STANDARD OPERATING PROCEDURE

INTERNAL AUDITS

LIABILITY COMPANIES

EDITORIAL			
Name	**Responsibility**	**Signature**	**Date**

REVIEW			
Name	**Responsibility**	**Signature**	**Date**

APPROVAL			
Name	**Responsibility**	**Signature**	**Date**

CHANGE HISTORY

Version	Date	Reason for change
1.0	June 2012	First Version of the Document
2.0	April 2016	2 Objective, including reference to legislation/regulations/regulations 3 Scope, including UITM. 4 References, including a document of requirements for phase I units of the Generalitat de Catalunya. 4 the version of the ISO standards is deleted and replaced by the phrase "in its current version". 8.4.2.1 legislation on clinical trials is added

TABLE OF CONTENTS

.

1. PURPOSE

The purpose of this procedure is to specify the planning and execution of internal quality audits at VHIO.

2. OBJECTIVE

The objective of this procedure is to ensure that the VHIO has an adequate methodology to verify that its operations comply with the requirements of the quality management system and the regulations/legislation/standards that apply in each case.

3. SCOPE

This document concerns all activities related to the planning, conduct and results of internal audits of the Quality Management System, carried out by the auditor or audit team.

This procedure is mandatory for the technical and management elements of VHIO's quality system.

Also included in the scope of this procedure are specific audits of VHIO's Genomics and Molecular Oncology laboratories, as well as the UITM (Molecular Therapy Research Unit) of the Clinical Trials Office.

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 current version
[5]	PR_GENER_0007 Non-conformities, in 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**
Internal audit	It is the organization's internal and systematic tool for validating the effectiveness of its management system and ensuring the quality of its operations.
Nonconformity	Non-compliance with a requirement

Corrective actions	Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.

6. RESPONSIBILITY

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

- **Quality manager:** Plan and organize internal audits. Select the auditor or audit team. Once the reports with the results of the audit are available, it will be his responsibility to ensure the follow-up of the corrective actions t o be carried out.
- **Auditor or audit team:** Responsible for the execution of the audit. It is also responsible for the subsequent report of the audit results.
- **Responsible for the processes, departments or research groups as established in the procedures:** Collaborate with the Quality Manager in the selection of auditors, and with the auditor or audit team before, during and after the audit.
- **Management:** Collaborate if necessary in establishing the audit plan and be responsible for the review and approval of the audit results.

7. RESOURCES

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

- Office automation tools for editing reports.
- Disk storage space and the possibility of backup copies.
- Archiving space for hard copies.

8. PROCEDURE

The VHIO, through its quality management system, defines and implements a system for planning and executing internal audits.

8.1. Tickets

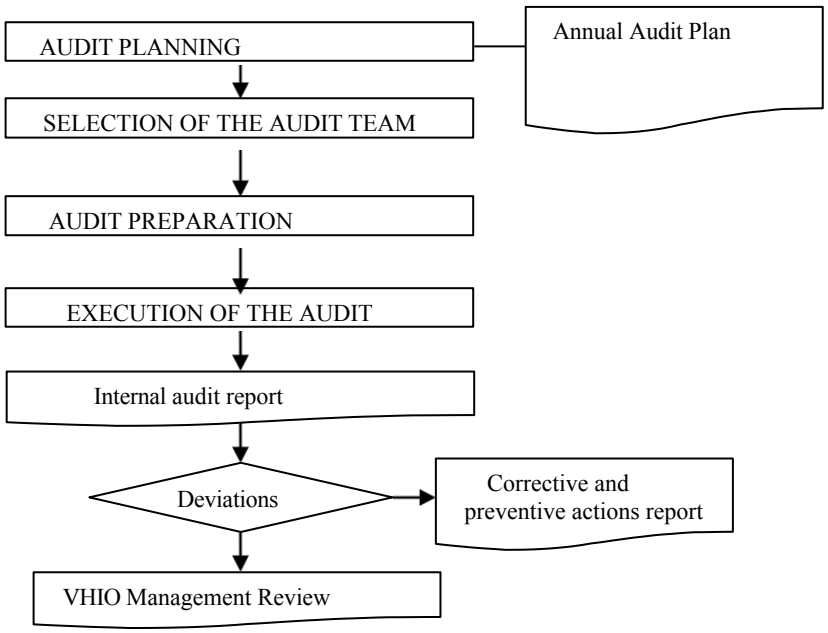
The input to the procedure is the need to verify that both the management and technical elements of the operations meet the requirements applicable to them and those of the quality management system.

8.2. Exits

Report of the auditor or audit team with the results of the statement of operations.

8.3. Diagram of flow

The following flow chart provides a simplified description of the procedure:



8.4. Procedure

8.4.1. Planning of internal audits

The quality manager establishes the planning of internal audits, which will be approved by the VHIO Management, which is reflected in the document entitled Annual Audit Plan.

The following criteria are taken into account when planning internal audits:

- Periodicity of specific audits of certain services or laboratories.
- Importance of the activities involved. As a general rule, the main activities of the quality management system are subject to an internal audit every twelve months.
- Results of previous internal or external audits.

8.4.2. Selection of the auditor or audit team

The internal audits planned at the VHIO will be carried out by external subcontracted auditing companies or by qualified internal personnel. The quality manager will be the one who considers the most convenient option.

8.4.2.1. External auditor or audit team

In the event that the internal audit is performed by an external auditing company (PG_GENER_0004 in its current version), it must comply with the following training and experience requirements:

- Demonstrable knowledge in the application and interpretation of the UNE-EN-ISO 9001 Standard, of the UNE EN ISO 15189 Standard in its current versions, of the technical-sanitary requirements of phase I units and of the legislation applicable to clinical trials, depending on the scope of the audit.
- Previous experience in internal audits: it is required to have performed at least 2 internal audits in the standard/regulation of reference (if possible one of them in the same sector).

8.4.2.2. Internal auditor or audit team

In the event that the internal audit is performed by VHIO personnel, they must be independent of the department or area being audited and meet the following training and experience requirements:

- Knowledge of the audit objectives.
- Specific knowledge of the VHIO and the service it offers.
- Knowledge and experience in the application and interpretation of the UNE-EN-ISO 9001 Standard and/or the UNE-EN ISO 15189 Standard in its current versions (depending on the standard in which the audit is performed) and/or applicable regulations in clinical trials.
- Training on the development of auditing techniques.

The quality manager, where appropriate, shall arrange for the self-auditor to comply with the above requirements.

8.4.3. Preparation of internal audits

Prior to the internal audit, the Quality Manager informs the heads of the areas to be audited that the audit will be carried out and determines with the auditor or audit team the timetable for the execution of the audit in accordance with the availability of each department.

The auditor or audit team prepares the documents to be used in the execution of the audits.

8.4.4. Execution of internal audits

The execution of internal audits, by the auditor or audit team, consists of:

- verification that the quality procedures are necessary and sufficient to meet the requirements of the audited Standards,
- validation of the correct application of the procedures through: dialogue with the Quality Manager or the required personnel; consultation of the documentation related to the quality system, inspection of spaces and any other action deemed necessary to carry out the validation.

8.4.5. Report of internal audits

At the end of the evaluation, the auditors draw up an Internal Audit Record document. This record includes the date of the audit, the areas involved in the audit and the results where the non-conformities and observations detected are mentioned. The purpose of these observations is to try to correct the current situation so that in the future, these aspects do not result in a nonconformity.

8.4.6. Follow-up of corrective actions

Of the non-conformities and observations detected in the audit, the Quality Manager carries out a follow-up so that, as established in the procedure for corrective actions and preventive actions PR_GENER_0002 in its current version, the implementation and effectiveness of the established actions is verified. In this way, the corresponding audit will be finalized.

In the event that the object of the audit has been a specific service or laboratory, the person in charge of the same shall carry out such follow-up.

8.4.7. Management review of VHIO

VHIO management validates the results of the report made by the auditor or audit team and gives its approval.

9. METRICS

The following metrics are considered for this procedure:

- Number of total deviations
- Number of deviations according to criticality

10. RECORDS

The following records are generated as a result of the application of this procedure:

- Audit planning
- Audit report and record

11. APPENDICES

There are no appendices for this procedure.