

# Regulation of Refurbished Devices

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# TGA - existing framework

- Only at import or export of refurbished device
- Not evaluated - unless high risk device
- No quality system requirement
- Record device and manufacturer (refurbisher) on Australian Register of Therapeutic Goods

# Elements of Australian Regulatory Framework

- 12 Essential Principles of safety and performance
- 20 Rules of Classification based on Risk to patient and/or user
- Quality Systems - ISO 13485/13488
- Independent Assessment and on-going surveillance of Quality Systems
- Entry on the **Australian Register of Therapeutic Goods**

# TGA - new framework

- Definitions
  - manufacturer
  - refurbishing
- Quality System
- Compliance with specification(s)

# The Manufacturer

- .....the manufacturer of the device is the person who, with a view to supplying the device under the person's name, does one or more of the following using ready made products:
  - a) assembles the device;
  - b) packages the device;
  - c) processes the device;
  - **d) fully re-furbishes the device;**
  - e) labels the device
  - .....

# Refurbishment

- A refurbishment of a medical device is taken to have occurred if the medical device is **substantially re-built** from one or more used medical devices of that kind so so as to create a **virtually new** medical device that is:
  - able to be used for the purpose originally intended by the manufacturer of the original device; and
  - intended to be supplied for that use under the name of the manufacturer who carried out the rebuilding

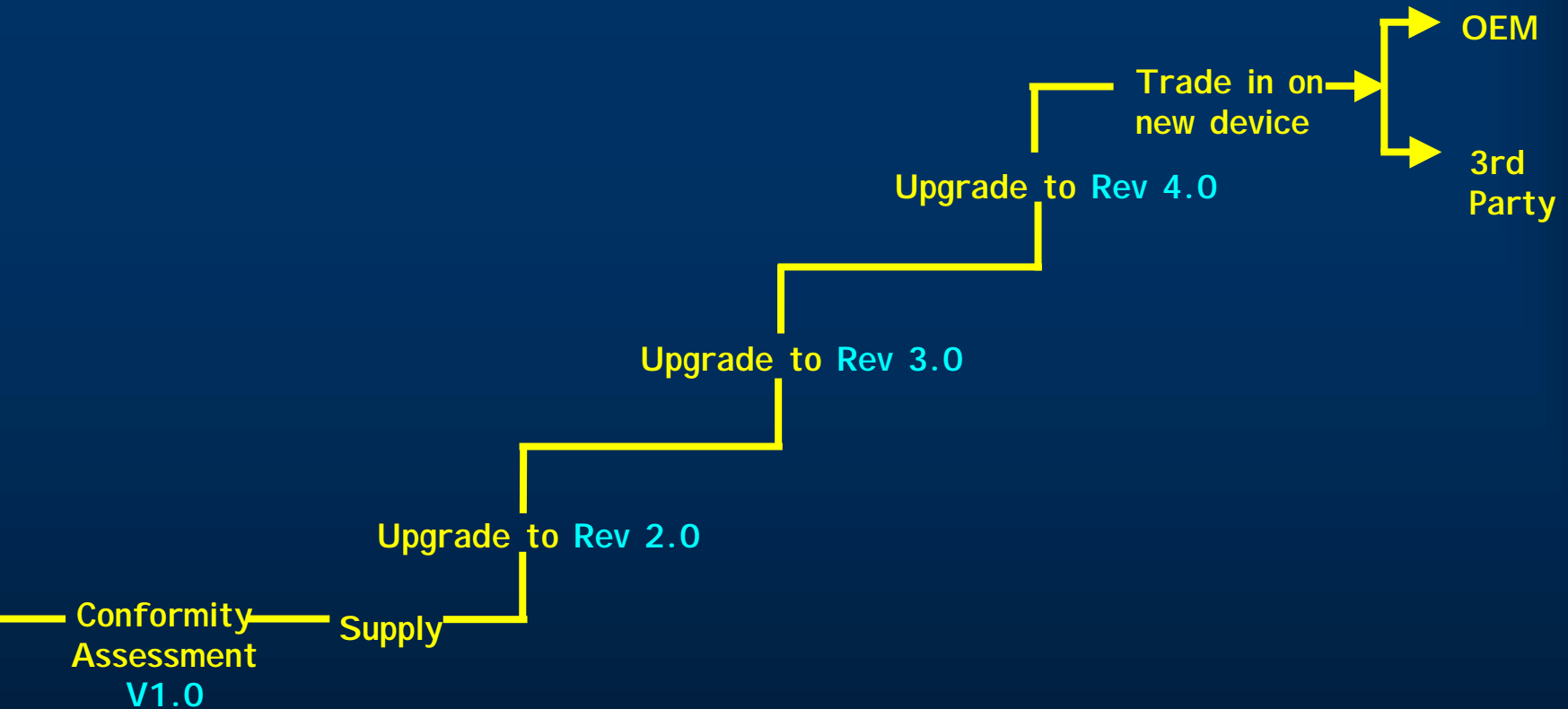
- .....

# Refurbishment

- ..... Refurbishment of a medical device involves at least several of the following actions:
  - **stripping the device** into components or sub-assemblies;
  - checking parts of the device for suitability for re-use;
  - **replacing components or parts** of the device which are not suitable for re-use;
  - **assembling reclaimed or replacement component parts** or sub-assemblies of the device or another used device
  - **testing the device against the specifications** of the original device or, **if the manufacturer has revised those specifications, the revised specifications**
  - **identifying** an assembled device



# Product Lifecycle part 1



- Questions -**
- ?? Upgrades performed by original manufacturer or 3rd party
  - ?? Ongoing maintenance by manufacturer or 3rd party
  - ?? All Upgrades to manufacturers spec, or are some 'local' mod's

# Product Lifecycle part 2

## OEM

Refurbishing Process  
(ISO 13485/8)



Place on the market

## 3rd Party

Refurbishing Process  
(ISO 13488)



Test against OEM  
(revised) specification's



Record on  
ARTG



Place on the  
market

Sale by  
equipment  
owner



???

## Questions -

- ?? 3rd Party access to full manufacturer's specification
- ?? Which revision of specification for upgraded devices
- ?? Application of changes 'environmental' spec's - eg EMC
- ?? Impact of 'local' mod's

