



AUDITOR's HANDBOOK

for initial approval and continued surveillance



TABLE OF CONTENTS

1	INTRODUCTION.....	3
2	GATHERING INFORMATION BEFORE THE AUDIT	4
3	PREPARATION OF THE VISIT.....	5
4	OPENING MEETING	6
5	AUDIT PERFORMANCE.....	6
5.1	The adequacy audit	7
5.2	The compliance audit.....	8
5.2.1	Management.....	8
5.2.2	Operational level.....	9
5.2.3	Checklists.....	10
6	TIME FOR THE AUDITOR'S RECAPITULATION.....	11
7	CLOSING MEETING AND DEBRIEFING NOTES	12
8	REPORTING.....	13
9	CORRECTIVE ACTIONS AND VERIFICATION	13
10	APPENDICES	14



1 INTRODUCTION

This handbook will guide the individual auditor through a list of check items for the purpose of an initial approval or a continued surveillance.

Depending on the size and scope of work of the organization the check items and paragraphs given in this handbook are to be used case by case. This implies that not each and every check item and paragraph is required as to be applicable for an organization. Selections must to be made in order to fit the best to the organization's scope of work.

The handbook is intended to verify in depth the capabilities of the organizations to comply with applicable standards. Such standards specify minimum requirements and implementation should result in a well documented system with continuing effectiveness.



2 GATHERING INFORMATION BEFORE THE AUDIT

Before an audit can be scheduled sufficient information needs to be available.

- a) Make sure that the auditor has a controlled copy of the system manuals and supporting documents. Determine and study the updates / changes since the last external audit.
- b) Verify compliance with the latest version of the applicable standards.
- c) If the system manuals do not hold a cross reference list which reflects the relation between the standards on one side and the procedures of the company on the other side (*visa versa*), then make one.
- d) Request for an organization chart with updated names of the managers. Check for changes in critical positions.
- e) Request copies of internal audit reports, corrective actions, reports of system performance, reports of management review meetings. (*Some reports may not yet be available at the time of the first certification audit*).
- f) Collect previous external audit reports and reports of subject follow-up actions
- g) Determine whether other Quality Systems are in place (e.g. ISO) and referenced.

Based on this information determine specific area's of interest and with that the responsible managers. Use it to make checklists in advance (See also paragraph 5.2.3)



3 PREPARATION OF THE VISIT

The following items must be used to brief management of the organization about the intent of the evaluation and to arrange for the evaluation visit in order to work efficiently.

- a) Arrange for the evaluation date.
- b) Name the auditor to visit the organization.
- c) Request for the organization's management to meet:
 - Accountable Manager
 - System Coordinator or manager often the Quality Assurance Manager
 - All Managers of departments who are involved.
Such managers can be for example:
 - Sales Manager
 - Shipping Manager
 - Material Manager
 - Purchasing Manager
 - Manager Personnel Affaires
 - Manager Accounting
 - Manager Archives
 - Manager Information Technologies
- d) Explain the intention of the visit
 - Initial certification audit (e.g. emphasis on adequacy of manuals procedures, training etc.)
 - Second certification audit (e.g. emphasis on self correcting capabilities of the organization, i.e. internal audits, corrective actions, effectiveness of corrective actions, system review)
 - Annual surveillance audit (e.g. results of management review meetings, extensive product sampling, continuation of know how with employees and re-training, comparison of observations with management review)
 - Audit for specific reason, for example the rectification of a systematic non-conformance.
 - The latest version of the standards to be used.
- e) State the departments (locations) you need to visit.
Such departments can be for example:
 - Sales department
 - Shipping department
 - Personnel department
 - Archives
 - Accounting
- d) State the department heads, managers, supervisors, etc. you like to speak.
Prepare them for the specific areas of interest that resulted from the information gathering. Include newly appointed managers in this list.
- e) Make a time schedule and make sure that time for the auditors recapitulation and the closing meeting are part of the time schedule



- f) Request for full co-operation of the organization's staff members including the availability of security passes.
- g) Request for easy access to records, documents, work areas, etc.
- h) Request for office space during the audit
- i) Request to be accompanied during the audit.

4 OPENING MEETING

The purpose of the opening meeting is to ensure that preparation was received well. It is the auditors meeting so he must eventually take the chair.

- a) Introduce yourself or if more auditors are present, introduce them all. Explain the role of each and every one of them. One must have the lead.
- b) State the position of the auditor e.g. dependent or independent, who the audit report will be send to.
- c) State that confidentiality will be maintained.
- d) Re-confirm the purpose of the audit as communicated during the preparation.
- e) Re-confirm the revision status of the applicable System manuals.
- f) If necessary, explain what a non-conformance is, the grading, the method of reporting and the time schedule for the report.
- g) Make sure that domestic arrangements are in place (office accommodation, breaks, guides and their briefing, if necessary a translator, security passes).
- h) Communicate the time schedule for the day, including the time for the auditor's recapitulation and the closing meeting.
- i) Verify that staff is informed and available.
- j) Record who is present (In general this should be the managers of departments that will be audited). Use the named organization chart for this purpose (chapter 2). Those present at the opening meeting normally should be present at the closing meeting as well.
- k) Invite people to ask questions about the audit.
- l) Close the meeting and stick to the plan for the day.

5 AUDIT PERFORMANCE

Bear in mind that an auditing is only a sampling process. Therefore put more emphasis on specific areas of interest determined by:



- Elaboration of gathered information (checklist)
- The kind of audit.
- Non-conformances observed during the audit

In order to get the most out of the available time, time management is essential (plan breaks for meals, no alcoholic drinks, have security passes arranged in advance, be aware of long friendly chatting, false trails on time consuming many, long D-tours in the premises, time wasting discussion instead of fact finding).

5.1 The adequacy audit

The first part of the audit consists of the adequacy audit, sometimes also referred to as documentation, system or management audit. The purpose of this part of the audit is to determine the extent to which the documented system of the replicator complies with the latest standards.

The cross reference list as mentioned in chapter 2 is a very useful tool for the adequacy audit, not only for the auditor, but also for the organization. Especially when the standards change, it can be easily determined where the system of the organization may have to be changed.

To a large extent the adequacy audit can be and should be performed in advance before the visit. In some cases the organization may be reluctant to release confidential documentation from their supervision. This may lead to the adequacy audit to be performed at the auditee's premises and may lead to additional cost for such organization.

The documentation may comprise a multi-layered structure. In most cases the top tier is not confidential. It holds general policies, management commitment statements and a description of the documentation structure.

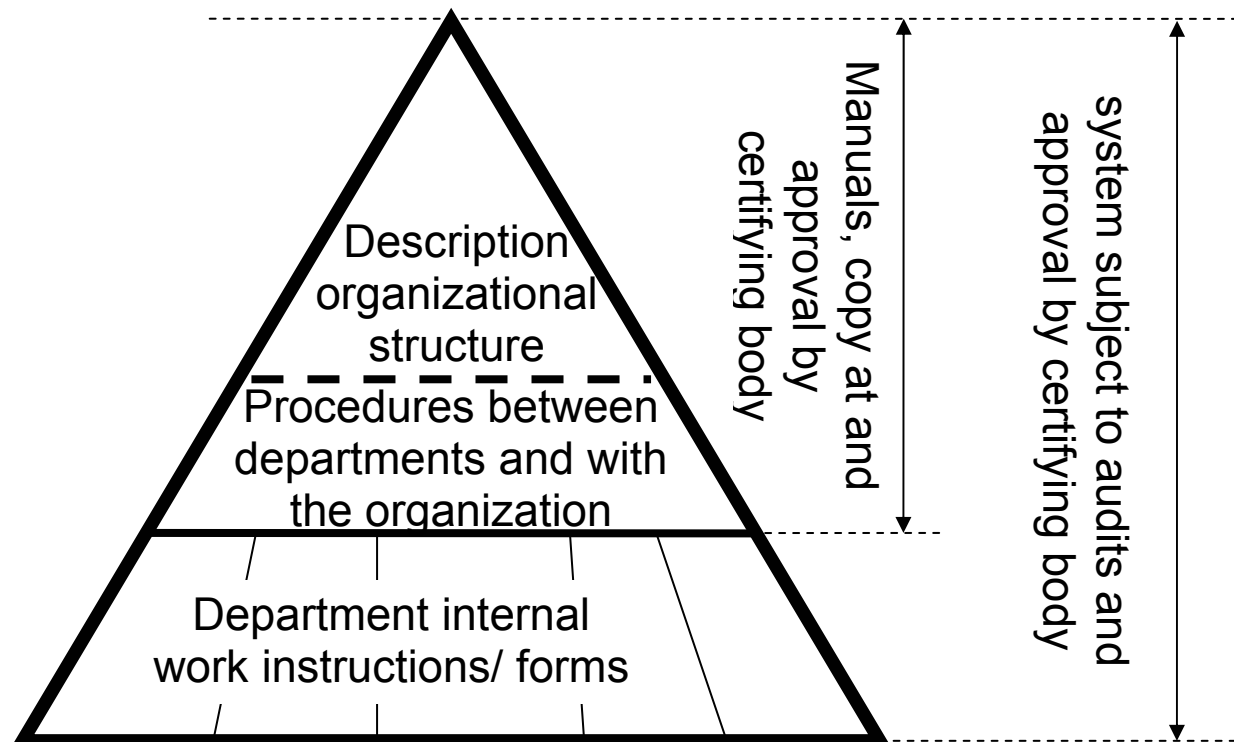
The middle tiers define how the company operates. In this part of the documentation the auditor should pay attention to the following issues:

1. The requirements of the standards need to be addressed.
2. In addressing the requirements there must be harmony within and between the different tiers. The system should stand together as an integrated whole.
3. The documentation must be understandable to the users and responsibilities must be clearly defined, free from ambiguities and conflicts.

The bottom tier often comprises forms to support the operation and make it work. The auditor should pay attention that lay-outs and instructions for use are fit for the purpose and understandable to the employees.

During the audit the condition of manuals must be determined (signatures of management at designated places, controlled copies having the correct revision status, the absence of uncontrolled copies)

A typical documentation structure is shown in next figure.



5.2 The compliance audit

The aim of the compliance audit is to determine the extent to which the documented system is implemented and observed at the operational level and by management.

5.2.1 Management

The standards specify the minimum requirements for a system. The major objective of the system as a whole is to ensure that it is self correcting and self improving. In this respect the auditor must pay much attention to the performance of management, how do they deal with the requirements.

1. Did the accountable management actually endorse by a signature the policy and intensions of the standards? Does this include the appointment of a coordinator or manager? Are sufficient resources available?
2. All personnel involved should have the authority to initiate preventive actions, identify problems and recommend solutions etc. Now how receptive and responsive is management?
If all corrective and preventive actions are listed, then how many were the result of an audit and how many resulted from the day-to-day operation?
3. Corrective and preventive actions must be dealt with in time and by removing the root causes. Just correcting the one specific observation is not a corrective action. Removing the root cause requires changes; changes in procedures, work instructions or other forms or material. Now how energetic was management in this respect? In time? Determination of root causes or just product related corrections?

The system requires the recording of the implementation and the determination of



the effectiveness of the corrective action. Did procedures etc. change? Do the non-conformances still occur?

4. The system coordinator or manager should report system performance for management review. He is expected to play an active role; the report must be more than simply a listing of non-conformances and corrective actions. Verify that not only the internal audits but also other sources should contribute to the report. External audits, non-conformances observed during product inspection give also indications about the system performance. But also the outside world may be taken into account such as new technologies and practices, complaints of customers, etc.
5. The review meeting is supposed to secure continuing system effectiveness. Verify the input by the coordinator; verify the corrective and preventive actions. Determine what aspects (internal, external, administrative, technical, grey area's, new guidelines, etc.) can be expected to be discussed at the review meeting based on the input. Compare this with what was actually discussed. Verify that the meeting is not postponed frequently and for long periods. Verify that senior management attends the meeting, not deputies. Verify that results are documented and distributed.

Last but not least, during interviews ask management what can be improved on the standards. What are their expectations? A certifying body needs this kind of feed back in order to keep up with the developments.

5.2.2 Operational level

Basically two kinds of approaches can be used to audit the operational level of the organization: the product and the process oriented audits:

Product					
Department	CD-ROM	Players	Books	Magazines	etc.
Sales					
Customer Service					
Manufacturing					
Purchasing					
Planning					
Shipping					
etc.					

Product oriented audits are practical in small organizations where process oriented audits tend to be more practical at large organizations. It should be noted however that if during a process oriented audit non-conforming products are observed, it often proves to be useful to follow the trail of those specific products through the departments in order to pinpoint where exactly the non-conformance should have been observed in the first place.



An effective way of interviewing employees is by witnessing them while performing their duties. After a short introduction the basic question is 'show me'. While people show what they are doing, appropriate questions are 'how', 'why', 'what', 'where', 'who'. An important aspect of auditing is to identify activities which are not documented. Leading questions which supply their own answer should be avoided ('do you file that form?'). The answers to such questions provide little useful information.

During the inspection notes should be made also if the observed products and activities are correct. If problems are observed, notes should also be taken, even if the problems can be solved right away. Gather evidence in the form of photo copies or otherwise form- and serial numbers etc. to ensure retrievability.

5.2.3 Checklists

Checklists do not make a script how the audit should proceed nor does it make a list of questions to ask the auditee. The checklist should only prompt the auditor as to the topics to be covered to ensure that the scope is covered as well as possible. It can also serve as a notepad during the audit not only for non-conformances but also for positive observations.

The making of checklists is part of the information gathering of chapter 2. The items on the lists depend on previous audits and the particular organization. For instance training records are sometime kept at department heads, sometimes at the Department for Personnel affairs.

The format of a checklist can be as follows:

Organization: Manufacturer Inc.				Date: / /
Department: Sales				
Auditee: Mr. Salesman			Auditor:	
Item	System Ref.	Description	Observations	Non-Conf. report nbr.
1	10.1.E	Corrective action NC x, audit dd/mm/yy		
2	2.4	Appropriate docs. at workstations		
3	3.2	Acknowledgement of customer		
Etc.				

A master blank checklist is provided in appendix 1

When the checklists of all departments are taken together, all system requirements must be covered at least once. Issues like recordkeeping and training will be covered more frequently.



6 TIME FOR THE AUDITOR'S RECAPITULATION.

Before the closing meeting the auditor needs time to recapitulate the observations made during the day. This time should be sufficient to:

- a) To review and evaluate his notes.
- b) If necessary time to complete evidence or ask / confirm specific information.
- c) Categorize non-conformances (major, minor, remark)
- d) Decide on proposed corrective actions.
- e) Basically draft the final report and make sure that sufficient material and evidence is available for the final report.



7 CLOSING MEETING AND DEBRIEFING NOTES

The following items are to be used to debrief management of the organization.

- a) Make a list of the attendees at the debriefing and include their position. Preferably as a minimum the heads of the departments visited should attend the debriefing but normally they are the same people who attended the opening meeting.
- b) Recapitulate the basics of the audit:
 - The purpose of the audit (certification, re-certification, annual surveillance, specific reason)
 - Standards used (latest version)
- c) Re-stipulate the position of the auditor, whether he will recommend or whether he decides on certification. The certifying body in most cases being the principal to receive the report. The organization will receive a copy.
- d) Stipulate the disclaimer. An audit is only a sample and not all non-conformances may have been observed.
- e) Request to hold questions to the end and invite auditee's to discuss specific points at the end.
- f) Make sure that the debriefing does not contain surprises to the attendees. The individual heads of departments must know the observations in advance.
- g) Include acknowledgement of individuals who contributed to the evaluation (heads, coordinators, guides, employees etc.)
- h) Explain the classification of major, minor and remark.
- i) Report on observations and obvious recommendations for corrective actions. Also include successes.
- j) Agree on dates for the completion of corrective actions as per standards requirements. Deviations of terms of the standard can only be made in concert with the certifying body.



8 REPORTING

Audit reports are used to convey the auditor's observations to the certifying body and the organization. It has become common practice to use e-mail for this purpose, but a properly signed confirmation copy is to be sent to the certifying body for record keeping purpose.

The main report consists of a summary of the visit and the interviews. Therefore the report should not concentrate on negative aspects, but positive aspects must be recorded as well.

In the main report the observed non-conformances are numbered which references to separate non-conformance reports. The non-conformance reports are attachments to the main report. Elements which must be present in the main report are:

- Audit date, place, replicator and auditor.
- The purpose of the audit.
- Standard version number used.
- The condition / status of the system documentation.
- The persons interviewed mentioning their position.
- Interview reports and observations.
- Summary / Conclusions.

It should be noted that depending on the position of auditor he will either give a recommendation to the certifying body or he will decide on the certification.

The non-conformance reporting is done by using the form of appendix 2. Essential is, that the non-conformance should also indicate which item of the standards is violated. If the auditor and the auditee during the interview can agree on the root cause, then it should also be possible to include at least one proposed corrective action.

This non-conformance report form is designed in such a way that it can be used for communicating the implementation of the corrective action to the auditor. This can be done by e-mail or regular mail.

9 CORRECTIVE ACTIONS AND VERIFICATION

Standards in most cases prescribe how non-conformances should be dealt with; who will have to approve corrective actions, what time schedule is applicable and when a re-audit is required.



10 APPENDICES

Appendix 1

Blank audit checklist

Appendix 2

Blank audit non-conformance report.



External Audit Checklist				Audit date (dd/mm/yyyy)	
Company:				____/____/____	
Department:					
Auditee:				Auditor:	
Item	Standard Ref.	Description	Observations	Non-Conf. Rep. Nbr.	



NON-CONFORMANCE REPORT

Company:

Subject:

Report nbr:

Audit date (dd/mm/yyyy)

____/____/____

Auditee:

Auditor:

Findings:

In conflict with standard item number:

Classification:

Major

Minor

Remark

Proposed Corrective action:

Review of Corrective Action:

Remarks: