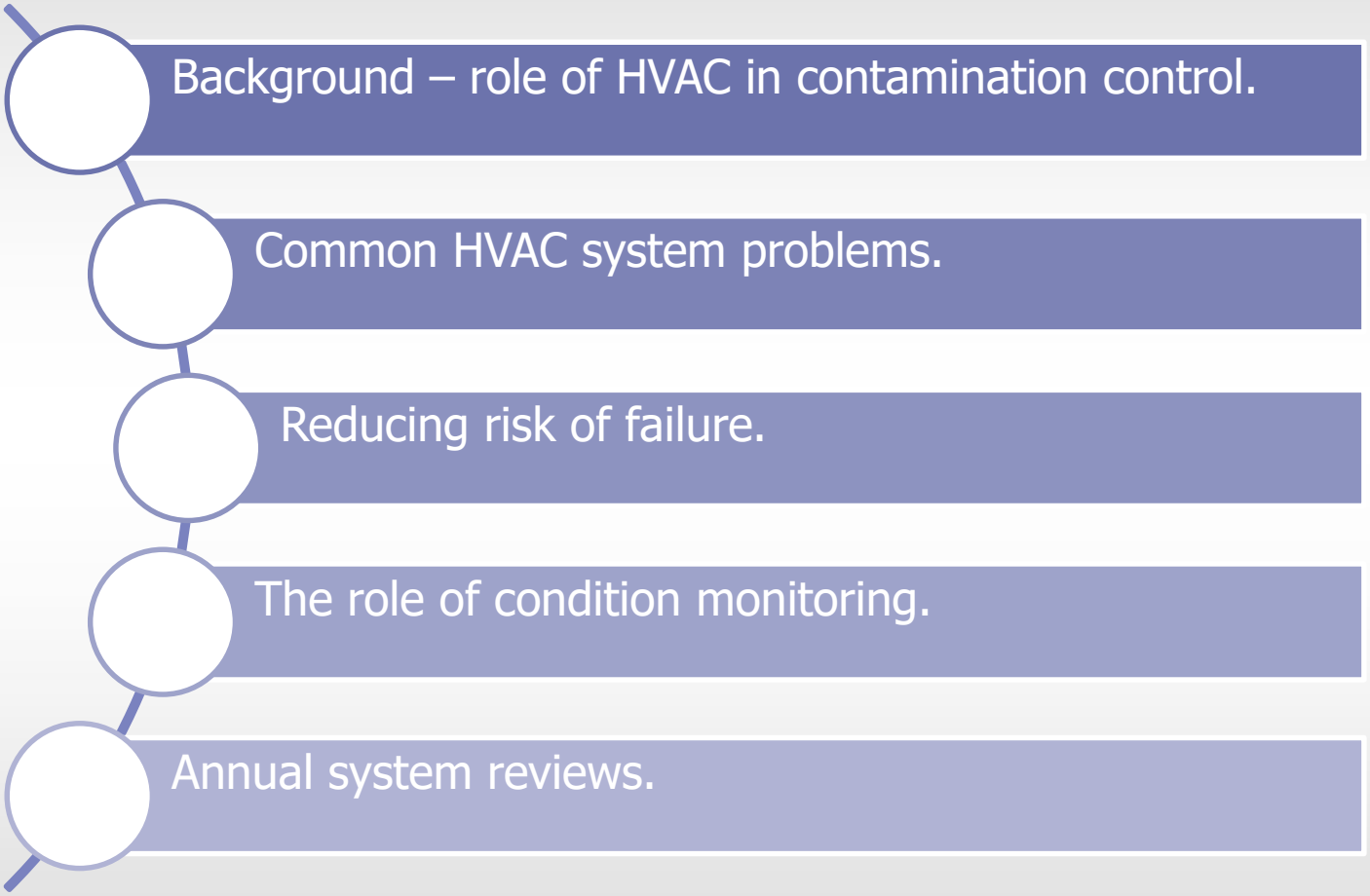
HVAC Systems Failure Modes

Gordon Farquharson

August 2015

Agenda



Role of HVAC systems in cross-contamination control

HVAC nearly always works in conjunction with the facility and the process equipment to do some or all of the following:

- Create the pressure differential regime.
- Deliver a source of clean air to dilute airborne contaminants in a process room.
- Provide process extract systems to dust collection systems:
  - LEV point extract.
  - Extract to machine enclosures and de-dusters.
- Where appropriate, recirculation systems to contain HEPA filters to prevent airborne contamination.

Essential starting point

- GEP (Good Engineering Practices) – the essential foundation.
- Technical design review, checking calculations, design file. [beyond DQ]
- Effective QC during installation.
- Rigorous commissioning programme.
- Effective, added value installation records.
- Practical tested operational procedures.
- Implemented planned preventative maintenance programme.
- Periodic systems reviews (12 or 24 monthly).
- Effective qualification programme.

Looking at the failure modes

I will look at typical failures I have experienced in the context of cross-contamination control.

- Consider the effect of the failure,
- how it might be detected,
- the likely severity,
- and a mitigation measure that might be considered.

Fans & drives

Failure mode	Cause / Effect	Severity	Mitigation
Motor or contactor failure.	Loss of control of critical parameters. -Air flow. -Pressurisation.	Prod/process criticality dependent: BMS detected. -Bio-containment. -Chem-containment. -Sterile. -Non-sterile.	Standby motors. Assess Risk/cost balance. Temperature detection in control panels.
Drive belt break.	Loss of control of critical parameters. Air flow. -Pressurisation.	Prod/process criticality dependent: BMS detected. -Bio-containment. -Chem-containment. -Sterile. -Non-sterile.	Direct drive fans. Standby drives. Assess Risk/cost balance.
Fan failure.	Loss of control of critical parameters. Air flow. -Pressurisation.	Prod/process criticality dependent: BMS detected. -Bio-containment. -Chem-containment. -Sterile. -Non-sterile.	Standby fans. Assess Risk/cost balance. Vibration monitor.

Air filtration

Failure mode	Cause / Effect	Severity	Mitigation
Outside air filtration blockage. (normal & abnormal events)	Loss of ventilation. Loss of pressurisation air. Disruption to replace.	Prod/process criticality dependent: BMS detected. -Bio-containment. -Chem-containment. -Sterile. -Non-sterile.	Predictive fouling rate. Design for live change-out. Duplicate outside air filtration.
Pre-filtration blockage.	Loss of ventilation. Loss of pressurisation air. Disruption to replace flters.	Prod/process criticality dependent: BMS detected. -Bio-containment. -Chem-containment. -Sterile. -Non-sterile.	Predictive fouling rate. Design adequate life/capacity.
Final HEPA fouling	Loss of ventilation. Loss of pressurisation air. Disruption to replace filters.	Severe in pact on cleanroom or containment facility operation.	Monitor fouling by periodic test, or predictive fouling rate. Improve pre-filtration.

Air filtration

Failure mode	Cause / Effect	Severity	Mitigation
Final HEPA filter leak test failure.	Housing problems. Filter damage. Testing errors. Too great airflow	Safety and GMP ventilation systems. Non compliance. Failure to control contamination levels.	Specification. Installation QC. Commissioning. Periodic tests.

Psychometric processes

(physical and thermodynamic properties of gas-vapour mixtures)

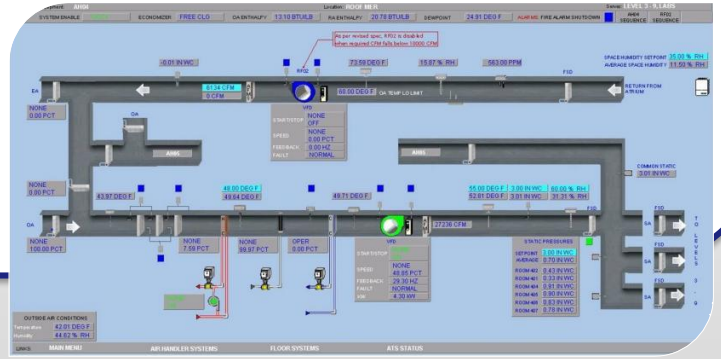
Failure mode	Cause / Effect	Severity	Mitigation
Flooding of cooling coil chamber	Water carry-over. Micro problems. Corrosion. Disruption to repair.	Difficult to detect, until flooding occurs.	Effective maintenance; inspection; water detection.
Heating coil or heating utility failure	Inability to maintain conditions.	GMP or non-GMP parameter.	Detect parameter drift by BMS or FMS. Detect system failure by BMS.
Cooling coil or cooling utility failure	Inability to maintain conditions.	GMP or non-GMP parameter.	Detect parameter drift by BMS or FMS. Detect system failure by BMS.

Room pressurisation

Failure mode	Cause / Effect	Severity	Mitigation
Differentials fail.	Doors left open. Leakage change. Process impact in room.	GMP or Safety deviation.	Door alarms. Auto-pressure control.
All levels rise/fall simultaneously.	Wind effect on intake. Airflow unstable.	May not lead to a Δp issue.	Design. Commission, monitor & correct.
General note:	My experience about room or device pressurisation: • HVAC - Most frequent CPP to go wrong. • Δp is defined requirement in GMP and Bio0-safety guidance. • Often inadequate design allowance for leakage. • Poor installation quality means leakage often greater than expected. • Instability of active control systems; and adverse affect of air volume reduction systems for energy saving. • HVAC fiddling to rectify can lead to other system performance problems.		

Thoughts on condition monitoring

- Becomes more valuable if we have labour cost reduction as a target.
- Easily added to most BMS systems.
- Engineering responsibility principally.
- Parameters to consider:
  - Energy consumption.
  - Air filter fouling rate – predictive endpoint. Can avoid excessive time-based filter change.
  - Vibration monitoring – bearings, fan impellers, drives.
  - Temperature monitoring in Motor control centres and control panels.
  - Water leakage detection.



And finally:
Annual HVAC system reviews

- Engineering driven reviews.
- May be an indicator of need for replacement or upgrade.
- I'm a great believer in these to look for trends in deterioration:
  - Generally engineering systems deteriorate with age.
  - From the PPM programme. Nature and frequency of repairs.
  - Performance of outsourced parties (maintenance & testing).
  - Failures – type, severity & frequency.
  - Spares holding and obsolescence.

PharmOut
Regulatory Knowledge, Practically Applied.

Thank you for your time.
Questions?

Gordon Farquharson
Executive Consultant

gordon.farquharson@pharmout.net
www.pharmout.net