Revision History

Rev No	DCN #	Changes	Effective Date	Approved
01	0145	Initial Release	11/30/05	CL
02	0471	Content change	08/04/08	YC
03	0714	Process Owner, format change, Correct typo	07/28/09	YC
04	0972	Simplified the category of non-conformity. Added the requirements and re-wording, etc.	03/28/11	A. Qin
05	1033	Changed the audit interval to twice a year on section # 6.1. Re-wording.	10/06/11	A. Qin
06	1086	1. Changed the sequence of section 6.10&6.11; 2. Added the clauses that only need once per year on sec.6.1; 3. Added the Form D006 on sec .7.0	05/29/12	A. Qin
07	1109	Changed the audit interval to once a year on section 6.1.	10/10/12	A. Qin
08	1201	Change process owner. Clarify the definition of non conforming	05/28/14	H. Li

Internal Quality Audit Procedure

Process Owner: Nancy Guo Date: 05/19/14

Department Manager: Hong Li Date: 05/22/14

1.0 Purpose

This procedure establishes and defines the internal auditing process, monitor and assure the Quality Management System (QMS) is effectively implemented and maintained.

2.0 Scope

This procedure applies to QMS of Optoplex system and all processes that affect products quality.

3.0 Authorities and Responsibilities

• Management Representative	• Set up the annual internal audit plan. • Organize the internal audit teams. • Approve the internal audit notice, schedule and report. • Assure the related corrective actions are taken and closed. • Report audit results on management review meeting.
• QA	• Devises Internal Audit Notice and Internal Audit Check List. • Prepare the auditor list and conduct the trainings on auditors. • Monitor the status of audits are conducted as the schedule. • Collect checklists, confirm Corrective Action Requests are issued.
• Lead Auditor	• Leads the auditor team to conduct internal audit. • Add/adjust the option audit items on the checking list. • Finalize the audit results (Non-conformity) with teams. • Communicate with auditee department about the findings. • Initiate the corrective action request for the non-conformity.
• Auditor	• Conducts internal audit under the lead of Lead Auditor. • Reports the audit results to the lead auditor.
• Auditee	• Cooperates with internal auditor(s) during the auditing process. • Answering questions and providing objective evidences. • Feedback on corrective / preventative action(s).

4.0 Definitions and Acronyms

CAR	Corrective Action Request Form

5.0 Flow Chart of Procedure

Flow Chart	Responsible	Notes	Form
Prepare Annual Internal Audit Plan	QA Mgt. Rep.	• Define the audit interval, the specific processes and corresponding areas.	
Create Internal Audit Schedule	QA	• Obtain approval from Management. Rep.	Internal Audit Notice
Distribute Internal Audit Notice	QA	• Timely release the notice and schedule to auditees and auditors.	
Prepare Internal Audit Check List	Lead Auditor	• Collected from ISO 9001 Standard, QA Manual, Procedures, Work Instructions.	Internal Audit Check List"
Conduct the Pre-meeting with Audit Teams	Lead Auditor	• Highlight the key points and previous records.	
Conduct Internal Audit	Auditing Team Auditees	• Auditing against the audit checklist.	Internal Audit Check List
Decide the Classification of the Findings	Lead Auditor	• Record all the findings during the audit. • Forward the Checklist to QA with classifications.	Internal Audit Check List
Issue ICAR	Lead Auditor	• Issue the ICAR for the findings to responsible department.	Internal Corrective & Preventative Action Request
Prepare the Internal Audit Report	QA	• Collect the Checklists and organize them into audit report.	Internal Audit Report

6.0 General Requirements

6.1 Prepare Annual Internal Audit Plan

An annual internal audit plan (Programme) had been prepared by QA and approved by Management Representative.

Audit plan shall be defined from the overall status of the QMS and the importance of the specific processes and corresponding areas, as well as the results of previous audits.

The minimum internal audit interval in Optoplex is every 12 months (Annually). .

The audit items shall cover whole clauses of the quality management system of Optoplex within 12 months.

6.2 Conduct the Additional Audits

If there is a necessary, additional audits (Non-pre-defined auditing) will be initiated from management or QA department for following conditions: (Not limited)

1. The special quality events,
2. Significant changes that will impact the quality system/organization,
3. Major non-conformities found or requests of interest party.
4. Etc.

6.3 Release the Internal Quality Notice

Audit notice shall be prepared by QA and released (via e-mail) to auditors and auditees after approval from Quality Representative.

Audit Notice shall contain the schedule, the departments or areas to be audited, the scope of auditing, auditor names, etc.

The notice shall be released at least two weeks before the auditing. Due to special reasons such as customer visiting, change to the schedule will be notified to the auditee department

in advance.

6.4 Perform Auditor Training and Assign the Tasks

All of the auditors shall complete the Internal Auditor Training course. Quality Auditor List shall be kept in QA department.

Auditors (that come from multiple departments) are assigned by QA department for the specified areas to be audited.

Auditor shall not audit their own work or department with direct conflict relations for keeping the objectivity and impartiality. But the auditor is allowed to audit the other sections on the same working groups when there is no conflict in responsibilities.

If there is a team for the audit activity, one of the auditors will be assigned as lead auditor by QA in the team.

For the auditors can not attend the auditing from business trip or urgent job, If necessary, QA will assign a replacing auditor to conduct the task.

6.5 Prepare the Internal Quality Audit Checklist

Internal quality auditing check list shall be prepared by QA and documented before the auditing.

The check list shall be condensed and abstracted from Quality Manual, procedures and work Instructions or other inputs.

Audit checklist is a guild line for the auditors. In order to keep flexibility in coverage, additional check items can be added by auditor team members from their concerns, other inputs such as previous nonconforming issues, customer feedbacks, etc.

The lead auditor or QA will review the audit check list before the auditing and make adjustment (Add) on the list for the auditee department assigned if necessary.

6.6 Conduct the Opening Meeting

Opening meeting will be conducted by lead auditor. The major purpose is to introduce the audit team members, highlight the audit scope and detail schedule with auditee management.

If the auditor and auditee had already understood the audit scope or schedule, the opening meeting will be simplified or skipped.

6.7 Fill out of the Check Lists

The auditors shall follow the check list and review the QMS implementation results on auditee areas.

The auditor shall check the evidence (Both conforming and non-conforming) by sampling as necessary.

For those areas that are conformed to our request, the auditors shall keep the evidences and record the items/info (such as P/O #, work station #, document #, etc.) that had been checked.

The auditors shall make records on the audit findings (Including Conformity and Non-conforming and Observation) on the checklist.

A NA mark will be used for those areas that request is not applied for the checklist or had not been checked during the auditing.

6.8 Make Decision on the Classification of the Non-conforming Items

Auditor teams shall exchange/discuss the information and reach the consensus on the decision of nonconforming that found during the audit.

Nonconformity	Objective evidence had been found that the practice is not meet the requirement of ISO 9001 international quality standard, internally defined documents such as procedures or work instructions. Those non-conformities have the direct big impact on the quality management system belong to major non-conformity. The rest of them belong to minor non-conformity.
Observation	Did follow the ISO 9001 international quality standard, internally defined procedures or work instructions. However, from system point of view, the execution is not smooth and discrepancy can be found occasionally. Has potential impact on product quality. A reasonable explanation on rejection shall be documented for the response.
Opportunity for improvement	Not a requirement of ISO 9001 international quality standard, but proper correction can help continually improving company's QMS and/or product and service quality The owner shall review the suggestion and no obligation to make action plan on it

6.9 Conduct the Closing Meeting

The closing meeting will be conducted by audit team with auditee. The lead auditor shall address and explain the findings during the audit.

If the auditee has the questions or concerns on the results, communications shall be conducted between the auditor and auditee.

If the questions or findings have been clarified between auditor and auditee, the closing meeting will be simplified or skipped. In such condition, no meeting records needed.

6.10 Release the ICAR for the Findings

The lead auditor shall forward the internal checklist to QA and notify QA to release the ICAR

to the findings. The monitoring and close the ICAR issues, please refer to the Corrective and Preventive Action Procedure (QP 85201)

6.11 Complete the Internal Audit Report

Audit report shall be completed by QA. The report shall be reviewed by QA Manager and send to Quality Representative and auditee departments.

Audit report shall contain the audit date, auditor teams, the area/department being audited, audit scope, audit results.

7.0 Reference Documents

QM-001	Quality Manual
QP 56001	Management Review Procedure
QP 85201	Corrective and Preventive Action Procedure
Form D004	Internal Audit Notice
Form D005	Internal Quality Audit Checklist
Form D006	Internal Quality Audit Report