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Internal/External quality audits in ISO: an introduction

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ABSTRACT

This paper gives details of Internal Quality Audit and External Quality Audit of ISO9001 standard which help to achieve the Quality Management System (QMS). For ISO certification most of the organization/Institution should go for ISO implementation. Quality audits are the basic process of ISO done by the internal or external quality auditors or by the audit team. Quality Audits should be performed at regular time intervals and ensure that the institution has clearly defined internal audit systems monitoring ISO procedures with effective action. This will enable the institution to grow faster with minimizing the errors and failures of ISO procedure executions. This paper explains about procedures of IQA and EQA and corrective, preventive actions taken on the NCRs, which help for the better improvement. This brings higher customer satisfaction that intern brings new customers.

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INTRODUCTION

A Quality Management system (QMS) is a set of procedures, policies, processes and reports essential for planning and execution of it. This is the basic function towards maintaining ISO 9001:2008 standards. An organization or educational institution which wants to improve the customer satisfaction should opt for this ISO certification. In number of advertisements we see that the respective organization has been displayed as an ISO certified organization along with NBA and AICTE certifications. System improvement is the basic improvement of any Total Quality Management policy. ISO 9001:2008 is based on number of quality management principles including customer focus, the motivation and implementation of top management, the process approach and continual improvement. This helps to ensure that customers get consistent, good quality products and services, which in turn brings many to avail the benefits of the concern institution.

1. Steps in ISO certification:

Depending upon the size of the organization and the complexity of the process, the followings steps are suggested to implement an ISO 9001:2008 Quality Management System successfully.

1. Top management commitment

2. Establishment of a team to implement.
3. Awareness program on ISO
4. First initial status survey and providing training
5. Documented implementation plan
6. Documentation of the procedures
7. Document control and implementation
8. Management review and Internal quality audit
9. External Quality Audit or Certification audit and certification.
10. Registration and Continual improvement

2. Internal quality Audits:

Quality Audit is the process of systematic examination and checking of the quality system carried out by internal or external quality auditors. It is very important for any organization or institutions which follow the QMS like ISO 9001. It has to conduct Internal Quality Audit to verify that the installed quality management systems include confirmation of the quality procedures, checking its effectiveness at each and every step in every department. Few staff members are given proper internal quality audit training to do it. The management reviews are conducted to ensure the continuing suitability, adequacy and effectiveness of the quality management system. The review should suggest any needed change in the quality policy,

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quality objective, quality procedure, customer feedback, process performance and product conformity, status of preventive and corrective actions, and the recommendations for improvements are given to Management representatives for better progress. IQA is the process that is performed at regular intervals to ensure that the institution has clearly defined internal audit monitoring the procedures linked with corrective action..

It is an essential management tool used for verifying objective evidence of processes to identify, how the successful process has been implemented. It helps the institution to identify the problem also the reduction and elimination of problematic areas. IQA should produce the NCR (Non Compliance Report) or the report on the audit; it will enable the concerned to take the corrective action also.

3.1 Objectives of Internal Quality Audit:

- Determine that actual performance conforms to the documented QMS.
- Initiate corrective action activities in response of deficiencies
- Follow up on Non Compliance items from previous audit
- Provide continued improvement in a system through feedback.
- Cause the auditee to think about the process and encourage possible improvement.

3. Procedure followed in Internal Quality Audit:

1. A circular mentioning about the IQA is given by the organization or the institution prior to the date of conduction IQA. This circular always gives information regarding the internal auditor who has to check for the particular part of the institution, and enables the auditors and the auditee to be ready on that particular day for the Internal Quality Audit.

2. Internal audit should be scheduled at planned intervals to check the quality system and confirms the requirements for the system to be effective. Requirement includes the standard (ISO) itself (ie. its own procedures and policies). It is not possible to audit every process once. External audits may be in this manner, but the internal audits should be done with different pre audits at various intervals. That is number of series like mini audits should be done. It is the management that decides and recommends the series of mini audits before the external audit of certification. This is enough to audit all the process of the ISO.

3. Particular department which has to go for IQA will keep all the records and supporting documents ready for the audit. Auditor will come along with the NCR (Non Compliance Report) format so that if any discrepancy or delay in work occurs it will be reported in the NCR. This problem which has been highlighted in the NCR should be solved or completed within seven working days from

the date of audit. (The days may vary from organization to organization).

4. NCR format should also give the information about place of audit, date of audit with reference to ISO standards. Details of standards with clause numbers should be given, along with cross reference with procedure numbers.

5. Auditee would surely know about the NCR (Non Compliance Report) of ISO Standards and procedures. The NCR may be written from the Objective of the department to the ranking rate of the vendors of the library. Auditee who has attended the internal quality audit training program and ISO triaging program would surely answer the query of the auditors then and there. If the NCR has been raised that would be answered in the same format mentioning the corrective action taken against it with supporting document Xerox copies.

6. Finally the NCR is closed with the new modification solving the particular problem.

4. Techniques of IQA:

The main objective of the audit is to collect evidence, there are number of techniques that the auditor should employ. There are three methods

4.1. Examination of Documents:

the auditor should start with the quality manual to determine that the policies cover the ISO standard. 1. Documents are examined in a systematic manner. 2. Documents are identified with title, revision date and responsible owner. 3. A master list by department or procedures should be located, 4. Both obsolete documents at workstations. 5. Changes follow the prescribed procedure.

4.2. Observation of activities:

It is a easy method that requires an aptitude for details. For example from the objective of the department to the last procedure it should go.

4.3. Interviews:

Most difficult method of collecting evidence is by interviewing the employees. Auditor should spend much time listening and little time as possible to conversing. Employee should be encouraged to talk on the processes. Reserve the major issues for report and minor ones for auditee. Openend, closed end or clarifying questions may be asked by the auditors.

5. Procedure followed in External Quality Audit:

1. Open Meeting of the External quality Audit. Discussed about the location date and sections of audit. External audit committee may consist of two to three persons. Location of audit might be vast and decides the person who has to go which section and also the time in which it should happened.

2. Auditors should cover from top management down to the level of low workers, the organization or the institution. They should cover the

Control manual and apex manual of the ISO standard.

3. They conduct the audit as per the standards of ISO and if any NCR rises they ask the organization to complete it with in the short duration. If the problem is high and cannot be solved with in the short duration the ISO Certification may be cancelled for that particular organization. Mostly the institution should be in a position to complete the NCR produced by the External Quality Audits.

4. Closing meeting of the External Audit.

7. Functional role of the Auditors:

- Each auditor who comes for IQD should have attended at least two audit training programs.
- Auditors should be impartial.
- Auditors should plan and identify the area of audit by going through the procedure manual of the particular department.
- They should check the previous NCRS.
- Questions or check list may be kept ready by the auditors to ask.
- Check list may be from objective achievements, procedures achievements, list of files, list of records etc.
- Auditee should show the required documents at the time of audit.

➤ Auditors should write the comments as per the check list mentioning NCR and also the one without NCR.

8. Observation by the Auditors:

1. Objective of the library is not achieved.
2. Raking of vendors is not available in the required format.
3. Records not maintained for network users.

9. Corrective action to be taken by the auditee. (Clause 8.5.2):

- Objective of the library should be achieved by purchasing the required quantity of books.
- Raking of vendors should be modified in the required format and updated in the file.
- Record no.23 should be kept for the network user's signature.
- Xerox copies of the above should be kept along with the NCRs which is closed for future reference.
- Copies may be given to auditors for their reference too.
- NCR number and date of audit and the evidence should be given to office also to fill in the overall NCR file.

10. Model of NCR-Non Compliance Report (Internal/External Quality Audit) Format:

Non Compliance Report			Date:
	Pre audit meeting		
Date	start time	End time	Venue
Audit Location Details			
Location	Date and Time	Auditee Details	Auditors
	Reference standards list		
	Audit Space		
	Signature of the auditor		Date
Auditees report			
List of modification done as per clause is given			
1.Corrective actions			
2.Preventive actions			
Signature of the Auditee			
Signature of the Auditor after checking the Closing of NCR.			

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1. Preventive action:

- NCR has been given for a particular problem in a library. Corrective action is also over on it. In spite of it, some preventive action should be taken to avoid the particular situation in future.
- If the quality system indicates that the possible problem may develop in future, a preventive action must be implemented to avoid the potential problem.

This paper has given a detail study of Internal and External Quality audit of ISO. It also explains how to take preventive action for the out coming problem and how to implement the corrective action against the NCR. This will definitely enhance the auditors and the auditees to improve their quality in taking audit. Mini/Internal audits are the essential procedures for any institution to opt for external quality audit of certification.

Conclusion:

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