

Workshop B – Cold Chain

Topic - Purchasing and installing a new fridge or freezer

1. What do you need to do?

- Determine need i.e. new or replacement
 - Determine design i.e. walk in, freestanding
 - Determine capacity
 - Produce specification of requirement- e.g. Maintain 2-6C throughout
 - Alarm for temperature deviations
 - Door open alarms
 - Calibrated probes
 - Calibrated chart recorder or digital read out
 - Service maintenance contract
 - Fridge monitoring system to be included? (This will need to be validated)
 - Write a business case
 - Tender process and set up of contract
 - On receipt check manufacturers instruction
 - Sign, check and file manufacturers installation documentation
 - Perform validation- IQ->OQ->PQ
- IQ-** Check installation paper work and reference in validation doc
Check functionality- on/off switch, temperature log, alarms working,
Set alarms Upper/lower limits; Door open, Alarm delays
Check link to external/ remote alarm monitoring system working,
Set up probes as air/sample temperature alarms
Check calibration certificates are in date, check calibration certificate of the test equipment and ensure this is in date,
Record of cleaning
Set up temperature logs (electronic/ manual)
Set up alarm log
Power supply, generator test, UPS test
- OQ-** Temperature map – dataloggers on each shelf (or more if large fridge/freezer)
Run for 24 hrs door closed
Run for 24hrs opening and closing door
Simulate receipt of large order. (How long would door be open?)
Check/challenge alarms work as set
Check accuracy of displays/chart recorder
Check /challenge alarms for external /remote alarm monitoring system
Set up probes so that they are in hot or cold spots
- PQ-** Monitor during routine use
Check loggers/ display or remote system daily
Check alarm logs
Check daily temperature log (manual or electronic)
- Continuous power supply, if not available perform risk assessment

2. What documentation would you put in place to support this?

- Equipment specification
- Contract with manufacturer
- Installation documentation
- Calibration certificates for displays and probes
- Validation documentation IQ, OQ, PQ

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- SOPs - use of equipment, routine recording of temps etc
Management of alarms – to include reason for the alarm sounding.
Immediate action, corrective and preventative action
Out of hours management
- Alarm log
- Daily temperature log
- Details of actions if maintenance contract not met
- Maintenance log (critical setting checked prior to placing back in use)
- Training and competency records
- Audit records

- Fridge failure – contingency plan

3. What are the barriers? (staff and money are givens)

- Getting specification right in the first place – space, access, security, satellite issues, maintained power supply
- Complexity of validation
- Ensuring records kept, alarms responded to – training
- Training of staff outside department if they are responding to alarms

4. What processes will you introduce to manage deviations?

- Alarm logs should be annotated with action taken or linked to an Incident report.
Corrective action – can you use product or should it be discarded. Who can make this decision?
- Was product moved, does equipment need repair etc
- Contingency plan in case of failure
- Incident log to include trending
- Audit for deviations

5. What can OIG/BSMS do to help?

- Standards – see reference list
- Produce examples of model validation scripts/specifications/maintenance records
- Share documents