

A new system of registration

Setting the bar

A framework for our regulatory
response for existing providers

Introduction

Our overall vision for registration is that it will result in people experiencing services that meet essential standards of quality and safety and respect their dignity and rights.

This guidance provides a framework from which we can make consistent and robust decisions about what we will do to make sure that services meet the essential standards.

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.

The guidance shows our approach to 'setting the bar' for existing providers and divides it into two responses:

- **Response 1:** where we have identified concerns in one regulation only.
- **Response 2:** where we have identified concerns in more than one regulation.

Note: The guidance does not apply to brand new providers or existing providers applying for a new regulated activity. These must be compliant on registration and the guidance is not relevant in these circumstances.

How to use this guidance

You need to read this guidance in conjunction with the judgement framework and guidance on conditions.

You should use it when you have completed **Stage 4** of the judgement framework.

At Stage 4, you will have reached a decision about whether the location is fully compliant or whether we have concerns about compliance.

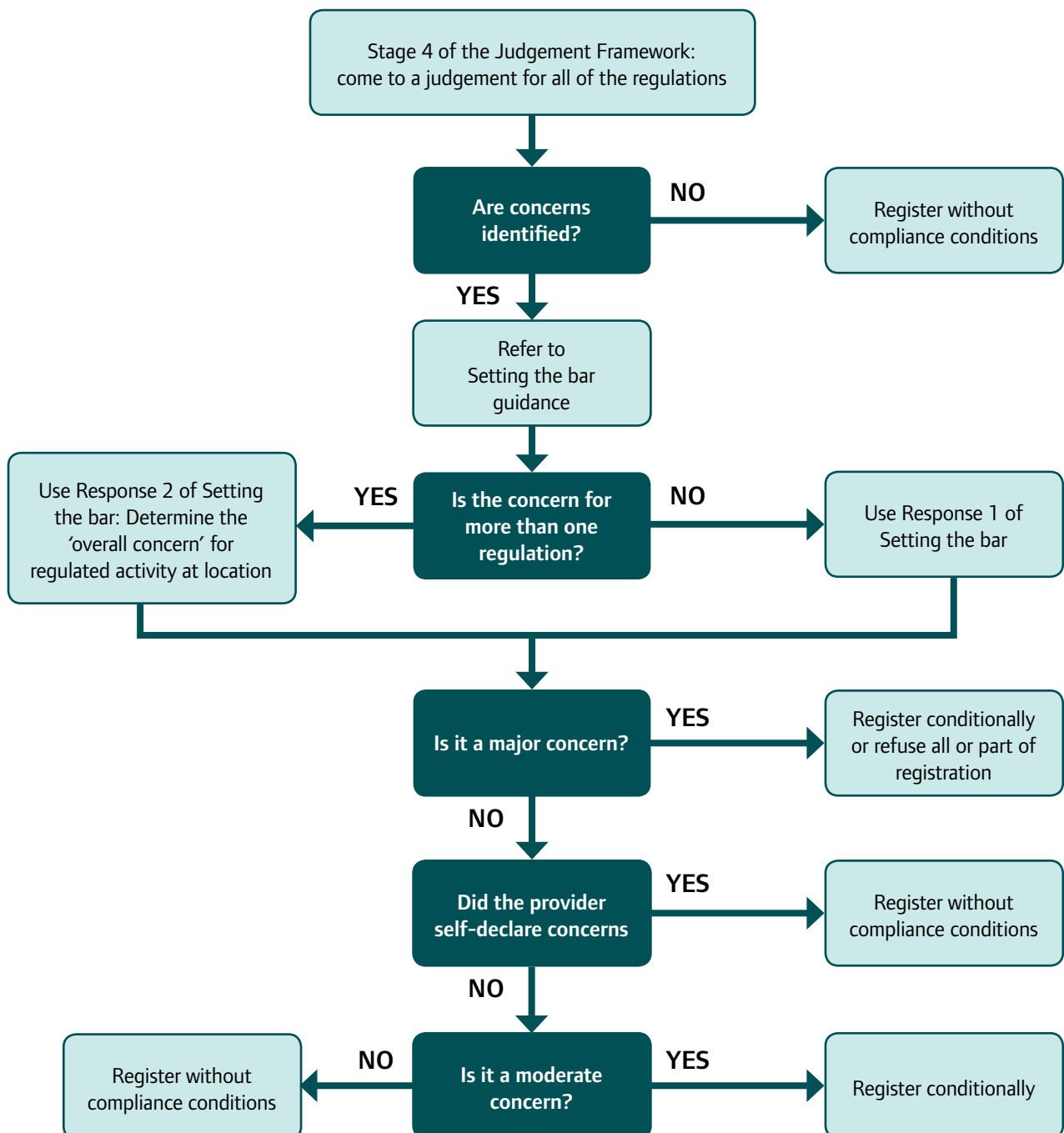
You will have made a decision about all of the 16 registration regulations (out of the 28) that most directly relate to the quality and safety of care. The example below shows the outputs following a check of all 16 regulations.

Example: Location: Anywhere hospital

Section	Outcome	Regulation	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	✓			
Suitability of staffing	12	21	✓			
	13	22	✓			
	14	23	✓			
Quality and management	16	10				
	17	19	✓	✓		
	21	20	✓			
Suitability of management	N/A					

You then need to identify the appropriate regulatory response that will ensure that the action we take is proportionate and targeted. This guidance explains how to do this.

If there are concerns about more than one regulation, you will need to determine the overall level of concern. The following flowchart gives an overview of the whole approach.



What principles are we basing our approach on?

We want to encourage providers of services to make honest and accurate declarations, and feel confident to declare non-compliance when they know they have to make improvements to meet the essential standards.

The reasons for this are:

- To put the emphasis on the provider to identify and manage non-compliance, as they are responsible for the quality of care they provide.
- To ensure that we have an accurate assessment of providers' compliance in relation to each of the new regulations.
- To enable us to identify any themes or trends that may be managed effectively through a different method, for example, special reviews, surveys or national audit.

What do we do if a provider declares non-compliance?

When a provider declares non-compliance, it must have identified what the shortfalls are and what it is going to do about it, in a timely way, to ensure that people who use services experience the essential standards of quality and safety.

We will assess the robustness of its action plan using the 'SMART' technique, which requires an action plan to be:

Specific – Does it identify the details of what the non-compliance is, and what action needs to be taken? Does it explicitly say what the provider wants to achieve and who is going to make these changes?

Measurable – Does the action plan say how the provider is going to ensure that improvements have been made? What measures are they going to put in place? Who will do this?

Achievable – Are these measures achievable, attainable and sustainable?

Relevant – Has the provider described the resources needed to implement the changes? Are these in place?

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

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

Will we have a different regulatory response for providers who have declared non-compliance, and for where we find concerns that providers haven't declared?

Yes, our regulatory response **may** be different for a provider that has declared non-compliance, but we must have confidence from their action plan that they can make the necessary improvements to achieve compliance.

We will **always** take enforcement action where we have major concerns about a provider's non-compliance (regardless of whether they have declared non-compliance or not).

Where we have minor or moderate concerns about a provider, our regulatory response will consider whether the provider declared non-compliance. We are incentivising providers and encouraging them to identify and own necessary improvements, rather than CQC having to enforce action.

If we have identified concerns at a location level, are there any additional checks we need to do at the provider level?

Yes, where we have identified concerns that fall 'below the bar' (see page 9 that shows where the bar is set), we should always make additional checks at the provider level. This will involve sampling other locations to see if the concern is systemic or localised.

If we identify the same concern across other locations, we should impose a compliance condition for the regulated activity at the provider level, rather than imposing a condition at the location level.

If our enquiries at other locations show that the concern is localised, our regulatory response should be for the regulated activity at the location level only.

Determining our regulatory response

Response 1: Where we have identified a concern about compliance for **only one** regulation

Use the 'setting the bar' table on page 9 to determine what our regulatory response should be where we have identified a concern for only one regulation.

For example, if a provider has **declared** that it is not complying with a registration regulation and, by using the judgement framework, we have concluded that this is a **moderate** concern, we would not automatically undertake enforcement action. We would register the provider without compliance conditions and then send an improvement letter as part of our monitoring of ongoing compliance. This will identify what actions we want the provider to take to support improvements in the service to meet essential standards.

However, if a provider did **not declare** that it was not complying with a regulation, and we concluded that we have **moderate** concerns about their compliance, we would undertake enforcement action and register the provider with compliance conditions, in line with the guidance on conditions.

Response 2: Where we have identified concerns about compliance for more than one regulation

If we have identified concerns for more than one registration regulation, we need to determine the overall level of concern using the following table below. This will influence the regulatory response for the regulated activity at the location.

Number of concerns	Overall concern
Less than 4 minor concerns	Minor
4 or more minor concerns, but less than 12	Moderate
12 or more minor concerns	Major
Less than 4 moderate concerns	Moderate
4 or more moderate concerns	Major
One major concern or more	Major

For example:

11 minor concerns and 3 moderate concerns =	Moderate concern
4 minor concerns and 1 moderate concern =	Moderate concern
3 minor concerns and 3 moderate concerns =	Moderate concern
3 minor concerns and 4 moderate concerns =	Major concern
1 minor and 1 major concern =	Major concern

Then, use the overall concern and the 'setting the bar' table on page 9 to determine what our regulatory response should be.

For example, if we have minor concerns for four registration regulations and a moderate concern for one, then our overall concern about the location would be **moderate**.

If the provider declared non-compliance, we would register it without compliance conditions and would send an improvement letter as part of ongoing monitoring of compliance. If it had not declared, we would register it with compliance conditions.

If we had minor concerns for 12 regulations, we would escalate our regulatory response to a **major concern**. Regardless of whether a provider declared compliance or not, we would take enforcement action, which may result in imposing compliance conditions to the provider's registration.

When applying compliance conditions, we may impose one overall condition or more than one, depending on the concerns.

Setting the bar

	Concern	* CQC reserves the right to exercise discretion	
		Declared	Not declared
Register WITHOUT compliance conditions	Minor	No regulatory action (action plan already received)	Action plan and monitor
	Moderate	Improvement letter and monitor (action plan already received)	BAR Compliance condition
BAR			
Register WITH compliance conditions or refuse registration	Major	Compliance condition or refuse part of registration	Compliance condition or refuse part of registration

Appendix: Putting the guidance into practice

Case study example: Woodside Hospital

Outcome 12 (Regulation 21 – Requirements relating to workers)

A safeguarding concern has been raised about Woodside Hospital, caused by serious failings in recruitment procedures.

It is clear that staff have been employed without CRB and ISA checks being undertaken.

The recruitment process does not include checking that relevant nurses are on the appropriate part of the nursing register that enables them to deliver care to children.

Step 1:

Using the judgement framework, we have identified the following:

- This is a **high** impact for people as there are no checks to ensure that people being employed are safe to work with children.
- The likelihood of it recurring is **almost certain** as there are significant problems with the recruitment process.
- This means that it is a **major concern**.

Step 2:

Using the 'setting the bar' guidance, we identify that this places the service provider **below the bar** and we need to register it with compliance conditions.

Step 3:

As the concern means that the location is providing a service that is below the bar, we make additional checks on recruitment procedures at other locations within the service provider's application, and we find that failings in recruitment are a systemic problem.

Step 4:

We use the **guidance on conditions** and impose condition(s) for the regulated activity at the provider level.