

Title:	Internal Audits		
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1. PURPOSE

The aim of this SOP is to describe the procedure for performing internal audits of our Quality Management System and processes, to ensure it complies with applicable standards and regulations, the CLS Quality Manual (MAN-54) requirements and QCI Core Guidelines.

2. SCOPE

This procedure applies to all internal audits, and it establishes the requirements for planning, preparation, performing, reporting, follow-up and close out of actions raised in internal audits. The internal audit evaluates our existing quality management system (QMS) through auditing of our processes, functions, policies, and procedures. The output of internal audits is an input into SOP 6 Self-Evaluation, Management Review and Continuous Improvement.

3. RESPONSIBILITIES

Quality Manager and the Internal Auditor are responsible for scheduling and initiating the audits and maintaining the QMS Calendar of Events, reference FOR-75.

4. PROCEDURE

4.1 Overview

The Quality Manager and the Internal Auditor prepare an internal audit schedule at the beginning of each year, QMS Calendar of Events FOR-75, and this determines when the audits will take place and what processes will be audited.

- 4.1.1 Each process will be audited a minimum of once per year.
- 4.1.2 The internal audit schedule is evaluated at the management review per SOP 6 Self-Evaluation, Management Review and Continuous Improvement. It is revised based on:
 - a) The results of the audits.
 - b) The number of corrective actions generated.
 - c) System problems identified by corrective actions
 - d) Other relevant information.

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- 4.1.3 The internal auditor communicates to the process owner when an audit will take place, the scope and personnel required for the audit.
- 4.1.4 The internal auditor documents the scope of the audit on the QMS internal audit checklist and the procedures of the quality system that apply to that process/area.
- 4.1.5 The internal auditor reviews previous audit reports for the process. All corrective actions that have been completed from previous audits that require follow-up are identified on the internal QMS audit checklist (FOR-81)
- 4.1.6 The internal auditor performs the audit according to the internal QMS audit checklist (FOR-81).
- 4.1.7 The internal auditor follows up on previous corrective actions and their completion or status and documents same on the corrective action form (FOR-82)
- 4.1.8 If the corrective action has been effective, the internal auditor closes the corrective action by checking the “Effective box” along with signature and date.
- 4.1.9 If the corrective action was not effective, the audit team will check the “Not Effective” box.
- 4.1.10 The internal auditor records the results of the audit on the audit checklist (FOR-81) and completes the internal audit report (FOR-83) with a summary and conclusion of the audit.
- 4.1.11 The internal auditor initiates corrective actions for non-conformances identified during the audit.
- 4.1.12 The internal auditor communicates the audit findings to the process owner and on a quarterly bases provides update to academic process as an input into SOP 6 Self-Evaluation, Management Review and Continuous Improvement.

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5. ABBREVIATIONS AND DEFINITIONS

5.1 Abbreviations

Abbreviation	Description
QMS	Quality Management System

5.2 Definitions

Term	Definition
Auditor	Person assigned to complete process audit per QMS Calendar of Events,
Non-conformance	The absence of/or failure to implement and maintain one or more required QM system elements or raise significant doubt as to the capability of the QM system to achieve the policies and objectives of the organization.
Observation	An opportunity for improvement or a request for clarification identified by the audit team and defined within the report.

6. RELATED DOCUMENTS

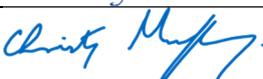
Doc ID	Title
MAN-54	Quality Manual
SOP-6	Self-Evaluation, Management Review and Continuous Improvement
FOR-75	QMS Calendar of Events
FOR-81	QMS Internal Audit Checklist
FOR-82	Corrective Action Form
FOR-83	Internal Audit Report

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7. SOP HISTORY

Revision #	Reason for Revision
1	Original Version.

8. DOCUMENT APPROVALS

Role	Name	Signature and Date
Author	Maria Ryan	 24/02/2022
Approver	Christy Murphy	 24/02/2022