

Workshop B – Cold Chain

Topic - Routine management of a fridge or freezer

1. What do you need to do?

- Daily checks on max/min thermometers or daily download of data loggers or check of electronic records
- Daily checks on alarm logs
- Check for all recorded alarms appropriate action has been
- Ensure routine maintenance and calibration contract is in place
- Routine calibration of probes traceable to National standards (as found and as left measurements)
- Review frequency of calibration
- Regularly review SOPs
- Monitor contents/ stock rotation

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

- SOPs
- Temperature logs
- Alarm logs
- Quality incident reports
- Calibration records
- Maintenance records/maintenance check list, critical settings check list
- Calibration test equipment certificates
- Training and competency records
- Audit records

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

- Ensuring records kept
- Ensuring correct actions taken in event of alarms
- Ensuring alarms are acted upon
- Calibration/temperature mapping of equipment
- Training – diversity of staff

4. What processes will you introduce to manage deviations?

- As for purchasing
- SOP on incident monitoring
- Reporting SAE/SAR
- Corrective action templates

5. What can OIG/BSMS do to help?

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