PHSS Guidance Document for Cold Storage Temperature Monitoring and Mapping for Blood Products

Gap analysis for blood transfusion laboratories,

	Compliance			
Summary of item			Action required	Responsible person(s) & timeframe
Section 1.1.2 All Blood Establishments, Hospital Blood Banks and organisations holding blood, components, medicinal products, reagents and test kits must ensure that GxP risk assessments are performed to minimise or negate risk to product and to prevent temperature excursions causing a detrimental effect on the integrity of any blood component or medicinal product				
5.1.2 User requirement specification produced and validated before equipment purchase				
5.1.3 Operational qualification includes assessment of performance during power outage				
5.2.1 Risk assessment to include method of monitoring and frequency of mapping				

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6.1.1 Specification of data loggers used for mapping defined as described in this section.				
6.1.2 New equipment mapped during qualification and before being put into use				
6.1.3 After delivery to the equipments final operating location all new fridges, freezers and incubators must be allowed to stand for 24 hours without electrical power to allow time for any oils or refrigerants to settle.				
6.1.4 Prior to mapping the equipment must be allowed time to run in order for all storage areas to reach the required temperature. In addition the mapping must be performed with the equipment running at the temperature it is expected to operate at and with the equipment classed as empty.				
6.1.5 Quality Assurance must approve each mapping before the next stage can take place.				

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6.2.1 The number of mapping locations will be dependant on the size and volume of the unit and the table [guidelines p. 5] is a guideline as to the numbers required and the potential location.				
6.3.1 Positioning of data loggers takes into consideration items listed. Areas designated as hot and cold spots should be clearly delineated and not used for storage				
6.4.1 Use multiple data loggers to reduce risk of logger failure				
6.5 In summary, assessment needed to show similarity of readings between those obtained by data loggers and monitoring probes.				
6.6 Data loggers set up as described				

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6.7 Requirement to map new equipment empty and fully loaded. Requirement for same post significant repair. Simulated load recommended. If a re-mapping can be carried out “in use” then the number of units present at the start and end of the mapping exercise must be included in the report. Also required for the report will be a log of all door opening events covering dates & times.				

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6.8.1 If equipment has been repaired or has had preventative maintenance performed upon it by internal or external engineers then documented checks should be performed before sign off.				
6.8.3 Immediate check post maintenance should be made on any monitoring probes to check that the engineer has not silenced them to prevent nuisance alarms during the maintenance and may have not reset them.				
6.8.4 A recorded check on the temperature should be made every 15 minutes for an hour to check for any unexpected drift from the expected temperature. Following the first hours then checks should be made at times when compressor changeover occurs to ensure that all settings are as expected.				
6.9 Post-significant repair procedures				

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6.10.1 Time interval for sampling during mapping not >5 minutes				
6.10.2 Primary mapping data must unaltered and stored securely.				
6.11.1 If a fridge or freezer in use has to be moved from one area of a department to another then the equipment should be moved with CTMDs present and set to record temperature. The data should be downloaded 24 hours after the move to ensure that temperatures have not been affected both during and after the move.				
6.12 Transport boxes – map when new. Annual remapping may not be necessary – determine by risk assessment. Take into account seasonal variation				

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7.1.1 All storage facilities for blood components, products and reagents to be continuously monitored, with alarms linked either to a manned service or a telephone alert system.				
7.2 Action in event of power failure				
7.3.1 Delay settings on alarms				
7.4 Temperature monitoring				
7.4.4 Max/min temperatures exceeded. Discard product if duration of deviation unknown. Daily check required, including weekend and holidays				
7.4.6 Chart recorder must be calibrated. Review to ensure the pen is in the same position after the chart was changed as previous				
7.5.1 Data loggers to be calibrated at a minimum of three points to cover temperature range required				
7.7.4 Blood transport boxes may require data logger when used, depending on journey time				

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8.0 Out of specification temperatures				
8.1.5 Activation of an air probe must be treated as an early warning. When core temperature limits are exceeded a Quality Incident / Adverse Event must be raised irrespective of whether products are removed or not.				
8.2.1 Guidance on action if continuous temperature monitoring fails. Log for manual monitoring should be available for each piece of equipment				
8.2.3 Items to consider				