Environmental Monitoring methods for Decontamination Units
The decontamination of Reusable Invasive Medical Devices (RIMD) should take place in a designated and controlled area. This optimises the effect of the decontamination process:

1. minimises contamination
2. provides a safe working environment
3. safeguards the products
Suitability of decontamination facilities

- **Statement**
- Decontamination facilities are designed, constructed, maintained and controlled to provide effective segregation of clean and dirty activities and to provide an environment that minimizes adventitious contamination of clean and disinfected reusable invasive medical devices (RIMD) including flexible scopes.
Suitability of decontamination facilities

Rationale

- It is essential that decontamination facilities are appropriately designed, maintained and controlled. This is important in order to reduce the risk of cross-contamination and to provide a safe place of work.
Environmental control

- The environment in which clean non-sterile RIMD are inspected, assembled and packed are controlled as a clean room to ISO 14644-1: 1999 Class 8 (manned/unmanned)

Environmental control

- **Cleaning**
  - The environment in which decontamination of reusable invasive medical devices (RIMD) takes place is cleaned in accordance with policies, procedures, protocols, guidelines and schedules agreed by the decontamination coordinator (with advice from the Consultant). Dedicated cleaning provision (both equipment and storage) is provided for the wash room, clean room and the inspection, assembly and packaging room.
Unit Design

- The department should be designed so that it is physically separated from all other work areas.
- The department should be designed to allow segregation of ‘dirty’ and ‘clean’ activities.
- The department should be designed to facilitate a unidirectional flow from the ‘dirty’ area to the ‘clean’ area.
- The department should not be used for any other purpose.
- The department should not be used as a thoroughfare.
- The department should not be part of any service user treatment area.
Unit Design

- There should be a changing area for donning work wear which includes shower, toilet facilities and lockers in proximity to the department.
- Access to the wash room and to the clean room, inspection and packaging room (IAP) should be through dedicated gowning rooms provided with hand hygiene facilities.
- The wash room, clean room, inspection and packaging room (IAP) and steriliser unloading area should be free from ‘opening’ windows, ledges, and uncleanable areas.
- The wash room and clean room, inspection and packaging room (IAP) should be designed to minimise the ambient sound levels within the rooms. (This will require attention to the installation of equipment, building finish, etc.).
Section Two: Lighting and electricity

- There should be adequate lighting available to permit good working practices and visual examination of RIMD.
- Task lighting and magnification should also be in situ.
- There should be sufficient electricity supply points, computer terminal points and work stations in the department.
Section Three: Ventilation and temperature

All rooms in the department should be mechanically ventilated and controlled to provide a comfortable working environment, (typically temperatures should be controlled between 18-22ºCelsius and relative humidity should be controlled within the range 35-60%)
Section Four: Walls, floors and ceilings

- The finishes on the walls and other surfaces should be flush, smooth, non-linting, water resistant and able to withstand frequent cleaning.
- The junctions between the walls and floors should be coved and flush.
- The fitments (where possible) should be flush with wall surfaces.
- Floors should be covered in a washable non-slip material which is securely sealed.
Section Five: Workstations, furniture, shelving and equipment

- All work surfaces, fittings, fixtures and furniture should be made of easily cleanable and robust material and maintained in good condition.

- The workstations should be equipped for the preparation of single or composite packs. They should be of adequate size to accommodate the wrapping material to be used and should be height adjustable.

- There should be adequate space between workstations for equipment and staff movement.

- The shelving should be manufactured from non-shedding material, easily cleanable and with a smooth surface which will not damage packaging.

- The shelving should be of sufficient depth for all the materials to be held and should not be more than two metres high, unless special provision is made for loading and un-loading higher shelves.
Section Six: Restricted entry and movement between areas

- The area should be managed by trained staff whose sole or primary responsibility is management of the decontamination unit.
- Entry to the decontamination unit should be restricted to authorised personnel only.
- Staff movement between dirty and clean areas should not be possible without passing through a clothing change and hand wash area.
Environmental control

- The clean room, inspection and packaging room (IAP) should be controlled as a clean room to ISO 14644-1: 1999 Class 8 (manned/unmanned).

Environmental cleaning

- The environment in which decontamination of RIMD takes place should be cleaned in accordance with methods, procedures and schedules agreed by the decontamination coordinator (with advice from the Consultant Microbiologist and Infection Prevention and Control Nurse).

- Dedicated cleaning provision (both equipment and storage) should be provided for the clean room, inspection and packaging area and the wash room.
Contents

- Section One:
  - Cleaning equipment
- Section Two:
  - Cleaning frequency and cleaning efficacy
- Section Three:
  - Floor cleaning equipment and method
- Section Four:
  - Floor cleaning agents
- Section Five:
  - Spillage kits
- Section Six:
  - Records
- Section Seven
  - Environmental monitoring
Environmental monitoring

- Environmental monitoring applies to all units reprocessing RIMD including flexible scopes irrespective of whether a formal classification can be achieved.

- It is useful to know/monitor the level of cleanliness/environmental hygiene achieved, as the RIMD/flexible scope is manually cleaned, thermally/high level disinfected it is imperative that on release from the unit to ensure the decontamination status of the RIMD/flexible scope has not been compromised.
Environmental monitoring should be capable of....

- **Detecting** - in a timely manner, an adverse trend in microbial populations
- **Facilitate** - the identification that trends source(s), such as equipment failure, sanitisation practices, personnel habits, or training deficiencies, so that they may be promptly corrected

- If the critical elements of a robust environmental-monitoring system are performed and documented regularly, environmental control can be easily demonstrated and monitored
Endoscope reprocessing units may not only process diagnostic flexible endoscopes, many of the scopes processed are now invasively intent (therapeutic) resulting in a need for awareness of the environmental (decontamination status) of processed endoscopes.
Environmental monitoring

- Regular audits carried out by appropriately trained staff should form part of the management of environmental cleaning
- Audit frequency should be agreed locally
- Microbiological or bio contamination monitoring of the environment within a controlled area should include:
  - Air
  - Contact surfaces and if present water and compressed air or gases
  - It may also monitor staff and personal protective equipment in the course of routine activity by using contact plates
Microbiological sampling methods suited to locations and purpose should be chosen.

*Note:* Warning action limits should be set for microbial contamination in each area, after a period of baseline monitoring.
Air sampling

- *Air may be sampled in two ways:*
  - By passive settling of microbes using 90mm diameter ‘settle’ plates which contain either
    - Tryptone Soya Agar (TSA)
    - Sabaroud Dextrose Agar (SDA)
  - By active sampling using a microbiological air sampler to physically draw a known volume of air over an agar plate at a standard speed and capture the microbes present on the agar
### Parameters for assessment of microbiological air quality by ‘settle plate’ method

<table>
<thead>
<tr>
<th>Settle Plates</th>
<th>Tryptose soya agar (TSA)</th>
<th>Sabaroud Dextrose agar (SDA)</th>
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<tbody>
<tr>
<td><strong>Target microbes</strong></td>
<td>Broad range of bacteria, some yeasts and moulds</td>
<td>Mainly yeasts and moulds</td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>1 – 4 hours</td>
<td>1 - 4 hours</td>
</tr>
<tr>
<td><strong>Incubation temperature</strong></td>
<td>30 -35°C</td>
<td>20 -25°C</td>
</tr>
<tr>
<td><strong>Incubation time</strong></td>
<td>3 days (5 days to show moulds)</td>
<td>5 days</td>
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<tr>
<td><strong>Results reported as:</strong></td>
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Contact surface sampling

- Flat surfaces
- Irregular surfaces
- Alternative sampling procedure
Flat surfaces

- Where surfaces to be sampled are flat small petri dishes (c.50mm diameter) with protruding agar referred to as ‘contact plates’ can be used to directly sample the surface by pressing firmly against it.

- Alternatively, small ‘paddle’ like devices coated with agar can be used in a similar fashion.

- When incubated the colony count is indicative of the bio contamination load of the exact area sampled (colony forming units per sq cm).

- The agar can again be TSA or SDA but they should additionally contain disinfectant neutralisers.

  - *These are available commercially & incubation details are identical to those for contact plates or settle plates.*
Irregular surfaces

- Where surfaces are not flat and contact plates cannot be used, sterile sampling swabs can be used.
- These are pre-moistened with neutralising buffer prior to use, enabling it to pick up organisms easily.
- Carefully remove the swab from its tube allowing any excess moisture to remain in the tube.
- Then rub the swab against the sample surface using a twisting motion and replace it in the tube.
- The swab can later be rubbed on the surface of a TSA or SDA agar plate to transfer the sample and the plate incubated as for the settle plates and contact plates.
Note: Swabs for environmental sampling are commercially available and these types should be used rather than swabs designed for clinical sampling. The swab comes as a sealed pack containing a sealed plastic tube with neutralising buffer and a capped swab.
Alternative sampling procedure

- Rapid screening of surfaces for microbial contamination following cleaning can be undertaken using commercially available adenosine triphosphate (ATP) detection or nicotinamide adenine dinucleotide (NAD) detection tests.
- These tests identify where there has been a failure of cleaning and disinfection procedures designed to minimise microbial contamination on surfaces.
Samples from surfaces are collected using swabs moistened with treatment agents that release ATP or NAD from intact microorganisms

ATP release is detected by bioluminescence

The more light released the greater the number of viable microorganisms on the surface sampled

NAD release is measured by a colour change rather than light output

These tests are useful for monitoring the efficacy of cleaning and disinfection
A monitoring plan (locations) of the sampling sites should be prepared.
**Air flows**

- A scale drawing of the decontamination unit should be obtained
  - On this should be marked all points of air intake and extract
  - The path that airflow takes during normal working conditions should be mapped using a small smoke generator
  - This can show anomalies e.g. during filter malfunction or can aid in choosing sampling sites for air quality
**Sampling sites**

- Drawings of rooms should be prepared and sampling sites marked clearly on them using a simple numbering system such as S Series (S1, S2, S3 etc.) for settle plate locations
  - C Series for contact sample locations
  - A Series for active air sampling
  - W Series for water samples etc.

- The number of sites will vary with the size of the facility
- Settle plates sampling locations should be close to areas where medical devices are handled and stored or at points of air inflow but should not interfere with normal work flow
- Active air sampling locations should be in front of air inflows or areas of high activity
- Contact sampling locations should be critical areas such as work surfaces, control panels and personal protective equipment
Monitoring plan

- A number of sampling locations may be chosen and identified on the plan but not all of these will be sampled regularly.
- Just a limited core number will be sampled regularly to obtain baseline values whilst some may be sampled on a rotating programme.
- A monitoring programme (frequency and timing sampling) should be prepared; this will define when the samples are to be taken.

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A typical programme for a Class 8 facility are as follows:

- Settle plates carried out every month
- Contact plates carried out weekly
- Active air sampling ideally should be carried out monthly (where a sampler is available)
  - Additional sampling rounds may occur in response to unusual circumstances e.g. Breakdown in air supply, maintenance of ventilation system
  - Part of the sampling programme should be carried out when the facility is unoccupied to achieve a baseline contamination level prior to active sampling.
‘Alert’ limits and ‘action’ limits

- Environmental monitoring should be used as an early warning system to alert staff when environmental quality is drifting out of control.

- Any formal environmental-monitoring system requires the establishment of alert and action levels (threshold numbers of viable microbial colony-forming units (CFUs) that indicate a facility’s loss of control).

- The absolute CFU value has limited scientific meaning but is used to identify adverse trends and deviations from a known baseline of microorganisms within controlled environment.

- Each healthcare organisation should have its own unique baseline patterns.

- The limit values chosen should be based on averaged values achieved over at least a six month or twelve month period.
Microbial levels

- **Alert level**
  - Are CFU levels that when exceeded signal a possible deviation from normal operating conditions and may not require action but may need to be monitored more closely.

- **Action level**
  - Are CFU levels that, when exceeded, indicate a deviation from normal operating conditions and require immediate action.
Investigation and corrective procedures

- That all control samples gave appropriate results
- This could include:
  - Checking that plate media were within expiry date
  - Were not excessively wet or dry or contaminated prior to use
- Do counts when area is unmanned show similar patterns
- Any unusual activity or circumstances prior to and including sampling time
- Any possibility of abuse of samples in transit (not inverted, open lids, damaged etc)
- Any maintenance work undertaken e.g. changing or adjusting air filters
Investigation and corrective procedures

- Any malfunction of the air handling system
- Any problems with water quality
- Any problems with cleaning equipment
- Are disinfectants or detergents free from contamination
- Have shoes and PPE been checked for contamination
If so conduct a Risk Assessment
develop control measures
Assurance patient safety