Title: Internal Audit

1.0 Scope

The procedure covers the internal quality audit process from audit planning and scheduling to follow-up audits and reporting.

2.0 Objective

To document, establish, implement and maintain an internal audit procedure for an effective implementation of the established quality management system.

3.0 Reference Documents

ISO 9001:2008 : International Standard Quality Management System Requirements
ISO 19011:2011 : Guidelines for Auditing Management Systems
LSPU-QM : Quality Manual
LSPU-PM-01 : Control of Documents and Records
LSPU-PM-03 : Control of Non-Conformance, Corrective and Preventive Actions

4.0 Procedure

4.1 Planning and Scheduling

4.1.1 All quality system process elements shall be audited at least once a year as per Annual Audit Schedule (LSPU-IQA-SF-005) which shall be approved by the Quality Management Representative (QMR). The schedule shall be formulated on the basis of the status and importance of the activity. However, a particular area of the entire quality system maybe audited more frequently, when deemed necessary.

4.1.2 The Lead Auditor shall furnish the auditors with the objectives and scope of audit, the names of the team members, the department to be audited and other pertinent details before the scheduled audit date. This is to ensure the effectiveness of the audit.

4.1.3 The Lead Auditor shall ensure that all copies of the necessary documents such as quality manual, procedures, previous audit results and all other relevant documents are available during audit.

4.1.4 The Audit Plan (LSPU-IQA-SF-006) should include but not limited to the audit date, audit scope, audit objectives, criteria, audit team/auditors, time of audit, elements and areas to be audited and auditees.

4.1.5 The audit team shall prepare the necessary audit checklists to ensure that all the important items/ elements are covered.

4.1.6 The audit checklist shall be referenced on the ISO standards, the quality manual, quality procedures and necessary work instructions, where applicable.

4.1.7 The section clauses or elements in the audit checklist shall be based on the audit plan.

4.1.8 The Lead Auditor shall discuss the necessary preparations, formulations of the audit plan and other audit activities, timetable and preparation and review of the audit checklist.

4.2 Selection of Auditors/Audit Team

4.2.1 Selection of lead auditor and auditors will be based on the competence of the auditors from the "List of Qualified Auditors". Independence in conducting of audits shall be ensured by the QMR and the lead auditor for objectivity and impartiality to avoid conflict of interest and bias in opinion during audit.

4.2.2 The QMR shall maintain the integrity of the audit by ensuring that neither the lead auditor nor any member of the audit team is/are member/s of the department or function to be audited. They shall have no direct responsibility on the activity being audited.

4.2.3 The audit team shall be composed of qualified and trained internal quality auditors. The minimum qualification for the internal quality auditors must at least be a bachelor degree holder, a total work experience of at least one (1) year and have attended an IQA training/seminar of at least 24 hrs.

4.2.4 The audit team consisting of the qualified auditors shall be nominated by the Lead Auditor prior to the audit.

4.3 Opening Meeting

4.3.1 An opening meeting shall be conducted by the lead auditor prior to proceeding with the audit; to be participated by the audit team, auditees and involved departments if necessary. The objective of the meeting is for familiarization and awareness of the participants on the mechanics of the entire audit process.

4.4 Conduct of Audit

4.4.1 Using the applicable documents and the prepared audit checklists, the lead auditor and the team members shall conduct the audit by interviewing the auditee at the area being audited or desk audit (review of the applicable documents), and/or checking of actual implementation against documented procedures.

4.4.2 The auditor shall note down on the checklist all the necessary findings during the time of audit, including the objective evidences of conformities and/or non-conformities.

4.4.3 The QMR should evaluate the competence of the lead auditor while the lead auditor and/or the QMR will evaluate the competence of the internal quality auditors. Refer to Auditors Performance Evaluation form (LSPU-IQA-SF-009).

4.4.4 All findings whether major or minor non-conformities shall be classified as Non-conformity (NC) and Improvement Potential (IP) for those which can lead to potential non-conformity or can still be improved.

4.4.5 a) Non-Conformity (NC)

- Absence of procedure required by the standard.

- Non-implementation of a procedure required by the standard.
- A lapse in the implementation of the management system.
- An isolated lapse in an implemented management system requirement.
- Health and safety requirement not implemented.

b) Improvement Potential (IP)

- All areas of concern that would lead to non-conformities.
- Suggestions or recommendations of best practices.
- Improvement possibilities of the system.

4.4.6 The lead auditor shall discuss with the auditee the results of the audit.

4.4.7 The audit team shall evaluate their findings and deliberate on the non-conformity found during the audit. Final decision as agreed upon by the audit team must be reflected on the audit report. Unresolved issue by the team shall be decided by the QMR or the Lead Auditor.

4.5 Closing Meeting

4.5.1 Closing meeting shall be conducted as soon as the audit has been finished. Similar participants during the opening meeting are expected to attend the closing meeting.

4.5.2 The lead auditor will discuss the results of the audit. For the findings called-out during the audit, non-conformity reports are issued to the concerned department. Unresolved issues with the auditee are elevated to the department head. They will likewise agree to the follow-up action to be taken as scheduled.

4.6 Reporting

4.6.1 The final basis for the results of the audit shall be formalized through internal audit report which will be prepared by the lead auditor for review and approval of the QMR.

4.6.2 All auditees with findings shall be issued with a Non-conformity, Corrective and Preventive Action Report (NCPAR) but distribution of audit report will be as per discretion of the QMR.

4.6.3 Correction as necessary, corrective and preventive action shall be initiated and implemented by the auditee/Department Head to be documented through the NCPAR and coordinated with the lead auditor. For details on the investigation, refer to control of non-conformity, corrective and preventive action procedures.

4.6.4 All results of the internal quality audit shall be an input to the management review meeting for continuous improvement.

4.6.5 Corrective actions not implemented on the committed date shall be elevated to the QMR for further disposition.

4.6.6 Corrective actions are then declared "closed" once verified to be effective upon approval of the QMR.

4.7 Follow-up Audit

4.7.1 A follow-up audit shall be conducted minimum of two (2) days after implementation of the corrective action even without prior announcements to verify if the committed action is implemented and preferably minimum of one (1) month after another follow-up audit will be done to verify the effectiveness of the implemented action. This must be recorded in the Corrective and Preventive Action Monitoring Log form no. LSPU-NCPAR-SF-011.

4.7.2 To maintain the continuity of the audit, preferably, the same audit team may be assigned to do the follow-up audit if necessary.

5.0 Records

5.1 List of Qualified Auditors

LSPU-IQA-SF-001	: Audit Master Schedule
LSPU-IQA-SF-002	: Audit Plan
LSPU-IQA-SF-003	: Audit Checklist
LSPU-IQA-SF-004	: Audit Report
LSPU-IQA-SF-005	: Auditors Evaluation Checklist
LSPU-IQA-SF-006	: Auditors Performance Evaluation form
LSPU-NCPAR-SF-01	: Corrective and Preventive Action Monitoring Log

5.2 Internal quality audit records will be maintained and filed by the lead auditor in accordance to control of documents and records procedure.

6.0 Responsibility

It is the responsibility of the QMR and the lead auditor to ensure that the above procedure is implemented.

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