

# Centralisation of Endoscope Decontamination



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# Endoscope Decontamination

## WHY?

- ❖ To prevent infection from patient to patient.
- ❖ To make equipment safer to handle.
- ❖ To prolong the life of the equipment which is very expensive.
- ❖ To protect the quality of diagnostic samples.



# Centralisation

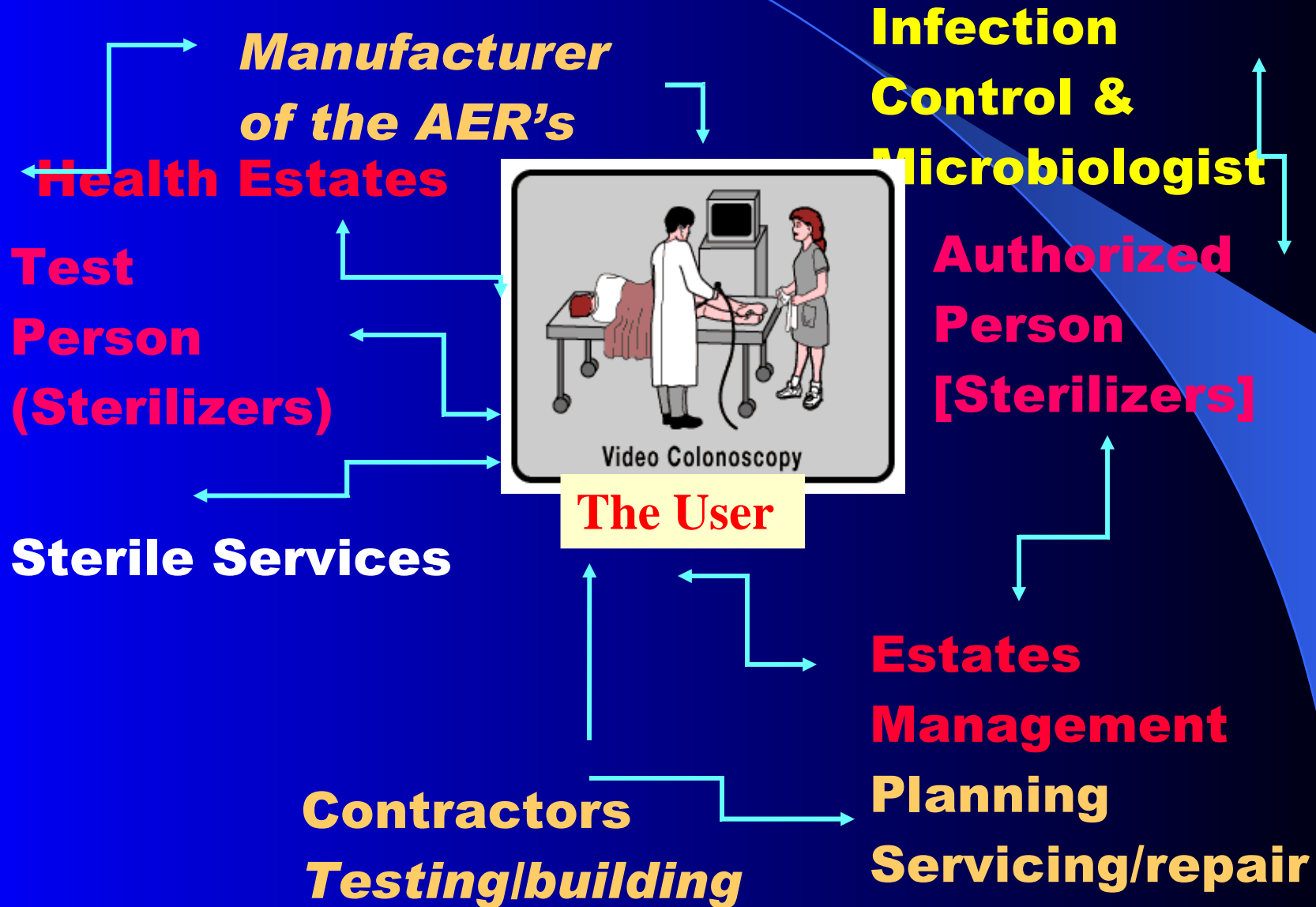
## WHY?

- ❖ Provide a quality process that is consistent, controlled and validated
- ❖ Patient safety
- ❖ Dedicated trained staff
- ❖ Improve working environment
- ❖ Update equipment
- ❖ Cost efficiency

# **Endoscopy Decontamination Pre-Centralisation**

- ❖ **Service fragmented**
- ❖ **Physical environment unsuitable**
- ❖ **AER's and water did not meet HTM standards**
- ❖ **Inconsistent staff training**
- ❖ **Inadequate traceability**
- ❖ **No quality control**

# ***The Team***



# Guidelines

- ❖ **MDA DB2002(05) Decontamination of Endoscopes July 2002**
- ❖ **HTM 2030**
- ❖ **BSG Guidelines For Decontamination of Equipment for Gastrointestinal Endoscopy October 2003**
- ❖ **EN/ISO 15883 part 4 – Requirements and Tests for WD's Employing Chemical Disinfection for Thermo-labile Endoscopes 2005**
- ❖ **NHS Model specification C32 - Automated Endoscope Reprocessors for Flexible Endoscopes.**

# **Hine Independent Review**

## **Northern Ireland March 2005**

- ❖ **Decontamination areas must be large enough to accommodate centralisation and ensure a dirty in clean out cycle**
- ❖ **Automated Endoscope Reprocessors must be validated and tested in accordance with HTM 2030**
- ❖ **Water used in AER's should be HTM 2030 standard**
- ❖ **Decontamination must be carried out by personnel who have been appropriately trained**
- ❖ **All decontamination units must have a traceability system capable of tracing all scopes to the point of use on patient**
- ❖ **A documented quality system is needed and should be**

# Endoscopy Service Confusion

- ❖ What machines do we buy ?
- ❖ What model and design ?
- ❖ Will they comply with the standards?
- ❖ Where do we locate the machines?
- ❖ What testing is needed?
- ❖ What disinfectant can we use ?
- ❖ Is it compatible with our scopes?
- ❖ What standard of water do we need?
- ❖ How many scopes will we need?
- ❖ How do we perform traceability
- ❖ *Too many questions and not enough answers!!!*





# Do You Feel Like This?



Or This



# Tenders

- ❖ **Building** – including worktops and finishes
- ❖ **AER's** – pass through
- ❖ **Dryers** – vertical or diagonal storage
- ❖ **Sinks** – height adjustable
- ❖ **Hatches** – pass through and interlocking
- ❖ **Traceability** – Trace all stages of the decontamination process to the patient

# Options for Location

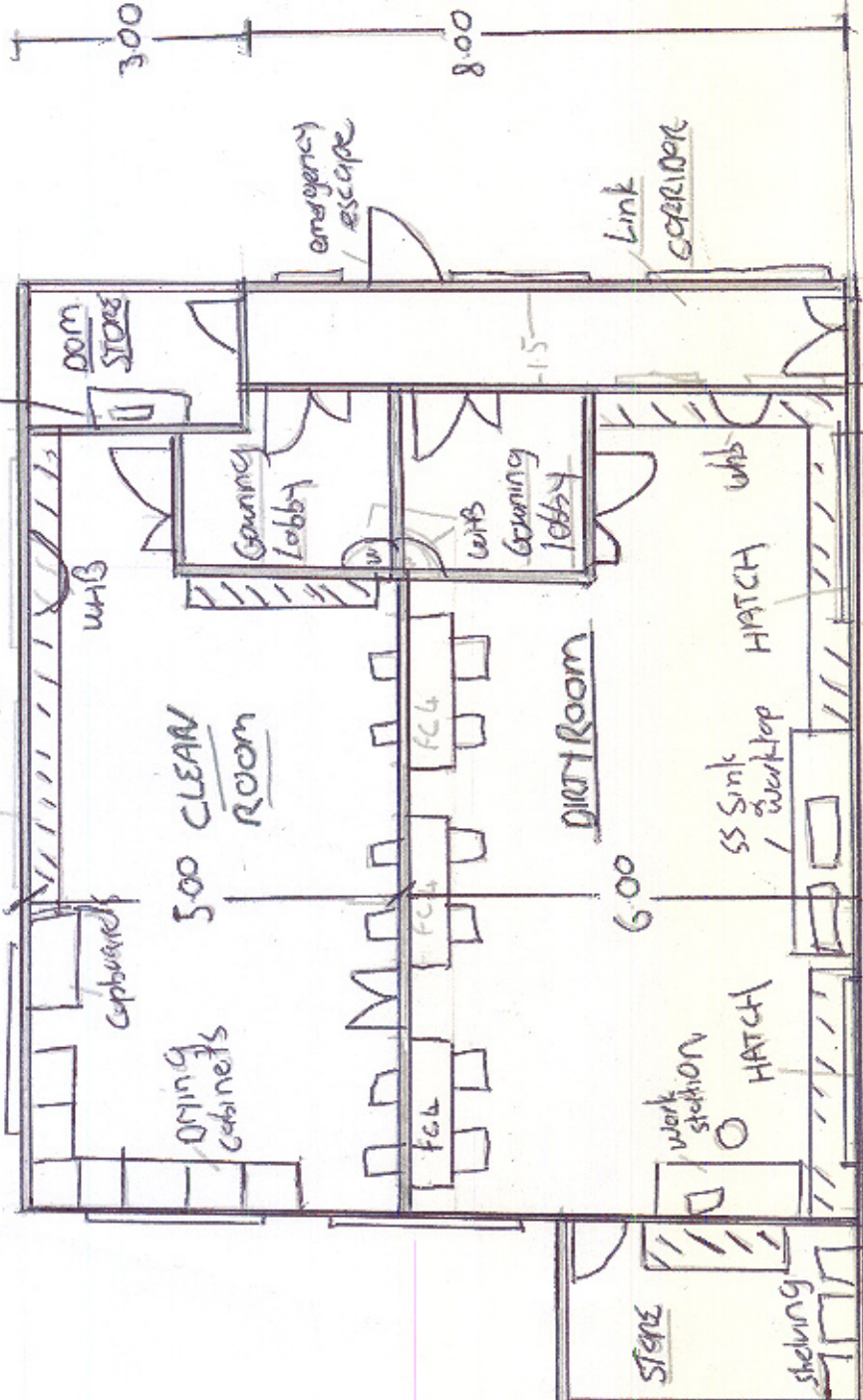
- ❖ Renovate within the footplate of the existing endoscopy suite
- ❖ Relocate the service to HSDU
- ❖ Create a unit elsewhere within the Hospital building
- ❖ Build a new unit somewhere on the hospital site
- ❖ Outsource the service completely
- ❖ **Expand the existing facility**

# Guidelines

- ❖ **HBN 52 part 2 - Accommodation for Day Care – Endoscopy Unit 1994 – needs revised**
- ❖ **HBN 13 - Sterile Service Departments 2004**

300 1100 15

benchings/shelving  
sluice



Endoscopy Room

Endoscopy Room







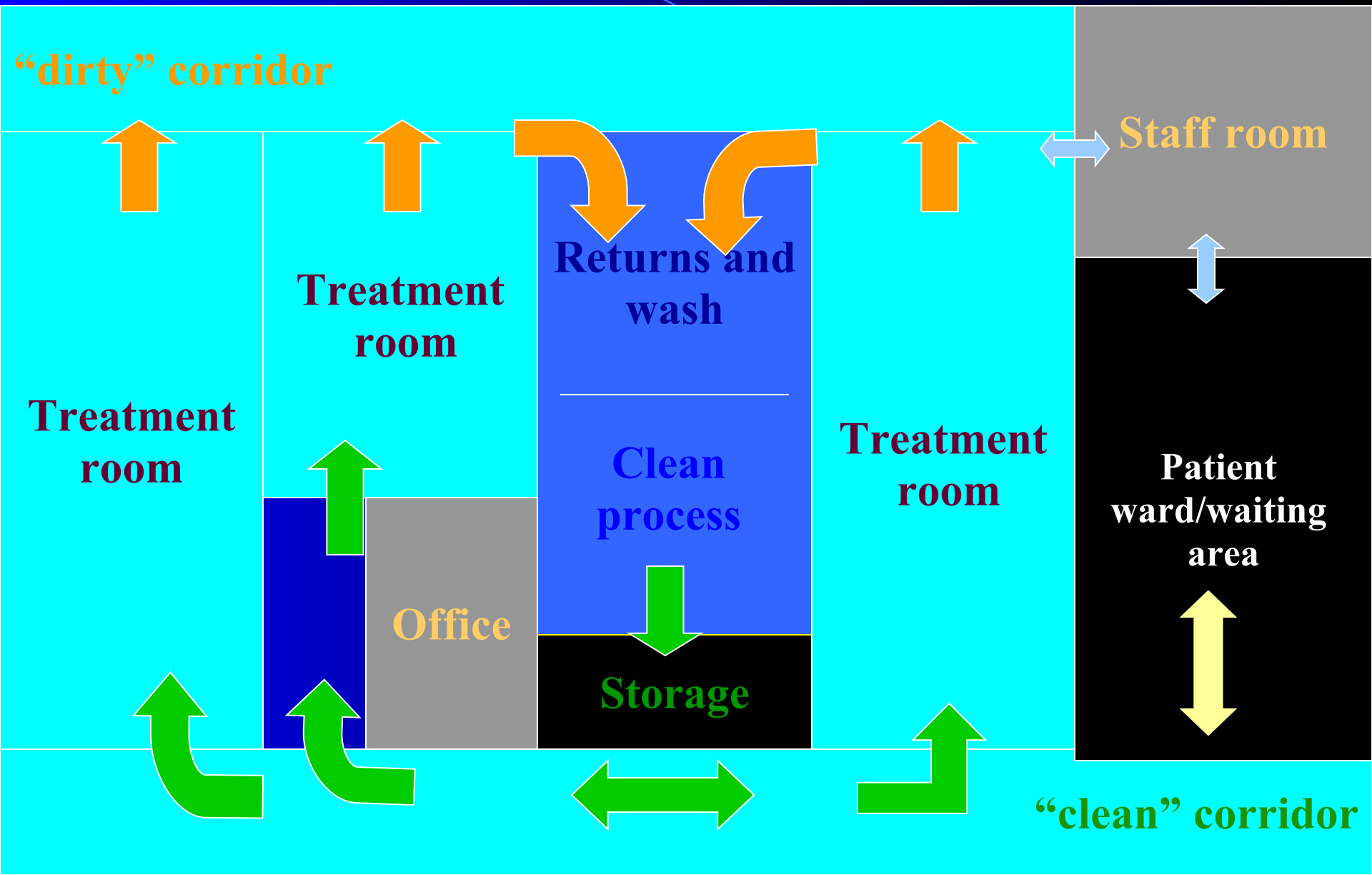








# The Future Endoscopy Department



# What type of AER?



WASSENBURG APPARATUS  
ENDOSCOPE TREATMENT



WASHING  
DISINFECTION  
DRYING



# ***AER Requirements***

- ❖ Self disinfection cycle available
- ❖ **Printer and chart recorders fitted**
- ❖ **Single chamber or double**
- ❖ **Pass through with printout**
- ❖ **Channel patency monitoring.**
- ❖ Interlocked doors etc. (HTM 2030, EN15883 part 4)
- ❖ **Leak test facility**
- ❖ **Test connections for TP(S) and equipment**
- ❖ **Single shot doses of disinfectant**
- ❖ **Water requirements and standards etc...**

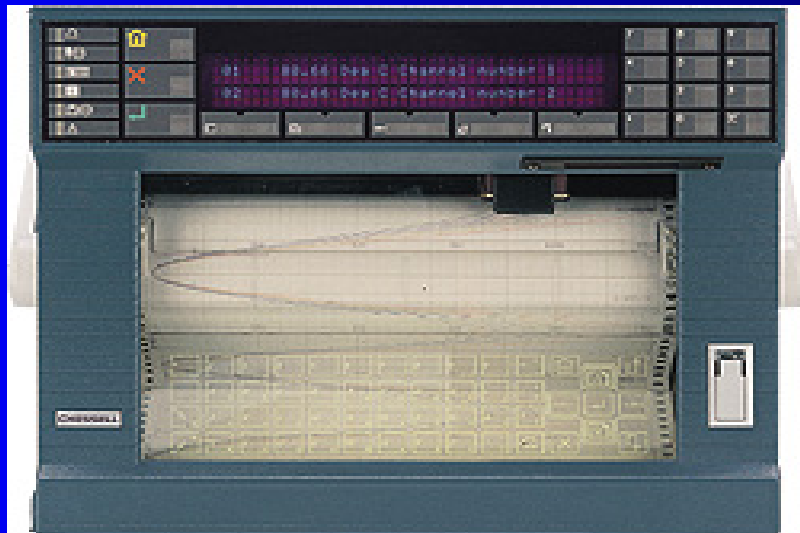
**How many AER's????**

# Independent Data

- ❖ Cycle number, date and time
- ❖ Leak test
- ❖ Channel patency
- ❖ Detergent dosage
- ❖ Rinse
- ❖ Disinfectant dosage and **concentration**
- ❖ **Holding time for disinfection**

# Testing requirements to HTM 2030

- Schedule of operational tests for WD's for endoscopes
- Table 2e, chapter 5 details the installation tests by the contractor, and operational tests by the appointed TP(S)



- Schedule of periodic tests for WD's for endoscopy
- Table 5e, chapter 7 details the schedule
  - ❖ **Daily Tests User**
  - ❖ **Weekly Tests User or TP(s)**
    - Automatic control test
    - Water hardness/conductivity
    - TVC's
    - Cleaning efficacy
- Last two need to be controlled and involve microbiologist – Documented procedures**
- ❖ **Quarterly Tests TP(s)**
- ❖ **Annual Tests TP(s)**
- ❖ **Audits test reports AP(s)**

# What Solutions?

- ❖ Glutaraldehyde[Cidex,Asep,Totacide}
- ❖ Peracetic Acid - Aperlan
- ❖ Chlorine Dioxide [Tristel]
- ❖ Superoxidised Water [Sterilox]{locations and on-costs must be considered}
- ❖ Cidex OPA
  - ❖ What do we use?
  - ❖ It must be correct for the scopes, AER and effective.
  - ❖ It must be safe for the patient and staff handling the equipment - COSHH



# Dryers

- ❖ Warm (30°C ) HEPA filtered air dries and circulates through each channel preventing contamination.
  - ❖ Warm (30°C ) HEPA filtered air dries and circulates throughout the chamber in a circular movement.
  - ❖ Microprocessor controls and alarms connected to a printer
  - ❖ Recorded time limits on scopes
  - ❖ **Independent validation**
    - Temperature
    - UV readings
    - Humidity
    - Endoscope air flow
    - Chamber air flow
- \* Validated**  
**microbial testing**  
**Graph & printed data**



# Scopes

- ❖ All scopes are compatible with AER's and disinfection solution
- ❖ Sufficient stock to accommodate a 2hr turnover
- ❖ Manufacturers instructions for decontamination are available and written in to procedures

**Tender included requirements for compatibility with AER's and supply of all attachments needed.**

**THIS MEANT MANUFACTURERS OF SCOPES HAD TO COMMUNICATE WITH MANUFACTURER OF AER !!!**



# Staffing and Training

## Staffing

- ❖ Sufficient staff to accommodate clean and dirty areas
- ❖ Quality controller
- ❖ Full time technical maintenance staff have been appointed so that all machinery is regularly tested and maintained to HTM standards.

## Training

- ❖ Staff are trained in all aspects of decontamination so that they recognise if any part of the process has failed
  - ❖ Training is in house and external
  - ❖ Competencies are assessed and documented
  - ❖ Procedures for each scope with details on each channel. **If possible manufacturers drawings!**
- TRAINING MUST BE CONTINUAL!!**

# Documentation and Traceability

## Traceability

- ❖ Operator at each stage
- ❖ Patient ID
- ❖ Manual wash
- ❖ Detergent used
- ❖ Disinfection used and expiration date
- ❖ Cycle number
- ❖ Scope and accessories
- ❖ Loading AER time and date
- ❖ Unloading AER time and date
- ❖ Dryer loading and unloading
- ❖ Issue time and date
- ❖ Barcode Label – use by date

## Documentation

- ❖ Operational Procedures
- ❖ Training records
- ❖ AER validation and test reports
- ❖ Water TVC and chemical reports
- ❖ Dryer validation reports
- ❖ COSHH file
- ❖ Environmental Procedures
- ❖ Audit records

**ISO 13485:2003 standard**

# **Decontamination Services Post Centralisation**

- ❖ **Dirty in/Clean out environment**
- ❖ **Environmental testing and control**
- ❖ **AER's validated and tested to HTM 2030**
- ❖ **Reverse Osmosis water quality**
- ❖ **Designated decontamination staff**
- ❖ **Competency assessed training**

***You never know who could be  
next  
It maybe you!!!***

