

A new system of registration

**Setting the bar:
Monitoring of compliance**

Guidance for inspectors

Contents

Introduction	3
How to use this guidance	4
Where do we set the bar?	6
Determining our regulatory responses	8
Guidance on the overall approach	11
The different types of regulatory action	18

Introduction

The aim of registration is that people can expect services to meet essential standards of quality and safety and respect their dignity and rights.

This guidance explains where the bar is set when monitoring compliance of registered health and adult social care services – in other words, the difference between complying and failing to comply with the essential standards – and how this helps to determine what our regulatory response should be following stage 4 of the Judgement framework.

It provides a framework from which we can make consistent decisions about what we will do in order to ensure that services meet essential standards of quality and safety.

It includes:

- What we should do when we have identified concerns about compliance using the judgement framework.
- What this means for the location at which the regulated activity is carried out.
- What this means for the provider as a whole.

How to use this guidance

You should read this guidance in conjunction with the Judgement framework, guidance on how we monitor and check providers, and our enforcement policy in order to make consistent and robust decisions about the type of regulatory response we should take when we identify concerns.

It will help us to take the right action to ensure that improvements are made in services where there are identified shortfalls in meeting essential standards of quality and safety.

Following stage 4 of the Judgement framework, you will have made a decision about some or all of the 16 key quality and safety essential standards. If you have carried out a planned review of compliance, you will come to a judgement on all 16 key standards. If you have carried out a responsive review, you will come to a judgement on the essential standards that you targeted in the review.

You will have reached a decision about whether the location is compliant for all the outcomes you have reviewed, or whether you have concerns about compliance with one or more of those outcomes.

The following table is an example of the judgements made following a planned review of compliance.

Location: Anywhere hospital

Guidance about compliance section	Outcome	Regulation	Full compliance	Concern		
				Minor concern	Moderate concern	Major concern
Information and involvement	1	17	✓			
	2	18	✓			
Personalised care, treatment and support	4	9		✓		
	5	14	✓			
	6	24			✓	
Safeguarding and safety	7	11	✓			
	8	12				✓
	9	13		✓		
	10	15		✓		
	11	16	✓			

Guidance about compliance section	Outcome	Regulation	Full compliance	Concern		
				Minor concern	Moderate concern	Major concern
Suitability of staffing	12	21	✓			
	13	22	✓			
	14	23	✓			
Quality and management	16	10		✓		
	17	19	✓			
	21	20	✓			
Suitability of management	N/A					

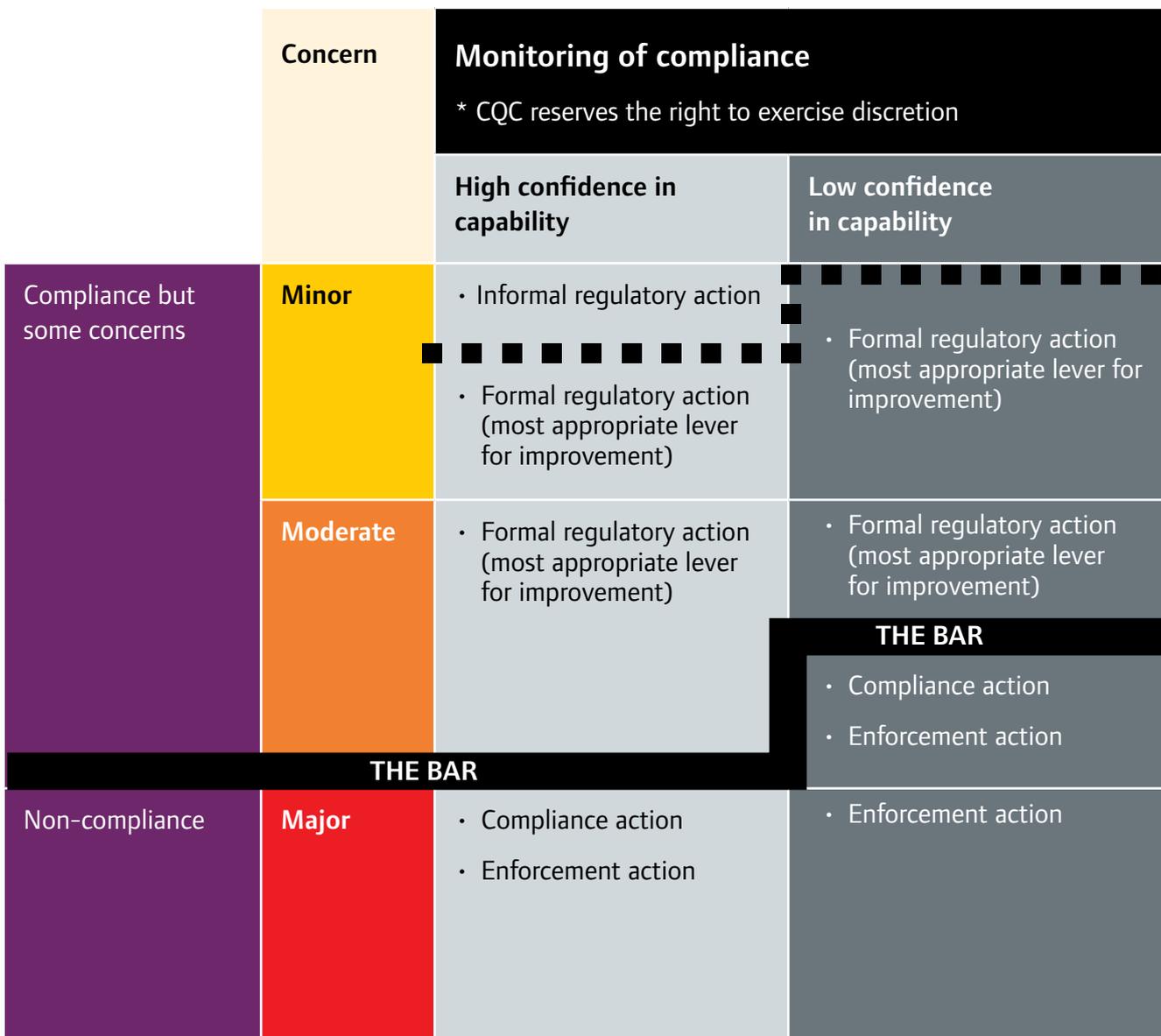
When you have reached a decision about compliance, the question is 'so what?' What does this mean for the regulatory response that we need to take?

We need to make sure that the action we take is proportionate and targeted. This framework helps us do this.

Where do we set the bar?

When we refer to the 'bar' being set at a particular level, we mean the difference between complying with the essential standards of quality and safety ('above the bar') and not complying with them ('below the bar').

The following diagram shows where the bar is set and the regulatory response that applies to each set of circumstances:



Major concerns always indicate non-compliance (below the bar).

Minor concerns usually indicate compliance (above the bar) but we will suggest improvements to make sure the provider maintains this.

Moderate concerns can be either, depending on the confidence we have in the provider's ability to make improvements and on our professional judgement as to whether our findings represent compliance or non-compliance.

Confidence in the provider's capability to improve

Our level of confidence in the provider's capability to make improvements is important in determining the appropriate response.

For example, if we concluded that we had a moderate concern, we would not automatically take enforcement action if we had high confidence in a provider's capability to make improvements.

We could set an improvement action (one of the 'formal' options) requiring the provider to send us a report showing how they are maintaining compliance with essential standards and any action needed to do so.

If, however, we had low confidence in their capability to make improvements, we are more likely to set compliance actions or take enforcement action to ensure that improvements are made to achieve compliance with the essential standards.

The overall regulatory response(s) we take also depends on the **combination of concerns**. The next section explains how to determine your responses.

Determining our regulatory responses

If there are no concerns, then the location is compliant for all the outcomes reviewed and no further action is needed.

If there are concerns, the process is as follows:

Major concerns

Firstly, are there any major concerns?

- If you identify three or more major concerns (regardless of the number of minor or moderate concerns), this is indicative of a serious problem. The rules below do not apply and a decision about our response should be made through discussion at a management review.
- If you identify one or two major concerns only, you should take the appropriate response for each concern. Follow the setting the bar diagram on page 6 (the choice is between setting compliance actions or taking enforcement action). If there are also minor or moderate concerns, you should also follow the procedure below in respect of these.

Minor and moderate concerns

Secondly, for any combination of minor and moderate concerns, you need to work out whether or not these amount to a systemic problem.

Use the matrix below.

- If there are only a small number of concerns (the grey area), you should apply the appropriate response to each outcome individually using the setting the bar diagram (and therefore there can be different actions for different outcomes).
- If there are more concerns (the orange and red areas), this is indicative of a systemic problem. You should treat this as an overall moderate (orange) or major (red) concern for the outcomes in question. You should choose the appropriate response using the setting the bar diagram and apply this to all these outcomes. Where systemic concerns have been identified, the provider should be seen as having low confidence.

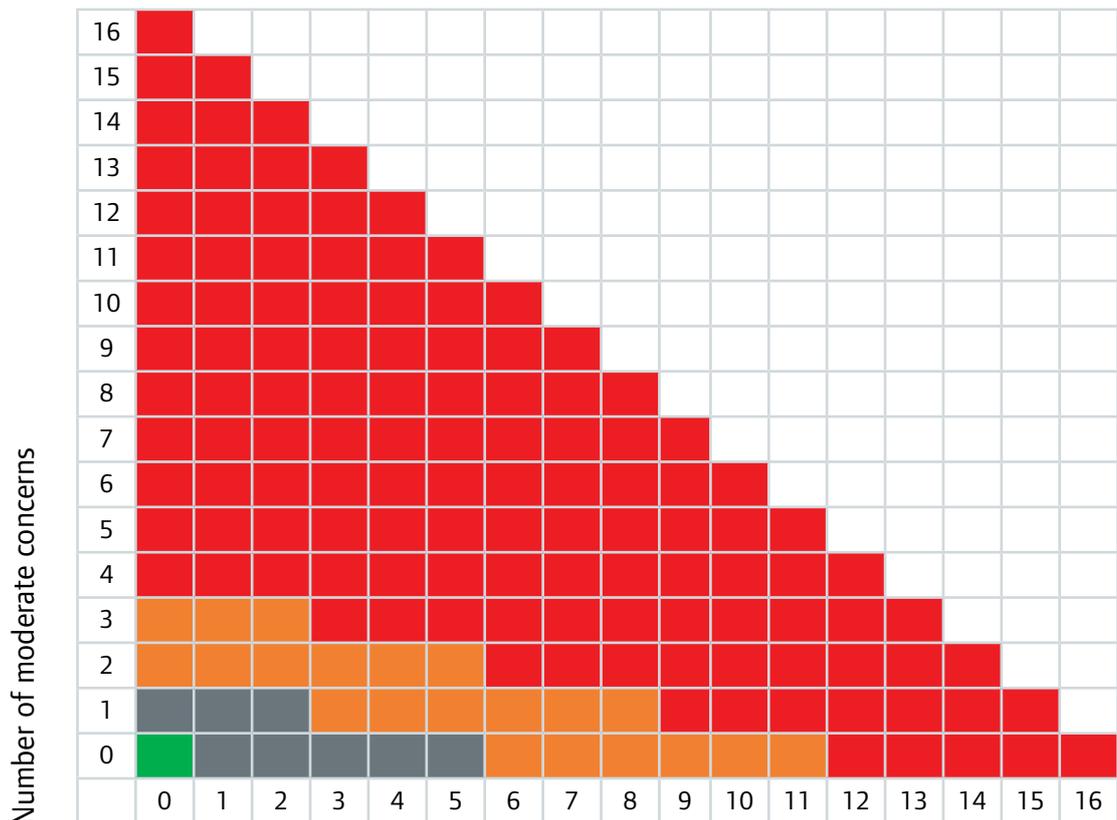
The matrix uses a points system:

Minor concern = 1 point

Moderate concern = 3 points

An aggregate score of 6-11 points gives an overall moderate concern.

An aggregate score of 12+ points gives an overall major concern.



Number of minor concerns

- No concerns
- Treat minor/moderate concerns individually and apply appropriate regulatory response to each outcome individually (therefore can have different actions for different outcomes)
- A systemic problem. Treat as an overall moderate concern for all the outcomes in question, with low confidence. Select an appropriate regulatory response for the outcomes, such as setting compliance actions.
- A systemic problem. Treat as an overall major concern for all the outcomes in question, with low confidence. Select an appropriate regulatory response for the outcomes, such as taking enforcement action.

Example of minor/moderate combination:

If we have minor concerns about compliance with four of the outcomes, and a moderate concern about compliance with two, our overall concern about the location would be moderate.

As this is a systemic problem, we have low confidence in their capability and therefore would consider setting a compliance action or taking enforcement action such as imposing or varying a condition of registration.

If we had minor concerns in 12 of the regulations for a provider, our concern about that provider would increase to a 'major concern'. As there is a systemic problem we would have low confidence in a provider's capability and we would take enforcement action.

Concerns about specific regulated activities

In addition, you may decide, on an exceptional basis, that you have a level of concern for an outcome for a specific regulated activity that requires a specific regulatory response. In this case, you can also apply a regulatory response to that concern for that activity only.

Example: you review a hospital and identify major concerns about nutrition in the maternity service. However, there are no concerns about nutrition across the rest of the hospital. You could take enforcement action against the nutrition regulation for the regulated activity "maternity and midwifery services" only, as the location is compliant across the other regulated activities for outcome 5.

Guidance on the overall approach

What principles underpin our approach?

- We want to be proportionate and targeted. We also want to encourage the provider to identify and manage non compliance. This means they take responsibility for making improvements, as they are responsible for the quality of care they provide.
- If we have high confidence in a provider's capability to make improvements, our regulatory response may be different than that if we have a low confidence in their capability to make improvements.
- In order for us to have a high confidence in their capability they must demonstrate that they:
 - Are willing to cooperate with us.
 - Understand the concern and what is needed to be implemented to resolve it.
 - Are a previously compliant provider (we cannot have high confidence in providers who are repeatedly non compliant in the same areas or continue to drift between compliance and non compliance).
 - Are aware of their shortfalls, include them in their Provider Compliance Assessment (PCA), and have appropriate plans in place to manage them.
 - Have the resources needed to make improvements to meet essential standards of quality and safety where systemic problems have been identified.
- We need to decide whether the provider meets the above criteria, and record this on our assessment record. This provides us with an important audit trail and will influence our approach to the provider. If the provider does not make necessary changes to improve its services, we would need to amend the details in our assessment record, as this would impact on our confidence in the provider in the future and our decisions on what regulatory activity to undertake. This information is then included in the Quality and Risk Profile.

How does a provider's capability to improve affect our response?

- Yes – our regulatory response may be different for a provider that we judge to have a high capability to make improvements themselves, but we must have confidence in their action plan that they can make the necessary improvements needed in order to achieve compliance.
- Where we have minor or moderate concerns about a provider, the action we will take may vary as we consider the capability of the provider to make improvements in their services. We want to encourage providers to identify and own necessary improvements, rather than us automatically taking enforcement action. We should use the most appropriate lever for change.

What do we do if a provider has concerns about their own compliance?

- If a provider tells us that they are concerned about their compliance they will have identified what the shortfalls are, and what they are going to do about it in a timely way, in order to ensure people who use services experience required outcomes.
- We will assess the robustness of their action plan using the 'SMART' approach, SMART action plans are:

Specific – does it identify the details of what the concern 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 the action plan say how they are going to ensure that improvements 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 concern identified?

Time bound – is there an appropriate date by which the improvements will have been made? How will this date impact on people who use services?

- If an action plan is not SMART, we have the option of asking them to redo it, or provide us with further information.

How do we decide whether a provider is above the bar or below the bar when we determine moderate concerns and low confidence?

- This is dependent on whether the concerns identify non-compliance or not.
- Where we identify moderate concerns but the provider is meeting essential standards, they are above the bar.
- Where we identify moderate concerns but the provider is not meeting the essential standards, they are below the bar.
- All decisions rely on robust evidence, local knowledge and professional judgement supported by our quality framework that ensures appropriate and proportionate decisions are made.

If we have identified concerns at a location level, are there any additional checks we need to make, where the provider has more than one location?

- Yes. Where we have identified concerns that fall below the bar we should always make additional checks at the provider level.
- This could involve sampling other locations to see if the same concern is across other locations or localised.

For example, we may ask to see a random sample of other locations' Provider Compliance Assessments for the regulation(s) that are causing concerns. We may also want to do some responsive compliance check site visits.

- If we identify that the same concern is across other locations, we should consider carrying out enforcement action against the regulated activity at the provider level, rather than for the regulated activity at the location level.
- If our enquiries at other locations show the concern is localised, the action we should take should be for the regulated activity at the location level only.

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 have identified concerns when carrying out a review of compliance, we will have reached a decision about whether the concern is across the location or specific to a regulated activity.
- Where it is specific to one regulated activity we have to ensure we act proportionately and take the appropriate regulatory action for that regulated activity.
- The level of concern identified should be used to determine what regulatory action to take by applying the same rules as you would when deciding what regulatory action should be taken across a location.
- In this scenario, the regulatory action is specific to the regulated activity and does not apply across the location. Where concerns are identified across the location setting the bar should be applied, excluding the concerns specific to the regulated activity.

For example: A review of compliance for a hospital identifies minor concerns across the location for outcome 17 complaints, in addition there are major concerns for outcome 13 staffing within the maternity unit only. This would result in regulatory action for a minor concern across the location, such as an improvement action, as well as regulatory action for the specific regulated activity, maternity and midwifery services, such as enforcement action.

- This ensures our regulatory response is proportionate and encourages the necessary improvements.

What are our options for the regulatory actions we take?

- We can use a range of regulatory actions to encourage improvement when monitoring compliance.
- We will use the most appropriate lever for change where we have concerns about a provider. This may not always involve enforcement action and different responses may be needed for different types of services.
- We can define regulatory actions in four groups:

Above the bar (complying with essential standards):

- Informal regulatory action
- Formal regulatory action (with the potential to escalate)

Below the bar (not complying with essential standards):

- Compliance action
- Enforcement action

Above the bar (complying with essential standards):

What is 'informal' regulatory action?

- **Informal** regulatory action will involve an informal discussion with a provider following monitoring compliance activity. We can make suggestions for improvement where there are only minor concerns. It is essential that we maintain our role as the regulator.
- This approach is only used when issues can be resolved quickly and easily and we have high confidence in a providers capability.
- We must always record our informal regulatory activity so we have an audit trail of our regulatory response.

What is 'formal' regulatory action?

- **Formal** regulatory action is aimed at encouraging improvement through bringing about change without taking enforcement action.
- **There are two basic types of formal regulatory action:**
 - Improvement action – you can set an improvement action following a meeting the provider, by sending the provider an improvement letter, or by setting it out in the review of compliance report.
 - Referring the concerns to another agency or regulator.
- Professional judgement should be used when reaching a decision about which regulatory response to use.
- The most appropriate method that is proportionate and will achieve the changes required should be used.
- All formal regulatory action needs to be recorded and monitored, even if we are not responsible for monitoring the actions.
- If, through monitoring, we find that necessary improvements are not made the concerns can be escalated to take further regulatory action, or enforcement action where appropriate.
- Where regulatory action requires a report showing how the provider is maintaining or achieving compliance and any action needed to do so to be submitted to us, the report will need to be robust and of good quality and demonstrate SMART principles. If not we can either ask the provider to amend and resubmit it, or it will reflect our confidence in the provider's capability to bring about change in their service

Below the bar (not complying with essential standards):

What are 'compliance actions'?

- We can set compliance actions (as an alternative to enforcement action) where there is a major concern but we have confidence in the provider.
- We can also set compliance actions (as an alternative to enforcement action) where there is a moderate concern but this constitutes non-compliance and we do not have confidence in the provider.
- The action we take will be influenced by the impact of the concern and whether it is containable or systemic.
- Compliance actions are set in a similar way to improvement actions. Providers have to send us a report showing how the provider is achieving compliance and any action needed to do so. We then monitor progress.
- As with the formal regulatory actions, if the necessary improvement and compliance are not achieved the concern can be escalated for consideration of further appropriate enforcement action using the management review process.
- Please see the enforcement policy on our website for further details.

What is 'enforcement action'?

- Where a major concern is identified and we do not have confidence in the provider, we will take enforcement action.
- We can also take enforcement action where there is a major concern but we have confidence in the provider.
- We can also take enforcement action where there is a moderate concern but this constitutes non-compliance and we do not have confidence in the provider.
- The action we take will be influenced by the impact of the concern and whether it is containable or systemic.
- Please see the enforcement policy on our website for further details.

What if concerns are identified that require a joint approach to managing the concerns?

- Where we identify concerns that would benefit from a joint approach involving other bodies, such as Councils or Monitor we can trigger a risk summit.
- Triggered risk summits are business planning meetings to enable effective and efficient coordination between all relevant health and social care partners.
- Summits involve detailed discussions and assessment of risk in response to the emergence of serious concerns and determine an appropriate response to encourage improvement.
- A triggered risk summit would usually take place in addition to any internal regulatory response.
- Refer to the triggered risk summit guidance for further details.

The different types of regulatory action

The table below shows the different kinds of regulatory action we can take. This is not an exhaustive list. Other action may be just as appropriate and effective, for example, closer scrutiny of the provider.

Consider the type of service, the level of concern, the capability of the provider and the impact on people when selecting which approach to use.

You may need to use one or more of these options.

Regulatory action	Outcome from the action
Informal action	
	Informal discussions with the provider
Formal action	
Refer to another agency/regulator/commissioners	Agree with the other agency/regulator/commissioners that they will take responsibility for achieving the improvement Feedback from the other agency/regulator/commissioners on the provider's progress and completion
Improvement action	Set either at a meeting with the provider, or by sending an improvement letter, or by setting it out in the review of compliance report. Provider submits a robust report showing how it will maintain compliance and any action needed to do so Update from the provider on progress and completion
Compliance action	
	Provider submits a robust report showing how it will become compliant and any actions needed to do so Update from the provider on progress and completion

Regulatory action	Outcome from the action
Enforcement action (civil enforcement)	
Conditions (including urgent conditions)	Provider makes the necessary improvements to become compliant Follow up to check the necessary improvements have been made
Warning notice	Provider makes the necessary improvements to become compliant Follow up to check the necessary improvements have been made
Suspension of registration (including urgent suspension)	Provider makes the necessary improvements to become compliant Follow up to check the necessary improvements have been made prior to removing the suspension
Cancellation of registration (including urgent cancellation)	Provider makes the necessary improvements to become compliant prior to re-applying to register
Enforcement action (criminal enforcement)	
Fixed penalty notice	Provider pays a fine and makes the necessary improvements to become compliant Follow up to check the necessary improvements have been made
Caution	Provider is cautioned for breaching legislation
Prosecution	Provider is prosecuted for breaching legislation