



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Multidisciplinary Policy and Procedure		
Title:	Corrective Action Taken for Fridge and other Temperature Dependent Equipment Temperature Changes		
Applies To:	All Laboratory Staff and Biomedical Engineers		
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1. PURPOSE:

- 1.1 To ensure the integrity of the materials stored in the Temperature Dependent Equipment (TDE) and determine if any deterioration has occurred to them during TDE out of range temperature event.

2. DEFINITIONS:

- 2.1 Temperature Dependent Equipment (TDE) is any equipment in the LAB that must be set for specific range of temperature e.g.: Refrigerators, Freezers.

3. POLICY:

- 3.1 If the TDE's temperature found to be outside of the permitted range, then corrective action should be taken. The length of time, room ambient temperature, the degree of variance in the TDE temperature and the manufacturer's recommendations for material storage and their stability are used to determine what actions are necessary.

4. PROCEDURE:

- 4.1 All TDE should be temperature monitored.
- 4.2 While regular checking of the TDE temperature, any readings falls outside the permitted range should be recorded in the log sheet along with the corrective action taken.
- 4.3 If the TDE cannot be repaired or temperature cannot be corrected within 60 minutes for refrigerator or 30 minutes for freezer, then the stored materials should be transferred to another TDE with same temperature range.
- 4.4 Mark the equipment with sticker (out of order don't use) where the temperature maintenance has failed to prevent further use till corrective action is completed and the temperature check is satisfactory.
- 4.5 The materials inside the TDE should be checked to determine if any deterioration has occurred like any changes in the physical appearance.
- 4.6 The affected materials should be separated and marked to indicate possible quality problems and transferred to another equipment of same temperature range.
- 4.7 Corrective actions for those materials should at least include parallel testing as done when new materials are received in the laboratory such as Quality Control Testing.

5. MATERIALS AND EQUIPMENT:

- 5.1 Table is used to record the corrective action done in the event of out of range temperature of any TDE in the **Appendix 7.1**

6. RESPONSIBILITIES:

- 6.1 Laboratory staff - If the temperature reading of a TDE is outside the permitted range, it is the responsibility of the laboratory staff to report it and any other findings to the Lab Director and biomedical engineering Department immediately and do the corrective actions needed according to the LAB policy.
- 6.2 Biomedical engineers

7. APPENDICES:

- 7.1 Table is used to record the corrective action done in the event of out of range temperature of any TDE in the LAB.

8. REFERENCES:

- 8.1 Food Safety manual, Durham University, January 2006.
- 8.2 House Rules Temperature Control, Cook Safe Food Safety Assurance System Issue 1.1, July 2005.
- 8.3 Assessment of a remote alarm system for vaccine storage in Albania, July 2011.

9. APPROVALS:

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المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

TEMPERATURE DEPENDENT EQUIPMENT CORRECTIVE ACTION FORM

Problem	
Date:	Time:
Section:	Equipment Type:
Serial Number:	Room Ambient Temp.:
Assigned Temperature Range:	Out of Range Temperature Reading:
Length of Temperature Change:	
Problem Description:	
Corrective Action	
Date:	Time:
Check Equipment Power Source?	<input type="radio"/> Yes <input type="radio"/> No
Can the equipment be repaired within recommended time? (Refrigerator – Within 60 Min) (Freezer – Within 30 Min)	<input type="radio"/> Yes <input type="radio"/> No
Biomedical Engineer Notified at (Date / Time):	
Items Removed / Transferred to Another Equipment?	<input type="radio"/> Yes <input type="radio"/> No
New location of the items moved:	
Corrective Action Taken: 1. For Equipment: 2. For Material:	
Reporting Laboratory Staff Name and Signature:	
Laboratory Director Name and Signature:	