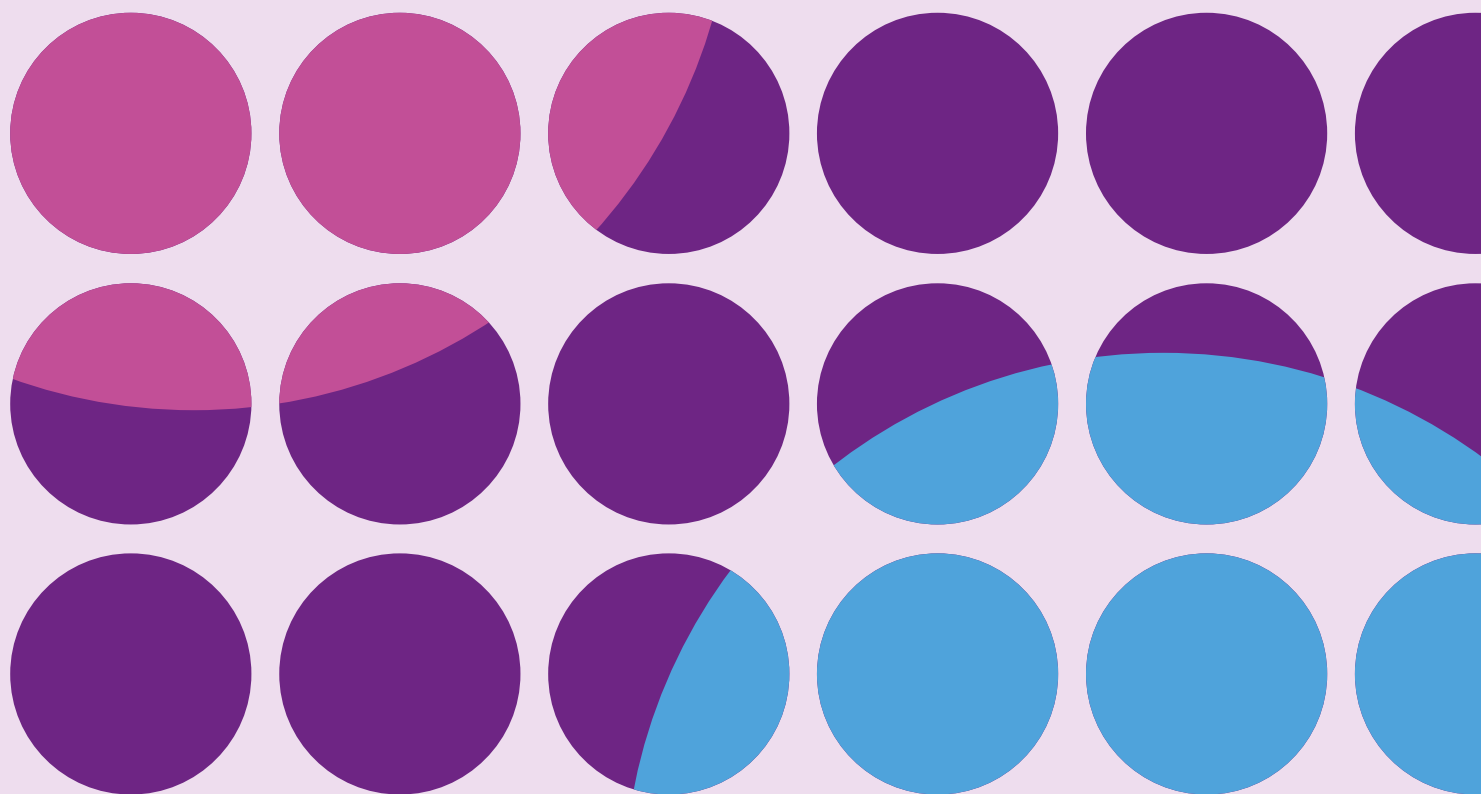


# Right-touch regulation

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# About the Professional Standards Authority

**The Professional Standards Authority for Health and Social Care (PSA) is the UK's oversight body for the regulation of people working in health and social care.**

Our statutory remit, independence and expertise underpin our commitment to the safety of patients and service-users, and to the protection of the public.

There are 10 organisations that regulate health professionals in the UK and social workers in England by law. We audit their performance and review their decisions on practitioners' fitness to practise. We also accredit and set standards for organisations holding registers of health and care practitioners not regulated by law.

We collaborate with all of these organisations to improve standards. We share good

practice, knowledge and our right-touch regulation expertise. We also conduct and promote research on regulation. We monitor policy developments in the UK and internationally, providing guidance to governments and stakeholders. Through our UK and international consultancy, we share our expertise and broaden our regulatory insights.

Our core values of integrity, transparency, respect, fairness, and teamwork, guide our work. We are accountable to the UK Parliament. More information about our activities and approach is available at [www.professionalstandards.org.uk](http://www.professionalstandards.org.uk)



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# Introduction

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# Summary

**Right-touch regulation is the approach we apply in our work, and we encourage others to adopt it as well.**

It involves assessing the level of risk of harm to the public and deciding on the most proportionate and effective response to mitigate that risk – whether through regulation or other means.

Right-touch regulation is about doing enough to mitigate risk to an acceptable level and no more. Recognising that there is no such thing as zero risk, regulators need to determine the appropriate level of risk management in their areas of responsibility and do only enough to achieve it. This should be based on the best evidence available. They should only intervene when other systems closer to a risk cannot manage it effectively.

Regulators need to be clear and transparent about how they have decided what the tolerable level of risk is in any situation. They should show how regulating beyond that level would have other, undesirable

consequences. These could include limiting access to services, inhibiting innovation and growth, wasting resources or creating unnecessary burdens on those regulated.



**Regulation therefore is for unmanaged risks of significant harm that cannot be resolved locally and can be delivered in line with the principles of good regulation.**

In Box 1 we set out what right-touch regulation offers the public.

## Box 1: What does right-touch regulation offer the public?

Where right-touch regulation is being practised, the public can expect that:



regulators will put the interests of the public at the centre of all policy and decision-making



regulators will involve the public in policy and decision-making



regulators will be clear in how they make their decisions



regulators will be clear about what risks they manage and how



regulators will be clear about the evidence on which they base their decisions, and open to new evidence which might change their approach



regulators will support innovation and growth by setting out how the risks involved should be managed

### Further information



Read through more resources explaining the basic principles of right-touch regulation [www.professionalstandards.org.uk/improving-regulation/right-touch-regulation](http://www.professionalstandards.org.uk/improving-regulation/right-touch-regulation)

# 1. Introduction

**This new version of *Right-touch regulation* sets out the PSA's thinking as we continue to explore the role and value of regulation in controlling risks of harm to the public.**

It describes the approach we adopt in the work we do, and frames the contributions we make to wider debates about quality and safety in our sector and beyond.

Since our last edition in 2015 the work of regulators has become more complex and challenging in the face of technological, social and political change, and at an ever-accelerating pace. We summarise some of those changes in Box 2. Attitudes to different risks can change rapidly as social and cultural norms shift and evolve. Things previously seen as harmful or dangerous as they arose might now be well managed and normalised; some developments seen as innovative and ground-breaking are shown over time to come with previously unseen risk.

Day-to-day therefore, regulators manage a complex balancing act between risk, their resources, their capability to deliver, and the public and others' interest in safety,

innovation, growth, and access to services. So, even more than in 2015, regulators need to have the capacity for agility in all their work.

While this daily challenge becomes ever more complex, we believe that the central ideas of right-touch regulation remain the same: regulate only when necessary; be led by evidence of risk of harm; identify the optimum level of assurance to which risk should be managed.

When we discuss regulation in this paper, we do so mindful of the variety of approaches, interventions and tools that it encompasses. In our sector this includes both statutory regulation and accredited registration of professions in the health and care workforce. Recognising the contribution of the range of approaches to managing risk of harm is central to right-touch regulation, as is creative-thinking about how they might best work together to keep people safe.



The principles and decision-making process set out in this document will lead to efficient identification of what needs to be regulated, and how, on the basis of evidence. It will result in proportionate approaches to regulatory delivery which maximise positive impact and benefits that drive improvements, while minimising negative consequences, costs and burdens. It will enable rapid responses in evolving and changing situations.

Overall, right-touch regulation should be seen as an investment that adds value – not in itself a cost, barrier, or constraint. This is particularly the case where regulation is proactively anticipating future risks of harm and taking action to mitigate them before harm has occurred.

We will be starting to publish further supporting resources on the application of right-touch regulation on our website from early 2026, supporting ongoing stakeholder engagement through, for example, sharing good practice, case studies, and more in-depth discussion of how right-touch regulation can be applied in practice.

## Box 2: Why update *Right-touch regulation* now?

Several factors have led us to conclude that the time is right for a new edition of *Right-touch regulation*, in which we provide more detail on its central ideas to support regulators in responding to current challenges and opportunities. These include:

- the pace and scale of worldwide transformations in politics, economics, social attitudes and technology
- challenges to regulation to prove its effectiveness, and to demonstrate its value, often in the face of failures of delivery
- challenges to regulation to support innovation and economic growth
- greater understanding of risk and harm, including the differential harms experienced by some groups in society
- increasing recognition that regulation can offer value and benefit more widely across public and private services.



# What is right-touch regulation?

- ➔ 2. What is regulation?
- ➔ 3. What is harm?
- ➔ 4. What is right-touch regulation?
- ➔ Box 3: The 'lines of defence' model of risk management
- ➔ Figure 1: The lines of defence model
- ➔ 5. What are the six principles of right-touch regulation?
- ➔ 6. Who is right-touch regulation for?

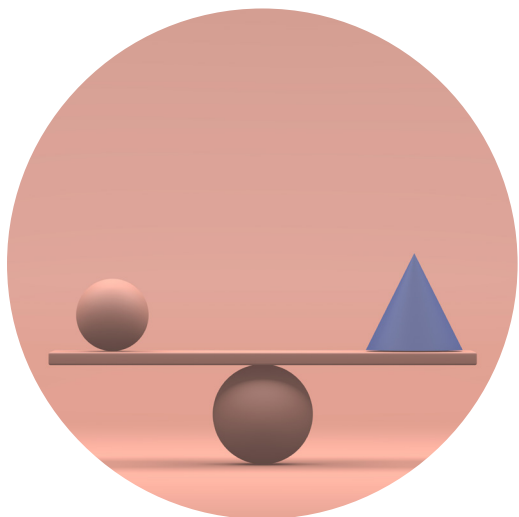


## 2. What is regulation?

**The overarching purpose of regulation is to protect the interests of the public, by mitigating risks of harm in situations and circumstances where they can be vulnerable.**

In doing so it makes an essential contribution to public safety and wellbeing. We say more in **Section 3** about what we mean by harm.

We use the term regulation to mean the delivery of regulatory activity, as well as specific rules or requirements. Regulators, meanwhile, are the organisations that are responsible for that activity within the scope of their legislation.



Regulation works by using rules, guidance and incentives to influence individuals, organisations, products, processes and markets. Regulation usually involves the advancement of rules and standards that should be met, and operating processes to monitor compliance. Regulators are typically statutory organisations established to operate regulatory frameworks, developing their rules and policies on the basis of powers and duties set out in legislation.

Regulation builds trust and confidence in those individuals, organisations, products, processes and markets. It does this by upholding and promoting the rules and standards that must be met, and by holding people and systems to account for failing to do what they should.

### 3. What is harm?

**Regulation has an important part to play in protecting the public against risk of harm.**

By harm we mean physical or psychological injury, or other loss or detriment. For example, this may include:

- harm to the physical, psychological and emotional health and wellbeing of members of the public
- financial and other kinds of loss, such as digital exclusion, loss of control of personal data, and damage to earnings, career and/or career progression
- harm to the reputation of an organisation delivering services – and resulting damage to public trust, both to specific organisations and to institutions more generally
- disruption to the work of teams, and to the availability and quality of services in the future

- damage to the trust and perceived legitimacy of the regulator by those regulated, which may result in disengagement
- in consequence of the above, damage to trust and confidence in services and professions.

In whichever sector they operate, regulators need to understand the range of possible physical, psychological, financial, and other harms that may result to the public from the entities they oversee, and what factors increase and decrease the risk of harm occurring.

## 4. What is right-touch regulation?

**Right-touch regulation is a principles-based framework that can apply to the decision-making and risk management of all regulators regardless of sector or jurisdiction.**

It advances a set of guiding principles and a decision-making tree which support the identification of the most proportionate, efficient and effective solution in situations requiring the management of risk of harm. It is about good regulation.



**Right-touch regulation is all about balance.**

It means risk of harm being controlled to an optimum level of assurance but not further. This guards against either too little control of risks, meaning too great exposure to the possibility of harm; or excessive attempts to control, resulting in wasted resources, false assurance, inhibition of innovation and growth, and difficulty in realising benefits and value.

Regulators are often blamed for tolerating risks or being ineffective where services fail and people are harmed. Conversely, regulation is criticised for being excessively burdensome, where it is seen to be a barrier to growth or is not demonstrably adding value. Right-touch regulation addresses these concerns by offering a way for regulators to work with transparency and clarity about how and why their decisions about risk are made, and how the balance is struck.

We see right-touch regulation as being consistent with the three lines of defence model of risk management within an organisation, which we summarise below in **Box 3** and **Figure 1**.

## Box 3: The ‘lines of defence’ model of risk management

**First line:** the professionalism of front-line individuals and teams delivering a service.

**Second line:** internal, local organisational control mechanisms, including governance, quality assurance, internal audit, reporting mechanisms for concerns, safeguarding arrangements, local and team cultures.

**Third line:** external and independent protection, quality and safety systems, including regulation, that set standards and operate corrective mechanisms to address non-compliance.

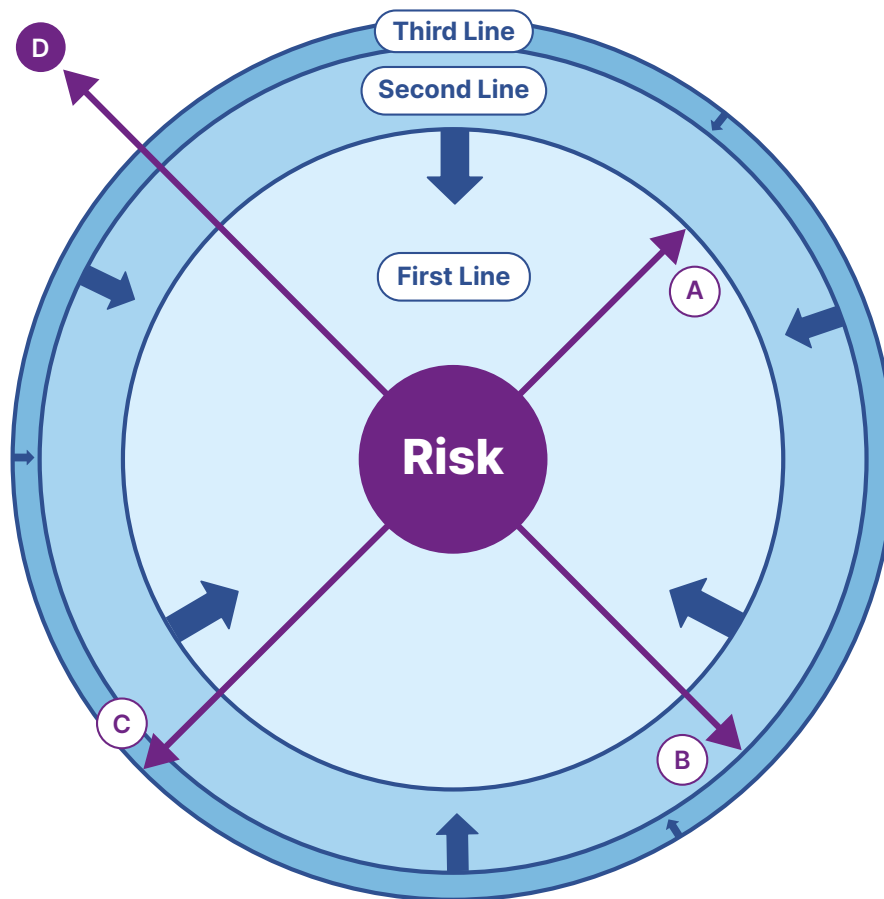
In a well-functioning system, there is an inward positive influence, for example:

- regulation in the third line having a positive influence on mechanisms in the second line and professional competence and conduct in the first line
- effective mechanisms in the second line having a positive influence on professionals in the first line.

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### Figure 1: The lines of defence model for managing risk

The first line makes the greatest contribution, then the second line and finally the third line (regulation). The inward-facing arrows represent a positive influence on the risk and on the lines of defence under the layer in question. The outward-facing arrows represent a risk being ‘captured’ (prevented from becoming an issue) by the first, second and third lines in A, B and C respectively. Arrow D represents a risk becoming an issue as it has not been captured by the lines of defence and it may cause harm (this may be by design if the risk is deemed tolerable).



Right-touch regulation requires that the first and second lines of defence usually mitigate risks effectively – only when necessary should the third line assume this responsibility.

## 5. What are the six principles of right-touch regulation?

The idea of right-touch regulation arose from the principles of good regulation identified by the Better Regulation Executive in 2000, to which the PSA added agility as a sixth principle.

The principles are that regulation should be:

**Proportionate:** regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised.

**Consistent:** rules and standards should be joined up and implemented fairly. Regulators should work for consistent outcomes with disparity only where this can be justified.

**Targeted:** regulation should be focused on the problem it is seeking to solve, and minimise unwanted side effects.

**Transparent:** regulators should work openly, be accessible to scrutiny, and keep regulations simple and user-friendly.

**Accountable:** regulators must work transparently, and be open and accessible to scrutiny.

**Agile:** regulators must look forward, anticipating and adapting to change.

We see the concept of right-touch regulation as emerging from the application of these six principles.

We recognise that in some circumstances the principles may appear to be in conflict. For example, seeking to be consistent over time and across a sector may conflict with agile responses that are adapting to rapidly changing situations. The challenge to regulators is to strike the best possible balance, and to be able to demonstrate how they have done so and why – and therefore, be both transparent and accountable for their decisions and actions.



## 6. Who is right-touch regulation for?

**Right-touch regulation is relevant for all regulators.**

It has been developed in the context of health and care professional regulation, and the PSA's oversight of the UK health and care professional regulators and Accredited Registers.

However, it is relevant for all regulators, including those involved with the regulation of professions, products, places, and markets. It can apply to any situation where regulation is being considered as the solution for managing risk, across different sectors and jurisdictions, or where existing regulatory or risk management controls are being evaluated. It can also apply where regulatory failure is being assessed, when the focus should be on whether the solution in place had become the problem.

Therefore, it is also intended for others involved in, or with an interest in, the effective management of risk, including governments, policy makers, public and other representative organisations, professional bodies, and organisations providing services.



We are aware that right-touch regulation has been adopted as an approach in a number of different sectors and settings internationally, and collected some examples of these in our 2018 publication [Right-touch regulation in practice: international perspectives](#)<sup>1</sup>



Right-touch regulation has been recognised and adopted in policy-making in other countries including for example, in the WHO's [Health practitioner regulation: design, reform and implementation guidance \(2024\)](#)<sup>2</sup>



# Risks and benefits

- ➔ 7. The risks and benefits of risk-based regulation
- ➔ 8. Striking the right balance
- ➔ Figure 2: Balancing risk with regulatory force



## 7. The risks and benefits of risk-based regulation

**To understand a problem fully, we must be able to quantify and qualify the risks it entails.**

This allows us to understand how frequently harm occurs, to whom, what impact it has, and what causes it. This approach will inform decisions about which harms need to be addressed. Both quantifying and qualifying risks is essential if we are to describe regulation as 'risk-based', and the term 'risk-based regulation' should only be used where it has taken place.



One of the key strengths of risk-based regulation is that when used well it provides a clear, transparent and rational basis for determining what and how to regulate.

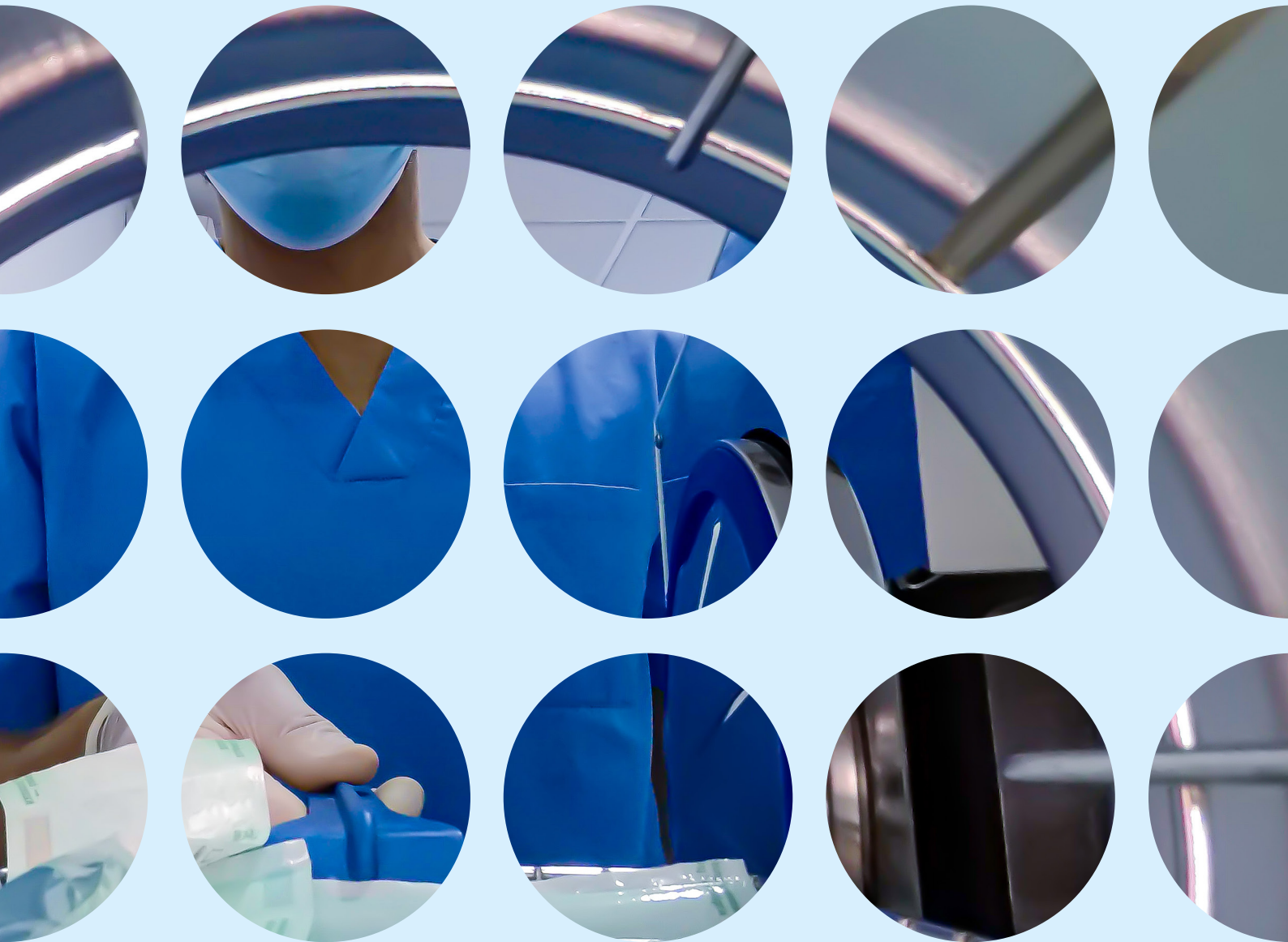
For risk-based regulation to be effective, regulators must communicate their approach clearly to the public, their registrants and other stakeholders, explaining the rationale for their risk appetite and, therefore, how they determine a desired outcome or level of assurance in relation to different risks.

Once a risk has been evaluated a decision needs to be made about its tolerability. This can be a difficult moral exercise, and a decision will require clear and transparent justification. If the risk cannot be tolerated, action is needed to manage it in accordance with right-touch regulation principles. This may, as we have set out, be a regulatory solution, or a local solution, closer to the problem. Reaching a balance in this way promotes clearer public understanding of what regulation can and cannot offer.

Risk-based regulation offers a central organising principle with advantages such as enabling systematic and transparent prioritisation in the allocation of regulatory resources. However, it is not without risks of its own. These include the potential for false assurance, where assumptions are made on the basis of poor quality data about risks of harm, and ambiguity and conflict around the desired outcome in relation to any specific risk.

Regulators must work tirelessly for better understanding of the nature of the risks for whose management they are responsible, including through improved data collection and analysis. They must be transparent about the ways in which the desired outcome is determined, and open to challenge and review as circumstances demand. It is inevitable that regulators will be involved in controversial discussions about the level at which the tolerance for some risks is set. This should not be seen as a weakness of regulation but as a strength.





## 8. Striking the right balance

**Applying right-touch regulation means identifying the regulatory force needed to achieve the desired effect – an acceptable level of assurance that risks are being managed appropriately.**

Our analogy is finding the right balance on a set of scales, as demonstrated in Figure 2. When using scales, you apply weight until a balance is achieved. Once the scales are balanced, any further weight is ineffectual. The right amount of regulation, similarly, balances the scale with the risk of harm – it achieves the desired result and no further. Too little is ineffective; too much is a waste and may impose unnecessary burdens or costs. It may even be harmful, if for example it gives false assurance or creates difficulties in the provision of services.

By regulatory force, we mean the range of regulatory resources and interventions that can be addressed to a risk. At the balancing point the desired outcome is achieved with the minimum input. By the 'desired outcome' we mean an acceptable level of assurance is reached by the decision or approach taken. This does not mean that any outcome is predetermined or a foregone conclusion, nor does it mean that all risk has been eliminated.



Good regulation mitigates – but does not eliminate – the risks of harm.

# Regulatory force

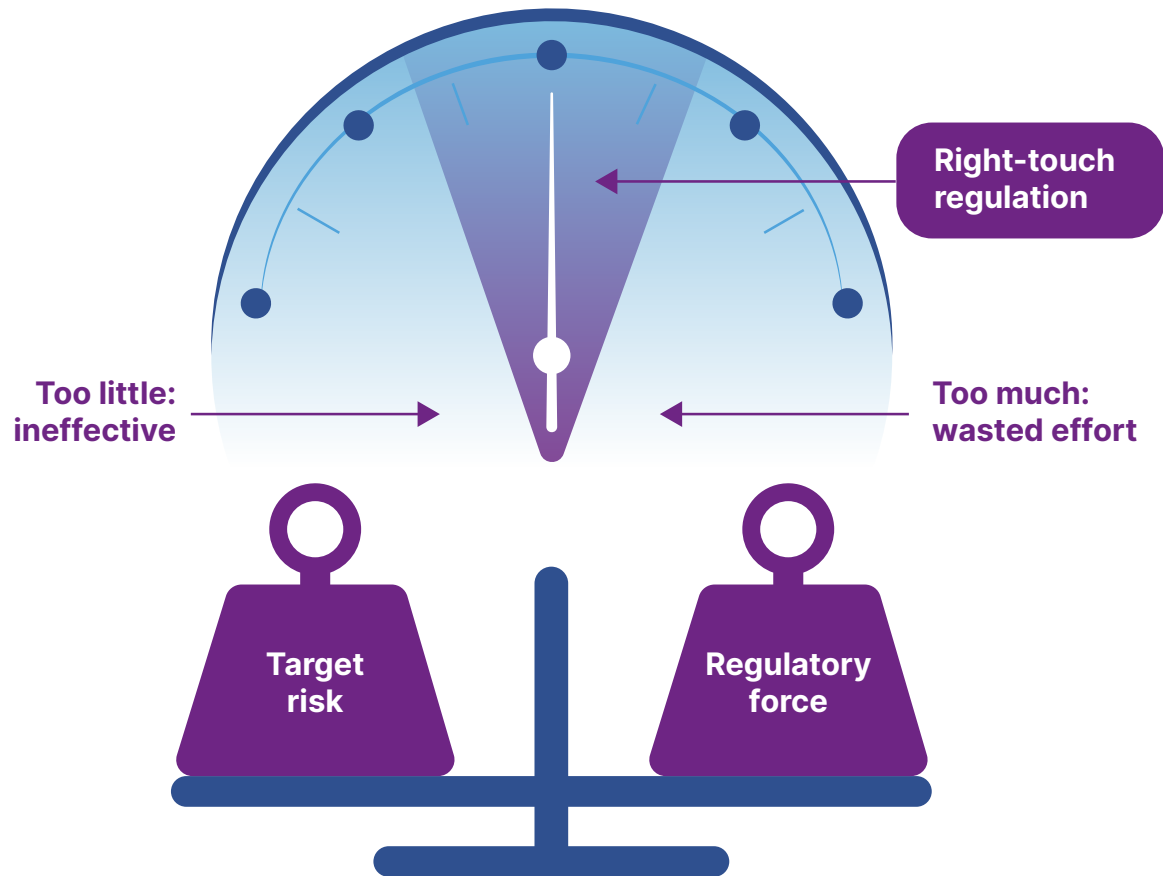


Figure 2: Balancing risk with regulatory force



# Right-touch regulation in practice

- ➔ 9. Right-touch regulation in practice: the eight elements and the decision-making tree
- ➔ Figure 3: The continuum of assurance
- ➔ Figure 4: Decision-making tree
- ➔ 10. Ways of working
- ➔ Box 4: Improving collaboration
- ➔ Box 5: Tools available to regulators for positive influence
- ➔ Box 6: The safety of care: an illustrative example of distributed responsibility
- ➔ 11. Alignment with other regulatory principles and priorities
- ➔ Box 7: Mapping the smarter regulation principles to right-touch principles
- ➔ 12. Applying right-touch regulation



## 9. Right-touch regulation in practice: the eight elements and the decision-making tree

Through our work with regulators we have identified eight elements that are central to applying the concept of right-touch regulation in practice.

These elements comprise a sequence of actions through which to identify whether regulation is the most appropriate risk management approach in any given situation. Moving through the sequence involves answering a series of questions, which we have brought together as a decision-making tree at **Figure 4**. We believe that the application of this tree will support decisions which are consistent with the six principles set out in **Section 5**.

Running through all of the elements of the decision-making tree is a commitment to:

- use evidence to identify, understand, and prevent risk of harm
- draw on the roles and responsibilities of different parts of the system to deliver the best regulatory response, including through collaborative approaches where they would be most effective

- have concern for equality, diversity, and inclusion at every stage of decision-making.

The result of applying this approach to decision-making may be more or less regulation but certainly better regulation.

The decision-making tree can be applied both to known current problems, and anticipated future risks of harm identified through horizon-scanning. For future risks, there may be limited data and intelligence to inform assessment, but the principles remain the same.

The decision-making tree can also be applied to situations where a lighter regulatory touch may be appropriate. This may be the case, for example, where once new and poorly understood risks have become better understood and well-managed over time, including through

improvements to the first and second lines of defence (see **Box 3** and **Figure 1**). In this case, the same principles apply: seek to understand the risks now and explore the potential effectiveness of alternative approaches to their management.



If the scales have tipped to over-regulation, resource is being wasted, and the agile regulatory response is to re-evaluate the approach to how the risks are being managed.

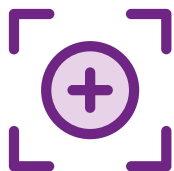
We recognise that many regulators face barriers to working efficiently through the stages set out below because of limitations that are placed on them by outdated and inflexible legislation. This can inhibit regulators from working with agility and adaptability and may indicate the need for reform. Nonetheless, regulators should explore what might be possible within the scope of existing legislation, such as collaboration and sharing of good practice.



## One: identify the problem before the solution

The first stage is to identify the problem that needs to be solved. Too often in regulatory policy development, the need for change is prescribed, and appealing solutions are pursued before the issue at hand has been properly described and understood. This can lead to waste and inefficiency when resources are spent implementing an excessively risk-averse regulatory solution when the issue may be better addressed in other ways. This in turn can lead to duplication, confusion and scope creep, while adding little if any benefit or value.

A 'problem' may be an existing risk of harm that has been identified or future risks that have been identified through horizon-scanning, and other situations where regulation may make a positive contribution and other approaches cannot.



## Two: get as close to the problem as possible

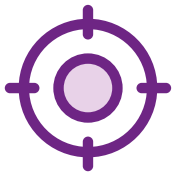
The next stage is to achieve a rounded understanding of the problem or risk in question. Regulation needs to be based on understanding the full range of hazards and factors that affect the risk of them resulting in harm. In practice, this means understanding the context in which the problem or issue arises (or is expected to arise), and the different tools that may be available to tackle it. This may involve working with organisations and individuals who are close to the problem.



## Three: quantify and qualify the risks

Quantifying risks means gauging the likelihood of harm occurring and its severity in quantitative terms. Qualifying risks means looking closely at the nature of the harm that is or will be caused, and understanding how and why it occurs in specific contexts. This includes understanding the impact of the harm; who is affected, and, for example, whether it is associated with groups with particular shared characteristics.

Without this twofold evaluation, which must be based on the best evidence available, it is difficult to judge what type of regulatory response might be needed, or whether it would be better to use other means of managing the issues. Simply identifying a real or potential risk is not sufficient. We have to understand whether the risk is unmanaged.



## Four: focus on the outcome

Adopting a right-touch approach means staying focused on the outcome we are looking to achieve, rather than being concerned about process, or prioritising interests other than public safety. The outcome we are looking to achieve will always be one which provides an acceptable level of assurance that risk is being managed with the least regulatory force. In determining what constitutes an acceptable level of assurance, regulators should not rely on assumptions about what risks the public will and will not consider tolerable.

The outcome should be both tangible and measurable, and it must be directed towards the reduction of risk of harm. Staying focused on it helps to identify the most appropriate solution. Having a clearly defined and measurable outcome helps to evaluate impact and effectiveness.



## Five: use regulation only when necessary

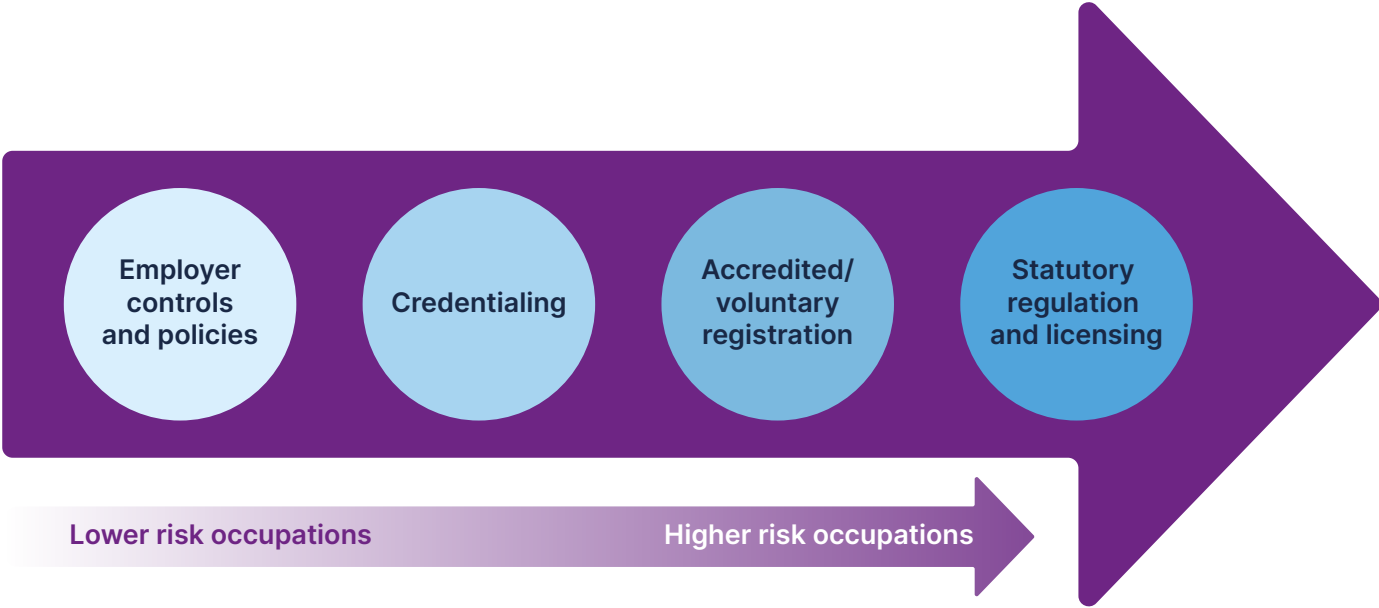
Regulation should only be used when it clearly provides the best solution to achieve the desired result. Having reached an understanding of the problem, we can examine whether a regulatory change is the right proposal, evaluating this against the options of doing nothing, and the benefits of intervening. Making changes to regulation, especially statutory regulation, can be a slow and costly process.

A regulatory solution must keep to the six principles of right-touch regulation and build on existing approaches where possible. This will always involve looking first for solutions other than regulation and may require regulators to work collaboratively with other organisations and people to bring about change. It involves thinking laterally and looking broadly for solutions, including from other jurisdictions, and learning from successful measures implemented in other sectors and countries.

Any regulatory response should be proportionate to the risk identified, including in relation to cost-effectiveness and the efficient use of resources. The range of possible responses can be thought of as a risk-based continuum of assurance (Figure 3), with those risks requiring the greatest regulatory force at one end of the continuum and diminishing amounts of regulatory force as the risk decreases. Regulation should only

be used where the risk of harm is sufficient to warrant it, and other means will be ineffective.

Figure 3 is an illustration from health and social care professional regulation. Other sectors and contexts will have their own continua of assurance, providing a range of regulatory solutions proportionate to different risks.



**Figure 3: The continuum of assurance**



## Six: keep it simple

A regulatory response should be as simple as it can be while achieving the desired outcome; avoiding complexity will lead to greater impact. We recognise that many problems addressed by regulators are extremely complex, with wide-ranging risks of harm, but the simplest possible solution may have the greatest effect. This is true in any sector.

For regulation to work it should be clearly explained and easily understood, including, for example, by those who are regulated, the public, employers, and the regulator itself. Decisions should be followed and supported by clear guidance, which balances the need for clarity on what constitutes compliance with appropriate room for professional judgement in how regulations and standards will be applied in practice. Regulators should not overcomplicate regulation by attempting to foresee every possible circumstance to which their guidance could be applied.



## Seven: understand the consequences

Assessing the probable impact of a particular solution is an essential step to understanding the full range of consequences that will ensue, and to anticipating unintended consequences in interconnected and complex systems. Some of these may be beneficial, others not.

For example, if new regulations are not straightforward, people will work around them, and in doing so potentially create new risks. Regulating to remove one risk without a proper analysis of its consequences may move the risk to another place, and expose a new or different group to harm.



## **Eight: review, evaluate impact and respond to change**

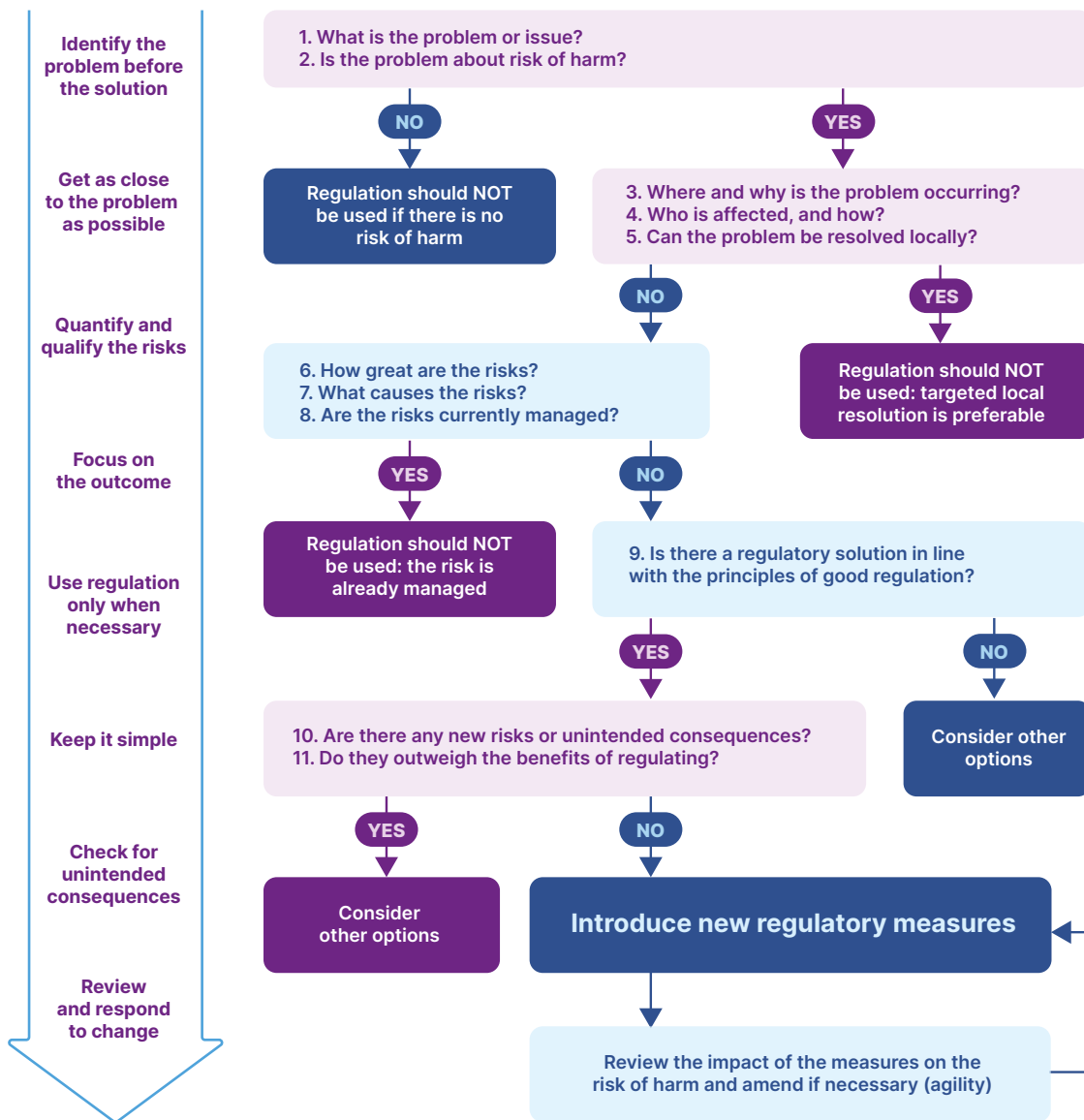
Regulators must not just manage crises of the past, whilst ignoring or being unable to react to new evidence that calls for change. This is what we mean by agility: building flexibility into regulators' ways of working, to enable them to respond to change. Regulatory approaches must be reviewed, evaluated and assessed. Unintended consequences and their impacts must be identified. Adjustments can then be made accordingly to reach the balancing point that we described earlier and at **Figure 2**.

An example of agility in practice is the way that regulators set their thresholds for action. The scope of the issues that regulators are concerned with, and that trigger a regulatory response, is an ongoing balancing act including between statutory and other duties, risk, evidence of harm, evidence of impact and effectiveness, resource and capability.

Thresholds will inevitably need to shift and change over time both in how they are both defined and interpreted.

The eight elements are shown in the decision-making tree in **Figure 4**. The eight elements form a sequence of actions. To move through the eight elements involves answering a series of related questions also shown in the tree.





**Figure 4: Decision-making tree**



Assessment of existing measures should include analysis of how well regulatory standards reflect real world work, and the constant interactions between people and hazards. This will help regulators to judge the effectiveness of their standards as a preventative intervention. Are standards readily understandable, and supported by clear guidance on how they are intended to apply in practice? Does the regulator support and engage in ongoing dialogue to help people work out what the standards mean in their specific setting or circumstances? Do standards and guidance also provide a clear understanding of non-compliance, integrated with guidance on how to act when non-compliance occurs?



Our thinking on the interaction between regulatory standards and the realities of the workplace has been influenced in particular by Huising and Silbey's work on relational regulation including: [Governing the gap: Forging safe science through relational regulation](#)<sup>3</sup>

Assessment may result in a view that a lighter regulatory touch could be taken, or even, at the extreme, that deregulation might be warranted. This would include circumstances such as:

- risk management measures have become outdated because of technological improvement and greater technological capacity to manage the risk
- risks have been well managed over time resulting in a view that responsibility can safely be transferred to a more local arrangement ('earned autonomy')
- the first and second lines of defence have developed and improved
- the originating cause of risk no longer exists, because, for example, a process or procedure subject to regulation is no longer in use.



Reviewing, evaluating impact and responding to change embeds continuous learning and improvement in regulatory practice.

## 10. Ways of working

**In addition to the eight elements and decision-making tree, we have identified a number of ways of working that should run throughout how regulators seek to arrive at the right balance in this process, and in decision-making more generally.**

### **Collaborative**

Regulators work alongside other stakeholder organisations in their sector with differing purposes and objectives but who have a shared interest in protecting the public. This may include public representative organisations, organisations delivering services, other standard-setting organisations, other regulators concerned with different aspects of a sector, and organisations representing particular interest groups, such as trades unions and professional associations. Each of these stakeholders has a part to play in the management of risks.

For regulation to be effective and to contribute to the wider goals of the system within which it operates, and the objectives

of Government, a collaborative approach should be taken wherever possible and beneficial. This applies from horizon scanning and the identification of future risks, through to the exploration of options, development of solutions, their implementation and evaluation. To achieve this requires good relationship management and communication, including the sharing of information, data, insights and good practice, and a sense of collective responsibility among the organisations involved in managing different risks in a particular setting or context.

This will help to identify where regulatory demands may overlap, and necessary action to reduce duplication and burden which is

not adding value. It will also enable the identification of regulatory gaps, and prompt urgent action to highlight and allocate these to relevant decision-makers. It will help regulators and other stakeholders to work together effectively and achieve consistency where required across jurisdictions and boundaries, particularly where regulatory frameworks are fragmented, complex and working to different priorities.

Regulators should work with their stakeholders in continuing dialogue to reach collective understanding of who does what and who is responsible for what risks. This is essential for consistent external communication to the public and stakeholders, in particular to those who may wish to raise concerns. Clarity on collective and individual responsibilities is also an essential precursor to the analysis called for by right-touch regulation, in order to determine where in a system risks should best be managed, and to ensure that solutions are as effective as possible.

Collaborations can sometimes experience difficulties because of real and perceived barriers to sharing information arising from data protection and information governance legislation. Where a collaboration involves exchange of data, potential problems should be explored and addressed early.

Regulators must also work to understand how they are perceived by stakeholders. Stakeholder opinion may differ from the regulator's in relation to particular risks under consideration, the meaning of standards and guidance, or of regulation more broadly. Achieving right-touch regulation may involve working to influence these perceptions to achieve optimum effectiveness, including through understanding how they change over time.

Continuing dialogue and engagement with stakeholders, and in particular those regulated, supports the identification of new issues at the earliest stage, agile responses and effective delivery. It builds trust and confidence, communicates purpose and approach, and in doing so consolidates the recognition of the regulator's legitimacy.

As well as improving effectiveness and the quality of decision-making this is likely to enhance compliance with regulatory requirements.

At Box 4 we summarise previous PSA work on how to make collaboration work better.

## Box 4: Improving collaboration

The PSA has identified seven actions that can improve collaboration:

- Involve the beneficiaries of the collaboration (the users of services) in design and operation.
- Communicate with collaborators, beneficiaries, and the wider public.
- Articulate the value being added, the influence and impact being achieved, and keep doing so throughout the life of the collaboration to sustain momentum.
- Be honest and candid, in particular about areas of challenge, conflict, ambiguity, compromise, and cultural difference.
- Create safe space and trust between collaborators to enable difficulties to be overcome.
- Be proactive, inclusive and innovative, encouraging creativity and as wide a range of views as possible to be brought into play.
- Evaluate, feed back and learn.

Adapted from PSA (2023) [\*Collaboration for safer care for all - a visual summary\*](#)<sup>4</sup>

## Efficient

Regulators should be efficient and demonstrate this efficiency as far as possible. They will often work with limited resources, but this should not of itself be seen as a barrier to improvement, and can be a stimulus for innovative solutions. (An example from the literature on creativity in resource constrained situations, sometimes referred to as frugal innovation:

[Improvisation during a crisis: hidden innovation in healthcare systems](#).<sup>5)</sup>

Efficiency, however, is also about taking collective responsibility with stakeholders for the efficiency of the system within which they all work. This will ensure that that matters are addressed quickly and effectively in the right place.

An example of this would be where a regulator identifies a risk of harm, or such a risk is brought to its attention. Often, the regulator will be able to mitigate the risk to an acceptable level within its own remit, capability, and capacity; or contribute to a collaborative solution with others, in line with right-touch principles that we discuss in this paper.

In the latter case, the regulator needs to notify others who can help mitigate the risk and may retain ownership of it, or pass ownership to one of these partners. The risk must never be left without an owner and needs to be treated with appropriate urgency. If the regulator perceives that one or more of the partners cannot or will not undertake its mitigating activities effectively then the regulator should (i) increase its mitigating activities within its remit, capability and capacity; and (ii) notify relevant authorities about the weaknesses in the response of the partner(s) and the possibility of the risk not being managed effectively, despite the additional efforts by the regulator.

In other circumstances, a regulator may be referred a risk for which it does not have the remit, capability or capacity to undertake any mitigation. In this case, the regulator should signpost the risk to the relevant partner(s) and not relinquish ownership of the risk until it is taken up by one of the partners. If there are no suitable partners, then the regulator should notify relevant authorities about the possibility of the risk not being managed effectively.

## Focused on equality, diversity and inclusion

Regulators must place considerations of equality, diversity and inclusion at the centre of their decision-making. Within the specific context of right-touch regulation, this includes, for example, assessing differential harms by groups with particular shared characteristics when exploring the impacts of a new risk. It also includes seeking the views of services users, those affected by decisions and those at particular risk of harm.

As part of their ongoing evaluation, regulators must explore the impacts of their interventions and decisions on service users, with a particular focus on differential impacts and outcomes, seeking to understand their underlying causes. This will often require close working with other stakeholders, as any differential impacts of regulatory activities are likely to be complex and may be deeply rooted in discrimination across various social structures, institutions and processes.

In matters of wider societal inequalities, regulators should look to achieve positive influence within the boundaries of their remit, in particular through sharing their insights and intelligence.

## Fair

In addition to the fairness that is central to the issues expressed above, regulators must also strive for fairness in their processes and procedures. Recognising that the outcomes of these processes and procedures are often by their nature contested, they must recognise the impacts on all parties of how the processes are conducted at all stages. This will involve balancing the need for a just outcome, which tests evidence appropriately, with a sensitive approach to the harm caused to participants – both by the issues under examination and by the process itself. This will enable all participants to provide the best possible evidence and therefore support the quality of decision-making.

Regulators should seek to understand differential impacts and outcomes of their processes for different groups and work to eliminate these where it is within their powers to do so.

## Evidence-led

Qualitative and quantitative evidence about the risks of harm and the impacts of regulatory action are central to a right-touch assessment. Regulators should be continuously working to better understand both of these forms of evidence relating to the risks that are active in the areas they regulate, as part of their ongoing evaluation of their impact and effectiveness. We recognise that evidence of the impacts of regulation can be difficult to gauge, even

more so when regulators are working collaboratively with others and undertaking explicitly preventative activity.

Regulators will be assisted by having a data strategy in place to identify gaps in the evidence they hold. This will support ongoing improvement in their understanding and effective management of risks.



## Anticipatory and preventative

It seeks to identify the nature and impacts of harm at as early a stage as possible and encourages the development of effective solutions before the risk of harm has been realised. The ways of working that we have described, and in particular collaborative and focused on equality, diversity and inclusion, are crucial to realising regulation's potential to be upstream of harm occurring. Regulators should seek, as far as possible, to shift the balance away from post-hoc action and towards preventing harm in the first place, making full use of tools available to them to exert positive influence, of which we set out some examples at Box 5.



Right-touch regulation by its nature is about preventing harm.

It requires regulators to understand their influence on the different stages of prevention, from promoting compliance with standards, to supporting the identification of problems at an early stage, and responding to harm where it has occurred. It should also involve the preventative effects of retrospective action – the potential for learning from situations where things have gone wrong to make their occurrence in future less likely.<sup>6</sup> This forward-looking attitude is sometimes called anticipatory regulation, although that approach has a specific emphasis on data and technology.



Preventing harm requires regulators to be forward-looking, seeking to manage future risks rather than fix the problems of the past.



## Box 5: Tools available to regulators for positive influence

The tools available to regulators to influence positive change, and to support improvements in the first and second lines of defence, include:

- issuing standards, guidance and supporting explanatory and supportive materials
- analysing data on trends and themes, including cases where things have gone wrong and harm has been caused, to share insights across their sector with stakeholders to support prevention and preventative interventions
- continuing dialogue and engagement with the public, to understand their perspectives, including on the balance between risks and benefits and where the balance should be set; and on differential impacts and harm of regulatory activity on different groups
- engagement with stakeholder organisations, including those representing regulated entities, to understand different contributions to safety, share learning and good practice, and exchange data
- learning from successful approaches in other sectors and countries
- input controls such as quality assurance of higher education courses in professional regulation.



## Innovative

The management of risk and prevention of harm involves many different people and organisations. Regulators should be creative and inquiring, considering innovative solutions and collaborations to manage risk in ways involving the full range of potential contributors. In Box 6 we provide an illustrative example of the potential contributors to safety and risk management in a healthcare setting. In other settings and contexts there will be a different range of contributors amongst whom responsibility for managing risks is distributed.

We recognise that in many instances regulators' creativity and innovativeness can be constrained by out of date and inflexible legislation. Given that legislative reform is usually a lengthy and costly business, regulators need to focus on what their legislation will permit and enable and exercise creativity within that remit.



**As the PSA has written elsewhere, 'with co-operation, innovation, imagination and determination much may be achieved' (*Regulation rethought*, 2016).<sup>7</sup>**

### **Box 6: The safety of care: an illustrative example of distributed responsibility**

The safety of care received by individual patients and service users is the end result of a wide range of actions and decisions by different people, processes, organisations and systems. Principally, however, it is the professionalism of individuals and teams who deliver care that keeps the public safe, in keeping with the lines of defence model described at **Box 3**.



**Regulators should be creative and inquiring.**

The role and potential contribution of all contributors to safety and risk management should be taken into account when considering the most effective (and therefore right-touch) solution to achieving the desired result. Regulation is most likely to be effective where this wider perspective is taken, and the contributions of all are taken into account.

In care this includes:

- **Patients and the public:** for example, self-management decisions taken or not taken.
- **Professionals:** including their education, training and professional development.
- **Providers/employers:** including their policies, guidance, governance, and local processes for dealing with concerns.

- **Commissioners:** via arrangements for assessing local health and care needs and how these will be met.
- **Regulators:** through standard setting, control of entry to professions, and actions in response to concerns.
- **Other bodies:** other organisations that impact standards of practice and the quality of care, such as Accredited Registers, professional organisations, royal colleges, and government departments.
- **Legislation:** including equality, human rights, consumer protection, and health and safety.

Right-touch regulation in health and care recognises the value and importance of the involvement of patients and service user in assessing risks for themselves, and making appropriate choices.

## 11. Alignment with other regulatory principles and priorities

Right-touch regulation principles are consistent with other articulations of the qualities and principles of good regulation, including the Department of Business and Trade's [Smarter regulation \(2024\)](#),<sup>8</sup> the Institute of Regulation's [Good regulation \(2024\)](#)<sup>9</sup> and the better Regulation Delivery Office's [Regulators' code \(2014\)](#).<sup>10</sup> They are also broadly consistent with statements of good regulatory practice in other countries such as those produced by the [New Zealand Ministry for Regulation](#).<sup>11</sup>

It can be considered 'intelligent' regulation, although it is different from 'light-touch' regulation, which seeks to reduce regulatory burden at the expense of other considerations. Right-touch regulation seeks to determine the necessary amount of regulation to achieve an acceptable level of assurance, with no predetermined outcome.

To illustrate, in Box 7 we have mapped the principles of smarter regulation against those of right-touch regulation, to demonstrate their consistency and alignment. Like smarter regulation, the right-touch regulation framework can protect people from harm while supporting innovation, business development and sustainable growth.



# Box 7: Mapping the smarter regulation principles to right-touch principles

| Smarter regulation principle (SR)                           | Right-touch regulation principle (RTR) | Comments   |
|---|--|--|
| 1. Clear guidance, transparency and accountability          | Accountable, transparent               | Both sets of principles emphasise the importance of communicating clearly to stakeholders how decisions have been made as central to both transparency and accountability. SR’s focus on clear guidance to consumers and businesses is reflected in RTR’s definition of how to ‘keep it simple’ – clear guidance which allows for judgement. |
| 2. International recognition and awareness of best practice | Agile                                  | A regulator’s horizon-scanning should include identifying issues arising in other jurisdictions, which includes learning from the best practices of others in how to address them.   |
| 3. Avoid unnecessary risk aversion                          | Proportionate, targeted                | RTR recognises that risk cannot be eliminated, and instead focuses on achieving a balance which delivers optimum benefit with a tolerable risk level.  |

| Smarter regulation principle (SR)  | Right-touch regulation principle (RTR) | Comments   |
|--|--|--|
| <b>4. Always act proportionately</b>   | <b>Proportionate</b>                   | Both sets of principles are clear on the importance of proportionality in regulation. SR in particular here emphasises unnecessary cost of regulating. RTR includes efficient as a way of working, and highlights the wastefulness of regulating beyond the point of tolerable risk. |
| <b>5. Be pro-innovation in regulatory approach</b>                                   | <b>Agile</b>                           | RTR encourages creative thinking in identifying the best possible way to manage risk.  |
| <b>6. Collaborate and join-up with fellow regulators</b>                             | <b>Consistent, agile</b>               | RTR includes collaborative as a way of working that applies at all stages from horizon-scanning, to identification of options and solutions, to evaluation and assessment.   |
| <b>7. Be collaborative and responsive when engaging with businesses and citizens</b> | <b>Transparent, accountable</b>        | Stakeholder engagement and consultation is central to the right-touch approach at all stages, including understanding the impacts of harm on different groups, forecasting the consequences of different solutions, and evaluating impacts.  |

| Smarter regulation principle (SR)   | Right-touch regulation principle (RTR) | Comments  |
|---|--|---|
| 8. Permissiveness and self-certification  | Targeted, proportionate                | SR is focused on the best outcomes possible with the least regulatory intervention. This mirrors ‘focus on the outcome’ as a stage in RTR thinking, and re-evaluation with the possibility of a lighter touch being taken where risks are demonstrably well-managed over time.  |
| 9. Ensure a skilled and capable workforce   | Targeted, agile                        | The regulatory workforce in SR needs to have the right skills and sector knowledge. RTR thinking also requires these skills, in assessing future risks, assessing costs impacts within a sector, and understanding consequences. RTR also supports workforce developments being managed without increasing the risks of harm. |
| 10. Understand how regulation is applied at local levels and felt by businesses and consumers | Targeted, accountable                  | RTR requires the impacts of risks of harm and measures to address them to be explored and understood, as part of getting close to the problem, and quantifying and qualifying risks. This is a prerequisite to being able later to demonstrate that the right balance has been struck in the approach adopted.                |

## 12. Applying right-touch regulation

**Right-touch regulation can be applied to any situation where a risk has been identified, and consideration is being given to it being mitigated through regulation.**

This includes both current risks and those anticipated through horizon-scanning. It also provides an approach to assessing an existing arrangement for risk management, including within a regulatory framework, to assess whether that arrangement remains appropriate and effective.

While right-touch regulation has been developed in the context of health and care professional regulation, it can be widely applied; its principles align with and are complementary to those developed in other sectors (see **Box 7**). Right-touch regulation recognises that there is always a range of possible solutions, both local and national, as illustrated by the continuum of assurance at **Figure 3**. Within the PSA's sector, as well as local approaches and solutions, this includes both the Accredited Registers and statutory regulatory bodies. A right-touch regulation approach will always look at issues in the

round, and seek collaborative and creative solutions where these will be most effective to manage risk.

With its emphasis on accountability, outcomes, efficiency, and purpose, right-touch regulation can also be used to inform assessment (or self-assessment) of regulatory performance. This in turn can underpin quality improvement initiatives, identifying areas where impact can be enhanced, waste can be reduced, or there are gaps in protection that need to be bridged. This places right-touch regulation at the centre of good governance. Right-touch regulation builds on an accurate and informed assessment and analysis of the sector regulated, and the risks of harm within it. It is common sense in that it describes the role regulation should play, building on its strengths, and working with its capabilities and influence.



Right-touch regulation recognises that there is no such thing as zero risk, and that harm can occur in all regulated sectors.



All decisions about what and how to regulate will involve a trade-off between competing risks, benefits and interests.

It also recognises that there is usually more than one way to manage risks and that often regulation is not the best one. Regulation should therefore only be used as a last resort, when other solutions that are closer to the harm have been demonstrated to be ineffective.





# Conclusions

## ➔ 13. Conclusions



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## Right-touch regulation is an approach to regulatory decision-making.

Right-touch regulation is an approach to regulatory decision-making. It means always asking what risk we are trying to address, being proportionate and targeted in regulating that risk, or finding ways other than regulation to promote good practice and manage risks of harm. It supports the appropriate contribution of the regulatory regime to the delivery of wider aims.

It promotes creative use of the existing mechanisms for the reduction of harm and supports professionalism and a joined-up approach to regulation. It is agile and responsive to the ever-changing circumstances and risks.

In practical terms, the benefits of right-touch regulation can be seen in a number of ways:

- outcomes are described in terms of the beneficiaries of regulation rather than the needs of organisations, systems and processes
- the approach includes ongoing review and evaluation, to ensure that arrangements put in place for managing risks of harm remain effective, up to date, fit for purpose, and to initiate change if they do not
- it provides a coherent framework for tackling a range of regulatory issues, such as the regulation of new groups and areas of practice
- the policies that emerge from a right-touch approach are well-informed, built on the best possible evidence of risk of harm.

The analogy of the weighing scales demonstrates the impact we want regulation to have. At the balancing point, regulation has its most efficient impact on the risk being tackled.

Right-touch regulation creates transparency. It highlights the benefits that regulatory interventions will bring, recognising that a degree of risk is inevitable in order that services can be accessed, and that regulated practices are rarely completely safe. It demonstrates that the investment of regulatory resources is adding value.

The right-touch approach enhances trust and confidence. It encourages regulators to keep all of their approaches under review, such that regulation remains relevant to the needs of today and reacts appropriately to new issues as they arise. Adopting a right-touch approach allows people to feel confident that regulation is acting in their best interests, with clear purpose, responsibilities and limits.

The PSA will continue to promote this approach, which we believe has led to improvements to regulation in the UK and elsewhere. It provides a valuable set of guiding principles to help regulation work efficiently and to enhance confidence in the contribution of regulatory systems to society.

# Endnotes

- 1 [https://www.professionalstandards.org.uk/sites/default/files/attachments/right-touch-regulation-in-practice---international-perspectives\\_0.pdf](https://www.professionalstandards.org.uk/sites/default/files/attachments/right-touch-regulation-in-practice---international-perspectives_0.pdf)
- 2 <https://iris.who.int/bitstream/handle/10665/378775/9789240095014-eng.pdf?sequence=1>
- 3 [https://anthropology.mit.edu/files/anthropology/imce/people/papers/Silbey\\_Huising\\_Governing%20the%20gap.pdf](https://anthropology.mit.edu/files/anthropology/imce/people/papers/Silbey_Huising_Governing%20the%20gap.pdf)
- 4 <https://www.professionalstandards.org.uk/sites/default/files/attachments/Collaborating%20for%20Safer%20care%20for%20all%20-%20a%20visual%20summary.pdf>
- 5 <https://bmjleader.bmj.com/content/leader/early/2020/06/17/leader-2020-000259.full.pdf>
- 6 The PSA intends to publish guidance on realising preventative regulation in 2026/27
- 7 <https://www.professionalstandards.org.uk/publications/regulation-rethought-0>
- 8 <https://assets.publishing.service.gov.uk/media/664c8e09b7249a4c6e9d38a3/smarter-regulation-delivering-a-regulatory-environment-for-innovation-investment-and-growth.pdf>
- 9 <https://static1.squarespace.com/static/6569b0fe3da42c3c2ca26885/t/6698de6d097b9f020cf427aa/1721294447439/loR+Good+Regulation+Report%2C+Jul24.pdf>
- 10 <https://assets.publishing.service.gov.uk/media/5f4e14e2e90e071c745ff2df/14-705-regulators-code.pdf>
- 11 <https://www.regulation.govt.nz/support-for-regulators/quick-guides-to-good-regulatory-practice>







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