STANDARD OPERATING PROCEDURE FOR TEMPERATURE MONITORING OF R&D FRIDGES AND FREEZERS

SOP NUMBER:	**Fife R&D SOP 46**
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1. PURPOSE

This document describes the procedure for dealing with Kelsius alerts when there are temperature excursions out of the specified range for the fridges and freezers in both the R&D Department at Queen Margaret Hospital (QMH) and the Clinical Research Facility (CRF) at Victoria Hospital Kirkcaldy (VHK).

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via NHS Fife StaffLink, EDGE and the R&D section of the NHS Fife website (www.nhsfife.org/research). For guidance, contact the R&D Department via fife.randd@nhs.scot.

2. APPLICABILITY

This SOP applies to all staff in the NHS Fife R&D Department and any other staff using the fridges and freezers in the CRF at Victoria Hospital and/or the laboratory area within the R&D Department at Queen Margaret Hospital.

3. POLICY

3.1 All fridges and freezers used for the storage of research samples (e.g. blood and tissue samples and Investigational Medicinal Products (IMPs)) require temperature monitoring to ensure each piece of equipment is working within its specified range. See R&D SOP43 for additional requirements relating to the storage of IMP outside of the Pharmacy Department.

3.2 For use of fridges and freezers refer to R&D WI13.

3.3 Acceptable ranges for the fridges and freezers are as follows:

Appliance Type	Nominal Temperature (°C)	Acceptable Range (°C)
Lab Fridge	+4	+2 to +8
Lab Freezer	-20	-15 to -25
Lab Freezer	-40	-30 to -50
Lab Freezer	-80	-60 to -100

3.4 The temperatures of all fridges and freezers in the Laboratory Areas in the Clinical Research Facility, VHK and R&D Department, QMH are monitored and recorded every 5 minutes using the KELSIUS system.

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3.5 Kelsius is a wireless automated system which uses sensors in the fridges and freezers to continuously monitor the temperature of each of piece of equipment and the temperature data is then sent back to the Kelsius website.

3.6 Current temperature information for the sensors is shown on the 'network controller' - a small box which is wall mounted in each lab area (see Figure 1).

Figure 1. Network Controller

3.7 User Manuals for the Kelsius Web Based Portal (Kelsius CoolCheck User Manual USM001) and the wall mounted Network Controller in each laboratory area (Kelsius Network Controller User Manual USM002) are available via the SOP46 folder in the R&D section of StaffLink or can be downloaded by authorised users from the Web based Kelsius portal https://portal.kelsius.com/current/portal/logon.php via the 'Documents and Manuals' Tab.

4. PROCEDURE

4.1 Dealing with Temperature Excursions

If there is a temperature excursion outside of the specified range an alert will register on the Network Controller in the relevant lab area and an audible and/or visible alarm will be activated. An email and text alert will also be sent to the Assistant R&D Director, Lead R&D Research Nurse, R&D Quality & Performance Lead (fife.researchquality@nhs.scot) and generic R&D email address (fife.randd@nhs.scot).

Instructions (see Appendix 1) for silencing the alarm on the Network Controller can be found on the wall beside the Network Controller in each lab area.

4.1.1 During Normal Office Hours

4.1.1.1 Any member of staff becoming aware of an alarm must investigate to determine the cause of the alarm.

4.1.1.2 The alarm must be disabled using the network controller (see Fig 1) as follows:
- Press the '#' key
- Enter personal 4 digit pin number (if available) or the generic R&D Pin Number available via the instruction in each lab area.
- Select the number of the fridge or freezer sensor - usually no:1
- Press '1' - this changes the channel to SERVICE.
- Press '1' again - this changes the channel to MAINTAIN.

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- Press the 'A' key to accept the changes.

The channel should now read as 'MAINTAIN'.

Details of the steps above are also provided in a laminated poster (see Appendix 1) located in each R&D laboratory area on the wall beside the Network Controller.

4.1.1.3 If the temperature excursion is due to a fault with the fridge or freezer the contents must be transferred to another fridge/freezer and the faulty equipment reported to the Estates Department via the MICAD – Estates online job request portal which can be found in QuickLinks in the Business System List.

4.1.1.4 The reason for the temperature excursion and any actions taken must be recorded in the Kelsius Alarm Log located within each Laboratory Area (Doc Ref 46-01). If the fridge/freezer contents are transferred then the time of transfer must also be recorded, and the details added to the new Fridge/Freezer Inventory Log.

A copy of the Kelsius alert log must be emailed to the R&D Quality & Performance Team (fife.researchquality@nhs.scot).

4.1.1.5 Once set to 'MAINTAIN' – the alarm will be disabled indefinitely and will NOT become active again until it is set it back to 'NORMAL'. Once the issue with the equipment has been rectified, the R&D Quality & Performance Lead or delegate must monitor the temperature of the fridge/freezer via the Kelsius portal and then reset the sensor to 'Normal' once the temperature is within the required range specified for that particular piece of equipment.

4.1.1.6 The R&D Quality & Performance Lead or delegate must record details of the temperature excursion and corrective action on Kelsius via the web portal following instructions below:
- Log onto Kelsius - https://portal.kelsius.com/current/portal/logon.php using their Username and Password.
- The home page will show the fridge or freezer which has alerted.
- Click onto 'Alert Events'.
- Click on ✎ to add a corrective action specific to the alarm.
- Type in word verification.
- Enter a 4-digit pin code.
- Click next.
- Enter corrective action either by selecting an option from the drop-down list or type in the reason and any action taken.
- Close alert and save.
- This must be done for both sensors.
- The 'Home' page should now be clear of that alert.

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Page 3 of 6

4.1.2 Outside of Normal Office Hours

4.1.2.1 On receiving a text or email alert the R&D Quality & Performance Lead or delegate must log in to the Kelsius Web based portal to try to confirm if the alert is due to a system communication failure, temporary temperature fluctuation or an issue which may require immediate action to protect the integrity of the fridge/freezer contents.

4.1.2.2 Having reviewed the details of the alert on the Kelsius Web based Portal, the R&D Quality & Performance Lead or delegate must contact the Lead R&D Research Nurse to advise of the nature of the alert.

4.1.2.3 Where the alert appears to indicate a failure of the fridge/freezer the Lead R&D Research nurse (or delegate) must investigate immediately to determine the cause and steps 4.1.1.2 – 4.1.1.6 above must then be followed.

4.1.3 Once a faulty fridge or freezer has been repaired, samples can be transferred back to their original location.

4.1.4 Where clear evidence of defrosting has occurred, the affected samples must be kept separate from unaffected samples, clearly labelled and stored at the correct temperature at the earliest opportunity.

4.1.5 For each study with samples affected by any temperature excursion, a file note must be prepared by the appropriate study team, detailing which samples were affected and the length of time samples were affected. A copy of this file note must be added to the relevant site file and circulated to the study Sponsor. Advice must be sought from Sponsors as to the viability and eventual disposal of any affected samples.

4.2 Monthly Review of Kelsius Reports

4.2.1 At the start of each month the KELSIUS report for the preceding month should be accessed by the R&D Quality and Performance Lead or delegate through the Kelsius website by following the steps below:
- Log into website using personal account https://portal.kelsius.com/current/portal/logon.php.
- From the menu, click on Sensor Graphs then Temperature Sensor Groups.
- Select the required sensors from the sensor list. Multiple sensors can be selected by holding down the 'shift' key on your keyboard.
- Select 'Last Month' from the drop-down menu.
- Click on 'Display'
- Download the detailed record and save in the relevant Temperature Monitoring Folder (T:\Research and Development\TEMPERATURE MONITORING - QMH & CRF depending on the location (QMH or VHK)). A copy must also be uploaded to the Monthly Kelsius Reports folder in the General Documents in EDGE. The file name should follow the standard format (YEAR-MONTH – LOCATION BASE e.g. 2018-07-VHK).

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Page 4 of 6

4.2.3 If there have been any temperature excursions, a detailed printout of the temperature data for the locations that had the excursion should be obtained by the R&D Quality and Performance Lead or delegate as follows:

- From the menu, click on 'Sensor Graphs' then 'Temperature Sensors'.
- The date range should be changed to generate a report for the specific date(s) and time(s) of the excursion(s).
- Select the appropriate sensor from the drop-down menu.
- Click on 'Display Chart'.
- Download the detailed record as a PDF and save as detailed in 4.2.1.

5. ASSOCIATED DOCUMENTS

R&D WI13 Use and Control of Fridges and Freezers
Doc Ref WI13-01 - Temperature Log
R&D SOP43 Temperature Monitoring of Investigational Medicinal Products Stored outside Pharmacy
Kelsius Cool Check User Manual USM001
Kelsius Network Controller User Manual USM002 Revision

6. ABBREVIATIONS

CRF   Clinical Research Facility
IMP   Investigational Medicinal Product
QMH   Queen Margaret Hospital
R&D   Research & Development
SOP   Standard operating procedure
VHK   Victoria Hospital Kirkcaldy
WI   Working Instruction

7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Quality & Performance Lead	30 Aug 2021	New

8. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature:	02 Aug 2021

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APPENDIX 1

INSTRUCTIONS FOR DEALING WITH KELSIUS ALARM

1. Disable the alarm – using the network controller

   - Press the '#' key
   - Enter your 4 personal digit pin number (if available) or the generic R&D Pin Number
   - Select the number of the fridge or freezer sensor - usually no:1
   - Press '1' - this changes the channel to SERVICE.
   - Press '1' again - this changes the channel to MAINTAIN.
   - Press the 'A' key to accept the changes.

   The channel should now read as 'MAINTAIN' and will be disabled indefinitely.

3. Telephone the R&D Quality & Performance Lead to discuss the best course of action.

4. Record details of the temperature excursion, and any actions taken on the Kelsius Alert log which can be found in the lab area.

5. Scan the Kelsius Alert log and email to the R&D Quality & Performance Lead (Fife.Researchquality@nhs.scot).

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Page 6 of 6

Fife R&D SOP 46, Version 1   Effective Date: 30 Aug 2021