A MATTER OF PRINCIPLE

Developing regulatory principles with the help of STAMP

David Wotton
DISCLAIMER

I have previously worked for a number of government agencies.

The comments in this presentation are solely my own and do not constitute claims of any position being held, or not, by the Australian Government.
Dealing with a regulator
Working for a regulator
Public’s view of regulators
Government’s view
CHAPTER ONE

Why for regulators
Regulator’s toolkit
Regulations, Rules, and Principles
Why for regulators

- Social/common good
- Market failure
- Political ends
Regulator’s toolkit
Regulations, Rules, and Principles
EXAMPLE REGULATORY PRINCIPLE

Benefit must outweigh the risk

—International Medical Device Regulator’s Forum
Essential Principles of Safety and Performance
Benefit must outweigh the risk

Assumptions

That it is possible to:
  • quantify the benefit
  • quantify the risk
  • compare the two and determine an outcome
Benefit must outweigh the risk

Assumptions

That it is possible to:
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• quantify the risk
• compare the two and determine an outcome

Most important question:
Is enforcing adherence to this regulatory principle a useful thing to do?
EXAMPLE REGULATORY PRINCIPLE

Benefit must outweigh the risk

Example: High-rate infusion pump
ASSOCIATED REGULATORY PRINCIPLE

state of the art

Example: High-rate infusion pump
ASSOCIATED REGULATORY PRINCIPLE

Generally acknowledged state of the art

Example: High-rate infusion pump
COMBINED

Benefit must outweigh the risk
+

Generally acknowledged state of the art

—International Medical Device Regulator’s Forum
Essential Principles of Safety and Performance
PRESCRIPTION VS PRINCIPLE

Rules (prescriptive)

**Advantages**
- Less arguments
- Easy to administer
- Easy to follow

**Disadvantages**
- Inflexible
- High regulator burden
- Possibly less efficient
- Slow to change
- Compliance ≠ safety
- Can be inappropriate

Principles

**Advantages**
- Flexible
- More resilient to external changes
- Arguing the essence rather than compliance / checkbox mindset

**Disadvantages**
- By nature, are subject to interpretation and case-by-case dispute
- Difficult or impossible to administer for checkbox thinkers
- Can be inappropriate

* Please note: these lists are neither exhaustive nor complete...!
## Prescription vs Principle

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BALANCE

Hybrid

Rules (prescriptive)  Principles
BALANCE

Hybrid

Rules (prescriptive)  Principles
WRITING GOOD PRINCIPLES

Aims
Challenges
Other considerations
Aims

Efficient
Effective
Acceptable
Challenges
Other considerations
CHAPTER TWO

What STAMP can offer
POTENTIALLY USEFUL STAMP TOOLS

- EWaSAP
- STECAD
- STPA-Sec
- CAST
- HCS/FCS
- STPA-Priv

Others I missed because I was rushing to finish this presentation…

Future developments…
STAMP TOOLS POTENTIALLY OFFER...

Principles
- IDn of system-level hazards
- Transparency
- Rigour
- Testing of completeness

Reg. framework
- Holistic view
- Concept analysis for new challenges
- New capabilities
- Gap analysis
- Removal of some bias
- Effectiveness
- Signals
STAMP TOOLS POTENTIALLY OFFER…

two really important things that are frequently missing:

- A holistic view
- A proactive regulatory framework
ROUGH STEPS

(Iterative procedure)
ROUGH (ITERATIVE) STEPS

Aims  System-level hazards  Terminology translations

Assumptions  Unwritten aims

Regulatory Actors  Scoping

STECAD/STPA/STPA-Sec  Actors & Actions

Calculus…  Mechanisms & Timings
# SOME ELEMENTS AND EXAMPLES

Regulated environment: consumer safety, protection of river quality, etc.

<table>
<thead>
<tr>
<th>Example</th>
<th>Actor I</th>
<th>Actor II</th>
<th>Actor III</th>
<th>Actor IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actor</td>
<td>Regulator</td>
<td>Regulatee</td>
<td>Expert advisory group</td>
<td>Consumer advocacy group</td>
</tr>
<tr>
<td>Action (verb)</td>
<td>• Inspect site</td>
<td>• Generate documents</td>
<td>• Assess scientific evidence</td>
<td>• Monitor available information</td>
</tr>
<tr>
<td></td>
<td>• Assess/evaluate data</td>
<td>• Conduct clinical trials</td>
<td></td>
<td>Advoccate</td>
</tr>
<tr>
<td>Method / mechanism</td>
<td>Scientific method Pblc service mthds</td>
<td>• Scientific/clinical studies</td>
<td>Scientific methods based on discipline</td>
<td>• Read reports/news</td>
</tr>
<tr>
<td>Timing</td>
<td>• Inspection frequency</td>
<td>• Market timings and cycles</td>
<td>As dictated by regulatory agencies (pre and post market)</td>
<td>• Write to agencies</td>
</tr>
<tr>
<td>Calculus</td>
<td>How to maximise regulatory aims within constraints</td>
<td>How to maximise profit</td>
<td>Meeting the TOR; professionalism and integrity</td>
<td>Are consumers being ripped off?</td>
</tr>
</tbody>
</table>
CHAPTER THREE

Complications…
Threats
Insecurities
Inertia
HERE BE DRAGONS...

RfID chips

• Credit card

• Passport

• Access card for work
HOW ARE YOU FEELING?
HOW ARE YOU FEELING?

My guess

• Anxious
• Vulnerable
• Angry
A top-down view can be a little scary.
Bureaucratic capture
The three articles of civil service faith

- it takes longer to do things quickly;
- it's more expensive to do them cheaply;
- it's more democratic to do them in secret.

— James Hacker MP
Operating environment
Herculean efforts... sometimes just get you to a bigger fish bowl
CHAPTER FOUR

Observations…
No-go areas
Communication difficulties
Framing
No-go areas
BLOODY (DAMN) ENGINEERS

Engineers

- Arrogant?
- Unfriendly?
- Emotional?
- Contrary?
- Unhelpful?
- Political?
COMMUNICATION DIFFICULTIES

- Systematic, critical, and flexible thinking
- Different disciplines, different meanings
## A CYNICAL TRANSLATION OF TERMS

<table>
<thead>
<tr>
<th></th>
<th>Risk management</th>
<th>Regulation</th>
</tr>
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<tbody>
<tr>
<td><strong>Technical officers</strong></td>
<td>A method of managing technical risk.</td>
<td>Looking after the public good.</td>
</tr>
<tr>
<td><strong>Management</strong></td>
<td>Something the technical officers do; something to do with safety.</td>
<td>Looking after the public good while managing available resources and political capital.</td>
</tr>
<tr>
<td><strong>Politicians</strong></td>
<td>Management of political risk and a good way to justify fixed or reduced resourcing levels.</td>
<td>A way of managing public expectations.</td>
</tr>
</tbody>
</table>
FRAMING AND TIMING

- Politics
- Society
- Disciplines
CONCLUDING
THOUGHTS
Language and acceptance
Change champions
Automation
CONTACT

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