# **HTM 01-01: Decontamination of Surgical Instruments (FRCPath Revision Notes)**

## **Part A – Management and Provision**

* **Scope**: Policy and management framework for surgical instrument decontamination in acute care.
* **Essential Quality Requirements (EQR)**: Minimum statutory and regulatory compliance (Medical Devices Directive, Care Quality Commission).
* **Best Practice**: Beyond EQR, non-mandatory but encouraged for improved safety, efficiency, and innovation.
* **Governance**:
  + **Director of Infection Prevention and Control (DIPC)** – ultimate responsibility.
  + **Decontamination lead / surgical instrument manager**.
  + **AE(D), AP(D), CP(D)** (see below for roles).
* **Instrument management**:
  + Audit trails, contingency for dropped/unavailable instruments, maintenance of set integrity.
  + Instruments used on **high-risk tissues**: separate pools for patients born before vs after 1 Jan 1997 (due to vCJD exposure risk).
* **Regulatory drivers**: Health & Social Care Act 2008 (Regulated Activities Regulations 2014, Reg. 12(2)(h), Reg. 15).
* **Prion-specific policy**:
  + Move towards **in situ residual protein testing**.
  + Threshold: **≤5 µg bovine serum albumin (BSA) equivalent per instrument side**.
  + Neurosurgical instruments require **stricter thresholds**.
  + **Implementation deadlines**: by 2017 (neuro/high-risk) and 2018 (all providers).

## **Part B – Common Elements**

* **Applies to all reprocessing methods** (sterilization, washer-disinfectors, etc.).
* **Covers**:
  + **Test equipment & calibration**:
    - UKAS-accredited calibration, ISO/IEC 17025.
    - Temperature accuracy ±0.5 °C, pressure ±0.5% absolute.
    - Data recorders: ≥180 measurements in 3-min cycle (1/s).
  + **Validation & verification**:
    - **Installation Qualification (IQ):** Verifies that equipment is installed correctly to manufacturer’s specifications and site requirements.
    - **Operational Qualification (OQ):** Demonstrates the equipment operates as intended across the full operating range under test conditions.
    - **Performance Qualification (PQ):** Confirms the equipment consistently delivers reproducible results with actual loads under routine conditions.
* **Key focus**: ensuring removal of **residual protein**, not just visible soiling.
* **Testing**:
  + **Daily**: Process challenge devices (PCDs).
  + **Quarterly**: Residual protein testing (≤5 µg/instrument side).
* **Priority**: Instruments contacting high prion-risk tissues (Annex J, ACDP-TSE).

## **Part C – Steam Sterilization**

* **Preferred method**: high-temperature steam (porous-load sterilizers).
* **Conditions**:
  + 121 °C, 15 min OR 134 °C, 3 min (plateau phase).
* **Tests**:
  + **Daily**: Bowie–Dick test (steam penetration).
    - **Purpose**:
      * Daily check of **porous-load steam sterilizers** (autoclaves).
      * Confirms **air removal & steam penetration**.
    - **Method**:
      * Use **Bowie–Dick test pack** (towels or commercial chemical indicator sheet/device).
      * Place in **empty chamber**, above drain (worst-case position).
      * Run cycle: **134 °C for 3.5 min, no drying phase**.
    - **Results**:
      * **Pass** = uniform colour change (adequate steam penetration).
      * **Fail** = patchy colour change (air pockets, vacuum pump failure, non-condensable gases).
    - **Standards**:
      * Required under **HTM 01-01** and **EN 285**.
      * Part of **daily QA** for surgical instrument sterilizers.
    - **Scope**:
      * Applies to **all surgical instruments processed in porous-load autoclaves**.
      * **Not used for flexible endoscopes** → EWDs use **process challenge devices, protein residual testing, microbiological water tests**.
  + **Weekly**: Air leakage test, automatic control test.
  + **Quarterly**: Calibration, thermometric test (small load).
  + **Yearly**: Full revalidation, including steam quality (dryness, non-condensable gases).
* **Validation**: per BS EN 285 and ISO 17665.
* **Critical factors**:
  + Removal of air/non-condensable gases (air detector required).
  + Steam quality: dryness fraction ≥0.95, non-condensable gases ≤3.5%.
* **Prion relevance**: Steam sterilization alone does **not inactivate prions** → reliance on prior protein removal critical.

## **Part D – Washer-Disinfectors**

* **Purpose**: Automated cleaning & disinfection before sterilization.
* **Process**:
  + Cleaning → microbial inactivation (thermal or chemical).
  + Drying integral or via separate cabinets.
* **Design considerations**:
  + Single- vs multi-chamber.
  + Critical variables: detergent dosing, pump pressure, water quality, cycle duration.
* **Tests**:
  + **Daily**: PCDs (simulate prion protein adhesion).
  + **Quarterly**: Residual protein test.
  + Continuous monitoring with trend analysis (not pass/fail).
* **Prion-specific guidance**:
  + Aim for **≤5 µg protein per instrument side**.
  + Elution/swabbing methods (ninhydrin, ATP assays) **not acceptable**.
  + Instruments should be kept moist post-procedure to aid prion removal.
* **Regulation**: BS EN ISO 15883 (washer-disinfectors).

## **Part E – Low Temperature (Non-Steam) Sterilization**

* **Scope**: For **thermolabile devices** (damaged by steam).
* **Methods**:
  + **Vapourised hydrogen peroxide (VHP) plasma**.
  + **Ethylene oxide (ETO)**.
  + **Ozone** (emerging).
* **Considerations**:
  + Device compatibility essential (plastics, optics).
  + Safety: toxic residues (ETO requires long aeration).
  + Regulatory oversight: CE-marking, MHRA conformity.
* **Role in prion risk**:
  + Not proven to inactivate prions.
  + Thus, **protein removal in washer-disinfectors is essential before low-T sterilization**.

## **Prions – Core Notes (cross-cutting all parts)**

* **Pathogen**: Transmissible spongiform encephalopathies (TSEs), incl. vCJD.
* **Risks**: Standard sterilization insufficient → require meticulous cleaning.
* **Policy drivers**: ACDP-TSE guidance (Annex C, J).
* **Protein detection threshold**: ≤5 µg BSA equivalent/instrument side.
* **Testing**:
  + PCDs mimicking prion adhesion.
  + In situ detection methods (still developing).
* **Priority instruments**:
  + Neurosurgery, ophthalmology, tonsillectomy, and other high-prion-risk procedures.
* **Operational measures**:
  + Minimise time to decontamination.
  + Keep instruments moist post-use.
  + Segregated pools for neuro sets depending on patient DOB (before/after 1997).