Australian Government
Department of Health

Health Regulatory Policy Framework

Foreword

The Health portfolio plays a crucial role as a regulator and developer of regulatory policy through administering legislation that covers thousands of professionals, organisations and businesses that support or impact on the health and safety of Australians and the environment.

Together, as policy makers and regulators, we have a shared responsibility to efficiently and effectively manage our regulation and ensure we deliver on the Government's policy objectives. Health's regulatory responsibilities are very broad and embrace a wide range of regulatory systems of varying complexity.

This requires us to work collaboratively with many different co-regulators and partners across the Commonwealth and the states and territories, and in some cases, internationally. Just as important, we need to engage in genuine and meaningful consultation with all those impacted by our regulations.

This framework is the first of its kind for the department, filling a gap in our strategic policy capability. It sets out the principles that underpin our approach to regulation; first of which is protecting the health and safety of Australians, as well as outlining the things we can do to achieve real action on these principles.

Too often, we take a 'set and forget' approach to our regulations, failing to ensure they remain fit-for-purpose. To this end, the HRPF also encourages a holistic view of our regulations. This means we need to regularly review our regulations to ensure that they are implemented as efficiently as possible, minimising the red tape impost faced by business and individuals in complying with them. It is clear that all of us involved in regulation in Health need to be active participants in managing our regulation and to commit to a process of continuous improvement and evaluation.

I commend this framework to all policy makers and regulators within the department and those they regulate.

Secretary

Dr Brendan Murphy

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Section 1

Regulation in Health

'protecting the health and safety of Australians while minimising unnecessary compliance burdens'

Purpose of this framework

The HRPF is a high-level statement of our regulatory principles. It provides clarity and consistency around Health's approach to regulation so we can maximise our efforts to protect the health and wellbeing of Australians.

It does not seek to cover all the administrative strategies and processes available, but provides a framework upon which our policy makers and regulators can draw when developing their systems and processes.

There is no single approach to applying the principles outlined in this framework as the way regulation is administered is influenced by a number of factors including the specific activity being regulated, its risk profile, a regulator's legislated powers and authority, stakeholder expectations, and the ability and willingness of regulated entities to meet their obligations.

Further guidance on operationalising the HRPF principles may be provided through a series of best practice regulation guides, covering such topics as risk-based approaches and effective compliance and enforcement strategies.

Health Regulatory Policy Framework

The HRPF is intended to:

- Provide an overarching set of principles to guide our approach to regulation
- Promote consistency in the design, implementation and evaluation of regulation
- Foster a culture of best practice, innovation, learning and improvement
- Build our regulatory capability
- Encourage more effective and ongoing communication between policy makers and regulators and with our stakeholders

The HRPF sets out:

- What is regulated by the Department
- Who is involved in regulation and how those parties interact
- Our approach to the management of our regulatory systems
- Our regulatory principles
- How policy makers and regulators work with each other and with our stakeholders
- How we go about delivering on our regulatory policy objectives

Regulation – getting the balance right

> **'Regulation is any rule endorsed by government where there is an expectation of compliance'**
> *The Australian Government Guide to Regulation (Department of the Prime Minister and Cabinet, 2020)*

The role of regulatory policy in Health is to contribute to an affordable, accessible, efficient, and high quality health and aged care system through "regulation that protects the health and safety of the community, while minimising unnecessary compliance burdens" (*Strategic Intent 2017-21*).

To do this, our regulations needs to be both:

- **Effective** – deliver on our desired outcomes and provide public value AND
- **Efficient** – deliver maximum productivity while minimising regulatory burden

Good regulation creates <u>public value</u> by protecting people and the environment, ensuring the proper use of public funds and enhancing consumer rights. It can also help build a fairer and more productive society. However, there are often costs for business, community groups and individuals in complying with regulation and we need to consider this when making and applying regulation.

Examples of rules that may increase costs

- Keeping records and notifying government
- Making applications including for grants funding
- Complying with standards and guidelines
- Certification and accreditation processes
- Training and education requirements
- Other compliance requirements (e.g. inspections)
- For individuals, the time required to engage with government

Section 2

The systems we regulate

Our regulatory systems

A **regulatory system** is a system of rules, institutions and practices, established to regulate a specific activity or to achieve desired behaviours or defined public interest objectives.

They often cross portfolio and jurisdictional boundaries, encompassing different sets of legislation. Thus, various agencies may have regulatory roles within the same system, each contributing to system performance.

Health is involved in the regulation of a wide range of systems, sometimes in partnership with, or alongside other government regulators:

Health's Regulatory Systems

- Ageing and aged care services
- Controlled drugs
- Food standards
- Gene technology
- Grants
- Health promotion and support bodies
- Health research and data
- Health security and international health
- Human cloning and embryo research
- Industrial chemicals
- Medical, pharmaceutical, dental, hearing benefits
- Organ and tissue donation
- Private health insurance
- Radiation protection and nuclear safety
- Security sensitive biological agents
- Sport and sport integrity including anti-doping
- Therapeutic goods (e.g. medicines, medical devices)
- Tobacco advertising and plain paper packaging
- Workforce and health professional regulation

Stakeholders in our regulatory systems

We work with other Commonwealth agencies and the states/territories to achieve national outcomes and engage with business and the broader community to ensure our regulation remains fit for purpose.

	Government/Health	Co-regulators	Regulated entities	Influencers	Community/Clients
WHO	Government sets the laws, provides strategic direction and the funding. We administer the law, develop policy, advise government and monitor and enforce our regulations.	Includes other Commonwealth agencies, state, territory and local governments, international and other organisations. They operate as partners or parallel regulators.	Those with current or potential regulatory obligations or who may influence the health, aged care and sporting sectors.	Influencers aim to shape the regulatory system and outcomes to meet the needs of those they represent.	Individuals in the community are the consumers of our products and services. Their needs and values are the foundation of our regulatory systems.
WHAT THEY WANT	We seek to deliver solutions to ensure the health and welfare of the Australian community and the integrity of our program outcomes.	They seek clarity of roles and responsibilities, and access to information.	They seek fairness and respect for their expertise, efficiency, transparency in regulation, certainty of obligations, and guidance on how to comply so they can get on with business or service delivery.	They seek to ensure the regulatory system operates effectively, transparently and accountably.	They seek confidence, transparency and accountability in laws and regulation and clear opportunities to voice concerns.
HOW THE HRPF HELPS THEM	▪ Sets out the principles under which we operate. ▪ Explains our responsibilities. ▪ Ensures a consistent and structured approach to regulation. ▪ Encourages regulators and policy makers to work together more effectively. ▪ Enables more effective stakeholder engagement.	▪ Clarifies roles and responsibilities in Health. ▪ Identifies areas of common ground and opportunities for cross-referral and collaboration. ▪ Improves communication with the department. ▪ Identifies and promotes best practice.	▪ Explains our regulatory approach. ▪ Enables them to hold us to account. ▪ Explains our regulatory systems.	▪ Explains principles for engagement. ▪ Enables them to hold us to account. ▪ Explains our regulatory systems.	▪ Explains our regulatory approach. ▪ Enables them to hold us to account. ▪ Explains our regulatory systems.

Our policy makers

Our policy makers (on behalf of government) provide our regulators with the policy and legal framework within which they must operate.

They:

- ✓ provide advice to government on regulatory policy and the impacts (including costs) and effectiveness of our regulation

- ✓ in consultation with our regulators and key stakeholders, decide the shape and scope of the regulations

- ✓ manage passage of the laws that bring regulations into effect

- ✓ work with our regulators to improve policy outcomes and to review regulation to ensure it remains efficient and effective

- ✓ where appropriate, assist in reviewing the performance of our regulators
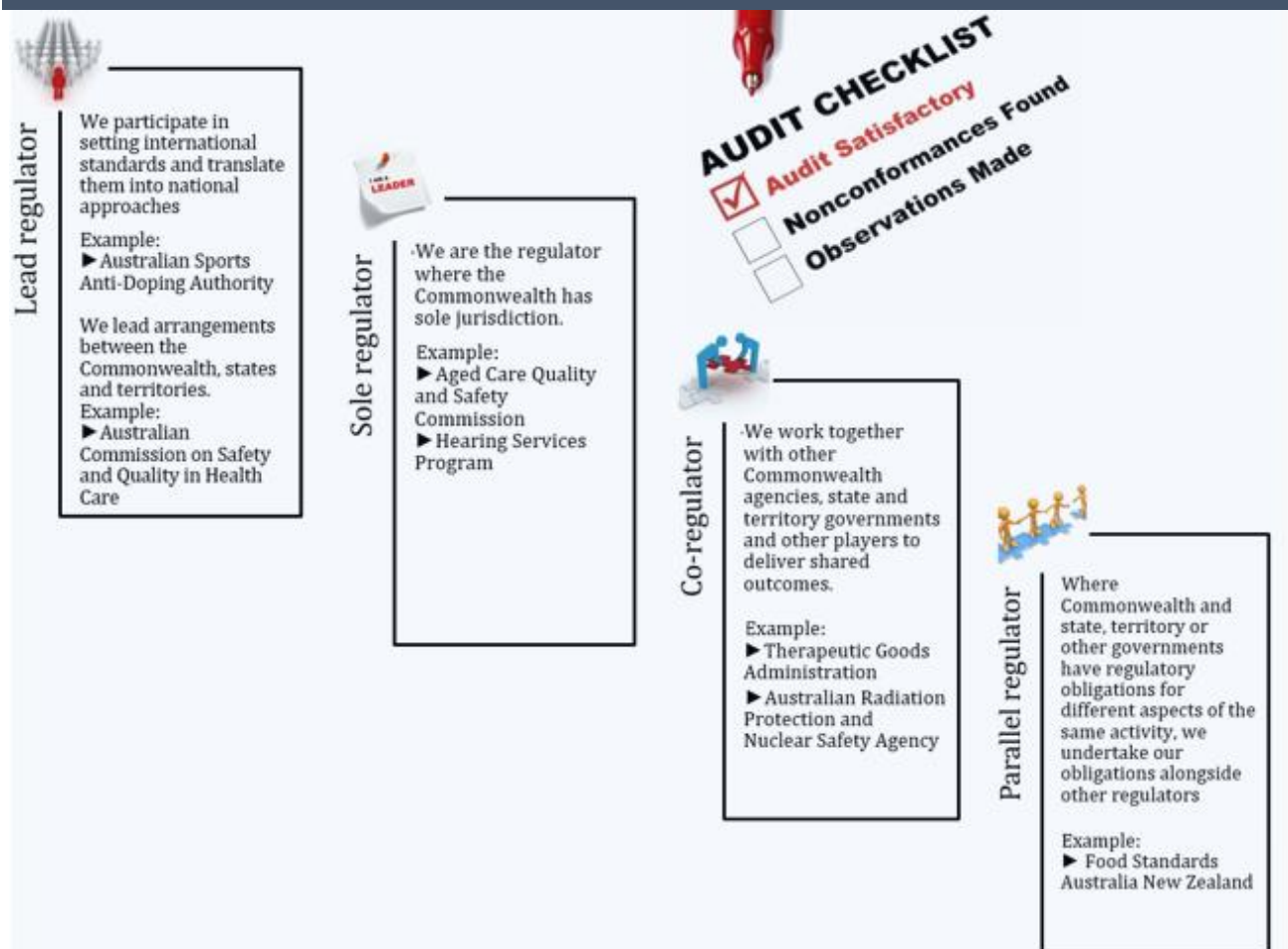
Our regulators

Our regulators work with our policy makers to ensure our regulations remain efficient and effective. They independently implement our regulations using evidence established by technically informed, expert analysis, while operating within the given policy and legal framework.

They are involved in some or all of the following:

✓ licensing and/or approval processes, including registration or accreditation that control entry to or participation in a market

✓ monitoring and compliance activities, including imposing and collecting fees

✓ enforcement action for non-compliance and complaints resolution

✓ providing advice and guidance regarding compliance with regulation

(Productivity Commission 2014, *Regulator Audit Framework*, Canberra)

Lead regulator

We participate in setting international standards and translate them into national approaches

Example:
► Australian Sports Anti-Doping Authority

We lead arrangements between the Commonwealth, states and territories.
Example:
► Australian Commission on Safety and Quality in Health Care

Sole regulator

·We are the regulator where the Commonwealth has sole jurisdiction.

Example:
► Aged Care Quality and Safety Commission
► Hearing Services Program

AUDIT CHECKLIST
☑ Audit Satisfactory
☐ Nonconformances Found
☐ Observations Made

Co-regulator

·We work together with other Commonwealth agencies, state and territory governments and other players to deliver shared outcomes.

Example:
► Therapeutic Goods Administration
► Australian Radiation Protection and Nuclear Safety Agency

Parallel regulator

Where Commonwealth and state, territory or other governments have regulatory obligations for different aspects of the same activity, we undertake our obligations alongside other regulators

Example:
► Food Standards Australia New Zealand

Case Study

Australia's response to emerging gene technology

Office of the Gene Technology Regulator

[*Gene Technology Act 2000*]

RISK

Gene technology has the potential to harm human health and the environment if not regulated.

OBJECTIVE

Protect the health and safety of people and the environment by identifying risks posed by or as a result of gene technology, and managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

Government and the Department (policy)

Work with the Regulator (a statutory office holder under the Act) to ensure government policy is implemented efficiently and effectively. Example: Third Review of the National Gene Technology Scheme.

Partners and Co-Regulators

States/Territories maintain corresponding legislation. Other agencies regulate specific uses of GMOs and GM products, e.g. dealings with a human medicine that is a GMO requires a licence from the Therapeutic Goods Administration. Approval for a GM product to be sold as food requires the approval of Food Standards Australia New Zealand.

Regulated Entities

Includes researchers and industry. They require authorisation under the Act, which can include licensing by the Regulator, and undertake activities based on licence conditions and co-operate with compliance activities.

Influencers

Organisations with concerns about the safety of gene technology and industry groups seeking to facilitate innovation. They provide input into policy through consultation mechanisms.

Community

Participate in community consultation processes.

Regulatory Role

✓ regulate activities with GMOs as per the law

✓ issue guidelines about activities with GMOs

✓ provide advice to the Ministerial Council

✓ give information and advice to the public and agencies

✓ promote harmonisation of GMO regulation

✓ engage with similar international organisations

✓ monitor and enforce the law

✓ reporting

Obligations

Our **regulated entities** represent a broad cross-section of the Australian community. They seek proportionate application of regulation and certainty so they can get on with their business.

As regulators, we need to be consistent, responsive, transparent, and act proportionately and appropriately when dealing with them.

In turn, we expect them to understand their obligations under law and why we have regulation (i.e. the goals of the program in which they are operating), comply with their obligations and act in accordance with their conditions of approval or operation.

Our obligations

Educate them about the purpose of the regulations, their obligations and how to comply including what to expect if found to be non-compliant

Assess applications in a timely manner

Assess and set conditions using a risk-based approach

Deter non-compliance by having easy to follow processes

Detect compliance risks through ongoing monitoring and evaluation

Respond using a range of actions proportionate to the risk

Evaluate our regulation to ensure it remans fit for purpose and does not impose unnecessary costs

Obligations of our regulated entities

Understand the relevant laws and their obligations to comply with those laws

Provide the right information when making applications

Receive approval and abide by conditions

Seek out information to answer questions and reduce uncertainty

Remain compliant at all times

Participate in compliance action

Commit to a process of continuous improvement to minimise the need for government intervention

Change behaviour if necessary

Section 3

Our regulatory approach and outcome

Regulatory stewardship: a better way

Together, as policy makers and regulators we have a shared responsibility for the stewardship of our regulatory systems.

We need to work together to ensure that our systems remains fit for purpose. Rather than take a 'set and forget' approach, we will:

- look at our regulatory systems as assets that need to be regularly reviewed and well managed to deliver effectively over time,

- take a whole-of-system, life-cycle view of our regulation, and

- adopt a proactive, collaborative approach to the monitoring and evaluation of our systems to ensure they remain fit for purpose
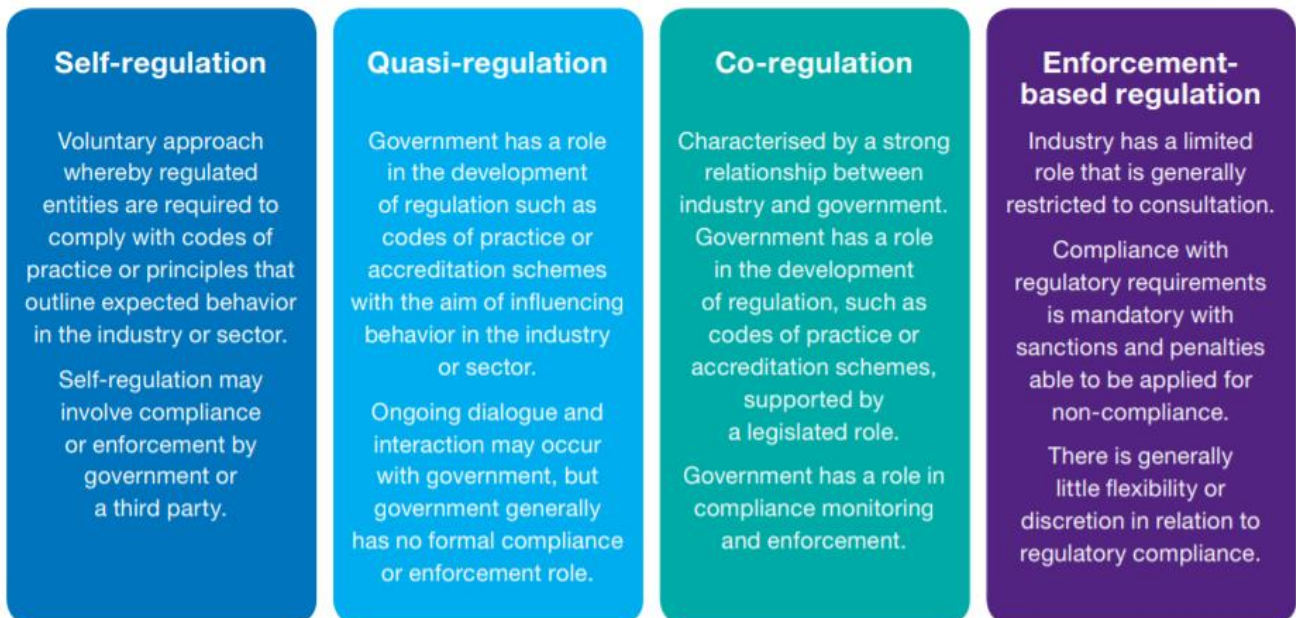
Regulatory Life Cycle
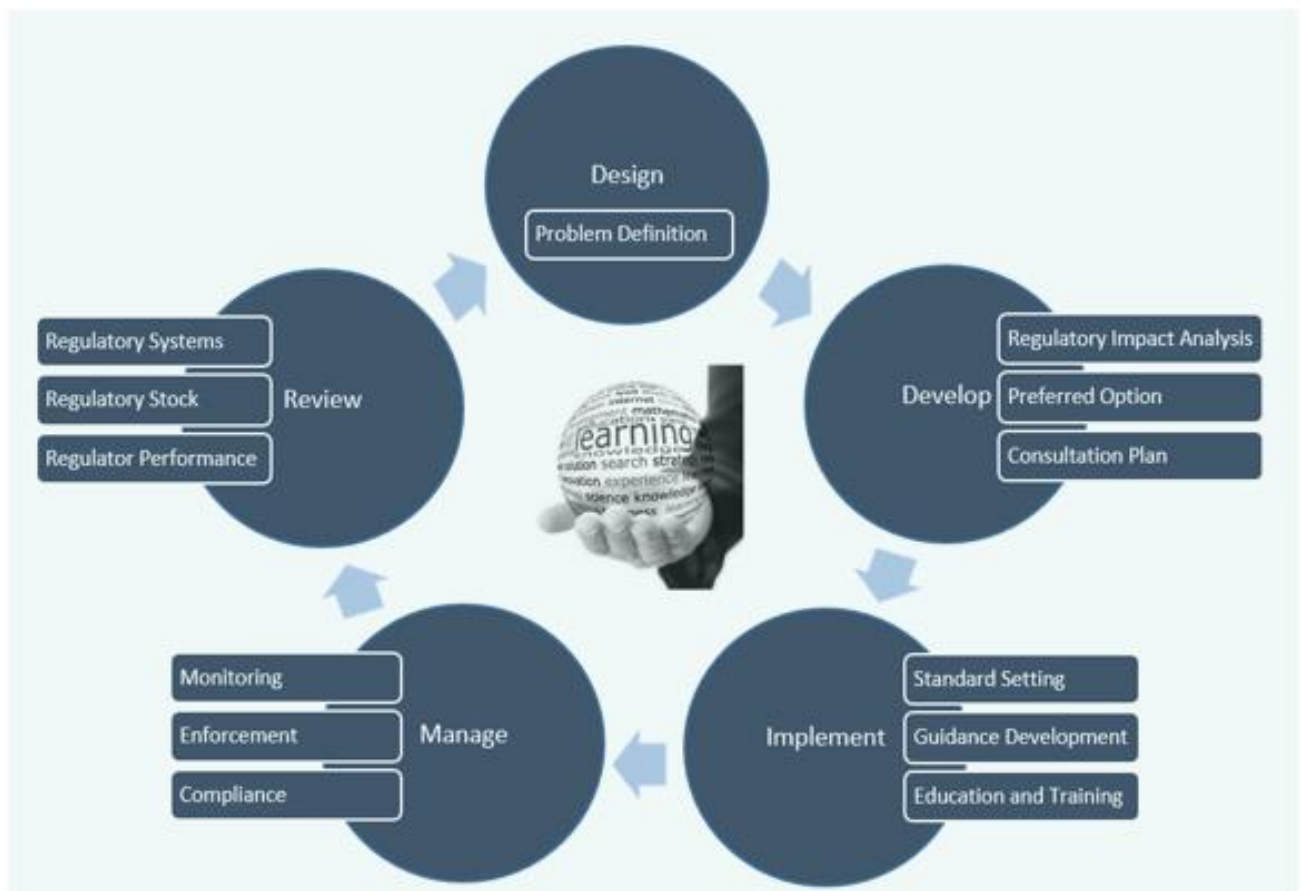
Regulatory responses

When considering options to address a public policy issue, policy makers must always ask themselves if there are alternatives to regulation.

Sometimes the solution may lie in better enforcement of existing regulation. This could involve a different focus such as moving towards a risk-based approach that better targets harmful behaviour, better staff training or more targeted education of stakeholders. Even doing nothing could be the best option in some circumstances.

The process of regulation commences when policy makers determine, having considered the available policy options, that the most appropriate response to a social, economic or environmental risk is regulation.
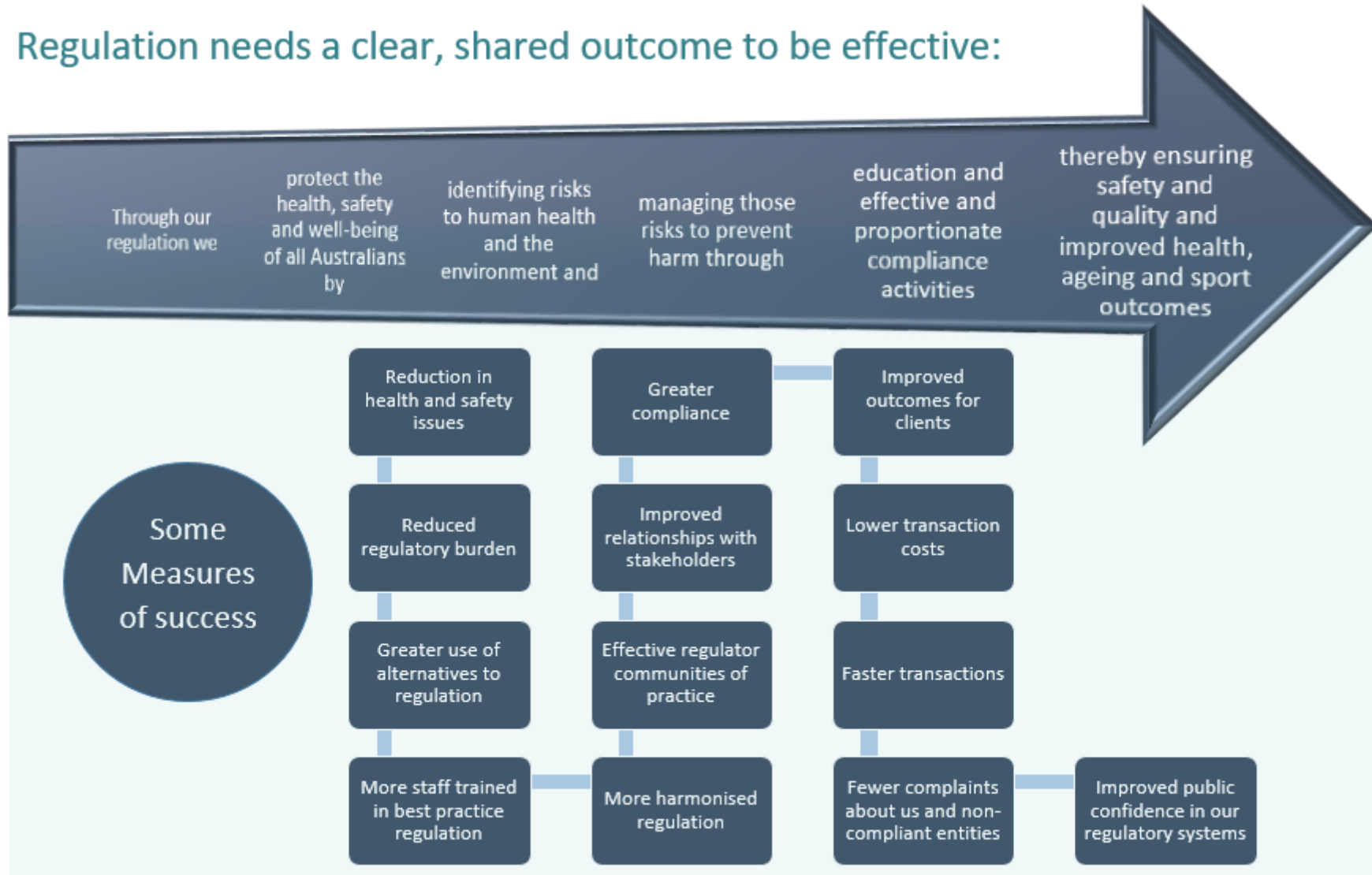
Sound regulatory administration is risk-based and should generally be proportionate to the risk of non-compliance or regulatory failure.

Depending on the risks being addressed and their context, regulation can take many forms including self-regulation, such as compliance with industry codes of practice, through to an enforcement-based approach.

Self-regulation	Quasi-regulation	Co-regulation	Enforcement-based regulation
Voluntary approach whereby regulated entities are required to comply with codes of practice or principles that outline expected behavior in the industry or sector. Self-regulation may involve compliance or enforcement by government or a third party.	Government has a role in the development of regulation such as codes of practice or accreditation schemes with the aim of influencing behavior in the industry or sector. Ongoing dialogue and interaction may occur with government, but government generally has no formal compliance or enforcement role.	Characterised by a strong relationship between industry and government. Government has a role in the development of regulation, such as codes of practice or accreditation schemes, supported by a legislated role. Government has a role in compliance monitoring and enforcement.	Industry has a limited role that is generally restricted to consultation. Compliance with regulatory requirements is mandatory with sanctions and penalties able to be applied for non-compliance. There is generally little flexibility or discretion in relation to regulatory compliance.

Outcomes

Regulation needs a clear, shared outcome to be effective:

Through our regulation we **protect the health, safety and well-being of all Australians by** identifying risks to human health and the environment and managing those risks to prevent harm through education and effective and proportionate compliance activities thereby ensuring safety and quality and improved health, ageing and sport outcomes

Some Measures of success

Reduction in health and safety issues	Greater compliance	Improved outcomes for clients
Reduced regulatory burden	Improved relationships with stakeholders	Lower transaction costs
Greater use of alternatives to regulation	Effective regulator communities of practice	Faster transactions
More staff trained in best practice regulation	More harmonised regulation	Fewer complaints about us and non-compliant entities

Improved public confidence in our regulatory systems

Section 4

Our guiding principles

Guiding principles

There is no one-size fits all approach to our regulatory systems. Health adopts a principles-based approach to regulatory policy because each risk and problem needs to be considered on its merits.

Our guiding principles reflect our role as stewards of our regulatory systems and guide the decisions and behaviours of our policy makers and regulators in managing regulation.

1. We will value regulation as an asset that protects the health and safety of Australians
2. We will take into account the regulatory impact of our decisions and minimise regulatory costs
3. We will effectively engage with our stakeholders
4. We will adopt a best practice approach to the compliance and enforcement of our regulation
5. We will build our regulatory capability
6. We will ensure good governance
7. We will regularly monitor and review our regulation to ensure it remains fit-for-purpose

1 We value regulation as an asset that protects the health and safety of Australians

We value regulation as an asset that adds public value through protecting the health and safety of Australians and the environment, now and for future generations.

This will achieve a regulatory system that:	✓ is focussed on protecting the health and safety of Australians ✓ captures the experiences and insights of our stakeholders ✓ manages regulation throughout its life-cycle ✓ achieves its outcomes ✓ continually gets better at what it does

How we will achieve this

- understand how regulation contributes to protecting the health and safety of Australians and to better health, ageing and sporting outcomes
- understand the needs and expectations of business and the community
- understand the obligations and regulatory costs faced by our regulated entities

- adopt a life cycle approach to regulation rather than a 'set and forget' approach
- ensure review and evaluation planning is embedded in regulatory design
- be accountable and transparent, e.g. publish documents on our regulatory approach
- communicate and celebrate our regulatory achievements

- actively engage and work with our stakeholders
- collaborate with other regulators to share intelligence, ideas and best practice processes
- work better together as regulators and policy makers to achieve our desired outcomes

2 We take into account the regulatory impact of our decisions and minimise regulatory costs

Consistent with the Government's Deregulation Agenda, we balance our desired regulatory outcomes against the potential regulatory costs imposed on businesses, community organisations and individuals.

This will achieve a regulatory system that:

- ✓ when designing regulation identifies the policy option with the greatest net benefit
- ✓ uses alternatives to regulation where feasible
- ✓ takes a risk-based approach to regulatory design and implementation
- ✓ is innovative and forward thinking
- ✓ minimises regulatory burden on stakeholders

How we will achieve this

- consider regulatory impacts throughout the regulatory life cycle including during implementation

- take into account evidence and stakeholder views as to where our efforts to reduce red tape should be targeted and how they should be implemented

- be open to new and different ideas and information

- ensure government intervention is necessary and appropriate

- identify and remove unnecessary, duplicative, redundant or inefficient regulation

- consider both regulatory and non-regulatory options

- identify the regulatory policy option with the greatest net benefit

- harmonise regulatory requirements for assessment and monitoring with equivalent international regulators

- minimise the regulatory burden of new regulation on our stakeholders

- as a minimum, produce 'fit-for-purpose' Regulation Impact Statements (as assessed by the Office of Best Practice Regulation)

- accurately cost the impact of new or changed regulation in accordance with the Government's Regulatory Burden Measurement framework

3 We effectively engage with our stakeholders

We engage with our stakeholders in a genuine and timely way at all stages of the regulatory cycle, as appropriate, to achieve the best outcomes for the Australian community.

This will achieve a regulatory system that:	✓ genuinely listens to consumers and the regulated community ✓ builds stakeholder understanding of the purpose and outcome of regulation, of expectations and obligations ✓ tests the relevance of our regulatory approaches with stakeholders ✓ embeds a culture of ongoing consultation

How we will achieve this

- engage stakeholders throughout the regulatory cycle in a genuine and timely way

- ensure stakeholder feedback is taken into account and communicated back to them

- consult with other policy makers to avoid creating cumulative or overlapping regulatory burdens

- make things simple to understand and accessible

- be open about what we do, how we do it and our desired objectives

- regularly review for unintended consequences

- share information and analysis and help build regulatory literacy in consumers

- monitor and assess the outcomes of engagement activities

- educate regulated entities about their obligations and support them to meet these

- ensure a voice for the consumer (separate from the regulated entity, lobby group or peak body)

- measure the 'felt-effect' of new regulation on business post-implementation

4 We adopt a best practice approach to the compliance and enforcement of our regulation

We adopt a best practice approach to the compliance and enforcement of our regulations, informed by the best available evidence, data analytics and contemporary regulatory theory including behavioural insights.

This will achieve a regulatory system that:

✓ is outcomes-focussed
✓ is evidence-based
✓ is risk-based and proportionate
✓ is accountable, transparent and timely
✓ is efficient and effective

How we will achieve this

- clearly define our regulatory objectives and approach

- use intelligence and data to assess risk and provide more accurate and responsive compliance activities

- develop clear guidance and education material for our regulated entities so they are better able to comply with their obligations & change behaviour if necessary

- implement regulation with common sense, empathy and respect

- make sure we are open and consistent in our decision-making and processes

- make sure we have available the full range of compliance tools and that our actions are targeted towards areas of greatest risk and proportionate to the risk being addressed

- where appropriate, co-ordinate our compliance response with co-regulators and relevant external agencies

- act in a timely manner to minimise harmful impacts, maximise deterrence and provide certainty

- where practicable, communicate changes to stakeholders and provide them with time to deal with them

- where appropriate, harmonise regulatory requirements with equivalent Australian and international regulators

5   We build our regulatory capability

We ensure our people are well-trained to perform their roles and that our regulators and policy makers work with each other to produce the best outcomes.

This will achieve a regulatory system that:	✓ has the right capability – people, tools and resources ✓ considers the needs of all parties – the regulator, the regulated and the Australian community ✓ promotes a culture of continuous improvement ✓ values collaboration between regulators and policy makers ✓ makes best use of technology and data

How we will achieve this

- ensure staff are well trained and have the right tools to do the job

- periodically review training, retention and recruitment programs to make certain they focus on the competencies that are essential for effective regulatory administration

- ensure policy makers and regulators engage in genuine collaboration throughout the regulatory cycle

- provide opportunities for policy makers to increase their technical knowledge of the regulatory systems they manage

- establish communities of practice to share expertise and knowledge and benchmark performance

- contribute to wider regulator capability building initiatives across government

- explore innovative approaches to regulation

- develop working relationships with other regulatory agencies with the same or similar regulatory systems

- benchmark our work against international standards

- make better use of technology and data capability

6 We ensure good governance

We have effective governance and assurance arrangements that enable our regulatory decisions to be made in an objective, independent and consistent manner in accordance with our legislative frameworks.

This will achieve a regulatory system that:	✓ has effective governance and assurance arrangements ✓ is accountable and transparent ✓ engages with stakeholders ✓ is free of undue influence and promotes public confidence in the system ✓ measures and evaluates our regulatory performance

How we will achieve this

- ensure our governance and assurance arrangements provide for effective functioning

- have clear and transparent objectives, activities and outcomes

- conduct ourselves with the highest integrity

- promote a culture that mitigates the risk of misconduct

- ensure proper use of public authority and resources

- make decisions that are objective, consistent and based on expert advice

- where appropriate, make public the information upon which our policy decisions are based

- act within the powers given to us by legislation, exercising independence where provided for

- ensure our regulatory decisions are not influenced by extraneous factors

- evaluate our regulatory performance with stakeholder input as appropriate, for example, through the Government's *Regulator Performance Framework*

- look beyond agency performance metrics to measure the effectiveness of our activities on a system-wide basis

7 We regularly monitor and review our regulation to ensure it remains fit-for-purpose

We review our regulations at appropriate intervals to ensure they remain fit-for-purpose, deliver on our desired outcomes and continue to provide public value.

This will achieve a regulatory system that:

- ✓ is 'fit-for-purpose' (i.e. is well designed for its intended outcomes)
- ✓ takes into account the latest innovations
- ✓ is efficient to comply with and administer
- ✓ is effective in achieving its outcomes
- ✓ is fair, transparent and resilient

How we will achieve this

- embed monitoring and review into our planning processes and the regulatory cycle

- adequately engage stakeholders and consider feedback provided

- be responsive to change and explore new and alternative approaches

- analyse reviews and use lessons learned to mitigate unintended consequences and improve how we do things

- seek to reduce or minimise the burden of compliance

- focus on removing redundant, duplicative or inefficient regulation

- measure effectiveness and efficiency of the regulatory approach across the whole system

- benchmark against other similar regulatory systems

- ensure our technical standards are accurate and reflect the latest scientific data

Section 5

Enabling the framework

Enabling this framework

This framework is the Department's commitment to continuous improvement of our regulatory policy.

It is a high-level document that is supported by the following complementary plans and frameworks:

- Corporate Plan and Strategic Intent
- Other Frameworks (e.g. Strategic Policy, Risk, Stakeholder)
- Individual Regulator Plans
- Australian Government Guide to Regulation
- Best Practice Regulation Training
- Regulator Communities of Practice
- Best Practice Guides

Our commitment

- To have an effective and responsive regulatory policy framework we recognise that we need regulatory systems that enable us to deliver on our objectives.

- Delivering this framework will take time and require a range of supporting activities and regular evaluation of our regulation and performance.

- We are committed to ensuring that this framework is a contemporary and relevant document that will need to evolve over time.

Glossary

Term	Definition
Business	Any organisation engaged in commercial, industrial or professional activities operating under Australian law for the purpose of making a profit.
Community organisation	Any organisation engaged in charitable or other community-based activity operating under Australian law and not established for the purpose of making a profit.
Compliance costs	The direct costs incurred by a regulated entity to comply with regulation.
Consultation	The practice of advising stakeholders of the intention to regulate which involves information sharing, dialogue and genuine consideration of feedback received.
Co-regulation	Refers to situations where regulators work together with other Commonwealth agencies, state and territory governments and others to deliver shared outcomes.
Direct government regulation	Direct government regulation comprises primary and subordinate legislation and is the most commonly used form of regulation.
Individual	Any person subject to Australian law who interacts with government or is impacted by regulation, and whose activities have an impact in Australia.
Office of Best Practice Regulation (OBPR)	The Division within the Department of the Prime Minister and Cabinet responsible for providing advice to Portfolios on whether a RIS is required, assessing estimates of regulatory costs and vetting the adequacy of RIS drafts.
Policy maker	Policy makers undertake policy development, providing analysis and advice, to support agency/government policy initiatives and commitments. They may also provide a range of project and program management support services relating to the delivery of policy.
Public value	As coined by Harvard professor Mark H. Moore, refers to 'the value created by government through services, laws regulation and other actions' (Kelly et al. 2002).
Quasi-regulation	Any rule or requirement that is not established by parliamentary process, but which can influence the behaviour of business, community organisations or individuals. Examples include guidance notes, industry codes of practice and industry-government agreements (co-regulation).
Regulated entities	Any person, business or organisation that is required to comply with prescribed regulatory requirements.

Term	Definition
Regulation	Regulation is any rule endorsed by government where there is an expectation of compliance, including primary and subordinate legislation, quasi-regulations and any other aspect of regulator behaviour that can influence or compel specific behaviour by business and the community.
Regulation Impact Statement	A document that informs decision makers and stakeholders of the regulatory impacts and costs of a policy proposal. In Australia, a RIS is mandatory for Cabinet decisions and any other new policy that has a substantive regulatory impact.
Regulator	A government entity that has one or more of the following legislated powers in relation to businesses, community organisations or individuals: licencing and approvals, monitoring and compliance including imposing and collecting fees, enforcement action for non-compliance including complaints resolution, and advice and guidance regarding compliance.
Regulator behaviour	Any aspect of the way regulation is applied or administered which has the effect of altering its impact, positively or negatively.
Regulatory approach	The strategies and interventions adopted by a regulator in administering a regulatory regime. These can be influenced by government policy, the behaviour of regulated entities and other stakeholders, and the broader operating environment.
Regulatory Impact Analysis	The systematic approach to critically examining the positive and negative effects of proposed and existing regulations and non-regulatory alternatives.
Regulatory risk	An actual or potential circumstance that interferes with the achievement of a regulatory policy objective. It can be categorised into two broad groups: risk that affects a regulator's ability to effectively administer regulation; and risk that decreases a regulated entity's ability or willingness to comply with regulatory requirements.
Regulatory stewardship	Stewardship looks at regulatory systems as assets that need to be well managed to deliver effectively over time. All parties involved in a regulatory system need to work together to ensure that the system remains fit for purpose over its whole life cycle.
Regulatory system	A system of rules, institutions and practices, usually established by a government to regulate a specific activity or to achieve desired behaviours or outcomes.
Self-regulation	Self-regulation is generally characterised by industry-formulated rules and codes of conduct, with industry solely responsible for enforcement.
Stakeholder	The wide range of groups and individuals with which a regulator interacts, including regulated entities, other regulators, the community and peak industry groups.