Australian Government
Department of Health
Therapeutic Goods Administration

The regulation of medical device software

Presentation to Radiation Health Committee

David Wotton
Medical Devices and Product Quality Division
Therapeutic Goods Administration

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TGA Health Safety Regulation

When is software a medical device?

When is software a medical device?

It's not based on…

- what colour it is
- what shape it is
- whether or not it looks good
- what it is called
- whether it is novel or not
- what technology is used
- how it is supplied (online, in hardware, through the sneaker net, …)

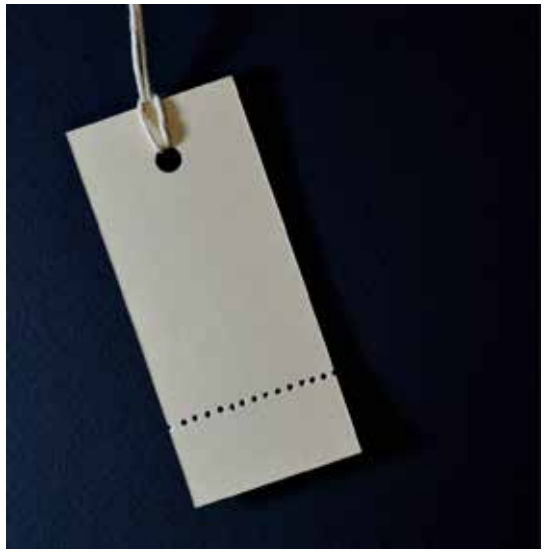
When is software a medical device?

When the manufacturer intends for its product to be used for:

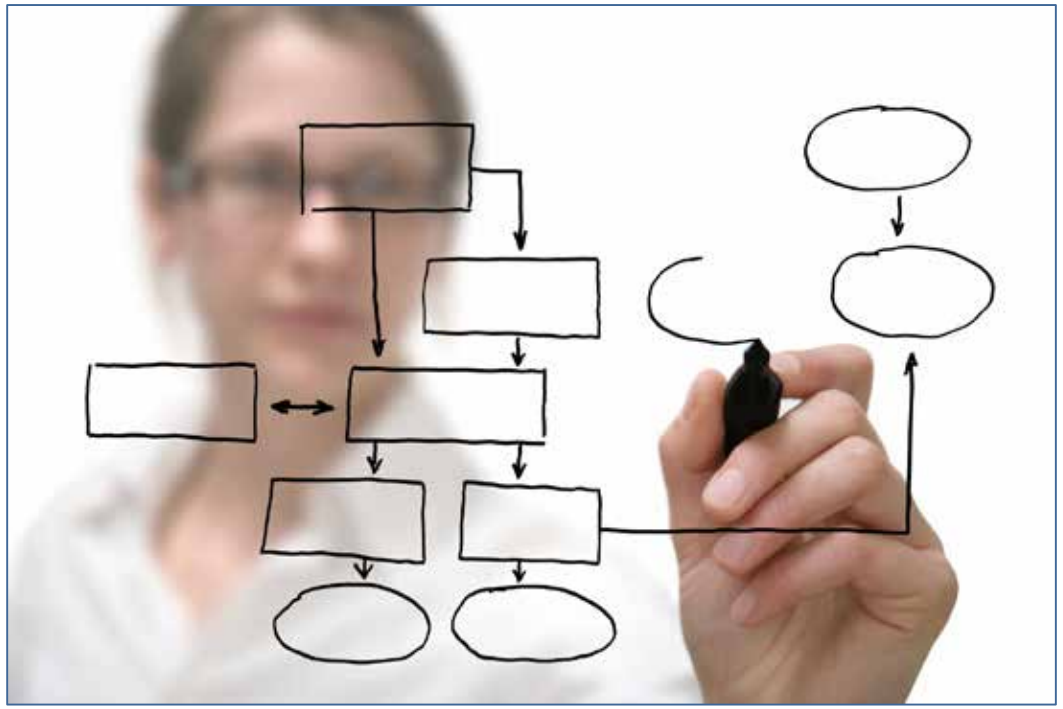
- diagnosis,
- prevention,
- monitoring,
- treatment, or
- alleviation, of disease, injury or disability

Who is the manufacturer?

- It’s not necessarily who physically makes the device.
- It’s who has her, his, or its name on the label



Regulatory requirements for medical devices



Regulatory requirements for medical devices

Manufacturer:

- determines if the product is a medical device!
- applies the classification rules
- generates evidence of safety, quality, and performance
- obtains 3rd-party certification (if required) incl.
  - assessment of technical files
  - inspection of QMS, manufacturing site(s)

Regulatory requirements for medical devices

Sponsor and/or manufacturer:

- applies for market access (entry in the ARTG)
- meets ongoing post-market requirements
  - monitors post-market performance
  - reports problems to the TGA
  - manufacturing inspections

Regulatory requirements for medical devices

3rd-party certification

1. Involves a review by an independent body
    a) Manufacturer must meet certain requirements
    b) Inspection/audit by 3rd party against those requirements
2. Manufacturers certified against the requirements
    a) Certificates issued for a certain scope of manufacture or design/type

Regulatory requirements for medical devices

Certification options in Australia

- European Union
- MDSAP + US FDA / Health Canada
- MDSAP/QMS + Japan
- TGA
- EU–Aus MRA

* Approximately 96% of 3rd-party certified devices come in via overseas certification.

Quality management systems for medical devices

Simply put, it is a system to assure quality in manufacturing.

More broadly, it's also a means for manufacturers to meet customer and regulatory requirements.

In therapeutic goods regulatory schemes, a QMS is used for the management of **quality** but also for the management of **safety** and **performance/efficacy** of therapeutic goods.

Quality management systems for medical devices

What does it look like?

Quality management systems comprise:

- people
- processes and procedures
- facility(ies)
- tools (including IT systems) and equipment

Introducing ISO 13485

ISO 13485 is…

- a technical standard
- based on ISO 9001
- recognised by regulatory jurisdictions worldwide
- principles based
- not mandatory in most jurisdictions (including Australia)

Medical devices—Quality management systems—Requirements for regulatory purposes — ISO 13485: 2016

Software development and quality management

- Version control
- Release management
- Design validation
- Bug/issue reporting and correction
- Clinical validation

Documentation is key!

Quality management systems and Small and Medium Enterprises (SMEs)

There are many SMEs who successfully operate a QMS.

Some are just 1 and 2-person companies.

Inspections

The manufacturer is expected to:

- **design** for safety and performance
- **develop** for quality, robustness, resilience, and predictability
- **monitor**, **report**, and **improve**

using appropriate, sufficient, robust, and defensible tools, approaches, and methods.

With sufficient breadth and depth of expertise.

Inspections cont.

Software used in manufacturing

- Production, sterilisation, water, and cleaning systems…
- Building-management systems
- Statistical-process control
- Lab equipment used in manufacturing

Applies only to systems used for or affecting production (manufacture)

Inspections cont.

Software for maintaining quality management systems

- Enterprise resource planning systems
- Documentation management systems
- Corrective Action Preventive Action systems
- Training and record-keeping systems
- Other compliance systems

Applies only QMS/GMP/compliance (not divorced business) systems

Inspections cont.

Software with a therapeutic purpose (medical device software)

Infusion pumps and blood-pressure monitors

IVD instruments and equipment

Portable electronic devices

Patient monitor, ECG, MRI, and radiation-therapy machines

And many more!

Inspections cont.

Software with a therapeutic purpose (medical device software)

Embedded software (firmware, EPROM, etc.)

Mobile, server (cloud), desktop programs and apps

Programmable hardware (e.g., FPGAs)

Software that drives or controls other medical devices

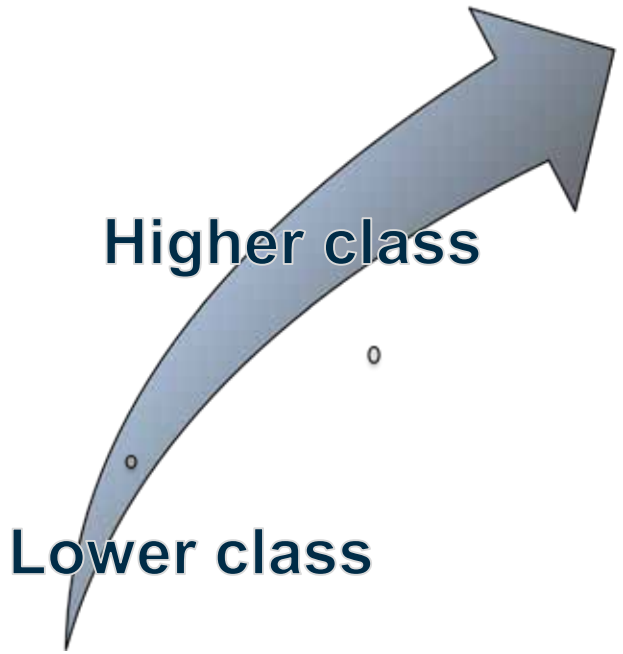
Remember: It's not the manner, form, material, technology, etc.
The key is the manufacturer's *intended purpose*.

Inspections cont.

- Backup, fail-over, and redundant systems
- Infrastructure and security systems (networks, firewalls, etc.)
- Software-development toolsets (IDEs, compilers, etc.)
- Monitoring and management systems (incl. load, performance, analysis)

Easily overlooked but important aspects of QMS/GMP, performance, and safety

Regulatory classification correlates to requirements, oversight



Classification	Requirements	Degree of oversight
Class III	✓✓✓	3rd-Party, High
Class IIb	✓✓✓	3rd-Party, Medium
Class IIa, Im, Is	✓✓	3rd-Party, Low
Class I	✓	Self-certification

(IVD medical device classes: Class 1 to Class 4)

Device reforms | Classification rules

New classification rules

Programmed and programmable medical devices, and software products that are medical devices in their own right

- **Diagnosing** and **screening** for a disease or condition
- **Monitoring** the state or progression of a disease, condition, etc.
- **Specifying** or **recommending** a treatment
- **Providing therapy** (via provision of information)
- **Patient images** and **anatomical models**
  (introduced as part of the personalised medical device reforms)

What about safety?

The Essential Principles of Safety and Performance

Schedule 1,

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

The Essential Principles

With freedom comes responsibility

- Manufacturers have freedom on how they demonstrate compliance
- Allows for evidence to be adapted for a type of medical device
- Facilitates novel products and technology

The Essential Principles

With freedom comes responsibility

- Means that manufacturers have to think about which evidence they need
- Evidence is assessed by experts
    - Engineering is assessed by engineers
    - Science is assessed by scientists
    - etc.

Evidence of compliance

- Risk and quality management
  - Total product lifecycle (TPLC)
- State-of-the-art
  - Standards published and unpublished
- Best practice
  - Software engineering, clinical, other
- Product validation
  - Engineering, clinical, other

Device reforms | Essential principles

Recent updates to the Essential Principles

Clarifying current expectations

- safety, performance, and other characteristics
- management of fault conditions
- resilience to unsafe component interactions
- delivery of timely safety warnings, especially regarding service disruption or performance degradation
- providing means for verifying correct operation

***** Some of the key points particularly pertinent to AI highlighted in purple

Recent updates to the Essential Principles

Clarifying current expectations

- where relevant for safety, management of data and information integrity, quality, and privacy.
- meeting the state-of-the-art for systems engineering
- considering the resource, environment, configuration, and capability of related platforms used to support operation of the device

***** Some of the key points particularly pertinent to AI highlighted in purple

Recent updates to the Essential Principles

Clarifying current expectations

- provision of information to users on resource, information, security, and environmental requirements
- cybersecurity
- data (representative, of sufficient quality, maintenance of integrity, management of bias)

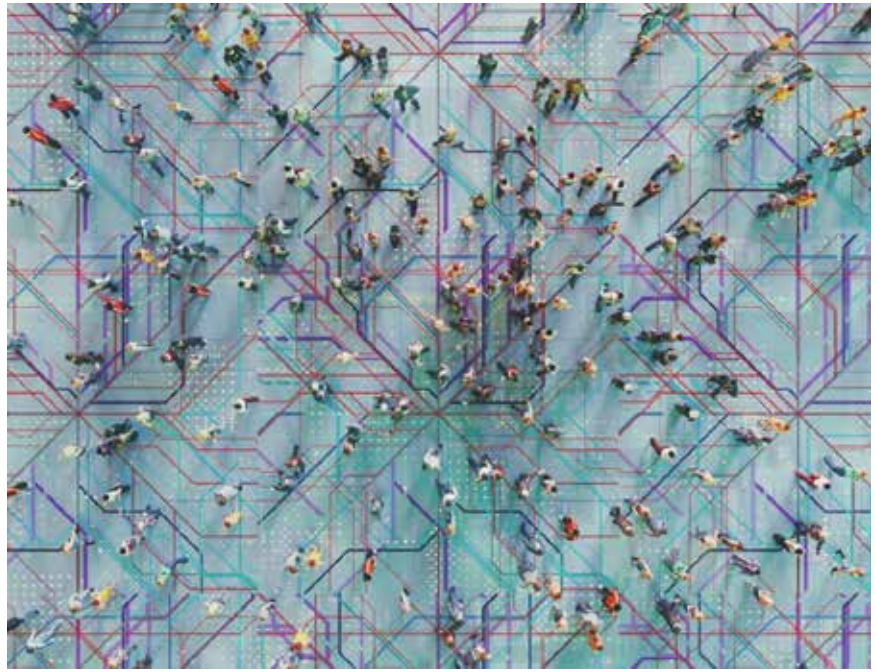
***** Some of the key points particularly pertinent to AI highlighted in purple

Artificial intelligence

Some of our activities

- International standards work

  (ISO/IEC JTC1/SC42 Artificial Intelligence via SA IT-043)
- International Medical Device Regulators Forum (IMDRF)
- Ongoing policy work relating to digital health
- Submissions to consultations



Further information

Medical device regulation basics
http://www.tga.gov.au/medical-devices-regulation-basics

Regulation of Software as a Medical Device (SaMD):
https://www.tga.gov.au/regulation-software-medical-device

General medical device enquiries
devices@tga.gov.au

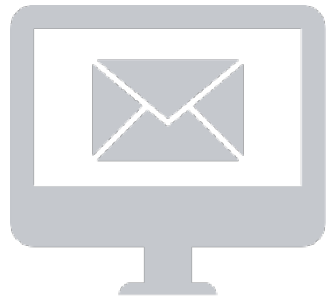
The TGA's Digital Devices team
digital.devices@tga.gov.au

The TGA's SME Assist team
tga.gov.au/sme-assist

Regulatory Assistance Support

info@tga.gov.au

1800 020 653



www.tga.gov.au

Other resources

Social media

Website—tga.gov.au

Facebook—TGA Australia

Twitter—@TGAgovau

YouTube—TGA Australia

TGA blog—tga.gov.au/blogs/tga-topics

TGA information services

- Safety alerts
- Recall actions
- Medical Devices Safety Update
- Consultations
- Publications
- Scheduling

www.tga.gov.au

Questions?

Australian Government

Department of Health

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