



Australian Government
Department of Health
Therapeutic Goods Administration

Cybersecurity for medical devices



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TGA Webinar

3 Oct 2019

TGA Health Safety
Regulation

Welcome

- Slides will be made available on the TGA website
- To ask a question, use the message feature on the left of the screen
 - Messages will only be visible to the moderator and speaker
 - Questions will be answered at the end of the presentation
- Relevant links will be posted in the message box (below)
- Live polls will be conducted throughout this event.



Difficulties hearing sound from your computer? Please feel free to listen to the event via telephone:

- 1. **Dial 1800 896 323**
- 2. Enter Pass Code 1330247191
- 3. If difficulties continue please contact *Redback* for support on 1800 733 416

The challenge

- Cybersecurity of medical devices is a shared responsibility
 - *e.g. manufacturers, sponsors, government, hospitals/clinics, researchers, health professionals, media, patients and consumers*
- Accurate and timely information is fundamental
- Security of medical devices affect, and are affected by, the whole health system
- In healthcare, cybersecurity is a patient safety issue



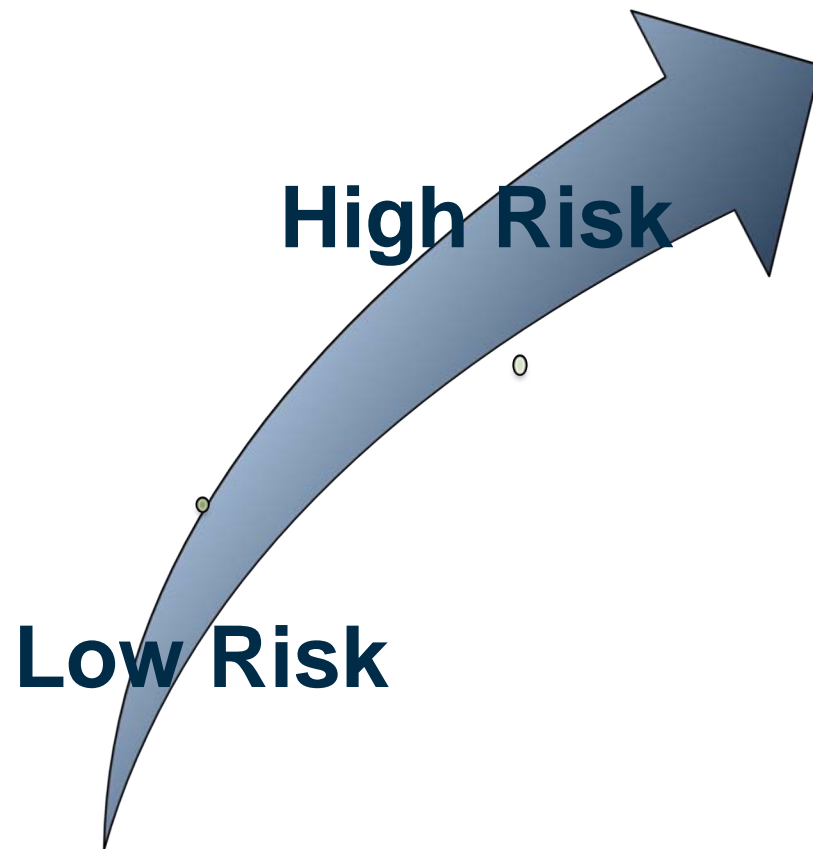
The TGA's role

- Australia's regulator of medical devices and their manufacturers and sponsors
 - *i.e **not** hospitals/clinics, researchers, health professionals, media, patients or consumers*
- Australia's regulator of medical device cybersecurity
 - *But not the environments they connect to*
- The TGA's regulatory powers are applied through sponsors and manufacturers
- Interactions with other stakeholders are collaborative





Higher potential harm, more oversight



Regulatory Scrutiny

Class III



Class IIb



Class IIa



Class I



The essential principles

Schedule 1, *Therapeutic Goods (Medical Devices) Regulations (2002)*

General principles

1. Use of medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
4. Long-term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any side effects

Principles about design and construction

7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Medical devices with a measuring function
11. Protection against radiation
12. Medical devices connected to or equipped with an energy source
13. Information to be provided with medical devices
14. Clinical evidence
15. Principles applying to IVD medical devices only

www.legislation.gov.au

From research to guidance

A joint venture between the TGA and the CSIRO

- The CSIRO:
 - Researched
 - Consulted
 - Drafted guidance
- The TGA:
 - Consulted
 - Published the draft guidance for comment
 - Published the submissions
 - Reviewed and published the guidance



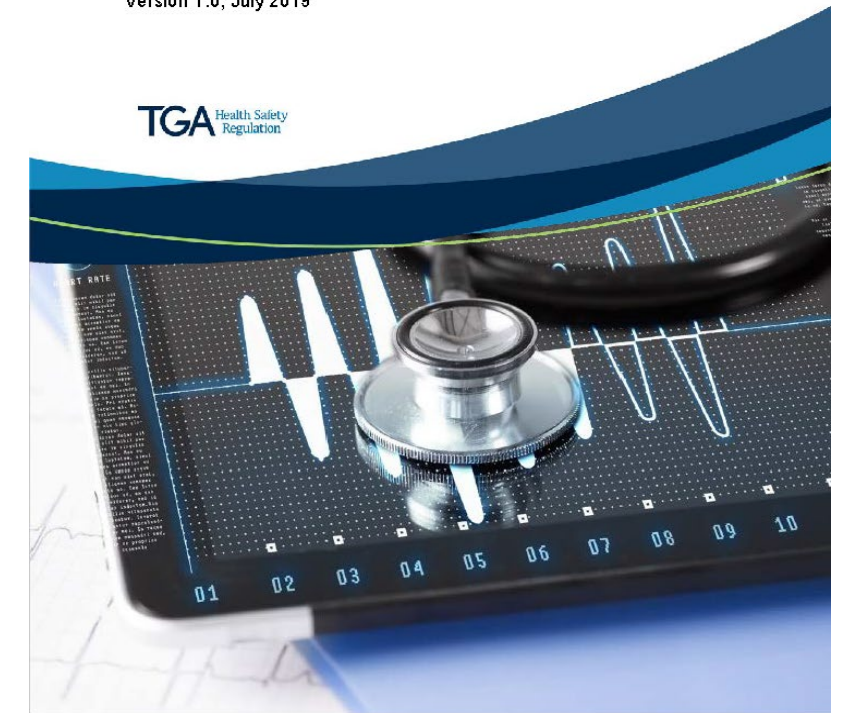
Regulatory guidance

For industry

- <https://www.tga.gov.au/sites/default/files/medical-device-cyber-security-guidance-industry.pdf>
- Total product life cycle
- Applying the Essential Principles
- Relevant standards
- Strategies for risk management
- Design and testing considerations
- Supply chain and platform security
- Post market monitoring, response and change control

Medical device cyber security guidance for industry

Version 1.0, July 2019



Cybersecurity information

For stakeholders that the TGA does not regulate

- <https://www.tga.gov.au/sites/default/files/medical-device-cyber-security-information-users.pdf>
- Patients and consumers
- Health and medical professionals
- Small business (e.g. medical practice)
- Large scale providers (e.g. hospitals)
- Intelligence and threat sharing

Medical device cyber security information for users

Consumers, health professionals, small
business operators and large scale service
providers

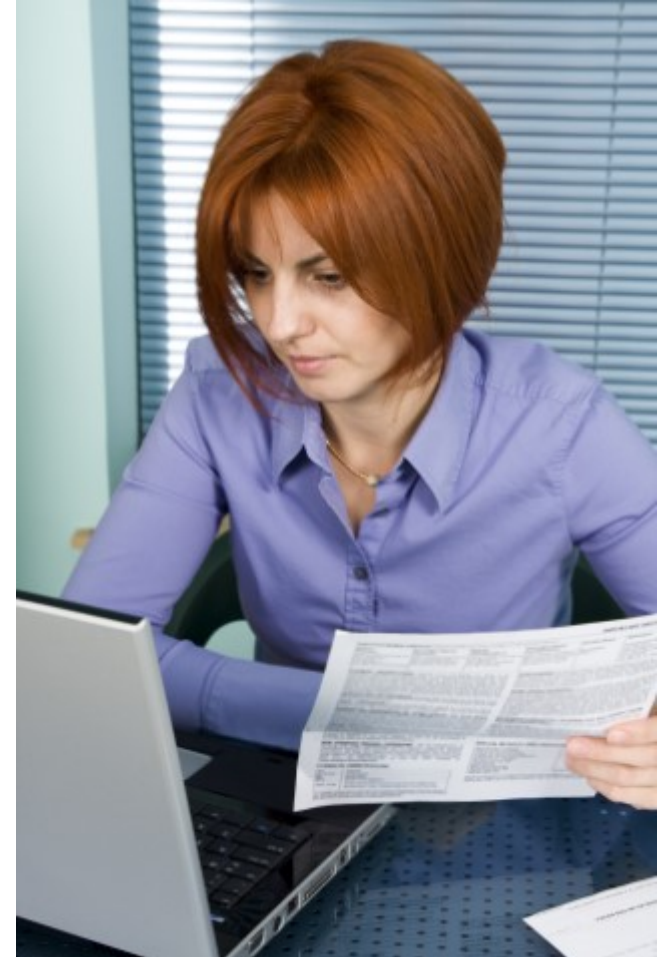
Version 1.0, July 2019



Consumer information

The basics for users of medical devices

- <https://www.tga.gov.au/medical-device-cyber-security-consumer-information>
- Questions to ask
- Incidents
- Tip for:
 - Securing your medical devices
 - Securing other related equipment
 - Managing information



Working together

Expectations for communication and response

- Responsible vulnerability disclosure is good security practice
- This does not mean that disclosure must be ASAP
 - *Researchers need to respect the need for patient safety*
- The TGA expects that manufacturers will disclose vulnerabilities in medical devices
 - *Media, consumers, patients, and health care providers need to understand that this is good practice and improves safety*
- Compliant medical devices get hacked too
 - *Medical device cybersecurity compliance is about planning, threat management, response and disclosure*



Registration questions

Thank you

- Helps speakers prepare
- Identifies gaps and informs future activities

Answers to registration questions

**Does TGA require cybersecurity assessment for applicable medical devices for Australian registration?
If the application uses abridged route, e.g. FDA PMA approval, is the cyber assessment still required?**

- The TGA requires compliance with the Essential Principles.
- Expected evidence includes assessment of the cybersecurity risk or threat.
- Assessment of risk is always required.

Answers to registration questions

Is NIST framework implementation satisfy the cybersecurity requirement from TGA?

- This will depend upon the product and situation.
- The NIST framework will not always be applicable, and is not itself required by the legislation.
- The Australian regulation is principles and risk based.

Therapeutic goods regulation can be difficult to navigate!

What kind of device **application** do I need to submit?

My therapeutic good is for a **life-threatening illness** – is there a quicker approval pathway?

What are the **time frames** for applications?



Can I **advertise** my product?

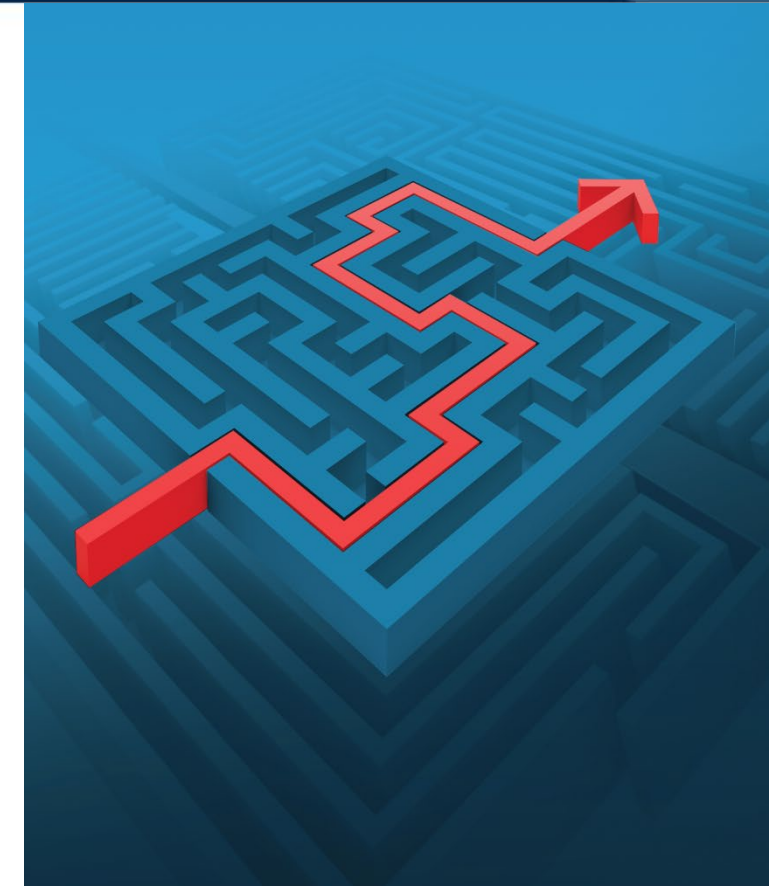
My product has been granted approval **overseas** – is this valid in Australia?




What are my regulatory **obligations**?

What **information** do I need to provide to the TGA?

SME Assist

- **Targets** the needs of small to medium enterprises (SMEs), start-ups, researchers and those unfamiliar with therapeutic goods regulation
- **Assists** users with navigating the ‘regulatory maze’
- Offers:
 - Guidance articles
 - Interactive decision tools (including ‘[What classification is my medical device?](#)’)
 - Educational face-to-face workshops across Australia (including a dedicated medical device focus session)
 - Email and phone support
 - A subscription service to keep up-to-date with news and events



 tga.gov.au/sme-assist
 sme.assist@tga.gov.au
 1800 020 653

Lee is currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation to complete our live poll.

LIVE POLL

Contact us

Digital Devices

digital.devices@tga.gov.au



Question time

More information



TGA website – tga.gov.au



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YouTube – TGA Australia



TGA topics blog - tga.gov.au/blogs/tga-topics

Contact us

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digital.devices@tga.gov.au



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