a regulatory response must be proportionate to all of the facts and circumstances.

Provider or manager: When using the phrase 'provider' or 'manager' throughout this guidance, we mean 'registered person' as defined under the Health and Social Care Act 2008. The Regulations apply to both registered providers and registered managers as they are the 'registered persons' whom CQC is required to regulate. This is referenced in the Enforcement policy as registered person.

Reasonably practicable: Considering what is reasonably practicable is a test that is referred to, but not defined in the legislation. To form a conclusion on what is reasonably practicable involves weighing a risk against the effort, time and money needed to control the risk. It will be the standard of behaviour we would expect from a provider or manager who is meeting the essential standards of quality and safety. Evidence of a lack of effort, time or money will not, in itself, be accepted as a rationale for a provider or manager failing to achieve and maintain compliance with regulations, but where complete control of a risk would require a disproportionate and unjustifiable expenditure of resource, partial mitigation of the risk may be acceptable.

Regulations: This refers to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009. It is used to describe whether a provider or manager is compliant with one or more of these regulations. The Enforcement policy uses the term 'legal requirements' instead of regulations, for example a registered person may be failing to comply with legal requirements (please note: legal requirements in the Enforcement policy refers to a broader remit than just the regulations).

Regulatory response escalator: This sets out the regulatory responses and steps that CQC can take against any provider or manager who fails to comply with legal requirements, and illustrates the way CQC might respond to certain situations to achieve compliance and protect people using services. Where a provider or manager fails to become compliant with legal requirements as a result of one particular response, we will generally take the next appropriate action. This may not always follow the escalator in a linear order as our response always depends on particular circumstances and the risk to people who use services.

Note: Please refer to the glossary in the Enforcement policy for further clarification.

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