# Internal Quality Audits: What They Are and How To Carry Them Out

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### 1 Introduction

These notes support a one-day course to train internal quality auditors. The course does not assume that internal quality audits will be part of an ISO 9000-based quality system. It does, however, use the ISO model as a point of reference.

The course describes the elements of a typical Internal Quality Audit System (IQAS). The details of the design of the system will depend on the way that the quality management system has been implemented and the company itself. The form of the system is not mandated within the ISO 9000 standard but the standard does state requirements for its functions.

The course assumes that delegates have some awareness of quality systems and quality management in general.

The purpose of the course is to:

- Make delegates aware of the need for IQAS
- Describe a practical IQAS
- Train people to become internal auditors

The intention is that delegates should leave the course feeling that they understand the basics of the IQAS including why it's there, how to construct one and who has what responsibility. Auditors will also get to understand the audit management process, so that they will get a better idea of how their individual audits come together to form a picture of how the entire organisation is operating.

So, during the day we will look at:

- Why audit?
- What is an audit?
- Who do you audit?
- When do you audit?
- Where do you audit?
- How do you audit?

We will look at the theory and have a go at the practice.

# 2 Why Audit?

Quality systems control the mechanisms that develop and deliver products and services to customers. If we rely on customers to tell us of the effectiveness of the controls, it may be too late and we will not retain their custom. An effective quality system will contain constant checks, tests and systems for corrective action (because things 'will go wrong'). However, all of these need the support of independent checks of the organization from within the organization. These independent checks are Internal Quality Audits.

We need to open our quality systems to audit or they become closed system. As all those physicists amongst us will immediately point out, closed systems tend to chaos. Take the tea cup!



All nicely focused at one point. If it is dropped, pieces are scattered. Chaos ensues. If this happens continuously, we can loose our entire tea set. If it happens unbeknown to us, someone is going to get a shock when they look in the sideboard! Audits are a routine activity to avoid nasty surprises at critical times.

Most short cuts are made with good intentions and sometimes you can keep all the cups on the tray when you run. However, thought out and reviewed procedures are put in place to make sure that we carry out tasks in ways most likely to succeed with as few risks of failure as possible. Such as, limiting the number of cups on a tray or how fast you move with the tray.

Audits make sure that we don't overload the tray. Audits are needed to find not only the disasters (often all too obvious) but also the frequency of near disasters (which are usually covered up). We need audits to remind us of the correct way of doing things and to make sure that problems are avoided.



# 3 The Purpose of an Internal Audit System

The purpose of the IQAS is to monitor conformance, to both the documented quality system in operation and subsequently, to the requirements of any standard upon which the system is based.

The IQAS provides the mechanism for discovering non-conformances within the operating quality management system by:

- Ensuring that appropriate corrective action is planned
- Ensuring that appropriate corrective action is implemented
- Monitoring the effectiveness of the action

Internal audit records form part of the Quality Records maintained by the organization. From these records trends, critical problems, persistent problems and so on, can be identified. Third party assessors (also probably second party assessors) will examine these records. They will be looking to satisfy themselves that the non-conformances identified during internal audits have been cleared and that the internal audits themselves are operating effectively.

### 4 What is an Audit?

The internal audit function is the mechanism through which the operation of the quality management system is formally monitored and conformance with the documented quality system is assured. Audits are carried out by auditors selected from within the company but who are independent of the area, function or procedure being audited.

Internal audits are the mechanism through which information about the effectiveness of the quality system is gathered. The purpose of the audit function is to verify, or otherwise, conformance of practice with the documented quality system and with the requirements of the Standard.

Very often this is seen as a **policing** function, so great care must be taken to promote the audit as a positive contribution to improvement. The nature of audits, of course, makes this difficult - recording non-conformances appears to be quite negative. However, where an effort is made to note positive aspects the overhead in time seems to be unsupportable. In other words, it is probably not practical (although it is not impossible) to introduce 'positive' auditing.

Some people do positively welcome audits as a rare opportunity to show off their day-to-day activities and have their successes visibly reported to management.

# **5 Types of Audit**

### 5.1 Internal and External Audits

There are three different types of audit:

- · First party audits
- · Second party audits
- · Third party audits

The first party audit is the mechanism by which the company monitors adherence to the documented quality system. It carries little weight externally, except as confirmation that the quality management system is operating correctly. Its benefit is to the company. It provides objective data used to highlight the potential for improvement and a basis on which to plan improvements. The audits are carried out by people who understand both the company and its activities.

Second party audits are usually performed by the customer, or a representative of the customer, when the customer needs to establish confidence in the processes contributing to a particular product or service.

Third party audits are performed by agencies, independent of both customer and supplier, recognised as competent to assess quality management systems against a standard. In recognition of meeting the requirements of the standard, the supplier will achieve certification to the standard. Certification has the benefit of reducing, if not completely removing, the need to perform second party audits.

# 5.2 The Basic Approaches to Auditing

Within these three types of audits, there are two approaches that auditors can take:

- · Vertical auditing
- · Horizontal auditing

Vertical audits look, in depth, at a particular function or department. This type of audit would monitor the use of all relevant procedures as they are used to support the function or activity. Internal audits are usually vertical audits.

Horizontal audits follow a process from start to end. This type of audit would look at procedures as they support the process itself and is likely to span many different functions or departments. Audits or assessments leading to certification are likely to be horizontal.

# 6 The Structure of an Internal Audit System

The Internal Quality Audit System is a documented system covering the planning, execution and follow-up of quality audits carried out within the scope of the quality management system. It is part of the quality management system itself.

A typical IQAS will combine three functions (required by the ISO 9000):

- Management Representative (usually the Quality Manager)
- Internal Quality Auditors
- Management Review Body

All three of these elements are required by ISO 9000 but the method and style of construction of the IQAS itself is not mandated. In practice, and again it is required in ISO 9000, the IQAS needs the support of a corrective action system to be effective.

Taking this model as a typical example, we now look at little more deeply into the function and role of each of these elements.

Let us now look in more detail at who is involved in Internal Quality Audits.

# 7 Organising Audits: Management

Internal Quality Audits, like the rest of a quality system, require backing from the organization's senior management. This requires a champion on the management team - a Management Representative. The Management Representative would usually be the Quality Manager with responsibility for the day-to-day running of the quality management system.

As the title implies, the Management Representative is the link between the operating quality management system and the company Management through the Management Review function. The Management Representative will bring to the attention of Management persistent or recurring problems or those which cannot be actioned at any other level. These problems may be highlighted through normal quality control and assurance activities but will also include the results of internal audits.

The Management Representative is responsible for ensuring that the requirements of the organization in terms of policy, objectives and supporting procedures, are implemented and maintained. Usually the Quality Manager is also responsible for running the quality management system on a day-to-day basis. The role must carry the necessary authority to be able to fulfil these responsibilities. The Quality Manager may hold other, but not conflicting, roles.

# 8 Auditors . . .

The Quality Manager will normally be responsible for selecting, training and managing the quality auditors, scheduling internal audits, monitoring the implementation of the audit schedule and reporting to the Management Review Body. Like most activities this set can be delegated.

The number of auditors required will depend on the size of the company, the scope of the quality management system and the diversity of the functions carried out within the quality management system. For example, a manufacturing company of about 800, spread over 3 sites, could manage with a team of 24 internal auditors representing all major functions covered by the quality management system.

The auditors must be independent of the function or department being audited. This prevents (or at least minimises) conflicts of interest and company politics intruding into what should be seen as a constructive and helpful activity.

Auditing is about communication with emphasis on listening. After all, 'auditor' means 'hearer' or 'listener'. The auditor must also be equipped to ask the right questions in order to get the information required. Good auditors have, or will develop, a very definite set of qualities such as those listed above. We will look at the qualities of auditors (and their auditees!) in more detail later.

Usually internal auditors will be selected from the functions which are covered by the scope of the quality management system. The idea is to provide a large enough pool of auditors to be able to carry out the audit schedule and still provide the necessary degree of independence. In general, internal auditors will continue with their primary role within the company. Auditing will be a second role and, of course this has to be borne in mind by the Quality Manager when scheduling audits.

# 9 A Short Exercise in Auditing

- (1) Divide yourselves into pairs.
- (2) Each take a turn to be first, auditee and then auditor.

Note: The purpose of the exercise is to become familiar with not only asking questions, but asking the right kind of questions.

As the auditor, it is your task to find out all about your auditee's tasks, what their job entails and how they can show that they are telling the truth. (Auditees can often forget that in an internal quality audit, they are amongst friends!)

- (3) Spend up to 15 minutes in each role.
- (4) Auditors should make notes.
- (5) Auditors will report their findings to the others at the end of the exercise.

# 10 Questions, Questions - Interviewing Techniques for Auditing

How did you get on with your questioning? What kind of questions did you ask? Which of your questions were effective? Are you starting to get a picture of the theme of this workshop?

When you leave the workshop you will be laden with tools such as forms, checklists and reports. These are secondary to the real tools of auditing, the gentlemen that taught Kipling all he knew:

- What?
- Why?
- How?
- Who?
- When?
- Where?

These are the keys to your auditees. They are the foundation of open questions. Open questions keep your auditees talking. You have come to hear them. You can guide them in what they are saying but you don't want to take over the conversation. Do this by avoiding questions with 'yes' or 'no' answers (closed questions) except where you already know what you are looking for.

# 10.1 Examples of Open Questions

- What do you do with that report?
- How do you find out your customer's requirements?
- Why do you use this piece of equipment?
- Who has authorised this piece of work?
- When are units tested for conformance to the specification?
- Where are the records stored?
- Tell me about your role in the department (It may not sound like a question but it is.)

# 10.2 Examples of Closed Questions

- Have you completed the approval form?
- Did you test this before you delivered it?
- Is this the latest version?

These questions have their place in an audit but don't rely on them. Let the auditees do the talking.

There is one more 'question' missing from the set. We'll look at it later.

# 10.3 When to Use 'Open' and 'Closed' Questions

Use 'open' questions to search and probe for the unknown. You may be looking for:

- New practices
- Changes to existing processes
- Failures (or indeed successes)

These are areas that may not be anticipated by existing procedures.

Use 'closed' questions to check known or expected facts such as:

- A stage in a procedure being complete
- Compliance with a standard

# 11 Practical Auditing

Don't for one moment think that you can just go in and start questioning auditees. You are going to have to deal with all types people. This part of the course will help you to know what to expect and how to deal with it. We will look at:

- Mutual understanding of the purpose of an audit interview
- Planning and preparation for an audit
- Conduct of the audit interview
- Consolidation of your audit findings

Plan the sequence of your interviews. Decide:

• Who do you need to see



• Where is the best place to interview them? (Where will records be available?)



• What will you want them to talk about?





Use a checklist to structure each interview with an auditee. Always explain the purpose of the interview. An audit is nothing more than fact finding. Put your auditees at rest. Explain what will be done with audit results, how the results will fit into problem analysis for the organisation.

Analyse the procedures to make sure that you are going to audit relevant personnel. Plan the sequence of interviews but remember that what you find during the course of one interview may affect who you interview next. This may differ from what you had planned.

You may need a preliminary interview with the head of department or team leaders to help you identify auditees. Sometimes you may need their permission!

Collect as much background information as possible. The key information should be supplied by whoever is managing your audit.

Use a checklist as an initial set of questions. You may be able to follow a checklist through to the end or you may find it worthwhile to abandon it after the first question. However, maintain your focus on the procedures that you are auditing. Your authority is only unquestionable if you find non-conformances to the documented procedures. Never get distracted with how you think something should be done; let your auditees do the talking. Take one input to a procedure or process and follow it through. Check for outputs not resulting from inputs as well as loose threads.

Don't barge in and start questioning! Put your auditees at ease. Explain the purpose of the audit. Reassure them that non-conformances are just problems to be corrected. Audits are not looking to apportion blame but rather just to see that if something is wrong, it is put right.

Make a good first impression. This means appropriate dress and a reasonable degree of formality.



Your auditees may have (of feel that they have) little time to spare. Keep their attention with short questions. Don't let them distract you by their wanting to leave.



Sometimes you may be made very welcome, but just as some auditees can't wait to get away, some auditees are happy to talk and talk.



Steer your auditees to the issue in question. Make sure that each moment of an audit interview is time well-spent.

# **11.1 Personality Traits**

There are three types of people who, if not properly managed by you the auditor, will prevent you getting to the level of detail needed to identify if a process is working properly. These types are:

• Remote



### Antagonistic



### Reserved



Don't match your auditee's style by remaining remote, get close! Be prepared to follow them if necessary, but get them to agree to sit down with you. Remind them that they have agreed to your appointment. As a last resort, reschedule the audit.

Auditees can be very antagonistic, seeing you as an unnecessary invasion of their time or a threat to their authority. Let them do the shouting! Don't be tempted to match their mood. Bring them back to earth by staying calm and explaining your objectives, more than once if necessary.

Sometimes auditees will want you to do the talking. Make them feel at ease; start with general questions (possibly not wholly focused on the audit) and slowly focus on the important issues. Use open questions to guide the auditee's side of the conversation.

# 11.2 Interviewing Style

There are three keys to good interviewing style:

• Be a good listener



Don't be defensive



• Don't make assumptions about what you are being told



Be a good listener. Don't dominate the conversation. You are there to collect information, not give it. Similarly, when your auditees are giving you information, make sure that you show a level of interest commensurate with what they are telling you.

Steer the interview with your questions.

Don't be defensive. Your position as auditor gives you the authority to probe. You will have made an effort to prepare for the audit. Don't let the audit interview turn into an opportunity for the auditee to make unjustified criticisms of areas of the quality system outside the focus of your audit.

Ask! Don't make assumptions about what you are being told. Don't record anything that the auditee has not told you.

When conducting the interview, accept ideas, but do not promise solutions. You can record observations to be fed into the corrective actions system but your authority, and probably your involvement, stops there.

Keep questions direct. Do not lead the auditee. Beware user jargon - ask for explanations when you need them.

Record evidence but you don't need to take it away with you -record it on the notes proforma (this is featured later).



Make it clear to your auditees that you don't just note the problems; it is good practice to record successes also.

Summarise your findings at the end of the audit interview. Always aim to end in agreement, with auditees signing off the audit reports as well as you, the auditor.

If you need to cross refer to something to aid your understanding, ask for further information. You may need to make a lot of notes that will need consolidation after the interview. Don't waste the interview time; do this soon after, while it is all fresh in your mind.



Send auditees a copy of notes and reports that you raise.

# 12 Scheduling Audits

# 12.1 When do You Carry Out Audits?

Most activities covered by the scope of the quality management system should be the subject of an internal audit with a frequency of once per year. Some will need to be audited less frequently.

The frequency of audit will depend on many factors such as the size of the organization and the complexity of the work done.

As part of the scheduling process, the Quality Manager will allocate auditors ensuring independence of the auditor from the area being audited. Very often the Quality Manager will also identify the auditee, or an appropriate person for the auditor to contact to make arrangements for the audit.

The results of the internal audits together with an analysis of those results will be reported to Management through the Management Review body. Normally this report will identify those issues which require the attention of management and will not be a full report of every non-conformance raised.

# 13 How to Carry Out an Audit: An Overview

The audit is conducted against an objective reference base - the documented quality system and/or a standard. It is conducted by auditors who are independent of the area they are auditing. This means, in practice, that there must be no conflict of interest, for example line-management control, for the auditor.

The objective reference base and the independence of the auditor help to ensure that company politics and personal prejudice do not influence what ought to be an unbiased assessment of practice.

The typical audit cycle will include:

- A preparation stage during which the auditor will carry out a reconnaissance or pre-audit of the function to be audited
- Deciding the scope of the audit
- Preparing a checklist of pertinent questions to be covered during the audit

The auditee, often the manager or supervisor of the function being audited, may receive a copy of the checklist prior to the audit.

The execution of the audit usually starts with an opening meeting, to clarify the scope of the audit and answer any questions that the auditee might have about the process. As everyone becomes familiar with the audit process this stage will become quite short. During the audit, any non-conformances will be noted and cross-referenced to either the documented quality system or the Standard. Any audit trails which lead out of the scope of the audit will be noted and picked up by other auditors during the appropriate audit. The execution of the audit closes with another meeting with the auditee to agree the non-conformances, perhaps discuss corrective action and decide dates for actions to be completed.

Non-conformances, corrective action and dates for completion will form the audit report. The report should be prepared immediately the audit is completed but certainly within 24 hours.

The audit is not considered to be closed until all corrective actions have been completed and the auditor has confirmed that this is the case. This confirmation is the follow-up audit and will be confined to the corrective actions. In other words the follow-up audit is not a complete re-audit.

# 14 Audit Results

The data provided by audits needs to be analysed to:

- Discover trends and confirm improvements
- Highlight difficulties in the application of procedures or in particular activities or parts of a process
- Give an idea of the types of corrective action being carried out and how long corrective action takes to implement

The types and numbers of non-conformances may highlight the need for more training, either technical training or training in the use of the procedures themselves.

The results of audits will also influence the scheduling of future audits.

Collating and analysing audit results is usually the responsibility of the Quality Manager. Trends and highlighted problems, or problem areas, will form the basis of the report to the Management Review body.

# 15 The Missing Question and the Forbidden Word

# 15.1 The Missing Question

Before we look at the top level of analysis of audit results, let us look at the matter of the missing question that we left out earlier.

During an audit you will ask auditees question after question that they will usually be able to answer on the spot. They will usually be honest and mistakes, similarly, will be honestly made. However, treat all auditees, not with an air of suspicion but with a degree of enthusiasm. When they answer your questions about areas where tangible evidence should exist, tell them:

### **SHOW ME!**

### 15.2 The Forbidden Word

Auditing reinforces the quality system and can only be effective if auditees feel ready to come under scrutiny. This doesn't happen however, when auditors feel that they have failed to audit properly if no non-conformances are found. Just as you must be prepared to request evidence of auditee's statements, you must never say:

### GOTCHA!

when they fail to present it.

# 16 Management Review Function

The purpose of this body is to review, regularly, the performance and continued relevance of the quality system. It is expected to respond to problems which cannot be solved at any other level within the quality system for whatever reason.

The body will review information from a number of sources in addition to the results from the internal audit system, including reports from the Corrective Action System and customer feedback and complaints. Again, the collation of this information is usually the responsibility of the Quality Manager.

Without review and action at this level the quality system will become irrelevant to the business, inflexible and bureaucratic.

# 17 Corrective Action System

The Corrective Action System is actually independent of the IQAS. However, it is often the mechanism by which non-conformances are progressed and is worth mentioning here.

In brief, the system is a means of recording the occurrence of a non-conformance, ensuring the problem is passed to the person able to progress it (the person with the responsibility and the authority to respond effectively) and monitoring the effectiveness of the implemented solution. The solution must both solve the immediate problem and put in place a mechanism that will prevent the problem recurring.

Often, non-conformances raised during an audit result in the raising of a Corrective Action request, particularly where the appropriate respondent is not the auditee. Once in the Corrective Action System the progress of the non-conformance can be formally monitored (probably by the Quality Manager) until appropriate action has been taken and shown to be satisfactory in outcome.

# 18 Helpful Forms

It is possible to design a form for practically anything but I would strongly advise against that. Forms must be usable. This means that not only must they be well laid out and record the information that is really required, but that there should be no great decision making involved about which one to use.

To give an idea of the kind of forms that might support the IQAS I have listed the ones that I personally found useful. The layout and content of the forms evolved as we understood better what we did and did not need to know and how much space we needed. You may use a different set.

# 18.1 The Internal Quality Audit Register

In scheduling audits try using a matrix format, with function-to-be-audited as the y-axis and date as the x-axis. This gives a good overview of when audits were due and the loading on both auditors and auditees. You will also find it useful to log the progress of audits recording the dates of receiving and returning audit checklists, the actual planned date of the audit, the date of receiving the audit report form and the latest date for completion of any corrective actions. This will allow you to prompt the follow-up audits.

Audit trails have been mentioned and you will find it useful to record background information to the raising of the trail on a separate form so that other auditors could pick up the trail later. This form records the auditor's name, the department where the trail arose, the department where it should be picked up and details of any documentation involved.

A practical audit register is shown in these notes.

There are software packages on the market designed to support the internal audit system. Don't feel driven to a technological aid before you understand the problem.

IQAN	Department/ Function/ Procedure	Auditor(s)	Scheduled Date of Audit	Date of receipt of Checklist	Date of receipt of Report	Date of Follow- up

**Table 1: Internal Quality Audit Register** 

# 18.2 The Internal Quality Audit Checklist Proforma

The Checklist form should simply record:

- The department being audited
- The auditor(s)
- The questions to be asked and a reference either to the Standard or procedures that prompted the question

An example format is shown in these note:

**Table 2: Internal Quality Audit Checklist** 

AUDITOR(S):	DATE OF AUDIT:	IQAN:
DEPARTMENT /FUNCTION /PROCEDURE:	AUDITEE(S):	
REFERENCE TO STANDARD OR PROCEDURE:	QUESTION/PROMPT:	NOTES Y/N
Copy to Quality Manager		

# 18.3 The Internal Quality Audit/Non-conformance Report

The non-conformance report form should record:

- The department being audited
- The auditor
- The auditee
- A description of the non-conformance
- A reference to the procedure or standard against which the non-conformance was being raised
- A brief description of the corrective action to be taken
- A date for completion of the corrective action
- Space for the signatures of the auditor and auditee to agree the content of the report.

It is often the case that non-conformance forms are designed to record a single non-conformance and the corrective action in some detail. This makes closing non-conformances much easier as each non-conformance is recorded separately and can be signed off as closed as soon as it is corrected.

The form in the example also shows how the audit can be used as an opportunity to record improvements that are often only spotted by an independent pair of eyes. These are the observations that don't relate to a specific problem but point to preventive rather than corrective action.

.

**Table 3: Internal Quality Audit Report** 

IQAN:	Date:
☐ Non-conformance ☐ Observation (tick as appr	ropriate)
Description:	
Continue overleaf if necessary.	
Signature of Internal Auditor:	Signature of Auditee:
Proposed Corrective Action:	
Continue overleaf if necessary.	
Agreed Target Completion Date:	Signature of Auditee:
	or Departmental Manager
Actual Corrective Action if different from above:	
Continue overleaf if necessary.	
Follow-up Audit Required: ☐ No	□ Yes
(see 'Confirmation of Action Taken' below)	After follow-up audit: Confirmation (by auditor) of action taken (signature):
	Date:
Confirmation of Action Taken: (If no follow-up aud Manager or 'Other' shall confirm actions have bee the completed form to the Quality Manager.)	•
Auditee/Departmental Manager/Other:	Date:

# **18.4 Internal Quality Audit Notes**

Notes to record the type of information exchanges during an audit should also be retained. A useful proforma is included here:

**Table 4: Internal Quality Audit Notes** 

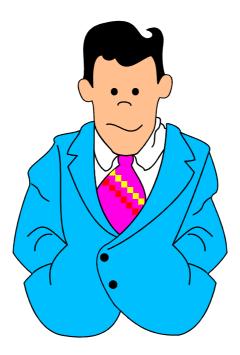
IQAN:	Reference to procedure or standard:
Notes:	
Copy to: Quality Manager	

# 19 Preparing an Audit: An Exercise

Before we 'walk through' an audit, let's consolidate the information we have collected so far and scrutinise a procedure to see how we can audit conformance to it.

# 19.1 Auditing a Consultancy Assignment

Meet the consultant!



Here he is; ready to continue with what **he** thinks is successful assignment.

He is not supposed to be acting without controls. His organization has invested time and money to design a procedure to harness the consultant's talents. It dictates **what** he has to do but it doesn't prescribe **how** he has to do it. You are going to audit him to check conformance to an Assignment Management procedure.

- (1) Split yourselves up into groups of two or three (safety in numbers!).
- (2) Read the Assignment Management procedure.
- (3) Prepare a checklist to guide yourselves (and your auditee) through the audit.
- (4) Use the checklist the probe whether or not the consultant is following the procedure.
- (5) Raise non-conformances if you find them.
- (6) Remember to look for evidence.

# 20 A Step by Step Approach to Carrying Out an Audit

Now that we have covered all the aspects of internal quality auditing, this part of the course looks at the practical application. It covers the activities associated with the scheduling, organising and reporting of Internal Quality Audits.

### 20.1 Introduction

To recap, the objective of the internal audit is to ensure that:

- The Quality System continues to operate in line with specified policies and procedures
- Improvements to the Quality System are identified and initiated

# 20.2 The Scope of an Internal Quality Audit System (IQAS)

Internal Audits cover, as a minimum, all departments, functions and procedures included in the scope of the Quality System.

The procedure applies to:

- The Quality Manager
- Internal Quality Auditors

### 20.3 Useful Documents

This procedure uses:

- An Internal Quality Audit Register
- A proforma for Internal Quality Audit Checklists
- A form for Internal Quality Audit Notes
- A simple presentation technique for Internal Quality Audit Reports

# 20.4 How to Manage and Carry Out an Internal Quality Audit

The Quality Manager produces an Internal Quality Audit (IQA) Schedule at least annually - not forgetting the quality functions within it!

The IQA schedule records the departments, functions and procedures to be audited. To help with collating audit reports, an Internal Quality Audit Number (IQAN) is allocated for each audit. The schedule also records the scheduled month of the audit and shows suitable auditor(s) to carry out the audit. The Quality Manager appoints suitably trained and experienced Internal Quality Auditors to audit departments/functions/procedures of which they are independent in terms of management reporting.

Every department, function and procedure included within the scope of the Quality Management System should be thoroughly audited at least every three years and usually annually. The particular frequency of audits for departments, functions or procedures will take into account:

- The results of any previous audits
- The importance of the function or procedure to the quality of products and services
- The newness of the function, procedure or staff

Record the department/function/procedure to be audited, the IQAN for the audit and the name(s) of the Internal Quality Auditor(s) appointed to conduct the audit into the IQA Register. Prepare a Register file and keep the IQA Register in it.

# 20.5 Organising Internal Quality Audits

Give timely notification to the appointed Internal Quality Auditor(s) when an IQA is due to be carried out.

Specify the department/function/procedure to be audited, suggest a suitable auditee(s) and identify the manager of the department/function/procedure to be audited to the appointed auditor(s).

Supply the appointed Auditor(s) with:

- Copies of the IQA Checklist forms
- IQA Notes forms
- IQA Report forms
- Copies of previous audit reports
- Existing (or previous) checklists

### 20.6 Preparing for an Audit - Creating the Audit Checklist

Prepare a checklist of questions or specific aspects to be covered during the audit. Use the IQA Checklist proforma. Refer your approach to the Quality Manager for approval.

The Quality Manager should be satisfied that all necessary aspects have been covered by the checklist, make any comments or amendments, and return the checklist to the auditor.

File a copy of the numbered, approved checklist in the IQA Register file.

# 20.7 Preparing for the Internal Quality Audit: Pre-audit Meetings

Contacting the auditee(s) arrange a pre-audit meeting. Work with the Quality Manager if you cannot arrange this within, say, five days of when you need to carry out the audit.

The Quality Manager takes any action appropriate to progress the audit.

At the pre-audit meeting, explain the purpose of the audit to your auditees. Arrange a mutually convenient date for the audit.

The audit should be conducted within 5 working days of the pre-audit meeting and preferably within 2 working days. If neither timescale is possible the auditor should inform the Quality Manager.

The Quality Manager takes action appropriate to progress the audit.

# 20.8 Conducting the Audit

Record non-conformances found during the audit on the IQA Report form. Enter the IQAN on every page of your reports and notes. Clearly record the audited department, function or procedure.

### 20.9 Completing the Audit.

Agree the non-conformances recorded on each IQA Report with the auditee. Agree corrective action and timescales for corrective action with auditee(s) or the departmental manager (as appropriate) and document it on the IQA Report.

Indicate on the IQA Report form if a follow-up audit is required.

Complete the IQA Report completed within 2 working days of the completion of the audit, ideally within 24 hours. If this is not possible, the auditor(s) inform the Quality Manager (who will take any action appropriate to progress the audit).

Send the IQA Report to the Quality Manager and to the auditee, departmental manager or another named individual responsible for corrective action.

The Quality Manager enters the requirement for a follow-up audit, or alternatively the latest date for completion of the corrective actions, as indicated on the IQA Report, on the IQA Register in the 'Date for follow-up audit' column. The Quality Manager files the IQA Report in the IQA Register file.

### 20.10 Closing the Audit: The Follow-Up Audit

If an auditor has indicated the need for a follow-up audit on the IQA Report form then the Quality Manager prompts the auditor(s) at the due date sends the auditor(s) a copy of the original IQA Report detailing the corrective action agreed between auditee(s) and auditor(s).

In the case of a follow-up audit, arrange with the auditee(s) a mutually convenient date for the follow-up audit.

On completion of the follow-up audit, sign and date the IQA Report to indicate that the corrective action has been carried out.

Return the completed IQA Report to the Quality Manager (who will file the completed IQA Report with the checklist and notes in the IQA Register file). The audit of this item is then deemed to be closed.

# **20.11 Completion of Corrective Actions**

When the Auditor(s) do not indicate that a follow-up audit will be necessary, then the Quality Manager ensures that timely notification of completed corrective action is received from the auditee(s).

The Quality Manager files the written notification of completion of corrective action with the relevant IQA Report and notes in the IQA Register file. The audit of this item is then deemed to be closed.

# 20.12 Handling Disputes

If the auditee(s) cannot agree with the non-conformances documented in the IQA Report, send the incomplete IQA Report form and an indication of the nature of the disagreement to the Quality Manager to take action to resolve the issue. Record the action taken and file it with the checklist of the same IQAN in the IQA Register file.

# 20.13 Executive Audit Report

The Quality Manager reviews the findings of all recent audits and prepares an Executive Audit Report for Management at least annually as part of the Quality System Review.

# 21 Conclusion

So, in summary, the IQAS is a mechanism for collecting objective data. The data can then be used to identify and plan improvements. The IQAS is part of the Quality Management System itself and operates through internal auditors who understand the company and its activities.

The IQAS is not a replacement for project planning or monitoring activities nor is it a mechanism for achieving political or personal ends. It is objective.

The purpose of the IQAS is to monitor the effectiveness of the Quality System. It is not an exercise to apportion blame to individuals and it is important that this is understood by everyone, particularly those who are auditees.