HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Selection, Installation and Identification of Critical Laboratory Equipment		
Applies To:	All Laboratory and Blood Bank Staff		
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1. PURPOSE:

1.1 The management of the laboratory ensures that equipment is properly selected, installed, validated, maintained and disposed of according to established procedures and manufacturer's instructions to meet the needs of the laboratory to perform quality diagnostic testing.

2. DEFINITONS:

2.1 Critical laboratory equipment: Analytical instrumentation and equipment affecting the accuracy or precision of a test method.

3. POLICY:

3.1 This policy applies to the critical laboratory equipment used by the laboratory, upon selection, installation, and validation of new equipment.

4. PROCEDURE:

4.1 Selecting the best instrument for the laboratory is a very important part of equipment management. Some criteria to consider when selecting laboratory equipment are listed below:

- 4.1.1 The instrument should be matched against the service the laboratory provides;
- 4.1.2 The performance characteristics of the instrument, it should be sufficiently accurate and reproducible to suit the needs of the testing to be done;
- 4.1.3 Facility requirements, including the requirements for physical space;
- 4.1.4 Reagents are readily available. And reagents should be provided free of charge for a limited period of time;
- 4.1.5 Easy to be operated by most staff;
- 4.1.6 Presence of a retailer for the equipment in the country, with available services.

4.2 Sources used for reviewing potential critical laboratory equipment:

- 4.2.1 A literature review;
- 4.2.2 Consultation with experts;
- 4.2.3 Requests for data and research results from clinical trials;
- 4.2.4 Discussions with other healthcare providers who use the same equipment;
- 4.2.5 Review of the history and fiscal standing of potential vendors.

4.3 On reception of the new instrument, it is the role of the laboratory it in cooperation with the biomedical engineers to check that the new instrument package contain all of the parts and it arrived in a good condition and it meets all the manufacturer's specifications.

4.4 Installation of critical laboratory equipment: Before equipment is installed, verify that all physical requirements (electrical, space, doors, ventilation, water supply, and waste drainage) have been met.

4.5 A checklist of the expected performance specifications should be developed, so that performance can be quickly verified as soon as the equipment is installed.

4.6 Whenever possible, it is best to have the manufacturer install laboratory equipment; this will likely improve the conditions of the warranty, and also may ensure that the installation is done properly and quickly.

4.7 After installation, the following should be addressed before putting into service:

- 4.7.1 Provide training for all operators; only personnel who have been trained specifically to properly use the equipment should be authorized as operators;
- 4.7.2 Assign responsibility for performing the maintenance and operation programs;
- 4.7.3 Establish a scheduled maintenance program that includes daily, weekly, and monthly maintenance tasks;
- 4.7.4 Prior to testing patient specimens, the performance of new equipment is to ensure it is working correctly with respect to accuracy and precision.

4.8 The laboratory shall evaluate each new piece of equipment: The validation process depends on the type of equipment and its use in the laboratory. Reproducibility and accuracy tests are performed, documented, reviewed and approved before the instrument is used in the testing environment.

4.9 The laboratory shall prepare a file for every critical laboratory equipment identifying:

- 4.9.1 Name of the equipment;
- 4.9.2 Brand (manufacturer);
- 4.9.3 Serial number;
- 4.9.4 Model and year;
- 4.9.5 Location;
- 4.9.6 Date of first use;
- 4.9.7 Type of maintenance (contract with an external company, in house, etc.);
- 4.9.8 Regular preventive maintenance to be performed and frequency to perform these activities;
- 4.9.9 Record of preventive maintenance activities.

5. MATERIALS AND EQUIPMENT:

5.1 File for critical equipment

6. RESPONSIBILITIES:

6.1 Laboratory manager
6.2 Head of sections

7. APPENDICES:

N/A

8. REFERENCES:

8.1 DAIDS Guidelines for Good Clinical Laboratory Practice Standards, Good Clinical Laboratory Practice Standards Final Version 3.0, 09 July 2013.

9. APPROVALS:

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