STANDARD OPERATING PROCEDURE MAINTENANCE AND CALIBRATION OF EQUIPMENT

LIABILITY COMPANIES

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CHANGE HISTORY

Version	Date	Reason for change
1.0	June 2012	First Version of the Document
2.0	December 2012	Adequacy of the procedure to the real equipment maintenance and calibration circuit.
3.0	January 2014	The procedure is modified to incorporate the agreements regarding responsibilities, owners of the inventory Excels, and the quarterly review of the Excel by General Services is incorporated.
4.0	April 2016	1 laboratories are modified for facilities 4 reference is added to the technical-sanitary requirements for phases I of the Generalitat de Catalunya, 4 the version of the ISO standards is deleted and replaced by the phrase "in its current version". 6, 8.1, 8.4.1, 8.4.2, 8.4.3, 8.4.4, 8.5, 10 added UITM

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1. PURPOSE

The purpose of this procedure is to establish the methodology and records necessary to maintain and calibrate VHIO equipment used in its facilities.

2. OBJECTIVE

The objective of this procedure is to guarantee the rigor and maximum accuracy of the measurements taken by the equipment.

3. SCOPE

This procedure is mandatory for all sampling, measuring, testing and control equipment that directly or indirectly affect or may affect the quality of the service provided to customers.

4. REFERENCES

	Document
[1]	ISO 9001, in its current version, Quality management systems: requirements
[2]	ISO 15189, in its current version, Clinical laboratories. Particular requirements for quality and competence
[3]	MA-GENER_0001 Quality Manual, current version
[4]	PR_GENER_0002 Preventive and corrective actions, in its current version
[5]	PR_GENER_0004 Supplier management and purchasing, in its current version
[6]	Document de treball Requisits EC phase I actualització 2014 Proposta 02-12-2014 versió Generalitat de Catalunya, Departament de Salut, Direcció General d'Ordenació i Regulació Sanitàries (Generalitat de Catalunya, Department of Health, Directorate General of Health Planning and Regulation)

5. DEFINITIONS

Terms	**Definition and activity**
Preventive maintenance	Maintenance activities carried out periodically according to criteria defined by the official equipment maintainer.
Corrective maintenance	Maintenance activities performed on equipment when an incident is detected in its normal operation.
Calibration	A set of operations that make it possible to establish the relationship between the values indicated by a measuring instrument and the values corresponding to a standard. The basic objective of calibration is to determine the degree of uncertainty of the measurements made with the equipment.
Supplier	Supplier of products and/or services.
Inventoriable equipment	Equipment susceptible to be controlled and monitored throughout its useful life to ensure its correct operation.

Generic equipment	Laboratory equipment that has a simple and standard functionality within the processes performed in the laboratory. They do not require specific maintenance.
Special equipment	Those laboratory equipments that have a complex functionality within the processes performed in the laboratory. They require specific maintenance.
SAP Integrated Management System (SIGS)	Software, based on SAP, that integrates all the information and management processes of VHIO.
Inventory control sheet	Sheet that collects all the inventoriable equipment and the associated characteristics and information. Complementary tool to GISS

6. RESPONSIBILITY

The responsibilities for the execution of this procedure are listed below:

- **Laboratory/ITU staff: Ensure** that work is performed on properly calibrated and functioning equipment.
- **Laboratory Quality Manager/ITMU**: person responsible for reviewing the alerts when the next calibration and/or maintenance dates are approaching in order to take the necessary steps, as well as to manage corrective maintenance incidents. They can have access to the corrective maintenance application of Vall d'Hebron Hospital.
- **VHIO General Services Manager:** Person responsible for identifying equipment, inventorying it and periodically reviewing its preventive and corrective maintenance.
- **Staff of the HVH electromedical department**: In charge of the corrective maintenance of generic equipment.

7. RESOURCES

The resources assumed to be available in this procedure are as follows:

- Inventory control sheet
- SIGS
- Corrective maintenance application for the Vall d'Hebron Hospital.
- Office tools for editing documents and databases.
- Disk storage space and the possibility of backup copies.
- Archiving space for hard copies.

8. PROCEDURE

The VHIO, through its Quality System, defines the methods and criteria to perform maintenance and calibration of the equipment and also record the interventions performed on each piece of equipment.

8.1. Tickets

The input of the procedure is the need to maintain and/or calibrate the equipment for its correct operation and compliance with applicable requirements. The input is also what is established in the current Maintenance Plan, prepared by each laboratory/ITU.

8.2. Exits

Optimal commissioning of equipment requiring systematic maintenance and calibration.

8.3. Diagram of flow

No diagram is specified for this procedure.

8.4. Procedure

8.4.1. Identification and registration of equipment

Upon receipt of the equipment by the laboratory/ITU, an e-mail is sent to the VHIO General Services Manager indicating receipt of the equipment. This e-mail must contain, at least, the following information:

- Date of receipt
- Name of equipment / model
- Date of commissioning
- Equipment location
- Location of equipment instructions
- Serial no.

The VHIO laboratory/UITM Quality Manager updates the equipment inventory Excel file with the above information. The rest of the necessary data will be filled in as General Services has them and communicates them to him/her.

After the acquisition of an inventoriable equipment (see PG_GENER_0004 Suppliers and Purchases Management) or the acceptance of an equipment on loan to the VHIO, the VHIO general services manager assigns a unique identification code to the equipment. Subsequently, he/she creates a label with this code and attaches it to a surface of the equipment where it is visible and does not interfere with its correct operation.

With this information, the database of suppliers of inventoriable products is updated in the GISS and the database of inventoriable products is updated in an Excel spreadsheet, containing the following information:

- Equipment identification code
- Name of equipment / model
- Name of manufacturer / supplier
- Serial number or other unique identification.
- Manufacturer's contact person and telephone number
- Date of receipt
- Date of commissioning
- Location
- Condition when received (new, used...), if applicable
- Location of manufacturer's instructions (default is at the purchasing laboratory)
- Nature of the right (Ownership of VHIO or Assignment of use)

- Price
- Termination of the warranty.
- Amortization time
- Maintenance contract

8.4.2. Preventive maintenance of special equipment

For this type of equipment, it is VHIO's policy to outsource the preventive (and corrective) maintenance service. To this end, following the provisions of PG_GENER_0004 Supplier and Purchasing Management, the VHIO's General Services Manager requests technical and economic offers from the supplier(s), always prioritizing the manufacturer's recommendations, and the procedure is followed until the final acceptance of the most suitable offer.

This preventive maintenance normally consists of a periodic visit (date to be agreed between the principal investigator / laboratory manager / quality manager and the supplier) of the contracted supplier's personnel to verify the correct operation of the equipment and to carry out the preventive maintenance actions.

The laboratory/ITMU quality manager records preventive maintenance operations performed on special equipment.

The supplier issues a certificate of the maintenance performed. This record is kept on file by the Laboratory / Quality Manager.

8.4.3. Corrective maintenance of equipment

For the corrective maintenance methodology for VHIO equipment, a distinction is made between two types of equipment.

8.4.3.1. Corrective maintenance of special equipment

The laboratory/ITU manager or the laboratory/ITU quality manager contacts the supplier and arranges with him a date for the *on-site* inspection of the equipment in question by a specialized operator.

The laboratory/ITMU manager or the laboratory/ITMU quality manager, after verifying correct operation, and updates the equipment inventory Excel file with this information.

In the event that the repair requires additional billing, the Laboratory/ITU Quality Manager contacts the equipment supplier for a quotation for the repair. When this quotation arrives, it is forwarded to the VHIO General Services Manager to follow, if applicable, the procedure PG_GENER_0004 for supplier management and purchasing for the processing of the quotation.

8.4.3.2. Corrective maintenance of generic equipment

Corrective maintenance for these types of equipment is carried out by the Electromedical Service of the Hospital de la Vall d'Hebron (HUVH).

If the equipment is under warranty, follow the process described in 8.4.3.1.

If the equipment is no longer under warranty, it is registered in the HUVH corrective maintenance application.

In the event that the laboratory/ITMU staff detects that there is an incidence related to the correct operation of any generic equipment, they communicate this fact to the laboratory quality manager. This person accesses the HUVH corrective maintenance application and makes a correction request through this application.

The HUVH Electromedicine Service staff, after receiving the correction request, travels to the laboratory and collects the equipment for repair, or performs the repair action on site.

The staff of the Electromedical Service of HUVH repairs the equipment and ensures its correct operation.

In the event that the HUVH Electromedicine Service staff cannot perform the repair, they contact the equipment supplier to make an offer for the repair. When this offer arrives, it is forwarded to the VHIO general services manager so that, if necessary, he can follow the procedure PG_GENER_0004 of supplier and purchase management for the processing of the offer.

Once the equipment has been repaired, the HUVH Electromedical Service or the external supplier verifies the correct operation in the original location of the laboratory.

The VHIO general services manager has access to the HUVH corrective maintenance application and keeps track of the equipment repair history. He also has a record of all corrective maintenance operations performed on generic equipment and their associated amounts.

8.4.4. Calibration of measuring equipment

The laboratory/ITU quality manager should periodically review to alert about calibrations nearing their expiration date.

Calibration of measuring equipment is managed in the same way as if it were another preventive maintenance activity.

It is VHIO policy to outsource the calibration service of all equipment (scales, thermometers, blood pressure monitors, medication dispensers, centrifuges, etc.). To this end, following the provisions of PG_GENER_0004 Supplier and Purchasing Management, the VHIO General Services Manager requests technical and economic offers from the supplier(s) and the established procedure is followed until the final acceptance of the most suitable offer.

There is a register with all the equipment to be calibrated and the date of the last time it has been verified, which is updated by the Laboratory/ITMU quality manager.

The calibration service normally consists of a periodic visit (date to be agreed between the laboratory/ITMU quality manager and the supplier) of the contracted supplier's personnel to calibrate the agreed equipment. Once this is done, and the inventory Excel file is updated.

The calibration supplier, a few days after the calibration has been performed, sends a report with the results and calibration certificates to the laboratory/ITU quality manager. These certificates indicate the approximate validity of the calibration and the original certificates are kept on file by the principal investigators/laboratory/quality managers.
The external company that has performed the calibration, whenever possible, attaches a label to the equipment indicating the validity of the calibration status.

8.5. Inventory review

On a quarterly basis, the Head of General Services performs a review of the maintenance and calibration Excel sheets maintained by each of the laboratories. The objective of this review is to ensure the correct compliance with the maintenance and/or calibration dates, the correct identification of the equipment and its traceability.
In the event that a discrepancy is detected, it should be discussed with the Laboratory/ITU Quality Manager to ensure correct data.
Evidence of the reviews performed shall be maintained by means of an e-mail communication from General Services to the Laboratory Manager/ITMU and the Laboratory Quality Manager, confirming their completion and summarizing the findings.

9. METRICS

There are no metrics identified in this procedure.

10. RECORDS

- Equipment status log.
- Record with the history of maintenance (preventive and corrective) and actions performed for each equipment.
- Calibration reports.
- Calibration certificates.
- Quarterly review mail of the Laboratory/ITU Maintenance Plan Excel sheet.

11. APPENDICES

There are no appendices for this procedure.