Environmental Monitoring, risk assessment and responsibilities

Medical Devices Directive -93/42/EEC

- ANNEX I ESSENTIAL REQUIREMENTS
- 8. Infection and microbial contamination
- 8.1. The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.
- 8.5. Devices intended to be sterilized must be manufactured in appropriately controlled (e. g. environmental) conditions.
- 7.2. That devices be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients

National Standard Requirements for Sterile Services Units (Ireland)

HSE Standards and Recommended Practices for Central Decontamination Units. QPSD-D-003-2. V2.0

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

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

National Standard Requirements for Sterile Services Units (Northern Ireland)

- **Decontamination Health Technical Memorandum 01-01: Decontamination of reusable medical devices Part A: Management and environment**
  - The environmental conditions in such facilities should be controlled to prevent contamination (this includes both microbial and particulate contamination).
- **HBN 13 Sterile Services Department**
  - Environmental conditions under which devices are prepared should be controlled to prevent adventitious contamination (this includes both microbial and particulate contamination). ("Environmental conditions" refers to the cleanliness of surfaces, fittings and equipment, and also to ventilation and air quality in respect of filtration, airflow patterns and relative air pressures.)

- 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).

- The inspection, assembly and packaging area (IAP) is monitored microbiologically. (Reference EN ISO 14698: Part 1:2003 and EN ISO 14698 Part 2:2003).

Routes of microbial contamination

- Indirect Transmission
- Transfer of a microorganism from person to person via an inanimate object. I.e. Improperly cleaned instruments endoscopes, equipment or environment

- Direct Contact Transmission

  Hand to hand

- Droplet and air transmission

  Droplets of water (aerosolised) of less than 5µm or dust particles can remain airborne for long periods of time and travel long distances

- Water Transmission

  Contaminated supply or purified waters, bio-film formation

Instrument contamination

- Contamination of instruments following washing and disinfection.
- Instruments following washing and disinfection have shown to harbour organisms such as :-
- Staphylococcus, Micrococcus, Stenotrophomonas species. Lavobacterium, Agrobacterium, Bacillus, Orchrobactrum, Sphingomonas species. Yeast, moulds, Pseudomonas species Comamonas species.

- Levels of naturally occurring microorganisms on surgical instruments after clinical use and after washing. American Journal of Infection Control Volume 27, Issue 4 , Pages 315-319, August 1999

RMID processing including Endoscopes

- Increasingly Automated Endoscope Reprocessing washer disinfectors are placed in series with Instrument reprocessing.

- Is there potential for cross contamination with organisms associated with endoscopy procedures and with final rinse water i.e

- *Serratia marcescens* , Bacillus species , *Heliobacter pylori, Methylobacter mesophilica,*
- *Mycobacterium gordonae, intracellulare, xenopi, chelonae, abscessus, avium*
- Pneumococcus species, *Pseudomonas aeruginosa, Salmonella oslo, newport, Staphylococcus aureus*

- *Aerosols*

Airborne contamination – ventilation

Filtration

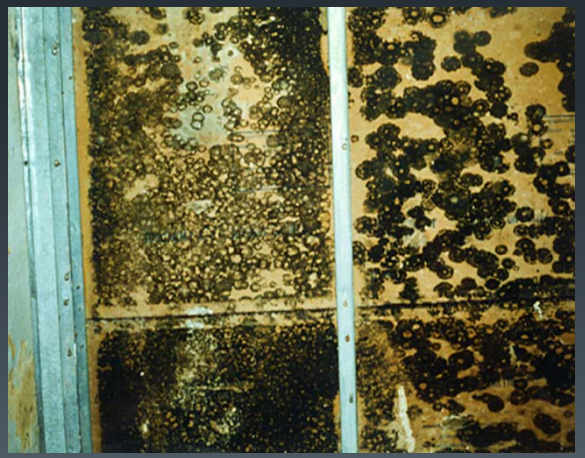
Ill fitting filters
Compromised filters
Clogged Filters

Ductwork

Dirt
Corrosion
condensation

Plant

Operating below specification
i) pressures
ii) air changes



Badly Maintained

Airborne Contamination -Ventilation

Klebsiella pneumoniae
Pseudomonas pseudomallei
Acinetobacter
Moraxella catarrhalis
Moraxella lacunata
Haemophilus influenzae
Haemophilus parainfluenzae
Bordetella pertussis
Francisella tularensis
Legionella pneumophila
Mycobacterium tuberculosis
Mycobacterium kansasii
Mycobacterium avium-intracell.
Nocardia asteroides
Bacillus anthracis
Staphylococcus aureus
Streptococcus pyogenes
Streptococcus pneumoniae
Corynebacteria diphtheria
Mycoplasma pneumonia

Aspergillus spp.
Absidia corymbifera
Rhizopus stolonifer
Mucor plumbeus
Cryptococcus neoformans
Histoplasma capsulatum
Blastomyces dermatitidis
Penicillium spp.
Alternaria alternata
Cladosporium spp.
Helminthosporium
Stachybotrys spp.

Airborne contamination- general

- Ingress of air (and particulate materials) from common areas into clean areas

- Open doors,
- Windows,
- Incorrect balancing of air circulation,
- Breakdown,
- Maintenance

Surface contamination

- Including floors, walls
- Tables – work stations
- Computers, printers and other ancillary apparatus
- Cleaning protocols
- Chemical disinfection efficacy and protocols

Personnel

- Human body flora (microbiological).
- Assumption is that the occupants are contaminated and will shed skin cells, hair ,bacteria.
- The type and rate at which bacteria are shed will be dependant on the individual.
- *Staphylococcus epidermidis/*aureus, *Streptococcus mitis/salivarius/ mutans, Enterococcus faecalis Streptococcus pneumoniae , Streptococcus pyogenes* , Neisseria sp. Enterobacteriaceae, *Escherichia coli* , Proteus sp. *Pseudomonas aeruginosa, Haemophilus influenzae*, Bacteroides sp, *Bifidobacterium bifidum,* Lactobacillus sp. Clostridium sp. ie *Clostridium tetani/difficile,* Corynebacteria, Mycobacteria, Actinomycetes, Spirochetes Mycoplasmas
- Personal hygiene /health

Water

L.

- Legionella bacteria
- Aeromonas
- Pseudomonas aeruginosa
- Filimentous fungi.

- “Taken collectively, this degree of challenge to sterilization and disinfection systems is extraordinarily excessive”.

Incidences

- Surgical site infections linked to contaminated surgical instruments.
- Skin flora including coagulase-negative staphylococci and Bacillus spp. were recovered from a range of patient specimens. Microbiological processing of surgical packs revealed coagulase-negative staphylococci and Bacillus spp. from inner packaging as well as from instruments themselves.
- Inspection of the sterilization plant highlighted inadequate maintenance of autoclave components and poor handling practices by staff.
- This was compounded by lapses in inspection of surgical sets by theatre staff.

Dancer SJ, Stewart M, Coulombe C, Gregori A, Virdi MSurgical site infections linked to contaminated surgical instruments. J Hosp Infect. 2012 Aug;81(4):231-8

- It is critical to provide evidence that control systems, individually and in combination, are effective in maintaining the environment, thus ensuring the decontamination status of the RIMD/flexible scope has not been compromised

- To best ensure the welfare and safety of personnel working within that environment.

International Standards

- ISO 14644-1:1999 Cleanrooms and associated controlled environments. Classification of air cleanliness
- ISO 14644-2:2005 Cleanrooms and associated controlled environments. Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
- ISO 14644-3:2005 Cleanrooms and associated controlled environments. Test methods
- ISO 14644-4:2001 Cleanrooms and associated controlled environments. Design, construction and start-up
- ISO 14644-5:2004 Cleanrooms and associated controlled environments. Operations
- ISO 14644-6:2007 Cleanrooms and associated controlled environments. Vocabulary
- ISO 14644-7:2004 Cleanrooms and associated controlled environments. Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
- ISO 14644-8:2006 Cleanrooms and associated controlled environments. Classification of airborne molecular contamination
- ISO 14698-1, Cleanrooms and associated controlled environments --Biocontamination control, Part 1: General principles and methods
- ISO 14698-2, Cleanrooms and associated controlled environments--Biocontamination control, Part 2: Evaluation and interpretation of biocontamination data