

Schedule 3.4 – Temperature Mapping Service

AGREEMENT NUMBER:	
PROJECT REFERENCE:	
NUMBER OF VISITS:	
MINIMUM MAPPING PERIOD:	

	Service Options	Included
1	Refrigerated fixture temperature mapping	
2	Cold storage & walk in freezer temperature mapping	
3	Ambient warehouse temperature mapping	

1.0 Temperature Mapping Service

- 1.1 From the commencement date of this Agreement for an initial period of the minimum term and thereafter, TMS will undertake temperature mapping of Customer specified Monitored Equipment, located at Customer's sites that were listed during the system installation or are otherwise agreed in writing to be included under this Agreement.
- 1.2 TMS commitment under the terms of this Agreement is to provide an onsite temperature mapping service at frequencies agreed with the Customer on pre-agreed dates. The number and duration of planned visits are detailed in this Agreement.
- 1.3 On site temperature mapping will be carried out using UKAS accredited ISO17025 calibrated and traceable electronic temperature data loggers, and documented in accordance with the appropriate TMS standard operating procedure.
- 1.4 The dates of the temperature mapping work will be pre-agreed with the customer before our engineers visit site.
- 1.5 If we attend site on the agreed dates and are unable to perform the temperature mapping work for reasons outside of our control. This may result in extra charges being levied in the form of return visits.
- 1.6 TMS fixture temperature mapping protocols are fully described in our Temperature Mapping Protocol SOP QD-811 and guidance on process and acceptance criteria is derived from the Pharmaceutical & Healthcare Sciences Society's 'Guidance Document for Cold Storage Temperature Monitoring and Mapping for Blood Products', 01/03/2003.
- 1.7 A temperature mapping report will be provided to enable Customer to determine the temperature profile of their storage refrigerators, freezers and incubators (fixtures) containing time and temperature sensitive products.
- 1.8 The temperature mapping protocols are dependent on the status of the fixture under test. Regulators require that new storage fixture installations are mapped for a minimum period of 24-hours unloaded and thereafter for a further minimum period of 24 hours with the fixture loaded.
- 1.10 In the case of an existing fixture the requirement is for the fixture to be mapped for a minimum of 24-hours fully loaded.
- 1.11 The frequency of repeat temperature mapping is at the absolute discretion of the customer.
- 1.12 **During each mapping process the fixture door must be kept closed/sealed for the duration of the mapping period. The fixture will not be available to the customer personnel until the mapping period has ended. Further, no adjustment of the fixture operating temperature is permitted during the mapping period.**
- 1.13 Temperature mapping results will be reported to customer using standard report template QD-812.

2.0 Service Process

- 2.1 2 weeks prior to attending site we will send the customer a schedule of all fixtures that we have on record that we are intending to temperature map during our visit. The customer should review this schedule and notify us of any anomalies or missing fixtures that we should be made aware of.
- 2.2 Our technicians will require exclusive unrestricted access to customer fixtures in groups. During the actual mapping process these fixtures will not be available to the customer's personnel until mapping has been completed.

- 2.3 Our technician will need to freely access the fixtures to install the data loggers and this may require customer staff to assist by partially emptying a fixture if requested to do so. Our technicians are not permitted to remove product from any fixture.
- 2.4 In extreme circumstances, due to the build-up of ice, it may not be possible to carry out a temperature mapping on specific fixtures on the day. In these circumstances, we will notify you of the fixtures that may require defrosting and a further visit to site may be necessary to complete the mapping work.

Subsequent additional visits to site will be charged extra to the Agreement price.

3.0 Service Levels

3.1 TMS

- Pre-agree dates of site visits with customer.
- Issue a schedule of fixtures to customer prior to site visit.
- Review mapping processes with customer prior to starting work.
- Highlight fixtures will be unavailable during mapping process.
- Agree the scope of mapping with the customer.
- Issue compliant mapping reports on completion of work.

CUSTOMER

- Notify TMS of any planned replacement of fixtures necessitating follow up mapping work.
- Provide TMS with all reasonable support and access to the onsite Monitored Equipment being mapped.
- Ensure that the fixture door remains sealed at all time during the mapping process.

4.0 Key Performance Indicators

- TMS continues to hold UKAS ISO17025 accreditation.
- 2 week notice of planned site attendance.
- Mapping reports issued within 2 weeks of completion of work.