

# **Endoscopy Reprocessing Trends**

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# The Poor Relation?



# The Concept Of A level Playing Field?

- Irrespective of where the decontamination is performed or who it is performed by the aim should be the same, ***patient safety***,
- So:
  - The standards and legislative framework should be the same
  - The attention paid to the reprocessing should be the same and appropriate for the use of the device

The move of reprocessing

# **DRIVERS FOR MOVEMENT**

Driver	Impact
Medical Device Directive 1993 and a level playing field	Need for improvement to many facilities in hospitals that serve others. Move to larger central departments – cannot afford to improve all
vCJD	As above but applying to all hospitals – capital costs escalate
Increase in number of endoscopy procedures and perceived importance	Move to pass through endoscope washers and dedicated Endoscope Decontamination Units (EDU)
Device Complexity and Spaulding Category Crossover	More endoscopic devices needing sterilisation. Combined decontamination units (EDU and SSD)
Death due from “apparent low risk devices”	Growing realisation that there is more than just endoscopy out there! So a need to <u>control</u> the process

High risk



**Endoscopes that enter sterile body tissues:**

Manual cleaning, automated cleaning and disinfection; rinse-water with limited bacterial contamination, followed by sterilization.  
(Guidance on these endoscopes is not included in this CFPP.)

**Endoscopes that enter sterile body cavities via contaminated body cavities:**

Manual cleaning, automated cleaning and disinfection; rinse-water with very low bacterial contamination

**Endoscopes that enter contaminated body cavities:**

Manual cleaning, automated cleaning and disinfection; rinse-water with limited bacterial contamination

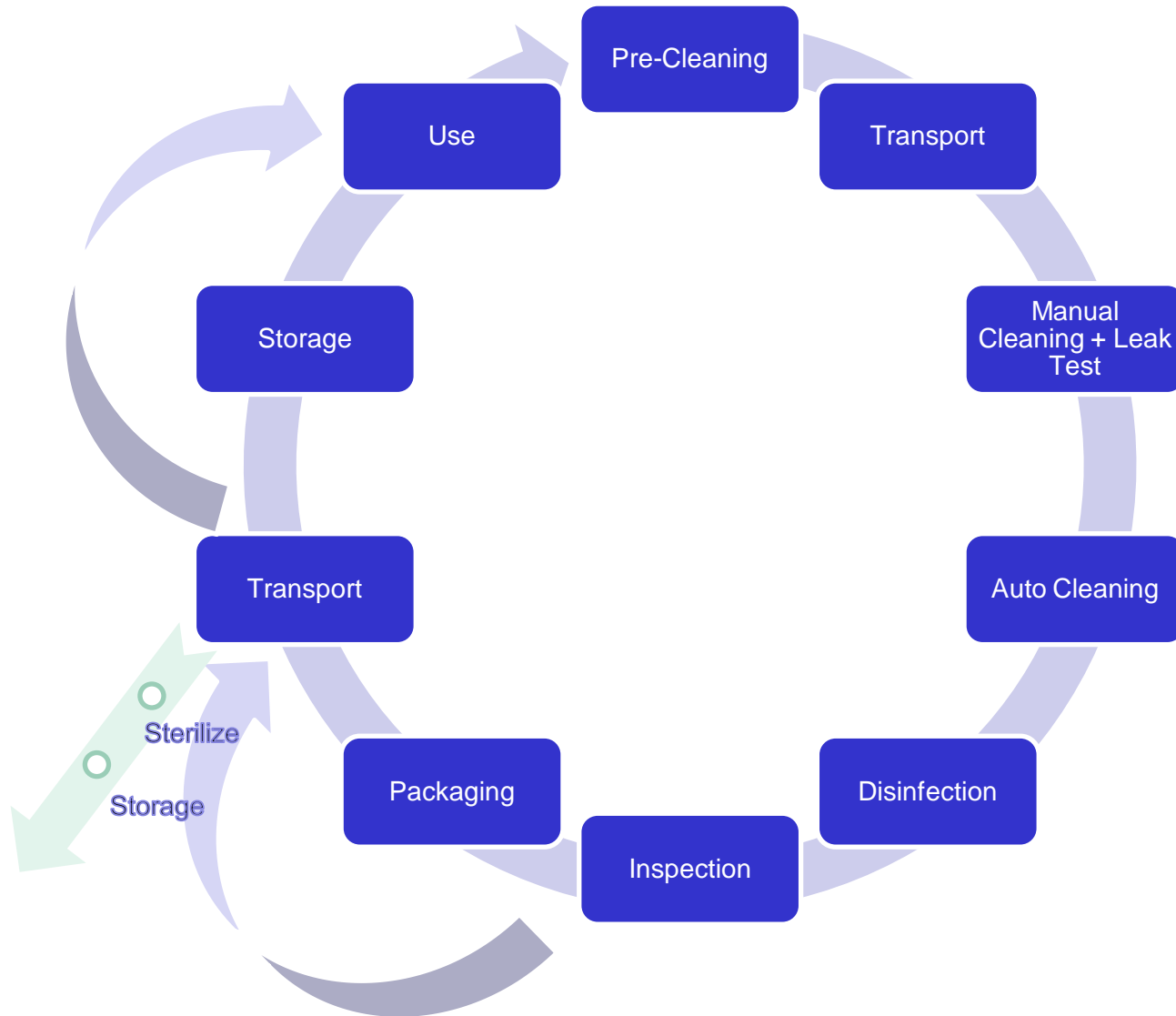
**Endoscopes without lumens:**

Manual cleaning and manual disinfection as EQR and use of manual cleaning followed by an endoscope washer-disinfector (EWD) as possible Best Practice

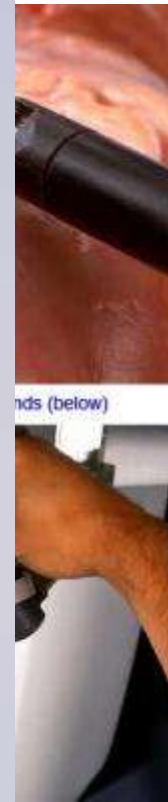
Low risk

Spaulding  
Classification is  
not always  
straight forward  
with some  
endoscopes!

# Reprocessing Cycle



# Device Complexity - The Challenges

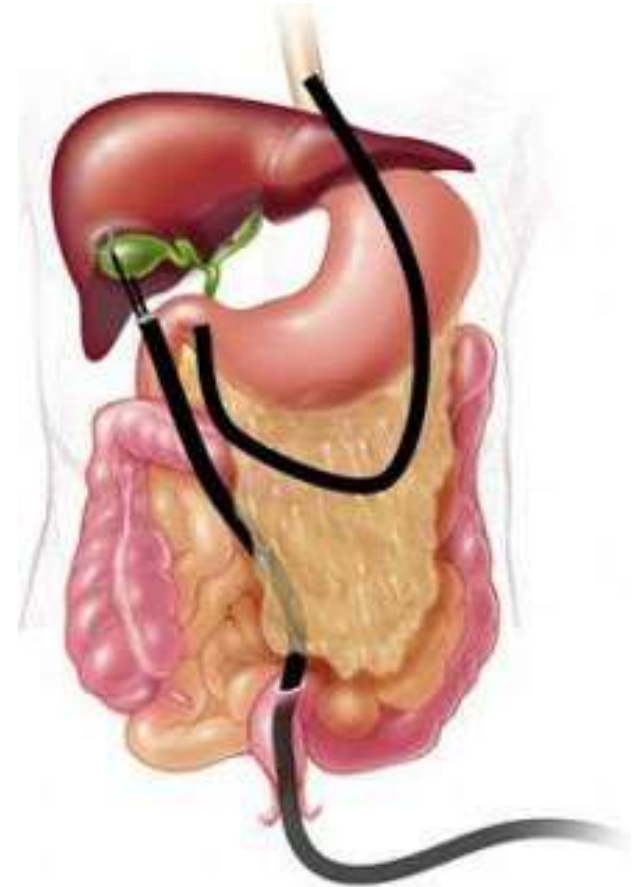




# Natural orifice transluminal endoscopic surgery (NOTES)

An experimental surgical technique whereby "scarless" abdominal operations can be performed with an endoscope passed through a natural orifice (mouth, urethra, anus, etc.) then through an internal incision in the stomach, vagina, bladder or colon, thus avoiding any external incisions or scars

*Source: Wiki via International Journal of Surgery!!! – Must be true*



The move of reprocessing

**NEW SOLUTIONS**

# What came first?

THE OLD CHICKEN AND EGG PROBLEM ...



The double door endoscope reprocessor ...or  
the twin room layout?...

# EN ISO 15883

- Part 1 2006 introduced double-ended washer-disinfectors :
  - defined as a Washer-disinfector with separate doors for loading and unloading
  - Allows for a two room configuration
- Part 4 2008 encouraged:
  - Channel blockage and disconnect leading to...
  - On board endoscope databases
  - Automatic leak testing
- Many of these had been described in the UK guidance document, HTM2030 but 15883 formalised them internationally and encouraged their adoption.



# CFPP01-06 – UK Guidance

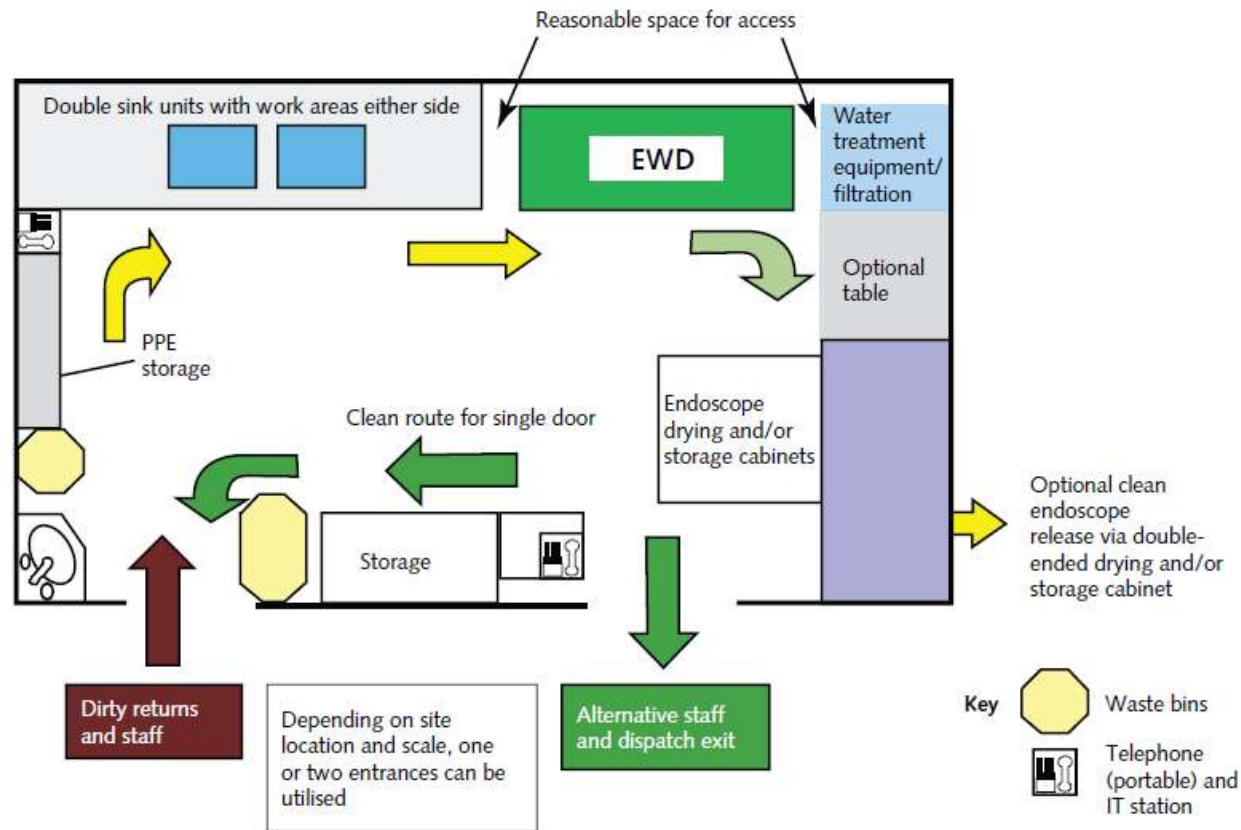
- Endoscope reprocessing units should have in place the medical devices **quality management system BS EN ISO 13485** and operate in a manner consistent with the Medical Devices Regulations.
- This may be addressed by:
  - the use of double-ended endoscope washer-disinfectors
  - with separate clean and dirty rooms (two-room option).
  - Where this approach is not available, single ended EWDs should be used with separation of clean and dirty areas.



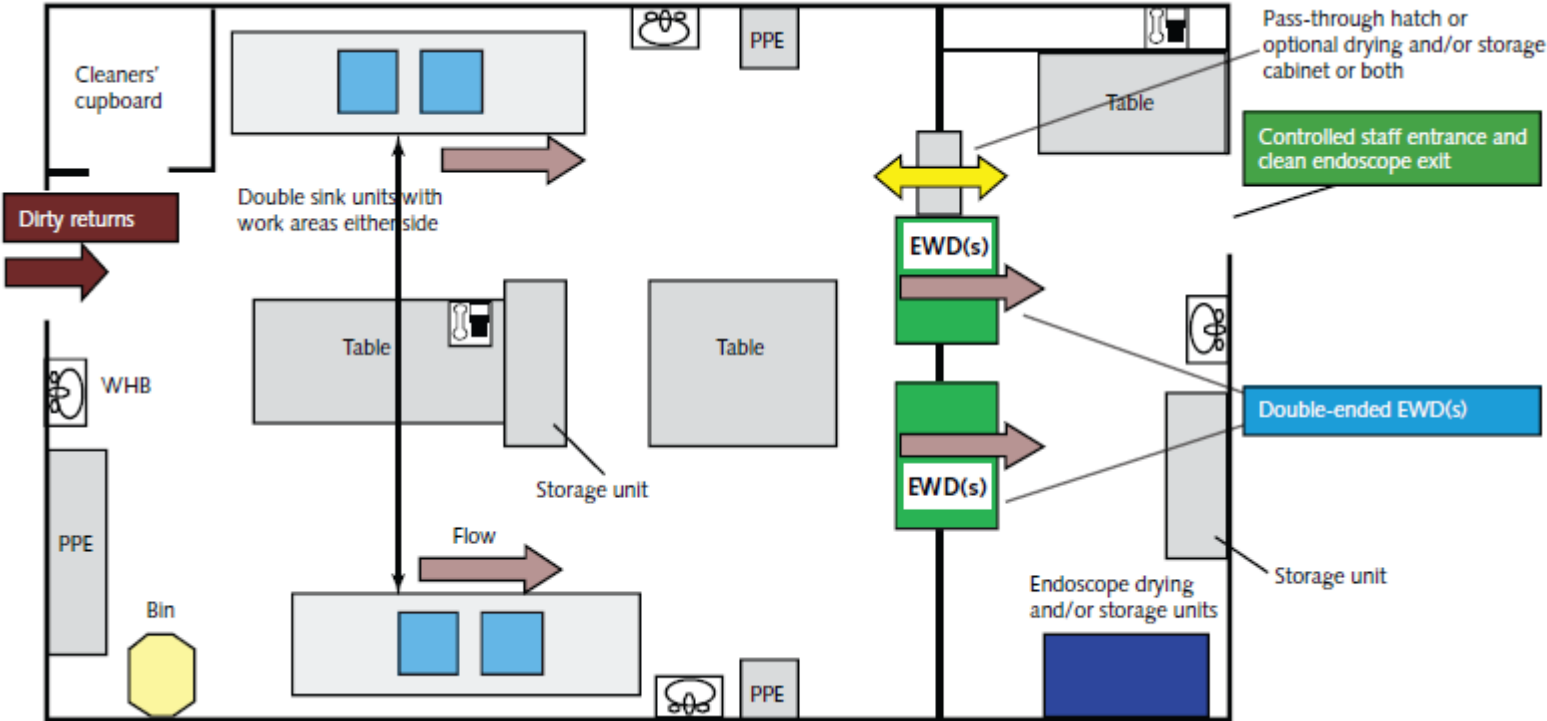
# CFPP01-06 – UK Guidance

- It is important to ensure that the workflow within the department is from dirty to clean to avoid the possibility of recontamination of reprocessed endoscopes from surfaces contaminated by unprocessed devices.
- There must be a clearly designated flow from dirty to decontaminated such that there can never be uncertainty about which stage of decontamination an endoscope has reached as it progresses from dirty to clean.

# CFPP01-06 – UK Guidance Essential Quality Requirement



# CFPP01-06 – UK Guidance Best Practice Requirement



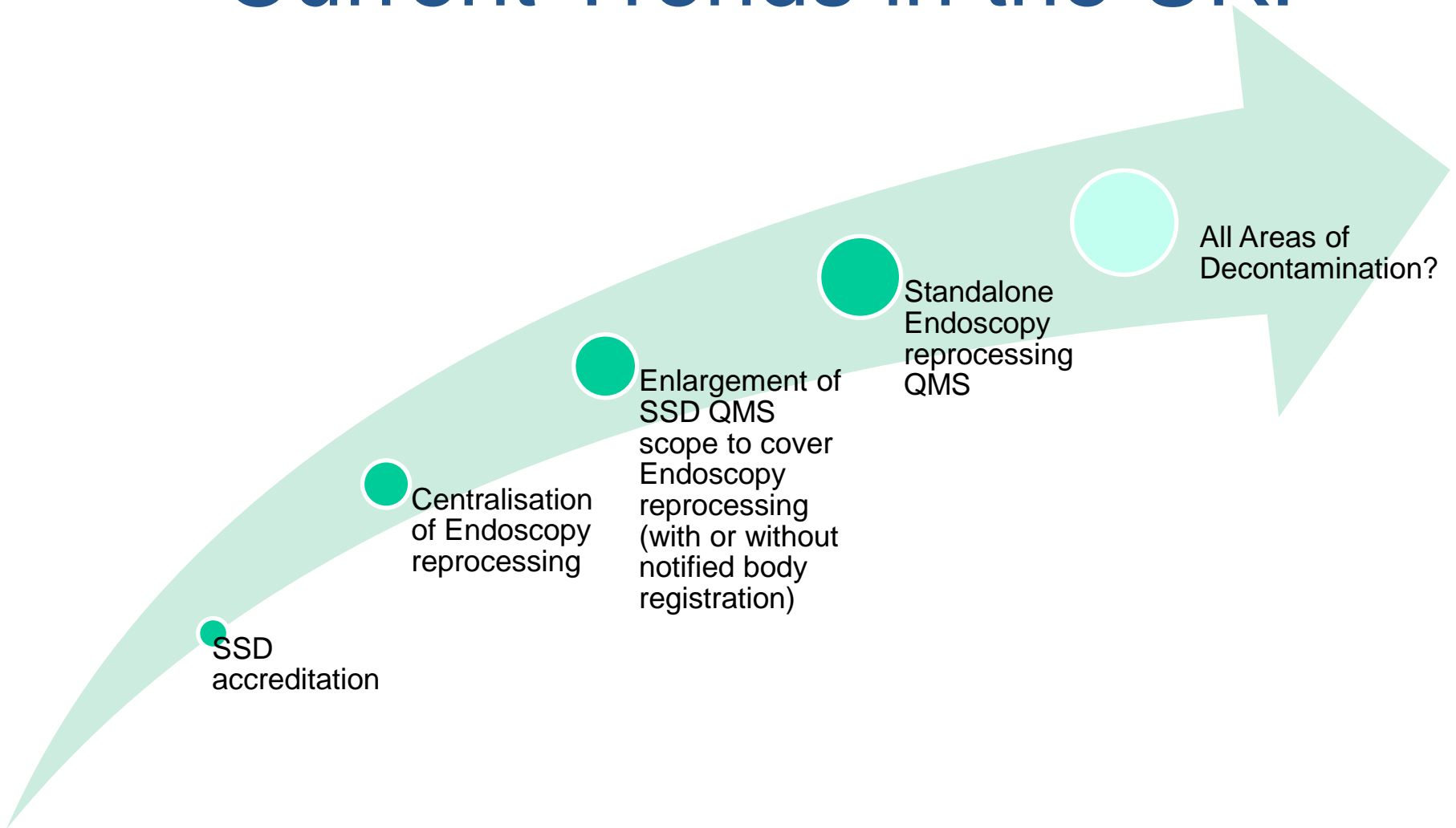


# The Advent Of Active Storage Cabinets

- Traditional 3 hour rule in UK – if an endoscope was not used within 3 hours of disinfection it needed to be reprocessed before use
- The arrival of active cabinets with extended storage periods (72 hrs, 30 days) has facilitated greater centralisation
- Vacuum type storage has helped this further by allowing transportation



# Quality Management Systems - Current Trends in the UK:



# State Of The Art



# Conclusions

- Guidance issued has encouraged two room solutions and increased the requirements for best practice.
- There has been a reduction in the number of endoscope reprocessing departments in many hospitals as it is difficult and expensive to keep many locations at best practice.
- Device complexity and the need for sterilization pushed endoscopy towards SSD type quality systems and environments.
- Technology has facilitated centralisation.

# Sometimes we still have further to go!

