Southend University Hospital NHS
NHS Foundation Trust

Centralized Decontamination Services

Environmental control in the Inspection, Assembly & Packaging (IAP) Room

Exactly what is the ‘environment’?

- The atmosphere?
- The building, walls, floor, ceiling and doors etc.?
- The furniture, cleaning the clean room?
- Anything else in the area, including the people?
- What about the raw materials including the reusable invasive medical devices (RIMD’s - instruments) ?

How are you going to control the environment ?

- What environmental controls do you need?
- What are you going to measure?
- How are you going to measure?
- When will measurements take place?
- Who is going to measure?
- What are you hoping to achieve?

What do you have already to help reduce adverse impact?

- Building regulations
- Ventilation requirements
- Access controls
- Raw materials – ISO's
- Washer disinfectors
- ??People controls

Building regulations

- Health Building Note 13 – Sterile Services Departments
- Floor finishes should turn up the wall & avoid dust traps
- Walls should be of solid construction with an epoxy coating or sprayed paint finish.
- Ceilings should be designed so that no access is required from within the IAP room
- Doors should be interlocked and open towards the higher pressure

Ventilation requirements

- Class 8 clean room – BS EN ISO 14664
- 20 air changes an hour
- Not less than 10 Pa differential between adjoining rooms
- Door alarms
- Sealed, non-opening windows

Access Controls

- Interlocking doors
- Transfer hatches
- Alarms – lights? Noise?
- Key-pad control
- Work instructions

Cleaning the IAP room

- Internal cleaners store
- Only source of running water/drain
- Dedicated cleaning materials/preferably dedicated cleaner
- Protective IAP clothing must be worn
- Time of cleaning

Cleaning - continued

- Protocols of cleaners tasks
- Agree which chemistries are used
- Non linting cloths
- Wear IAP clothing – the same way as technicians
- Maintenance programmes for equipment used – filters etc.

Yet more cleaning -

- Technician responsibility
- Tidy work space
- Clean work surfaces before every work session
- Weekly clean of any shelves or other flat surfaces
- Clean trolleys, air hose and fume cabinet daily,
- What about paper racks, computer, printer, telephone, scanners tape dispensers?????

Raw materials

- ISO’s – how effective are they?
- How do you demonstrate that?
- Dedicated feeder store
- RIMD’s direct from washer disinfectors
- Acceptance work procedure

RIMD's – the non automated clean?

- Cleaned by hand, not disinfected?
- Transfer via hatch
- Gloves?
- Hand washing?
- Door handles?
- Any impact?

People

- Hand hygiene
- IAP clothing
- Entry and exit procedures, physical movement
- Mobile phones
- Make-up
- ~~Food & drink~~

Validation

- Microbial contamination – viable or potentially viable elements of bacteria, fungi or viruses
- Prions
- Airborne microbial count using settle plates, standard swab technique work surfaces
- Record keeping, setting alert limits and action levels
- Raw materials, RIMD’s – bio burden testing

Downside of methods

- Test media
- Universal growth culture
- What don’t we know
- False sense of security
- What we need is not available

Challenges – what will impact on results?

- Number of people in the IAP room
- General health, head colds
- Type of RIMD's in room – some harder to clean than others
- Time of testing compared to time of room cleaning
- Settle plates – false picture?
- Comparison data – what is our starting point?

What do we want to achieve?

- Safe to produce product
- Consistent results?
- Is a ‘snap shot’ enough?
- Where are the products if you get a failure in your testing?

Is it achievable?

- Monitor the results
- Evaluate and investigate changes in results
- Reduce the risk
- Record actions taken
- Re-evaluate alert levels

Any questions??

Thank you for listening:

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